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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	11/03/2015	9173942	244168.000007US9	3806

6980 7590 10/14/2015

TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

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):

Helsinn Healthcare S.A., Lugano, SWITZERLAND;
Roche Palo Alto LLC, Palo Alto, CA;
Simone Macciocchi, Melide, SWITZERLAND, Legal Representative;
Giulio Macciocchi, Breganzona, SWITZERLAND, Legal Representative;
Giorgio Calderari, Rancate, SWITZERLAND;
Daniele Bonadeo, Casalzuigno, ITALY;
Roberta Cannella, Varese, ITALY;
Alberto Macciocchi, Melide, SWITZERLAND, Deceased;
Andrew Miksztal, Palo Alto, CA;
Thomas Malefyt, Carmel Valley, CA;
Kathleen M. Lee, Palo Alto, CA;

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Andrew Miksztal, Palo Alto, CA;
Thomas Malefyt, Carmel Valley, CA;
Kathleen M. Lee, Palo Alto, CA;

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor	Giorgio Calderari
				Art Unit	
				Examiner Name	
Sheet	1	of	12	Attorney Docket Number	23278.2.US.9

U.S. PATENTS

Examiner Initials	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,272,137	12-00-1993	Blase et al.	
	2	US-4,695,578	09-22-1987	Coates et al.	
	3	US-4,753,789	06-28-1988	Tyers et al.	
	4	US-4,886,808	12-12-1989	King	
	5	US-4,906,755	03-06-1990	Gittos	
	6	US-4,929,632	05-29-1990	Tyers et al.	
	7	US-4,937,247	06-26-1990	King	
	8	US-5,011,846	04-30-1991	Gittos et al.	
	9	US-5,034,398	07-23-1991	King	
	10	US-5,240,954	08-31-1993	Tyers et al.	
	11	US-5,344,658	09-06-1994	Collin	
	12	US-5,578,628	11-26-1996	Tyers et al.	
	13	US-5,578,632	11-26-1996	Tyers et al.	
	14	US-5,622,720	04-22-1997	Collin	
Change(s) applied to document, /K.S.S./ 9/23/2015	15	US-5,922,749 07/1999	~~07-13-1997~~	Tyers et al.	
	16	US-5,955,488	09-21-1999	Winterborn	
	17	US-6,063,802	05-16-2000	Winterborn	
	18	US-6,294,548	09-25-2001	James	
	19	US-5,854,270	12-29-1998	Gambhir	
	20	US-5,202,333	04-13-1993	Berger et al.	
	21	US-6,287,592	09-11-2001	Dickinson	
	22	US-6,284,749	09-04-2001	Castillo et al.	
	23	US-6,132,758	10-17-2000	Farah J. Munayyer et al. (Schering Corporation)	
	24	US-6,699,852	03-02-2004	Albert Robichaud (Bristol-Myers Squibb Pharma Co.)	
	25	US-7,109,339	09-19-2006	Tackyu Lee et al. (Bristol-Myers Squibb Company)	
	26	US-7,947,724	05-14-2011	Giorgio Calderari, et al.	
	27	US-7,947,725	05-14-2011	Giorgio Calderari et al.	
	28	US-7,960,424	06-14-2011	Giorgio Calderari et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9	3806

6980 7590 09/04/2015

TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

EXAMINER
GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
09/04/2015	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):

jim.schutz@troutmansanders.com
ryan.schneider@troutmansanders.com
patents@troutmansanders.com

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Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
13/901,830	24 May, 2013	CALDERARI ET AL.	244168.000007US9

TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

EXAMINER	
SHIRLEY V. GEMBEH	
ART UNIT	PAPER
1628	20150901

DATE MAILED:

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

Commissioner for Patents

The information disclosure statement (IDS) submitted on 3/27/14 have been received and acknowledged

/SHIRLEY V GEMBEH/
Primary Examiner, Art Unit 1628

PTO-90C (Rev.04-03)

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13901830	CALDERARI ET AL.
	Examiner	**Art Unit**
	SHIRLEY V GEMBEH	1628

CPC						
Symbol					**Type**	**Version**
A61K		47	/	26	F	2013-01-01
A61K		47	/	183	I	2013-01-01
A61K		47	/	12	I	2013-01-01
A61K		47	/	00	I	2013-01-01
A61K		31	/	473	I	2013-01-01
A61K		47	/	02	I	2013-01-01
A61K		9	/	0019	I	2013-01-01
A61K		9	/	0095	I	2013-01-01
B65B		7	/	16	I	2013-01-01
B65B		55	/	02	I	2013-01-01
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CPC Combination Sets							
Symbol				**Type**	**Set**	**Ranking**	**Version**
			/				
			/				

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 19	
/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628	7/27/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13901830	CALDERARI ET AL.
	Examiner	**Art Unit**
	SHIRLEY V GEMBEH	1628

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
514	397	A	0	1	N	43 / 52 (2006.01.01)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628	7/27/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13901830	CALDERARI ET AL.
	Examiner	**Art Unit**
	SHIRLEY V GEMBEH	1628

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	26	17	42												
2	27	18	43												
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12	37														
13	38														
14	39														
15	40														
16	41														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	19	
/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628	7/27/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio CALDERARI
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	1	of	2	Attorney Docket Number	244168.000007.US.9

U.S. PATENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	36	US-8,518,981	08-27-2013	Calderari et al.	
	37	US-8,598,218	12-3-2013	Calderari et al.	
	38	US-8,598,219	12-3-2013	Calderari et al.	

U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials*	Cite No.[3]	Document Number Number-Kind Code[4] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	39	US-2013/0261149	10-03-2013	Calderari et al.	
	40	US-2013/0261150	10-03-2013	Calderari et al.	
	41	US-2013/0289065	10-31-2013	Calderari et al.	
	42	US-2014/0039000	02-06-2014	Calderari et al.	
	43	US-2004/0147510	07-29-2004	Landau et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	343	February 9, 2009 Bonadeo Declaration.	
	546	Perez, et al., Comparable safety and antiemetic efficacy of a brief (30-second bolus) intravenous granisetron infusion and a standard (15-minute) intravenous ondansetron infusion in breast cancer patients receiving moderately emetogenic chemotherapy. Cancer J. Sci. Am. Vol. 4, No 1, pp. 52-8, 1998.	
	748	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, and 7,960,424, dated August 13, 2013.	
	751	Aurobindo Pharma Ltd. Paragraph IV notice regarding U.S. Patent No. 8,518,981, dated September 19, 2013.	
	752	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c), dated July 8, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated).	
	754	Sandoz Inc.'s Second Amended Invalidity Contentions Pursuant to L. Pat. R. 3.7, dated July 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	756	Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s First Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c), dated July 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	758	Opening Expert Report of Dr. Bert Spilker, dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	759	Expert Report of David G. Frame, Pharm.D., dated September 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	760	Expert Report of Lee Kirsch, Ph.D., dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio CALDERARI
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	2	of	2	Attorney Docket Number	244168.000007.US.9

NONPATENT LITERATURE DOCUMENTS			
	761	Expert Report of Patrick P. DeLuca, Ph.D., dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	762	Expert Report of Paul Myrdal, Ph.D., dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	763	Complaint for patent infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, and 8,518,981 dated September 25, 2013 (D. Del. Case No. 13-1612).	
	765	Reply Expert Report of Patrick P. DeLuca, Ph.D., dated November 22, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	766	Reply Expert Report of David G. Frame, Pharm. D., dated November 27, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	767	Reply Expert Report of Jack Geltosky, Ph.D., dated November 22, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	768	Reply Expert Report of Lee Kirsch, Ph.D., dated November 22, 2013 (D.N.J. Case No. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	769	Reply Expert Report of Paul Myrdal, Ph.D., dated November 22, 2013 (D.N.J. Case No. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	770	Reply Expert Report of Dr. Bert Spilker, dated November 22, 2013 (D.N.J. Case No. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	771	Accord Healthcare, Inc. Paragraph IV Letter regarding U.S. Patent No. 8,518,981 dated October 2, 2013 (portions redacted).	
	772	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent No. 8,518,981 dated October 16, 2013 (portions redacted).	
	773	Sandoz Inc. Paragraph IV Letter regarding U.S. Patent No. 8,518,981 dated December 16, 2013.	
	774	Aurobindo Pharma Ltd. Paragraph IV Letter regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated January 21, 2014 (portions redacted).	
	775	Sandoz Inc. Paragraph IV Letter regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated February 3, 2014 (portions redacted).	
	776	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated February 6, 2014 (portions redacted).	
	777	Defendants Aurobindo Pharma Ltd.'s and Auromedics Pharma LLC's Amended Answer, Affirmative Defenses, and Counterclaims regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219, dated February 11, 2014 (D. Del. Case No. 13-688).	
	778	Ben Venue Laboratories, Inc.'s Answer and Counterclaims to Amended Complaint regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219, dated February 24, 2014 (D. Del. Case No. 13-1612).	
	782	Complaint for Patent Infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated December 27, 2013 (D. Del. Case No. 13-2101).	
	783	Cipla Limited Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219 dated February 24, 2014 (portions redacted).	
	784	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Invalidity Contentions regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219 dated March 17, 2014 (D.N.J. Case No. 13-5815) (confidentiality designation and other portions redacted).	
	785	Sandoz Inc.'s Invalidity Contentions Pursuant to L. Pat. R. 3.3 and 3.6(c) regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219 dated March 17, 2014 (D.N.J. Case No. 13-5815) (confidentiality designation and other portions redacted).	
	786	Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.'s Invalidity Contentions Pursuant to L. Pat. R. 3.6(c) regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219 dated March 17, 2014 (D.N.J. Case No. 13-5815) (confidentiality designation and other portions redacted).	

Examiner Signature	/Shirley Gembeh/ (04/09/2014)	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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NOTICE OF ALLOWANCE AND FEE(S) DUE

6980 7590 08/25/2015

TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

EXAMINER
GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 08/25/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9	3806

TITLE OF INVENTION: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

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	11/25/2015

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.

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)

6980 7590 08/25/2015
TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

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.

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.

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9	3806

TITLE OF INVENTION: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

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	11/25/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
GEMBEH, SHIRLEY V	1628	514-397000

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.
1 _____
2 _____
3 _____

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 _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ 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 — 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.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — 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.
- ❑ Applicant changing to regular undiscounted fee 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 signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9	3806

6980 7590 08/25/2015

TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 08/25/2015

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.

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.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/901,830	CALDERARI ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

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

(1) *SHIRLEY V. GEMBEH*. (3)_____.

(2) *Clark Sullivan*. (4)_____.

Date of Interview: *27 July 2015*.

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: *26,28,29,33,37,41 and 42*.

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...)

In order to avoid a 112-2nd issue, Examiner called Applicant's representative Clarke Sullivan to which an agreement was reached and a supplemental claim set was filed.,, .

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

/SHIRLEY V GEMBEH/ Primary Examiner, Art Unit 1628	

Notice of Allowability	Application No. 13/901,830	Applicant(s) CALDERARI ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1628	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 *7/28/15*.
   ☐ 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 *26-44 now renumbered 1-19*. 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/patents/init_events/pph/index.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. ☒ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 3/5/15; 7/28/15
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *7/27/15* .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/SHIRLEY V GEMBEH/
Primary Examiner, Art Unit 1628

DETAILED ACTION

Status of claims

1. Claims 26-44 are under examination.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Clarke Sullivan on 7/28/15. A supplemental set of claims are filed with the deletion of the term "about" from the claims

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 7/28/15 and 3/5/15 has being considered by the examiner.

Allowable Subject Matter

4. The following is an examiner's statement of reasons for allowance: The closest prior art are already made of record. Additionally the reference Tang (Anesth Analg 1998; 87 462-467; Ref. 105 submitted on May 24, 2013) specifically teach that implications in administering palonosetron (i.e., RS-25259) was effective only at a

higher dose (i.e., 30 µg/kg which is 2.1 mg when an average weight 70 kg of the patient is considered). This dose is far greater than that recited by the applicant. Yes Tang teaches a concentration of 3.0 µg/kg which is the closest to the dose recited, however Tang also teaches that it fails to provide or reduce the post-operative vomiting.

Also as carefully argued by Applicant these applications have been examined and interviewed on many occasions and the arguments have been found persuasive.

5. 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.”

6. Claims 26-44 are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, WU-CHENG SHEN can be reached on 571-272-3157. 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.

/SHIRLEY V GEMBEH/
Primary Examiner, Art Unit 1628
7/27/15

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/901,830	CALDERARI ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

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

(1) *SHIRLEY V. GEMBEH*. (3)_____.

(2) *Clark Sullivan*. (4)_____.

Date of Interview: *27 July 2015*.

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: *26,28,29,33,37,41 and 42*.

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...)

In order to avoid a 112-2nd issue, Examiner called Applicant's representative Clarke Sullivan to which an agreement was reached and a supplemental claim set was filed.,, .

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

/SHIRLEY V GEMBEH/ Primary Examiner, Art Unit 1628	

Notice of References Cited	Application/Control No. 13/901,830	Applicant(s)/Patent Under Reexamination CALDERARI ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1628	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A	US-				
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Tang et al., (Anesth Analg 1998; 87 462-467; Ref. 105
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	0	("(nitricoxide)ans(sulindac)").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2007/11/01 15:09
S2	233015	(nitricoxide)ans(sulindac)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 15:10
S3	233366	(nitric-oxide)ans(sulindac)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 15:10
S4	21	(nitric-oxide)and(sulindac)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 15:38
S5	23	"9509831"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 15:40
S6	3	"7199141"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 16:23
S7	65	"6297260"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 16:47
S8	14	"6593347"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 16:48
S9	9	"9727749"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2007/11/01 16:48
S10	23	"6861422"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/22 19:47
S11	8	"7507531"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 14:14
S12	2	"20050282855"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 14:23
S13	2	"20060019269"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 14:26
S14	1	"7759347"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 17:51
S15	11	"7371753"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 17:57
S16	16	"7332491"	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	2010/07/23 18:18

			DERWENT			
S17	15	"7414053"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 18:19
S18	4	"7521457"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 18:20
S19	7	"4851435"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 19:40
S20	19	"5594153"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 19:48
S21	3	"9614841"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 19:52
S22	9	"5817364"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/23 21:45
S23	7	"4851435"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/26 10:50
S24	3	"9614841"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/26 10:51
S25	19	"5594153"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2010/07/26 10:53
S26	1	"13901830"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2015/07/27 13:05

7/ 27/ 2015 3:08:58 PM
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BIB DATA SHEET

CONFIRMATION NO. 3806

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/901,830	05/24/2013	514	1628	244168.000007US9

APPLICANTS

Helsinn Healthcare S.A., Lugano, SWITZERLAND;
Roche Palo Alto LLC, Palo Alto, CA;
Simone Macciocchi, Melide, SWITZERLAND, Legal Representative;
Giulio Macciocchi, Breganzona, SWITZERLAND, Legal Representative;

INVENTORS

Giorgio Calderari, Rancate, SWITZERLAND;
Daniele Bonadeo, Casalzuigno, ITALY;
Roberta Cannella, Varese, ITALY;
Alberto Macciocchi, Melide, SWITZERLAND, Deceased;
Andrew Miksztal, Palo Alto, CA;
Thomas Malefyt, Carmel Valley, CA;
Kathleen M. Lee, Palo Alto, CA;

**** CONTINUING DATA ***************************

This application is a CON of 13/901,437 05/23/2013 PAT 8598219
which is a CIP of 13/087,012 04/14/2011 PAT 8518981
which is a CON of 11/186,311 07/21/2005 PAT 7947724
which is a CON of PCT/EP2004/000888 01/30/2004
which claims benefit of 60/444,351 01/30/2003

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

06/17/2013

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No		SWITZERLAND	0	9	2
Verified and Acknowledged	/SHIRLEY V GEMBEH/ Examiner's Signature	Initials				

ADDRESS

TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308
UNITED STATES

TITLE

LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

FILING FEE RECEIVED	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue)

BIB (Rev. 05/07).

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13901830	CALDERARI ET AL.
	Examiner	**Art Unit**
	SHIRLEY V GEMBEH	1628

CPC						
Symbol					**Type**	**Version**
A61K		47	/	26	F	2013-01-01
A61K		47	/	183	I	2013-01-01
A61K		47	/	12	I	2013-01-01
A61K		47	/	00	I	2013-01-01
A61K		31	/	473	I	2013-01-01
A61K		47	/	02	I	2013-01-01
A61K		9	/	0019	I	2013-01-01
A61K		9	/	0095	I	2013-01-01
B65B		7	/	16	I	2013-01-01
B65B		55	/	02	I	2013-01-01
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CPC Combination Sets							
Symbol				**Type**	**Set**	**Ranking**	**Version**
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NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 19	
/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628	7/27/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

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US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
514	397	A	0	1	N	43 / 52 (2006.01.01)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628	7/27/15	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

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	Examiner	**Art Unit**
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	26	17	42												
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16	41														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 19	
/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628 (Primary Examiner)	7/27/15 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13901830	CALDERARI ET AL.
	Examiner	Art Unit
	SHIRLEY V GEMBEH	1628

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
514	397	7/27/15	SVG

SEARCH NOTES		
Search Notes	Date	Examiner
Updated Search in East (OCR,USPGPUB, USPAT, DERWENT and Inventors Name search)	7/27/15	SVG
See prosecution history in eDAN	7/27/15	SVG
interview summary		

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
514	397	7/27/15	SVG

	/SHIRLEY V GEMBEH/ Primary Examiner.Art Unit 1628

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	1	of	2	Attorney Docket Number	244168.000007US9

U.S. PATENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	45	US-9,066,980	06-30-2015	Calderari et al.	

U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials*	Cite No.[3]	Document Number Number-Kind Code[4] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	46	US 2015/0141454	05-21-2015	Calderari et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	461	Amendment and Response, USSN 13/902,132, dated October 9, 2013 (Exhibit 1039 of IPR2015-01550, -01151, -01553, -01554).	
	462	Amendment After Final, USSN 13/902,132, dated February 21, 2014 (Exhibit 1009 of IPR2015-01550, -01151, -01553, -01554).	
	463	USPTO Non-Final Office Action, USSN 14/597,489, mailed February 26, 2015.	
	464	USPTO Final Office Action, USSN 14/070,981, mailed June 16, 2015.	
	957	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Second Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c) dated March 12, 2015 (D.N.J. 11-3962, consolidated).	
	958	Opening Expert Report of Edward P. Gelmann, M.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (confidentiality designation and other portions redacted).	
	959	Opening Expert Report of James E. Kipp, Ph.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (redacted).	
	960	Opening Expert Report of Max Talbott, Ph.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (confidentiality designation and other portions redacted).	
	961	Affirmative Expert Report of Elizabeth M. Topp, Ph.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (confidentiality designation and other portions redacted).	
	962	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01550).	
	963	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01551).	
	964	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01553).	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	2	of	2	Attorney Docket Number	244168.000007US9

NONPATENT LITERATURE DOCUMENTS			
	965	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01554).	
	966	Exhibit 1021 to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petitions for Inter Partes Review of U.S. Patent No. 8,729,094, Declaration of William P. McGuire, Ph.D., dated July 2, 2015 (IPR2015-01550, -01151, -01553, -01554).	
	967	Exhibit 1023 to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petitions for Inter Partes Review of U.S. Patent No. 8,729,094, Declaration of David G. Frame, Pharm.D., dated July 1, 2015 (IPR2015-01550, -01151, -01553, -01554).	
	968	Exhibit 1040 to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petitions for Inter Partes Review of U.S. Patent No. 8,729,094, Declaration of Dr. Patrick P. DeLuca dated July 1, 2015 (IPR2015-01550, -01151, -01553, -01554).	
	969	R. J. Gralla, et al., "Recommendations for the Use of Antiemetics: Evidence-Based, Clinical Practice Guidelines," *J. Clin. Oncol.* 17(9):2971-94 (1999) (Exhibit 1013 of IPR2015-01550, -01151, -01553, -01554).	
	970	L. P. Cohen, "Many Medicines Prove Potent for Years Past Their Expiration Dates," *Wall St. J.*, March 28, 2000 (Exhibit 1020 of IPR2015-01550, -01151, -01553, -01554).	
	971	D. R. Gandara, et al., "Consensus Proposal for 5HT3 Antagonists in the Prevention of Acute Emesis Related to Highly Emetogenic Chemotherapy: Dose, Schedule, and Route of Administration," *Support Care Cancer* 6:237-243 (1998) (Exhibit 1027 of IPR2015-01550, -01151, -01553, -01554).	
	972	U.S. Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, "Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers," Draft Guidance, December 2002 (Exhibit 1031 of IPR2015-01550, -01151, -01553, -01554).	
	973	"Helsinn & MGI Pharma Announce Completion of Pivotal Phase 3 Trials of Palonosetron," 2002 (Exhibit 1033 of IPR2015-01550, -01151, -01553, -01554).	
	974	"Helsinn Healthcare Announce the Completion of Patient Enrollment for First Palonosetron Phase 3 Pivotal Trial," 2001 (Exhibit 1034 of IPR2015-01550, -01151, -01553, -01554).	
	975	"MGI Pharma Sign Exclusive License Agreement with Helsinn Healthcare SA, for Palonosetron, a Phase 3 Anti-emetic," 2001 (Exhibit 1035 of IPR2015-01550, -01151, -01553, -01554).	
	976	G. W. Brown, et al., "The Effectiveness of a Single Intravenous Dose of Ondansetron," *Oncology* 49:273-278 (1992) (Exhibit 1044 of IPR2015-01550, -01151, -01553, -01554).	
	977	Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd., Claim Construction Order, dated February 19, 2015 (D.N.J. 12-2867) (Exhibit 1045 of IPR2015-01550, -01151, -01553, -01554).	
	978	K. Mikawa, et al., "Optimal Dose of Granisetron for Prophylaxis Against Postoperative Emesis after Gynecological Surgery," *Anesth Analg* 85:652-6 (1997) (Exhibit 1049 of IPR2015-01550, -01151, -01553, -01554).	
	979	Pharmaceutical Dosage Forms: Parenteral Medications, Vol. 1, pp. 17-25, 115-6, 140-43, 150-51, 173-5, 190-203, 207-12 (Avis, Lieberman, Lachman eds., Marcel Dekker Inc. 2d ed. 1992) (Exhibit 1050 of IPR2015-01550, -01151, -01553, -01554).	
	980	Exhibit 1053 to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petitions for Inter Partes Review of U.S. Patent No. 8,729,094, Dose response curves for Chelly 1996 Exh. 1012 and Tang 1998 Exh. 1019.	
	981	Kytril amended label, August 16, 2002 (Exhibit 1054 of IPR2015-01550, -01151, -01553, -01554).	

Examiner Signature	/Shirley Gembeh/ (07/29/2015)	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

PTO Notes regarding this form:

[1] Applicant's unique citation designation number (optional).
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[7] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[8] Applicant is to place a check mark here if English language Translation is attached.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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				Application Number	13/901,830
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				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	1	of	5	Attorney Docket Number	244168.000007.US.9

U.S. PATENTS

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	44	US-8,729,094	05-20-2014	Calderari et al.	

U.S. PUBLISHED PATENT APPLICATIONS

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	338	USPTO Notice of Allowance and Fees Due, USSN 13/087,012, mailed July 3, 2013.	
	339	USPTO Non-Final Office Action and Examiner-Initiated Interview Summary, USSN 13/901,437, mailed July 29, 2013.	
	340	USPTO Non-Final Office Action, USSN 13/902,132, mailed August 8, 2013.	
	341	USPTO Interview Summary, USSN 13/087,012 dated June 13, 2013.	
	342	USPTO Notice of Allowance and Fees Due and Examiner-Initiated Interview Summary, USSN 13/901,288, mailed September 6, 2013.	
	344	CDER Approval Package for NDA 21-372, Clinical Pharmacology and Biopharmaceutics Review (2002).	
	454	USPTO Non-Final Office Action and Applicant-Initiated Interview Summary, USSN 13/900,174, mailed November 19, 2013.	
	455	USPTO Non-Final Office Action, USSN 14/184,305, mailed May 29, 2014.	
	456	USPTO Applicant-Initiated Interview Summary, USSN 14/184,305, dated July 18, 2014.	
	457	USPTO Non-Final Office Action, USSN 13/902,299, mailed December 5, 2013.	
	458	USPTO Final Office Action, USSN 13/902,132, mailed December 6, 2013.	
	459	USPTO Non-Final Office Action, USSN 14/052,925, dated December 4, 2013.	
	460	USPTO Non-Final Office Action, USSN 14/070,981, mailed November 4, 2014.	
	749	Defendants Aurobindo Pharma Ltd.'s and Aurobindo Pharma USA Inc.'s Answer, Affirmative Defenses, and Counterclaims, dated August 23, 2013 (D. Del. Case No. 13-688).	

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				Examiner Name	Shirley V. GEMBEH
Sheet	2	of	5	Attorney Docket Number	244168.000007.US.9

NONPATENT LITERATURE DOCUMENTS			
	750	Plaintiff's Answer to the Counterclaims of Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd., dated September 13, 2013 (D. Del. Case No. 13-688).	
	753	Plaintiffs' Responses to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.'s Amended Invalidity Contentions, dated August 19, 2013 (D. N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	755	Plaintiffs' Responses to Sandoz Inc.'s Second Amended Invalidity Contentions, dated August 19, 2013 (D. N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	757	Plaintiffs' Responses to Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s First Amended Invalidity Contentions, dated August 19, 2013 (D. N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	764	Complaint for patent infringement filed by Helsinn Healthcare SA and Roche Palo Alto LLC against Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Sandoz Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. regarding U.S. Patent No. 8,518,981 dated September 30, 2013 (D.N.J. Case No. (13-5815)).	
	779	Answer and Counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to Amended Complaint for Patent Infringement regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated February 3, 2014 (D.N.J. Case No. 13-5815).	
	780	Sandoz Inc.'s Answer, Affirmative Defenses, and Counterclaims to Amended Complaint regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated February 3, 2014 (D.N.J. Case No. 13-5815).	
	781	Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.'s Answer to Amended Complaint for Patent Infringement regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated February 3, 2014 (D.N.J. Case No. 13-5815).	
	787	Teva Pharmaceuticals USA, Inc Paragraph IV Letter regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated April 29, 2014 (portions redacted).	
	788	Mylan Institutional LLC Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219, dated May 16, 2014 (portions redacted).	
	789	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated May 29, 2014 (portions redacted).	
	790	Defendants' Opening Claim Construction Brief regarding U.S. Patent No. 8,598,219, dated June 19, 2014 (D.N.J. 11-3962, consolidated).	
	791	Answer, Affirmative Defenses and Counterclaims of Defendants Cipla Ltd. and Cipla USA, Inc. regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218 and 8,598,219 dated April 29, 2014 (D. Del. Case No. 14-427).	
	792	Complaint for Patent Infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Mylan Inc. and Mylan Institutional LLC regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,598,219, and 8,729,094, dated June 4, 2014 (D. Del. Case No. 14-709).	
	793	G. Steele, Preformulation predictions from small amounts of compound as an aid to candidate drug selection, in Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form, Ch. 3, pp. 21-95 (Gibson ed., CRC Press 1st ed. 2001).	
	794	G. Steele, Preformulation as an aid to product design in early drug development, in Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form, Ch. 6, pp. 175-237 (Gibson ed., CRC Press 1st ed. 2001).	
	795	M. Gibson, Product optimisation, in Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form, Ch. 8, pp. 295-329 (Gibson ed., CRC Press 1st ed. 2001).	
	796	Mylan Institutional LLC Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated June 27, 2014 (portions redacted).	
	797	Ben Venue Laboratories, Inc.'s Opening Claim Construction Brief, dated April 17, 2014 (D. Del. Case No. 13-688, consolidated).	
	798	Ben Venue Laboratories, Inc.'s Answering Claim Construction Brief, dated July 8, 2014 (D. Del. Case No. 13-688, consolidated).	
	799	Answer, Defenses and Counterclaims of Mylan Institutional LLC regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,598,219, and 8,729,094, dated June 26, 2014 (D. Del. Case No. 14-709).	
	900	Aurobindo Pharma Ltd. Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated July 25, 2014 (portions redacted).	
	901	Defendants' Responsive Claim Construction Brief regarding U.S. Patent No. 8,598,219, dated July 17, 2014 (D.N.J. 11-3962, consolidated).	

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NONPATENT LITERATURE DOCUMENTS			
	902	Cipla Ltd. Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated August 6, 2014 (portions redacted).	
	903	Teva Pharmaceuticals USA, Inc Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated August 29, 2014.	
	904	Expert Report of Patrick P. DeLuca, Ph.D. with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated).	
	905	Expert Report of David G. Frame, Pharm.D. with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation redacted).	
	906	Opening Expert Report of John P. Fruehauf, M.D., Ph.D. for U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	907	Opening Expert Report of Lee Kirsch, Ph.D. for U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	908	Expert Report of Maurie Markman, M.D. with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	909	Opening Expert Report of Paul Myrdal, Ph.D. for U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	910	Second Opening Expert Report of Dr. Bert Spilker with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	911	K. A. Connors, Introduction to Chemical Kinetics, Chemical Kinetics The Study of Reaction Rates in Solution, John Wiley & Sons, Inc., 1990, Ch. 1, pp. 1-15.	
	912	R. G. Strickley, Parenteral formulations of small molecule therapeutics marketed in the United States (1999)—Part I. *PDA J. Pharm. Sci. Technol.* 53:324-349 (1999).	
	913	Physicians' Desk Reference, entries for Hespan® (pp. 933-35) and Hyperstat® I.V. Diazoxide Injection (pp. 2848-49) (53rd ed. 1999).	
	914	Physicians' Desk Reference for Astromorph/PF® (pp. 594-95); Baxter's Atrophine Sulfate Injection (p. 858); Baxter's Dobutamine Hydrochloride Injection (p. 861); Duramorph® (p. 863); Baxter's Fentanyl Citrate Injection (p. 868); Baxter's Metoclopramide Injection (p. 871); Baxter's Phenylephrine Hydrochloride Injection (pp. 872-73); Robinul® (p. 873; 2940-42); Phenytoin Sodium Injection (p. 1312); and Diflucan® (pp. 2681-85) (56th ed. 2002).	
	915	The United States Pharmacopeia (USP 26) The National Formulary (NF 21), Official from January 1, 2003, entries for Atrophine Sulfate Injection (p. 192); Diazoxide Injection (p. 591); Dobutamine Hydrochloride Injection (p. 652); Fentanyl Citrate Injection (p. 781); Glycopyrrolate Injection (p. 870); Lidocaine Hydrochloride and Dextrose Injection (pp. 1079-80); Metoclopramide Injection (pp. 1217-18); Morphine Sulfate Injection (pp. 1254-55); Phenylephrine Hydrochloride Injection (pp. 1459-60); Phenytoin Sodium Injection (pp. 1471-72); Potassium Chloride for Injection (pp. 1503-04) (2002).	
	916	HELSN0004208 (2002) (redacted).	
	917	Full Prescribing Information for Aloxi (palonosetron HCl) Injection for Intravenous Use (2014).	
	918	Preformulation Book, Syntex Research, pp. C1-7, C1-19, and C1-26 (1993) (redacted).	
	919	Accord Healthcare, Inc.'s Petition for Post Grant Review of U.S. Patent No. 8,598,219 dated September 2, 2014.	
	920	Exhibit 1015 to Accord Healthcare, Inc.'s Petition for Post Grant Review of U.S. Patent No. 8,598,219, Declaration of Arnold J. Repta, Ph.D. dated September 2, 2014.	
	921	Rebuttal Expert Report of Gordon L. Amidon, Ph.D. concerning U.S. Patent No. 8,598,219, dated September 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	922	Rebuttal Expert Report of Keith A. Candiotti, M.D. with respect to U.S. Patent No. 8,598,219, dated September 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	923	Second Rebuttal Expert Report of Carl C. Peck, M.D. dated September 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	924	Rebuttal Expert Report of Tanios Bekaii-Saab, M.D. with respect to U.S. Patent No. 8,598,219, dated September 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	925	Answer and Counterclaims of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to Complaint for Patent Infringement regarding U.S. Patent No. U.S. Patent No. 8,729,094 dated September 5, 2014 (D.N.J. Case No. 14-4274).	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	4	of	5	Attorney Docket Number	244168.000007.US.9

NONPATENT LITERATURE DOCUMENTS			
	926	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated September 19, 2014 (portions redacted).	
	927	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated September 24, 2014 (portions redacted).	
	928	R. M. Eglen and D. W. Bonhaus, "5-Hydroxytryptamine (5-HT)$_3$ Receptors: Molecular Biology, Pharmacology and Therapeutic Importance," Curr Pharm Des. 2:367-74 (1996).	
	929	"Helsinn Announces That Patient Enrollment For Phase III Palonosetron Trials Progresses Both in USA and Europe," PR Newswire, September 14, 2000.	
	930	G. Piraccini, et al., "A Novel Anti-Emetic Agent, Palonosetron (RS 25259-197): Evidence From Phase I Trials," Support Care Cancer, June 2001, Vol. 9, No. 4, Abstract no. P-41 and associated poster presentation.	
	931	RS-25259-197, Drugs Fut. 1996, 21(9):906-910 (1996).	
	932	Palonosetron Hydrochloride RS-25259-197, Drugs Fut. 2000, 25(9):982 (Sept 2000).	
	933	Palonosetron Hydrochloride, Drugs Fut. 2001, 26(9):911 (Sept 2001).	
	934	R. E. Leak and J. D. Woodford, "Pharmaceutical Development of Ondansetron Injection," Eur J Cancer Clin Oncol. 25(Suppl 1):S67-69 (1989).	
	935	Reply Expert Report of David G. Frame, Pharm. D. with respect to U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designations redacted).	
	936	Reply Expert Report of Maurie Markman, M.D. with respect to U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designations redacted).	
	937	Reply Expert Report of John P. Fruehauf, M.D., Ph.D. for U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation redacted).	
	938	Reply Expert Report of Lee Kirsch, Ph.D. for U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation redacted).	
	939	Reply Expert Report of Paul Myrdal, Ph.D. for U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation redacted).	
	940	Second Reply Expert Report of Dr. Bert Spilker regarding U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designations redacted).	
	941	Exela Pharma Sciences LLC's Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated October 16, 2014 (portions redacted).	
	942	Final Joint Claim Construction Chart regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,598,219, and 8,729,094 dated October 24, 2014 (D. Del. Case Nos. 13-688 and 14-709).	
	943	Mylan Institutional LLC's Opening Claim Construction Brief dated December 5, 2014 (D. Del. Case No. 13-688, consolidated).	
	944	Defendants Cipla Ltd. And Cipla USA, Inc.'s Corrected Opening Claim Construction Brief dated January 27, 2015 (D. Del. Case No. 13-688, consolidated).	
	945	Plaintiffs' Opening Claim Construction Brief dated December 5, 2014 (D. Del. Case No. 13-688, consolidated).	
	946	Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. Corrected Answer to Complaint for Patent Infringement and Counterclaim for Declaratory Judgment regarding U.S. Patent No. 8,729,094 dated January 8, 2015 (D.N.J. Case No. 14-6341).	
	947	Termination of the Proceeding (Case No. PGR2014-00010) dated November 24, 2014.	
	948	Declaration of Dr. Neervalur Raghavan, Ph.D. with Exhibits 1-25, dated September 28, 2014.	
	949	Gavis Pharma LLC's Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated December 31, 2014 (portions redacted).	
	950	Answer, Defenses, and Counterclaims of Defendants Exela Pharma Sciences, LLC, Exela Pharmsci, Inc. and Exela Holdings, Inc. to Complaint regarding U.S. Patent Nos. 8,518,981 and 8,598,218 redacted version dated December 29, 2014 (D. Del. Case No. 14-1444).	
	951	Defendant Mylan Institutional, LLC's Responsive Claim Construction Brief dated January 14, 2015 (D. Del. Case No. 13-688, consolidated).	
	952	Defendants Cipla Ltd. and Cipla USA, Inc.'s Corrected Answering Claim Construction Brief dated January 27, 2015 (D. Del. Case No. 13-688, consolidated).	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	5	of	5	*Attorney Docket Number*	244168.000007.US.9

NONPATENT LITERATURE DOCUMENTS			
	953	Plaintiffs' Responsive Claim Construction Brief, redacted public version dated January 20, 2015 (D. Del. Case No. 13-688, consolidated).	
	954	On Sale and Public Use Bars to Patentability After AIA: Minimizing the Risk of Patent Ineligibility or Invalidation, Cover and Slide 74, November 7, 2013.	
	955	Hospira Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated February 10, 2015 (portions redacted).	
	956	Par Pharmaceutical, Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated February 10, 2015 (portions redacted).	

Examiner Signature	/Shirley Gembeh/ (07/27/2015)	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

PTO Notes regarding this form:

[1] Applicant's unique citation designation number (optional).
[2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3] Applicant's unique citation designation number (optional).
[4] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
[5] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).
[6] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[7] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.
[8] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR 1.14. This collection is estimated to take 2 hours 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**.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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)

6986 7590 08/25/2015
TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

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.

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.

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9	3806

TITLE OF INVENTION: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

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	11/25/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
GEMBEH, SHIRLEY V	1628	514-397000

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.

1 TROUTMAN SANDERS LLP
2
3

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)
HELSINN HEALTHCARE SA	PAMBIO-NORANCO, SWITZERLAND
ROCHE PALO ALTO LLC	PALO ALTO, CALIFORNIA

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)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 20-1507 (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
  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.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
  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.
- ☐ Applicant changing to regular undiscounted fee 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 signature requirements and certifications.

Authorized Signature /Kenneth Ma 63,839/ Date AUGUST 25, 2015
Typed or printed name KENNETH MA Registration No. 63,839

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Kenneth B. Ma/Dwight Peck
Attorney Docket Number:	244168.000007US9

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	23305380
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	6980
Filer:	Kenneth B. Ma/Dwight Peck
Filer Authorized By:	Kenneth B. Ma
Attorney Docket Number:	244168.000007US9
Receipt Date:	25-AUG-2015
Filing Date:	24-MAY-2013
Time Stamp:	15:06:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	1271
Deposit Account	201507
Authorized User	MA, KENNETH
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	FEE_US9.pdf	378355 ae3319785ee194f0b93db2cc4363239312d8cb15	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30862 c086645b4ce5bda77be2abaafd772fda749c5652	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	409217		

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.

ATTORNEY DOCKET NO. 244168.000007US9
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	
	)	Examiner: Shirley V. GEMBEH
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

SUPPLEMENTAL AMENDMENT

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

TROUTMAN SANDERS
Customer Number 06980

Dear Sir:

Further to the Supplemental Amendment and Response to Office Action entered in this application, and the call between the undersigned and the Examiner on July 27, 2015, please enter the following amendments and consider the following remarks.

A REPLACEMENT CLAIM SET begins on page 2.

REMARKS begin on page 4.

REPLACEMENT CLAIM SET

1-25. (Canceled)

26. (Currently Amended) A formulation comprising a pharmaceutical sterile aqueous intravenous solution, wherein said pharmaceutical sterile aqueous intravenous solution comprises:

palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron at a concentration of 0.05 mg/mL based on the weight of the palonosetron free base; and

from ~~about~~ 10 mg/mL to ~~about~~ 80 mg/mL mannitol;

wherein the pharmaceutical sterile aqueous intravenous solution has a pH of 4.0 to 6.0.

27. (Previously Presented) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron is in an amount of 0.25 mg.

28. (Currently Amended) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises from ~~about~~ 20 mg/mL to ~~about~~ 60 mg/mL mannitol.

29. (Currently Amended) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises from ~~about~~ 40 mg/mL to ~~about~~ 45 mg/mL mannitol.

30. (Previously Presented) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises 41.5 mg/mL mannitol.

31. (Previously Presented) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises a chelating agent.

32. (Previously Presented) The formulation of claim 31, wherein said chelating agent is EDTA.

33. (Currently Amended) The formulation of claim 32, wherein said pharmaceutical sterile aqueous intravenous solution comprises from ~~about~~ 0.3 mg/mL to ~~about~~ 0.7 mg/mL EDTA.

34. (Previously Presented) The formulation of claim 32, wherein said pharmaceutical sterile aqueous intravenous solution comprises 0.5 mg/mL EDTA.

35. (Previously Presented) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution has a pH of 5.0 ± 0.5.

36. (Previously Presented) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises a citrate buffer.

37. (Currently Amended) A formulation comprising a pharmaceutical sterile aqueous intravenous solution, wherein said pharmaceutical sterile aqueous intravenous solution comprises:

palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron at a concentration of 0.05 mg/mL based on the weight of the palonosetron free base;

from ~~about~~ 10 mg/mL to ~~about~~ 80 mg/mL mannitol; and

from ~~about~~ 0.3 mg/mL to ~~about~~ 0.7 mg/mL EDTA.

38. (Previously Presented) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron is in an amount of 0.25 mg.

39. (Previously Presented) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution has a pH of 4.0 to 6.0.

40. (Previously Presented) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution has a pH of 5.0 ± 0.5.

41. (Currently Amended) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises from ~~about~~ 20 mg/mL to ~~about~~ 60 mg/mL mannitol.

42. (Currently Amended) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises from ~~about~~ 40 mg/mL to ~~about~~ 45 mg/mL mannitol.

43. (Previously Presented) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises 41.5 mg/mL mannitol and 0.5 mg/mL EDTA.

44. (Previously Presented) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises a citrate buffer.

REMARKS

Status of Claims

Upon entry of this Supplemental Amendment, claims 26-44 will be pending in this application. Claims 26, 28, 29, 33, 37, 41 and 42 are amended to remove the term "about," as requested by the Examiner. No new matter is added by this amendment.

CONCLUSION

Should the Examiner have any questions regarding this submission, the Applicants invite her to call the undersigned at 212.704.6105.

Respectfully submitted,

/Clark G. Sullivan/

Clark G. Sullivan
Reg. No. 36,942

Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
212-704-6105

July 28, 2015

Customer No. 06980

Attorney Docket No.:
244168.000007US9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	Examiner: Shirley V. GEMBEH
	)	
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

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

Commissioner:

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents on the attached listing. This Third Supplemental Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. §1.97(c), this Third Supplemental Information Disclosure Statement is accompanied by a fee of $180.00 as specified by Section 1.17(p).

Copies of the listed nonpatent literature documents corresponding to Cite Nos. 461-464 and 957-981 are enclosed. In addition, copies of the listed U.S. patent (Cite No. 45) and listed U.S. published patent application (Cite No. 45) are not enclosed.

Some of the documents listed come from related pending litigations. Some of those documents have been redacted. Assignee, Helsinn Healthcare SA, has confirmed that the documents listed may be placed in the public record without violating any confidentiality

agreement, protective order, or court order, and has given permission to place in the public record any and all documents submitted herewith.

Certain confidential information has been redacted from some of those documents. Applicant hereby acknowledges that at least some of the redacted information includes non-zero U.S. dollar amounts. If the Examiner believes that any of the redacted information is necessary for purposes of examination, would like further information regarding the general nature of the redacted information, or would like to see any of the exhibits, documents, testimony, or references cited in the documents listed, please let the undersigned know immediately.

Furthermore, some exhibits to the Petitions for Inter Partes Review corresponding to Cite Nos. 962-965 include excerpts from voluminous trial transcripts of pending litigation involving related patents. The Examiner is invited to contact Applicant if she would like to see publicly-available copies of those transcripts.

There are no documents numbered 1-44, 47-460, or 465-956 associated with this Information Disclosure Statement.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this statement, please charge the fee to Deposit Account No. 201507.

Respectfully submitted,

/Clark G. Sullivan/

Clark G. Sullivan
Reg. No. 36,942

Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
Customer No.: 06980
Attorney Docket No. 244168.000007.US.9

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	1	of	2	Attorney Docket Number	244168.000007US9

U.S. PATENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	45	US-9,066,980	06-30-2015	Calderari et al.	

U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials*	Cite No.[3]	Document Number Number-Kind Code[4] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	46	US 2015/0141454	05-21-2015	Calderari et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	461	Amendment and Response, USSN 13/902,132, dated October 9, 2013 (Exhibit 1039 of IPR2015-01550, -01151, -01553, -01554).	
	462	Amendment After Final, USSN 13/902,132, dated February 21, 2014 (Exhibit 1009 of IPR2015-01550, -01151, -01553, -01554).	
	463	USPTO Non-Final Office Action, USSN 14/597,489, mailed February 26, 2015.	
	464	USPTO Final Office Action, USSN 14/070,981, mailed June 16, 2015.	
	957	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Second Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c) dated March 12, 2015 (D.N.J. 11-3962, consolidated).	
	958	Opening Expert Report of Edward P. Gelmann, M.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (confidentiality designation and other portions redacted).	
	959	Opening Expert Report of James E. Kipp, Ph.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (redacted).	
	960	Opening Expert Report of Max Talbott, Ph.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (confidentiality designation and other portions redacted).	
	961	Affirmative Expert Report of Elizabeth M. Topp, Ph.D., dated June 24, 2015 (D. Del. 13-688, consolidated) (confidentiality designation and other portions redacted).	
	962	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01550).	
	963	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01551).	
	964	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01553).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	2	of	2	Attorney Docket Number	244168.000007US9

NONPATENT LITERATURE DOCUMENTS			
	965	Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petition for Inter Partes Review of U.S. Patent No. 8,729,094 dated July 3, 2015 (IPR2015-01554).	
	966	Exhibit 1021 to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. Petitions for Inter Partes Review of U.S. Patent No. 8,729,094, Declaration of William P. McGuire, Ph.D., dated July 2, 2015 (IPR2015-01550, -01151, -01553, -01554).	
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	969	R. J. Gralla, et al., "Recommendations for the Use of Antiemetics: Evidence-Based, Clinical Practice Guidelines," *J. Clin. Oncol.* 17(9):2971-94 (1999) (Exhibit 1013 of IPR2015-01550, -01151, -01553, -01554).	
	970	L. P. Cohen, "Many Medicines Prove Potent for Years Past Their Expiration Dates," *Wall St. J.*, March 28, 2000 (Exhibit 1020 of IPR2015-01550, -01151, -01553, -01554).	
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	972	U.S. Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, "Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers," Draft Guidance, December 2002 (Exhibit 1031 of IPR2015-01550, -01151, -01553, -01554).	
	973	"Helsinn & MGI Pharma Announce Completion of Pivotal Phase 3 Trials of Palonosetron," 2002 (Exhibit 1033 of IPR2015-01550, -01151, -01553, -01554).	
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	975	"MGI Pharma Sign Exclusive License Agreement with Helsinn Healthcare SA, for Palonosetron, a Phase 3 Anti-emetic," 2001 (Exhibit 1035 of IPR2015-01550, -01151, -01553, -01554).	
	976	G. W. Brown, et al., "The Effectiveness of a Single Intravenous Dose of Ondansetron," *Oncology* 49:273-278 (1992) (Exhibit 1044 of IPR2015-01550, -01151, -01553, -01554).	
	977	Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Ltd., Claim Construction Order, dated February 19, 2015 (D.N.J. 12-2867) (Exhibit 1045 of IPR2015-01550, -01151, -01553, -01554).	
	978	K. Mikawa, et al., "Optimal Dose of Granisetron for Prophylaxis Against Postoperative Emesis after Gynecological Surgery," *Anesth Analg* 85:652-6 (1997) (Exhibit 1049 of IPR2015-01550, -01151, -01553, -01554).	
	979	Pharmaceutical Dosage Forms: Parenteral Medications, Vol. 1, pp. 17-25, 115-6, 140-43, 150-51, 173-5, 190-203, 207-12 (Avis, Lieberman, Lachman eds., Marcel Dekker Inc. 2d ed. 1992) (Exhibit 1050 of IPR2015-01550, -01151, -01553, -01554).	
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	981	Kytril amended label, August 16, 2002 (Exhibit 1054 of IPR2015-01550, -01151, -01553, -01554).	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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This collection of information is required by 37 CFR 1.97 and 1.98. 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 CFR 1.14. This collection is estimated to take 2 hours 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**.

Electronic Patent Application Fee Transmittal

Application Number:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Dwight Peck
Attorney Docket Number:	244168.000007US9

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	23046058
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	6980
Filer:	Clark G. Sullivan/Dwight Peck
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	244168.000007US9
Receipt Date:	28-JUL-2015
Filing Date:	24-MAY-2013
Time Stamp:	15:08:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	1355
Deposit Account	201507
Authorized User	SULLIVAN, CLARK G.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		PTO-supplementalamendment-7US9.PDF	77191 06be35fa9dc83c16a924471ab476721f3cfd035f	yes	4

Multipart Description/PDF files in .zip description

Document Description	Start	End
Supplemental Response or Supplemental Amendment	1	1
Claims	2	3
Applicant Arguments/Remarks Made in an Amendment	4	4

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2	Non Patent Literature	NPL-461-13902132-Amend-Resp-10-9-13.PDF	972017 c1fc41b0506c1f4eae25783aef377f916f629992	no	11
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3	Non Patent Literature	NPL-462-13902132-Amend-After-Final-2-21-14.PDF	2654730 2e568bcfd05e062cd28a38de746bfaedaad7597a	no	19
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4	Non Patent Literature	NPL-463-14597489-NFOA-2-26-15.PDF	497941 1c93ecdb13e9bc6b72f035e64f4788309b2ea7b9	no	9
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6	Non Patent Literature	NPL-958-Gelmann-Opening-Report-6-24-15-redacted.PDF	566171 b5d3a86f6087e4ac9a751b7c535dcb4ff3eb5d27	no	63

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7	Non Patent Literature	NPL-959-Kipp-Opening-Report-6-24-15-redacted.PDF	342181 ea30954b02177fa3e95d7e4bb6b3c6b5aeeced02	no	31
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15	Non Patent Literature	NPL-967-Exhibit-1023-Frame-Decl.PDF	4117262 f4aa4463da456d4cfb1c1101000fa6ca2a7d1637	no	34

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16	Non Patent Literature	NPL-968-Exhibit-1040-DeLuca-Decl.PDF	3384128 7b316a1576dfac54d2ee45ac39237306e9661f8c	no	27
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18	Non Patent Literature	NPL-970-Cohen-2000.PDF	481358 bb7356367333019 61ff8f3691e0d45f129baa4ed	no	2
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19	Non Patent Literature	NPL-971-Gandara-1998.PDF	1792027 87b966e97fbc92b3ef299679de158297adabc3fb	no	10
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Information:					
20	Non Patent Literature	NPL-972-FDA-Draft-Guidance-2002.PDF	4269401 c118d389b6c41279b621f6a01d674b23fc245855	no	29
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21	Non Patent Literature	NPL-973-Helsinn-2002.PDF	238044 2c12c2a44d8a187acfd01de4f069457a98300e5f	no	2
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22	Non Patent Literature	NPL-974-Helsinn-2001.PDF	267379 1d6229142a058e267c087c1268c2db7525315bc9	no	2
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23	Non Patent Literature	NPL-975-Helsinn-2001-b.PDF	314690 d498ff0d316440f99181bcf6c9d8a18edbfa6165	no	2
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24	Non Patent Literature	NPL-976-Brown-1992.PDF	1293339 bc76a9435b29346c09db21e6899d0596a234ddc8	no	6

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25	Non Patent Literature	NPL-977-Order-2-19-15.PDF	112177 b9340ee0e7c455659ba4f0a201ece2ee6ae5c6f8	no	2
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26	Non Patent Literature	NPL-978-Mikawa-1997.PDF	1224209 41fd57fe776a64a642e3adaaf6d3b8ea7ef266ef	no	5
Warnings:					
Information:					
27	Non Patent Literature	NPL-979-Avis-1992.PDF	10211478 02bef14ce6be1a226c5fdfefb11dd2a8607f37f1	no	42
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28	Non Patent Literature	NPL-980-Exhibit-1053.PDF	100635 e41d4f1bfcb3dbd74be27b36321e69f7ccc0c7a8	no	1
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Information:					
30	Non Patent Literature	PTO-957-DRL2ndAmendInvaliditContentions031215.PDF	1408643 638da2e3579db6b1588eff18bf6a23278ec022df	no	49
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31	Transmittal Letter	PTO-IDSTrans-7US9.PDF	83157 ba71cff2c67ef6d7c3d9a29520ca4379897e5eae	no	3
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32	Information Disclosure Statement (IDS) Form (SB08)	PTO-thirdSuppIDSSB08-7US9.PDF	93622 63c7b063ef84f13a33cc68522557feaab7dc0ae7	no	3
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New Applications Under 35 U.S.C. 111

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

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/901,830	Filing Date 05/24/2013	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	07/28/2015	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 11	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						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 number found in the appropriate box in column 1.

SLIE
/HELENA PAYTON/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	1	of	5	Attorney Docket Number	244168.000007.US.9

U.S. PATENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	44	US-8,729,094	05-20-2014	Calderari et al.	

U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials*	Cite No.[3]	Document Number Number-Kind Code[4] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	338	USPTO Notice of Allowance and Fees Due, USSN 13/087,012, mailed July 3, 2013.	
	339	USPTO Non-Final Office Action and Examiner-Initiated Interview Summary, USSN 13/901,437, mailed July 29, 2013.	
	340	USPTO Non-Final Office Action, USSN 13/902,132, mailed August 8, 2013.	
	341	USPTO Interview Summary, USSN 13/087,012 dated June 13, 2013.	
	342	USPTO Notice of Allowance and Fees Due and Examiner-Initiated Interview Summary, USSN 13/901,288, mailed September 6, 2013.	
	344	CDER Approval Package for NDA 21-372, Clinical Pharmacology and Biopharmaceutics Review (2002).	
	454	USPTO Non-Final Office Action and Applicant-Initiated Interview Summary, USSN 13/900,174, mailed November 19, 2013.	
	455	USPTO Non-Final Office Action, USSN 14/184,305, mailed May 29, 2014.	
	456	USPTO Applicant-Initiated Interview Summary, USSN 14/184,305, dated July 18, 2014.	
	457	USPTO Non-Final Office Action, USSN 13/902,299, mailed December 5, 2013.	
	458	USPTO Final Office Action, USSN 13/902,132, mailed December 6, 2013.	
	459	USPTO Non-Final Office Action, USSN 14/052,925, dated December 4, 2013.	
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	749	Defendants Aurobindo Pharma Ltd.'s and Aurobindo Pharma USA Inc.'s Answer, Affirmative Defenses, and Counterclaims, dated August 23, 2013 (D. Del. Case No. 13-688).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio Calderari
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
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NONPATENT LITERATURE DOCUMENTS			
	750	Plaintiff's Answer to the Counterclaims of Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd., dated September 13, 2013 (D. Del. Case No. 13-688).	
	753	Plaintiffs' Responses to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.'s Amended Invalidity Contentions, dated August 19, 2013 (D. N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	755	Plaintiffs' Responses to Sandoz Inc.'s Second Amended Invalidity Contentions, dated August 19, 2013 (D. N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	757	Plaintiffs' Responses to Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s First Amended Invalidity Contentions, dated August 19, 2013 (D. N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	764	Complaint for patent infringement filed by Helsinn Healthcare SA and Roche Palo Alto LLC against Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Sandoz Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. regarding U.S. Patent No. 8,518,981 dated September 30, 2013 (D.N.J. Case No. (13-5815)).	
	779	Answer and Counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to Amended Complaint for Patent Infringement regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated February 3, 2014 (D.N.J. Case No. 13-5815).	
	780	Sandoz Inc.'s Answer, Affirmative Defenses, and Counterclaims to Amended Complaint regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated February 3, 2014 (D.N.J. Case No. 13-5815).	
	781	Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.'s Answer to Amended Complaint for Patent Infringement regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated February 3, 2014 (D.N.J. Case No. 13-5815).	
	787	Teva Pharmaceuticals USA, Inc Paragraph IV Letter regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219, dated April 29, 2014 (portions redacted).	
	788	Mylan Institutional LLC Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219, dated May 16, 2014 (portions redacted).	
	789	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated May 29, 2014 (portions redacted).	
	790	Defendants' Opening Claim Construction Brief regarding U.S. Patent No. 8,598,219, dated June 19, 2014 (D.N.J. 11-3962, consolidated).	
	791	Answer, Affirmative Defenses and Counterclaims of Defendants Cipla Ltd. and Cipla USA, Inc. regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218 and 8,598,219 dated April 29, 2014 (D. Del. Case No. 14-427).	
	792	Complaint for Patent Infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Mylan Inc. and Mylan Institutional LLC regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,598,219, and 8,729,094, dated June 4, 2014 (D. Del. Case No. 14-709).	
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	796	Mylan Institutional LLC Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated June 27, 2014 (portions redacted).	
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	799	Answer, Defenses and Counterclaims of Mylan Institutional LLC regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,598,219, and 8,729,094, dated June 26, 2014 (D. Del. Case No. 14-709).	
	900	Aurobindo Pharma Ltd. Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated July 25, 2014 (portions redacted).	
	901	Defendants' Responsive Claim Construction Brief regarding U.S. Patent No. 8,598,219, dated July 17, 2014 (D.N.J. 11-3962, consolidated).	

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				Application Number	13/901,830
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				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
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NONPATENT LITERATURE DOCUMENTS			
	902	Cipla Ltd. Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated August 6, 2014 (portions redacted).	
	903	Teva Pharmaceuticals USA, Inc Paragraph IV Letter regarding U.S. Patent No. 8,729,094, dated August 29, 2014.	
	904	Expert Report of Patrick P. DeLuca, Ph.D. with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated).	
	905	Expert Report of David G. Frame, Pharm.D. with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation redacted).	
	906	Opening Expert Report of John P. Fruehauf, M.D., Ph.D. for U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	907	Opening Expert Report of Lee Kirsch, Ph.D. for U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	908	Expert Report of Maurie Markman, M.D. with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	909	Opening Expert Report of Paul Myrdal, Ph.D. for U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	910	Second Opening Expert Report of Dr. Bert Spilker with Respect to U.S. Patent No. 8,598,219, dated August 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	911	K. A. Connors, Introduction to Chemical Kinetics, Chemical Kinetics The Study of Reaction Rates in Solution, John Wiley & Sons, Inc., 1990, Ch. 1, pp. 1-15.	
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	915	The United States Pharmacopeia (USP 26) The National Formulary (NF 21), Official from January 1, 2003, entries for Atrophine Sulfate Injection (p. 192); Diazoxide Injection (p. 591); Dobutamine Hydrochloride Injection (p. 652); Fentanyl Citrate Injection (p. 781); Glycopyrrolate Injection (p. 870); Lidocaine Hydrochloride and Dextrose Injection (pp. 1079-80); Metoclopramide Injection (pp. 1217-18); Morphine Sulfate Injection (pp. 1254-55); Phenylephrine Hydrochloride Injection (pp. 1459-60); Phenytoin Sodium Injection (pp. 1471-72); Potassium Chloride for Injection (pp. 1503-04) (2002).	
	916	HELSN0004208 (2002) (redacted).	
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	921	Rebuttal Expert Report of Gordon L. Amidon, Ph.D. concerning U.S. Patent No. 8,598,219, dated September 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
	922	Rebuttal Expert Report of Keith A. Candiotti, M.D. with respect to U.S. Patent No. 8,598,219, dated September 15, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designation and other portions redacted).	
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	925	Answer and Counterclaims of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to Complaint for Patent Infringement regarding U.S. Patent No. U.S. Patent No. 8,729,094 dated September 5, 2014 (D.N.J. Case No. 14-4274).	

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				Filing Date	May 24, 2013
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				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
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NONPATENT LITERATURE DOCUMENTS			
	926	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated September 19, 2014 (portions redacted).	
	927	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated September 24, 2014 (portions redacted).	
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	940	Second Reply Expert Report of Dr. Bert Spilker regarding U.S. Patent No. 8,598,219 dated October 10, 2014 (D.N.J. 11-3962, consolidated) (confidentiality designations redacted).	
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	942	Final Joint Claim Construction Chart regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,598,219, and 8,729,094 dated October 24, 2014 (D. Del. Case Nos. 13-688 and 14-709).	
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	946	Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. Corrected Answer to Complaint for Patent Infringement and Counterclaim for Declaratory Judgment regarding U.S. Patent No. 8,729,094 dated January 8, 2015 (D.N.J. Case No. 14-6341).	
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	948	Declaration of Dr. Neervalur Raghavan, Ph.D. with Exhibits 1-25, dated September 28, 2014.	
	949	Gavis Pharma LLC's Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated December 31, 2014 (portions redacted).	
	950	Answer, Defenses, and Counterclaims of Defendants Exela Pharma Sciences, LLC, Exela Pharmsci, Inc. and Exela Holdings, Inc. to Complaint regarding U.S. Patent Nos. 8,518,981 and 8,598,218 redacted version dated December 29, 2014 (D. Del. Case No. 14-1444).	
	951	Defendant Mylan Institutional, LLC's Responsive Claim Construction Brief dated January 14, 2015 (D. Del. Case No. 13-688, consolidated).	
	952	Defendants Cipla Ltd. and Cipla USA, Inc.'s Corrected Answering Claim Construction Brief dated January 27, 2015 (D. Del. Case No. 13-688, consolidated).	

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				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
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NONPATENT LITERATURE DOCUMENTS			
	953	Plaintiffs' Responsive Claim Construction Brief, redacted public version dated January 20, 2015 (D. Del. Case No. 13-688, consolidated).	
	954	On Sale and Public Use Bars to Patentability After AIA: Minimizing the Risk of Patent Ineligibility or Invalidation, Cover and Slide 74, November 7, 2013.	
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	956	Par Pharmaceutical, Inc.'s Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, 8,598,219, and 8,729,094, dated February 10, 2015 (portions redacted).	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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EFS ID:	21682275
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	6980
Filer:	Breda Donovan/Dwight Peck
Filer Authorized By:	Breda Donovan
Attorney Docket Number:	244168.000007US9
Receipt Date:	05-MAR-2015
Filing Date:	24-MAY-2013
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Application Type:	Utility under 35 USC 111(a)

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28	Non Patent Literature	PTO-902-CiplaParaIVNotice094redacted-7US15.PDF	2024815 a7960ce4eb14007e688c5d6cc2396558bf5e5377	no	41
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29	Non Patent Literature	PTO-903-Teva-ParaIV-Notice-094-7-7US15.PDF	347556 1660a9820ff63793cdc2ebbca7d6990045562 67d	no	17
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The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
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30	Non Patent Literature	PTO-904-DeLuca-219-Report-7US15.PDF	151783 199cdfebe732675c953054b3ba5b2be8aa9e914e	no	18
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31	Non Patent Literature	PTO-905-Frame-219-Report-redacted-7US15.PDF	188561 edc39163a5c0a992f8e8e56256edbd9611a4362e	no	11
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32	Non Patent Literature	PTO-906-Fruehauf-219-Reportredacted-7US15.PDF	325005 aac49ad51d4dc00e4a01286e75fc7227f952a248	no	34
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33	Non Patent Literature	PTO-907-Kirsch-219-Report-redacted-7US15.PDF	305204 3d559421f9582b814a89f085ca266cd8cc3ad505	no	29
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34	Non Patent Literature	PTO-908-Markman-219-Report-redacted-7US15.PDF	2793445 d0c2a6427a4bd45c03064126c02645f854ee9786	no	25
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35	Non Patent Literature	PTO-909-Myrdal-219-Report-redacted-7US15.PDF	286992 cf041893e867d522cb621697d928659709e39729	no	26
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36	Non Patent Literature	PTO-910-Spilker-219-Report-redacted-2-7US15.PDF	1876546 411c4db7f5538c9a6ed0ea62b05b71233c9e68de	no	64

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41	Non Patent Literature	PTO-913-1999-PDR-entries-7US15.PDF	2923619 ee55b0b8bf708de011fc7023f740a93f6180a769	no	6
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42	Non Patent Literature	PTO-914-2002-PDR-entries-7US15.PDF	6089487 d37a857952c40274f0d0f6147ce03404e331e836	no	19
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43	Non Patent Literature	PTO-915-2003-USP-entries-7US15.PDF	4950207 1e37d185c16bdc1aa52de1e985dd0d55d55d2478	no	20
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44	Non Patent Literature	PTO-916-HELSN0004208-redacted-07-7US15.PDF	55775 3292110e070fdfe5a1746aed5cae490d417bb15d	no	1
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49	Non Patent Literature	PTO-921-Amidon-219-Report-redacted-7US15.PDF	2549301 14a9c704474f95a99729856f2b74545302857856	no	30
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51	Non Patent Literature	PTO-923-Peck-219-Report-redacted-7US15.PDF	226037 06bef285ce5cc055ce59b6a4bb3b26038b74ea0a	no	24
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53	Non Patent Literature	PTO-925-DRL-Answer-and-Counterclaims-094-09052014-7US15.PDF	127468 6c875305d4230ede19b9ab6889faa4b0b87ca4cd	no	13
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55	Non Patent Literature	PTO-927-DRL-ParaIV-Notice-981-218-219-094-092414-redacted-7US15.PDF	5955879 1a3b3e10d4ff68a5c2b5be60af42c56152c2efd8	no	61
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56	Non Patent Literature	PTO-928-Eglen-5-HT3-Receptors-Curr-Pharm-Des-1996-7US15.PDF	1596157 7ffec90b33a14af172ea8244e83a7867f998f8a6	no	8
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57	Non Patent Literature	PTO-929-Helsinn-announces-that-patient-enrollment-for-phase-7US15.PDF	27327 385119774ef682ac0fcbe8798a83ef8df80e5702	no	2
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58	Non Patent Literature	PTO-930-Piraccini-A-Novel-AntiEmetic-Agent-Palonosetro-7US15.PDF	856255 ead2249a58ed614584b8472590c4d373294ca001	no	4
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59	Non Patent Literature	PTO-931-RS-25259-197-Drugs-Fut-1996-7US15.PDF	562925 a79f86333412f3f7ade06ac4eddcac5c0bd90ee9	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	131376926		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	Examiner: Shirley V. GEMBEH
	)	
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806
	)	
	)	
	)	
	)	

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

Commissioner:

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents on the attached listing. This Second Supplemental Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. §1.97(c), this Second Supplemental Information Disclosure Statement is accompanied by a fee of $180.00 as specified by Section 1.17(p).

Copies of the listed nonpatent literature documents corresponding to Cite Nos. 339, 344, 454-460, 779-781, 787-799, 900-956 are enclosed. Nonpatent literature documents corresponding to Cite Nos. 338, 340-342, 749, 750, 753, 755, 757, 764 were cited and/or made of record in this application or prior U.S. Application No. 11/186,311 filed July 21, 2005 (now U.S. Patent No. 7,947,724), U.S. Application No. 13/087,012 filed April 14, 2011 (now U.S. Patent No. 8,518,981), or U.S. Application No. 13/901,437 filed May 23, 2013 (now U.S. Patent

No. 8,598,219), all to which the present application claims priority. Accordingly, copies of those documents are not enclosed. In addition, a copy of listed U.S. patent (Cite Nos. 44) is not enclosed.

Some of the documents listed come from related pending litigations. Some of those documents have been redacted. Assignee, Helsinn Healthcare SA, has confirmed that the documents listed may be placed in the public record without violating any confidentiality agreement, protective order, or court order, and has given permission to place in the public record any and all documents submitted herewith.

Certain confidential information has been redacted from some of those documents. Applicant hereby acknowledges that at least some of the redacted information includes non-zero U.S. dollar amounts. If the Examiner believes that any of the redacted information is necessary for purposes of examination, would like further information regarding the general nature of the redacted information, or would like to see any of the exhibits, documents, testimony, or references cited in the documents listed, please let the undersigned know immediately.

Furthermore, Applicant wishes to bring to the Office's attention an allegation of unclean hands that has been made against Applicant in pending litigation involving a related patent. The allegation surrounds Applicant's decision to file a CIP application post-AIA, and thereafter to invoke changes in the law post-AIA to disqualify an alleged on-sale bar as prior art. Applicant previously discussed this change in law with the Examiner during a June 13, 2013 interview, and documented the issue in several subsequent written submissions to the Patent Office. See, e.g., June 13, 2013, Examiner Interview Summary discussion of "Jedi Master Mixer" in U.S.S.N. 13/087,012. A defendant in litigation involving a related patent accused Applicant in a sealed pleading of gaming the system by invoking this change in law to disqualify an alleged on-sale bar, and compares Applicant's conduct to the submarine patent strategy employed by Lemelson. Applicant does not believe that the allegation has any merit, or that the allegation constitutes material information covered by its duty of disclosure, but nonetheless cites the allegation out of an abundance of caution. The Examiner is invited to contact Applicant if she wants further information about this allegation.

There are no documents numbered 1-43, 45-337, 343, 345-453, 461-748, 751, 752, 754, 756, 758-763, 765-778, 782-786, or 800-899 associated with this Information Disclosure Statement.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this statement, please charge the fee to Deposit Account No. 201507.

Respectfully submitted,

By:/Clark G. Sullivan/
Clark G. Sullivan
Reg. No. 36,942

Troutman Sanders LLP
Chrysler Bldg, 405 Lexington Ave
New York, NY 10174
Customer No.: 06980
Attorney Docket No. 244168.000007.US.9

Electronic Acknowledgement Receipt

EFS ID:	21682823
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	6980
Filer:	Breda Donovan/Dwight Peck
Filer Authorized By:	Breda Donovan
Attorney Docket Number:	244168.000007US9
Receipt Date:	05-MAR-2015
Filing Date:	24-MAY-2013
Time Stamp:	11:41:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	PTO-932-Palonosetron-Hydrochloride-RS-25259-97-Drugs-Fut-2000-7US15.PDF	423912 a29da69391c61c1168ada73ff07ed98414112dba	no	3
Warnings:					
Information:					

2	Non Patent Literature	PTO-933-Palonosetron-Hydrochloride-Drugs-Fut-2001-7US15.PDF	405712 79c92271f62eb40f5ad47cac3a33d374f9455ec8	no	3
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Information:					
3	Non Patent Literature	PTO-934-Leak-Pharmaceutical-Development-of-Ondansetron-Inj-1989-7US15.PDF	575865 9b04bc63503c14bd9607e06d767b8973626c4977	no	4
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4	Non Patent Literature	PTO-935-Frame-reply-20141010-7US15.PDF	2492560 87bec88d683ef9333ff2f64639dac4381c6aab81	no	19
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Information:					
5	Non Patent Literature	PTO-941-Exela-ParaIV-20141016redacted-7US15.PDF	2872178 5e732683f5acc2e0bf337217aee9a17cb18cc904	no	56
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6	Non Patent Literature	PTO-943-MylanOpeningClaimConstruction.PDF	161666 a47b8772ff1a0bf89b850eef8c32a2f5c9b6ba87	no	14
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Information:					
7	Non Patent Literature	PTO-944-CiplaCorrectedOpeningClaimConstBrief.PDF	1509357 d4536431842125cca49d9d7095a33311dd6d696c	no	14
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8	Non Patent Literature	PTO-945-HelsinnOpeningClaimConstruction.PDF	277693 ed6bec85cd9b6c88a8a1672399ddef1dab8c5177	no	28
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9	Non Patent Literature	PTO-946-TevaCorrectedAnswerCounterclaim.PDF	162021 d484751e61a7cd00c3ed7401febfcb4e2d6bd0ed	no	15
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10	Non Patent Literature	PTO-947-TerminationofProceeding.PDF	153959 07575c395a43aaf467e7754e4727dabc3a307c4c	no	3
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11	Non Patent Literature	PTO-948-Exhibit18-24-7US15.PDF	8798015 2759a3204bd3cea0bbcd5e00ba81f9212557dc57	no	52
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12	Non Patent Literature	PTO-948-Exhibits1-5-7US15.PDF	3702251 b8ee5d555f7dfa597b0ce2ec31c07d2143c15877	no	77
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14	Non Patent Literature	PTO-948-Exhibits12-17-7US15.PDF	15819769 4df45ccf843bac1e20d5dff97365e32b5b1873c8	no	106
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Information:					
15	Non Patent Literature	PTO-936-Markman-reply-20141010redacted-7US15.pdf	8989789 ef239f3ddcfa84d00f182fbaa70a05294052f09a	no	24
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16	Non Patent Literature	PTO-937-Fruehauf-reply-20141010redacted-7US15.pdf	447764 4dec4098efd6a5c62f803e9101fc4265c50157f1	no	34
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17	Non Patent Literature	PTO-938-Kirsch-reply-20141010redacted-7US15.pdf	372851 af92d3da67c93319606f8dbdcc7e279fb0a1b7fd	no	20
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18	Non Patent Literature	PTO-939-Myrdal-reply-20141010redacted-7US15.pdf	154619 5eb3973eb93272b3ae88c076a3ef2a6ef73b146b	no	14
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19	Non Patent Literature	PTO-940-Spilker-2ndReply-20141010redacted-7US15.pdf	2326928 d138b3173a727b2606b707d6e0ba3db8fe2e52ae	no	38
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Information:					
23	Non Patent Literature	PTO-950-ExelaAnswerCounterclaims.PDF	1825907 717830ac601b597566fd7b7c167fb694a1f079f5	no	29
Warnings:					
Information:					
24	Non Patent Literature	PTO-951-MylanRespClaimContBrief.PDF	174898 8742e076c65518ee59d078cb9c34466cddb16d78	no	15
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25	Non Patent Literature	PTO-953-HelsinnRespClaimConstBrief.PDF	9110177 19594d71e7ef7d264cd269b92ee60ae4a2174180	no	24
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Information:					
26	Non Patent Literature	PTO-954-Slide-2013-7US15.PDF	245628 b515111aac25480339d5e3eac8c50c4ce9597312	no	2
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The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
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27	Non Patent Literature	PTO-955-Hospira_Para_IV_2-10-15_redacted.PDF	8537858 40ed34a07e1be620fbe680cad32d7b7651946be0	no	44
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Information:					
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New Applications Under 35 U.S.C. 111
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New International Application Filed with the USPTO as a Receiving Office
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	
	)	Examiner: Shirley V. GEMBEH
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

SUPPLEMENTAL AMENDMENT AND RESPONSE TO OFFICE ACTION

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

TROUTMAN SANDERS
Customer Number 06980

Dear Sir:

In further response to the Office Action mailed November 22, 2013, please enter the following amendments and consider the following remarks.

A REPLACEMENT CLAIM SET begins on page 2.

REMARKS begin on page 4.

REPLACEMENT CLAIM SET

1-25. (Canceled)

26. (New) A formulation comprising a pharmaceutical sterile aqueous intravenous solution, wherein said pharmaceutical sterile aqueous intravenous solution comprises:

palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron at a concentration of 0.05 mg/mL based on the weight of the palonosetron free base; and

from about 10 mg/mL to about 80 mg/mL mannitol;

wherein the pharmaceutical sterile aqueous intravenous solution has a pH of 4.0 to 6.0.

27. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron is in an amount of 0.25 mg.

28. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises from about 20 mg/mL to about 60 mg/mL mannitol.

29. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises from about 40 mg/mL to about 45 mg/mL mannitol.

30. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises 41.5 mg/mL mannitol.

31. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises a chelating agent.

32. (New) The formulation of claim 31, wherein said chelating agent is EDTA.

33. (New) The formulation of claim 32, wherein said pharmaceutical sterile aqueous intravenous solution comprises from about 0.3 mg/mL to about 0.7 mg/mL EDTA.

34. (New) The formulation of claim 32, wherein said pharmaceutical sterile aqueous intravenous solution comprises 0.5 mg/mL EDTA.

35. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution has a pH of 5.0 ± 0.5.

36. (New) The formulation of claim 26, wherein said pharmaceutical sterile aqueous intravenous solution comprises a citrate buffer.

37. (New) A formulation comprising a pharmaceutical sterile aqueous intravenous solution, wherein said pharmaceutical sterile aqueous intravenous solution comprises:

palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron at a concentration of 0.05 mg/mL based on the weight of the palonosetron free base;

from about 10 mg/mL to about 80 mg/mL mannitol; and

from about 0.3 mg/mL to about 0.7 mg/mL EDTA.

38. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron is in an amount of 0.25 mg.

39. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution has a pH of 4.0 to 6.0.

40. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution has a pH of 5.0 ± 0.5.

41. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises from about 20 mg/mL to about 60 mg/mL mannitol.

42. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises from about 40 mg/mL to about 45 mg/mL mannitol.

43. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises 41.5 mg/mL mannitol and 0.5 mg/mL EDTA.

44. (New) The formulation of claim 37, wherein said pharmaceutical sterile aqueous intravenous solution comprises a citrate buffer.

REMARKS

Status of Claims

Upon entry of this Supplemental Amendment, claims 26-44 will be pending in this application. Claims 1-9 were previously canceled and claims 10-25 are canceled herein, all without prejudice or disclaimer. New claims 26-44 are added by this amendment. Support for the new claims can be found throughout the specification of the priority application (U.S. Provisional Application No. 60/444,351), for instance at:

- page 2, lines 4-6;
- page 5, line 3 to page 6, line 2;
- page 6, line 16 to page 7, line 1;
- page 7, line 29 to page 8, line 8;
- page 8 lines 14-25;
- page 8, line 26 to page 9, line 23;
- page 10, lines 9-25; and
- Examples 1-3.

No new matter is added by this amendment.

Status of Application

On February 21, 2014, Applicants filed a timely and complete response to the Office Action mailed November 22, 2013. On April 17, 2014, Applicants requested a three-month suspension of prosecution to consider the strategic direction of this application relative to Applicants' other pending applications. On August 25, 2014, Applicants requested an additional three-month suspension to continue such consideration. Applicants hereby request that prosecution of this application be resumed and examination extended to include new claims 26-44 presented herein.

The remarks presented in the Response filed February 21, 2014, regarding the patentability of claims 10-18 remain in full force and are incorporated herein by reference. In the

pages that follow, Applicants provide reasons why the previous obviousness rejection of claims 10-18 does not apply to new claims 26-44.

Rejection Under 35 U.S.C. § 103

In the Office Action mailed November 22, 2103, the Office rejected claims 10-18 under pre-AIA[1] 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,202,333 to Berger et al. ("Berger") in view of Barton "Citric Buffer Calculation" (2000) ("Barton") and U.S. Patent No. 6,284,749 to Castillo et al. ("Castillo"), and further in view of U.S. Patent No. 5,854,270 to Gambhir ("Gambhir") as evidenced by Matsumoto et al. "Manual for Practical Pharmacy" (1989) ("Matsumoto"). Office Action at pp. 3-8. For the reasons discussed below, Applicants respectfully traverse this rejection with respect to new claims 26-44.

A. The Concentration of Palonosetron Hydrochloride Recited in Claims 26-44 Would Not Have Been Obvious

Applicants have prosecuted several applications in the same family as this application, including U.S. Patent No. 8,598,219 ("the '219 patent"), which is the parent of this application. Like the claims of the '219 patent, claims 26-44 recite a specific concentration of palonosetron hydrochloride of 0.05 mg/mL based on the weight of its free base. The Office has already acknowledged that Berger is directed toward much higher concentrations of 10 to 100 mg/mL and thus, would have led the POSITA away from using the claimed concentration in intravenous formulations. *See* Interview Summary dated October 11, 2013 in the '219 file history.

Specifically, the Office stated, in distinguishing the 0.05 mg/mL (*i.e.*, 0.25 mg/5 mL) palonosetron hydrochloride concentration recited in the '219 claims, that Berger describes "high concentrations." The Office supported that conclusion by referencing Berger's Example 13,

[1] As discussed in the Response filed February 21, 2014, Applicants believe that this case should be examined under post-AIA 35 U.S.C. § 103 because it claims priority to an application that presented a claim having a priority date after March 16, 2013. *See also* the "Choice of Law" section of the Preliminary Amendment filed May 24, 2013. Nevertheless, Applicants do not believe that the choice of law has any bearing on the patentability of the claims.

which describes concentrations (10 to 100 mg/mL) that are approximately 200-2,000 times higher[2] than the currently claimed concentrations:

> This is commensurate with the low concentration described in the claims (0.25 mg/5 mL) relative to the high concentrations described in the prior art (Berger 5,202,333, Example 13).

Id.

As Applicant argued, and the Office agreed, nothing in Berger suggests moving from Berger's broad range of concentrations to the low claimed concentration, especially when the high concentrations exemplified in Example 13 are considered. In fact, the high concentrations in Berger's examples (*i.e.*, 10 mg/mL and 100 mg/mL), would have moved the POSITA away from the lower claimed concentration. Thus, claims 26-44, which recite the same concentration of palonosetron hydrochloride as the concentration claimed in the '219 patent, are allowable for at least the same reasons as the claims of the '219 patent.

Nevertheless, Applicants submit the following additional arguments to explain why the subject matter of claims 26-44 would not have been obvious in view of the Office's cited references when the claimed invention was made.

B. The POSITA Would Not Have Arrived at the Claimed Concentration via "Routine Experimentation/Optimization"

The Office has concluded that the primary reference, Berger, would have rendered the claims obvious, *inter alia*, because it teaches "the concentration of palonosetron is from 0.000001% w to 10% weight" and, "optimization of the concentration is within the purview of one of ordinary skill in the art." *Id.* at pp. 10, 12.

Applicants respectfully disagree and submit that "routine experimentation/ optimization" does not support a rejection of claims 26-44. The POSITA would have found nothing routine about going from Berger's enormously broad concentration ranges to the specific concentration

[2] 10 mg/mL, the lowest of Berger's exemplified concentrations and is 200 times higher than the claimed concentration of 0.05 mg/mL. 100 mg/mL, the highest of Berger's exemplified concentrations, is 2,000 times higher than the claimed concentration of 0.05 mg/mL.

recited in claims 26-44. Such a modification would have required a vast amount of work, with no reasonable expectation of success and no direction leading to the claimed values.

Berger describes a "general" concentration range spanning seven orders of magnitude (*i.e.*, "from 0.000001% w to 10.0% w"; col. 12, ll. 64-65; *see also* Office Action at p. 10), and subsequently leads the POSITA to a preferred concentration range that spans five orders of magnitude (*i.e.*, "preferably 0.00001% w to 1.0% w"; col. 12, ll. 66-67), and eventually to a concentration range of 10-100 mg/mL in Example 13.

Thus, Berger's teachings would have led the POSITA along the following path:

(1) "In general, the final composition will comprise from 0.000001% w to 10% w" (col. 12, ll. 64-65).

↓

(2) "preferably 0.00001% w to 1.0% w" (col. 12, ll. 66-67).

↓

(3) only exemplified composition for intravenous administration (Example 13): 1% w to 10% w concentrations.

It would have taken a prodigious amount of work by the POSITA, with no reasonable expectation of success and no direction (*i.e.*, no sign posts or trail markers), to go from the wide concentration ranges disclosed by Berger to the specific concentration described in claims 26-44. This is especially true when Berger's only exemplified intravenous concentration range in Example 13 (10-100 mg/mL) is 200-2,000 times greater than the claimed concentration (*see* above). Thus, to the extent that Berger gave the POSITA any direction whatsoever, it was direction, such as the range in Example 13, that would have led the POSITA away from the claimed invention.

Because of the large amount of work needed for the POSITA to go from Berger's broad concentration disclosures, and because there was absolutely no guidance in Berger leading to the

claimed concentration, it would have taken far more than "routine experimentation" for the POSITA to arrive at the invention of claims 26-44.

The doctrine of "routine experimentation" cannot be applied to claims 26-44 for additional reasons. In particular, the concept of "routine experimentation" can be found in the Office's *KSR* Examination Guidelines in its "obvious to try" discussion, which makes clear that the doctrine is limited. As stated in the Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, published at 75 Fed. Reg. 53643, at 53654 ("Guidelines"):

> This rationale is only appropriate when there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success.

As this discussion makes clear, the "obvious to try" rationale is only appropriate when there are a finite number of predictable solutions. Berger's broad concentration ranges spanning five and seven orders of magnitude are, for practical purposes, anything but a finite number of predictable solutions made available to the POSITA. *See* Office Guidelines at 53655, 53660 (citing *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.* 520 F.3d 1358 (Fed. Cir. 2008), which notes that "several" unpredictable alternatives is not a "finite number of identified, predictable solutions," and "several" is certainly far less than 10^4, 10^5, 10^6, and 10^7).

Of *Ortho-McNeil*, MPEP 2143, E, Example 5 states that "finite" means "small or easily traversed":

> The Federal Circuit affirmed. The Federal Circuit pointed out that . . . there would have been no reason to test that intermediate for anticonvulsant properties if treating diabetes had been the goal. . . . Summarizing their conclusion with regard to Mylan's obvious to try argument, the Federal Circuit stated:
>
> > [T]his invention, contrary to Mylan's characterization, does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness. . . . KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that

> would convince an ordinarily skilled artisan of obviousness. . . . [T]his clearly is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness. *Id.* at 1364, 86 USPQ2d at 1201.
>
> Thus, Ortho-McNeil helps to clarify the Supreme Court's requirement in KSR for "a finite number" of predictable solutions when an obvious to try rationale is applied: under the Federal Circuit's case law "finite" means "small or easily traversed" in the context of the art in question. (Emphasis added.)[3]

The MPEP further elaborates on the "obvious to try" doctrine, and gives two classes of situations in section 2143 in which it is improper to apply an "obvious to try" rationale. According to MPEP 2143 I E (Example 3), the Office should not use an obvious to try rationale to reject an application:

> (1) when what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; and
>
> (2) when what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

---

[3] In the Patent Trial & Appeal Board's ("Board") decision in *International Flavors & Fragrances Inc. v. U.S.A.*, IPR2013-00124, Paper 12, at 15 (P.T.A.B. May 20, 2014), the Board relied on *Ortho McNeil's* characterization of "finite" as "small or easily traversed" when finding that patentee's amended claims directed to modified insect repellant compounds would have been nonobvious. After considering evidence of what the POSITA would have understood, the Board stated that the prior art failed to provide any reason to modify the known insect repellant to arrive at the modified compounds or a reasonable expectation that such modifications would result in a compound with the desired insect repellent activity. *Id.* at 16. Berger and its enormous concentration ranges also do nothing to point the POSITA towards the presently claimed concentration.

Both of those situations apply here. Berger, as noted, provides a "general" range of concentrations that spans seven orders of magnitude (*i.e.*, 0.000001% w to 10.0% w), involving at least 10^7 choices. To be sure, Berger narrows the broad concentration range to encompass five orders of magnitude (*i.e.* "preferably 0.00001% w to 1.0% w"), involving at least 10^5 choices. But even that narrowed range remains very broad and to arrive at the presently claimed concentration based on these general teachings in Berger, the POSITA would have had to try a practically infinite number of possible choices of concentrations. And the POSITA would have faced that practically impossible task with absolutely nothing pointing her towards the presently claimed concentration. Berger's general guidance providing a range of 10^5 or 10^7 concentrations would have been no reasonable guidance at all.

To be sure, Berger also exemplifies a single representative intravenous formulation, itself having a range of concentrations of active ingredients spanning 1% w to 10% w (*i.e.*, "10-100 mg" in "1 mL"), involving fewer choices than the general concentration ranges discussed above. *See* Example 13, col. 29, ll. 1-13. But that example of Berger moves in an opposite direction within Berger's broad concentration ranges compared to the much LOWER claimed concentration of 0.05 mg/mL.

These differences between Berger's disclosure and the claimed invention are significant. As is well established, "[e]vidence that others were 'going in different ways' is strong evidence that the [inventor's] way would not have been obvious." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012) (citing *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985), which MPEP §§ 2144.08, 1504.03, and 2141.02, all cite with approval for other reasons).

There is no rationale of record that would have motivated the POSITA to decrease Berger's exemplified range of high concentrations for intravenous formulations and thereby obtain the presently claimed concentration. Rather, Berger would have led the POSITA away from the presently claimed value.

And, of course, the fact that the claimed concentration (*i.e.*, a species) is encompassed by Berger's broad genera of 10^5 and 10^7 concentrations is not sufficient by itself to establish a *prima facie* case of obviousness. The Office must establish that the POSITA would have been

motivated to select the claimed concentration from Berger's broad disclosure. *See* MPEP § 2144.08 II A (4) (a)-(f).

The secondary references cited by the Office fail to provide such a motivation. None of those references even deals with palonosetron hydrochloride, much less would have indicated to the worker of ordinary skill any direction within Berger's broad concentration ranges that span 10^5 and 10^7 orders of magnitude.

For all these reasons, Applicants respectfully submit that the Office Action lacks a *prima facie* case of obviousness with respect to claims 26-44.

C. Applicants Rebut Any *Prima Facie* Case of Obviousness That Might Have Been Established

Even assuming, *arguendo*, that the Office Action had set forth a *prima facie* case of obviousness, which Applicants respectfully submit it did not, Applicants have rebutted any such alleged *prima facie* case. Rebuttal evidence may include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. M.P.E.P. § 2145.

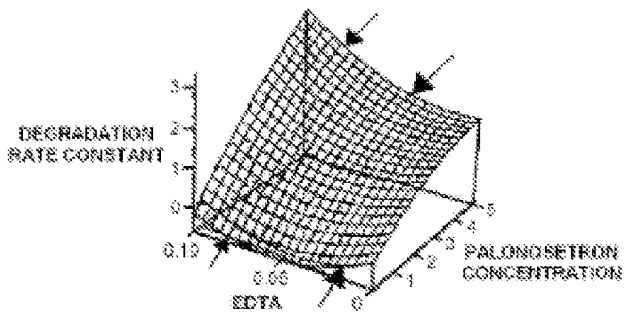
"Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the 'objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.'" *Id.* at § 716.02(d) (citing *In re Clemens*, 622 F.2d 1029, 1036 (C.C.P.A. 1980)). However, "[w]hen considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. " *Id.* at § 2145 (internal citations omitted).

Here, Applicants unexpectedly discovered that as the concentration of palonosetron hydrochloride in a pharmaceutical formulation decreases, the stability of the formulation increases. For example as discussed in Example 2, a formulation optimization study was

performed using experimental design software. Twenty-four lots of drug product were analyzed to investigate, *inter alia*, the appropriate concentration ranges for palonosetron hydrochloride.

The results of that study indicated that palonosetron hydrochloride concentration was a critical factor in chemical stability, "with greatest stability seen at the lowest palonosetron hydrochloride concentrations." *See* Example 2.

A visual representation of that discovery is depicted in the following graph, which is adapted from a Figure of the Bonadeo Declaration dated February 9, 2009 (of record):



As can be seen from this Figure, Applicants unexpectedly discovered that as the concentration of palonosetron hydrochloride decreases from 5 mg/mL toward the presently claimed low concentration of 0.05 mg/mL, the palonosetron degradation rate decreases (follow the line on the right-hand side of the figure from back to front). *See also* Supplemental Bonadeo Declaration (of record) at Exhibit 3 (demonstrating reduced chemical stability of palonosetron hydrochloride at 10 mg/mL and 50 mg/mL, which are the lower end and middle of Berger's Example 13 range of concentrations).

This stability of formulations comprising different concentrations of palonosetron hydrochloride would have been unpredictable. *See, e.g.*, Stella Declaration dated September 19, 2007 (of record). Indeed, Berger provided no reason to expect improved stability by lowering the palonosetron hydrochloride concentration. Thus, the unexpected stability of compositions comprising palonosetron hydrochloride at the presently claimed concentration could not have been reasonably predicted based on Berger's teachings.

For all these reasons, Applicants respectfully submit that claims 26-44 would not have been obvious over the Office's cited combination of references.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. Should the Examiner disagree or have any questions regarding this submission, the Applicants invite the Examiner to call the undersigned at 212.704.6105.

Respectfully submitted,

By:/Clark G. Sullivan/
Clark G. Sullivan
Reg. No. 36,942

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Chrysler Bldg, 405 Lexington Ave
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Electronic Acknowledgement Receipt

EFS ID:	21655764
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	6980
Filer:	Breda Donovan/Dwight Peck
Filer Authorized By:	Breda Donovan
Attorney Docket Number:	244168.000007US9
Receipt Date:	03-MAR-2015
Filing Date:	24-MAY-2013
Time Stamp:	15:36:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		PTO-SupplementalAmendmentandRspnsetoOA-7US9.PDF	146219 febc7dff205963bb73b7196e478ce7f93c3b331d	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	13
Warnings:			
Information:			
	Total Files Size (in bytes):	146219	

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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.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/901,830	Filing Date 05/24/2013	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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.			TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)		
AMENDMENT	03/03/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 19	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

		(Column 1)		(Column 2)	(Column 3)		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						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 number found in the appropriate box in column 1.

LIE
/MOLIKI MAY/

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9

CONFIRMATION NO. 3806

6980
TROUTMAN SANDERS LLP
600 Peachtree Street
Suite 5200
Atlanta, GA 30308

POA ACCEPTANCE LETTER

OC000000072908575

Date Mailed: 01/21/2015

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/12/2015.

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.

/dtdinh/

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

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9

CONFIRMATION NO. 3806

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POWER OF ATTORNEY NOTICE

OC000000072908573

Date Mailed: 01/21/2015

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/12/2015.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/dtdinh/

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

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
13/901,830	05-24-2013

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 06980

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

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OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Helsinn Healthcare S.A.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Matteo Missaglia		
Title	Senior Director, Legal Affairs		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

Doc Code: PA..
Document Description: Power of Attorney

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Application Number	Filing Date
13/901,830	05-24-2013

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Address					
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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Roche Palo Alto LLC

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Kevin A. Marks		
Title	Vice President		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	21183491
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Dwight Peck
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	244168.000007US9
Receipt Date:	12-JAN-2015
Filing Date:	24-MAY-2013
Time Stamp:	15:04:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	PTO-POAHelsinn-US9.PDF	146159 5a22a5a23921aa5b873aaa6abf86e7410e3c4651	no	1
Warnings:					

The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
2	Power of Attorney	PTO-POARoche-US9.PDF	160052 8578020f04db3be5b9ef942b8543e09acb9f0f2c	no	1
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
			Total Files Size (in bytes):	306211	

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.

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.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	244168.000007US9	3806

53449 7590 12/10/2014

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 12/10/2014

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

The request for deferral/suspension of action under 37 CFR 1.103 has been approved.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
13/901,830	24 May, 2013	CALDERARI ET AL.	244168.000007US9

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
SHIRLEY V. GEMBEH	
ART UNIT	PAPER
1628	20141203

DATE MAILED:

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

Commissioner for Patents

The request for Suspension of Action filed 8/25/14 under 37 C.F.R. 1.103(a) has been received.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHEN WU-CHENG can be reached on 571-272-3157. 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

/SHIRLEY V GEMBEH/
Primary Examiner, Art Unit 1628

PTO-90C (Rev.04-03)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	
	)	Examiner: Shirley V. GEMBEH
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

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

Commissioner:

SECOND REQUEST FOR SUSPENSION OF ACTION UNDER 37 C.F.R. § 1.103(a)

In accordance with 37 C.F.R. § 1.103(a) and MPEP § 709(I)(A), Applicants hereby notify the Office that the three-month suspension granted on April 23, 2014, in this application ended on July 17, 2014 (three months after the first request). Applicants hereby request a second suspension of action by the Office for an additional three (3) months. The requisite fee of $200.00, as set forth in 37 C.F.R. 1.17(g), is filed herewith.

A second suspension of action is necessary so that Applicants can continue consideration of the strategic direction of this application relative to the pending claims of reissue continuation SN 14/184,305 ("the '305 application"), as well as other pending applications of the assignee, Helsinn Healthcare S.A. Both applications, as well as others not identified herein by application number, are assigned to Examiner Gembeh and relate to Applicants' FDA-approved Aloxi® product. The patent sought to be reissued in the '305 application (*i.e.*, U.S. 7,947,725) is

involved in litigation. The '305 application received an Office Action on May 29, 2014, and Applicants filed a response on June 24, 2014.

The requested suspension is necessary in order to provide Applicants and Examiner Gembeh time in which to reach agreement as to patentability of the pending claims of the pending litigation-related '305 application. Applicants will reassess the strategic direction of this application once an agreement has been reached regarding the claims of the '305 application, which applicants believe contain allowable subject matter, as do the claims of the present application.

Therefore, having paid the requisite fee and having shown good and sufficient cause for suspension, it is respectfully requested that the examination of the present application be suspended an additional three (3) months.

Should the Office disagree or have any questions regarding this submission, Applicants invite the Examiner to call the undersigned at 212.704.6105.

Respectfully submitted,

By:/Clark G. Sullivan/
Clark G. Sullivan
Reg. No. 36,942

Troutman Sanders LLP
Chrysler Bldg, 405 Lexington Ave
New York, NY 10174
Phone: (212) 704-6000

Electronic Patent Application Fee Transmittal

Application Number:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Angelina Stantini
Attorney Docket Number:	23278.2.US.9

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:				
Petition fee- 37 CFR 1.17(g) (Group II)	1463	1	200	200
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt

EFS ID:	19957524
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Angelina Stantini
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	25-AUG-2014
Filing Date:	24-MAY-2013
Time Stamp:	16:37:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$200
RAM confirmation Number	3365
Deposit Account	201507
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Letter Requesting Suspension of Action	PTO-SUSPENDACTION-244168000007US9.pdf	76723 870bfce9e0fddade531b77b4e35822baf44a1abe	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30209 681a462821cf8bcd33161c825b283e5335246212	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	106932		

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.

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.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	23278.2.US.9	3806

53449 7590 04/23/2014

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 04/23/2014

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

The request for deferral/suspension of action under 37 CFR 1.103 has been approved.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
13/901,830	24 May, 2013	CALDERARI ET AL.	23278.2.US.9

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
SHIRLEY V. GEMBEH	
ART UNIT	PAPER
1628	20140418

DATE MAILED:

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

Commissioner for Patents

The request for Suspension of Action filed 4/17/14 under 37 C.F.R. 1.103(a) has been received.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHEN WU-CHENG can be reached on 571-272-3157. 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

/SHIRLEY V GEMBEH/
Primary Examiner, Art Unit 1628

PTO-90C (Rev.04-03)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	
	)	Examiner: Shirley V. GEMBEH
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

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

Commissioner:

REQUEST FOR SUSPENSION OF ACTION UNDER 37 C.F.R. § 1.103(a)

In accordance with 37 C.F.R. 1.103(a) Applicants hereby request a suspension of action by the Office for three (3) months. The requisite fee of $200.00, as set forth in 37 C.F.R. 1.17 (g), is filed herewith.

Suspension of action is necessary so that Applicants can consider the strategic direction of this application relative to the pending claims of reissue continuation SN 14/184,305 ("the '305 application"), as well as other pending applications of the assignee, Helsinn Healthcare S.A. Both applications, as well as others not identified herein by application number, are assigned to Examiner Gembeh and relate to Applicants' FDA-approved Aloxi® product. The patent sought to be reissued in the '305 application (*i.e.*, U.S. 7,947,725) is involved in litigation. The parent reissue application (SN 13/900,174) received an Office Action on November 19, 2013; however, substantive examination has not yet begun in the '305 application.

The requested suspension is necessary in order to provide Applicants and Examiner Gembeh time in which to reach agreement as to patentability of the pending claims of the pending litigation-related '305 application. Applicants will reassess the strategic direction of this application once an agreement has been reached regarding the claims of the '305 application, which applicants believe contain allowable subject matter, as do the claims of the present application.

Therefore, having paid the requisite fee and having shown good and sufficient cause for suspension, it is respectfully requested that the examination of the present application be suspended three (3) months.

Should the Office disagree or have any questions regarding this submission, Applicants invite the Examiner to call the undersigned at 212.704.6105. To the extent any additional fees are due for this submission, the Commissioner is authorized to charge Deposit Account No. 20-1507 of Customer No. 06980.

Respectfully submitted,

By:/Clark G. Sullivan/
Clark G. Sullivan
Reg. No. 36,942

Troutman Sanders LLP
Chrysler Bldg, 405 Lexington Ave
New York, NY 10174
Phone: (212) 704-6000
Attorney Docket No. 244168.000007.US9

Electronic Patent Application Fee Transmittal

Application Number:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Alwina Oyewoleturner
Attorney Docket Number:	23278.2.US.9

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:				
Petition fee- 37 CFR 1.17(g) (Group II)	1463	1	200	200
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt

EFS ID:	18789883
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Alwina Oyewoleturner
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	17-APR-2014
Filing Date:	24-MAY-2013
Time Stamp:	12:42:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$200
RAM confirmation Number	14259
Deposit Account	201507
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Letter Requesting Suspension of Action	US9-JMMCON1-SuspensionOfAction.PDF	53957 decf15de4a0b6cd399d858c4fd263d9adf6ac982	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30310 64f06e14c60aaedae3c70d9235c936da56054f22	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	84267		

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.

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/25 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**
Application Number	13901830
Filing Date	24-May-2013
First Named Inventor	Giorgio Calderari
Attorney Docket Number	23278.2.US.9
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Helsinn Healthcare SA	50 %
Roche Palo Alto LLC	50 %

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)

14052925 filed on 10/14/2013

14070981 filed on 11/04/2013

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.

- (•) 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.

Applicant 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 36942

- ( ) 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	/Clark G. Sullivan/
Name	Clark G. Sullivan

*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:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Angelina Stantini
Attorney Docket Number:	23278.2.US.9

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.: 13901830

Filing Date: 24-May-2013

Applicant/Patent under Reexamination: Calderari et al.

Electronic Terminal Disclaimer filed on April 9, 2014

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	18717752
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Angelina Stantini
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	09-APR-2014
Filing Date:	24-MAY-2013
Time Stamp:	16:02:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$160
RAM confirmation Number	2458
Deposit Account	201507
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	35439 8a5623d4ab57724c605e96b2a2ec3a7cb85e5df1	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30144 3bba7f837d1d44aae814c6b5ff338e99a0770877	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	65583		

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
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio CALDERARI
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	1	of	2	Attorney Docket Number	244168.000007.US.9

U.S. PATENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	36	US-8,518,981	08-27-2013	Calderari et al.	
	37	US-8,598,218	12-3-2013	Calderari et al.	
	38	US-8,598,219	12-3-2013	Calderari et al.	

U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials*	Cite No.[3]	Document Number Number-Kind Code[4] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	39	US-2013/0261149	10-03-2013	Calderari et al.	
	40	US-2013/0261150	10-03-2013	Calderari et al.	
	41	US-2013/0289065	10-31-2013	Calderari et al.	
	42	US-2014/0039000	02-06-2014	Calderari et al.	
	43	US-2004/0147510	07-29-2004	Landau et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	343	February 9, 2009 Bonadeo Declaration.	
	546	Perez, et al., Comparable safety and antiemetic efficacy of a brief (30-second bolus) intravenous granisetron infusion and a standard (15-minute) intravenous ondansetron infusion in breast cancer patients receiving moderately emetogenic chemotherapy. Cancer J. Sci. Am. Vol. 4, No 1, pp. 52-8, 1998.	
	748	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, and 7,960,424, dated August 13, 2013.	
	751	Aurobindo Pharma Ltd. Paragraph IV notice regarding U.S. Patent No. 8,518,981, dated September 19, 2013.	
	752	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c), dated July 8, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated).	
	754	Sandoz Inc.'s Second Amended Invalidity Contentions Pursuant to L. Pat. R. 3.7, dated July 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	756	Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s First Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c), dated July 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	758	Opening Expert Report of Dr. Bert Spilker, dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	759	Expert Report of David G. Frame, Pharm.D., dated September 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	760	Expert Report of Lee Kirsch, Ph.D., dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	13/901,830
				Filing Date	May 24, 2013
				First Named Inventor	Giorgio CALDERARI
				Art Unit	1628
				Examiner Name	Shirley V. GEMBEH
Sheet	2	of	2	Attorney Docket Number	244168.000007.US.9

NONPATENT LITERATURE DOCUMENTS			
	761	Expert Report of Patrick P. DeLuca, Ph.D., dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	762	Expert Report of Paul Myrdal, Ph.D., dated September 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	763	Complaint for patent infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, and 8,518,981 dated September 25, 2013 (D. Del. Case No. 13-1612).	
	765	Reply Expert Report of Patrick P. DeLuca, Ph.D., dated November 22, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	766	Reply Expert Report of David G. Frame, Pharm. D., dated November 27, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	767	Reply Expert Report of Jack Geltosky, Ph.D., dated November 22, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	768	Reply Expert Report of Lee Kirsch, Ph.D., dated November 22, 2013 (D.N.J. Case No. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	769	Reply Expert Report of Paul Myrdal, Ph.D., dated November 22, 2013 (D.N.J. Case No. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).	
	770	Reply Expert Report of Dr. Bert Spilker, dated November 22, 2013 (D.N.J. Case No. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).	
	771	Accord Healthcare, Inc. Paragraph IV Letter regarding U.S. Patent No. 8,518,981 dated October 2, 2013 (portions redacted).	
	772	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent No. 8,518,981 dated October 16, 2013 (portions redacted).	
	773	Sandoz Inc. Paragraph IV Letter regarding U.S. Patent No. 8,518,981 dated December 16, 2013.	
	774	Aurobindo Pharma Ltd. Paragraph IV Letter regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated January 21, 2014 (portions redacted).	
	775	Sandoz Inc. Paragraph IV Letter regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated February 3, 2014 (portions redacted).	
	776	Bedford Laboratories division of Ben Venue Laboratories, Inc. Paragraph IV Letter regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated February 6, 2014 (portions redacted).	
	777	Defendants Aurobindo Pharma Ltd.'s and Auromedics Pharma LLC's Amended Answer, Affirmative Defenses, and Counterclaims regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219, dated February 11, 2014 (D. Del. Case No. 13-688).	
	778	Ben Venue Laboratories, Inc.'s Answer and Counterclaims to Amended Complaint regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219, dated February 24, 2014 (D. Del. Case No. 13-1612).	
	782	Complaint for Patent Infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding U.S. Patent Nos. 8,598,218 and 8,598,219 dated December 27, 2013 (D. Del. Case No. 13-2101).	
	783	Cipla Limited Paragraph IV Letter regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219 dated February 24, 2014 (portions redacted).	
	784	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Invalidity Contentions regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219 dated March 17, 2014 (D.N.J. Case No. 13-5815) (confidentiality designation and other portions redacted).	
	785	Sandoz Inc.'s Invalidity Contentions Pursuant to L. Pat. R. 3.3 and 3.6(c) regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219 dated March 17, 2014 (D.N.J. Case No. 13-5815) (confidentiality designation and other portions redacted).	
	786	Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.'s Invalidity Contentions Pursuant to L. Pat. R. 3.6(c) regarding U.S. Patent Nos. 8,518,981, 8,598,218, and 8,598,219 dated March 17, 2014 (D.N.J. Case No. 13-5815) (confidentiality designation and other portions redacted).	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Electronic Patent Application Fee Transmittal

Application Number:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Katherine Harihar
Attorney Docket Number:	23278.2.US.9

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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	18603002
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Katherine Harihar
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	27-MAR-2014
Filing Date:	24-MAY-2013
Time Stamp:	18:17:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	7162
Deposit Account	201507
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	546-Perez_1998.PDF	4219384 3a7cdbc1d79df1bf86a82ad5cd738ae847543cc0	no	7
Warnings:					
Information:					
2	Non Patent Literature	766-Frame_Reply_Expert_Report_11272013_with_redactions.PDF	2152480 f86fa91e9e7119034bb05810b47381e6c5143a86	no	17
Warnings:					
Information:					
3	Non Patent Literature	767-Geltosky_Reply_Expert_Report_11222013_with_redactions.PDF	2752901 c907d0139221d65e891a6c75ea9ce39d4b203e5b	no	15
Warnings:					
Information:					
4	Non Patent Literature	771-Accord_ParaIV_Notice_981_redacted.PDF	2728318 f28f8eabffaf065e01fe0b45a06d6a33289cb723	no	26
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
5	Non Patent Literature	772-Bedford_ParaIV_Notice_981_redacted.PDF	2889069 a0c03b9f4c9d91090c982f0ab43c1b660db15e8e	no	11
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
6	Non Patent Literature	773-Sandoz_ParaIV_Notice_981.PDF	1161012 80d0f77abab5217e7a89b506d0498b658f4742e6	no	24
Warnings:					
Information:					
7	Non Patent Literature	774-Aurobindo_ParaIV_Notice_218_219_redacted.PDF	786432 2eb3f69163fa0e53711512ef88002d35c0666506	no	15
Warnings:					
Information:					
8	Non Patent Literature	775-Sandoz_ParaIV_Notice_218_219_redacted.PDF	1754940 ec0aa555001e0b49ebb0943b506a4e6c31b001a6	no	37

Warnings:					
Information:					
9	Non Patent Literature	776-Bedford_ParaIV_Notice_218_219_redacted.PDF	6335030 636f4fc299516148ee8a3d4458094ae5416bb741	no	16
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The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
10	Non Patent Literature	777-Aurobindo_Amended_Answer_Defenses_Counterclaims_02112014.PDF	116605 868962cf84f4e44853f5f18cd58c64212049db4b	no	22
Warnings:					
Information:					
11	Non Patent Literature	778-BenVenue_Answer_Counterclaims_to_Amended_Complaint_02242014.PDF	149466 aee6427e8860e6ec2613e04aefe9cf7f51cd15eb	no	19
Warnings:					
Information:					
12	Non Patent Literature	783-Cipla_ParaIV_Notice_redacted.PDF	14918858 7f2afda3f0ab8f54a34ec825431610a102c61916	no	58
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Information:					
13	Non Patent Literature	765-DeLuca_Reply_Expert_Report_11222013_with_redactions.PDF	13475236 bb5021ad9933ca3774bc8bfdd1ab2f78abc996f5	no	39
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Information:					
14	Non Patent Literature	768-Kirsch_Reply_Expert_Report_11222013_with_redactions.PDF	420247 e467413587d20285e2b34c3e4610b8f5b072d1cd	no	38
Warnings:					
Information:					
15	Non Patent Literature	769-Myrdal_Reply_Expert_Report_11222013_with_redactions.PDF	386742 a0529c68139661148eac66bbbe5b799598d222474	no	28
Warnings:					
Information:					
16	Non Patent Literature	770-Spilker_Reply_Expert_Report_11222013_with_redactions.PDF	1299778 8a8f9dae9eadb86bda064003d083956a4e2a5c82	no	85
Warnings:					
Information:					

17	Non Patent Literature	782-Helsinn_v_Accord_complaint_12272013.PDF	118599 ba5f3cd11744310f491f70e41a4d14684db69631	no	8
Warnings:					
Information:					
18	Non Patent Literature	784-DRL_Invalidity_Contentions_13-5815_03172014_redacted.PDF	15979648 6e1670d843b194c062efd90789f7f2fd7cc8b29c	no	126
Warnings:					
Information:					
19	Non Patent Literature	785-Sandoz_Invalidity_Contentions_13-5815_03172014_redacted.PDF	16498401 8b0383ae133ccbe358e96552a45ce93409ac04a7	no	130
Warnings:					
Information:					
20	Non Patent Literature	786-Teva_Invalidity_Contentions_13-5815_03172014_redacted.PDF	15649780 fa82ea93dca6c7cd4d0f1260c5b59f7f9b18a987	no	130
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Information:					
21	Transmittal Letter	US09-PTO-IDS.PDF	86350 925f29068e82faf1a4508ebd0b9916ddb4414f7a	no	3
Warnings:					
Information:					
22	Information Disclosure Statement (IDS) Form (SB08)	US09-PTO-IDSSB08.PDF	95094 d0ee7be9d2a5915401390869 0b3a497e3f31803c	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
23	Fee Worksheet (SB06)	fee-info.pdf	30444 8a5f6fa6fef9aeb186cd87b82206e35436662a7a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	104004814		

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	Examiner: Shirley V. GEMBEH
	)	
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

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

Commissioner:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents on the attached listing. This Supplemental Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Supplemental Information Disclosure Statement is accompanied by a fee of $180.00 as specified by Section 1.17(p).

Copies of the listed nonpatent literature documents corresponding to Cite Nos. 546, 765-778, and 782-786 are enclosed. Nonpatent literature documents corresponding to Cite Nos. 343, 748, 751, 752, 754, 756, and 758-763 were cited and/or made of record in prior Application No. 13/901,437, filing date May 23, 2013, upon which Applicant relies for the benefits provided in 35 U.S.C. § 120 and accordingly, copies of those documents are not enclosed. Copies of U.S.

patents (Cite Nos. 36-38) and U.S. published patent applications (Cite Nos. 39-43) are not enclosed.

Some of the documents listed come from related pending litigations. Some of those documents are labeled with confidentiality designations (*e.g.*, "HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY"). Assignee, Helsinn Healthcare SA, has confirmed that such documents may be placed in the public record without violating any confidentiality agreement, protective order, or court order, and has given permission to place in the public record any and all documents submitted herewith. For some documents, confidentiality designations have been redacted.

Certain confidential information has been redacted from some of the documents. At least some of the redacted information includes non-zero U.S. dollar amounts. **If the Examiner believes that any of the redacted information is necessary for purposes of examination, or would like to see any of the exhibits, documents, testimony, or references cited in the documents listed, please let the undersigned know immediately so that such documents can be provided**.

There are no documents numbered 1-35, 44-342, 344-545, 547-747, 749, 750, 753, 755, 757, 764, or 779-781 associated with this Supplemental Information Disclosure Statement.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any

claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this statement, please charge the fee to Deposit Account No. 201507.

Respectfully submitted,

By:/Clark G. Sullivan/
Clark G. Sullivan
Reg. No. 36,942

Troutman Sanders LLP
Chrysler Bldg, 405 Lexington Ave
New York, NY 10174
Customer No.: 06980
Attorney Docket No. 244168.000007.US.9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1628
	)	
Application No.: 13/901,830	)	
	)	Examiner: Shirley V. GEMBEH
Filed: May 24, 2013	)	
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

AMENDMENT AND RESPONSE TO OFFICE ACTION

Commissioner of Patents
United States Patent Office
Alexandria, Virginia

TROUTMAN SANDERS
Customer Number 06980

Dear Sir:

In response to the Office Action mailed November 22, 2013, please consider the following Remarks.

A Replacement Claim Set begins on page 2.

Remarks begin on page 4.

A Terminal Disclaimer is being filed concurrently herewith.

REPLACEMENT CLAIM SET

1-9) (CANCELLED)

10) (PREVIOUSLY PRESENTED) A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of 5.0 ± 0.5, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

optionally a chelating agent; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 24 months when stored at room temperature.

11) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 10, wherein said mannitol is in an amount of 41.5 mg/mL.

12) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 10, wherein said solution further comprises a chelating agent.

13) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 12, wherein said chelating agent is EDTA.

14) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 13, wherein said EDTA is in an amount of from 0.005 mg/mL to 1.0 mg/mL.

15) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 14, wherein said EDTA is in an amount of 0.5 mg/mL.

16) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 10, wherein said solution further comprises a citrate buffer.

17) (PREVIOUSLY PRESENTED) The pharmaceutical formulation of claim 16, wherein said citrate buffer is at a concentration of 20 millimolar.

18) (PREVIOUSLY PRESENTED) A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-

induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of 5.0 ± 0.5, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

optionally a chelating agent; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 18 months when stored at room temperature.

19) (NEW) The pharmaceutical formulation of claim 18, wherein said mannitol is in an amount of 41.5 mg/mL.

20) (NEW) The pharmaceutical formulation of claim 18, wherein said solution further comprises a chelating agent.

21) (NEW) The pharmaceutical formulation of claim 20, wherein said chelating agent is EDTA.

22) (NEW) The pharmaceutical formulation of claim 21, wherein said EDTA is in an amount of from 0.005 mg/mL to 1.0 mg/mL.

23) (NEW) The pharmaceutical formulation of claim 21, wherein said EDTA is in an amount of 0.5 mg/mL.

24) (NEW) The pharmaceutical formulation of claim 18, wherein said solution further comprises a citrate buffer.

25) (NEW) The pharmaceutical formulation of claim 16, wherein said citrate buffer is at a concentration of 20 millimolar.

REMARKS

Claims 10-25 are currently pending in this application. Claims 1-9 were previously canceled without prejudice or disclaimer. Claims 10-18 were previously presented and are unamended. Claims 19-25 are newly presented. Because claims 19-25 mirror claims 11-17, but depend from claim 18 instead of claim 10, support for the new claims can be found in currently pending claims 11-17. No new matter is added by the amendment.

REJECTION UNDER 35 U.S.C. § 103

Claims 10-18 are rejected under pre-AIA[1] 35 U.S.C. § 103 as obvious over U.S. 5,202,333 to Berger et al. ("Berger") in view of Barton "Citric Buffer Calculation" (2000) ("Barton") and U.S. 6,284,749 to Castillo et al. ("Castillo"), and further in view of U.S. 5,854,270 to Gambhir ("Gambhir") as evidenced by Matsumoto et al. "Manual for Practical Pharmacy" (1989) ("Matsumoto"). Office Action at pp. 3-8.

As an initial matter, Applicants note that they have prosecuted several applications in the same family as this application. Those applications have resulted in patents directed toward pharmaceutically stable intravenous solutions of palonosetron hydrochloride, single-use unit-dose formulations of palonosetron hydrochloride, and methods of making single unit dose vials of palonosetron hydrochloride. *See, e.g.*, U.S. 7,947,724 (claiming "stable intravenous solution"); U.S. 8,598,219 (claiming "single-use, unit-dose formulation"); and U.S. 8,598,218 (claiming "method of manufacturing and terminally sterilizing").

Like the '219 patent, the current patent application claims a "single-use unit-dose formulation" of palonosetron hydrochloride. All of the claims also recite (directly or indirectly): (1) a 0.25 mg dose of palonosetron hydrochloride based on the weight of its free base; and (2) a palonosetron hydrochloride concentration of 0.05 mg/mL (*i.e.*, 0.25 mg in 5 mL). As argued

[1] Applicants respectfully submit that this case should be examined under post-AIA 35 U.S.C. § 103 because it claims priority to an application that presented a claim that has a priority date after March 16, 2013. *See also* the "AIA Status" section below. Nevertheless, Applicants do not believe that the AIA has any impact on the examination of this application based on the pending rejections.

below, Applicants respectfully submit that these features were not obvious when this invention was made, and that these features further support the patentability of the claimed invention.

A. The Rejection Fails to Consider the Invention as a Whole

Applicants disagree with the rejection firstly because the Office's primary reference, Berger, fails to suggest the claimed dose (0.25 mg), and hence, fails to account for the invention as a whole. As stated in MPEP 2142:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

The Office Action does not account for the invention as a whole because it does not properly address the dose feature recited in the claims. The Office Action addresses the 0.05 mg/mL concentration, and the obviousness of this concentration in view of Berger. In particular, the Office Action concludes that Berger renders the 0.05 mg/mL concentration obvious because Berger teaches palonosetron concentrations "from 0.000001% w to 10% weight." Office Action at p. 4. However, the claims are not limited solely to concentration; they also impose limitations on the actual dose of palonosetron hydrochloride in the formulation based on the weight of the free base (*i.e.*, 0.25 mg). The claimed invention cannot be obvious unless the formulation as a whole, including the dose, would have been obvious, which for the reasons discussed in the remainder of this paper, it clearly is not.

Importantly, the palonosetron hydrochloride dose recited in the currently pending claims was addressed previously during the prosecution of the parent continuation-in-part application,

now U.S. Patent No. 8,958,219, and was cited specifically in the Reasons for Allowance as a basis for allowing that case. That application, like the currently pending claims, included a dose limitation of 0.25 mg palonosetron hydrochloride based on the weight of its free base. As stated in the Reasons for Allowance in the parent application:

> The closest prior art Tang (Anesth Analg 1998; 87 462-467; Ref 105 on May 23, 2013) specifically teach that implications in administering palonosetron (i.e., RS-25259) was effective only at a higher dose (i.e. 30 μg/kg which is 2.1 when an average weight 70 kg of the patient is considered). This dose is far greater than that recited by the applicant. Yes Tang teaches a concentration of 3.0 ug/kg which is the closest to the dose recited, however Tang also teaches that it fails to provide or reduce the post-operative vomiting.

Like the claims in the parent application, the currently pending claims define the palonosetron hydrochloride dose in the currently claimed formulation as 0.25 mg. The Office Action has failed to account for this feature and thus, has failed to address the invention "as a whole." As a consequence, the references do not support a prima facie case of obviousness, and the rejection should be withdrawn.

B. A Worker of Ordinary Skill Would Not Have Arrived at the Claimed Concentration and Dose via "Routine Experimentation/Optimization"

Applicants also respectfully question the propriety of using "routine experimentation/optimization" as the basis for rejecting the claims. There is nothing routine about going from Berger's broad concentration and dosing ranges to the specific concentration and dose recited in the claims. This would have required an enormous amount of work, with absolutely no guarantee of success and no direction leading to the concentration and dose recited in the claims.

With respect to concentration, Berger describes a "general" concentration range spanning seven orders of magnitude (*i.e.*, "from 0.000001% w to 10.0% w"; col. 12, ll. 64-65; *see also* Office Action at p. 4), and subsequently leads the worker of ordinary skill to a preferred concentration range that spans five orders of magnitude (*i.e.*, "preferably 0.00001% w to 1.0% w"; col. 12, ll. 66-67), and eventually to a concentration range of 10-100 mg/mL in Example 13. It would have taken an enormous amount of work, and would have been practically impossible,

to go from the wide concentration ranges disclosed by Berger to the 0.05 mg/mL concentration described in the claims, especially when Berger's only exemplified intravenous concentration range in Example 13 (10-100 mg/mL) is 200-2,000 times greater than the 0.05 mg/mL concentration described in the claims. The concentration range in Example 13 would have led a worker of ordinary skill away from the claimed invention.

Berger also does not provide adequate dosing guidance to support a "routine experimentation" rejection. Applicants' claims are limited to a very specific dose of 0.25 mg. However, Berger gives a much broader range, stating in column 12, lines 11-18 that:

> [A] therapeutically effective amount for a 70 Kg human may range from 70 ng/day to 70 mg/day, preferably 700 ng/day to 7.0 mg/day.

Thus, Berger describes a general dose range spanning six orders of magnitude (*i.e.*, "from 70 ng/day to 70 mg/day"), and subsequently leads the worker of ordinary skill to a preferred dose range that spans four orders of magnitude (*i.e.*, 700 ng/day to 7.0 mg/day), and eventually to a dose range of 10-100 mg/day in Example 13. Once again, it would have taken an enormous amount of work, and would have been practically impossible, to go from Berger's large range of doses to the 0.25 mg dose recited in the claims, particularly when the 0.25 mg dose falls well below the only exemplified intravenous dose of 10-100 mg described by Example 13. Once again, Berger's Example 13 teaches away from the claimed invention.

Because of the large amount of work needed to go from Berger's broad concentration disclosure, the breadth of Berger's dosing disclosure, and because there was absolutely no guidance in Berger leading to either the claimed concentration or the claimed dose, it would have taken far more than "routine experimentation" to arrive at the claimed 0.05 mg/mL concentration and 0.25 mg dose.

The concept of "routine experimentation" can be found in the Office's KSR Examination Guidelines in its "obvious to try" discussion, which makes clear that the doctrine is very limited. As stated in the Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, published at 75 Fed. Reg. 53643, at 53654 ("Guidelines"):

> This rationale is only appropriate when there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of

> ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success.

According to this discussion, the "obvious to try" rationale is only appropriate when there are a finite number of predictable solutions. Berger's broad concentration ranges spanning five and seven orders of magnitude, and Berger's broad dose ranges spanning four and six orders of magnitude, are, for practical purposes, anything but a finite number of predictable solutions. *See* Guidelines at 53655, 53660 (citing *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.* 520 F.3d 1358 (Fed. Cir. 2008), which notes that "several" unpredictable alternatives is not a "finite number of identified, predictable solutions," and "several" is certainly far less than 10^4, 10^5, 10^6, and 10^7); *see also Wyeth and Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385 (Fed. Cir. 2013) (noting, in the context of an enablement analysis, that "having to synthesize and screen each of at least tens of thousands of candidate compounds constitutes undue experimentation.").

The MPEP elaborates further on the "obvious to try" doctrine, and gives two classes of situations in section 2143 in which it is improper to apply an "obvious to try" rationale. According to MPEP 2143, the Office should not use an obvious to try rationale to reject an application:

> (1) when what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; and
>
> (2) when what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

Both of those situations apply here. Berger, as noted, provides a "general" range of concentrations that spans seven orders of magnitude (*i.e.*, 0.000001% w to 10.0% w), involving at least 10^7 choices, and a broad range of doses that spans six orders of magnitude (*i.e.*, 70 ng/day to 70 mg/day), involving at least 10^6 choices. To be sure, Berger narrows the broad concentration range to encompass five orders of magnitude (*i.e.*, "preferably 0.00001% w to

1.0% w," col. 12, ll. 66-67), involving at least 10^5 choices, and narrows the broad dose range to encompass four orders of magnitude (*i.e.*, "preferably 700 ng/day to 7.0 mg/day"), involving at least 10^4 choices.

But to arrive at the presently claimed concentration and dose, the worker of ordinary skill would have had to try a practically infinite number of possible choices of concentrations and doses. And he or she would have faced that practically impossible task with absolutely nothing ointing her towards the presently claimed concentration of 0.05 mg/mL or the presently claimed dose of 0.25 mg. Berger's general guidance providing a range of 10^5 or 10^7 concentrations and a range of 10^4 or 10^6 doses is no reasonable guidance at all.

The Federal Circuit has made clear that when the worker of ordinary skill would have merely been "throwing metaphorical darts at a board in hopes of arriving at a successful result," an invention is not obvious. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1071 (Fed. Cir. 2012) (internal citations omitted). This rejection falls precisely within that situation, where the Office's primary reference gives an immense number of possible choices spanning at least 10^5 or 10^7 concentrations and 10^4 or 10^6 doses, and is totally devoid of any direction to arrive at the presently claimed concentration of 0.05 mg/mL or the presently claimed dose of 0.25 mg.

The secondary references cited by the Office fail to cure Berger's deficiency; none of those references even deals with palonosetron hydrochloride, much less indicates to the worker of ordinary skill any direction within Berger's broad concentration ranges that span 10^5 and 10^7 orders of magnitude or Berger's broad dose ranges that span 10^4 and 10^6 orders of magnitude.

C. A Species/Genus Theory of Obviousness Does Not Apply to the Claims

The fact that the claimed concentration of 0.05 mg/mL and the claimed dose of 0.25 mg (both species) are encompassed by Berger's broad genera of 10^5 and 10^7 concentrations and 10^4 and 10^6 doses is not sufficient by itself to establish a *prima facie* case of obviousness. *See* M.P.E.P. § 2144.08. The Office must establish that the worker of ordinary skill would have been motivated to select the claimed concentration and dose from Berger's broad disclosure. *Id.* The factors that must be considered include, for example:

(a) The size of the genus: Berger's genera are enormously broad, encompassing a range of concentrations spanning seven orders of magnitude (*i.e.*, 10^7 % w and at least 10^7 choices) and a range of doses spanning six orders of magnitude (*i.e.*, 70 ng/day to 70 mg/day). Col. 12, ll. 16-18 and 64-65.

(b) Any "preferred" species or subgenus: in addition to those broad genera, Berger also recites a slightly smaller, but still practically infinite, range of concentrations spanning five orders of magnitude (*i.e.*, "preferably 0.00001% w to 1.0% w"), and a slightly smaller, but still practically infinite, range of doses spanning four orders of magnitude (*i.e.*, "preferably 700 mg/day to 7.0 mg/day"). Col. 12, ll. 18 and 64-67.

(c) Any other express teachings: Berger exemplifies a single representative intravenous formulation, itself having a range of concentrations of active ingredients spanning 1% w to 10% w and a range of doses spanning 10 mg to 100 mg (*i.e.*, "10-100 mg" in "1 mL"). Example 13, col. 29, ll. 1-13. That example, of course, moves in an opposite direction within Berger's broad concentration and dose ranges compared to the much LOWER claimed concentration of 0.05 mg/mL and the much LOWER claimed dose of 0.25 mg.

(d) The significance of the differences between the prior art and the claimed invention: The differences between Berger's disclosure and the claimed invention are significant. For example:

First, Berger's general range of concentrations spans at least 10^7 possibilities, and Berger's preferred range spans at least 10^5 possibilities. Similarly, Berger's general range of doses spans at least 10^6 possibilities, and Berger's preferred range spans at least 10^4 possibilities. In contrast, the present claims recite a single concentration of 0.05 mg/mL and a single dose of 0.25 mg. Thus, Berger's disclosed ranges, which span 10^5 and 10^7 concentrations and 10^4 and 10^6 doses, are infinitely broader, from a practical point of view, than the claimed specific concentration.

Second, Berger only exemplifies one intravenous formulation, and that formulation is disclosed as having a range of concentrations spanning 10 to 100 mg/mL and a range of doses spanning 10 to 100 mg. *See* Example 13, col. 29, ll. 1-13. Thus, Berger, as illustrated immediately below, points the worker of ordinary skill to concentrations that are approximately

200-2000 times higher than the claimed concentration, and to doses that are 40-400 times higher than the claimed dose:

> (1) "In general, the final composition will comprise from 0.000001% w to 10% w" (col. 12, ll. 64-65); and
>
> "a therapeutically effective amount for a 70 Kg human may range from 70 ng/day to 70 mg/day" (col. 12, ll. 16-18).
>
> ↓
>
> (2) "preferably 0.00001% w to 1.0% w" (col. 12, ll. 66-67); and
>
> "preferably 700 ng/day to 7.0 mg/day" (col. 12, ln. 18).
>
> ↓
>
> (3) only exemplified composition for intravenous administration: 1% w to 10% w concentrations and 10 mg to 100 mg doses (i.e., 10-100 mg in 1 mL) (Example 13).

As is well established, "[e]vidence that others were 'going in different ways' is strong evidence that the [inventor's] way would not have been obvious." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012) (citing *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985), which M.P.E.P. § 2144.08 cites with approval for other reasons).

In fact, the Office has already correctly recognized that Berger directs toward concentrations of 10 to 100 mg/mL and thus would have led the worker of ordinary skill away from using the claimed concentration of 0.05 mg/mL in intravenous formulations. *See* Application No. 13/901,437 (now U.S. Patent No. 8,598,219). In the Interview Summary for that application, the Office stated, in distinguishing the 0.25 mg/5 mL (*i.e.*, 0.05 mg/mL) palonosetron hydrochloride concentration recited in those claims, that Berger describes "high concentrations." The Office supported that conclusion by referencing Berger's Example 13,

which, as noted above, describes concentrations (10 to 100 mg/mL) that are 200-2000 times higher than the currently claimed 0.05 mg/mL concentration:

> This is commensurate with the low concentration described in the claims (0.25 mg/5 mL) relative to the high concentrations described in the prior art (Berger 5,202,3[3]3, Example 13).

The Office's own rationale in that case was that nothing in Berger suggests moving within Berger's broad range of concentrations, from the high concentrations exemplified in Example 13 to the low claimed concentrations. Rather, the Office's rationale indicates that Berger's high concentrations, such as those specifically exemplified (*i.e.,* 10 mg/mL and 100 mg/mL), would have moved the worker of ordinary skill away from the lower concentrations encompassed within Berger's vast range of general concentrations (and hence also away from concentrations such as the presently claimed concentration of 0.05 mg/mL), and towards far higher concentrations.

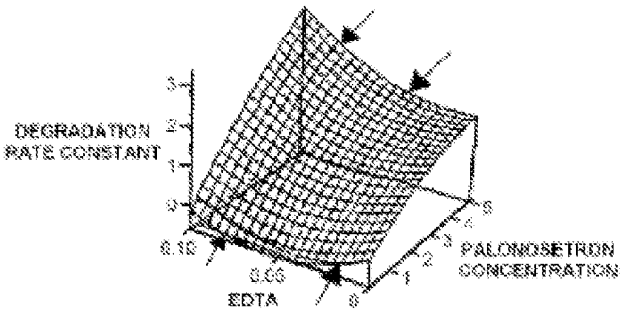
There is thus no rationale of record that would have motivated the worker of ordinary skill to decrease Berger's exemplified range of high concentrations for intravenous formulations and thereby obtain the presently claimed concentration. Rather, as the Office has acknowledged, Berger would have led away from the presently claimed 0.05 mg/mL.

(e) The unpredictability of the technology: stability of formulations comprising palonosetron hydrochloride in the presently claimed concentration was unpredictable. For example:

As discussed in Example 2 of the instant specification, a formulation optimization study was performed using experimental design software. Twenty-four lots of drug product were analyzed to investigate, *inter alia*, the appropriate concentration ranges for palonosetron hydrochloride.

The results of that study indicated that palonosetron hydrochloride concentration was a critical factor in chemical stability, "with greatest stability seen at the lowest palonosetron hydrochloride concentrations." As-filed specification at p. 13, ll. 18-20; *see also* the '351 priority application at p. 11, ll. 22-24.

A visual representation of that discovery is depicted in the following graph, which is adapted from a Figure of the Declaration of Daniele Bonadeo dated February 9, 2009 (of record):



As can be seen from this Figure, Applicants unexpectedly discovered that as the concentration of palonosetron hydrochloride decreases from 5 mg/mL toward the presently claimed concentration, the palonosetron degradation rate decreases (follow the line on the right-hand side of the figure from back to front). *See also* Supplemental Declaration of Daniele Bonadeo (of record) at Exhibit 2 (demonstrating chemical instability of palonosetron hydrochloride at 10 mg/mL, which is the lower end of Berger's Example 13 range of concentrations).

This stability of formulations comprising different concentrations of palonosetron hydrochloride was unpredictable. Indeed, Berger provided no reason to expect improved stability by lowering the palonosetron hydrochloride concentration. Thus, the unexpected stability of compositions comprising palonosetron hydrochloride at the presently claimed concentration of 0.05 mg/mL could not have been reasonably predicted based on Berger's teachings.

For all these reasons, Applicants respectfully submit that the obviousness rejection should be withdrawn.

OBVIOUSNESS TYPE DOUBLE PATENTING

The Office Action also rejects the pending claims based on obviousness-type double patenting over co-pending Application No. 14/052,925. Solely to advance prosecution of this application, Applicants submit herewith an additional Terminal Disclaimer over this application to obviate any putative double patenting issues. See M.P.E.P. § 804.02 ("The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of

the propriety of the rejection." (citing Quad Envtl. Techss Corp. v. Union Sanitary Dist., 946 F.2d 870 (Fed. Cir. 1991)).)

PATENTABLE WEIGHT OF INTENDED PURPOSE LIMITATION

The Office contends "the limitations to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting and is stable for 24 months and 18 months is given no patentable weight" for the reasons expressed in the Office Action at page 8, which are of record and will not be repeated here. Applicants respectfully disagree and do not admit the point. But, in view of the above explanation, the point is irrelevant to allowance.

AIA STATUS

Applicants note that the Application Data page for this application in the USPTO's PAIR database designates the "AIA (First Inventor to File)" status of this application as "No." Similarly, Item 1 on page 2 of the Office Action states that "[t]he present application is being examined under the pre-AIA first to invent provisions." Applicants respectfully submit that the USPTO's designation of this application as a pre-AIA application is in error.

As indicated on the Application Data Sheet, and as discussed in the Preliminary Amendment and Choice of Law document, both filed May 23, 2013, this application falls under transition provisions 3(n)(1)[2] and 3(n)(2)[3] of the America Invents Act (AIA) because claims 10-

[2] SEC. 3(n)(1): "Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act *[i.e., March 16, 2013]*, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time— (A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph *[i.e., March 16, 2013]*; or (B) a specific reference under section 120, 121, 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such claim." (Commentary added for emphasis.)

[3] SEC. 3(n)(2): "The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection *[i.e., March 15, 2013]*, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent

18 have an effective filing date ("EFD") prior to March 16, 2013, and the parent CIP application contained a claim (original claim 9) that found support under 35 U.S.C. § 112 only in Example 8, which was newly added to the parent continuation-in-part application. Thus, claim 9 had an EFD after March 15, 2013.

In other words, this application is popularly referenced as a Jedi Master Mixer (JMM). The Examiner expressly acknowledged that phrase in the Interview Summary of June 13, 2013 in Application No. 13,087: "Applicant explained why there is no on sale bar also discussed 6 other pending applications, 4 of which are JMM. According to the USPTP POSITION THE ALLEGED ON SALE BARS DO NOT APPLY TO THE JMM applications.. For disclosure JMM means Jedi Master Mixer."

For that reason, all of claims 10-18 should, for prior art purposes, be examined only through the lenses of AIA §§ 102(a)(1), (a)(2), and 103, as well as pre-AIA § 102(g). That point is clearly explained by the USPTO:

> If an application (1) contains or contained at any time a claimed invention having an effective filing date that is before March 16, 2013, or ever claimed a right of priority or the benefit of an earlier filing date under 35 U.S.C. 119, 120, 121, or 365 based upon an earlier application that ever contained a claimed invention having an effective filing date that is before March 16, 2013 *[such as claims 10-18]*, and (2) also contains or contained at any time any claimed invention having an effective filing date that is on or after March 16, 2013, or ever claimed a right of priority or the benefit of an earlier filing date under 35 U.S.C. 119, 120, 121, or 365 based upon an earlier application that ever contained a claimed invention having an effective filing date that is on or after March 16, 2013 *[here that is original claim 9 of the parent CIP]*, then AIA 35 U.S.C. 102 and 103 apply to the application, and each claimed invention in the application is also subject to pre-AIA 35 U.S.C. 102(g).

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contains or contained at any time— (A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection *[i.e., March 16, 2013]*; or (B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim." (Commentary added for emphasis.)

See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,072 (February 14, 2013) (commentary and bold added for emphasis).

Accordingly, Applicants respectfully submit that this application should not be examined solely through the lens of the pre-AIA first to invent provisions, as indicated in the Office Action. Instead, as explained above, this application should be examined solely under the prior art provisions of AIA §§ 102(a)(1), (a)(2), and 103, as well as pre-AIA § 102(g). Applicants respectfully request that the Office acknowledge the applicable law for this application in the next Office Action or in Statement of Reasons for Allowance, and change the "AIA (First Inventor to File)" status of this application in the USPTO's PAIR database to "Yes."

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. Should the Examiner disagree or have any questions regarding this submission, the Applicants invite the Examiner to call the undersigned at 212.704.6105.

Dated: February 21, 2014

Respectfully submitted,

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Electronic Acknowledgement Receipt

EFS ID:	18268653
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Angelina Stantini
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	21-FEB-2014
Filing Date:	24-MAY-2013
Time Stamp:	15:51:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		US9-Amendment-Response-TerminalDisclaimer.PDF	178262 7f2a62e977b2ef76b411fe920f9864fde358ec89	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	16
Warnings:			
Information:			
	Total Files Size (in bytes):	178262	

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.

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/25 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**
Application Number	13901830
Filing Date	24-May-2013
First Named Inventor	Giorgio Calderari
Attorney Docket Number	23278.2.US.9
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
ROCHE PALO ALTO LLC	50 %
HELSINN HEALTHCARE SA	50 %

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)

14052925 filed on 10/14/2013

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.

- (•) 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.

Applicant 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 36942

- ( ) 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	/Clark G. Sullivan/
Name	Clark G. Sullivan

*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:	13901830
Filing Date:	24-May-2013
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Angelina Stantini
Attorney Docket Number:	23278.2.US.9

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.: 13901830

Filing Date: 24-May-2013

Applicant/Patent under Reexamination: Calderari et al.

Electronic Terminal Disclaimer filed on February 21, 2014

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	18268759
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Angelina Stantini
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	21-FEB-2014
Filing Date:	24-MAY-2013
Time Stamp:	15:56:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$160
RAM confirmation Number	2530
Deposit Account	201507
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	34657 3945266617b64189fb636f93391603851d030f67	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30145 a2e120e5dd886b625a695a766c3b530e698e41d1	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	64802		

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/901,830	Filing Date 05/24/2013	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	02/21/2014	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 15	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						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 number found in the appropriate box in column 1.

LIE
/CHERYL CLARK/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	23278.2.US.9	3806

53449 7590 11/22/2013

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1628	

NOTIFICATION DATE	DELIVERY MODE
11/22/2013	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):

patents@agg.com

Office Action Summary	Application No. 13/901,830	Applicant(s) CALDERARI ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1628	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/24/13*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *10-18* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *10-18* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, 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/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/13*.

3) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/7/13* .

4) ☐ Other: _____.

DETAILED ACTION

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

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 5/24/13 is acknowledged and has been reviewed.

Double patenting Rejection

3. Examiner acknowledges the filing of the terminal disclaimers.

Claim Rejections - 35 USC § 103

4. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 10-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US 5,202,333) in view of Barton (Citrate Buffer Calculation, 2000,

2pgs and Castillo et al., US 6,284,749 further in view of Gambhir, US 5,854,270 and as evidenced by Matsumoto (All references have already been made of record).

Berger et al. teaches a pharmaceutical solution for reducing emesis, comprising palonosetron in a pharmaceutical acceptable carrier. See col. 2, lines 20 to 25 and col. 12, lines 41-52 and col. 3, lines 17-21). Palonosetron is (as shown) is represented by formula I, at col. 8, lines 35 to 40). The reference also discloses that the pharmaceutically acceptable salt is hydrochloride and can be in an injectable form (see col. 12, lines 25-29).. See col. 5, lines 2-3. With regard to the concentration palonosetron, the reference discloses the concentration is from 0.000001% w to 10% weight. Interpreting that assuming 100 % is 100 ml, therefore in 1 ml (1000 mg) the equivalent of 0.03mg/ml is 0.00003 wt % which is within the disclosed range, see col. 12, lines 65-67 (claims 10) in a preferred single unit dosage form (see col. 13, lines 1-5). Berger also teaches the addition of citric acid buffer (see col. 28, lines 62-67, as required by instant claim 16)

However Berger fails to teach that the composition comprises mannitol (from 10 – 80 mg/ml) and EDTA (from 0.005-1.0 mg/ml) wherein the formulation is stable for 24 months in a 5 ml sterile aqueous solution (as required by instant claims 12-15)

Barton is introduced for the teaching of the use of buffers in solution therefore in order to buffer solution that that is close to the desired ranges. In the instant claim the pH is 4-6, the pK's used for citric acid are 3.15, 4.50 and 5.75, therefor it is best to buffer at a pH close to one of the pK's, therefore use citrate buffers only in the pH range 3-6, since the required pH is from 4.0-6.0 (claim 4). Additionally Barton

teaches buffers are used to adjust the pH of liquid drugs to keep the solubility and chemical stability and to decrease the irritation of the drugs. Thus the concentration of the citric acid will depend on the buffering condition of the solution.

Castillo et al. teach the most preferred chelating agent in pharmaceuticals composition is EDTA. The chelating agents can be added to pharmaceutical compositions in the form of a pharmaceutically acceptable salt. For example, EDTA may be added in the form of edetate disodium. In general, the amount of chelating agent present in the compositions is from about 0.001 to about 1%, preferably about 0.01 to about 0.2%, and most preferably about 0.01 to about 0.1%, which is within the claimed concentration in instant claim 7. See col. 3, lines 1-16. Therefore it would have been obvious to one of ordinary skill in the art to substitute citric acid for EDTA as the chelating agent since substituting one for another will have the same effect, stabilizing the formulation. Castillo teaches unit dose of their composition in the range of 1- 15 ml (see col. 4, lines 65-67). Thus it would have been obvious to one of ordinary skill in the art to formulate the unit dose formulation in 5 ml as required by the instant claim. Additionally Berger specifically teach that their formulations can be in a preferred unit dosage form, therefore, since the concentration can be at the dosage range/ml thus can be formulated in any amount as a single dosage use with a reasonable expectation of success.

Gambhir et al. teach that the liquid composition for oral administration comprises ondansetron and a sweetener wherein the sweetener comprises one or more polyhydric

alcohol (see column 2 lines 11-16). Column 2 line 40 of Gambhir lists mannitol as one species of polyhydric alcohol for use in the invention.

Gambhir further teaches (column 2 lines 44-48) that the total polyhydric alcohol content of the liquid composition conveniently lies in the range of 20 to 85% weight by volume. Gambhir discloses a liquid composition for oral administration comprising another 5HT3 receptor antagonist, ondansetron, wherein the pH of the composition lies in the range of 2.0 to 5.0 (see column 2 lines 11-16 and abstract as required by instant claim 6). The composition disclosed in Gambhir is also generally used to treat emesis regardless of the cause (see column 4 lines 23-26). Therefore it would be obvious to an ordinary skilled artisan to formulate the composition of Berger et al. at a pH of about 2.0 to 5.0 which overlaps with the ranges of pH claimed in the instant application since palonosetron and ondansetron (claim 1 of Gambhir) have similar structures that both block 5HT3 receptors and have the same utility of treating emesis.

It would have been obvious to one of ordinary skill in the art to have used the teaching of Berger et al. administer the 5-HT3 receptor antagonist -palonosetron for the treatment of emesis because the reference teaches palonosetron is used in treating emesis.

Also, it would have been obvious to one of ordinary skill in the art to substitute glucose (Berger's reference) to mannitol because absent factual evidence mannose is identical to glucose except for the orientation of the H and OH on carbon 2. Therefore one of ordinary skill in the art would be motivated to substitute glucose for mannose or vis--versa and would expect the same result. Although, the reference do not teach

EDTA, it is known in the art that EDTA is a chelating agent, one of ordinary skill in the art would have been motivated to use the teaching of Castillo et al. add a concentration of EDTA that will be capable of stabilizing the solution, therefore, one of ordinary skill in the art would be motivated to add a carrier salt of EDTA to a pharmaceutical solution for stability and its antioxidant action as taught (see above discussion). Optimization of the concentration is within the purview of one of ordinary skill in the art, since it is known that these salts aid in stability one of ordinary skill in the art would be motivated to optimize and use the range or concentration that will s prolong stability.

One of ordinary skill in the art would be motivated to use citric acid in buffering a solution to obtain the a pH of 4.0-6.0 because the art teaches its best to buffer at a pH close to one of the pK's, so use citrate buffers only in the pH range 3-6. See underlining. Based on the teaching it is well within the level of one of ordinary skill in the art to incorporate citrate buffer to a pharmaceutical composition having the pH in the range of 4-6 because it is known in the art.

With regards to a single unit dosage form, although Berger did not per say teach a single dosage form, nonetheless Berger specifically teach that the amount of Palonosetron may vary widely depending upon the type of formulation, size of the unit dosage etc., therefore based on Berger's teaching alone, it would have been obvious to one of ordinary skill in the art to have formulated a single, unit dosage form having a volume of 5 ml comprising 0.05 mg/ml with a reasonable expectation of success because Berger makes it obvious to do so (see col. 12, lines 60-68).

As to the limitations to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting and is stable for 24 months and 18 months is given no patentable weight because the claimed structure is already known. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir.1997). While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *Id.* at 1477-78; *see also Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1468 (Fed. Cir. 1990). "[A]pparatus claims cover what a device is, not what a device does."

Therefore the claim invention is prima facie obvious at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 56-58 of US patent application 14/052,925.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Bothe application recites the same pharmaceutical composition comprising the same agents for reducing emesis and is stable for 18 to 245 months.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. 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.

/SHIRLEY V GEMBEH/
Primary Examiner, Art Unit 1628
11/8/13

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/901,830	CALDERARI ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

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

(1) *SHIRLEY V. GEMBEH*. (3)_____.

(2) _____. (4)_____.

Date of Interview: _____.

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: _____.

Identification of prior art discussed: _____.

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 recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the 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

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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U.S. PATENTS

Examiner Initials	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,272,137	12-00-1993	Blase et al.	
	2	US-4,695,578	09-22-1987	Coates et al.	
	3	US-4,753,789	06-28-1988	Tyers et al.	
	4	US-4,886,808	12-12-1989	King	
	5	US-4,906,755	03-06-1990	Gittos	
	6	US-4,929,632	05-29-1990	Tyers et al.	
	7	US-4,937,247	06-26-1990	King	
	8	US-5,011,846	04-30-1991	Gittos et al.	
	9	US-5,034,398	07-23-1991	King	
	10	US-5,240,954	08-31-1993	Tyers et al.	
	11	US-5,344,658	09-06-1994	Collin	
	12	US-5,578,628	11-26-1996	Tyers et al.	
	13	US-5,578,632	11-26-1996	Tyers et al.	
	14	US-5,622,720	04-22-1997	Collin	
	15	US-5,922,749	07-13-1997	Tyers et al.	
	16	US-5,955,488	09-21-1999	Winterborn	
	17	US-6,063,802	05-16-2000	Winterborn	
	18	US-6,294,548	09-25-2001	James	
	19	US-5,854,270	12-29-1998	Gambhir	
	20	US-5,202,333	04-13-1993	Berger et al.	
	21	US-6,287,592	09-11-2001	Dickinson	
	22	US-6,284,749	09-04-2001	Castillo et al.	
	23	US-6,132,758	10-17-2000	Farah J. Munayyer et al. (Schering Corporation)	
	24	US-6,699,852	03-02-2004	Albert Robichaud (Bristol-Myers Squibb Pharma Co.)	
	25	US-7,109,339	09-19-2006	Tackyu Lee et al. (Bristol-Myers Squibb Company)	
	26	US-7,947,724	05-14-2011	Giorgio Calderari, et al.	
	27	US-7,947,725	05-14-2011	Giorgio Calderari et al.	
	28	US-7,960,424	06-14-2011	Giorgio Calderari et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials*	Cite No.[3]	Document Number Number-Kind Code[4] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	29	US-20010020029	09-06-2001	James	
	30	US-20030095926	05-22-2003	Dugger, III	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]
	31	WO-2004067005	08-12-2004	Helsinn Healthcare S.A.		
	32	WO-2003100091	12-04-2003	Brockmöller		
	33	WO-2004703714	09-02-2004	Helsinn Healthcare S.A.		
	34	WO-2004045615	06-03-2004	Helsinn Healthcare S.A.		
	35	EP-0 512 400 A1	04-29-1992	Hallinan, E. Ann (G.D. Searle & Co.)		

NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	100	R. M. Eglen et al., "Pharmacological characterization of RS 25259-197, a novel and selective 5-HT3 receptor antagonist, in vivo," Br. J Pharmacology 114:860-866 (1995)	
	101	Chelly, Jacques et al., Oral RS-25259 Prevents Postoperative Nausea and Vomiting Following Laparoscopic Surgery, Anesthesiology, 1996, Vol., 85, No. 3A, p. A21	
	102	Sorbe, Bengt, 5-HT-3 Receptor Antagonists as Antiemetic Agents in Cancer Chemotherapy, extracted from Expert Opinion on Investigational Drugs, 1996, vol. 5 no. 4, pp. 389-407	
	103	Gaster, Laramie M. and King, Frank D., Serotonin 5-HT3 and 5-HT4 Receptor Antagonists, extracted from Medicinal Research Reviews, 1997 vol. 17, no. 2, pp. 163-214	
	104	Tang, Jun et al., "Efficacy of RS-25259, a Novel 5-HT3 Antagonist, In the Prevention of Postoperative Nausea and Vomiting after Major Gynecologic Surgery," Anesthesiology, 1997, vol. 85, No. 3 suppl. p. A329	
	105	Tang, Jun et al., The Efficacy of RS-25259, a Long-Acting Selective 5-HT3 Receptor Antagonist, for Preventing Postoperative Nausea and Vomiting After Hysterectomy Procedures, Anesthesia and Analgesia, 1998, vol. 87, pp. 462-467	
	106	Adis R&D Profile, Palonosetron RS 25259 197, Drugs in R&D, October 1999, vol. 2, no. 4, pp. 251-252	
	107	Piraccini Gaia et al., An Interesting 5-HT3 Receptor Antagonist Antiemetic for Patients Undergoing Chemotheraphy-based Conditioning Regimens," Blood, Nov. 16, 2001, vol. 98, no. 11, part 2, p. 350b, abstract no. 5169	
	108	Stacher, Georg, Palonosetron Helsinn, Current Opinion in Investigational Drugs. October 2002, vol. 3, no. 10, pp. 1502-7	
	109	Navari, Rudolph M., Pathogenesis-Based Treatment of Chemotherapy-Induced Nausea and Vomiting - Two New Agents, Journal of Supportive Oncology, 2003, vol. 1(2), pp. 89-103	
	110	Chaitow, 1990, 3 pages	
	111	Opposition Brief filed by Dr. Reddy's Laboratories (UK) Limited, opposition to European Patent No. 1601359 B1 dated July 7, 2009	
	112	Photolytic and oxidative degradation of an antiemetic agent, RG 12915 (Won C. M. et al., International Journal of Pharmaceutics 121, 95-105 (1995)	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.G./

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	113	Palonosetron: a phase II dose ranging study to assess over a 7 day period the single dose pharmacokinetic profile of palonosetron in patients receiving highly emetogenic chemotherapy. Piraccini et al., Proc. Am. Soc. Clin. Oncol 2002 21 Abs 449 (2002)	
	114	Formulation and administration techniques to minimize injection pain and tissue damage associated with parenteral products. Larry A. Gatlin and Carol A. Brister Gatlin, from Injectable Drug Development: Techniques to Reduce Pain and Irritation (Edited by Pramod K. Gupta and Gayle A. Brazeau; published by Informa Health Care) 1999; ISBN 1574910957, 9781574910957, p. 401-421	
	115	Parenteral Dosage Forms. Joanne Broadhead, from Part 11-Early drug development, pharmaceutical preformulation and formulation: a practice guide from candidate drug selection to commercial dosage form (Edited by Mark Gibson; Published by Interpharma Press, 2001; ISBN 1574911201, 9781574911206), p. 331-353	
	116	Opposition Brief filed by Tecnimede Sociedade Tecnico-Medicinal S.A. in opposition to European Patent No. 1601359 B1, July 8, 2009	
	117	Response brief filed by Helsinn Healthcare S.A. dated July 13, 2007, in response to the communication pursuant to Art. 96(2) EPC of 3 January 2007 regarding Serial Number 04 706 657.6-2123	
	118	European Patent Office official communication dated July 19, 2006, regarding Serial No. 04 706 657.6	
	119	Response of Helsinn Healthcare S.A. dated November 29, 2006, regarding EPO official communication date July 19, 2006	
	120	Lachman et al., The Theory and Practice of Industrial Pharmacy, 1986, third edition, pp. 652-784	
	121	Declaration of Valentino J. Stella, Ph.D. dated September 19, 2007	
	122	Opposition Brief filed by Martin Paul White, opposition to European Patent No. 1601359 B1, July 8, 2009	
	123	Wong et al. (1995), in British Journal of Pharmacology, volume 114, pages 851-859	
	124	Cover page and pages 642-644 and 783-784 of The Theory and Practice of Industrial Pharmacy, Third Edition, Lea and Febiger (1986)	
	125	Cover page and pages 514-515 of Modern Pharmaceutics, Second Edition, Marcel Dekker (1990)	
	126	Cover page and pages 142-143 of Pharmaceutical Dosage Forms: Parenteral Medications Volume 1, Second Edition, Marcel Dekker (1992)	
	127	Mitsuo Matsumoto et al., "Yakuzaigaku Manual", 1st edition, Nanzando Co., Ltd. (1989) 2 pages	
	128	Michael J. Pikal, "Freeze Drying", Encyclopedia of Pharmaceutical Technology, Third Edition, January 2007, Pages 1824-1825, Volume 3, Informa Pharmaceuticals and Healthcare	
	129	Daniele Bonadeo, "Supplemental Declaration of Daniele Bonadeo Under 37 C.F.R. 1.132", filed in U.S. Patent Application Serial No. 11/388,270, June 8, 2009	
	130	Kranke et al., 2007 "Recent advances, trends, and economic considerations in..." Expert Opinion Pharmacotherp., 8(18): 3217-3235	
	131	Morrow et al., 1995, "Progress in reducing nausea and emesis: Comparisons of ondansetron, granisetron, and tropisetron." Cancer, Volume 76, No. 3 pages 343-357.	
	132	USPTO Notice of Allowance and Fees Due, USSN 11/388,270, Filing Date 03/24/2006, Date Mailed 01/26/2010	
	133	USPTO Office Action, USSN 11/129,839, Date Mailed 01/15/2010	
	134	Israili, Zafar H., "Clinical Pharmacology of Serotonin Receptor Type (5-HT3) Antagonists," Curr. Med. Chem. Central Nervous System Agents, 2001:1, 171-199	
	135	Barton (Citrate Buffer Calculation) 2000, 2 pages	
	136	USPTO Office Action, USSN 11/201,035, Date Mailed 08/19/2009	
	137	Response of Helsinn Healthcare to opposition of EP Serial No. 04 706 657.6, dated February 11, 2010	
	138	Annex 1 (Statement of Walso Mossi, Ph.D.) to Response of Helsinn Healthcare to Opposition of EP Serial No. 04 706 657.6 dated February 11, 2010	

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	139	Annex 2 to Response of Helsinn Healthcare to Opposition of EP Serial No. 04 706 657.6 dated February 11, 2010	
	140	Annex 3 to Response of Helsinn Healthcare to Opposition of EP Serial No. 04 706 657.6 dated February 11, 2010	
	200	Summary of Product Characteristics for Aloxi 250 (2009)	
	201	Scientific Discussion from the European Public Assessment Report for Aloxi (Palonoseteron Hydrochloride) 2006	
	202	6th Edition, Handbook of Pharmaceutical Excipients (2009), pp. 247-250 (RPS Publishing)	
	203	Lewis, Gareth A (2006) 'Optimization Methods,' Encyclopedia of Pharmaceutical Technology, 1:1, 2452-2467	
	204	May 24, 2011 Para. IV notice from Teva Pharmaceuticals re '724 and '725 patents	
	205	May 24, 2011 Para. IV notice from Sandoz re '724 and '725 patents	
	206	May 24, 2011 Para. IV notice from Dr. Reddy's re '724 and '725 patents	
	207	Aug. 9, 2011 Para. IV notice from Dr. Reddy's re '424 patent	
	208	Aug. 19, 2011 Para. IV notice from Teva Pharmaceuticals re '424 patent	
	209	Sept. 22, 2011 Para. IV notice from Sandoz re '724, '725 and '424 patents	
	210	July 8, 2011 Complaint for patent infringement (D. N.J. case No. 11-03962)	
	211	Sept. 23, 2011 Complaint for patent infringement (D. N.J. case No. 11-5579)	
	212	August 31, 2011 Answer and counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (D. N.J. case No. 11-03962)	
	213	Sept. 13, 2011 Sandoz Inc.'s answer to complaint for patent infringement and counterclaims (D. N.J. case No. 11-03962)	
	214	Sept. 13, 2011 Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.'s answer (D. N.J. case No. 11-03962)	
	215	Oct. 5, 2011 Plaintiff's reply to answer and counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy Laboratories, Inc. (D. N.J. case No. 11-03962)	
	216	Oct. 21, 2011 Plaintiff's reply to Sandoz Inc.'s answer to complaint for patent infringement and counterclaims (D. N.J. case No. 11-03962)	
	217	Oct. 24, 2011 Answer and counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (D. N.J. case No. 11-5579)	
	218	Oct. 24, 2011 Sandoz Inc.'s answer to complaint for patent infringement and counterclaims (D. N.J. case No. 11-5579)	
	219	Oct. 27, 2011 Order consolidating the two cases (D. N.J. case No. 11-5579)	
	220	Nov. 17, 2011 Plaintiffs' reply to answer and counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (D. N.J. case No. 11-03962)	
	221	Nov. 17, 2011 Plaintiffs' reply to Sandoz Inc.'s answer to complaint for patent infringement and counterclaims (D. N.J. case No. 11-03962)	
	222	Dec. 5, 2011 Teva Pharmaceuticals USA Inc. and Teva Pharmaceuticals Industries Ltd.'s answer to complaint for patent infringement of the '424 patent (D. N.J. case No. 11-03962)	
	223	May 21, 2012 Defendants' opening claim construction brief (including exhibits 1-31)	
	224	May 21, 2012 Plaintiffs' opening claim construction brief (including exhibits 1-15)	

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	225	July 20, 2012 Defendants' responsive claim construction brief (including exhibits 1-3)	
	226	July 20, 2012 Plaintiffs' responsive claim construction brief (including Exhibits A and B)	
	227	Sept. 7, 2012 Court transcript from September 7, 2012 Markman hearing and Plaintiffs' PowerPoint presentation (D. N.J. case No. 11-03962)	
	228	Dec. 1, 2011 Sandoz Inc.'s invalidity contentions pursuant to L. Pat. R. 3.6(c) (D. N.J. case No. 11-03962)	
	229	Dec. 1, 2011 Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s invalidity contentions, pursuant to L. Pat. R. 3.6(c)(D. N.J. case No. 11-03962)	
	230	Dec. 1, 2011 Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s invalidity contentions pursuant to L. Pat. R. 3.6(c) (D. N.J. case No. 11-03962)	
	231	Jan. 31, 2012 Plaintiff's responses to defendants' invalidity contentions (D. N.J. case No. 11-03962)	
	232	Sept. 25, 2012 Sandoz Inc.'s first amended invalidity contentions pursuant to L. Pat. R. 3.6(c) (D. N.J. case No. 11-03962)	
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	234	L.G. Wade Jr., Organic Chemistry, Ch. 19: Amines, pp. 867-936 (Prentice Hall 3d ed. 1995)	
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	239	L.A. Trissel, Drug Stability and Compatibility Issues, Handbook on Injectable Drugs, pp. XI-XVI (ASHP 7th ed. 1992)	
	240	J. Broadhead, Parenteral Dosage Forms, Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form, Ch. 9, pp. 331-54 (Gibson ed., CRC Press 1st ed. 2001)	
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	242	ZOFRAN®, in The Physician's Desk Reference, op. 1503-07 (5th ed. 2001)	
	243	ANZEMET®, in The Physician's Desk Reference, pp. 680-83 (5th ed. 2001)	
	244	KYTRIL®, in The Physician's Desk Reference, pp. 3104-06 (5th ed. 2001)	
	245	L.A. Trissel, Ondansetron HCl, in Handbook on Injectable Drugs, pp. 683-88 (ASHP 7th ed. 1992)	
	246	NAVOBAN® (tropisetron HCl) Malaysian Prescribing Information (Sep. 2000)	
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	248	S. Motola and S. Agharkar, Preformulation Research of Parenteral Medications, Pharmaceutical Dosage Forms: Parenteral Medications, Vol. 1, Ch. 4, pp. 115-72 (Avis, Lieberman, Lachman eds., Marcel Dekker Inc. 2d ed. 1992)	
	249	J. Wells, Pharmaceutical Preformuatlion: The Physicochemical Properties of Drug Substances, Ch. 5: Drug Stability, pp. 152-91 (Ellis Horwod Ltd. 1988)	
	250	J. Swarbrick and Boylan, Encyclopedia of Pharmaceutical Technology, Excipients Chapter: Their Role in Parenteral Dosage Forms, Vol. 19(2):137-172 (Marcel Dekker, Inc. 2000)	
	251	Handbook of Pharmaceutical Excipients, 3d Ed., (Kibbe ed. Pharmaceutical Press 2000); pp. 140-143, 191-194, 324-238	

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	252	G. Stacher, Palonosetron (Helsinn), Curro. Opin. Investig. Drugs, 3(10) 1502-7 (2002)	
	253	Handbook of Modern Pharmaceutical Analysis, (S. Ahuja et al. ed., Academic Press, 2001)	
	254	June 8, 2009 Bonadeo Declaration	
	255	June 8, 2009 Bonadeo Declaration, Exhibit 2	
	256	June 8, 2009 Bonadeo Declaration, Exhibit 3	
	257	HELSN0117262-69 (2008)	
	258	HELSN0117270-312 (2012)	
	259	February 13, 2007 Statutory Declaration of Daniele Bonadeo, with Exhibit A	
	260	November 21, 2007 Statutory Declaration of Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Enrico Braglia, and Riccardo Braglia	
	261	Reddy's Paragraph IV notice regarding all three patents (D. N.J. Case No. 12-2867), dated March 30, 2012	
	262	May 11, 2012 Complaint for patent infringement filed by Helsinn and Roche (D. N.J. Case No. 12-2867)	
	263	June 26, 2012 Notice of Reddy's motion to dismiss (D. N.J. Case. No. 12-2867)	
	264	June 26, 2012 Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s memorandum of law in support of their motion to dismiss or for summary judgment of non-infringement of U.S. patent No. 7,947,724 (D. N.J. Case No. 12-2867) (including Exhibits 1-10)	
	265	Aug. 16, 2012 Notice of Plaintiffs' cross-motion for partial summary judgment of infringement (D. N.J. Case No. 12-2867)	
	266	Aug. 6, 2012 Plaintiffs' opposition to Defendants' motion to dismiss or for summary judgment of noninfringement and cross-motion for partial summary judgment of infringement (D. N.J. Case No. 12-1867) (including exhibits 1-4)	
	267	Schöneich declaration (D. N.J. Case No. 12-2867) (Including Exhibits A and 1-24), dated August 6, 2012	
	268	Sept. 4, 2012 Reddy's brief in opposition to Plaintiffs' cross-motion for partial summary judgment and reply memorandum of law in further support of Reddy's motion to dismiss or for summary judgment of non-infringement (D. N.J. Case No. 12-2867)(Including Exhibits 1-4)	
	269	DeLuca Declaration (D. N.J. Case No. 12-2867)(Including exhibits A-J), dated September 3, 2012	
	270	Sept. 10, 2012 Plaintiffs' letter to Judge Cooper in response to Reddy's combined opposition to Plaintiffs' cross-motion for partial summary judgment and reply in support of Reddy's motion to dismiss or for summary judgment of noninfringement (D. N.J. Case No. 12-2867)(including exhibits A and B)	
	271	Sept. 14, 2012 Dr. Reddy's letter in response to Plaintiffs' September 10, 2012 letter (D. N.J. Case No. 12-2867)	
	272	USPTO Office Action, USSN 11/388,268, Filing Date 03/24/2006, Mail Date 03/29/2010	
	300	USPTO Non-Final Office Action, USSN 11/186,311, mailed August 30, 2006.	
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	742	Sandoz Inc.'s Redacted Memorandum of Law in Support of its Motion to Amend its Invalidity Contentions dated February 15, 2013 (D.N.J. Case No. 11-3962).	
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	803	English-language translation of Cite No. 802 (2012).	

Examiner Signature	/Shirley Gembeh/ (11/07/2013)	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

5582040v1

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BIB DATA SHEET

CONFIRMATION NO. 3806

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/901,830	05/24/2013	514	1628	23278.2.US.9

APPLICANTS

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Andrew Miksztal, Palo Alto, CA;
Thomas Malefyt, Carmel Valley, CA;
Kathleen M. Lee, Palo Alto, CA;

**** CONTINUING DATA ***************************

This application is a CON of 13/901,437 05/23/2013
which is a CIP of 13/087,012 04/14/2011 PAT 8518981
which is a CON of 11/186,311 07/21/2005 PAT 7947724
which is a CON of PCT/EP2004/000888 01/30/2004
which claims benefit of 60/444,351 01/30/2003

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

06/17/2013

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /SHIRLEY V GEMBEH/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		SWITZERLAND	0	9	2

ADDRESS

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363
UNITED STATES

TITLE

LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

FILING FEE RECEIVED		
2040	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue)

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	3387700	(peroxycarboxylic acid)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/07/02 09:59
S2	1031225	(peroxycarboxylic acid)and(alcohol)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/07/02 10:00
S3	1828	(peroxycarboxylic acid)and(alcohol)	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 10:05
S4	53	"6111963"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 10:07
S5	1293	(peroxycarboxylic acid)and(ethanol or methanol)	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 10:37
S6	5	"7473675"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 12:42
S7	87	(peroxycarboxylic acid)and(alcohol)and(malodor)	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 14:21
S8	4430	(dodecyl benzene sulfonic acid)	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 15:16
S9	890	(dodecyl benzene sulfonic acid)and(anionic surfactant)	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 15:16
S10	9	"7622606"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 16:12

S11	0	"40386739"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 16:29
S12	2	"20090061017"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 16:30
S13	115	"5084239"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 19:58
S14	9	"7622606"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 20:03
S15	32	"823917"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 20:22
S16	2	"8231917"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 20:23
S17	3	"8241624"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 20:25
S18	1	"13331304"	US-PGPUB; USPAT; USOCR; DERWENT	WITH	OFF	2013/07/02 20:26
S19	115173	(acetic acid or octanoic acid)and (peracetic acid)and (hydroen peroxide)and(methanol)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/07/10 21:03
S20	5771	(acetic acid or octanoic acid)and(peracetic acid)and (hydroen peroxide)and(methanol)and(Bacillus)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/07/10 21:03
S21	5771	(acetic acid or octanoic acid)and(peracetic acid)and (hydroen peroxide)and(methanol)and(Bacillus)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/07/10 21:04
S22	1	(acetic acid or octanoic acid)and(peracetic acid)and (hydroen peroxide)and(methanol)and(Bacillus)	US-PGPUB; USPAT;	AND	OFF	2013/07/10 21:04

			USOCR; FPRS; EPO; JPO; DERWENT			
S23	5771	(acetic acid or octanoic acid)with(peracetic acid)and (hydroen peroxide)and(methanol)and(Bacillus)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/07/10 21:04
S24	477	(acetic acid or octanoic acid)with(peracetic acid)and (hydroen peroxide)with(methanol)and(Bacillus)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/07/10 21:04
S25	24	"5296239"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/07/10 21:56
S26	32	"6627657"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/07/10 22:04
S27	41	"6257253"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/07/10 22:24
S28	5	"7473675"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/10/09 18:06
S29	3	"2004067485"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/10/09 18:11
S30	50	"4917815"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/10/09 18:18
S31	15	"8105810"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/10/09 18:19
S32	4	"12572059"	US-	OR	OFF	2013/10/09

			PGPUB; USPAT; USOCR; DERWENT			18:19
S33	384290	(peroxycarboxylic acid)and(alcohol)and(stable)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/10/09 18:23
S34	1381	(peroxycarboxylic acid)and(alcohol)and(stable)	US-PGPUB; USPAT; USOCR; DERWENT	AND	OFF	2013/10/09 18:23
S35	5	"7,473,675"	US-PGPUB; USPAT; USOCR; DERWENT	AND	OFF	2013/10/09 18:46
S36	9	"7498051"	US-PGPUB; USPAT; USOCR; DERWENT	AND	OFF	2013/10/09 20:52
S37	41	"6257253"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/06 23:47
S38	77	"5202333"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/07 10:23
S39	16	"6284749"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/07 10:24
S40	16	"5854270"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/07 10:25
S41	478	(palonosetron)and(sodium chloride)and(EDTA)and(sodium citrate)and(citric acid)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 15:06
S42	983	(palonosetron)and(sodium chloride)and(sodium citrate)and(citric acid)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 15:17
S43	1035	(palonosetron)and(sodium chloride)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 16:09
S44	158	(odansetron)and(sodium chloride)	US-	OR	OFF	2013/11/08

			PGPUB; USPAT; USOCR; DERWENT			16:21
S45	16	"5854270"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 16:32
S46	103	(odansetron)and(intravenous)and(sodium chloride)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 16:33
S47	0	(odansetron)near(intravenous)near(sodium chloride)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 16:38
S48	3	(palonosetron)near(sodium chloride)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2013/11/08 16:44
S49	863	(palonosetron)and(sodium chloride)	US-PGPUB; USPAT; USOCR; DERWENT	AND	OFF	2013/11/08 16:45
S50	863	(palonosetron)and(sodium chloride)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 16:45
S51	672	(palonosetron)and(sodium chloride)and(intravenous)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 16:46
S52	206	(palonosetron)and(sodium chloride)and(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 17:14
S53	121796	(sodium chloride)and(intravenous formulation)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 17:15
S54	2529	(sodium chloride)and(intravenous formulation)	US-PGPUB; USPAT;	NEAR	OFF	2013/11/08 17:16

			USOCR; FPRS; EPO; JPO; DERWENT			
S55	0	(sodium chloride)near(intravenous formulation)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	OFF	2013/11/08 17:16
S56	0	(sodium chloride)near(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	OFF	2013/11/08 17:18
S57	0	(sodium chloride)near(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 17:18
S58	0	(sodium chloride)near(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/11/08 17:18
S59	8451	(sodium chloride)and(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/11/08 17:18
S60	6688	(sodium chloride)and(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 17:19
S61	3474	(sodium chloride)and(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	OFF	2013/11/08 17:19
S62	4455	(sodium chloride)and(emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	WITH	OFF	2013/11/08 17:19
S63	6	(sodium chloride)with(emesis)	US-	WITH	OFF	2013/11/08

			PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT			17:19
S64	11	(odansetron) and (sodium chloride) and (emesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	OFF	2013/11/08 18:03

11/8/2013 7:31:11 PM
C:\Users\sgembeh\Documents\EAST\Workspaces\13542735.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/901,830	CALDERARI ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
East (USOCR, USPGPUB, USPAT, EPO, JPO, DERWENT, Inventors name search in palm	11/8/2013	SVG
Updated search in Edan, checked for double patenting of related applications	11/8/2013	SVG

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/901,830	CALDERARI ET AL.	

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/901,830	05/24/2013	Giorgio Calderari	23278.2.US.9

CONFIRMATION NO. 3806

53449
PATENT CORRESPONDENCE
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ATLANTA, GA 30363

PUBLICATION NOTICE

OC000000064181245

Title:LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

Publication No.US-2013-0261149-A1
Publication Date:10/03/2013

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Application

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Application Number	13/901,830
Filing Date	05/24/2013
First Named Inventor	Giorgio Calderari, Rancate, (CH)
Art Unit	1628
Examiner Name	Gembeh, Shirley V.
Attorney Docket Number	23278.2.US.9 / 3086

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☑ Attorney or agent of record. Registration Number 36,942.

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Signature	\Clark G. Sullivan\
Typed or Printed Name	Clark G. Sullivan
Date 09/20/2013	Telephone (212) 704-6105

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EFS ID:	16923484
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Angelina Stantini
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	23-SEP-2013
Filing Date:	24-MAY-2013
Time Stamp:	11:43:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Change of Address	13901830COCA.pdf	282508 f08df3d2c21e3421df60812524a5aa0fcf4f9f5e	no	2
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New International Application Filed with the USPTO as a Receiving Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/901,830	05/24/2013	Giorgio Calderari	23278.2.US.9	3806

53449 7590 09/16/2013

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1628	

NOTIFICATION DATE	DELIVERY MODE
09/16/2013	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):

patents@agg.com

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
13/901,830	24 May, 2013	CALDERARI ET AL.	23278.2.US.9

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
ANTHONY LOVER	
ART UNIT	PAPER
OPIM	20130909

DATE MAILED:

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

Commissioner for Patents

Attached is a communication to applicant explaining that the instant application is being identified as a pre-AIA application despite applicant's statement under 37 CFR 1.55 or 1.78 made in the instant application, either on the Application Data Sheet (ADS) or in an otherwise filed paper.

PTO-90C (Rev.04-03)

Application Identified as a Pre-AIA Application
Despite the 37 CFR 1.55 or 1.78 Statement of Record

The statement under 37 CFR 1.55 or 1.78 ("the 1.55/1.78 statement") and the domestic benefit/national stage information in this application conflict as to whether this application is to be examined under the AIA (First Inventor to File) or pre-AIA (First to Invent) law.

This application, with a filing date on or after March 16, 2013, contains the 1.55/1.78 statement indicating that this application should be examined under the AIA (First Inventor to File). This statement was either (1) on the Application Data Sheet (ADS) by virtue of the 1.55/1.78 statement for AIA (First Inventor to File) Transition Applications check box being selected or (2) in an otherwise filed paper. The 1.55/1.78 statement provided:

> This application * * * contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

However, this application is separately identified in the Domestic Benefit/National Stage Information section of the ADS as a continuation (CON) or divisional (DIV) of an application filed before March 16, 2013, indicating that this application should be examined under pre-AIA (First to Invent) law because it does not contain, or did not contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. DUE TO THIS APPLICATION BEING IDENTIFIED AS A CONTINUATION OR DIVISIONAL OF AN APPLICATION FILED BEFORE MARCH 16, 2013, THIS APPLICATION IS BEING IDENTIFIED AS A PRE-AIA (FIRST TO INVENT) APPLICATION DESPITE THE 1.55/1.78 STATEMENT OF RECORD.

Accordingly, this application is/will be examined under pre-AIA (First to Invent) law; all forthcoming Office actions on the merits will be labeled "**AIA (First Inventor to File) Status: No**" (see upper right box on form PTOL-37/37D and/or PTOL-326/326AE).

Moreover, if applicant has received any Office action on the merits, which identified the instant application as "**AIA (First Inventor to File) Status**: **Yes**," said Status information was in error and is hereby corrected to "**No**" to indicate that that the present application is a pre-AIA (First to Invent) application.

NO RESPONSE TO THIS COMMUNICATION IS REQUIRED UNLESS APPLICANT BELIEVES THAT THE APPLICATION CONTAINS, OR EVER CONTAINED A CLAIM TO A CLAIMED INVENTION HAVING AN EFFECTIVE FILING DATE ON OR AFTER MARCH 16, 2013 AND IS AN AIA (FIRST INVENTOR TO FILE) APPLICATION.

If applicant believes that the application is an AIA (First Inventor to File) application, applicant must file a corrected ADS (with appropriate markings as set forth in 37 CFR 1.76(c)(2)) identifying the instant application as a **continuation-in-part (CIP)** application in the Domestic Benefit/National Stage Information section of the ADS and request in writing that the application

be examined under the AIA (First Inventor to File) because the identification of the application as a CON/DIV application on filing was an error. IN THIS SITUATION, APPLICANT'S RESPONSE IS DUE WITHIN TWO MONTHS OF THE MAILING DATE OF THIS COMMUNICATION; THE RESPONSE PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136.

Questions regarding this communication may be directed to a TC AIA Specialist as appropriate.

Technology Center	TC AIA Specialist	Contact Information
1600, 1700, 2900	Kathleen Bragdon	(571) 272-0931
2100, 2400	Christopher Grant	(571) 272-7294
2600, 2800	Cassandra Spyrou	(571) 272-1624
3600, 3700	Tom Hughes	(571) 272-4357

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Alexandria, VA 22313-1450
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PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA GA 30363

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 13/901,830

1. THE REQUEST FILED 5/24/13 IS **GRANTED**.

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

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:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
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.

Telephone inquiries with regard to this decision should be directed to Cheryl Gibson-Baylor at (571)272-3213, Office of Petitions. In his/her absence, calls may be directed to Brian W. Brown, (571)272-5338.

Cheryl Gibson-Baylor
/Cheryl Gibson-Baylor/
[*Signature*]

Petitions Examiner
(Title)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/901,830	05/24/2013	1629	2040	23278.2.US.9	9	2

CONFIRMATION NO. 3806

53449
PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

FILING RECEIPT

OC000000062031397

Date Mailed: 06/25/2013

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)

Giorgio Calderari, Rancate, SWITZERLAND;
Daniele Bonadeo, Casalzuigno, ITALY;
Roberta Cannella, Varese, ITALY;
Alberto Macciocchi, Melide, SWITZERLAND, Deceased;
Andrew Miksztal, Palo Alto, CA;
Thomas Malefyt, Carmel Valley, CA;
Kathleen M. Lee, Palo Alto, CA;

Applicant(s)

Giulio Macciocchi, Breganzona, SWITZERLAND, Legal Representative;
Roche Palo Alto LLC, Palo Alto, CA
Helsinn Healthcare S.A., Lugano, SWITZERLAND
Simone Macciocchi, Melide, SWITZERLAND, Legal Representative;

Assignment For Published Patent Application

Helsinn Healthcare S.A., Lugano, SWITZERLAND
Roche Palo Alto LLC, Palo Alto, CA

Power of Attorney: The patent practitioners associated with Customer Number 53449

Domestic Priority data as claimed by applicant

This application is a CON of 13/901,437 05/23/2013
which is a CIP of 13/087,012 04/14/2011
which is a CON of 11/186,311 07/21/2005 PAT 7947724
which is a CON of PCT/EP2004/000888 01/30/2004
which claims benefit of 60/444,351 01/30/2003

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.

If Required, Foreign Filing License Granted: 06/17/2013
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/901,830**
Projected Publication Date: 10/03/2013
Non-Publication Request: No
Early Publication Request: No
Title

LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes

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 AssetsControl, 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: 13/901,830

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
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(i))	9 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
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1600

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	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))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	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))									
	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
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/901,830	05/24/2013	Giorgio Calderari	23278.2.US.9

CONFIRMATION NO. 3806

53449
PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

POA ACCEPTANCE LETTER

OC000000062029343

Date Mailed: 06/25/2013

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/24/2013.

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.

/mbelay/

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

ATTORNEY DOCKET NO. 23278.2.US.9
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1629
	)	
Application No.: 13/901,830	)	Examiner: Not Yet Assigned
	)	
Filed: May 24, 2013	)	Examiner in Parent: Shirley V. GEMBEH
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	Confirmation No.: 3806

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

Commissioner:

SUBSTANCE OF THE INTERVIEW

Pursuant to 37 C.F.R. § 1.133 and MPEP § 713.04, Applicants herein provide a written statement as to the substance of the in-person interview conducted on June 13, 2013, between Applicants' representatives, Clark Sullivan, Mariagrazia Zotti, Amanda Murphy, and Tom Irving, and Examiner Gembeh and her supervisor Brandon Fetterolf.

MPEP § 713.04 provides the following guidelines:

(A) **a brief description of the nature of any exhibit shown or any demonstration conducted**:

Applicants' representatives showed slides that were attached to the Examiner's Interview Summary, and are attached again. In addition, Applicants' representatives provided a binder to each of the Examiners containing the

evidence and allegations of the alleged on-sale bar from the pending related litigation, which were also previously filed in an Information Disclosure Statement;

(B) **identification of the claims discussed**:

all claims were discussed;

(C) **identification of specific prior art discussed**:

the alleged on-sale bar allegations and evidence from the pending related litigation were discussed;

(D) **identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary form completed by the examiner**:

no amendments were proposed;

(E) **the general thrust of the principal arguments of the applicant and the examiner should also be identified, even where the interview is initiated by the examiner. The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner**:

Applicants' representatives explained why the allegations of on-sale bar are erroneous, as set forth in the slides;

(F) **a general indication of any other pertinent matters discussed**:

Applicants' representatives explained the previously filed Information Disclosure Statement. The Examiners also requested appropriate Terminal Disclaimers, and such disclaimers have been filed. In addition, there was a general discussion of other co-pending related applications;

(G) **if appropriate, the general results or outcome of the interview**:

As reflected in the Examiner's Interview Summary, the Examiners agreed that the on-sale allegations do not apply to this JMM ("Jedi Master Mixer") application. *See also* "Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act," Federal Register/Vol. 78, No. 31/Thursday, February 14, 2013/Rules and Regulations 11059, at 11062, 11084, n. 8. The Examiners also agreed to consider the Terminal Disclaimers;

(H) **in the case of an interview via electronic mail, a paper copy of the Internet e-mail contents MUST be made and placed in the patent application file as required by the Federal Records Act in the same manner as an Examiner Interview Summary Form, PTOL 413, is entered**:

Because the interview was conducted in person, this element is not applicable.

Applicants believe the claims are in condition for allowance. If there are any fees due in connection with the filing of this Substance of the Interview, please charge the fees to Deposit Account 504667.

Respectfully submitted,

ARNALL GOLDEN GREGORY LLP

By:_____
Clark G. Sullivan
Reg. No. 36,942

ARNALL GOLDEN GREGORY LLP
(404) 873-8500
(404) 873-8501 (fax)
Customer No.: 53449

Attorney Docket No.: 23278.2.US.9

ATTACHMENT

Aloxi®
Helsinn Healthcare

Patent Application Overview

June 13, 2013

Application No. 13/087,012

Aloxi®

- Fourth 5-HT_3 Antagonist to Market
- FDA approval 7/25/2003
- About $600 million in worldwide sales annually
- Unexpected ability to treat nausea and vomiting resulting from chemotherapy for five consecutive days

Aloxi®

- At least four patent challengers, including:
  - Teva
  - Sandoz
  - Dr. Reddy's

- Those three defendants have erroneously raised on sale bar defenses against the patents covering Aloxi®, which Examiner Gembeh properly issued:
  - US 7,947,725
  - US 7,960,424
  - US 7,947,724

RCE of 13/087,012

- "Terminal Sterilization Application"
- Allowed February 27, 2013
- Motions to amend invalidity contentions served by the defendants shortly before allowance
- Duty of disclosure required us to file an RCE
- Critical date: 1/30/02

Other New Applications

- An application to reissue '725 patent (13/900,174)
  - Added limitations for the dose (0.25 mg)
- One new TRACK 1 CON
- Four new TRACK 1 CIPs (pre- and post-AIA claims)
  - Cover a new formulation for Japanese market
  - Choice of Law: governed by AIA 102(a)(1), (a)(2), and 103, and by pre-AIA 102(g)

Defendants' On Sale Bar Arguments

- Litigation challengers raised three on sale bar defenses
  - Two Development and Manufacturing agreements:
    - Oread Toll Manufacturing Agreement[1] (7/98)
    - SP/Osobio Toll Manufacturing Agreement (6/02) preceded by letter of intent (10/00)
  - One Distribution Agreement
    - MGI/Eisai Supply and Purchase Agreement (4/01)

[1] A toll manufacturing agreement is an arrangement in which a firm, which has a specialized equipment, processes raw materials or semi-finished goods for another firm.

SP Pharmaceuticals: No On-Sale Bar

- SP Pharmaceuticals (toll manufacturer) allegedly "sold" the finished clinical trial drug product materials to Helsinn
  - But title at all times remained with Helsinn:

Section 2.08 Ownership of Materials. ***Title*** to all API, work in process and finished Products ***shall at all times remain with Helsinn***. SP and Helsinn shall maintain insurance with respect to such property as provided in Article XIII hereof.

  - SP merely had a license:

Section 10.01 Limited License. Helsinn grants a non-exclusive, royalty-free license to SP to use Helsinn patents and other intellectual property supplied by Helsinn solely for the purpose of manufacturing the Product for Helsinn under this Agreement.

SP Pharmaceuticals: No On-Sale Bar

- MPEP 2133.03(b):
  - "A sale is a contract between parties wherein the ***seller*** agrees 'to give and ***to pass rights of property***' in return for the ***buyer's*** payment or promise 'to pay the ***seller*** for the things bought or sold.'"
- Because title remained with Helsinn at all times, there was no on-sale bar.

Oread: No On-Sale Bar

- Oread Labs (toll manufacturer) allegedly "sold" the finished clinical trial drug product materials to Helsinn
  - But title at all times remained ***proprietary*** with Helsinn ("the Client"):

Article 7 – Use of Materials, Confidential Information and Intellectual Property

7.1 The parties hereto acknowledge that all samples, development materials, and confidential information are ***proprietary to Client*** and are part of the confidential information of Client. Oread agrees (i) to account for all materials provided by Client; (ii) not to provide samples of any Client supplied materials to any third party without the express written consent of Client; (iii) not to attempt to analyze or characterize Client supplied materials, except as necessary for the Projects; (iv) to return (or destroy if Client so directs) all unused quantities of materials to Client upon completion of the subject studies, or sooner if Client so directs, and (v) not to use any Client confidential or proprietary information except as provided herein or in the Confidentiality Agreement.

  - Therefore, no sale (*see* MPEP 2133.03(b))

MGI: No On-Sale Bar

- Helsinn entered into two agreements with MGI: "License Agreement" and "Supply and Purchase Agreement"

License Agreement Section 4.1

MGI hereby acknowledges and agrees that

4.1.1 at the Effective Date of this Agreement the Products are under development by HHC for the purpose of submitting the relevant Registration application to the Regulatory Authorities of the Territory,

4.1.4 HHC makes no warranty and nothing in this Agreement may or shall be construed as a warranty by HHC that the Products will obtain the Registration or that a Product can be developed and registered from the Know-how and MGI shall have no claim against HHC arising out of any delay or refusal by the Regulatory Authorities to issue the Registration in any way whatsoever.

MGI: No On-Sale Bar

- Helsinn allegedly "offered to sell" drug substance to MGI (licensee / distributor)
  - But, in fact, agreement contemplated MGI would only make offers to buy
  - Helsinn (HBP) had full discretion to accept or reject MGI's offers, and only in writing

Supply and Purchase Agreement Section 4.2

The Products will be supplied to MGI only against MGI's written order and ***all orders shall be subject to written acceptance and confirmation by HBP before becoming binding***. Such acceptance and confirmation may be by facsimile or otherwise. Each order by MGI shall be for a minimum quantity corresponding to the size of one production batch of Products, as shall be indicated in due time by HBP, or multiples thereof.

MGI: No On-Sale Bar

- MGI did not place any orders before the critical date

- And, even if an order had been placed, those orders were not binding until "written acceptance and confirmation" by Helsinn.

MGI: No On-Sale Bar

- MPEP 2133.03(b) addresses this situation exactly, citing *Linear Technology Corp. v. Micrel, Inc.*, 275 F.3d 1040 (Fed. Cir. 2001):
  - "(Court held there was no sale within the meaning of 35 U.S.C. 102(b) where prospective purchaser submitted an order for goods at issue, but received an order acknowledgement reading 'will advise-not booked.' ***Prospective purchaser would understand that order was not accepted***.)."

MGI: No On-Sale Bar

- MPEP 2133.03(b):
  - "A contract for the sale of goods requires a concrete offer and acceptance of that offer."

- Because Helsinn never accepted an order before the critical date, there was no on-sale bar.

Electronic Acknowledgement Receipt

EFS ID:	16061430
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Susan Wray
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	17-JUN-2013
Filing Date:	24-MAY-2013
Time Stamp:	16:49:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	23278_2_US9_SUBSTANCE_OF_THE_INTERVIEW.pdf	949894 a69b7619a44f00c2202fb660044a89dbca4aa9a7	no	19
Warnings:					
Information:					

Total Files Size (in bytes):	949894

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
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New International Application Filed with the USPTO as a Receiving Office
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ATTORNEY DOCKET NO. 23278.2.US.9
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Giorgio CALDERARI et al.	)	Group Art Unit: 1629
	)	
Application No.: 13/901,830	)	Examiner: Not Yet Assigned
	)	
Filed: May 24, 2013	)	Confirmation No.: 3806
	)	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)	

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

Commissioner:

TERMINAL DISCLAIMER

Helsinn Healthcare SA, duly organized under the laws of Switzerland and having its principal place of business at P.O. Box 357, Pambio-Noranco, Switzerland 6915, and Roche Palo Alto LLC, duly organized under the laws of the United States and having its principal place of business at 3431 Hillview Avenue, Palo Alto, California 94394 (collectively "the Applicant"), represent that they are the owners of 100% of the instant application, as indicated by the assignments recorded for U.S.S.N. 13/901,437 (the parent of U.S.S.N. 13/901,830) at Reel 030478, Frame 0960 on May 23, 2013, and at Reel 030479, Frame 0001 on May 23, 2013.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of U.S. Patent No. 7,960,424, as indicated by the assignments recorded at Reel 025816, Frame 0283 on February 16, 2011, and at Reel 025816, Frame 0579 on February 16, 2011.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of U.S. Patent No. 7,947,724, as indicated by the assignments

recorded at Reel 017831, Frame 0234 on June 21, 2006, and at Reel 025450, Frame 0180 on December 6, 2010.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of U.S. Patent No. 7,947,725, as indicated by the assignments recorded at Reel 025819, Frame 0244 on February 16, 2011, and at Reel 025819, Frame 0334 on February 16, 2011.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of co-pending Reissue U.S.S.N. 13/900,174, as indicated by the assignment recorded at Reel 030469, Frame 0674 on May 22, 2013, and the assignments recorded for U.S. Patent No. 7,947,725 (the parent of Reissue U.S.S.N. 13/900,174) at Reel 025819, Frame 0244 on February 16, 2011, and at Reel 025819, Frame 0334 on February 16, 2011.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of co-pending U.S.S.N. 13/087,012, as indicated by the assignments recorded at Reel 028899, Frame 0100 on September 5, 2012, and at Reel 029302, Frame 0296 on November 15, 2012.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of co-pending U.S.S.N. 13/901,288, as indicated by the assignments recorded at Reel 030478, Frame 0304 on May 23, 2013, and the assignments recorded for the parent of co-pending U.S.S.N. 13/901,288 (U.S.S.N. 13/087,012) at Reel 028899, Frame 0100 on September 5, 2012, and at Reel 029302, Frame 0296 on November 15, 2012.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of co-pending U.S.S.N.13/901,437, as indicated by the assignments recorded at Reel 030478, Frame 0960 on May 23, 2013, and at Reel 030479, Frame 0001 on May 23, 2013.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of co-pending U.S. Application No. 13/902,132, as indicated by the assignments recorded for U.S.S.N. 13/901,437 (the parent of U.S.S.N. 13/902,132) at

Reel 030478, Frame 0960 on May 23, 2013, and at Reel 030479, Frame 0001 on May 23, 2013.

Helsinn Healthcare SA and Roche Palo Alto LLC further represent that they are the owners of 100% of co-pending U.S.S.N. 13/902,299, as indicated by the assignments recorded for U.S. Application No. 13/901,437 (the parent of U.S. Application No. 13/902,299) at Reel 030478, Frame 0960 on May 23, 2013, and at Reel 030479, Frame 0001 on May 23, 2013.

PRIOR PATENT NO. 7,960,424

Helsinn Healthcare SA and Roche Palo Alto, LLC hereby disclaim 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** No. 7,960,424 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The Applicant 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 Applicant 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;

has all claims canceled by an *inter partes* review 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.

PRIOR PATENT NO. 7,947,724

Helsinn Healthcare SA and Roche Palo Alto, LLC hereby disclaim 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** No. 7,947,724 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The Applicant 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.

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PRIOR PATENT NO. 7,947,725

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is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;

has all claims canceled by a reexamination certificate;

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.

REFERENCE APPLICATION NO. 13/900,174

Helsinn Healthcare SA and Roche Palo Alto, LLC hereby disclaim 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** Reissue Application Number 13/900,174, filed on May 22, 2013, 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 Applicant 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 Applicant 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, has all claims canceled by an *inter partes* review 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.

REFERENCE APPLICATION NO. 13/087,012

Helsinn Healthcare SA and Roche Palo Alto, LLC hereby disclaim 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 13/087,012, filed on April 14, 2011, 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 Applicant 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.

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REFERENCE APPLICATION NO. 13/901,288

Helsinn Healthcare SA and Roche Palo Alto, LLC hereby disclaim 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 13/901,288, filed on April 14, 2011, 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 Applicant 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.

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REFERENCE APPLICATION NO. 13/901,437

Helsinn Healthcare SA and Roche Palo Alto, LLC hereby disclaim 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 13/901,437, filed on May 23, 2013, 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 Applicant 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.

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REFERENCE APPLICATION NO. 13/902,132

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REFERENCE APPLICATION NO. 13/902,299

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* * * * * * *

In accordance with the fee schedule in 37 C.F.R. § 1.20(d), the required fee of $160.00 is being filed with this disclaimer.

If there are any additional fees due in connection with the filing of this Terminal Disclaimer, please charge the fees to Deposit Account 504667.

The undersigned is an attorney of record.

Respectfully submitted,

ARNALL GOLDEN GREGORY LLP

By: _____
Clark G. Sullivan
Reg. No. 36,942

ARNALL GOLDEN GREGORY LLP
(404) 873-8500
(404) 873-8501 (fax)
Customer No.: 53449

Attorney Docket No.: 23278.2.US.9

Electronic Patent Application Fee Transmittal

Application Number:	13901830
Filing Date:	
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Susan Wray
Attorney Docket Number:	23278.2.US.9

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:				
Statutory or Terminal Disclaimer	1814	1	160	160
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	16044145
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Susan Wray
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	14-JUN-2013
Filing Date:	
Time Stamp:	14:31:30
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	901
Deposit Account	504667
Authorized User	SULLIVAN, CLARK
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	23278_2_US9-13_901830_TD.pdf	624746 5b13e427b5bc64bf868925d3069450bc87aca798	no	11
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30131 f02314fc08773f605087c8273b8489a4d03c3ace	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	654877		

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National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
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PTO/AIA/15 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	23278.2.US.9
First Named Inventor	Giorgio Calderari
Title	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✓] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [ ] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✓] **Specification** [*Total Pages* 20] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [ ] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* ____]
6. **Inventor's Oath or Declaration** [*Total Pages* 10] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [✓] A copy from a prior application (37 CFR 1.63(d))
7. [✓] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ACCOMPANYING APPLICATION PAPERS

10. [✓] **Assignment Papers** (cover sheet & document(s)) Name of Assignee Helsinn Healthcare SA and Roche Palo Alto LLC
11. [✓] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [✓] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [✓] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [✓] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [✓] **Other:** Authorization to Act in a Representative Capacity; Certification and Request for Prioritized Examination; Exhibit A to Preliminary Amendment

***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

[✓] The address associated with Customer Number: 53,449 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature		Date	May 24, 2013
Name (Print/Type)	Clark G. Sullivan	Registration No. (Attorney/Agent)	36,942

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.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-13)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Giorgio CALDERARI	Nonprovisional Application Number (if known):	
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON		

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, examination fee, and any required excess claims and application size fees are filed with the request or have been already been paid.
2. The application contains or is amended to contain no more than four independent claims and no more than thirty total claims, and no multiple dependent claims.
3. The applicable box is checked below:

I. ☑ 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.

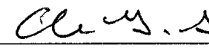
---OR---

(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. The executed inventor's oath or declaration is filed with the application. (37 CFR 1.63 and 1.64)

II. ☐ 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 	Date May 24, 2013
Name (Print/Typed) Clark G. Sullivan	Practitioner Registration Number 36,942

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.**

☑ *Total of 1 forms are submitted.

Exh. 1002

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.

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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.
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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).
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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)).
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PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

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.
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.

Secrecy Order 37 CFR 5.2

☐ 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
	Giorgio		Calderari	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Rancate	Country of Residence [i]	CH

Mailing Address of Inventor:

Address 1	Via Scer 35		
Address 2			
City	Rancate	State/Province	TC
Postal Code	6862	Country [i]	CH

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Daniele		Bonadeo	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Casalzuigno	Country of Residence [i]	IT

Mailing Address of Inventor:

Address 1	Via Ronco Capo Caccia, 32-I		
Address 2			
City	Casalzuigno	State/Province	VA
Postal Code	21030	Country [i]	IT

Inventor 3 Remove

Legal Name

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Roberta		Cannella	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Varese	Country of Residence [i]	IT

Mailing Address of Inventor:

Address 1	Via Al Colle 42		
Address 2			
City	Varese	State/Province	VA
Postal Code	21030	Country [i]	IT

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alberto		Macciocchi (Deceased)	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Melide	Country of Residence [i]	CH

Mailing Address of Inventor:

Address 1	Via Alla Bola, 2		
Address 2			
City	Melide	State/Province	TC
Postal Code	6815	Country [i]	CH

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		Miksztal	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Palo Alto	State/Province	CA	Country of Residence [i]	US

Mailing Address of Inventor:

Address 1	743 Cereza Drive		
Address 2			
City	Palo Alto	State/Province	CA
Postal Code	94306	Country [i]	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas		Malefyt	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Carmel Valley	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	20 Sleepy Hollow Drive		
Address 2			
City	Carmel Valley	State/Province	CA
Postal Code	93924	Country	US

Inventor 7 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kathleen	M	Lee	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Palo Alto	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4173 El Camino Real, Apt. 20		
Address 2			
City	Palo Alto	State/Province	CA
Postal Code	94306	Country	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).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	53449		
Email Address		Add Email	Remove Email

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Application Information:

Title of the Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON		
Attorney Docket Number	23278.2.US.9	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **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:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	53449		

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.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	13901437	2013-05-23
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation in part of	13087012	2011-04-14
Prior Application Status	Patented		Remove

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13087012	Continuation of	11/186311	2005-07-21	7947724	2011-05-24

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11/186311	Continuation of	PCT/EP2004/000888	2004-01-30
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/EP2004/000888	non provisional of	60/444351	2003-01-30

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

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)[i] 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).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

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 o f 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

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.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ 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. ☒

Organization Name	Helsinn Healthcare S.A.

Mailing Address Information For Applicant:

Address 1	P.O. Box 357, Pambio-Noranco		
Address 2			
City	Lugano	**State/Province**	TC
Country	CH	Postal Code	6915
Phone Number	+41 (0) 91 985.21.21	Fax Number	+41 (0) 91993.21.22

PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Email Address	info-HHC@helsinn.com

Additional Applicant Data may be generated within this form by selecting the Add button.

Applicant 2

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.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ 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. ☒

Organization Name	Roche Palo Alto LLC

Mailing Address Information For Applicant:

Address 1	3431 Hillview Avenue		
Address 2			
City	Palo Alto	**State/Province**	CA
Country	US	Postal Code	94304
Phone Number	(650) 225-1000	Fax Number	(650) 225-6000
Email Address	info@roche.com		

Additional Applicant Data may be generated within this form by selecting the Add button.

Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Assignee 1

Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section 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), as the patent application publication will include the name of the applicant(s).

If the Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country [i]		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button.

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				Date (YYYY-MM-DD)	2013-05-24
First Name	Clark G.	Last Name	Sullivan	Registration Number	36942

Additional Signature may be generated within this form by selecting the Add button.

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

Privacy Act Statement

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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 the Freedom of Information Act requires disclosure of these records.

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 Co o p eration 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 inspections 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.

UNITED PATENT NON-PROVISIONAL PATENT APPLICATION

FOR

LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

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LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

FIELD OF THE INVENTION

The present invention relates to shelf-life stable liquid formulations of palonosetron that are especially useful in the preparation of injectable and oral medicaments.

BACKGROUND OF THE INVENTION

Emesis is a devastating consequence of cytotoxic therapy, radiotherapy, and post-operative environments that drastically affects the quality of life of people undergoing such treatments. In recent years a class of drugs referred to as 5-HT_3 (5-hydroxytryptamine) receptor antagonists has been developed that treat such emesis by antagonizing cerebral functions associated with the 5-HT_3 receptor. See *Drugs Acting on 5-Hydroxytryptamine Receptors*: The Lancet Sep. 23, 1989 and references cited therein. Drugs within this class include ondansetron, granisetron, alosetron, tropisetron, and dolasetron. These 5-HT_3 antagonists are often administered intravenously shortly before chemotherapy or radiotherapy is initiated, and can be administered more than once during a cycle of chemotherapy or radiotherapy. In addition, they are often supplied as tablets or oral elixirs to either supplement an intravenous administration, or to ease home usage of the drug if the patient is self-administering the chemotherapeutic regimen.

Because some chemotherapeutic agents can induce emesis over extended periods of several days even when they are administered only once, it would be desirable to administer an emesis-inhibiting drug such as a 5-HT_3 antagonist every day until the risk of emesis has substantially subsided. The present class of 5-HT_3 antagonists has not proven especially helpful meeting this need, however, because the 5-HT_3 receptor antagonists currently marketed have proven to be less effective in controlling delayed nausea and vomiting than they are at controlling

acute emesis. Sabra, K, *Choice of a 5HT$_3$ Receptor Antagonist for the Hospital Formulary*. EHP, Oct. 1996;2 (suppl 1):S19-24.

Recently, clinical investigations have been made concerning palonosetron, a new 5-HT$_3$ receptor antagonist reported in U.S. Patent No. 5,202,333. These investigations have shown that the drug is an order of magnitude more potent than most existing 5-HT$_3$ receptor antagonists, has a surprising half-life of about 40 hours, and is effective to reduce delayed-onset nausea induced by chemotherapeutic agents. However, formulating palonosetron in liquid formulations has not proven an easy task, typically due to shelf- stability issues. U.S. Pat. No. 5,202,333 discloses an intravenous formulation of palonosetron in example 13 that contains the following ingredients:

Ingredient	**Mg**
Palonosetron HCI	10-100 mg.
Dextrose Monohydrate	q.s. to make Isotonic
Citric Acid Monohydrate	1.05 mg.
Sodium Hydroxide	0.18 mg.
WFJ	To 1.0 ml.

The formulation has a pH of 3.7 and a shelf stability of less than the 1-2 year time period required by health authorities in various countries.

Ondansetron, its uses, and medicaments made with ondansetron are disclosed in U.S. Patent Numbers 4,695,578, 4,753,789, 4,929,632, 5,240,954, 5,344,658, 5,578,628, 5,578,632, 5,922,749, 5,622,720, 5,955,488, and 6,063,802. Commercially it is distributed by GlaxoSmithKline as Zofran® and is indicated for prevention of postoperative nausea and vomiting (PONV), cancer

chemotherapy-induced nausea and vomiting (CINV), and radiotherapy-induced nausea and vomiting (RINV) and it is available as an injection, tablets and solution, and as Zofran ODT® (ondansetron) Orally Disintegrating Tablets.

Granisetron, its uses, and medicaments made with granisetron are disclosed in U.S. Patent Numbers 4,886,808, 4,937,247, 5,034,398 and 6,294,548. Commercially it is distributed by Roche Laboratories Inc. as Kytril®, indicated for the prevention of nausea and vomiting associated with chemotherapy or radiation therapy, and is offered in tablet form, oral solution, and as an injection.

Alosetron, its uses, and medicaments made with alosetron are disclosed in U.S. Patent Numbers 5,360,800 and 6,284,770. Commercially it is distributed by GlaxoSmithKline as Lotronex®.

Tropisetron is commercially available as Navoban® (Novartis) CAS-89565-68-4 (tropisetron); CAS - 105826-92-4 (tropisetron hydrochloride) and it is indicated for treatment of PONV and CINV.

Dolasetron, its uses, and medicaments made with ondansetron are disclosed in U.S. Patent Numbers 5,011,846, and 4,906,755. Commercially it is distributed by Aventis Pharmaceuticals Inc. as Anzemet®, indicated for prevention of both PONV and CINV, and it is offered in the form of a tablet or an intravenous solution.

Therefore, there exists a need for a palonosetron formulation with increased stability and thereby increased shelf life. There also exists a need for an appropriate range of concentrations for both the 5-HT_3 receptor antagonist and its pharmaceutically acceptable carriers that would facilitate making a formulation with this increased stability.

It is an object of the present invention to provide a formulation of Palonosetron hydrochloride with increased pharmaceutical stability for preventing and/or reducing emesis.

It is another object of the invention to provide an acceptable range of concentrations which will stabilize a formulation containing Palonosetron hydrochloride.

It is a further object of the invention to provide a formulation of Palonosetron which would allow for prolonged storage.

It is also an object of the invention to provide a formulation of Palonosetron which would allow terminal sterilization.

SUMMARY OF THE INVENTION

The inventors have made a series of discoveries that support a surprisingly effective and versatile formulation for the treatment and prevention of emesis using palonosetron. These formulations are shelf stable for periods greater than 24 months at room temperature, and thus can be stored without refrigeration, and manufactured using non-aseptic, terminal sterilization processes.

In one aspect, the inventors have discovered that formulations which include the active ingredient palonosetron require in some instances only $1/10^{th}$ the amount of other previously known compounds for treating emesis, which surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected. Thus, in one embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier.

The inventors have further discovered that by adjusting the formulation's pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations. Therefore, in another embodiment, the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. In

another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof; from about 10 to about 100 millimoles citrate buffer; and from about 0.005 to about 1.0 mg/ml EDTA.

The inventors have further discovered that the addition of mannitol and a chelating agent can increase the stability of palonosetron formulations. Therefore, in still another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises a chelating agent and mannitol.

DETAILED DESCRIPTION OF THE INVENTION

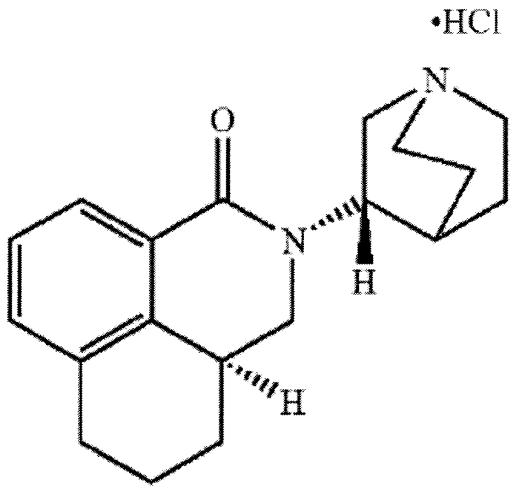
DEFINITIONS

"Vial" means a small glass container sealed with the most suitable stopper and seal, other suitable primary containers may be used, for instance, but not limited to, pre-filled syringes. Vial also means a sealed container of medication that is used one time only, and includes breakable and non-breakable glass vials, breakable plastic vials, miniature screw-top jars, and any other type of container of a size capable of holding only one unit dose of palonosetron (typically about 5 mls.).

Throughout this specification the word "comprise," or variations such as "comprises" or "comprising," will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps

"Palonosetron" means (3aS)-2,3,3a,4,5,6-Hexahydro-2-[(S)-l-Azabicyclo[2.2.2]oct-3-yl]2,3,3a,4,5,6-hexahydro-l-oxo-1*H*benz[*de*]isoquinoline,

and is preferably present as the monohydrochloride. Palonosetron monohydrochloride can be represented by the following chemical structure:



Concentrations -- When concentrations of palonosetron are given herein, the concentration is measured in terms of the weight of the free base. Concentrations of all other ingredients are given based on the weight of ingredient added to the solution.

"Pharmaceutically acceptable" means that which is useful in preparing a pharmaceutical composition that is generally safe, non-toxic and neither biologically nor otherwise undesirable and includes that which is acceptable for veterinary use as well as human pharmaceutical use.

"Pharmaceutically acceptable salts" means salts which are pharmaceutically acceptable, as defined above, and which possess the desired pharmacological activity. Such salts include acid addition salts formed with inorganic acids such as hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, and the like; or with organic acids such as acetic acid, propionic acid, hexanoic acid, heptanoic acid, cyclopentanepropionic acid, glycolic acid, pyruvic acid, lactic acid, malonic acid, succinic acid, malic acid, maleic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, o-(4-

hydroxybenzoyl)benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, 1,2,-ethanedisulfonic acid, 2-hydroxyethanesulfonic acid, benzenesulfonic acid p-chlorobenzenesulfonic acid, 2-naphthalenesulfonic acid, p-toluenesulfonic acid, camphorsulfonicacid, 4-methylbicyclo[2.2.2]oct-2-ene-1-carboxylic acid, glucoheptonic acid, 4,4'-methylenebis(3-hydroxy-2-ene-1-carboxylic acid), 3-phenylpropionic acid, trimethylacetic acid, tertiary butylacetic acid, lauryl sulfuric acid, gluconic acid, glutamic acid, hydroxynaphthoic acid, salicylic acid, stearic acid, muconic acid, and the like.

In addition, pharmaceutically acceptable salts may be formed when an acidic proton present is capable of reacting with inorganic or organic bases. Acceptable inorganic bases include sodium hydroxide, sodium carbonate, potassium hydroxide, aluminum hydroxide and calcium hydroxide. Acceptable organic bases include ethanolamine, diethanolamine, triethanolamine, tromethamine, N-methylglucamine and the like.

DISCUSSION

The fact that palonosetron can be formulated in some instances at concentrations of only about $1/10^{th}$ the amount of other previously known compounds for treating emesis, surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected. Thus, in one embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof; with a pharmaceutically acceptable carrier. In alternative embodiments, the formulation includes palonosetron or a pharmaceutically acceptable salt thereof in a

concentration from about 0.02 mg/mL to about 1.0 mg/mL, from about 0.03 mg/mL to about 0.2 mg/mL, and most optimally about 0.05 mg/ml.

A particular advantage associated with the lower dosages of intravenous palonosetron is the ability to administer the drug in a single intravenous bolus over a short, discrete time period. This time period generally extends from about 10 to about 60 seconds, or about 10 to about 40 seconds, and most preferably is about 10 to 30 seconds. In one particular embodiment the palonosetron is supplied in vials that comprise 5 ml. of solution, which equates to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml.

The inventors have further discovered that by adjusting the formulation's pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations. Therefore, in another embodiment, the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing a) palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. In alternative embodiments, the pH is from about 4.5 to about 5.5, and most optimally about 5.0. There are many examples to those of skill in the art of suitable solutions to adjust the pH of a formulation. Two exemplary solutions are sodium hydroxide and hydrochloric acid solution, either of which could be used to adjust the pH of the formulation.

In another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof and (i) from about 10 to about 100 millimoles citrate buffer, and/or (ii) from about 0.005 to

about 1.0 mg/ml EDTA. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof and (i) from about 10 to about 100 millimoles citrate buffer, and/or (ii) from about 0.005 to about 1.0 mg/ml EDTA. The citrate buffer can be in the form of citric acid and/or a salt of citric acid such as trisodium citrate. In various embodiments, the ranges of one or more of the foregoing ingredients can be modified as follows:

- The formulation may comprise palonosetron or a pharmaceutically acceptable salt thereof in a concentration from about 0.02 mg/mL to about 1.0 mg/mL, from about 0.03 mg/mL to about 0.2 mg/mL palonosetron hydrochloride, and most optimally about 0.05 mg/ml.

- The formulation may comprise citrate buffer in a concentration of from about 10 to about 40 millimoles, or 15-30 millimoles.

- The formulation may comprise EDTA in a concentration of from about 0.005 mg/ml to about 1.0 mg/ml, or about 0.3 to about 0.7 mg/ml, and most optimally about 0.5 mg/ml.

The inventors have further discovered that the addition of mannitol and a chelating agent can increase the stability of palonosetron formulations. Therefore, in still another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises a chelating agent and mannitol. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing a) palonosetron or a pharmaceutically acceptable salt

thereof and b) a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises a chelating agent and mannitol. The chelating agent is preferably EDTA, and, in various embodiments the chelating agent is present in a concentration of from about 0.005 to about 1.0 mg/mL or from about 0.05 mg/mL to about 1.0 mg/mL or from about 0.3 to about 0.7 mg/ml, or most optimally about 0.5 mg/mL. In various embodiments the mannitol is present in a concentration of from about 10.0 mg/ml to about 80.0 mg/ml, from about 20.0 mg/mL to about 60.0 mg/ml, or from about 40.0 to about 45.0 mg/ml.

Injectable formulations are typically formulated as aqueous solutions in which water is the primary excipient. Oral formulations will differ from injectable formulations generally by the additional presence of flavoring agents, coloring agents, or viscosity agents. Natural or synthetic sweeteners include, among others, mannitol, sorbitol, saccharose, saccharine, aspartame, acelsulphame K, or cyclamate. These agents are generally present in concentrations in excess of 100 mg/ml or 250 mg/ml when used as sweetening agents, in contrast to the 41.5 mg/ml concentration of mannitol described in some of the embodiments of the invention, in which mannitol is acting simply as a tonicifying agent.

The formulations of the present invention are particularly suited for use in injectable and oral liquid formulations, but it will be understood that the solutions may have alternative uses. For example, they may be used as intermediates in the preparation of other pharmaceutical dosage forms. Similarly, they may have other routes of administration including intranasal or inhalation. Injectable formulations may take any route including intramuscular, intravenous or subcutaneous.

Still further embodiments relate to improvements in the ease with which the palonosetron formulation can be stored or manufactured. In particular, the

inventors have discovered that the formulations of the present invention allow storage of the product for extended periods at room temperature. Thus, in yet another embodiment the invention provides a method of storing one or more containers in which are contained a solution of palonosetron or a pharmaceutically acceptable salt thereof comprising: a) providing a room comprising said one or more containers; b) adjusting or maintaining the temperature of the room at greater than about ten, 15, or 20 degrees celcius; and c) storing said containers in said room for one month, 3 months, 6 months, one year, 18 months, 24 months or more (but preferably not exceeding 36 months), wherein (i) the palonosetron or pharmaceutical salt thereof is present in a concentration of from about 0.01 mg/mL to about 5.0 mg/mL, (ii) the pH of the solution is from about 4.0 to about 6.0, (iii) the solution comprises from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof, from about 10 to about 100 millimoles citrate buffer and from about 0.005 to about 1.0 mg/ml EDTA, (iv) the solution comprises a chelating agent, or (v) the solution comprises from about 10 to about 100 milliMoles of a citrate buffer.

The stability of the foregoing formulations also lends itself well to terminal sterilization processes in the manufacturing process. Therefore, in still another embodiment the invention provides a method of filling a container in which is contained a solution of palonosetron or a pharmaceutically acceptable salt thereof comprising: a) providing one or more sterile open containers (preferably 5 ml. vials); b) filling said containers with a solution of palonosetron in a non-aseptic environment; c) sealing said filled containers; and d) sterilizing said sealed, filled containers, wherein (i) the palonosetron or pharmaceutical salt thereof is present in a concentration of from about 0.01 mg/mL to about 5 mg/mL, (ii) the pH of the solution is from about 4.0 to about 6.0, (iii) the solution comprises from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof, from about 10 to about 100 millimoles citrate buffer and

from about 0.005 to about 1.0 mg/ml EDTA, (iv) the solution comprises a chelating agent, or (v) the solution comprises from about 10 to about 100 milliMoles of a citrate buffer.

EXAMPLES

EXAMPLE 1: STABILIZING PH

A study was conducted to determine the effect of pH on formulations containing palonosetron hydrochloride, measuring the stability at 80°C at pH 2.0, 5.0, 7.4, and 10.0. The results indicated that palonosetron hydrochloride is most stable at pH 5.0.

EXAMPLE 2: STABILIZING CONCENTRATION RANGES

A formulation optimization study was performed using an experimental design software. Twenty-four lots of drug product were analyzed to investigate the appropriate concentration ranges for palonosetron hydrochloride (0.05 mg/mL to 5.0 mg/mL), citrate buffer (0 to 80 mM) and EDTA (0 to 0.10%). The level of EDTA and citrate buffer were selected based on the optimal formulation, which was shown to be formulated with EDTA 0.05% and 20 mM citrate buffer at pH 5.0. The results of this study indicated that palonosetron concentration was also a critical factor in chemical stability, with greatest stability seen at the lowest palonosetron concentrations.

EXAMPLE 3: TONICIFYING AGENT

Formulations of palonosetron hydrochloride in citrate buffer were prepared including either a) sodium chloride or b) mannitol. The palonosetron hydrochloride formulation including mannitol showed superior stability. The optimum level of mannitol required for an isotonic solution was found to be 4.15%.

EXAMPLE 4: FORMULATION I

The following is a representative pharmaceutical formulation containing palonosetron that is useful for intravenous formulations, or other liquid formulations of the drug.

Ingredient	mg/mL
Palonosetron Hydrochloride	0.05*
Mannitol	41.5
EDTA	0.5
Trisodium citrate	3.7
Citric acid	1.56
WFJ	q.s. to 1 ml
Sodium hydroxide solution and/or hydrochloric acid solution	pH 5.0 ± 0.5

* calculated as a free base

EXAMPLE 5: FORMULATION II

The following is a representative pharmaceutical formulation containing palonosetron that is useful for oral formulations, or other liquid formulations of the drug.

Ingredient	mg/mL
Palonosetron Hydrochloride	0.05*
Mannitol	150
EDTA	0.5
Trisodium citrate	3.7
Citric acid	1.56
WFJ	q.s. to 1 ml

Sodium hydroxide solution and/or hydrochloric acid solution	pH 5.0 ± 0.5
Flavoring	q.s.

*calculated as a free base

EXAMPLE 6 – STABILITY OF PALONOSETRON WITHOUT DEXAMETHASONE

The physical and chemical stability of palonosetron HCl was studies in concentrations of 5 µg/mL and 30 µg/mL in 5% dextrose injection, 0.9% sodium chloride injection, 5% dextrose in 0.45% sodium chloride injection, and dextrose 5% in lactated Ringer's injection. The admixtures were evaluated over 14 days at 4 °C in the dark and for 48 hours at 23 °C under fluorescent light.

Test samples of palonosetron HCl were prepared in polyvinyl chloride (PVC) bags of the infusion solutions at concentrations of 5 and 30 µg/mL. Evaluations for physical and chemical stability were performed on samples taken initially and after 1, 3, 5, 7, and 14 days of storage at 4 °C and after 1, 4, 24, and 48 hours at 23 °C. Physical stability was assessed using visual observation in normal room light and using a high-intensity monodirectional light beam. In addition, turbidity and particle content were measured electronically. Chemical stability of the drug was evaluated by using a stability-indicating high performance liquid chromatographic (HPLC) analytical technique.

All samples were physically stable throughout the study. The solution remained clear, and little or no change in particulate burden and haze level were found. Additionally, little or no loss of palonosetron HCl occurred in any of the samples at either temperature throughout the entire study period.

EXAMPLE 7 – STABILITY OF PALONOSETRON WITH DEXAMETHASONE

The physical and chemical stability of palonosetron HCl 0.25 mg admixed with dexamethasone (as sodium phosphate) 10 mg or 20 mg in 5% dextrose injection or 0.9% sodium chloride injection in polyvinyl chloride (PVC)

minibags, and also admixed with dexamethasone (as sodium phosphate) 3.3 mg in 5% dextrose injection or 0.9% sodium chloride injection in polypropylene syringes at 4 °C in the dark for 14 days and at 23 °C exposed to normal laboratory fluorescent light over 48 hours, was studied.

Test samples of palonosetron HCl 5 μg/mL with dexamethasone (as sodium phosphate) 0.2 mg/mL and also 0.4 mg/mL were prepared in polyvinyl chloride (PVC) minibags of each infusion solution. Additionally, palonosetron HCl 25 μg/mL with dexamethasone (as sodium phosphate) 0.33 mg/mL in each infusion solution were prepared as 10 mL of test solution in 20-mL polypropylene syringes. Evaluations for physical and chemical stability were performed on samples taken initially and after 1, 3, 7, and 14 days of storage at 4 °C and after 1, 4, 24, and 48 hours at 23 °C. Physical stability was assessed using visual observation in normal room light and using a high-intensity monodirectional light beam. In addition, turbidity and particle content were measured electronically. Chemical stability of the drug was evaluated by using a stability-indicating high performance liquid chromatographic (HPLC) analytical technique.

All samples were physically compatible throughout the study. The solutions remained clear, and little or no change in particulate burden and haze level were found. Additionally, little or no loss of palonosetron HCl and dexamethasone occurred in any of the samples at either temperature throughout the entire study period.

EXAMPLE 8: FORMULATION III

The following is a representative pharmaceutical formulation and container closure for palonosetron that is useful for intravenous infusion formulations.

Ingredient	Amount (mg)

Palonosetron Hydrochloride	0.75[a)]
Sodium Chloride	450.0
EDTA	2.5
Sodium citrate	18.5
Citric acid monohydrate	7.8
WFJ	q.s. to 50 mL
Sodium hydroxide solution and/or hydrochloric acid solution	pH 4.8 ± 0.5
Container closure system	plastic container[b)] plus rubber stopper[c)]

[a)] Calculated based on the weight of free base.
[b)] Polyethylene multilayer film infusion bag.
[c)] Isoprene rubber stopper.

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This invention has been described with reference to its preferred embodiments. Variations and modifications of the invention will be obvious to those skilled in the art from the foregoing detailed description of the invention.

CLAIMS

What is claimed is:

1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 24 months when stored at room temperature.

2. The pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL.

3. The pharmaceutical formulation of claim 1, wherein said mannitol is in an amount of 41.5 mg/mL.

4. The pharmaceutical formulation of claim 1, wherein said solution further comprises a citrate buffer.

5. The pharmaceutical formulation of claim 4, wherein said citrate buffer is at a concentration of 20 millimolar.

6. The pharmaceutical formulation of claim 1, wherein said solution is buffered at a pH of 5.0 ± 0.5.

7. The pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL, wherein said mannitol is in an amount of 41.5 mg/mL,

wherein said solution further comprises a citrate buffer at a concentration of 20 millimolar, and wherein said solution is buffered at a pH of 5.0 ± 0.5.

8. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 18 months when stored at room temperature.

9. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 50 mL sterile isotonic solution buffered at a pH of 4.8 ± 0.5 comprising:

palonosetron hydrochloride in an amount of 0.75 mg based on the weight of its free base;

450.0 mg sodium chloride;

2.5 mg EDTA;

18.5 mg sodium citrate; and

7.8 mg citric acid monohydrate,

wherein said formulation is contained in a polyethylene multilayer film infusion bag comprising an isoprene rubber stopper.

ABSTRACT

The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron. The formulations are particularly useful in the preparation of intravenous and oral liquid medicaments.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Giorgio CALDERARI et al.	Group Art Unit: *Not Yet Assigned*
Application No.: *Not Yet Assigned*	Examiner: *Not Yet Assigned*
Continuation of U.S. Application No. 13/901,437	
Filed: *Herewith*	Confirmation No.: *Not Yet Assigned*
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Commissioner for Patents
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Alexandria, VA 22313-1450

Commissioner:

PRELIMINARY AMENDMENT AND CHOICE OF LAW

Prior to the examination of the above application, please amend this application as follows:

Amendments to the Specification are included in this paper.

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks/Arguments follow the amendment sections of this paper.

AMENDMENTS TO THE SPECIFICATION:

Please amend the specification as follows:

Please delete the paragraph at page 1, line 2 and replace it with the following new paragraph:

This is a continuation of U.S.S.N. 13/901,437, filed May 23, 2013, which is a continuation-in-part of U.S.S.N. 13/087,012 filed April 14, 2011, which is a continuation of U.S.S.N. 11/186,311 filed July 21, 2005 (now U.S. Patent No. 7,947,724), which is a continuation of PCT/EP04/000888, filed January 30, 2004, which claims priority to U.S. Provisional Application 60/444,351, filed January 30, 2003. The content of these applications is incorporated herein by reference.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1-9. (Canceled)

10. (New) A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of 5.0 ± 0.5, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

optionally a chelating agent; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 24 months when stored at room temperature.

11. (New) The pharmaceutical formulation of claim 10, wherein said mannitol is in an amount of 41.5 mg/mL.

12. (New) The pharmaceutical formulation of claim 10, wherein said solution further comprises a chelating agent.

13. (New) The pharmaceutical formulation of claim 12, wherein said chelating agent is EDTA.

14. (New) The pharmaceutical formulation of claim 13, wherein said EDTA is in an amount of from 0.005 mg/mL to 1.0 mg/mL.

15. (New) The pharmaceutical formulation of claim 14, wherein said EDTA is in an amount of 0.5 mg/mL.

16. (New) The pharmaceutical formulation of claim 10, wherein said solution further comprises a citrate buffer.

17. (New) The pharmaceutical formulation of claim 16, wherein said citrate buffer is at a concentration of 20 millimolar.

18. (New) A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of 5.0 ± 0.5, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

optionally a chelating agent; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 18 months when stored at room temperature.

REMARKS

I. Status of the Specification and Claims

The specification has been amended to update the priority information of this new continuing application.

Upon entry of this amendment, claims 10-18 are currently pending in this application. Claims 1-9 of the copending parent continuation-in-part (CIP) application are canceled without prejudice or disclaimer. New claims 10-18 find support under 35 U.S.C. § 112 in the provisional application, 60/444,351 ("the '351 Application") filed January 30, 2003, of the copending parent CIP (*see* Domestic Benefit/National Stage Information in the accompanying Application Data Sheet, which establishes a chain of copendency and specific reference from the copending CIP back to the '351 Application). Thus, claims 10-18 have an effective filing date (EFD) prior to March 16, 2013.

II. Choice of Law

This application falls under both transition provisions 3(n)(1) and 3(n)(2)[1] of the America Invents Act (AIA) because claims 10-18 have an EFD prior to March 16, 2013,

[1] SEC. 3(n)(1): "Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act ***[March 16, 2013]***, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time— (A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph ***[i.e., March 16, 2013]***; or (B) a specific reference under section 120, 121, 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such claim." (Commentary added for emphasis.)

and the copending parent CIP application contains a claim (claim 9) that finds support under 35 U.S.C. § 112 only in Example 8, which was newly added to the parent continuation-in-part application. Thus, claim 9 has an EFD after March 15, 2013.

For that reason, all of claims 10-18 should, for prior art purposes, be examined solely through the lenses of AIA §§ 102(a)(1), (a)(2), and 103, as well as pre-AIA § 102(g). That point is clearly explained by the USPTO:

> If an application (1) contains or contained at any time a claimed invention having an effective filing date that is before March 16, 2013, or ever claimed a right of priority or the benefit of an earlier filing date under 35 U.S.C. 119, 120, 121, or 365 based upon an earlier application that ever contained a claimed invention having an effective filing date that is before March 16, 2013 ***[such as claims 10-18]***, and (2) also contains or contained at any time any claimed invention having an effective filing date that is on or after March 16, 2013, or ever claimed a right of priority or the benefit of an earlier filing date under 35 U.S.C. 119, 120, 121, or 365 based upon an earlier application that **ever contained** a claimed invention having an effective filing date that is on or after March 16, 2013 ***[here that is claim 9 of the copending parent CIP]***, then AIA 35 U.S.C. 102 and 103 apply to the application, and each claimed invention in the application is also subject to pre-AIA 35 U.S.C. 102(g).

SEC. 3(n)(2): "The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection ***[March 15, 2013]***, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time— (A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection ***[March 16, 2013]***; or (B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim." (Commentary added for emphasis.)

See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,072 (February 14, 2013) (commentary and bold added for emphasis).

III. Claims 10-18 Find Support in the '351 Application

A. Claim 10

Claim 10 is an independent claim, reciting "[a] pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of 5.0 ± 0.5, said solution comprising: palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base; optionally a chelating agent; and from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 24 months when stored at room temperature." Support for claim 10 can be found throughout the specification of the '351 Application, for instance at:

- the abstract at page 21;
- page 2, lines 3-6 and lines 24-29;
- page 3, lines 1-5, lines 11-20;
- page 3, lines 21 to page 4, line 13;
- page 4, lines 19-21;
- page 5, lines 5-15;
- page 5, line 26 to page 6, line 2;
- page 6, lines 16-20;
- page 6, line 21 to page 7, line 1;

- page 7, lines 3-6;

- page 8, lines 2-5, lines 9-11, lines 13-25;

- page 9, lines 12-17, lines 21-23;

- page 10, lines 3-18; and

- original claims 1, 4, 5, 7, 8, 10, 12, 15, 18, 19, 21, 23, 25, 33, 36, 38, 39, 41, 43, 44, 46, 47, 50, 51, 54, 56, and 57.

Claim 10 recites "wherein said formulation is stable at 24 months when stored at room temperature." Support for this phrase can be found throughout the specification of the '351 Application, for instance at page 3, lines 11-12, page 5, lines 5-7, and page 10, lines 9-18. On July 25, 2003, furthermore, US FDA approved Helsinn's Aloxi® (palonosetron hydrochloride injection) product, which is within the scope of the claims, for a 2 year shelf life. *See* Exhibit A, FDA approval letter ("[B]ased on the primary stability data submitted, we are granting a 24-month expiration period for this product."). Hence, the written description and enablement of the new claims is tightly bound to the drug product approved by FDA and within the scope of the claims.

B. Claim 11

Claim 11 depends from claim 10, and recites "[t]he pharmaceutical formulation of claim 10, wherein said mannitol is in an amount of 41.5 mg/mL." Support for claim 11 can be found throughout the specification of the '351 Application, such as the support for claim 10 as set forth above. Additional support may be found, for instance at:

- page 9, lines 28 to page 10, line 2;

- page 11, line 25 to page 12, line 2; and

- page 12, Example 4.

C. Claims 12-15

Claim 12 depends from claim 10, and recites "[t]he pharmaceutical formulation of claim 10, wherein said solution further comprises a chelating agent." Claim 13 depends from claim 12, and recites "[t]he pharmaceutical formulation of claim 12, wherein said chelating agent is EDTA." Claim 14 depends from claim 13, and recites "[t]he pharmaceutical formulation of claim 13, wherein said EDTA is in an amount of from 0.005 mg/mL to 1.0 mg/mL." Claim 15 depends from claim 14, and recites "[t]he pharmaceutical formulation of claim 14, wherein said EDTA is in an amount of 0.5 mg/mL." Support for claims 12-15 can be found throughout the specification of the '351 Application, such as the support for claim 10 as set forth above. Additional support may be found, for instance at:

- page 9, lines 9-11, lines 17-21;
- page 12, Example 4; and
- original claims 9, 20, 34, 35, and 52.

D. Claims 16-17

Claim 16 depends from claim 10, and recites "[t]he pharmaceutical formulation of claim 10, wherein said solution further comprises a citrate buffer." Claim 17 depends from claim 16, and recites "[t]he pharmaceutical formulation of claim 16, wherein said citrate buffer is at a concentration of 20 millimolar." Support for claims 16-17 can be found throughout the specification of the '351 Application, such as the support for claim 10 as set forth above. Additional support may be found, for instance at:

- page 11, Example 2; and

- pages 11-12, Example 3.

E. Claim 18

Claim 18 is an independent claim, reciting "[a] pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of 5.0 ± 0.5, said solution comprising: palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base; optionally a chelating agent; and from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 18 months when stored at room temperature." Support for claim 18 can be found throughout the specification of the '351 Application such as the support for claim 10 as set forth above. Additional support may be found, for instance, at:

- page 5, lines 5-7.

Furthermore, US FDA approved Helsinn's Aloxi® (palonosetron hydrochloride injection) product, which is within the scope of the claims, for a 2 year shelf life. *See* Exhibit A, FDA approval letter ("[B]ased on the primary stability data submitted, we are granting a 24-month expiration period for this product."). And of course, that which is stable at 24 months is also stable at 18 months. Hence, the written description and enablement of the new claims is tightly bound to the drug product approved by FDA and within the scope of the claims.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to Deposit Account No. 504667.

Respectfully submitted,

By: _____
Clark G. Sullivan
Reg. No. 36,942

ARNALL GOLDEN GREGORY LLP
(404) 873-8500
(404) 873-8501 (fax)
Customer No.: 53449

Attorney Docket No.: 23278.2.US.9

Attachment:
- Exhibit A, FDA approval letter for Aloxi®

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-372

Helsinn Healthcare S.A.
c/o August Consulting
Attention: Craig Lehmann, Pharm. D.
515 Capital of Texas Highway, Suite 150
Austin, TX 78746

Dear Dr Lehmann:

Please refer to your new drug application (NDA) dated September 26, 2002, received September 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aloxi™ (palonosetron hydrochloride injection).

We acknowledge receipt of your submissions dated October 11 and November 21, 2002 and January 24, April 9, April 24, May 15, June 6, June 9, June 13, June 16, June 18, June 20, June 25, July 1, July 17, and July 22, 2003.

This new drug application provides for the use of Aloxi™ (palonosetron hydrochloride injection) for:
1) the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy, and
2) the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please note that, based on the primary stability data submitted, we are granting a 24-month expiration period for this product. When additional stability data are available, an extension of the expiration period may be requested by submission of a prior approval supplemental new drug application.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (carton label submitted June 25, 2003 and immediate container label submitted July 1, 2003). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-372.**" Approval of this submission by FDA is not required before the labeling is used.

FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. We acknowledge your June 26, 2003 "Proposed Pediatric Study Request" submitted under (b)(4)--------- We are reviewing your submission and will respond to your proposal in a separate letter. FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). In addition, we request that you initiate a 15-day report [21 CFR 314.80(c)] for each of the following:

- All spontaneous reports of constipation requiring hospitalization or emergency room visit
- All spontaneous reports of possible complications of constipation such as obstruction, perforation, intestinal ulceration, toxic megacolon, ileus, or impaction resulting in hospitalization or emergency room visit
- All spontaneous reports of any cardiovascular adverse event

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics

qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www. fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Brian Strongin, R.Ph., M.B.A., Regulatory Project Manager at (301) 827-7473.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Deputy Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Julie Beitz
7/25/03 08:45:03 AM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: *Not Yet Assigned*
Giorgio CALDERARI et al.	
Application No.: *Not Yet Assigned*	
Continuation of U.S. Application No. 13/901,437	Examiner: *Not Yet Assigned*
Filed: *Herewith*	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	Confirmation No.: *Not Yet Assigned*

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

Commissioner:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed simultaneously with the filing of the above-referenced application. Thus, no additional fees are required.

All of the listed documents were cited or made of record in prior Application No. 13/901,437, filing date May 23, 2013, upon which Applicant relies for the benefits provided in 35 U.S.C. § 120. Accordingly, copies are not enclosed.

It is noted that some of the documents listed on the SB-08 come from the files of related pending litigations. Some of those documents are noted "HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY." Assignee, Helsinn Healthcare SA, has given permission for such documents to be placed in the public record. And

furthermore, in general, Helsinn has given permission to place in the public record any and all documents submitted herewith. The undersigned understands from Helsinn that disclosure of these documents does not violate any court seal.

Certain confidential information has been redacted from some of those documents. Applicant hereby acknowledges that at least some of the redacted information includes non-zero U.S. dollar amounts. **If the Examiner believes that any of the redacted information is necessary or would like further information regarding the general nature of the redacted information, please let the undersigned know immediately**.

In addition, some of the submitted documents contain handwriting. In cases in which the unredacted handwriting may not be legible, Applicant has provided an electronic rendition of the handwritten information in the document.

There are no documents numbered 36-99, 141-199, 273-299, 338-399, 414-449, 453-499, 546-599, 608-699, or 748-799 associated with this Information Disclosure Statement.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines

that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this statement, please charge the fee to Deposit Account No. 504667.

Respectfully submitted,

By: _____
Clark G. Sullivan
Reg. No. 36,942

ARNALL GOLDEN GREGORY LLP
(404) 873-8500
(404) 873-8501 (fax)
Customer No.: 53449

Attorney Docket No.: 23278.2.US.9

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor	Giorgio Calderari
				Art Unit	
				Examiner Name	
Sheet	1	of	12	Attorney Docket Number	23278.2.US.9

U.S. PATENTS					
Examiner Initials	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,272,137	12-00-1993	Blase et al.	
	2	US-4,695,578	09-22-1987	Coates et al.	
	3	US-4,753,789	06-28-1988	Tyers et al.	
	4	US-4,886,808	12-12-1989	King	
	5	US-4,906,755	03-06-1990	Gittos	
	6	US-4,929,632	05-29-1990	Tyers et al.	
	7	US-4,937,247	06-26-1990	King	
	8	US-5,011,846	04-30-1991	Gittos et al.	
	9	US-5,034,398	07-23-1991	King	
	10	US-5,240,954	08-31-1993	Tyers et al.	
	11	US-5,344,658	09-06-1994	Collin	
	12	US-5,578,628	11-26-1996	Tyers et al.	
	13	US-5,578,632	11-26-1996	Tyers et al.	
	14	US-5,622,720	04-22-1997	Collin	
	15	US-5,922,749	07-13-1997	Tyers et al.	
	16	US-5,955,488	09-21-1999	Winterborn	
	17	US-6,063,802	05-16-2000	Winterborn	
	18	US-6,294,548	09-25-2001	James	
	19	US-5,854,270	12-29-1998	Gambhir	
	20	US-5,202,333	04-13-1993	Berger et al.	
	21	US-6,287,592	09-11-2001	Dickinson	
	22	US-6,284,749	09-04-2001	Castillo et al.	
	23	US-6,132,758	10-17-2000	Farah J. Munayyer et al. (Schering Corporation)	
	24	US-6,699,852	03-02-2004	Albert Robichaud (Bristol-Myers Squibb Pharma Co.)	
	25	US-7,109,339	09-19-2006	Tackyu Lee et al. (Bristol-Myers Squibb Company)	
	26	US-7,947,724	05-14-2011	Giorgio Calderari, et al.	
	27	US-7,947,725	05-14-2011	Giorgio Calderari et al.	
	28	US-7,960,424	06-14-2011	Giorgio Calderari et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor	Giorgio Calderari
				Art Unit	
				Examiner Name	
Sheet	2	of	12	Attorney Docket Number	23278.2.US.9

U.S. PUBLISHED PATENT APPLICATIONS

Examiner Initials	Cite No.[3]	Document Number Number-Kind Code[4] (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	29	US-20010020029	09-06-2001	James	
	30	US-20030095926	05-22-2003	Dugger, III	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country Code[5] Number[6] Kind Code[7] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[8]
	31	WO-2004067005	08-12-2004	Helsinn Healthcare S.A.		
	32	WO-2003100091	12-04-2003	Brockmöller		
	33	WO-2004703714	09-02-2004	Helsinn Healthcare S.A.		
	34	WO-2004045615	06-03-2004	Helsinn Healthcare S.A.		
	35	EP-0 512 400 A1	04-29-1992	Hallinan, E. Ann (G.D. Searle & Co.)		

NONPATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
	100	R. M. Eglen et al., "Pharmacological characterization of RS 25259-197, a novel and selective 5-HT3 receptor antagonist, in vivo," Br. J Pharmacology 114:860-866 (1995)	
	101	Chelly, Jacques et al., Oral RS-25259 Prevents Postoperative Nausea and Vomiting Following Laparoscopic Surgery, Anesthesiology, 1996, Vol., 85, No. 3A, p. A21	
	102	Sorbe, Bengt, 5-HT-3 Receptor Antagonists as Antiemetic Agents in Cancer Chemotherapy, extracted from Expert Opinion on Investigational Drugs, 1996, vol. 5 no. 4, pp. 389-407	
	103	Gaster, Laramie M. and King, Frank D., Serotonin 5-HT3 and 5-HT4 Receptor Antagonists, extracted from Medicinal Research Reviews, 1997 vol. 17, no. 2, pp. 163-214	
	104	Tang, Jun et al., "Efficacy of RS-25259, a Novel 5-HT3 Antagonist, In the Prevention of Postoperative Nausea and Vomiting after Major Gynecologic Surgery," Anesthesiology, 1997, vol. 85, No. 3 suppl. p. A329	
	105	Tang, Jun et al., The Efficacy of RS-25259, a Long-Acting Selective 5-HT3 Receptor Antagonist, for Preventing Postoperative Nausea and Vomiting After Hysterectomy Procedures, Anesthesia and Analgesia, 1998, vol. 87, pp. 462-467	
	106	Adis R&D Profile, Palonosetron RS 25259 197, Drugs in R&D, October 1999, vol. 2, no. 4, pp. 251-252	
	107	Piraccini Gaia et al., An Interesting 5-HT3 Receptor Antagonist Antiemetic for Patients Undergoing Chemotheraphy-based Conditioning Regimens," Blood, Nov. 16, 2001, vol. 98, no. 11, part 2, p. 350b, abstract no. 5169	
	108	Stacher, Georg, Palonosetron Helsinn, Current Opinion in Investigational Drugs. October 2002, vol. 3, no. 10, pp. 1502-7	
	109	Navari, Rudolph M., Pathogenesis-Based Treatment of Chemotherapy-Induced Nausea and Vomiting - Two New Agents, Journal of Supportive Oncology, 2003, vol. 1(2), pp. 89-103	
	110	Chaitow, 1990, 3 pages	
	111	Opposition Brief filed by Dr. Reddy's Laboratories (UK) Limited, opposition to European Patent No. 1601359 B1 dated July 7, 2009	
	112	Photolytic and oxidative degradation of an antiemetic agent, RG 12915 (Won C. M. et al., International Journal of Pharmaceutics 121, 95-105 (1995)	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Art Unit	
				Examiner Name	
Sheet	3	of	12	Attorney Docket Number	23278.2.US.9

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				First Named Inventor	Giorgio Calderari
				Art Unit	
				Examiner Name	
Sheet	10	of	12	Attorney Docket Number	23278.2.US.9

NONPATENT LITERATURE DOCUMENTS			
	530	Italian Group for Antiemetic Research. Dexamethasone alone or in combination with ondansetron for the prevention of delayed nausea and vomiting induced by chemotherapy. N Engl J Med, Vol. 342, No. 21, pp. 1554-1559, May 25, 2000.	
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	601	ROCHE0008749-876 (1995) (portions redacted).	
	602	HELSN0135068-82 (1998) (portions redacted).	Yes (Cite No. 603)
	603	English-language translation of Italian-language portions of HELSN0135068-82 (1998).	
	604	HELSN0161327-348 (2000) (portions redacted).	
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Sheet	11	of	12	Attorney Docket Number	23278.2.US.9

NONPATENT LITERATURE DOCUMENTS			
	700	Dr. Reddy's Labs., Ltd.'s and Dr. Reddy's Labs., Inc.'s Memorandum of Law in Support of Their Motion to Amend Their Invalidity Contentions dated February 15, 2013 (D.N.J. Case No. 11-3962).	
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	702	HELSN0376722-23 (2001) (cited in 700).	
	703	HELSN0376724 (2002) (cited in 700).	
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	705	Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Reply Memorandum of Law in Further Support of Their Motion to Amend Their Invalidity Contentions dated March 15, 2013 (D.N.J. Case No. 11-3962).	
	706	Teva Pharm. Indus., Ltd.'s and Teva Pharm. USA, Inc.'s Memorandum in Support of Their Motion to Amend Invalidity Contentions dated February 15, 2013 (D.N.J. Case No. 1-3962).	
	707	HELSN0388553-65 (1998) (cited in 706; portions redacted).	
	708	HELSN0388566-68 (1998) (cited in 706; portions redacted).	
	709	HELSN0388569-74 (1998) (cited in 706; portions redacted).	
	710	HELSN0388587-91 (1998) (cited in 706; portions redacted).	
	711	HELSN0388592-95 (1998) (cited in 706; portions redacted).	Yes (Cite No. 712)
	712	English-language translation of HELSN0388592-95 (1998) (cited in 706; portions redacted).	
	713	HELSN0388596-97 (1998) (cited in 706; portions redacted).	
	714	HELSN0388604 (1998) (cited in 706; portions redacted).	
	715	HELSN0388605-06 (1998) (cited in 706; portions redacted).	
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	718	HELSN0389145-48 (1999) (cited in 706; portions redacted).	
	719	HELSN0389149-61 (2000) (cited in 706; portions redacted).	
	720	HELSN0392047-48 (1998) (cited in 706; portions redacted).	
	721	HELSN0392393-94 (1998) (cited in 706; portions redacted).	
	722	HELS0393657-61 (2000) (cited in 706; portions redacted).	Yes (Cite No. 723)
	723	English-language translation of Italian-language portions of HELSN039657-61 (2000) (cited in 706; portions redacted).	
	724	Excerpts from Calderari Deposition Transcript, pp. 1-4, 229-232, and 278-393 (2013) (cited in 706 and 728; portions redacted).	
	725	HELSN0000093-9 (2006) (cited in 724; portions redacted).	
	726	HELSN0004207 (2002) (cited in 724).	
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	728	Teva Pharm. Indus., Ltd.'s and Teva Pharm. USA, Inc.'s Reply in Support of Their Motion to Amend Their Invalidity Contentions dated March 15, 2013 (D.N.J. Case No. 1-3962).	
	729	HELSN00388448-542 (1998-1999) (cited in 728; portions redacted).	Yes (Cite No. 730)
	730	English-language translation of Italian-language portions of HELSN00388448-542 (1998-1999) (portions redacted).	

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Sheet	12	of	12	Attorney Docket Number	23278.2.US.9

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	731	HELSN0388543-44 (1999) (cited in 728; portions redacted).	
	732	HELSN0388545-52 (1998) (cited in 728; portions redacted).	
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	738	HELSN0388586 (1998) (cited in 728; portions redacted).	
	739	HELSN0388598-601 (1998) (cited in 728; portions redacted).	
	740	HELSN0388602-03 (1998) (cited in 728; portions redacted).	
	741	HELSN0388610 (1998) (cited in 728; portions redacted).	
	742	Sandoz Inc.'s Redacted Memorandum of Law in Support of its Motion to Amend its Invalidity Contentions dated February 15, 2013 (D.N.J. Case No. 11-3962).	
	743	Exhibit G to Sandoz Inc.'s Redacted Memorandum of Law in Support of its Motion to Amend its Invalidity Contentions dated February 15, 2013 (D.N.J. Case No. 11-3962) (cited in 742).	
	744	Sandoz Inc.'s Redacted Reply Memorandum of Law in Support of its Motion to Amend its Invalidity Contentions dated March 15, 2013 (D.N.J. Case No. 11-3962).	
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	746	Complaint for patent infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. dated April 16, 2013 (D. Del. Case No. 13-688).	
	747	Accord Healthcare, Inc. Paragraph IV notice regarding U.S. Patent Nos. 7,947,724; 7,947,725; and 7,960,424, dated April 3, 2013.	
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	801	English-language translation of Cite No. 800 (2012).	
	802	Approval of Partial Changes in Drug Marketing Approved Items for Aloxi I.V. Drip Infusion Bag 0.75 mg, Japanese Ministry of Health, Labour and Welfare (2012).	Yes (Cite No. 803)
	803	English-language translation of Cite No. 802 (2012).	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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AIA DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION FILED ON OR AFTER SEPTEMBER 16, 2012 (37 CFR 1.63)			ATTORNEY DOCKET NUMBER	
			FIRST NAMED INVENTOR	GIORGIO CALDERARI
			COMPLETE IF KNOWN	
☒ DECLARATION SUBMITTED WITH INITIAL FILING	OR	☐ DECLARATION SUBMITTED AFTER INITIAL FILING (SURCHARGE (37 CFR 1.16(F)) REQUIRED	APPLICATION NUMBER	
			FILING DATE	
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			EXAMINER NAME	

LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

(Title of the Invention)

As a below named inventor, I hereby declare that: (1) This declaration is directed to the application which ☒ is attached and is a continuation-in-part of United States Application No. 13/087,012; (2) the application was made or authorized to be made by me; (3) my residence and mailing address are as stated below next to my name; and (4) I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

As a below named inventor, I have reviewed and understand the contents of the application, including the claims, and am aware of the duty to disclose to the USPTO all information known to me to be material to patentability as defined in 37C.F.R. § 1.56.

I hereby acknowledge that any willful false statements made in this declaration are punishable by fine or imprisonment of not more than five (5) years, or both, under section 1001 of Title 18 of the United States Code.

Legal Name of First Inventor **Giorgio CALDERARI**	Inventor's Signature	Date 6 May 2013
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Residence Varese, Italy		
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Legal Name of Third Inventor **Roberta CANNELLA**	Inventor's Signature	Date 06/05/2013
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Legal Name of Second Inventor **Daniele BONADEO**	Inventor's Signature	Date 06/05/2013
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Legal Name of Fourth Inventor **Andrew MIKSZTAL**	Inventor's Signature Andrew Miksztal	Date May 15, 2013
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Mailing Address il 06/05/2013 VIA AL COLLE 42 ~~Via Europa, 60-I-21040, Morazzone~~, Varese, Italy		

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Legal Name of Sixth Inventor **Kathleen M. LEE**	Inventor's Signature Kathleen M Lee	Date 14 May 2013
Residence Palo Alto, CA, U.S.A.		
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Legal Name of Seventh Inventor **Carmine PANUCCIO**	Inventor's Signature × Carmine Panuccio	Date 06 MAY, 2013
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SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)

Title of Invention: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

This statement is directed to:

☒ The attached application,

OR

☐ United States application or PCT international application number _____ filed on _____.

LEGAL NAME of inventor to whom this substitute statement applies: **ALBERTO MACCIOCCHI**

Residence (except for a deceased or legally incapacitated inventor):

Mailing Address (except for a deceased or legally incapacitated inventor):

I believe the above-named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application.

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

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

Relationship to the inventor to whom this substitute statement applies:

☒ Legal Representative (for deceased or legally incapacitated inventor only),

☐ Assignee,

☐ Person to whom the inventor is under an obligation to assign,

☐ Person who otherwise shows a sufficient proprietary interest in the matter, or

☐ Joint Inventor.

Circumstances permitting execution of this substitute statement:

☒ Inventor is deceased,

☐ Inventor is under legal incapacity,

☐ Inventor cannot be found or reached after diligent effort, or

☐ Inventor has refused to execute the oath or declaration under 37 CFR 1.63

If there are joint inventors, please check the appropriate box below:

☒ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) naming the entire inventive entity has been or is currently submitted

OR

☐ An application data sheet under 37 CFR 1.76 (PTO/AIA/14 or equivalent) has not been submitted. Thus, a Substitute Statement Supplemental Sheet (PTO/AIA/11 or equivalent) naming the entire inventive entity and providing inventor information is attached. See 37 CFR 1.64(b).

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.

SIGNATURE OF PERSONS EXECUTING THIS SUBSTITUTE STATEMENT

Name	Simone Macciocchi		Date
Signature	X		8.5.2013
Residence	City: 6815 Melide	State:	Country: Switzerland
Mailing Address	Via Alla Bola, 2		Country: Switzerland

Name	Giulio Macciocchi		Date
Signature	X		8.5.2013
Residence	City: 6932 Breganzona	State:	Country: Switzerland
Mailing Address	Via Rovere, 7		Country: Switzerland

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Giorgio CALDERARI et al. Application No.: *Not Yet Assigned* Continuation-in-Part of U.S. Application No. 13/087,012 Filed: *Herewith* For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	Group Art Unit: *Not Yet Assigned* Examiner: *Not Yet Assigned* Confirmation No.: *Not Yet Assigned*

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

Commissioner:

POWER OF ATTORNEY

1. I, Luigi CALETTI, am authorized to act on behalf of Helsinn Healthcare S.A. My title and position with Helsinn Healthcare S.A. is Chief Financial Officer.
2. Helsinn Healthcare S.A. is the assignee of an undivided interest in the entirety of the above-identified continuation-in-part application by virtue of an assignment, concurrently being submitted for recordation pursuant to 37 C.F.R. §§ 3.11 and 3.73, and accompanying this application, from Giorgio CALDERARI, Daniele BONADEO, Roberta CANNELLA, Simone MACCIOCCHI (legal representative of Alberto MACCIOCCHI (deceased)), Giulio MACCIOCCHI (legal representative of Alberto MACCIOCCHI (deceased)), and Carmine PANUCCIO to Helsinn Healthcare S.A.
3. As a representative authorized to act on behalf of Assignee, Helsinn Healthcare S.A., I hereby appoint the patent practitioners associated with **Arnall Golden**

Gregory LLP, Customer No. 53,449, including, without limitation, Clark G. Sullivan, Reg. No, 36,942, to prosecute this reissue application and transact all business in the U.S. Patent and Trademark Office connected therewith. Please address all correspondence to the correspondence address associated with **Customer No. 53,449**:

ARNALL GOLDEN GREGORY LLP
171 17th Street, NW
Suite 2100
Atlanta, GA 30363-1031
404-873-8500 (phone)
404-873-8501 (fax).

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.

On behalf of Helsinn Healthcare S.A.

Date: 6.5.2013

By: _____
(signature)

Name: Luigi CALETTI

Title: Chief Financial Officer

SOLE/JOINT INVENTION
(U.S. Rights Only)
Attorney Docket No.

ASSIGNMENT

WHEREAS, **Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Andrew Miksztal, Thomas Malefyt, Kathleen M. Lee, Alberto Macciocchi**, and **Carmine Panuccio** have jointly invented certain inventions and improvements disclosed in a continuation-in-part application entitled "***Liquid Pharmaceutical Formulations of Palonosetron***" filed concurrently herewith in the U.S. Patent and Trademark Office;

WHEREAS, **Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Simone Macciocchi** (legal representative of **Alberto Macciocchi** (deceased)), **Giulio Macciocchi** (legal representative of **Alberto Macciocchi** (deceased)), and **Carmine Panuccio** are hereinafter referred to as Assignor(s);

WHEREAS, **Helsinn Healthcare SA** has a principal place of business at P.O. Box 357, Pambio-Noranco, Switzerland 6915 and is hereinafter referred to as Assignee;

NOW THEREFORE, be it known that, for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I/WE, as Assignor(s), have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, our entire right, title, and interest in and to this invention and this continuation-in-part application, and all divisions, and continuations thereof, and all Letters Patent of the United States which may be granted thereon, and all reissues thereof; and I/WE hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I/WE HEREBY further covenant and agree that I/We will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to us respecting this invention and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors and assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

AND, I/WE HEREBY authorize and request the attorneys who have been appointed in the Power of Attorney in this application, to insert here in parentheses (Application No._____, filed _____) the filing date and application number of said continuation-in-part application when known.

IN TESTIMONY WHEREOF, I/We have hereunto set our hand(s).

1. FULL NAME OF FIRST ASSIGNOR **Giorgio Calderari**	ASSIGNOR'S SIGNATURE x	DATE 6 May 2013
ADDRESS Via Scer 35, 6862, Rancate, Switzerland		CITIZENSHIP CH
2. FULL NAME OF SECOND ASSIGNOR **Daniele Bonadeo**	ASSIGNOR'S SIGNATURE x	DATE 06/05/2013
ADDRESS Via Ronco Capo Caccia, 32-I-21030, Casalzuigno, Varese, Italy		CITIZENSHIP IT
3. FULL NAME OF THIRD ASSIGNOR **Roberta Cannella**	ASSIGNOR'S SIGNATURE x	DATE 06/05/2013
ADDRESS VIA AL COLLE 42 ~~Via Europa, 50-I-21040, Morazzone~~, Varese, Italy RC 6 May 2013		CITIZENSHIP IT
4. FULL NAME OF FOURTH ASSIGNOR **Simone Macciocchi** Legal Representative of **Alberto Macciocchi**	ASSIGNOR'S SIGNATURE x	DATE 8/5/2013
ADDRESS 6815 Melide, Via Alla Bola, 2		CITIZENSHIP CH

SOLE/JOINT INVENTION
(U.S. Rights Only)
Attorney Docket No.

5. FULL NAME OF FIFTH ASSIGNOR **Giulio Macciocchi** Legal Representative of **Alberto Macciocchi**	ASSIGNOR'S SIGNATURE	DATE 8.5.2013
ADDRESS 6932 Breganzona, Via Rovere 7		CITIZENSHIP CH
6. FULL NAME OF SIXTH ASSIGNOR **Carmine Panuccio**	ASSIGNOR'S SIGNATURE Carmine Panuccio	DATE 06 MAY, 2013
ADDRESS Via XXV Aprile, No. 10, I-22070 Casnate con Bernate, Como, Italy		CITIZENSHIP IT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: *Not Yet Assigned*
Giorgio CALDERARI et al.	
Application No.: *Not Yet Assigned*	Examiner: *Not Yet Assigned*
Continuation-in-Part of U.S. Application No. 13/087,012	
Filed: *Herewith*	Confirmation No.: *Not Yet Assigned*
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

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

Commissioner:

POWER OF ATTORNEY

1. I, Frederick Kentz, am authorized to act on behalf of Roche Palo Alto LLC.
2. Roche Palo Alto LLC is the assignee of an undivided interest in the entirety of the above-identified continuation-in-part application by virtue of an assignment, concurrently being submitted for recordation pursuant to 37 C.F.R. §§ 3.11 and 3.73, and accompanying this application, from Andrew MIKSZTAL, Thomas MALEFYT, and Kathleen M. LEE to Roche Palo Alto LLC.
3. As a representative authorized to act on behalf of Assignee, Roche Palo Alto LLC, I hereby appoint the patent practitioners associated with **Arnall Golden Gregory LLP, Customer No. 53,449**, including, without limitation, Clark G. Sullivan, Reg. No, 36,942, to prosecute this reissue application and transact all business in the U.S.

Patent and Trademark Office connected therewith. Please address all correspondence to the correspondence address associated with **Customer No. 53,449**:

ARNALL GOLDEN GREGORY LLP
171 17th Street, NW
Suite 2100
Atlanta, GA 30363-1031
404-873-8500 (phone)
404-873-8501 (fax).

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.

On behalf of Roche Palo Alto LLC

Date: 5/16/2013

By: _____
(signature)

Name: FREDERICK C. KENTZ III

Title: VICE PRESIDENT

SOLE/JOINT INVENTION
(U.S. Rights Only)
Attorney Docket No.

ASSIGNMENT

WHEREAS, **Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Andrew Miksztal, Thomas Malefyt, Kathleen M. Lee**, **Alberto Macciocchi**, and **Carmine Panuccio** have jointly invented certain inventions and improvements disclosed in a continuation-in-part application entitled ***"Liquid Pharmaceutical Formulations of Palonosetron"*** filed concurrently herewith in the U.S. Patent and Trademark Office;

WHEREAS, **Andrew Miksztal, Thomas Malefyt,** and **Kathleen M. Lee** are hereinafter referred to as Assignor(s);

WHEREAS, **Roche Palo Alto LLC** has a principal place of business at 3431 Hillview Avenue, Palo Alto, California 94304 and is hereinafter referred to as Assignee;

NOW THEREFORE, be it known that, for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I/WE, as Assignor(s), have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, our entire right, title, and interest in and to this invention and this continuation-in-part application, and all divisions, and continuations thereof, and all Letters Patent of the United States which may be granted thereon, and all reissues thereof; and WE hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I/WE HEREBY further covenant and agree that I/We will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to us respecting this invention and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors and assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

AND, I/WE HEREBY authorize and request the attorneys who have been appointed in the Power of Attorney in this application, to insert here in parentheses (Application No._____, filed _____) the filing date and application number of said continuation-in-part application when known.

IN TESTIMONY WHEREOF, I/We have hereunto set our hand(s).

1. FULL NAME OF FIRST ASSIGNOR **Andrew Miksztal**	ASSIGNOR'S SIGNATURE Andrew Miksztal	DATE May 15, 2013
ADDRESS 743 Cereza Drive, Palo Alto, CA, 94306 U.S.A.		CITIZENSHIP U.S.A.
2. FULL NAME OF SECOND ASSIGNOR **Thomas Malefyt**	ASSIGNOR'S SIGNATURE	DATE
ADDRESS 20 Sleepy Hollow Drive, Carmel Valley, CA, 93924 U.S.A.		CITIZENSHIP U.S.A.
3. FULL NAME OF THIRD ASSIGNOR **Kathleen M. Lee**	ASSIGNOR'S SIGNATURE	DATE
ADDRESS 4173 El Camino Real, Apt. 20, Palo Alto, CA, 94306 U.S.A.		CITIZENSHIP U.S.A.

SOLE/JOINT INVENTION
(U.S. Rights Only)
Attorney Docket No.

ASSIGNMENT

WHEREAS, **Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Andrew Miksztal, Thomas Malefyt, Kathleen M. Lee**, **Alberto Macciocchi**, and **Carmine Panuccio** have jointly invented certain inventions and improvements disclosed in a continuation-in-part application entitled ***"Liquid Pharmaceutical Formulations of Palonosetron"*** filed concurrently herewith in the U.S. Patent and Trademark Office;

WHEREAS, **Andrew Miksztal, Thomas Malefyt,** and **Kathleen M. Lee** are hereinafter referred to as Assignor(s);

WHEREAS, **Roche Palo Alto LLC** has a principal place of business at 3431 Hillview Avenue, Palo Alto, California 94304 and is hereinafter referred to as Assignee;

NOW THEREFORE, be it known that, for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I/WE, as Assignor(s), have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, our entire right, title, and interest in and to this invention and this continuation-in-part application, and all divisions, and continuations thereof, and all Letters Patent of the United States which may be granted thereon, and all reissues thereof; and WE hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I/WE HEREBY further covenant and agree that I/We will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to us respecting this invention and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors and assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

AND, I/WE HEREBY authorize and request the attorneys who have been appointed in the Power of Attorney in this application, to insert here in parentheses (Application No._____, filed _____) the filing date and application number of said continuation-in-part application when known.

IN TESTIMONY WHEREOF, I/We have hereunto set our hand(s).

1. FULL NAME OF FIRST ASSIGNOR **Andrew Miksztal**	ASSIGNOR'S SIGNATURE	DATE
ADDRESS 743 Cereza Drive, Palo Alto, CA, 94306 U.S.A.		CITIZENSHIP U.S.A.
2. FULL NAME OF SECOND ASSIGNOR **Thomas Malefyt**	ASSIGNOR'S SIGNATURE Thomas R Malefyt	DATE 16 May, 2013
ADDRESS 20 Sleepy Hollow Drive, Carmel Valley, CA, 93924 U.S.A.		CITIZENSHIP U.S.A.
3. FULL NAME OF THIRD ASSIGNOR **Kathleen M. Lee**	ASSIGNOR'S SIGNATURE	DATE
ADDRESS 4173 El Camino Real, Apt. 20, Palo Alto, CA, 94306 U.S.A.		CITIZENSHIP U.S.A.

SOLE/JOINT INVENTION
(U.S. Rights Only)
Attorney Docket No.

ASSIGNMENT

WHEREAS, **Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Andrew Miksztal, Thomas Malefyt, Kathleen M. Lee**, **Alberto Macciocchi**, and **Carmine Panuccio** have jointly invented certain inventions and improvements disclosed in a continuation-in-part application entitled ***"Liquid Pharmaceutical Formulations of Palonosetron"*** filed concurrently herewith in the U.S. Patent and Trademark Office;

WHEREAS, **Andrew Miksztal, Thomas Malefyt,** and **Kathleen M. Lee** are hereinafter referred to as Assignor(s);

WHEREAS, **Roche Palo Alto LLC** has a principal place of business at 3431 Hillview Avenue, Palo Alto, California 94304 and is hereinafter referred to as Assignee;

NOW THEREFORE, be it known that, for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, I/WE, as Assignor(s), have sold, assigned, transferred, and set over, and do hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, our entire right, title, and interest in and to this invention and this continuation-in-part application, and all divisions, and continuations thereof, and all Letters Patent of the United States which may be granted thereon, and all reissues thereof; and WE hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment;

AND, I/WE HEREBY further covenant and agree that I/We will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to us respecting this invention and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors and assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention in the United States, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

AND, I/WE HEREBY authorize and request the attorneys who have been appointed in the Power of Attorney in this application, to insert here in parentheses (Application No._____, filed _____) the filing date and application number of said continuation-in-part application when known.

IN TESTIMONY WHEREOF, I/We have hereunto set our hand(s).

1. FULL NAME OF FIRST ASSIGNOR **Andrew Miksztal**	ASSIGNOR'S SIGNATURE	DATE
ADDRESS 743 Cereza Drive, Palo Alto, CA, 94306 U.S.A.		CITIZENSHIP U.S.A.
2. FULL NAME OF SECOND ASSIGNOR **Thomas Malefyt**	ASSIGNOR'S SIGNATURE	DATE
ADDRESS 20 Sleepy Hollow Drive, Carmel Valley, CA, 93924 U.S.A.		CITIZENSHIP U.S.A.
3. FULL NAME OF THIRD ASSIGNOR **Kathleen M. Lee**	ASSIGNOR'S SIGNATURE Kathleen M Lee	DATE 14 May 2013
ADDRESS 4173 El Camino Real, Apt. 20, Palo Alto, CA, 94306 U.S.A.		CITIZENSHIP U.S.A.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: *Not Yet Assigned*
Giorgio CALDERARI et al.	
Application No.: *Not Yet Assigned*	
Continuation of U.S. Application No. 13/901,437	Examiner: *Not Yet Assigned*
Filed: *Herewith*	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	Confirmation No.: *Not Yet Assigned*

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

Commissioner:

AUTHORIZATION TO ACT IN A REPRESENTATIVE CAPACITY

I hereby authorize Thomas L. Irving, Registration No. 28,619, to act in a representative capacity on behalf of assignee Helsinn Healthcare S.A. ("Helsinn"). Mr. Irving is authorized to conduct interviews with me in the above-identified application but only on behalf of assignee Helsinn, pursuant to 37 C.F.R. § 1.34.

Mr. Irving is not granted authority to act in a representative capacity on behalf of assignee Roche Palo Alto LLC ("Roche"). Thus, Mr. Irving is not authorized to conduct interviews with me in the above-identified application on behalf of assignee Roche, or to file correspondence with me in the above-identified application on behalf of assignee Roche.

This is not a Power of Attorney to Thomas L. Irving. Accordingly, Mr. Irving does not have authority to sign a request to change the correspondence address, a request for an express abandonment, a disclaimer, a power of attorney, or other document requiring the signature of the applicant, assignee of the entire interest, or an attorney of record. Rather, his authority is limited to what is described above.

Power of attorney in the above-identified application is currently to Arnall Golden Gregory LLP, Customer No. 53,449 and remains with the firm to represent both Helsinn and Roche Palo Alto.

If there is any fee due in connection with the filing of this statement, please charge the fee to Deposit Account No. 504667.

Respectfully submitted,

By:_____
Clark G. Sullivan
Reg. No. 36,942

ARNALL GOLDEN GREGORY LLP
(404) 873-8500
(404) 873-8501 (fax)
Customer No.: 53449

Attorney Docket No.: 23278.2.US.9

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Filer:	Clark G. Sullivan/Susan Wray
Attorney Docket Number:	23278.2.US.9

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($)
Processing Fee, Except for Provis. Apps	1053	1	140	140
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300
OTHER PUBLICATION PROCESSING FEE	1808	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**6170**

Electronic Acknowledgement Receipt

EFS ID:	15864437
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Susan Wray
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	24-MAY-2013
Filing Date:	
Time Stamp:	12:33:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$6170
RAM confirmation Number	41
Deposit Account	504667
Authorized User	SULLIVAN, CLARK

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1	Transmittal of New Application	1-23278_2_US9-CIP_CON_Application_Transmittal.pdf	346753 f31605b403d7c93c4004783df6f5ddbf105c956f	no	2
Warnings:					
Information:					
2	TrackOne Request	2-23278_2_US9-Certification_and_Request_for_Track_1.pdf	291593 dd7ad0956ec2bfc65055ebdd9cf81a7b27b74985	no	2
Warnings:					
Information:					
3	Application Data Sheet	3-23278_2_US9-Application_Data_Sheet.pdf	1289294 2360ceddfb3eba8024a8d3b21df08b3c32e184df	no	9
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
4		4-23278_2_US9_JMM_CIP_Application_as_filed.pdf	1602192 6384a789ce341f9ab5f93cd8dbf6b237ee3870f9	yes	20
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	17	
	Claims		18	19	
	Abstract		20	20	
Warnings:					
Information:					
5	Preliminary Amendment	5-23278_2_US9-Preliminary_Amendment_and_Choice_of_Law_with_ExhA.pdf	1242696 69673aa711e4f15c5f761ca959fed00bc21d478f	no	16
Warnings:					
Information:					
6	Transmittal Letter	7-23278_2_US9-IDS_Transmittal.pdf	227310 90a952c73c7b34d10e68384026bf115413a8f082	no	3
Warnings:					
Information:					

7	Information Disclosure Statement (IDS) Form (SB08)	8-23278_2_US9-IDS_SB08.pdf	2315618 85ac9b19d1ccb219e71f00bf1c41d32b7687263a	no	13
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
8	Oath or Declaration filed	9-23278_2_US9-CIP_Declarations.pdf	989101 8e66b3d0d598b7537c0f34db7e81e8a78131348f	no	10
Warnings:					
Information:					
9	Power of Attorney	10-23278_2_US9-CIP_Power_of_Attorney.pdf	1035625 37adb8d1166b157ca534195daec65160655f60d3	no	9
Warnings:					
Information:					
10	Miscellaneous Incoming Letter	11-23278_2_US9-Authorization_to_Act_in_Representative_Capacity.pdf	132203 3c23b98beef7eea5566bc120507531debf71b711	no	2
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	41931 eca07f6d3a8eee0e7835642a79e693ba7724bad3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	9514316		

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.

ATTORNEY DOCKET NO. 23278.2.US.9
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
Giorgio CALDERARI et al.	) Group Art Unit: *Not Yet Assigned*
Application No.: 13/901,830	) Examiner: *Not Yet Assigned*
Continuation of U.S. Application No. 13/901,437	)
Filed: May 24, 2013	) Confirmation No.: *Not Yet Assigned*
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	)

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

Sir:

Filed herewith please find an amended Application Data Sheet ("ADS"). The section entitled "Domestic Benefit/National Stage Information" on page 4, has been amended to include U.S.S.N. 13/901,437 on the second line entitled "Application Number." The application number for this application, U.S.S.N. 13/901,830, has also been added to the same section in the first line entitled "Application Number."

Respectfully submitted,

By: _____
Clark G. Sullivan
Reg. No. 36,942

ARNALL GOLDEN GREGORY LLP
(404) 873-8500
(404) 873-8501 (fax)
Customer No.: 53449
Attorney Docket No.: 23278.2.US.9

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

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.
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.

Secrecy Order 37 CFR 5.2

☐ 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
	Giorgio		Calderari	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Rancate	Country of Residence [i]	CH

Mailing Address of Inventor:

Address 1	Via Scer 35		
Address 2			
City	Rancate	State/Province	TC
Postal Code	6862	Country [i]	CH

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Daniele		Bonadeo	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Casalzuigno	Country of Residence [i]	IT

Mailing Address of Inventor:

Address 1	Via Ronco Capo Caccia, 32-I		
Address 2			
City	Casalzuigno	State/Province	VA
Postal Code	21030	Country [i]	IT

Inventor 3 Remove

Legal Name

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Roberta		Cannella	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Varese	Country of Residence [i]	IT

Mailing Address of Inventor:

Address 1	Via Al Colle 42		
Address 2			
City	Varese	State/Province	VA
Postal Code	21030	Country [i]	IT

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alberto		Macciocchi (Deceased)	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Melide	Country of Residence [i]	CH

Mailing Address of Inventor:

Address 1	Via Alla Bola, 2		
Address 2			
City	Melide	State/Province	TC
Postal Code	6815	Country [i]	CH

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		Miksztal	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Palo Alto	State/Province	CA	Country of Residence [i]	US

Mailing Address of Inventor:

Address 1	743 Cereza Drive		
Address 2			
City	Palo Alto	State/Province	CA
Postal Code	94306	Country [i]	US

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas		Malefyt	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Carmel Valley	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	20 Sleepy Hollow Drive		
Address 2			
City	Carmel Valley	State/Province	CA
Postal Code	93924	Country	US

Inventor 7 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kathleen	M	Lee	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Palo Alto	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4173 El Camino Real, Apt. 20		
Address 2			
City	Palo Alto	State/Province	CA
Postal Code	94306	Country	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).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	53449		
Email Address		Add Email	Remove Email

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Application Information:

Title of the Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON		
Attorney Docket Number	23278.2.US.9	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **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:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	53449		

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.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13901830	Continuation of	13901437	2013-05-23
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13901437	Continuation in part of	13087012	2011-04-14
Prior Application Status	Patented		Remove

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13087012	Continuation of	11/186311	2005-07-21	7947724	2011-05-24

Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11186311	Continuation of	PCT/EP2004/000888	2004-01-30
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/EP2004/000888	non provisional of	60/444351	2003-01-30

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

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)[i] 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).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

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 o f 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

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.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) 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. ☒

Organization Name	Helsinn Healthcare SA

Mailing Address Information For Applicant:

Address 1	P.O. Box 357, Pambio-Noranco		
Address 2			
City	Lugano	**State/Province**	TC
Country	CH	Postal Code	6915
Phone Number	+41 (0) 91 985.21.21	Fax Number	+41 (0) 91993.21.22

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Email Address	info-HHC@helsinn.com

Additional Applicant Data may be generated within this form by selecting the Add button.

Applicant 2

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.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ 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. ☒

Organization Name	Roche Palo Alto LLC		
Mailing Address Information For Applicant:			
Address 1	3431 Hillview Avenue		
Address 2			
City	Palo Alto	**State/Province**	CA
Country	US	Postal Code	94304
Phone Number	(650) 225-1000	Fax Number	(650) 225-6000
Email Address	info@roche.com		

Additional Applicant Data may be generated within this form by selecting the Add button.

Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	23278.2.US.9
	Application Number	
Title of Invention	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	

Assignee 1

Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section 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), as the patent application publication will include the name of the applicant(s).

If the Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

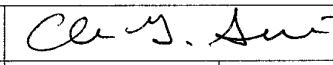
Mailing Address Information For Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button.

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				Date (YYYY-MM-DD)	2013-05-24
First Name	Clark G.	Last Name	Sullivan	Registration Number	36942

Additional Signature may be generated within this form by selecting the Add button.

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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 the Freedom of Information Act requires disclosure of these records.

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 Co o p eration 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 inspections 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.

Electronic Acknowledgement Receipt

EFS ID:	15866085
Application Number:	13901830
International Application Number:	
Confirmation Number:	3806
Title of Invention:	LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON
First Named Inventor/Applicant Name:	Giorgio Calderari
Customer Number:	53449
Filer:	Clark G. Sullivan/Susan Wray
Filer Authorized By:	Clark G. Sullivan
Attorney Docket Number:	23278.2.US.9
Receipt Date:	24-MAY-2013
Filing Date:	
Time Stamp:	13:54:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	1-23278_2_US9_Amended_Application_Data_Sheet_Transmittal.pdf	65915 c507121da9d97850929cab59e657d6c0c2e3825e	no	1
Warnings:					
Information:					

2	Application Data Sheet	2-23278_2_US9_Amended_Application_Data_Sheet.pdf	1274478 2bfd04cf0fd7519db6b1bc55ad3fa2a643ee113a	no	9

Warnings:	
Information:	
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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.