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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

27777 7590 03/13/2015

BERNARD F. PLANTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 03/13/2015

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.

Notice of Allowability	Application No. 12/337,144	Applicant(s) VERMEULEN ET AL.	
	Examiner Renee Claytor	Art Unit 1627	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 *the RCE filed on 11/17/2014*.
   ☐ 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 *1-5,13,15-20,22 and 24*. 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. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

DETAILED ACTION

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

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2014 has been entered.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: please see the original Notice for Allowance given on 6/25/2013.

It is noted that Applicants have filed an IDS, which has been considered and no art was found to be relevant to the present invention.

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."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. 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.

/Renee Claytor/

Primary Examiner, Art Unit 1627

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		Kazuo YAMADA et al., Future Potentiality of Pharmacotherapy for Schizophrenia in Acute Phase, Clinical Psychopharmacology, Vo. 8, No. 10 (2005), pp.1563-1568	

Examiner Signature	/Renee Claytor/	Date Considered	03/09/2015

*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. /R.C./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	Art Unit
	Renee Claytor	1627

CPC- SEARCHED		
Symbol	Date	Examiner
A61K 31/519	3/9/2015	RC

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM Inventor Search	3/9/2015	RC
EAST (updated)	3/9/2015	RC

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61K	31/519	3/9/2015	RC

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		Kazuo YAMADA et al., Future Potentiality of Pharmacotherapy for Schizophrenia in Acute Phase, Clinical Psychopharmacology, Vo. 8, No. 10 (2005), pp.1563-1568	
		Takashi YOSHIO, Sustained-release Antipsychotic Drugs (depot drugs), Psychiatric Nursing, Vol. 33, No.4 (2006), pp.64-67	

Examiner Signature	/Renee Claytor/	Date Considered	03/09/2015

*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. /R.C./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1353	paliperidone	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2015/03/09 11:41
L2	189	L1 and @ad<="20071219"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2015/03/09 11:41
L3	52983	schizophren$2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2015/03/09 11:41
L4	104	L2 and L3	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2015/03/09 11:41
L5	4	"20090163519"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2015/03/09 11:53
S1	414	paliperidone	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 14:00
S2	4	S1 and @ad="20071219"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 14:01
S3	169	S1 and @ad<="20071219"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 14:01
S4	37089	schizophren$2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 14:01
S5	93	S3 and S4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 14:02
S6	9	dosing adj escalation	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 16:24
S7	0	S1 and S6	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 16:24
S8	31	"5254556"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 19:03
S9	19	"6077843"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 19:31
S10	11	"6555544"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/11/29 19:35
S11	20655	psychiatri$2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/12/03 10:28
S12	417	paliperidone	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/12/03 10:29
S13	139	S12 and S11	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/12/03 10:29
S14	14	S11 same S12	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2010/12/03 10:29
S15	895	paliperidone	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2013/06/14 08:53
S16	185	S15 and @ad<="20071219"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2013/06/14 08:53
S17	46189	schizophren$2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2013/06/14 08:53

S18	102	S16 and S17	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2013/06/14 08:53
S19	102	S18	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2013/06/14 08:53
S20	1217	paliperidone	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:55
S21	187	S20 and @ad<="20071219"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:55
S22	50743	schizophren$2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:55
S23	103	S21 and S22	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:55
S24	103	S23	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:55
S25	50743	schizophren$2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:56
S26	103	S24 and S25	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/08/11 13:56

3/9/2015 11:58:46 AM
C:\Users\dclaytor\Documents\EAST\Workspaces\337144.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015			
1	1	÷	✓	✓	=	=	=			
2	2	÷	✓	✓	=	=	=			
3	3	÷	✓	✓	=	=	=			
4	4	÷	✓	✓	=	=	=			
5	5	÷	✓	✓	=	=	=			
	6	÷	✓	✓	-	-	-			
	7	÷	✓	✓	-	-	-			
	8	÷	✓	✓	-	-	-			
	9	÷	✓	✓	-	-	-			
	10	÷	✓	✓	-	-	-			
	11	÷	✓	✓	-	-	-			
	12	÷	N	N	-	-	-			
6	13	÷	✓	✓	=	=	=			
	14	÷	N	-	-	-	-			
7	15	÷	✓	✓	=	=	=			
8	16	÷	✓	✓	=	=	=			
9	17	÷	✓	✓	=	=	=			
10	18	÷	✓	✓	=	=	=			
11	19	÷	✓	✓	=	=	=			
12	20	÷	✓	✓	=	=	=			
	21	÷	N	N	-	-	-			
13	22	÷	✓	✓	=	=	=			
	23	÷	N	-	-	-	-			
14	24	÷	✓	✓	=	=	=			
	25	÷	✓	✓	-	-	-			
	26	÷	✓	✓	-	-	-			
	27	÷	✓	✓	-	-	-			
	28	÷	✓	✓	-	-	-			
	29	÷	✓	✓	-	-	-			
	30	÷	N	N	-	-	-			
	31	÷	✓	✓	-	-	-			
	32	÷	N	-	-	-	-			
	33	÷	✓	✓	-	-	-			

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/337,144	Filing Date	2008-12-17	Docket Number (if applicable)	PRD2901USNP	Art Unit	1627
First Named Inventor	An Vermeulen			Examiner Name	Claytor, D. Renee		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☒ Affidavit(s)/ Declaration(s)
- ☒ Other Application Data Sheet

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 100750

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Hal Brent Woodrow/	Date (YYYY-MM-DD)	2015-06-12
Name	Hal. B. Woodrow	Registration Number	32501

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

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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 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 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.

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Kristin Miele	/Kristin Miele/	June 12, 2015
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: An Vermeulen et al. **Art Unit:** 1627

Serial No.: 12/337,144 **Examiner:** Claytor, D.

Filed: 12/17/2008 **Confirmation Number:** 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

Mail Stop: IDS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statements filed on April 11, 2011, December 12, 2011, September 18, 2013, November 17, 2014 and December 5, 2014.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) (attached) and the fee of $180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications and/or nonpatent literature which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2901USNP/HBW.

Respectfully submitted,

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Phone: (732) 524-2976
Dated: 12 June 2015

By: /Hal Brent Woodrow/
Hal B. Woodrow, Reg. No. 32,501

PTO/SB/08A (08-00)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		Gibaldi's Drug Delivery Systems in Pharmaceutical Care. edited by Mary Lee, Archana Desai, American Society of Health-System Pharmacists, Inc. (2007), pages 103-108	

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.

COMBINED DECLARATION AND ASSIGNMENT

Title of Invention: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

This declaration and assignment is directed to:

☐ The attached or filed herewith application of (list of named inventors)_____,

or

☒ The United States application or PCT international application number 12/337,144 filed on December 17, 2008.

Declaration

As the below named inventor, I hereby declare that:

The above-identified application ("Application") was made or authorized by me.

I believe that I am the original inventor or an original inventor of a claimed invention or discovery in the Application.

I have reviewed and understood the contents of the Application, including the claims, and I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, the United States Code of Federal Regulations, §1.56 for filings of this Application in the United States of America.

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

Assignment

☐ I hereby acknowledge that I have previously assigned the above-identified invention by previous assignment (attached hereto) which is hereby conformed for recordation in the US Patent Office.

or

☒ For good and valuable consideration, the sufficiency of which is acknowledged, I hereby assign and transfer and/or have assigned and transferred to:

Janssen Pharmaceutica NV
Turnhoutseweg 30, Beerse, Belgium B-2340

A corporation of the state or country of Belgium

(hereinafter designated as the "Assignee"), my entire right, title, and interest in, to, and under the Application, including all priority rights for other countries arising therefrom, all inventions or discoveries therein disclosed, and any and all Letters Patent of the United States, European Patent Office and of all other countries, which may be granted for such inventions or discoveries, or any of them, all such inventions or discoveries and all rights in such Application including any and all provisionals, substitutions, divisions, and continuations thereof, and to all Letters Patent that may be granted for said inventions and discoveries, and in and to all extensions, supplementary protection certificates, reexaminations, renewals, and reissues thereof, to be held and enjoyed by Assignee for its own use and enjoyment to the full end of the term or terms for which such Letters Patent may be granted, as fully and entirely as the same would have been held and enjoyed by me had this assignment and sale not been made.

I shall execute all papers necessary in connection with the Application in the United States Patent and Trademark Office, European Patent Office, any other patent offices, and under the Patent Cooperation Treaty, and any continuing, divisional, or reissue applications thereof, any reexamination of any of such applications, and any patent term extensions or supplementary protection certificates of any such applications and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

I shall execute all papers necessary in connection with any litigation or any other judicial proceeding in the United States or other country, or any administrative proceeding in the United States Patent and Trademark Office, European Patent Office, any other patent office, or under the Patent Cooperation Treaty concerning the Application(s) or any continuation, divisional, or reissue applications thereof, or any reexamination of any such applications, or any Letters Patent issued therefrom or any patent term extensions or supplementary protection certificates of any such applications and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such litigation or proceeding.

I shall execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.

I shall do all other acts which, in the opinion of Assignee, may be necessary or desirable to secure the grant of Letters Patent to Assignee or its nominees, in the United States, by the European Patent Office and in all other countries where Assignee may desire to have such inventions or discoveries, or any of them, patented, with specifications and claims in such form as shall be approved by Assignee and to vest and confirm in Assignee or its nominees the full and complete legal and equitable title to all such Letters Patent.

I hereby (i) authorize and request the Commissioner of Patents to issue any and all Letters Patent of the United States resulting from the Application or any divisional, continuation, or reissue applications thereof, and any reexamination of any of such applications, to Assignee, and (ii) covenant that I have full right to convey the interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

I hereby grant the attorney of record the power to insert on this assignment any further identification which may be necessary or desirable in order to obtain legal recordation of this document.

Srihari Gopal

S. [signature]

Signature

May 26, 2015

Date

Attorney Docket No.: PRD2901USNP

COMBINED DECLARATION AND ASSIGNMENT

Title of Invention: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

This declaration and assignment is directed to:

☐ The attached or filed herewith application of (list of named inventors)_____,

or

☒ The United States application or PCT international application number 12/337,144 filed on December 17, 2008.

Declaration

As the below named inventor, I hereby declare that:

The above-identified application ("Application") was made or authorized by me.

I believe that I am the original inventor or an original inventor of a claimed invention or discovery in the Application.

I have reviewed and understood the contents of the Application, including the claims, and I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, the United States Code of Federal Regulations, §1.56 for filings of this Application in the United States of America.

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

Assignment

☐ I hereby acknowledge that I have previously assigned the above-identified invention by previous assignment (attached hereto) which is hereby conformed for recordation in the US Patent Office.

or

☒ For good and valuable consideration, the sufficiency of which is acknowledged, I hereby assign and transfer and/or have assigned and transferred to:

Janssen Pharmaceutica NV
Turnhoutseweg 30, Beerse, Belgium B-2340

A corporation of the state or country of Belgium

(hereinafter designated as the "Assignee"), my entire right, title, and interest in, to, and under the Application, including all priority rights for other countries arising therefrom, all inventions or discoveries therein disclosed, and any and all Letters Patent of the United States, European Patent Office and of all other countries, which may be granted for such inventions or discoveries, or any of them, all such inventions or discoveries and all rights in such Application including any and all provisionals, substitutions, divisions, and continuations thereof, and to all Letters Patent that may be granted for said inventions and discoveries, and in and to all extensions, supplementary protection certificates, reexaminations, renewals, and reissues thereof, to be held and enjoyed by Assignee for its own use and enjoyment to the full end of the term or terms for which such Letters Patent may be granted, as fully and entirely as the same would have been held and enjoyed by me had this assignment and sale not been made.

I shall execute all papers necessary in connection with the Application in the United States Patent and Trademark Office, European Patent Office, any other patent offices, and under the Patent Cooperation Treaty, and any continuing, divisional, or reissue applications thereof, any reexamination of any of such applications, and any patent term extensions or supplementary protection certificates of any such applications and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

I shall execute all papers necessary in connection with any litigation or any other judicial proceeding in the United States or other country, or any administrative proceeding in the United States Patent and Trademark Office, European Patent Office, any other patent office, or under the Patent Cooperation Treaty concerning the Application(s) or any continuation, divisional, or reissue applications thereof, or any reexamination of any such applications, or any Letters Patent issued therefrom or any patent term extensions or supplementary protection certificates of any such applications and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such litigation or proceeding.

I shall execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.

I shall do all other acts which, in the opinion of Assignee, may be necessary or desirable to secure the grant of Letters Patent to Assignee or its nominees, in the United States, by the European Patent Office and in all other countries where Assignee may desire to have such inventions or discoveries, or any of them, patented, with specifications and claims in such form as shall be approved by Assignee and to vest and confirm in Assignee or its nominees the full and complete legal and equitable title to all such Letters Patent.

I hereby (i) authorize and request the Commissioner of Patents to issue any and all Letters Patent of the United States resulting from the Application or any divisional, continuation, or reissue applications thereof, and any reexamination of any of such applications, to Assignee, and (ii) covenant that I have full right to convey the interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

I hereby grant the attorney of record the power to insert on this assignment any further identification which may be necessary or desirable in order to obtain legal recordation of this document.

Peter H. Lewyn-Briscoe

Signature

20 May 2015

Date

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Kristin Miele	/Kristin Miele/	June 12, 2015
Type or print name	Signature	Date

In The United States Patent And Trademark Office

Applicants: An Vermeulen et al. **Art Unit:** 1627

Serial No.: 12/337,144 **Examiner:** Claytor, D. Renee

Filed: 12/17/2008 **Confirmation Number:** 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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

AMENDMENT

Sir:

This paper is in response to the Notice of Allowance dated March 13, 2015.

Entry of the following amendment is respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

Amendments to the Claims:

This listing of claims replaces all prior versions, and listings, of claims in the captioned application.

Listing of Claims:

1. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising

(1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and

(3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose. ~~on about the 34th to about the 38th day of treatment.~~

2. (Currently Amended) The dosing regimen of claim 1 wherein after administration of the first maintenance dose ~~of a sustained release depot formulation of paliperidone palmitate is administered~~, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7 days) intervals ~~after the 30th day of treatment~~ .

3. (Previously Presented) The dosing regimen of claim 1 wherein the sustained release formulation is an aqueous nanoparticle suspension.

4. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for psychotic disorder comprising

(a) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose. ~~on about the 36th day of treatment.~~

5. (Previously Presented) The dosing regimen of claim 4 wherein the sustained release formulation is an aqueous nanoparticle suspension of.

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Cancelled)

12. (Cancelled)

13. (Previously Presented) The dosing regimen of claim 4 wherein the psychiatric patient is in need of treatment for psychotic disorder wherein the psychotic disorder is schizophrenia.

14. (Canceled)

15. (Previously Presented) The dosing regimen of claim 4 wherein the psychiatric patient is in need of treatment for a psychotic disorder wherein the psychotic disorder is schizoaffective disorder.

16. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising

(a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a <u>first</u> maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release

formulation a month (±7 days) after the second loading dose. ~~on about the 34th to about the 38th day of treatment.~~

17. (Currently Amended) The dosing regimen of claim 16 wherein after the first maintenance dose ~~of a sustained release formulation of paliperidone palmitate is administered monthly~~, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7) intervals ~~after the 30th day of treatment~~.

18. (Previously Presented) The dosing regimen of claim 16 wherein the sustained release formulation is an aqueous nanoparticle suspension.

19. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for psychotic disorder comprising

(a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 50 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose. ~~on about the 36th day of treatment.~~

20. (Previously Presented) The dosing regimen of claim 19 wherein the sustained release formulation is an aqueous nanoparticle suspension.

21. (Cancelled)

22. (Previously Presented) The dosing regimen of claim 4 wherein the psychiatric patient is in need of treatment for of a psychotic disorder wherein the psychotic disorder is schizophrenia.

23. (Canceled)

24. (Previously Presented) The dosing regimen of claim 4 wherein the psychiatric patient is in need of treatment for a psychotic disorder wherein the psychotic disorder is schizoaffective.

25-33 (Cancelled)

34 (New) The dosing regimen of claim 4 wherein after administration of the first maintenance dose, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7 days) intervals.

35 (New) The dosing regimen of claim 19 wherein after administration of the first maintenance dose, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7 days) intervals.

36. (new) The dosing regimen of claim 1, 4, 16 or 19 wherein the formulation is an aqueous nanoparticle suspension comprises

(a) from 3 to 20% (w/v) of the paliperidone palmitate having an average particle size (d50) of from about 1600nm to about 900 nm;
(b) from 0.5 to 3% (w/v) of a wetting agent wherein the wetting agent is polysorbate 20;

(c) one or more buffering agents sufficient to render the composition neutral to very slightly basic (pH 8.5);
(d) from 0.5 to 3% (w/v) of a suspending agent wherein the suspending agent is polyethylene glycol 4000; and
(e) up to 2% (w/v) preservatives; and
(f) water q.s. ad 100%.

37. (New) The dosage regimen of claim 36 wherein the concentration of paliperidone palmitate is 156 mg/ml in the aqueous nanoparticle suspension.

38. (New) The dosing regimen of claim 1, 4, 16 and 19 wherein the sustained release depot formulation is an aqueous nanoparticle suspension consists essentially of

(a) 156 mg/ml of the paliperidone palmitate having an average particle size (d50) of from about 1600nm to about 900 nm;
(b) 12mg/ml of polysorbate 20;
(c) one or more buffering agents sufficient to render the composition neutral to very slightly basic (pH 8.5);
(d) 30 mg/ml of a suspending agent wherein the suspending agent is polyethylene glycol 4000; and
(f) water q.s. ad 100%..

39. (New) The dosage regimen of claim 38 wherein in the buffering agents contained in the aqueous nanoparticle suspension are citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide.

40. (New) The dosage regimen of claim 38 wherein in the pH of the aqueous nanoparticle suspension is in the range of pH 7 to 7.5.

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-33 were originally filed in the present application. Claims 1, 2, 4, 16, 17 and 19 have been amended. Claims 34-40 have been added. Claims 6-12, 14, 21, 23 and 25-33 have been cancelled. After entry of this amendment, claims 1-5, 13, 15-20, 22, 24 and 34-40 will be pending.

Amendments to the Claims

Claims 1, 4, 16 and 19 have be amended to more clearly describe what applicants' invention. The first maintenance dose is now described as being from about 25 mg-eq. to 150 mg-eq. administered monthly (±7 days). Support for this amendment may be found on page 7, lines 23-25 and page 8, lines 18-20. No new matter is added by these amendments. Entry and consideration of these amendments is respectfully requested.

Claim 2 and 17 have been amended by clarify that the subsequent maintenance doses will be from about 25 mg-eq. to 150 mg-eq. administered monthly (±7 days). Support for this amendment can be found on page 7, lines 29-31 and page 8, lines 18-20 of the specification. No new matter is added by these amendments. Entry and consideration of these amendments is respectfully requested.

New claims 34 and 35 have been added to clarify that the subsequent maintenance doses will be from about 25 mg-eq. to 150 mg-eq. administered monthly (±7 days). Support for this amendment can be found on page 7, lines 29-31 and page 8, lines 18-20 of the specification. No new matter is added by these new claims. Entry and consideration of these claims is respectfully requested.

New claims describe formulations of suitable aqueous nanoparticle suspensions. Support for these new claims may be found on pages 10-16 and Table 2, on page 22 of the specification. No new matter is added by these new claims. Entry and consideration of these claims is respectfully requested.

CONCLUSION

Applicants respectfully request reconsideration and allowance of claims 1-5, 13, 15-20, 22, 24 and 34-20. The Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this Amendment to Deposit Account No. 10-0750/PRD2901USNP/HBW.

Respectfully submitted,

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Phone: (732) 524-2976
Dated: 12 June 2015

By: /Hal Brent Woodrow/
Hal B. Woodrow, Reg. No. 32,501

Doc code: Oath
Document Description: Oath or declaration filed

PTO/AIA/02 (07-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SUBSTITUTE STATEMENT IN LIEU OF AN OATH OR DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (35 U.S.C. 115(d) AND 37 CFR 1.64)

Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

This statement is directed to:

☐ The attached application,

OR

■ United States application or PCT international application number 12/337144 filed on 12/17/2008.

LEGAL NAME of inventor to whom this substitute statement applies:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Vivek Kusumakar

Residence (except for a deceased or legally incapacitated inventor):

City	State	Country

Mailing Address (except for a deceased or legally incapacitated inventor):

City	State	Zip	Country

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 made 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 (petition under 37 CFR 1.46 is required), or

☐ Joint Inventor.

PTO/SB/AIA02 (07-13)
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SUBSTITUTE STATEMENT

Circumstances permitting execution of this substitute statement:

- [x] 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:

- [x] 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.

PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

Name: Hal B. Woodrow	Date (Optional):

Signature: /Hal B. Woodrow/

APPLICANT NAME AND TITLE OF PERSON EXECUTING THIS SUBSTITUTE STATEMENT:

If the applicant is a juristic entity, list the applicant name and the title of the signer:

Applicant Name: Janssen Pharmaceutica NV

Title of Person Executing This Substitute Statement: Proxy Holder, Janssen Pharmaceutica NV

The signer, whose title is supplied above, is authorized to act on behalf of the applicant.

Residence of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent):

City	State	Country

Mailing Address of the signer (unless provided in an application data sheet, PTO/AIA/14 or equivalent)

City	State	Zip	Country

Note: Use an additional PTO/AIA/02 form for each inventor who is deceased, legally incapacitated, cannot be found or reached after diligent effort, or has refused to execute the oath or declaration under 37 CFR 1.63.

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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
	Srihari		Gopal	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Belle Mead	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	173 Berkley Avenue		
Address 2			
City	Belle Mead	State/Province	NJ
Postal Code	08502	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Vivek		Kusumaker	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City		State/Province		Country of Residence	

Mailing Address of Inventor:

Address 1			
Address 2			
City		State/Province	
Postal Code		Country	

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Peter	H.	Lewyn-Briscoe	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

City	Newtown	State/Province	PA	Country of Residence	US

Mailing Address of Inventor:

Address 1	28 Sibelius Road		
Address 2			
City	Newtown	State/Province	PA
Postal Code	18940	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mahesh		Samtani	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Flemington	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	2 Sheppard Drive		
Address 2			
City	Flemington	State/Province	NJ
Postal Code	08822	Country	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	An		Vermeulen	

Residence Information (Select One) ( ) US Residency (•) Non US Residency ( ) Active US Military Service

City	Beerse	Country of Residence	BE

Mailing Address of Inventor:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	State/Province	
Postal Code	B-2340	Country	BE

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alfons		Wouters	

Residence Information (Select One) ( ) US Residency (•) Non US Residency ( ) Active US Military Service

PTO/AIA/14 (12-13)
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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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

City	Beerse	Country of Residence i	BE

Mailing Address of Inventor: 12/337144

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Postal Code	B-2340	**Country** i	BE

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	27777		
Email Address	jnjuspatent@corus.jnj.com	Add Email	Remove Email

Application Information:

Title of the Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		
Attorney Docket Number	PRD2901USNP	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	3	**Suggested Figure for Publication (if any)**	2

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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	27777		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/014918	2007-12-19
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/120276	2008-12-05

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).

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Remove

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.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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	Janssen Pharmaceutica NV

Mailing Address Information For Applicant:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Country	BE	Postal Code	B-2340
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including 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.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

Organization Name	Janssen Pharmaceutica NV

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Country	BE	Postal Code	B-2340
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant 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	/Hal Brent Woodrow/			Date (YYYY-MM-DD)	2015-06-12
First Name	Hal B.	Last Name	Woodrow	Registration Number	32501

Additional Signature may be generated within this form by selecting the Add button.

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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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 C o 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.

COMBINED DECLARATION AND ASSIGNMENT

Title of Invention: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

This declaration and assignment is directed to:

☐ The attached or filed herewith application of (list of named inventors)_____,

or

☒ The United States application or PCT international application number 12/337,144 filed on December 17, 2008.

Declaration

As the below named inventor, I hereby declare that:

The above-identified application ("Application") was made or authorized by me.

I believe that I am the original inventor or an original inventor of a claimed invention or discovery in the Application.

I have reviewed and understood the contents of the Application, including the claims, and I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, the United States Code of Federal Regulations, §1.56 for filings of this Application in the United States of America.

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

Assignment

☐ I hereby acknowledge that I have previously assigned the above-identified invention by previous assignment (attached hereto) which is hereby conformed for recordation in the US Patent Office.

or

☒ For good and valuable consideration, the sufficiency of which is acknowledged, I hereby assign and transfer and/or have assigned and transferred to:

Janssen Pharmaceutica NV
Turnhoutseweg 30, Beerse, Belgium B-2340

A corporation of the state or country of Belgium

(hereinafter designated as the "Assignee"), my entire right, title, and interest in, to, and under the Application, including all priority rights for other countries arising therefrom, all inventions or discoveries therein disclosed, and any and all Letters Patent of the United States, European Patent Office and of all other countries, which may be granted for such inventions or discoveries, or any of them, all such inventions or discoveries and all rights in such Application including any and all provisionals, substitutions, divisions, and continuations thereof, and to all Letters Patent that may be granted for said inventions and discoveries, and in and to all extensions, supplementary protection certificates, reexaminations, renewals, and reissues thereof, to be held and enjoyed by Assignee for its own use and enjoyment to the full end of the term or terms for which such Letters Patent may be granted, as fully and entirely as the same would have been held and enjoyed by me had this assignment and sale not been made.

I shall execute all papers necessary in connection with the Application in the United States Patent and Trademark Office, European Patent Office, any other patent offices, and under the Patent Cooperation Treaty, and any continuing, divisional, or reissue applications thereof, any reexamination of any of such applications, and any patent term extensions or supplementary protection certificates of any such applications and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

I shall execute all papers necessary in connection with any litigation or any other judicial proceeding in the United States or other country, or any administrative proceeding in the United States Patent and Trademark Office, European Patent Office, any other patent office, or under the Patent Cooperation Treaty concerning the Application(s) or any continuation, divisional, or reissue applications thereof, or any reexamination of any such applications, or any Letters Patent issued therefrom or any patent term extensions or supplementary protection certificates of any such applications and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such litigation or proceeding.

I shall execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.

I shall do all other acts which, in the opinion of Assignee, may be necessary or desirable to secure the grant of Letters Patent to Assignee or its nominees, in the United States, by the European Patent Office and in all other countries where Assignee may desire to have such inventions or discoveries, or any of them, patented, with specifications and claims in such form as shall be approved by Assignee and to vest and confirm in Assignee or its nominees the full and complete legal and equitable title to all such Letters Patent.

I hereby (i) authorize and request the Commissioner of Patents to issue any and all Letters Patent of the United States resulting from the Application or any divisional, continuation, or reissue applications thereof, and any reexamination of any of such applications, to Assignee, and (ii) covenant that I have full right to convey the interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

I hereby grant the attorney of record the power to insert on this assignment any further identification which may be necessary or desirable in order to obtain legal recordation of this document.

Mahesh Samtani

MAHESH SAMTANI

Digitally signed by MAHESH SAMTANI
DN: c=US, o=JNJ, ou=Employees, ou=361380, cn=MAHESH SAMTANI, email=MSamtani@its.jnj.com
Reason: I am approving this document.
Date: 2015.05.20 12:45:14 -04'00'

Signature

05/20/2015

Date

Electronic Patent Application Fee Transmittal

Application Number:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Hal Brent Woodrow/Kristin Miele
Attorney Docket Number:	PRD2901USNP

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:				
Late Filing Fee for Oath or Declaration	1051	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1840**

Electronic Acknowledgement Receipt

EFS ID:	22620474
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Hal Brent Woodrow/Kristin Miele
Filer Authorized By:	Hal Brent Woodrow
Attorney Docket Number:	PRD2901USNP
Receipt Date:	12-JUN-2015
Filing Date:	17-DEC-2008
Time Stamp:	16:32:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1840
RAM confirmation Number	3331
Deposit Account	100750
Authorized User	WOODROW, HAL B.

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 1.19 (Document supply 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	Request for Continued Examination (RCE)	PRD2901USNP_RCE_06_12_15.pdf	697878 e5328ccc907a23395869f36204ac78608c5601f7	no	3
Warnings:					
Information:					
2	Transmittal Letter	PRD2901USNP_SupplIDS_06_12_15.pdf	117914 8757091791a99e0c8b7199e8aa1308b880939d6e	no	4
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SupplDS1449_06_12_15.pdf	150039 180a4a17979fbb92da1015955c9f6afabe705261	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Non Patent Literature	Gibaldi_103_2007.pdf	962845 897bbb23ee8ea2227c1b78dbb49c2bf0bb0ec44f	no	3
Warnings:					
Information:					
5	Oath or Declaration filed	PRD2901USNP_ExDEC_Asst_Gopal.pdf	112820 3b89b2bef5eef8d5a392c9f147119325afb59644	no	2
Warnings:					
Information:					
6	Oath or Declaration filed	PRD2901USNP_ExDEC_Asst_LewynBriscoe.pdf	474783 3103716150d5b13458e591b48fd6ffa03754d333	no	2
Warnings:					
Information:					
7		PRD2901USNP_Amend_06_12_15.pdf	140303 92c5e313fbe4ffd30cda975aed3a382af3e9138b	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**

	Amendment Submitted/Entered with Filing of CPA/RCE		1		1
	Claims		2		7
	Applicant Arguments/Remarks Made in an Amendment		8		9
Warnings:					
Information:					
8	Oath or Declaration filed	PRD2901USNP_SubstStatement_DeceasedInventor.pdf	202385 b5066fb5215f5f2a644f4572fd375f42e4b88b22	no	3
Warnings:					
Information:					
9	Application Data Sheet	PRD2901USNP_ADS.pdf	103625 55e3475620398ce27ac81acfbe1570f35a5b9b1b	no	8
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
10	Oath or Declaration filed	PRD2901USNP_ExDEC_Asst_Samtani.pdf	100669 411d0bfdf12de8bacf858051201ff55054159057	no	2
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	32659 50a353a8d6bb4388edb491ec548828c99ffd9dcc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3095920		

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
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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/337,144	Filing Date 12/17/2008	☐ 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	06/12/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 36	Minus	** 33	= 3	X $80 =	240
	Independent (37 CFR 1.16(h))	* 4	Minus	***6	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☒ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						**780**
						TOTAL ADD'L FEE	**1020**

		(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
/PAUL STANBACK/

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 06/17/2015

PSTANBAC	SALE	#00000001	Mailroom Dt:	06/12/2015		100750	12337144
		01	FC : 1202	240.00	DA		
		02	FC : 1203	780.00	DA		

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		Third Party Observations filed during prosecution of corresponding EP Appl No. 08863534.7 (J&J Ref. PRD2901EPEPT)	

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 Acknowledgement Receipt

EFS ID:	23087020
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Hal Brent Woodrow/Kristin Miele
Filer Authorized By:	Hal Brent Woodrow
Attorney Docket Number:	PRD2901USNP
Receipt Date:	31-JUL-2015
Filing Date:	17-DEC-2008
Time Stamp:	17:00:34
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	Other Reference-Patent/App/Search documents	PRD2901USNP_SupplIDS_07_31_15.pdf	117914 492afaad032b8ee425f99a134908eb39c79901c0	no	4

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SuppIDS1449_07_31_15.pdf	149800 b36dabefbc81630bfab0de715a8dca734b7ec529	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	PRD2901EPEPT_EP088635347_ThirdPartyObs.pdf	2872078 c2a22948b47e2a3c941010303f59757bbea58466	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	3139792		

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.

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Kristin Miele	/Kristin Miele/	July 31, 2015
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: An Vermeulen et al. **Art Unit:** 1627

Serial No.: 12/337,144 **Examiner:** Claytor, D.

Filed: 12/17/2008 **Confirmation Number:** 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

Mail Stop: IDS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statements filed on April 11, 2011, December 12, 2011, September 18, 2013, November 17, 2014, December 5, 2014 and June 12, 2015.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) (attached) and the fee of $180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications and/or nonpatent literature which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2901USNP/HBW.

Respectfully submitted,

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Phone: (732) 524-2976
Dated: 31 July 2015

By: /Hal Brent Woodrow/
Hal B. Woodrow, Reg. No. 32,501

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

27777 7590 08/11/2015

BERNARD F. PLANTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
KAROL, JODY LYNN

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 08/11/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	11/12/2015

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)

27777 7590 08/11/2015
BERNARD F. PLANTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

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.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	11/12/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAROL, JODY LYNN	1627	514-257000

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. _____

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.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

27777 7590 08/11/2015

BERNARD F. PLANTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 08/11/2015

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)	
	12/337,144	VERMEULEN ET AL.	
	Examiner	Art Unit	
	JODY KAROL	1627	

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

(1) *JODY KAROL*. (3)_____.

(2) *Hal Woodward*. (4)_____.

Date of Interview: *31 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: *5,22,24 and 38*.

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...)

Obtained approval for the Examiner's amendment described in detail in the Allowability Notice.

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

/JODY KAROL/ Examiner, Art Unit 1627	

Notice of Allowability	Application No. 12/337,144	Applicant(s) VERMEULEN ET AL.	
	Examiner JODY KAROL	Art Unit 1627	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 *6/12/2015*.
   ☐ 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 *1-5,13,15-20,22,24 and 34-40*. 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 See Continuation Sheet
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20150805* .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 6/12/2015 and 7/31/2015.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/12/2015 has been entered.

Receipt is acknowledged of applicant's Amendment/Remarks filed 6/12/2015. Claims 1, 2, 4, 16, 17, and 19 have been amended. Claims 6-12, 14, 21, 23, and 25-33 are cancelled. Claims 34-40 are newly added. Claims 1-5, 13, 15-20, 22, 24, and 34-40 are pending and are currently under consideration.

Information Disclosure Statement

2. The information disclosure statement (IDS) filed on 2/20/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

EXAMINER'S AMENDMENT

3. 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 Hal Woodward on 7/31/2015.

The application has been amended as follows:

In claim 5, line 2, after "suspension"; **delete** "of".

In claim 22, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 24, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 38, line 1, after "claim 1, 4, 16"; **delete** "and" and **insert** --or--.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: Claims 1-5, 13, 15-20, 22, 24, and 34-40 are directed a dosing regimen for administering paliperidone palmitate to a psychiatric patient or a renally impaired psychiatric treatment in need of treatment for schizophrenia, schizoaffective disorder, schizophreniform disorder or a psychotic disorder comprising administering a intramuscularly in the deltoid a first loading dose of paliperidone palmitate formulated in a sustained release formulation, administering intramuscularly in the deltoid a second loading dose of paliperidone palmitate formulated in a sustained release formulation on the 6^{th} to about the 10^{th} day of treatment, and administering intramuscularly in the deltoid or gluteal muscle to the patient in need of treatment a first maintenance dose of paliperidone palmitate formulated in a sustained release formulation a month ($\pm$ 7 days) after the

second loading dose. The claims are allowable over the closest cited prior art, François et al. (US 6,555,544 B2), because the cited prior art does not teach, disclose, nor render obvious the instantly claimed dosing regimen. While François et al. teach a pharmaceutical composition for intramuscular injection comprising 9-hydroxy-risperidone fatty acid ester (i.e. paliperidone palmitate) in submicron form for use in the treatment of psychosis, schizophrenia, schizoaffective disorders, etc., François et al. teach the composition is administering every three weeks or even at longer intervals where possible (see abstract; column 8, lines 8-20). There is nothing in François et al. that teaches or suggests using two loading doses 6-10 days apart followed by a monthly maintenance dose at the specific dosages as instantly claimed.

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.”

Conclusion

Claims 1-5, 13, 15-20, 22, 24, and 34-40 are allowed.

Correspondence

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	12/337,144	VERMEULEN ET AL.	
	Examiner	Art Unit	
	JODY KAROL	1627	

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

(1) *JODY KAROL*. (3)_____.

(2) *Hal Woodward*. (4)_____.

Date of Interview: *31 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: *5,22,24 and 38*.

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...)

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☐ Attachment

/JODY KAROL/ Examiner, Art Unit 1627	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015	08/05/2015		
1	1	÷	✓	✓	=	=	=	=		
2	2	÷	✓	✓	=	=	=	=		
3	3	÷	✓	✓	=	=	=	=		
4	4	÷	✓	✓	=	=	=	=		
5	5	÷	✓	✓	=	=	=	=		
	6	÷	✓	✓	-	-	-	-		
	7	÷	✓	✓	-	-	-	-		
	8	÷	✓	✓	-	-	-	-		
	9	÷	✓	✓	-	-	-	-		
	10	÷	✓	✓	-	-	-	-		
	11	÷	✓	✓	-	-	-	-		
	12	÷	N	N	-	-	-	-		
6	13	÷	✓	✓	=	=	=	=		
	14	÷	N	-	-	-	-	-		
7	15	÷	✓	✓	=	=	=	=		
8	16	÷	✓	✓	=	=	=	=		
9	17	÷	✓	✓	=	=	=	=		
10	18	÷	✓	✓	=	=	=	=		
11	19	÷	✓	✓	=	=	=	=		
12	20	÷	✓	✓	=	=	=	=		
	21	÷	N	N	-	-	-	-		
13	22	÷	✓	✓	=	=	=	=		
	23	÷	N	-	-	-	-	-		
14	24	÷	✓	✓	=	=	=	=		
	25	÷	✓	✓	-	-	-	-		
	26	÷	✓	✓	-	-	-	-		
	27	÷	✓	✓	-	-	-	-		
	28	÷	✓	✓	-	-	-	-		
	29	÷	✓	✓	-	-	-	-		
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	31	÷	✓	✓	-	-	-	-		
	32	÷	N	-	-	-	-	-		
	33	÷	✓	✓	-	-	-	-		
15	34							=		
16	35							=		
17	36							=		

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015	08/05/2015		
18	37							=		
19	38							=		
20	39							=		
21	40							=		

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
/J.K./		Gibaldi's Drug Delivery Systems in Pharmaceutical Care. edited by Mary Lee, Archana Desai, American Society of Health-System Pharmacists, Inc. (2007), pages 103-108	

Examiner Signature	/Jody Karol/	Date Considered	08/05/2015

*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.

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
/J.K./		Third Party Observations filed during prosecution of corresponding EP Appl No. 08863534.7 (J&J Ref. PRD2901EPEPT)	

Examiner Signature	/Jody Karol/	Date Considered	08/05/2015

*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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	Art Unit
	Renee Claytor	1627

CPC- SEARCHED		
Symbol	Date	Examiner
A61K 31/519	3/9/2015	RC
A61K31/519; A61K9/0019; A61K9/0024	8/5/2015	JLK

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM Inventor Search	3/9/2015	RC
EAST (updated)	3/9/2015	RC
Inventor and EAST Search updated (see attached)	8/5/2015	JLK
Google Scholar NPL Search	8/5/2015	JLK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61K	31/519	3/9/2015	RC
A61K	31/519; 9/0019; 9/0024	8/5/2015	JLK

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	**Art Unit**
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CPC						
Symbol					**Type**	**Version**
A61K		31	/	519	F	2013-01-01
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/JODY KAROL/ Examiner.Art Unit 1627	08/05/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/SREENI PADMANABHAN/ Supervisory Patent Examiner.Art Unit 1627	08/05/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
514	257

CROSS REFERENCE(S)					
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**				
514	323	360	379		

INTERNATIONAL CLASSIFICATION																
CLAIMED					**NON-CLAIMED**											
C	0	7	D	471 / 04 (2006.01.01)												
A	6	1	K	31 / 445 (2006.01.01)												
A	6	1	K	31 / 41 (2006.01.01)												
A	6	1	K	31 / 42 (2006.01.01)												

/JODY KAROL/ Examiner.Art Unit 1627 (Assistant Examiner)	08/05/2015 (Date)	**Total Claims Allowed:** 21
/SREENI PADMANABHAN/ Supervisory Patent Examiner.Art Unit 1627 (Primary Examiner)	08/05/2015 (Date)	O.G. Print Claim(s) 1 O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
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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	1	9	17		33										
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/JODY KAROL/ Examiner.Art Unit 1627	08/05/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/SREENI PADMANABHAN/ Supervisory Patent Examiner.Art Unit 1627	08/05/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	"20090163519"	US-PGPUB	ADJ	ON	2015/08/05 09:22
L2	98237	(A61K31/519 OR A61K9/0019 OR A61K9/0024).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 09:22
L3	1414	(A61K31/519).CPC. and (A61K9/0019 OR A61K9/0024).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 09:23
L4	65	l3 and (paliperidone or $hydroxyrisperidone)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 09:23
L5	25	L4 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 09:23
S1	4	EP-1033987-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:35
S2	2074	paliperidone or $hydroxyrisperidone	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:46
S3	961	S2 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:47
S4	525	S2 and (schizophrenia or schizoaffective or schizophreniform) and (sustained or prolonged or delayed)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:48
S5	251	S2 and (schizophrenia or schizoaffective or schizophreniform) and (sustained or prolonged or delayed) and maintenance	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:51
S6	125	(paliperidone or $hydroxyrisperidone) same	US-PGPUB; USPAT; USOCR;	ADJ	ON	2015/08/05 08:52

		palmitate	FPRS; EPO; JPO; DERWENT; IBM_TDB			
S7	61	S6 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:53
S8	51	(Vermeulen, An).in. or (Wouters, Alfons).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:56
S9	10	S8 and (paliperidone or $hydroxyrisperidone)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/05 08:57

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	7062	(A61K31/519 OR A61K9/0019 OR A61K9/0024).CPC.	USPAT; UPAD	ADJ	ON	2015/08/05 09:23
L7	109	(A61K31/519).CPC. and (A61K9/0019 OR A61K9/0024).CPC.	USPAT; UPAD	ADJ	ON	2015/08/05 09:23
L8	12	l7 and (paliperidone or $hydroxyrisperidone)	USPAT; UPAD	ADJ	ON	2015/08/05 09:24
L9	21	L7 and (schizophrenia or schizoaffective or schizophreniform)	USPAT; UPAD	ADJ	ON	2015/08/05 09:24

8/5/2015 9:25:56 AM
C:\Users\jkarol\Documents\EAST\Workspaces\12337144 - Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters.wsp

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/337,144	Filing Date	2008-12-17	Docket Number (if applicable)	PRD2901USNP	Art Unit	1627
First Named Inventor	An Vermeulen			Examiner Name	Karol, Jody Lynn		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, to any international application that does not comply with the requirements of 35 U.S.C. 371, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV.

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 100750

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Hal Brent Woodrow/	Date (YYYY-MM-DD)	2015-10-11
Name	Hal B. Woodrow	Registration Number	32501

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether 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 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 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.

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Kristin Miele	/Kristin Miele/	November 11, 2015
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: An Vermeulen et al. **Art Unit:** 1627

Serial No.: 12/337,144 **Examiner:** Karol, Jody Lynn

Filed: 12/17/2008 **Confirmation Number:** 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

Mail Stop: IDS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statements filed on April 11, 2011, December 12, 2011, September 18, 2013, November 17, 2014, December 5, 2014, June 12, 2015 and July 31, 2015.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) (attached) and the fee of $180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications and/or nonpatent literature which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2901USNP/HBW.

Respectfully submitted,

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Phone: (732) 524-2976
Dated: November 11, 2015

By: /Hal Brent Woodrow/
Hal B. Woodrow, Reg. No. 32,501

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		Australian Patent Opposition for AU Patent Appl No. 2008340101 dated 20 May 2015 (J&J File Ref. PRD2901AUPCT)	
		Statement of Grounds and Particulars dated 19 August 2015 re: Australian Patent Opposition for AU Patent Appl No. 2008340101 (J&J File Ref. PRD2901AUPCT)	
		Cleton A, Rossenu S, Crauwels H, et al. A single-dose, open-label, parallel, randomized, dose-proportionality study of paliperidone after intramuscular injections of paliperidone palmitate in the deltoid or gluteal muscle in patients with schizophrenia. *J Clin Pharmacol.* 2014;54(9):1048-1057	
		Cleton A, Rossenu S, Hough D, Crauwels H, Vandebosch A, Berwaerts J, Eerdekens M, Francetic, I. "Evaluation of the pharmacokinetic profile of gluteal versus deltoid intramuscular Injections of paliperidone palmitate 100 mg equivalent in patients with schizophrenia" *Clin.Pharmacal. Therapeutics.* Published March 2008	
		Cockshott WP, Thompson GT, Howlett LJ, Seeley ET. Intramuscular or intralipomatous injections? *N Engl J Med.* 1982;307(6):356-358	
		Haramati N, Lorans R, Lutwin M, Kaleya RN. Injection granulomas. Intramuscle or intrafat? *Arch Fam Med.* 1994;3(2):146-148	
		Janicak, P. G. and Winans, E. A. "Paliperidone ER: a review of the clinical trial data" *Neuropsychiatr. Dis. Treat.* 2007, Dec 3(6): 869 - 897	
		Rosen, H, and Abribat, T. "The rise and rise of drug delivery" *Nat. Rev. Drug Discov.* 2005, May 4(5): 381-5.	
		Rossenu S, Cleton A, Hough D, et al. Pharmacokinetic profile after multiple deltoid or gluteal intramuscular injections of paliperidone palmitate in patients with schizophrenia. *Clinical Pharmacology in Drug Development.* 2015;4(4):270-278	
		Samtani MN, Vermeulen A, Stuyckens K. Population pharmacokinetics of intramuscular paliperidone palmitate in patients with schizophrenia: a novel once-monthly, long-acting formulation of an atypical antipsychotic. *Clin Pharmacokinet.* 2009;48(9):585-600	
		Synopsis of the Phase III clinical study described at Example 8 of the opposed application accessed at http://yoda.yale.edu/sites/default/files/nct00590577.pdf on 17 August 2015	
		Yin J, Collier AC, Barr AM, Honer WG, Procyshyn RM. Paliperidone Palmitate Long-Acting Injectable Given Intramuscularly in the Deltoid Versus the Gluteal Muscle: Are They Therapeutically Equivalent? *J Clin Psychopharmacol.* 2015;35(4):447-449	

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:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Hal Brent Woodrow/Kristin Miele
Attorney Docket Number:	PRD2901USNP

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($)
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1700**

Electronic Acknowledgement Receipt

EFS ID:	24053501
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Hal Brent Woodrow/Kristin Miele
Filer Authorized By:	Hal Brent Woodrow
Attorney Docket Number:	PRD2901USNP
Receipt Date:	11-NOV-2015
Filing Date:	17-DEC-2008
Time Stamp:	16:20:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1700
RAM confirmation Number	12323
Deposit Account	100750
Authorized User	WOODROW, HAL B.

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 1.19 (Document supply 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	Request for Continued Examination (RCE)	PRD2901USNP_RCE_11_11_15.pdf	1350052 229aae4dddbf07295db5c289053d9c1df9bb9b6a	no	3
Warnings:					
Information:					
2	Transmittal Letter	PRD2901USNP_SupplIDS_11_11_15.pdf	118324 d4e2718ae6b0491137cec88fa0e112c2f51ff4f6	no	4
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SupplDS1449_11_11_15.pdf	127359 c9ad363519c81d62134791fdc200f39f3e2277a7	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Non Patent Literature	PRD2901AUPCT_StatementofGroundsParticulars_08_19_15.pdf	9557409 8d01402ca5add6b61594a4c33e6f3b25547f53b1	no	20
Warnings:					
Information:					
5	Non Patent Literature	Cleton_1048_2014.pdf	875677 0897d2604f42e0d9972a9de7ab897a37d893fa69	no	10
Warnings:					
Information:					
6	Non Patent Literature	Cleton_ClinPharmTher_S31.pdf	43913 eee772e03eeec46d41b475d84582183fea97e517	no	1
Warnings:					
Information:					
7	Non Patent Literature	Cockshott_356_1982.pdf	172480 dfe2e84f1cfc23cf1c93bd3a03537bc3c7361e0c	no	3
Warnings:					
Information:					

8	Non Patent Literature	Janicek_869_2007.pdf	175073 c9a1cd7261bd6151a4c8c5c705ba19f9ba3f2afe	no	16
Warnings:					
Information:					
9	Non Patent Literature	Rosen_2005.pdf	225397 62fb72bb61739d1bcc76e5eebfbd0297271897b1	no	5
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10	Non Patent Literature	Rossenu_270_2015.pdf	141292 616bf367a575fdd0670235caac2345372b94270a	no	9
Warnings:					
Information:					
11	Non Patent Literature	Samtani_585_2009.pdf	453126 850147913cbde9725cf15dc63615fbf898562cbe	no	16
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Information:					
12	Non Patent Literature	Synopsis_PaliperidonePalmitateClinicalStudy.pdf	184454 d6784e0bc634bd1f299d95e3f971f4f977c04d5f	no	8
Warnings:					
Information:					
13	Non Patent Literature	PRD2901AUPCT_Opposition_05_20_15.pdf	990436 64c0a1e04f742c31723ce71b6b53c57d29572c2f	no	2
Warnings:					
Information:					
14	Non Patent Literature	Haramati_146_1994.pdf	9562833 a6328853ac78758c53f59969c8dc47da2b9b3c0d	no	3
Warnings:					
Information:					
15	Non Patent Literature	Yin_447_2015.pdf	118716 e87ab8db7aa9861afff6dad962ca4e7e716e89bc	no	3
Warnings:					
Information:					
16	Fee Worksheet (SB06)	fee-info.pdf	30675 b17d4f7cae7a9cc9638e3b68a7cf748cb90546b7	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	24127216

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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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

27777 7590 12/02/2015

BERNARD F. PLANTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
KAROL, JODY LYNN

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 12/02/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	03/02/2016

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)

27777 7590 12/02/2015
BERNARD F. PLANTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

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.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	03/02/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAROL, JODY LYNN	1627	514-257000

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. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

27777 7590 12/02/2015

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EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 12/02/2015

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.

Notice of Allowability	Application No. 12/337,144	Applicant(s) VERMEULEN ET AL.	
	Examiner JODY KAROL	Art Unit 1627	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 *11/11/2015*.
   ☐ 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 *1-5,13,15-20,22,24 and 34-40*. 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 11/11/2015
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/SHENGJUN WANG/
Primary Examiner, Art Unit 1627

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/12/2015 has been entered.

Receipt is acknowledged of applicant's Amendment/Remarks filed 6/12/2015. Claims 1, 2, 4, 16, 17, and 19 have been amended. Claims 6-12, 14, 21, 23, and 25-33 are cancelled. Claims 34-40 are newly added. Claims 1-5, 13, 15-20, 22, 24, and 34-40 are pending and are currently under consideration.

Information Disclosure Statement

2. The information disclosure statement (IDS) filed on 11/11/2015 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

It is noted that three of the references cited on the IDS and used in the Australian grounds for opposition for Au Patent Application No. 2008340101 dates 8/19/20015 are after the priority date of 12/10/2007 for US Provisional Application No. 61/014,918, but before the priority date of 12/5/2008 for US Provisional Application No. 61/120,276. The

Synopsis of the Phase III clinical study was issued on 9/12/2008; Janicak et al. was published on 1/15/2008; and Cleton et al. ("Evaluation of the pharmacokinetic profile of gluteal versus deltoid intramuscular injections of paliperidone palmitate 100 mg equivalent in patients with schizophrenia") was published March 2008. However, the instant claims are fully supported by US Provisional Application No. 61/014,918 and thus these references are not applicable as prior art.

EXAMINER'S AMENDMENT

3. 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 Hal Woodward on 7/31/2015.

The application has been amended as follows:

In claim 5, line 2, after "suspension"; **delete** "of".

In claim 22, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 24, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 38, line 1, after "claim 1, 4, 16"; **delete** "and" and **insert** --or--.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: Claims 1-5, 13, 15-20, 22, 24, and 34-40 are directed a dosing regimen for administering paliperidone palmitate to a psychiatric patient or a renally impaired psychiatric treatment in need of treatment for schizophrenia, schizoaffective disorder, schizophreniform disorder or a psychotic disorder comprising administering a intramuscularly in the deltoid a first loading dose of paliperidone palmitate formulated in a sustained release formulation, administering intramuscularly in the deltoid a second loading dose of paliperidone palmitate formulated in a sustained release formulation on the 6^{th} to about the 10^{th} day of treatment, and administering intramuscularly in the deltoid or gluteal muscle to the patient in need of treatment a first maintenance dose of paliperidone palmitate formulated in a sustained release formulation a month ($\pm$ 7 days) after the second loading dose. The claims are allowable over the closest cited prior art, François et al. (US 6,555,544 B2), because the cited prior art does not teach, disclose, nor render obvious the instantly claimed dosing regimen. While François et al. teach a pharmaceutical composition for intramuscular injection comprising 9-hydroxy-risperidone fatty acid ester (i.e. paliperidone palmitate) in submicron form for use in the treatment of psychosis, schizophrenia, schizoaffective disorders, etc., François et al. teach the composition is administered every three weeks or even at longer intervals where possible (see abstract; column 8, lines 8-20). There is nothing in François et al. that teaches or suggests using two loading doses 6-10 days apart followed by a monthly maintenance dose at the specific dosages as instantly claimed.

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."

Conclusion

Claims 1-5, 13, 15-20, 22, 24, and 34-40 are allowed.

Correspondence

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/SHENGJUN WANG/

Primary Examiner, Art Unit 1627

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	Renee Claytor	1627

CPC- SEARCHED		
Symbol	**Date**	**Examiner**
A61K 31/519	3/9/2015	RC
A61K31/519; A61K9/0019; A61K9/0024	8/5/2015	JLK
updated (see attached)	11/18/2015	JLK

CPC COMBINATION SETS - SEARCHED		
Symbol	**Date**	**Examiner**

US CLASSIFICATION SEARCHED			
Class	**Subclass**	**Date**	**Examiner**

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
PALM Inventor Search	3/9/2015	RC
EAST (updated)	3/9/2015	RC
Inventor and EAST Search updated (see attached)	8/5/2015	JLK
Google Scholar NPL Search	8/5/2015	JLK
Inventor and EAST Search updated (see attached)	11/25/2015	JLK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
A61K	31/519	3/9/2015	RC
A61K	31/519; 9/0019; 9/0024	8/5/2015	JLK
	updated (see attached)	11/18/2015	JLK

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

CPC						
Symbol					**Type**	**Version**
A61K		31	/	519	F	2013-01-01
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
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/JODY KAROL/ Examiner.Art Unit 1627	11/18/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/SHENGJUN WANG/ Primary Examiner.Art Unit 1627	11/19/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
514	257

CROSS REFERENCE(S)					
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**				
514	323	360	379		

INTERNATIONAL CLASSIFICATION														
CLAIMED					**NON-CLAIMED**									
C	0	7	D	471 / 04 (2006.01.01)										
A	6	1	K	31 / 445 (2006.01.01)										
A	6	1	K	31 / 41 (2006.01.01)										
A	6	1	K	31 / 42 (2006.01.01)										

/JODY KAROL/ Examiner.Art Unit 1627 (Assistant Examiner)	11/18/2015 (Date)	**Total Claims Allowed:** 21	
/SHENGJUN WANG/ Primary Examiner.Art Unit 1627 (Primary Examiner)	11/19/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

☒ **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	1	9	17		33										
2	2	10	18	15	34										
3	3	11	19	16	35										
4	4	12	20	17	36										
5	5		21	18	37										
	6	13	22	19	38										
	7		23	20	39										
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6	13		29												
	14		30												
7	15		31												
8	16		32												

/JODY KAROL/ Examiner.Art Unit 1627	11/18/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/SHENGJUN WANG/ Primary Examiner.Art Unit 1627	11/19/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
/J.K./		Australian Patent Opposition for AU Patent Appl No. 2008340101 dated 20 May 2015 (J&J File Ref. PRD2901AUPCT)	
/J.K./		Statement of Grounds and Particulars dated 19 August 2015 re: Australian Patent Opposition for AU Patent Appl No. 2008340101 (J&J File Ref. PRD2901AUPCT)	
/J.K./		Cleton A, Rossenu S, Crauwels H, et al. A single-dose, open-label, parallel, randomized, dose-proportionality study of paliperidone after intramuscular injections of paliperidone palmitate in the deltoid or gluteal muscle in patients with schizophrenia. *J Clin Pharmacol.* 2014;54(9):1048-1057	
/J.K./		Cleton A, Rossenu S, Hough D, Crauwels H, Vandebosch A, Berwaerts J, Eerdekens M, Francetic, I. "Evaluation of the pharmacokinetic profile of gluteal versus deltoid intramuscular Injections of paliperidone palmitate 100 mg equivalent in patients with schizophrenia" *Clin.Pharmacal. Therapeutics.* Published March 2008	
/J.K./		Cockshott WP, Thompson GT, Howlett LJ, Seeley ET. Intramuscular or intralipomatous injections? *N Engl J Med.* 1982;307(6):356-358	
/J.K./		Haramati N, Lorans R, Lutwin M, Kaleya RN. Injection granulomas. Intramuscle or intrafat? *Arch Fam Med.* 1994;3(2):146-148	
/J.K./		Janicak, P. G. and Winans, E. A. "Paliperidone ER: a review of the clinical trial data" *Neuropsychiatr. Dis. Treat.* 2007, Dec 3(6): 869 - 897 Published 1/15/2008.	
/J.K./		Rosen, H, and Abribat, T. "The rise and rise of drug delivery" *Nat. Rev. Drug Discov.* 2005, May 4(5): 381-5.	
/J.K./		Rossenu S, Cleton A, Hough D, et al. Pharmacokinetic profile after multiple deltoid or gluteal intramuscular injections of paliperidone palmitate in patients with schizophrenia. *Clinical Pharmacology in Drug Development.* 2015;4(4):270-278	
/J.K./		Samtani MN, Vermeulen A, Stuyckens K. Population pharmacokinetics of intramuscular paliperidone palmitate in patients with schizophrenia: a novel once-monthly, long-acting formulation of an atypical antipsychotic. *Clin Pharmacokinet.* 2009;48(9):585-600	
/J.K./		Synopsis of the Phase III clinical study described at Example 8 of the opposed application accessed at http://yoda.yale.edu/sites/default/files/nct00590577.pdf on 17 August 2015 Issue Date: 12 September 2008. /J.K./	
/J.K./		Yin J, Collier AC, Barr AM, Honer WG, Procyshyn RM. Paliperidone Palmitate Long-Acting Injectable Given Intramuscularly in the Deltoid Versus the Gluteal Muscle: Are They Therapeutically Equivalent? *J Clin Psychopharmacol.* 2015;35(4):447-449	

Examiner Signature	/Jody Karol/	Date Considered	11/17/2015

*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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4	EP-1033987-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L2	2177	paliperidone or $hydroxyrisperidone	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L3	1011	L2 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L4	557	L2 and (schizophrenia or schizoaffective or schizophreniform) and (sustained or prolonged or delayed)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L5	262	L2 and (schizophrenia or schizoaffective or schizophreniform) and (sustained or prolonged or delayed) and maintenance	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L6	136	(paliperidone or $hydroxyrisperidone) same palmitate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L7	62	L6 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L8	54	(Vermeulen, An).in. or (Wouters, Alfons).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L9	13	L8 and (paliperidone or $hydroxyrisperidone)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L10	3	"20090163519"	US-PGPUB	ADJ	ON	2015/11/18 13:47
L11	102099	(A61K31/519 OR A61K9/0019 OR A61K9/0024).CPC.	US-PGPUB; USPAT; USOCR;	ADJ	ON	2015/11/18 13:47

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
L12	1484	(A61K31/519).CPC. and (A61K9/0019 OR A61K9/0024).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L13	72	L12 and (paliperidone or $hydroxyrisperidone)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47
L14	28	L13 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/11/18 13:47

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L15	7335	(A61K31/519 OR A61K9/0019 OR A61K9/0024).CPC.	USPAT; UPAD	ADJ	ON	2015/11/18 13:47
L16	113	(A61K31/519).CPC. and (A61K9/0019 OR A61K9/0024).CPC.	USPAT; UPAD	ADJ	ON	2015/11/18 13:47
L17	14	L16 and (paliperidone or $hydroxyrisperidone)	USPAT; UPAD	ADJ	ON	2015/11/18 13:47
L18	24	L16 and (schizophrenia or schizoaffective or schizophreniform)	USPAT; UPAD	ADJ	ON	2015/11/18 13:47

11/18/2015 1:52:17 PM
C:\Users\jkarol\Documents\EAST\Workspaces\12337144 - Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015	08/05/2015	11/18/2015	
1	1	÷	✓	✓	=	=	=	=	=	
2	2	÷	✓	✓	=	=	=	=	=	
3	3	÷	✓	✓	=	=	=	=	=	
4	4	÷	✓	✓	=	=	=	=	=	
5	5	÷	✓	✓	=	=	=	=	=	
	6	÷	✓	✓	-	-	-	-	-	
	7	÷	✓	✓	-	-	-	-	-	
	8	÷	✓	✓	-	-	-	-	-	
	9	÷	✓	✓	-	-	-	-	-	
	10	÷	✓	✓	-	-	-	-	-	
	11	÷	✓	✓	-	-	-	-	-	
	12	÷	N	N	-	-	-	-	-	
6	13	÷	✓	✓	=	=	=	=	=	
	14	÷	N	-	-	-	-	-	-	
7	15	÷	✓	✓	=	=	=	=	=	
8	16	÷	✓	✓	=	=	=	=	=	
9	17	÷	✓	✓	=	=	=	=	=	
10	18	÷	✓	✓	=	=	=	=	=	
11	19	÷	✓	✓	=	=	=	=	=	
12	20	÷	✓	✓	=	=	=	=	=	
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13	22	÷	✓	✓	=	=	=	=	=	
	23	÷	N	-	-	-	-	-	-	
14	24	÷	✓	✓	=	=	=	=	=	
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	32	÷	N	-	-	-	-	-	-	
	33	÷	✓	✓	-	-	-	-	-	
15	34							=	=	
16	35							=	=	
17	36							=	=	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015	08/05/2015	11/18/2015	
18	37							=	=	
19	38							=	=	
20	39							=	=	
21	40							=	=	

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/337,144	Filing Date	2008-12-17	Docket Number (if applicable)	PRD2901USNP	Art Unit	1627
First Named Inventor	An Vermeulen			Examiner Name	Karol, Jody Lynn		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, to any international application that does not comply with the requirements of 35 U.S.C. 371, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV.

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 100750

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Hal Brent Woodrow/	Date (YYYY-MM-DD)	2016-02-26
Name	Hal B. Woodrow	Registration Number	32501

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether 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 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 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.

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Kristin Miele	/Kristin Miele/	March 1, 2016
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: An Vermeulen et al. **Art Unit:** 1627

Serial No.: 12/337,144 **Examiner:** Karol, Jody Lynn

Filed: 12/17/2008 **Confirmation Number:** 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

Mail Stop: IDS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statements filed on November 11, 2015, April 11, 2011, December 12, 2011, September 18, 2013, November 17, 2014, December 5, 2014, June 12, 2015, July 31, 2015 and November 11, 2015.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) (attached) and the fee of $180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications and/or nonpatent literature which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2901USNP/HBW.

Respectfully submitted,

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Phone: (732) 524-2976
Dated: February 26, 2016

By: /Hal Brent Woodrow/
Hal B. Woodrow, Reg. No. 32,501

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		Third Party Observations dated 01/28/16 filed during prosecution of EP Application No. 10773821.3 (J&J ref. PRD3131EPEPT)	

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.

SUBMISSION UNDER MPEP 609.06 Page 1 of 1	*Application Number*	12/337,144
	Filing Date	12/17/2008
	First Named Inventor	An Vermeulen
	Group Art Unit	1627
	Examiner Name	Claytor, Deirdre
	Attorney Docket Number	PRD2901USNP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	U.S. Patent Document Number	Kind Code[2] (if known)	Pages, Columns, Lines, where relevant passages or relevant figures appear

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	Foreign Patent Document Office[3]	Number[4]	KindCode[5]	Pages, Columns, Lines, where relevant passages or relevant figures appear	T[6]

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITOL 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	T[2]
		Office Action mailed March 24, 2015 in US Serial No. 13/903,638; Attorney Docket No. PRD3131USDIV1	
		Final Office Action mailed October 22, 2015 in US Serial No. 13/903,638; Attorney Docket No. PRD3131USDIV1	

Examiner Signature		Date Considered	

Electronic Patent Application Fee Transmittal

Application Number:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Hal Brent Woodrow/Kristin Miele
Attorney Docket Number:	PRD2901USNP

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($)
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1700**

Electronic Acknowledgement Receipt

EFS ID:	25064885
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Hal Brent Woodrow/Kristin Miele
Filer Authorized By:	Hal Brent Woodrow
Attorney Docket Number:	PRD2901USNP
Receipt Date:	01-MAR-2016
Filing Date:	17-DEC-2008
Time Stamp:	14:35:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1700
RAM confirmation Number	673
Deposit Account	100750
Authorized User	WOODROW, HAL B.

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	PRD2901USNP_RCE_03_01_16.pdf	1350053 ba66c1668c1c38b0b7209963bfc9aceda16c5465	no	3
Warnings:					
Information:					
2	Transmittal Letter	PRD2901USNP_SupplIDS_03_01_16.pdf	117827 0f8f8435566633633a6863f00d9fd59ee0acacec	no	4
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SuppIDS1449_03_01_16.pdf	121402 13d51e283155ec13c8f249416bd13b521e57efa4	no	1
Warnings:					
Information:					
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4	Other Reference-Patent/App/Search documents	PRD2901USNP_IDS609d_03_01_16.pdf	80865 5294f86b8e43732a0e3414a1468b36573bd49480	no	1
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	PRD3131EPEPT_3rdPartyObv_01_28_16.pdf	117735 afc44c7e6b977e07c09f98345acaeffa4499077 4	no	3
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	PRD3131USDIV1_FinalOA_10_22_15.pdf	18657019 1cbcf40cc567b779dd145cb173b782ed8a3b9571	no	19
Warnings:					
Information:					
7	Other Reference-Patent/App/Search documents	PRD3131USDIV1_OA_03_24_15.pdf	15708404 e18b2f27af209d77082c5c81576105c9f601bad4	no	16
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8	Fee Worksheet (SB06)	fee-info.pdf	30675 eff92fa11250f8f073fbb027433f4800829be1cb	no	2

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Dawn H. Wilson	/Dawn H. Wilson/	April 7, 2016
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: An Vermeulen et al. **Art Unit:** 1627

Serial No.: 12/337,144 **Examiner:** Karol, Jody Lynn

Filed: 12/17/2008 **Confirmation Number:** 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

Mail Stop: IDS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statements filed on November 11, 2015, April 11, 2011, December 12, 2011, September 18, 2013, November 17, 2014, December 5, 2014, June 12, 2015 and July 31, 2015 and March 1, 2016.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ the fee of $180.00 as set forth in §1.17(p).

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☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

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- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications and/or nonpatent literature which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2901USNP/MB.

Respectfully submitted,

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Phone: (732) 524-5352
Dated: April 7, 2016

By: /Melissa Wenk Reg. No. 53,759/
Melissa Wenk, Reg. No. 53,759

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		CIRINCIONE, et al., "Population pharmacokinetics of paliperidone ER in healthy subjects and patients with schizophrenia", clinical Pharmacology & Therapeutics, Vol. 81, Issue Supplement SI, P. S19 (published in March 2007)	

Examiner Signature		Date Considered	

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EFS ID:	25425931
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	07-APR-2016
Filing Date:	17-DEC-2008
Time Stamp:	13:53:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

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1	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SupplIDS_APRIL2016.pdf	298639 9c5bb989a044466eb35bd9b1b92adc148c20c4e5	no	4

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2	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SuppIDS1449A PRIL2016.pdf	289174 81ca0eec7c9d0233d570b701e5a0aee3e41b2c2b	no	1
Warnings:					
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This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	CIRINCIONE.pdf	439677 6264bb2a34b3a2b61b1d3406c85bf119787c0f62	no	35
Warnings:					
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		2009/0163519	A1	Vermeulen et al.	06-25-2009	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	KindCode[5]	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T[6]
		WO	2009/080651		Janssen Pharm. NV	07-02-2009		

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Sheet 2 of 2

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
		KREYENBUHl, et al., "Adding or Switching Antipsychotic Medications in Treatment-Refractory Schizophrenia", Psychiatr Serv., July 2007, pp. 983-990, Vol. 58(7)	

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 July 2009 (02.07.2009)

PCT

(10) International Publication Number
WO 2009/080651 A1

(51) International Patent Classification:
A61K 31/519 (2006.01) *A61P 25/18* (2006.01)

(21) International Application Number:
PCT/EP2008/067738

(22) International Filing Date:
17 December 2008 (17.12.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/014,918 19 December 2007 (19.12.2007) US
61/120,276 5 December 2008 (05.12.2008) US

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(75) Inventors/Applicants *(for US only)*: **VERMEULEN, An, Margriet, Cornelia** [BE/BE]; c/o Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse (BE). **WOUTERS, Alfons, Jeanne** [BE/BE]; c/o Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse (BE).

(74) Common Representative: **JANSSEN PHARMACEUTICA NV**; Turnhoutseweg 30, B-2340 Beerse (BE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:
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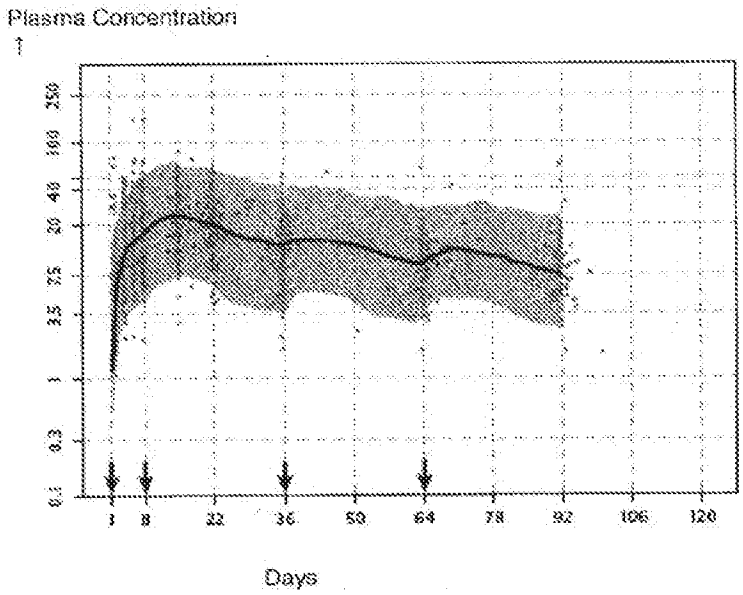
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report*

(54) Title: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

FIGURE 1



(57) Abstract: The present invention provides a method of treating patients in need of treatment with long acting injectable paliperidone palmitate formulations.

WO 2009/080651 A1

DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

FIELD OF THE INVENTION

This invention relates to a method of treating patients in need of treatment with long acting injectable paliperidone palmitate formulations.

BACKGROUND OF THE INVENTION

Antipsychotic medications are the mainstay in the treatment of schizophrenia, schizoaffective disorder, and schizophreniform disorders. Conventional antipsychotics were introduced in the mid-1950s. These typical or first generation drugs are usually effective in controlling the positive symptoms of schizophrenia, but are less effective in moderating the negative symptoms or the cognitive impairment associated with the disease. Atypical antipsychotics or second generation drugs, typified by risperidone and olanzapine, were developed in the 1990s, and are generally characterized by effectiveness against both the positive and negative symptoms associated with schizophrenia.

Paliperidone palmitate is the palmitate ester of paliperidone (9-hydroxy-risperidone), a monoaminergic antagonist that exhibits the characteristic dopamine D_2 and serotonin (5-hydroxytryptamine type 2A) antagonism of the second-generation, atypical antipsychotic drugs. Paliperidone is the major active metabolite of risperidone. Extended release (ER) osmotic controlled release oral delivery (OROS) paliperidone, as a tablet formulation, is marketed in the United States (U.S.) for the treatment of schizophrenia and maintenance of effect.

Paliperidone palmitate is being developed as a long-acting, intramuscular (i.m.), injectable aqueous nanosuspension for the treatment of schizophrenia and other diseases that are normally treated with antipsychotic mediations. Because of extreme low water solubility, paliperidone esters such as paliperidone palmitate dissolve slowly

after an i.m. injection before being hydrolyzed to paliperidone and made available in the systemic circulation.

Many patients with these mental illnesses achieve symptom stability with available oral antipsychotic medications; however, it is estimated that up to 75% have difficulty adhering to a daily oral treatment regimen, i.e. compliance problems. Problems with adherence often result in worsening of symptoms, suboptimal treatment response, frequent relapses and re-hospitalizations, and an inability to benefit from rehabilitative and psychosocial therapies.

Paliperidone palmitate injection has been developed to provide sustained plasma concentrations of paliperidone when administered once monthly, which may greatly enhance compliance with dosing. Paliperidone palmitate was formulated as an aqueous nano suspension as is described in US Patents 6,577,545 and 6,555,544. However, after the data was analyzed from the clinical trials of this formulation it was discovered that the absorption of paliperidone from these injections was far more complex than was originally anticipated. Additionally, attaining a potential therapeutic plasma level of paliperidone in patients was discovered to be dependent on the site of injection until steady state concentration is reached. Due to the challenging nature of ensuring an optimum plasma concentration-time profile for treating patients with paliperidone it is desirable to develop a dosing regimen that fulfills this goal in patients in need of treatment.

SUMMARY OF THE INVENTION

In one embodiment of the present invention there is provided a dosing regimen for administering paliperidone esters to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid a first loading dose from about 100 mg-eq. to about 150 mg-eq. of paliperidone as a paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly a second loading dose from about 100 mg to about 150 mg-eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation

between about the 6th to 10th day of treatment; and administering intramuscularly in the gluteal a maintenance dose of about 25 to about 150 mg-eq. of paliperidone as a paliperidone ester in a sustained release formulation on between about the 34th and about the 38th day of treatment.

In one embodiment of the present invention there is provided a dosing regimen for administering paliperidone esters to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid a first loading dose from about 100 mg-eq. to about 150 mg-eq. of paliperidone as a paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly a second loading dose from about 100 mg to about 150 mg-eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation between about the 6th to 10th day of treatment; and administering intramuscularly in the gluteal a maintenance dose of about 25 to about 150 mg-eq. of paliperidone as a paliperidone ester in a sustained release formulation approximately monthly from the date of the second loading dose.

In another embodiment of the present invention there is provided a dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose from about 100 mg-eq. to about 150 mg-eq of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose from about 100 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on between about the 34th day and the 38th day of treatment.

In another embodiment of the present invention there is provided a dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid of a patient in need

of treatment a first loading dose of about 150 mg-eq of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose from about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation approximately monthly from the date of the second loading dose.

In another embodiment of the present invention there is provided a dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose from about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation approximately monthly from the date of the second loading dose.

In yet another embodiment of the present invention there is provided a dosing regimen for administering paliperidone esters to a renally impaired psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid a first loading dose of about 75mg-eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly a second loading dose of about 75 mg-eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation between about the 6th to 10th day of treatment; and administering intramuscularly in the gluteal a maintenance dose of about 25 mg-eq. to about 75 mg-eq of paliperidone as a

paliperidone palmitate in a sustained release formulation on between about the 34th and about the 38th day of treatment.

In yet another embodiment of the present invention there is provided a dosing regimen for administering paliperidone esters to a renally impaired psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid a first loading dose of about 100mg-eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly a second loading dose of about 75 mg-eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation between about the 6th to 10th day of treatment; and administering intramuscularly in the gluteal a maintenance dose of about 25 mg-eq. to about 75 mg-eq of paliperidone as a paliperidone palmitate in a sustained release formulation approximately monthly from the date of the second loading dose.

In a further embodiment of the present invention there is provided a dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 75 mg-eq of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of from about 25 mg-eq. to about 50 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 34th day and the 38th day of treatment.

In one embodiment of the present invention there is provided a dosing regimen for administering paliperidone esters to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid a first loading dose of about 150 mg-eq. of paliperidone as a paliperidone palmitate formulated in a sustained release formulation on the first day of treatment; thereafter administering intramuscularly a second maintenance dose of from about 25 mg-eq. to about 100 mg-

eq of paliperidone as a paliperidone palmitate formulated in a sustained release formulation between about the 6th to 10th day of treatment; and administering intramuscularly in the gluteal a maintenance dose of about 25 to about 100 mg-eq. of paliperidone as a paliperidone palmitate in a sustained release formulation on between about the 34th and about the 38th day of treatment.

In a further embodiment of the present invention there is provided a dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose from about 150 mg-eq. of paliperidone as a paliperidone palmitate ester in a sustained release formulation on the first day of treatment; thereafter administering intramuscularly in the deltoid muscle of the patient in need of treatment a maintenance dose from about 25 mg-eq. to about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 100 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 34th day and the 38th day of treatment.

This and other objects and advantages of the present invention may be appreciated from a review of the present applications.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 shows the observed versus the population pharmacokinetics model simulation for plasma paliperidone concentrations for paliperidone palmitate 150 mg eq. in the deltoid on day 1, followed by 25 mg eq. in either the deltoid or gluteus on days 8, 36, and 64.

Figure 2 shows the observed versus the population pharmacokinetics model simulation for plasma paliperidone concentrations for paliperidone palmitate 150 mg eq. in the deltoid on day 1, followed by 100 mg eq. in either the deltoid or gluteus on days 8, 36, and 64.

Figure 3 shows the observed versus the population pharmacokinetics model simulation for plasma paliperidone concentrations for paliperidone palmitate 150 mg eq. in the deltoid on day 1, followed by 150 mg eq. in either the deltoid or gluteus on days 8, 36, and 64.

DETAILED DESCRIPTION

We have discovered after extensive analysis of the clinical data that paliperidone palmitate due to its dissolution rate-limited absorption exhibits flip-flop kinetics, where the apparent half-life is controlled by the absorption rate constant. Additionally the volume of injected drug product also impacts the apparent rate constant. It was also discovered that deltoid injections result in a faster rise in initial plasma concentration, facilitating a rapid attainment of potential therapeutic concentrations. Consequently, to facilitate patients' attaining a rapid therapeutic concentration of paliperidone it is preferred to provide the initial loading dose of paliperidone palmitate in the deltoids. The loading dose should be from about 100 mg-eq. to about 150 mg-eq. of paliperidone provided in the form of paliperidone palmitate. After the first or more preferably after the second loading dose injection patients will be approaching a steady state concentration of paliperidone in their plasma and may be injected in either the deltoid or the gluteal muscle thereafter. However, it is preferred that the patients receive further injections in the gluteal muscle.

In view of these discoveries the recommended dosing regimen for patients to attain a therapeutic plasma level of paliperidone is for patients to receive the first dose of paliperidone palmitate on day 1 of treatment, followed by a second dose between days 6 to 10 of treatment, then a third dose between days 34 to 38 of treatment or monthly ±7days after the second dose. More preferably the patients will be administered a first dose on day 1, a second dose on day 8 and a third dose on or about day 36 of treatment or approximately monthly ±3 days after the second dose. The first two doses will preferably be injected in the deltoid muscle. Thereafter paliperidone palmitate will be administered by injection approximately once a month (e.g. monthly ±7days or approximately once every four weeks) thereafter. To assure that a potential therapeutic plasma level of paliperidone is attained at least a first loading dose of 150 mg-eq of paliperidone as a

paliperidone palmitate ester should be administered on day one of treatment. Preferably the first two doses will be loading dose of between from about 100 mg-eq. to about 150 mg-eq. of paliperidone as a paliperidone palmitate ester to assure that a potential therapeutic plasma level of paliperidone is attained by the patient. The subsequent doses thereafter will drop to a therapeutic maintenance dose of from about 25 mg-eq. to 150 mg-eq. per month (±7 days). Preferably the maintenance dose will be from about 25mg eq. to about 100 mg eq; more preferably the maintenance dose will be from about 25mg eq. to about 75 mg eq; and most preferably the maintenance dose initially will be about 50 mg eq., or more preferably the maintenance dose initially will be about 75 mg eq.which may be administered intramoscularly into the deltoid or gluteal muscle, but more preferably will be administered in the gluteal muscle. Those of ordinary skill in the art will understand that the maintenance dose may be titrated up or down in view of the patients condition (response to the medication and renal function).

Since paliperidone is mainly eliminated through the kidneys, patients with renal impairment will have a higher total exposure to paliperidone after i.m. injections of paliperidone palmitate. For patients with renal impairment it would desirable to adjust the loading doses to account for the increased exposure levels of patients with renal impairment. For patients with mild renal impairment the loading doses should be reduced to 75 mg-eq. for the first two loading doses. The maintenance doses should range from about 25 mg-eq. to about 75 mg-eq. and more preferably with range from about 25 mg-eq. to about 50 mg-eq. The doses would be administered on day 1 of treatment, followed by a second dose between days 6 to 10 of treatment, then a third dose between days 34 to 38 of treatment. More preferably the patients will be administered a first dose on day 1, a second dose on day 8 and a third dose on day 36 of treatment. The first two doses will preferably be injected in the deltoid muscle. Thereafter paliperidone palmitate will be administered by injection approximately once a month (e.g. one a month ±7 days or once every four weeks) thereafter. For the purpose of this patent application renal function is estimated by glomerular filtration rate (GFR) usually measured by the creatinine clearance (best calculated from a 24-hour urine collection). Creatine clearance may be estimated by the Cockcroft and Gault method based on serum creatinine concentration, as described in Prediction of creatinine clearance from serum creatinine.

Nephron 1976; vol 16, pages 31-41. Patients with mild renal impairment have a creatinine clearance of 50 to <80 mL/minute.

It is recommended that the second initiation dose of paliperidone palmitate be given about one week (6-10 days) after the first dose. To avoid a missed dose, patients may be given the second dose 2 days before or after the one-week timepoint. Similarly, the third and subsequent injections after the initiation regimen are recommended to be given monthly. To avoid a missed monthly dose, patients may be given the injection up to 7 days before or after the monthly timepoint.

After initiation, the recommended injection cycle of paliperidone palmitate is monthly. If less than 6 weeks have elapsed since the last injection, then the previously stabilized dose should be administered as soon as possible, followed by injections at monthly intervals.

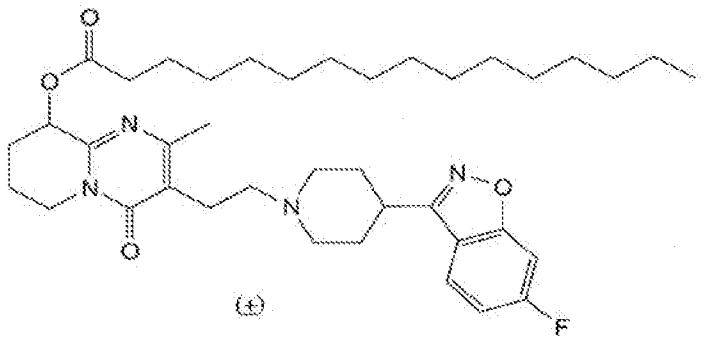
If more than 6 weeks have elapsed since the last injection, reinitiation with the same dose the patient was previously stabilized to should be resumed in the following manner: 1) a deltoid injection as soon as practically possible, followed by 2) another deltoid injection one week later, and 3) resumption of either deltoid or gluteal dosing at monthly intervals.

If more than 6 months have elapsed since the last injection, it is recommended to re-initiate dosing as described above.

Additionally, in this patient population needle length and BMI index are two related variables that need to be considered to assure patients attain therapeutic concentration of paliperidone in the desired time frame. Patients with high BMI had lower plasma concentration of paliperidone and a lessened treatment response. The lower initial plasma concentration in high BMI patients was likely due to unintended partial or complete injection into adipose tissue, instead of deep injection into muscle. However, once steady-state plasma concentration are attained BMI no longer influenced plasma concentrations or clinical efficacy. From these observations it was determined that for patients weighing <90 kg (< 200 lb) a 1-inch needle will be of adequate length to use in injections to reach the muscle tissue for deltoid injections with preferably a 23 gauge needle. However, for patients with high BMIs, ≥90 kg (≥ 200 lb) a 1.5-inch needle

should be used for deltoid injections. For gluteal muscle injections a 1.5-inch needle should be used. Preferably the 1.5-inch needle will be a 22-gauge needle.

Paliperidone esters are psychotic agents belonging to the chemical class of benzisoxazole derivatives, which contains a racemic mixture of (+)- and (-)-paliperidone, which are described in US Patent 5,254,556 (incorporated herein by reference). The chemical name for paliperidone palmitate is (±)-3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4-oxo-4*H*-pyrido[1,2-*a*]pyrimidin-9-yl hexadecanoate. The structural formula is:



(±)

Paliperidone esters may be formulated with pharmaceutical excipients into injectable dosage forms as described in US Patent 5,254,556 and US Patent 6,077,843 (incorporated herein by reference). Injectable formulations may be formulated in aqueous carriers.

Currently it is preferred to administer paliperidone palmitate in a once monthly aqueous depot. Suitable aqueous depot formulations are described in US Patent 6,077,843 (incorporated herein by reference). The aqueous formulation would preferably be a nano particle suspension of wherein the nano particles would be of an averages size of less than 2000 nm to about 100 nm. Preferably the nano particles would have an average particle size (d50) of from about 1600 nm to 400 nm and most preferably about 1400 nm to 900 nm. Preferably the d90 will be less than about 5000 nm and more preferably less than about 4400 nm. As used herein, an effective average particle size (d50) of less than 2,000 nm means that at least 50% of the particles have a diameter of less than 2,000 nm when measured by art-known conventional techniques, such as sedimentation field flow fractionation, photon correlation spectroscopy or disk

centrifugation. With reference to the effective average particle size, it is preferred that at least 90%, e.g. 5,000 nm. Most preferably, 90% of the particles have a size of less than 4,400 nm.

Suitable aqueous nano particle depot formulations are described in US Patent 6,555,544 (incorporated herein by reference). In one embodiment of the present invention the formulation would comprise nanoparticles, a surfactant, a suspending agent, and optionally one or more additional ingredients selected from the group consisting of preservatives, buffers and an isotonizing agents.

Useful surface modifiers are believed to include those that physically adhere to the surface of the active agent but do not chemically bond thereto.

Suitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients. Such excipients include various polymers, low molecular weight oligomers, natural products and surfactants. Preferred surface modifiers include nonionic and anionic surfactants. Representative examples of excipients include gelatin, casein, lecithin (phosphatides), gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glyceryl monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, e.g., macrogol ethers such as cetomacrogol 1000, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, e.g., the commercially available TWEENS™, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose phtalate, noncrystalline cellulose, magnesium aluminate silicate, triethanolamine, polyvinyl alcohol (PVA), poloxamers, tyloxapol and polyvinylpyrrolidone (PVP). Most of these excipients are described in detail in the Handbook of Pharmaceutical Excipients, published jointly by the American Pharmaceutical Association and The Pharmaceutical Society of Great Britain, the Pharmaceutical Press, 1986. The surface modifiers are commercially available and/or can be prepared by techniques known in the art. Two or more surface modifiers can be used in combination.

Particularly preferred surface modifiers include polyvinylpyrrolidone; tyloxapol; poloxamers, such as PLURONIC™. F68, F108 and F127 which are block copolymers of ethylene oxide and propylene oxide available from BASF; poloxamines, such as TETRONIC™ 908 (T908) which is a tetrafunctional block copolymer derived from sequential addition of ethylene oxide and propylene oxide to ethylenediamine available from BASF; dextran; lecithin; Aerosol OT™ (AOT) which is a dioctyl ester of sodium sulfosuccinic acid available from Cytec Industries; DUPONOL™ P which is a sodium lauryl sulfate available from DuPont; TRITON™ X-200 which is an alkyl aryl polyether sulfonate available from Rohm and Haas; TWEEN™. 20, 40, 60 and 80 which are polyoxyethylene sorbitan fatty acid esters available from ICI Speciality Chemicals; SPAN™ 20, 40, 60 and 80 which are sorbitan esters of fatty acids; ARLACEL™ 20, 40, 60 and 80 which are sorbitan esters of fatty acids available from Hercules, Inc.; CARBOWAX™ 3550 and 934 which are polyethylene glycols available from Union Carbide; CRODESTA™ F110 which is a mixture of sucrose stearate and sucrose distearate available from Croda Inc.; CRODESTA™ SL-40 which is available from Croda, Inc.; hexyldecyl trimethyl ammonium chloride (CTAC); bovine serum albumin and SA90HCO which is C_{18} H_{17} CH_2 $(CON(CH_3)CH_2$ $(CHOH)_4$ CH_2 $OH)_2$. The surface modifiers which have been found to be particularly useful include tyloxapol and a poloxamer, preferably, Pluronic.TM. F108 and Pluronic.TM. F68.

Pluronic.TM. F108 corresponds to poloxamer 338 and is the polyoxyethylene, polyoxypropylene block copolymer that conforms generally to the formula $HO[CH_2$ CH_2 $O]_x$ $[CH(CH_3)CH_2$ $O]_y$ $[CH_2$ CH_2 $O]_z$ H in which the average values of x, y and z are respectively 128, 54 and 128. Other commercial names of poloxamer 338 are Hodag NONIONIC™ 1108-F available from Hodag, and SYNPERONIC™ PE/F108 available from ICI Americas.

The optimal relative amount of paliperidone palmitate and the surface modifier depends on various parameters. The optimal amount of the surface modifier can depend, for example, upon the particular surface modifier selected, the critical micelle concentration of the surface modifier if it forms micelles, the surface area of the antipsychotic agent, etc. The specific surface modifier preferably is present in an amount of 0.1 to 1 mg per square meter surface area of the paliperidone palmitate. It is

preferred in the case of paliperidone palmitate (9-hydroxyrisperidone palmitate) to use PLURONIC™ F108 as a surface modifier, a relative amount (w/w) of both ingredients of approximately 6:1 is preferred.

The particles of this invention can be prepared by a method comprising the steps of dispersing paliperidone palmitate in a liquid dispersion medium and applying mechanical means in the presence of grinding media to reduce the particle size of the antipsychotic agent to an effective average particle size of less than 2,000 nm. The particles can be reduced in size in the presence of a surface modifier. Alternatively, the particles can be contacted with a surface modifier after attrition.

A general procedure for preparing the particles of this invention includes (a) obtaining paliperidone palmitate in micronized form; (b) adding the micronized paliperidone palmitate to a liquid medium to form a premix; and (c) subjecting the premix to mechanical means in the presence of a grinding medium to reduce the effective average particle size.

The paliperidone palmitate in micronized form may be prepared using techniques known in the art. It is preferred that the particle size of the micronized paliperidone palmitate be less than about 100 μm as determined by sieve analysis. If the particle size of the micronized paliperidone palmitate is greater than about 100 μm, then it is preferred that the particles of paliperidone palmitate be reduced in size to less than 100 μm.

The micronized paliperidone palmitate can then be added to a liquid medium in which it is essentially insoluble to form a premix. The concentration of paliperidone palmitate in the liquid medium (weight by weight percentage) can vary widely and depends on the selected antipsychotic agent, the selected surface modifier and other factors. Suitable concentrations of paliperidone palmitate in compositions vary between 0.1 to 60%, preferably is from 0.5 to 30%, and more preferably, is approximately 7% (w/v). It is currently preferred to use a concentration of about 100mg eq of paliperidone per ml or about 156 mg of paliperidone palmitate per ml.

A more preferred procedure involves the addition of a surface modifier to the premix prior to its subjection to mechanical means to reduce the effective average particle size. The concentration of the surface modifier (weight by weight percentage)

can vary from 0.1% to 90%, preferably from 0.5% to 80%, and more preferably is approximately 7% (w/v).

The premix can be used directly by subjecting it to mechanical means to reduce the effective average particle size in the dispersion to less than 2,000 nm. It is preferred that the premix be used directly when a ball mill is used for attrition. Alternatively, the antipsychotic agent and, optionally, the surface modifier, can be dispersed in the liquid medium using suitable agitation such as, for example, a roller mill or a Cowles type mixer, until a homogeneous dispersion is achieved.

The mechanical means applied to reduce the effective average particle size of the antipsychotic conveniently can take the form of a dispersion mill. Suitable dispersion mills include a ball mill, an attritor mill, a vibratory mill, a planetary mill, media mills--such as a sand mill and a bead mill. A media mill is preferred due to the relatively shorter milling time required to provide the desired reduction in particle size. For media milling, the apparent viscosity of the premix preferably is anywhere between 0.1 and 1 Pa•s. For ball milling, the apparent viscosity of the premix preferably is anywhere between 1 and 100 mPa•s.

The grinding media for the particle size reduction step can be selected from rigid media preferably spherical or particulate in form having an average size less than 3 mm and, more preferably, less than 1 mm. Such media desirably can provide the particles of the invention with shorter processing times and impart less wear to the milling equipment. The selection of the material for the grinding media is believed not to be critical. However, 95% ZrO stabilized with magnesia, zirconium silicate, and glass grinding media provide particles having levels of contamination which are acceptable for the preparation of pharmaceutical compositions. Further, other media, such as polymeric beads, stainless steel, titania, alumina and 95% ZrO stabilized with yttrium, are useful. Preferred grinding media have a density greater than 2.5 g/cm.sup.3 and include 95% ZrO stabilized with magnesia and polymeric beads.

The attrition time can vary widely and depends primarily upon the particular mechanical means and processing conditions selected. For rolling mills, processing times of up to two days or longer may be required.

The particles must be reduced in size at a temperature which does not significantly degrade the antipsychotic agent. Processing temperatures of less than 30°C to 40°C are ordinarily preferred. If desired, the processing equipment may be cooled with conventional cooling equipment. The method is conveniently carried out under conditions of ambient temperature and at processing pressures which are safe and effective for the milling process.

The surface modifier, if it was not present in the premix, must be added to the dispersion after attrition in an amount as described for the premix above. Thereafter, the dispersion can be mixed by, for example, shaking vigorously. Optionally, the dispersion can be subjected to a sonication step using, for example, a ultrasonic power supply.

Aqueous compositions according to the present invention conveniently further comprise a suspending agent and a buffer, and optionally one or more of a preservative and an isotonizing agent. Particular ingredients may function as two or more of these agents simultaneously, e.g. behave like a preservative and a buffer, or behave like a buffer and an isotonizing agent.

Suitable suspending agents for use in the aqueous suspensions according to the present invention are cellulose derivatives, e.g. methyl cellulose, sodium carboxymethyl cellulose and hydroxypropyl methyl cellulose, polyvinylpyrrolidone, alginates, chitosan, dextrans, gelatin, polyethylene glycols, polyoxyethylene- and polyoxy-propylene ethers. Preferably sodium carboxymethyl cellulose is used in a concentration of 0.5 to 2%, most preferably 1% (w/v). Suitable wetting agents for use in the aqueous suspensions according to the present invention are polyoxyethylene derivatives of sorbitan esters, e.g. polysorbate 20 and polysorbate 80, lecithin, polyoxyethylene- and polyoxypropylene ethers, sodium deoxycholate. Preferably polysorbate 20 is used in a concentration of 0.5 to 3%, more preferably 0.5 to 2%, most preferably 1.1% (w/v).

Suitable buffering agents are salt of weak acids and should be used in amount sufficient to render the dispersion neutral to very slightly basic (up to pH 8.5), preferably in the pH range of 7 to 7.5. Particularly preferred is the use of a mixture of disodium hydrogen phosphate (anhydrous) (typically about 0.9% (w/v)) and sodium

dihydrogen phosphate monohydrate (typically about 0.6% (w/v)). This buffer also renders the dispersion isotonic and, in addition, less prone to flocculation of the ester suspended therein.

Preservatives are antimicrobials and anti-oxidants which can be selected from the group consisting of benzoic acid, benzyl alcohol, butylated hydroxyanisole, butylated hydroxytoluene, chlorbutol, a gallate, a hydroxybenzoate, EDTA, phenol, chlorocresol, metacresol, benzethonium chloride, myristyl-gamma-piccolinium chloride, phenylmercuric acetate and thimerosal. In particular, it is benzyl alcohol which can be used in a concentration up to 2% (w/v), preferably up to 1.5% (w/v).

Isotonizing agents are, for example, sodium chloride, dextrose, mannitol, sorbitol, lactose, sodium sulfate. The suspensions conveniently comprise from 0 to 10% (w/v) isotonizing agent. Mannitol may be used in a concentration from 0 to 7% More preferably, however, from about 1 to about 3% (w/v), especially from about 1.5 to about 2% (w/v) of one or more electrolytes are used to render the suspension isotonic, apparently because ions help to prevent flocculation of the suspended ester. In particular, electrolytes of the buffer serve as isotonizing agent.

A particularly desirable feature for an injectable depot formulation relates to the ease with which it can be administered. In particular such an injection should be feasible using a needle as fine as possible in a span of time which is as short as possible. This can be accomplished with the aqueous suspensions of the present invention by keeping the viscosity below about 75 mPa•s, preferably below 60 mPa•s. Aqueous suspensions of such viscosity or lower can both easily be taken up in a syringe (e.g. from a vial), and injected through a fine needle (e.g a 21 G $1^1/_2$ inch, 22 G 2 inch, 22 G $1^1/_4$ inch or 23G 1 inch needle). The preferred needles for injection are 22G 22G 1 ½ inch regular wall and 23G 1 inch regular wall needles.

Ideally, aqueous suspensions according to the present invention will comprise as much prodrug as can be tolerated so as to keep the injected volume to a minimum, and as little of the other ingredients as possible. In particular, such a composition will comprise by weight based on the total volume of the composition: (a) from 3 to 20% (w/v) of the prodrug; (b) from 0.5 to 2% (w/v) of a wetting agent; (c) one or more buffering agents sufficient to render the composition neutral to very slightly basic (pH

8.5); (d) from 0.5 to 2% (w/v) of a suspending agent; (e) up to 2% (w/v) preservatives; and (f) water q.s. ad 100%. Preferably the aqueous suspension will be made under sterile conditions and no preservatives will be used. Appropriate methods to aseptically prepare paliperidone palmitate are described in WO 2006/114384 which is hereby incorporated by reference herein.

The preferred aqueous dosage form contains inactive ingredients that are polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide, and water for injection. The mg of compound delivered in such a dosage form to the patient may be from 25 to about 150 mg (e.g. 25 mg, 50 mg, 75 mg, 100 mg, 150 mg.) injectable dosage form.

The term "**psychiatric patient**" as used herein, refers to a human, who has been the object of treatment, or experiment for a "mental disorder" and "mental illness" refer to those provided in the Diagnostic and Statistical Manual (DSM IV), American Psychological Association (APA). Those of ordinary skill in the art will appreciate that paliperidone esters (e.g. paliperidone palmitate), can be administered to psychiatric patients for all the known uses of risperidone. These mental disorders include, but are not limited to, schizophrenia; bipolar disorder or other disease states in which psychosis, aggressive behavior, anxiety or depression is evidenced. Schizophrenia refers to conditions characterized as schizophrenia, schizoaffective disorder and schizophreniform disorders, in DSM-IV-TR such as category 295.xx. Bipolar Disorder refers to a condition characterized as a Bipolar Disorder, in DSM-IV-TR such as category 296.xx including Bipolar I and Bipolar Disorder II. The DSM-IV-TR was prepared by the Task Force on Nomenclature and Statistics of the American Psychiatric Association, and provides clear descriptions of diagnostic categories. Pathologic psychological conditions, which are psychoses or may be associated with psychotic features include, but are not limited to the following disorders that have been characterized in the DSM-IV-TR. Diagnostic and Statistical Manual of Mental Disorders, Revised, 3rd Ed. (1994). The numbers in parenthesis refer to the DSM-IV-TR categories. The skilled artisan will recognize that there are alternative nomenclatures, nosologies, and classification systems for pathologic psychological conditions and that these systems

evolve with medical scientific progress. Examples of pathologic psychological conditions which may be treated include, but are not limited to, Mild Mental Retardation (317), Moderate Mental Retardation (318.0), Severe Mental Retardation (318.1), Profound Mental Retardation (318.2), Mental Retardation Severity Unspecified (319), Autistic Disorders (299.00), Rett's Disorder (299.80), Childhood Disintegrative Disorders (299.10), Asperger's Disorder (299.80), Pervasive Developmental Disorder Not Otherwise Specified (299.80), Attention-Deficit/Hyperactivity Disorder Combined Type (314.01), Attention-Deficit/Hyperactivity Disorder Predominately Inattentive Type (314.00), Attention-Deficit/Hyperactivity Disorder Predominately Hyperactive-Impulsive Type (314.01), Attention-Deficit/Hyperactivity Disorder NOS (314.9), Conduct Disorder (Childhood-Onset and Adolescent Type 312.8), Oppositional Defiant Disorder (313.81), Disruptive Behavior Disorder Not Otherwise Specified (312.9), Solitary Aggressive Type (312.00), Conduct Disorder, Undifferentiated Type (312.90), Tourette's Disorder (307.23), Chronic Motor Or Vocal Tic Disorder (307.22), Transient Tic Disorder (307.21), Tic Disorder NOS (307.20), Alcohol Intoxication Delirium (291.0), Alcohol Withdrawal Delirium (291.0), Alcohol-Induced Persisting Dementia (291.2), Alcohol-Induced Psychotic Disorder with Delusions (291.5), Alcohol-Induced Psychotic Disorder with Hallucinations (291.3), Amphetamine or Similarly Acting Sympathomimetic Intoxication (292.89), Amphetamine or Similarly Acting Sympathomimetic Delirium (292.81), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Delusions (292.11), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Hallucinations (292.12), Cannabis-Induced Psychotic Disorder with Delusions (292.11), Cannabis-Induced Psychotic Disorder with Hallucinations (292.12), Cocaine Intoxication (292.89), Cocaine Intoxication Delirium (292.81), Cocaine-Induced Psychotic Disorder with Delusions (292.11), Cocaine-Induced Psychotic Disorder with Hallucinations (292.12), Hallucinogen Intoxication (292.89), Hallucinogen Intoxication Delirium (292.81), Hallucinogen-Induced Psychotic disorder with Delusions (292.11), Hallucinogen-Induced Psychotic disorder with Delusions (292.12), Hallucinogen-Induced Mood Disorder (292.84), Hallucinogen-Induced Anxiety Disorder (292.89), Hallucinogen-

Related Disorder Not Otherwise Specified (292.9), Inhalant Intoxication (292.89), Inhalant Intoxication Delirium (292.81), Inhalant-Induced Persisting Dementia (292.82), Inhalant-Induced Psychotic Disorder with Delusions (292.11), Inhalant-Induced Psychotic with Hallucinations (292.12), Inhalant-Induced Mood Disorder (292.89), Inhalant-Induced Anxiety Disorder (292.89), Inhalant-Related Disorder Not Otherwise Specified (292.9), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Delusions (292.11), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Hallucinations (292.12), Opioid-Induced Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication Delirium (292.81), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Delusions (292.11), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Hallucinations (292.12), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Anxiety Disorder (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Related Disorder Not Otherwise Specified (292.9), Sedative, Hypnotic or Anxiolytic Intoxication (292.89), Sedation, Hypnotic or Anxiolytic Intoxication Delirium (292.81), Sedation, Hypnotic or Anxiolytic Withdrawal Delirium (292.81), Sedation, Hypnotic or Anxiolytic Induced Persisting Dementia (292.82), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Delusions (292.11), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Hallucinations (292.12), Sedation, Hypnotic or Anxiolytic-Induced Mood Disorder (292.84), Sedation, Hypnotic or Anxiolytic-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Intoxication (292.89), Other (or Unknown) Substance-Induced Delirium (292.81), Other (or Unknown) Substance-Induced Persisting Dementia (292.82), Other (or Unknown) Substance-Induced Psychotic Disorder with Delusions (292.11), Other (or Unknown) Substance-Induced Psychotic Disorder with Hallucinations (292.12), Other (or Unknown) Substance-Induced Mood Disorder (292.84), Other (or Unknown) Substance-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Disorder Not Otherwise Specified (292.9), Obsessive

Compulsive Disorder (300.3), Post-traumatic Stress Disorder (309.81), Generalized Anxiety Disorder (300.02), Anxiety Disorder Not Otherwise Specified (300.00), Body Dysmorphic Disorder (300.7), Hypochondriasis (or Hypochondriacal Neurosis) (300.7), Somatization Disorder (300.81), Undifferentiated Somatoform Disorder (300.81), Somatoform Disorder Not Otherwise Specified (300.81), Intermittent Explosive Disorder (312.34), Kleptomania (312.32), Pathological Gambling (312.31), Pyromania (312.33), Trichotillomania (312.39), and Impulse Control Disorder NOS (312.30), Schizophrenia, Paranoid Type, (295.30), Schizophrenia, Disorganized (295.10), Schizophrenia, Catatonic Type, (295.20), Schizophrenia, Undifferentiated Type (295.90), Schizophrenia, Residual Type (295.60), Schizophreniform Disorder (295.40), Schizoaffective Disorder (295.70), Delusional Disorder (297.1), Brief Psychotic Disorder (298.8), Shared Psychotic Disorder (297.3), Psychotic Disorder Due to a General Medical Condition with Delusions (293.81), Psychotic Disorder Due to a General Medical Condition with Hallucinations (293.82), Psychotic Disorders Not Otherwise Specified (298.9), Major Depression, Single Episode, Severe, without Psychotic Features (296.23), Major Depression, Recurrent, Severe, without Psychotic Features (296.33), Bipolar Disorder, Mixed, Severe, without Psychotic Features (296.63), Bipolar Disorder, Mixed, Severe, with Psychotic Features (296.64), Bipolar Disorder, Manic, Severe, without Psychotic Features (296.43), Bipolar Disorder, Manic, Severe, with Psychotic Features (296.44), Bipolar Disorder, Depressed, Severe, without Psychotic Features (296.53), Bipolar Disorder, Depressed, Severe, with Psychotic Features (296.54), Bipolar II Disorder (296.89), Bipolar Disorder Not Otherwise Specified (296.80), Personality Disorders, Paranoid (301.0), Personality Disorders, Schizoid (301.20), Personality Disorders, Schizotypal (301.22), Personality Disorders, Antisocial (301.7), and Personality Disorders, Borderline (301.83).

The following non-limiting examples are provided to further illustrate the present invention.

The term "**therapeutically effective amount**" as used herein, means that amount of active compound or pharmaceutical agent that elicits the biological or medicinal response in human that is being sought by a researcher, medical doctor or other clinician, which includes alleviation of the symptoms of the disease or disorder being treated.

Those of skill in the treatment of diseases could easily determine the effective amount of paliperidone to administer for the treatment of the diseases listed above. In general it is contemplated that an effective amount of paliperidone for the treatment of mental disorders would be from about 0.01mg/kg to about 2 mg/kg body weight. For the present invention it is preferred to dose patients with 25 mg- eq. to about 150 mg eq. paliperidone. The amount of paliperidone palmitate is provided in sufficient amount to provide the equivalent dose of paliperidone after the palmitic acid moiety is removed from the ester (e.g. 156 mg corresponds to paliperidone 100mg,). In one embodiment of present invention wherein paliperidone palmitate is administered by intramuscular injection once per month is preferred.

EXAMPLE 1

Paliperidone Palmitate Formulations

a) Crystallization in stainless steel reactor of 50L

All equipment was sterilized using dry heat sterilization.

A stainless steel reactor was charged with 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-*4H*-pyrido[1,2-a]-pyrimidin-4-one palmitate ester and ethanol parenteral grade (8 L/kg) and heated to reflux temperature (78 - 79 °C) while stirring. The product dissolved at about 70 °C. The solution was filtered at 76 °C over a sterile 0.22 µm filter into a sterile crystallization reactor. The sterile filter was then washed with heated ethanol (1 L/kg).

The filtrate was reheated to reflux and then cooled to room temperature whereupon the product crystallized. The thus obtained suspension was reheated again. The solution was cooled using differing cooling gradients (in consecutive experiments, the mixture was reheated and cooled again; after each cooling gradient, a sample was taken and isolated using a filter. The crystals were dried in vacuo at 50 °C in Tyvek bags so as to prevent dust formation and the particle characteristics were determined.

Different batches were run, yielding product with a particle size distribution measured by laser diffraction as shown in Table 1.

Table 1

Cooling rate	Crystallization					Particle size distribution		
	Calculated cooling gradient (°C/min)	Tmax Treactor	start at … (°C) Treactor	Tjacket	start cooling (°C) Treactor	d(10 (µm)	d(50 (µm)	d(90 (µm)
1 °C/min	0.95	78	63.5	60.2	77.5	156	65	16
ASAP	3.2	75.7	61.2	17.5	75	119	36	9.2
0.5 °C/min	0.48	75.7	63.8	62.7	75	192	80	20
0.5 °C/min	0.48	75.7	63.8	62.7	75	189	81	23
0.7 °C/min	0.81	75.7	61.7	58.9	75	113	41	11
1 °C/min	0.92	75.7	62.1	54.9	75	128	52	13

b) Formulation of Composition

Table 2 provides the formulation for the F013 formulation. The F011 formulation contained the same ingredients, with the exception of citric acid and NaOH, which were not present in the F011 formulation. Since the F011 formulation does not contain NaOH or citric acid, they are not part of the aqueous phase that is added to the milled concentrate of the F011 formulation. Therefore, the concentration of buffer salts in the aqueous phase of the F011 formulation is slightly different to make the formulation isotonic.

Table 2

Name	Amount Required			
	Per ml		Quantity for 24 L	
Paliperidone palmitate (sterile grade)	156	mg	3.744	kg
Polysorbate 20 parenteral	12	mg	288	g
Citric acid monohydrate parenteral	5	mg	120	g
Disodium hydrogen phosphate anhydrous parenteral	5	mg	120	g
Sodium dihydrogen phosphate monohydrate parenteral	2.5	mg	60	g
Sodium Hydroxide all use	2.84	mg	68	g
Polyethylene Glycol 4000 parenteral	30	mg	720	g
Water for injections q.s. ad	1000	µl	24	L

Equipment

- stainless steel (SS) containers
- Grinding media (Zirconium beads) + stainless steel (SS) grinding chamber
- 0.2 µm filters
- 40 µm filter
- Filling unit
- Autoclave
- Dry heat oven

Manufacturing

Zirconium beads were cleaned and rinsed using water for injections and then depyrogenised by dry heat (120 min at 260°C). Water for injections was transferred into a SS container. Polysorbate 20 was added and dissolved by mixing. The solution was sterilized by filtration through a sterile 0.2 µm filter into a sterilized SS container. Paliperidone palmitate ester (sterile grade) as prepared in the previous examples was dispersed into the solution and mixed until homogeneous. The suspension was milled aseptically in the grinding chamber using Zirconium beads as grinding media until the

required particle size was reached. The suspension was filtered aseptically through a 40 µm filter into a sterilized SS container

Water for injections was transferred into a SS container, citric acid monohydrate parenteral, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide all use, polyethylene glycol 4000 were added and mixed until dissolved. This solution was sterilized by filtration through a sterile 0.2 µm filter and transferred aseptically into the suspension. The final suspension was mixed until homogeneous. The suspension was filled aseptically into sterile syringes. The target dose volume was between 0.25 ml and 1.50 ml depending on the dose needed.

Table 3

Dose volume	Target limit	lower limit	upper limit
0.25 ml - 1.00 ml	identical to dose volume	target limit – (target limit x 0.05)	target limit x 1.05
1.25 ml - 1.50 ml	identical to dose volume	target limit – (target limit x 0.025)	target limit x 1.025

Sterilization

All aseptic manipulations and sterilization processes were carried out according to FDA and European regulatory guidelines.

Apparatus

Sterilization was done by steam sterilization ($F_0 \geq 15$) of following equipment :

- SS containers
- Zirconium beads + grinding chamber
- 0.2 µm filters
- 40 µm filter

- filling pump

Immediate container

- 1 ml long transparent plastic (COC) syringe with luer lock.
- rubber tip cap, FM257/2 dark grey
- rubber plunger stopper, 1 ml long, 4023/50, Flurotec B2-40

- 2.25ml transparent plastic (COC) syringe with luer lock.
- rubber tip cap, FM257/2 dark grey
- rubber plunger stopper, 1-3 ml, 4023/50, Flurotec B2-40

The empty syringes with pre-assembled tip-caps were sterilized by gamma-irradiation (dose ≥ 25 kGy). The rubber plunger stoppers were sterilized by means of steam sterilization ($F_0 \geq 15$).

EXAMPLE 2

Evaluation of the Pharmacokinetic Profile of Gluteal Versus Deltoid Intramuscular Injections of paliperidone palmitate 100 mg Equivalent in patients with Schizophrenia

This study was performed to characterize and compare the pharmacokinetic profile of paliperidone palmitate (formulated as described above) following four intramuscular injections in the deltoid or gluteal muscle.

Method

In this multiple-dose, open-label, parallel-group study, patients with schizophrenia were randomized to receive four consecutive intramuscular injections (days 1, 8, 36 and 64) of paliperidone palmitate 100 mg-eq. administered into either the deltoid (n=24) or gluteal muscle (n=25). Plasma samples for pharmacokinetic analyses

were collected. The total paliperidone concentration was calculated as the sum of both enantiomers.

Results

The median C_{max} for paliperidone was higher in the deltoid versus the gluteal muscle after the second (31.3 versus 24.1 ng/mL) and fourth (23.7 versus 22.3 ng/mL) injections. After four injections, median AUC_{∞} was similar for both injection sites; C_{max} and AUC_{τ} for paliperidone were 30% (90% CI= 100.56% - 168.93%) and 20% (90% CI = 93.09% - 154.69%) higher in deltoid versus gluteal muscle, respectively. Median T_{max} was similar between injection sites after the second (10 day versus 10 day) and fourth injections (5 versus 6.5 days). After four injections, the median peak-to-trough ratio was higher (2.3 versus 1.9), with a larger intersubject variability for deltoid versus gluteal injection. An increase in median predose plasma concentration between days 8, 36 and 64 for both sites suggested subjects were not completely at steady state after four injections. Relative exposure after the fourth injection was slightly lower than after the second injection in both the deltoid and gluteal muscle. Most commonly reported adverse events (combined injection sites) were orthostatic hypotension (24%), hypotension (14%), diastolic hypotension (12%) and injection site pain (14%). There were four serious adverse events (worsening of psychosis) that led to discontinuations. There were no deaths in the study. Paliperidone palmitate was well tolerated with more favorable local tolerability profile in the gluteal versus deltoid; mean injection site pain VSA score was 3.3 for gluteal versus 10.8 for deltoid muscle (day 1, 8 hours after injection.

Conclusion

Paliperidone palmitate 100 mg-eq. injections resulted in an increased AUC_{τ} higher C_{max}, greater FI, but similar T_{max} following four consecutive injections into the deltoid versus gluteal muscle. Paliperidone palmitate 100 mg-eq. was systemically and locally well tolerated in this study.

EXAMPLE 3

Assessment of the Dose Proportionality of Paliperidone Palmitate 25, 50,100, and 150 mg eq. following Administration in the Deltoid or Gluteal Muscles

This study evaluated dose proportionality of paliperidone palmitate injections when administered into either the gluteal or deltoid muscle.

Method

A single-dose, open label, parallel-group study of 201 randomized schizophrenia subjects was performed. The subjects were assigned into eight treatment groups: paliperidone palmitate 25 (n=48), 50 (n=50), 100 (n=51) or 150 (n=52) mg-eq. injected into either the deltoid or gluteal muscle. Serial plasma samples were collected for pharmacokinetic evaluation over 126-day period. The total paliperidone concentration was calculated as the sum of both enantiomers. Dose proportionality was assessed by linear regression model, for each injection site, with log-transformed dose-normalized AUC_∞ and C_{max} as dependent variables and log-transformed dose as predictor, respectively of C_{max} and AUC_∞ ratios of the enantiomers were documented.

Results

Slopes for log-transformed dose–normalized AUC_∞ were not significantly different from zero for deltoid (slope –0.06; p=0.036) and gluteal injections (slope –0.02; p=0.760 indicating a dose-proportional increase in AUC_∞. T_{max}, was comparable between doses but slightly earlier for deltoid (13-14 days) versus gluteal injections (13-17 days). Median C_{max} was higher with deltoid (range 5.3-11.0 ng/mL) versus gluteal (range 5.1-8.7 ng/mL) injections except for the 100 mg-eq. deltoid (slope -0.22, p=0.0062) and gluteal (slope –0.31; p<0.0001) injections, indicating a less than dose-proportional increase in C_{max}. Results of C_{max} and AUC were confirmed using pairwise comparisons. Plasma concentrations of (+)-enantiomer were consistently higher than (-)-enantiomer; (+)/(-) plasma concentrations ratio was approximately 2.4 shortly after administration and decreased to ~1.7 for both injection sites, independent of dose. After a single dose of paliperidone palmitate, subjects received concomitant oral antipsychotics. Treatment-emergent AEs (TEAs) included tachycardia (10%),

headache (7%), schizophrenia (6%), insomnia (5%). Only 2% of subjects discontinued due to TEAs. No deaths were reported.

Conclusion

AUC_∞ increased proportionality with increasing paliperidone palmitate doses (5-150 mg-eq.), regardless of gluteal or deltoid injection. Overall, deltoid injection was associated with a higher C_{max} (except for 100 mg-eq.) and slightly earlier T_{max} compared with gluteal injections.

EXAMPLE 4

Comparison of the PK profile in the deltoid to that in the gluteal

The plasma concentration-time profile of paliperidone after single i.m. injection of the paliperidone palmitate formulation at 25-150mg-eq. has been documented in several studies (Table 4). Details of how the comparison of injection sites study and the dose proportionality studies were performed are provided in Examples 2 and 3.

Table 4: Table of Clinical Studies Summarized

Study	Design / Treatment / PK Objective
PHASE 1 STUDIES IN SUBJECTS WITH SCHIZOPHRENIA	
R092670-INT-12 (dose-proportionality)	S.D., OL, parallel group / single i.m. injection of F011*, 25, 50, 100 or 150 mg eq. / document PK of the F011* formulation at different doses, enantiomer disposition
R092670-USA-3	M.D., OL, randomized, parallel groups / 2 i.m. injections of R092670 (F011*) 25 or 150 mg eq., gluteal or deltoid, separated by 1 week / compare the PK after deltoid and gluteal injections, explore the relationship between R092670 PK parameters and CYP P450 genotypes
R092670-PSY-1001 (comparison of injection site)	M.D., OL, randomized, parallel groups / 4 i.m. injections of R092670 (F013) 100 mg eq. in the gluteal or deltoid muscle (on Day 1, 8, 36 and 64) / compare the PK at steady state between deltoid and gluteal injection sites
R092670-PSY-1004 (dose-proportionality)	S.D., OL, randomized, parallel groups / single i.m. injection of R092670 (F013) 25, 50, 100 or 150 mg eq. in the gluteal or deltoid muscle / evaluate dose proportionality of F013 formulation over a dose range of 25 – 150 mg eq., compare the PK after deltoid and gluteal injections

S.D.: single dose; M.D.: multiple dose; OL: open-label; DB: double blind; PK: pharmacokinetic; PC: placebo-controlled; AC: active-controlled; pali ER: paliperidone extended release; pali IR: paliperidone immediate release
F011* : Sterilized by gamma-irradiation. Otherwise, sterilized by aseptic crystallization.

The total exposure (AUC_∞) of paliperidone increased proportionally with dose after single-dose injections of 25 to 150 mg eq. paliperidone palmitate in both the deltoid and gluteal muscle. The increase in C_{max} was slightly less than dose proportional for both injections sites at doses greater than 50 mg eq. The apparent half-life (reflecting the absorption rate for this type of formulations) increased with dose from 25 days (median) after the 25 mg eq. dose to 40-49 days (median) after the 100 and 150 mg eq. dose, for both injection sites. The C_{max} of paliperidone was generally higher after single-dose injection of paliperidone palmitate in the deltoid muscle compared to the gluteal muscle (geometric mean ratio ranging from 108.75% to 164.85%) whereas this was much less pronounced for AUC_∞, (geometric mean ratio ranging from 103.00% to 117.83%). The median apparent half-life was comparable between injection sites.

EXAMPLE 5

Description of the PK profile in the gluteal after multiple administrations

Paliperidone palmitate is a long-acting i.m. injectable, intended to release over a period of 1 month. In order to attain this long injection interval, an ester of paliperidone was prepared that has a limited solubility in a physiological environment. The ester was subsequently formulated as an aqueous suspension for i.m. injection. The rate of dissolution is governed by the particle size distribution whereby it was experimentically determined that an optimal particle size range is contained within xx – yy microm (d_{50v}). In fact, the rate of dissolution (and thus the particle size distribution) fully determines the in vivo behaviour, as was nicely demonstrated in study PSY-1002. It was found that the median C_{max} increases and t_{max} shortens with decreasing particle size, which is consistent with the hypothesis that particle size is driving the release rate. The point estimates suggest that paliperidone exposure (AUC, C_{max}) after injection of paliperidone palmitate is similar between the to-be-marketed formulation F013 and formulation F011.

Table 5: Table of Clinical Studies Summarized in Module 2.7.2

Study	Design / Treatment / PK Objective
PHASE I STUDIES IN SUBJECTS WITH SCHIZOPHRENIA	
R092670-BEL-4 (pilot, dose-proportionality)	M.D., OL, sequential, parallel groups / 4-6 monthly i.m. injections of F004, 50 mg eq. or 100 mg eq. or 150 mg eq. / explore M.D. PK and dose-proportionality
R092670-BEL-7 (dosing regimen)	M.D., OL, parallel groups / F004 formulation: Panel I: 100 mg eq. i.m. followed by 3 monthly i.m. injections of 50 mg eq.; Panel II: 200 mg eq. i.m. followed by 3 monthly i.m. injections of 100 mg eq.; Panel III: 300 mg eq. i.m. followed by 3 monthly i.m. injections of 150 mg eq.; Panel IV: 50 mg eq. i.m. followed by 1 week later by 4 monthly i.m. injections of 50 mg eq.; Panel V: 150 mg eq. i.m. followed by 1 week later by 4 monthly i.m. injections of 150 mg eq. / explore the M.D. PK with various dosing regimens
R092670-INT-11 (compare F004 and F011)	M.D., DB, randomized, 4-group 2-way cross-over / 4 monthly i.m. injections of F004 or F011*, 2x50 and 2x150 mg eq. / compare PK of F004 and F011* formulations; compare S.D. and M.D. PK of both formulations
R092670-PSY-1002 (IVIVC)	S.D., OL, randomized, parallel groups / single i.m. injections of 1 mg paliperidone IR, followed by single i.m. injection of 50 mg eq. R092670: 1 of 4 F013 formulations with different particle sizes, or F011 formulation with medium particle size / explore IVIVC of 4 F013 formulations, compare the PK of F011 and F013 formulations
R092670-PSY-1001 (comparison of injection site)	M.D., OL, randomized, parallel groups / 4 i.m. injections of R092670 (F013) 100 mg eq. in the gluteal or deltoid muscle (on Day 1, 8, 36 and 64) / compare the PK at steady state between deltoid and gluteal injection sites

S.D.: single dose; M.D.: multiple dose; OL: open-label; DB: double blind; PK: pharmacokinetic; PC: placebo-controlled; AC: active-controlled; pali ER: paliperidone extended release; pali IR: paliperidone immediate release

F011* : Sterilized by gamma-irradiation. Otherwise, sterilized by aseptic crystallization.

Pharmacokinetic theory also implies that for a formulation with such a long apparent half-life it takes 4-5 times this half-life for steady-state to be achieved. For individual patients, this means that following the first few injections, only subtherapeutic plasma concentrations are achieved. In order to overcome this problem, a loading dose regimen was developed (BEL-7), that was subsequently used in phase 2 and 3 of drug development.The dosing regimen consisting of two initial i.m. injections separated by one week followed by subsequent doses at monthly intervals resulted in a faster attainment of apparent steady state compared with a dosing regimen of one initial injection of twice the monthly dose followed by subsequent doses at monthly intervals. Somewhat higher peak-to-through fluctuations were observed with the first dosing

regimen as compared with the latter one. The dosing regimen consisting of two initial i.m. injections separated by one week followed by subsequent doses at monthly intervals was selected for further studies and is also the recommended regimen for treatment.

EXAMPLE 6

Description of the exposure range needed for efficacy using Invega data

All antipsychotic drugs currently on the market have one feature in common: they antagonize the D_2 receptor at the level of the brain. It has been empirically derived and is currently widely excepted that 65-70% occupancy is needed for antipsychotics to show clinical efficacy (Farde et al.), i.e. improvement on the PANSS scale. A too high occupancy (80-85%) will typically increase the risk to develop EPS. In order to determine the central D_2 occupancy, PET trials in human healthy volunteers are typically performed. Two such studies have been done for paliperidone: SWE-1 and SIV-101, showing that the K_D^{app} for D_2 occupancy was ranging from 4.4 to 6.4 ng/mL. Using the 65-85% occupancy window, it can be calculated that the exposure range for efficacy without an increased risk to develop EPS as compared to placebo (<5% difference in probability) is contained in the window of 7.5-40 ng/mL.

In addition, based on the results of the phase 3 program of 6 mg paliperidone ER, in which plasma samples were collected at several time points, a plasma concentration of 7.5 ng/mL was identified as the cut-off value above which 90% of the plasma concentrations were observed. The risk to develop EPS was clearly higher for dose above 9 mg Invega. Calculating back, this roughly corresponds to an exposure level of 35-40 ng/mL at steady-state. This implies that there is ample evidence to support a target exposure efficacy range of 7.5-40 ng/mL. This should be the target exposure range for paliperidone after injection of the paliperidone palmitate formulation.

EXAMPLE 7

Optimal way of dosing

During the development of paliperidone palmitate, as the result of an extensive population PK analysis (refer to popPK report for paliperidone palmitate), several factors were found to slow down the release of paliperidone from the formulation, resulting in a slower build-up of plasma concentrations at the start of therapy and in

more time required to reach steady-state. One factor was body mass index: the higher the BMI, the slower the dissolution (probably related to local physiological factors such as diminished blood flow at the site of injection); the other one being volume administered: the higher the volume injected, the slower the dissolution (probably related to the nonlinear relationship between surface area and volume). This has resulted in a lower than expected exposure using the originally proposed loading dose regimen, and the need to come up with an improved loading dose scheme for all patients irrespective of BMI in order to avoid drop-out due to lack of efficacy at the start of therapy. The aim was to get patients as quickly as possible above the 7.5 ng/mL, certainly after 1 week for all doses considered (25 mg-eq. and above).

Simulation scenarios with the statistically significant covariates from the population PK analysis revealed the following features about the paliperidone PK after injection of paliperidone palmitate:

- Compared to deltoid injections, repeated administration in the gluteal muscle resulted in a delayed time to achieve steady-state (~ 4 wk longer), but did not influence the overall exposure (in terms of steady-state concentrations) to paliperidone.

- Deltoid injections resulted in a faster rise in initial plasma concentrations, facilitating a rapid attainment of potential therapeutic plasma concentrations. The deltoid injection site is therefore recommended as the initiation site for dosing paliperidone palmitate.

- Higher doses, associated with larger injection volumes, increased the apparent half-life of paliperidone, which in turn increased the time to achieve steady-state.

- Needle length was an important variable for the absorption kinetics from the deltoid injection-site and it is recommended to use a longer 1.5-inch needle for deltoid administration in heavy subjects (≥ 90 kg). Simulations indicated that the use of a longer needle in the deltoid muscle for the heavy individuals might be associated with an initial faster release of paliperidone into the systemic circulation, which could help overcome the slower absorption observed in heavier individuals described below.

- The body size variable BMI was another important covariate for paliperidone palmitate. A slower rise in initial concentrations was observed in the obese population, which possibly occurred due to the reduced speed of initial influx

from the injection site. Initiating the first two injections in the deltoid muscle and using a longer 1.5-inch needle for deltoid injection in heavy subjects can mitigate this effect. These observations are consistent with the expectation that in heavy subjects, administration into the adipose layer of the deltoid muscle can be avoided with the use of a longer injection needle.

Summarize what the optimized loading dose regimens would be here:

- 150 deltoid (day 1), 100 mg deltoid (day 8), then every 4 weeks maintenance (gluteal or deltoid) (PSY-3006, simulations – popPK report palmitate)
- 100 deltoid (day 1), 100 mg deltoid (day 8), then every 4 weeks maintenance (gluteal or deltoid) (simulations – popPK report palmitate, proposed for the label)
- 150 mg deltoid day 1, maintenance dose day 8 and then every 4 weeks (gluteal or deltoid) (PSY-3007)

EXAMPLE 8

TITLE OF STUDY: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia

PHASE OF DEVELOPMENT: Phase 3

OBJECTIVES: The primary objectives of this study were to evaluate the efficacy and safety of 3 fixed doses of paliperidone palmitate administered intramuscularly (i.m.) after an initial dose of 150 mg equivalent (eq.) in the deltoid muscle followed by either deltoid or gluteal injections for a total of 13 weeks of treatment as compared with placebo in subjects with schizophrenia.

The secondary objectives were to:

- Assess the benefits in personal and social functioning (key secondary endpoint) associated with the use of paliperidone palmitate compared with placebo;

- Assess the global improvement in severity of illness associated with the use of paliperidone palmitate compared with placebo;
- Assess the dose-response and exposure-response relationships of paliperidone palmitate.

METHODS: This was a randomized, double-blind, placebo-controlled, parallel-group, multicenter, dose-response study of men and women, 18 years of age and older, who had a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of schizophrenia. The study included a screening period of up to 7 days and a 13-week double-blind treatment period. The screening period included a washout of disallowed psychotropic medications.

Subjects without source documentation of previous exposure to at least 2 doses of oral risperidone or paliperidone extended-release (ER), at least 1 dose of i.m. RISPERDAL® CONSTA® or paliperidone palmitate, or who were not currently receiving an antipsychotic medication were given 4 to 6 days of paliperidone ER 6 mg/day (or the option of oral risperidone 3 mg/day for subjects in Malaysia) for tolerability testing. Subjects who had source documentation of previous exposure to the above medications and were currently taking another antipsychotic regimen continued their current treatment through Day–1. At the beginning of the double-blind treatment period, subjects were randomly assigned in a 1:1:1:1 ratio to 1 of 4 treatment groups: placebo or paliperidone palmitate 25 mg eq., 100 mg eq., or 150 mg eq. Study medication was administered as 4 doses: an initial i.m. injection of 150 mg eq. of paliperidone palmitate or placebo followed by 3 fixed i.m. doses of placebo or paliperidone palmitate [25, 100, or 150 mg eq.] on Days 8, 36, and 64. The initial injection of study medication was given in the deltoid muscle. Subsequent injections were given either in the deltoid or gluteal muscle at the discretion of the investigator. Randomized subjects were to remain in the study for 28 days after the last injection on Day 64 with the end of study visit scheduled for Day 92 during the double-blind period. The entire study, including the screening period, lasted approximately 14 weeks.

Samples for pharmacokinetic (PK) evaluation were collected on Day 1, prior to the first injection and on Days 2, 4, 6, 8, 15, 22, 36, 64 and 92. Efficacy and safety were evaluated regularly throughout the study. A pharmacogenomic blood sample (10 mL)

was collected from subjects who gave separate written informed consent for this part of the study. Participation in the pharmacogenomic research was optional. Approximately 105 to 115 mL of whole blood was collected during the study.

Number of Subjects (Planned and Analyzed): It was planned to include approximately 644 men and women in this study. A total of 652 eligible subjects from 72 centers in 8 countries were randomized and received at least 1 dose of double-blind study medication (safety analysis set); 636 subjects had both baseline and post baseline efficacy data (intent-to-treat analysis set).

Diagnosis and Main Criteria for Inclusion: Male or female subjects ≥18 years of age who met the DSM-IV diagnostic criteria for schizophrenia for at least 1 year before screening, had a Positive and Negative Syndrome Scale (PANSS) total score at screening of between 70 and 120, inclusive, and at baseline of between 60 and 120, inclusive, and had a body mass index (BMI) of >17.0 kg/m^2 to <40 kg/m^2 were eligible.

Test Product, Dose and Mode of Administration, Batch No.: Paliperidone ER was supplied as a 6-mg capsule-shaped tablet for the oral tolerability test (batch number 0617714/F40). Paliperidone palmitate was supplied as 25, 100, or 150 mg eq. injectable suspension (batch numbers 06K22/F13 and 07D23/F13). For the oral tolerability test, a 6-mg tablet of paliperidone ER (or the option of oral risperidone 3 mg/day for subjects in Malaysia) was administered daily for 4 to 6 days. On Day 1 of the double-blind treatment period, 150 mg eq. of paliperidone palmitate was injected in the deltoid muscle followed by 25, 100, or 150 mg eq. i.m. injections of paliperidone palmitate on Days 8, 36, and 64, injected into the deltoid or gluteal muscle at the investigator's discretion.

Reference Therapy, Dose and Mode of Administration, Batch No.: Placebo was supplied as 20% Intralipid (200 mg/mL) injectable emulsion (batch numbers 06K14/F00 and 07F12/F00). An injection was given on Days 1, 8, 36 and 64.

Duration of Treatment: The study consisted of a screening and washout phase of 7 days and a double-blind treatment period of 13 weeks, starting with the first injection in the deltoid muscle followed by a second injection 1 week later. All injections after Day 1 were given in either the deltoid or the gluteal muscle at the discretion of the investigator. Two subsequent injections were given at 4-week intervals.

CRITERIA FOR EVALUATION:

Pharmacokinetic Evaluations: A sparse blood sampling procedure was followed to study the paliperidone concentration-time profiles. Paliperidone plasma concentration-time data were subject to population PK analysis using nonlinear mixed-effects modeling, and details are described in a separate report.

Efficacy Evaluations/Criteria: The primary endpoint was the change in the PANSS total score from baseline (i.e., the start of double-blind treatment, Day 1) to the end of the double-blind treatment period (i.e., Day 92 or the last post baseline assessment). The key secondary efficacy endpoint was the change in the Personal and Social Performance Scale (PSP) from baseline to the end of the double-blind treatment period. The other secondary efficacy endpoint was the change in the Clinical Global Impression-Severity (CGI-S) scores from baseline to the end of the double-blind treatment period. Other endpoints included the change from baseline in subject ratings of sleep quality and daytime drowsiness using a visual analogue scale (VAS), the onset of therapeutic effect, responder rate, and the change from baseline to end point in PANSS subscales and Marder factors.

Safety Evaluations: Safety was monitored by the evaluation of adverse events, extrapyramidal symptom (EPS) rating scales (Abnormal Involuntary Movement Scale [AIMS], Barnes Akathisia Rating Scale [BARS], Simpson and Angus Rating Scale [SAS]) scores, clinical laboratory test results, vital signs measurements, electrocardiograms (ECGs), and physical examination findings. In addition, the tolerability of injections was assessed; the investigators evaluated injection sites and the subjects assessed injection pain.

STATISTICAL METHODS:

All randomized subjects who received at least 1 dose of double-blind study drug and had both baseline and at least one post baseline efficacy measurement (PANSS, PSP, or CGI-S) during the double-blind treatment period were included in the intent-to-treat efficacy analyses. The overall type I error rate for testing all paliperidone palmitate doses versus placebo for both the primary endpoint (change in PANSS total score at

end point) and the key secondary efficacy endpoint (change in PSP total score at end point) was controlled at the 2-sided 0.05 significance level. The 2 families of hypotheses (in each family, 3 comparisons for each of the paliperidone palmitate doses versus placebo) were tested using a parallel gatekeeping procedure that adjusts for multiplicity using Dunnett's method in each family of hypotheses and using Bonferroni's inequality between different families of hypotheses. This procedure is referred to as the Dunnett-Bonferroni-based parallel gatekeeping procedure.

The change from baseline in PANSS total score at each visit and at end point was analyzed using an analysis of covariance (ANCOVA) model. The last observation carried forward (LOCF) method was used. The model included treatment and country as factors and baseline PANSS total score as a covariate. Treatment effect was based on the difference in least-squares mean change. Dunnett's test was used to adjust for multiple comparisons of the 3 paliperidone palmitate dosages versus placebo. Unadjusted 2-sided 95% confidence intervals were presented for the difference in least-squares mean change of each paliperidone palmitate dosage group compared with placebo. Treatment-by-country and treatment-by-baseline PANSS total score interactions were explored using the same ANCOVA model as the one for the analysis of the primary endpoint. If either term was statistically significant at the predefined 2-sided significance level of 0.10, further evaluations of the effect of other covariates were to be performed to assess the nature of the interaction and identify possible causes. In addition, to address the dose-response relationship and to facilitate the discussion of dosage selection, an analysis to compare the 3 active paliperidone palmitate dosages with each other was performed without adjustment for multiple comparisons.

The analysis of the key secondary endpoint, change in PSP score at end point, was conducted by means of an ANCOVA model with treatment and country as factors and the baseline score as the covariate. The Dunnett-Bonferroni-based parallel gatekeeping approach was used to adjust for multiple testing.

Between-group comparisons of CGI-S were performed by using an ANCOVA model on the ranks of change from baseline, with treatment and country as factors and the baseline score as the covariate.

Change from baseline over time (observed case) in the PANSS total score was explored using mixed effects linear models for repeated measures with time, treatment, country, and treatment-by-time as factors and baseline score as a covariate.

The number and percentage of subjects with treatment-emergent adverse events were summarized. Adverse events of potential clinical interest were summarized separately, including events related to EPS or changes in serum glucose or prolactin levels.

Changes from baseline in clinical laboratory tests, vital sign measurements, ECGs, body weight, BMI, and EPS scale scores were summarized by treatment group. Prolactin levels were summarized by sex. Subjects with potentially abnormal values or changes in clinical laboratory tests, vital signs, orthostatic parameters, and ECG parameters were summarized based on predefined criteria. Frequency distributions were presented for the investigator's evaluation of the injection site, and descriptive statistics were presented for VAS scores corresponding to the subject's evaluation of injection pain.

RESULTS:

The majority of subjects in the paliperidone palmitate treatment groups (56% - 61%) received all 4 injections compared with 48% of the placebo-treated subjects. Completion rates were also higher for the paliperidone palmitate groups (52% - 55%) than for the placebo group (43%). More subjects were discontinued for lack of efficacy in the placebo group (27%) compared with the paliperidone palmitate groups (14% - 19%).

Demographic and Baseline Characteristics: The double-blind treatment groups were well matched with respect to demographic and baseline disease characteristics and psychiatric history. The 636 subjects who comprised the intent-to-treat analysis set were mainly male (67%), racially diverse (54% White, 30% Black, 14% Asian, 1% other races), and predominately between the ages of 26 and 50 years (75%). Most subjects had a primary diagnosis of paranoid schizophrenia (88%), and were highly symptomatic as indicated by a mean PANSS total score of 87.1 at baseline. There were notable differences between countries with respect to BMI and gender, with subjects

enrolled at centers in the U.S. being more likely to be male and obese (i.e., BMI ≥30 kg/m^2) than those from centers in other countries.

Pharmacokinetics: A total of 488 subjects who were randomly assigned to receive paliperidone palmitate treatment had scheduled pharmacokinetic blood samples taken over the course of the study. The median paliperidone predose concentration for the 25 mg eq. treatment group was highest on Day 8, which is the result of the initial 150 mg eq. dose on Day 1. After Day 8, paliperidone concentrations decreased and seemed to reach steady state levels on Day 92 based on visual inspection. The median paliperidone predose concentration for the 100 mg eq. treatment group remained in the same range from Day 8 onwards. The median predose concentration for the 150 mg eq. treatment group seemed to increase up to the last study day, Day 92. The median paliperidone plasma concentrations on Day 8 were lower in subjects with high BMI (≥25 to <30 kg/m² and ≥30 kg/m^2; overweight/obese) compared to subjects with low BMI (<25 kg/m²) for the 3 dose groups. After Day 8, no consistent trends were observed for the 3 paliperidone palmitate dose groups with respect to paliperidone plasma concentrations as a function of baseline BMI classification.

The mean and median paliperidone plasma concentrations on Day 64 for the 100 mg eq. treatment group were approximately 2-fold higher than those for the 25 mg eq. treatment group. Thus, the PK profile for the 25 mg eq. and 100 mg eq. dose groups appeared to be less than dose proportional, which is the result of the initial paliperidone palmitate 150 mg eq. injection on Day 1 in all active treatment groups. The mean and median paliperidone plasma concentrations on Day 64 for the 100 mg eq. dose were apparently dose proportional compared to the 150 mg eq. dose. A high inter-subject variability was observed in the paliperidone plasma concentrations on Days 1 and 2 with a %CV of 118.9% (Day 1) and 153.1% (Day 2). After Day 2, the inter-subject variability decreased and the %CV ranged from 50.4 to 83.4%.

Primary Efficacy Analysis: Adult subjects with schizophrenia achieved statistically significant improvements in the PANSS total score (primary efficacy endpoint) with all 3 doses of paliperidone palmitate compared to placebo (25 mg eq.: p=0.034; 100 mg eq.: p<0.001; 150 mg eq.: p<0.001) based on the intent-to-treat LOCF analysis and the Dunnett's test to control for multiplicity.

Positive and Negative Syndrome Scale for Schizophrenia (PANSS) Total Score - Change from Baseline to End Point-LOCF with the Dunnett-Bonferroni-Based Parallel Gatekeeping Procedure

(Study R092670-PSY-3007: Intent-to-Treat Analysis Set)

	Placebo (N=160)	R092670 25 mg eq. (N=155)	R092670 100 mg eq. (N=161)	R092670 150 mg eq. (N=160)
Baseline Mean (SD)	86.8 (10.31)	86.9 (11.99)	86.2 (10.77)	88.4 (11.70)
End point Mean (SD)	83.9 (21.44)	78.8 (19.88)	74.6 (18.06)	75.2 (18.59)
Change from Baseline				
Mean (SD)	-2.9 (19.26)	-8.0 (19.90)	-11.6 (17.63)	-13.2 (18.48)
P-value (minus Placebo)[a]		0.034	<0.001	<0.001
Diff. of LS Means (SE)		-5.1 (2.01)	-8.7 (2.00)	-9.8 (2.00)

[a] Based on analysis of covariance (ANCOVA) model with treatment (Placebo, R092670 25 mg eq., R092670 100 mg eq., R092670 150 mg eq.) and country as factors, and baseline value as a covariate. P-values were adjusted for multiplicity for comparison with placebo using Dunnett's test.

Note: Negative change in score indicates improvement.

Other Efficacy Results: There was a dose-response pattern with respect to the primary efficacy variable, with the mean decreases (improvement) in the PANSS total score at end point (LOCF).

Prespecified treatment-by-country and treatment-by-baseline PANSS total score interactions in the primary efficacy model were not statistically significant at the 0.10 level. An exploratory analysis additionally provided no statistical evidence for a BMI effect on treatment.

All 3 paliperidone palmitate dose groups showed a statistically significant improvement over placebo in the change in PANSS total score as of Day 22 and at every subsequent

time point, and as early as Day 8 in the paliperidone palmitate 25 mg eq. and 150 mg eq. groups.

The mean improvements in the PSP score from baseline to end point, the key secondary efficacy outcome measure, showed a dose response among the 3 paliperidone palmitate groups (25 mg eq.: 2.9; 100 mg eq.: 6.1; 150 mg eq.: 8.3); all were numerically higher than the mean improvement in the PSP score seen in the placebo group (1.7). Based on the intent-to-treat LOCF analysis of this key secondary efficacy variable, using the Dunnett-Bonferroni-based parallel gatekeeping procedure to adjust for multiplicity, the improvement in the paliperidone palmitate 100 and 150 mg eq. treatment groups reached statistical significance (100 mg eq.: $p=0.007$; 150 mg eq.: $p<0.001$) when compared with the placebo group.

The paliperidone palmitate 100 mg eq. and 150 mg eq. groups were statistically significantly superior to placebo in improving the CGI-S scores from baseline to end point (LOCF) (without multiplicity adjustment, 100 mg eq.: $p=0.005$; 150 mg eq.: $p<0.001$). Significantly more subjects treated with paliperidone palmitate 25 mg eq. (33.5%; $p=0.007$), 100 mg eq. (41.0%; $p<0.001$), and 150 mg eq. (40.0%, $p<0.001$) achieved responder status (30% or larger decrease on PANSS total scores) than with placebo (20.0%).

Based on the intent-to-treat LOCF analysis of the change from baseline to end point without statistical adjustment for multiplicity, the paliperidone palmitate 100 and 150 mg eq. groups were statistically significantly superior to the placebo group for all 5 PANSS Marder factors ($p\leq0.010$). The improvements in both negative symptoms and disorganized thoughts factor scores were statistically significantly greater in the paliperidone palmitate 25 mg eq. group compared with placebo ($p=0.032$).

Based on the intent-to-treat LOCF analysis using an ANCOVA model with no adjustment for multiplicity, the mean improvement in sleep quality in the paliperidone palmitate 100 mg eq. and 150 mg eq. groups were statistically significant ($p<0.001$ and $p=0.026$, respectively) when compared with placebo. The mean changes in daytime drowsiness in the paliperidone palmitate treatment groups were not statistically significantly different from that in the placebo group (25 mg eq.: $p=0.541$; 100 mg eq.: $p=0.340$; 150 mg eq.: $p=0.261$).

Safety Results: Paliperidone palmitate, injected at a dose of 150 mg eq. into the deltoid muscle followed by 3 i.m. injections at fixed doses of 25 mg eq., 100 mg eq., or 150 mg eq. on Days 8, 36, and 64, was generally well tolerated by adult subjects with schizophrenia during this 13-week study. Overall, the safety and tolerability results were consistent with previous clinical studies involving paliperidone palmitate, and no new safety signals were detected.

The overall summary of treatment-emergent adverse events is given below.

Overall Summary of Treatment-Emergent Adverse Events

(Study R092670-PSY-3007: Safety Analysis Set)

	Placebo (N=164) n (%)	R092670 25 mg eq. (N=160) n (%)	R092670 100 mg eq. (N=165) n (%)	R092670 150 mg eq. (N=163) n (%)	Total (N=652) n (%)
TEAE	107 (65.2)	101 (63.1)	99 (60.0)	103 (63.2)	410 (62.9)
Possibly related TEAE[a]	47 (28.7)	45 (28.1)	49 (29.7)	51 (31.3)	192 (29.4)
TEAE leading to death	0	0	0	1 (0.6)	1 (0.2)
1 or more serious TEAE	23 (14.0)	15 (9.4)	22 (13.3)	13 (8.0)	73 (11.2)
TEAE leading to permanent stop	11 (6.7)	10 (6.3)	10 (6.1)	13 (8.0)	44 (6.7)

[a] Study drug relationships of possible, probable, and very likely are included in this category.

Adverse events are coded using MedDRA version 10.1

There was 1 death in a subject in the paliperidone palmitate 150 mg eq. group after withdrawal from the study due to an adverse event (cerebrovascular accident) that began during the study. This subject received 2 injections of study medication, with the last injection administered approximately 2 weeks before the subject died. While this event was assessed as doubtfully related to study treatment by the investigator, an unblinded review by the sponsor assessed this event to be possibly related to study treatment.

The number of subjects who experienced treatment-emergent serious adverse events was higher in the placebo group than in any of the paliperidone palmitate groups (see table above). Most serious adverse events in all treatment groups were psychiatric disorders (e.g., schizophrenia, psychotic disorder) that were likely the result of the natural course of the underlying schizophrenia. Adverse events leading to study discontinuation occurred at a similar low incidence across treatment groups.

Common treatment-emergent adverse events (≥2% of subjects in any treatment group) that occurred more frequently in the total paliperidone palmitate group (all 3 active dose groups combined) than in the placebo-treated subjects (i.e., ≥1% difference between the combined paliperidone palmitate group and the placebo group) were: injection site pain, dizziness, sedation, pain in extremity, and myalgia. An examination of treatment-emergent adverse events of potential clinical importance revealed no reports of seizure or convulsion, tardive dyskinesia, dermatologic events, neuroleptic malignant syndrome, hyperthermia, anaphylactic reaction, rhabdomyolysis, syndrome of inappropriate secretion of antidiuretic hormone, ventricular tachycardia, ventricular fibrillation, or torsades de pointes.

In general, the type and incidence of treatment-emergent adverse events did not differ as a function of baseline BMI categories (normal: <25 kg/m^2; overweight: ≥25 to <30 kg/m^2; obese: ≥30 kg/m^2).

The incidence of treatment-emergent EPS-related adverse events was low and comparable to placebo. Akathisia was the most frequently reported EPS-related adverse event (4.9% for the placebo group and 1.3%, 4.8%, 5.5% for the paliperidone palmitate 25, 100, and 150 mg eq. groups, respectively). None of the EPS-related adverse events reported in subjects receiving paliperidone palmitate were serious or treatment limiting, and only 1 was severe (musculoskeletal stiffness). Results of EPS rating scales and use of anti-EPS medication were consistent in indicating that paliperidone palmitate was associated with a low incidence of EPS.

No clinically relevant mean changes from baseline to end point in supine or standing pulse rates were apparent for any of the paliperidone palmitate doses. A similar, low percentage of subjects had pulse rate of ≥100 bpm with an increase of ≥15 bpm in the

placebo and paliperidone palmitate groups (6% to 11% for standing measurements; 2% to 5% for supine measurements).

Assessment of ECG data did not demonstrate evidence of clinically significant QTc prolongation with paliperidone palmitate at doses up to 150 mg eq. No subject had a maximum QTcLD value >480 ms or a maximal change in QTcLD >60 ms during the study.

The increases in body weight with paliperidone palmitate over the 13-week double-blind treatment period were modest in a dose-related manner, averaging 0.4, 0.7, and 1.4 kg for the 25 mg eq., 100 mg eq., and 150 mg eq. groups, respectively (-0.2 kg for placebo); corresponding mean changes in BMI from baseline to end point were 0.1, 0.3, and 0.5 kg/m^2, respectively (-0.1 kg/m^2 for placebo). A clinically relevant weight increase of at least 7% relative to baseline was seen in 13% of subjects receiving the highest dose of paliperidone palmitate (compared with 5% for placebo).

Consistent with the known pharmacology of paliperidone, increases in prolactin levels were observed with greater frequency in subjects who received paliperidone palmitate, with the largest increase seen in the 150 mg eq. group. Overall, there was a low incidence of potentially prolactin-related adverse events, despite the known propensity of paliperidone palmitate to increase serum prolactin levels. This suggests that the clinical importance of this increase in serum prolactin levels is of questionable clinical significance.

Based on mean changes from baseline to end point and the occurrence of treatment-emergent markedly abnormal laboratory test values and adverse events related to abnormal laboratory analyte findings, except for prolactin, the effects of paliperidone palmitate on the results of chemistry and hematology laboratory tests (including liver and renal function tests, serum lipid levels, and glucose levels) did not show clinically relevant differences from those of placebo.

Local injection site tolerability was good. Occurrences of induration, redness, or swelling as assessed by blinded study personnel were infrequent, generally mild, decreasing over time, and similar in incidence for the paliperidone palmitate and placebo groups. Investigator ratings of injection pain were similar for the placebo and paliperidone palmitate groups.

STUDY LIMITATIONS:

This study investigated the efficacy and safety of paliperidone palmitate for acute treatment of schizophrenia over 13 weeks and does not provide information on longer term treatment. The study was not designed to detect differences between doses of paliperidone palmitate; thus, dose-related trends in efficacy and safety can only be described descriptively. The study was also not designed to demonstrate efficacy for specific subgroups of subjects, such as those from a particular country. An independent, centralized blinded rating service was used for performing all ratings of PANSS, PSP and CGI-S for all subjects enrolled at U.S. sites. The investigators at these sites did not complete any of the ratings, which would have provided a reference for ratings provided by the rating service. Thus, data from this study cannot be used to fully evaluate the utility of using blinded independent raters for detecting treatment differences.

CONCLUSION:

All 3 doses of paliperidone palmitate tested in this study - 25, 100, and 150 mg eq. - were efficacious in adult subjects with schizophrenia who were experiencing acutely exacerbated schizophrenia. Specifically, the results of the primary efficacy endpoint (change from baseline to end point in PANSS total score) demonstrated statistical superiority of paliperidone palmitate 25 mg eq., 100 mg eq., and 150 mg eq. over placebo. Significantly greater improvement in subjects' personal and social functioning (as measured by the PSP score) was also seen for the paliperidone palmitate 100 mg eq. and 150 mg eq. doses compared with placebo, and global improvement was validated by a favorable and statistically significant CGI-S change for these 2 dose groups. There was a dose response in the primary and secondary efficacy endpoints (PANSS, PSP, and CGI-S). All 3 doses of paliperidone palmitate, including the highest dose of 150 mg eq., were well tolerated, suggesting a positive benefit-risk ratio across the dose range currently studied. No new safety signal was detected.

Figures

Figures 1-3 graphically presents the observed versus population pharmacokinetics model simulation for plasma paliperidone concentrations. The line indicates the median values calculated from population pharmacokinetic simulation. The shading indicates 90% prediction interval representing the between and within subject, variability obtained using the population pharmacokinetic simulation. The circles indicate observed plasma paliperidone concentrations. The arrows indicate the days when paliperidone palmitate injection was given. As is apparent from the Figures the plasma profiles provided by initiating paliperidone with 150 mg eq. followed by a subsequent dose of 100 or 150 for days 1-36 provide a rapid rise to a therapeutic dose levels. Most preferably the dosing of paliperidone to patients should be maintained within ±25%, preferably 20% of the median plasma concentrations provided in these figures for days 1-36. For patients whose dosing continues at 100 mg eq. the preferably the dosing of paliperidone to patients should be maintained within ±25%, preferably 20% of the median plasma concentrations provided in Figures 2 for days 1-64. For patients whose dosing continues at 150 mg eq. the preferably the dosing of paliperidone to patients should be maintained within ±25%, preferably 20% of the median plasma concentrations provided in Figures 3 for days 1-64.

WE CLAIM:

1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising

(1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of from about 100mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 100 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and

(3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 34th to about the 38th day of treatment.

2. The method of claim 1 wherein the maintenance dose of a sustained release formulation of paliperidone palmitate is administered monthly in the deltoid or gluteal muscle of the psychiatric patient in need after the 30th day of treatment.

3. The method of claim 1 wherein the sustained release formulation is an aqueous nanoparticle suspension.

4. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising

(a) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of from about 100mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 100 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 36th day of treatment.

5. The method of claim 4 wherein the sustained release formulation is an aqueous nanoparticle suspension.

6. The method of claim 4 wherein the first loading dose is 150 mgs-eq. of paliperidone as paliperidone palmitate.

7. The method of claim 4 wherein the first loading dose is 100 mg-eq. of paliperidone as paliperidone palmitate.

8. The method of claim 4 wherein the second loading dose is 150 mg-eq. of paliperidone as paliperidone palmitate.

9. The method of claim 4 wherein the second loading dose is 100 mg-eq. of paliperidone as paliperidone palmitate.

10. The method of claim 4 wherein the first loading dose and the second loading dose are 150 mg-eq. of paliperidone as paliperidone palmitate.

11. The method of claim 4 wherein the first loading dose and the second loading dose are 150 mg of paliperidone as paliperidone palmitate.

12. The method of claim 4 wherein the psychiatric patient is in need of treatment for psychosis.

13. The method of claim 4 wherein the psychiatric patient is in need of treatment for schizophrenia.

14. The method of claim 4 wherein the psychiatric patient is in need of treatment for bipolar disorder.

15. The method of claim 4 wherein the psychiatric patient is in need of treatment for a mental disorder selected from the group consisting of Mild Mental Retardation (317), Moderate Mental Retardation (318.0), Severe Mental Retardation (318.1), Profound Mental Retardation (318.2), Mental Retardation Severity Unspecified (319), Autistic Disorders (299.00), Rett's Disorder (299.80), Childhood Disintegrative Disorders (299.10), Asperger's Disorder (299.80), Pervasive Developmental Disorder Not Otherwise Specified (299.80), Attention-Deficit/Hyperactivity Disorder Combined Type (314.01), Attention-Deficit/Hyperactivity Disorder Predominately Inattentive Type (314.00), Attention-Deficit/Hyperactivity Disorder Predominately Hyperactive-Impulsive Type (314.01), Attention-Deficit/Hyperactivity Disorder NOS (314.9), Conduct Disorder (Childhood-Onset and Adolescent Type 312.8), Oppositional Defiant Disorder (313.81), Disruptive Behavior Disorder Not Otherwise Specified (312.9), Solitary Aggressive Type (312.00), Conduct Disorder, Undifferentiated Type (312.90), Tourette's Disorder (307.23), Chronic Motor Or Vocal Tic Disorder (307.22), Transient Tic Disorder (307.21), Tic Disorder NOS (307.20), Alcohol Intoxication Delirium (291.0), Alcohol Withdrawal Delirium (291.0), Alcohol-Induced Persisting

Dementia (291.2), Alcohol-Induced Psychotic Disorder with Delusions (291.5), Alcohol-Induced Psychotic Disorder with Hallucinations (291.3), Amphetamine or Similarly Acting Sympathomimetic Intoxication (292.89), Amphetamine or Similarly Acting Sympathomimetic Delirium (292.81), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Delusional (292.11), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Hallucinations (292.12), Cannabis-Induced Psychotic Disorder with Delusions (292.11), Cannabis-Induced Psychotic Disorder with Hallucinations (292.12), Cocaine Intoxication (292.89), Cocaine Intoxication Delirium (292.81), Cocaine-Induced Psychotic Disorder with Delusions (292.11), Cocaine-Induced Psychotic Disorder with Hallucinations (292.12), Halluciogen Intoxication (292.89), Hallucinogen Intoxication Delirium (292.81), Hallucinogen-Induced Psychotic disorder with Delusions (292.11), Hallucinogen-Induced Psychotic disorder with Delusions (292.12), Halhucinogen-Induced Mood Disorder (292.84), Hallucinogen-Induced Anxiety Disorder (292.89), Hallucinogen-Related Disorder Not Otherwise Specified (292.9), Inhalant Intoxication (292.89), Inhalant Intoxication Delirium (292.81), Inhalant-Induced Persisting Dementia (292.82), Inhalant-Induced Psychotic Disorder with Delusions (292.11), Inhalant-Induced Psychotic with Hallucinations (292.12), Inhalant-Induced Mood Disorder (292.89), Inhalant-Induced Anxiety Disorder (292.89), Inhalant-Related Disorder Not Otherwise Specified (292.9), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Delusions (292.11), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Hallucinations (292.12), Opioid-Induced Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication Delirium (292.81), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Delusions (292.11), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Hallucinations (292.12), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Anxiety Disorder (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Related Disorder Not Otherwise Specified

(292.9), Sedative, Hypnotic or Anxiolytic Intoxication (292.89), Sedation, Hypnotic or Anxiolytic Intoxication Delirium (292.81), Sedation, Hypnotic or Anxiolytic Withdrawal Delirium (292.81), Sedation, Hypnotic or Anxiolytic Induced Persisting Dementia (292.82), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Delusions (292.11), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Hallucinations (292.12), Sedation, Hypnotic or Anxiolytic-Induced Mood Disorder (292.84), Sedation, Hypnotic or Anxiolytic-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Intoxication (292.89), Other (or Unknown) Substance-Induced Delirium (292.81), Other (or Unknown) Substance-Induced Persisting Dementia (292.82), Other (or Unknown) Substance-Induced Psychotic Disorder with Delusions (292.11), Other (or Unknown) Substance-Induced Psychotic Disorder with Hallucinations (292.12), Other (or Unknown) Substance-Induced Mood Disorder (292.84), Other (or Unknown) Substance-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Disorder Not Otherwise Specified (292.9), Obsessive Compulsive Disorder (300.3), Post-traumatic Stress Disorder (309.81), Generalized Anxiety Disorder (300.02), Anxiety Disorder Not Otherwise Specified (300.00), Body Dysmorphic Disorder (300.7), Hypochondriasis (or Hypochondriacal Neurosis) (300.7), Somatization Disorder (300.81), Undifferentiated Somatoform Disorder (300.81), Somatoform Disorder Not Otherwise Specified (300.81), Intermittent Explosive Disorder (312.34), Kleptomania (312.32), Pathological Gambling (312.31), Pyromania (312.33), Trichotillomania (312.39), and Impulse Control Disorder NOS (312.30), Schizophrenia, Paranoid Type, (295.30), Schizophrenia, Disorganized (295.10), Schizophrenia, Catatonic Type, (295.20), Schizophrenia, Undifferentiated Type (295.90), Schizophrenia, Residual Type (295.60), Schizophreniform Disorder (295.40), Schizoaffective Disorder (295.70), Delusional Disorder (297.1), Brief Psychotic Disorder (298.8), Shared Psychotic Disorder (297.3), Psychotic Disorder Due to a General Medical Condition with Delusions (293.81), Psychotic Disorder Due to a General Medical Condition with Hallucinations (293.82), Psychotic Disorders Not Otherwise Specified (298.9), Major Depression, Single Episode, Severe, without Psychotic Features (296.23), Major Depression, Recurrent, Severe, without Psychotic Features (296.33), Bipolar Disorder, Mixed, Severe, without Psychotic Features

(296.63), Bipolar Disorder, Mixed, Severe, with Psychotic Features (296.64), Bipolar Disorder, Manic, Severe, without Psychotic Features (296.43), Bipolar Disorder, Manic, Severe, with Psychotic Features (296.44), Bipolar Disorder, Depressed, Severe, without Psychotic Features (296.53), Bipolar Disorder, Depressed, Severe, with Psychotic Features (296.54), Bipolar II Disorder (296.89), Bipolar Disorder Not Otherwise Specified (296.80), Personality Disorders, Paranoid (301.0), Personality Disorders, Schizoid (301.20), Personality Disorders, Schizotypal (301.22), Personality Disorders, Antisocial (301.7), and Personality Disorders, Borderline (301.83).

16. A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment comprising

(a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 34th to about the 38th day of treatment.

17. The method of claim 16 wherein the maintenance dose of a sustained release formulation of paliperidone palmitate is administered monthly in the deltoid or gluteal muscle of the psychiatric patient in need after the 30th day of treatment.

18. The method of claim 16 wherein the sustained release formulation is an aqueous nanoparticle suspension.

19. A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment comprising

(a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 50 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 36th day of treatment.

20. The method of claim 19 wherein the sustained release formulation is an aqueous nanoparticle suspension.

21. The method of claim 19 wherein the psychiatric patient is in need of treatment for psychosis.

22. The method of claim 4 wherein the psychiatric patient is in need of treatment for schizophrenia.

23. The method of claim 4 wherein the psychiatric patient is in need of treatment for

bipolar disorder.

24. The method of claim 4 wherein the psychiatric patient is in need of treatment for a mental disorder selected from the group consisting of Mild Mental Retardation (317), Moderate Mental Retardation (318.0), Severe Mental Retardation (318.1), Profound Mental Retardation (318.2), Mental Retardation Severity Unspecified (319), Autistic Disorders (299.00), Rett's Disorder (299.80), Childhood Disintegrative Disorders (299.10), Asperger's Disorder (299.80), Pervasive Developmental Disorder Not Otherwise Specified (299.80), Attention-Deficit/Hyperactivity Disorder Combined Type (314.01), Attention-Deficit/Hyperactivity Disorder Predominately Inattentive Type (314.00), Attention-Deficit/Hyperactivity Disorder Predominately Hyperactive-Impulsive Type (314.01), Attention-Deficit/Hyperactivity Disorder NOS (314.9), Conduct Disorder (Childhood-Onset and Adolescent Type 312.8), Oppositional Defiant Disorder (313.81), Disruptive Behavior Disorder Not Otherwise Specified (312.9), Solitary Aggressive Type (312.00), Conduct Disorder, Undifferentiated Type (312.90), Tourette's Disorder (307.23), Chronic Motor Or Vocal Tic Disorder (307.22), Transient Tic Disorder (307.21), Tic Disorder NOS (307.20), Alcohol Intoxication Delirium (291.0), Alcohol Withdrawal Delirium (291.0), Alcohol-Induced Persisting Dementia (291.2), Alcohol-Induced Psychotic Disorder with Delusions (291.5), Alcohol-Induced Psychotic Disorder with Hallucinations (291.3), Amphetamine or Similarly Acting Sympathomimetic Intoxication (292.89), Amphetamine or Similarly Acting Sympathomimetic Delirium (292.81), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Delusional (292.11), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Hallucinations (292.12), Cannabis-Induced Psychotic Disorder with Delusions (292.11), Cannabis-Induced Psychotic Disorder with Hallucinations (292.12), Cocaine Intoxication (292.89), Cocaine Intoxication Delirium (292.81), Cocaine-Induced Psychotic Disorder with Delusions (292.11), Cocaine-Induced Psychotic Disorder with Hallucinations (292.12), Hallucinogen Intoxication (292.89), Hallucinogen Intoxication Delirium (292.81), Hallucinogen-Induced Psychotic disorder with Delusions (292.11), Hallucinogen-Induced Psychotic disorder with Delusions (292.12), Hallucinogen-Induced Mood

Disorder (292.84), Hallucinogen-Induced Anxiety Disorder (292.89), Hallucinogen-Related Disorder Not Otherwise Specified (292.9), Inhalant Intoxication (292.89), Inhalant Intoxication Delirium (292.81), Inhalant-Induced Persisting Dementia (292.82), Inhalant-Induced Psychotic Disorder with Delusions (292.11), Inhalant-Induced Psychotic with Hallucinations (292.12), Inhalant-Induced Mood Disorder (292.89), Inhalant-Induced Anxiety Disorder (292.89), Inhalant-Related Disorder Not Otherwise Specified (292.9), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Delusions (292.11), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Hallucinations (292.12), Opioid-Induced Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication Delirium (292.81), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Delusions (292.11), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Hallucinations (292.12), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Anxiety Disorder (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Related Disorder Not Otherwise Specified (292.9), Sedative, Hypnotic or Anxiolytic Intoxication (292.89), Sedation, Hypnotic or Anxiolytic Intoxication Delirium (292.81), Sedation, Hypnotic or Anxiolytic Withdrawal Delirium (292.81), Sedation, Hypnotic or Anxiolytic Induced Persisting Dementia (292.82), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Delusions (292.11), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Hallucinations (292.12), Sedation, Hypnotic or Anxiolytic-Induced Mood Disorder (292.84), Sedation, Hypnotic or Anxiolytic-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Intoxication (292.89), Other (or Unknown) Substance-Induced Delirium (292.81), Other (or Unknown) Substance-Induced Persisting Dementia (292.82), Other (or Unknown) Substance-Induced Psychotic Disorder with Delusions (292.11), Other (or Unknown) Substance-Induced Psychotic Disorder with Hallucinations (292.12), Other (or Unknown) Substance-Induced Mood Disorder (292.84), Other (or Unknown) Substance-Induced Anxiety Disorder (292.89), Other (or

Unknown) Substance Disorder Not Otherwise Specified (292.9), Obsessive Compulsive Disorder (300.3), Post-traumatic Stress Disorder (309.81), Generalized Anxiety Disorder (300.02), Anxiety Disorder Not Otherwise Specified (300.00), Body Dysmorphic Disorder (300.7), Hypochondriasis (or Hypochondriacal Neurosis) (300.7), Somatization Disorder (300.81), Undifferentiated Somatoform Disorder (300.81), Somatoform Disorder Not Otherwise Specified (300.81), Intermittent Explosive Disorder (312.34), Kleptomania (312.32), Pathological Gambling (312.31), Pyromania (312.33), Trichotillomania (312.39), and Impulse Control Disorder NOS (312.30), Schizophrenia, Paranoid Type, (295.30), Schizophrenia, Disorganized (295.10), Schizophrenia, Catatonic Type, (295.20), Schizophrenia, Undifferentiated Type (295.90), Schizophrenia, Residual Type (295.60), Schizophreniform Disorder (295.40), Schizoaffective Disorder (295.70), Delusional Disorder (297.1), Brief Psychotic Disorder (298.8), Shared Psychotic Disorder (297.3), Psychotic Disorder Due to a General Medical Condition with Delusions (293.81), Psychotic Disorder Due to a General Medical Condition with Hallucinations (293.82), Psychotic Disorders Not Otherwise Specified (298.9), Major Depression, Single Episode, Severe, without Psychotic Features (296.23), Major Depression, Recurrent, Severe, without Psychotic Features (296.33), Bipolar Disorder, Mixed, Severe, without Psychotic Features (296.63), Bipolar Disorder, Mixed, Severe, with Psychotic Features (296.64), Bipolar Disorder, Manic, Severe, without Psychotic Features (296.43), Bipolar Disorder, Manic, Severe, with Psychotic Features (296.44), Bipolar Disorder, Depressed, Severe, without Psychotic Features (296.53), Bipolar Disorder, Depressed, Severe, with Psychotic Features (296.54), Bipolar II Disorder (296.89), Bipolar Disorder Not Otherwise Specified (296.80), Personality Disorders, Paranoid (301.0), Personality Disorders, Schizoid (301.20), Personality Disorders, Schizotypal (301.22), Personality Disorders, Antisocial (301.7), and Personality Disorders, Borderline (301.83).

25. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising

(a) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a maintenance dose of from about 25 mg-eq. to about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 100 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 34th to about the 38th day of treatment.

26. The method of claim 25 wherein the maintenance dose of a sustained release formulation of paliperidone palmitate is administered monthly in the deltoid or gluteal muscle of the psychiatric patient in need after the 30th day of treatment.

27. The method of claim 25 wherein the sustained release formulation is an aqueous nanoparticle suspension.

28. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment comprising

(a) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a maintenance dose of from about 25 mg-eq. to about 100 mg-eq. of

paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and

(c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a maintenance dose of about 25 mg-eq. to about 100 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation on about the 36th day of treatment.

29. The method of claim 28 wherein the sustained release formulation is an aqueous nanoparticle suspension.

30. The method of claim 28 wherein the psychiatric patient is in need of treatment for psychosis.

31. The method of claim 28 wherein the psychiatric patient is in need of treatment for schizophrenia.

32. The method of claim 28 wherein the psychiatric patient is in need of treatment for bipolar disorder.

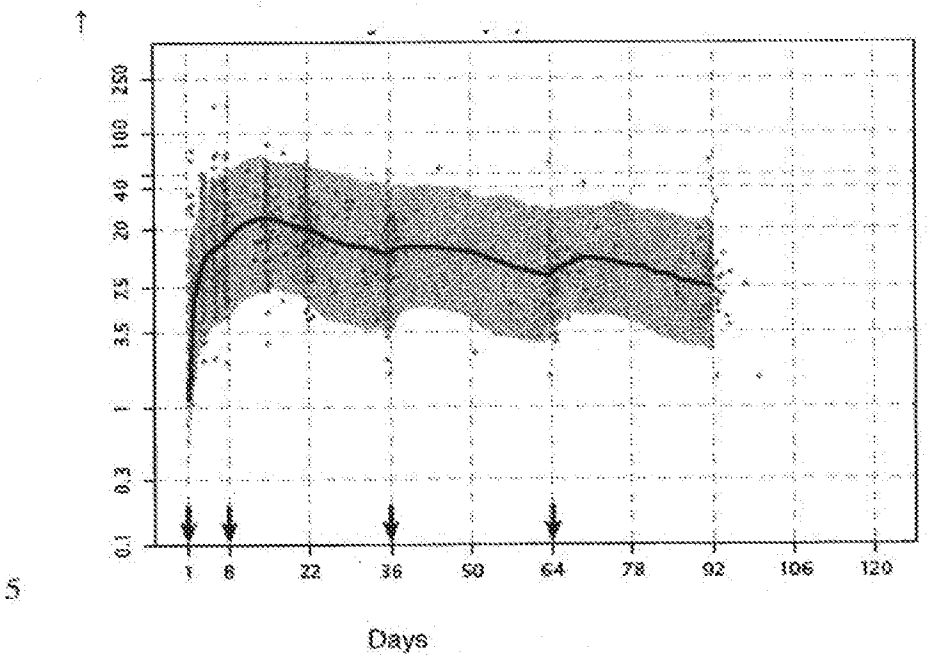
33. The method of claim 28 wherein the psychiatric patient is in need of treatment for a mental disorder selected from the group consisting of Mild Mental Retardation (317), Moderate Mental Retardation (318.0), Severe Mental Retardation (318.1), Profound Mental Retardation (318.2), Mental Retardation Severity Unspecified (319), Autistic Disorders (299.00), Rett's Disorder (299.80), Childhood Disintegrative Disorders (299.10), Asperger's Disorder (299.80), Pervasive Developmental Disorder Not Otherwise Specified (299.80), Attention-Deficit/Hyperactivity Disorder Combined Type (314.01), Attention-Deficit/Hyperactivity Disorder Predominately Inattentive Type (314.00), Attention-Deficit/Hyperactivity Disorder Predominately Hyperactive-Impulsive Type (314.01), Attention-Deficit/Hyperactivity Disorder NOS (314.9), Conduct Disorder (Childhood-Onset and Adolescent Type 312.8), Oppositional Defiant Disorder (313.81), Disruptive Behavior Disorder Not Otherwise Specified

(312.9), Solitary Aggressive Type (312.00), Conduct Disorder, Undifferentiated Type (312.90), Tourette's Disorder (307.23), Chronic Motor Or Vocal Tic Disorder (307.22), Transient Tic Disorder (307.21), Tic Disorder NOS (307.20), Alcohol Intoxication Delirium (291.0), Alcohol Withdrawal Delirium (291.0), Alcohol-Induced Persisting Dementia (291.2), Alcohol-Induced Psychotic Disorder with Delusions (291.5), Alcohol-Induced Psychotic Disorder with Hallucinations (291.3), Amphetamine or Similarly Acting Sympathomimetic Intoxication (292.89), Amphetamine or Similarly Acting Sympathomimetic Delirium (292.81), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Delusional (292.11), Amphetamine or Similarly Acting Sympathomimetic Induced Psychotic with Hallucinations (292.12), Cannabis-Induced Psychotic Disorder with Delusions (292.11), Cannabis-Induced Psychotic Disorder with Hallucinations (292.12), Cocaine Intoxication (292.89), Cocaine Intoxication Delirium (292.81), Cocaine-Induced Psychotic Disorder with Delusions (292.11), Cocaine-Induced Psychotic Disorder with Hallucinations (292.12), Hallucinogen Intoxication (292.89), Hallucinogen Intoxication Delirium (292.81), Hallucinogen-Induced Psychotic disorder with Delusions (292.11), Hallucinogen-Induced Psychotic disorder with Delusions (292.12), Hallucinogen-Induced Mood Disorder (292.84), Hallucinogen-Induced Anxiety Disorder (292.89), Hallucinogen-Related Disorder Not Otherwise Specified (292.9), Inhalant Intoxication (292.89), Inhalant Intoxication Delirium (292.81), Inhalant-Induced Persisting Dementia (292.82), Inhalant-Induced Psychotic Disorder with Delusions (292.11), Inhalant-Induced Psychotic with Hallucinations (292.12), Inhalant-Induced Mood Disorder (292.89), Inhalant-Induced Anxiety Disorder (292.89), Inhalant-Related Disorder Not Otherwise Specified (292.9), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Delusions (292.11), Opioid Intoxication Delirium (292.81), Opioid-Induced Psychotic Disorder with Hallucinations (292.12), Opioid-Induced Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Intoxication Delirium (292.81), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic Disorder with Delusions (292.11), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Psychotic

Disorder with Hallucinations (292.12), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Mood Disorder (292.84), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Induced Anxiety Disorder (292.89), Phencyclidine (PCP) or Similarly Acting Arylcyclohexylamine Related Disorder Not Otherwise Specified (292.9), Sedative, Hypnotic or Anxiolytic Intoxication (292.89), Sedation, Hypnotic or Anxiolytic Intoxication Delirium (292.81), Sedation, Hypnotic or Anxiolytic Withdrawal Delirium (292.81), Sedation, Hypnotic or Anxiolytic Induced Persisting Dementia (292.82), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Delusions (292.11), Sedation, Hypnotic or Anxiolytic-Induced Psychotic Disorder with Hallucinations (292.12), Sedation, Hypnotic or Anxiolytic-Induced Mood Disorder (292.84), Sedation, Hypnotic or Anxiolytic-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Intoxication (292.89), Other (or Unknown) Substance-Induced Delirium (292.81), Other (or Unknown) Substance-Induced Persisting Dementia (292.82), Other (or Unknown) Substance-Induced Psychotic Disorder with Delusions (292.11), Other (or Unknown) Substance-Induced Psychotic Disorder with Hallucinations (292.12), Other (or Unknown) Substance-Induced Mood Disorder (292.84), Other (or Unknown) Substance-Induced Anxiety Disorder (292.89), Other (or Unknown) Substance Disorder Not Otherwise Specified (292.9), Obsessive Compulsive Disorder (300.3), Post-traumatic Stress Disorder (309.81), Generalized Anxiety Disorder (300.02), Anxiety Disorder Not Otherwise Specified (300.00), Body Dysmorphic Disorder (300.7), Hypochondriasis (or Hypochondriacal Neurosis) (300.7), Somatization Disorder (300.81), Undifferentiated Somatoform Disorder (300.81), Somatoform Disorder Not Otherwise Specified (300.81), Intermittent Explosive Disorder (312.34), Kleptomania (312.32), Pathological Gambling (312.31), Pyromania (312.33), Trichotillomania (312.39), and Impulse Control Disorder NOS (312.30), Schizophrenia, Paranoid Type, (295.30), Schizophrenia, Disorganized (295.10), Schizophrenia, Catatonic Type, (295.20), Schizophrenia, Undifferentiated Type (295.90), Schizophrenia, Residual Type (295.60), Schizophreniform Disorder (295.40), Schizoaffective Disorder (295.70), Delusional Disorder (297.1), Brief Psychotic Disorder (298.8), Shared Psychotic Disorder (297.3), Psychotic Disorder Due to a General Medical Condition with Delusions (293.81), Psychotic Disorder Due to a

General Medical Condition with Hallucinations (293.82), Psychotic Disorders Not Otherwise Specified (298.9), Major Depression, Single Episode, Severe, without Psychotic Features (296.23), Major Depression, Recurrent, Severe, without Psychotic Features (296.33), Bipolar Disorder, Mixed, Severe, without Psychotic Features (296.63), Bipolar Disorder, Mixed, Severe, with Psychotic Features (296.64), Bipolar Disorder, Manic, Severe, without Psychotic Features (296.43), Bipolar Disorder, Manic, Severe, with Psychotic Features (296.44), Bipolar Disorder, Depressed, Severe, without Psychotic Features (296.53), Bipolar Disorder, Depressed, Severe, with Psychotic Features (296.54), Bipolar II Disorder (296.89), Bipolar Disorder Not Otherwise Specified (296.80), Personality Disorders, Paranoid (301.0), Personality Disorders, Schizoid (301.20), Personality Disorders, Schizotypal (301.22), Personality Disorders, Antisocial (301.7), and Personality Disorders, Borderline (301.83).

FIGURE 1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0.3
0.1
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22
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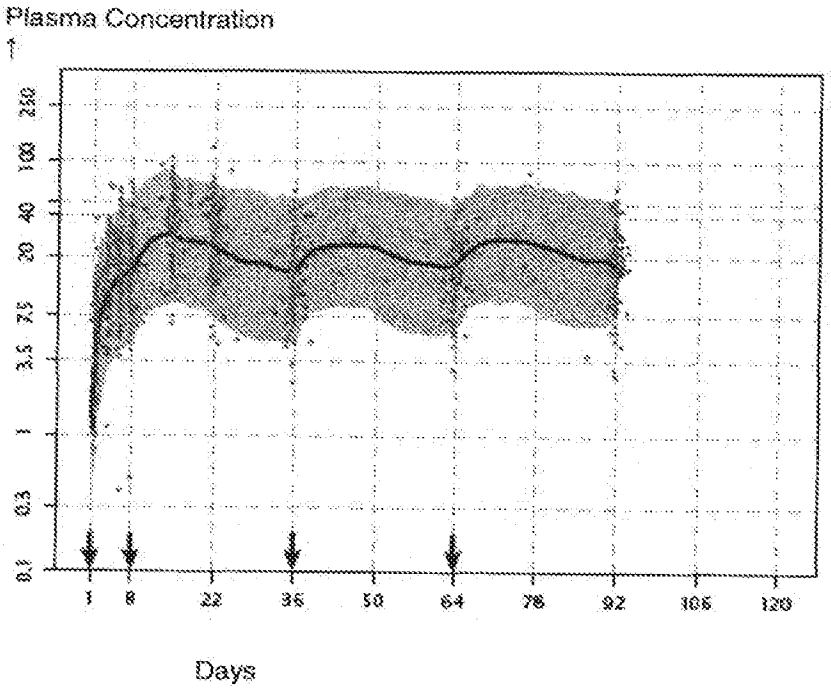
64
78
92
106
120
Days

Figure 2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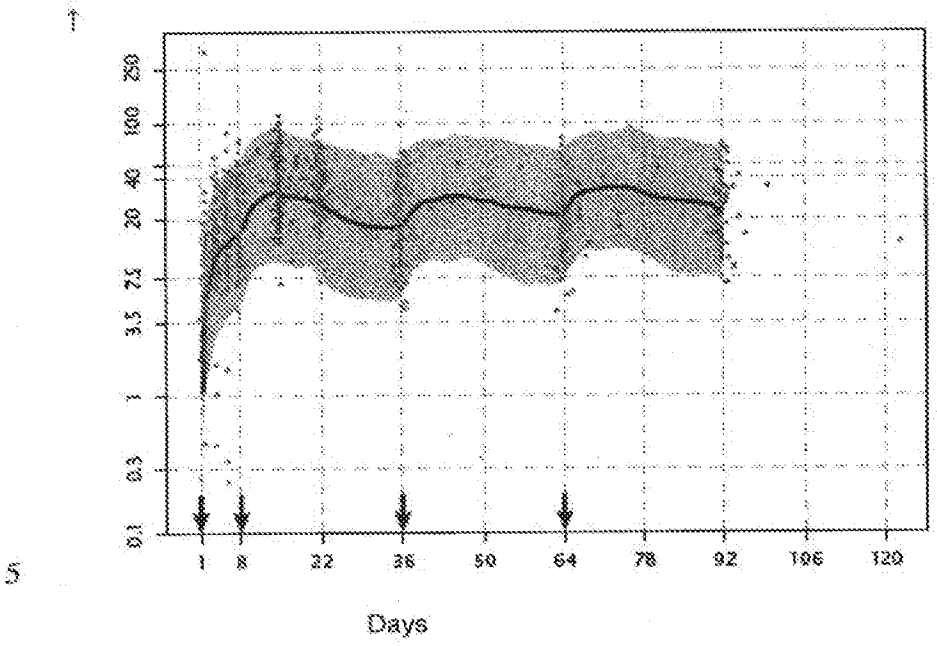
250
100
40
20
7.5
3.5
1
0.3
0.1
1
8
22
36
50
64
78
92
106
120
Days

Figure 3


Plasma Concentration
250
100
40
20
7.5
3.5
1
0.3
0.1
1
8
22
36
50
64
78
92
106
120
Days

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/067738

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K31/519 A61P25/18

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K A61P

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/197591 A1 (BOOM SANDRA [NL] ET AL) 23 August 2007 (2007-08-23) paragraphs [0016] - [0018], [0020]	1-34
Y	REVILL P ET AL: "Paliperidone - Antipsychotic agent, treatment of bipolar disorder, dual dopamine D2/5-HT2A receptor antagonist" DRUGS OF THE FUTURE, PROUS SCIENCE, ES, vol. 31, no. 7, 1 July 2006 (2006-07-01), pages 579-584, XP008096915 ISSN: 0377-8282 page 580, left-hand column, last paragraph	1-34

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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 March 2009	27/03/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Loher, Florian

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CLETON A ET AL: "Effects of renal impairment on the pharmacokinetic profile of paliperidone extended-release tablets" CLINICAL PHARMACOLOGY & THERAPEUTICS, MOSBY-YEAR BOOK, ST LOUIS, MO, US, vol. 81, no. Suppl. 1, 1 March 2007 (2007-03-01), page S63, XP009114090 ISSN: 0009-9236 the whole document	17-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/067738

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007197591 A1	23-08-2007	AR 058328 A1	30-01-2008
		UY 30007 A1	30-03-2007

Electronic Acknowledgement Receipt

EFS ID:	25427827
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	07-APR-2016
Filing Date:	17-DEC-2008
Time Stamp:	15:10:20
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	Information Disclosure Statement (IDS) Form (SB08)	PRD2901USNP_SuppIDS1449APRIL2016_2.pdf	298344 db5fa8779b4bb10a0beb9264f6d747ecdaf40d86	no	2

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO2009080651.pdf	12628996 9143d0d7e4608e8347863456ff068e729af85fdd	no	69
Warnings:					
Information:					
3	Non Patent Literature	KREYENBUHI.pdf	3096247 e2d4a5a0de534309bf501a79b6529a7ba28f6a73	no	14
Warnings:					
Information:					
		Total Files Size (in bytes):	16023587		

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

27777 7590 05/05/2016

JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
KAROL, JODY LYNN

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 05/05/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	08/05/2016

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)

27777 7590 05/05/2016
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

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.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	08/05/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAROL, JODY LYNN	1627	514-257000

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. _____

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.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

27777 7590 05/05/2016

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NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 05/05/2016

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.

Notice of Allowability	Application No. 12/337,144	Applicant(s) VERMEULEN ET AL.	
	Examiner JODY KAROL	Art Unit 1627	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 *3/1/2016*.
   ☐ 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 *1-5,13,15-20,22,24 and 34-40*. 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 3/1/2016; 4/7/2016; 4/7/2016
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/1/2016 has been entered.

Receipt is acknowledged of applicant's Amendment/Remarks filed 6/12/2015. Claims 1, 2, 4, 16, 17, and 19 have been amended. Claims 6-12, 14, 21, 23, and 25-33 are cancelled. Claims 34-40 are newly added. Claims 1-5, 13, 15-20, 22, 24, and 34-40 are pending and are currently under consideration.

Information Disclosure Statement

2. The information disclosure statements (IDS) filed on 3/1/2016, 4/7/2016, and 4/7/2016 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered.

EXAMINER'S AMENDMENT

3. 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 Hal Woodward on 7/31/2015.

The application has been amended as follows:

In claim 5, line 2, after "suspension"; **delete** "of".

In claim 22, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 24, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 38, line 1, after "claim 1, 4, 16"; **delete** "and" and **insert** --or--.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: Claims 1-5, 13, 15-20, 22, 24, and 34-40 are directed a dosing regimen for administering paliperidone palmitate to a psychiatric patient or a renally impaired psychiatric treatment in need of treatment for schizophrenia, schizoaffective disorder, schizophreniform disorder or a psychotic disorder comprising administering a intramuscularly in the deltoid a first loading dose of paliperidone palmitate formulated in a sustained release formulation, administering intramuscularly in the deltoid a second loading dose of paliperidone palmitate formulated in a sustained release formulation on the 6^{th} to about the 10^{th} day of treatment, and administering intramuscularly in the deltoid or gluteal muscle to the patient in need of treatment a first maintenance dose of paliperidone palmitate formulated in a sustained release formulation a month ($\pm$ 7 days) after the

second loading dose. The claims are allowable over the closest cited prior art, François et al. (US 6,555,544 B2), because the cited prior art does not teach, disclose, nor render obvious the instantly claimed dosing regimen. While François et al. teach a pharmaceutical composition for intramuscular injection comprising 9-hydroxy-risperidone fatty acid ester (i.e. paliperidone palmitate) in submicron form for use in the treatment of psychosis, schizophrenia, schizoaffective disorders, etc., François et al. teach the composition is administered every three weeks or even at longer intervals where possible (see abstract; column 8, lines 8-20). There is nothing in François et al. that teaches or suggests using two loading doses 6-10 days apart followed by a monthly maintenance dose at the specific dosages as instantly claimed.

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."

Conclusion

Claims 1-5, 13, 15-20, 22, 24, and 34-40 are allowed.

Correspondence

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
/J.K./		2009/0163519	A1	Vermeulen et al.	06-25-2009	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	KindCode[5]	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T[6]
/J.K./		WO	2009/080651		Janssen Pharm. NV	07-02-2009		

Examiner Signature	/Jody Karol/	Date Considered	04/11/2016

*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.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
/J.K./		KREYENBUHl, et al., "Adding or Switching Antipsychotic Medications in Treatment-Refractory Schizophrenia", Psychiatr Serv., July 2007, pp. 983-990, Vol. 58(7)	

Examiner Signature	/Jody Karol/	Date Considered	04/11/2016

*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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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
Filing Date	12/17/2008
First Named Inventor	An Vermeulen
Group Art Unit	1627
Examiner Name	Claytor, Deirdre
Attorney Docket Number	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's 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	T[2]
/J.K./		Third Party Observations dated 01/28/16 filed during prosecution of EP Application No. 10773821.3 (J&J ref. PRD3131EPEPT)	

Examiner Signature	/Jody Karol/	Date Considered	03/31/2016

*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.

SUBMISSION UNDER MPEP 609.06 Page 1 of 1		
	Application Number	12/337,144
	Filing Date	12/17/2008
	First Named Inventor	An Vermeulen
	Group Art Unit	1627
	Examiner Name	Claytor, Deirdre
	Attorney Docket Number	PRD2901USNP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	U.S. Patent Document Number	Kind Code[2] (if known)	Pages, Columns, Lines, where relevant passages or relevant figures appear

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	Foreign Patent Document Office[3]	Number[4]	KindCode[5]	Pages, Columns, Lines, where relevant passages or relevant figures appear	T[6]

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITOL 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	T[2]
/J.K./		Office Action mailed March 24, 2015 in US Serial No. 13/903,638; Attorney Docket No. PRD3131USDIV1	
/J.K./		Final Office Action mailed October 22, 2015 in US Serial No. 13/903,638; Attorney Docket No. PRD3131USDIV1	

Examiner Signature	/Jody Karol/	Date Considered	03/31/2016

PTO/SB/08A (08-00)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	12/337,144
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First Named Inventor	An Vermeulen
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
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/J.K./		CIRINCIONE, et al., "Population pharmacokinetics of paliperidone ER in healthy subjects and patients with schizophrenia", clinical Pharmacology & Therapeutics, Vol. 81, Issue Supplement SI, P. S19 (published in March 2007)	

Examiner Signature	/Jody Karol/	Date Considered	04/11/2016

*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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	Renee Claytor	1627

CPC- SEARCHED		
Symbol	**Date**	**Examiner**
A61K 31/519	3/9/2015	RC
A61K31/519; A61K9/0019; A61K9/0024	8/5/2015	JLK
updated (see attached)	11/18/2015	JLK
updated (see attached)	3/31/2016	JLK

CPC COMBINATION SETS - SEARCHED		
Symbol	**Date**	**Examiner**

US CLASSIFICATION SEARCHED			
Class	**Subclass**	**Date**	**Examiner**

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
PALM Inventor Search	3/9/2015	RC
EAST (updated)	3/9/2015	RC
Inventor and EAST Search updated (see attached)	8/5/2015	JLK
Google Scholar NPL Search	8/5/2015	JLK
Inventor and EAST Search updated (see attached)	11/25/2015	JLK
Inventor and EAST Search updated (see attached)	3/31/2016	JLK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
A61K	31/519	3/9/2015	RC
A61K	31/519; 9/0019; 9/0024	8/5/2015	JLK
	updated (see attached)	11/18/2015	JLK
	updated (see attached)	3/31/2016	JLK

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

CPC						
Symbol					**Type**	**Version**
A61K		31	/	519	F	2013-01-01
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			/			
			/			
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			/			

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/JODY KAROL/ Examiner.Art Unit 1627	03/31/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/SREENI PADMANABHAN/ Supervisory Patent Examiner.Art Unit 1627	03/31/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
514	257

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
514	323	360	379		

INTERNATIONAL CLASSIFICATION														
CLAIMED					**NON-CLAIMED**									
C	0	7	D	471 / 04 (2006.01.01)										
A	6	1	K	31 / 445 (2006.01.01)										
A	6	1	K	31 / 41 (2006.01.01)										
A	6	1	K	31 / 42 (2006.01.01)										

/JODY KAROL/ Examiner.Art Unit 1627 (Assistant Examiner)	03/31/2016 (Date)	**Total Claims Allowed:** 21	
/SREENI PADMANABHAN/ Supervisory Patent Examiner.Art Unit 1627 (Primary Examiner)	03/31/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

☒ **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	1	9	17		33										
2	2	10	18	15	34										
3	3	11	19	16	35										
4	4	12	20	17	36										
5	5		21	18	37										
	6	13	22	19	38										
	7		23	20	39										
	8	14	24	21	40										
	9		25												
	10		26												
	11		27												
	12		28												
6	13		29												
	14		30												
7	15		31												
8	16		32												

/JODY KAROL/ Examiner.Art Unit 1627	03/31/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/SREENI PADMANABHAN/ Supervisory Patent Examiner.Art Unit 1627	03/31/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015	08/05/2015	11/18/2015	03/31/2016
1	1	÷	✓	✓	=	=	=	=	=	=
2	2	÷	✓	✓	=	=	=	=	=	=
3	3	÷	✓	✓	=	=	=	=	=	=
4	4	÷	✓	✓	=	=	=	=	=	=
5	5	÷	✓	✓	=	=	=	=	=	=
	6	÷	✓	✓	-	-	-	-	-	-
	7	÷	✓	✓	-	-	-	-	-	-
	8	÷	✓	✓	-	-	-	-	-	-
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	10	÷	✓	✓	-	-	-	-	-	-
	11	÷	✓	✓	-	-	-	-	-	-
	12	÷	N	N	-	-	-	-	-	-
6	13	÷	✓	✓	=	=	=	=	=	=
	14	÷	N	-	-	-	-	-	-	-
7	15	÷	✓	✓	=	=	=	=	=	=
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9	17	÷	✓	✓	=	=	=	=	=	=
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	33	÷	✓	✓	-	-	-	-	-	-
15	34							=	=	=
16	35							=	=	=
17	36							=	=	=

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12337144	VERMEULEN ET AL.
	Examiner	**Art Unit**
	RENEE CLAYTOR	1627

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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

CLAIM		DATE								
Final	Original	07/01/2010	12/03/2010	06/28/2011	06/14/2013	08/11/2014	03/09/2015	08/05/2015	11/18/2015	03/31/2016
18	37							=	=	=
19	38							=	=	=
20	39							=	=	=
21	40							=	=	=

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4	EP-1033987-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L2	2325	paliperidone or $hydroxyrisperidone	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L3	1083	L2 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L4	598	L2 and (schizophrenia or schizoaffective or schizophreniform) and (sustained or prolonged or delayed)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L5	280	L2 and (schizophrenia or schizoaffective or schizophreniform) and (sustained or prolonged or delayed) and maintenance	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L6	155	(paliperidone or $hydroxyrisperidone) same palmitate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L7	69	L6 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L8	54	(Vermeulen, An).in. or (Wouters, Alfons).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L9	13	L8 and (paliperidone or $hydroxyrisperidone)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L10	3	"20090163519"	US-PGPUB	ADJ	ON	2016/03/31 07:25
L11	108235	(A61K31/519 OR A61K9/0019 OR A61K9/0024).CPC.	US-PGPUB; USPAT; USOCR;	ADJ	ON	2016/03/31 07:25

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
L12	1598	(A61K31/519).CPC. and (A61K9/0019 OR A61K9/0024).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L13	79	L12 and (paliperidone or $hydroxyrisperidone)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25
L14	33	L13 and (schizophrenia or schizoaffective or schizophreniform)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/31 07:25

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L15	7842	(A61K31/519 OR A61K9/0019 OR A61K9/0024).CPC.	USPAT; * No UPAD	ADJ	ON	2016/03/31 07:25
L16	119	(A61K31/519).CPC. and (A61K9/0019 OR A61K9/0024).CPC.	USPAT; * No UPAD	ADJ	ON	2016/03/31 07:25
L17	14	L16 and (paliperidone or $hydroxyrisperidone)	USPAT; * No UPAD	ADJ	ON	2016/03/31 07:25
L18	24	L16 and (schizophrenia or schizoaffective or schizophreniform)	USPAT; * No UPAD	ADJ	ON	2016/03/31 07:25

3/31/2016 7:28:39 AM
C:\Users\jkarol\Documents\EAST\Workspaces\12337144 - Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters.wsp

PTO/AIA/14 (13-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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
	Srihari		Gopal	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Postal Code	08502	Country i	US

Inventor 2 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Vivek		Kasumaker Kasumakar	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City		State/Province		Country of Residence	

Mailing Address of Inventor:

Address 1			
Address 2			
City		State/Province	
Postal Code		Country i	

Inventor 3 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Peter	H.	Lewyn-Briscoe	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

City	Newtown	State/Province	PA	Country of Residence	US

Mailing Address of Inventor:

Address 1	28 Sibelius Road		
Address 2			
City	Newtown	State/Province	PA
Postal Code	18940	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mahesh		Samtani	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Flemington	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

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Address 2			
City	Flemington	State/Province	NJ
Postal Code	08822	Country	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	An		Vermeulen	

Residence Information (Select One) ( ) US Residency (•) Non US Residency ( ) Active US Military Service

City	Beerse	Country of Residence	BE

Mailing Address of Inventor:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	State/Province	
Postal Code	B-2340	Country	BE

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alfons		Wouters	

Residence Information (Select One) ( ) US Residency (•) Non US Residency ( ) Active US Military Service

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

City	Beerse	Country of Residence i	BE

Mailing Address of Inventor:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	State/Province	
Postal Code	B-2340	Country i	BE

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	27777		
Email Address	jnjuspatent@corus.jnj.com	Add Email	Remove Email

Application Information:

Title of the Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		
Attorney Docket Number	PRD2901USNP	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	3	Suggested Figure for Publication (if any)	2

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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	27777		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/014918	2007-12-19
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/120276	2008-12-05

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)[1] 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).

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[j] (if applicable)

Remove

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.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

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.

PTO/AIA/14 (12-13)
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	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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	Janssen Pharmaceutica NV

Mailing Address Information For Applicant:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Country	BE	Postal Code	B-2340
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including 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.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

Organization Name	Janssen Pharmaceutica NV		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Country i	BE	Postal Code	B-2340
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant 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	/ Melissa Wenk Reg. No. 53,759 /			Date (YYYY-MM-DD)	2016-06-28
First Name	Melissa	Last Name	Wenk	Registration Number	53,759

Additional Signature may be generated within this form by selecting the Add button.

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 C o 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:	26195608
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	28-JUN-2016
Filing Date:	17-DEC-2008
Time Stamp:	13:59:01
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	Application Data Sheet	PRD2901USNP_JUNE2016ADS.pdf	1774975 f50a7512f38a4a7ed3e74f5c2e023a1148772a22	no	8

Warnings:

Information:	
This is not an USPTO supplied ADS fillable form	
Total Files Size (in bytes):	1774975

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP

CONFIRMATION NO. 3172

27777
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

37 CFR 1.48 ACKNOWLEDGEMENT LETTER

OC000000084120325

Date Mailed: 07/05/2016

IMPROPER SUBMISSION OF REQUEST UNDER 37 CFR 1.48(a)

The request under 37 CFR 1.48(a) (request to change inventorship) submitted on 06/12/2016 in the above-identified application is not accepted because:

- The request to correct inventorship under 37 CFR 1.48(a) is deficient because a corrected or updated application data sheet (ADS) in compliance with 37 CFR 1.76 (including markings showing the changes) has not been submitted. Any renewed request must include a corrected or updated ADS in compliance with 37 CFR 1.76 that identifies the information being changed, with underlining for insertions, and strike-through or brackets for text removed.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/byemane/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP

CONFIRMATION NO. 3172

IMPROPER CFR REQUEST

27777
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

OC000000084120417

Date Mailed: 07/05/2016

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Power of Attorney, Claims, Fees, System Limitations, and Miscellaneous

In response to your request for a corrected Filing Receipt, the Office is unable to comply with your request because:

- The ADS submitted on 06/12/2015 was not properly marked up to show the desired changes. For information being changed relative to the information already of record, additions must be shown with underlining, and deletions must be shown with strike-through or brackets. See 37 CFR 1.76(c)(2)

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/byemane/

PTO/AIA/14 (12-13)
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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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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
	Srihari		Gopal	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Belle Mead	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	173 Berkley Avenue		
Address 2			
City	Belle Mead	State/Province	NJ
Postal Code	08502	Country i	US

Inventor 2 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Vivek		Kusumaker Kusumakar	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City		State/Province		Country of Residence	

Mailing Address of Inventor:

Address 1			
Address 2			
City		State/Province	
Postal Code		Country i	

Inventor 3 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Peter	H	Lewyn-Briscoe	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

City	Newtown	State/Province	PA	Country of Residence	US

Mailing Address of Inventor:

Address 1	28 Sibelius Road		
Address 2			
City	Newtown	State/Province	PA
Postal Code	18940	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mahesh		Samtani	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Flemington	State/Province	NJ	Country of Residence	US

Mailing Address of Inventor:

Address 1	2 Sheppard Drive		
Address 2			
City	Flemington	State/Province	NJ
Postal Code	08822	Country	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	An		Vermeulen	

Residence Information (Select One) ( ) US Residency (•) Non US Residency ( ) Active US Military Service

City	Beerse	Country of Residence	BE

Mailing Address of Inventor:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	State/Province	
Postal Code	B-2340	Country	BE

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alfons		Wouters	

Residence Information (Select One) ( ) US Residency (•) Non US Residency ( ) Active US Military Service

PTO/AIA/14 (12-13)
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City	Beerse	Country of Residence i	BE

Mailing Address of Inventor:

Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	State/Province	
Postal Code	B-2340	Country i	BE

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	27777		
Email Address	jnjuspatent@corus.jnj.com	Add Email	Remove Email

Application Information:

Title of the Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		
Attorney Docket Number	PRD2901USNP	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	3	Suggested Figure for Publication (if any)	2

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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.

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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	27777		

Domestic Benefit/National Stage Information:

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When referring to the current application, please leave the application number blank.

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/014918	2007-12-19
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/120276	2008-12-05

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)[1] 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).

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

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.

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

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	Janssen Pharmaceutica NV		
Mailing Address Information For Applicant:			
Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Country	BE	Postal Code	B-2340
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including 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.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

PTO/AIA/14 (12-13)
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	PRD2901USNP
	Application Number	12/337144
Title of Invention	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	

Organization Name	Janssen Pharmaceutica NV		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	Turnhoutseweg 30		
Address 2			
City	Beerse	**State/Province**	
Country	BE	Postal Code	B-2340
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant 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	/ Melissa Wenk Reg. No. 53,759 /			Date (YYYY-MM-DD)	2016-07-25
First Name	Melissa	Last Name	Wenk	Registration Number	53,759

Additional Signature may be generated within this form by selecting the Add button.

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 C o 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:	26447271
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	25-JUL-2016
Filing Date:	17-DEC-2008
Time Stamp:	16:25:07
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	Application Data Sheet	PRD2901USNP_ADSJULY2016.pdf	1803313 0aa599a0ffe7a48f214e3a71d9d975dd9fc92b29	no	8

Warnings:

Information:	
This is not an USPTO supplied ADS fillable form	
Total Files Size (in bytes):	1803313

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

27777 2890 05/05/2016

JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 05/05/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	08/05/2016

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)

27777 7890 05/05/2016
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

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.

Dawn H. Wilson	(Depositor's name)
/Dawn H. Wilson/	(Signature)
August 3, 2016	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	08/05/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAROL, JODY LYNN	1627	514-257000

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. reel/frame 024932/0365

(A) NAME OF ASSIGNEE: Janssen Pharmaceutica NV

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

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 10-0750 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

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

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

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

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

Authorized Signature /Melissa Wenk Reg. No. 53,759/ Date August 3, 2016

Typed or printed name Melissa Wenk Registration No. 53,759

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.
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP	3172

27777 7590 05/05/2016

JOSEPH F. SHIRTZ
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NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 05/05/2016

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.

Notice of Allowability	Application No. 12/397,144	Applicant(s) VERMEULEN ET AL.	
	Examiner JODY KAROL	Art Unit 1627	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 3/1/2016.
   ☐ 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 1-6,13,15-20,22,24 and 34-40. 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 3/1/2016; 4/7/2016; 4/7/2016
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/1/2016 has been entered.

Receipt is acknowledged of applicant's Amendment/Remarks filed 6/12/2015. Claims 1, 2, 4, 16, 17, and 19 have been amended. Claims 6-12, 14, 21, 23, and 25-33 are cancelled. Claims 34-40 are newly added. Claims 1-5, 13, 15-20, 22, 24, and 34-40 are pending and are currently under consideration.

Information Disclosure Statement

2. The information disclosure statements (IDS) filed on 3/1/2016, 4/7/2016, and 4/7/2016 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered.

EXAMINER'S AMENDMENT

3. 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 Hal Woodward on 7/31/2015.

The application has been amended as follows:

In claim 5, line 2, after "suspension"; **delete** "of".

In claim 22, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 24, line 1, after "claim"; **delete** "4" and **insert** --19--.

In claim 38, line 1, after "claim 1, 4, 16"; **delete** "and" and **insert** --or--.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: Claims 1-5, 13, 15-20, 22, 24, and 34-40 are directed a dosing regimen for administering paliperidone palmitate to a psychiatric patient or a renally impaired psychiatric treatment in need of treatment for schizophrenia, schizoaffective disorder, schizophreniform disorder or a psychotic disorder comprising administering a intramuscularly in the deltoid a first loading dose of paliperidone palmitate formulated in a sustained release formulation, administering intramuscularly in the deltoid a second loading dose of paliperidone palmitate formulated in a sustained release formulation on the 6th to about the 10th day of treatment, and administering intramuscularly in the deltoid or gluteal muscle to the patient in need of treatment a first maintenance dose of paliperidone palmitate formulated in a sustained release formulation a month (± 7 days) after the

second loading dose. The claims are allowable over the closest cited prior art, François et al. (US 6,555,544 B2), because the cited prior art does not teach, disclose, nor render obvious the instantly claimed dosing regimen. While François et al. teach a pharmaceutical composition for intramuscular injection comprising 9-hydroxy-risperidone fatty acid ester (i.e. paliperidone palmitate) in submicron form for use in the treatment of psychosis, schizophrenia, schizoaffective disorders, etc., François et al. teach the composition is administered every three weeks or even at longer intervals where possible (see abstract; column 8, lines 8-20). There is nothing in François et al. that teaches or suggests using two loading doses 6-10 days apart followed by a monthly maintenance dose at the specific dosages as instantly claimed.

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."

Conclusion

Claims 1-5, 13, 15-20, 22, 24, and 34-40 are allowed.

Correspondence

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

Electronic Acknowledgement Receipt

EFS ID:	26531082
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	03-AUG-2016
Filing Date:	17-DEC-2008
Time Stamp:	11:17:53
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	Issue Fee Payment (PTO-85B)	PRD2901USNP_ISSUEFEE_AUG 2016.pdf	1973178 2759ffec37961f783c6e58732fcecdaae50c7946	no	9

Warnings:

Information:	
Total Files Size (in bytes):	1973178

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.

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)

27771 7590 05/05/2016
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

OPAP AKIMA-16
AUG 03 2016
PATENT & TRADEMARK OFFICE

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.

Dawn H. Wilson	(Depositor's name)
/Dawn H. Wilson/	(Signature)
August 3, 2016	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	12/17/2008	An Vermeulen	PRD2301USNP	3172

TITLE OF INVENTION: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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	08/05/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAROL, JODY LYNN	1627	514-257000

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. reel/frame 024932/0365

(A) NAME OF ASSIGNEE
Janssen Pharmaceutica NV

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

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 10-0750 (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 /Melissa Wenk Reg. No. 53,759/
Typed or printed name Melissa Wenk
Date August 3, 2016
Registration No. 53,759

08/04/2016 HVUONG2 00000020 100750 12337144
01 FC:1501 960.00 DA

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP

CONFIRMATION NO. 3172

27777
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

37 CFR 1.48(f)
ACKNOWLEDGEMENT LETTER

OC000000084959333

Date Mailed: 08/10/2016

IMPROPER SUBMISSION OF REQUEST UNDER 37 CFR 1.48(f)

The request under 37 CFR 1.48(f) (request to change inventorship) submitted on 07/25/2016 in the above-identified application is not accepted because:

- The request to correct inventorship under 37 CFR 1.48(f) is deficient because the fee set forth in 37 CFR 1.17(i) has not been submitted.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/mmasfaw/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/337,144	12/17/2008	An Vermeulen	PRD2901USNP

CONFIRMATION NO. 3172

27777
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

37 CFR 1.48 ACKNOWLEDGEMENT LETTER

OC000000084959332

Date Mailed: 08/10/2016

IMPROPER SUBMISSION OF REQUEST UNDER 37 CFR 1.48(a)

The request under 37 CFR 1.48(a) (request to change inventorship) submitted on 07/25/2016 in the above-identified application is not accepted because:

- The request to correct inventorship under 37 CFR 1.48(a) is deficient because the fee set forth in 37 CFR 1.17(i) has not been submitted.
- The request to correct inventorship under 37 CFR 1.48(a), which was filed after the first Office action on the merits, is deficient because it was not accompanied by the fee set forth in 37 CFR 1.17(d) or a statement that the request to correct or change inventorship was due solely to the cancelation of claims in the application. See 37 CFR 1.48(c).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/mmasfaw/

Electronic Patent Application Fee Transmittal

Application Number:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Melissa B. Wenk/Dawn Wilson
Attorney Docket Number:	PRD2901USNP

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($)
Miscellaneous:				
Correction of Inventorship on Merits	1819	1	600	600
		Total in USD ($)		**600**

Electronic Acknowledgement Receipt

EFS ID:	26601072
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	10-AUG-2016
Filing Date:	17-DEC-2008
Time Stamp:	13:23:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$600
RAM confirmation Number	10137
Deposit Account	100750
Authorized User	WENK, MELISSA
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 CFR 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	Fee Worksheet (SB06)	fee-info.pdf	30976 cfc9465abac4ed9bb8c7051178f5166f6bc68b79	no	2

Warnings:

Information:

Total Files Size (in bytes):	30976

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.

Electronic Patent Application Fee Transmittal

Application Number:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Melissa B. Wenk/Dawn Wilson
Attorney Docket Number:	PRD2901USNP

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($)
Miscellaneous:				
Correction of Inventorship on Merits	1819	1	600	600
		Total in USD ($)		**600**

Electronic Acknowledgement Receipt

EFS ID:	26711104
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	22-AUG-2016
Filing Date:	17-DEC-2008
Time Stamp:	16:29:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$600
RAM confirmation Number	3241
Deposit Account	100750
Authorized User	WENK, MELISSA

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 CFR 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	Fee Worksheet (SB06)	fee-info.pdf	30976 9cd9ca1f2eeebcba2d84fc73a516f2bd6733325e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	30976		

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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Electronic Patent Application Fee Transmittal

Application Number:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Melissa B. Wenk/Dawn Wilson
Attorney Docket Number:	PRD2901USNP

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($)
Miscellaneous:				
Correction of Inventorship on Merits	1819	1	600	600
		Total in USD ($)		**600**

Electronic Acknowledgement Receipt

EFS ID:	26711001
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	22-AUG-2016
Filing Date:	17-DEC-2008
Time Stamp:	16:26:00
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	Fee Worksheet (SB06)	fee-info.pdf	30977 c00f68b5b3a8445468d5aad76ffca5c351381244	no	2

Warnings:

Information:	
Total Files Size (in bytes):	30977

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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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/337,144	09/13/2016	9439906	PRD2901USNP	3172

27777 7590 08/24/2016

JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

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 770 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):

An Vermeulen, Beerse, BELGIUM;
Alfons Wouters, Beerse, BELGIUM;

Docket No. PRD2901USNP

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Dawn H. Wilson	/Dawn H. Wilson/	January 13, 2017
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK

Patentee	:	Janssen Pharmaceutica NV	Confirmation No.: 3172
Patent No.	:	9,439,906	Serial No.: 12/337,144
Filed	:	December 17, 2008	
Title	:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	
Art Unit	:	1627	
Examiner	:	KAROL, JODY LYNN	

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(b)

Dear Commissioner:

This is an application for Patent Term Adjustment and a request for reconsideration of patent term indicated on the patent issued on September 13, 2016. This request is being submitted within four months of the issuance of US Patent 9,439,906 and complies with the relevant deadline specified in 37 CFR §1.705(b) as it is accompanied by payment of a fee for a two month extension of time. Thus, Patentee contends this request is timely.

Patentee respectfully requests that an additional 53 days of Patent Term Adjustment be added to the 770 days of additional patent term for Patent Office delay already calculated by the Patent Office, resulting in a total Patent Term Adjustment of at least 823 days.

1. Statement of Facts

USPTO Delays

Patentee agrees with the Patent Office that the USPTO delays total 1361 days.

Applicant Delays

The USPTO alleges that there were 591 days of Applicant delay. Patentee respectfully submits that Applicant delay should be 538 days (which is 53 days less than the USPTO calculation) for the reasons set forth below.

A corrected Application Data Sheet (ADS) was submitted on June 28, 2016 in an effort to correct inventorship of the above-identified patent. This was treated as 1.704(c)(10) reduction since the Notice of Allowance had already been mailed on May 5, 2016. The issue date (September 13, 2016) was treated as the responsive USPTO notice thus resulting in a **78 day** reduction in Patent Term Adjustment. We believe that this is an error for the reasons set forth below.

The USPTO did in fact respond to the submission of the correct ADS on July 5, 2016 by mailing an Improper Submission of Request Under CFR 1.48(a). Thus the 1.704(c)(10) reduction should have been stopped at **8 days**. The period from July 6, 2016 through September 13, 2016 should not have been deducted from the Patent Term Adjustment calculation for the June 28, 2016 filing.

Patentee submitted a second corrected ADS on July 25, 2016 in a second attempt to correct inventorship of the above-identified patent. The USPTO responded on August 10, 2016 by mailing an Improper Submission of Request Under CFR 1.48(a) thus generating an additional 1.704(c)(10) reduction of **17 days**.

Thus, Patentee believes that the correct amount of 1.704(c)(10) reduction is **25 days** which represents 8 days+17 days.

Because the USPTO Patent Term Adjustment calculation includes a 1.704(c)(10) reduction of 78 days rather than 25 days, Patentee believes that **53 days** are should be deducted from the Applicant delay making it 538 days. In this case, the Patent Term Adjustment should be **823 days** instead of the currently awarded 770 days.

Patentee also attempted to pay fees associated with the failed attempt to correct inventorship on August 10, 2016 and August 22, 2016. If payment of fees counts as a paper submission for the purposes of 1.704(c)(10), then an additional delay should be added from August 10, 2016 (the date of the first fee payment) until September 13, 2016 (the issue date of the patent) which is **34 days** after accounting for a one day overlap on August 10, 2016 with the prior reduction described above.

In this alternative case, Patentee believes that the correct amount of 1.704(c)(10) reduction is **59 days** which represents 8 days+17 days+34 days.

Because the USPTO Patent Term Adjustment calculation includes a 1.704(c)(10) reduction of 78 days rather than 59 days, Patentee believes that **19 days** should be deducted from the Applicant delay making it 572 days. In this alternative case, the Patent Term Adjustment should be **789 days** instead of the currently awarded 770 days.

2. Other Circumstances

As required under 37 CFR §1.705(b)(iii) and (iv)(B), Patentee confirms that, (1) this application is not subject to a Terminal Disclaimer; and (2) except for the Patentee's delay periods set forth above, if any, there were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 CFR §1.704.

3. Payment of Fees

The fee set forth in 37 CFR §1.18(e) required by 37 CFR §1.705(b)(1) is being paid electronically herewith via EFS-Web. A two month extension fee as required under 37 CFR §1.17(A)(2) is being paid electronically herewith via EFS-Web. The Commissioner is hereby authorized to change any additional fees required by this paper or credit any overpayment to deposit account 10-0750.

4. Conclusion

In light of the foregoing, the Patentee respectfully requests that an additional 53 days of Patent Term Adjustment be added to the Patent Office's Patent Term Adjustment determination, resulting in a total Patent Term Adjustment of 823 days.

However, if the fee payments described above are considered paper submissions, then the Patentee respectfully requests that an additional 19 days of Patent Term Adjustment be added to the Patent Office's Patent Term Adjustment determination, resulting in a total Patent Term Adjustment of 789 days.

Respectfully submitted,

/Melissa Wenk Reg. No. 53,759/
Melissa Wenk
Attorney for Patentee

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-5352
Dated: January 13, 2017

Electronic Acknowledgement Receipt

EFS ID:	28061169
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	13-JAN-2017
Filing Date:	17-DEC-2008
Time Stamp:	15:12:03
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	Patent Term Adjustment Petition	PRD2901USNP_PTA_PETITION_JAN2017.pdf	84143 16ca6e6ad95b6f66dd7d01295a1c5f8a6f2c49d9	no	4

Warnings:

Information:	
Total Files Size (in bytes):	84143

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.

CERTIFICATE OF EFS TRANSMISSION		
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).		
Dawn H. Wilson	/Dawn H. Wilson/	January 13, 2017
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK

Patentee	:	Janssen Pharmaceutica NV	Confirmation No.: 3172
Patent No.	:	9,439,906	Serial No.: 12/337,144
Filed	:	December 17, 2008	
Title	:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS	
Art Unit	:	1627	
Examiner	:	KAROL, JODY LYNN	

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(b)

Dear Commissioner:

This is an application for Patent Term Adjustment and a request for reconsideration of patent term indicated on the patent issued on September 13, 2016. This request is being submitted within four months of the issuance of US Patent 9,439,906 and complies with the relevant deadline specified in 37 CFR §1.705(b) as it is accompanied by payment of a fee for a two month extension of time. Thus, Patentee contends this request is timely.

Patentee respectfully requests that an additional 53 days of Patent Term Adjustment be added to the 770 days of additional patent term for Patent Office delay already calculated by the Patent Office, resulting in a total Patent Term Adjustment of at least 823 days.

1. Statement of Facts

USPTO Delays

Patentee agrees with the Patent Office that the USPTO delays total 1361 days.

Applicant Delays

The USPTO alleges that there were 591 days of Applicant delay. Patentee respectfully submits that Applicant delay should be 538 days (which is 53 days less than the USPTO calculation) for the reasons set forth below.

A corrected Application Data Sheet (ADS) was submitted on June 28, 2016 in an effort to correct inventorship of the above-identified patent. This was treated as 1.704(c)(10) reduction since the Notice of Allowance had already been mailed on May 5, 2016. The issue date (September 13, 2016) was treated as the responsive USPTO notice thus resulting in a **78 day** reduction in Patent Term Adjustment. We believe that this is an error for the reasons set forth below.

The USPTO did in fact respond to the submission of the correct ADS on July 5, 2016 by mailing an Improper Submission of Request Under CFR 1.48(a). Thus the 1.704(c)(10) reduction should have been stopped at **8 days**. The period from July 6, 2016 through September 13, 2016 should not have been deducted from the Patent Term Adjustment calculation for the June 28, 2016 filing.

Patentee submitted a second corrected ADS on July 25, 2016 in a second attempt to correct inventorship of the above-identified patent. The USPTO responded on August 10, 2016 by mailing an Improper Submission of Request Under CFR 1.48(a) thus generating an additional 1.704(c)(10) reduction of **17 days**.

Thus, Patentee believes that the correct amount of 1.704(c)(10) reduction is **25 days** which represents 8 days+17 days.

Because the USPTO Patent Term Adjustment calculation includes a 1.704(c)(10) reduction of 78 days rather than 25 days, Patentee believes that **53 days** are should be deducted from the Applicant delay making it 538 days. In this case, the Patent Term Adjustment should be **823 days** instead of the currently awarded 770 days.

Patentee also attempted to pay fees associated with the failed attempt to correct inventorship on August 10, 2016 and August 22, 2016. If payment of fees counts as a paper submission for the purposes of 1.704(c)(10), then an additional delay should be added from August 10, 2016 (the date of the first fee payment) until September 13, 2016 (the issue date of the patent) which is **34 days** after accounting for a one day overlap on August 10, 2016 with the prior reduction described above.

In this alternative case, Patentee believes that the correct amount of 1.704(c)(10) reduction is **59 days** which represents 8 days+17 days+34 days.

Because the USPTO Patent Term Adjustment calculation includes a 1.704(c)(10) reduction of 78 days rather than 59 days, Patentee believes that **19 days** should be deducted from the Applicant delay making it 572 days. In this alternative case, the Patent Term Adjustment should be **789 days** instead of the currently awarded 770 days.

2. Other Circumstances

As required under 37 CFR §1.705(b)(iii) and (iv)(B), Patentee confirms that, (1) this application is not subject to a Terminal Disclaimer; and (2) except for the Patentee's delay periods set forth above, if any, there were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 CFR §1.704.

3. Payment of Fees

The fee set forth in 37 CFR §1.18(e) required by 37 CFR §1.705(b)(1) is being paid electronically herewith via EFS-Web. A two month extension fee as required under 37 CFR §1.17(A)(2) is being paid electronically herewith via EFS-Web. The Commissioner is hereby authorized to change any additional fees required by this paper or credit any overpayment to deposit account 10-0750.

4. Conclusion

In light of the foregoing, the Patentee respectfully requests that an additional 53 days of Patent Term Adjustment be added to the Patent Office's Patent Term Adjustment determination, resulting in a total Patent Term Adjustment of 823 days.

However, if the fee payments described above are considered paper submissions, then the Patentee respectfully requests that an additional 19 days of Patent Term Adjustment be added to the Patent Office's Patent Term Adjustment determination, resulting in a total Patent Term Adjustment of 789 days.

Respectfully submitted,

/Melissa Wenk Reg. No. 53,759/
Melissa Wenk
Attorney for Patentee

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-5352
Dated: January 13, 2017

Electronic Patent Application Fee Transmittal

Application Number:	12337144
Filing Date:	17-Dec-2008
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Filer:	Melissa B. Wenk/Dawn Wilson
Attorney Docket Number:	PRD2901USNP

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($)
Extension - 2 months with $0 paid	1252	1	600	600
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt

EFS ID:	28058324
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	13-JAN-2017
Filing Date:	17-DEC-2008
Time Stamp:	13:16:38
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	Patent Term Adjustment Petition	PRD2901USNP_PTA_PETITION_JAN2017.pdf	84143 16ca6e6ad95b6f66dd7d01295a1c5f8a6f2c49d9	no	4

Warnings:

Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31211 a7c5cdce9259f9fe8177fb0774b076300c2e9a0d	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	115354	

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.

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Vermeulen et al.

Patent No. 9,439,906
Issue Date: 09-13-2016

Appln No. : 12/337,144

Confirmation No.: 3172

Filed : December 17, 2008

Title : DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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

REQUEST PURSUANT TO RULE 37 CFR 1.324 FOR CORRECTION OF INVENTORSHIP

Dear Sir:

Applicants hereby requests under 37 C.F.R. § 1.324 a correction of the inventorship of the above application adding the following inventors: **Srihari Gopal**, a citizen of the United States of America, **Vivek Kusumakar** who is deceased, **Peter H. Lewyn-Briscoe** a citizen of the United States of America and **Mahesh Samtani**, a citizen of the United States of America.

Statements from Srihari Gopal, Peter H. Lewyn-Briscoe and Mahesh Samtani are submitted herewith. The undersigned attorney asserts that inventor Vivek Kusumakar is deceased thus no Statement is being submitted for this added inventor.

Statements from the currently named inventors, An Vermeulen and Alfons Wouters, are submitted herewith.

The undersigned attorney states that the Inventorship errors occurred without deceptive intent.

Please charge the fee set forth in 37 CFR §1.17(i), $140.00, to Deposit Account No.: 10-0750/PRD2901USNP/MW.

Please charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

/Melissa Wenk Reg. No. 53,759/
Melissa Wenk, Ph.D.
Reg. No.: 53,759
Registered Attorney for Patentee

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel. No.: (732) 524-5352
Date: March 15, 2015

Docket No. *PRD 2901USNP*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172
Title	: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		

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

STATEMENT BY PERSON BEING ADDED BY AMENDMENT TO CORRECT INVENTORSHIP IN PATENT (37 CFR 1.324)

Dear Sir:

I, the undersigned, agree that I should be a named inventor of US Patent No. 9,439,906 along with An Vermeulen, Alfons Wouters, Vivek Kusumakar, Mahesh Samtani and Peter H. Lewyn-Brisco. I do hereby declare that the inventorship error occurred without any deceptive intent.

Date: 01 NOV 2016

Srihari Gopal

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172
Title	: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		

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

STATEMENT BY PERSON BEING ADDED BY AMENDMENT TO CORRECT INVENTORSHIP IN PATENT (37 CFR 1.324)

Dear Sir:

I, the undersigned, agree that I should be a named inventor of US Patent No. 9,439,906 along with An Vermeulen, Alfons Wouters, Vivek Kusumakar, Mahesh Samtani and Srihari Gopal. I do hereby declare that the inventorship error occurred without any deceptive intent.

Date: 01 NOVEMBER, 2016

Peter H. Lewyn-Briscoe

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172
Title	: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		

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

STATEMENT BY NAMED INVENTOR TO CORRECT INVENTORSHIP IN PATENT (37 CFR 1.324)

Dear Sir:

I, the undersigned, agree with the change of inventorship to add Srihari Gopal, Vivek Kusumakar, Peter H. Lewyn-Brisco and Mahesh Samtani as inventors to US Patent No. 9,439,906. I do hereby declare that the inventorship error occurred without any deceptive intent.

Date: January 17th, 2017

An Vermeulen

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172
Title	: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		

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

STATEMENT BY NAMED INVENTOR TO CORRECT INVENTORSHIP IN PATENT (37 CFR 1.324)

Dear Sir:

I, the undersigned, agree with the change of inventorship to add Srihari Gopal, Vivek Kusumakar, Peter H. Lewyn-Brisco and Mahesh Samtani as inventors to US Patent No. 9,439,906. I do hereby declare that the inventorship error occurred without any deceptive intent.

Date: Nov 18, 2016

Alfons Wouters

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172

Title : DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

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

STATEMENT BY PERSON BEING ADDED BY AMENDMENT TO CORRECT INVENTORSHIP IN PATENT (37 CFR 1.324)

Dear Sir:

I, the undersigned, agree that I should be a named inventor of US Patent No. 9,439,906 along with An Vermeulen, Alfons Wouters, Srihari Gopal, Vivek Kusumakar and Peter H. Lewyn-Briscoe. I do hereby declare that the inventorship error occurred without any deceptive intent.

Date: 11/1/2016

MN Samtani

Mahesh N. Samtani

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172
Title	: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		

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

WRITTEN CONSENT FROM ASSIGNEE TO CORRECT INVENTORSHIP IN PATENT UNDER 37 CFR 1.324

Dear Sir:

Janssen Pharmaceutica NV is the assignee of the entire right, title and interest in the above referenced patent application by virtue of assignments recorded at the U.S. Patent and Trademark Office on Reel/Frame 024932/0365 on September 2, 2010 and on Reel/Frame 038996/0158 on June 23, 2016. On behalf of the assignee, and in accordance with 37 CFR 1.324, the undersigned hereby consents to the change in Inventorship by adding Srihari Gopal, a citizen of the United States of America, Vivek Kusumakar, who is deceased, Peter H. Lewyn-Briscoe, a citizen of the United States of America, and Mahesh Samtani, a citizen of the United States of America, as joint inventors along with the originally named inventors An Vermeulen and Alfons Wouters.

/Melissa Wenk Reg. No. 53,759/
Melissa Wenk, Ph.D.
Reg. No.: 53,759
Registered Attorney for Patentee

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel. No.: (732) 524-5352
Date: March 15, 2017

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: JANSSEN PHARMACEUTICA NV

Application No./Patent No.: 12/337,144/9,439,906 Filed/Issue Date: 12-17-2008/09-13-2016

Titled: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS

JANSSEN PHARMACEUTICA NV, a CORPORATION

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

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

1. [✓] The assignee of the entire right, title, and interest.

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

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

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

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

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

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

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

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

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

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

1. From: An Vermeulen & Alfons Wouters To: Janssen Pharmaceutica NV

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

   Reel 024932, Frame 0365, or for which a copy thereof is attached.

2. From: Srihari Gopal, Peter H. Lewyn-Briscoe & Mahesh Samtani To: Janssen Pharmaceutica NV

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

   Reel 038996, Frame 0158, or for which a copy thereof is attached.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

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

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

4. From: _____ To: _____

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

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

5. From: _____ To: _____

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

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

6. From: _____ To: _____

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

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

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

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

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

/Melissa Wenk Reg. No. 53,759/	March 15, 2017
Signature	Date
Melissa Wenk	53,759
Printed or Typed Name	Title or Registration 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.
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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).
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.

Electronic Acknowledgement Receipt

EFS ID:	28637495
Application Number:	12337144
International Application Number:	
Confirmation Number:	3172
Title of Invention:	DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS
First Named Inventor/Applicant Name:	An Vermeulen
Customer Number:	27777
Filer:	Melissa B. Wenk/Dawn Wilson
Filer Authorized By:	Melissa B. Wenk
Attorney Docket Number:	PRD2901USNP
Receipt Date:	15-MAR-2017
Filing Date:	17-DEC-2008
Time Stamp:	15:14:11
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	Transmittal Letter	PRD2901USNP_TRANSMITTAL MARCH2017.pdf	86240 dca7c51dacbdaca0540af8e32d96488a2265eb0d	no	2

Warnings:

Information:					
2	Miscellaneous Incoming Letter	PRD2901USNPRequestAddInventorsMARCH2017.pdf	86794 6398241a2aef63c3a97cd5f38fc54f2175da4827	no	2
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	PRD2901USNP_EXECUTEDSTATEMENT_SG2017pdf.pdf	116507 d6e9cb6771f4fa643962536379b6500661d2e0fb	no	1
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	PRD2901USNP_PLB_PDFMARCH2017.pdf	187752 6306a8ea25006e9435ffea3960a40dc8bb6540b0	no	1
Warnings:					
Information:					
5	Miscellaneous Incoming Letter	PRD2901USNP_STATEMENT_AV.pdf	26760 0306032880de264410c829266e387d7ea01c3c33	no	1
Warnings:					
Information:					
6	Miscellaneous Incoming Letter	PRD2901USNP_STATMENT_AW_2017.pdf	101736 e397e2dd810aa0d594071b77825bd3ffec416b38	no	1
Warnings:					
Information:					
7	Miscellaneous Incoming Letter	PRD2901USNP_STATEMENT_MS2017.pdf	115260 991340ab03bc6eba74a6ce4477bd5b14d792e2ed	no	1
Warnings:					
Information:					
8	Miscellaneous Incoming Letter	PRD2901USNP_WRITTENCONSENTFROMASSIGNEE_MARCH2017.pdf	77110 e3bbfef54d614ecb2fe57d593244e19f3bc6fbfd	no	1
Warnings:					
Information:					

9	Miscellaneous Incoming Letter	PRD2901USNP_STATMENT373.pdf	636650 73f17dc7569c3113643700b29f500f2831db9c82	no	3

Warnings:	
Information:	
Total Files Size (in bytes):	1434809

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.

Docket No. PRD 2901USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Vermeulen et al.	Patent No.:	9,439,906
Appln No.	: 12/337,144	Issue Date:	September 13, 2016
Filed	: December 17, 2008	Confirmation No.:	3172
Title	: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE PALIPERIDONE ESTERS		

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

TRANSMITTAL OF PETITION TO CORRECT INVENTORSHIP IN PATENT PURSUANT TO 37 CFR 1.324

Dear Sir:

Patentees hereby submit the following documents in support of correcting inventorship pursuant to 37 CFR 1.324 for the patent listed above:

1. Request Pursuant to Rule 37 CFR §1.324 For Correction of Inventorship.
2. Written consent from Assignee Under 37 CFR §1.324.
3. Statement Under CFR 3.73(c).
4. Statements By Person Being Added by Amendment to Correct Inventorship in Patent (37 CFR 1.324) by the following inventors: **Srihari Gopal,** a citizen of the United States of America, **Peter H. Lewyn-Briscoe** a citizen of the United States of America and **Mahesh Samtani**, a citizen of the United States of America.
5. Statements by Named Inventor to Correct Inventorship In Patent (37 CFR 1.324) from the currently named inventors, **An Vermeulen** and **Alfons Wouters,** are submitted herewith.

The undersigned attorney states that the Inventorship errors occurred without deceptive intent.

Please charge the fee set forth in 37 CFR §1.20(b), $130.00, to Deposit Account No.: 10-0750/PRD2901USNP/MW.

Please charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

/Melissa Wenk Reg. No. 53,759/

Melissa Wenk, Ph.D.
Reg. No.: 53,759
Registered Attorney for Patentee

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Date: March 15, 2017