

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,858,996 B2
APPLICATION NO. : 14/244471
DATED : October 14, 2014
INVENTOR(S) : John R. Plachetka

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On The Title Page

Item (56) References Cited - Foreign Patent Documents, delete the 27th reference on page 3
“WO WO 93/11750 11/1991” and replace with --WO WO 93/11750 6/1993-- therefor.

Item (56) References Cited - Foreign Patent Documents, insert --JP 2005-145894 6/2005--.

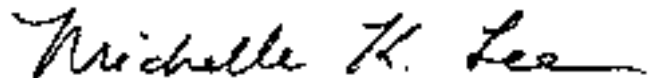
Item (56) References Cited - Other Publications, insert --Goldstein et al., “PA32540 (Enteric-coated aspirin 325 mg + immediate-release omeprazole 40mg) is associated with significantly fewer gastric ulcers and significantly less endoscopic erosive esophagitis than enteric-coated aspirin (EC-ASA) alone: Results of two phase 3 studies,” *The American Journal of Gastroenterology*, vol. 107, Suppl. 1, pp. S53-S54, 2012.--.

Item (56) References Cited - Other Publications, insert --Miner et al., “PA32540, a tablet containing enteric-coated (EC) aspirin 325 mg and unbuffered immediate-release omeprazole 40 mg, provides percent time gastric pH >4 significantly less than EC omeprazole 40 mg, but with faster onset and less exposure to omeprazole,” *Gastroenterology*, vol. 142, Issue 5, Supplement 1, p. S-3, 2012.--.

In The Claims

In claim 12, column 22, line 23, delete “said layer is has” and replace with --said layer has-- therefor.

Signed and Sealed this
Twenty-seventh Day of January, 2015



Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

DATE : 12-30-14
TO SPE OF : ART UNIT 1618
SUBJECT : Request for Certificate of Correction for Appl. No.: 14/244471 Patent No.: H858996

CofC mailroom date: 10-30-14

Please respond to this request for a certificate of correction within 7 days.

FOR IFW FILES:

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

FOR PAPER FILES:

Please review the requested changes/corrections as shown in the attached certificate of correction. Please complete this form (see below) and forward it with the file to:

Certificates of Correction Branch (CofC)
Randolph Square – 9D10-A
Palm Location 7580

Angela Green

Note: _____

Angela Green 571.272.9005
CofC Branch 703-756-1814

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriate box.

☐ **Approved**

All changes apply.

☐ **Approved in Part**

Specify below which changes **do not** apply:

☐ **Denied**

State the reasons for denial below.

Comments: _____

SPE

Art Unit

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

DATE : 12-30-14
 TO SPE OF : ART UNIT 1612
 SUBJECT : Request for Certificate of Correction for Appl. No.: 14/244471 Patent No.: 8858996

CofC mailroom date: 10-30-14

Please respond to this request for a certificate of correction within 7 days.

FOR IFW FILES:

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

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 Palm Location 7580

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Note: _____

Angela Green 571.272.9005

CofC Branch 703-756-1814

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Note your decision on the appropriate box.

☒ **Approved**

All changes apply.

☐ **Approved in Part**

Specify below which changes do not apply.

☐ **Denied**

State the reasons for denial below.

Comments: Changes correct year of document and minor typographical
error. Added documents were considered as can be seen on
documents mailed 7/20/14

SPE / *Frederick Kross* Art Unit *1612*

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,858,996
APPLICATION NO.: 14/244,471
ISSUE DATE : October 14, 2014
INVENTOR(S) : John R. PLACHETKA

Page 1 of 1

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In claim 12, column 22, line 23, delete "said layer is has" and replace with --said layer has-- therefor.

MAILING ADDRESS OF SENDER:
Parker Highlander PLLC
1120 S. Capital of Texas Highway, Building One, Suite 200
Austin, Texas 78746

Electronic Patent Application Fee Transmittal

Application Number:	14244471			
Filing Date:	03-Apr-2014			
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
First Named Inventor/Applicant Name:	John R. PLACHETKA			
Filer:	Steven Lee Highlander/Richard Ortiz			
Attorney Docket Number:	POZN.P0004US.CP1C4			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Certificate of Correction	1811	1	100	100
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				100

Electronic Acknowledgement Receipt

EFS ID:	20559371
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard Ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	30-OCT-2014
Filing Date:	03-APR-2014
Time Stamp:	12:21:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	POZNP0004USCP1C4_Req-Cert-Corr-Trans-Letter.pdf	32603 f79144c2f255ab4b682a932f9eafbc315c8b d63a	no	2

Warnings:

Information:

2	Request for Certificate of Correction	POZNP0004USCP1C4_Req-Cert-Corr.pdf	118194 c921bf2e9371e05e381518393f6691e3a6222693	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	29944 f6839f3626c87454e64c4169909f7969242705b3	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			180741		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John R. PLACHETKA

Patent No.: 8,858,996

Serial No.: 14/244,471

Issue Date: October 14, 2014

Filing Date: April 3, 2014

Attorney Docket No.: POZN.P0004US.CP1C4

Title: PHARMACEUTICAL
COMPOSITIONS FOR THE
COORDINATED DELIVERY OF
NSAIDS

Confirmation No.: 3047

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the
United States Patent and Trademark Office via EFS-Web on the date below:

October 30, 2014

Date

/Steven L. Highlander/

Steven L. Highlander

REQUEST FOR CERTIFICATE OF CORRECTION

Commissioner for Patents
Attention: Certificates of Correction Branch
P.O. Box 1450
Alexandria, Virginia 22313-1450

Commissioner:

Attached is a modified form PTO/SB/44. Errors of a minor nature are thereon corrected.
The errors are due to both Patent Office oversight and applicant. A Certificate of Correction is
requested under 35 U.S.C. §§ 254 and 255.

The required fee set forth in 37 C.F.R. § 1.20(a) is included. If the fee is inadvertently
omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason
relating to this document, or should an overpayment be included, the Commissioner is authorized

to deduct or credit said fees from or to Parker Highlander PLLC Deposit Account No. 50-5902/POZN.P0004US.CP1C4.

Respectfully submitted,

/Steven L. Highlander/

Steven L. Highlander
Reg. No. 37,642
Attorney for Applicant

Parker Highlander PLLC
1120 S. Capital of Texas Highway
Building One, Suite 200
Austin, Texas 78746
512-334-2900 (Telephone)
512-334-2999 (Fax)

Date: October 30, 2014

Electronic Patent Application Fee Transmittal

Application Number:	14244471			
Filing Date:	03-Apr-2014			
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
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Filer:	Steven Lee Highlander/Richard Ortiz			
Attorney Docket Number:	POZN.P0004US.CP1C4			
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Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Certificate of Correction	1811	1	100	100
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				100

Electronic Acknowledgement Receipt

EFS ID:	20559618
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard Ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	30-OCT-2014
Filing Date:	03-APR-2014
Time Stamp:	12:36:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 100
RAM confirmation Number	13464
Deposit Account	505902
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Fee Worksheet (SB06)	fee-info.pdf	29944 47f308778a5ae1b1afafae9e1f87c45a2e943a8c	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			29944		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/244,471	10/14/2014	8858996	POZN.P0004US.CP1C4	3047

108197 759 09/24/2014

Parker Highlander PLLC
1120 South Capital of Texas Highway
Bldg. 1, Suite 200
Austin, TX 78746

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Pozen Inc., Chapel Hill, NC, Assignee (with 37 CFR 1.172 Interest);
John R. PLACHETKA, Chapel Hill, NC;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A101	5,750,531	05/12/98	Lee <i>et al.</i>
	A102	5,817,338	10/06/98	Bergstrand <i>et al.</i>
	A103	5,817,340	10/06/98	Roche <i>et al.</i>
	A104	5,840,737	11/24/98	Phillips
	A105	5,872,145	02/16/99	Plachetka
	A106	5,877,192	03/02/99	Lindberg <i>et al.</i>
	A107	5,900,424	05/04/99	Kallstrom <i>et al.</i>
	A108	5,955,451	09/21/99	Lichtenberger <i>et al.</i>
	A109	6,013,281	01/11/00	Lundberg <i>et al.</i>
	A110	6,025,395	02/15/00	Breitner <i>et al.</i>
	A111	6,060,499	05/09/00	Plachetka
	A112	6,093,734	07/25/00	Garst <i>et al.</i>
Change(s) applied to document, /C.C./ 9/11/2014	A113	6,126,816 6,162,816	12/19/00	Bohlin <i>et al.</i>
	A114	6,132,768	10/17/00	Sachs <i>et al.</i>
	A115	6,132,771	10/17/00	Depui <i>et al.</i>
	A116	6,136,344	10/24/00	Depui <i>et al.</i>
	A117	6,160,020	12/12/00	Ohannesian <i>et al.</i>
	A118	6,162,816	12/19/00	Bohlin <i>et al.</i>
	A119	6,183,776	02/06/01	Depui <i>et al.</i>
	A120	6,183,779	02/06/01	Ouali <i>et al.</i>
	A121	6,207,188	03/27/01	Gustavsson <i>et al.</i>
	A122	6,231,888	05/15/01	Lerner <i>et al.</i>
	A123	6,287,600	09/11/01	Ouali <i>et al.</i>
	A124	6,365,184	04/02/02	Depui <i>et al.</i>
	A125	6,369,085	04/09/02	Cotton <i>et al.</i>

{00147031}

EXAMINER: /Nissa Westerberg/

DATE CONSIDERED: 07/17/2014

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A76	4,965,065	10/23/90	Lukacsko <i>et al.</i>
	A77	5,026,560	06/25/91	Makino <i>et al.</i>
	A78	5,035,899	07/30/91	Saeki <i>et al.</i>
	A79	5,037,815	08/06/91	Lukacsko <i>et al.</i>
	A80	5,043,358	08/27/91	Lukacsko <i>et al.</i>
	A81	5,051,262	09/24/91	Panoz <i>et al.</i>
	A82	5,093,132	03/03/92	Makino <i>et al.</i>
	A83	5,204,118	04/20/93	Goldman <i>et al.</i>
	A84	5,260,333	11/09/93	Lukacsko <i>et al.</i>
	A85	5,364,616	11/5/94	Singer <i>et al.</i> <i>to be included</i>
	A86	5,373,022	12/13/94	Fawzi <i>et al.</i> <i>to document,</i>
	A87	5,409,709	04/25/95	Ozawa <i>et al.</i> <i>/C.C./</i>
	A88	5,417,980	05/23/95	Goldman <i>et al.</i> <i>9/11/2014</i>
	A89	5,466,436	11/14/95	Stables
	A90	5,514,663	05/07/96	Mandel
	A91	5,601,843	02/11/97	Gimet
	A92	5,631,022	05/20/97	Mandel <i>et al.</i>
	A93	5,643,960	07/01/97	Breitner <i>et al.</i>
	A94	5,667,802	09/16/97	Grimberg
	A95	5,679,376	10/21/97	Stevens <i>et al.</i>
	A96	5,686,105	11/11/97	Kelm <i>et al.</i>
	A97	5,690,960	11/25/97	Bengtsson <i>et al.</i>
	A98	5,702,723	12/30/97	Griffin
	A99	5,714,504	02/03/98	Lindberg <i>et al.</i>
	A100	5,716,648	02/10/98	Halskov <i>et al.</i>

{00147031}

EXAMINER: /Nissa Westerberg/	DATE CONSIDERED: 07/17/2014
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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A51	2009-0297594	12/03/09	Depui <i>et al.</i>
	A52	2010-0062064	03/11/10	Ault <i>et al.</i>
	A53	2010-0172983	07/08/10	Plachetka
	A54	2010-0178334	07/15/10	Johansson <i>et al.</i>
	A55	2010-0330179	12/30/10	Ault <i>et al.</i>
	A56	2012-0064156	03/15/12	Plachetka
	A57	2013-0078305	03/28/13	Plachetka
	A58	4,198,390	04/15/80	Rider
	A59	4,255,431	03/10/81	Junggren <i>et al.</i>
	A60	4,344,929	08/17/82	Bonsen <i>et al.</i>
	A61	4,508,905	04/02/85	Junggren <i>et al.</i>
	A62	4,554,276	11/19/82 1985	LaMatina
	A63	4,562,261	12/31/85	Hirata <i>et al.</i>
	A64	4,619,934	10/28/86	Sunshine <i>et al.</i>
	A65	4,676,984	06/30/87	Wu <i>et al.</i>
	A66	4,704,278	11/03/87	Wu <i>et al.</i>
	A67	4,726,951	02/23/88	Panoz <i>et al.</i>
	A68	4,738,974	04/19/88	Brandstrom
	A69	4,757,060	07/12/88	Lukacsko <i>et al.</i>
	A70	4,758,579	07/19/88	Kohl <i>et al.</i>
	A71	4,766,117	08/23/88	Crawford <i>et al.</i>
	A72	4,786,505	11/22/88	Lovgren <i>et al.</i>
	A73	4,853,230	08/01/89	Lovgren <i>et al.</i>
	A74	4,865,847	09/12/89	Gosswein
	A75	4,948,581	08/14/90	Sawayangi <i>et al.</i>

{00147031}

EXAMINER: /Nissa Westerberg/

DATE CONSIDERED: 07/17/2014

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A26	2005-0004171	01/06/05	Phillips
	A27	2005-0042304	02/24/05	Phillips
	A28	2005-0054682	03/10/05	Phillips
	A29	2005-0147668	07/07/05	Bertelsen <i>et al.</i>
	A30	2005-0163847	07/28/05	Cheng <i>et al.</i>
	A31	2005-0227949	10/13/05	Edalatpour <i>et al.</i>
	A32	2005-0249806	11/10/05	Proehl <i>et al.</i>
	A33	2005-0249811	11/10/05	Plachetka
	A34	2006-0165797	07/27/06	Plachetka
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	A37	2006-0178349	08/10/06	Plachetka
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	A39	2007-0122470	05/31/07	Johansson <i>et al.</i>
	A40	2007-0154542	07/05/07	Tananbaum <i>et al.</i>
	A41	2007-0184078	08/09/07	Chen
	A42	2007-0207200	09/06/07	Plachetka <i>et al.</i>
	A43	2007-0237820	10/11/07	Cheng <i>et al.</i>
	A44	2007-0243251	10/18/07	Taneja
	A45	2008-0031941	02/07/08	Pettersson
	A46	2008-0031950	02/07/08	Sesha
	A47	2008-0103169	05/01/08	Phillips
	A48	2009-0074863	03/19/09	Taneja
	A49	2009-0075950	03/19/09	Taneja
	A50	2009-0163551	06/25/09	Earnest

{00147031}

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	A8	2002-0090395	07/11/02	Woolfe <i>et al.</i>
	A9	2002-0111370	08/15/02	Bergman <i>et al.</i>
	A10	2002-0155153	12/24/02	Depui <i>et al.</i> (language applied
	A11	2002-0160046	10/31/02	Robinson <i>et al.</i> to document,
	A12	2003-0008903	01/09/03	Barberich <i>et al.</i> /C.C./
	A13	2003-0040537	02/27/03	Plachetka <i>et al.</i> 9/17/2014
	A14	2003-0069255	08/09/05	Plachetka 04/2003
	A15	2003-0113375	06/19/03	Lundberg <i>et al.</i>
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	A18	2003-0232080	12/18/03	Pather <i>et al.</i>
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PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying paper. Each filing paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

108197 7590 07/24/2014
 Parker Highlander PLLC
 1120 South Capital of Texas Highway
 Bldg. 1, Suite 200
 Austin, TX 78746

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Steven L. Highlander	(Depositor's name)
/Steven L. Highlander/	(Signature)
September 9, 2014	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4	3047

TITLE OF INVENTION: PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	10/24/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
WESTERBERG, NISSA M	1618	424-463000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of address (or Change of Correspondence Address form PTO/SB/47, Rev 03-02 attached).

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm, as a member a registered attorney or agent) and the names of up to 3 registered patent attorneys or agents. If no name is listed, no name will be printed.

Parker Highlander PLLC

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE (CITY AND STATE OR COUNTRY)

Pozen Inc.

Chapel Hill, NC

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

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☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-5902 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be filed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for filing requirements and certifications.

Authorized Signature /Steven L. Highlander/
 Typed or printed name Steven L. Highlander

Date September 9, 2014
 Registration No. Attorney - Reg. No. 37,642

Electronic Patent Application Fee Transmittal

Application Number:	14244471			
Filing Date:	03-Apr-2014			
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
First Named Inventor/Applicant Name:	John R. PLACHETKA			
Filer:	Steven Lee Highlander/Richard Ortiz			
Attorney Docket Number:	POZN.P0004US.CP1C4			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				960

Electronic Acknowledgement Receipt

EFS ID:	20088617
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard Ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	09-SEP-2014
Filing Date:	03-APR-2014
Time Stamp:	15:45:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$960
RAM confirmation Number	13839
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Post Allowance Communication - Incoming	POZNP0004USCP1C4_Resp-Exam-Stmt-Allowance.pdf	44830 a9b4a4d4d1cc36db38f8a1f35a68467faa10c00	no	3
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	POZNP0004USCP1C4_Issue-Fee-Trans-Letter.pdf	1601514 baf9ff44a25b3e9ef16358f34cb5cb7868642ad7	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30367 02d87cc5f5603f7731432d417cc8a6bffa27491	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1676711		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p>New Applications Under 35 U.S.C. 111 If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John R. PLACHETKA

Group Art Unit: 1618

Serial No.: 14/244,471

Examiner: Nissa M. Westerberg

Filing Date: April 3, 2014

Attorney Docket No.: POZN.P0004US.CP1C4

Title: PHARMACEUTICAL
COMPOSITIONS FOR THE
COORDINATED DELIVERY OF
NSAIDS

Confirmation No.: 3047

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the
United States Patent and Trademark Office via EFS-Web on the date below:

September 9, 2014 /Steven L. Highlander/
Date Steven L. Highlander

**APPLICANT'S RESPONSE TO EXAMINER'S STATEMENT OF REASONS FOR
ALLOWANCE**

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Commissioner:

This submission is in response to the examiner's statement of reasons for allowance ("Statement"), mailed on July 24, 2014, regarding the captioned application. According to the Statement, "the general state of the art is that solid oral dosage forms comprising proton pump inhibitors (PPIs) such as esomeprazole are enterically coated to prevent the acid sensitive PPI from being degraded by the acidic environment of the stomach before it can be absorbed." The Statement next states: **"While some art teaches that enteric coatings need not be applied to dosage forms containing PPIs for oral administration like those of the instant claims, those**

prior art documents do not disclose a combination dosage form as in the present claims of esomeprazole with naproxen” (emphasis added).

While agreeing with the underlined statement above, Applicant does not understand the bolded statement. First, it should be pointed out that the identity of the “some art” referred to is not clear from the record, and the statement does not identify with particularity what art is being referenced. Moreover, Applicant is unaware of any prior art “*that teaches enteric coatings need not be applied to dosage forms containing PPIs for oral administration like those of the instant claims.*”

The Statement also states that “[c]ompositions in which at least a portion of the esomeprazole is released regardless of the pH of the medium in combination with naproxen have been previously allowed (US 8,557,285).” Applicant is unsure of the scope of the referenced compositions that have been previously allowed, and as such, Applicant cannot agree that the instant claims are narrower (nor does this statement explain with particularity how the claims compare with such previously allowed claims and how any one claim is “narrower” than others).

Applicant can agree, however, that the subject matter of the allowed claims recites “a pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising: naproxen in an amount of 200-600 mg per unit dosage form; esomeprazole in an amount of from 5 to 100 mg per unit dosage form; wherein upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium, and release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher.” In addition, the subject matter of the allowed claims recites “a pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising: a core layer comprising naproxen, wherein said core layer has a coating that inhibits

release of said naproxen from said core layer unless said dosage form is in a medium with a pH of 3.5 or higher; and a layer comprising esomeprazole, wherein said layer has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient.” This subject matter is neither taught nor suggested by any art of record.

It is believed that no fee is due with this communication. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to the enclosed document, the Commissioner is authorized to deduct or credit said fees from or to Parker Highlander PLLC Deposit Account No. 50-5902/POZN.P0004US.CP1C4.

The examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Steven L. Highlander/

Steven L. Highlander
Reg. No. 37,642
Attorney for Applicant

Parker Highlander PLLC
1120 S. Capital of Texas Highway
Building One, Suite 200
Austin, Texas 78746
512-334-2900 (Telephone)
512-334-2999 (Fax)

Date: September 9, 2014



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4	3047
108197	7590	08/20/2014	EXAMINER	
Parker Highlander PLLC 1120 South Capital of Texas Highway Bldg. 1, Suite 200 Austin, TX 78746			WESTERBERG, NISSA M	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			08/20/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@phiplaw.com



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U.S. Patent and Trademark Office**

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Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
14/244,471	03 April, 2014	PLACHETKA, JOHN R.	POZN.P0004US.CP1C4

Parker Highlander PLLC 1120 South Capital of Texas Highway Bldg. 1, Suite 200 Austin, TX 78746		EXAMINER	
		Nissa Westerberg	
		ART UNIT	PAPER
		1618	20140814

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The IDS filed May 29, 2014 was considered by the Examiner. Previously lined through documents B24, C66 and C109 were submitted in application 13/215,855 on May 31, 2013, March 21, 2013 and February 1, 2013 respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa Westerberg/
Primary Examiner, Art Unit 1618

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DATE CONSIDERED: 08/14/2014

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	A37	2006-0178349	08/10/06	Plachetka
	A38	2006-0287284	12/21/06	Schutze <i>et al.</i>
	A39	2007-0122470	05/31/07	Johansson <i>et al.</i>
	A40	2007-0154542	07/05/07	Tananbaum <i>et al.</i>
	A41	2007-0184078	08/09/07	Chen
	A42	2007-0207200	09/06/07	Plachetka <i>et al.</i>
	A43	2007-0237820	10/11/07	Cheng <i>et al.</i>
	A44	2007-0243251	10/18/07	Taneja
	A45	2008-0031941	02/07/08	Pettersson
	A46	2008-0031950	02/07/08	Sesha
	A47	2008-0103169	05/01/08	Phillips
	A48	2009-0074863	03/19/09	Taneja
	A49	2009-0075950	03/19/09	Taneja
	A50	2009-0163551	06/25/09	Earnest

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A51	2009-0297594	12/03/09	Depui <i>et al.</i>
	A52	2010-0062064	03/11/10	Ault <i>et al.</i>
	A53	2010-0172983	07/08/10	Plachetka
	A54	2010-0178334	07/15/10	Johansson <i>et al.</i>
	A55	2010-0330179	12/30/10	Ault <i>et al.</i>
	A56	2012-0064156	03/15/12	Plachetka
	A57	2013-0078305	03/28/13	Plachetka
	A58	4,198,390	04/15/80	Rider
	A59	4,255,431	03/10/81	Junggren <i>et al.</i>
	A60	4,344,929	08/17/82	Bonsen <i>et al.</i>
	A61	4,508,905	04/02/85	Junggren <i>et al.</i>
	A62	4,554,276	11/19/82	LaMatina
	A63	4,562,261	12/31/85	Hirata <i>et al.</i>
	A64	4,619,934	10/28/86	Sunshine <i>et al.</i>
	A65	4,676,984	06/30/87	Wu <i>et al.</i>
	A66	4,704,278	11/03/87	Wu <i>et al.</i>
	A67	4,726,951	02/23/88	Panoz <i>et al.</i>
	A68	4,738,974	04/19/88	Brandstrom
	A69	4,757,060	07/12/88	Lukacsko <i>et al.</i>
	A70	4,758,579	07/19/88	Kohl <i>et al.</i>
	A71	4,766,117	08/23/88	Crawford <i>et al.</i>
	A72	4,786,505	11/22/88	Lovgren <i>et al.</i>
	A73	4,853,230	08/01/89	Lovgren <i>et al.</i>
	A74	4,865,847	09/12/89	Gosswein
	A75	4,948,581	08/14/90	Sawayangi <i>et al.</i>

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A76	4,965,065	10/23/90	Lukacsko <i>et al.</i>
	A77	5,026,560	06/25/91	Makino <i>et al.</i>
	A78	5,035,899	07/30/91	Saeki <i>et al.</i>
	A79	5,037,815	08/06/91	Lukacsko <i>et al.</i>
	A80	5,043,358	08/27/91	Lukacsko <i>et al.</i>
	A81	5,051,262	09/24/91	Panoz <i>et al.</i>
	A82	5,093,132	03/03/92	Makino <i>et al.</i>
	A83	5,204,118	04/20/93	Goldman <i>et al.</i>
	A84	5,260,333	11/09/93	Lukacsko <i>et al.</i>
	A85	5,364,616	11/15/91	Singer <i>et al.</i>
	A86	5,373,022	12/13/94	Fawzi <i>et al.</i>
	A87	5,409,709	04/25/95	Ozawa <i>et al.</i>
	A88	5,417,980	05/23/95	Goldman <i>et al.</i>
	A89	5,466,436	11/14/95	Stables
	A90	5,514,663	05/07/96	Mandel
	A91	5,601,843	02/11/97	Gimet
	A92	5,631,022	05/20/94	Mandel <i>et al.</i>
	A93	5,643,960	07/01/97	Breitner <i>et al.</i>
	A94	5,667,802	09/16/97	Grimberg
	A95	5,679,376	10/21/97	Stevens <i>et al.</i>
	A96	5,686,105	11/11/97	Kelm <i>et al.</i>
	A97	5,690,960	11/25/97	Bengtsson <i>et al.</i>
	A98	5,702,723	12/30/97	Griffin
	A99	5,714,504	02/03/98	Lindberg <i>et al.</i>
	A100	5,716,648	02/10/98	Halskov <i>et al.</i>

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A101	5,750,531	05/12/98	Lee <i>et al.</i>
	A102	5,817,338	10/06/98	Bergstrand <i>et al.</i>
	A103	5,817,340	10/06/98	Roche <i>et al.</i>
	A104	5,840,737	11/24/98	Phillips
	A105	5,872,145	02/16/99	Plachetka
	A106	5,877,192	03/02/99	Lindberg <i>et al.</i>
	A107	5,900,424	05/04/99	Kallstrom <i>et al.</i>
	A108	5,955,451	09/21/99	Lichtenberger <i>et al.</i>
	A109	6,013,281	01/11/00	Lundberg <i>et al.</i>
	A110	6,025,395	02/15/00	Breitner <i>et al.</i>
	A111	6,060,499	05/09/00	Plachetka
	A112	6,093,734	07/25/00	Garst <i>et al.</i>
	A113	6,126,816	12/19/00	Bohlin <i>et al.</i>
	A114	6,132,768	10/17/00	Sachs <i>et al.</i>
	A115	6,132,771	10/17/00	Depui <i>et al.</i>
	A116	6,136,344	10/24/00	Depui <i>et al.</i>
	A117	6,160,020	12/12/00	Ohannesian <i>et al.</i>
	A118	6,162,816	12/19/00	Bohlin <i>et al.</i>
	A119	6,183,776	02/06/01	Depui <i>et al.</i>
	A120	6,183,779	02/06/01	Ouali <i>et al.</i>
	A121	6,207,188	03/27/01	Gustavsson <i>et al.</i>
	A122	6,231,888	05/15/01	Lerner <i>et al.</i>
	A123	6,287,600	09/11/01	Ouali <i>et al.</i>
	A124	6,365,184	04/02/02	Depui <i>et al.</i>
	A125	6,369,085	04/09/02	Cotton <i>et al.</i>

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U.S. Patent Documents <i>See Page 1-7</i>		Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A126	6,372,255	04/16/02	Saslowski
	A127	6,387,410	05/14/02	Woolfe
	A128	6,395,298	05/28/02	Flannagan <i>et al.</i>
	A129	6,428,810	08/06/02	Bergstrand <i>et al.</i>
	A130	6,485,747	11/26/02	Flanagan <i>et al.</i>
	A131	6,489,346	12/03/02	Phillips
	A132	6,544,556	04/08/03	Chen <i>et al.</i>
	A133	6,599,529	07/29/03	Skinhoj <i>et al.</i>
	A134	6,610,323	08/26/03	Lundberg <i>et al.</i>
	A135	6,613,354	09/02/03	Depui <i>et al.</i>
	A136	6,632,451	10/14/03	Penhasi <i>et al.</i>
	A137	6,641,838	11/04/03	Pather <i>et al.</i>
	A138	6,645,988	11/11/03	Phillips
	A139	6,673,819	01/06/04	Bergman <i>et al.</i>
	A140	6,685,964	02/03/04	Bartholomaeus <i>et al.</i>
	A141	6,699,885	03/02/04	Phillips
	A142	6,713,089	03/30/04	Bertelsen <i>et al.</i>
	A143	6,749,867	06/15/04	Robinson <i>et al.</i>
	A144	6,780,882	08/24/04	Phillips
	A145	6,787,164	09/07/04	Gelber <i>et al.</i>
	A146	6,797,283	09/28/04	Edgren <i>et al.</i>
	A147	6,869,615	03/22/05	Chen <i>et al.</i>
	A148	6,875,872	04/05/05	Lindberg <i>et al.</i>
	A149	6,926,907	08/09/05	Plachetka
	A150	7,029,701	04/18/06	Chen

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A151	7,030,162	04/18/06	Plachetka <i>et al.</i>
	A152	7,060,694	06/13/06	Plachetka <i>et al.</i>
	A153	7,094,425	08/22/06	Scott <i>et al.</i>
	A154	7,332,183	02/19/08	Plachetka <i>et al.</i>
	A155	7,399,772	07/15/08	Phillips
	A156	7,411,070	08/12/08	Cotton <i>et al.</i>
	A157	7,488,497	02/10/09	Depui <i>et al.</i>
	A158	7,745,466	06/29/10	Cotton <i>et al.</i>
	A159	7,785,626	08/31/10	Pettersson <i>et al.</i>
	A160	7,846,914	12/07/10	Petrus
	A161	8,206,741	06/26/12	Plachetka <i>et al.</i>

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B1	AU 2006235929	11/30/06	Australia	Pozen Inc.
	B2	CA 2,139,653	07/10/01	Canada	Astra Aktiebolag
	B3	DE 198 01 811	01/19/98	Germany	Stada Arzneimittel AG German (English abstract)
	B4	DE 40 35 455	05/14/92	Germany	Byk Gulden Lomberg Chem Fab German (English Abstract)
	B5	EP 0 005 129	10/31/79	Europe	Haessle AB
	B6	EP 0 124 495	11/07/84	Europe	Haessle AB
	B7	EP 0 166 287	01/02/86	Europe	Byk Gulden Lomberg Chem Fab German (English Abstract)
	B8	EP 0 167 958	01/15/86	Europe	Paolo Colombo
	B9	EP 0 174 726	03/19/86	Europe	Takeda Chemical Industries Ltd.

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B10	EP 0 244 380	11/04/87	Europe	Haessle AB
	B11	EP 0 320 550	06/21/89	Europe	Bristol Myers Co.
	B12	EP 0 320 551	06/21/89	Europe	Bristol Myers Co.
	B13	EP 0 426 479 A1	05/08/91	Europe	McNeil PPC Inc.
	B14	EP 0 426 479 B1	05/08/91	Europe	McNeil PPC Inc.
	B15	EP 0 550 083	07/07/93	Europe	Glaxo Group Ltd.
	B16	EP 1 020 461	07/19/00	Europe	AstraZeneca AB
	B17	EP 1 068 867	01/17/01	Europe	Bernard Charles Sherman
	B18	EP 1 411 900	07/21/10	Europe	Pozen Inc.
	B19	EP 1 726 300	11/29/06	Europe	Flamel Technologies
	B20	EP 1 726 301	11/29/06	Europe	Flamel Technologies
	B21	GB 2 105 193	03/23/83	United Kingdom	Glaxo Group Limited
	B22	GB 2 163 747	03/05/86	United Kingdom	Nippon Chemiphar Co.
	B23	GB 2 216 413	10/11/89	United Kingdom	Glaxo Limited Group
	B24	JP 2005-145894	06/09/05	Japan	Takeda Chemical Industries Ltd. Japanese (English abstract)
	B25	WO 1985/003433	08/15/85	WIPO	Gustavsson <i>et al.</i>
	B26	WO 1990/006925	06/28/90	WIPO	Aktiebolaget Hässle
	B27	WO 1991/016886	11/14/91	WIPO	G.D. Searle & Co.
	B28	WO 1991/016895	11/14/91	WIPO	G.D. Searle & Co.
	B29	WO 1991/016896	11/14/91	WIPO	G. D. Searle & Co.
	B30	WO 1991/019711	12/26/91	WIPO	Aktiebolaget Astra
	B31	WO 1991/019712	12/26/91	WIPO	Aktiebolaget Astra
	B32	WO 1993/011750	11/14/91	WIPO	Fuisz Technologies Ltd.

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B33	WO 1993/012817	07/08/93	WIPO	Warner-Lambert Company
	B34	WO 1994/007541	04/14/94	WIPO	Merck & Co., Inc.
	B35	WO 1994/027988	12/08/94	WIPO	Astra Aktiebolag
	B36	WO 1995/001977	01/19/95	WIPO	Astra Aktiebolag
	B37	WO 1995/032959	12/07/95	WIPO	Astra Aktiebolag
	B38	WO 1996/005177	02/22/96	WIPO	Yuhan Corporation
	B39	WO 1996/005199	02/22/96	WIPO	BYK Gulden Lomberg Chemische Fabrik GMBH German (English Abstract)
	B40	WO 1996/014839	05/23/96	WIPO	Farmarc Nederland BV
	B41	WO 1996/022780	08/01/96	WIPO	The Board Of Regents of The University of Texas System
	B42	WO 1997/011701	04/03/97	WIPO	Merck-Frosst Canada Inc.
	B43	WO 1997/025064	07/17/97	WIPO	Astra Aktiebolag
	B44	WO 1998/013073	04/02/98	WIPO	Board of Regents, The University of Texas System
	B45	WO 1998/022117	05/28/98	WIPO	The Procter & Gamble Company
	B46	WO 1998/022118	05/28/98	WIPO	The Procter & Gamble Company
	B47	WO 1998/054171	12/03/98	WIPO	Astra Aktiebolag
	B48	WO 1999/000380	01/07/99	WIPO	Astra Aktiebolag
	B49	WO 1999/012524	03/18/99	WIPO	Nycomed Danmark A/S
	B50	WO 1999/029320	06/17/99	WIPO	BYK Gulden Lomberg Chemische Fabrik GMBH German
	B51	WO 1999/066919	12/29/99	WIPO	McNeil-PPC, Inc.

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Foreign Patent Documents

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	B52	WO 2000/001368	01/13/00	WIPO	Norton Healthcare Ltd.
	B53	WO 2000/015195	03/23/00	WIPO	Nycomed Danmark A/S
	B54	WO 2000/056339	09/28/00	WIPO	Pharmascience Inc.
	B55	WO 2000/071122	11/30/00	WIPO	PAR Pharmaceutical, INC.
	B56	WO 2000/072838	12/07/00	WIPO	AstraZeneca AB
	B57	WO 2000/078293	12/28/00	WIPO	AstraZeneca AB
	B58	WO 2001/024777	04/12/01	WIPO	American Home Products Corporation
	B59	WO 2001/066088	03/13/01	WIPO	AstraZeneca AB
	B60	WO 2002/022108	03/21/02	WIPO	Andrx Corporation
	B61	WO 2002/066002	08/29/02	WIPO	Glaxo Wellcome S.A.
	B62	WO 2002/098352	12/12/02	WIPO	Pozen Inc.
	B63	WO 2003/017980	03/06/03	WIPO	Takeda Chemical Industries, Ltd.
	B64	WO 2004/062552	07/29/04	WIPO	Galephar M/F
	B65	WO 2004/064815	08/05/04	WIPO	Smatrix Technologies Inc.
	B66	WO 2005/074536	08/18/05	WIPO	EISAI Co., Ltd.
	B67	WO 2005/074930	08/18/05	WIPO	Altana Pharma AG
	B68	WO 2006/044202	04/27/06	WIPO	James W. Ayres
	B69	WO 2007/064274	06/07/07	WIPO	AstraZeneca AB
	B70	WO 2007/078874	07/12/07	WIPO	Cogentus Pharmaceuticals, Inc.
	B71	WO 2008/101060	08/21/08	WIPO	Logical Therapeutics, Inc.
	B72	WO 2009/012393	01/22/09	WIPO	The Curators Of The University Of Missouri

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Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B73	WO 2009/145905	12/03/09	WIPO	Pozen Inc.
	B74	WO 2010/151697	12/29/10	WIPO	Pozen Inc.

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C1	"A 12 month, phase 3, open-label, multi-center study to evaluate the long -term safety of PN 400," <i>ClinicalTrials.gov</i> , September 11, 2007, accessed from < http://clinicaltrials.gov/ct2/show/NCT00527904 > on September 6, 2012.
	C2	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.: Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd's. Invalidity contentions pursuant to L. Pat. R. 3.6(c)," dated November 23, 2011.
	C3	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. V Lupin Ltd. And Lupin Pharmaceuticals, Inc.: Defendants Lupin Ltd. And Lupin Pharmaceuticals, Inc's Amended Invalidity Contentions Pursuant to L. PAT. R. 3.3 and 3.6(c)," dated April 20, 2012.
	C4	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v Lupin Ltd. And Lupin Pharmaceuticals Inc.: Defendants Lupin Ltd. And Lupin Pharmaceuticals, Inc.'s Invalidity Contentions Pursuant to L. Pat. R. 3.3 and 3.6(c)," dated November 23, 2011.
	C5	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v. Anchen Pharmaceuticals, Inc.: Anchen's Initial Invalidity Contentions," dated May 11, 2012.
	C6	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.: Plaintiffs' Response to DRL's First Set of Interrogatories to Plaintiffs (Nos. 1-5)," dated March 5, 2012.
	C7	"Histamine H2 antagonist," accessed from < drugs.com > on September 6, 2012.
	C8	"Notice of Paragraph IV Certification Re: Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Naproxen and Esomeprazole Magnesium Delayed Release Tablets; U.S. Patent No. 6,926,907, from Dr. Reddy's Laboratories, Ltd./Dr. Reddy's Laboratories, Inc., dated March 11, 2011.

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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C9	"PK Study to evaluate esomeprazole plasma levels following the administration of PN 400," <i>ClinicalTrials.gov</i> , January 11, 2008, accessed from < http://clinicaltrials.gov/ct2/show/NCT00599404 > on September 6, 2012.
	C10	"Study evaluating the bioavailability of Naproxen 500 mg in three formulations," <i>ClinicalTrials.gov</i> , April 23, 2008, accessed from < http://clinicaltrials.gov/ct2/show/NCT00665743 >, on September 6, 2012.
	C11	Abelo <i>et al.</i> , "Pharmacodynamic modeling of reversible gastric acid pump inhibition in dog and man," <i>European Journal of Pharmaceutical Sciences</i> , 14:339-346, 2001.
	C12	Alberts <i>et al.</i> , "Efficacy and Safety of PA, a Novel Combination of Enteric-Coated Aspirin and Immediate-Release Omeprazole," <i>International Stroke Conference</i> , 2009, retrieved from the Internet at: http://www.pozen.com/wp-content/uploads/2011/08/ISC2009Albertsfile.pdf , retrieved December 14, 2012.
	C13	Alexander <i>et al.</i> , "Pilot evaluation of a novel combination table (PN 400) containing a proton pump inhibitor and a nonsteroidal anti-inflammatory drug in prevention of upper gastrointestinal mucosal injury," <i>American Journal of Gastroenterology</i> , 100(9), S68, 135, 2005.
	C14	Andersson, "Pharmacokinetics, metabolism and interactions of acid pump inhibitors," <i>Clin. Pharmacokinet.</i> , 31(1):9-28, 1996.
	C15	Anonymous, "Evaluate Relative Bioavailability of PA32540 (Asa/Omeprazole), Its Aspirin Component, and Ecotrin in Healthy Volunteers," <i>ClinicalTrials.gov</i> , March 7, 2008, retrieved from the Internet at: http://www.clinicaltrials.gov/ct2/show/NCT00632086?term=aspirin+omeprazole&rank=18 , retrieved on December 28, 2012.
	C16	Anonymous, "POZEN's PA32520 Study Data Demonstrated Better Upper Gastrointestinal Protection," <i>Drugs.com</i> , November 11, 2008, retrieved from the Internet at: http://www.drugs.com/clinical_trials/pozen-s-pa32520-study-data-demonstrated-better-upper-gastrointestinal-protection-6195.html , retrieved December 17, 2012.
	C17	Anonymous, "Study Evaluating the Effect of Gastroduodenal Mucosa of PA32540, A32540 and Celecoxib, and Aspirin with Celecoxib (PA32540-109)," <i>ClinicalTrials.gov</i> , January 9, 2009, retrieved from the Internet at: http://www.clinicaltrials.gov/ct2/show/NCT00700687?term=aspirin+omeprazole&rank=36 , retrieved December 18, 2012.

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Exam. Init.	Ref. Des.	Citation
	C18	Anonymous, "Study to Evaluate the Incidence of Gastric Ulcers Following Administration of Either PA32540 or Enteric Coated Aspiring 325 mg in Subjects Who Are at Risk for Developing Aspirin-Associated Ulcers," <i>ClinicalTrials.gov</i> , August 17, 2009, retrieved from the Internet at: http://clinicaltrials.gov/archive/NCT00960869/2009_08_17 , retrieved December 18, 2012.
	C19	Approval of Amendments/correction filed May 10, 2010 dated June 21, 2010 (European application issued as EP 1 411 900 B1). (Attorney Docket No.: POZN.P0004EP)
	C20	Awtry <i>et al.</i> , "Aspirin," <i>Circulation</i> , 101:1206-1218, 2000.
	C21	Bajbouj <i>et al.</i> , "A prospective multicenter clinical and endoscopic follow-up study of patients with gastroesophageal reflux disease," <i>Z. Gastroenterol.</i> , 43:1303-1307, 2005.
	C22	Ballinger <i>et al.</i> , "COX-2 inhibitors versus NSAIDs in gastrointestinal damage and prevention," <i>Exp. Opin. Pharmacother.</i> , 2(1):31-40, 2001.
	C23	Barnett <i>et al.</i> , "Effects of SCH 32651 on resting and stimulated acid secretion in guinea-pig isolated fundic mucosa," <i>Br. J. Pharmac.</i> , 83:75-82, 1984.
	C24	Berardi <i>et al.</i> , "Elevation of gastric pH with ranitidine does not affect the release characteristics of sustained release ibuprofen tablets," <i>Biopharmaceutics & Drug Disposition</i> , 9:337-347, 1998.
	C25	Bergmann <i>et al.</i> , "Protection against aspirin-induced gastric lesions by lansoprazole: simultaneous evaluation of functional and morphologic responses," <i>Clin. Pharmacol. Ther.</i> , 52:413-416, 1992.
	C26	Bianchi Porro <i>et al.</i> , "Pantoprazole versus placebo in prevention of NSAID-induced ulcers," <i>Gastroenterology</i> , 114(4):A74, 1998.
	C27	Bianchi Porro <i>et al.</i> , "Prevention of gastroduodenal damage with omeprazole in patients receiving continuous NSAIDs treatment. A double blind placebo controlled study," <i>Ital. J. Gastroenterol. Hepatol.</i> , 30:43-47, 1998.
	C28	Bianchi Porro <i>et al.</i> , "Why are non-steroidal anti-inflammatory drugs important in peptic ulcers?" <i>Aliment. Pharmacol. Therap.</i> , 1:540S-547S, 1987.
	C29	Bigard <i>et al.</i> , "Complete prevention by omeprazole of aspirin induced gastric lesions in healthy subjects," <i>Gut</i> , 29(5):A712, T49, 1988.

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	C30	Bigard <i>et al.</i> , "Effet protecteur de l'omeprazole sur les lésions gastriques induites par une prise unique d'aspirine chez l'homme," <i>Gastroenterol. Clin. Biol.</i> , 12:770-771, 1998.
	C31	Bombardier <i>et al.</i> , "Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis," <i>N. Engl. J. Med.</i> , 343:1520-1528, 2000.
	C32	Brown <i>et al.</i> , "Aspirin- and indomethacin-induced ulcers and their antagonism by antihistamines," <i>Euro. J. Pharm.</i> , 51:275-283, 1978.
	C33	Brown <i>et al.</i> , "Prevention of the gastrointestinal adverse effects of nonsteroidal anti-inflammatory drugs," <i>Pract. Drug Safety</i> , 21:503-512, 1999.
	C34	Byrn <i>et al.</i> , "Pharmaceutical solids: A strategic approach to regulatory considerations," <i>Pharm. Res.</i> , 12(7): 945-954, 1995.
	C35	Carrasco-Portugal <i>et al.</i> , "Bioavailability of a formulation containing a diclofenac-rantidine combination," <i>Proc. West. Pharmacol. Soc.</i> , 45:8-10, 2002.
	C36	Chan <i>et al.</i> , "Clopidogrel versus Aspirin and Esomeprazole to prevent recurrent ulcer bleeding," <i>New Eng. J. Med.</i> , 352:238-244, 2005.
	C37	Chan <i>et al.</i> , "Eradication of H. Pylori versus maintenance acid suppression to prevent recurrent ulcer hemorrhage in high risk NSAID users: A prospective randomized study," <i>Gastroenterology</i> , 114: A87, G0356, 1998.
	C38	Chandramouli <i>et al.</i> , "Prevention and management of NSAID-Induced gastropathy," <i>Journal of Pharmaceutical Pain and Symptom Control</i> , 8(4):27-40, 2000.
	C39	Chang <i>et al.</i> , "Polymethacrylates," In: Handbook of Pharmaceutical Excipients, Fifth Edition, Ed. Raymond C. Rowe, Paul J. Sheskey and Sian C. Owen, London: Pharmaceutical Press, pages 553-560, 2006.
	C40	Chen <i>et al.</i> , "Esomeprazole tablet vs. omeprazole capsule in treating erosive esophagitis," <i>World Journal of Gastroenterology</i> , 11(20):3112-3117, 2005.
	C41	Cullen <i>et al.</i> , "Primary gastroduodenal prophylaxis with omeprazole for non-steroidal anti-inflammatory drug users," <i>Aliment. Pharmacol. Ther.</i> , 12:135-140, 1998.
	C42	Dajani, "Perspective on the gastric antisecretory effects of misoprostol in man," <i>Prostaglandins</i> , 33:68-77, 1987.

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Exam. Init.	Ref. Des.	Citation
	C43	Daneshmend <i>et al.</i> , "Abolition by omeprazole of aspirin induced gastric mucoasal injury in man," <i>Gut</i> , 31:514-517, 1990.
	C44	Daneshmend <i>et al.</i> , "Use of microbleeding and an ultrathin endoscope to assess gastric mucosal protection by famotidine," <i>Gastroenterology</i> , 97:944-9, 1989.
	C45	Data sheet for "Arthrotec," 2009. (Document D8 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C46	Dent, "Why proton pump inhibition should heal and protect against nonsteroidal anti-inflammatory drug users," <i>Am. J. Med.</i> , 104:52S-55S, 1998.
	C47	Ehsanullah <i>et al.</i> , "Prevention of gastroduodenal damage induced by non-steroidal anti-inflammatory drugs: controlled trial of ranitidine," <i>BMJ</i> , 297:1017-1021, 1998.
	C48	Ekstrom <i>et al.</i> , Prevention of peptic ulcer and dyspeptic symptoms with omeprazole in patients receiving continuous non-steroidal anti-inflammatory drug therapy," <i>Scand. J. Gastroenterol.</i> , 31:753-758, 1996.
	C49	Ene <i>et al.</i> , "A study of the inhibitory effects of SCH 28080 on gastric secretion in man," <i>Br. J. Pharmac.</i> , 76:389-391, 1982.
	C50	English translation of Bigard, <i>et al.</i> , <i>Gastroenterol. Clin. Biol.</i> , 12:770-771, 1998.
	C51	English translation of Muller <i>et al.</i> , <i>Arzneimittel Forschung</i> , 47:758-760, 1997.
	C52	English translation of Muller <i>et al.</i> , <i>Arzneimittel-Forschung/Drug Res.</i> , 41(1):638-639, 1991.
	C53	English translation of Simon <i>et al.</i> , <i>Arzneimittel Forschung</i> , 45:701-703, 1995.
	C54	Erlandsson <i>et al.</i> , "Resolution of the enantiomers of omeprazole and some of its analogues by liquid chromatography on a trisphenylcarbamoylcellulose-based stationary phase," <i>J. Chromatogr.</i> , 532:305-319, 1990.
	C55	European Search Report and Opinion issued in European application No. EP 09 17 8773, dated February 11, 2010. (Attorney Docket No. POZN.P0004EP.D1)
	C56	European Search Report issued in European application No. EP 02 734 602.2, dated May 29, 2007. (Attorney Docket No.: POZN.P0004EP)
	C57	Extended European Search Report issued in European Patent Application No. 10792681.8, dated January 4, 2013. (Attorney Docket No.: POZN.P0006EP)

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	C58	Fass, "Erosive Esophagitis and Nonerosive Reflux Disease (NERD): Comparison of Epidemiologic, Physiologic, and Therapeutic Characteristics," <i>J. Clin. Gastroenterol.</i> , 41(2):131-137, 2007.
	C59	Feldman and Carlstedt, "Effect of antacid on absorption of enteric-coated aspirin," <i>JAMA</i> , 227(6):660-1, 1974.
	C60	Florence and Jani, "Novel oral drug formulations their potential in modulating adverse effects," <i>Drug Safety</i> , 10(3):233-66, 1994.
	C61	Fort <i>et al.</i> , "Pa, a novel combination of delayed release (DR) aspirin (ASA) and immediate-release (IR) omeprazole, is associated with a decreased risk of gastroduodenal mucosal injury: Pooled data from three Phase I, 4-week endoscopic studies," <i>American Journal of Gastroenterology</i> , 103(Suppl. S):S487-S488, 2008.
	C62	Frank <i>et al.</i> , "Reduction of indomethacin induced gastroduodenal mucosal injury and gastrointestinal symptoms with cimetidine in normal subjects," <i>J. Rheum.</i> , 16:1249-1252, 1989.
	C63	Gengo <i>et al.</i> , "Prevalence of platelet nonresponsiveness to aspirin in patients treated for secondary stroke prophylaxis and in patients with recurrent isochemic events," <i>J. Clin. Pharmacol.</i> , 48:335-343, 2008.
	C64	Goldstein <i>et al.</i> , "PN400 significantly reduces the incidence of gastric ulcers compared with enteric-coated naproxen in patients requiring chronic NSAID therapy regardless of low-dose aspirin use: Results from two prospective, randomized controlled trials," POZEN Inc. sponsored study, 2009. (Document D16 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C65	Goldstein <i>et al.</i> , "116 A single table multilayer formulation of enteric-coated naproxen coupled with no-enteric-coated omeprazole is associated with a significantly reduced incidence of gastric ulcers vs. enteric-coated naproxen: A prospective, randomized double-blind study," 134(4), Supplement 1, A-19, 2008.
	C66	Goldstein <i>et al.</i> , "PA32540 (Enteric-coated aspirin 325 mg + immediate-release omeprazole 40mg) is associated with significantly fewer gastric ulcers and significantly less endoscopic erosive esophagitis than enteric-coated aspirin (EC-ASA) alone: Results of two phase 3 studies," <i>The American Journal of Gastroenterology</i> , Vol. 107, Suppl. 1, pages S53-S54, 2012.

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	C67	Goldstein <i>et al.</i> , "PN400 significantly improves upper gastrointestinal tolerability compared with enteric-coated naproxen alone in patients requiring chronic NSAID therapy: Results from Two Prospective, Randomized, Controlled Trials," POZEN Inc. sponsored study, 2009. (Document D15 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C68	Graham <i>et al.</i> , "Duodenal and gastric ulcer prevention with misoprostol in arthritis patients taking NSAIDs," <i>Ann. Intern. Med.</i> , 119(4):257-262, 1993.
	C69	Grosser <i>et al.</i> , "Thromboxane generation," In: Platelets, Alan Michelson Ed., pages 565-574, Elsevier Science, 2007.
	C70	Gurbel <i>et al.</i> , "Abstract 4267; PA32520 (Single-tablet of enteric-coated aspirin 325 mg + Immediate-release Omeprazole 20 mg); Aspirin therapy combining greater thromboxane suppression and lower upper gastrointestinal damage," <i>Circulation</i> , 118:S_855, 2008.
	C71	Gurbel <i>et al.</i> , "PA32520 (Single-tablet of Immediate-Release Omeprazole 20 mg + Enteric-Coated Aspirin 325 mg): Safer Aspirin Therapy with Greater Thromboxane Suppression," July 2009, retrieved from the Internet at: http://www.pozen.com/wp-content/themes/pozen/images/pdf/ISTH2009%20Pozen%20draft0701.pdf , retrieved December 18, 2012.
	C72	Hart <i>et al.</i> , "Aspirin dosage and thromboxane synthesis in patients with vascular disease," <i>Pharmacotherapy</i> , 23(5):579-584, 2003.
	C73	Hassan-Alin <i>et al.</i> , "Lack of drug-drug interaction between esomeprazole and naproxen in healthy subjects," <i>Gastroenterology</i> , 124(4), Suppl.1, A541, 2003.
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	C75	Hawkey <i>et al.</i> , "Prophylaxis of aspirin-induced gastric mucosal bleeding with ranitidine," <i>Aliment. Pharmacol. Therap.</i> , 2:245-252, 1988.
	C76	Hawkey <i>et al.</i> , "Strategies for preventing aspirin-induced gastric bleeding," <i>Scandinavian Journal of Gastroenterology</i> , Vol. 21, Supplement 125, pages 170-173, 1986.
	C77	Hawkey, "Non-steroidal anti-inflammatory drug gastropathy: causes and treatment," <i>Scand. J. Gastroenterol.</i> , 31 Suppl. 220:124-7, 1996.

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	C79	Hawkins <i>et al.</i> , "The Gastroduodenal Toxicity of Nonsteroidal Anti-Inflammatory Drugs. A Review of the Literature," <i>J. Pain and Symptom Management</i> , 20(2):140-151, 2000.
	C80	Helander <i>et al.</i> , "Structure and function of rat parietal cells during treatment with omeprazole, SCH 28080, SCH 32651, or ranitidine," <i>Scand. J. Gastroenterol.</i> , 25:799-809, 1990.
	C81	Hogan <i>et al.</i> , "Prescription of nonsteroidal anti-inflammatory drugs for elderly people in Alberta," <i>Can. Med. Assoc.</i> , 151(3):315-322, 1994.
	C82	Howden, "Clinical pharmacology of omeprazole," <i>Clin. Pharmacokinet.</i> , 20:38-49, 1991.
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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C92	Konturek <i>et al.</i> , "Effects of omeprazole, a substituted benzimidazole, on gastrointestinal secretions, serum gastrin, and gastric mucosal blood flow in dogs," <i>Gastroenterology</i> , 86(1): 71-77, 1984.
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	C94	Lad <i>et al.</i> , "Management of nonsteroidal anti-inflammatory drug-induced gastroduodenal disease by acid suppression," <i>Can. J. Gastroenterol.</i> , 13:135-142, 1999.
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	C102	Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009. (Attorney Docket No.: POZN.P0004EP)
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	C105	Maggi <i>et al.</i> , "Press-coated tablets for the sequential pulsed administration of two different drugs," <i>Int. J. Pharm.</i> , 99:173-179, 1993.
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	C111	Miner <i>et al.</i> , "T1969 Gastric acid suppression with PN400, a single-tablet, multilayer, fixed dose formulation combining an immediate-release esomeprazole layer and an enteric-coated (EC) naproxen core," <i>Gastroenterology</i> , 136(5), Suppl. 1, A-611, 2009.
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	C113	Morgner <i>et al.</i> , "Esomeprazole: prevention and treatment of NSAID-induced symptoms and ulcers," <i>Expert Opin Pharmacother.</i> , 8(7):975-988, 2007.
	C114	Morris <i>et al.</i> , "Gastric cytoprotection is secondary to increased mucosal fluid secretion: A study of six cytoprotective agents in the rat," <i>J. Clin. Gastroenterol.</i> , 27(Suppl. 1):S53-63, 1998.

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	C118	Naesdal <i>et al.</i> , "Gastro-duodenal protection in an era of cyclo-oxygenase-2-selective nonsteroidal anti-inflammatory drugs," <i>European Journal of Gastroenterology & Hepatology</i> , 13(12):1401-1406, 2001.
	C119	Nefesoglu <i>et al.</i> , "Interaction of omeprazole with enteric-coated Salicylate tablets," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , 36(10):549-553, 1998.
	C120	Neuvonen and Kivisto, "Enhancement of drug absorption by antacids," <i>Clin. Pharmacokinet.</i> , 27(2):120-8, 1994.
	C121	Notice of Allowance issued in United States Patent Application No. 10/158,216, dated March 29, 2005. (Attorney Docket No. POZN.P0004US)
	C122	Notice of Allowance issued in United States Patent Application No. 11/129,320, dated May 11, 2012. (Attorney Docket No. POZN.P0004US.CP1)
	C123	Notice of Opposition to a European Patent, submitted against European Patent application No. EP 1 411 900 on April 15, 2011. (Attorney Docket No.: POZN.P0004EP)
	C124	Notice of Opposition to a European Patent, submitted against European Patent application No. EP 1 411 900 on April 20, 2011. (Attorney Docket No.: POZN.P0004EP)
	C125	Oddsson <i>et al.</i> , "Comparison between ranitidine and omeprazole for protection against gastroduodenal damage caused by naproxen," <i>Scand. J. Gastroenterol.</i> , 27:1045-1048, 1992.
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	C127	Office Communication issued in Australian Patent Application No. 2010266026, dated December 11, 2013. (Attorney Docket No. POZN.P0006AU)

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	C128	Office Communication issued in Canadian Patent Application No. 2,449,098, dated November 6, 2008. (Attorney Docket No.: POZN.P0004CA)
	C129	Office Communication issued in Chinese Patent Application No. 201080037566.1, dated January 10, 2014. (Attorney Docket No. POZN.P0006CN) (English translation of Chinese text)
	C130	Office Communication issued in Egyptian Patent Application No. 2121/2001, dated April 13, 2013. (Attorney Docket No. PZAZ.P0003EG)
	C131	Office Communication issued in Eurasian Patent Application No. 201270071, dated August 5, 2013. (Attorney Docket No. POZN.P0006EA) (English translation of Russian text)
	C132	Office Communication issued in European Patent Application 10 177 150.9, dated November 4, 2010. (Attorney Docket No.: POZN.P0004EP.D1D1)
	C133	Office Communication issued in European Patent Application No. 02 734 602.2, dated June 30, 2008. (Attorney Docket No.: POZN.P0004EP)
	C134	Office Communication issued in European Patent Application No. 02 734 602.2, dated December 18, 2007. (Attorney Docket No. POZN.P0004EP)
	C135	Office Communication issued in European Patent Application No. 02 734 602.2, dated February 22, 2010. (Attorney Docket No.: POZN.P0004EP)
	C136	Office Communication issued in European Patent Application No. 02 734 602.2, dated April 29, 2010. (Attorney Docket No.: POZN.P0004EP)
	C137	Office Communication issued in European Patent Application No. 10 177 150.9, dated November 12, 2010. (Attorney Docket No.: POZN.P0004EP.D1D1)
	C138	Office Communication issued in Israeli Patent Application No. 159129, dated August 22, 2010. (English translation) (Attorney Docket No. POZN.P0004IL)
	C139	Office Communication issued in Israeli Patent Application No. 159129, dated February 16, 2010. (English translation) (Attorney Docket No. POZN.P0004IL)
	C140	Office Communication issued in Israeli Patent Application No. 159129, dated July 7, 2009. (English translation) (Attorney Docket No. POZN.P0004IL)
	C141	Office Communication issued in Israeli Patent Application No. 159129, dated August 8, 2007. (English translation) (Attorney Docket No. POZN.P0004IL)

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	C142	Office Communication issued in Japanese Patent Application No. 2003-501394, dated July 25, 2008. (English translation) (Attorney Docket No. POZN.P0004JP)
	C143	Office Communication issued in Japanese Patent Application No. 2003-501394, dated January 5, 2010. (English translation) (Attorney Docket No. POZN.P0004JP)
	C144	Office Communication issued in Norwegian Patent Application No. 20035275, dated July 14, 2011. (English Translation) (POZN.P0004NO)
	C145	Office Communication issued in United States Patent Application No. 10/158,216, dated April 22, 2004. (Attorney Docket No.: POZN.P0004US)
	C146	Office Communication issued in United States Patent Application No. 10/158,216, dated October 20, 2004. (Attorney Docket No.: POZN.P0004US)
	C147	Office Communication issued in United States Patent Application No. 13/215,855, dated February 28, 2013. (Attorney Docket No. POZN.P0004US.CP1D2)
	C148	Office Communication issued in United States Patent Application No. 13/215,855, dated June 6, 2012. (Attorney Docket No. POZN.P0004US.CP1D2)
	C149	Office Communication issued in United States Patent Application No. 11/129,320, dated October 25, 2010. (Attorney Docket No. POZN.P0004US.CP1)
	C150	Office Communication issued in United States Patent Application No. 11/129,320, dated November 19, 2009. (Attorney Docket No. POZN.P0004US.CP1)
	C151	Office Communication issued in United States Patent Application No. 11/129,320, dated March 30, 2009. (Attorney Docket No. POZN.P0004US.CP1)
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	C155	Office Communication issued in United States Patent Application No. 12/823,082, dated July 18, 2013. (Attorney Docket No. POZN.P0006US)

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	C166	Okabe <i>et al.</i> , "Antisecretory effect of leminoprazole on histamine-stimulated gastric acid secretion in guinea pigs: local effect," <i>J. Pharmacol.</i> , 69:91-100, 1995.
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	C169	Pang <i>et al.</i> , "Modeling of intestinal drug absorption: roles of transporters and metabolic enzymes (for the Gillette review series)" <i>Drug Metabolism and Disposition</i> , 31(12): 1507-1519, 2003.
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	C173	PCT International Preliminary Report on Patentability issued in International Patent Application No. PCT/GB2009/051108, dated March 24, 2011. (Attorney Docket No. PZAZ.P0003WO)
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	C176	PCT International Search Report and Written Opinion issued in International Patent Application No. PCT/SE2010/050712, dated September 20, 2010. (Attorney Docket No. PZAZ.P0002WO)
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Exam. Init.	Ref. Des.	Citation
	C182	Petersen, "Doubts are raised on the safety of 2 popular arthritis drugs," <i>NY Times</i> , page C1, Published May 22, 2001.
	C183	Pilbrant <i>et al.</i> , "Development of an oral formulation of omeprazole," <i>Scand. J. Gastroenterol.</i> , 20(Suppl. 109):113-120, 1985.
	C184	Pirmohamed <i>et al.</i> , "Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients," <i>Br. Med. J.</i> , 329:15-19, 2004.
	C185	Porter S.C., "Coating of Pharmaceutical Dosage Forms," in: A. Gennaro (Ed.), <i>Remington: the Science and Practice of Pharmacy</i> , 19 th edition. 1650-1651, 1995.
	C186	Preliminary Amendment filed in United States Patent Application No. 13/475,446, filed May 18, 2012. (Attorney Docket No. POZN.P0004US.CP1C1)
	C187	Press Release for "Vimovo, October 16, 2009. (Document D14 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C188	Qureshi <i>et al.</i> , "Pharmacokinetics of two enteric-coated ketoprofen products in humans with or coadministration of omeprazole and comparison with dissolution findings," <i>Pharmaceutical Research</i> , 11(11):1669-1672, 1994.
	C189	Ramage <i>et al.</i> , "Inhibition of food stimulated acid secretion by misoprostol, an orally active synthetic E1 analogue prostaglandin," <i>Br. J. Clin Pharmacol.</i> , 19:9-12, 1985.
	C190	Raskin <i>et al.</i> , "Misoprostol dosage in the prevention of nonsteroidal anti-inflammatory drug-induced gastric and duodenal ulcers: a comparison of three regimens," <i>Ann. Intern. Med.</i> , 123(5):344-350, 1995.
	C191	<i>Remington's Pharmaceutical Sciences</i> , 17th ed., University of Sciences in Philadelphia, 1985.
	C192	Reply to EPO communication of April 29, 2010, dated May 10, 2010 (German and French translation of claims omitted).
	C193	Richardson <i>et al.</i> , "Proton pump inhibitors, pharmacology and rationale for use in gastrointestinal disorders," <i>Drugs</i> , 56(3):307-35, 1998.
	C194	Robinson <i>et al.</i> , "Effects of ranitidine gastroduodenal mucosal damage induced by nonsteroidal anti-inflammatory drugs," <i>Dig. Disc. Sci.</i> , 34(3):424-428, 1989.
	C195	Roche Naproxen EC label, copyright 1999.

{00147031}

EXAMINER:

/Nissa Westerberg/

DATE CONSIDERED:

08/14/2014

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents See Page 1-7	Foreign Patent Documents See Page 7-11	Other Art See Page 11-29

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C196	Roth <i>et al.</i> , "Cimetidine therapy in nonsteroidal anti-inflammatory drug gastropathy: double-blind long-term evaluation," <i>Arch. Intern. Med.</i> , 147:1798-1801, 1987.
	C197	Rubinstein, "Gastrointestinal anatomy physiology and permeation pathways," <i>Enhancement in Drug Discovery</i> , CRC Press, 3-35, 2007.
	C198	Sangiah <i>et al.</i> , "Effects of misoprostol and omeprazole on basal gastric pH and free acid content in horses," <i>Res. Vet. Sci.</i> , 47(3):350-354, 1989.
	C199	Savarino <i>et al.</i> , "Effect of one-month treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) on gastric pH of rheumatoid arthritis patients," <i>Digestive Diseases and Sciences</i> , 43:459-463, 1998.
	C200	Scarpignato <i>et al.</i> , "Towards a GI safer anti-inflammatory therapy," <i>Gastroenterology International</i> , 186-215, 1999.
	C201	Scheiman <i>et al.</i> , "Omeprazole ameliorates aspirin-induced gastroduodenal injury," <i>Digestive Diseases and Sciences</i> , 39(1):97-103, 1994.
	C202	Scheiman, "NSAID-induced peptic ulcer disease: a critical review of pathogenesis and management," <i>Dig. Dis.</i> , 12:210-222, 1994.
	C203	Scheiman, "Pathogenesis of gastroduodenal injury due to nonsteroidal and anti-inflammatory drug: Implications for prevention and therapy," <i>Seminars in Arthritis and Rheumatism</i> , 21(4):259-268, 1992.
	C204	Scott and Sundell, "Inhibition of H+K+ ATPase by SCH 28080 and SCH 32651," <i>European Journal of Pharmacology</i> , 112:268-270, 1985.
	C205	Seitz <i>et al.</i> , "Tablet Coating," In: The Theory and Practice of Industrial Pharmacy. Eds. Leon Lachman, Herbert A. Lieberman and Joseph L. Kanig. Philadelphia: Lea & Febiger, pages 346-373, 1986.
	C206	Selway, "Potential hazards of long-term acid suppression," <i>Scand. J. Gastroenterol.</i> , 25(Suppl. 178):85-92, 1990.
	C207	Sharma <i>et al.</i> , "Comparison of 24-hour intragastric pH using four liquid formulations of lansoprazole and omeprazole," <i>Am. J. Health-Syst. Pharm.</i> , 56(Suppl. 4):S18-21, 1999.
	C208	Silverman, <i>The Organic Chemistry of Drug Design and Drug Action</i> , 2 nd Edition, Academic Press, p. 102 & p. 527, 2004.

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	Filing Date: April 3, 2014	Group: 1615
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C209	Silverstein <i>et al.</i> , "Gastrointestinal toxicity with Celecoxib versus nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis; the CLASS study: A randomized controlled trial," <i>JAMA</i> , 284:1247-1255, 2000.
	C210	Silverstein <i>et al.</i> , "Misoprostol reduces serious gastrointestinal complications in patients with rheumatoid arthritis receiving nonsteroidal anti-inflammatory drugs," <i>Ann. Intern. Med.</i> , 123(4):241-249, 1995.
	C211	Simon <i>et al.</i> , "Schutzwirkung von omeprazol gegenüber niedrig dosierter acetylsalicylsäure," <i>Arzneimittel Forschung</i> , 45:701-703, 1995.
	C212	Summons to Attend Oral Proceedings Pursuant to Rule 116(1): EPC, dated September 3, 2009, issued in European Patent Application No. 02, 734 602.2. (Attorney Docket No.: POZN.P0004EP)
	C213	Sung, "Management of nonsteroidal anti-inflammatory drug-related peptic ulcer bleeding," <i>Am. J. Med.</i> , 110(1A): 29S-32S, 2001.
	C214	Taha <i>et al.</i> , "Famotidine for the prevention of peptic ulcers and oesophagitis in patients taking low-dose aspirin (FAMOUS): a phase III, randomized, double-blind, placebo-controlled trial," <i>Lancet</i> , 374:119-25, 2009.
	C215	Takeuchi <i>et al.</i> , "Effects of topical application of acidified omeprazole on acid secretion and transmucosal potential difference in anesthetized rat stomachs," <i>Japan J. Pharmacol.</i> , 47:397-408, 1988.
	C216	Tronstad <i>et al.</i> , "Gastroscopic findings after treatment with enteric-coated and plain naproxen tablets in healthy subjects," <i>Scand. J. Gastroenterol.</i> , 20:239-242, 1985.
	C217	Vane <i>et al.</i> , "The future of NSAID therapy: selective COX-2 inhibitors," <i>IJCP</i> , 54(1):7-9, January/February 2000.
	C218	von Unge <i>et al.</i> , "Stereochemical assignment of the enantiomers of omeprazole from X-ray analysis of a fenchyloxymethyl derivative of (+)-(R)- omeprazole," <i>Tetrahedron</i> , 8(12):1967-1970, 1997.
	C219	Wagner <i>et al.</i> , "Effects of nonsteroidal anti-inflammatory drugs on ulcerogenesis and gastric secretion in pylorus-ligated rat," <i>Digestive Diseases and Sciences</i> , 40:134-140, 1995.
	C220	Wakitani <i>et al.</i> , "Profile of JTE-522 as a human cyclooxygenase-2 inhibitor," <i>Jpn. J. Pharmacol.</i> , 78:365-371, 1998.

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/Nissa Westerberg/

DATE CONSIDERED:

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List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C221	Wallmark <i>et al.</i> , "The relationship between gastric acid secretion and gastric H ⁺ , K ⁺ -ATPase activity," <i>J. Biol. Chem.</i> , 260(25): 13681-13684, 1985.
	C222	Warner <i>et al.</i> , "Nonsteroidal drug selectives for cyclo-oxygenase-1 rather than cyclo-oxygenase-2 are associated with human gastrointestinal toxicity: a full in vitro analysis," <i>Proc. Natl. Acad. Sci. USA</i> , 96:7563-7568, 1999.
	C223	Weil <i>et al.</i> , "Prophylactic aspirin and risk of peptic ulcer bleeding," <i>BMJ</i> , 310: 827-830, 1995.
	C224	Wilson <i>et al.</i> , "Effects of misoprostol on gastric acid and mucus secretion in man," <i>Digestive Diseases and Sciences</i> , 31(2): 126S-129S, 1986.
	C225	Wolfe <i>et al.</i> , "Acid suppression: optimizing therapy for gastroduodenal ulcer healing, gastroesophageal reflux disease, and stress related erosive syndrome," <i>Gastroenterology</i> , 118(2):S9-S31, 2000.
	C226	Wolfe <i>et al.</i> , "Gastrointestinal toxicity of nonsteroidal anti-inflammatory drugs," <i>N. Engl. J. Med.</i> , 340:1888-1899, 1999.
	C227	Yeomans <i>et al.</i> , "A comparison of omeprazole with ranitidine for ulcers associated with nonsteroidal anti-inflammatory drugs," <i>N. Engl. J. Med.</i> , 338:719-726, 1998.
	C228	Yeomans <i>et al.</i> , "Efficacy of esomeprazole (20 mg once daily) for reducing the risk of gastroduodenal ulcers associated with continuous use of low-dose aspirin," <i>American Journal of Gastroenterology</i> , 103:1-9, 2008.
	C229	Yeomans <i>et al.</i> , "New data on healing of nonsteroidal anti-inflammatory drug-associated ulcers and erosions," <i>Am. J. Med.</i> , 104:56S-61S, 1998.

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4

CONFIRMATION NO. 3047

108197
Parker Highlander PLLC
1120 South Capital of Texas Highway
Bldg. 1, Suite 200
Austin, TX 78746

PUBLICATION NOTICE



OC00000069927912

Title:PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

Publication No.US-2014-0212489-A1

Publication Date:07/31/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

108197 7590 07/24/2014
Parker Highlander PLLC
1120 South Capital of Texas Highway
Bldg. 1, Suite 200
Austin, TX 78746

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/24/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CPIC4	3047

TITLE OF INVENTION: PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	10/24/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4	3047

TITLE OF INVENTION: PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	10/24/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
WESTERBERG, NISSA M	1618	424-463000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

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- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for requirements and certifications.

Authorized Signature

Typed or printed name

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Registration No.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4	3047

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Austin, TX 78746

EXAMINER

WESTERBERG, NISSA M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 07/24/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/244,471	Applicant(s) PLACHETKA, JOHN R.	
	Examiner Nissa Westerberg	Art Unit 1618	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to TDs filed 7/14/14.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 57-75. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see <http://www.uspto.gov/patentprosecutionhighway/articles.jsp> or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____ |
| 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ | |

/Nissa Westerberg/
Primary Examiner, Art Unit 1618

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: the general state of the art is that solid oral dosage forms comprising proton pump inhibitors (PPIs) such as esomeprazole are enterically coated to prevent the acid sensitive PPI from being degraded by the acidic environment of the stomach before it can be absorbed. While some art teaches that enteric coatings need not be applied to dosage forms containing PPIs for oral administration like those of the instant claims, those prior art documents do not disclose a combination dosage form as in the present claims of esomeprazole with naproxen. Prior art that discloses a combination of an NSAID such as naproxen enterically coat the naproxen and PPI portions of the dosage form. Compositions in which at least a portion of the esomeprazole is released regardless of the pH of the medium in combination with naproxen have been previously allowed (US 8,557,285). The instant claims are narrower, specifying dosages in milligrams or having a non-enteric film coat layer with esomeprazole that releases the esomeprazole to the stomach upon ingestion.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Notice of Pre-AIA or AIA Status

2. The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

3. The terminal disclaimer filed on July 14, 2014 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,926,907, 8,206,741 or 8,557,285 or any patent granted on U.S. Application Nos. 14/045,156 or 14/231,971 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

4. Copies of the lined through documents could not be located in the file wrappers of any of the family members in this case.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa Westerberg/
Primary Examiner, Art Unit 1618

<i>Examiner-Initiated Interview Summary</i>	Application No. 14/244,471	Applicant(s) PLACHETKA, JOHN R.	
	Examiner Nissa Westerberg	Art Unit 1618	

All participants (applicant, applicant's representative, PTO personnel):

(1) Nissa Westerberg. (3) ____.

(2) Steve Highlander. (4) ____.

Date of Interview: 09 July 2014.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
 If Yes, brief description: ____.

Issues Discussed ☐ 101 ☐ 112 ☐ 102 ☐ 103 ☒ Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: Pending.

Identification of prior art discussed: None.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant was called to discuss double patenting issues of the instant claims. While there were ODP issues with several issued patents and one co-pending application, statutory double patenting was present with another application that cannot be overcome by the filing of a terminal disclaimer. Applicant decided to amend the claims of the other application so statutory double patenting was no longer present and then to file the appropriate terminal disclaimers.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Nissa Westerberg/ Primary Examiner, Art Unit 1618	
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BIB DATA SHEET

CONFIRMATION NO. 3047


SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.	
14/244,471	04/03/2014	424	1618	POZN.P0004US.CP1C4	
RULE					
APPLICANTS Pozen Inc., Chapel Hill, NC, Assignee (with 37 CFR 1.172 Interest); INVENTORS John R. PLACHETKA, Chapel Hill, NC; ** CONTINUING DATA ***** This application is a CON of 14/045,156 10/03/2013 which is a CON of 13/215,855 08/23/2011 PAT 8557285 which is a DIV of 12/553,804 09/03/2009 ABN which is a DIV of 11/129,320 05/16/2005 PAT 8206741 which is a CIP of 10/158,216 05/31/2002 PAT 6926907 which claims benefit of 60/294,588 06/01/2001 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 04/24/2014					
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input type="checkbox"/> No Verified and /NISSA M Acknowledged WESTERBERG/ Examiner's Signature	<input type="checkbox"/> Met after Allowance Initials	STATE OR COUNTRY NC	SHEETS DRAWINGS 2	TOTAL CLAIMS 19	INDEPENDENT CLAIMS 2
ADDRESS Parker Highlander PLLC 1120 South Capital of Texas Highway Bldg. 1, Suite 200 Austin, TX 78746 UNITED STATES					
TITLE PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS					
FILING FEE RECEIVED 1740	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other <input type="checkbox"/> Credit		

Issue Classification 	Application/Control No. 14244471	Applicant(s)/Patent Under Reexamination PLACHETKA, JOHN R.	
	Examiner NISSA WESTERBERG	Art Unit 1618	

CPC					
Symbol				Type	Version
A61K	31	:	4439	I	2013-01-01
A61K	31	:	192	I	2013-01-01
A61K	9	:	209	F	2013-01-01
		:			
		:			
		:			
		:			
		:			
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		:			
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		:			
		:			

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner) (Date)		19	
/NISSA WESTERBERG/ Primary Examiner.Art Unit 1618	7/17/14	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification 	Application/Control No. 14244471	Applicant(s)/Patent Under Reexamination PLACHETKA, JOHN R.	
	Examiner NISSA WESTERBERG	Art Unit 1618	

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION									
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED				
424		474				A	6	1	K	9 / 28 (2006.01.01)					
CROSS REFERENCE(S)															
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)														
424	464														

NONE		Total Claims Allowed:	
		19	
(Assistant Examiner)	(Date)	O.G. Print Claim(s)	O.G. Print Figure
/NISSA WESTERBERG/ Primary Examiner.Art Unit 1618	7/17/14	1	1
(Primary Examiner)	(Date)		

Session Began July 17, 2014 at 09:13 AM

Task Began July 17, 2014 09:14 AM

Explore references by research topic: non-enteric proton pump inhibitors

Research Topic: non-enteric proton pump inhibitors
Result Count: 1

Candidates Selected (ID 1)

11 references were found containing the concept "non enteric proton pump inhibitors".

Answer Type: *References*
Result Count: 11

Detailed display

From ID: 1
Type: Oral administration form containing an acid-labile active agent

Task Began July 17, 2014 09:29 AM

Explore references by research topic: non-enteric proton pump inhibitors NSAID

Research Topic: non-enteric proton pump inhibitors NSAID
Result Count: 4

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EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S4	0	(method or process) same (layer\$4 or coal\$4 or spray\$4; same (maproxen or escitraprazole; ESOMEPRAZOLE	USPAT; UFAC	AND	ON	2014/07/17 09:57
S5	122	(method or process) same (layer\$4 or coal\$4 or spray\$4; same (maproxen or escitraprazole;	USPAT; UFAC	AND	ON	2014/07/17 09:57
S6	20	S5.clin.	USPAT; UFAC	AND	ON	2014/07/17 09:58

7/ 17/ 2014 1:44:12 PM

Search Notes 	Application/Control No. 14244471	Applicant(s)/Patent Under Reexamination PLACHETKA, JOHN R.
	Examiner NISSA WESTERBERG	Art Unit 1618

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM - Inventor name search	7/9/14	NMW
SciFinder - see attached search history	7/17/14	NMW

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	see attached search history	7/17/14	NMW

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Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A1	2001-0025107	09/27/01	Barberich <i>et al.</i>
	A2	2002-0012676	01/31/02	Lundberg <i>et al.</i>
	A3	2002-0042433	04/11/02	Yelle <i>et al.</i>
	A4	2002-0044962	04/18/02	Cherukuri <i>et al.</i>
	A5	2002-0045184	04/18/02	Chen
	A6	2002-0051814	05/02/02	Chen
	A7	2002-0086029	07/04/02	Lundberg <i>et al.</i>
	A8	2002-0090395	07/11/02	Woolfe <i>et al.</i>
	A9	2002-0111370	08/15/02	Bergman <i>et al.</i>
	A10	2002-0155153	12/24/02	Depui <i>et al.</i>
	A11	2002-0160046	10/31/02	Robinson <i>et al.</i>
	A12	2003-0008903	01/09/03	Barberich <i>et al.</i>
	A13	2003-0040537	02/27/03	Plachetka <i>et al.</i>
	A14	2003-0069255	08/09/05	Plachetka
	A15	2003-0113375	06/19/03	Lundberg <i>et al.</i>
	A16	2003-0129235	07/10/03	Chen <i>et al.</i>
	A17	2003-0215527	11/20/03	Phillips
	A18	2003-0232080	12/18/03	Pather <i>et al.</i>
	A19	2003-0232876	12/18/03	Plachetka
	A20	2004-0022846	02/05/04	Depui <i>et al.</i>
	A21	2004-0048896	03/11/04	Phillips
	A22	2004-0121004	06/24/04	Taneja
	A23	2004-0131676	07/08/04	Taneja
	A24	2004-0171646	09/02/04	Phillips
	A25	2004-0180089	09/16/04	Plachetka <i>et al.</i>

{00147031}

EXAMINER: /Nissa Westerberg/	DATE CONSIDERED: 07/17/2014
------------------------------	-----------------------------

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A26	2005-0004171	01/06/05	Phillips
	A27	2005-0042304	02/24/05	Phillips
	A28	2005-0054682	03/10/05	Phillips
	A29	2005-0147668	07/07/05	Bertelsen <i>et al.</i>
	A30	2005-0163847	07/28/05	Cheng <i>et al.</i>
	A31	2005-0227949	10/13/05	Edalatpour <i>et al.</i>
	A32	2005-0249806	11/10/05	Proehl <i>et al.</i>
	A33	2005-0249811	11/10/05	Plachetka
	A34	2006-0165797	07/27/06	Plachetka
	A35	2006-0177504	08/10/06	Sudharadas
	A36	2006-0178348	08/10/06	Plachetka
	A37	2006-0178349	08/10/06	Plachetka
	A38	2006-0287284	12/21/06	Schutze <i>et al.</i>
	A39	2007-0122470	05/31/07	Johansson <i>et al.</i>
	A40	2007-0154542	07/05/07	Tananbaum <i>et al.</i>
	A41	2007-0184078	08/09/07	Chen
	A42	2007-0207200	09/06/07	Plachetka <i>et al.</i>
	A43	2007-0237820	10/11/07	Cheng <i>et al.</i>
	A44	2007-0243251	10/18/07	Taneja
	A45	2008-0031941	02/07/08	Pettersson
	A46	2008-0031950	02/07/08	Sesha
	A47	2008-0103169	05/01/08	Phillips
	A48	2009-0074863	03/19/09	Taneja
	A49	2009-0075950	03/19/09	Taneja
	A50	2009-0163551	06/25/09	Earnest

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EXAMINER: /Nissa Westerberg/

DATE CONSIDERED: 07/17/2014

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A51	2009-0297594	12/03/09	Depui <i>et al.</i>
	A52	2010-0062064	03/11/10	Ault <i>et al.</i>
	A53	2010-0172983	07/08/10	Plachetka
	A54	2010-0178334	07/15/10	Johansson <i>et al.</i>
	A55	2010-0330179	12/30/10	Ault <i>et al.</i>
	A56	2012-0064156	03/15/12	Plachetka
	A57	2013-0078305	03/28/13	Plachetka
	A58	4,198,390	04/15/80	Rider
	A59	4,255,431	03/10/81	Junggren <i>et al.</i>
	A60	4,344,929	08/17/82	Bonsen <i>et al.</i>
	A61	4,508,905	04/02/85	Junggren <i>et al.</i>
	A62	4,554,276	11/19/82	LaMatina
	A63	4,562,261	12/31/85	Hirata <i>et al.</i>
	A64	4,619,934	10/28/86	Sunshine <i>et al.</i>
	A65	4,676,984	06/30/87	Wu <i>et al.</i>
	A66	4,704,278	11/03/87	Wu <i>et al.</i>
	A67	4,726,951	02/23/88	Panoz <i>et al.</i>
	A68	4,738,974	04/19/88	Brandstrom
	A69	4,757,060	07/12/88	Lukacsko <i>et al.</i>
	A70	4,758,579	07/19/88	Kohl <i>et al.</i>
	A71	4,766,117	08/23/88	Crawford <i>et al.</i>
	A72	4,786,505	11/22/88	Lovgren <i>et al.</i>
	A73	4,853,230	08/01/89	Lovgren <i>et al.</i>
	A74	4,865,847	09/12/89	Gosswein
	A75	4,948,581	08/14/90	Sawayangi <i>et al.</i>

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U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A76	4,965,065	10/23/90	Lukacsko <i>et al.</i>
	A77	5,026,560	06/25/91	Makino <i>et al.</i>
	A78	5,035,899	07/30/91	Saeki <i>et al.</i>
	A79	5,037,815	08/06/91	Lukacsko <i>et al.</i>
	A80	5,043,358	08/27/91	Lukacsko <i>et al.</i>
	A81	5,051,262	09/24/91	Panoz <i>et al.</i>
	A82	5,093,132	03/03/92	Makino <i>et al.</i>
	A83	5,204,118	04/20/93	Goldman <i>et al.</i>
	A84	5,260,333	11/09/93	Lukacsko <i>et al.</i>
	A85	5,364,616	11/15/91	Singer <i>et al.</i>
	A86	5,373,022	12/13/94	Fawzi <i>et al.</i>
	A87	5,409,709	04/25/95	Ozawa <i>et al.</i>
	A88	5,417,980	05/23/95	Goldman <i>et al.</i>
	A89	5,466,436	11/14/95	Stables
	A90	5,514,663	05/07/96	Mandel
	A91	5,601,843	02/11/97	Gimet
	A92	5,631,022	05/20/94	Mandel <i>et al.</i>
	A93	5,643,960	07/01/97	Breitner <i>et al.</i>
	A94	5,667,802	09/16/97	Grimberg
	A95	5,679,376	10/21/97	Stevens <i>et al.</i>
	A96	5,686,105	11/11/97	Kelm <i>et al.</i>
	A97	5,690,960	11/25/97	Bengtsson <i>et al.</i>
	A98	5,702,723	12/30/97	Griffin
	A99	5,714,504	02/03/98	Lindberg <i>et al.</i>
	A100	5,716,648	02/10/98	Halskov <i>et al.</i>

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A101	5,750,531	05/12/98	Lee <i>et al.</i>
	A102	5,817,338	10/06/98	Bergstrand <i>et al.</i>
	A103	5,817,340	10/06/98	Roche <i>et al.</i>
	A104	5,840,737	11/24/98	Phillips
	A105	5,872,145	02/16/99	Plachetka
	A106	5,877,192	03/02/99	Lindberg <i>et al.</i>
	A107	5,900,424	05/04/99	Kallstrom <i>et al.</i>
	A108	5,955,451	09/21/99	Lichtenberger <i>et al.</i>
	A109	6,013,281	01/11/00	Lundberg <i>et al.</i>
	A110	6,025,395	02/15/00	Breitner <i>et al.</i>
	A111	6,060,499	05/09/00	Plachetka
	A112	6,093,734	07/25/00	Garst <i>et al.</i>
	A113	6,126,816	12/19/00	Bohlin <i>et al.</i>
	A114	6,132,768	10/17/00	Sachs <i>et al.</i>
	A115	6,132,771	10/17/00	Depui <i>et al.</i>
	A116	6,136,344	10/24/00	Depui <i>et al.</i>
	A117	6,160,020	12/12/00	Ohannesian <i>et al.</i>
	A118	6,162,816	12/19/00	Bohlin <i>et al.</i>
	A119	6,183,776	02/06/01	Depui <i>et al.</i>
	A120	6,183,779	02/06/01	Ouali <i>et al.</i>
	A121	6,207,188	03/27/01	Gustavsson <i>et al.</i>
	A122	6,231,888	05/15/01	Lerner <i>et al.</i>
	A123	6,287,600	09/11/01	Ouali <i>et al.</i>
	A124	6,365,184	04/02/02	Depui <i>et al.</i>
	A125	6,369,085	04/09/02	Cotton <i>et al.</i>

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A126	6,372,255	04/16/02	Saslowski
	A127	6,387,410	05/14/02	Woolfe
	A128	6,395,298	05/28/02	Flannagan <i>et al.</i>
	A129	6,428,810	08/06/02	Bergstrand <i>et al.</i>
	A130	6,485,747	11/26/02	Flanagan <i>et al.</i>
	A131	6,489,346	12/03/02	Phillips
	A132	6,544,556	04/08/03	Chen <i>et al.</i>
	A133	6,599,529	07/29/03	Skinhoj <i>et al.</i>
	A134	6,610,323	08/26/03	Lundberg <i>et al.</i>
	A135	6,613,354	09/02/03	Depui <i>et al.</i>
	A136	6,632,451	10/14/03	Penhasi <i>et al.</i>
	A137	6,641,838	11/04/03	Pather <i>et al.</i>
	A138	6,645,988	11/11/03	Phillips
	A139	6,673,819	01/06/04	Bergman <i>et al.</i>
	A140	6,685,964	02/03/04	Bartholomaeus <i>et al.</i>
	A141	6,699,885	03/02/04	Phillips
	A142	6,713,089	03/30/04	Bertelsen <i>et al.</i>
	A143	6,749,867	06/15/04	Robinson <i>et al.</i>
	A144	6,780,882	08/24/04	Phillips
	A145	6,787,164	09/07/04	Gelber <i>et al.</i>
	A146	6,797,283	09/28/04	Edgren <i>et al.</i>
	A147	6,869,615	03/22/05	Chen <i>et al.</i>
	A148	6,875,872	04/05/05	Lindberg <i>et al.</i>
	A149	6,926,907	08/09/05	Plachetka
	A150	7,029,701	04/18/06	Chen

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U.S. Patent Documents <i>See Page 1-7</i>		Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A151	7,030,162	04/18/06	Plachetka <i>et al.</i>
	A152	7,060,694	06/13/06	Plachetka <i>et al.</i>
	A153	7,094,425	08/22/06	Scott <i>et al.</i>
	A154	7,332,183	02/19/08	Plachetka <i>et al.</i>
	A155	7,399,772	07/15/08	Phillips
	A156	7,411,070	08/12/08	Cotton <i>et al.</i>
	A157	7,488,497	02/10/09	Depui <i>et al.</i>
	A158	7,745,466	06/29/10	Cotton <i>et al.</i>
	A159	7,785,626	08/31/10	Pettersson <i>et al.</i>
	A160	7,846,914	12/07/10	Petrus
	A161	8,206,741	06/26/12	Plachetka <i>et al.</i>

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B1	AU 2006235929	11/30/06	Australia	Pozen Inc.
	B2	CA 2,139,653	07/10/01	Canada	Astra Aktiebolag
	B3	DE 198 01 811	01/19/98	Germany	Stada Arzneimittel AG German (English abstract)
	B4	DE 40 35 455	05/14/92	Germany	Byk Gulden Lomberg Chem Fab German (English Abstract)
	B5	EP 0 005 129	10/31/79	Europe	Haessle AB
	B6	EP 0 124 495	11/07/84	Europe	Haessle AB
	B7	EP 0 166 287	01/02/86	Europe	Byk Gulden Lomberg Chem Fab German (English Abstract)
	B8	EP 0 167 958	01/15/86	Europe	Paolo Colombo
	B9	EP 0 174 726	03/19/86	Europe	Takeda Chemical Industries Ltd.

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B10	EP 0 244 380	11/04/87	Europe	Haessle AB
	B11	EP 0 320 550	06/21/89	Europe	Bristol Myers Co.
	B12	EP 0 320 551	06/21/89	Europe	Bristol Myers Co.
	B13	EP 0 426 479 A1	05/08/91	Europe	McNeil PPC Inc.
	B14	EP 0 426 479 B1	05/08/91	Europe	McNeil PPC Inc.
	B15	EP 0 550 083	07/07/93	Europe	Glaxo Group Ltd.
	B16	EP 1 020 461	07/19/00	Europe	AstraZeneca AB
	B17	EP 1 068 867	01/17/01	Europe	Bernard Charles Sherman
	B18	EP 1 411 900	07/21/10	Europe	Pozen Inc.
	B19	EP 1 726 300	11/29/06	Europe	Flamel Technologies
	B20	EP 1 726 301	11/29/06	Europe	Flamel Technologies
	B21	GB 2 105 193	03/23/83	United Kingdom	Glaxo Group Limited
	B22	GB 2 163 747	03/05/86	United Kingdom	Nippon Chemiphar Co.
	B23	GB 2 216 413	10/11/89	United Kingdom	Glaxo Limited Group
	B24	JP 2000-151111	09/09/00	Japan	Glaxo Group Limited Japanese (English abstract)
	B25	WO 1985/003433	08/15/85	WIPO	Gustavsson <i>et al.</i>
	B26	WO 1990/006925	06/28/90	WIPO	Aktiebolaget Hässle
	B27	WO 1991/016886	11/14/91	WIPO	G.D. Searle & Co.
	B28	WO 1991/016895	11/14/91	WIPO	G.D. Searle & Co.
	B29	WO 1991/016896	11/14/91	WIPO	G. D. Searle & Co.
	B30	WO 1991/019711	12/26/91	WIPO	Aktiebolaget Astra
	B31	WO 1991/019712	12/26/91	WIPO	Aktiebolaget Astra
	B32	WO 1993/011750	11/14/91	WIPO	Fuisz Technologies Ltd.

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B33	WO 1993/012817	07/08/93	WIPO	Warner-Lambert Company
	B34	WO 1994/007541	04/14/94	WIPO	Merck & Co., Inc.
	B35	WO 1994/027988	12/08/94	WIPO	Astra Aktiebolag
	B36	WO 1995/001977	01/19/95	WIPO	Astra Aktiebolag
	B37	WO 1995/032959	12/07/95	WIPO	Astra Aktiebolag
	B38	WO 1996/005177	02/22/96	WIPO	Yuhan Corporation
	B39	WO 1996/005199	02/22/96	WIPO	BYK Gulden Lomberg Chemische Fabrik GMBH German (English Abstract)
	B40	WO 1996/014839	05/23/96	WIPO	Farmarc Nederland BV
	B41	WO 1996/022780	08/01/96	WIPO	The Board Of Regents of The University of Texas System
	B42	WO 1997/011701	04/03/97	WIPO	Merck-Frosst Canada Inc.
	B43	WO 1997/025064	07/17/97	WIPO	Astra Aktiebolag
	B44	WO 1998/013073	04/02/98	WIPO	Board of Regents, The University of Texas System
	B45	WO 1998/022117	05/28/98	WIPO	The Procter & Gamble Company
	B46	WO 1998/022118	05/28/98	WIPO	The Procter & Gamble Company
	B47	WO 1998/054171	12/03/98	WIPO	Astra Aktiebolag
	B48	WO 1999/000380	01/07/99	WIPO	Astra Aktiebolag
	B49	WO 1999/012524	03/18/99	WIPO	Nycomed Danmark A/S
	B50	WO 1999/029320	06/17/99	WIPO	BYK Gulden Lomberg Chemische Fabrik GMBH German
	B51	WO 1999/066919	12/29/99	WIPO	McNeil-PPC, Inc.

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B52	WO 2000/001368	01/13/00	WIPO	Norton Healthcare Ltd.
	B53	WO 2000/015195	03/23/00	WIPO	Nycomed Danmark A/S
	B54	WO 2000/056339	09/28/00	WIPO	Pharmascience Inc.
	B55	WO 2000/071122	11/30/00	WIPO	PAR Pharmaceutical, INC.
	B56	WO 2000/072838	12/07/00	WIPO	AstraZeneca AB
	B57	WO 2000/078293	12/28/00	WIPO	AstraZeneca AB
	B58	WO 2001/024777	04/12/01	WIPO	American Home Products Corporation
	B59	WO 2001/066088	03/13/01	WIPO	AstraZeneca AB
	B60	WO 2002/022108	03/21/02	WIPO	Andrx Corporation
	B61	WO 2002/066002	08/29/02	WIPO	Glaxo Wellcome S.A.
	B62	WO 2002/098352	12/12/02	WIPO	Pozen Inc.
	B63	WO 2003/017980	03/06/03	WIPO	Takeda Chemical Industries, Ltd.
	B64	WO 2004/062552	07/29/04	WIPO	Galephar M/F
	B65	WO 2004/064815	08/05/04	WIPO	Smatrix Technologies Inc.
	B66	WO 2005/074536	08/18/05	WIPO	EISAI Co., Ltd.
	B67	WO 2005/074930	08/18/05	WIPO	Altana Pharma AG
	B68	WO 2006/044202	04/27/06	WIPO	James W. Ayres
	B69	WO 2007/064274	06/07/07	WIPO	AstraZeneca AB
	B70	WO 2007/078874	07/12/07	WIPO	Cogentus Pharmaceuticals, Inc.
	B71	WO 2008/101060	08/21/08	WIPO	Logical Therapeutics, Inc.
	B72	WO 2009/012393	01/22/09	WIPO	The Curators Of The University Of Missouri

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B73	WO 2009/145905	12/03/09	WIPO	Pozen Inc.
	B74	WO 2010/151697	12/29/10	WIPO	Pozen Inc.

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	"A 12 month, phase 3, open-label, multi-center study to evaluate the long -term safety of PN 400," <i>ClinicalTrials.gov</i> , September 11, 2007, accessed from < http://clinicaltrials.gov/ct2/show/NCT00527904 > on September 6, 2012.
	C2	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.: Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd's. Invalidity contentions pursuant to L. Pat. R. 3.6(c)," dated November 23, 2011.
	C3	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. V Lupin Ltd. And Lupin Pharmaceuticals, Inc.: Defendants Lupin Ltd. And Lupin Pharmaceuticals, Inc's Amended Invalidity Contentions Pursuant to L. PAT. R. 3.3 and 3.6(c)," dated April 20, 2012.
	C4	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v Lupin Ltd. And Lupin Pharmaceuticals Inc.: Defendants Lupin Ltd. And Lupin Pharmaceuticals, Inc.'s Invalidity Contentions Pursuant to L. Pat. R. 3.3 and 3.6(c)," dated November 23, 2011.
	C5	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v. Anchen Pharmaceuticals, Inc.: Anchen's Initial Invalidity Contentions," dated May 11, 2012.
	C6	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.: Plaintiffs' Response to DRL's First Set of Interrogatories to Plaintiffs (Nos. 1-5)," dated March 5, 2012.
	C7	"Histamine H2 antagonist," accessed from < drugs.com > on September 6, 2012.
	C8	"Notice of Paragraph IV Certification Re: Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Naproxen and Esomeprazole Magnesium Delayed Release Tablets; U.S. Patent No. 6,926,907, from Dr. Reddy's Laboratories, Ltd./Dr. Reddy's Laboratories, Inc., dated March 11, 2011.

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C9	"PK Study to evaluate esomeprazole plasma levels following the administration of PN 400," <i>ClinicalTrials.gov</i> , January 11, 2008, accessed from < http://clinicaltrials.gov/ct2/show/NCT00599404 > on September 6, 2012.
	C10	"Study evaluating the bioavailability of Naproxen 500 mg in three formulations," <i>ClinicalTrials.gov</i> , April 23, 2008, accessed from < http://clinicaltrials.gov/ct2/show/NCT00665743 >, on September 6, 2012.
	C11	Abelo <i>et al.</i> , "Pharmacodynamic modeling of reversible gastric acid pump inhibition in dog and man," <i>European Journal of Pharmaceutical Sciences</i> , 14:339-346, 2001.
	C12	Alberts <i>et al.</i> , "Efficacy and Safety of PA, a Novel Combination of Enteric-Coated Aspirin and Immediate-Release Omeprazole," <i>International Stroke Conference</i> , 2009, retrieved from the Internet at: http://www.pozen.com/wp-content/uploads/2011/08/ISC2009Albertsfile.pdf , retrieved December 14, 2012.
	C13	Alexander <i>et al.</i> , "Pilot evaluation of a novel combination table (PN 400) containing a proton pump inhibitor and a nonsteroidal anti-inflammatory drug in prevention of upper gastrointestinal mucosal injury," <i>American Journal of Gastroenterology</i> , 100(9), S68, 135, 2005.
	C14	Andersson, "Pharmacokinetics, metabolism and interactions of acid pump inhibitors," <i>Clin. Pharmacokinet.</i> , 31(1):9-28, 1996.
	C15	Anonymous, "Evaluate Relative Bioavailability of PA32540 (Asa/Omeprazole), Its Aspirin Component, and Ecotrin in Healthy Volunteers," <i>ClinicalTrials.gov</i> , March 7, 2008, retrieved from the Internet at: http://www.clinicaltrials.gov/ct2/show/NCT00632086?term=aspirin+omeprazole&rank=18 , retrieved on December 28, 2012.
	C16	Anonymous, "POZEN's PA32520 Study Data Demonstrated Better Upper Gastrointestinal Protection," <i>Drugs.com</i> , November 11, 2008, retrieved from the Internet at: http://www.drugs.com/clinical_trials/pozen-s-pa32520-study-data-demonstrated-better-upper-gastrointestinal-protection-6195.html , retrieved December 17, 2012.
	C17	Anonymous, "Study Evaluating the Effect of Gastroduodenal Mucosa of PA32540, A32540 and Celecoxib, and Aspirin with Celecoxib (PA32540-109)," <i>ClinicalTrials.gov</i> , January 9, 2009, retrieved from the Internet at: http://www.clinicaltrials.gov/ct2/show/NCT00700687?term=aspirin+omeprazole&rank=36 , retrieved December 18, 2012.

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	C18	Anonymous, "Study to Evaluate the Incidence of Gastric Ulcers Following Administration of Either PA32540 or Enteric Coated Aspiring 325 mg in Subjects Who Are at Risk for Developing Aspirin-Associated Ulcers," <i>ClinicalTrials.gov</i> , August 17, 2009, retrieved from the Internet at: http://clinicaltrials.gov/archive/NCT00960869/2009_08_17 , retrieved December 18, 2012.
	C19	Approval of Amendments/correction filed May 10, 2010 dated June 21, 2010 (European application issued as EP 1 411 900 B1). (Attorney Docket No.: POZN.P0004EP)
	C20	Awtry <i>et al.</i> , "Aspirin," <i>Circulation</i> , 101:1206-1218, 2000.
	C21	Bajbouj <i>et al.</i> , "A prospective multicenter clinical and endoscopic follow-up study of patients with gastroesophageal reflux disease," <i>Z. Gastroenterol.</i> , 43:1303-1307, 2005.
	C22	Ballinger <i>et al.</i> , "COX-2 inhibitors versus NSAIDs in gastrointestinal damage and prevention," <i>Exp. Opin. Pharmacother.</i> , 2(1):31-40, 2001.
	C23	Barnett <i>et al.</i> , "Effects of SCH 32651 on resting and stimulated acid secretion in guinea-pig isolated fundic mucosa," <i>Br. J. Pharmac.</i> , 83:75-82, 1984.
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	C25	Bergmann <i>et al.</i> , "Protection against aspirin-induced gastric lesions by lansoprazole: simultaneous evaluation of functional and morphologic responses," <i>Clin. Pharmacol. Ther.</i> , 52:413-416, 1992.
	C26	Bianchi Porro <i>et al.</i> , "Pantoprazole versus placebo in prevention of NSAID-induced ulcers," <i>Gastroenterology</i> , 114(4):A74, 1998.
	C27	Bianchi Porro <i>et al.</i> , "Prevention of gastroduodenal damage with omeprazole in patients receiving continuous NSAIDs treatment. A double blind placebo controlled study," <i>Ital. J. Gastroenterol. Hepatol.</i> , 30:43-47, 1998.
	C28	Bianchi Porro <i>et al.</i> , "Why are non-steroidal anti-inflammatory drugs important in peptic ulcers?" <i>Aliment. Pharmacol. Therap.</i> , 1:540S-547S, 1987.
	C29	Bigard <i>et al.</i> , "Complete prevention by omeprazole of aspirin induced gastric lesions in healthy subjects," <i>Gut</i> , 29(5):A712, T49, 1988.

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	C30	Bigard <i>et al.</i> , "Effet protecteur de l'omeprazole sur les lésions gastriques induites par une prise unique d'aspirine chez l'homme," <i>Gastroenterol. Clin. Biol.</i> , 12:770-771, 1998.
	C31	Bombardier <i>et al.</i> , "Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis," <i>N. Engl. J. Med.</i> , 343:1520-1528, 2000.
	C32	Brown <i>et al.</i> , "Aspirin- and indomethacin-induced ulcers and their antagonism by antihistamines," <i>Euro. J. Pharm.</i> , 51:275-283, 1978.
	C33	Brown <i>et al.</i> , "Prevention of the gastrointestinal adverse effects of nonsteroidal anti-inflammatory drugs," <i>Pract. Drug Safety</i> , 21:503-512, 1999.
	C34	Byrn <i>et al.</i> , "Pharmaceutical solids: A strategic approach to regulatory considerations," <i>Pharm. Res.</i> , 12(7): 945-954, 1995.
	C35	Carrasco-Portugal <i>et al.</i> , "Bioavailability of a formulation containing a diclofenac-rantidine combination," <i>Proc. West. Pharmacol. Soc.</i> , 45:8-10, 2002.
	C36	Chan <i>et al.</i> , "Clopidogrel versus Aspirin and Esomeprazole to prevent recurrent ulcer bleeding," <i>New Eng. J. Med.</i> , 352:238-244, 2005.
	C37	Chan <i>et al.</i> , "Eradication of H. Pylori versus maintenance acid suppression to prevent recurrent ulcer hemorrhage in high risk NSAID users: A prospective randomized study," <i>Gastroenterology</i> , 114: A87, G0356, 1998.
	C38	Chandramouli <i>et al.</i> , "Prevention and management of NSAID-Induced gastropathy," <i>Journal of Pharmaceutical Pain and Symptom Control</i> , 8(4):27-40, 2000.
	C39	Chang <i>et al.</i> , "Polymethacrylates," In: Handbook of Pharmaceutical Excipients, Fifth Edition, Ed. Raymond C. Rowe, Paul J. Sheskey and Sian C. Owen, London: Pharmaceutical Press, pages 553-560, 2006.
	C40	Chen <i>et al.</i> , "Esomeprazole tablet vs. omeprazole capsule in treating erosive esophagitis," <i>World Journal of Gastroenterology</i> , 11(20):3112-3117, 2005.
	C41	Cullen <i>et al.</i> , "Primary gastroduodenal prophylaxis with omeprazole for non-steroidal anti-inflammatory drug users," <i>Aliment. Pharmacol. Ther.</i> , 12:135-140, 1998.
	C42	Dajani, "Perspective on the gastric antisecretory effects of misoprostol in man," <i>Prostaglandins</i> , 33:68-77, 1987.

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	C43	Daneshmend <i>et al.</i> , "Abolition by omeprazole of aspirin induced gastric mucoasal injury in man," <i>Gut</i> , 31:514-517, 1990.
	C44	Daneshmend <i>et al.</i> , "Use of microbleeding and an ultrathin endoscope to assess gastric mucosal protection by famotidine," <i>Gastroenterology</i> , 97:944-9, 1989.
	C45	Data sheet for "Arthrotec," 2009. (Document D8 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C46	Dent, "Why proton pump inhibition should heal and protect against nonsteroidal anti-inflammatory drug users," <i>Am. J. Med.</i> , 104:52S-55S, 1998.
	C47	Ehsanullah <i>et al.</i> , "Prevention of gastroduodenal damage induced by non-steroidal anti-inflammatory drugs: controlled trial of ranitidine," <i>BMJ</i> , 297:1017-1021, 1998.
	C48	Ekstrom <i>et al.</i> , Prevention of peptic ulcer and dyspeptic symptoms with omeprazole in patients receiving continuous non-steroidal anti-inflammatory drug therapy," <i>Scand. J. Gastroenterol.</i> , 31:753-758, 1996.
	C49	Ene <i>et al.</i> , "A study of the inhibitory effects of SCH 28080 on gastric secretion in man," <i>Br. J. Pharmac.</i> , 76:389-391, 1982.
	C50	English translation of Bigard, <i>et al.</i> , <i>Gastroenterol. Clin. Biol.</i> , 12:770-771, 1998.
	C51	English translation of Muller <i>et al.</i> , <i>Arzneimittel Forschung</i> , 47:758-760, 1997.
	C52	English translation of Muller <i>et al.</i> , <i>Arzneimittel-Forschung/Drug Res.</i> , 41(1):638-639, 1991.
	C53	English translation of Simon <i>et al.</i> , <i>Arzneimittel Forschung</i> , 45:701-703, 1995.
	C54	Erlandsson <i>et al.</i> , "Resolution of the enantiomers of omeprazole and some of its analogues by liquid chromatography on a trisphenylcarbamoylcellulose-based stationary phase," <i>J. Chromatogr.</i> , 532:305-319, 1990.
	C55	European Search Report and Opinion issued in European application No. EP 09 17 8773, dated February 11, 2010. (Attorney Docket No. POZN.P0004EP.D1)
	C56	European Search Report issued in European application No. EP 02 734 602.2, dated May 29, 2007. (Attorney Docket No.: POZN.P0004EP)
	C57	Extended European Search Report issued in European Patent Application No. 10792681.8, dated January 4, 2013. (Attorney Docket No.: POZN.P0006EP)

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Exam. Init.	Ref. Des.	Citation
	C58	Fass, "Erosive Esophagitis and Nonerosive Reflux Disease (NERD): Comparison of Epidemiologic, Physiologic, and Therapeutic Characteristics," <i>J. Clin. Gastroenterol.</i> , 41(2):131-137, 2007.
	C59	Feldman and Carlstedt, "Effect of antacid on absorption of enteric-coated aspirin," <i>JAMA</i> , 227(6):660-1, 1974.
	C60	Florence and Jani, "Novel oral drug formulations their potential in modulating adverse effects," <i>Drug Safety</i> , 10(3):233-66, 1994.
	C61	Fort <i>et al.</i> , "Pa, a novel combination of delayed release (DR) aspirin (ASA) and immediate-release (IR) omeprazole, is associated with a decreased risk of gastroduodenal mucosal injury: Pooled data from three Phase I, 4-week endoscopic studies," <i>American Journal of Gastroenterology</i> , 103(Suppl. S):S487-S488, 2008.
	C62	Frank <i>et al.</i> , "Reduction of indomethacin induced gastroduodenal mucosal injury and gastrointestinal symptoms with cimetidine in normal subjects," <i>J. Rheum.</i> , 16:1249-1252, 1989.
	C63	Gengo <i>et al.</i> , "Prevalence of platelet nonresponsiveness to aspirin in patients treated for secondary stroke prophylaxis and in patients with recurrent isohemic events," <i>J. Clin. Pharmacol.</i> , 48:335-343, 2008.
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	C65	Goldstein <i>et al.</i> , "116 A single table multilayer formulation of enteric-coated naproxen coupled with no-enteric-coated omeprazole is associated with a significantly reduced incidence of gastric ulcers vs. enteric-coated naproxen: A prospective, randomized double-blind study," 134(4), Supplement 1, A-19, 2008.
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	C68	Graham <i>et al.</i> , "Duodenal and gastric ulcer prevention with misoprostol in arthritis patients taking NSAIDs," <i>Ann. Intern. Med.</i> , 119(4):257-262, 1993.
	C69	Grosser <i>et al.</i> , "Thromboxane generation," In: Platelets, Alan Michelson Ed., pages 565-574, Elsevier Science, 2007.
	C70	Gurbel <i>et al.</i> , "Abstract 4267; PA32520 (Single-tablet of enteric-coated aspirin 325 mg + Immediate-release Omeprazole 20 mg); Aspirin therapy combining greater thromboxane suppression and lower upper gastrointestinal damage," <i>Circulation</i> , 118:S_855, 2008.
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	C75	Hawkey <i>et al.</i> , "Prophylaxis of aspirin-induced gastric mucosal bleeding with ranitidine," <i>Aliment. Pharmacol. Therap.</i> , 2:245-252, 1988.
	C76	Hawkey <i>et al.</i> , "Strategies for preventing aspirin-induced gastric bleeding," <i>Scandinavian Journal of Gastroenterology</i> , Vol. 21, Supplement 125, pages 170-173, 1986.
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	C80	Helander <i>et al.</i> , "Structure and function of rat parietal cells during treatment with omeprazole, SCH 28080, SCH 32651, or ranitidine," <i>Scand. J. Gastroenterol.</i> , 25:799-809, 1990.
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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C92	Konturek <i>et al.</i> , "Effects of omeprazole, a substituted benzimidazole, on gastrointestinal secretions, serum gastrin, and gastric mucosal blood flow in dogs," <i>Gastroenterology</i> , 86(1): 71-77, 1984.
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	C94	Lad <i>et al.</i> , "Management of nonsteroidal anti-inflammatory drug-induced gastroduodenal disease by acid suppression," <i>Can. J. Gastroenterol.</i> , 13:135-142, 1999.
	C95	Lanas, "Prevention of aspirin-induced gastroduodenal damage: <i>H. Pylori</i> infection eradication versus proton pump inhibitors or both," <i>Digestive and Liver Disease</i> , 36:655-657, 2004.
	C96	Lanza <i>et al.</i> , "A double-blind placebo-controlled comparison of the efficacy and safety of 50, 100, and 200 µg of misoprostol QID in the prevention of ibuprofen-induced gastric and duodenal mucosal lesions and symptoms," <i>Am. J. Gastroenterol.</i> , 84(6):633-636, 1989.
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	C98	Larsson <i>et al.</i> , "Animal pharmacodynamics of omeprazole. A survey of its pharmacological properties in vivo," <i>Scand J Gastroenterol Suppl.</i> , 108:23-35, 1985.
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	C104	Lin and Lu, "Role of pharmacokinetics and metabolism in drug discovery and development," <i>Pharmacological Reviews</i> , 49(4):403-449, 1997.
	C105	Maggi <i>et al.</i> , "Press-coated tablets for the sequential pulsed administration of two different drugs," <i>Int. J. Pharm.</i> , 99:173-179, 1993.
	C106	Mason and Winer, "Kinetics of aspirin, salicylic acid, and salicylic acid, and salicylic acid following oral administration of aspirin as a tablet and two buffered solutions," <i>Journal of Pharmaceutical Sciences</i> , 70(3):262-5, 1981.
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	C114	Morris <i>et al.</i> , "Gastric cytoprotection is secondary to increased mucosal fluid secretion: A study of six cytoprotective agents in the rat," <i>J. Clin. Gastroenterol.</i> , 27(Suppl. 1):S53-63, 1998.

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	C118	Naesdal <i>et al.</i> , "Gastro-duodenal protection in an era of cyclo-oxygenase-2-selective nonsteroidal anti-inflammatory drugs," <i>European Journal of Gastroenterology & Hepatology</i> , 13(12):1401-1406, 2001.
	C119	Nefesoglu <i>et al.</i> , "Interaction of omeprazole with enteric-coated Salicylate tablets," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , 36(10):549-553, 1998.
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	C121	Notice of Allowance issued in United States Patent Application No. 10/158,216, dated March 29, 2005. (Attorney Docket No. POZN.P0004US)
	C122	Notice of Allowance issued in United States Patent Application No. 11/129,320, dated May 11, 2012. (Attorney Docket No. POZN.P0004US.CP1)
	C123	Notice of Opposition to a European Patent, submitted against European Patent application No. EP 1 411 900 on April 15, 2011. (Attorney Docket No.: POZN.P0004EP)
	C124	Notice of Opposition to a European Patent, submitted against European Patent application No. EP 1 411 900 on April 20, 2011. (Attorney Docket No.: POZN.P0004EP)
	C125	Oddsson <i>et al.</i> , "Comparison between ranitidine and omeprazole for protection against gastroduodenal damage caused by naproxen," <i>Scand. J. Gastroenterol.</i> , 27:1045-1048, 1992.
	C126	Oddsson <i>et al.</i> , "Endoscopic findings in the stomach and duodenum after treatment with enteric-coated and plain naproxen tablets in healthy subjects," <i>Scand. J. Gastroenterol.</i> , 25:231-234, 1990.
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	C128	Office Communication issued in Canadian Patent Application No. 2,449,098, dated November 6, 2008. (Attorney Docket No.: POZN.P0004CA)
	C129	Office Communication issued in Chinese Patent Application No. 201080037566.1, dated January 10, 2014. (Attorney Docket No. POZN.P0006CN) (English translation of Chinese text)
	C130	Office Communication issued in Egyptian Patent Application No. 2121/2001, dated April 13, 2013. (Attorney Docket No. PZAZ.P0003EG)
	C131	Office Communication issued in Eurasian Patent Application No. 201270071, dated August 5, 2013. (Attorney Docket No. POZN.P0006EA) (English translation of Russian text)
	C132	Office Communication issued in European Patent Application 10 177 150.9, dated November 4, 2010. (Attorney Docket No.: POZN.P0004EP.D1D1)
	C133	Office Communication issued in European Patent Application No. 02 734 602.2, dated June 30, 2008. (Attorney Docket No.: POZN.P0004EP)
	C134	Office Communication issued in European Patent Application No. 02 734 602.2, dated December 18, 2007. (Attorney Docket No. POZN.P0004EP)
	C135	Office Communication issued in European Patent Application No. 02 734 602.2, dated February 22, 2010. (Attorney Docket No.: POZN.P0004EP)
	C136	Office Communication issued in European Patent Application No. 02 734 602.2, dated April 29, 2010. (Attorney Docket No.: POZN.P0004EP)
	C137	Office Communication issued in European Patent Application No. 10 177 150.9, dated November 12, 2010. (Attorney Docket No.: POZN.P0004EP.D1D1)
	C138	Office Communication issued in Israeli Patent Application No. 159129, dated August 22, 2010. (English translation) (Attorney Docket No. POZN.P0004IL)
	C139	Office Communication issued in Israeli Patent Application No. 159129, dated February 16, 2010. (English translation) (Attorney Docket No. POZN.P0004IL)
	C140	Office Communication issued in Israeli Patent Application No. 159129, dated July 7, 2009. (English translation) (Attorney Docket No. POZN.P0004IL)
	C141	Office Communication issued in Israeli Patent Application No. 159129, dated August 8, 2007. (English translation) (Attorney Docket No. POZN.P0004IL)

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	C142	Office Communication issued in Japanese Patent Application No. 2003-501394, dated July 25, 2008. (English translation) (Attorney Docket No. POZN.P0004JP)
	C143	Office Communication issued in Japanese Patent Application No. 2003-501394, dated January 5, 2010. (English translation) (Attorney Docket No. POZN.P0004JP)
	C144	Office Communication issued in Norwegian Patent Application No. 20035275, dated July 14, 2011. (English Translation) (POZN.P0004NO)
	C145	Office Communication issued in United States Patent Application No. 10/158,216, dated April 22, 2004. (Attorney Docket No.: POZN.P0004US)
	C146	Office Communication issued in United States Patent Application No. 10/158,216, dated October 20, 2004. (Attorney Docket No.: POZN.P0004US)
	C147	Office Communication issued in United States Patent Application No. 13/215,855, dated February 28, 2013. (Attorney Docket No. POZN.P0004US.CP1D2)
	C148	Office Communication issued in United States Patent Application No. 13/215,855, dated June 6, 2012. (Attorney Docket No. POZN.P0004US.CP1D2)
	C149	Office Communication issued in United States Patent Application No. 11/129,320, dated October 25, 2010. (Attorney Docket No. POZN.P0004US.CP1)
	C150	Office Communication issued in United States Patent Application No. 11/129,320, dated November 19, 2009. (Attorney Docket No. POZN.P0004US.CP1)
	C151	Office Communication issued in United States Patent Application No. 11/129,320, dated March 30, 2009. (Attorney Docket No. POZN.P0004US.CP1)
	C152	Office Communication issued in United States Patent Application No. 11/129,320, dated September 22, 2008. (Attorney Docket No. POZN.P0004US.CP1)
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	C154	Office Communication issued in United States Patent Application No. 11/129,320, dated January 17, 2012. (Attorney Docket No. POZN.P0004US.CP1)
	C155	Office Communication issued in United States Patent Application No. 12/823,082, dated July 18, 2013. (Attorney Docket No. POZN.P0006US)

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	C156	Office Communication issued in United States Patent Application No. 12/823,082, dated September 17, 2012. (Attorney Docket No. POZN.P0006US)
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	C161	Office Communication issued in United States Patent Application No. 12/822,612, dated July 18, 2013. (Attorney Docket No. POZN.P0027US)
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	C166	Okabe <i>et al.</i> , "Antisecretory effect of leminoprazole on histamine-stimulated gastric acid secretion in guinea pigs: local effect," <i>J. Pharmacol.</i> , 69:91-100, 1995.
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	C170	Patrono <i>et al.</i> , "Low-dose aspirin for the prevention of Atherothrombosis," <i>New Eng. J. Med.</i> , 353:2373-2383, 2005.
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	C184	Pirmohamed <i>et al.</i> , "Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients," <i>Br. Med. J.</i> , 329:15-19, 2004.
	C185	Porter S.C., "Coating of Pharmaceutical Dosage Forms," in: A. Gennaro (Ed.), <i>Remington: the Science and Practice of Pharmacy</i> , 19 th edition. 1650-1651, 1995.
	C186	Preliminary Amendment filed in United States Patent Application No. 13/475,446, filed May 18, 2012. (Attorney Docket No. POZN.P0004US.CP1C1)
	C187	Press Release for "Vimovo, October 16, 2009. (Document D14 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C188	Qureshi <i>et al.</i> , "Pharmacokinetics of two enteric-coated ketoprofen products in humans with or coadministration of omeprazole and comparison with dissolution findings," <i>Pharmaceutical Research</i> , 11(11):1669-1672, 1994.
	C189	Ramage <i>et al.</i> , "Inhibition of food stimulated acid secretion by misoprostol, an orally active synthetic E1 analogue prostaglandin," <i>Br. J. Clin Pharmacol.</i> , 19:9-12, 1985.
	C190	Raskin <i>et al.</i> , "Misoprostol dosage in the prevention of nonsteroidal anti-inflammatory drug-induced gastric and duodenal ulcers: a comparison of three regimens," <i>Ann. Intern. Med.</i> , 123(5):344-350, 1995.
	C191	<i>Remington's Pharmaceutical Sciences</i> , 17th ed., University of Sciences in Philadelphia, 1985.
	C192	Reply to EPO communication of April 29, 2010, dated May 10, 2010 (German and French translation of claims omitted).
	C193	Richardson <i>et al.</i> , "Proton pump inhibitors, pharmacology and rationale for use in gastrointestinal disorders," <i>Drugs</i> , 56(3):307-35, 1998.
	C194	Robinson <i>et al.</i> , "Effects of ranitidine gastroduodenal mucosal damage induced by nonsteroidal anti-inflammatory drugs," <i>Dig. Disc. Sci.</i> , 34(3):424-428, 1989.
	C195	Roche Naproxen EC label, copyright 1999.

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EXAMINER: /Nissa Westerberg/	DATE CONSIDERED: 07/17/2014
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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents See Page 1-7	Foreign Patent Documents See Page 7-11	Other Art See Page 11-29

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C196	Roth <i>et al.</i> , "Cimetidine therapy in nonsteroidal anti-inflammatory drug gastropathy: double-blind long-term evaluation," <i>Arch. Intern. Med.</i> , 147:1798-1801, 1987.
	C197	Rubinstein, "Gastrointestinal anatomy physiology and permeation pathways," <i>Enhancement in Drug Discovery</i> , CRC Press, 3-35, 2007.
	C198	Sangiah <i>et al.</i> , "Effects of misoprostol and omeprazole on basal gastric pH and free acid content in horses," <i>Res. Vet. Sci.</i> , 47(3):350-354, 1989.
	C199	Savarino <i>et al.</i> , "Effect of one-month treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) on gastric pH of rheumatoid arthritis patients," <i>Digestive Diseases and Sciences</i> , 43:459-463, 1998.
	C200	Scarpignato <i>et al.</i> , "Towards a GI safer anti-inflammatory therapy," <i>Gastroenterology International</i> , 186-215, 1999.
	C201	Scheiman <i>et al.</i> , "Omeprazole ameliorates aspirin-induced gastroduodenal injury," <i>Digestive Diseases and Sciences</i> , 39(1):97-103, 1994.
	C202	Scheiman, "NSAID-induced peptic ulcer disease: a critical review of pathogenesis and management," <i>Dig. Dis.</i> , 12:210-222, 1994.
	C203	Scheiman, "Pathogenesis of gastroduodenal injury due to nonsteroidal and anti-inflammatory drug: Implications for prevention and therapy," <i>Seminars in Arthritis and Rheumatism</i> , 21(4):259-268, 1992.
	C204	Scott and Sundell, "Inhibition of H+K+ ATPase by SCH 28080 and SCH 32651," <i>European Journal of Pharmacology</i> , 112:268-270, 1985.
	C205	Seitz <i>et al.</i> , "Tablet Coating," In: The Theory and Practice of Industrial Pharmacy. Eds. Leon Lachman, Herbert A. Lieberman and Joseph L. Kanig. Philadelphia: Lea & Febiger, pages 346-373, 1986.
	C206	Selway, "Potential hazards of long-term acid suppression," <i>Scand. J. Gastroenterol.</i> , 25(Suppl. 178):85-92, 1990.
	C207	Sharma <i>et al.</i> , "Comparison of 24-hour intragastric pH using four liquid formulations of lansoprazole and omeprazole," <i>Am. J. Health-Syst. Pharm.</i> , 56(Suppl. 4):S18-21, 1999.
	C208	Silverman, <i>The Organic Chemistry of Drug Design and Drug Action</i> , 2 nd Edition, Academic Press, p. 102 & p. 527, 2004.

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EXAMINER: /Nissa Westerberg/	DATE CONSIDERED: 07/17/2014
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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C209	Silverstein <i>et al.</i> , "Gastrointestinal toxicity with Celecoxib versus nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis; the CLASS study: A randomized controlled trial," <i>JAMA</i> , 284:1247-1255, 2000.
	C210	Silverstein <i>et al.</i> , "Misoprostol reduces serious gastrointestinal complications in patients with rheumatoid arthritis receiving nonsteroidal anti-inflammatory drugs," <i>Ann. Intern. Med.</i> , 123(4):241-249, 1995.
	C211	Simon <i>et al.</i> , "Schutzwirkung von omeprazol gegenüber niedrig dosierter acetylsalicylsäure," <i>Arzneimittel Forschung</i> , 45:701-703, 1995.
	C212	Summons to Attend Oral Proceedings Pursuant to Rule 116(1): EPC, dated September 3, 2009, issued in European Patent Application No. 02, 734 602.2. (Attorney Docket No.: POZN.P0004EP)
	C213	Sung, "Management of nonsteroidal anti-inflammatory drug-related peptic ulcer bleeding," <i>Am. J. Med.</i> , 110(1A): 29S-32S, 2001.
	C214	Taha <i>et al.</i> , "Famotidine for the prevention of peptic ulcers and oesophagitis in patients taking low-dose aspirin (FAMOUS): a phase III, randomized, double-blind, placebo-controlled trial," <i>Lancet</i> , 374:119-25, 2009.
	C215	Takeuchi <i>et al.</i> , "Effects of topical application of acidified omeprazole on acid secretion and transmucosal potential difference in anesthetized rat stomachs," <i>Japan J. Pharmacol.</i> , 47:397-408, 1988.
	C216	Tronstad <i>et al.</i> , "Gastroscopic findings after treatment with enteric-coated and plain naproxen tablets in healthy subjects," <i>Scand. J. Gastroenterol.</i> , 20:239-242, 1985.
	C217	Vane <i>et al.</i> , "The future of NSAID therapy: selective COX-2 inhibitors," <i>IJCP</i> , 54(1):7-9, January/February 2000.
	C218	von Unge <i>et al.</i> , "Stereochemical assignment of the enantiomers of omeprazole from X-ray analysis of a fenchyloxymethyl derivative of (+)-(R)- omeprazole," <i>Tetrahedron</i> , 8(12):1967-1970, 1997.
	C219	Wagner <i>et al.</i> , "Effects of nonsteroidal anti-inflammatory drugs on ulcerogenesis and gastric secretion in pylorus-ligated rat," <i>Digestive Diseases and Sciences</i> , 40:134-140, 1995.
	C220	Wakitani <i>et al.</i> , "Profile of JTE-522 as a human cyclooxygenase-2 inhibitor," <i>Jpn. J. Pharmacol.</i> , 78:365-371, 1998.

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EXAMINER: /Nissa Westerberg/	DATE CONSIDERED: 07/17/2014
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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.M.W./

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C221	Wallmark <i>et al.</i> , "The relationship between gastric acid secretion and gastric H ⁺ , K ⁺ -ATPase activity," <i>J. Biol. Chem.</i> , 260(25): 13681-13684, 1985.
	C222	Warner <i>et al.</i> , "Nonsteroidal drug selectives for cyclo-oxygenase-1 rather than cyclo-oxygenase-2 are associated with human gastrointestinal toxicity: a full in vitro analysis," <i>Proc. Natl. Acad. Sci. USA</i> , 96:7563-7568, 1999.
	C223	Weil <i>et al.</i> , "Prophylactic aspirin and risk of peptic ulcer bleeding," <i>BMJ</i> , 310: 827-830, 1995.
	C224	Wilson <i>et al.</i> , "Effects of misoprostol on gastric acid and mucus secretion in man," <i>Digestive Diseases and Sciences</i> , 31(2): 126S-129S, 1986.
	C225	Wolfe <i>et al.</i> , "Acid suppression: optimizing therapy for gastroduodenal ulcer healing, gastroesophageal reflux disease, and stress related erosive syndrome," <i>Gastroenterology</i> , 118(2):S9-S31, 2000.
	C226	Wolfe <i>et al.</i> , "Gastrointestinal toxicity of nonsteroidal anti-inflammatory drugs," <i>N. Engl. J. Med.</i> , 340:1888-1899, 1999.
	C227	Yeomans <i>et al.</i> , "A comparison of omeprazole with ranitidine for ulcers associated with nonsteroidal anti-inflammatory drugs," <i>N. Engl. J. Med.</i> , 338:719-726, 1998.
	C228	Yeomans <i>et al.</i> , "Efficacy of esomeprazole (20 mg once daily) for reducing the risk of gastroduodenal ulcers associated with continuous use of low-dose aspirin," <i>American Journal of Gastroenterology</i> , 103:1-9, 2008.
	C229	Yeomans <i>et al.</i> , "New data on healing of nonsteroidal anti-inflammatory drug-associated ulcers and erosions," <i>Am. J. Med.</i> , 104:56S-61S, 1998.

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EXAMINER: /Nissa Westerberg/

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/25 PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce	
Electronic Petition Request	TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION AND TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT		
Application Number	14244471		
Filing Date	03-Apr-2014		
First Named Inventor	John PLACHETKA		
Attorney Docket Number	POZN.P0004US.CP1C4		
Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		
<input checked="" type="checkbox"/> Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action <input checked="" type="checkbox"/> This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.			
Owner		Percent Interest	
Pozen Inc.		100 %	
The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)			
14231971 filed on 04/01/2014 14045156 filed on 10/03/2013 as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.			

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicants claims the following fee status:

☐ Small Entity

☐ Micro Entity

☒ Regular Undiscounted

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.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 37642

☐ A sole inventor

☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

☐ A joint inventor; all of whom are signing this request

Signature	/Steven L. Highlander/
Name	Steven L. Highlander

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	14244471			
Filing Date:	03-Apr-2014			
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
First Named Inventor/Applicant Name:	John R. PLACHETKA			
Filer:	Steven Lee Highlander/Richard Ortiz			
Attorney Docket Number:	POZN.P0004US.CP1C4			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Statutory or Terminal Disclaimer	1814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				160

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 14244471

Filing Date: 03-Apr-2014

Applicant/Patent under Reexamination: PLACHETKA et al.

Electronic Terminal Disclaimer filed on July 14, 2014

☒ APPROVED

This patent is subject to a terminal disclaimer

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U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	19570902
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard Ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	14-JUL-2014
Filing Date:	03-APR-2014
Time Stamp:	15:10:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	1480
Deposit Account	
Authorized User	

File Listing:

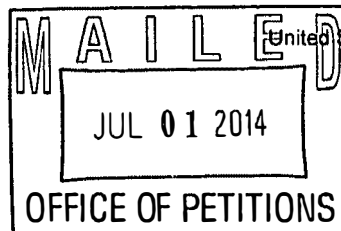
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1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	37650 94ee1fc584005be8a0fac613e68de446cc9c6c8e	no	3
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30276 74e5612627b4f484260f42948ab749965b906342	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			67926		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



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Parker Highlander PLLC
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Austin TX 78746



Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/244,471
<p>1. THE REQUEST FILED <u>April 3, 2014</u> IS GRANTED.</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I). B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims,</u> or a multiple dependent claim; C. filing a <u>request for continued examination</u>; D. filing a notice of appeal; E. filing a request for suspension of action; F. mailing of a notice of allowance; G. mailing of a final Office action; H. completion of examination as defined in 37 CFR 41.102; or I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.</p> <p>/Brian W. Brown/ [Signature]</p> <p>Petitions Examiner, Office of Petitions (Title)</p>	



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APPLICATION NUMBER	FILING or 371(c) DATE	CLASS NO.	FIL FEE REC'D	ATTY. DOCKET NO.	CLASS NO.	CLASS NO.
14/244,471	04/03/2014	1615	1740	POZN.P0004US.CP1C4	19	2

CONFIRMATION NO. 3047

UPDATED FILING RECEIPT



OC000000069211019

108197
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1120 South Capital of Texas Highway
Bldg. 1, Suite 200
Austin, TX 78746

Date Mailed: 06/27/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

John R. PLACHETKA, Chapel Hill, NC;

Applicant(s)

Pozen Inc., Chapel Hill, NC

Assignment For Published Patent Application

Pozen Inc., Chapel Hill, NC

Power of Attorney: The patent practitioners associated with Customer Number 108197**Domestic Priority data as claimed by applicant**

This application is a CON of 14/045,156 10/03/2013
which is a CON of 13/215,855 08/23/2011 PAT 8557285
which is a DIV of 12/553,804 09/03/2009 ABN
which is a DIV of 11/129,320 05/16/2005 PAT 8206741
which is a CIP of 10/158,216 05/31/2002 PAT 6926907
which claims benefit of 60/294,588 06/01/2001

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 04/24/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/244,471**

Projected Publication Date: 07/31/2014

Non-Publication Request: No

Early Publication Request: No

Title

PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
14/244,471

APPLICATION AS FILED - PART I

(Column 1)		(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(j))	19	minus 20 = *			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
			TOTAL			TOTAL	1600

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
		Total (37 CFR 1.16(i))	*	Minus	**	-	x	=	OR	x	=
		Independent (37 CFR 1.16(h))	*	Minus	***	-	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))								OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY		
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
		Total (37 CFR 1.16(i))	*	Minus	**	-	x	=	OR	x	=
		Independent (37 CFR 1.16(h))	*	Minus	***	-	x	=	OR	x	=
	Application Size Fee (37 CFR 1.16(s))								OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4

CONFIRMATION NO. 3047

POA ACCEPTANCE LETTER



OC000000069211047

108197
Parker Highlander PLLC
1120 South Capital of Texas Highway
Bldg. 1, Suite 200
Austin, TX 78746

Date Mailed: 06/27/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/23/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/cnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:



Practitioners associated with Customer Number:

108197

OR



Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:



The address associated with Customer Number:

108197

OR

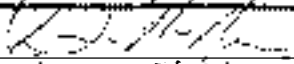
<input type="checkbox"/>	Firm or Individual Name			
	Address			
	City	State	Zip	
	Country			
	Telephone	Email		

Assignee Name and Address: Pozen Inc.
1414 Raleigh Road, Suite 400
Chapel Hill, NC 27517

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	18 June 2014
Name	Dennis M. Harmon	Telephone	919 913 1030
Title	SVP Chief Business Officer		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	14244471			
Filing Date:	03-Apr-2014			
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
First Named Inventor/Applicant Name:	John R. PLACHETKA			
Filer:	Steven Lee Highlander/Richard Ortiz			
Attorney Docket Number:	POZN.P0004US.CP1C4			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Late Filing Fee for Oath or Declaration	1051	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				140

Electronic Acknowledgement Receipt

EFS ID:	19380969
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard Ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	23-JUN-2014
Filing Date:	03-APR-2014
Time Stamp:	15:12:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 140
RAM confirmation Number	1589
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		POZNP0004USCP1C4_Resp-MPS-Decl-POA.pdf	1989204 3f09c34470ec226f84d273302f30232f8d1	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Response to Pre-Exam Formalities Notice		1	2	
	Assignee showing of ownership per 37 CFR 3.73.		3	4	
	Oath or Declaration filed		5	5	
	Power of Attorney		6	6	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	29951 c598dce63f899bb4334e80044c0db8345d364ac	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			2019155		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p>New Applications Under 35 U.S.C. 111 If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John R. PLACHETKA

Group Art Unit: 1615

Serial No.: 14/244,471

Examiner: To Be Assigned

Filing Date: April 3, 2014

Attorney Docket No.: POZN.P0004US.CP1C4

Title: PHARMACEUTICAL
COMPOSITIONS FOR THE
COORDINATED DELIVERY OF
NSAIDS

Confirmation No.: 3047

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the
United States Patent and Trademark Office via EFS-Web on the date below:

June 23, 2014

/Steven L. Highlander/

Date

Steven L. Highlander

**RESPONSE TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL
APPLICATION FILED UNDER 37 C.F.R. § 1.53(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Commissioner:

Applicant respectfully submits this response to the Notice to File Missing Parts of
Nonprovisional Application filed under 37 C.F.R. § 1.53(b), dated April 25, 2014, for which a
response is due June 25, 2014. In response to the Notice, attached are:

- 1) Declaration executed by John R. PLACHETKA;
- 2) Statement Under 37 CFR § 3.73(c);
- 3) Power of Attorney on behalf of Pozen Inc; and

- 4) Payment via credit card through EFS-Web in the amount of \$140.00 to cover the late filing of an oath/declaration for a Large Entity.

The required fee in the amount of \$140.00 in connection with the filing of this paper is being charged to a credit card through EFS-Web concurrently with this submission. The Commissioner is hereby authorized to deduct any underpayment of fees or any additional fees required under 37 C.F.R. §§ 1.16 to 1.21 in connection with the filing of this paper from Parker Highlander PLLC Deposit Account No. 50-5902/POZN.P0004US.CP1C4.

Respectfully submitted,

/Steven L. Highlander/

Steven L. Highlander
Reg. No. 37,642
Attorney for Applicant

Parker Highlander PLLC
1120 S. Capital of Texas Highway
Building One, Suite 200
Austin, Texas 78746
512-334-2900 (Telephone)
512-334-2999 (Fax)

Date: June 23, 2014

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: John R. PLACHÉ-KA

Application No./Patent No.: 14/244,471

Filed/Issue Date: April 3, 2014

Titled: PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

Pozen Inc., a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose one of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

☐ The extent (by percentage) of its ownership interest is ____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

--

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

--

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose one of options A or B below):

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 025110 Frame 0242 or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____ or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____ or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.☐ Additional documents in the chain of title are listed on a supplemental sheet(s).☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Steven L. Highlander/

June 23, 2014

Signature

Date

Steven L. Highlander

Attorney - Reg. No. 37,642

Printed or Typed Name

Title or Registration Number

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
---------------------------	---

As the below named inventor, I hereby declare that:

This declaration is directed to: ☐ The attached application, or

☒ United States application or PCT international application number 14/244,471

filed on April 3, 2014

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: John R. PLACHETKADate of Declaration: March 27, 2014Signature: 

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Form PTO-1449 (modified)		Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: John R. PLACHETKA	
		Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>		Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Exam. Init.	Ref. Des.	Document Number	Date	Name
	A1	2001-0025107	09/27/01	Barberich <i>et al.</i>
	A2	2002-0012676	01/31/02	Lundberg <i>et al.</i>
	A3	2002-0042433	04/11/02	Yelle <i>et al.</i>
	A4	2002-0044962	04/18/02	Cherukuri <i>et al.</i>
	A5	2002-0045184	04/18/02	Chen
	A6	2002-0051814	05/02/02	Chen
	A7	2002-0086029	07/04/02	Lundberg <i>et al.</i>
	A8	2002-0090395	07/11/02	Woolfe <i>et al.</i>
	A9	2002-0111370	08/15/02	Bergman <i>et al.</i>
	A10	2002-0155153	12/24/02	Depui <i>et al.</i>
	A11	2002-0160046	10/31/02	Robinson <i>et al.</i>
	A12	2003-0008903	01/09/03	Barberich <i>et al.</i>
	A13	2003-0040537	02/27/03	Plachetka <i>et al.</i>
	A14	2003-0069255	08/09/05	Plachetka
	A15	2003-0113375	06/19/03	Lundberg <i>et al.</i>
	A16	2003-0129235	07/10/03	Chen <i>et al.</i>
	A17	2003-0215527	11/20/03	Phillips
	A18	2003-0232080	12/18/03	Pather <i>et al.</i>
	A19	2003-0232876	12/18/03	Plachetka
	A20	2004-0022846	02/05/04	Depui <i>et al.</i>
	A21	2004-0048896	03/11/04	Phillips
	A22	2004-0121004	06/24/04	Taneja
	A23	2004-0131676	07/08/04	Taneja
	A24	2004-0171646	09/02/04	Phillips
	A25	2004-0180089	09/16/04	Plachetka <i>et al.</i>

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Form PTO-1449 (modified)		Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: John R. PLACHETKA	
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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A26	2005-0004171	01/06/05	Phillips
	A27	2005-0042304	02/24/05	Phillips
	A28	2005-0054682	03/10/05	Phillips
	A29	2005-0147668	07/07/05	Bertelsen <i>et al.</i>
	A30	2005-0163847	07/28/05	Cheng <i>et al.</i>
	A31	2005-0227949	10/13/05	Edalatpour <i>et al.</i>
	A32	2005-0249806	11/10/05	Proehl <i>et al.</i>
	A33	2005-0249811	11/10/05	Plachetka
	A34	2006-0165797	07/27/06	Plachetka
	A35	2006-0177504	08/10/06	Sudharadas
	A36	2006-0178348	08/10/06	Plachetka
	A37	2006-0178349	08/10/06	Plachetka
	A38	2006-0287284	12/21/06	Schutze <i>et al.</i>
	A39	2007-0122470	05/31/07	Johansson <i>et al.</i>
	A40	2007-0154542	07/05/07	Tananbaum <i>et al.</i>
	A41	2007-0184078	08/09/07	Chen
	A42	2007-0207200	09/06/07	Plachetka <i>et al.</i>
	A43	2007-0237820	10/11/07	Cheng <i>et al.</i>
	A44	2007-0243251	10/18/07	Taneja
	A45	2008-0031941	02/07/08	Pettersson
	A46	2008-0031950	02/07/08	Sesha
	A47	2008-0103169	05/01/08	Phillips
	A48	2009-0074863	03/19/09	Taneja
	A49	2009-0075950	03/19/09	Taneja
	A50	2009-0163551	06/25/09	Earnest

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A51	2009-0297594	12/03/09	Depui <i>et al.</i>
	A52	2010-0062064	03/11/10	Ault <i>et al.</i>
	A53	2010-0172983	07/08/10	Plachetka
	A54	2010-0178334	07/15/10	Johansson <i>et al.</i>
	A55	2010-0330179	12/30/10	Ault <i>et al.</i>
	A56	2012-0064156	03/15/12	Plachetka
	A57	2013-0078305	03/28/13	Plachetka
	A58	4,198,390	04/15/80	Rider
	A59	4,255,431	03/10/81	Junggren <i>et al.</i>
	A60	4,344,929	08/17/82	Bonsen <i>et al.</i>
	A61	4,508,905	04/02/85	Junggren <i>et al.</i>
	A62	4,554,276	11/19/82	LaMatina
	A63	4,562,261	12/31/85	Hirata <i>et al.</i>
	A64	4,619,934	10/28/86	Sunshine <i>et al.</i>
	A65	4,676,984	06/30/87	Wu <i>et al.</i>
	A66	4,704,278	11/03/87	Wu <i>et al.</i>
	A67	4,726,951	02/23/88	Panoz <i>et al.</i>
	A68	4,738,974	04/19/88	Brandstrom
	A69	4,757,060	07/12/88	Lukacsko <i>et al.</i>
	A70	4,758,579	07/19/88	Kohl <i>et al.</i>
	A71	4,766,117	08/23/88	Crawford <i>et al.</i>
	A72	4,786,505	11/22/88	Lovgren <i>et al.</i>
	A73	4,853,230	08/01/89	Lovgren <i>et al.</i>
	A74	4,865,847	09/12/89	Gosswein
	A75	4,948,581	08/14/90	Sawayangi <i>et al.</i>

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A76	4,965,065	10/23/90	Lukacsko <i>et al.</i>
	A77	5,026,560	06/25/91	Makino <i>et al.</i>
	A78	5,035,899	07/30/91	Saeki <i>et al.</i>
	A79	5,037,815	08/06/91	Lukacsko <i>et al.</i>
	A80	5,043,358	08/27/91	Lukacsko <i>et al.</i>
	A81	5,051,262	09/24/91	Panoz <i>et al.</i>
	A82	5,093,132	03/03/92	Makino <i>et al.</i>
	A83	5,204,118	04/20/93	Goldman <i>et al.</i>
	A84	5,260,333	11/09/93	Lukacsko <i>et al.</i>
	A85	5,364,616	11/15/91	Singer <i>et al.</i>
	A86	5,373,022	12/13/94	Fawzi <i>et al.</i>
	A87	5,409,709	04/25/95	Ozawa <i>et al.</i>
	A88	5,417,980	05/23/95	Goldman <i>et al.</i>
	A89	5,466,436	11/14/95	Stables
	A90	5,514,663	05/07/96	Mandel
	A91	5,601,843	02/11/97	Gimet
	A92	5,631,022	05/20/94	Mandel <i>et al.</i>
	A93	5,643,960	07/01/97	Breitner <i>et al.</i>
	A94	5,667,802	09/16/97	Grimberg
	A95	5,679,376	10/21/97	Stevens <i>et al.</i>
	A96	5,686,105	11/11/97	Kelm <i>et al.</i>
	A97	5,690,960	11/25/97	Bengtsson <i>et al.</i>
	A98	5,702,723	12/30/97	Griffin
	A99	5,714,504	02/03/98	Lindberg <i>et al.</i>
	A100	5,716,648	02/10/98	Halskov <i>et al.</i>

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A101	5,750,531	05/12/98	Lee <i>et al.</i>
	A102	5,817,338	10/06/98	Bergstrand <i>et al.</i>
	A103	5,817,340	10/06/98	Roche <i>et al.</i>
	A104	5,840,737	11/24/98	Phillips
	A105	5,872,145	02/16/99	Plachetka
	A106	5,877,192	03/02/99	Lindberg <i>et al.</i>
	A107	5,900,424	05/04/99	Kallstrom <i>et al.</i>
	A108	5,955,451	09/21/99	Lichtenberger <i>et al.</i>
	A109	6,013,281	01/11/00	Lundberg <i>et al.</i>
	A110	6,025,395	02/15/00	Breitner <i>et al.</i>
	A111	6,060,499	05/09/00	Plachetka
	A112	6,093,734	07/25/00	Garst <i>et al.</i>
	A113	6,126,816	12/19/00	Bohlin <i>et al.</i>
	A114	6,132,768	10/17/00	Sachs <i>et al.</i>
	A115	6,132,771	10/17/00	Depui <i>et al.</i>
	A116	6,136,344	10/24/00	Depui <i>et al.</i>
	A117	6,160,020	12/12/00	Ohannesian <i>et al.</i>
	A118	6,162,816	12/19/00	Bohlin <i>et al.</i>
	A119	6,183,776	02/06/01	Depui <i>et al.</i>
	A120	6,183,779	02/06/01	Ouali <i>et al.</i>
	A121	6,207,188	03/27/01	Gustavsson <i>et al.</i>
	A122	6,231,888	05/15/01	Lerner <i>et al.</i>
	A123	6,287,600	09/11/01	Ouali <i>et al.</i>
	A124	6,365,184	04/02/02	Depui <i>et al.</i>
	A125	6,369,085	04/09/02	Cotton <i>et al.</i>

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A126	6,372,255	04/16/02	Saslawski
	A127	6,387,410	05/14/02	Woolfe
	A128	6,395,298	05/28/02	Flannagan <i>et al.</i>
	A129	6,428,810	08/06/02	Bergstrand <i>et al.</i>
	A130	6,485,747	11/26/02	Flanagan <i>et al.</i>
	A131	6,489,346	12/03/02	Phillips
	A132	6,544,556	04/08/03	Chen <i>et al.</i>
	A133	6,599,529	07/29/03	Skinhoj <i>et al.</i>
	A134	6,610,323	08/26/03	Lundberg <i>et al.</i>
	A135	6,613,354	09/02/03	Depui <i>et al.</i>
	A136	6,632,451	10/14/03	Penhasi <i>et al.</i>
	A137	6,641,838	11/04/03	Pather <i>et al.</i>
	A138	6,645,988	11/11/03	Phillips
	A139	6,673,819	01/06/04	Bergman <i>et al.</i>
	A140	6,685,964	02/03/04	Bartholomaeus <i>et al.</i>
	A141	6,699,885	03/02/04	Phillips
	A142	6,713,089	03/30/04	Bertelsen <i>et al.</i>
	A143	6,749,867	06/15/04	Robinson <i>et al.</i>
	A144	6,780,882	08/24/04	Phillips
	A145	6,787,164	09/07/04	Gelber <i>et al.</i>
	A146	6,797,283	09/28/04	Edgren <i>et al.</i>
	A147	6,869,615	03/22/05	Chen <i>et al.</i>
	A148	6,875,872	04/05/05	Lindberg <i>et al.</i>
	A149	6,926,907	08/09/05	Plachetka
	A150	7,029,701	04/18/06	Chen

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Exam. Init.	Ref. Des.	Document Number	Date	Name
	A151	7,030,162	04/18/06	Plachetka <i>et al.</i>
	A152	7,060,694	06/13/06	Plachetka <i>et al.</i>
	A153	7,094,425	08/22/06	Scott <i>et al.</i>
	A154	7,332,183	02/19/08	Plachetka <i>et al.</i>
	A155	7,399,772	07/15/08	Phillips
	A156	7,411,070	08/12/08	Cotton <i>et al.</i>
	A157	7,488,497	02/10/09	Depui <i>et al.</i>
	A158	7,745,466	06/29/10	Cotton <i>et al.</i>
	A159	7,785,626	08/31/10	Pettersson <i>et al.</i>
	A160	7,846,914	12/07/10	Petrus
	A161	8,206,741	06/26/12	Plachetka <i>et al.</i>

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B1	AU 2006235929	11/30/06	Australia	Pozen Inc.
	B2	CA 2,139,653	07/10/01	Canada	Astra Aktiebolag
	B3	DE 198 01 811	01/19/98	Germany	Stada Arzneimittel AG German (English abstract)
	B4	DE 40 35 455	05/14/92	Germany	Byk Gulden Lomberg Chem Fab German (English Abstract)
	B5	EP 0 005 129	10/31/79	Europe	Haessle AB
	B6	EP 0 124 495	11/07/84	Europe	Haessle AB
	B7	EP 0 166 287	01/02/86	Europe	Byk Gulden Lomberg Chem Fab German (English Abstract)
	B8	EP 0 167 958	01/15/86	Europe	Paolo Colombo
	B9	EP 0 174 726	03/19/86	Europe	Takeda Chemical Industries Ltd.

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	B10	EP 0 244 380	11/04/87	Europe	Haessle AB
	B11	EP 0 320 550	06/21/89	Europe	Bristol Myers Co.
	B12	EP 0 320 551	06/21/89	Europe	Bristol Myers Co.
	B13	EP 0 426 479 A1	05/08/91	Europe	McNeil PPC Inc.
	B14	EP 0 426 479 B1	05/08/91	Europe	McNeil PPC Inc.
	B15	EP 0 550 083	07/07/93	Europe	Glaxo Group Ltd.
	B16	EP 1 020 461	07/19/00	Europe	AstraZeneca AB
	B17	EP 1 068 867	01/17/01	Europe	Bernard Charles Sherman
	B18	EP 1 411 900	07/21/10	Europe	Pozen Inc.
	B19	EP 1 726 300	11/29/06	Europe	Flamel Technologies
	B20	EP 1 726 301	11/29/06	Europe	Flamel Technologies
	B21	GB 2 105 193	03/23/83	United Kingdom	Glaxo Group Limited
	B22	GB 2 163 747	03/05/86	United Kingdom	Nippon Chemiphar Co.
	B23	GB 2 216 413	10/11/89	United Kingdom	Glaxo Limited Group
	B24	JP 2005-145894	06/09/05	Japan	Takeda Chemical Industries Ltd. Japanese (English abstract)
	B25	WO 1985/003433	08/15/85	WIPO	Gustavsson <i>et al.</i>
	B26	WO 1990/006925	06/28/90	WIPO	Aktiebolaget Hässle
	B27	WO 1991/016886	11/14/91	WIPO	G.D. Searle & Co.
	B28	WO 1991/016895	11/14/91	WIPO	G.D. Searle & Co.
	B29	WO 1991/016896	11/14/91	WIPO	G. D. Searle & Co.
	B30	WO 1991/019711	12/26/91	WIPO	Aktiebolaget Astra
	B31	WO 1991/019712	12/26/91	WIPO	Aktiebolaget Astra
	B32	WO 1993/011750	11/14/91	WIPO	Fuisz Technologies Ltd.

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	B33	WO 1993/012817	07/08/93	WIPO	Warner-Lambert Company
	B34	WO 1994/007541	04/14/94	WIPO	Merck & Co., Inc.
	B35	WO 1994/027988	12/08/94	WIPO	Astra Aktiebolag
	B36	WO 1995/001977	01/19/95	WIPO	Astra Aktiebolag
	B37	WO 1995/032959	12/07/95	WIPO	Astra Aktiebolag
	B38	WO 1996/005177	02/22/96	WIPO	Yuhan Corporation
	B39	WO 1996/005199	02/22/96	WIPO	BYK Gulden Lomberg Chemische Fabrik GMBH German (English Abstract)
	B40	WO 1996/014839	05/23/96	WIPO	Farmarc Nederland BV
	B41	WO 1996/022780	08/01/96	WIPO	The Board Of Regents of The University of Texas System
	B42	WO 1997/011701	04/03/97	WIPO	Merck-Frosst Canada Inc.
	B43	WO 1997/025064	07/17/97	WIPO	Astra Aktiebolag
	B44	WO 1998/013073	04/02/98	WIPO	Board of Regents, The University of Texas System
	B45	WO 1998/022117	05/28/98	WIPO	The Procter & Gamble Company
	B46	WO 1998/022118	05/28/98	WIPO	The Procter & Gamble Company
	B47	WO 1998/054171	12/03/98	WIPO	Astra Aktiebolag
	B48	WO 1999/000380	01/07/99	WIPO	Astra Aktiebolag
	B49	WO 1999/012524	03/18/99	WIPO	Nycomed Danmark A/S
	B50	WO 1999/029320	06/17/99	WIPO	BYK Gulden Lomberg Chemische Fabrik GMBH German
	B51	WO 1999/066919	12/29/99	WIPO	McNeil-PPC, Inc.

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Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B52	WO 2000/001368	01/13/00	WIPO	Norton Healthcare Ltd.
	B53	WO 2000/015195	03/23/00	WIPO	Nycomed Danmark A/S
	B54	WO 2000/056339	09/28/00	WIPO	Pharmascience Inc.
	B55	WO 2000/071122	11/30/00	WIPO	PAR Pharmaceutical, INC.
	B56	WO 2000/072838	12/07/00	WIPO	AstraZeneca AB
	B57	WO 2000/078293	12/28/00	WIPO	AstraZeneca AB
	B58	WO 2001/024777	04/12/01	WIPO	American Home Products Corporation
	B59	WO 2001/066088	03/13/01	WIPO	AstraZeneca AB
	B60	WO 2002/022108	03/21/02	WIPO	Andrx Corporation
	B61	WO 2002/066002	08/29/02	WIPO	Glaxo Wellcome S.A.
	B62	WO 2002/098352	12/12/02	WIPO	Pozen Inc.
	B63	WO 2003/017980	03/06/03	WIPO	Takeda Chemical Industries, Ltd.
	B64	WO 2004/062552	07/29/04	WIPO	Galephar M/F
	B65	WO 2004/064815	08/05/04	WIPO	Smartrix Technologies Inc.
	B66	WO 2005/074536	08/18/05	WIPO	EISAI Co., Ltd.
	B67	WO 2005/074930	08/18/05	WIPO	Altana Pharma AG
	B68	WO 2006/044202	04/27/06	WIPO	James W. Ayres
	B69	WO 2007/064274	06/07/07	WIPO	AstraZeneca AB
	B70	WO 2007/078874	07/12/07	WIPO	Cogentus Pharmaceuticals, Inc.
	B71	WO 2008/101060	08/21/08	WIPO	Logical Therapeutics, Inc.
	B72	WO 2009/012393	01/22/09	WIPO	The Curators Of The University Of Missouri

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Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Name
	B73	WO 2009/145905	12/03/09	WIPO	Pozen Inc.
	B74	WO 2010/151697	12/29/10	WIPO	Pozen Inc.

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	C1	"A 12 month, phase 3, open-label, multi-center study to evaluate the long –term safety of PN 400," <i>ClinicalTrials.gov</i> , September 11, 2007, accessed from < http://clinicaltrials.gov/ct2/show/NCT00527904 > on September 6, 2012.
	C2	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.: Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd's. Invalidity contentions pursuant to L. Pat. R. 3.6(c)," dated November 23, 2011.
	C3	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. V Lupin Ltd. And Lupin Pharmaceuticals, Inc.: Defendants Lupin Ltd. And Lupin Pharmaceuticals, Inc's Amended Invalidity Contentions Pursuant to L. PAT. R. 3.3 and 3.6(c)," dated April 20, 2012.
	C4	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v Lupin Ltd. And Lupin Pharmaceuticals Inc.: Defendants Lupin Ltd. And Lupin Pharmaceuticals, Inc.'s Invalidity Contentions Pursuant to L. Pat. R. 3.3 and 3.6(c)," dated November 23, 2011.
	C5	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v. Anchen Pharmaceuticals, Inc.: Anchen's Initial Invalidity Contentions," dated May 11, 2012.
	C6	"Astrazeneca AB, Astrazeneca LP, KBI-E Inc., and Pozen, Inc. v. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.: Plaintiffs' Response to DRL's First Set of Interrogatories to Plaintiffs (Nos. 1-5)," dated March 5, 2012.
	C7	"Histamine H2 antagonist," accessed from < drugs.com > on September 6, 2012.
	C8	"Notice of Paragraph IV Certification Re: Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Naproxen and Esomeprazole Magnesium Delayed Release Tablets; U.S. Patent No. 6,926,907, from Dr. Reddy's Laboratories, Ltd./Dr. Reddy's Laboratories, Inc., dated March 11, 2011.

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	C9	"PK Study to evaluate esomeprazole plasma levels following the administration of PN 400," <i>ClinicalTrials.gov</i> , January 11, 2008, accessed from < http://clinicaltrials.gov/ct2/show/NCT00599404 > on September 6, 2012.
	C10	"Study evaluating the bioavailability of Naproxen 500 mg in three formulations," <i>ClinicalTrials.gov</i> , April 23, 2008, accessed from < http://clinicaltrials.gov/ct2/show/NCT00665743 >, on September 6, 2012.
	C11	Abelo <i>et al.</i> , "Pharmacodynamic modeling of reversible gastric acid pump inhibition in dog and man," <i>European Journal of Pharmaceutical Sciences</i> , 14:339-346, 2001.
	C12	Alberts <i>et al.</i> , "Efficacy and Safety of PA, a Novel Combination of Enteric-Coated Aspirin and Immediate-Release Omeprazole," <i>International Stroke Conference</i> , 2009, retrieved from the Internet at: http://www.pozen.com/wp-content/uploads/2011/08/ISC2009Albertsfile.pdf , retrieved December 14, 2012.
	C13	Alexander <i>et al.</i> , "Pilot evaluation of a novel combination table (PN 400) containing a proton pump inhibitor and a nonsteroidal anti-inflammatory drug in prevention of upper gastrointestinal mucosal injury," <i>American Journal of Gastroenterology</i> , 100(9), S68, 135, 2005.
	C14	Andersson, "Pharmacokinetics, metabolism and interactions of acid pump inhibitors," <i>Clin. Pharmacokinet.</i> , 31(1):9-28, 1996.
	C15	Anonymous, "Evaluate Relative Bioavailability of PA32540 (Asa/Omeprazole), Its Aspirin Component, and Ecotrin in Healthy Volunteers," <i>ClinicalTrials.gov</i> , March 7, 2008, retrieved from the Internet at: http://www.clinicaltrials.gov/ct2/show/NCT00632086?term=aspirin+omeprazole&rank=18 , retrieved on December 28, 2012.
	C16	Anonymous, "POZEN's PA32520 Study Data Demonstrated Better Upper Gastrointestinal Protection," <i>Drugs.com</i> , November 11, 2008, retrieved from the Internet at: http://www.drugs.com/clinical_trials/pozen-s-pa32520-study-data-demonstrated-better-upper-gastrointestinal-protection-6195.html , retrieved December 17, 2012.
	C17	Anonymous, "Study Evaluating the Effect of Gastroduodenal Mucosa of PA32540, A32540 and Celecoxib, and Aspirin with Celecoxib (PA32540-109)," <i>ClinicalTrials.gov</i> , January 9, 2009, retrieved from the Internet at: http://www.clinicaltrials.gov/ct2/show/NCT00700687?term=aspirin+omeprazole&rank=36 , retrieved December 18, 2012.

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	C18	Anonymous, "Study to Evaluate the Incidence of Gastric Ulcers Following Administration of Either PA32540 or Enteric Coated Aspiring 325 mg in Subjects Who Are at Risk for Developing Aspirin-Associated Ulcers," <i>ClinicalTrials.gov</i> , August 17, 2009, retrieved from the Internet at: http://clinicaltrials.gov/archive/NCT00960869/2009_08_17 , retrieved December 18, 2012.
	C19	Approval of Amendments/correction filed May 10, 2010 dated June 21, 2010 (European application issued as EP 1 411 900 B1). (Attorney Docket No.: POZN.P0004EP)
	C20	Awtry <i>et al.</i> , "Aspirin," <i>Circulation</i> , 101:1206-1218, 2000.
	C21	Bajbouj <i>et al.</i> , "A prospective multicenter clinical and endoscopic follow-up study of patients with gastroesophageal reflux disease," <i>Z. Gastroenterol.</i> , 43:1303-1307, 2005.
	C22	Ballinger <i>et al.</i> , "COX-2 inhibitors versus NSAIDs in gastrointestinal damage and prevention," <i>Exp. Opin. Pharmacother.</i> , 2(1):31-40, 2001.
	C23	Barnett <i>et al.</i> , "Effects of SCH 32651 on resting and stimulated acid secretion in guinea-pig isolated fundic mucosa," <i>Br. J. Pharmac.</i> , 83:75-82, 1984.
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	C25	Bergmann <i>et al.</i> , "Protection against aspirin-induced gastric lesions by lansoprazole: simultaneous evaluation of functional and morphologic responses," <i>Clin. Pharmacol. Ther.</i> , 52:413-416, 1992.
	C26	Bianchi Porro <i>et al.</i> , "Pantoprazole versus placebo in prevention of NSAID-induced ulcers," <i>Gastroenterology</i> , 114(4):A74, 1998.
	C27	Bianchi Porro <i>et al.</i> , "Prevention of gastroduodenal damage with omeprazole in patients receiving continuous NSAIDs treatment. A double blind placebo controlled study," <i>Ital. J. Gastroenterol. Hepatol.</i> , 30:43-47, 1998.
	C28	Bianchi Porro <i>et al.</i> , "Why are non-steroidal anti-inflammatory drugs important in peptic ulcers?" <i>Aliment. Pharmacol. Therap.</i> , 1:540S-547S, 1987.
	C29	Bigard <i>et al.</i> , "Complete prevention by omeprazole of aspirin induced gastric lesions in healthy subjects," <i>Gut</i> , 29(5):A712, T49, 1988.

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	C30	Bigard <i>et al.</i> , "Effet protecteur de l'omeprazole sur les lesions gastriques induites par une prise unique d'aspirine chez l'homme," <i>Gastroenterol. Clin. Biol.</i> , 12:770-771, 1998.
	C31	Bombardier <i>et al.</i> , "Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis," <i>N. Engl. J. Med.</i> , 343:1520-1528, 2000.
	C32	Brown <i>et al.</i> , "Aspirin- and indomethacin-induced ulcers and their antagonism by antihistamines," <i>Euro. J. Pharm.</i> , 51:275-283, 1978.
	C33	Brown <i>et al.</i> , "Prevention of the gastrointestinal adverse effects of nonsteroidal anti-inflammatory drugs," <i>Pract. Drug Safety</i> , 21:503-512, 1999.
	C34	Byrn <i>et al.</i> , "Pharmaceutical solids: A strategic approach to regulatory considerations," <i>Pharm. Res.</i> , 12(7): 945-954, 1995.
	C35	Carrasco-Portugal <i>et al.</i> , "Bioavailability of a formulation containing a diclofenac-rantidine combination," <i>Proc. West. Pharmacol. Soc.</i> , 45:8-10, 2002.
	C36	Chan <i>et al.</i> , "Clopidogrel versus Aspirin and Esomeprazole to prevent recurrent ulcer bleeding," <i>New Eng. J. Med.</i> , 352:238-244, 2005.
	C37	Chan <i>et al.</i> , "Eradication of H. Pylori versus maintenance acid suppression to prevent recurrent ulcer hemorrhage in high risk NSAID users: A prospective randomized study," <i>Gastroenterology</i> , 114: A87, G0356, 1998.
	C38	Chandramouli <i>et al.</i> , "Prevention and management of NSAID-Induced gastropathy," <i>Journal of Pharmaceutical Pain and Symptom Control</i> , 8(4):27-40, 2000.
	C39	Chang <i>et al.</i> , "Polymethacrylates," In: Handbook of Pharmaceutical Excipients, Fifth Edition, Ed. Raymond C. Rowe, Paul J. Sheskey and Sian C. Owen, London: Pharmaceutical Press, pages 553-560, 2006.
	C40	Chen <i>et al.</i> , "Esomeprazole tablet vs. omeprazole capsule in treating erosive esophagitis," <i>World Journal of Gastroenterology</i> , 11(20):3112-3117, 2005.
	C41	Cullen <i>et al.</i> , "Primary gastroduodenal prophylaxis with omeprazole for non-steroidal anti-inflammatory drug users," <i>Aliment. Pharmacol. Ther.</i> , 12:135-140, 1998.
	C42	Dajani, "Perspective on the gastric antisecretory effects of misoprostol in man," <i>Prostaglandins</i> , 33:68-77, 1987.

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	C43	Daneshmend <i>et al.</i> , "Abolition by omeprazole of aspirin induced gastric mucoasal injury in man," <i>Gut</i> , 31:514-517, 1990.
	C44	Daneshmend <i>et al.</i> , "Use of microbleeding and an ultrathin endoscope to assess gastric mucosal protection by famotidine," <i>Gastroenterology</i> , 97:944-9, 1989.
	C45	Data sheet for "Arthrotec," 2009. (Document D8 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C46	Dent, "Why proton pump inhibition should heal and protect against nonsteroidal anti-inflammatory drug users," <i>Am. J. Med.</i> , 104:52S-55S, 1998.
	C47	Ehsanullah <i>et al.</i> , "Prevention of gastroduodenal damage induced by non-steroidal anti-inflammatory drugs: controlled trial of ranitidine," <i>BMJ</i> , 297:1017-1021, 1998.
	C48	Ekstrom <i>et al.</i> , Prevention of peptic ulcer and dyspeptic symptoms with omeprazole in patients receiving continuous non-steroidal anti-inflammatory drug therapy," <i>Scand. J. Gastroenterol.</i> , 31:753-758, 1996.
	C49	Ene <i>et al.</i> , "A study of the inhibitory effects of SCH 28080 on gastric secretion in man," <i>Br. J. Pharmac.</i> , 76:389-391, 1982.
	C50	English translation of Bigard, <i>et al.</i> , <i>Gastroenterol. Clin. Biol.</i> , 12:770-771, 1998.
	C51	English translation of Muller <i>et al.</i> , <i>Arzneimittel Forschung</i> , 47:758-760, 1997.
	C52	English translation of Muller <i>et al.</i> , <i>Arzneimittel-Forschung/Drug Res.</i> , 41(1):638-639, 1991.
	C53	English translation of Simon <i>et al.</i> , <i>Arzneimittel Forschung</i> , 45:701-703, 1995.
	C54	Erlandsson <i>et al.</i> , "Resolution of the enantiomers of omeprazole and some of its analogues by liquid chromatography on a trisphenylcarbamoylcellulose-based stationary phase," <i>J. Chromatogr.</i> , 532:305-319, 1990.
	C55	European Search Report and Opinion issued in European application No. EP 09 17 8773, dated February 11, 2010. (Attorney Docket No. POZN.P0004EP.D1)
	C56	European Search Report issued in European application No. EP 02 734 602.2, dated May 29, 2007. (Attorney Docket No.: POZN.P0004EP)
	C57	Extended European Search Report issued in European Patent Application No. 10792681.8, dated January 4, 2013. (Attorney Docket No.: POZN.P0006EP)

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	C58	Fass, "Erosive Esophagitis and Nonerosive Reflux Disease (NERD): Comparison of Epidemiologic, Physiologic, and Therapeutic Characteristics," <i>J. Clin. Gastroenterol.</i> , 41(2):131-137, 2007.
	C59	Feldman and Carlstedt, "Effect of antacid on absorption of enteric-coated aspirin," <i>JAMA</i> , 227(6):660-1, 1974.
	C60	Florence and Jani, "Novel oral drug formulations their potential in modulating adverse effects," <i>Drug Safety</i> , 10(3):233-66, 1994.
	C61	Fort <i>et al.</i> , "Pa, a novel combination of delayed release (DR) aspirin (ASA) and immediate-release (IR) omeprazole, is associated with a decreased risk of gastroduodenal mucosal injury: Pooled data from three Phase I, 4-week endoscopic studies," <i>American Journal of Gastroenterology</i> , 103(Suppl. S):S487-S488, 2008.
	C62	Frank <i>et al.</i> , "Reduction of indomethacin induced gastroduodenal mucosal injury and gastrointestinal symptoms with cimetidine in normal subjects," <i>J. Rheum.</i> , 16:1249-1252, 1989.
	C63	Gengo <i>et al.</i> , "Prevalence of platelet nonresponsiveness to aspirin in patients treated for secondary stroke prophylaxis and in patients with recurrent isochemic events," <i>J. Clin. Pharmacol.</i> , 48:335-343, 2008.
	C64	Goldstein <i>et al.</i> , "PN400 significantly reduces the incidence of gastric ulcers compared with enteric-coated naproxen in patients requiring chronic NSAID therapy regardless of low-dose aspirin use: Results from two prospective, randomized controlled trials," POZEN Inc. sponsored study, 2009. (Document D16 from Letter to European Patent Office for counterpart European Application No. 02 734 602.2, regarding Oral Proceedings dated December 18, 2009).
	C65	Goldstein <i>et al.</i> , "116 A single table multilayer formulation of enteric-coated naproxen coupled with no-enteric-coated omeprazole is associated with a significantly reduced incidence of gastric ulcers vs. enteric-coated naproxen: A prospective, randomized double-blind study," 134(4), Supplement 1, A-19, 2008.
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	C68	Graham <i>et al.</i> , "Duodenal and gastric ulcer prevention with misoprostol in arthritis patients taking NSAIDs," <i>Ann. Intern. Med.</i> , 119(4):257-262, 1993.
	C69	Grosser <i>et al.</i> , "Thromboxane generation," In: Platelets, Alan Michelson Ed., pages 565-574, Elsevier Science, 2007.
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	C73	Hassan-Alin <i>et al.</i> , "Lack of drug-drug interaction between esomeprazole and naproxen in healthy subjects," <i>Gastroenterology</i> , 124(4), Suppl.1, A541, 2003.
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	C80	Helander <i>et al.</i> , "Structure and function of rat parietal cells during treatment with omeprazole, SCH 28080, SCH 32651, or ranitidine," <i>Scand. J. Gastroenterol.</i> , 25:799-809, 1990.
	C81	Hogan <i>et al.</i> , "Prescription of nonsteroidal anti-inflammatory drugs for elderly people in Alberta," <i>Can. Med. Assoc.</i> , 151(3):315-322, 1994.
	C82	Howden, "Clinical pharmacology of omeprazole," <i>Clin. Pharmacokinet.</i> , 20:38-49, 1991.
	C83	Ife <i>et al.</i> , "Reversible inhibitors of the Gastric (H ⁺ /K ⁺)-ATPase. 3. 3-Substituted-4-(phenylamino)quinolines," <i>J. med. Chem.</i> , 35:3413-3422, 1992.
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Form PTO-1449 (modified)		Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
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		Filing Date: April 3, 2014	Group: 1615
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	C92	Konturek <i>et al.</i> , "Effects of omeprazole, a substituted benzimidazole, on gastrointestinal secretions, serum gastrin, and gastric mucosal blood flow in dogs," <i>Gastroenterology</i> , 86(1): 71-77, 1984.
	C93	Labenz <i>et al.</i> , "Risk factors for erosive esophagitis: A multivariate analysis based on the proGERD study initiative," <i>American Journal of Gastroenterology</i> , 99:1652-1656, 2004.
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	C113	Morgner <i>et al.</i> , "Esomeprazole: prevention and treatment of NSAID-induced symptoms and ulcers," <i>Expert Opin Pharmacother.</i> , 8(7):975-988, 2007.
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	C119	Nefesoglu <i>et al.</i> , "Interaction of omeprazole with enteric-coated Salicylate tablets," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , 36(10):549-553, 1998.
	C120	Neuvonen and Kivisto, "Enhancement of drug absorption by antacids," <i>Clin. Pharmacokinet.</i> , 27(2):120-8, 1994.
	C121	Notice of Allowance issued in United States Patent Application No. 10/158,216, dated March 29, 2005. (Attorney Docket No. POZN.P0004US)
	C122	Notice of Allowance issued in United States Patent Application No. 11/129,320, dated May 11, 2012. (Attorney Docket No. POZN.P0004US.CP1)
	C123	Notice of Opposition to a European Patent, submitted against European Patent application No. EP 1 411 900 on April 15, 2011. (Attorney Docket No.: POZN.P0004EP)
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	C128	Office Communication issued in Canadian Patent Application No. 2,449,098, dated November 6, 2008. (Attorney Docket No.: POZN.P0004CA)
	C129	Office Communication issued in Chinese Patent Application No. 201080037566.1, dated January 10, 2014. (Attorney Docket No. POZN.P0006CN) (English translation of Chinese text)
	C130	Office Communication issued in Egyptian Patent Application No. 2121/2001, dated April 13, 2013. (Attorney Docket No. PZAZ.P0003EG)
	C131	Office Communication issued in Eurasian Patent Application No. 201270071, dated August 5, 2013. (Attorney Docket No. POZN.P0006EA) (English translation of Russian text)
	C132	Office Communication issued in European Patent Application 10 177 150.9, dated November 4, 2010. (Attorney Docket No.: POZN.P0004EP.D1D1)
	C133	Office Communication issued in European Patent Application No. 02 734 602.2, dated June 30, 2008. (Attorney Docket No.: POZN.P0004EP)
	C134	Office Communication issued in European Patent Application No. 02 734 602.2, dated December 18, 2007. (Attorney Docket No. POZN.P0004EP)
	C135	Office Communication issued in European Patent Application No. 02 734 602.2, dated February 22, 2010. (Attorney Docket No.: POZN.P0004EP)
	C136	Office Communication issued in European Patent Application No. 02 734 602.2, dated April 29, 2010. (Attorney Docket No.: POZN.P0004EP)
	C137	Office Communication issued in European Patent Application No. 10 177 150.9, dated November 12, 2010. (Attorney Docket No.: POZN.P0004EP.D1D1)
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	C139	Office Communication issued in Israeli Patent Application No. 159129, dated February 16, 2010. (English translation) (Attorney Docket No. POZN.P0004IL)
	C140	Office Communication issued in Israeli Patent Application No. 159129, dated July 7, 2009. (English translation) (Attorney Docket No. POZN.P0004IL)
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	C142	Office Communication issued in Japanese Patent Application No. 2003-501394, dated July 25, 2008. (English translation) (Attorney Docket No. POZN.P0004JP)
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	C145	Office Communication issued in United States Patent Application No. 10/158,216, dated April 22, 2004. (Attorney Docket No.: POZN.P0004US)
	C146	Office Communication issued in United States Patent Application No. 10/158,216, dated October 20, 2004. (Attorney Docket No.: POZN.P0004US)
	C147	Office Communication issued in United States Patent Application No. 13/215,855, dated February 28, 2013. (Attorney Docket No. POZN.P0004US.CP1D2)
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	C150	Office Communication issued in United States Patent Application No. 11/129,320, dated November 19, 2009. (Attorney Docket No. POZN.P0004US.CP1)
	C151	Office Communication issued in United States Patent Application No. 11/129,320, dated March 30, 2009. (Attorney Docket No. POZN.P0004US.CP1)
	C152	Office Communication issued in United States Patent Application No. 11/129,320, dated September 22, 2008. (Attorney Docket No. POZN.P0004US.CP1)
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	C155	Office Communication issued in United States Patent Application No. 12/823,082, dated July 18, 2013. (Attorney Docket No. POZN.P0006US)

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	C156	Office Communication issued in United States Patent Application No. 12/823,082, dated September 17, 2012. (Attorney Docket No. POZN.P0006US)
	C157	Office Communication issued in United States Patent Application No. 11/129,320, dated November 15, 2011. (Attorney Docket No. POZN.P0004US.CP1)
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	C166	Okabe <i>et al.</i> , "Antisecretory effect of leminoprazole on histamine-stimulated gastric acid secretion in guinea pigs: local effect," <i>J. Pharmacol.</i> , 69:91-100, 1995.
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	C186	Preliminary Amendment filed in United States Patent Application No. 13/475,446, filed May 18, 2012. (Attorney Docket No. POZN.P0004US.CP1C1)
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	C189	Ramage <i>et al.</i> , "Inhibition of food stimulated acid secretion by misoprostol, an orally active synthetic E1 analogue prostaglandin," <i>Br. J. Clin Pharmacol.</i> , 19:9-12, 1985.
	C190	Raskin <i>et al.</i> , "Misoprostol dosage in the prevention of nonsteroidal anti-inflammatory drug-induced gastric and duodenal ulcers: a comparison of three regimens," <i>Ann. Intern. Med.</i> , 123(5):344-350, 1995.
	C191	<i>Remington's Pharmaceutical Sciences</i> , 17th ed., University of Sciences in Philadelphia, 1985.
	C192	Reply to EPO communication of April 29, 2010, dated May 10, 2010 (German and French translation of claims omitted).
	C193	Richardson <i>et al.</i> , "Proton pump inhibitors, pharmacology and rationale for use in gastrointestinal disorders," <i>Drugs</i> , 56(3):307-35, 1998.
	C194	Robinson <i>et al.</i> , "Effects of ranitidine gastroduodenal mucosal damage induced by nonsteroidal anti-inflammatory drugs," <i>Dig. Disc. Sci.</i> , 34(3):424-428, 1989.
	C195	Roche Naproxen EC label, copyright 1999.

{00147031}

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: John R. PLACHETKA	
		Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C196	Roth <i>et al.</i> , "Cimetidine therapy in nonsteroidal anti-inflammatory drug gastropathy: double-blind long-term evaluation," <i>Arch. Intern. Med.</i> , 147:1798-1801, 1987.
	C197	Rubinstein, "Gastrointestinal anatomy physiology and permeation pathways," <i>Enhancement in Drug Discovery</i> , CRC Press, 3-35, 2007.
	C198	Sangiah <i>et al.</i> , "Effects of misoprostol and omeprazole on basal gastric pH and free acid content in horses," <i>Res. Vet. Sci.</i> , 47(3):350-354, 1989.
	C199	Savarino <i>et al.</i> , "Effect of one-month treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) on gastric pH of rheumatoid arthritis patients," <i>Digestive Diseases and Sciences</i> , 43:459-463, 1998.
	C200	Scarpignato <i>et al.</i> , "Towards a GI safer anti-inflammatory therapy," <i>Gastroenterology International</i> , 186-215, 1999.
	C201	Scheiman <i>et al.</i> , "Omeprazole ameliorates aspirin-induced gastroduodenal injury," <i>Digestive Diseases and Sciences</i> , 39(1):97-103, 1994.
	C202	Scheiman, "NSAID-induced peptic ulcer disease: a critical review of pathogenesis and management," <i>Dig. Dis.</i> , 12:210-222, 1994.
	C203	Scheiman, "Pathogenesis of gastroduodenal injury due to nonsteroidal and anti-inflammatory drug: Implications for prevention and therapy," <i>Seminars in Arthritis and Rheumatism</i> , 21(4):259-268, 1992.
	C204	Scott and Sundell, "Inhibition of H+K+ ATPase by SCH 28080 and SCH 32651," <i>European Journal of Pharmacology</i> , 112:268-270, 1985.
	C205	Seitz <i>et al.</i> , "Tablet Coating," In: The Theory and Practice of Industrial Pharmacy. Eds. Leon Lachman, Herbert A. Lieberman and Joseph L. Kanig. Philadelphia: Lea & Febiger, pages 346-373, 1986.
	C206	Selway, "Potential hazards of long-term acid suppression," <i>Scand. J. Gastroenterol.</i> , 25(Suppl. 178):85-92, 1990.
	C207	Sharma <i>et al.</i> , "Comparison of 24-hour intragastric pH using four liquid formulations of lansoprazole and omeprazole," <i>Am. J. Health-Syst. Pharm.</i> , 56(Suppl. 4):S18-21, 1999.
	C208	Silverman, <i>The Organic Chemistry of Drug Design and Drug Action</i> , 2 nd Edition, Academic Press, p. 102 & p. 527, 2004.

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EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)	Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: John R. PLACHETKA	
	Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C209	Silverstein <i>et al.</i> , "Gastrointestinal toxicity with Celecoxib versus nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis; the CLASS study: A randomized controlled trial," <i>JAMA</i> , 284:1247-1255, 2000.
	C210	Silverstein <i>et al.</i> , "Misoprostol reduces serious gastrointestinal complications in patients with rheumatoid arthritis receiving nonsteroidal anti-inflammatory drugs," <i>Ann. Intern. Med.</i> , 123(4):241-249, 1995.
	C211	Simon <i>et al.</i> , "Schutzwirkung von omeprazol gegenüber niedrig dosierter acetylsalicylsäure," <i>Arzneimittel Forschung</i> , 45:701-703, 1995.
	C212	Summons to Attend Oral Proceedings Pursuant to Rule 116(1): EPC, dated September 3, 2009, issued in European Patent Application No. 02, 734 602.2. (Attorney Docket No.: POZN.P0004EP)
	C213	Sung, "Management of nonsteroidal anti-inflammatory drug-related peptic ulcer bleeding," <i>Am. J. Med.</i> , 110(1A): 29S-32S, 2001.
	C214	Taha <i>et al.</i> , "Famotidine for the prevention of peptic ulcers and oesophagitis in patients taking low-dose aspirin (FAMOUS): a phase III, randomized, double-blind, placebo-controlled trial," <i>Lancet</i> , 374:119-25, 2009.
	C215	Takeuchi <i>et al.</i> , "Effects of topical application of acidified omeprazole on acid secretion and transmucosal potential difference in anesthetized rat stomachs," <i>Japan J. Pharmacol.</i> , 47:397-408, 1988.
	C216	Tronstad <i>et al.</i> , "Gastroscopic findings after treatment with enteric-coated and plain naproxen tablets in healthy subjects," <i>Scand. J. Gastroenterol.</i> , 20:239-242, 1985.
	C217	Vane <i>et al.</i> , "The future of NSAID therapy: selective COX-2 inhibitors," <i>IJCP</i> , 54(1):7-9, January/February 2000.
	C218	von Unge <i>et al.</i> , "Stereochemical assignment of the enantiomers of omeprazole from X-ray analysis of a fenchyloxymethyl derivative of (+)-(R)- omeprazole," <i>Tetrahedron</i> , 8(12):1967-1970, 1997.
	C219	Wagner <i>et al.</i> , "Effects of nonsteroidal anti-inflammatory drugs on ulcerogenesis and gastric secretion in pylorus-ligated rat," <i>Digestive Diseases and Sciences</i> , 40:134-140, 1995.
	C220	Wakitani <i>et al.</i> , "Profile of JTE-522 as a human cyclooxygenase-2 inhibitor," <i>Jpn. J. Pharmacol.</i> , 78:365-371, 1998.

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Form PTO-1449 (modified)		Atty. Docket No.: POZN.P0004US.CP1C4	Serial No.: 14/244,471
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: John R. PLACHETKA	
		Filing Date: April 3, 2014	Group: 1615
U.S. Patent Documents <i>See Page 1-7</i>	Foreign Patent Documents <i>See Page 7-11</i>	Other Art <i>See Page 11-29</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C221	Wallmark <i>et al.</i> , "The relationship between gastric acid secretion and gastric H ⁺ , K ⁺ -ATPase activity," <i>J. Biol. Chem.</i> , 260(25): 13681-13684, 1985.
	C222	Warner <i>et al.</i> , "Nonsteroidal drug selectives for cyclo-oxygenase-1 rather than cyclo-oxygenase-2 are associated with human gastrointestinal toxicity: a full in vitro analysis," <i>Proc. Natl. Acad. Sci. USA</i> , 96:7563-7568, 1999.
	C223	Weil <i>et al.</i> , "Prophylactic aspirin and risk of peptic ulcer bleeding," <i>BMJ</i> , 310: 827-830, 1995.
	C224	Wilson <i>et al.</i> , "Effects of misoprostol on gastric acid and mucus secretion in man," <i>Digestive Diseases and Sciences</i> , 31(2): 126S-129S, 1986.
	C225	Wolfe <i>et al.</i> , "Acid suppression: optimizing therapy for gastroduodenal ulcer healing, gastroesophageal reflux disease, and stress related erosive syndrome," <i>Gastroenterology</i> , 118(2):S9-S31, 2000.
	C226	Wolfe <i>et al.</i> , "Gastrointestinal toxicity of nonsteroidal anti-inflammatory drugs," <i>N. Engl. J. Med.</i> , 340:1888-1899, 1999.
	C227	Yeomans <i>et al.</i> , "A comparison of omeprazole with ranitidine for ulcers associated with nonsteroidal anti-inflammatory drugs," <i>N. Engl. J. Med.</i> , 338:719-726, 1998.
	C228	Yeomans <i>et al.</i> , "Efficacy of esomeprazole (20 mg once daily) for reducing the risk of gastroduodenal ulcers associated with continuous use of low-dose aspirin," <i>American Journal of Gastroenterology</i> , 103:1-9, 2008.
	C229	Yeomans <i>et al.</i> , "New data on healing of nonsteroidal anti-inflammatory drug-associated ulcers and erosions," <i>Am. J. Med.</i> , 104:56S-61S, 1998.

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From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

AstraZeneca AB
Global Intellectual Property
151 85 Södertälje
SUEDE

ANKOM/SCANNED

2009-11-17

Page(s) Scanned

Final CHECK

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

13/11/2009

Applicant's or agent's file reference

103526-1 WO

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/GB2009/051108

International filing date
(day/month/year)

03/09/2009

Applicant

ASTRAZENECA UK LIMITED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax. (+31-70) 340-3016

Authorized officer

Iris Hodzic

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1–10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion 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 (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 103526-1 WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2009/051108	International filing date (day/month/year) 03/09/2009	(Earliest) Priority Date (day/month/year) 09/09/2008
Applicant ASTRAZENECA UK LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out 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))

b. ☐ This International search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1
☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
 b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/051108

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/20 A61K31/192 A61K31/4439 A61P19/02 A61P1/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>ANONYMOUS: "PK Study to Evaluate Esomeprazole Plasma Levels Following Administration of PN 400"</p> <p>INTERNET ARTICLE, 11 February 2008 (2008-02-11), XP002553435 Retrieved from the Internet: URL: http://clinicaltrials.gov/show/NCT00599404 the whole document</p> <p style="text-align: center;">----- -/-</p>	1-20

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *G* document member of the same patent family

Date of the actual completion of the international search

4 November 2009

Date of mailing of the international search report

13/11/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Loher, Florian

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/051108

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>ANONYMOUS: "Study Evaluating the Bioavailability of Naproxen 500 mg in Three Formulations" INTERNET ARTICLE, 11 May 2008 (2008-05-11), XP002553436 Retrieved from the Internet: URL:http://clinicaltrials.gov/show/NCT00665743> the whole document</p> <p>-----</p>	1-20
X	<p>ANONYMOUS: "A 12-Month, Phase 3, Open-Label, Multi-Center Study to Evaluate the Long-Term Safety of PN 400" INTERNET ARTICLE, 11 September 2007 (2007-09-11), XP002553437 Retrieved from the Internet: URL:http://clinicaltrials.gov/show/NCT00527904> the whole document</p> <p>-----</p>	1-20
Y	<p>US 2005/249811 A1 (PLACHETKA JOHN R [US]) 10 November 2005 (2005-11-10) paragraphs [0012] - [0014], [0017], [0055]; examples 5,6</p> <p>-----</p>	1-20
Y	<p>US 2008/031950 A1 (SESHA RAMESH [US]) 7 February 2008 (2008-02-07) paragraph [0006]</p> <p>-----</p>	1-20
Y	<p>GOLDSTEIN J L ET AL: "116 A Single Tablet Multilayer Formulation of Enteric-Coated Naproxen Coupled with Non-Enteric-Coated OMEPRAZOLE Is Associated with a Significantly Reduced Incidence of Gastric Ulcers vs. Enteric-Coated Naproxen: A Prospective, Randomized, Double-Blind Study" GASTROENTEROLOGY, ELSEVIER, PHILADELPHIA, PA, vol. 134, no. 4, 1 April 2008 (2008-04-01), pages A-19, XP023431895 ISSN: 0016-5085 [retrieved on 2008-04-01] the whole document</p> <p>-----</p> <p style="text-align: center;">-/--</p>	1-20

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/051108

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	MINER P B ET AL: "T1969 Gastric Acid Suppression with PN400, a Single-Tablet, Multilayer, Fixed-Dose Formulation Combining An Immediate-Release Esomeprazole Layer and An Enteric-Coated (EC) Naproxen Core" GASTROENTEROLOGY, ELSEVIER, PHILADELPHIA, PA, vol. 136, no. 5, 1 May 2009 (2009-05-01), pages A-611, XP026113363 ISSN: 0016-5085 [retrieved on 2009-05-01] the whole document -----	1-20
P,X	MINER P B ET AL: "T1972 Pharmacokinetics of Naproxen and Esomeprazole in PN400, a Single-Tablet, Multilayer Formulation of Enteric-Coated Naproxen Coupled with Immediate-Release Esomeprazole" GASTROENTEROLOGY, ELSEVIER, PHILADELPHIA, PA, vol. 136, no. 5, 1 May 2009 (2009-05-01), pages A-612, XP026113366 ISSN: 0016-5085 [retrieved on 2009-05-01] the whole document -----	1-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/051108

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005249811	A1	10-11-2005	NONE
US 2008031950	A1	07-02-2008	NONE

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 below

International application No.

PCT/GB2009/051108

International filing date (day/month/year)

03.09.2009

Priority date (day/month/year)

09.09.2008

International Patent Classification (IPC) or both national classification and IPC

INV. A61K9/20 A61K31/192 A61K31/4439 A61P19/02 A61P1/04

Applicant

ASTRAZENECA UK LIMITED

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
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Loher, Florian

Telephone No. +49 89 2399-7839



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2009/051108

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. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1 (a))
3. 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.
4. ☐ 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.
5. Additional comments:

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>1-20</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-20</u>
Industrial applicability (IA)	Yes: Claims	<u>1-20</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

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

Re Item V

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

Reference is made to the following documents:

- D1: ANONYMOUS: "PK Study to Evaluate Esomeprazole Plasma Levels Following Administration of PN 400" INTERNET ARTICLE, 11 February 2008 (2008-02-11), XP002553435 Retrieved from the Internet: URL:<http://clinicaltrials.gov/show/NCT00599404>>
- D2: ANONYMOUS: "Study Evaluating the Bioavailability of Naproxen 500 mg in Three Formulations" INTERNET ARTICLE, 11 May 2008 (2008-05-11), XP002553436 Retrieved from the Internet: URL:<http://clinicaltrials.gov/show/NCT00665743>>
- D3: ANONYMOUS: "A 12-Month, Phase 3, Open-Label, Multi-Center Study to Evaluate the Long-Term Safety of PN 400" INTERNET ARTICLE, 11 September 2007 (2007-09-11), XP002553437 Retrieved from the Internet: URL:<http://clinicaltrials.gov/show/NCT00527904>>
- D4: US 2005/249811 A1 (PLACHETKA JOHN R [US]) 10 November 2005 (2005-11-10)
- D5: US 2008/031950 A1 (SESHA RAMESH [US]) 7 February 2008 (2008-02-07)
- D6: GOLDSTEIN J L ET AL: "116 A Single Tablet Multilayer Formulation of Enteric-Coated Naproxen Coupled with Non-Enteric-Coated OMEPRAZOLE Is Associated with a Significantly Reduced Incidence of Gastric Ulcers vs. Enteric-Coated Naproxen: A Prospective, Randomized, Double-Blind Study" GASTROENTEROLOGY, ELSEVIER, PHILADELPHIA, PA, vol. 134, no. 4, 1 April 2008 (2008-04-01), pages A-19, XP023431895 ISSN: 0016-5085 [retrieved on 2008-04-01]
- D7: MINER P B ET AL: "T1969 Gastric Acid Suppression with PN400, a Single-Tablet, Multilayer, Fixed-Dose Formulation Combining An Immediate-Release Esomeprazole Layer and An Enteric-Coated (EC) Naproxen Core" GASTROENTEROLOGY, ELSEVIER, PHILADELPHIA, PA, vol. 136, no. 5, 1 May 2009 (2009-05-01), pages A-611, XP026113363 ISSN: 0016-5085 [retrieved on 2009-05-01]
- D8: MINER P B ET AL: "T1972 Pharmacokinetics of Naproxen and Esomeprazole in PN400, a Single-Tablet, Multilayer Formulation of Enteric-Coated Naproxen Coupled with Immediate-Release Esomeprazole" GASTROENTEROLOGY, ELSEVIER, PHILADELPHIA, PA, vol. 136, no. 5, 1 May 2009 (2009-05-01), pages A-612, XP026113366 ISSN: 0016-5085 [retrieved on 2009-05-01]

If not mentioned otherwise, the relevant passages are those mentioned in the International Search Report.

Assuming a valid priority of the present application the P-documents (D7 and D8) cited in the International Search Report are not dealt with during the PCT-phase.

Art 33(2) The present application does not meet the requirements of Article 33(2) PCT, since the subject-matter of claims is not new.

D1 discloses the use of PN-400 in an open-label pharmacokinetic study which started in January 2008 and ended in February 2008. This means that a formulation as presently claimed was made available to the public before the priority date of the present application. Therefore, the subject-matter of claims 1-20 is not new in the light of D1.

D2 discloses the use of PN-400 in an open-label pharmacokinetic study which started in March 2008 and ended in June 2008. This means that a formulation as presently claimed was made available to the public before the priority date of the present application. Therefore, the subject-matter of claims 1-20 is not new in the light of D2.

D3 discloses the use of PN-400 in an open-label study concerning the safety of PN-400 in the treatment of osteoarthritis and rheumatoid arthritis. The study started in September 2007. This means that a formulation as presently claimed was made available to the public before the priority date of the present application. Therefore, the subject-matter of claims 1-20 is not new in the light of D3.

Art 33(3) Examination of inventive step (Article 33(3) PCT) is not relevant since the subject-matter of present claims 1-20 is not new.

Yet, for the sake of procedural economy the following comments are made:

With regard to the provision of a certain pharmacokinetic profile D4 is considered closest prior art, since it discloses a multilayer tablet comprising

- (i) a core containing naproxen,
- (ii) an enteric coating layer which releases the naproxen when the surrounding pH is above 3.5 and
- (iii) a second layer comprising a proton pump inhibitor (PPI) which is immediately released.

The present application differs from the disclosure of D4 in the use of esomeprazole instead of omeprazole or lansoprazole.

The problem to be solved by the present invention may therefore be regarded as how to provide an alternative formulation comprising an NSAID and a PPI.

The present application suggests to solve the problem posed by providing a formulation comprising naproxen and esomeprazole which is suitable to achieve a defined pharmacokinetic profile as defined in present claim 1.

D5 recommends the combination of naproxen and esomeprazole as the safest combination of an NSAID and PPI. D6 discloses PN-200 which is a tablet comprising enterically coated naproxen surrounded by non-enterically coated omeprazole. It is stated that it is well within the level of the skilled artisan to provide alternative formulations. In this particular case the combination of naproxen and esomeprazole is even recommended.

Consequently the presently claimed subject-matter is considered obvious and lacks an inventive step in the sense of Article 33(3) PCT.

Art 33(4) The subject-matter of claims 1-20 is considered industrially applicable in the sense of Art 33(4) PCT.

Re Item VI

Certain documents cited

D7 discloses the efficacy of PN-400 in the suppression of the gastric pH.

D8 discloses the pharmacokinetic properties of PN-400 in humans.

Re Item VIII

Certain observations on the international application

Art 6 The attention of the applicant is drawn to the fact that there are substantial defects within the application as filed that a lack of clarity within the meaning of Article 6 PCT arises. Present claim 1 and thereto dependent claims 2-12 define a pharmacokinetic profile. It is, however, not disclosed under which conditions and in which species this profile is to be achieved. This renders the scope for which protection is sought is unclear in the sense of Article 6 PCT.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

Bitte beachten Sie, dass angeführte Nichtpatentliteratur (wie z. B. wissenschaftliche oder technische Dokumente) je nach geltendem Recht dem Urheberrechtsschutz und/oder anderen Schutzarten für schriftliche Werke unterliegen könnte. Die Vervielfältigung urheberrechtlich geschützter Texte, ihre Verwendung in anderen elektronischen oder gedruckten Publikationen und ihre Weitergabe an Dritte ist ohne ausdrückliche Zustimmung des Rechtsinhabers nicht gestattet.

Veuillez noter que les ouvrages de la littérature non-brevets qui sont cités, par exemple les documents scientifiques ou techniques, etc., peuvent être protégés par des droits d'auteur et/ou toute autre protection des écrits prévue par les législations applicables. Les textes ainsi protégés ne peuvent être reproduits ni utilisés dans d'autres publications électroniques ou imprimées, ni rediffusés sans l'autorisation expresse du titulaire du droit d'auteur.

Please be aware that cited works of non-patent literature such as scientific or technical documents or the like may be subject to copyright protection and/or any other protection of written works as appropriate based on applicable laws. Copyrighted texts may not be copied or used in other electronic or printed publications or re-distributed without the express permission of the copyright holder.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To:

**ASTRAZENECA INTELLECTUAL
PROPERTY**
AstraZeneca AB
SE-151 85 Södertälje

Date of mailing 20-09-2010
(day/month/year)

Applicant's or agent's file reference

103786-1P WO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/SE2010/050712

International filing date
(day/month/year)

23-06-2010

Applicant

ASTRAZENECA AB et al

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statements under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the ISA/SE
Patent- och registreringsverket
Box 5055
S-102 42 STOCKHOLM

Facsimile No. + 46 8 666 02 86

Authorized officer

Monica Norlin

Telephone No. + 46 8 782 25 00

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 103786-1P WO	<div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> see Form PCT/ISA/220 as well as, where applicable, item 5 below. </div> </div>
International application No. PCT/SE2010/050712	<div style="display: flex; justify-content: space-between;"> <div> International filing date (day/month/year) 23-06-2010 </div> <div> (Earliest) Priority Date (day/month/year) 25-06-2009 </div> </div>
Applicant ASTRAZENECA AB et al	

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out 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)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II).

3. ☐ **Unity of invention is lacking** (See Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. --

- ☒ as suggested by the applicant.
- ☐ as selected by this Authority, because the applicant failed to suggest a figure.
- ☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2010/050712

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **1-63**
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 1-63 relate to a method for treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods, see PCT rule 39.1(iv). Nevertheless, a search has been made for these claims. The search has been directed to the technical content of the claims.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present disclosure is directed to a method for treating a disease or disorder in a patient at risk of developing an NSAID-associated ulcer by administering a pharmaceutical composition in unit dose form comprising naproxen, or pharmaceutically acceptable salt thereof, and esomeprazole, or pharmaceutically acceptable salt thereof. The unit dose is designed to release at least a part of the esomeprazole independent of pH (e.g. at a pH of 0 or more) whereas the naproxen is not released until the pH of the surrounding medium is 3.5 or higher.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2010/050712

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC:A61K, A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, PAJ, WPI data, BIOSIS, CHEM ABS Data, COMPENDEX, EMBASE, INSPEC, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	Miner P. et al., Clinical trial: evaluation of gastric acid suppression with three doses of immediate-release esomeprazole in the fixed-dose combination of PN 400 (naproxen/esomeprazole magnesium) compared with naproxen 500 mg and enteric-coated esomeprazole 20 mg: a randomized, open-label, phase 1 study in healthy volunteers, <i>Alimentary pharmacology and therapeutics</i> 2010, 32, 414-424; Table 1	1-63
X	Miner P.B. et al., T1969 Gastric acid suppression with PN400, a single-tablet, multilayer, fixed-dose formulation combining an immediate-release esomeprazole layer and an enteric-coated (EC) naproxen core. <i>Gastroenterology</i> , 2009, 136, 5, A-611; whole document; abstract	1-63
X	Miner P.B. et al., T1972 Pharmacokinetics of naproxen and esomeprazole in PN400, a single-tablet, multilayer formulation of enteric-coated naproxen coupled with immediate-release esomeprazole. <i>Gastroenterology</i> 2009, 136, 5, A-612; whole document; abstract	1-63

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17-09-2010

Date of mailing of the international search report

20-09-2010

Name and mailing address of the ISA/SE

Patent- och registreringsverket

Box 5055

S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Ingrid Eklund

Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2010/050712

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Goldstein J.L. et al., 116 A single tablet multilayer formulation of enteric coated naproxen coupled with non-enteric coated omeprazole is associated with a significantly reduced incidence of gastric ulcer vs. Enteric-coated naproxen: A prospective, randomized, double-blind study. Gastroenterology, 2008, 134, 4, A-19; whole document; abstract	1-63
A	Hassan-Alin M. et al., T1651 Lack of drug-drug interaction between esomeprazole and naproxen in healthy subjects. Digestive disease 2003, Orlando, Florida, USA May 17-22, 2003; whole document; abstract	1-63
A	McKeage K. et al., Esomeprazole A review of its use in the management of gastric acid-related diseases in adults. Drugs 2008, 68, 11, 1571-1607; whole document; abstract; page 1062, column 1, line 26 - page 1062, column 2, line 3	1-63
A	Morgner A. et al., Esomeprazole: prevention and treatment of NSAID-induced symptoms and ulcers. Expert opinion on pharmacotherapeutics 2007, 8, 7, 975-988; whole document; abstract; 7. Conclusion	1-63
X	Anonymous: "PK study to evaluate esomeprazole plasma levels following administration of PN 400" INTERNET ARTICLE, 11 Feb 2008, URL: http://clinicaltrials.gov/show/NCT00599404 >; whole document	1-63
X	US 20050249811 A1 (PLACHETKA JOHN R), 10 November 2005 (2005-11-10); abstract; claim 1; Examples 5-6, sections [0012]-[0014]	1-63
X	Anonymous: "Study evaluating the bioavailability of naproxen 500 mg in three formulations" INTERNET ARTICLE, 11 May 2008, URL: http://clinicaltrials.gov/show/NCT00665743 >; whole document	1-63
X	US 20030069255 A1 (PLACHETKA JOHN R), 10 April 2003 (2003-04-10); abstract; claims 1, 5, 10, 37; Examples 5-6	1-63
X	WO 2008101060 A1 (LOGICAL THERAPEUTICS INC ET AL), 21 August 2008 (2008-08-21); Section [0033]	1-63
X	Anonymous: "A 12-month, phase 3, open-label, multi-center study to evaluate the long-term safety of PN 400" INTERNET ARTICLE, 11 Sept 2007, URL: http://clinicaltrials.gov/show/NCT00527904 >; whole document	1-63
X	US 20050249806 A1 (PROEHL GERALD T ET AL), 10 November 2005 (2005-11-10); abstract; claims 1, 4, 12, 27	1-63
A	US 20080031950 A1 (SESHA RAMESH), 7 February 2008 (2008-02-07); Section [0006]	1-63

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2010/050712

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	US 20100062064 A1 (AULT BRIAN ET AL), 11 March 2010 (2010-03-11); abstract; claims 19, 40-45	1-63
E	US 20100172983 A1 (PLACHETKA JOHN R), 8 July 2010 (2010-07-08); abstract; claims 57-76	1-63

Continuation of: second sheet

International Patent Classification (IPC)

A61K 31/4439 (2006.01)

A61K 9/24 (2006.01)

A61P 19/02 (2006.01)

A61P 29/00 (2006.01)

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Use the application number as username. The password is **DGAPDUJQN**.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/SE2010/050712

US	20050249811 A1	10/11/2005	NONE		
US	20030069255 A1	10/04/2003	AU	2006235929 B2	11/12/2008
			AU	2002305758 C1	16/12/2002
			AU	2009200966 B2	10/06/2010
			CA	2449098 C	05/01/2010
			DE	60237087 D1	02/09/2010
			EA	006398 B1	29/12/2005
			EP	1411900 B1	21/07/2010
			EP	2163241 A1	17/03/2010
			JP	2004536809 T	09/12/2004
			MX	PA03011017 A	29/04/2005
			US	6926907 B2	09/08/2005
			WO	02098352 A3	26/06/2003
WO	2008101060 A1	21/08/2008	US	20100221337 A1	02/09/2010
			US	20100221336 A1	02/09/2010
			WO	2008101064 A1	21/08/2008
US	20050249806 A1	10/11/2005	AU	2005213472 A1	25/08/2005
			CA	2554271 A1	25/08/2005
			EP	1718303 A4	01/09/2010
			JP	2007522217 T	09/08/2007
			WO	2005076987 A3	08/06/2006
US	20080031950 A1	07/02/2008	NONE		
US	20100062064 A1	11/03/2010	NONE		
US	20100172983 A1	08/07/2010	NONE		

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: ASTRAZENECA INTELLECTUAL PROPERTY AstraZeneca AB SE-151 85 Södertälje	<div style="border: 1px solid black; padding: 2px;"> Date of mailing (day/month/year) 20-09-2010 </div>
Applicant's or agent's file reference 103786-1P WO	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/SE2010/050712	International filing date (day/month/year) 23-06-2010
Priority date (day/month/year) 25-06-2009	
International Patent Classification (IPC) or both national classification and IPC See Supplemental Box	
Applicant ASTRAZENECA AB et al	

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 and 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 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 no 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/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. + 46 8 686 02 86	Date of completion of this opinion 17-09-2010	Authorized officer Ingrid Eklund Telephone No. + 46 8 782 25 00
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2010/050712

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: cover sheet

International Patent Classification (IPC)

A61K 31/4439 (2006.01)

A61K 9/24 (2006.01)

A61P 19/02 (2006.01)

A61P 29/00 (2006.01)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2010/050712

Box No. I Basis of this 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. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
☐ on paper
☐ in electronic form
 - b. (time)
☐ in the international application as filed
☐ together with the international application in electronic form
☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing 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.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2010/050712

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 data (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/SE2010/050712

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. 1-63

because:

☒ the said international application, or the said claims Nos. 1-63 relate to the following subject matter which does not require an international search report:

Claims 1-63 relate to a method for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, see PCT rule 67.1.(iv). Nevertheless, an examination has been conducted for these claims. The examination has been made in respect of the technical content of the claims.

☐ 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 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 Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/SE2010/050712

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>see extra sheet</u>	YES
	Claims	<u>see extra sheet</u>	NO
Inventive step (IS)	Claims		YES
	Claims	1-63	NO
Industrial applicability (IA)	Claims	1-63	YES
	Claims		NO

2. Citations and explanations

Claims 1-63 relate to a method for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, see PCT rule 67.1.(iv). Nevertheless, an examination has been conducted for these claims. The examination has been made in respect of the technical content of the claims.

Documents found during the search

D1: Anonymous: "PK study to evaluate esomeprazole plasma levels following administration of PN 400" INTERNET ARTICLE, 11 Feb 2008,
URL:<http://clinicaltrials.gov/show/NCT00599404>> XP002553435

D2: Anonymous: "Study evaluating the bioavailability of naproxen 500 mg in three formulations" INTERNET ARTICLE, 11 May 2008,
URL:<http://clinicaltrials.gov/show/NCT00665743>> XP002553436

D3: Anonymous: "A 12-month, phase 3, open-label, multi-center study to evaluate the long-term safety of PN 400" INTERNET ARTICLE, 11 Sept 2007,
URL:<http://clinicaltrials.gov/show/NCT00527904>> XP002553437

D4: Miner P.B. et al., T1969 Gastric acid suppression with PN400, a single-tablet, multilayer, fixed-dose formulation combining an immediate-release esomeprazole layer and an enteric-coated (EC) naproxen core. Gastroenterology, 2009, 136, 5, A-611

D5: Miner P.B. et al., T1972 Pharmacokinetics of naproxen and esomeprazole in PN400, a single-tablet, multilayer formulation of enteric-coated naproxen coupled with immediate-release esomeprazole. Gastroenterology 2009, 136, 5, A-612

D6: US20050249811 A1

D7: US2003069255 A1

D8: WO2008101060 A1

D9: US2005249806 A1

D10: Goldstein J.L. et al., 116 A single tablet multilayer formulation of enteric coated naproxen coupled with non-enteric coated omeprazole is associated with a significantly reduced incidence of gastric ulcer vs. Enteric-coated naproxen: A prospective, randomized, double-blind study. Gastroenterology, 2008, 134, 4, A-19

D11: Hassan-Alin M. et al., T1651 Lack of drug-drug interaction between esomeprazole and naproxen in healthy subjects. Digestive disease 2003, Orlando, Florida, USA May 17-22, 2003

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2010/050712

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box No. V**

1. Statement

Novelty (N)	Claims	5, 9, 20-21, 26-28, 34, 38-41, 43, 46-50, 52-55, 57-63	YES
	Claims	1-4, 6-8, 10-19, 22-25, 29-33, 35-37, 42, 44-45, 51, 56	NO

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V

D12: McKeage K. et al., Esomeprazole A review of its use in the management of gastric acid-related diseases in adults. Drugs 2008, 68, 11, 1571-1607

D13: US2008031950 A1

D14: Morgner A. et al., Esomeprazole: prevention and treatment of NSAID-induced symptoms and ulcers. Expert opinion on pharmacotherapeutics 2007, 8, 7, 975-988.

Naproxen in combination with esomeprazole in a unit dose; documents relevant to novelty of the application.

D1-D3 disclose the use of PN-400 in open-label studies. In D1-D3 it is stated that PN-400 contains 500 mg delayed release naproxen/20 mg immediate release esomeprazole. The subjects are instructed to take 2 tablets a day. PN400 is proposed for the treatment of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis or other medical conditions expected to require daily nonsteroidal anti-inflammatory drug (NSAID) therapy for at least 12 months in patients at risk for developing NSAID-associated gastric ulcers.

D4 and D5 also refers to, and defines, the composition of PN400.

D6 shows a drug dosage form that first releases an agent that raises the pH of a patient's gastrointestinal tract, followed by a NSAID. The agent that raises pH is e.g. a proton pump inhibitor (PPI). In example 6, omeprazole (which is a racemate and thus contains both the S- and the R-form of omeprazole) is combined with naproxen. The dosage form is gastro-protective, antiarthritic/analgesic and is intended to achieve pain and symptom relief with a reduced risk of developing gastrointestinal damage such as ulcers, erosions and hemorrhages. See the abstract, examples 5-6, sections [0012]-[0014] and claim 1.

D7 corresponds to D6. See the abstract, examples 5-6 and claims 1, 5, 10 and 37.

The following documents disclose combined dosage forms containing a NSAID and a PPI, where the PPI is released prior to the NSAID and are relevant for a discussion of inventive step.

D8 discloses a method of treating arthritis, pain or inflammation with a naproxen ester and a PPI. In one embodiment, the naproxen ester is surrounded by a polymeric coating which does not dissolve at a pH of less than 4. See section [0033].

D9 relates to pharmaceutical compositions comprising a PPI, one or more buffering agents, and a NSAID. The design of the composition aims to give a fast rise in serum concentration of the PPI whereas at least some of the NSAID is coated. The compositions are intended for treating gastric acid related disorders and inflammatory disorders. See the abstract and claims 1,4,12 and 27.

D10 discusses a single tablet formulation of enteric coated naproxen coupled with non-enteric coated omeprazole. Omeprazole contains esomeprazole, see D6. Therefore, a

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box No. V**

discussion of novelty could depart also from D10.

Documents that discuss the combination of PPI's and NSAID's and represent the state of the art.

D11 states that there is no drug-drug interaction when esomeprazole and naproxen is co-administered.

D12 concludes that there is data that supports the use of esomeprazole for first-line treatment of NSAID-associated gastric ulcer disease. See p. 1062 column 1 line 26-column 2 line 3.

D13, section [0006] states that naproxen in combination with a PPI is the safest NSAID combination.

D14 also suggests that a combination drug of PPI, such as esomeprazole, plus an NSAID, would be worthwhile in order to increase compliance in cases where both medications are prescribed.

Novelty

Independent claims

Independent claims 1 and 25 of the present application define a composition comprising esomeprazole and naproxen, where naproxen is released when pH is at least 3.5 whereas esomeprazole is immediately soluble independent of pH. The compositions are intended for use in patients at risk for developing NSAID-associated gastric ulcers. Such compositions are known from D1-D7 and consequently, the application according to claims 1 and 25 lacks the requirement of novelty.

Independent claims 51 and 56 refer to further objectives of administration of the composition, namely reduction of dyspepsia- or heartburn associated symptoms. The skilled person is aware that esomeprazole is prescribed in order to reduce such symptoms (see e.g. D14). Therefore, the application according to claims 51 and 56 also lacks the requirement of novelty.

Dependent claims

From D6-D7 a composition where naproxen is released when pH has been elevated to a safe level by the release of a PPI, e.g. omeprazole (i.e. inherently esomeprazole), is known. The present application as defined in claims 2-4, 6-8, 13-19, 22-24, 29-33, 35-37, 42 and 44-45 is not novel when compared to the composition presented in D6-D7.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box No. V**

The construction of PN400 is not explicitly shown in D1-D5. However, the effect obtained corresponds to that of the composition of the present application. It is therefore concluded that the dosage form of PN400 implicitly contains features corresponding to that of the present application. Further, the patients receiving PN400 are instructed to take two tablets a day and they are on at least 12 month treatment with NSAID. Therefore, claims 10-12 also lack the requirement of novelty over D1-D5.

Inventive step

The remaining claims (5, 9, 20-21, 26-28, 34, 38-41, 43, 46-50, 52-55 and 57-63) are considered to involve measures or minor details obvious to a person skilled in the art. Therefore, the invention according to these claims is not considered to involve an inventive step.

A discussion of inventive step for all claims (1-63) could also depart from any of D8-D10.

Conclusion

The subject matter of claims 1-4, 6-8, 10-19, 22-25, 29-33, 35-37, 42, 44-45, 51 and 56 lacks novelty and an inventive step. The subject matter of claims 5, 9, 20-21, 26-28, 34, 38-41, 43, 46-50, 52-55, 57-63 is novel, but is not considered to involve an inventive step. The subject matter of all the claims is industrially applicable.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/SE2010/050712

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

	Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
E	US2010/0172983 A1	08.07.2010	03.09.2009	
P,X	US2010/0062064 A1	11.03.2010	03.09.2009	

P,X Miner P. et al., Clinical trial: evaluation of gastric acid suppression with three doses of immediate-release esomeprazole in the fixed-dose combination of PN 400 (naproxen/esomeprazole magnesium) compared with naproxen 500 mg and enteric-coated esomeprazole 20 mg: a randomized, open-label, phase 1 study in healthy volunteers. *Aliment pharmacology and therapeutics* 2010, 32: 414-424

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
_____	_____	_____

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:

Claims 1, 25, 51 and 56 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added.

The relative term "treated longer" used in claim 9 has no well-recognized meaning and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject matter of said claim unclear (Article 6 PCT).

The relative term "results in a relative risk reduction" used in claims 61-63 has no well-recognized meaning and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject matter of said claims unclear (Article 6 PCT).

PATENT COOPERATION TREATY

C179

From the AUTHORITY SPECIFIED FOR
SUPPLEMENTARY SEARCH

PCT

To:

ASTRAZENECA INTELLECTUAL PROPERTY
AstraZeneca AB
SE-151 85 Södertälje

NOTIFICATION OF TRANSMITTAL OF
SUPPLEMENTARY INTERNATIONAL
SEARCH REPORT OR DECLARATION

(PCT Rule 45bis.8(a))

Applicant's or agent's file reference 103526-1 WO	Date of mailing (day/month/year) 28-09-2010
International application No. PCT/GB2009/051108	International filing date (day/month/year) 03-09-2009
Applicant Astrazeneca UK Limited et al	

1. ☒ The applicant is hereby notified that the supplementary international search report has been established and is transmitted herewith.
2. ☐ The applicant is hereby notified that no supplementary international search report will be established and that the declaration under Article 17(2)(a) and Rule 45bis.5(c) to that effect is transmitted herewith.

A copy of this Notification has been sent to the International Bureau.

Name and mailing address of the SISA/ Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Telex 17978 PATOREG-S	Authorized officer Marita Öun
		Telephone No. 08-782 25 00

PATENT COOPERATION TREATY

PCT

SUPPLEMENTARY INTERNATIONAL SEARCH REPORT

(PCT Rule 45bis)

Applicant's or agent's file reference 103526-1 WO	International application No. PCT/GB2009/051108
International filing date (<i>day/month/year</i>) 03-09-2009	(Earliest) Priority Date (<i>day/month/year</i>) 09-09-2008
Applicant Astrazeneca UK Limited et al	

This supplementary international search report has been prepared by this Authority specified for supplementary search and it is transmitted to the applicant in accordance with Rule 45bis.8(a). A copy is being transmitted to the International Bureau.

☒ This report is a corrected version of a previously issued supplementary international search report

This supplementary international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the supplementary international search was carried out 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:
 - ☐ the international search (Rules 12.3(a) and 23.1(b)).
 - ☐ the international publication (Rule 12.4)
 - ☐ the supplementary international search (Rule 45bis.1(c)(i))

b. ☐ This supplementary international search report has been established taking into account the **rectification of an obvious mistake** notified to this Authority under Rule 91 (Rules 43.6bis(a) and 45bis7(c)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

d. ☐ This supplementary international search report has been established taking due account of the international search report, or the declaration under Article 17(2)(a) that no international search report will be established, and the written opinion established under Rule 43bis.1.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

The present claims refer to a composition where a specific pharmacokinetic (pk) profile for the active ingredients is achieved. However, the claims do not define how the pk profile is to be achieved; there is no information concerning excipients, ingredients in coatings etc. Therefore, the search has been focused on a composition which comprises naproxen and esomeprazole as active ingredients. The documents of international search report are considered relevant but are not listed, as this is a supplementary report.

It is to be noted that claim 1 covers all compositions where esomeprazole is released at any pH above about 0.

SUPPLEMENTARY INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB2009/051108

A. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic database consulted during the supplementary international search (name of database and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, CADATA, EMBASE, MEDLINE, BIOSIS**B. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008101060 A1 (LOGICAL THERAPEUTICS, INC.), 21 August 2008 (21.08.2008), claims 1-2, paragraph ⁵ 0033 --	1-20
X	US 20030069255 A1 (PLACHETKA, JOHN R.), 10 April 2003 (10.04.2003), figures 1-3, claims 1, 5, 10, abstract, examples 7, 8 --	1-20
X	US 20050249806 A1 (PROEHL, GERALD T. ET AL), 10 November 2005 (10.11.2005), claims 1, 12, abstract -- -----	1-20

☐ Further documents are listed on the continuation of second sheet B.☒ See patent family Annex.☐ See Scope Annex for details of the scope of the supplementary international search.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the supplementary international search

2 Sept. 2010

Date of mailing of the supplementary international search report

28 -09- 2010

Name and mailing address of the SISA/

Swedish Patent Office

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Authorized officer

Ingrid Eklund / EÖ

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Use the application number as username. The password is **HDTZXBLKHU**.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number +46-8-782 28 85).

Cited literature, if any, will be enclosed in paper form.

SUPPLEMENTARY INTERNATIONAL SEARCH REPORT

Information on Patent Family Members

08/05/00

International application No.

PCT/GB2009/051108

WO	2008101060	A1	21/08/2008	WO	2008101064 A	21/08/2008
US	20030069255	A1	10/04/2003	NONE		
US	20050249806	A1	10/11/2005	NONE		


PATENT COOPERATION TREATY
From the AUTHORITY SPECIFIED FOR SUPPLEMENTARY SEARCH

PCT

**NOTIFICATION OF TRANSMITTAL OF
SUPPLEMENTARY INTERNATIONAL
SEARCH REPORT OR DECLARATION**

To: ASTRAZENECA AB
AstraZeneca Intellectual Property
SE-151 85 Sodertalje
Sweden

(PCT Rule 45bis.8(a))

Applicant's or agent's file reference 103786-1 WO	Date of mailing (day/month/year) 20 October 2011 (20 10 2011)
International application No. PCT/SE 2010/050712	International filing date (day/month/year) 23 June 2010 (23 06 2010)
Applicant ASTRAZENECA AB	
<p>1. <input checked="" type="checkbox"/> The applicant is hereby notified that the supplementary international search report has been established and is transmitted herewith.</p> <p>2. <input type="checkbox"/> The applicant is hereby notified that no supplementary international search report will be established and that the declaration under Article 17(2)(a) and Rule 45bis.5(c) to that effect is transmitted herewith.</p>	
<p>A copy of this Notification has been sent to the International Bureau.</p>	
Name and mailing address of the Authority/RU Russia, 123995, Moscow, G-59, GSP-5, Berezhkovskaya nab., 30-1 Facsimile No. (499) 243-3337	Authorized officer  T. Vladimirova Telephone No. (499) 240-2591

PATENT COOPERATION TREATY
PCT
SUPPLEMENTARY INTERNATIONAL SEARCH REPORT

(PCT Rule 45bis)

Applicant's or agent's file reference 103786-1 WO	International application No. PCT/SE 2010/050712
International filing date (day/month/year) 23 June 2010 (23.06.2010)	(Earliest) Priority Date (day/month/year) 25 June 2009 (25.06.2009)
Applicant ASTRAZENECA AB	

This supplementary international search report has been prepared by this Authority specified for supplementary search and it is transmitted to the applicant in accordance with Rule 45bis.8(a). A copy is being transmitted to the International Bureau.

☐ This report is a corrected version of a previously issued supplementary international search report

This supplementary international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the supplementary international search was carried out 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:
- ☐ the international search (Rules 12.3(a) and 23.1(b)).
 - ☐ the international publication (Rule 12.4)
 - ☐ the supplementary international search (Rule 45bis.1(c)(i))

b. ☐ This supplementary international search report has been established taking into account the **rectification of an obvious mistake** notified to this Authority under Rule 91 (Rules 43.6bis (a) and 45bis.7(c)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

d. ☐ This supplementary international search report has been established taking due account of the international search report, or the **declaration** under Article 17(2)(a) that no international search report will be established, and the written opinion established under Rule 43bis.1.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

SUPPLEMENTARY INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2010/050712

A. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K , 9/24, 31/4439, A61P 19/02, 29/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the supplementary international search (name of database and, where practicable, search terms used): DWPI, NCBJ (PubMed), SpringerLink

B. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
X	EA 006398 B1 (POUZEN INC.) 29.12.2005, abstract, p.2,5, claims 1, 5, 9-16, 22-24	1-63
A	RU 2158138 C2 (ASTRA AKTIEBOLAG) 27.10.2000	1-63

The Search Reports scanned/saved into
Objective separate.

☐ Further documents are listed in the continuation of second sheet B ☐ See Patent Family Annex.

☐ See Scope Annex for details of the scope of the supplementary international search.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the supplementary international search
28 September 2011 (28.09.2011)

Date of mailing of the supplementary international search report
20 October 2011 (20.10.2011)

Name and mailing address of the Authority/
Russia, 123995, Moscow, G-59, GSP-5,
Berezhkovskaya nab., 30-1
Facsimile No. 243-3337

Authorized officer

M. Pustovalova

Telephone No. (499) 240-2591

SUPPLEMENTARY INTERNATIONAL SEARCH REPORT

Explanations with regard to the citations and/or the scope of the search
(Rule 45bis .7(e))

International application No.

PCT/SE 2010/050712

D1 : EA 006398 B1 (POZEN INC.), 29.12.2005

From D1 (abstract, claims 1,5,9-16, 22-24, pages 2,5 of the description) there is known a method for treating diseases or disorders of patients with the risk of development of the NSAID-associated ulcers by means of introduction of pharmaceutical composition, including the composition in the form of multi-layer tablets, in a single dosed form, including: a) esomeprazole in the amount, which is sufficient one in order to increase pH of stomach of the mentioned patient up to no less than 3.5 upon the introduction one or more the mentioned single dosed form, and b) therapeutically effective amount of naproxen, therewith, the mentioned single form envisages a coordinated releasing of the esomeprazole and naproxen, providing an indication, consisting in that the naproxen is not released from the mentioned single form until pH of environment will be equal to 3.5 or more, and wherein the mentioned pharmaceutical composition in the single dosed form decreases a risk of the mentioned patient ulcer development.

From D1 there is also known, that the naproxen, included in the pharmaceutical composition, may be surrounded by means of barrier covering, which is practically is not solvable upon pH, which is less than 3.5.

Therewith, from D1 it is known, that preferable doses of naproxen content in a composition make up from 200 to 600 mg, but for the esomeprazole these doses ranges from 5 to 100 mg. The compositions are destined for a long-term treatment.

Electronic Acknowledgement Receipt

EFS ID:	19158880
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard Ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	29-MAY-2014
Filing Date:	03-APR-2014
Time Stamp:	14:37:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	POZNP0004USCP1C4_IDS.pdf	139258 c3aef71fc4f0a80d45f872c5b7836af2596da 86	no	3

Warnings:

Information:

2	Information Disclosure Statement (IDS) Form (SB08)	POZNP0004USPC1C4_1449.pdf	347652 586a3899660d6c469051a581b1d61cc9f2d889c4	no	29
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	REFC12.pdf	575883 00deb1b325b203b4a22490f7dfc7314d36d05f95	no	1
Warnings:					
Information:					
4	Non Patent Literature	REFC15.pdf	1059222 632490ab605daad0b0093abe7a8843aff0ba3134	no	2
Warnings:					
Information:					
5	Non Patent Literature	REFC16.pdf	528106 a4111da613534bb3c7c3c931e92a636911495811	no	2
Warnings:					
Information:					
6	Non Patent Literature	REFC17.pdf	607381 9d6c5adff3a70731fe84689ebc9b2c98019ac19f9	no	3
Warnings:					
Information:					
7	Non Patent Literature	REFC18.pdf	1728849 6850b29cd01ba3d221840f0e57c2972e21178f96	no	4
Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	REFC57.pdf	790325 2f777dd6c3cacebfa9d44ebeb8c4c05acf4659d4	no	9
Warnings:					
Information:					
9	Non Patent Literature	REFC61.pdf	2913809 c96d1bef4b768eb188628fd05b20b98741432be7	no	2
Warnings:					
Information:					
10	Non Patent Literature	REFC71.pdf	656533 1ace1dcacac9804b588d4e998a0d3be835705c	no	1

Warnings:					
Information:					
11	Other Reference-Patent/App/Search documents	REFC121.pdf	782595	no	7
			b6c1b63cb7e83ba06e9e5cbf6ca6f6083ee78d		
Warnings:					
Information:					
12	Other Reference-Patent/App/Search documents	REFC122.pdf	848382	no	8
			3ca26c8397cb302b9006c0e6f4cc5992e5197bd		
Warnings:					
Information:					
13	Other Reference-Patent/App/Search documents	REFC127.pdf	639040	no	4
			28da86f4a2f59969259b4233dab04730cba9e5e4		
Warnings:					
Information:					
14	Other Reference-Patent/App/Search documents	REFC129.pdf	1613069	no	17
			e4ac206b74d9aab383c4cc0d6794d285161f7770		
Warnings:					
Information:					
15	Other Reference-Patent/App/Search documents	REFC131.pdf	432026	no	4
			cc53f971f8b8bb81ec8cb4a6c3fea9c8fdeb-c2b		
Warnings:					
Information:					
16	Other Reference-Patent/App/Search documents	REFC142.pdf	2934202	no	7
			74da8f84db40f536a64a7203925e22d8bca48e3		
Warnings:					
Information:					
17	Other Reference-Patent/App/Search documents	REFC147.pdf	925198	no	13
			8e374fe443db0f2795b0c6fb8c8323f5da1d9d1a		
Warnings:					
Information:					
18	Other Reference-Patent/App/Search documents	REFC148.pdf	729201	no	8
			023f9aab0c741ff2ae75db4f15f69babb85e07c7c		
Warnings:					
Information:					
19	Other Reference-Patent/App/Search documents	REFC155.pdf	763377	no	9
			b6a6ea59e2a1119ed6930c2be269df182ca4520d		

Warnings:					
Information:					
20	Other Reference-Patent/App/Search documents	REFC156.pdf	893384	no	11
			5aba62e416d827108530a3a22655199322771745		
Warnings:					
Information:					
21	Other Reference-Patent/App/Search documents	REFC157.pdf	617140	no	3
			5cb6cc960f23684ebc5089b4e94658995d11ea5f		
Warnings:					
Information:					
22	Other Reference-Patent/App/Search documents	REFC158.pdf	618126	no	3
			5c58e6368df39941214e610e46432998e891b69		
Warnings:					
Information:					
23	Other Reference-Patent/App/Search documents	REFC159.pdf	616821	no	3
			424a1477a53a02ecb5492f26f4cb3a928201614a		
Warnings:					
Information:					
24	Other Reference-Patent/App/Search documents	REFC160.pdf	735127	no	8
			6a2dff4f0763d91215390c3c4f4b3ab5ca85592bc		
Warnings:					
Information:					
25	Other Reference-Patent/App/Search documents	REFC161.pdf	717075	no	9
			117e684dfe44c3e27a73d89949a563e9b6a48f69		
Warnings:					
Information:					
26	Other Reference-Patent/App/Search documents	REFC162.pdf	984941	no	15
			1e43af3d74965e4a97533f1c252876a88ba45ca		
Warnings:					
Information:					
27	Other Reference-Patent/App/Search documents	REFC163.pdf	617544	no	3
			db8bcef048210c74b458331c1be99af0866240fd		
Warnings:					
Information:					
28	Other Reference-Patent/App/Search documents	REFC164.pdf	852003	no	11
			2be21ad4b4328ac0c3e31e06273b954450f66f		

Warnings:					
Information:					
29	Other Reference-Patent/App/Search documents	REFC165.pdf	777086 283ee1f06ca4a7b66698f50607f02de42d8669b1	no	9
Warnings:					
Information:					
30	Other Reference-Patent/App/Search documents	REFC173.pdf	814275 a706f29cab5b0cb32710f5594ca1ca0fee78c3a	no	9
Warnings:					
Information:					
31	Other Reference-Patent/App/Search documents	REFC174.pdf	912711 54cc1caae64df28907aee7f229bdf3588c9d71a7	no	13
Warnings:					
Information:					
32	Other Reference-Patent/App/Search documents	REFC175.pdf	1990957 4401e42b63d6def4a666c548d1020e8c1fc0d8	no	17
Warnings:					
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33	Other Reference-Patent/App/Search documents	REFC176.pdf	1522754 0f7596781a35b65b585db3508f2b7d28804b644	no	21
Warnings:					
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34	Other Reference-Patent/App/Search documents	REFC179.pdf	493863 5e73475344d78ee459107c3d067285198a536ce	no	6
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Information:					
35	Other Reference-Patent/App/Search documents	REFC180.pdf	413051 5f52eaa2ff7105c2345c67dccc0482db806192b38	no	4
Warnings:					
Information:					
36	Other Reference-Patent/App/Search documents	REFC186.pdf	571753 4ef6792861e5d5ff7081b744ca8a3534e119a23	no	6
Warnings:					
Information:					
Total Files Size (in bytes):			33162719		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John R. PLACHETKA

Group Art Unit: 1615

Serial No.: 14/244,471

Examiner: To Be Assigned

Filing Date: April 3, 2014

Attorney Docket No.: POZN.P0004US.CP1C4

Title: PHARMACEUTICAL
COMPOSITIONS FOR THE
COORDINATED DELIVERY OF
NSAIDS

Confirmation No.: 3047

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the
United States Patent and Trademark Office via EFS-Web on the date below:

May 29, 2014

/Steven L. Highlander/

Date

Steven L. Highlander

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Commissioner:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are attached for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g) and (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Parker Highlander PLLC Deposit Account No. 50-5902/POZN.P0004US.CP1C4.

This application is a continuation of application Serial No. 14/045,156, filed October 3, 2013, which is a continuation of application Serial No. 13/215,855, filed August 23, 2011, which is a divisional of application Serial No. 12/553,804, filed September 3, 2009, which is a divisional of application Serial No. 11/129,320, filed May 16, 2005, which is a continuation-in-part of application Serial No. 10/158,216, and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98(d), only copies of those documents not previously cited and submitted to the Patent and Trademark Office in prior application Serial No. 14/045,156, Serial No. 13/215,855, Serial No. 12/553,804, Serial No. 11/129,320 and Serial No. 10/158,216 are enclosed for the convenience of the Examiner.

Applicant respectfully requests that the listed documents be made of record in the present application. The examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Steven L. Highlander/

Steven L. Highlander
Reg. No. 37,642
Attorney for Applicant

Parker Highlander PLLC
1120 S. Capital of Texas Highway
Building One, Suite 200
Austin, Texas 78746
512-334-2900 (Telephone)
512-334-2999 (Fax)

Date: May 29, 2014

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
14/244,471

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)
FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(i))	19 minus 20 =	*
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))		

* If the difference in column 1 is less than zero, enter "0" in column 2.

SMALL ENTITY

RATE(\$)	FEE(\$)
N/A	
N/A	
N/A	
TOTAL	

OR

OTHER THAN SMALL ENTITY

RATE(\$)	FEE(\$)
N/A	280
N/A	600
N/A	720
x 80 =	0.00
x 420 =	0.00
	0.00
	0.00
TOTAL	1600

APPLICATION AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total (37 CFR 1.16(i))	*	Minus **
	Independent (37 CFR 1.16(h))	*	Minus ***
	Application Size Fee (37 CFR 1.16(s))		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))		

SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

OR

OTHER THAN SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total (37 CFR 1.16(i))	*	Minus **
	Independent (37 CFR 1.16(h))	*	Minus ***
	Application Size Fee (37 CFR 1.16(s))		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))		

SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

OR

OTHER THAN SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	CLASS NO.	FIL FEE REC'D	ATTY. DOCKET NO.	CLASS NO.	SECTION NO.
14/244,471	04/03/2014	16/24	1600	POZN.P0004US.CP1C4	19	2

CONFIRMATION NO. 3047

108197

Parker Highlander PLLC

1120 South Capital of Texas Highway

Bldg. 1, Suite 200

Austin, TX 78746

FILING RECEIPT



OC000000068029190

Date Mailed: 04/25/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

John R. PLACHETKA, Chapel Hill, NC;

Applicant(s)

Pozen Inc., Chapel Hill, NC

Assignment For Published Patent Application

Pozen Inc., Chapel Hill, NC

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 14/045,156 10/03/2013
which is a CON of 13/215,855 08/23/2011 PAT 8557285
which is a DIV of 12/553,804 09/03/2009 ABN
which is a DIV of 11/129,320 05/16/2005 PAT 8206741
which is a CIP of 10/158,216 05/31/2002 PAT 6926907
which claims benefit of 60/294,588 06/01/2001

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 04/24/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/244,471**

Projected Publication Date: 07/31/2014

Non-Publication Request: No

Early Publication Request: No

Title

PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/244,471	04/03/2014	John R. PLACHETKA	POZN.P0004US.CP1C4

CONFIRMATION NO. 3047

FORMALITIES LETTER



OC00000068029191

108197
Parker Highlander PLLC
1120 South Capital of Texas Highway
Bldg. 1, Suite 200
Austin, TX 78746

Date Mailed: 04/25/2014

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing.

Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.

The surcharge is due for any one of:

- late submission of the basic filing fee, search fee, or examination fee,
- late submission of inventor's oath or declaration,
- filing an application that does not contain at least one claim on filing, or
- submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- \$ 140 surcharge.
- \$(.00) previous unapplied payment amount.
- \$ 140 TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
John R. PLACHETKA

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".
<https://portal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/wkoroma/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	POZN.P0004US.CP1C4
	First Named Inventor	John R. PLACHETKA
	Title	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED...
	Express Mail label No.	Via EFS-Web on April 3, 2014

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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<ol style="list-style-type: none"> <input type="checkbox"/> Fee Transmittal Form (PTO/SB/17 or equivalent) <input type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27 <input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or E1 or equivalent. <input checked="" type="checkbox"/> Specification [Total Sheets 1] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets 2] <input type="checkbox"/> Inventor's Oath or Declaration [Total Pages] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) <ol style="list-style-type: none"> <input type="checkbox"/> Newly executed (original or copy) <input type="checkbox"/> A copy from a prior application (37 CFR 1.63(d)) <input checked="" type="checkbox"/> Application Data Sheet *See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) <input type="checkbox"/> Landscape Table on CD <input type="checkbox"/> Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. -- c. are required) <ol style="list-style-type: none"> <input type="checkbox"/> Computer Readable Form (CRF) <input type="checkbox"/> Specification Sequence Listing on: <ol style="list-style-type: none"> <input type="checkbox"/> CD-ROM or CD-R (2 copies); or <input type="checkbox"/> Paper <input type="checkbox"/> Statements verifying identity of above copies 	ACCOMPANYING APPLICATION PAPERS <ol style="list-style-type: none"> <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) Name of Assignee _____ <input type="checkbox"/> 37 CFR 3.73(c) Statement <input type="checkbox"/> Power of Attorney (when there is an assignee) <input type="checkbox"/> English Translation Document (if applicable) <input type="checkbox"/> Information Disclosure Statement (PTO/SB/08 or PTO-1449) <input type="checkbox"/> Copies of citations attached <input checked="" type="checkbox"/> Preliminary Amendment <input type="checkbox"/> Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed) <input type="checkbox"/> Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. <input checked="" type="checkbox"/> Other: Certification and Request for Prioritized Examination Under 37 CFR 1.102(e) _____ _____
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***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 must be included in an Application Data Sheet (ADS).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS	
<input checked="" type="checkbox"/> The address associated with Customer Number: 1450 OR <input type="checkbox"/> Correspondence address below	
Name	
Address	
City	State Zip Code
Country	Telephone Email
Signature	/Steven L. Highlander/ Date April 3, 2014
Name (Print/Type)	Steven L. Highlander Registration No. Attorney - 37,642 (Attorney/Agent)

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	POZN.P0004US.CP1C4
		Application Number	
Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2

<input type="checkbox"/>	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Inventor Information:

Inventor 1 Remove				
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	John	R.	PLACHETKA	
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Chapel Hill	State/Province	NC	Country of Residence i US
Mailing Address of Inventor:				
Address 1	321 Silver Creek Trail			
Address 2				
City	Chapel Hill	State/Province	NC	
Postal Code	27514	Country i	US	
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add				

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).	
<input type="checkbox"/> An Address is being provided for the correspondence Information of this application.	
Customer Number	108197
Email Address	docket@phiplaw.com Add Email Remove Email

Application Information:

Title of the Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		
Attorney Docket Number	POZN.P0004US.CP1C4	Small Entity Status Claimed	<input type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	2	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	POZN.P0004US.CP1C4
		Application Number	
Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		

Publication Information:

<input type="checkbox"/>	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
<input type="checkbox"/>	Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.			
Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	108197		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	14045156	2013-10-03		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14045156	Continuation of	13215855	2011-08-23	8557285	2013-10-15
Prior Application Status	Abandoned	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
13215855	Division of	12553804	2009-09-03		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12553804	Division of	11129320	2005-05-16	8206741	2012-06-26
Prior Application Status	Patented	Remove			

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		POZN.P0004US.CP1C4	
		Application Number			
Title of Invention		PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11129320	Continuation in part of	10158216	2002-05-31	6926907	2005-08-09
Prior Application Status		Expired		<input type="button" value="Remove"/>	
Application Number		Continuity Type		Prior Application Number	Filing Date (YYYY-MM-DD)
10158216		Claims benefit of provisional		60294588	2001-06-01
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					<input type="button" value="Add"/>

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

<input type="button" value="Remove"/>			
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			<input type="button" value="Add"/>

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

☐ NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	POZN.P0004US.CP1C4
		Application Number	
Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.		
Applicant 1	Remove	
<p>If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.</p>		
Clear		
<input checked="" type="radio"/> Assignee	<input type="radio"/> Legal Representative under 35 U.S.C. 117	<input type="radio"/> Joint Inventor
<input type="radio"/> Person to whom the inventor is obligated to assign.	<input type="radio"/> Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		

Name of the Deceased or Legally Incapacitated Inventor			
If the Applicant is an Organization check here. <input checked="" type="checkbox"/>			
Organization Name	Pozen Inc.		
Mailing Address Information:			
Address 1	1414 Raleigh Road, Suite 400		
Address 2			
City	Chapel Hill	State/Province	NC
Country ⁱ	US	Postal Code	27517
Phone Number		Fax Number	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	POZN.P0004US.CP1C4
		Application Number	
Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			<input type="button" value="Add"/>

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
			<input type="button" value="Remove"/>
If the Assignee or Non-Applicant Assignee is an Organization check here.			<input checked="" type="checkbox"/>
Organization Name	Pozen Inc.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	1414 Raleigh Road, Suite 400		
Address 2			
City	Chapel Hill	State/Province	NC
Country i	US	Postal Code	27517
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			<input type="button" value="Add"/>

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications					
Signature	/Steven L. Highlander/		Date (YYYY-MM-DD)	2014-04-03	
First Name	Steven	Last Name	Highlander	Registration Number	37642
Additional Signature may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	POZN.P0004US.CP1C4
		Application Number	
Title of Invention	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		

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Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs

Cross Reference to Related Applications

5 The present application is a continuation-in-part of U.S. application no. 10/158,216, filed on May 31, 2002. The '216 application claims the benefit of U.S. provisional application no. 60/294,588, filed on June 1, 2001.

Field of the Invention

10 The present invention is directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID). These compositions have a reduced likelihood of causing unwanted side effects, especially gastrointestinal side effects, when administered as a treatment for pain, arthritis and other conditions amenable to treatment with NSAIDs.

Background of the Invention

15 Although non-steroidal anti-inflammatory drugs are widely accepted as effective agents for controlling pain, their administration can lead to the development of gastroduodenal lesions, *e.g.*, ulcers and erosions, in susceptible individuals. It appears that a major factor contributing to the development of these lesions is the presence of acid in the stomach and upper small intestine of patients. This view is supported by clinical studies demonstrating an improvement in NSAID tolerability when patients are also taking independent doses of acid inhibitors (*Dig. Dis.* 12:210-222 (1994); *Drug Safety* 21:503-512 (1999); *Aliment. Pharmacol. Ther.* 12:135-140 (1998); *Am. J. Med.* 104(3A):67S-74S (1998); *Clin. Ther.* 17:1159-1173 (1995)). Other major factors contributing to NSAID-associated gastropathy include a local toxic effect of NSAIDs and inhibition of protective prostaglandins (*Can. J. Gastroenterol.* 13:135-142 (1999) and *Pract. Drug Safety* 21:503-512, (1999)), which may also make some patients more susceptible to the ulcerogenic effects of other noxious stimuli.

30 In general, more potent and longer lasting acid inhibitors, such as proton pump inhibitors, are thought to be more protective during chronic administration of NSAIDs than shorter acting agents, *e.g.*, histamine H₂ receptor antagonists (H₂ blockers) (*N. Eng. J. Med.* 338:719-726 (1998); *Am. J. Med.* 104(3A):56S-61S (1998)). The most likely

explanation for this is that gastric pH fluctuates widely throughout the dosing interval with short acting acid inhibitors leaving the mucosa vulnerable for significant periods of time. In particular, the pH is at its lowest point, and hence the mucosa is most vulnerable, at the end of the dosing interval (least amount of acid inhibition) and for some time after the subsequent dose of acid inhibitor. In general, it appears that when a short acting acid inhibitor and an NSAID are administered simultaneously, NSAID-related mucosal damage occurs before the pH of the gastrointestinal tract can be raised and after the acid inhibiting effect of the short acting acid inhibitor dissipates.

Although longer lasting agents, such as proton pump inhibitors (PPIs), usually maintain a consistently higher gastroduodenal pH throughout the day, their antisecretory effect may be delayed for several hours and may not take full effect for several days (*Clin. Pharmacokinet.* 20:38-49 (1991)). Their effect may be diminished toward the end of the usual dosing interval. Intragastric pH rises particularly slowly with the first dose in a course of treatment since this class of drugs is enteric coated to avoid destruction by stomach acid. As a result, absorption is delayed for several hours. Even then, some patients fail to respond consistently to drugs of this type and suffer from “acid breakthrough” which again leaves them vulnerable to NSAID-associated gastroduodenal damage (*Aliment. Pharmacol. Ther.* 14:709-714 (2000)). Despite a significant reduction in gastroduodenal lesions with the concomitant administration of a proton pump inhibitor during six months of NSAID therapy, up to 16% of patients still develop ulcers, indicating that there remains substantial room for improvement (*N. Eng. J. Med.* 338:727-734 (1998)). Thus, the addition of a pH sensitive enteric coating to an NSAID could provide additional protection against gastroduodenal damage not provided by the H₂ blocker or PPI alone. In addition, although long acting acid inhibitors may reduce the risk of GI lesions in chronic NSAID users, there are questions about the safety of maintaining an abnormally elevated pH in a patient’s GI tract for a prolonged period of time (*Scand. J. Gastroenterol. Suppl.* 178:85-92 (1990)).

Recognizing the potential benefits of PPIs for the prevention of NSAID-induced gastroduodenal damage, others have disclosed strategies for combining the two active agents for therapeutic purposes. However, these suggestions do not provide for coordinated drug release or for reducing intragastric acid levels to a non-toxic level prior to the release of NSAID (U.S. 5,204,118; U.S. 5,417,980; U.S. 5,466,436; and U.S. 5,037,815). In certain

cases, suggested means of delivery would expose the gastrointestinal tract to NSAIDs prior to onset of PPI activity (U.S. 6,365,184).

Attempts to develop NSAIDs that are inherently less toxic to the gastrointestinal tract have met with only limited success. For example, the recently developed cyclooxygenase-2 (COX-2) inhibitors show a reduced tendency to produce gastrointestinal ulcers and erosions, but a significant risk is still present, especially if the patient is exposed to other ulcerogens (*JAMA* 284:1247-1255 (2000); *N. Eng. J. Med.* 343:1520-1528 (2000)). In this regard, it appears that even low doses of aspirin will negate most of the benefit relating to lower gastrointestinal lesions. In addition, the COX-2 inhibitors may not be as effective as other NSAIDs at relieving some types of pain and have been associated with significant cardiovascular problems (*JADA* 131:1729-1737 (2000); *SCRIP* 2617, pg. 19, Feb. 14, 2001); *NY Times*, May 22, 2001, pg. C1)).

Other attempts to produce an NSAID therapy with less gastrointestinal toxicity have involved the concomitant administration of a cytoprotective agent. In 1998, Searle began marketing Arthrotec™ for the treatment of arthritis in patients at risk for developing GI ulcers. This product contains misoprostol (a cytoprotective prostaglandin) and the NSAID diclofenac. Although patients administered Arthrotec™ do have a lower risk of developing ulcers, they may experience a number of other serious side effects such as diarrhea, severe cramping and, in the case of pregnant women, potential damage to the fetus.

Another approach has been to produce enteric coated NSAID products. However, even though these have shown modest reductions in gastroduodenal damage in short term studies (*Scand. J. Gastroenterol.* 20: 239–242 (1985) and *Scand. J. Gastroenterol.* 25:231–234 (1990)), there is no consistent evidence of a long term benefit during chronic treatment.

Overall, it may be concluded that the risk of inducing GI ulcers is a recognized problem associated with the administration of NSAIDs and that, despite considerable effort, an ideal solution has not yet been found.

Summary of the Invention

The present invention is based upon the discovery of a new method for reducing the risk of gastrointestinal side effects in people taking NSAIDs for pain relief and for other conditions, particularly during chronic treatment. The method involves the administration of a single, coordinated, unit-dose product that combines: a) an agent that actively raises intragastric pH to levels associated with less risk of NSAID-induced ulcers; and b) an NSAID that is specially formulated to be released in a coordinated way that minimizes the adverse effects of the NSAID on the gastroduodenal mucosa. Either short or long acting acid inhibitors can be effectively used in the dosage forms. This method has the added benefit of being able to protect patients from other gastrointestinal ulcerogens whose effect may otherwise be enhanced by the disruption of gastroprotective prostaglandins due to NSAID therapy.

In its first aspect, the invention is directed to a pharmaceutical composition in unit dosage form suitable for oral administration to a patient. The composition contains an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5, preferably to at least 4, and more preferably to at least 5, when one or more unit dosage forms are administered. The gastric pH should not exceed 7.5 and preferably should not exceed 7.0. The term "acid inhibitor" refers to agents that inhibit gastric acid secretion and increase gastric pH. In contrast to art teaching against the use of H₂ blockers for the prevention of NSAID-associated ulcers (*N. Eng. J. Med.* 340:1888–1899 (1999)), these agents are preferred compounds in the current invention. Specific H₂ blockers that may be used include cimetidine, ranitidine, ebrotidine, pabutidine, lafutidine, loxidine or famotidine. The most preferred acid inhibitor is famotidine present in dosage forms in an amount of between 5 mg and 100 mg.

Other preferred agents that may be effectively used as acid inhibitors are the proton pump inhibitors such as omeprazole, esomeprazole, pantoprazole, lansoprazole, rabeprazole, pariprazole, leminoprazole and tenatoprazole. Examples of particular proton pump inhibitors include omeprazole, present in unit dosage forms in an amount of between 5 mg and 50 mg; lansoprazole, present in unit dosage forms in an amount of between 5 mg and 150 mg (and preferably at between 5 mg and 30 mg); and pantoprazole, present in unit dosage forms in an amount of between 10 mg and 200 mg. Recently, a newer class of acid

inhibitor has been developed which competes with potassium at the acid pump. The compounds in this class have been referred to as “reversible proton pump inhibitors” or “acid pump antagonists” and may also be used in the present invention. Examples include AZD-0865, AR-H047108, CS-526, pumaprazole, revaprazan and soraprazan (see
5 WO9605177 and WO9605199). Other compounds in this group are H-335/25 (AstraZeneca, Dialog file 128, accession number 020806); Sch-28080 (Schering Plough, Dialog file 128, accession number 009663); Sch-32651 (Schering Plough, Dialog file 128, accession number 006883) and SK&F-96067 (CAS Registry no. 115607-61-9).

10 The pharmaceutical composition also contains a non-steroidal anti-inflammatory drug in an amount effective to reduce or eliminate pain or inflammation. The NSAID may be celecoxib, rofecoxib, lumiracoxib, valdecoxib, parecoxib, etoricoxib, CS-502, JTE-522, L-745,337, NS398, aspirin, acetaminophen (considered to be an NSAID for the purposes of the present invention), ibuprofen, flurbiprofen, ketoprofen, naproxen, oxaprozin, etodolac,
15 indomethacin, ketorolac, lornoxicam, meloxicam, piroxicam, droxicam, tenoxicam, nabumetone, diclofenac, meclofenamate, mefenamic acid, diflunisal, sulindac, tolmetin, fenoprofen, suprofen, benoxaprofen, aceclofenac, tolfenamic acid, oxyphenbutazone, azapropazone, and phenylbutazone. The most preferred NSAID is naproxen in an amount of between 50 mg and 1500 mg, and more preferably, in an amount of between 200 mg and
20 600 mg. It will be understood that, for the purposes of the present invention, reference to an acid inhibitor, NSAID, or analgesic agent will include all of the common forms of these compounds and, in particular, their pharmaceutically acceptable salts. The amounts of NSAIDs which are therapeutically effective may be lower in the current invention than otherwise found in practice due to potential positive kinetic interaction and NSAID
25 absorption in the presence of an acid inhibitor.

Preferably, the pharmaceutical composition of the present invention is in the form of a tablet or capsule that has: (a) the acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5 upon the administration of one or more unit dosage
30 forms; and (b) the non-steroidal anti-inflammatory drug (NSAID) present in an amount effective to reduce or eliminate pain or inflammation in a patient upon administration of one or more of said unit dosage forms. The NSAID in the dosage form should be in a core, preferably a single core when tablets are used, that is surrounded by a coating that does not

release NSAID until the pH of the surrounding medium is 3.5 or higher. In the case of capsules, there may be several cores of NSAID, *i.e.*, there may be multiple particles, each being surrounded by a coating that does not release NSAID until the pH of the surrounding medium is 3.5 or higher. The acid inhibitor is in one or more layers outside of the core which do not contain any NSAID. These layers are not surrounded by an enteric coating and, upon ingestion of the tablet or capsule by a patient, release the acid inhibitor into the patient's stomach.

The term "unit dosage form" as used herein refers to a single entity for drug administration. For example, a single tablet or capsule combining both an acid inhibitor and an NSAID would be a unit dosage form. A unit dosage form of the present invention preferably provides for coordinated drug release in a way that elevates gastric pH and reduces the deleterious effects of the NSAID on the gastroduodenal mucosa, *i.e.*, the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the GI tract has risen.

In a preferred embodiment, the unit dosage form is a multilayer tablet, having an outer layer comprising the acid inhibitor and an inner core which comprises the NSAID. In the most preferred form, coordinated delivery is accomplished by having the inner core surrounded by a polymeric barrier coating that does not dissolve unless the surrounding medium is at a pH of at least 3.5, preferably at least 4 and more preferably, at least 5. Alternatively, a barrier coating may be employed which controls the release of NSAID by time, as opposed to pH, with the rate adjusted so that NSAID is not released until after the pH of the gastrointestinal tract has risen to at least 3.5, preferably at least 4, and more preferably at least 5. Thus, a time-release formulation may be used to prevent the gastric presence of NSAID until mucosal tissue is no longer exposed to the damage enhancing effect of very low pH.

One NSAID of special interest in dosage forms is aspirin which not only provides relief from pain and inflammation but may also be used in low doses by patients to reduce the risk of stroke, heart attack and other conditions. Thus, pharmaceutical compositions may contain an acid inhibitor in combination with aspirin in an amount effective, upon the administration of one or more unit dosage forms, to achieve any of these objectives. As with

the compositions described above the unit dosage form can be a tablet or capsule in which aspirin is present in a core and is surrounded by a coating that does not release the aspirin until the pH of the surrounding medium is 3.5 or higher. The acid inhibitor is in one or more layers outside the core, which do not include an NSAID, are not surrounded by an enteric coating; and, upon ingestion of the dosage form by a patient, release the acid inhibitor into the patient's stomach. Any of the acid inhibitors described herein may be used in the aspirin-containing dosage forms. In dosage forms designed for providing low dose aspirin therapy to patients, the aspirin should typically be present at 20-200 mg.

The invention includes methods of treating a patient for pain, inflammation and/or other conditions by administering the pharmaceutical compositions described above. Although the method may be used for any condition in which an NSAID is effective, it is expected that it will be particularly useful in patients with osteoarthritis or rheumatoid arthritis. Other conditions that may be treated include, but are not limited to: all forms of headache, including migraine headache; acute musculoskeletal pain; ankylosing spondylitis; dysmenorrhoea; myalgias; and neuralgias.

In a more general sense, the invention includes methods of treating pain, inflammation and/or other conditions by orally administering an acid inhibitor at a dose effective to raise a patient's gastric pH to at least 3.5, preferably to at least 4 or and more preferably to at least 5. The patient is also administered an NSAID, for example in a coordinated dosage form, that has been coated in a polymer that only dissolves at a pH of at least 3.5, preferably at least 4 and, more preferably, 5 or greater or which dissolves at a rate that is slow enough to prevent NSAID release until after the pH has been raised. When acid inhibitor and NSAID are administered in separate doses, *e.g.*, in two separate tablets, they should be given concomitantly (*i.e.*, so that their biological effects overlap) and may be given concurrently, *i.e.*, NSAID is given within one hour after the acid inhibitor. Preferably, the acid inhibitor is an H₂ blocker and, in the most preferred embodiment, it is famotidine at a dosage of between 5 mg and 100 mg. Proton pump inhibitors may also be used and offer advantages in terms of duration of action. Any of the NSAIDs described above may be used in the method but naproxen at a dosage of between 200 and 600 mg is most preferred. It is expected that the acid inhibitor and analgesic will be typically delivered as part of a single unit dosage form which provides for the coordinated release of therapeutic agents. The most

preferred dosage form is a multilayer tablet having an outer layer comprising an H2 blocker or a proton pump inhibitor and an inner core comprising an NSAID.

The invention also provides a method for increasing compliance in a patient requiring frequent daily dosing of NSAIDs by providing both an acid inhibitor and NSAID in a single convenient, preferably coordinated, unit dosage form, thereby reducing the number of individual doses to be administered during any given period.

Brief Description of the Drawings

Figure 1 is a schematic diagram of a four layer tablet dosage form. There is a naproxen core layer surrounded by a barrier layer. A third, enteric coating, layer delays the release of naproxen sodium until the pH is at a specific level, *e.g.*, above 4. Finally, there is an outer layer that releases an acid inhibitor such as famotidine.

Figure 2 illustrates a three layer dosage form. An acid inhibitor, *e.g.*, famotidine, is released immediately after ingestion by a patient in order to raise the pH of the gastrointestinal tract to above a specific pH, *e.g.*, above 4. The innermost layer contains naproxen. Thus, the dosage form has a naproxen core, an enteric film coat and an acid inhibitor film coat.

Figure 3 illustrates a naproxen sodium pellet which contains a subcoat or barrier coat prior to the enteric film coat.

Detailed Description of the Invention

The present invention is based upon the discovery of improved pharmaceutical compositions for administering NSAIDs to patients. In addition to containing one or more NSAIDs, the compositions include acid inhibitors that are capable of raising the pH of the GI tract of patients. All of the dosage forms are designed for oral delivery and provide for the coordinated release of therapeutic agents, *i.e.*, for the sequential release of acid inhibitor followed by analgesic.

The NSAIDs used in preparations may be either short or long acting. As used herein, the term "long acting" refers to an NSAID having a pharmacokinetic half-life of at least 2

hours, preferably at least 4 hours and more preferably, at least 8-14 hours. In general, its duration of action will equal or exceed about 6-8 hours. Examples of long-acting NSAIDs are: flurbiprofen with a half-life of about 6 hours; ketoprofen with a half-life of about 2 to 4 hours; naproxen or naproxen sodium with half-lives of about 12 to 15 hours and about 12 to 13 hours respectively; oxaprozin with a half life of about 42 to 50 hours; etodolac with a half-life of about 7 hours; indomethacin with a half-life of about 4 to 6 hours; ketorolac with a half-life of up to about 8-9 hours, nabumetone with a half-life of about 22 to 30 hours; mefenamic acid with a half-life of up to about 4 hours; and piroxicam with a half-life of about 4 to 6 hours. If an NSAID does not naturally have a half-life sufficient to be long acting, it can, if desired, be made long acting by the way in which it is formulated. For example, NSAIDs such as acetaminophen and aspirin may be formulated in a manner to increase their half-life or duration of action. Methods for making appropriate formulations are well known in the art (see *e.g.* Remington's Pharmaceutical Sciences, 16th ed., A. Oslo editor, Easton, PA (1980)).

It is expected that a skilled pharmacologist may adjust the amount of drug in a pharmaceutical composition or administered to a patient based upon standard techniques well known in the art. Nevertheless, the following general guidelines are provided:

Indomethacin is particularly useful when contained in tablets or capsules in an amount from about 25 to 75 mg. A typical daily oral dosage of indomethacin is three 25 mg doses taken at intervals during the day. However, daily dosages of up to about 150 mg are useful in some patients.

Aspirin will typically be present in tablets or capsules in an amount of between about 250 mg and 1000 mg. Typical daily dosages will be in an amount ranging from 500 mg to about 10 g. However, low dose aspirin present at 20-200 mg (and preferably 40-100 mg) per tablet or capsule may also be used.

Ibuprofen may be provided in tablets or capsules of 50, 100, 200, 300, 400, 600, or 800 mg. Daily doses should not exceed 3200 mg. 200 mg - 800 mg may be particularly useful when given 3 or 4 times daily.

Flurbiprofen is useful when in tablets at about from 50 to 100 mg. Daily doses of about 100 to 500 mg, and particularly from about 200 to 300 mg, are usually effective.

5 Ketoprofen is useful when contained in tablets or capsules in an amount of about 25 to 75 mg. Daily doses of from 100 to 500 mg and particularly of about 100 to 300 mg are typical as is about 25 to 50 mg every six to eight hours.

10 Naproxen is particularly useful when contained in tablets or capsules in an amount of from 250 to 500 mg. For naproxen sodium, tablets of about 275 or about 550 mg are typically used. Initial doses of from 100 to 1250 mg, and particularly 350 to 800 mg are also used, with doses of about 550 mg being generally preferred.

15 Oxaprozin may be used in tablets or capsules in the range of roughly 200 mg to 1200 mg, with about 600 mg being preferred. Daily doses of 1200 mg have been found to be particularly useful and daily doses should not exceed 1800 mg or 26 mg/kg.

20 Etodolac is useful when provided in capsules of 200 mg to 300 mg or in tablets of about 400 mg. Useful doses for acute pain are 200-400 mg every six-eight hours, not to exceed 1200 mg/day. Patients weighing less than 60 kg are advised not to exceed doses of 20 mg/kg. Doses for other uses are also limited to 1200 mg/day in divided doses, particularly 2, 3 or 4 times daily.

25 Ketorolac is usefully provided in tablets of 1-50 mg, with about 10 mg being typical. Oral doses of up to 40 mg, and particularly 10-30 mg/day have been useful in the alleviation of pain.

30 Nabumetone may be provided in tablets or capsules of between 500 mg and 750 mg. Daily doses of 1500-2000 mg, after an initial dose of 100 mg, are of particular use.

Mefenamic acid is particularly useful when contained in tablets or capsules of 50 mg to 500 mg, with 250 mg being typical. For acute pain, an initial dosage of 1-1000 mg, and particularly about 500 mg, is useful, although other doses may be required for certain patients.

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Lornoxicam is provided in tablets of 4 mg or 8 mg. Useful doses for acute pain are 8 mg or 16 mg daily, and for arthritis are 12 mg daily.

Other NSAIDs that may be used include: celecoxib, rofecoxib, meloxicam, piroxicam, droxicam, tenoxicam, valdecoxib, parecoxib, etoricoxib, CS-502, JTE-522, L-745,337, or NS398. JTE-522, L-745,337 and NS398 as described, *inter alia*, in Wakatani, *et al.* (*Jpn. J. Pharmacol.* 78:365-371 (1998)) and Panara, *et al.* (*Br. J. Pharmacol.* 116:2429-2434 (1995)). The amount present in a tablet or administered to a patient will depend upon the particular NSAID being used. For example:

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Celecoxib may be administered in a tablet or capsule containing from about 100 mg to about 500 mg or, preferably, from about 100 mg to about 200 mg.

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Piroxicam may be used in tablets or capsules containing from about 10 to 20 mg.

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Rofecoxib will typically be provided in tablets or capsules in an amount of 12.5, 25 or 50 mg. The recommended initial daily dosage for the management of acute pain is 50 mg.

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Meloxicam is provided in tablets of 7.5 mg, with a recommended daily dose of 7.5 or 15 mg for the management of osteoarthritis.

Valdecoxib is provided in tablets of 10 or 20 mg, with a recommended daily dose of 10 mg for arthritis or 40 mg for dysmenorrhea.

With respect to acid inhibitors, tablets or capsules may contain anywhere from 1 mg to as much as 1g. Typical amounts for H₂ blockers are: cimetidine, 100 to 800 mg/unit

dose; ranitidine, 50-300 mg/unit dose; famotidine, 5-100 mg/unit dose; ebrotidine 400 – 800 mg/unit dose; pabutidine 40 mg/unit dose; lafutidine 5–20 mg/unit dose; and nizatidine, 50-600 mg/unit dose. Proton pump inhibitors will typically be present at about 5 mg to 600 mg per unit dose. For example, the proton pump inhibitor omeprazole should be present in
5 tablets or capsules in an amount from 5 to 50 mg, with about 10 or 20 mg being preferred. Other typical amounts are: esomeprazole, 5–100 mg, with about 40 mg being preferred; lansoprazole, 5-150 mg (preferably 5-50 mg), with about 7.5, 15 or 30 mg being most preferred; pantoprazole, 10-200 mg, with about 40 mg being preferred; and rabeprazole, 5-100 mg, with about 20 mg being preferred.

10

Making of Pharmaceutical Preparations

The pharmaceutical compositions of the invention include tablets, dragees, liquids and capsules and can be made in accordance with methods that are standard in the art (see, *e.g.*, Remington's Pharmaceutical Sciences, 16th ed., A Oslo editor, Easton, Pa. (1980)).

15 Drugs and drug combinations will typically be prepared in admixture with conventional excipients. Suitable carriers include, but are not limited to: water; salt solutions; alcohols; gum arabic; vegetable oils; benzyl alcohols; polyethylene glycols; gelatin; carbohydrates such as lactose, amylose or starch; magnesium stearate; talc; silicic acid; paraffin; perfume oil; fatty acid esters; hydroxymethylcellulose; polyvinyl pyrrolidone; etc. The
20 pharmaceutical preparations can be sterilized and, if desired, mixed with auxiliary agents such as: lubricants, preservatives, disintegrants; stabilizers; wetting agents; emulsifiers; salts; buffers; coloring agents; flavoring agents; or aromatic substances.

Enteric coating layer(s) may be applied onto the core or onto the barrier layer of the
25 core using standard coating techniques. The enteric coating materials may be dissolved or dispersed in organic or aqueous solvents and may include one or more of the following materials: methacrylic acid copolymers, shellac, hydroxypropylmethcellulose phthalate, polyvinyl acetate phthalate, hydroxypropylmethylcellulose trimellitate, carboxymethylethylcellulose, cellulose acetate phthalate or other suitable enteric coating polymer(s). The pH at
30 which the enteric coat will dissolve can be controlled by the polymer or combination of polymers selected and/or ratio of pendant groups. For example, dissolution characteristics of the polymer film can be altered by the ratio of free carboxyl groups to ester groups. Enteric coating layers also contain pharmaceutically acceptable plasticizers such as triethyl citrate,

dibutyl phthalate, triacetin, polyethylene glycols, polysorbates or other plasticizers. Additives such as dispersants, colorants, anti-adhering and anti-foaming agents may also be included.

5 The Making of Tablet Dosage Forms

Preferably, the combination of an acid inhibitor and an NSAID will be in the form of a bi- or multi-layer tablet. In a bilayer configuration, one portion of the tablet contains the acid inhibitor in the required dose along with appropriate excipients, agents to aid dissolution, lubricants, fillers, etc. The second portion of the tablet will contain the NSAID,
10 preferably naproxen, in the required dose along with other excipients, dissolution agents, lubricants, fillers, etc. In the most preferred embodiment, the NSAID layer is surrounded by a polymeric coating which does not dissolve at a pH of less than 4. The NSAID may be granulated by methods such as slugging, low- or high- shear granulation, wet granulation, or fluidized-bed granulation. Of these processes, slugging generally produces tablets of less
15 hardness and greater friability. Low-shear granulation, high-shear granulation, wet granulation and fluidized-bed granulation generally produce harder, less friable tablets.

Examples

20 **Example 1: Enteric Coated Naproxen Sodium Core and Famotidine Immediate Release**

A schematic diagram of a four layer tablet dosage form is shown in Figure 1. The first layer contains naproxen sodium distributed throughout a matrix of pharmaceutically acceptable fillers, excipients, binding agents, disintegrants, and lubricants.

25

The second layer is a barrier layer which protects the first layer containing naproxen sodium. The barrier film coat is applied by conventional pan coating technology and the weight of the barrier coat may vary from 1% to 3% of the core tablet weight. In particular embodiments, the core naproxen sodium tablet is coated with coating ingredients such as
30 Opaspray® K-1-4210A or Opadry® YS-1-7006 (Colorcon, West Point, PA). Polymer film coating ingredients such as hydroxypropylmethylcellulose 2910 and polyethylene glycol 8000 in a coating suspension may also be used.

The function of the third layer is to prevent the release of naproxen sodium until the dosage form reaches an environment where the pH is above about 4 or 5. The enteric coating does not dissolve in areas of the GI tract where the pH may be below about 4 or 5 such as in an unprotected stomach. Methacrylic acid copolymers are used as the enteric coating ingredient, triethyl citrate and dibutyl phthalate are plasticizers, and ammonium hydroxide is used to adjust the pH of the dispersion. The coating dissolves only when the local pH is above, for example, 5.5 and, as a result, naproxen sodium is released.

The outermost layer contains an “acid inhibitor” in an effective amount which is released from the dosage form immediately after administration to the patient. The acid inhibitor in the present example is a proton pump inhibitor or, preferably the H2 blocker famotidine, which raises the pH of the gastrointestinal tract to above 4. The typical effective amount of famotidine in the dosage form will vary from 5 mg to 100 mg. A typical film coating formulation contains Opadry Clear® YS-1-7006 which helps in the formation of the film and in uniformly distributing famotidine within the fourth layer without tablets sticking to the coating pan or to each other during application of the film coat. Other ingredients may include: plasticizers such as triethyl citrate, dibutyl phthalate, and polyethylene glycol; anti-adhering agents such as talc; lubricating ingredients such as magnesium stearate; and opacifiers such as titanium dioxide. In addition, the pH of the film coating solution can be adjusted to aid in dissolution of the famotidine. The film coating is thin and rapidly releases famotidine for absorption.

	Core Tablet Ingredients	% W/W	mg/Tablet
	Naproxen sodium, USP	74.074	500.00
25	Microcrystalline cellulose, NF (Avicel PH 200)	17.166	115.87
	Povidone (K29/32), USP	3.450	23.29
	Talc, USP	4.350	29.36
	Magnesium Stearate, NF	0.960	6.48
30	Total	100.00	675.00

Barrier Film Coating Ingredients		% W/W
	Opadry Clear® YS-1-7006	5.00
	Purified water USP	95.00

5	Total	100.00

Enteric Coating Dispersion Ingredients		% W/W
10	Methacrylic Acid Copolymer, NF (Eudragit L-100-55)	7.30
	Methacrylic Acid Copolymer, NF (Eudragit L-100)	7.30
	Triethyl Citrate, NF	2.95
	Dibutyl Phthalate, NF	1.17
15	Ammonium Hydroxide (30%), NF	0.87
	Purified water, USP	80.41

	Total	100.00

Famotidine Coating Dispersion Ingredients		% W/W
	Famotidine, USP	3.0
	Opadry Clear® (YS-1-7006)	5.0
	Talc, USP	3.0
25	Purified Water, USP	89.0

	Total	100.0

Example 2: Enteric Coated Naproxen Core and Famotidine Immediate Release

Figure 2 illustrates a three layered dosage form which releases famotidine immediately after ingestion by the patient in order to raise the pH of the gastrointestinal tract to above about 4. The innermost layer contains naproxen uniformly distributed throughout a matrix of pharmaceutically acceptable excipients. These excipients perform specific functions and may serve as binders, disintegrants, or lubricants. A pharmaceutically acceptable enteric coating surrounds the naproxen core. The function of the enteric coat is to

delay the release of naproxen until the dosage form reaches an environment where the pH is above about 4. The coating does not dissolve in the harshly acidic pH of the unprotected stomach. It contains methacrylic acid copolymers which prevent the release of naproxen in the unprotected stomach. Also included are: triethyl citrate, a plasticizer; simethicone emulsion, an anti-foaming agent; and sodium hydroxide which is used to adjust the pH of the dispersion.

The outermost layer contains an “acid inhibitor” in an effective amount which is released from the dosage form immediately after administration to the patient. The acid inhibitor in this example is a proton pump inhibitor or, preferably, the H₂ blocker famotidine which raises the pH of the stomach to above 4. A typical film coating formulation contains Opadry Clear® YS-1-7006 which helps in the formation of the film and in uniformly distributing famotidine in the fourth layer without tablets sticking to the coating pan or sticking to each other during application of the film coat. Other ingredients are: plasticizers such as polyethylene glycol 8000; anti-adhering agents such as talc; lubricating ingredients such as magnesium stearate;, and opacifiers such as titanium dioxide. In addition, the pH of the film coating solution can be adjusted to aid in dissolution of the famotidine. The film coating is thin and rapidly releases famotidine for absorption.

	Core Tablet Ingredients	% W/W	mg /Tablet
20	Naproxen, USP	90.91	500.00
	Povidone K-90, USP	2.00	11.00
	Starch, USP	2.59	14.25
	Croscarmellose Sodium, USP	4.00	22.00
	Magnesium Stearate, NF	0.50	2.75
25	Total	-----	-----
	Purified Water, USP qs	100.00	550.00

	Enteric Coating Dispersion Ingredients	% W/W
30	Methacrylic Acid Copolymer Type C, NF (Eudragit L-100-55)	14.5
	Talc, USP	3.8
	Sodium Hydroxide, NF	0.2

	Triethyl Citrate, NF	1.7
	Simethicone Emulsion, USP	0.02
	Purified Water, USP	79.78

5	Total	100.00

Famotidine Coating Dispersion
Ingredients

% W/W

	Famotidine, USP	3.0
10	Opadry Clear® (YS-1-7006)	5.0
	Talc, USP	3.0
	Purified Water, USP	89.0

15	Total	100.0

Example 3: Naproxen Controlled Release Core and Famotidine Immediate Release

A trilayer tablet which separates famotidine contained in the film coat from controlled-release naproxen may be used in the present invention. The core tablet of naproxen is formulated using excipients which control the drug release for therapeutic relief from pain and inflammation for 24 hours. Figure 2 shows an example of an appropriate trilayer tablet. In this particular example, naproxen is mixed with a polymeric material, hydroxypropyl- methylcellulose and granulated with water. The granules are dried, milled, and blended with a lubricant, such as magnesium stearate. They are then compacted into tablets.

The controlled-release core tablet of naproxen is film coated with a pharmaceutically acceptable enteric coating. The function of the enteric coat is to delay the release of naproxen until the dosage form reaches an environment where the pH is above about 4. The coating does not dissolve in the extremely acidic pH of the unprotected stomach. The function of methacrylic acid copolymers is to prevent the release of naproxen until the pH of the stomach rises. Triethyl citrate is a plasticizer, simethicone emulsion is a anti-foaming agent, and sodium hydroxide is used to adjust the pH of the dispersion.

The outermost layer contains an “acid inhibitor” which is released from the dosage form immediately after administration to the patient. The acid inhibitor in the present example is a proton pump inhibitor or, preferably, the H₂ blocker famotidine which consistently raises the pH of the stomach to above 4. The typical effective amount of famotidine in the dosage will vary from 5 mg to 100 mg. A typical film coating formulation contains Opadry Blue® YS-1-4215 which is essential for film formation and for the uniform application of famotidine to the core tablet. Polymer film coating ingredients, hydroxypropylmethylcellulose or Opaspray® K-1-4210A (Colorcon, West Point, PA) may also be used. Other ingredients which help in the formation of the film and in the uniform application of famotidine to the core tablet are: plasticizers such as triethyl citrate and dibutyl phthalate; anti-adhering agents such as talc; lubricating ingredients such as magnesium stearate; and opacifiers such as titanium dioxide. In addition, the pH of the film coating solution can be adjusted to aid in dissolution of the famotidine. The film coating is thin and rapidly releases famotidine for absorption.

15	Core Tablet Ingredients	% W/W	mg/Tablet
	Naproxen, USP	94.00	750
	Hydroxypropyl methylcellulose 2208, USP (viscosity 15000 cps)	5.00	39.9
	Magnesium Stearate, NF	1.00	7.95
20	Total	100.00	797.85
	Enteric Coating Dispersion Ingredients	% W/W	
25	Methacrylic Acid Copolymer Type C, NF (Eudragit L-100-55)		14.5
	Talc, USP		3.8
	Sodium Hydroxide, NF		0.2
	Triethyl Citrate, NF		1.7
	Simethicone Emulsion, USP		0.02
30	Purified Water, USP		79.78
	Total		100.00

Famotidine Coating Dispersion Ingredients	% W/W
Famotidine, USP	2.0
Opadry Blue® (YS-1-4215)	10.0
Talc, USP	9.0
Purified Water, USP	79.0
Total	100.0

Example 4: Naproxen and Famotidine Controlled Release Core and Famotidine Immediate Release

A trilayer tablet which separates famotidine contained in the film coat from controlled-release naproxen and famotidine may be used in the present invention. The core tablet of naproxen and famotidine is formulated using excipients which control the drug release for therapeutic relief from pain and inflammation for 24 hours. Figure 2 is an example of an appropriate trilayer tablet. In this particular example, naproxen and famotidine are mixed with a polymeric material, hydroxypropylmethylcellulose and granulated with water. The granules are dried, milled, and blended with a lubricant, such as magnesium stearate. They are then compacted into tablets.

The controlled-release core tablet of naproxen and famotidine is film coated with a pharmaceutically acceptable enteric coating. The function of the enteric coat is to delay the release of naproxen until the dosage form reaches an environment where the pH is above about 4. The coating does not dissolve in the extremely acidic pH of the unprotected stomach. The function of methacrylic acid copolymers is to prevent the release of naproxen until the pH of the stomach rises. Triethyl citrate is a plasticizer, simethicone emulsion is a anti-foaming agent, and sodium hydroxide is used to adjust the pH of the dispersion

The outermost later contains an "acid inhibitor" which is released from the dosage form immediately after administration to the patient. The acid inhibitor in the present example is a proton pump inhibitor or, preferably, the H2 blocker famotidine which consistently raises the pH of the stomach to above 4. The typical effective amount of famotidine in the dosage will vary from 5 mg to 100 mg. A typical film coating formulation

contains Opadry Blue® YS-1-4215 which is essential for film formation and for the uniform application of famotidine to the core tablet. Polymer film coating ingredients, hydroxypropylmethylcellulose or Opaspray® K-1-4210A (Colorcon, West Point, PA) may also be used. Other ingredients which help in the formation of the film and in the uniform application of famotidine to the core tablet are: plasticizers such as triethyl citrate and dibutyl phthalate; anti-adhering agents such as talc; lubricating ingredients such as magnesium stearate; and opacifiers such as titanium dioxide. In addition, the pH of the film coating solution can be adjusted to aid in dissolution of the famotidine. The film coating is thin and rapidly releases famotidine for absorption.

10

Core Tablet Ingredients	% W/W	mg/Tablet
Naproxen, USP	88.05	500
Famotidine, USP	3.52	20.0
Hydroxypropyl methylcellulose		
2208, USP (viscosity 15000 cps)	7.03	39.9
Magnesium Stearate, NF	1.40	7.95
	-----	-----
Total	100.00	567.85

20

Enteric Coating Dispersion Ingredients	% W/W
Methacrylic Acid Copolymer Type C, NF (Eudragit L-100-55)	14.5
Talc, USP	3.8
Sodium Hydroxide, NF	0.2
Triethyl Citrate, NF	1.7
Simethicone Emulsion, USP	0.02
Purified Water, USP	79.78

30

Total	100.00
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Famotidine Coating Dispersion

Ingredients	% W/W
Famotidine, USP	2.0
Opadry Blue® (YS-1-4215)	10.0
5 Talc, USP	9.0
Purified Water, USP	79.0

Total	100.0

10 **Example 5: Enteric Coated Naproxen Sodium Core and Pantoprazole
Immediate Release in Film Coat**

15 A schematic diagram of a four layer tablet dosage form is shown in Figure 1. The first layer contains naproxen sodium distributed throughout a matrix of pharmaceutically acceptable fillers, excipients, binding agents, disintegrants, and lubricants.

20 The second layer is a barrier layer which protects the first layer containing naproxen sodium. The barrier film coat is applied by conventional pan coating technology and the weight of the barrier coat may vary from 1% to 3% of the core tablet weight. In particular embodiments, the core naproxen sodium tablet is coated with coating ingredients such as Opaspray® K-1-4210A or Opadry® YS-1-7006 (Colorcon, West Point, PA). Polymer film coating ingredients such as hydroxypropylmethylcellulose 2910 and polyethylene glycol 8000 in a coating suspension may also be used.

25 The third layer is an enteric film coat. It does not dissolve in areas of the GI tract where the pH may be below 4 such as in an unprotected stomach but it dissolves only when the local pH is above about 4. Therefore, the function of the third layer is to prevent the release of naproxen sodium until the dosage form reaches an environment where the pH is above 4. In this example, hydroxypropylmethylcellulose phthalate is the enteric coating ingredient, cetyl alcohol is a plasticizer and acetone and alcohol are solvents.

30 The fourth layer contains an "acid inhibitor" in an effective amount which is released from the dosage form as soon as the film coat dissolves. The acid inhibitor in this

example is a proton pump inhibitor, pantoprazole, which raises the pH of the gastrointestinal tract to above 4. The typical effective amount of pantoprazole in the dosage form may vary from 10 mg to 200 mg. The film coat is applied by conventional pan coating technology and the weight of film coat may vary from 4% to 8% of the core tablet weight.

- 5 Other ingredients are, plasticizers such as triethyl citrate, dibutyl phthalate, anti-adhering agents such as talc, lubricating ingredients such as magnesium stearate, opacifiers such as, titanium dioxide, and ammonium hydroxide to adjust the pH of the dispersion. The film coating is thin and rapidly releases pantoprazole for absorption. Therefore, pantoprazole releases first and then the core erodes and releases naproxen sodium.

10

Core Tablet Ingredients	% W/W	mg/tablet
Naproxen sodium, USP	74.075	500.00
Microcrystalline cellulose, NF (Avicel PH 200)	17.165	115.87
Povidone (K29/32), USP	3.450	23.29
Talc, USP	4.350	29.36
Magnesium Stearate, NF	0.960	6.48
Total	100.00	675.00

Naproxen sodium, 50% microcrystalline cellulose and povidone are dry mixed and wet granulated in an appropriate granulator with sufficient purified water. The wet granules are dried, milled, and blended with the remaining 50% microcrystalline cellulose, talc and magnesium stearate. The final granule blend is compressed into tablets.

15

Barrier Film Coating Ingredients	% W/W
Opadry® Clear YS-1-7006	5.00
Purified Water, USP	95.00
Total	100.00

Opadry clear is added slowly to purified water and mixing is continued until Opadry is fully dispersed. The solution is sprayed on to the tablet cores in a conventional coating pan until proper amount of Opadry clear is deposited on the tablets.

Enteric Coating Ingredients	% W/W
Hydroxypropyl methylcellulose phthalate, NF	5.5
Cetyl alcohol, NF	0.3
Acetone, NF	66.3
Alcohol, USP	27.9
Total	<hr/> 100.00

5

Hydroxypropylmethylcellulose phthalate and cetyl alcohol are dissolved in a mixture of alcohol and acetone. The solution is then sprayed on to the tablet bed in proper coating equipment. A sample of the tablets is tested for gastric resistance and the coating stopped if the tablets pass the test.

10

Pantoprazole Film Coating Ingredients	% W/W
Pantoprazole sodium, USP	5.00
Opadry® Clear YS-1-7006	5.00
Sodium carbonate, NF	1.20
Purified Water, USP	88.80
Total	<hr/> 100.00

Pantoprazole sodium is dissolved in purified water containing sodium carbonate in solution. After thorough mixing, Opadry clear is added slowly and mixing is continued until Opadry is fully dispersed. The suspension is sprayed on to the tablet cores in a conventional coating pan until the proper amount of pantoprazole sodium is deposited.

15

Example 6: Enteric Coated Naproxen Sodium Core and Omeprazole Immediate Release in Film Coat

A schematic diagram of a four layer tablet dosage form is shown in Figure 1. The first layer contains naproxen sodium distributed throughout a matrix of pharmaceutically acceptable fillers, excipients, binding agents, disintegrants, and lubricants.

20

The second layer is a barrier layer which protects the first layer containing naproxen sodium. The barrier film coat is applied by conventional pan coating technology and the weight of the barrier coat may vary from 1% to 3% of the core tablet weight. In particular embodiments, the core naproxen sodium tablet is coated with coating ingredients such as Opaspray® K-1-4210A or Opadry® YS-1-7006 (Colorcon, West Point, PA). Polymer film coating ingredients such as hydroxypropylmethylcellulose 2910 and polyethylene glycol 8000 in a coating suspension may also be used.

The third layer is an enteric film coat. It does not dissolve in areas of the GI tract where the pH is below 4 such as in an unprotected stomach but it dissolves only when the local pH is above 4. Therefore, the function of the third layer is to prevent the release of naproxen sodium until the dosage form reaches an environment where the pH is above about 4. In this example, hydroxypropylmethylcellulose phthalate is the enteric coating ingredient, cetyl alcohol is a plasticizer and acetone and alcohol are solvents.

The fourth layer contains an “acid inhibitor” in an effective amount which is released from the dosage form as soon as the film coat dissolves. The acid inhibitor in this example is a proton pump inhibitor, omeprazole, which raises the pH of the gastrointestinal tract to above 4. The typical effective amount of omeprazole in the dosage form may vary from 5 mg to 50 mg. The film coat is applied by conventional pan coating technology and the weight of film coat may vary from 4% to 8% of the core tablet weight. Other ingredients are, plasticizers such as triethyl citrate, dibutyl phthalate, anti-adhering agents such as talc, lubricating ingredients such as magnesium stearate, opacifiers such as, titanium dioxide, and ammonium hydroxide to adjust the pH of the dispersion. The film coating is thin and rapidly releases omeprazole for absorption. Therefore, omeprazole is released first and then the core erodes and releases naproxen sodium.

Core Tablet Ingredients	% W/W	mg/tablet
Naproxen sodium, USP	74.075	500.00
Microcrystalline cellulose, NF (Avicel PH 200)	17.165	115.87

Povidone (K29/32), USP	3.450	23.29
Talc, USP	4.350	29.36
Magnesium Stearate, NF	0.960	6.48
Total	100.00	675.00

Naproxen sodium, 50% microcrystalline cellulose and povidone are dry mixed and wet granulated in an appropriate granulator with sufficient purified water. The wet granules are dried, milled, and blended with the remaining 50% microcrystalline cellulose, talc and magnesium stearate. The final granule blend is compressed into tablets.

5

Barrier Film Coating Ingredients	%W/W
Opadry® Clear YS-1-7006	5.00
Purified Water, USP	95.00
Total	100.00

Opadry clear is added slowly to purified water and mixing is continued until Opadry is fully dispersed. The solution is sprayed on to the tablet cores in a conventional coating pan until the proper amount of Opadry clear is deposited on the tablets.

10

Enteric Coating Ingredients	%W/W
Methacrylic Acid Copolymer, NF (Eudragit L-100-55)	6.0
Triethyl Citrate, NF	0.6
Talc, USP	3.0
Purified Water, USP	5.0
Isopropyl Alcohol, USP	85.40
Total	100.00

Methacrylic acid copolymer, triethyl citrate, and talc are dissolved in a mixture of isopropyl alcohol and water. The solution is then sprayed on to the tablet bed in a proper

coating equipment. A sample of the tablets is tested for gastric resistance and the coating is stopped if the tablets pass the test.

Omeprazole Film Coating Ingredients	% W/W
Omeprazole, USP	5.00
Opadry® Clear YS-1-7006	5.00
Purified Water, USP	10.00
Isopropyl Alcohol, USP	80.00
Total	<hr/> 100.00

Omeprazole is dissolved in a purified water and isopropyl alcohol mixture. After thorough mixing, Opadry clear is added slowly and mixing is continued until Opadry is fully dispersed. The suspension is sprayed on to the tablet cores in a conventional coating pan until proper amount of omeprazole is deposited on the tablets.

Example 7: Naproxen Sodium Delayed Release and Omeprazole Immediate Release Capsule

A coordinated delivery dosage may be used to provide fast release of an acid inhibitor, a proton pump inhibitor, omeprazole which raises the pH of the gastrointestinal tract to above 4, and the delayed release of a non-steroidal anti-inflammatory drug, naproxen sodium. Omeprazole granules modify the pH of the stomach such that the drug readily dissolves and is absorbed in the stomach without significant degradation. The typical effective amount of omeprazole in the dosage form may vary from 5 mg to 50 mg. The release of naproxen sodium is delayed by enteric coating.

Omeprazole granules contain an alkalizing excipient such as sodium bicarbonate. Other soluble alkalizing agents such as potassium bicarbonate, sodium carbonate, sodium hydroxide, or their combinations may also be used. The alkalizing agent helps solubilize and protect omeprazole from degradation before its absorption. Sodium lauryl sulfate helps in the wetting of omeprazole. Other surfactants may be used to perform the same function. In the present example, hydroxypropyl methylcellulose helps in granule formation, sodium

starch glycolate is a disintegrant, and magnesium stearate is a lubricant. Other excipients may also be used to perform these functions.

Naproxen sodium pellets as shown in Figure 3 are prepared by the wet massing technique and the conventional extrusion and spheronization process. The excipients used in the formulation are microcrystalline cellulose, and povidone. The pellets after drying and classification are coated with a protective subcoating containing povidone. Other coating ingredients may also be used such as Opaspray K-1-4210A or Opadry YS-1-7006 (trademarks of Colorcon, West Point, PA). Polymer film coating ingredients such as hydroxypropylmethylcellulose 2910 and polyethylene glycol 8000 in a subcoating suspension are also alternatives. Other ingredients are, plasticizers such as triethyl citrate, dibutyl phthalate, anti-adhering agents such as talc, lubricating ingredients such as magnesium stearate, opacifiers such as, titanium dioxide.

The subcoated pellets are enteric coated using enteric coating polymers. In this example, the enteric coating polymer is methacrylic acid copolymer and the plasticizer is dibutyl phthalate which are dissolved in a mixture of acetone and alcohol. The enteric film does not dissolve in the acidic pH but dissolves when the pH in the gut is above about pH 6 and releases naproxen sodium.

mmmOmeprazole Granules	% W/W	mg/capsule
Omeprazole, USP	12.9	20.00
Sodium Bicarbonate, USP	82.40	127.72
Hydroxypropyl methylcellulose, USP	2.00	3.10
Sodium lauryl sulfate, NF	0.20	0.31
Sodium starch glycolate, NF	2.00	3.10
Magnesium stearate, NF	0.50	0.77
Total	100	100

Hydroxypropylmethylcellulose is dissolved in water, then sodium lauryl sulfate is added and the solution is mixed. Omeprazole, microcrystalline cellulose, and sodium bicarbonate are dry mixed together and granulated with the granulating solution. The

granulation is mixed until proper granule formation is reached. The granulation is then dried, milled, and blended with magnesium stearate.

Pellet Ingredients	% W/W	mg/tablet
Naproxen sodium, USP	86.80	250.00
Microcrystalline cellulose, NF (Avicel PH 200)	11.10	32.00
Povidone (K90), USP	2.10	6.00
Total	100.00	288.00

- 5 Povidone is dissolved in water. Naproxen sodium and microcrystalline cellulose are dry mixed and granulated with povidone solution. The wet mass is mixed until proper consistency is reached. The wet mass is then pressed through an extruder and spheronized to form pellets. The pellets are then dried and classified into suitable particle size range.

Subcoat Ingredients	% W/W
Povidone (K29-32), USP	10.00
Alcohol, USP	90.00
Total	100.00

- 10 The pellet cores are coated using povidone solution by a conventional coating pan method to a weight gain of 1-2%.

Enteric Coating Ingredients	% W/W
Methacrylic Acid Copolymer, NF (Eudragit L-100)	8.20
Diethyl Phthalate, NF	1.70
Acetone, NF	33.30
Isopropyl Alcohol, USP	56.80
Total	100.0

Eudragit L-100 is dissolved in isopropanol and acetone and diethyl phthalate is dissolved. The solution is sprayed on the pellet cores using proper film coating equipment. A sample of the pellets is tested for gastric resistance before stopping the coating process.

Omeprazole fast release granules and naproxen sodium delayed release pellets are blended together and filled into appropriate size capsules to contain 250 mg naproxen sodium and 20 mg omeprazole per capsule.

Example 8: Naproxen Delayed Release and Omeprazole Immediate Release Capsule

The present Example is directed to a coordinated delivery dosage form containing omeprazole and naproxen. The formulation contains 10 mg omeprazole and uses methylcellulose as a binder and croscarmellose sodium as a disintegrant. Naproxen pellets as shown in Figure 3 do not need a subcoating layer and are enteric coated with an aqueous dispersion of methacrylic acid copolymer. Optionally, these pellets could be compressed into a core and film coated with an acid inhibitor and thereby form a bilayer tablet.

Omeprazole Granules	% W/W	mg/capsule
Omeprazole, USP	6.45	10.00
Sodium Bicarbonate, USP	88.85	137.71
Methylcellulose, USP	2.00	3.10
Sodium lauryl sulfate, NF	0.20	0.31
Croscarmellose sodium, NF	2.00	3.10
Magnesium stearate, NF	0.50	0.78
Total	100	100

Methylcellulose is dissolved in water, then sodium lauryl sulfate is added to the solution and mixed. Omeprazole, microcrystalline cellulose, and sodium bicarbonate are dry mixed together and granulated with the granulating solution. The granulation is mixed until proper granule formation is reached. The granulation is then dried, milled, and blended with magnesium stearate.

Pellet Ingredients	% W/W	mg/tablet
Naproxen, USP	76.	250.00
Microcrystalline cellulose, NF (Avicel PH 200)	21.	71.44
Povidone (K90), USP	2.	6.56
Total	100.	328.00

Povidone is dissolved in water. Naproxen and microcrystalline cellulose are dry mixed and granulated with povidone solution. The wet mass is mixed until proper consistency is reached. The wet mass is then pressed through an extruder and spheronized to form pellets. The pellets are then dried and classified into a suitable particle size range.

Enteric Coating Ingredients	% W/W
Methacrylic Acid Copolymer, NF (Eudragit L30D 30% dispersion)	15.60
Talc, USP	7.60
Triethyl citrate, NF	1.60
Simethicone Emulsion, USP (Silicone antifoam emulsion SE 2)	0.20
Purified Water, USP	74.80

Eudragit 30D is dispersed in purified water and simethicone emulsion. Talc and triethyl citrate are then dispersed. The suspension is sprayed on the pellet cores using proper film coating equipment. A sample of the pellets is tested for gastric resistance before stopping the coating process. Omeprazole fast release granules and naproxen sodium delayed release pellets are blended together and filled into appropriate size capsules to contain 250 mg naproxen and 10 mg omeprazole per capsule.

Example 9: Clinical Study of the Relationship of Gastric pH to NSAID-induced Gastric Ulcers

Sixty-two subjects were enrolled in a clinical study and randomly assigned to three groups. The following three groups were administered study medication twice daily for five days: (a) 550 mg naproxen sodium (n=10), (b) 40 mg famotidine given with 550 mg of

naproxen or famotidine followed 90 minutes later by 550 mg naproxen, (n=39) or (c) 20 mg omeprazole followed by 550 mg naproxen sodium (n=13). Gastric pH was measured hourly beginning at the time of dosing of the final daily dose of study medication and for 8 – 10 hours thereafter. Subjects had a gastric endoscopy performed at the beginning and on Day 5 prior to the morning dose of study medication to identify gastric and duodenal irritation; no subjects were admitted to the study if gastric irritation was present at the time of initial endoscopy.

Five patients, three (33%) in the naproxen alone group and two (5%) in the famotidine/naproxen group, presented with gastroduodenal ulcers at the end of the study. In the naproxen alone group, the pH was greater than 4 only 4% of the time, and in the famotidine/naproxen group the pH was greater than 4 forty-nine percent of the time during the 8 – 10 hours following naproxen sodium dosing. Additionally, Lanza grade 3 or 4 damage was present in 28% (n=11) of the subjects receiving famotidine/naproxen sodium, and present 100% (n=10) in the naproxen sodium treatment group. Monitoring of gastric acidity on day 5 indicated that patients with Lanza scores of greater than 2 had integrated gastric acidity of greater than 100 mmol-hr/L. Only 20 – 40% of patients with integrated gastric acidity of less than 100 mmol-hr/L had gastric pathology, whereas all patients with integrated gastric acidity greater than 100 mmol-hr/L had pathology.

**Example 10. Famotidine and Enteric Coated Naproxen Reduce
Gastroduodenal Damage Due to NSAID Therapy**

Thirty-seven patients were randomized to two groups for a one week study of twice-daily dosing of: 500 mg enteric coated naproxen, and 500 mg enteric coated naproxen preceded by 40 mg famotidine. Endoscopies were conducted on all patients prior to first dosing and on the final day of the study. No subjects had evidence of gastroduodenal damage at the beginning of the study (at first endoscopy).

At the second endoscopy, Lanza scores for gastroduodenal damage were assessed for all subjects. 39% of the subjects in the enteric coated naproxen 500 mg group had grade 3-4 gastroduodenal damage. This is lower than the percentage that would be expected for the administration of 500 mg of non-enteric naproxen based upon previous work. Nevertheless, subjects administered 500 mg enteric coated naproxen and 40 mg famotidine

had an even lower incidence of grade 3 – 4 gastroduodenal damage (26%) than subjects who had previously taken enteric coated naproxen alone which demonstrates the value of combining acid inhibition with enteric coating of NSAID to minimize the gastrointestinal damage.

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All references cited herein are fully incorporated by reference. Having now fully described the invention, it will be understood by those of skill in the art that the invention may be performed within a wide and equivalent range of conditions, parameters and the like, without affecting the spirit or scope of the invention or any embodiment thereof.

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What is Claimed is:

1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:
 - (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
 - (b) a non-steroidal anti-inflammatory drug (NSAID) present in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;and wherein:
 - i) said unit dosage form is a tablet in which said NSAID is present in a core;
 - ii) said tablet comprises a coating, wherein said coating surrounds said core and does not release said NSAID until the pH of the surrounding medium is 3.5 or higher; and
 - iii) said acid inhibitor is in one or more layers outside said core, wherein said one or more layers:
 - A) do not include an NSAID;
 - B) are not surrounded by an enteric coating; and
 - C) upon ingestion of said tablet by a patient, release said acid inhibitor into said patient's stomach.
2. The pharmaceutical composition of claim 1, wherein there is a single core comprising said NSAID and said acid inhibitor is an H₂ blocker.
3. The pharmaceutical composition of claim 1, wherein there is a single core comprising said NSAID and said acid inhibitor is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine; loxtidine and famotidine.

4. The pharmaceutical composition of claim 3, wherein said acid inhibitor is famotidine, present in said unit dosage form in an amount of between 5 mg and 100 mg.
5. The pharmaceutical composition of claim 2 wherein said NSAID is selected from the group consisting of: aspirin; acetaminophen; ibuprofen; flurbiprofen; ketoprofen; lornoxicam; naproxen; oxaprozin; etodolac; indomethacin; ketorolac; nabumetone; diclofenac; ketorolac; mefenamic acid; diflunisal; sulindac; tolmetin, fenoprofen; suprofen; benoxaprofen; aceclofenac; tolfenamic acid; oxyphenbutazone; azapropazone; phenylbutazone; celecoxib; rofecoxib; meloxicam; piroxicam; droxicam; tenoxicam; valdecoxib; parecoxib; etoricoxib; lumiracoxib; CS-502; JTE-522; L-745,337; and NS398.
6. The pharmaceutical composition of claim 1, wherein there is a single core comprising NSAID and said acid inhibitor is a proton pump inhibitor.
7. The pharmaceutical composition of claim 1, wherein there is a single core comprising NSAID and said acid inhibitor is selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole, pariprazole and leminoprazole.
8. The pharmaceutical composition of claim 7, wherein said acid inhibitor is omeprazole, present in said unit dosage form in an amount of between 5 mg and 50 mg.
9. The pharmaceutical composition of claim 7, wherein said acid inhibitor is lansoprazole, present in said unit dosage form in an amount of between 5 mg and 150 mg.
10. The pharmaceutical composition of claim 9, wherein said lansoprazole is present in said unit dosage form in an amount of between 5 mg and 30 mg.

11. The pharmaceutical composition of claim 7, wherein said acid inhibitor is pantoprazole, present in said unit dosage form in an amount of between 10 mg and 200 mg.
12. The pharmaceutical composition of claim 1, wherein there is a single core comprising NSAID and said acid inhibitor is selected from the group consisting of: AZD-0865, AR-H047108, CS-526, pumaprazole, revaprazan and soraprazan.
13. The pharmaceutical composition of claim 12, wherein said acid inhibitor is selected from the group consisting of: pumaprazole, revaprazan and soraprazan.
14. The pharmaceutical composition of claim 7, wherein said NSAID is selected from the group consisting of: aspirin; acetaminophen; ibuprofen; flurbiprofen; ketoprofen; lornoxicam; naproxen; oxaprozin; etodolac; indomethacin; ketorolac; nabumetone; diclofenac; ketorolac; mefenamic acid; diflunisal; sulindac; tolmetin, fenoprofen; suprofen; benoxaprofen; aceclofenac; tolfenamic acid; oxyphenbutazone; azapropazone; phenylbutazone; celecoxib; rofecoxib; meloxicam; piroxicam; droxicam; tenoxicam; valdecoxib; parecoxib; etoricoxib; lumiracoxib; CS-502; JTE-522; L-745,337; and NS398.
15. The pharmaceutical composition of claim 1, wherein:
 - a) said acid inhibitor is selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole; pariprazole, leminoprazole, pumaprazole, revaprazan and soraprazan;
 - b) there is a single core comprising said NAID and said NSAID is selected from the group consisting of celecoxib; rofecoxib; meloxicam; piroxicam; droxicam; tenoxicam; valdecoxib, parecoxib, etoricoxib, flurbiprofen; ketoprofen; lornoxicam; naproxen; oxaprozin; etodolac; indomethacin; ketorolac; nabumetone; diclofenac; ketorolac; mefenamic acid; diflunisal; sulindac; tolmetin; fenoprofen; suprofen; benoxaprofen; aceclofenac; tolfenamic acid; oxyphenbutazone; azapropazone; and phenylbutazone.

16. A method of treating a patient for pain or inflammation, comprising administering to said patient a therapeutically effective amount of the pharmaceutical composition of claim 1.
17. The method of claim 16, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.
18. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:
 - (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
 - (b) a non-steroidal anti-inflammatory drug (NSAID) present in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;and wherein:
 - i) said unit dosage form is a capsule in which said NSAID is present in a core;
 - ii) said capsule comprises a coating, wherein said coating surrounds said core containing said NSAID and does not release said NSAID until the pH of the surrounding medium is 3.5 or higher; and
 - iii) said acid inhibitor is in one or more layers outside said core, wherein said one or more layers:
 - A) do not include an NSAID;
 - B) are not surrounded by an enteric coating; and
 - C) upon ingestion of said capsule by a patient, release said acid inhibitor into said patient's stomach.
19. The pharmaceutical composition of claim 18, wherein there are multiple particles of said NSAID each constituting a core surrounded by said coating that does not release said NSAID until the pH of the surrounding medium is 3.5 or higher.

20. The pharmaceutical composition of claim 18, wherein said acid inhibitor is an H₂ blocker.
21. The pharmaceutical composition of claim 18, wherein said acid inhibitor is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine; loxidine and famotidine.
22. The pharmaceutical composition of claim 21, wherein said acid inhibitor is famotidine, present in said unit dosage form in an amount of between 5 mg and 100 mg.
23. The pharmaceutical composition of claim 20, wherein said NSAID is selected from the group consisting of: aspirin; acetaminophen; ibuprofen; flurbiprofen; ketoprofen; lornoxicam; naproxen; oxaprozin; etodolac; indomethacin; ketorolac; nabumetone; diclofenac; ketorolac; mefenamic acid; diflunisal; sulindac; tolmetin, fenoprofen; suprofen; benoxaprofen; aceclofenac; tolfenamic acid; oxyphenbutazone; azapropazone; phenylbutazone; celecoxib; rofecoxib; meloxicam; piroxicam; droxicam; tenoxicam; valdecoxib; parecoxib; etoricoxib; lumiracoxib; CS-502; JTE-522; L-745,337; and NS398.
24. The pharmaceutical composition of claim 18, wherein said acid inhibitor is a proton pump inhibitor.
25. The pharmaceutical composition of claim 18, wherein acid inhibitor is selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole, pariprazole and leminoprazole.
26. The pharmaceutical composition of claim 25 wherein said acid inhibitor is omeprazole, present in said unit dosage form in an amount of between 5 mg and 50 mg.

27. The pharmaceutical composition of claim 25, wherein said acid inhibitor is lansoprazole, present in said unit dosage form in an amount of between 5 mg and 150 mg.
28. The pharmaceutical composition of claim 27, wherein said lansoprazole is present in said unit dosage form in an amount of between 5 mg and 30 mg.
29. The pharmaceutical composition of claim 25, wherein said acid inhibitor is pantoprazole, present in said unit dosage form in an amount of between 10 mg and 200 mg.
30. The pharmaceutical composition of claim 18, wherein said acid inhibitor is selected from the group consisting of: AZD-0865, AR-H047108, CS-526, pumaprazole, revaprazan and soraprazan.
31. The pharmaceutical composition of claim 30, wherein said acid inhibitor is selected from the group consisting of: pumaprazole, revaprazan and soraprazan.
32. The pharmaceutical composition of claim 24, wherein said NSAID is selected from the group consisting of: aspirin; acetaminophen; ibuprofen; flurbiprofen; ketoprofen; lornoxicam; naproxen; oxaprozin; etodolac; indomethacin; ketorolac; nabumetone; diclofenac; ketorolac; mefenamic acid; diflunisal; sulindac; tolmetin, fenoprofen; suprofen; benoxaprofen; aceclofenac; tolfenamic acid; oxyphenbutazone; azapropazone; phenylbutazone; celecoxib; rofecoxib; meloxicam; piroxicam; droxicam; tenoxicam; valdecoxib; parecoxib; etoricoxib; lumiracoxib; CS-502; JTE-522; L-745,337; and NS398.
33. A method of treating a patient for pain or inflammation, comprising administering to said patient a therapeutically effective amount of the pharmaceutical composition of claim 18.
34. The method of claim 33, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.

35. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:
- (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
 - (b) aspirin present in an amount effective, upon the administration of one or more of said unit dosage forms, to treat said patient for a condition that responds to NSAID treatment;
- and wherein:
- i) said unit dosage form is a tablet in which said aspirin is present in a core;
 - ii) said tablet comprises a coating, wherein said coating surrounds said core and does not release said aspirin until the pH of the surrounding medium is 3.5 or higher; and
 - iii) said acid inhibitor is in one or more layers outside said core, wherein said one or more layers:
 - A) do not include an NSAID;
 - B) are not surrounded by an enteric coating; and
 - C) upon ingestion of said tablet by a patient, release said acid inhibitor into said patient's stomach.
36. The pharmaceutical composition of claim 35, wherein said aspirin is present at 20-200 mg.
37. The pharmaceutical composition of claim 35, wherein there is a single core comprising said aspirin and said acid inhibitor is an H2 blocker.
38. The pharmaceutical composition of claim 35, wherein there is a single core comprising said aspirin and said acid inhibitor is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine; loxtidine and famotidine.

39. The pharmaceutical composition of claim 37, wherein said aspirin is present at 20-200 mg.
40. The pharmaceutical composition of claim 35, wherein there is a single core comprising said aspirin and said acid inhibitor is a proton pump inhibitor.
41. The pharmaceutical composition of claim 35, wherein there is a single core comprising NSAID and said acid inhibitor is selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole, pariprazole and leminoprazole.
42. The pharmaceutical composition of claim 35, wherein there is a single core comprising NSAID and said acid inhibitor is selected from the group consisting of: AZD-0865, AR-H047108, CS-526, pumaprazole, revaprazan and soraprazan.
43. The pharmaceutical composition of claim 40, wherein said aspirin is present at 20-200 mg.
44. A method of treating a patient for a condition in which an NSAID is effective comprising administering to said patient an effective amount of the pharmaceutical composition of claim 35.
45. A method of providing low dose aspirin therapy to a patient comprising administering to said patient an effective amount of the pharmaceutical composition of claim 36.
46. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:
 - (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;

- (b) aspirin present in an amount effective, upon the administration of one or more of said unit dosage forms, to treat said patient for a condition that responds to aspirin treatment;

and wherein:

- i) said unit dosage form is a capsule in which said aspirin is present in a core;
 - ii) said capsule comprises a coating, wherein said coating surrounds said core containing said aspirin and does not release said aspirin until the pH of the surrounding medium is 3.5 or higher; and
 - iii) said acid inhibitor is in one or more layers or particles outside said core, wherein said one or more layers or particles:
 - A) do not include an NSAID;
 - B) are not surrounded by an enteric coating; and
 - C) upon ingestion of said capsule by a patient, release said acid inhibitor into said patient's stomach.
47. The pharmaceutical composition of claim 46, wherein said aspirin is present at 20-200 mg.
48. The pharmaceutical composition of claim 46, wherein there are multiple particles of said aspirin each constituting a core surrounded by said coating that does not release said aspirin until the pH of the surrounding medium is 3.5 or higher.
49. The pharmaceutical composition of claim 46, wherein said acid inhibitor is an H₂ blocker.
50. The pharmaceutical composition of claim 46, wherein said acid inhibitor is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine; loxidine and famotidine.
51. The pharmaceutical composition of claim 46, wherein said aspirin is present at 20-200 mg.

52. The pharmaceutical composition of claim 46, wherein said acid inhibitor is a proton pump inhibitor.
53. The pharmaceutical composition of claim 46, wherein acid inhibitor is selected from the group consisting of: omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole, pariprazole and leminoprazole.
54. The pharmaceutical composition of claim 46, wherein said acid inhibitor is selected from the group consisting of: AZD-0865, AR-H047108, CS-526, pumaprazole, revaprazan and soraprazan.
55. A method of treating a patient for a condition for which aspirin is effective, comprising administering to said patient an effective amount of the pharmaceutical composition of claim 46.
56. A method of providing low dose aspirin therapy to a patient comprising administering to said patient an effective amount of the pharmaceutical composition of claim 47.

Abstract

The present invention is directed to drug dosage forms that release an agent that raises the pH of a patient's gastrointestinal tract, followed by a non-steroidal anti-inflammatory drug. The dosage form is designed so that the NSAID is not released until the
5 intragastric pH has been raised to a safe level. The invention also encompasses methods of treating patients by administering this coordinated release, gastroprotective, antiarthritic/analgesic combination unit dosage form to achieve pain and symptom relief with a reduced risk of developing gastrointestinal damage such as ulcers, erosions and hemorrhages.

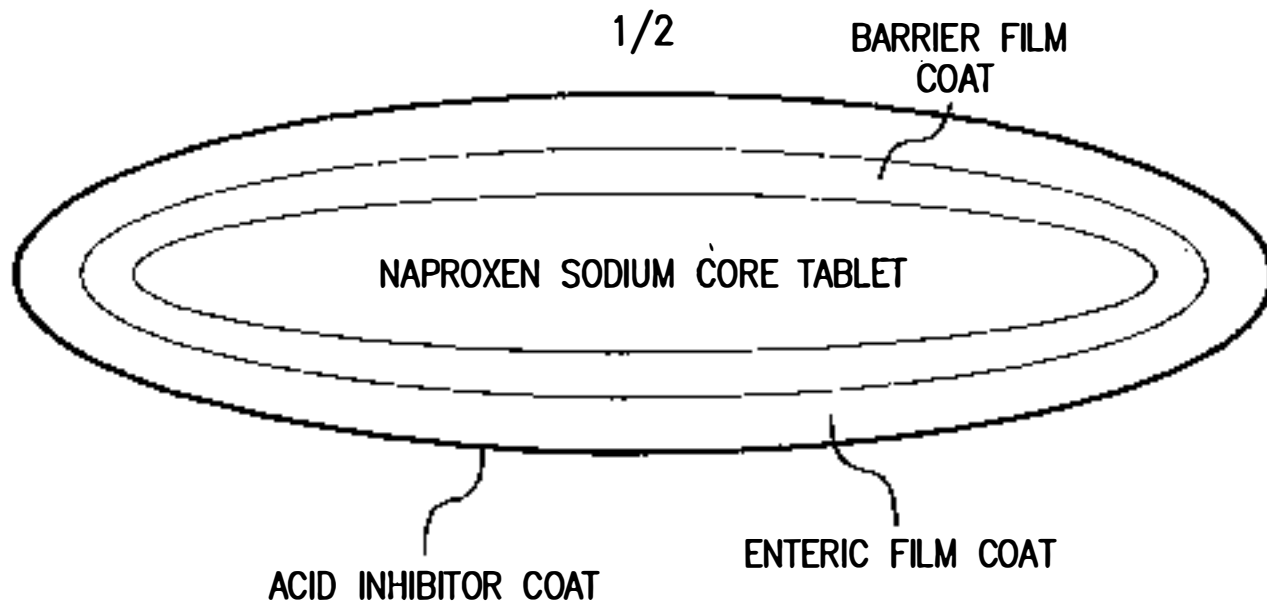


FIG.1

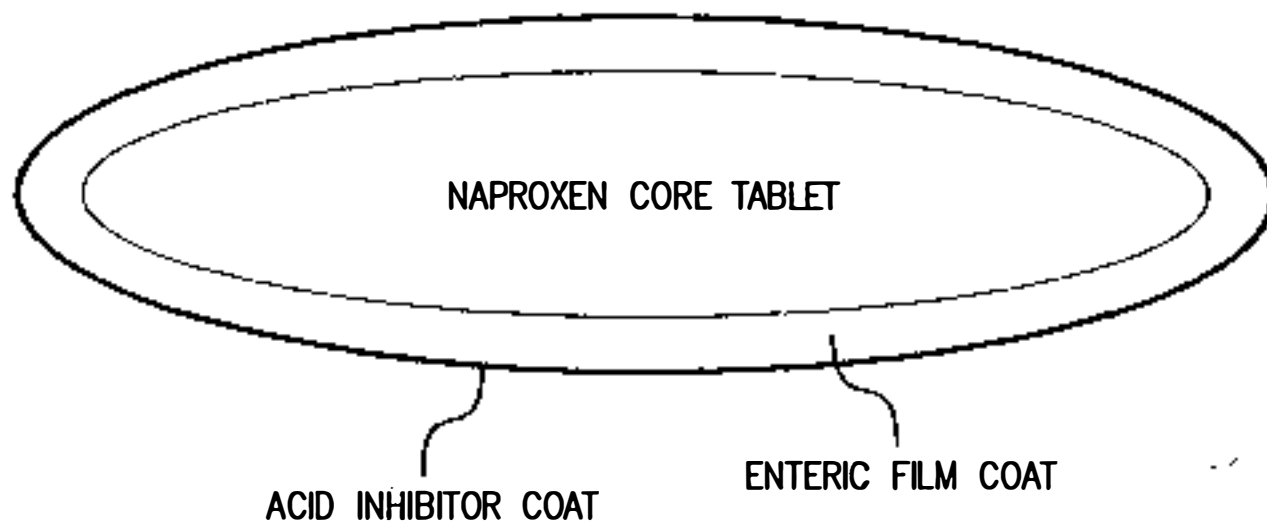


FIG.2

2/2

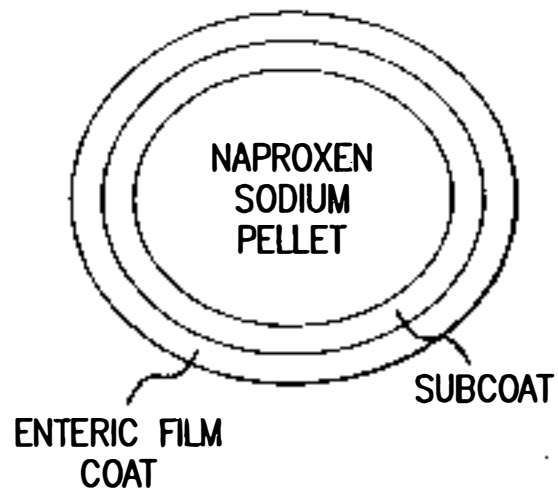


FIG.3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John R. PLACHETKA

Group Art Unit: To Be Assigned

Serial No.: To Be Assigned

Examiner: To Be Assigned

Filing Date: April 3, 2014

Attorney Docket No.: POZN.P0004US.CP1C4

Title: PHARMACEUTICAL
COMPOSITIONS FOR THE
COORDINATED DELIVERY OF
NSAIDS

Confirmation No.: To Be Assigned

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the
United States Patent and Trademark Office via EFS-Web on the date below:

April 3, 20124

/Steven L. Highlander/

Date

Steven L. Highlander

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Commissioner:

Applicant respectfully submits this Preliminary Amendment in the above referenced U.S. patent application. Consideration of this application in view of the amendments made herein is respectfully requested.

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 3.

Remarks begin on page 6.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification at page 1, lines 5-7, by inserting the following amended paragraph:

The present application is a continuation of co pending U.S. application No. 14/045,156, filed October 3, 2013, which is a continuation of U.S. application No. 13/215,855, filed August 23, 2011, issued as U.S. Patent No. 8,557,285 on October 15, 2013, which is a divisional of U.S. application No. 12/553,834 filed September 3, 2009, abandoned, which is a divisional of U.S. application No. 11/129,320 filed May 16, 2005, issued as U.S. Patent No. 8,206,741 on June 26, 2012, which is a continuation-in-part of U.S. application [[no.]]No. 10/158,216, filed on May 31, 2002, issued as U.S. Patent No. 6,926,907 on August 9, 2005, which. ~~The '216 application~~ claims the benefit of U.S. provisional application [[no.]]No. 60/294,588, filed on June 1, 2001. The entire contents of all applications are hereby incorporated by reference.

AMENDMENTS TO THE CLAIMS

Listing of Claims

The following listing of claim replaces all previous listings or versions thereof:

1-56. (Canceled)

57. (New) A pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising:

naproxen in an amount of 200-600 mg per unit dosage form; and

esomeprazole in an amount of from 5 to 100 mg per unit dosage form,

wherein upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium, and release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher.

58. (New) The pharmaceutical composition of claim 57, wherein said naproxen is present in a core layer, wherein said core layer has a coating that inhibits its release from said unit dosage form unless said dosage form is in a medium with a pH of 3.5 or higher.

59. (New) The pharmaceutical composition of claim 57, wherein said unit dosage form is a multilayer tablet comprising a core layer and one or more layers outside of said core layer.

60. (New) The pharmaceutical composition of claim 59, wherein said core layer comprises naproxen.

61. (New) The pharmaceutical composition of claim 59, wherein at least one of said one or more layers outside said core layer comprises esomeprazole.

62. (New) The pharmaceutical composition of claim 59, wherein said one or more layers outside of said core layer do not contain naproxen.

63. (New) The pharmaceutical composition of claim 57, further comprising at least one carrier.

64. (New) The pharmaceutical composition of claim 57, further comprising at least one auxiliary agent chosen from the group consisting of lubricants, preservatives, disintegrants, stabilizers, wetting agents, emulsifiers, salts, buffers, coloring agents, flavoring agents, and aromatic substances.

65. (New) The pharmaceutical composition of claim 57, further comprising at least one ingredient to adjust pH.

66. (New) A method of treating a patient for pain or inflammation, comprising administering to said patient the pharmaceutical composition of claim 57.

67. (New) The method of claim 66, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.

68. (New) A pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising:

a core layer comprising naproxen, wherein said core layer has a coating that inhibits release of said naproxen from said core layer unless said dosage form is in a medium with a pH of 3.5 or higher; and

a layer comprising esomeprazole, wherein said layer is has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient.

69. (New) The pharmaceutical composition of claim 68, wherein naproxen is present in said unit dosage form in an amount of 200-600 mg.

70. (New) The pharmaceutical composition of claim 68, wherein esomeprazole is present in said unit dosage form in an amount of from 5 to 100 mg.

71. (New) The pharmaceutical composition of claim 68, wherein naproxen is present in said unit dosage form in an amount of between 200-600 mg and esomeprazole in an amount of from 5 to 100 mg per unit dosage form.

72. (New) A method of treating a patient for pain or inflammation, comprising administering to said patient the pharmaceutical composition of claim 68.

73. (New) The method of claim 72, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.

74. (New) A method of treating a patient for pain or inflammation, comprising administering to said patient the pharmaceutical composition of claim 71.

75. (New) The method of claim 74, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.

REMARKS

The claims have been amended without prejudice or disclaimer. Claims 1-56 have been canceled. Claims 57-75 have been added. Claims 57-75 are pending.

Support for the new claims can be derived from the specification generally, and in particular the new claims are supported as follows:

- Claim 57: Page 5, lines 19-20, 28-29, page 5, line 32 to page 6, line 7, and page 12, line 6
- Claim 58: Fig. 1, legend, page 5, line 33, page 6, line 1, and page 13, lines 6-7
- Claim 59: Page 6, lines 17-18, and page 13, lines 6-7
- Claim 60: Fig. 1, legend
- Claim 61: Page 12, line 6, and page 13, lines 6-7
- Claim 62: Page 6, lines 5-7, and page 13, lines 6-7
- Claim 63: Page 12, line 16
- Claim 64: Page 12, lines 19-22
- Claim 65: Page 14, lines 5-6
- Claim 66: Page 5, line 11
- Claim 67: Page 7, lines 13-14
- Claim 68: Page 5, line 28 to page 6, line 7, Fig. 2, legend, and page 13, lines 6-7
- Claim 69: Page 5, lines 19-20
- Claim 70: Page 12, line 6
- Claim 71: Page 5, lines 19-20 and page 12, line 6
- Claim 72: Page 5, line 11
- Claim 73: Page 7, lines 13-14
- Claim 74: Page 5, line 11
- Claim 75: Page 7, lines 13-14

Applicant retains the right to pursue the subject matter as originally claimed at a later stage in this application or in future applications. No new matter is added by entry of this preliminary amendment.

The examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Steven L. Highlander/

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Date: April 3, 2014

Electronic Patent Application Fee Transmittal

Application Number:				
Filing Date:				
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS			
First Named Inventor/Applicant Name:	John R. PLACHETKA			
Filer:	Steven Lee Highlander/Richard ortiz			
Attorney Docket Number:	POZN.P0004US.CP1C4			
Filed as Large Entity				
Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				5740

Electronic Acknowledgement Receipt

EFS ID:	18667107
Application Number:	14244471
International Application Number:	
Confirmation Number:	3047
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS
First Named Inventor/Applicant Name:	John R. PLACHETKA
Customer Number:	108197
Filer:	Steven Lee Highlander/Richard ortiz
Filer Authorized By:	Steven Lee Highlander
Attorney Docket Number:	POZN.P0004US.CP1C4
Receipt Date:	03-APR-2014
Filing Date:	
Time Stamp:	16:26:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$5740
RAM confirmation Number	2935
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Information:					
Total Files Size (in bytes):			3667632		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

First Named Inventor:	John R. PLACHETKA	Nonprovisional Application Number (if known):	Filed Concurrently Herewith
Title of Invention:	PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.
3. The applicable box is checked below:

☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Steven L. Highlander/	Date April 3, 2014
Name (Print/Typed) Steven L. Highlander	Practitioner Registration Number 37642
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*	
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.	

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.