PTO/AIA/82A (07-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.

Application Number	
Filing Date	
First Named Inventor	Curt Wolfgang et al.
Title	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
Art Unit	
Examiner Name	
Attorney Docket Number	VAND-0002-US-CON2

SIGNATURE of Applicant or Patent Practitioner

Signature	/Jayme M. Torelli/	Date	01/08/2014
Name	Jayme M. Torelli	Telephone	518-449-0044
Registration Number	62,735		

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

☐ *Total of _____ forms are submitted.

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

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

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POWER OF ATTORNEY BY APPLICANT

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

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

23550

OR

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

Name	Registration Number	Name	Registration Number

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant:

☐ Inventor or Joint Inventor

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)

SIGNATURE of Applicant for Patent

Signature		Date	September 21, 2012
Name	Mihael H. Polymeropoulos	Telephone	202-734-3401
Title and Company	CEO, Vanda Pharmaceutical Inc,		

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

☐ *Total of _____ forms are submitted.

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

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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.
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-13)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Curt Wolfgang et al.	Nonprovisional Application Number (if known):	
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, examination fee, and any required excess claims and application size fees are filed with the request or have been already been paid.
2. The application contains or is amended to contain no more than four independent claims and no more than thirty total claims, and no multiple dependent claims.
3. The applicable box is checked below:

I. ☑ **Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)**

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

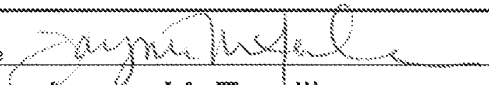
---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. The executed inventor's oath or declaration is filed with the application. (37 CFR 1.63 and 1.64)

II. ☐ **Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)**

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature 	Date 1/8/2014
Name (Print/Typed) Jayme M. Torelli	Practitioner Registration Number 62735

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	VAND-0002-US-CON2
	Application Number	
Title of Invention	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE	

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
	Curt		Wolfgang	

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

City	Germantown	State/Province	MD	Country of Residence i	US

Mailing Address of Inventor:

Address 1	2200 Pennsylvania Avenue		
Address 2			
City	Washington	State/Province	DC
Postal Code	20037	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mihael		Polymeropoulos	

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

City	Potomac	State/Province	MD	Country of Residence i	US

Mailing Address of Inventor:

Address 1	2200 Pennsylvania Avenue		
Address 2			
City	Washington	State/Province	DC
Postal Code	20037	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	VAND-0002-US-CON2
	Application Number	
Title of Invention	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE	

☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	23550		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		
Attorney Docket Number	VAND-0002-US-CON2	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	23550		

Domestic Benefit/National Stage Information:

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

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	14060978	2013-10-23
Prior Application Status	Patented		Remove

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	VAND-0002-US-CON2
	Application Number	
Title of Invention	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14060978	Continuation of	11/576178	2007-03-28	8586610	2013-11-19

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11/576178	a 371 of international	PCT/US2005/035526	2005-09-30

Prior Application Status	Expired	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US2005/035526	non provisional of	60614798	2004-09-30

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

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

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

Authorization to Permit Access:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	VAND-0002-US-CON2
	Application Number	
Title of Invention	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

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	Vanda Pharmaceuticals, Inc.

Mailing Address Information:

Address 1	2200 Pennsylvania Avenue		
Address 2			
City	Washington	**State/Province**	DC
Country [i]	US	Postal Code	20037
Phone Number		Fax Number	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	VAND-0002-US-CON2
	Application Number	
Title of Invention	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE	

Email Address	

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

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 only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest), as the patent application publication will include the name of the applicant(s).

Remove

If the Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1	
Address 2	

City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

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

Signature:

Remove

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

Signature	/Jayme M. Torelli/			Date (YYYY-MM-DD)	2014-01-08
First Name	Jayme	Last Name	Torelli	Registration Number	62735

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

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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)).

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Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Filer:	Jayme M. Torelli
Attorney Docket Number:	VAND-0002-US-CON2

Filed as Large Entity

Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**5740**

Electronic Acknowledgement Receipt

EFS ID:	17847953
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	08-JAN-2014
Filing Date:	
Time Stamp:	18:43:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$5740
RAM confirmation Number	5665
Deposit Account	500999
Authorized User	TORELLI, JAYME

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Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1		VAND-0002-US-CON2_Application_1-7-2014.pdf	204755 7acef04f0b87651b42f89d593e79523e9ca0cac2	yes	27
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	24	
	Claims		25	26	
	Abstract		27	27	
Warnings:					
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2	Oath or Declaration filed	VAND-0002-US-CON2_Declaration_signed.pdf	723798 63ff2ff286c9c571db37ab46d7632bb8e538e93f	no	2
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3	Power of Attorney	VAND-0002-US-CON2_TransmittalAndSignedPOA.pdf	664874 d079a9f18777796b2ad63baff23bd91c12e3f1d6	no	3
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4	TrackOne Request	VAND-0002-US-CON2_PTOSB424_01-08-14.pdf	2061280 cc892d403aa2b92070357d902c015d1568e3479f	no	2
Warnings:					
Information:					
5	Application Data Sheet	VAND-0002-US-CON2_ApplicationDataSheet.pdf	1503867 2ff39c35e68d76c916b7217314f9d58f55866937	no	7
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	40044 fc48ca52d75e7f5281ada7562cb6fe5fb9eb148a	no	2
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METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of co-pending U.S. Patent Application Serial No. 14/060,978, filed October 23, 2013, which is a continuation of U.S. Patent Application Serial No. 11/576,178, filed March 28, 2007 (now US Patent No. 8,586,610, issued November 19, 2013), which is a 35 U.S.C. § 371 national stage entry of International Patent Application No. PCT/US2005/035526, filed September 30, 2005, which claims the benefit of U.S. Provisional Patent Application No. 60/614,798, filed September 30, 2004. Each of the foregoing patent applications is incorporated herein.

BACKGROUND OF THE INVENTION

[0002] Several genes associated with drug metabolism have been found to be polymorphic. As a result, the abilities of individual patients to metabolize a particular drug may vary greatly. This can prove problematic or dangerous where an increased concentration of a non-metabolized drug or its metabolites is capable of producing unwanted physiological effects.

[0003] The *cytochrome P450 2D6* gene (*CYP2D6*), located on chromosome 22, encodes the Phase I drug metabolizing enzyme debrisoquine hydroxylase. A large number of drugs are known to be metabolized by debrisoquine hydroxylase, including many common central nervous system and cardiovascular drugs. One such drug is iloperidone (1-[4-[3-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]propoxy]-3-methoxyphenyl]ethanone). Iloperidone and methods for its production and use as an antipsychotic and analgesic are described in United States Patent No. 5,364,866 to Strupczewski *et al.* The diseases and disorders that can be treated by administration of iloperidone include all forms of schizophrenia (*i.e.*, paranoid, catatonic, disorganized, undifferentiated, and residual), schizoaffective disorders, bipolar mania/depression, cardiac

arrhythmias, Tourette's Syndrome, brief psychotic disorder, delusional disorder, psychotic disorder NOS (not otherwise specified), psychotic disorder due to a general medical condition, schizophreniform disorder, and substance-induced psychotic disorder. P88 is an active metabolite of iloperidone. See, e.g., PCT WO2003020707, which is incorporated herein by reference.

[0004] Among the unwanted physiological effects associated with an increased concentration of iloperidone or its metabolites is prolongation of the electrocardiographic QT interval. Mutations in the *CYP2D6* gene have been associated with a number of drug metabolism-related phenotypes. These include the ultra rapid metabolizer (UM), extensive metabolizer (EM), intermediate metabolizer (IM), and poor metabolizer (PM) phenotypes. Where a particular drug is capable of producing unwanted physiological effects in its metabolized or non-metabolized forms, it is desirable to determine whether a patient is a poor metabolizer of the drug prior to its administration.

[0005] A number of references are directed toward the identification of *CYP2D6* mutations and their corresponding phenotypes. For example, United States Patent Application Publication No. 2003/0083485 to Milos *et al.* describes a novel *CYP2D6* variant associated with the PM phenotype and methods for assessing whether an individual possesses the variant prior to the administration of a drug. United States Patent Application Publication No. 2004/0072235 to Dawson describes a primer set useful in identifying variants of the *CYP2D*6 gene. Similarly, United States Patent Application Publication No. 2004/0091909 to Huang describes methods for screening an individual for variants in the *CYP2D6* gene and other cytochrome P450 genes and tailoring the individual's drug therapy according to his or her phenotypic profile. Finally, United States Patent Application Publication No. 2004/0096874 to Neville *et al.* describes methods for identifying cytochrome P450 variants.

SUMMARY OF THE INVENTION

[0006] The present invention comprises the discovery that treatment of a patient, who has lower CYP2D6 activity than a normal person, with a drug that is pre-disposed to cause QT prolongation and is metabolized by the CYP2D6 enzyme, can be accomplishing more safely by administering a lower dose of the drug than would be administered to a person who has normal CYP2D6 enzyme activity. Such drugs include, for example, dolasetron, paroxetine, venlafaxin, and iloperidone. Patients who have lower than normal CYP2D6 activity are herein referred to as CYP2D6 Poor Metabolizers.

[0007] This invention also relates to methods for the identification of genetic polymorphisms that may be associated with a risk for QT prolongation after treatment with compounds metabolized by the CYP2D6 enzyme, particularly iloperidone or an active metabolite thereof or a pharmaceutically acceptable salt of either (including, e.g., solvates, polymorphs, hydrates, and stereoisomers thereof), and related methods of administering these compounds to individuals with such polymorphisms.

[0008] The present invention describes an association between genetic polymorphisms in the CYP2D6 locus, corresponding increases in the concentrations of iloperidone or its metabolites, and the effect of such increases in concentrations on corrected QT (QTc) duration relative to baseline. Any number of formulas may be employed to calculate the QTc, including, for example, the Fridericia formula (QTcF) and the Bazett formula (QTcB), among others. The present invention includes any such formula or method for calculating a QTc.

[0009] A first aspect of the invention provides a method for treating a patient with iloperidone or an active metabolite thereof or a pharmaceutically acceptable salt of either, comprising the steps of determining the patient's *CYP2D6* genotype and administering to the patient an effective amount of iloperidone or an active metabolite thereof or a

pharmaceutically acceptable salt of either based on the patient's *CYP2D6* genotype, such that patients who are CYP2D6 poor metabolizers receive a lower dose than patients who are CYP2D6 normal metabolizers.

[0010] Another aspect of the invention provides a method for treating a patient who is a CYP2D6 poor metabolizer with iloperidone or an active metabolite thereof or a pharmaceutically acceptable salt of either, wherein the patient is administered a lower dosage than would be given to an individual who is not a CYP2D6 poor metabolizer.

[0011] Another aspect of the invention provides a method of treating a patient with iloperidone or an active metabolite thereof or a pharmaceutically acceptable salt of either comprising the steps of determining whether the patient is being administered a CYP2D6 inhibitor and reducing the dosage of drug if the patient is being administered a CYP2D6 inhibitor.

[0012] Another aspect of the invention provides a method for determining a patient's CYP2D6 phenotype comprising the steps of administering to the patient a quantity of iloperidone or an active metabolite thereof or a pharmaceutically acceptable salt of either, determining a first concentration of at least one of iloperidone and an iloperidone metabolite in the patient's blood, administering to the patient at least one CYP2D6 inhibitor, determining a second concentration of at least one of iloperidone and an iloperidone metabolite in the patient's blood, and comparing the first and second concentrations.

[0013] Another aspect of the invention provides a method for determining whether a patient is at risk for prolongation of his or her QTc interval due to iloperidone administration comprising the step of: determining a patient's CYP2D6 metabolizer status by either determining the patient's CYP2D6 genotype or CYP2D6 phenotype. In the case that a patient is determined to be at risk for prolongation of his or her QTc interval, the dose of iloperidone administered to the patient may be reduced.

[0014] Another aspect of the invention provides a method of administering iloperidone or an active metabolite thereof, or a pharmaceutically acceptable salt of either, for the treatment of a disease or disorder in a human patient comprising the steps of determining the activity of the patient's CYP2D6 enzyme on at least one of iloperidone and its metabolites relative to the activity of a wild type CYP2D6 enzyme and reducing the dose of at least one of iloperidone and its pharmaceutically acceptable salts if the patient's CYP2D6 enzyme activity is less than that of the wild type CYP2D6.

[0015] Another aspect of the invention relates to modifying the dose and/or frequency of dosing with iloperidone or a pharmaceutically acceptable salt thereof based on the P88:P95 ratio and/or the (P88+iloperidone):P95 ratio in a blood sample of a patient being treated with iloperidone or P88, especially patients susceptible to QT prolongation or to harmful effects associated with QT prolongation.

[0016] Another aspect of the invention provides a kit for use in determining a *CYP2D6* genotype of an individual, comprising a detection device, a sampling device, and instructions for use of the kit.

[0017] Another aspect of the invention provides a kit for use in determining a CYP2D6 phenotype of an individual, comprising a detection device, a collection device, and instructions for use of the kit.

[0018] Another aspect of the invention provides a kit for use in determining at least one of a P88 to P95 ratio and a P88 and iloperidone to P95 ratio in an individual, comprising a detection device, a collection device, and instructions for use of the kit.

[0019] Yet another aspect of the invention provides a method for commercializing a pharmaceutical composition comprising at least one of iloperidone, a pharmaceutically acceptable salt of iloperidone, an active metabolite of iloperidone, and a pharmaceutically acceptable salt of an active metabolite of iloperidone, said method comprising: obtaining

regulatory approval of the composition by providing data to a regulatory agency demonstrating that the composition is effective in treating humans when administered in accordance with instructions to determine whether or not a patient is a CYP2D6 poor metabolizer prior to determining what dose to administer to the patient; and disseminating information concerning the use of such composition in such manner to prescribers or patients or both.

[0020] The foregoing and other features of the invention will be apparent from the following more particular description of embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0021] Iloperidone is a benzisoxazole-piperidinyl derivative, currently in development for the treatment of CNS disorders. Data from placebo-controlled Phase III studies of iloperidone showed a Fridericia correction of QT duration (QTcF) increase of 0.1 to 8.5 msec at doses of 4-24 mg, when comparing a single ECG at baseline to a single ECG at endpoint. At lower doses of iloperidone (4 mg – 16 mg) QTcF prolongation was minimal (0.1 – 5 msec). In the most recent study, a greater prolongation was observed when higher doses of iloperidone (20-24 mg/day) were studied. The mean change in the QTcF at doses 20-24 mg/day was 8.5 msec, and 4.6 msec in the 12-16 mg/day dose range in this study. These data suggest that treatment with iloperidone can be associated with prolongation of the QT interval similar to other drugs in this class, and that the effect may be dose sensitive in the clinical dose range.

[0022] The research leading to the present invention was designed to examine the effect of different doses of iloperidone relative to the effect of ziprasidone and quetiapine on QTc duration under carefully controlled conditions. To further evaluate the possible relationship between exposure to iloperidone and the comparators to QTc duration, reassessment after pharmacological inhibition of the principle metabolic pathways for each

drug, under steady-state conditions, was also planned.

[0023] Blood samples for pharmacogenetic analysis were collected at screening. Two polymorphisms previously associated with poor metabolizing status were genotyped in the *CYP2D6* locus and 251 genotypes were collected. The individual genotypes were studied for detection of association between genotype class and concentrations of iloperidone and its metabolites P88 and P95. The functional effect of the polymorphisms was also evaluated by analyzing the effect of the addition of the CYP2D6 inhibitor paroxetine on the concentrations of the parent drug and its metabolites.

[0024] The research leading to the present invention identified a significant association between *CYP2D6* genotype and concentrations of P88 before the addition of inhibitors as well as the effect of this association on QTc prolongation.

[0025] Iloperidone is a substrate for two P450 enzymes; CYP2D6 and CYP3A4. Most metabolic clearance of iloperidone depends on these two enzymes. CYP2D6 catalyzes hydroxylation of the pendant acetyl group to form metabolite P94, which is converted to P95 after some additional reactions. Addition of the CYP2D6 inhibitor fluoxetine, along with iloperidone resulted in increases of the area under the curve (AUC) for iloperidone and P88 of 131% and 119% respectively. Addition of the CYP3A4 inhibitor ketoconazole in interaction studies resulted in a 38-58% increase in the concentrations of iloperidone and its main metabolites P88 and P95. P88 has a pharmacological profile including affinity for the HERG channel similar to that of iloperidone. P95 is less lipophilic and is dissimilar in its binding profile compared to iloperidone, including having very low affinity for the HERG channel. For these reasons P95 is regarded as being pharmacologically inactive.

[0026] The addition of metabolic inhibitors in this study therefore allowed for an evaluation of the effect of increasing blood-concentration of iloperidone and/or its metabolites on QT duration. More specifically, this study allowed for an evaluation of the

effect of iloperidone on QTc before and after the addition of the CYP2D6 inhibitor, paroxetine, as well as before and after the addition of the CYP3A4 inhibitor, ketoconazole.

[0027] The *CYP2D6* gene is highly polymorphic, with more than 70 allelic variants described so far. *See*, *e.g.*, http://www.imm.ki.se/CYPalleles/cyp2d6.htm. Most embodiments of the present invention concern the two most common polymorphisms within the *CYP2D6* gene in Caucasian populations, *CYP2D6G1846A* and *CYP2D6P34S* (also referred to as *CYP2D6C100T*). These polymorphisms correspond to nucleotides 3465 and 1719, respectively, in GenBank sequence M33388.1 (GI:181303). The *CYP2D6P34S*/*CYP2D6C100T* polymorphism also corresponds to nucleotide 100 in GenBank mRNA sequence M20403.1 (GI:181349).

[0028] The *CYP2D6G1846A* polymorphism (known as the CYP2D6*4 alleles, encompassing *4A, *4B, *4C, *4D, *4E, *4F, *4G, *4H, *4J, *4K, and *4L) represents a G to A transition at the junction between intron 3 and exon 4, shifting the splice junction by one base pair, resulting in frameshift and premature termination of the protein (Kagimoto 1990, Gough 1990, Hanioka 1990). The *CYP2D6P34S*/*CYP2D6C100T* polymorphism (known as the CYP2D6*10 and CYP2D6*14 alleles) represents a C to T change that results in the substitution of a Proline at position 34 by Serine (Yokota 1993, Johansson 1994). Both of these polymorphisms have been associated with reduced enzymatic activity for different substrates (Johansson 1994, Dahl 1995, Jaanson 2002, see also review by Bertilsson 2002)

Methods

A. Samples

[0029] 128 individuals consented to the pharmacogenetic study. Blood samples were collected according to the pharmacogenetics protocol and after the consent of patients. The DNA was extracted from whole blood by Covance using the PUREGENE DNA isolation kit

(D-50K).

[0030] The 128 individuals that participated were a good representation of the total sample of 165 individuals that participated in the trial. 22 of 29 total were from the iloperidone 8 mg bid group, 30 of 34 were from the iloperidone 12 mg bid group, 22 of 31 from the 24 mg qd group, 3 of 5 of the risperidone group, 28 of 33 of the ziprazidone group, and 23 of 33 of the quetiapine group.

B. Genotyping

[0031] Genotypes for the *CYP2D6G1846A* polymorphism were ascertained for 123 of the 128 consenting individuals, while genotypes for the *CYP2D6C100T* polymorphism were identified for all 128 participants. Genotyping was performed on amplified DNA fragments. The *CYP2D6* genomic region was amplified using a triplex PCR strategy (Neville 2002). In brief, primers used were:

Exons 1 & 2	2D6L1F1:	CTGGGCTGGGAGCAGCCTC
	2D6L1R1:	CACTCGCTGGCCTGTTTCATGTC
Exons 3, 4, 5 &6	2D6L2F:	CTGGAATCCGGTGTCGAAGTGG
	2D6L2R2:	CTCGGCCCCTGCACTGTTTC
Exons 7, 8 & 9	2D6L3F:	GAGGCAAGAAGGAGTGTCAGGG
	2D6L3R5B:	AGTCCTGTGGTGAGGTGACGAGG

[0032] Amplification was performed on 40-100ng of genomic DNA using a GC-rich PCR kit (Roche Diagnostics, Mannheim, Germany) according to the manufacturer's recommendations. Thermocycling conditions were as follows: initial denaturation (3min 95°C), 10 cycles of 30s of denaturation (30s at 95°C), annealing (30s at 66°C), and extension, (60s at 72°C) followed by 22 cycles: 30s at 95°C, 30s at 66°C, 60s+5s/cycle at 72°C. A final extension followed (7min at 72°C).

[0033] Third Wave Technologies, Inc (Madison, WI) developed the probe sets for

genotyping. Genotyping was performed on PCR products using the Invader® assay (Lyamichev 1999) (Third Wave Technologies, Inc) according to the manufacturer's recommendations.

[0034] The genotypes of individuals distributed among the three iloperidone groups were not significantly different (Table 1A and1B).

Table 1A: Genotype frequencies by iloperidone dose class for *CYP2D6C100T*

Iloperidone dose group	**Genotype**			**Total**
	CC	**CT**	**TT**	
Ilo 8 mg bid	19[a]	2	1	**22**
Ilo 12 mg bid	23	6	1	**30**
Ilo 24 mg qd	15	6	1	**22**
Total	**57**	**14**	**3**	**74**

[a] number of individuals

Table 1B: Genotype frequencies by iloperidone dose class for *CYP2D6G1846A*

Iloperidone dose group	**Genotype**			**Total**
	AA	**AG**	**GG**	
Ilo 8 mg bid	0	3	17	**20**
Ilo 12 mg bid	1	6	23	**30**
Ilo 24 mg qd	1	5	15	**21**
Total	**2**	**14**	**55**	**71**

C. Statistical Analysis

[0035] The genotype effect of the two *CYP2D6* polymorphisms on period 1 concentrations was evaluated using the following ANOVA model. Concentrations of iloperidone, P88, and P95 at Period 1, without inhibitor, at the time at which maximum blood concentration of the parent compound or metabolite was reached (Tmax) were used as the dependent variable, the genotypes of each polymorphism as classes and the treatment as a covariate. In order to adjust for treatment effects after the single dose of iloperidone, the 8 mg bid was coded as 8, the 12 mg bid as 12 and the 24 mg qd as 24.

[0036] The function of these polymorphisms on the degree of inhibition of the CYP2D6 enzyme was calculated from the ratio of concentrations of P88 and P95 in period 2, after the addition of the inhibitor of CYP2D6. The concentrations of iloperidone and/or its metabolites (e.g., P88 and P95) may be determined in period 1 and/or period 2 by any known or later-developed method or device, including titration.

Results and Discussion

[0037] In order to understand the functional significance of the two *CYP2D6* polymorphisms on the activity of the enzyme, we examined the association of the various genotypes with the relative concentrations of the metabolites P88 and P95. It is known that P88 is degraded by CYP2D6 and that CYP2D6 is involved in the synthesis of P95. The relative amounts of P88 and P95 would therefore be controlled by the activity of the CYP2D6 enzyme. We calculated the ratio of P88/P95 before inhibition in Period 1 and at the Tmax of the two metabolites, as well as the ratio of P88/P95 in Period 2 after the addition of the CYP2D6 inhibitor paroxetine. In individuals with the wild type enzyme the concentration of P88 is expected to increase in Period 2, while in the same period the concentration of P95 is expected to decline.

[0038] For Period 1 the mean P88/P95 ratio among the 91 iloperidone treated patients was equal to 1.0 with a range from 0.14 to 8.19. Among the same individuals for Period 2

the mean ratio was 2.4 with a range from 0.5 to 8.49. The mean ratio of the ratios Period 1/Period 2 was equal to 0.37 with a range from 0.11 to 2.75.

[0039] Among the genotyped individuals the values were similar with means of 1, 2.45 and 0.37 for Period 1, Period 2 and Period 1/Period 2 respectively, indicating no sample bias. For polymorphism *CYP2D6G1846A* the means were significantly different between the three-genotype classes AA, AG and GG. For AA the respective values were 6.1, 3.41, and 1.89, for AG they were 2.4, 4.2, and 0.52 and for GG 0.57, 1.94 and 0.28 (Table 2).

Table 2: Ratios of P88, P95 concentrations according to genotype

Population	**P88/P95 Period1**	**P88/P95 Period 2**	**P88/P95 (Period1/Period2)**
All	1.0 (0.14-8.19)	2.45 (0.50-8.49)	0.37 (0.11-2.75)
CYP2D6G1846A			
AA	6.1 (3.96-8.19)	3.41 (2.96-3.87)	1.89 (1.0-2.75)
AG	2.4 (0.44-7.0)	4.20 (2.2-7.57)	0.52 (0.14-1.28)
GG	0.57 (0.14-2.2)	1.94 (0.52-4.71)	0.28 (0.11-0.61)

[0040] The differences between genotype classes were significant at the $p<0.0001$ level in ANOVA test. These data suggest that the AA class represent a CYP2D6 poor metabolizer as indicated by the high ratio of P88/P95 in period 1 and the relatively small effect of the addition of the inhibitor in Period 2. The AG class seems to exhibit an intermediate phenotype between the poor metabolizer and the wild type with an approximately 2-fold reduction of the CYP2D6 activity after the addition of the inhibitor, as indicated by the ratio of the ratios (Table 2). This analysis provides a phenotypic characterization of the *CYP2D6G1846A* polymorphism as it relates to the metabolism of iloperidone.

[0041] Having established a functional role of this polymorphism, we calculated the concentrations of P88 at Period 1 at the Tmax of P88 for each genotype class. P88 concentrations were significantly ($p<0.005$) higher for the AA and AG classes as compared to the GG class for each of the three iloperidone dose groups (Table 3).

Table 3: P88 concentrations in Period 1 according to *CYP2D6* genotype

Genotype	**N obs**	**LSMeans**	**P value**
AA	2	62.70	<0.0001
AG	14	31.40	
GG	55	21.03	
TRT dose			0.0015
***CYP2D6G1846A* *TRT dose**			0.0058

[0042] Although the number of individuals carrying the A allele is limited, the results obtained in the study consistently suggest that individuals of the AA and AG class are expected to experience higher concentrations of P88 at Tmax as compared with GG individuals. Similar results were obtained with polymorphism *CYP2D6C100T* (Table 4 and 5).

Table 4: Ratios of P88, P95 concentrations according to genotype

Population	**P88/P95 Period1**	**P88/P95 Period 2**	**P88/P95 (Period1/Period2)**
All	1.0 (0.14-8.19)	2.45 (0.50-8.49)	0.37 (0.11-2.75)
CYP2D6C100T			
CC	0.6 (0.14-2.28)	1.93 (0.52-4.71)	0.27 (0.11-0.61)
CT	2.2 (0.44-7.0)	4.14 (2.2-7.57)	0.49 (0.14-1.28)

TT	5.24 (3.56-8.19)	4.19 (2.96-5.74)	1.46 (0.62-2.75)

Table 5: P88 concentrations in Period 1 according to *CYP2D6* genotype

Genotype	N obs	LSMeans	P value
CC	57	21.03	
CT	14	33.16	<0.0001
TT	3	51.00	
TRT dose			<0.0001
***CYP2D6C100T* *TRT dose**			0.0015

[0043] This result is expected given the fact that this polymorphism is in almost complete linkage disequilibrium with the *CYP2D6G1846A* polymorphism.

[0044] In order to understand whether the difference in concentration of P88 at Period 1 Tmax was relevant to the increases in QTc after the addition of the inhibitors, we used the observed mean of P88 for the *CYP2D6G1846A* AG group to divide all individuals into two classes. The first includes individuals with P88 concentrations at Period 3, after the addition of both inhibitors, of equal to or less than 34 ng/mL and the second class includes individuals with P88 concentration greater than 34 ng/mL. We then compared the two classes in regards to the QTc change from baseline at Period 3. Using an ANOVA statistic for the first class P88 > 34 (n = 55) the QTc mean change from baseline in Period 3 was 22.7 msec and that for P88 ≤ 34 (n = 12) the mean QTc for the same period was 7.7 msec. The QTc changes from baseline for Period 1 and Period 2 according to genotype and iloperidone dose are given in Table 6 and 7.

Table 6: QTc change at Period 1 according to *CYP2D6* genotype and iloperidone dose

Genotype	iloperidone Dose		
	8 mg bid	12 mg bid	24 mg qd
CYP2D6G1846A			
AA		17.7 (1)[a]	38.4 (1)
AG	-0.8 (3)	5.8 (6)	19.0 (5)
GG	7.8 (17)	11.8 (23)	14.0 (14)
CYP2D6C100T			
TT	-8.4 (1)	17.7 (1)	38.4 (1)
CT	2.9 (2)	5.8 (6)	19.0 (5)
CC	7.8 (17)	11.8 (23)	9.5 (14)

[a] number of individuals

Table 7: QTc change at Period 2 according to *CYP2D6* genotype and iloperidone dose

Genotype	iloperidone dose		
	8 mg bid	12 mg bid	24 mg qd
CYP2D6G1846A			
AA		25.0 (1)	28.4 (1)
AG	8.1 (3)	8.7 (6)	20.6 (5)
GG	11.7(18)	14.5 (21)	16.4 (15)
CYP2D6C100T			
TT	-0.7 (1)	25.0 (1)	28.4 (1)
CT	12.5 (2)	8.7 (6)	20.6 (5)
CC	11.7(16)	14.5 (21)	16.4 (15)

[0045] These results however should be viewed with caution since the number of

observations is small. If one was, however, to focus on the iloperidone 24 mg qd, there is a trend for higher QTc among AA, and AG individuals for *CYP2D6G1846A* as compared to GG. This difference disappears after the addition of the CYP2D6 inhibitor in Period 2.

[0046] These observations suggest that the differences in P88 concentrations during Period 1 between the different classes of genotypes may be relevant to QTc changes from baseline. Given the small number of observations and the unbalanced in regards to genotype design of the study, a confirmatory prospectively designed study may be required before any further interpretation of this data is warranted. Notwithstanding these caveats, the results discussed above show that patients can be more safely treated with iloperidone if the dose of iloperidone is adjusted based on the CYP2D6 genotype of each patient. For example, if a patient has a genotype which results in decreased activity of the CYP2D6 protein relative to the wild type CYP2D6, then the dose of iloperidone administered to such patient would be reduced to, for example, 75% or less, 50% or less, or 25% or less of the dose typically administered to a patient having a CYP2D6 genotype that results in a CYP2D6 protein that has the same or substantially the same enzymatic activity on P88 as the wild type CYP2D6 genotype/protein. For example, where the normal dosage of iloperidone or other CYP2D6-metabolized compound administered to an individual is 24 mg per day, an individual with a genotype associated with decreased CYP2D6 activity may receive a reduced dosage of 18, 12, or 6 mg per day.

[0047] Decreased CYP2D6 activity may be the result of other mutations, including those described at http://www.imm.ki.se/CYPalleles/cyp2d6.htm, which is incorporated herein by reference. In particular, it is noted that the CYP2D6*2A mutation includes a CYP2D7 gene conversion in intron 1. In some cases, the lower CYP2D6 activity in a CYP2D6 poor metabolizer may be due to factors other than genotype. For example, a patient may be undergoing treatment with an agent, e.g., a drug that reduces CYP2D6

activity.

[0048] QTc prolongation is correlated to the ratios of P88/P95 and (iloperidone + P88)/P95. The mean ratios among CYP2D6 extensive metabolizers were 0.57 and 1.00, respectively. As shown above in Tables 3 and 5, CYP2D6 poor metabolizers have elevated P88 levels compared to CYP2D6 extensive metabolizers.

[0049] As CYP2D6 poor metabolizers comprise approximately 15% of the population, it was found that approximately 15% of those studied exhibited a P88/P95 ratio greater than 2.0 while the remaining 85% exhibited P88/P95 ratios less than 2.0. Table 8 below shows the least squares mean change in QTc for each dosage group. While the results for some groups are not statistically significant, they do indicate a trend supporting the hypothesis that QTc prolongation is correlated to P88/P95 ratio. Similar results were obtained when cutoff ratios of 3.0 and 4.0 were analyzed, providing further support to the hypothesis that the extent of QTc prolongation a patient may experience after treatment can be predicted by measuring P88 and P95 blood levels.

Table 8: Mean QTc Prolongation According to P88/P95 Ratio

P88/P95 Ratio	**LSMean QTc change from Baseline 8 mg bid**	**LSMean QTc change from Baseline 12 mg bid**	**LSMean QTc change from Baseline 8 + 12 mg bid**	**LSMean QTc change from Baseline 24 qd**	**LSMean QTc change from Baseline All Treatment Groups**
<2	7.2 (n=23)	8.7 (n=31)	8.3 (n=54)	13.9 (n=24)	10.244 (n=78)
>2	21.3	17.4	18.3	29.4	21.111

	(n=5)	(n=3)	(n=8)	(n=5)	(n=13)
P value	0.0725	0.392	0.0815	0.0329	0.0131

[0050] Similar results were observed when considering QTc correlation to the (iloperidone + P88)/P95 ratio. Again, as approximately 15% of the population are CYP2D6 poor metabolizers, it was found that approximately 15% of those studied exhibited (iloperidone + P88)/P95 ratios greater than 3.0 while the remaining 85% exhibited ratios less than 3.0. Table 9 below shows the least squares mean change in QTc for each dosage group. While the results for some groups are not statistically significant, they do indicate a trend supporting the hypothesis that QTc prolongation is correlated to (iloperidone + P88)/P95 ratio. Indeed, when cutoff ratios of 4 and higher were analyzed, similar results were obtained providing further support to the hypothesis that the extent of QTc prolongation a patient may experience after treatment can be predicted by measuring iloperidone, P88 and P95 blood levels.

Table 9: Mean QTc Prolongation According to (iloperidone + P88)/P95 Ratio

(ILO+P88)/P95 Ratio	**LSMean QTc change from Baseline 8 mg bid**	**LSMean QTc change from Baseline 12 mg bid**	**LSMean QTc change from Baseline 8 + 12 mg bid**	**LSMean QTc change from Baseline 24 qd**	**LSMean QTc change from Baseline All Treatment Groups**
<3	7.2 (n=23)	8.7 (n=31)	8.3 (n=54)	14.4 (n=24)	10.424 (n=78)

>3	21.3 (n=5)	15.2 (n=3)	17.3 (n=8)	30.5 (n=5)	20.031 (n=13)
P value	0.0725	0.4223	0.0857	0.0522	0.0278

[0051] The starting point for determining the optimum dose of iloperidone is, as discussed above, a dose that has been shown to be acceptably safe and effective in patients having a *CYP2D6* genotype that results in a protein having the same activity on iloperidone and P88 as the wild type CYP2D6 protein. Such doses are known in the art and are disclosed, for example, in U.S. Patent No. 5,364,866 discussed above.

[0052] Generally, the dose of iloperidone administered to a patient will be decreased, as discussed above, if the enzymatic activity of the CYP2D6 enzyme on iloperidone and P88 is less than about 75% of that of the wild type CYP2D6. Enzymatic activity may be determined by any number of methods, including, for example, measuring the levels of iloperidone and/or P88 in an individual's blood. In such a case, the iloperidone dose can be lowered such that measured levels of iloperidone and/or P88 are substantially the same as levels measured in the blood of individuals having normal CYP2D6 enzymatic activity. For example, if the CYP2D6 enzymatic activity of a patient is estimated by one or more methods (e.g., genotyping, determination of dextromorphan blood levels) to be 50% of the enzymatic activity normally observed in an individual having normal CYP2D6 enzymatic activity, the dose for the patient may need to be adjusted to one-half of the dose given to an individual having normal CYP2D6 enzymatic activity. Similarly, for ultrarapid metabolizers, an analogous calculation will lead to the conclusion that a dose adjustment of twice that given an individual having normal CYP2D6 enzymatic activity may be needed in order to achieve similar blood levels for the parent compound and active metabolites.

[0053] Alternatively, the dose of iloperidone administered to a patient may be

decreased based upon the patient's CYP2D6 genotype alone, or upon the patient's P88:P95 or (iloperidone+P88):P95 ratios. For example, if a patient has a "poor metabolizer" genotype, or has a high P88:P95 or (iloperidone+P88):P95 ratio, the patient's dose of iloperidone may be reduced by, for example, 25%, 50%, or 75%. A patient's genotype can be readily determined using standard techniques on samples of body fluids or tissue. Such techniques are disclosed, e.g., in PCT Application Publication Number WO03054226.

[0054] While the *CYP2D6G1846A* (AA or AG) genotype and the *CYP2D6C100T* (CT or TT) genotype are illustrated herein, the method of the invention can employ other genotypes that result in decreased activity of the CYP2D6 protein on iloperidone and P88. It is within the skill of the art, based on the disclosure herein, to identify additional *CYP2D6* genotypes that result in decreased enzymatic activity on iloperidone and P88.

[0055] Furthermore, while the disclosure herein focuses on genotype, it is apparent to one of skill in the art that phenotype can also be used as an indicator of decreased activity of the CYP2D6 protein on iloperidone and P88. For example, McElroy *et al.* describe a correlation between CYP2D6 phenotype and genotyping as determined by dextromethorphan/dextrorphan ratios. Therefore, although it is more convenient given the state of the art to look at genotype, if one were to determine that a given patient expressed a mutant CYP2D6 with lower activity on iloperidone and P88 than the wild type, or expressed abnormally low amounts of CYP2D6, then that patient would be given a lower dose of iloperidone than a patient with wild type CYP2D6, as discussed above. Alternative methods for determining the relative activity of a patient's CYP2D6 gene include biochemical assays to directly measure enzymatic activity, protein sequencing to examine the amino acid sequence of a patient's CYP2D6, monitoring transcription and translation levels, and sequencing the *CYP2D6* gene mRNA transcript. For example, Chainuvati *et al.* describe assessment of the CYP2D6 phenotype using a multi-drug phenotyping cocktail (the

Cooperstown 5+1 cocktail).

[0056] Iloperidone can be formulated into dosage units and administered to patients using techniques known in the art. See, e.g., PCT Application Publication Number WO03054226, US Patent Application Publication Number 20030091645, PCT Application Serial Number PCT EP03/07619, and PCT Application Publication Number WO02064141, all of which are incorporated herein by reference as though fully set forth.

[0057] In addition, the present invention provides a kit for determining a patient's *CYP2D6* genotype and/or phenotype. Such a kit may include, for example, a detection means, a collection device, containers, and instructions, and may be used in determining a treatment strategy for a patient having one or more diseases or disorders for which iloperidone treatment is indicated.

[0058] Detection means may detect a *CYP2D6* polymorphism directly or may detect the characteristic mRNA of the polymorphic gene or its polypeptide expression product. In addition, as will be recognized by one of skill in the art, detection means may also detect polymorphisms in linkage disequilibrium with a *CYP2D6* polymorphism. Accordingly, any polymorphism in linkage disequilibrium with the *CYP2D6* polymorphisms disclosed in this application may be used to indirectly detect such a *CYP2D6* polymorphism, and is within the scope of the present invention.

[0059] Detection means suitable for use in the methods and devices of the present invention include those known in the art, such as polynucleotides used in amplification, sequencing, and single nucleotide polymorphism (SNP) detection techniques, Invader® assays (Third Wave Technologies, Inc.), Taqman® assays (Applied Biosystems, Inc.), gene chip assays (such as those available from Affymetrix, Inc. and Roche Diagnostics), pyrosequencing, fluorescence resonance energy transfer (FRET)-based cleavage assays, fluorescent polarization, denaturing high performance liquid chromatography (DHPLC),

mass spectrometry, and polynucleotides having fluorescent or radiological tags used in amplification and sequencing.

[0060] A preferred embodiment of a kit of the present invention includes an Invader® assay, wherein a specific upstream "invader" oligonucleotide and a partially overlapping downstream probe together form a specific structure when bound to a complementary DNA sequence. This structure is recognized and cut at a specific site by the Cleavase enzyme, releasing the 5' flap of the probe oligonucleotide. This fragment then serves as the "invader" oligonucleotide with respect to synthetic secondary targets and secondary fluorescently-labeled signal probes contained in a reaction mixture. This results in the specific cleavage of the secondary signal probes by the Cleavase enzyme. Fluorescence signal is generated when this secondary probe, labeled with dye molecules capable of fluorescence resonance energy transfer, is cleaved. Cleavases have stringent requirements relative to the structure formed by the overlapping DNA sequences or flaps and can, therefore, be used to specifically detect single base pair mismatches immediately upstream of the cleavage site on the downstream DNA strand. *See*, *e.g.*, Ryan *et al.*, Molecular Diagnosis, 4;2:135-144 (1999); Lyamichev *et al.*, Nature Biotechnology, 17:292-296 (1999); and U.S. Patent Nos. 5,846,717 and 6,001,567, both to Brow *et al.*, all of which are hereby incorporated herein by reference.

[0061] Another preferred embodiment of a kit of the present invention includes a detection means comprising at least one *CYP2D6* genotyping oligonucleotide specific to alleles known to predict a patient's metabolizer phenotype. More particularly, the means comprises an oligonucleotide specific for the *CYP2D6G1846A* or *CYP2D6C100T* polymorphism. The means may similarly comprise oligonucleotides specific for each polymorphism as well as the wild type sequence.

[0062] Detection methods, means, and kits suitable for use in the present invention

are described in International Publication Nos. WO 03/0544266 and WO 03/038123, each of which is hereby incorporated herein by reference. It should also be understood that the methods of the present invention described herein generally may further comprise the use of a kit according to the present invention.

[0063] Collection devices suitable for use in the present invention include devices known in the art for collecting and/or storing a biological sample of an individual from which nucleic acids and/or polypeptides can be isolated. Such biological samples include, for example, whole blood, semen, saliva, tears, urine, fecal material, sweat, buccal smears, skin, hair, and biopsy samples of organs and muscle. Accordingly, suitable collection devices include, for example, specimen cups, swabs, glass slides, test tubes, lancets, and Vacutainer® tubes and kits.

[0064] The present invention encompasses treatment of a patient for any disease or condition that is ameliorated by administration of iloperidone. As discussed above, such diseases or conditions include, for example, schizoaffective disorders including schizophrenia, depression including bipolar depression, as well as other conditions such as cardiac arrythmias, Tourette's syndrome, psychotic disorders and delusional disorders.

[0065] A related aspect of the invention is a method for obtaining regulatory approval for a pharmaceutical composition comprising iloperidone or an active metabolite thereof, or a pharmaceutically acceptable salt of either, which comprises including in proposed prescribing information instructions to determine whether or not a patient is a CYP2D6 poor metabolizer prior to determining what dose to administer to the patient. In another related aspect, the invention is a method for commercializing (i.e., selling and promoting) pharmaceutical compositions comprising such compounds said method comprising obtaining regulatory approval of the composition by providing data to a regulatory agency demonstrating that the composition is effective in treating humans when administered in

accordance with instructions to determine whether or not a patient is a CYP2D6 poor metabolizer prior to determining what dose to administer to the patient and then disseminating information concerning the use of such composition in such manner to prescribers (e.g., physicians) or patients or both.

[0066] Another aspect of the invention is a method for obtaining regulatory approval for the administration of iloperidone based, in part, on labeling that instructs the administration of a lower dose if the patient is already being administered a CYP2D6 inhibitor, e.g., paroxetine, etc.

[0067] While this invention has been described in conjunction with the specific embodiments outlined above, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, the embodiments of the invention as set forth above are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the invention as defined in the following claims.

CLAIMS

What is claimed is:

1. A method of treating a patient, who is suffering from schizophrenia, with iloperidone, the method comprising:

if the patient is not also being treated with a drug that inhibits CYP2D6, then internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day, and

if the patient is also being treated with a drug that inhibits CYP2D6, then internally administering to the patient an amount of iloperidone that is 12 mg/day or less.

2. The method of claim 1, wherein the risk of QT prolongation is reduced in a patient that is also being treated with a drug that inhibits CYP2D6.

3. The method of claim 2 wherein the drug that inhibits CYP2D6 is paroxetine, dolasetron, venlaxafin, or fluoxetine.

4. The method of claim 3 wherein the patient is being treated with iloperidone and is also being treated with paroxetine or fluoxetine, the method comprising internally administering to the patient an amount of iloperidone that is 12 mg/day or less.

5. The method of claim 4 wherein the amount of iloperidone is 12 mg/day.

6. The method of claim 1 wherein the patient is not also being treated with a CYP2D6 inhibitor, the method comprising internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day.

7. The method of claim 2 wherein the patient is not also being treated with a CYP2D6 inhibitor, the method comprising internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day.

8. The method of claim 6 wherein the amount of iloperidone is 24 mg/day.

9. The method of claim 7 wherein the amount of iloperidone is 24 mg/day.

METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

ABSTRACT OF THE DISCLOSURE

The present invention relates to methods for the identification of genetic polymorphisms that may be associated with a risk for QT prolongation after treatment with iloperidone and related methods of administering iloperidone to patients with such polymorphisms.

DOCKET NUMBER: VAND-0002-US-CON2

DECLARATION (37 C.F.R. 1.63) FOR UTILITY PATENT APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. 1.76) AND ASSIGNMENT

Title of Invention: **METHODS FOR THE ADMINISTRATION OF ILOPERIDONE**

As a below named and undersigned inventor, I hereby declare that:

This declaration is directed to the attached application, or (if following box is checked):

[ ] United States application or PCT international application number _____ filed on _____.

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

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

I have reviewed and understand the contents of the application, including the claims.

I am aware of the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in 37 CFR Section 1.56.

Whereas, I ("ASSIGNOR") have made certain inventions, improvements, and discoveries (herein referred to as the "Invention") disclosed in the above-identified patent application and further identified by the Docket Number provided above in the header of this document;

Whereas, Vanda Pharmaceuticals, Inc. (herein referred to as the "ASSIGNEE"), a corporation of Delaware, having a place of business at Washington, DC, desires to acquire, and I desire to grant to the ASSIGNEE, my entire worldwide right, title, and interest in and to the Invention and in and to any and all patent applications and patents directed thereto;

Now, therefore, for good and valuable consideration, the receipt and sufficiency thereof being hereby acknowledged, I hereby sell or have sold, assign or have assigned, and otherwise transfer or have transferred to the ASSIGNEE, its successors, legal representatives, and assigns, my entire worldwide right, title, and interest in and to the Invention, the above-identified United States patent application, and any and all other patent applications and patents for the Invention which may be applied for or granted therefor in the United States and in all foreign countries and jurisdictions, including all divisions, continuations, reissues, reexaminations, renewals, extensions, counterparts, substitutes, and extensions thereof, and all rights of priority resulting from the filing of such applications and granting of such patents. In addition, I hereby authorize and request the Director of the United States Patent and Trademark Office to issue any United States Patent, and foreign patent authorities to issue any foreign patent, granted for the Invention, to the ASSIGNEE, its successors, legal representatives, and assigns, my entire worldwide right, title, and interest in and to the same to be held and enjoyed by the ASSIGNEE, its successors, legal representatives, and assigns to the full end of the terms for which any and all such patents may be granted, as fully and entirely as would have been held and enjoyed by me had this Assignment not been made; and I agree to execute any and all documents and instruments and perform all lawful acts reasonably related to recording this Assignment or perfecting title to the Invention and all related patents and applications, in the ASSIGNEE, its successors, legal representatives, and assigns, whenever requested by the ASSIGNEE, its successors, legal representatives, or assigns.

I acknowledge my prior and ongoing obligations to sell, assign, and transfer my rights under this Assignment to the ASSIGNEE and am unaware of any reason why I may not have the full and unencumbered right to sell, assign, and transfer my rights hereby sold, assigned, and transferred, and have not executed, and will not execute, any document or instrument in conflict herewith. I also hereby grant the ASSIGNEE, its successors, legal representatives, and assigns, the right to insert in this Assignment any further identification (including, but not limited to, patent Application Number) which may be necessary or desirable for recordation of this Assignment. This Assignment is governed by the substantive laws of the State of New York, and any disputes will be resolved in a New York state court or federal court sited in New York.

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.

(1) Legal Name of Inventor: **Curt Wolfgang**

Signature: _____ Date: 7 Jan 2014

(2) Legal Name of Inventor: **Mihael Polymeropoulos**

Signature: _____ Date: 1/7/14

<110> Wolfgang, Curt

<120> Methods for the Administration of Iloperidone

<130> VAND-0002-US-CON2

<140> US 14/150575

<141> 2014-01-08

<150> US 60/614,798

<151> 2004-09-30

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Electronic Acknowledgement Receipt

EFS ID:	17859657
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	08-JAN-2014
Filing Date:	
Time Stamp:	18:59:23
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.)
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New International Application Filed with the USPTO as a Receiving Office
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Application Number: 14150575 Document Date: 01/08/2014

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Validated By CRFValidator v 1.0.4

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

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	1	JOHANNSEN, Office Action Communication for US Application No. 11/576,178 dated March 15, 2012, Attorney Docket No. VAND-0002-US, 24 pages.	☐
	2	JOHANNSEN, Office Action Communication for US Application No. 11/576,178 dated December 20, 2012, Attorney Docket No. VAND-0002-US, 13 pages	☐

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Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-01-21
Name/Print	Jayme M. Torelli	Registration Number	62,735

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

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	2	20080166357	A1	2008-07-10	Golz et al.	
	3	20090298880	A1	2009-12-03	Wolfgang et al.	
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	1	02064141	WO	A1	2002-08-22	Novartis AG		☐

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	2	2004006886	WO	A2	2004-01-22	Novartis AG		☐

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	1	European Patent Office, European Search Report for Application No. EP12164353 dated 29 August 2012, Attorney Docket No. VAND-0002-EP-DIV, 13 pages.	☐
	2	SHERIDAN et al., "Empirical Regioselectivity Models for Human Cytochromes P450 3A4, 2D6, and 2C9," June 2007, pages 3173-3184, J. Med. Chem. Vol. 50, American Chemical Society.	☐
	3	RYAN et al., "Non-PCR-Dependent Detection of the Factor V Leiden Mutation From Genomic DNA Using a Homogeneous Invader Microtiter Plate Assay," 1999, pages 135-144, Molecular Diagnosis, Vol. 4, No. 2.	☐
	4	Shimada et al., "Characterization of Bufuralol Hydroxylation Activities in Liver Microsomes of Japanese and Caucasian Subjects Genotyped for CYP2D6," 2001, pages 143-156, Pharmacogenetics 2001.	☐
	5	Johannsen, Office Action Communication for Application Serial No. 12/208,027 dated March 30, 2011, Attorney Docket No. VAND-0002-US-CIP, 31 pages.	☐
	6	Johannsen, Notice of Allowance and Fee(s) Due for Application Serial No. 11/576,178 dated July 25, 2013, Attorney Docket No. VAND-0002-US, 18 pages.	☐
	7	Johannsen, Office Action Communication for Application Serial No. 12/208,027 dated August 31, 2011, Attorney Docket No. VAND-0002-US-CIP, 25 pages.	☐
	8	Johannsen, Office Action Communication for Application Serial No. 12/208,027 dated July 3, 2013, Attorney Docket No. VAND-0002-US-CIP, 22 pages.	☐

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	9	Johannsen, Office Action Communication for Application Serial No. 12/208,027 dated December 20, 2012, Attorney Docket No. VAND-0002-US-CIP, 19 pages.	☐

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Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-01-21
Name/Print	Jayme M. Torelli	Registration Number	62,735

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EFS ID:	17963790
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	21-JAN-2014
Filing Date:	
Time Stamp:	16:13:22
Application Type:	Utility under 35 USC 111(a)

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U.S.PATENTS						
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	1	6001567		1999-12-14	Brow et al.	
	2	5981174		1999-11-09	Wolf et al.	
	3	5846717		1998-12-08	Brow et al.	
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	Attorney Docket Number	VAND-0002-US-CON2

	1	20050032070	A1	2005-02-10	Raimundo et al.	
	2	20040133352	A1	2004-07-08	Bevilacqua et al.	
	3	20040096874	A1	2004-05-20	Neville et al.	
	4	20040091909	A1	2004-05-13	Huang	
	5	20040072235	A1	2004-04-15	Dawson	
	6	20030170176	A1	2003-09-11	Leyland-Jones	
	7	20030144220	A1	2003-07-31	Obach	
	8	20030083485	A1	2003-05-04	Milos et al.	
	9	20020127561	A1	2002-09-12	Bee et al.	
	10	20010034023	A1	2001-10-25	Stanton, Jr. et al.	
If you wish to add additional U.S. Published Application citation information please click the Add button.						
FOREIGN PATENT DOCUMENTS						

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2004009760	WO	A3	2004-01-29	Dawson		☐
	2	2004009760	WO	A2	2004-01-29	Dawson		☐
	3	2003054226	WO	A3	2003-07-03	Novartis AG		☐
	4	2003038123	WO	A2	2003-05-08	Novartis AG		☐
	5	2003020707	WO	A1	2003-03-13	Grimler et al.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	BRADFORD, "CYP2D6 Allele Frequency in European Caucasians, Asians, Africans and Their Descendants", pp.229-243, Ashley Publications Ltd. ISSN 1452-2416, Pharmacogenomics 2002Volume 3 Number 2	☐
	2	BERTILSSON et al., "Molecular Genetics of CYP2D6: Clinical Relevance with Focus on Psychotropic Drugs", 2002 pp.111-122, Blackwell Science Ltd.	☐
	3	CHAINUVATI et al., "Combined Phenotypic Assessment of Cytochrome p450, 1A2, 2C9, 2C19, 2D6, and 3A, N-acetyltransferase-2 and Xanthine Oxidase Activities with the Cooperstown 5+1 Cocktail", Clinical Pharmacology and Therapeutics, November 2003, Volume 74, Number 5	☐

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	4	DAHL et al., "Genetic Analysis of the CYP2D Locus in Relation to Debrisoquine Hydroxylation Capacity in Korean, Japanese, and Chinese Subjects", Pharmacogenetics, 1995, pp. 159-164, Volume 5	☐
	5	GOUGH et al., "Identification of the Primary Gene Defect at the Cytochrome P 450 CYP2D Locus", Nature, October 25, 1990, pp.773-776, Volume 374	☐
	6	HANIOKA et al., "The Human CYP2D Locus Associated with a Common Genetic Defect in Durg Oxidation: A G1934-A Base Change in Intron 3 of a Mutant CYP2D6 Allele Results in an Aberrant 3' Splice Recognition Site', American Journal Of Human Genetics, 1990, pp. 994-1001, Volume 47	☐
	7	JAANSON et al., "Maintenance Therapy with Zuclopenthixol Decanoate: Associations Between Plasma Concentrations, Neurological Side Effects and CYP2D6 Genotype, Psychopharmacology, 2002, pp.67-73, Volume 162	☐
	8	JAIN, "An Assessment of Iloperidone for the Treatment of Schizophrenia", Expert Opinion on Investigational Drugs, December 2000, Volume 9, Number 12	☐
	9	JOHANSSON et al., "Genetic Analysis of the Chinese Cytochrome P4502D Locus: Characterization of Variant CYP2D6 Genes Present In Subjects with Diminished Capacity for Debrisoquine Hydroxylation", Molecular Pharmacology, June 1994, pp. 452-459, Volume 46	☐
	10	KAGIMOTO et al., "Multiple Mutations of the Human Cytochrome P450IID6 Gene (CYP2D6) In Poor Metabolizers of Debrisoquine", The Journal of Biological Chemistry, October 1990, pp. 17209-17214, Volume 265, Number 28	☐
	11	KELLEHER et al., "Advances in Atypical Antipsychotics for the Treatment of Schizophrenia- New Formulations and New Agents", CNS, ADIS International, 2002, pp.249-261, Volume 16, Number 4, Auckland, NZ	☐
	12	LYAMICHEV et al., "Polymorphism Identification and Quantitative Detection of Genomic DNA by Invasive Cleavage of Oligonucleotide Probes", Nature Biotechnology, March 1999, pp. 292-296, Volume 17	☐
	13	MCELROY et al., "CYP2D6 Genotyping as an Alternative to Phenotyping for Determination of Metabolic Status in a Clinical Trial Setting", AAPS Pharmsci 2000, October 2000, pp. 1-11, Volume 2, Number 4, Article 33 (www.pharmsci.org)	☐
	14	MUTLIB et al., "Application of Liquid Chromatography/Mass Spectrometry in Accelerating the Identification of Human Liver Cytochrome P450 Isoforms Involved in the Metabolism of Iloperidone", The Journal of Pharmacology and Experimental Therapeutics, May 1998, pp. 1285-1293	☐

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	15	NEVILLE et al., "Characterization of Cytochrome P450 2D6 Alleles Using the Invader System", BioTechniques, June 2002, Volume 32	☐
	16	SUBRAMANIAN et al., "Receptor Profile of P88-8991 and P95-12133, Metabolites of the Novel Antipsychotic Iloperidone", Progress in Neuro-Psychopharmacology & Biological Psychiatry, March 2002, pp.553-560, Volume 26, Number 3, England	☐
	17	YOKOTA et al., "Evidence for a New Variant CYP2D6 Allele CYP2D6J in a Japanese Population Associated with Lower In Vivo Rates of Sparteine Metabolism", Pharmacogenetics, 1993, pp. 256-263, Volume 3	☐
	18	UNKNOWN et al., "Home Page of the Human Cytochrome P450 (CYP) Allele Nomenclature Committee", (www.cypalleles.ki.se/) May 2008	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-01-21
Name/Print	Jayme M. Torelli/	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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.

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	14150575
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First Named Inventor	Wolfgang et al.
Art Unit	
Examiner Name	
Attorney Docket Number	VAND-0002-US-CON2

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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U.S.PATENT APPLICATION PUBLICATIONS

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	1	2006039663	WO	A2	2006-04-13	Wolfgang et al.		☐
	2	2008121899	WO	A2	2008-10-09	Lavedan et al.		☐
	3	2008144599	WO	A2	2008-11-27	Lavedan et al.		☐

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NON-PATENT LITERATURE DOCUMENTS

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	1	Australian IP, Examination Report dated 13-November-2009, Australian Application No.: 2005292246, Attorney Docket No.: VAND-0002-AU, 2 pages.	☐
	2	Patent Cooperation Treaty, International Search Report and the Written Opinion of the International Searching Authority dated 27-November-2009, International Application No.: PCT/US2009/056517, Attorney Docket No.: VAND-0002-CIP-PCT, 18 pages.	☐
	3	CACCIA, "New Antipsychotic Agents for Schizophrenia: Pharmacokinetics and Metabolism Update", July 2002, pages 1073-1080, Current Opinion in Investigational Drugs, Vol. 3, No. 7.	☐

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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
HOFFMAN WARNICK LLC
Attn. Torelli, Jayme M.
75 State Street, 14th Floor
Albany, NY 12207
ETATS-UNIS D'AMERIQUE

PCT

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

(PCT Rule 44.1)

Applicant's or agent's file reference VAND0002-CIP-PCT	Date of mailing *(day/month/year)* 27/11/2009 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2009/056517	International filing date *(day/month/year)* 10/09/2009
Applicant VANDA PHARMACEUTICALS, INC.	

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

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

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

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

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

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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

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

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

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

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

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL–2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Authorized officer Jens Ambrosch

Form PCT/ISA/220 (October 2005) *(See notes on accompanying sheet)*

NOTES TO FORM PCT/ISA/220

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

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

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

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

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

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

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

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

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

Where not to file the amendments?

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

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

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

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

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

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

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

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

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

NOTES TO FORM PCT/ISA/220 (continued)

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

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

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

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1–10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

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

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

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

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

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

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

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

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

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

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

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

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

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

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference VAND0002-CIP-PCT	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2009/056517	International filing date *(day/month/year)* 10/09/2009	(Earliest) Priority Date *(day/month/year)* 10/09/2008
Applicant VANDA PHARMACEUTICALS, INC.		

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

This international search report consists of a total of 4 sheets.

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

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [X] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

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

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

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. _____
      [ ] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/056517

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:

   a. type of material

   [X] a sequence listing

   [ ] table(s) related to the sequence listing

   b. format of material

   [X] on paper

   [ ] in electronic form

   c. time of filing/furnishing

   [X] contained in the international application as filed

   [ ] filed together with the international application in electronic form

   [ ] furnished subsequently to this Authority for the purpose of search

2. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/056517

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K31/454 A61K31/4525 A61K31/439 A61K31/137 A61K31/138
A61P25/00 A61P25/18 A61P25/24 A61K49/00 G01N33/50

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 G01N

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, CHEM ABS Data, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/039663 A (VANDA PHARMACEUTICALS INC [US]; WOLFGANG CURT D [US]; POLYMEROPOULOS M) 13 April 2006 (2006-04-13)	1-37
Y	the whole document	1-21
X	WO 00/59486 A (PFIZER PROD INC [US]; OBACH RONALD SCOTT [US]) 12 October 2000 (2000-10-12) the whole document claims 1,4-6,8,9	1-33

-/--

[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 November 2009	27/11/2009

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	Jakobs, Andreas

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/056517

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CACCIA SILVIO: "New antipsychotic agents for schizophrenia: pharmacokinetics and metabolism update." CURRENT OPINION IN INVESTIGATIONAL DRUGS (LONDON, ENGLAND : 2000) JUL 2002, vol. 3, no. 7, July 2002 (2002-07), pages 1073-1080, XP008115201 ISSN: 1472-4472 the whole document	1-21
P,X	WO 2008/121899 A (VANDA PHARMACEUTICALS INC [US]; LAVEDAN CHRISTIAN [US]; VOLPI SIMONA [) 9 October 2008 (2008-10-09) the whole document	34,35
A	US 2004/091909 A1 (HUANG DOUG HUI [US]) 13 May 2004 (2004-05-13) the whole document	1-37
P,A	WO 2008/144599 A (VANDA PHARMACEUTICALS INC [US]; LAVEDAN CHRISTIAN [US]; VOLPI SIMONA [) 27 November 2008 (2008-11-27) the whole document	1-37
A	MUTLIB A E ET AL: "Application of liquid chromatography/mass spectrometry in accelerating the identification of human liver cytochrome P450 isoforms involved in the metabolism of iloperidone" JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, US, vol. 386, no. 3, 1 September 1998 (1998-09-01), pages 1285-1293, XP002493626 ISSN: 0022-3565 the whole document	1-37

3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/056517

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006039663 A	13-04-2006	AU 2005292246 A1	13-04-2006
		CA 2582022 A1	13-04-2006
		EP 1799865 A2	27-06-2007
		JP 2008514731 T	08-05-2008
WO 0059486 A	12-10-2000	AU 774923 B2	15-07-2004
		AU 3185000 A	23-10-2000
		BG 106075 A	28-06-2002
		BR 0009564 A	08-01-2002
		CA 2367052 A1	12-10-2000
		CN 1479628 A	03-03-2004
		CZ 20013599 A3	15-01-2003
		DZ 3032 A1	27-03-2004
		EE 200100524 A	16-12-2002
		EP 1242058 A1	25-09-2002
		HR 20010722 A2	31-08-2002
		HU 0300535 A2	28-07-2003
		ID 30355 A	22-11-2001
		IS 6083 A	25-09-2001
		JP 3704290 B2	12-10-2005
		JP 2003523936 T	12-08-2003
		MA 26728 A1	20-12-2004
		NO 20014858 A	05-12-2001
		NZ 514466 A	29-10-2004
		OA 11858 A	02-03-2006
		PA 8493401 A1	30-07-2002
		PL 359022 A1	23-08-2004
		SK 13832001 A3	08-01-2004
		SV 2002000049 A	02-12-2002
		TR 200102876 T2	21-12-2006
		UY 26092 A1	31-10-2000
		ZA 200108158 A	24-07-2003
WO 2008121899 A	09-10-2008	NONE	
US 2004091909 A1	13-05-2004	NONE	
WO 2008144599 A	27-11-2008	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2009/056517	10.09.2009	10.09.2008

International Patent Classification (IPC) or both national classification and IPC
INV. A61K31/454 A61K31/4525 A61K31/439 A61K31/137 A61K31/138 A61P25/00 A61P25/18 A61P25/24 A61K49/00 G01N33/50

Applicant
VANDA PHARMACEUTICALS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Jakobs, Andreas Telephone No. +31 70 340-2617

Form PCT/ISA/237 (Cover Sheet) (April 2005)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

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

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☒ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☒ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☒ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 1-21 (partially)

because:

☒ the said international application, or the said claims Nos. 1-21 (with respect to subject matter under Art. 34(4)(a)(i) and Rule 67.1(iv)) relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for the whole application or for said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

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

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-37
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-37
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

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

and / or

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

see form 210

Re Item III.

Claims 1-21 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the subject-matter of these claims as far as relating to methods for treatment of the human or animal body by therapy (Article 34(4)(a)(I) PCT). The opinion regarding these claims is based on the alleged effects of the compound/composition.

No Written Opinion will be formulated with respect to subject matter which is not covered by the search report.

Re Item V.

1 Reference is made to the following documents:

D1 : WO 2006/039663 A (VANDA PHARMACEUTICALS INC [US]; WOLFGANG CURT D [US]; POLYMEROPOULOS M) 13 April 2006 (2006-04-13)

D2 : WO 00/59486 A (PFIZER PROD INC [US]; OBACH RONALD SCOTT [US]) 12 October 2000 (2000-10-12)

D3: CACCIA SILVIO: "New antipsychotic agents for schizophrenia: pharmacokinetics and metabolism update." CURRENT OPINION IN INVESTIGATIONAL DRUGS (LONDON, ENGLAND : 2000) JUL 2002, vol. 3, no. 7, July 2002 (2002-07), pages 1073-1080, XP002556453 ISSN: 1472-4472

2 CLAIMS 1-37

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-37 is not new in the sense of Article 33(2) PCT.
Document D1 discloses the treating of a patient with iloperidone or its salt or metabolite, or a salt of an active metabolite of iloperidone, involving (a) determining

the patient's CYP2D6 genotype and modifying the patent response by use of an inhibitor of CYP2D6 The CYP2D6 inhibitor is chosen from paroxetine, ketoconazole and fluoxetine. The method prevents the risk of prolonged QT in poor metabolizers. A risk assessment for prolonged QT with iloperidone is also disclosed.

2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-33 is not new in the sense of Article 33(2) PCT.
Document D2 discloses the use of venlafaxine as an inhibitor of CYP2D6 for co-administration with drugs for wich the major clearance mechanism is CYP2D6 mediated biotransformation including iloperidone for improving pharmacokinetics of therapeutically useful compounds for their intended use (here the disorders specified in claim 11.

3 Should the applicant overcome the above raised objections of lack of novelty, an inventive step has to be demonstrated over D1-D3, as the present claimed subject matter, as far as novel, appears to be obvious over said documents (Art. 56 EPC).

3.1 The problem to be solved by the present application is to provide for compositions for use in therapy, especially for treating the diseases specified in claim 11.
The proposed solution is to use iloperidone or a salt or metabolite thereof.
The closest prior art (e.g. D1) discloses the use of iloperidone for treating said disorders.
The difference with the present application is that the dose is adjusted in order to prevent undesired side- effects.
The adjustment of the dosage of the active agent is within the normal skills of the practician. Accordingly, the solution proposed in claims 1-21 does not involve an inventive step.

3.2. With respect to the claims containing the specified patient groups having the specified genotypes claimed, the treatment of the same disease with the same compound could represent a novel therapeutic or diagnostic application, provided that two conditions are met:
- (i) the treatment must be carried out on a novel group of subjects which is clearly distinguishable with respect to its physiological or pathological status from and does

not overlap with the group previously treated (see sero-positive vs. sero-negative piglets (T 19/86) or haemophilic patient vs. normal, non-haemophilic subjects (T 893/90);
- (ii) the choice of the new group, if distinguishable from the known one, must not be arbitrary, which means that there must exist a functional relationship between the particular physiological or pathological status of this new group and the therapeutic effect obtained. In other words, the peculiar feature identifying the new group of patients must have a real impact on the result of the treatment, since it is able finally to "change" the treatment itself.

3.3 The attention of the applicant is drawn to the fact that in the present application, there is at least some overlap between the specified geneotypes, on one side and and the previously treated patients on the other side. Consequently, patentability of the claims is excluded because they would not be novel.

3.4 Should the applicant overcome the above raised objections of lack of novelty, an inventive step has to be demonstrated over D1,D3, as the present claimed subject matter, as far as novel, appears to be obvious over said documents (Art. 56 EPC). D3 clearly shows that CYP2D6 is not the only enzyme involved in metabolizing lloperidone. Accordingly, there is no a unique correlation between the genotype and the pharmacokinetics of lloperidone.
The attention of the Applicant is drawn to the fact that all embodiments covered by the claims should satisfy the criteria of inventive step. When the inventive step is solely based on the achievement of a technical effect, such as the determination of the amount of lloperidone in the present case, substantially all embodiments should exhibit this effect. It must be credible that all the alternatives claimed must be a solution to the problem.
However, it is evident that the CYP2D6 genotype is not the only factor to be comsidered for determining the amound of lloperidone and of the CYP2D6 inhibitors. Therefore, as part of the subject-matter of claims 1-21 does not exhibit the claimed activity in a credible manner, said subject-matter cannot involve an inventive step.

4 DEPENDENT CLAIMS 2-12, 14-18, 20, 21, 23-33, 35-37

Dependent claims 2-12, 14-18, 20, 21, 23-33, 35-37 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

5 Claims 1-21 relate to a subject-matter considered by this Authority to be covered by the provision of Rule 39.1(iv)/67.1(iv) PCT.
The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment

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

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

XS CPRTENFRDE

BNSDOCID: <XS____2006100103CF_I_>

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14150575
Filing Date	2014-01-08
First Named Inventor	Curt Wolfgang et al.
Art Unit	
Examiner Name	
Attorney Docket Number	VAND-0002-US-CON2

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	1	20020022054	A1	2002-02-21	Sawada et al.	

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	1	0055624	WO	A2	2000-09-21	Leyland-Jones et al.		☐
	2	0149883	WO	A2	2001-07-12	Katz et al.		☐
	3	0250283	WO	A2	2002-06-27	Guegler et al.		☐

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	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
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	4	03017946	WO	A2	2003-03-06	Druzgala		☐

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	1	JOHANNSEN, Office Action Communication for Application No. 11/576,178 dated September 29, 2011, Attorney Docket No. VAND-0002-US, 19 pages.	☐

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	Attorney Docket Number	VAND-0002-US-CON2

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

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International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	21-JAN-2014
Filing Date:	
Time Stamp:	16:11:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	VAND-0002-US-CON2_IDSPTOSB08a_1_PRIMO.pdf	78263 2f0d0c3f8f73dc990b6893d225444326d1d73369	no	7

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6	Foreign Reference	WO2004009760A3.pdf	125648 6d792fd155c170c0d821b84d56ba5b07c71d6552	no	3
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9	Non Patent Literature	CHAINUVATI_CombinedPhenotypicAssessmentOfCytochromeP450.pdf	237839 c86c1dfb69cc03f0822ff4dfd24a3dfd9ab0989f	no	11
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13	Non Patent Literature	HomePage_Cytochrome_P450_PA.pdf	88670 df75e08fe3e3504634d28c6f570ddd8dacaa5564	no	2
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19	Non Patent Literature	Lyamichev_PolymorphismIdentificationAndQuantitative_PA.pdf	618831 b194e330da9cc38be1c843a9c2ea8730a708d299	no	5

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31	Non Patent Literature	VAND-0002-CIP-PCT_SearchReport-WrittenOpinion_27Nov2009_PA.pdf	590100 27812ec35b7bf244baa9cf37aa576609ec17a8c1	no	18
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45	Non Patent Literature	VAND-0002-CIP-PCT_InternationalPreliminaryReportOnPatentability_24Mar2011.pdf	275599 3ebee68bcfa27cc105feae8544b8b4d75d926864	no	10
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46	Non Patent Literature	VAND-0002-US_FinalOfficeAction1_02-17-201_PA1.pdf	882969 eca9de3fba4325fc7c06010239a517a86d7de6b3	no	21
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48	Foreign Reference	WO2010030783A1_VAND-0002-PCT-CIP_Publication.pdf	1724734 87451f182e85fbba8122e50223caa41e7d052cc8	no	45
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59	Non Patent Literature	VAND-0002-US_OfficeAction2_9-29-11.pdf	734233 c0bf2bf28c4f9d6d44edce8ebc36dc98889ae0e6	no	19
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang, et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

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	1	2010030783	WO	A1	2010-03-18	Wolfgang et al.		☐
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang, et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

	1	Patent Cooperation Treaty, Notification of Transmittal of the International Search Report and The Written Opinion of the International Searching Authority, or the Declaration for PCT/US2005/035526 dated 23 August 2006, Attorney Docket No. VAND-0002-PCT, 11 pages.	☐
	2	Patent Cooperation Treaty, Notification of Transmittal of the International Preliminary Report on Patentability for PCT/US2005/035526 dated 8 June 2007, Attorney Docket No. VAND-0002-PCT, 5 pages.	☐
	3	European Patent Office, Extended Search Report for Application No. 05803436.4 dated 25 Feb 2008, Attorney Docket No. VAND-0002-EP, 12 pages.	☐
	4	European Patent Office, Examination Report for Application No. 05803436.4 dated 28 May 2008, Attorney Docket No. VAND-0002-EP, 1 page.	☐
	5	JOHANNSEN, Office Communication Restriction Requirement for Application No. 11/576,178 dated December 30, 2009, Attorney Docket No. VAND-0002-US, 7 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang, et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-01-21
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
STEPHEN F. SWINTON, JR.
HOFFMAN, WARNICK & D'ALESSANDRO LLC
75 STATE STREET, 14TH FLOOR
ALBANY, NY 12207

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	08 JUN 2007
Applicant's or agent's file reference VAND-0002-PC	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/35526	30 September 2005 (30.09.2005)	30 September 2004 (30.09.2004)

Applicant

VANDA PHARMACEUTICALS, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

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

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

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

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Diana B. Johannsen Telephone No. 571/272-1600

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference VAND-0002-PC	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US05/35526	International filing date *(day/month/year)* 30 September 2005 (30.09.2005)	Priority date *(day/month/year)* 30 September 2004 (30.09.2004)

International Patent Classification (IPC) or national classification and IPC

IPC: Please See Continuation Sheet
USPC: 435/6,7.1,287.2;424/9.2;514/321;536/23.2,23.5,24.31

Applicant

VANDA PHARMACEUTICALS, INC.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19 October 2006 (19.10.2006)	25 May 2007 (25.05.2007)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Diana B. Johannsen Telephone No. 571/272-1600

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/35526

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-24 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 25-35 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:
pages none as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Form PCT/IPEA/409 (Box No. I) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/35526

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-42 and 47-55	YES
	Claims 43-46	NO
Inventive Step (IS)	Claims 3-6,8,11-13,31,32 and 47-55	YES
	Claims 1-2,7,9-10,14-30,33-46	NO
Industrial Applicability (IA)	Claims 1-55	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-2, 7, 9-10, 14-28 and 33-42 lack an inventive step under PCT Article 33(3) as being obvious over Obach (US 2003/0144220 A1 [31 July 2003]). Obach discloses the use together of CYP2D6 inhibitors and drugs metabolized by CYP2D6 (see entire reference). Obach discloses that the activity of CYP2D6 varies with genotype (see, e.g., paragraphs 5-7), and teaches that iloperidone is one drug metabolized by CYP2D6 (see, e.g., paragraphs 28 and 42). Obach teaches administration of an appropriate amount of each drug to a patient, and discloses determining whether a patients is a poor or extensive metabolizer (see, e.g., paragraphs 52, 58-67) Obach further teaches CYP2D6 inhibitors of the claims (see, e.g., paragraphs 19 and 31), and teaches monitoring blood levels of compounds administered to patients (see, e.g., paragraphs 63-67). Accordingly, Obach suggests the claimed invention.

Claims 29-30 lack an inventive step under PCT Article 33(3) as being obvious over Jain (Expert Opinion on Investigational Drugs 9(12):2935-2943 [2000]). Jain discloses that both iloperidone and sertindole are antipsychotic agents that may be used to treat schizophrenia, and further teach that sertindole "may produce slowing of QT interval with risk of cardiac arrhythmias"(see entire reference, particular page 2941). It would have been obvious to an ordinary artisan to have assayed patients taking iloperidone for possible effects on QT interval, as set forth in the instant claims. An ordinary artisan would have been motivated to have conducted such assays to determine whether iloperidone affects QT interval in a patient (or, e.g., in a group or subgroup of patients), for the advantage of establishing whether iloperidone may be safely used in treating said patient(s). Regarding claim 30, it is noted that Jain also teach a 24 mg daily dose of iloperidone (see page 2940, right column).

Claims 43-46 lack novelty under PCT Article 33(2) as being anticipated by Bee et al (US 2002/0127561 A1). Bee et al disclose kits comprising components meeting all the requirements of the claims (see, e.g., paragraphs 54-60). Accordingly, Bee et al anticipate the claimed invention.

Claims 1-51 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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

Supplemental Box

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

Continuation of:

Continuation of IPC:
C12Q 1/68(2006.01);**G01N 33/53**(2006.01);**C12M 1/34**(2006.01);**A61K 49/00**(2006.01);**C07H 21/04**(2006.01)
A61K 38/00(2006.01)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
STEPHEN F. SWINTON, JR.
HOFFMAN, WARNICK & D'ALESSANDRO LLC
75 STATE STREET, 14TH FLOOR
ALBANY, NY 12207

PCT

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

(PCT Rule 44.1)

	Date of mailing (*day/month/year*)
Applicant's or agent's file reference VAND-0002-PC	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US05/35526	International filing date (*day/month/year*) 30 September 2005 (30.09.2005)
Applicant VANDA PHARMACEUTICALS, INC.	

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

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

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

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

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

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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

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

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

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

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

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Diana B. Johannsen Telephone No. 571/272-1600

Form PCT/ISA/220 (January 2004) (*See notes on accompanying sheet*)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
STEPHEN F. SWINTON, JR.
HOFFMAN, WARNICK & D'ALESSANDRO LLC
75 STATE STREET, 14TH FLOOR
ALBANY, NY 12207

PCT

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

(PCT Rule 44.1)

	Date of mailing (*day/month/year*) 23 AUG 2006
Applicant's or agent's file reference VAND-0002-PC	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US05/35526	International filing date (*day/month/year*) 30 September 2005 (30.09.2005)
Applicant VANDA PHARMACEUTICALS, INC.	

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

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

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

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

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

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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

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

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

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

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

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Diana B. Johannsen Telephone No. 571/272-1600

Form PCT/ISA/220 (January 2004) (*See notes on accompanying sheet*)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference VAND-0002-PC	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US05/35526	International filing date (*day/month/year*) 30 September 2005 (30.09.2005)	(Earliest) Priority Date (*day/month/year*) 30 September 2004 (30.09.2004)
Applicant VANDA PHARMACEUTICALS, INC.		

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

This international search report consists of a total of 4 sheets.

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

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☒ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

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

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

Form PCT/ISA/210 (first sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/35526

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

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

1. ☒ Claims Nos.: 52-55
because they relate to subject matter not required to be searched by this Authority, namely:
the claims are drawn to mere presentations of information, and/or methods of doing business, which subject matter need not be searched, as set forth in PCT Rule 39.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/35526

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **C12Q 1/68**(2006.01);**A61K 49/00**(2006.01);**C12M 1/34**(2006.01);**G01N 33/53**(2006.01);**C07H 21/04**(2006.01) A61K 38/00(2006.01)

USPC: 435/6,7.1,287.2;424/9.2;514/321;536/23.2,23.5,24.31
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)
U.S. : 435/6,7.1,287.2;424/9.2;514/321;536/23.2,23.5,24.31

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 practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0127561 A1 (BEE et al) 12 September 2002 (12.09.2002), see entire reference, particularly paragraphs 54-60.	43-46
X	US 2003/0144220 A1 (OBACH) 31 July 2003 (31.07.2003), see entire reference, particularly paragraphs 5-7, 19, 28, 31, 42, 52, 58-67.	1-2,7,9-10,14-28,33-42
X	JAIN, K.K. An assessment of iloperidone for the treatment of schizophrenia. Expert Opinion on Investigational Drugs. 2000, Vol. 9, No. 12, pages 2935-2943, see entire reference, particularly pages 2940-2941.	29-30

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

* Special categories of cited documents:

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

"E" earlier application or patent 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
21 July 2006 (21.07.2006)	23 AUG 2006
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Diana B. Johannsen Telephone No. 571/272-1600

Form PCT/ISA/210 (second sheet) (April 2005)

Continuation of B. FIELDS SEARCHED Item 3:
Biosis, Caplus, Drugu, Embase, Medline, Scisearch, Toxcenter, USPT, PGPB, DWPI
search terms: iloperidone, zomaril, hp 873, cyp####, p450####, p 450, cyp2d6, kit, probe, primer, oligonucleotide, polynucleotide, device, instructions, qt### interval; inventors' names

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
STEPHEN F. SWINTON, JR.
HOFFMAN, WARNICK & D'ALESSANDRO LLC
75 STATE STREET, 14TH FLOOR
ALBANY, NY 12207

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	23 AUG 2006
Applicant's or agent's file reference VAND-0002-PC	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/35526	30 September 2005 (30.09.2005)	30 September 2004 (30.09.2004)

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

IPC: Please See Continuation Sheet
USPC: 435/6,7.1,287.2;424/9.2;514/321;536/23.2,23.5,24.31

Applicant

VANDA PHARMACEUTICALS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	24 July 2006 (24.07.2006)	Diana B. Johannsen Telephone No. 571/272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/35526

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/35526

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

1. Statement

Novelty (N)	Claims 1-42 and 47-55	YES
	Claims 43-46	NO
Inventive step (IS)	Claims 3-6,8,11-13,31,32 and 47-55	YES
	Claims 1-2,7,9-10,14-30,33-46	NO
Industrial applicability (IA)	Claims 1-55	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-2, 7, 9-10, 14-28 and 33-42 lack an inventive step under PCT Article 33(3) as being obvious over Obach (US 2003/0144220 A1 [31 July 2003]). Obach discloses the use together of CYP2D6 inhibitors and drugs metabolized by CYP2D6 (see entire reference). Obach discloses that the activity of CYP2D6 varies with genotype (see, e.g., paragraphs 5-7), and teaches that iloperidone is one drug metabolized by CYP2D6 (see, e.g., paragraphs 28 and 42). Obach teaches administration of an appropriate amount of each drug to a patient, and discloses determining whether a patients is a poor or extensive metabolizer (see, e.g., paragraphs 52, 58-67) Obach further teaches CYP2D6 inhibitors of the claims (see, e.g., paragraphs 19 and 31), and teaches monitoring blood levels of compounds administered to patients (see, e.g., paragraphs 63-67). Accordingly, Obach suggests the claimed invention.

Claims 29-30 lack an inventive step under PCT Article 33(3) as being obvious over Jain (Expert Opinion on Investigational Drugs 9(12):2935-2943 [2000]). Jain discloses that both iloperidone and sertindole are antipsychotic agents that may be used to treat schizophrenia, and further teach that sertindole "may produce slowing of QT interval with risk of cardiac arrhythmias"(see entire reference, particular page 2941). It would have been obvious to an ordinary artisan to have assayed patients taking iloperidone for possible effects on QT interval, as set forth in the instant claims. An ordinary artisan would have been motivated to have conducted such assays to determine whether iloperidone affects QT interval in a patient (or, e.g., in a group or subgroup of patients), for the advantage of establishing whether iloperidone may be safely used in treating said patient(s). Regarding claim 30, it is noted that Jain also teach a 24 mg daily dose of iloperidone (see page 2940, right column).

Claims 43-46 lack novelty under PCT Article 33(2) as being anticipated by Bee et al (US 2002/0127561 A1). Bee et al disclose kits comprising components meeting all the requirements of the claims (see, e.g., paragraphs 54-60). Accordingly, Bee et al anticipate the claimed invention.

Claims 1-55 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/35526

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

Continuation of IPC:
C12Q 1/68(2006.01);**G01N 33/53**(2006.01);**C12M 1/34**(2006.01);**A61K 49/00**(2006.01);**C07H 21/04**(2006.01)
A61K 38/00(2006.01)

Form PCT/ISA/237 (Supplemental Box) (April 2005)

NOTES TO FORM PCT/ISA/220

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

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

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

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

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

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

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

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

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

Where not to file the amendments ?

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

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

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

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

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

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

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

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

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

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14150575
Filing Date	2014-01-08
First Named Inventor	Curt Wolfgang et al.
Art Unit	
Examiner Name	
Attorney Docket Number	VAND-0002-US-CON2

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0059486	WO	A2	2000-10-12	OBACH		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

	1	Australian IP, Examination Report dated 12 January 2011, Australian Application No.: 2005292246, Attorney Docket No.: VAND-0002-AU, 2 pages.	☐
	2	Patent Cooperation Treaty, International Preliminary Report on Patentability of the International Searching Authority dated 24 March 2011, International Application No.: PCT/US2009/056517, Attorney Docket No.: VAND0002-CIP-PCT, 10 pages.	☐
	3	JOHANNSEN, Final Office Action Communication for Application Serial Number 11/576,178 Dated February 17, 2011, Attorney Docket No. VAND-0002-US, 21 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-01-21
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

PATENT COOPERATION TREATY

ADVANCE E-MAIL

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

TORELLI, Jayme, M.
Hoffman Warnick LLC
75 State Street, 14th Floor
Albany, NY 12207
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)* 24 March 2011 (24.03.2011)	
Applicant's or agent's file reference VAND0002-CIP-PCT	IMPORTANT NOTICE

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2009/056517	10 September 2009 (10.09.2009)	10 September 2008 (10.09.2008)

Applicant: VANDA PHARMACEUTICALS, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Beate Giffo-Schmitt

e-mail: pt03.pct@wipo.int

Form PCT/IB/326 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference VAND0002-CIP-PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2009/056517	International filing date *(day/month/year)* 10 September 2009 (10.09.2009)	Priority date *(day/month/year)* 10 September 2008 (10.09.2008)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant VANDA PHARMACEUTICALS, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 15 March 2011 (15.03.2011)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Beate Giffo-Schmitt
Facsimile No. +41 22 338 82 70	e-mail: pt03.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2009/056517	10.09.2009	10.09.2008

International Patent Classification (IPC) or both national classification and IPC
INV. A61K31/454 A61K31/4525 A61K31/439 A61K31/137 A61K31/138 A61P25/00 A61P25/18 A61P25/24 A61K49/00 G01N33/50

Applicant
VANDA PHARMACEUTICALS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Jakobs, Andreas Telephone No. +31 70 340-2617

Form PCT/ISA/237 (Cover Sheet) (April 2005)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

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

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☒ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☒ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☒ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 1-21 (partially)

because:

☒ the said international application, or the said claims Nos. 1-21 (with respect to subject matter under Art. 34(4)(a)(i) and Rule 67.1(iv)) relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for the whole application or for said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

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

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-37
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-37
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

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

and / or

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

see form 210

Re Item III.

Claims 1-21 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the subject-matter of these claims as far as relating to methods for treatment of the human or animal body by therapy (Article 34(4)(a)(I) PCT). The opinion regarding these claims is based on the alleged effects of the compound/composition.

No Written Opinion will be formulated with respect to subject matter which is not covered by the search report.

Re Item V.

1 Reference is made to the following documents:

D1 : WO 2006/039663 A (VANDA PHARMACEUTICALS INC [US]; WOLFGANG CURT D [US]; POLYMEROPOULOS M) 13 April 2006 (2006-04-13)

D2 : WO 00/59486 A (PFIZER PROD INC [US]; OBACH RONALD SCOTT [US]) 12 October 2000 (2000-10-12)

D3: CACCIA SILVIO: "New antipsychotic agents for schizophrenia: pharmacokinetics and metabolism update." CURRENT OPINION IN INVESTIGATIONAL DRUGS (LONDON, ENGLAND : 2000) JUL 2002, vol. 3, no. 7, July 2002 (2002-07), pages 1073-1080, XP002556453 ISSN: 1472-4472

2 CLAIMS 1-37

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-37 is not new in the sense of Article 33(2) PCT.
Document D1 discloses the treating of a patient with iloperidone or its salt or metabolite, or a salt of an active metabolite of iloperidone, involving (a) determining

the patient's CYP2D6 genotype and modifying the patent response by use of an inhibitor of CYP2D6 The CYP2D6 inhibitor is chosen from paroxetine, ketoconazole and fluoxetine. The method prevents the risk of prolonged QT in poor metabolizers. A risk assessment for prolonged QT with iloperidone is also disclosed.

2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-33 is not new in the sense of Article 33(2) PCT.
Document D2 discloses the use of venlafaxine as an inhibitor of CYP2D6 for co-administration with drugs for wich the major clearance mechanism is CYP2D6 mediated biotransformation including iloperidone for improving pharmacokinetics of therapeutically useful compounds for their intended use (here the disorders specified in claim 11.

3 Should the applicant overcome the above raised objections of lack of novelty, an inventive step has to be demonstrated over D1-D3, as the present claimed subject matter, as far as novel, appears to be obvious over said documents (Art. 56 EPC).

3.1 The problem to be solved by the present application is to provide for compositions for use in therapy, especially for treating the diseases specified in claim 11.
The proposed solution is to use iloperidone or a salt or metabolite thereof.
The closest prior art (e.g. D1) discloses the use of iloperidone for treating said disorders.
The difference with the present application is that the dose is adjusted in order to prevent undesired side- effects.
The adjustment of the dosage of the active agent is within the normal skills of the practician. Accordingly, the solution proposed in claims 1-21 does not involve an inventive step.

3.2. With respect to the claims containing the specified patient groups having the specified genotypes claimed, the treatment of the same disease with the same compound could represent a novel therapeutic or diagnostic application, provided that two conditions are met:
- (i) the treatment must be carried out on a novel group of subjects which is clearly distinguishable with respect to its physiological or pathological status from and does

not overlap with the group previously treated (see sero-positive vs. sero-negative piglets (T 19/86) or haemophilic patient vs. normal, non-haemophilic subjects (T 893/90);
- (ii) the choice of the new group, if distinguishable from the known one, must not be arbitrary, which means that there must exist a functional relationship between the particular physiological or pathological status of this new group and the therapeutic effect obtained. In other words, the peculiar feature identifying the new group of patients must have a real impact on the result of the treatment, since it is able finally to "change" the treatment itself.

3.3 The attention of the applicant is drawn to the fact that in the present application, there is at least some overlap between the specified geneotypes, on one side and and the previously treated patients on the other side. Consequently, patentability of the claims is excluded because they would not be novel.

3.4 Should the applicant overcome the above raised objections of lack of novelty, an inventive step has to be demonstrated over D1,D3, as the present claimed subject matter, as far as novel, appears to be obvious over said documents (Art. 56 EPC). D3 clearly shows that CYP2D6 is not the only enzyme involved in metabolizing Iloperidone. Accordingly, there is no a unique correlation between the genotype and the pharmacokinetics of Iloperidone.
The attention of the Applicant is drawn to the fact that all embodiments covered by the claims should satisfy the criteria of inventive step. When the inventive step is solely based on the achievement of a technical effect, such as the determination of the amount of Iloperidone in the present case, substantially all embodiments should exhibit this effect. It must be credible that all the alternatives claimed must be a solution to the problem.
However, it is evident that the CYP2D6 genotype is not the only factor to be comsidered for determining the amound of Iloperidone and of the CYP2D6 inhibitors. Therefore, as part of the subject-matter of claims 1-21 does not exhibit the claimed activity in a credible manner, said subject-matter cannot involve an inventive step.

4 DEPENDENT CLAIMS 2-12, 14-18, 20, 21, 23-33, 35-37

Dependent claims 2-12, 14-18, 20, 21, 23-33, 35-37 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

5 Claims 1-21 relate to a subject-matter considered by this Authority to be covered by the provision of Rule 39.1(iv)/67.1(iv) PCT.
The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0244994	WO	A2	2002-06-06	Brower et al.		☐
	2	0179554	WO	A1	2001-10-25	Woosley		☐
If you wish to add additional Foreign Patent Document citation information please click the Add button							Add	

NON-PATENT LITERATURE DOCUMENTS	Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	JOHANNSEN, Office Action Summary for U.S. Application No. 11/576,178 dated 05/03/2010, Attorney Docket No. VAND-0002-US, 24 pages.	☐
	2	European Patent Office, Examination Report for Application No. 05803436.1 dated 04/21/2010, 8 pages.	☐
	3	FUSELLI et al., "Molecular diversity at the CYP2D6 locus in the Mediterranean region," November 2004, pages 916-924, European Journal of Human Genetics, Vol. 12, No. 11, ISSN: 1018-4813.	☐
	4	SACHSE et al., "Cytochrome P450 2D6 Variants in a Caucasian Population: Allele Frequencies and Phenotypic Consequences," February 1997, pages 284-295, American Journal of Human Genetics, Vol. 60, No. 2, ISSN: 0002-9297.	☐
	5	WANG et al., "G169R Mutation Diminishes the Metabolic Activity of CYP2D6 in Chinese," March 1999, pages 385-388, Drug Metabolism and Disposition, Vol. 27, No. 3, XP-001036785, ISSN: 0900-9558.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-01-21
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT2689904

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT

CONVEYING PARTY DATA

Name	Execution Date
CURT WOLFGANG	01/07/2014
MIHAEL POLYMEROPOULOS	01/07/2014

RECEIVING PARTY DATA

Name:	Vanda Pharmaceuticals, Inc.
Street Address:	2200 Pennsylvania Avenue
Internal Address:	Suite 300-E
City:	Washington
State/Country:	DISTRICT OF COLUMBIA
Postal Code:	20037

PROPERTY NUMBERS Total: 1

Property Type	Number
Application Number:	14150575

CORRESPONDENCE DATA

Fax Number: (518)449-0047
Phone: 518-449-0044
Email: vfleming@hoffmanwarnick.com
Correspondence will be sent via US Mail when the email attempt is unsuccessful.
Correspondent Name: HOFFMAN WARNICK LLC
Address Line 1: 540 BROADWAY
Address Line 2: 4TH FLOOR
Address Line 4: ALBANY, NEW YORK 12207

ATTORNEY DOCKET NUMBER:	VAND-0002-US-CON2
NAME OF SUBMITTER:	JAYME M. TORELLI
Signature:	/Jayme M. Torelli/

Date:	01/21/2014
	This document serves as an Oath/Declaration (37 CFR 1.63).
Total Attachments: 2 source=VAND-0002-US-CON2_Declaration_signed#page1.tif source=VAND-0002-US-CON2_Declaration_signed#page2.tif	

DOCKET NUMBER: VAND-0002-US-CON2

DECLARATION (37 C.F.R. 1.63) FOR UTILITY PATENT APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. 1.76) AND ASSIGNMENT

Title of Invention: **METHODS FOR THE ADMINISTRATION OF ILOPERIDONE**

As a below named and undersigned inventor, I hereby declare that:

This declaration is directed to the attached application, or (if following box is checked):

[X] United States application or PCT international application number 14/150,575 filed on January 8, 2014 .

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

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

I have reviewed and understand the contents of the application, including the claims.

I am aware of the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in 37 CFR Section 1.56.

Whereas, I ("ASSIGNOR") have made certain inventions, improvements, and discoveries (herein referred to as the "Invention") disclosed in the above-identified patent application and further identified by the Docket Number provided above in the header of this document;

Whereas, Vanda Pharmaceuticals, Inc. (herein referred to as the "ASSIGNEE"), a corporation of Delaware, having a place of business at Washington, DC, desires to acquire, and I desire to grant to the ASSIGNEE, my entire worldwide right, title, and interest in and to the Invention and in and to any and all patent applications and patents directed thereto;

Now, therefore, for good and valuable consideration, the receipt and sufficiency thereof being hereby acknowledged, I hereby sell or have sold, assign or have assigned, and otherwise transfer or have transferred to the ASSIGNEE, its successors, legal representatives, and assigns, my entire worldwide right, title, and interest in and to the Invention, the above-identified United States patent application, and any and all other patent applications and patents for the Invention which may be applied for or granted therefor in the United States and in all foreign countries and jurisdictions, including all divisions, continuations, reissues, reexaminations, renewals, extensions, counterparts, substitutes, and extensions thereof, and all rights of priority resulting from the filing of such applications and granting of such patents. In addition, I hereby authorize and request the Director of the United States Patent and Trademark Office to issue any United States Patent, and foreign patent authorities to issue any foreign patent, granted for the Invention, to the ASSIGNEE, its successors, legal representatives, and assigns, my entire worldwide right, title, and interest in and to the same to be held and enjoyed by the ASSIGNEE, its successors, legal representatives, and assigns to the full end of the terms for which any and all such patents may be granted, as fully and entirely as would have been held and enjoyed by me had this Assignment not been made; and I agree to execute any and all documents and instruments and perform all lawful acts reasonably related to recording this Assignment or perfecting title to the Invention and all related patents and applications, in the ASSIGNEE, its successors, legal representatives, and assigns, whenever requested by the ASSIGNEE, its successors, legal representatives, or assigns.

I acknowledge my prior and ongoing obligations to sell, assign, and transfer my rights under this Assignment to the ASSIGNEE and am unaware of any reason why I may not have the full and unencumbered right to sell, assign, and transfer my rights hereby sold, assigned, and transferred, and have not executed, and will not execute, any document or instrument in conflict herewith. I also hereby grant the ASSIGNEE, its successors, legal representatives, and assigns, the right to insert in this Assignment any further identification (including, but not limited to, patent Application Number) which may be necessary or desirable for recordation of this Assignment. This Assignment is governed by the substantive laws of the State of New York, and any disputes will be resolved in a New York state court or federal court sited in New York.

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.

(1) Legal Name of Inventor: **Curt Wolfgang**

Signature: _____ Date: 7 Jan 2014

(2) Legal Name of Inventor: **Mihael Polymeropoulos**

Signature: _____ Date: 1/7/14

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/150,575

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	9 minus 20 =	*			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1600

APPLICATION AS AMENDED - PART II

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

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

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

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

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2

CONFIRMATION NO. 1033

23550
HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

POA ACCEPTANCE LETTER

OC000000066251592

Date Mailed: 01/30/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/08/2014.

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

/tha/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/150,575	01/08/2014	1621	1600	VAND-0002-US-CON2	9	1

CONFIRMATION NO. 1033

23550
HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

FILING RECEIPT

OC000000066251563

Date Mailed: 01/30/2014

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

Inventor(s)

Curt Wolfgang, Germantown, MD;
Mihael Polymeropoulos, Potomac, MD;

Applicant(s)

Vanda Pharmaceuticals, Inc., Washington, DC

Assignment For Published Patent Application

Vanda Pharmaceuticals, Inc., Washington, DC

Power of Attorney: The patent practitioners associated with Customer Number 23550

Domestic Priority data as claimed by applicant

This application is a CON of 14/060,978 10/23/2013
which is a CON of 11/576,178 03/28/2007 PAT 8586610
which is a 371 of PCT/US05/35526 09/30/2005
which claims benefit of 60/614,798 09/30/2004

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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

If Required, Foreign Filing License Granted: 01/24/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/150,575**

Projected Publication Date: 05/08/2014

Non-Publication Request: No

Early Publication Request: No
Title

METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

Preliminary Class

514

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

NOT GRANTED

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

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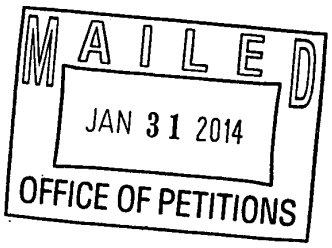

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/150,575

1. THE REQUEST FILED January 8, 2014 IS **GRANTED.**

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

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

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

/Brian W. Brown/
[*Signature*]

Petitions Examiner, Office of Petitions
(Title)

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1621
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

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NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1621
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

	1	RAIMUNDO et al., "A novel intronic mutation, 2988G>A, with high predictivity for impaired function of cytochrome P450 2D6 in white subjects," 2004, pages 128-138, Clinical Pharmacology & Therapeutics, Vol. 76, No. 2.	☐
	2	GAEDIGK et al., "Delection of the Entire Cytochrome P450 CYP2D6 Gene as a Cause of Impaired Drug Metabolism in Poor Metabolizers of the Debrisoquine/Sparteine Polymorphism," 1991, pages 943-950, Am. J. Hum. Genet., Vol. 48.	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1621
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-03-06
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

Electronic Acknowledgement Receipt

EFS ID:	18388418
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	06-MAR-2014
Filing Date:	08-JAN-2014
Time Stamp:	13:59:27
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)	VAND-0002-US-CON2_Suppl_IDSPTOSB08a_03-06-2014.pdf	612525 2bb2460e7ce6195f3b217d8220624185b00f8f94	no	4

Warnings:	
Information:	

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Non Patent Literature	Raimundo_ClinPharmacol.pdf	840590 3ed3cbe84c06e2f2c02ea8e3b16b3aaabecba949	no	12
Warnings:					
Information:					
3	Non Patent Literature	Gaedigk_AmJournalHum.pdf	489654 e85eddc3a0d53e38b708d78972300274c2ec85be	no	9
Warnings:					
Information:					
			Total Files Size (in bytes):	1942769	

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.

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 03/10/2014

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

NOTIFICATION DATE	DELIVERY MODE
03/10/2014	ELECTRONIC

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

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

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

PTOCommunications@hoffmanwarnick.com

Office Action Summary	Application No. 14/150,575	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	Art Unit 1634	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☐ Responsive to communication(s) filed on _____.

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

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

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

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

Disposition of Claims*

5)☒ Claim(s) 1-9 is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

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

9)☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

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

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Election/Restrictions

1. The present application is being examined under the pre-AIA first to invent provisions. Applicant is reminded that **this application is undergoing prioritized examination under Track 1**, and that the filing of any extensions of time will result in the loss of special status (see the Decision mailed January 31, 2014, particularly paragraph 2).

2. This application contains claims directed to the following patentably distinct species: the four different drugs "that inhibit CYP2D6" specified in dependent claim 3 (see also claims 4-5, dependent from claim 3). The species are independent or distinct because paroxetine (trade name Paxil), dolasetron (trade name Anzemet), venlaxafine (trade name Effexor) and fluoxetine (trade name Prozac) are structurally and functionally distinct drugs. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2 are generic with respect to the alternatives specified in dependent claims 3-5.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: the species require different fields of search including the use of different search strategies and queries (and it is noted that there are extensive [and non-overlapping] bodies of prior art

literature related to the different species set forth in the claims based on a preliminary text search).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the

evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA B. JOHANNSEN whose telephone number is (571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. 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.

/DIANA B JOHANNSEN/
Primary Examiner, Art Unit 1634

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Curt Wolfgang, et al.	**Conf. No**.:	1033
Serial No.:	14/150,575	**Art. Unit**:	1634
Filed:	January 8, 2014	**Examiner**:	Diana B. Johannsen
		Docket. No.:	VAND-0002-US-CON2

Title: METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

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

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

I. INTRODUCTORY COMMENTS

This paper is being filed in response to the Restriction Requirement dated March 10, 2014.

II. AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all previous and prior listings of the claims.

1. (Original) A method of treating a patient, who is suffering from schizophrenia, with iloperidone, the method comprising:

if the patient is not also being treated with a drug that inhibits CYP2D6, then internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day, and

if the patient is also being treated with a drug that inhibits CYP2D6, then internally administering to the patient an amount of iloperidone that is 12 mg/day or less.

2. (Original) The method of claim 1, wherein the risk of QT prolongation is reduced in a patient that is also being treated with a drug that inhibits CYP2D6.

3. (Currently amended) The method of claim 2 wherein the drug that inhibits CYP2D6 is ~~paroxetine, dolasetron, venlaxafin, or~~ fluoxetine.

4. (Currently amended) The method of claim 3 wherein the patient is being treated with iloperidone and is also being treated with ~~paroxetine or~~ fluoxetine, the method comprising internally administering to the patient an amount of iloperidone that is 12 mg/day or less.

5. (Original) The method of claim 4 wherein the amount of iloperidone is 12 mg/day.

6. (Original) The method of claim 1 wherein the patient is not also being treated with a CYP2D6 inhibitor, the method comprising internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day.

7. (Original) The method of claim 2 wherein the patient is not also being treated with a CYP2D6 inhibitor, the method comprising internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day.

8. (Original) The method of claim 6 wherein the amount of iloperidone is 24 mg/day.

9. (Original) The method of claim 7 wherein the amount of iloperidone is 24 mg/day.

10. (New, Withdrawn) The method of claim 2 wherein the drug that inhibits CYP2D6 is paroxetine, dolasetron, or venlaxafin.

11. (New, Withdrawn) The method of claim 10, wherein the patient is being treated with iloperidone and is also being treated with paroxetine, the method comprising internally administering to the patient an amount of iloperidone that is 12 mg/day or less.

12. (New, Withdrawn) The method of claim 11, wherein the amount of iloperidone is 12 mg/day.

III. REMARKS

Claims 1-12 are pending in this application. By this Response, claims 3-4 are amended, and claims 10-12 are newly added and concurrently withdrawn from consideration.

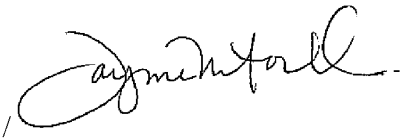
In the Restriction Requirement the Office requires election between the following four species, alleged to be patentably distinct: paroxetine, dolasetron, venlaxafin, and fluoxetine, identified in claim 3 (and also claims 4-5, which depend from claim 3).

By this Response, Applicants elect the species fluoxetine (claims 3-5), and have amended claims 3 and 4 to delete the non-elected paroxetine, dolasetron, and venlaxafin species therefrom.

New claims 10-12 are added and concurrently withdrawn from consideration, reciting the non-elected subject matter deleted from claims 3-5 as noted above. Applicants note that claims 1-2 are generic with respect to the alternatives claimed in original dependent claims 3-5 (now claims 3-5 and 10-12), as also noted by the Examiner at p. 2 of the Restriction Requirement. Upon allowance of a generic claim, Applicants respectfully request consideration and allowance of claims 10-12 in addition to those claims currently under consideration.

Should the Examiner require anything further from Applicants, the Examiner is invited to contact Applicants' undersigned representative at the number listed below.

Respectfully submitted,



/ /

Jayme M. Torelli
Reg. No. 62,735

Date: March 21, 2014

Hoffman Warnick LLC
540 Broadway, 4th Floor
Albany, New York 12207
Phone: (518) 449-0044
Fax: (518) 449-0047

Electronic Acknowledgement Receipt

EFS ID:	18554282
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	21-MAR-2014
Filing Date:	08-JAN-2014
Time Stamp:	19:12:58
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		VAND-0002-US-CON2_ResponseToRestriction.pdf	87278 f84796143f9ab314dbe2849aebf6685e460e30e3	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response to Election / Restriction Filed	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5
Warnings:			
Information:			
	Total Files Size (in bytes):	87278	

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/150,575	Filing Date 01/08/2014	☐ 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

AMENDMENT	03/21/2014	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 12	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DORRETTA BROOKS/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2

CONFIRMATION NO. 1033

23550
HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

PUBLICATION NOTICE

OC000000068318497

Title:METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

Publication No.US-2014-0128433-A1
Publication Date:05/08/2014

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 07/15/2014

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

NOTIFICATION DATE	DELIVERY MODE
07/15/2014	ELECTRONIC

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

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

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

PTOCommunications@hoffmanwarnick.com

Office Action Summary	Application No. 14/150,575	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	Art Unit 1634	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☒ Responsive to communication(s) filed on *21 March 2014*.

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

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

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

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

Disposition of Claims*

5)☒ Claim(s) *1-12* is/are pending in the application.

5a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-9* is/are rejected.

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

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

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

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

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *0114a-h; 0314*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

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

2. This action is responsive to the Amendments and Response filed March 21, 2014. Claims 3-4 have been amended, and claims 10-12 (withdrawn claims directed to non-elected species) have been added.

Election/Restrictions

3. Applicant's election of the species of fluoxetine in the reply filed on March 21, 2014 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 10-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 21, 2014.

Specification

5. While the abstract is acceptable, it appears to relate to an invention claimed in (a) parent application(s) rather that the invention of the claims presently under consideration. Applicant may wish to consider amending the abstract such that it corresponds more closely to the invention claimed herein.

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see, e.g., pages 8 and 16). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable

code. See MPEP § 608.01. It is noted that this objection may be overcome by amending the specification to delete the recitations of “http://" (i.e., inactivating the hyperlink(s)).

7. The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a) and (a)(2). However, the specification fails to comply with one or more of the requirements of 37 CFR 1.821 through 1.825 because the specification recites sequences that lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR 1.821(d). See, in particular, page 9. Appropriate corrections for compliance are required.

Claim interpretation

8. Claims 6-7 each recite the language “wherein the patient is not also being treated with a CYP2D6 inhibitor.” The term “CYP2D6 inhibitor” differs from the previously employed claim language “drug that inhibits CYP2D6” (see claims 1 and 2 from which claims 6-7 depend). However, claims 6-7 are interpreted as referencing the alternative embraced by claim 1 in which “the patient is not also being treated with a drug that inhibits CYP2D6,” as this is the only reasonable interpretation of the language of claims 6-7.

Claim Rejections - 35 USC § 112(b)/second paragraph

9. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-9 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 1-9 are indefinite over the recitation of the limitation "drug that inhibits CYP2D6" in claim 1; claims 2-3 and claims dependent therefrom are also indefinite over the use of this term in claims 2-3, and claims 6-7 (and claims dependent therefrom) are further indefinite over the use of the similar term "CYP2D6 inhibitor." Neither the specification nor the prior art provide a clear, limiting definition for these terms. While it is clear that some preferred drugs identified in the claims and specification (specifically, fluorexetine, as well as paroxetine, dolasetron, and venlaxafine) are encompassed by this term, the boundaries of the term (and therefore the claims) are not definite. Particularly, it is not clear what extent of inhibition of CYP2D6 might be required of a drug in order for it to be embraced by the claims. Further, the prior art as exemplified by Alfaro et al (J. Clin. Pharmacol. 40:58-66 [2000]; cited herein) teaches that different drugs exhibit different degrees of CYP2D6 inhibition in different individuals, such that a drug that functions as a CYP2D6 inhibitor in one individual, or which exhibits a particular degree of inhibition in one individual, would be expected to function differently in other individuals. Accordingly, the claims should be amended so as to clearly set forth what drugs and/or types of drugs are embraced by (and excluded from) the claims, such that the boundaries of the claims are clear.

Claims 2-5, 7 and 9 are indefinite over the recitation in claim 2 of the limitation "wherein the risk of QT prolongation is reduced in a patient that is also being treated with a drug that inhibits CYP2D6," as it is unclear how claim 2 further limits claim 1 (from which it depends). Particularly, claim 1 recites two alternative embodiments, one in which "the patient is not also being treated with a drug that inhibits CYP2D6" and one in which "the patient is also being treated with a drug that inhibits CYP2D6" (emphasis added). Claim 2 appears to reference a property or result that occurs in a patient "that is also being treated with a drug that inhibits CYP2D6;" however, claims dependent from claim 2 (such as claim 7) appear to be directed to the embodiment of claim 1 in which a patient is not being treated with "a drug that inhibits CYP2D6." It is thus not clear what is actually required by claim 2 and how it actually further limits claim 1; further clarification is required.

With further regard to claims 7 and 9, it is also unclear how these claims relate to and further limit claims 1-2, given that claim 2 appears to relate to a different embodiment of claim 1 than that specified in claim 7. It is not clear whether the steps of these claims are actually required, given that claim 2 species a patient "that is also being treated with a drug that inhibits CYP2D6." Further clarification is required.

Claim Rejections - 35 USC § 103

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

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the

time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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

13. Claims 1-3 and 6-9 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Jain (Exp. Opin. Invest. Drugs 9(12):2935 [2000]; cited in IDS).

This rejection applies to the claims to the extent that they are directed to the embodiment in which "the patient is not also being treated with a drug that inhibits CYP2D6."

Jain discloses that iloperidone is used in the treatment of schizophrenia (see entire reference). Jain provides an overview of several studies of iloperidone, teaching that daily dosages of iloperidone up to 24 mg/day have been "found to be well tolerated" (page 2940, right column), as well as clinical trials in which iloperidone was administered at dosages of 4 and 8 mg/day and at 0.25 - 3 mg b.i.d. (Table 4). Jain also discloses a long term study of dosages of 4-16 mg/day (page 2941, left column), as well as the finding of efficacy at a dosage of 8 mg/day, and tolerance of a dosage of 32 mg/day (page 2941). As Jain teaches both the safety of iloperidone dosages of up to

24 or 32 mg/day, and the efficacy of iloperidone in the treatment of schizophrenia at dosages as low as 8 mg/day, it would have been *prima facie* obvious to one of ordinary skill in the art to have administered a dosage of 12-24 mg/day of iloperidone to a schizophrenic patient (inclusive of a patient not receiving any other drugs or therapies that might potentially function in inhibiting CYP2D6). As discussed in MPEP 2144.05, optimization of conditions that are already generally disclosed in the prior art is not considered inventive absent evidence of the criticality of a particular range or concentration, etc. (which criticality has not been established in the present case). Jain suggests a range in dosages of 8-32 mg/day, and the instant claims are directed to a range falling essentially in the middle of this prior art range (which is clearly suggested by the teachings of the art).

With further regard to claim 2 and claims dependent therefrom, it is reiterated than the manner in which claim 2 might further limit claim 1 is unclear; further, this rejection applies to the claims as directed to the embodiment in which the patient is not being treated with other drugs (and claim 2 is clearly not further limiting of this embodiment). Claim 3 is also rejected as it is not further limiting of the embodiment of the claims rejected herein; the claim merely specifies an additional drug in relation to a different embodiment embraced by claim 1. Regarding claims 6-9, Jain suggests the range of 12-24 mg/day which is inclusive of the dosage of 24 mg/day, and also specifically teaches the safety of the dosage of 24 mg/day, as noted above. Jain thus also suggests the invention of claims 6-9.

14. Claims 1-2 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Jain as applied to claim 1, above, and further in view of Obach (US 2003/0144220 A1 [31 July 2003; filed 21 March 2000]; cited in IDS), and with regard to claim 2, as evidenced by Woosley (WO 01/79554 [25 Oct 2001]; cited in IDS).

This rejection applies to the claims as directed to the embodiment in which the patient "is also being treated with a drug that inhibits CYP2D6."

The teachings of Jain are set forth in the preceding paragraph. While Jain teaches a range of dosages of iloperidone of 8-32 mg/day, as well as the efficacy of a dosage as low as 8 mg/day in treating schizophrenia, Jain do not teach the administration of iloperidone to a patient receiving other drugs, including a patient receiving a drug that inhibits CYP2D6, and further does not suggest the use of a lower dosage of iloperidone in such a subject, as is set forth in the claims.

Obach discloses the use in combination of CYP2D6 inhibitors and drugs metabolized by CYP2D6 (see entire reference); Obach further discloses that iloperidone is one such drug metabolized by CYP2D6 (see, e.g., paragraphs 28 and 42, and claim 9). Obach teaches adjusting the dosages of drugs metabolized by CYP2D6 (such as iloperidone) in subjects also being treated with a CYP2D6 inhibitor so as to optimize the beneficial effects of both drugs (described by Obach as a "combination method")(see, e.g., paragraphs 52-53). Obach provides general guidance with regard to adjustment of dosage of the drug metabolized by CYP2D6, teaching that an appropriate dose regimen "will depend on the patient being treated," and that a therapeutic drug will generally "be administered in an amount ranging from one order of magnitude less than the amount

that is known to be efficacious and therapeutically acceptable….to the amount that is known to be efficacious and therapeutically acceptable" (see paragraphs 52-53).

In view of the teachings of Obach, it would have been *prima facie* obvious to one of ordinary skill in the art to have adjusted the dosages of iloperidone taught by Jain to dosages approximately an order of magnitude less that 8-32 mg/day up to 8-32 mg/day (i.e., the amount of iloperidone taught by Jain as being efficacious and safe for treatment of schizophrenia) in a subject also receiving a CYP2D6 inhibitor, such that the teachings of Jain in view of Obach suggest the claimed invention. Such a dosage adjustment for iloperidone is suggested by the teachings of Obach, with Jain providing the relevant dosages with respect to which the adjustment suggested by Obach would appropriately be made. An ordinary artisan would have been motivated to have made such a modification for the advantage of optimizing the dosage of iloperidone to achieve the beneficial effects taught by Obach in subjects receiving multiple therapies including a drug metabolized by CYP2D6 and a drug that inhibits CYP2D6. It is also again noted that optimization of conditions that are already generally disclosed in the prior art is not considered inventive absent evidence of the criticality of a particular range or concentration, etc. (which criticality has not been established in the present case)(MPEP 2144.05). The instant claims are directed to broad ranges of dosages suggested by the teachings of the prior art as opposed to, e.g., a particular narrow range for which unexpected results have been established.

With further regard to claim 2, the claim appears to simply recite an inherent benefit of the method of claim 1; the claim does not specify any further active or

manipulative steps that are to be performed. Furthermore, it is noted that Woosley teaches that CYP2D6 alleles that result in no enzyme activity "can result in excessive accumulation of drugs and thereby induce QT interval elongation" (see entire reference, particularly col 2, lines 23-38; col 7, lines 10-16). Thus, the teachings of Woosley establish that impaired CYP2D6 function is associated with QT interval elongation resulting from accumulation of drugs metabolized by CYP2D6, and that subjects in whom CYP2D6 function is impaired (which includes subjects being treated with CYP2D6 inhibitors) will inherently benefit from receiving lower dosages of drugs metabolized by CYP2D6 (with that benefit inherently including reduced risk of QT prolongation). Thus, the teachings of Woosley further establish that the property of claim 2 is simply an inherent benefit of the practice of the method of claim 1.

15. Claims 1-5 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Jain in view of Obach, as evidenced by Woosley, as applied to claims 1-2, above, and further in view of Cheer and Goa (Drugs 61(1):81 [2001]; cited herein).

This rejection applies against claims 1-2 to the extent that they are directed to the embodiment of claim 3 (which requires that "the drug that inhibits CYP2D6 is fluoxetine" [i.e., the elected species of the invention]).

The teachings of Jain, Obach and Woosley are set forth above. While Jain in view of Obach suggest methods in which iloperidone is administered within the range of dosages recited in the claims with respect to a patient who is "also being treated with a drug that inhibits CYP2D6," neither Jain nor Obach teaches that fluoxetine inhibits CYP2D6. Cheer and Goa provide a review of the antidepressant fluoxetine (trade name

Prozac), teaching that fluoxetine is known to inhibit cytochrome P450 genes including CYP2D6, and stating that this fact "is potentially important for patients with physical illness who may be taking multiple concomitant medications" (see entire reference, particularly page 82, as well as page 90, right column). In view of the teachings of Cheer and Goa, it would have been *prima facie* obvious to one of ordinary skill in the art to have administered to a schizophrenic patient receiving both iloperidone and fluoxetine a dosage of iloperidone 12 mg/day or less. An ordinary artisan would have been motivated to have employed such a dosage by the teaching of Cheer and Goa that fluoxetine is an inhibitor of CYP2D6, such that a patient receiving both iloperidone and fluoxetine would be expected to benefit from such a reduced dosage as is suggested by Obach with respect to any known CYP2D6 inhibitor. Additionally and/or alternatively, an ordinary artisan would have recognized such a modification as the simple substitution of a specific type of CYP2D6 inhibitor (fluoxetine) for the generally identified “CYP2D6 inhibitor” taught by Obach to achieve the predictable result of more effectively treating a subject receiving both iloperidone and fluoxetine (as is suggested by the teachings of Obach with regard to any “CYP2D6 inhibitor”). With further regard to claims 4-5, the dosages of the claims (like those of claim 1) fall within the range suggested by the prior art of Jain in view of Obach, such that the prior art suggests the dosages of the claims for the same reasons given above.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA B. JOHANNSEN whose telephone number is

(571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/DIANA B JOHANNSEN/
Primary Examiner, Art Unit 1634

Notice of References Cited	Application/Control No. 14/150,575	Applicant(s)/Patent Under Reexamination WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	Art Unit 1634	Page 1 of 1

U.S. PATENT DOCUMENTS

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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	First Named Inventor	Curt Wolfgang et al.
	Art Unit	
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WEST Search History for Application 14150575

Creation Date: 2014070716:40

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
(polymeropoulos-m$.in. or wolfgang-c$.in.)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014

((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.))) and dos$4	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((qt or qtc)same(prolong$8 or interval))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014

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	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
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	Examiner Name	
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	1	JOHANNSEN, Office Action Communication for US Application No. 11/576,178 dated March 15, 2012, Attorney Docket No. VAND-0002-US, 24 pages.	☐
	2	JOHANNSEN, Office Action Communication for US Application No. 11/576,178 dated December 20, 2012, Attorney Docket No. VAND-0002-US, 13 pages	☐

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SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/150,575	01/08/2014 RULE	435	1634	VAND-0002-US-CON2

APPLICANTS

Vanda Pharmaceuticals, Inc., Washington, DC, Assignee (with 37 CFR 1.172 Interest);

INVENTORS

Curt Wolfgang, Germantown, MD;
Mihael Polymeropoulos, Potomac, MD;

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

This application is a CON of 14/060,978 10/23/2013
which is a CON of 11/576,178 03/28/2007 PAT 8586610
which is a 371 of PCT/US05/35526 09/30/2005
which claims benefit of 60/614,798 09/30/2004

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

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Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /DIANA B JOHANNSEN/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
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	2	20080166357	A1	2008-07-10	Golz et al.	
	3	20090298880	A1	2009-12-03	Wolfgang et al.	
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	1	02064141	WO	A1	2002-08-22	Novartis AG		☐

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	2	2004006886	WO	A2	2004-01-22	Novartis AG		☐

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	1	European Patent Office, European Search Report for Application No. EP12164353 dated 29 August 2012, Attorney Docket No. VAND-0002-EP-DIV, 13 pages.	☐
	2	SHERIDAN et al., "Empirical Regioselectivity Models for Human Cytochromes P450 3A4, 2D6, and 2C9," June 2007, pages 3173-3184, J. Med. Chem. Vol. 50, American Chemical Society.	☐
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	9	Johannsen, Office Action Communication for Application Serial No. 12/208,027 dated December 20, 2012, Attorney Docket No. VAND-0002-US-CIP, 19 pages.	☐

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	1	2010030783	WO	A1	2010-03-18	Wolfgang et al.		☐
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	1	Patent Cooperation Treaty, Notification of Transmittal of the International Search Report and The Written Opinion of the International Searching Authority, or the Declaration for PCT/US2005/035526 dated 23 August 2006, Attorney Docket No. VAND-0002-PCT, 11 pages.	☐
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	2	Patent Cooperation Treaty, International Preliminary Report on Patentability of the International Searching Authority dated 24 March 2011, International Application No.: PCT/US2009/056517, Attorney Docket No.: VAND0002-CIP-PCT, 10 pages.	☐
	3	JOHANNSEN, Final Office Action Communication for Application Serial Number 11/576,178 Dated February 17, 2011, Attorney Docket No. VAND-0002-US, 21 pages.	☐

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	1	0244994	WO	A2	2002-06-06	Brower et al.		☐
	2	0179554	WO	A1	2001-10-25	Woosley		☐

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	1	JOHANNSEN, Office Action Summary for U.S. Application No. 11/576,178 dated 05/03/2010, Attorney Docket No. VAND-0002-US, 24 pages.	☐
	2	European Patent Office, Examination Report for Application No. 05803436.1 dated 04/21/2010, 8 pages.	☐
	3	FUSELLI et al., "Molecular diversity at the CYP2D6 locus in the Mediterranean region," November 2004, pages 916-924, European Journal of Human Genetics, Vol. 12, No. 11, ISSN: 1018-4813.	☐
	4	SACHSE et al., "Cytochrome P450 2D6 Variants in a Caucasian Population: Allele Frequencies and Phenotypic Consequences," February 1997, pages 284-295, American Journal of Human Genetics, Vol. 60, No. 2, ISSN: 0002-9297.	☐
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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1621
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

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	Art Unit	1621
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

	1	RAIMUNDO et al., "A novel intronic mutation, 2988G>A, with high predictivity for impaired function of cytochrome P450 2D6 in white subjects," 2004, pages 128-138, Clinical Pharmacology & Therapeutics, Vol. 76, No. 2.	☐
	2	GAEDIGK et al., "Delection of the Entire Cytochrome P450 CYP2D6 Gene as a Cause of Impaired Drug Metabolism in Poor Metabolizers of the Debrisoquine/Sparteine Polymorphism," 1991, pages 943-950, Am. J. Hum. Genet., Vol. 48.	☐

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Doc code: IDS
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	VAND-0002-US-CON2

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2006039663	WO	A2	2006-04-13	Wolfgang et al.		☐
	2	2008121899	WO	A2	2008-10-09	Lavedan et al.		☐
	3	2008144599	WO	A2	2008-11-27	Lavedan et al.		☐

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

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	Attorney Docket Number	VAND-0002-US-CON2

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	1	Australian IP, Examination Report dated 13-November-2009, Australian Application No.: 2005292246, Attorney Docket No.: VAND-0002-AU, 2 pages.	☐
	2	Patent Cooperation Treaty, International Search Report and the Written Opinion of the International Searching Authority dated 27-November-2009, International Application No.: PCT/US2009/056517, Attorney Docket No.: VAND-0002-CIP-PCT, 18 pages.	☐
	3	CACCIA, "New Antipsychotic Agents for Schizophrenia: Pharmacokinetics and Metabolism Update", July 2002, pages 1073-1080, Current Opinion in Investigational Drugs, Vol. 3, No. 7.	☐

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	Art Unit
	DIANA B JOHANNSEN	1634

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM search; reviewed 14/060,978; 11/576,178; 60/614,798; 14/044,183; 12/301,675	7 July 2014	DBJ
STN search - see search history printout	7 July 2014	DBJ
WEST search - see search history printout	7 July 2014	DBJ

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634

14/150,575 STN Search Strategy

INDEX 'ADISCTI, ADISINSIGHT, ADISNEWS, AGRICOLA, ANABSTR, BIOSIS, BIOTECHABS, BIOTECHDS, BIOTECHNO, CABA, CAPLUS, CEABA-VTB, CIN, CROPB, CROPU, DDFB, DDFU, DGENE, DISSABS, DRUGB, DRUGU, EMBAL, EMBASE, ESBIOBASE, FOMAD, FROSTI, FSTA, GENBANK, IFIALL, ...' ENTERED AT 15:17:37 ON 07 JUL 2014

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L3 93 SEA "WOLFGANG C"/AU

E WOLFGANG CURT/AU

L4 15 SEA "WOLFGANG CURT"/AU

L5 8505 SEA (ILOPERIDONE OR ZOMARIL OR ETHANONE)

L6 24 SEA (L2 OR L3 OR L4) AND L5

L7 10 DUP REM L6 (14 DUPLICATES REMOVED)

D L7 TI PY 1-10

L8 148 SEA L5 AND (PROZAC OR FLUOXETINE)

L9 130 DUP REM L8 (18 DUPLICATES REMOVED)

L10 17 SEA L9 NOT 2005-2014/PY

L11 36918 SEA (CYP2D6### OR 2D6### OR CYPIID6### OR IID6###)

L12 102 SEA L11 AND L5

L13 12 SEA L12 NOT 2005-2014/PY

L14 5 DUP REM L13 (7 DUPLICATES REMOVED)

L15 2059 SEA L11 AND (PROZAC OR FLUOXETINE)

L16 999 SEA L15 NOT 2005-2014/PY

L17 824 SEA L16 AND INHIBIT###

L18 364 DUP REM L17 (460 DUPLICATES REMOVED)

L19 63 SEA L18 AND (PROZAC OR FLUOXETINE)/TI

L20 222 SEA L5 AND ((QT OR QTC)(P)(INTERVAL OR PROLONG#########))

L21 12 SEA L20 NOT 2005-2014/PY

L22 10 DUP REM L21 (2 DUPLICATES REMOVED)

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	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

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	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

	1	JOHANNSEN, Office Action Communication for US Application No. 14/060,978 dated June 5, 2014, Attorney Docket No. VAND-0002-US-CON, 48 pages.	☐

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Examiner Signature		Date Considered	

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	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-09-04
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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.

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Electronic Acknowledgement Receipt

EFS ID:	20050737
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	04-SEP-2014
Filing Date:	08-JAN-2014
Time Stamp:	17:38:20
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	Non Patent Literature	VAND-0002-US-CON_OfficeAction1_06-05-2014.pdf	1892886 49a04ffdbde2847c5d238dfeac6c4e96a1f518e5	no	48

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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.

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Application Number: 14150575 Document Date: 10/14/2014

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Wolfgang, et al.	**Conf. No.:**	1033
Serial No.:	14/150,575	**Art. Unit:**	1634
Filed:	01/08/2014	**Examiner:**	Johannsen, Diana B.
Docket. No.:	VAND-0002-US-CON2		
Title:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		

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

AMENDMENT

Sir:

I. INTRODUCTORY COMMENTS

This paper is being filed in response to the non-final Office Action dated July 15, 2014.

Please amend the above-referenced patent application in accordance with the following:

Amendments to the Specification appear on pages 2-4 of this paper;

A Listing of the Claims appears beginning on page 5 of this paper;

Remarks begin on page 8 of this paper; and

A Supplemental IDS and an electronic copy of a Sequence Listing are provided herewith.

II. AMENDMENTS TO THE SPECIFICATION

Please amend the specification in accordance with the following items A-E:

A. On page 1, immediately following paragraph [0001] and prior to the "BACKGROUND OF THE INVENTION" section, please insert the following:

SEQUENCE LISTING

The sequence listing contained in the electronic file titled "VAND-0002-US-CON2_SeqID_2014-08-29," created August 29, 2014, comprising 14 KB, is hereby incorporated herein by reference.

B. Please amend paragraph [0027] at line 2 in accordance with the following:

[0027] The *CYP2D6* gene is highly polymorphic, with more than 70 allelic variants described so far. *See*, *e.g.*, CYP2D6 allele nomenclature, at [[http://]] www.imm.ki.se/CYPalleles/cyp2d6.htm. Most embodiments of the present invention concern the two most common polymorphisms within the *CYP2D6* gene in Caucasian populations, *CYP2D6G1846A* and *CYP2D6P34S* (also referred to as *CYP2D6C100T*). These polymorphisms correspond to nucleotides 3465 and 1719, respectively, in GenBank sequence M33388.1 (GI:181303). The *CYP2D6P34S*/*CYP2D6C100T* polymorphism also corresponds to nucleotide 100 in GenBank mRNA sequence M20403.1 (GI: 181349).

C. Please amend paragraph [0031] in accordance with the following:

[0031] Genotypes for the *CYP2D6G1846A* polymorphism were ascertained for 123 of the 128 consenting individuals, while genotypes for the *CYP2D6C100T* polymorphism were identified for all 128 participants. Genotyping was performed on amplified DNA fragments. The *CYP2D6* genomic region was amplified using a triplex PCR strategy (Neville 2002). In brief, primers used were:

Exons 1 & 2	SEQ. ID. 1, 2D6L1F1:	CTGGGCTGGGAGCAGCCTC
	SEQ. ID. 2, 2D6L1R1:	CACTCGCTGGCCTGTTTCATGTC
Exons 3, 4, 5 & 6	SEQ. ID. 3, 2D6L2F:	CTGGAATCCGGTGTCGAAGTGG
	SEQ. ID. 4, 2D6L2R2:	CTCGGCCCCTGCACTGTTTC
Exons 7, 8 & 9	SEQ. ID. 5, 2D6L3F:	GAGGCAAGAAGGAGTGTCAGGG
	SEQ. ID.6, 2D6L3R5B:	AGTCCTGTGGTGAGGTGACGAGG

D. Please amend paragraph [0047] at line 2 in accordance with the following:

[0047] Decreased CYP2D6 activity may be the result of other mutations, including those described at CYP2D6 allele nomenclature, at [[http://]] www.imm.ki.se/CYPalleles/cyp2d6.htm, which is incorporated herein by reference. In particular, it is noted that the CYP2D6*2A mutation includes a CYP2D7 gene conversion in intron 1. In some cases, the lower CYP2D6 activity in a CYP2D6 poor metabolizer may be due to factors other than genotype. For example, a patient may be undergoing treatment with an agent, e.g., a drug that reduces CYP2D6 activity.

E. Please amend the Abstract on p. 27 of the application as filed in accordance with the following:

The present invention relates to methods for treating a patient with iloperidone or a metabolite thereof, which patient is also being treated with fluoxetine, and lowering ~~the identification of genetic polymorphisms that may be associated with a~~ risk for QT prolongation ~~after treatment with iloperidone and related methods of administering iloperidone to patients with such polymorphisms~~.

III. LISTING OF THE CLAIMS

The following listing replaces any and all prior listings of the claims:

1. (Currently amended) A method of treating a patient[[,]] who is suffering from schizophrenia, with iloperidone, which patient is being treated with fluoxetine, the method comprising:

~~if the patient is not also being treated with a drug that inhibits CYP2D6, then internally administering to the patient an amount of iloperidone that is greater than 12 mg/day, up to 24 mg/day, and if the patient is also being treated with a drug that inhibits CYP2D6, then~~

internally administering to the patient an effective amount of iloperidone that is 12 mg/day or less.

2. (Currently amended) The method of claim 1, wherein the risk of QT prolongation is reduced relative to the risk of QT prolongation that would result from internally administering to the patient an amount of iloperidone that is greater than 12 mg/day while the ~~in a~~ patient ~~that~~ is also being treated with ~~a drug that inhibits CYP2D6~~ fluoxetine.

3-4. (Canceled)

5. (Currently amended) The method of claim 1, [[4]] wherein the amount of iloperidone is 12 mg/day.

6-12. (Canceled)

13. (New) The method of claim 1, wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to greater than 12 mg/day up to 24 mg/day.

14. (New) The method of claim 2, wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to greater than 12 mg/day up to 24 mg/day.

15. (New) The method of claim 5, wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to greater than 12 mg/day up to 24 mg/day.

16. (New) The method of claim 13, wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to 24 mg/day.

17. (New) The method of claim 14, wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to 24 mg/day.

18. (New) The method of claim 15, wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to 24 mg/day.

19. (New) A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:

a) determining whether the patient is a CYP2D6 poor metabolizer by:

obtaining or having obtained a biological sample from the patient; and

performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and

b) determining whether the patient is being coadministered fluoxetine; and

c) (i) if the patient has a CYP2D6 poor metabolizer genotype, is being coadministered fluoxetine, or both, then internally administering iloperidone to the patient in an effective amount of 12 mg/day or less, or

c) (ii) if the patient does not have a CYP2D6 poor metabolizer genotype and is not being coadministered fluoxetine, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,

wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype or being coadministered fluoxetine is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

IV. REMARKS

Claims 1, 2, 5, and 13-19 are pending in this application. By this Amendment, the specification at [0001], [0027], [0031] [0047], and the abstract, and claims 1, 2, and 5 have been amended, and claims 3-4 and 6-12 are canceled. Claims 13-19 have been added. No new matter is introduced in the amendments or new claims 13-19. Claim 19 merely combines the method claimed in U.S. 8,586,610 (the '610 patent)[1], which is related to the instant application and part of the priority chain of the instant application, with the method of claims 1, 2, 5, and 13-18. Applicants are not conceding in this application that any claims are not patentable over the art cited by the Examiner, as the present claim amendments are only for facilitating expeditious allowance of the claimed subject matter. Applicants respectfully reserve the right to pursue these and other claims in one or more continuation and/or divisional patent applications. Reconsideration in view of the following remarks is respectfully requested.

Supplemental IDS

Together with this Amendment, Applicants are providing a supplemental Information Disclosure Statement to bring to the attention of the Examiner the fact that the assignee of the above-captioned patent application, Vanda Pharmaceuticals Inc., has sued a generic drug manufacturer for infringement of the '610 patent. The defendant has filed a motion to dismiss on the grounds that the subject matter claimed in the '610 patent is invalid because it claims patent ineligible subject matter. The complaint, the defendant's motion to dismiss, the assignee's

[1] As described in the instant application at [0001], the present application is "a continuation of co-pending U.S. Patent Application Serial No. 14/060,978, filed October 23, 2013, which is a continuation of U.S. Patent Application Serial No. 11/576,178, filed March 28, 2007 (now US Patent No. 8,586,610, issued November 19, 2013)…"

answer to the motion to dismiss and supporting declaration from Dr. Mihael Polymeropoulos, and the defendant's reply are cited in the supplemental IDS and are appended thereto. Also disclosed in the IDS and provided herewith are copies of each of the drug labels referred to below.

Objections to the Specification

In the Office Action, the Examiner objects to the specification, in particular, the abstract and the disclosure at pp. 8 and 16. Applicants have amended the abstract herein per the Examiner's suggestion, and the specification at [0027] and [0047] to remove the embedded hyperlink.

The Examiner further objects to the specification as containing sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a) and (a)(2). Together with this Amendment, Applicants provide a Sequence Listing contained in an electronic file titled "VAND-0002-US-CON2_SeqID_2014-08-29.txt," created August 29, 2014 and comprising 14 KB, and accompanying specification amendments following paragraph [0001] and at paragraph [0031]. Applicants respectfully submit that these amendments to the application obviate this ground of objection, and request withdrawal of the same.

Claim interpretation

Applicants respectfully submit that in view of the present amendment to claim 1, the interpretation of "CYP2D6 inhibitor" relative to a "drug that inhibits CYP2D6" is moot.

Rejections under 35 U.S.C. § 112, second paragraph

In the Office Action, claims 1-9 are rejected under § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventors regard as the invention. In particular, the Examiner objects to the terms "CYP2D6 inhibitor" and "drug that inhibits CYP2D6," and the manner in which claims 2-5, 7, and 9 further limit claim 1. Without acquiescing in the Examiner's determination that the claims as previously presented are indefinite, Applicants have amended the claims herein to specifically recite "fluoxetine" as the specific CYP2D6-inhibiting drug, and respectfully submit that claims 1, 2, and 5 as presented herein are not indefinite under § 112, second paragraph. Applicants further submit that claims 2 and 5 as presented herein appropriately further limit claim 1. Claims 3-4 and 6-9 are cancelled herein, thereby rendering the rejections moot with respect to these claims.

Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1-3 and 6-9 are rejected under § 103(a) as being allegedly unpatentable over Jain[2]; claims 1 and 2 are rejected under § 103(a) as being allegedly unpatentable over Jain and further in view of Obach[3], and with regard to claim 2, as evidenced by Woosley[4]; and claims 1-5 are rejected under § 103(a) as being allegedly unpatentable over Jain in view of Obach, as evidenced by Woosley, and further in view of Cheer & Goa[5]. Applicants respectfully traverse these rejections for the reasons that follow.

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[2] Jain, Exp. Opin. Invest. Drugs 9(12):2935 (2000) ("Jain" herein).

[3] Obach, US Pat. Pub. 2003/0144220 ("Obach" herein).

[4] Woosley, WO 01/79554 ("Woosley" herein).

[5] Cheer & Goa, *Fluoxetine: A Review of its Therapeutic Potential in the Treatment of Depression Associated with Physical Illness*, Drugs 61(1):81 (2001) ("Cheer & Goa" herein).

Turning first to the rejection of claim 1 over Jain, in section 13 of the Office Action the Examiner notes that "this rejection applies to the claims to the extent that they are directed to the embodiment in which 'the patient is not also being treated with a drug that inhibits CYP2D6.'"[6] In view of the present amendment to claim 1, which specifies that the "patient is being treated with fluoxetine," a drug that inhibits CYP2D6, Applicants submit that this ground of rejection is moot. Without prejudice to the patentability of the claimed subject matter as previously presented, Applicants submit that Jain neither teaches nor is alleged to teach a "method of treating a patient who is suffering from schizophrenia with iloperidone, which patient is being treated with fluoxetine, the method comprising: internally administering to the patient an effective amount of iloperidone that is 12 mg/day or less"[7] as claimed herein. Accordingly, Applicants respectfully request withdrawal of the rejection of claim 1 under § 103(a) as being allegedly unpatentable over Jain.

In section 14 of the Office action, claims 1-2 are rejected under pre-AIA 35 USC § 103(a) over Jain and Obach and, with regard to claim 2, as evidenced by Woosley. As admitted in the Office Action, "neither Jain nor Obach teaches that fluoxetine inhibits CYP2D6."[8] Applicants respectfully submit that this rejection is inapplicable to the claims as amended because in the claims as amended the CYP2D6 inhibitor is limited to fluoxetine. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1 and 2 over the proposed combination of Jain and Obach as evidenced by Woosley.

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[6] Office Action, p. 6 (emphasis added).

[7] Claim 1.

[8] Office Action, p. 10.

In section 15 of the Office Action, claims 1-5 are rejected under pre-AIA 35 USC § 103(a) over Jain and Obach as evidenced by Woosley and further in view of Cheer & Goa. Applicants submit that this proposed combination also fails to teach a "method of treating a patient who is suffering from schizophrenia, with iloperidone, which patient is being treated with fluoxetine, the method comprising: internally administering to the patient an effective amount of iloperidone that is 12 mg/day or less." Applicants submit that none of the cited references, either alone or in any combination, teaches or suggests a dose of iloperidone of up to 12 mg/day in schizophrenia patients who are also being treated with fluoxetine.

Putting aside for present purposes the question of what Jain teaches or does not teach regarding the dose of iloperidone that is effective in treating schizophrenia in patients who are not also being treated with fluoxetine, Jain clearly does not teach that the dose of iloperidone should be reduced by one-half (i.e., reduced from up to 24 mg/day to 12 mg/day or less) in schizophrenia patients who are being treated with fluoxetine.[9]

Applicants respectfully submit that the Examiner is incorrect in stating that,

> "Obach teaches adjusting the dosages of drugs metabolized by CYP2D6 (such as iloperidone) in subjects also being treated with a CYP2D6 inhibitor so as to optimize the beneficial effects of both drugs (described by Obach as a "combination method")(see, e.g., paragraphs 52-53)."[10]

Obach says nothing about optimizing the beneficial effects of both drugs.

Obach at most teaches that a CYP2D6 inhibitor can be administered to patients being treated with a drug for which the major clearance mechanism is CYP2D6 mediated oxidative

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[9] *See*, Novartis Pharmaceuticals Corporation, *Fanapt Full Prescribing Information*, p. 1 (April 2014) (stating that "the recommended target dosage of FANAPT tablets is 12 to 24 mg/day administered twice daily.").

[10] Office Action, p. 8.

biotransformation in order to "convert" those patients to CYP2D6 Poor Metabolizers (PMs). This is not equivalent to optimizing the beneficial effects of both drugs. With respect to iloperidone, Obach purports to teach only that iloperidone is a drug for which the major clearance mechanism is CYP2D6 mediated oxidative biotransformation.

As for the dose of the drug for which the major clearance mechanism is CYP2D6, i.e., the "Therapeutic Drug," Obach teaches that:

> "Generally, in carrying out the methods of this invention, the Therapeutic Drug will be administered in an amount ranging from one order of magnitude less than the amount that is known to be efficacious and therapeutically acceptable for use of the Therapeutic Drug alone (i.e., as a single active agent) to the amount that is known to be efficacious and therapeutically acceptable for use of the Therapeutic Drug alone. … In some instances, dosage levels below the lower limit of the aforesaid range may be more than adequate, while in other cases still larger doses may be employed without causing any harmful side effect, provided that such larger doses are first divided into several small doses for administration throughout the day."[11]

Obach introduces further ambiguity, disclosing that "[t]he appropriate dose regimen, the amount of each dose administered, and specific intervals between doses of each active agent will depend on the patient being treated, and the source and severity of the condition."[12] Additionally, Obach states, "Thus, CYP2D6 cleared compounds can be subject to increased incidences of adverse effects, due to elevated systemic exposures observed in PMs."[13] Yet, neither Obach nor the other cited references tell the skilled person anything about whether or not iloperidone is a drug that is "subject to increased incidences of adverse effects, due to elevated

[11] Obach, [0053].

[12] Obach, [0053].

[13] Obach, [0007] (emphasis added).

systemic exposures." With respect to adverse effects, Obach states that "if the therapeutic index for a CYP2D6 cleared compound approaches 10, increased incidences of adverse effects are likely to be observed."[14] But, again, neither Obach nor the other cited references say anything about iloperidone's therapeutic index.

Obach proceeds to disclose a protocol "to determine the impact that coadministration of a CYP2D6 inhibitor with a Therapeutic Drug … would have on the pharmacokinetics of the Therapeutic Drug."[15] Thus, Obach admits to not knowing what effect coadministration of a given CYP2D6 inhibitor will have on the pharmacokinetic profile of a given Therapeutic Drug. In view of this, Applicants submit that it cannot be argued that Obach discloses that the dose of any particular Therapeutic Drug should be reduced, much less that the dose of iloperidone should be reduced at all. It is even clearer that Obach does not disclose reducing the dose of iloperidone to no more than 12 mg/day, in patients who are also being treated with a CYP2D6 inhibitor, specifically, fluoxetine.

Cheer & Goa also fail to teach such reduction of the iloperidone dose in patients who are being co-treated with fluoxetine. For the reasons discussed above, "the simple substitution of a specific type of CYP2D6 inhibitor (fluoxetine) for the generally identified 'CYP2D6 inhibitor' taught by Obach"[16] does not lead the skilled person to the invention as claimed. In brief, the mere facts that fluoxetine is a CYP2D6 inhibitor and that iloperidone is cleared by CYP2D6 mediated oxidative biotransformation do not mean that the risk of QT prolongation can be

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[14] Obach, [0008].

[15] Obach, [0057] - [0067].

[16] Office Action, p. 11.

lowered by reducing the dose of iloperidone in patients being coadministered iloperidone and fluoxetine, or that the dose of iloperidone should be reduced for any reason at all.

In support of the points raised above, Applicants observe that at paragraphs [0028]-[0029], Obach provides "examples of other drugs for which the major clearance mechanism in humans is CYP2D6 mediated oxidative biotransformation," one of which is the atypical antipsychotic iloperidone. Risperidone is the only other atypical antipsychotic drug included in Obach's list,[17] and is structurally and pharmacologically the most closely related listed drug to iloperidone. The US FDA-approved full prescribing information ("Label") for Risperdal® risperidone as of the September 30, 2004 priority date of the instant application included the following passage:

> "CYP 2D6, also called debrisoquin hydroxylase, is the enzyme responsible for metabolism of many neuroleptics, antidepressants, antiarrhythmics, and other drugs. CYP 2D6 is subject to genetic polymorphism (about 6%-8% of Caucasians, and a very low percentage of Asians, have little or no activity and are "poor metabolizers") and to inhibition by a variety of substrates and some non-substrates, notably quinidine. Extensive CYP 2D6 metabolizers convert risperidone rapidly into 9-hydroxyrisperidone, whereas poor CYP 2D6 metabolizers convert it much more slowly. Although extensive metabolizers have lower risperidone and higher 9-hydroxyrisperidone concentrations than poor metabolizers, the pharmacokinetics of the active moiety, after single and multiple doses, are similar in extensive and poor metabolizers.
>
> Risperidone could be subject to two kinds of drug-drug interactions (see Drug Interactions under PRECAUTIONS). First, inhibitors of CYP 2D6 interfere with conversion of risperidone to 9-hydroxyrisperidone. This occurs with quinidine, giving essentially all recipients a risperidone pharmacokinetic profile typical of poor metabolizers. The therapeutic benefits and adverse effects of risperidone in patients receiving quinidine have not been evaluated, but observations in a modest number (n≅70) of poor metabolizers given risperidone do not suggest

[17] Obach, [0028]-[0029].

important differences between poor and extensive metabolizers."[18]

Specifically with respect to drugs that inhibit CYP2D6, the then-current Label states:

> "Risperidone is metabolized to 9-hydroxyrisperidone by CYP 2D6, an enzyme that is polymorphic in the population and that can be inhibited by a variety of psychotropic and other drugs (see CLINICAL PHARMACOLOGY). Drug interactions that reduce the metabolism of risperidone to 9-hydroxyrisperidone would increase the plasma concentrations of risperidone and lower the concentrations of 9-hydroxyrisperidone. Analysis of clinical studies involving a modest number of poor metabolizers (n≅70) does not suggest that poor and extensive metabolizers have different rates of adverse effects. No comparison of effectiveness in the two groups has been made."[19]

In other words, rates of adverse events associated with risperidone, which is metabolized via CYP2D6 and is structurally and pharmacologically similar to iloperidone, are not affected by whether or not a patient is a CYP2D6 Poor Metabolizer (regardless of whether the Poor Metabolizer phenotype is a result of genotype or of drug interactions). Consequently, the only instruction in the then-current Label regarding concomitant administration of fluoxetine is to "re-evaluate" the dosing of risperidone in patients who are initiating or discontinuing concomitant fluoxetine therapy:

> "Fluoxetine (20 mg QD) has been shown to increase the plasma concentration of risperidone 2.5-2.8 fold, while the plasma concentration of 9-hydroxyrisperidone was not affected. When concomitant fluoxetine is initiated or discontinued, the physician should re-evaluate the dosing of RISPERDAL®. The effects of discontinuation of concomitant fluoxetine therapy on the pharmacokinetics of

[18] Janssen Pharmaceutica Products, L.P., *Risperdal® (Risperidone) tablets/oral solution; Risperdal® M-TAB™ (Risperidone) Orally Disintegrating Tablets December 2003 Label*, p. 3 (emphasis added).

[19] *Id.*, p. 14 (emphasis added).

risperidone and 9-hydroxyrisperidone have not been studied."[20,21]

In contrast, the Label for Fanapt® iloperidone, which was first approved May 6, 2009, specifically instructs that "Iloperidone doses should be reduced by one-half when administered with fluoxetine. When fluoxetine is withdrawn from the combination therapy, the iloperidone dose should be returned to the previous level."[22]

Applicants respectfully submit that, taken together with the Risperdal® risperidone Label as of September 30, 2004, Obach in combination with Jain, Woosley, and Cheer & Goa, fails to teach or suggest to one of skill in the art the claimed method, including administering to a patient a reduced dosage of 12 mg/day or less of iloperidone based on the patient's concurrent administration with fluoxetine. In the Office Action, the Examiner alleges that "Obach discloses the use in combination of CYP2D6 inhibitors and drugs metabolized by CYP2D6 (citation omitted); Obach further discloses that iloperidone is one such drug metabolized by CYP2D6 (citation omitted).[23] However, as discussed above, these pieces of information do not suggest the claimed method. Applicants submit that the methods of the pending claims cannot be obvious where the FDA recognizes a need for specific dose adjustment based on co-administration of a

[20] *Id.*, p. 14.

[21] For the record, the current Risperdal® Label, revised April 2014, provided herewith, states that the recommended dose in adults is 4 to 8 mg/day and, with respect to fluoxetine, now states "When fluoxetine or paroxetine is co-administered with RISPERDAL®, the dose of RISPERDAL® should be reduced. The RISPERDAL® dose should not exceed 8 mg per day in adults when co-administered with these drugs. When initiating therapy, RISPERDAL® should be titrated slowly. It may be necessary to increase the RISPERDAL® dose when enzyme inhibitors such as fluoxetine or paroxetine are discontinued [see Drug Interactions (7.1)]." (Sec. 2.5, p. 7.) This language did not appear until the July 2012 revision of the Risperdal® Label, approved by the US FDA in August 2012. Copies of the September 2011 Label and of the July 2012 Label are provided herewith.

[22] Novartis Pharmaceuticals Corporation, *Fanapt Full Prescribing Information*, p. 13, § 7.1 (April 2014), provided herewith. A copy of the April 2009 Label is also provided herewith.

[23] Office Action, p. 8.

CYP2D6 inhibitor in the case of iloperidone, but not in the case of risperidone, a drug to which iloperidone is more similar than the selective serotonin reuptake inhibitors[24], N-methyl-D-aspartate receptor antagonists[25], neruokinin-1 receptor antagonists[26], and tricyclic antidepressants[27], and the drugs (2S,3S)-2-phenyl-3-(2-methoxy-5-trifluoromethoxyphenyl)methylamino-piperidine[28] and sunipetron[29] which are particularly identified as specifically contemplated and preferred embodiments of Obach's "Combination Method" invention.

Returning to Jain, Applicants submit that even if, *arguendo*, one of skill in the art were motivated to modify Obach's method with the teachings of Cheer & Goa as modified by Jain, the references collectively would still fail to disclose the claimed "method of treating a patient who is suffering from schizophrenia, with iloperidone, which patient is being treated with fluoxetine, the method comprising: internally administering to the patient *an effective amount of iloperidone that is 12 mg/day or less*."[30]

Applicants acknowledge that Jain discloses that data "from Phase II trials demonstrated efficacy in patients at doses of 8 mg/day and tolerability was good up to 32 mg/day."[31] However,

[24] Obach, [0019].

[25] Obach, [0020].

[26] Obach, [0021].

[27] Obach, [0022].

[28] Obach, [0023].

[29] Obach, [0024].

[30] Claim 1.

[31] Jain, previously of record.

this very general statement fails not only to "teach the administration of iloperidone to a patient receiving other drugs, including a patient receiving a drug that inhibits CYP2D6, and further … the use of a lower dosage of iloperidone in such a subject"[32] as admitted by the Office, but also fails to teach or even suggest a dosage within the range of 8-32 mg/day that would provide an effective amount and that would reduce the risk of QT prolongation in a patient who is also being treated with fluoxetine.

In Obach's combination method, the Therapeutic Drug may be administered in an amount that is from 10% (or less) to 100% (or more) of the amount typically administered in the absence of a CYP2D6 inhibitor (i.e., 10-fold (or greater) reduction to no reduction (or an increase)).[33] Given the breadth of this range and Obach's caveats regarding situations where less than 10% of a typical therapeutic dose or "still larger" doses than 100% may be used, it is hard to see what possibilities Obach actually excludes. At best it appears that Jain as modified by Obach teaches administration of iloperidone as a therapeutic drug in an amount of 10% (or less) to 100% (or more) of the range of 8-32 mg/day when concomitantly administered with a CYP2D6 inhibitor. Even if each of the other claim features was taught by the proposed combination of references, which Applicants do not concede for at least the reasons discussed above, Applicants submit that the internal administration of iloperidone as claimed, in an amount of up to 12 mg/day, is not obvious in view of Jain and Obach's collective teaching of a dosage of 0.8 mg/day (or less) to 32 mg/day (or more).

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[32] Office Action, p. 8.

[33] *See* Obach at [0053].

With further respect to the prior art rejections discussed above, the attention of the Examiner is respectfully directed to the Declaration by Dr. Mihael Polymeropoulos, provided herewith. Dr. Polymeropoulos' Declaration was appended to the memorandum submitted by Vanda Pharmaceuticals Inc.[34] in connection with the patent infringement action noted at the beginning of this submission. In that Declaration, Dr. Polymeropoulos provides additional reasons why it was not obvious that the dose of iloperidone given to a patient who is a CYP2D6 poor metabolizer should be reduced by any amount and, in particular, to one-half of the normal dose. For example, he explains,

> "At the time of the invention, it was not known how CYP2D6 metabolism affected the overall efficacy of iloperidone or the risk of QTc prolongation. For example, it was unknown whether all of iloperidone's metabolites were biologically active or affected the risk of QTc prolongation, or what the relative potencies of all those metabolites were as compared to iloperidone itself. It was also unknown how all the other metabolic pathways affected the amount of CYP2D6 metabolites formed in the body; it was also unknown whether those other metabolic pathways affected the amount of P88 formed in the body. Thus, it was not known whether the dose of iloperidone needed to be adjusted based on the patient's CYP2D6 metabolizer status, and it was not known how much to adjust the dose if a dose adjustment was needed."[35]

In view of at least the foregoing amendments and remarks, Applicants submit that the proposed combination of Jain, Obach, and Cheer & Goa, as evidenced by Woosley does not teach or suggest the claimed method including all of the features claimed herein. In view of at least the foregoing amendments and remarks, Applicants respectfully request withdrawal of the rejections under § 103(a).

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[34] As previously noted, Vanda Pharmaceuticals Inc. is the assignee of both US 8,586,610 and the instant application.

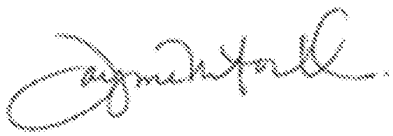
[35] Polymeropoulis Declaration, p. 3.

Applicants respectfully submit that dependent claims 2 and 5 are allowable for the reasons stated above relative to independent claim 1, as well as for their own additional limitations. Accordingly, Applicants respectfully request that the Office withdraw the rejections under 35 U.S.C. § 103(a) to claims 2 and 5.

Applicant also request allowance of new claims 13-18, which recite an additional implicit step, namely, re-adjustment to a normal dose if fluoxetine administration is discontinued, and of new claim 19 which combines the method claimed in the '610 patent with the method of claims 1, 2, 5, and 13-18.

Applicants respectfully submit that the Application as presented is in condition for allowance. Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



/ /

Date: October 14, 2014

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Electronic Patent Application Fee Transmittal

Application Number:	14150575
Filing Date:	08-Jan-2014
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Filer:	Jayme M. Torelli
Attorney Docket Number:	VAND-0002-US-CON2

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	20391056
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	14-OCT-2014
Filing Date:	08-JAN-2014
Time Stamp:	15:42:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Sequence Listing	VAND-0002-US-CON2_SeqID_2014-08-29.pdf	13981 034a54a1385bb0c0a839077a2f0424fc9cf0d638	no	3
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4	Non Patent Literature	081114_RoxaneOpeningBrief_ISO_MotiontoDismiss.pdf	201506 9db45d668a5f3e621a7736de0d95c1af6e4ca4a2	no	18
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16		VAND-0002-US-CON2_AmendmentToOfficeAction1_2014-10-14.pdf	193417 261650912bdfe803a0225aa6f1e0b9a8f7b15447	yes	21

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	4

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	Applicant Arguments/Remarks Made in an Amendment		8	21	
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<110> Wolfgang, Curt D.
Polymeropoulos, Mihael H.

<120> Methods for the Administration of Iloperidone

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

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	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

	1	Complaint For Patent Infringement, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-_____ (22 pages) (US Dist. for the Dist. of Delaware filed June 16, 2014).	☐
	2	Defendant's Motion to Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (4 pages) (US Dist. for the Dist. of Delaware filed August 11, 2014).	☐
	3	Memorandum of Defendant Roxane Laboratories, Inc. In Support Of Its Motion To Dismiss, C.A. No. 14-757-GMS (18 pages) (US Dist. for the Dist. of Delaware filed August 11, 2014).	☐
	4	Vanda's Answering Brief In Opposition To Roxane's Motion To Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (25 pages) (US Dist. for the Dist. of Delaware filed September 11, 2014).	☐
	5	Declaration Of Mihael H. Polymeropoulos In Support Of Vanda's Opposition To Roxane's Motion To Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (290 pages) (US Dist. for the Dist. of Delaware filed September 11, 2014).	☐
	6	Reply Memorandum Of Defendant Roxane Laboratories, Inc. In Support Of Its Motion To Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (15 pages) (US Dist. for the Dist. of Delaware filed September 29, 2014).	☐
	7	Novartis Pharmaceuticals Corporation, Fanapt Full Prescribing Information (20 pages) (April 2014).	☐
	8	Janssen Pharmaceutica Products, L.P., Risperdal(R) (Risperidone) tablets/oral solution; Risperdal(R) M-TAB(TM) (Risperidone) Orally Disintegrating Tablets (34 pages) (December 2003).	☐
	9	Janssen Pharmaceuticals, Inc., Risperdal Full Prescribing Information (58 pages) (April 2014).	☐
	10	Janssen Pharmaceuticals, Inc., Risperdal Full Prescribing Information (57 pages) (Revised July 2012, accepted by the US FDA August 2012).	☐
	11	Janssen Pharmaceuticals, Inc., Risperdal Full Prescribing Information (57 pages) (September 2011).	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

	12	Vanda Pharmaceuticals Inc., Fanapt (iloperidone) Tablets Full Prescribing Information (23 pages) (May 2009).	☐

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Examiner Signature		Date Considered	

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

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	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2014-10-14
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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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.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/150,575	Filing Date 01/08/2014	☐ 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

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	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
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* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

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	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

	1	GOUGH et al., "Identification of the Primary Gene Defect at the Cytochrome P 450 CYP2D Locus", Nature, October 25, 1990, pp.773-776, Volume 347.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2015-01-13
Name/Print	Jayme M. Torelli	Registration Number	62,735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

Electronic Acknowledgement Receipt

EFS ID:	21191106
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	13-JAN-2015
Filing Date:	08-JAN-2014
Time Stamp:	18:45:16
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	VAND-0002-CON2_SupplDSTransmittal.pdf	48465 0d3d593b96cd53517a2ec74c09c06241b58268df	no	1

Warnings:

Information:

2	Information Disclosure Statement (IDS) Form (SB08)	VAND-0002-US-CON2_Suppl_IDSPTOSB08a.pdf	612313 3850ff495a7dc7ee739d643c62b10bee45699c15	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
3	Non Patent Literature	GOUGH_IdentificationOfThePrimaryGeneDefect.pdf	567961 9a12dd1b098d64d45fee54fb94f4c7d51f0412f5	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	1228739		

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of: Wolfgang et al. Serial No.: 14/150,575

Confirmation No.: 1033 Group Art Unit: 1634

Date Filed: January 8, 2014 Examiner: Johannsen, Diana B.

Title: METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure set forth in 37 C.F.R. 1.56, and further pursuant to the provisions of 37 C.F.R. 1.97 and 1.98, applicants hereby respectfully submit copies of the non-US patents and publications as listed on Form PTO-1449, attached hereto.

Applicant notes that the information disclosure statement as filed January 21, 2014 had an error, in which the Volume Number of non-patent literature reference "Gough et al." was listed incorrectly. Applicant notes that the incorrect listing of this reference was initialed and considered on July 15, 2014; therefore, the correction of this error is for the completeness of record. Applicant submits herewith the corrected listing of this non-patent literature document.

In citing these documents, no representation is made nor intended as to the pertinency or non-pertinency of the art, that better art than that listed is not available, nor that other art is not applicable.

If any fees are required, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 500999.

Respectfully submitted,

Date: January 13, 2015

/Jayme M. Torelli/
Jayme M. Torelli
Reg. No.: 62,735

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 01/28/2015

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
01/28/2015	ELECTRONIC

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

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

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

PTOCommunications@hoffmanwarnick.com

Office Action Summary	Application No. 14/150,575	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	Art Unit 1634	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☒ Responsive to communication(s) filed on *14 Oct 2014*.

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

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

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

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

Disposition of Claims*

5)☒ Claim(s) *1,2,5 and 13-19* is/are pending in the application.

5a) Of the above claim(s) *19* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,5 and 13-18* is/are rejected.

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

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

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

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

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *0914; 1014; 0115*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

FINAL ACTION

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

2. This action is responsive to the Amendment and Response filed October 14, 2014. Claims 1-2 and 5 have been amended, claims 3-4 and 6-12 have been canceled, and claims 13-19 have been added. All prior rejections of claims 3-4 and 6-9 are moot in view of the cancellation of those claims. New claim 19 is withdrawn (see paragraph 5 below) and claims 1-2, 5, and 13-18 are now under consideration. Applicant's amendments and arguments have been thoroughly reviewed, and have overcome the following objections/rejections set forth in the prior Office action:

a. The objections to the specification (although one of applicant's amendments has raised a new objection, as set forth below);

b. The prior rejections of claims under 35 USC 112(b)/second paragraph for indefiniteness (although the amended/new claims are indefinite for the reasons given below);

c. The rejection of claims under 35 USC 103(a) as being unpatentable over Jain (in view of the amendment of claim 1 to require a patient "being treated with fluoxetine"); and

d. The rejection of claims 1-2 under 35 USC 103(a) as being unpatentable over Jain in view of Obach as evidenced by Woosley (in view of the amendment of claim 1 noted above).

Claims 1-2, 5 and 13-18 are rejected for the reasons given below, which include new grounds of rejection necessitated by applicant's amendments. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4. Applicant's election of the species of fluoxetine in the reply filed on March 21, 2014 is again acknowledged.

5. Newly submitted claim 19 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. The methods of claim 1 and claims dependent therefrom are patentably distinct from those of new claim 19. The methods of claim 1 involve administering iloperidone to a patient receiving another drug (fluoxetine) without regard to genotype, whereas new claim 19 is drawn to a method in which information is gathered regarding both genotype and fluoxetine therapy status in determining a dosage of iloperidone. The methods of claims 1 and 19 are separately classified (with claim 1 being classified in, for example, A61K 31/454 and A61K 31/138, and claim 19 in, for example, C12Q1/6883 C12Q/2600/106), and the methods require different fields of search and consideration of different prior art references (such that search and examination of both inventions together would pose a serious burden). Had claim 19 been originally presented, it would have been restricted from the methods of claim 1 and claims dependent therefrom.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim19 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

6. The amendment filed October 14, 2014 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the addition of the recitation "CYP2D6 allele nomenclature" in paragraphs 27 and 47. Applicant has not provided any evidence that this terminology corresponded to the referenced website at the time of applicant's invention, such that the added material constitutes new matter (as it is not referenced or otherwise disclosed elsewhere in the application). (It is also noted that the website referenced is no longer active; the examiner was thus unable to ascertain, e.g., whether the recitation added to the specification appears to have been associated with the recited web address at the time of applicant's invention).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112(b)/second paragraph

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

7. Claims 1-2, 5 and 13-18 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 1-2, 5 and 13-18 are indefinite over the recitation of the limitation “an effective amount of iloperidone that is 12 mg/day or less” in independent claim 1. It is unclear whether this language “effective amount” is simply descriptive with respect to the amount of "12 mg/day or less" (i.e., that 12 mg/day or less constitutes an “effective amount” of iloperidone for the patient specified in the claims), or whether this language is indicating, e.g., that only a sub-range within the range of "12 mg/day or less” may constitute an "effective amount" for the patient; it is thus not clear what is meant or encompassed by the limitation “an effective amount of iloperidone that is 12 mg/day or less”. Further, to the extent that the claim may be directed to the latter, the specification does not indicate what might constitute an “effective amount” for such a patient within the range of “12 mg/day or less.” Rather, the specification discloses the use of “an effective amount of iloperidone…..based on” a patient’s genotype (see paragraph 9 at pages 3-4), and also separately provides a disclosure of the use of dosages of 12 mg/day or less (such as in paragraph 46 at page 16); however, there is no guidance in the specification with regard to what might constitute “an effective amount of iloperidone that is 12 mg/day or less” for a patient as specified in claim 1. Accordingly, further clarification is required with respect to what actual amounts/dosages of iloperidone are embraced by (and excluded from) the claims.

Claims 13-18 are each indefinite over the recitations “wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to….”. Claim

1, from which each of the claims depend, requires a patient “being treated with fluoxetine." Given that the claim from which each of the claims depend requires a method practiced on such a patient, it is unclear how the further recitations of claim 13-18 might actually limit the claims; these further limitations are in conflict with the requirement of claim 1 that the patient of the claims "is being treated with fluoxetine." Accordingly, amendment of the claims is required to make clear what is actually being claimed (which could be achieved by amending claims 13-18 in such a way that they might properly depend from claim 1, or by amending the independent claim in some manner such that the claims may potentially embrace the embodiments of claims 13-18). (It is also noted that claims 13-18 as presently written are considered non-limiting as the claims recite actions only taken “if treatment of the patient with fluoxetine is discontinued;” such an action is both optional in nature and contradictory to a requirement of the patient specified of claim 1).

Claim Rejections - 35 USC § 112(a)/first paragraph – new matter

8. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

9. Claims 1-2, 5 and 13-18 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Claim 1 as amended October 14, 2014 is drawn to a method of "treating a patient who is suffering from schizophrenia, with iloperidone, which patient is being treated with fluoxetine, the method comprising: internally administering to the patient an effective amount of iloperidone that is 12 mg/day or less." As was noted above, it is unclear what is meant by the recitation of the limitation "an effective amount of iloperidone that is 12 mg/day or less;" however, this language appears to potentially encompass, e.g., sub-ranges within the range of "12 mg/day or less" that might be considered "an effective amount" in a patient "being treated with fluoxetine." The application as filed does not disclose such an "effective amount of iloperidone that is 12 mg/day or less." Rather, the original application provides a general disclosure of dosages of 12 mg/day or less of iloperidone, as well as a disclosure of the use of "an effective amount of iloperidone…..based on" a patient's genotype (see paragraph 9 at pages 3-4). As the type of dosages specified in amended claim 1 were not disclosed in the original application, applicant's amendment of October 14, 2014 adds new matter to the claims.

Claim Rejections - 35 USC § 112(d)/fourth paragraph

10. The following is a quotation of 35 U.S.C. 112(d):

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), fourth paragraph:

> Subject to the [fifth paragraph of 35 U.S.C. 112 (pre-AIA)], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

11. Claims 13-18 are rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claims 13-18 each recite a limitation "wherein if treatment of the patient with fluoxetine is discontinued, the dose of iloperidone is adjusted to _____". However, claim 1, from which each of claims 13-18 depend, requires a patient "being treated with fluoxetine." Given that independent claim 1 requires a patient "being treated with fluoxetine," claims 13-18 cannot properly depend from claim 1 as presently written; the claims are not further limiting of the claim from which they depend. Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 103

THE FOLLOWING INCLUDES NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

12. Claims 1-2, 5, and 13-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Jain (Exp. Opin. Invest. Drugs 9(12):2935 [2000]; cited in IDS) in view of Obach (US 2003/0144220 A1 [31 July 2003; filed 21 March 2000]; cited in IDS) and of Cheer and Goa (Drugs 61(1):81 [2001]; previously cited), and with regard to claim 2, as evidenced by Woosley (WO 01/79554 [25 Oct 2001]; cited in IDS).

Jain discloses that iloperidone is used in the treatment of schizophrenia (see entire reference). Jain provides an overview of several studies of iloperidone, teaching that daily dosages of iloperidone up to 24 mg/day have been "found to be well tolerated" (page 2940, right column), as well as clinical trials in which iloperidone was administered at dosages of 4 and 8 mg/day and at 0.25 - 3 mg b.i.d. (Table 4). Jain also discloses a long term study of dosages of 4-16 mg/day (page 2941, left column), as well as the finding of efficacy at a dosage of 8 mg/day, and tolerance of a dosage of 32 mg/day (page 2941). Jain thus teaches both the safety and efficacy of iloperidone dosages embraced by the instant claims (which appear to embrace any dosages "12 mg/day or less"). However, Jain does not teach the administration of iloperidone to a patient being treated with fluoxetine.

Obach discloses the use in combination of CYP2D6 inhibitors and drugs metabolized by CYP2D6 (see entire reference); Obach further discloses that iloperidone is one such drug metabolized by CYP2D6 (see, e.g., paragraphs 28 and 42, and claim

9). Obach teaches adjusting the dosages of drugs metabolized by CYP2D6 (such as iloperidone) in subjects also being treated with a CYP2D6 inhibitor so as to “obtain the benefits” of a therapy including both drugs (described by Obach as a “combination method”)(see, e.g., paragraphs 52-53). Obach provides general guidance with regard to adjustment of dosage of the drug metabolized by CYP2D6, teaching that an appropriate dose regimen "will depend on the patient being treated," and that a therapeutic drug will generally "be administered in an amount ranging from one order of magnitude less than the amount that is known to be efficacious and therapeutically acceptable….to the amount that is known to be efficacious and therapeutically acceptable” (see paragraphs 52-53). Obach thus teaches and provides motivation to one of ordinary skill in the art to adjust the dosage of drugs such as iloperidone by reducing the dosage in a subject also receiving a CYP2D6 inhibitor. However, Obach does not teach that fluoxetine is a CYP2D6 inhibitor.

Cheer and Goa provide a review of the antidepressant fluoxetine (trade name Prozac), teaching that fluoxetine is known to inhibit cytochrome P450 genes including CYP2D6, and stating that this fact "is potentially important for patients with physical illness who may be taking multiple concomitant medications" (see entire reference, particularly page 82, as well as page 90, right column).

In view of the teachings of Jain, Obach, and Cheer and Goa, it would have been *prima facie* obvious to one of ordinary skill in the art to have administered to a schizophrenic patient receiving both iloperidone and fluoxetine a dosage of iloperidone of 12 mg/day or less. As noted above, Jain discloses the efficacy of iloperidone in

treating schizophrenia at a dosage as low as 8 mg/day, as well as tolerance of a dosage of up to 32 mg/day (page 2941); Obach teaches and provides motivation to one of ordinary skill in the art to adjust the dosage of drugs such as iloperidone by reducing the dosage in a subject also receiving a CYP2D6 inhibitor (with the reduced dosage being "administered in an amount ranging from one order of magnitude less than the amount that is known to be efficacious and therapeutically acceptable….to the amount that is known to be efficacious and therapeutically acceptable" (see again paragraphs 52-53). An ordinary artisan would have been further motivated to have employed a dosage of iloperidone as recited in the instant claims in a patient receiving fluoxetine by the teaching of Cheer and Goa that fluoxetine is an inhibitor of CYP2D6 (such that a patient receiving both iloperidone and fluoxetine would be expected to benefit from a reduced dosage as is suggested by Obach with respect to any known CYP2D6 inhibitor). Additionally and/or alternatively, an ordinary artisan would have recognized such a modification as the simple substitution of a specific type of CYP2D6 inhibitor (fluoxetine) for the generally identified "CYP2D6 inhibitor" taught by Obach to achieve the predictable result of more effectively treating a subject receiving both iloperidone and fluoxetine (as is suggested by the teachings of Obach with regard to any "CYP2D6 inhibitor").

With further regard to claim 2, the claim simply recites an inherent benefit of the method of claim 1; the claim does not specify any further active or manipulative steps that are to be performed. Furthermore, it is noted that Woosley teaches that CYP2D6 alleles that result in no enzyme activity "can result in excessive accumulation of drugs

and thereby induce QT interval elongation" (see entire reference, particularly col 2, lines 23-38; col 7, lines 10-16). Thus, the teachings of Woosley establish that impaired CYP2D6 function is associated with QT interval elongation resulting from accumulation of drugs metabolized by CYP2D6, and that subjects in whom CYP2D6 function is impaired (which includes subjects being treated with CYP2D6 inhibitors) will inherently benefit from receiving lower dosages of drugs metabolized by CYP2D6 (with that benefit inherently including reduced risk of QT prolongation). Thus, the teachings of Woosley further establish that the property of claim 2 is simply an inherent benefit of the practice of the method of claim 1.

With regard to claim 5, the dosage of the claim is suggested by the teachings of the cited art for the reasons discussed above. With regard to new claims 13-18 (as discussed above), the claims only apply to a patient in whom fluoxetine treatment has been discontinued, whereas claim 1 (from which the claims depend) requires a patient "being treated with fluoxetine." Claims 13-18 thus do not appear to further limit the method of claim 1 (and further the claims only apply "if" fluoxetine is discontinued, which does not appear to be a possibility actually embraced by the instant claims). Additionally, it is noted that Jain clearly teaches iloperidone dosages in the ranges specified in these claims in treating schizophrenia patients not being treated with other therapies.

13. With regard to the prior rejection of claims based upon the same combination of references (in the Office action of July 15, 2014), the reply of October 14, 2014 **traverses the rejection** on the following grounds. It is noted that the instant claims

generally involve the same subject matter as canceled claims 3-4 (which required administering “an amount of iloperidone that is 12 mg/day or less” to a patient “being treated with fluoxetine;” this rejection is traversed at pages 12-20 of applicant’s reply).

The reply argues that Jain “does not teach that the dose of iloperidone should be reduced by one-half (i.e., reduced from up to 24 mg/day to 12 mg/day or less) in schizophrenic patients who are being treated with fluoxetine, and further that Obach “says nothing about optimizing the beneficial effects of both drugs” (pages 12-13). The reply summarizes the teachings of Obach, essentially urging that Obach does not provide sufficient guidance with regard to how (or even whether) iloperidone dosages should be adjusted in a patient being treating with a CYP2D6 inhibitor (pages 13-14). The reply also notes that Cheer and Goa do not teach a reduction of iloperidone dosage in a patient being treated with fluoxetine, and that “the mere facts that fluoxetine is a CYP2D6 inhibitor and that iloperidone is cleared by CYP2D6 mediated oxidative biotransformation do not mean that the risk of QT prolongation can be lowered by reducing the dose of iloperidone in patients being coadministered iloperidone and fluoxetine, or that the dose of iloperidone should be reduced for any reasons at all.” The reply also discusses prescribing information for risperidone (which the reply notes is, like iloperidone, an atypical antipsychotic) and fluoxetine that was available at the time the instant application was filed, noting that that guidance indicates only that risperidone dosing should be "re-evaluated" when initiating or discontinuing fluoxetine (pages 15-18). Applicant contrasts this guidance with 2009 (post-filing date) prescribing information for iloperidone, which calls for reducing iloperidone dosage by one-half

when co-administering fluoxetine, and essentially argues that the FDA guidance regarding risperidone amounts to a “teaching away” from the claimed invention based on the guidance available at the time of filing of the application. Applicant also argues that the teachings of the cited art (and particularly Jain) "fails to teach or even suggest a dosage within the range of 8-32 mg/day that would provide an effective amount and that would reduce the risk of QT prolongation in a patient who is also being treated with fluoxetine” (pages 18-19), and further that the range of dosages suggested by the references (and particularly by the teachings of Obach) is so broad that it cannot render the dosages of the claims obvious (page 19). Additionally, the reply cites a provided Declaration of Dr. Mihael Polymeropoulos (provided in the IDS of October 14, 2014) in support of the argument that "it was not obvious that the dose of iloperidone given to a patient who is a CYP2D6 poor metabolizer should be reduced by any amount, and in particular, to one-half the normal amount." (It is noted that this Declaration was not filed as a Declaration in the instant application; rather, it is a copy of a document relevant to legal action in a parent application).

These arguments have been thoroughly considered but are not persuasive. First, with regard to applicant’s arguments pertaining to teachings absent in individual references (such as that Jain “does not teach that the dose of iloperidone should be reduced by one-half (i.e., reduced from up to 24 mg/day to 12 mg/day or less) in schizophrenic patients who are being treated with fluoxetine”), it is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The instant claims simply require administering any of a range of dosages corresponding to the low end of the effective range taught by Jain in a patient "being treated with fluoxetine," and the prior art provides clear motivation to employ lower dosages of drugs metabolized by CYP2D6 (of which iloperidone is one) in subjects being treated with CYP2D6 inhibitors (of which fluoxetine is one). While applicant's reply references benefits of reduced QT prolongation, these benefits are disclosed in the specification as being achieved in patients having impaired CYP2D6 function due to genotype, not due to fluoxetine treatment (in fact, the original disclosure contains only a single mention of fluoxetine [paragraph 25]; the data reported in the specification involved the use of the inhibitor paroxetine [see, e.g., paragraphs 37), and the focus of the specification is on variations in CYP2D6 genotype that relate to iloperidone metabolism and risk of QT prolongation – no unexpected results related to fluoxetine are referenced). Absent a showing of unexpected results in the type of patient specified in the claims, the teachings of the references are sufficient to suggest that which is actually claimed. Further, to the extent that the use of a lower known dosage of iloperidone reduces the risk of QT prolongation, this is an inherent benefit of the use of such of dosage (and the dosage is suggested by the teachings of the art). With regard to applicant's arguments pertaining to differences in prescribing information for iloperidone as compared to risperidone, applicant has provided only arguments and allegations that an ordinary artisan would have sought information regarding risperidone when evaluating appropriate dosages for iloperidone (and subsequently drawn

conclusions regarding iloperidone based on FDA guidance pertaining specifically to risperidone). The instant rejection is based on teachings of the prior art regarding iloperidone (i.e., relevant to the drug actually recited in the claims), and applicant has not provided any teachings in the art (or other evidence) that establishes that one of ordinary skill in the art at the time of applicant's invention would have reasonably considered the prescribing information for risperidone as relevant to the appropriate dosing of iloperidone (such that the prescribing information for risperidone might reasonably constitute a "teaching away" from the claimed invention). Accordingly, these arguments are not persuasive. Regarding applicant's arguments pertaining to the breadth of the range of iloperidone dosages suggested by the cited art, it is noted that the dosages of the claims clearly fall within the range taught in and suggested by the art. As discussed in MPEP 2144.05 (as well as the prior Office action), optimization of conditions that are already generally disclosed in the prior art is not considered inventive absent evidence of the criticality of a particular range or concentration, etc. (which criticality has not been established in the present case). Finally, regarding applicant's arguments pertaining to the Declaration of Dr. Mihael Polymeropoulos, it is noted that the instant claims differ from those in the patent to which the Declaration pertains; the instant claims do not involve a "patient who is a CYP2D6 poor metabolizer" but rather a patient being treated with another drug (fluoxetine) that is known to inhibit CYP2D6. Accordingly, these arguments are also non-persuasive.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA B. JOHANNSEN whose telephone number is (571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. 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.

/DIANA B JOHANNSEN/
Primary Examiner, Art Unit 1634

WEST Search History for Application 14150575

Creation Date: 2015011617:04

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
(polymeropoulos-m$.in. or wolfgang-c$.in.)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014

((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.))) and dos$4	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((qt or qtc)same(prolong$8 or interval))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
(polymeropoulos-m$.in. or wolfgang-c$.in.)		ADJ	YES		01-16-2015

	PGPB, USPT, DWPI				
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or	PGPB, USPT,	ADJ	YES		01-16-2015

iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((qt or qtc)same(prolong$8 or interval))	DWPI				
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

	1	Complaint For Patent Infringement, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-_____ (22 pages) (US Dist. for the Dist. of Delaware filed June 16, 2014).	☐
	2	Defendant's Motion to Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (4 pages) (US Dist. for the Dist. of Delaware filed August 11, 2014).	☐
	3	Memorandum of Defendant Roxane Laboratories, Inc. In Support Of Its Motion To Dismiss, C.A. No. 14-757-GMS (18 pages) (US Dist. for the Dist. of Delaware filed August 11, 2014).	☐
	4	Vanda's Answering Brief In Opposition To Roxane's Motion To Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (25 pages) (US Dist. for the Dist. of Delaware filed September 11, 2014).	☐
	5	Declaration Of Mihael H. Polymeropoulos In Support Of Vanda's Opposition To Roxane's Motion To Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (290 pages) (US Dist. for the Dist. of Delaware filed September 11, 2014).	☐
	6	Reply Memorandum Of Defendant Roxane Laboratories, Inc. In Support Of Its Motion To Dismiss, Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc., C.A. No. 14-757-GMS (15 pages) (US Dist. for the Dist. of Delaware filed September 29, 2014).	☐
	7	Novartis Pharmaceuticals Corporation, Fanapt Full Prescribing Information (20 pages) (April 2014).	☐
	8	Janssen Pharmaceutica Products, L.P., Risperdal(R) (Risperidone) tablets/oral solution; Risperdal(R) M-TAB(TM) (Risperidone) Orally Disintegrating Tablets (34 pages) (December 2003).	☐
	9	Janssen Pharmaceuticals, Inc., Risperdal Full Prescribing Information (58 pages) (April 2014).	☐
	10	Janssen Pharmaceuticals, Inc., Risperdal Full Prescribing Information (57 pages) (Revised July 2012, accepted by the US FDA August 2012).	☐
	11	Janssen Pharmaceuticals, Inc., Risperdal Full Prescribing Information (57 pages) (September 2011).	☐

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Wolfgang et al.
	Art Unit	1634
	Examiner Name	Johannsen, Diana B.
	Attorney Docket Number	VAND-0002-US-CON2

	12	Vanda Pharmaceuticals Inc., Fanapt (iloperidone) Tablets Full Prescribing Information (23 pages) (May 2009).	☐

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EXAMINER SIGNATURE

Examiner Signature	/Diana B. Johannsen/	Date Considered	01/16/2015

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	Art Unit
	DIANA B JOHANNSEN	1634

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM search; reviewed 14/060,978; 11/576,178; 60/614,798; 14/044,183; 12/301,675	7 July 2014	DBJ
STN search - see search history printout	7 July 2014	DBJ
WEST search - see search history printout	7 July 2014	DBJ
updated PALM search; updated WEST search - see search history printout	16 Jan 2015	DBJ

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

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	First Named Inventor	Curt Wolfgang et al.
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

	1	GOUGH et al., "Identification of the Primary Gene Defect at the Cytochrome P 450 CYP2D Locus", Nature, October 25, 1990, pp.773-776, Volume 347.	☐

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Examiner Signature	/Diana B. Johannsen/	Date Considered	01/16/2015

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

	1	JOHANNSEN, Office Action Communication for US Application No. 14/060,978 dated June 5, 2014, Attorney Docket No. VAND-0002-US-CON, 48 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/Diana B. Johannsen/	Date Considered	01/16/2015

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Attorney Docket Number	VAND-0002-US-CON2

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	1	8586610	B2	2013-11-19	Wolfgang et al.	

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	1	02099118	WO	A2	2002-12-12	DNA Laboratories Sciences, Inc.		☐
	2	2004074456	WO	A2	2004-09-02	Mayo Foundation for Medical Education and Research		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
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	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

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	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2015-04-01
Name/Print	Jayme M. Torelli	Registration Number	62735

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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 record s.

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.

Electronic Patent Application Fee Transmittal

Application Number:	14150575
Filing Date:	08-Jan-2014
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Filer:	Jayme M. Torelli
Attorney Docket Number:	VAND-0002-US-CON2

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	21944625
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	01-APR-2015
Filing Date:	08-JAN-2014
Time Stamp:	17:42:53
Application Type:	Utility under 35 USC 111(a)

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Payment Type	Credit Card
Payment was successfully received in RAM	$180
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1	Foreign Reference	WO2002099118.pdf	1523247 176643b3dc12dd8f4d0041469fced4a29368c7f8	no	32
Warnings:					
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2	Foreign Reference	WO2004074456A2.pdf	3077313 26a2a7076d4020f0fba0c6ff9211bb23cc442b53	no	62
Warnings:					
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3	Information Disclosure Statement (IDS) Form (SB08)	VAND-0002-US-CON2_SupplDS_04-01-15.pdf	612339 22b7b6afa856242f1cf8dfb697e0137919848bb5	no	4
Warnings:					
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4	Fee Worksheet (SB06)	fee-info.pdf	30340 6d1b21d2888e2bb216d879b21198dc4d317caaf5	no	2
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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 04/22/2015

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
04/22/2015	ELECTRONIC

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

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

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

PTOCommunications@hoffmanwarnick.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	14/150,575	WOLFGANG ET AL.	
	Examiner	Art Unit	
	DIANA B. JOHANNSEN	1634	

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

(1) *Diana Johannsen*. (3)_____.

(2) *Jayme Torelli*. (4)_____.

Date of Interview: *16 April 2015*.

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

Exhibit shown or demonstration conducted: ☒ Yes ☐ No.
If Yes, brief description: *interview agenda/proposed amendments (attached)*.

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: *proposed amended claims, particularly 1 and 20 (see attachment)*.

Identification of prior art discussed: *art currently applied under 35 USC 103, particularly Obach*.

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...)

See Continuation Sheet.

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

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

☒ Attachment

/DIANA B JOHANNSEN/ Primary Examiner, Art Unit 1634	

Summary of Record of Interview Requirements

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

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

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

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

———

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

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

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

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

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

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

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

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

Examiner to Check for Accuracy

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

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: It was agreed that the proposed amendments would overcome the rejections under 35 USC 112(a), (b), and (d), as well as the objection to the specification (regarding the proposed amendments to the specification, the examiner also noted that it was not necessary to delete the originally recited web address in order to overcome the objection). Regarding proposed new claim 20, the examiner suggested clarifying the language of the claim by referencing a single patient in the preamble and referencing that same patient in the body of the claim (as the current language is confusing with regard to whether the method pertains to a single or multiple patients). The examiner indicated that prior art would not apply against claim 20 in view of the specific dosages recited (as the teachings of the art at the time of applicant's invention were not sufficient to suggest the use of the specific dosage of 24 mg/day of iloperidone in a patient being treated for schizophrenia and not being treating with fluoxetine, and the use of the specific dosage of 12 mg/day in such a patient when the patient is being treated with fluoxetine). However, the examiner indicated that she was not yet persuaded as to the patentability of claim 1 in view of the broad range of dosages embraced by the claims; the examiner reiterated that (as stated in the outstanding Office action) the art taught a range of dosages for iloperidone that overlaps that of the claims, and further provided motivated to employ a lower dosage in a patient also being treated with a CYP2D6 inhibitor. Applicant's representative argued that the examiner's position is incorrect for several reasons: applicant's representative urged that metabolism of iloperidone is complicated and differs from that of other drugs using the same pathways (such as oxycodone), particularly noting that iloperidone has multiple metabolites (P88, P95, P89) and the fact that iloperidone and P88 (but not P89 and P95) may interconvert, that P88 (but not the other metabolites) has been found to be involved in causing QT prolongation; and that P89 may also be metabolized by CYP3A4; Applicant's representative also argued that the teachings of Obach are too broad and general to suggest the method and dosages encompassed by the claims. The examiner suggested the possibility of providing evidence and/or references supporting a conclusion that the prior art is/was insufficient to suggest the use of the dosages of iloperidone embraced by the claims in a patient also being treated with fluoxetine (as the examiner agrees that the teachings of Obach are general and that Obach recites many different drugs, whereas the claims are directed only to use of iloperidone in a patient being treated with fluoxetine). The examiner reiterated that the claims embrace a range of dosages overlapping those taught in the art, and that the methods claimed appear to be the result of routine optimization based on the art considered by the examiner (see MPEP 2144.05 regarding the obviousness of ranges; the examiner noted that no evidence of unexpected results has been provided (either in the specification or a declaration), nor does the art of record teach away from the claimed invention). The examiner stated that she would fully consider applicant's arguments and re-consider whether the optimization involved in the present case was in fact routine. Applicant plans to file an after final amendment (likely under AFCP 2.0); the examiner will review the amendment and contact applicant's representative to discuss allowable subject matter and a possible examiner's amendment if needed (as it appears that at least some claims may be allowable after final).

Attachment to interview summary (for discussion only)
/D.B.J./ 04/16/2015

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Wolfgang, et al.	**Conf. No.**:	1033
Serial No.:	14/150,575	**Art Unit**:	1634
Filed:	01/08/2014	**Examiner**:	Johannsen, Diana B.
Docket. No.:	VAND-0002-US-CON2		
Title:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		

[redacted]

/D.B.J./

AGENDA FOR TELEPHONE INTERVIEW

I. INTRODUCTORY COMMENTS

The following proposed amendments and remarks are provided in advance of the telephone interview scheduled for Thursday, April 16, 2015 at 2pm EDT, in which the above-captioned related cases are to be discussed.

/D.B.J./

Proposed Amendments to the Specification - 14/150,575

[0027] The *CYP2D6* gene is highly polymorphic, with more than 70 allelic variants described so far. ~~*See, e.g.*, CYP2D6 allele nomenclature, at www.imm.ki.se/CYPalleles/cyp2d6.htm.~~ Most embodiments of the present invention concern the two most common polymorphisms within the *CYP2D6* gene in Caucasian populations, *CYP2D6G1846A* and *CYP2D6P34S* (also referred to as *CYP2D6C100T*). These polymorphisms correspond to nucleotides 3465 and 1719, respectively, in GenBank sequence M33388.1 (GI:181303). The *CYP2D6P34S*/*CYP2D6C100T* polymorphism also corresponds to nucleotide 100 in GenBank mRNA sequence M20403.1 (GI:181349).

[0047] Decreased CYP2D6 activity may be the result of other mutations~~, including those described at CYP2D6 allele nomenclature, at www.imm.ki.se/CYPalleles/cyp2d6.htm, which is incorporated herein by reference~~. In particular, it is noted that the CYP2D6*2A mutation includes a CYP2D7 gene conversion in intron 1. In some cases, the lower CYP2D6 activity in a CYP2D6 poor metabolizer may be due to factors other than genotype. For example, a patient may be undergoing treatment with an agent, e.g., a drug that reduces CYP2D6 activity.

FOR DISCUSSION ONLY /D.B.J./ 04/16/2015

Proposed Amendments to the Claims - 14/150,575

The following listing is proposed for purposes of discussion in the interview only.

1. (Currently amended) A method of treating a patient who is suffering from schizophrenia, with iloperidone, which patient is being treated with fluoxetine, the method comprising:

internally administering to the patient an ~~effective~~ amount of iloperidone that is 12 mg/day or less.

2. (Previously presented) The method of claim 1, wherein the risk of QT prolongation is reduced relative to the risk of QT prolongation that would result from internally administering to the patient an amount of iloperidone that is greater than 12 mg/day while the patient is also being treated with fluoxetine.

3-4. (Canceled)

5. (Previously presented) The method of claim 1, wherein the amount of iloperidone is 12 mg/day.

6-19. (Canceled)

20. (New) A method of decreasing a risk of QT prolongation in patients being treated for schizophrenia with iloperidone, the method comprising:

administering to a patient a dose of iloperidone that is 24 mg/day if the patient is not being treated with fluoxetine; and

administering to a patient a dose of iloperidone that is 12 mg/day if the patient is being treated with fluoxetine.

Remarks - 14/150,575

Elections/Restrictions

Applicant proposes to cancel claim 19 herein.

Objections to the Specification

Applicant proposes to delete the objected-to language from paragraphs [0027] and [0047].

Rejections under 35 U.S.C. § 112, second paragraph

Applicant proposes to amend claim 1 to delete "effective," such that claim 1 now recites "an amount of iloperidone that is 12 mg/day or less"[1]. Applicant submits that as presented herein, claim 1 (and claims 2 and 5 which depend therefrom) is definite. Applicant proposes to cancel claims 13-18, thereby rendering these rejections moot.

Rejections under 35 U.S.C. § 112, first paragraph

Applicant proposes to amend claim 1 to delete "effective," such that claim 1 now recites "an amount of iloperidone that is 12 mg/day or less"[2]. Applicant submits that as presented herein, the features of claim 1 (and respective dependent claims) are disclosed in the application as filed, as acknowledged the the Office[3].

Rejections under 35 U.S.C. § 112, fourth paragraph

Applicant proposes to cancel claims 13-18, thereby rendering these rejections moot.

Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1, 2, 5, and 13-18 are rejected under § 103(a) as being allegedly unpatentable over Jain[4] in view of Obach[5] and Cheer & Goa[6], and with regard to claim

---

[1] Claim 1.

[2] Claim 1.

[3] Final Office Action, p. 7.

[4] Jain, Exp. Opin. Invest. Drugs 9(12):2935 (2000) ("Jain" herein).

[5] Obach, US Pat. Pub. 2003/0144220 ("Obach" herein).

[6] Cheer & Goa, *Fluoxetine: A Review of its Therapeutic Potential in the Treatment of Depression Associated with Physical Illness*, Drugs 61(1):81 (2001) ("Cheer & Goa" herein).

2, as evidenced by Woosley[7]. Applicant proposes to cancel claims 13-18 herein without prejudice, and respectfully traverses the rejections of claims 1, 2, and 5.

In addition to reasons previously discussed in responses of record, Applicant notes that the Examiner objects in the Final Office Action to "attacking references individually where the rejections are based on combinations of references."[8] Without conceding that this is an accurate interpretation of Applicant's previous arguments, Applicant submits that taking the references collectively, and giving Jain the full weight accorded it by the examiner[9], what the skilled person learns is that:

- iloperidone was shown to be safe and effective in clinical trials at doses of 4-16 mg/day, or at 8-32 mg/day, and
- that iloperidone may be prescribed with a CYP2D6 inhibitor and,
- if it is co-prescribed, then the normal dose of iloperidone, which is 4-16 mg/day or 8-32 mg/day, may need to be adjusted or it may not need to be adjusted and,
- if it is adjusted, the adjusted dose could be as much as an order of magnitude lower than the normal dose on up to greater than the normal dose.

Adding in Woosley, the collective teaching appears to Applicant to be that:

- iloperidone was shown to be safe and effective in clinical trials at doses of 4-16 mg/day, or at 8-32 mg/day, and
- iloperidone may be prescribed with a CYP2D6 inhibitor and,
- if it is co-prescribed, then the normal dose of iloperidone, which is 4-16 mg/day or 8-32 mg/day, may need to be adjusted or it may not need to be adjusted and,
- if it is adjusted, the adjusted dose could be as much as an order of magnitude lower than the normal dose on up to greater than the normal dose, and
- if the patient has "genetic mutations or polymorphisms … located in two or more of the group of genes consisting of (1) *LQT* genes, (2) altered sensitivity genes, and (3)

[7] Woosley, WO 01/79554 ("Woosley" herein).

[8] Final Office Action, p. 14.

[9] Without acquiescing in the examiner's characterization of that reference as being accurate.

increased exposure genes,"[10] the latter of which "can include cytochrome P450 genes,"[11] then the patient is at risk of QT prolongation.

Applicants are respectfully a loss to understand how this collective teaching, with or without Woosley, leads the skilled person to the method of Applicant's claim 1, which is limited to:

> "A method of treating a patient who is suffering from schizophrenia, with iloperidone, which patient is being treated with fluoxetine, the method comprising:
>
> internally administering to the patient an amount of iloperidone that is 12 mg/day or less"[12].

[10] Woosley, p. 11, lines 2-4.

[11] Woosley, p. 16, lines 25-27.

[12] Claim 1.

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
VAND-0002-US-CON2	14/150,575	01/08/2014
First Named Inventor:	**Title:**	
Wolfgang, et al.	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Jayme M. Torelli/	2015-04-28
Name (Print/Typed) Jayme M. Torelli	**Practitioner Registration No.** 62735

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

Privacy Act Statement

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

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

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.

REPLY UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
TECHNOLOGY CENTER 1600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Wolfgang, et al.	**Conf. No.**:	1033
Serial No.:	14/150,575	**Art Unit**:	1634
Filed:	01/08/2014	**Examiner**:	Johannsen, Diana B.
Docket. No.:	VAND-0002-US-CON2		
Title:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		

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

AMENDMENT AFTER FINAL

Sir:

I. INTRODUCTORY COMMENTS

This paper is being filed in response to the final Office Action dated January 28, 2015, and is submitted concurrently with a Certification and Request for Consideration under the AFCP 2.0 pilot program. Please amend the above-referenced patent application in accordance with the following:

Amendments to the Specification appear on page 2 of this paper;

A Listing of the Claims appears beginning on page 3 of this paper;

Applicant's summary of telephone interview with the Examiner appears on page 4 of this paper; and

Remarks begin on page 5 of this paper.

II. AMENDMENTS TO THE SPECIFICATION

Please amend the specification in accordance with the following items A-B:

A. Please amend paragraph [0027] at line 2 in accordance with the following:

[0027] The *CYP2D6* gene is highly polymorphic, with more than 70 allelic variants described so far. ~~*See, e.g.*, CYP2D6 allele nomenclature, at www.imm.ki.se/CYPalleles/cyp2d6.htm.~~ Most embodiments of the present invention concern the two most common polymorphisms within the *CYP2D6* gene in Caucasian populations, *CYP2D6G1846A* and *CYP2D6P34S* (also referred to as *CYP2D6C100T*). These polymorphisms correspond to nucleotides 3465 and 1719, respectively, in GenBank sequence M33388.1 (GI:181303). The *CYP2D6P34S*/*CYP2D6C100T* polymorphism also corresponds to nucleotide 100 in GenBank mRNA sequence M20403.1 (GI:181349).

B. Please amend paragraph [0047] at lines 1-3 in accordance with the following:

[0047] Decreased CYP2D6 activity may be the result of other mutations~~, including those described at CYP2D6 allele nomenclature, at www.imm.ki.se/CYPalleles/cyp2d6.htm, which is incorporated herein by reference~~. In particular, it is noted that the CYP2D6*2A mutation includes a CYP2D7 gene conversion in intron 1. In some cases, the lower CYP2D6 activity in a CYP2D6 poor metabolizer may be due to factors other than genotype. For example, a patient may be undergoing treatment with an agent, e.g., a drug that reduces CYP2D6 activity.

III. LISTING OF THE CLAIMS

The following listing replaces any and all prior listings of the claims:

1-19. (Canceled)

20. (New) A method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising:

administering to the patient a dose of iloperidone that is 24 mg/day if the patient is not being treated with fluoxetine; and

administering to the patient a dose of iloperidone that is 12 mg/day if the patient is being treated with fluoxetine.

21. (New) A method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising:

administering to the patient a dose of iloperidone that is greater than 12 mg/day and up to 24 mg/day if the patient is not being treated with fluoxetine; and

administering to the patient a dose of iloperidone that is 12 mg/day or less if the patient is being treated with fluoxetine.

IV. APPLICANT'S SUMMARY OF TELEPHONE INTERVIEW WITH EXAMINER

Initially, Applicants wish to thank Examiner Johannsen for the courtesies extended during the telephone interview with Applicants' undersigned representative on April 16, 2015.

During the interview, a proposed amendment dated April 15, 2015 was discussed. Applicant proposed to amend the specification at paragraphs [0027] and [0047] and claim 1; cancel claims 13-18; and add new claim 20.

It was agreed that the proposed amendments to paragraphs [0027] and [0047] obviated the objections to the specification, and the proposed amendment to claim 1 and cancellation of claims 13-18 obviated the rejections under 35 U.S.C. § 112, first, second, and fourth paragraphs.

The Examiner suggested minor amendments to proposed new claim 20, to more clearly reference "a single patient in the preamble and referencing that same patient in the body of the claim"[1]. These suggestions are embodied in the presently presented claim 20. It was agreed that proposed claim 20 was patentable over the cited art in view of the specific dosages recited.[2] No agreement was reached as to the allowability of claims 1, 2, and 5 over the cited art, as discussed by the Examiner in her Applicant-Initiated Interview Summary of April 22, 2015.

As also noted in the Examiner's Applicant-Initiated Interview Summary of April 22, 2015, in the event that anything further is required to place the application in condition for allowance, Applicants would very much appreciate the opportunity to address any issues via telephone in the interest of expeditious allowance.

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[1] Applicant-Initiated Interview Summary, Continuation Sheet (April 22, 2015).

[2] *Id.*

V. REMARKS

Claims 20 and 21 are pending in this application. By this Amendment, the specification is amended at paragraphs [0027] and [0047]; claims 20 and 21 are added; and claims 1, 2, 5, and 13-19 are canceled. Claims 3-4 and 6-12 were previously canceled. No new matter is introduced in new claims 20-21.

Applicants are not conceding in this application that any claims are not patentable over the art cited by the Examiner, as the present claim amendments are only for facilitating expeditious allowance of the claimed subject matter. Applicants respectfully reserve the right to pursue these and other claims in one or more continuation and/or divisional patent applications. Reconsideration in view of the following remarks is respectfully requested.

Entry of these amendments is proper under 37 C.F.R. 1.116(b) because the amendments: (a) place the application in condition for allowance as discussed below; (b) do not raise any new issues requiring further search and/or consideration; and (c) place the application in better form for appeal.

Elections/Restrictions

In the Office Action, the Examiner alleges that claim 19, presented in the Amendment dated October 14, 2014, "is directed to an invention that is independent or distinct from the invention originally claimed,"[3] and is therefore withdrawn from consideration. Applicant has canceled claim 19 herein.

Objections to the Specification

In the Office Action, the Examiner objects to the specification, in particular, paragraphs [0027] and [0047]. Without acquiescing in the correctness of the Examiner's position that the recitation of "CYP2D6 allele nomenclature" represents new matter, Applicant has deleted the objected-to language from paragraphs [0027] and [0047], thereby obviating the rejection as agreed in the interview.

[3] Office Action, p. 3.

Rejections under 35 U.S.C. § 112, second paragraph

In the Office Action, claims 1, 2, 5, and 13-18 are rejected under § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventors regard as the invention. In particular, the Examiner objects to the term "an effective amount of iloperidone that is 12 mg/day or less" in claim 1. Without acquiescing in the Examiner's determination that the claims as previously presented are indefinite, Applicants have canceled claims 1, 2, 5, and 13-18 herein, thereby rendering the rejection moot.

Rejections under 35 U.S.C. § 112, first paragraph

In the Office Action, claims 1, 2, 5, and 13-18 are rejected under § 112, first paragraph as allegedly failing to comply with the written description requirement. In particular, the Examiner objects to the term "an effective amount of iloperidone that is 12 mg/day or less" in claim 1 as being new matter. Without acquiescing in the Examiner's determination that the claims as previously presented include new matter, Applicants have canceled claims 1, 2, 5, and 13-18 herein, thereby rendering the rejection moot.

Rejections under 35 U.S.C. § 112, fourth paragraph

In the Office Action, claims 13-18 are rejected under § 112, fourth paragraph as allegedly being of improper dependent form. Without acquiescing in the Examiner's determination that the claims as previously presented fail to further limit the subject matter of the claim upon which they depend, Applicants have canceled claims 13-18 herein, thereby rendering the rejection moot.

Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1, 2, 5, and 13-18 are rejected under § 103(a) as being allegedly unpatentable over Jain[4] in view of Obach[5] and Cheer & Goa[6], and with regard to claim 2, as evidenced by Woosley[7].

As noted above, Applicants have cancelled claims 1, 2, 5, and 13-18 without prejudice to the patentability of these claims, thereby rendering the rejections moot.

With respect to new claim 20, Applicants submit that this claim includes all of the features of proposed claim 20, which was agreed to be patentable over the cited art during the telephone interview. Further, new claim 20 includes each of the Examiner's suggested amendments to improve clarity. Accordingly, Applicants respectfully submit that this claim is allowable for the reasons discussed in the telephone interview.

With respect to claim 21, Applicants submit that this claim is identical to claim 20, discussed above, except that it recites:

> "A method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising:
>
> administering to the patient a dose of iloperidone that is greater than 12 mg/day and up to 24 mg/day if the patient is not being treated with fluoxetine; and
>
> administering to the patient a dose of iloperidone that is 12 mg/day or less if the patient is being treated with fluoxetine."[8]

Applicants respectfully submit that the same rationales which underlie the agreement as to the allowability of claim 20, apply equally to claim 21. In particular, "the teachings of [Jain, Obach, Cheer & Goa, and Woosley] were not sufficient to suggest the use of the specific dosage [range of greater than 12 mg/day and up to] 24 mg/day of iloperidone in a patient being treated for

---

[4] Jain, Exp. Opin. Invest. Drugs 9(12):2935 (2000) ("Jain" herein).

[5] Obach, US Pat. Pub. 2003/0144220 ("Obach" herein).

[6] Cheer & Goa, *Fluoxetine: A Review of its Therapeutic Potential in the Treatment of Depression Associated with Physical Illness*, Drugs 61(1):81 (2001) ("Cheer & Goa" herein).

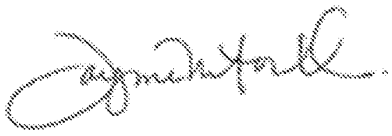
[7] Woosley, WO 01/79554 ("Woosley" herein).

[8] Claim 20.

schizophrenia and not being treated with fluoxetine, and the use of the specific dosage [range of] 12 mg/day [or less] in such a patient when the patient is being treated with fluoxetine."[9] Accordingly, Applicants respectfully submit that claim 21 is also allowable for the reasons discussed in the telephone interview.

Applicants respectfully submit that the Application as presented is in condition for allowance. Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



/ /

Date: April 28, 2015

Jayme M. Torelli
Reg. No. 62,735

Hoffman Warnick LLC
540 Broadway, 4th Floor
Albany, New York 12207
Phone: (518) 449-0044
Fax: (518) 449-0047

[9] Applicant-Initiated Interview Summary, Continuation Sheet (April 22, 2015).

Electronic Acknowledgement Receipt

EFS ID:	22185182
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	28-APR-2015
Filing Date:	08-JAN-2014
Time Stamp:	10:13:02
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	After Final Consideration Program Request	VAND-0002-US-CON2_AfterFinalConsiderationPilotProgram_2015-04-28.pdf	226316 caac23007c4bccadfa497fb7e7cf747d070d0328	no	2

Warnings:

Information:

2		VAND-0002-US-CON2_AmendmentToFinalOfficeAction1_2015-04-28.pdf	137361 940fdb9641ef8830ea55fc2cbefbfb8ce5b0f6da	yes	8

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Response After Final Action	1	1
Specification	2	2
Claims	3	3
Applicant summary of interview with examiner	4	4
Applicant Arguments/Remarks Made in an Amendment	5	8

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New International Application Filed with the USPTO as a Receiving Office
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/150,575	Filing Date 01/08/2014	☐ 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)		
	04/28/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 2	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)		
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	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
/HENRIETT K. DENDY/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

	1	Roden, "Drug-induced prolongation of the QT interval," N Engl J Med. 350(10):1013-22 (2004).	☐
	2	Office Action for Canadian Patent Application No. 2,582,022, dated April 28, 2015, Attorney Docket No. VAND-0002-CA (4 pages).	☐

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Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jayme M. Torelli/	Date (YYYY-MM-DD)	2015-05-22
Name/Print	Jayme M. Torelli	Registration Number	62735

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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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 Patent Application Fee Transmittal

Application Number:	14150575
Filing Date:	08-Jan-2014
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Filer:	Jayme M. Torelli
Attorney Docket Number:	VAND-0002-US-CON2

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	22418651
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	22-MAY-2015
Filing Date:	08-JAN-2014
Time Stamp:	11:50:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	9068
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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)	VAND-0002-US-CON2_SuppIDS_22MAY2015.pdf	612376 dbffa5235b0c1ba840931f5239eddfaa5e2db8e3	no	4
Warnings:					
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A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	Roden_2004.pdf	258056 d5b2647c64db3a7cc71885c8d0c732035b7e460f	no	10
Warnings:					
Information:					
3	Non Patent Literature	VAND-0002-CA_OfficeAction2_28APR2015.pdf	577921 b4f7a175a77f21eef22a49aa10b35013fb72d998	no	4
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30339 9c315819224c51705ff77cc14e356df8dc53f55e	no	2
Warnings:					
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		Total Files Size (in bytes):	1478692		

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Electronic Patent Application Fee Transmittal

Application Number:	14150575
Filing Date:	08-Jan-2014
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Filer:	Jayme M. Torelli
Attorney Docket Number:	VAND-0002-US-CON2

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 - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
		Total in USD ($)		**200**

Electronic Acknowledgement Receipt

EFS ID:	22472483
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	28-MAY-2015
Filing Date:	08-JAN-2014
Time Stamp:	15:07:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$200
RAM confirmation Number	1446
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

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	30505 508f6a5b8733333828c87b5693727093c66e3f8c	no	2

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Information:	
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HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/02/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

TITLE OF INVENTION: METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

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	09/02/2015

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)

23550 7590 06/02/2015
HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

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.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

TITLE OF INVENTION: METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

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	09/02/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
JOHANNSEN, DIANA B	1634	435-006100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

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

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

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

4a. The following fee(s) are submitted:
❑ Issue Fee
❑ Publication Fee (No small entity discount permitted)
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
❑ A check is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
❑ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
❑ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
❑ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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

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.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 06/02/2015

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/02/2015

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. 14/150,575	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	Art Unit 1634	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 *See Continuation Sheet*.
   ☐ 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 *20*. 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 0415; 0515
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *part of 20150508* .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☒ Other *PTOL-2323*.

/DIANA B JOHANNSEN/
Primary Examiner, Art Unit 1634

Continuation of Item 1. This communication is responsive to : the Amendment After Final filed 04/28/15; the interview concluding 5/12/15.

EXAMINER'S AMENDMENT

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

2. This action is responsive to the Amendment After Final filed April 28, 2015 and the interview concluding May 12, 2015. The After Final Amendment (including amendments to the claims and specification) has been entered and claim 20 is now allowed. In accordance with 37 CFR 1.126, claim 20 will be renumbered as claim 1 in the issued patent. Original claim numbering is employed in the examiner's amendment below.

3. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. Applicant's representative, Jayme M. Torelli, has submitted a $200.00 credit card payment for the required one month extension of time, and authorized the following examiner's amendment. 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.

4. **Amend the application** as follows:

a. **Enter the after final amendment** (including amendments to the claims and specification) filed April 28, 2015.

b. **Cancel** claim 21.

c. **At page 1, paragraph 1, line 2 of the specification**, after "14/060,978, filed October 23, 2013," insert--now abandoned,--.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA B. JOHANNSEN whose telephone number is (571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. 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.

/DIANA B JOHANNSEN/
Primary Examiner, Art Unit 1634

Examiner-Initiated Interview Summary	Application No. 14/150,575	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	Art Unit 1634	

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

(1) *Diana Johannsen*. (3)_____.

(2) *Jayme Torelli*. (4)_____.

Date of Interview: *12 May 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: *20 and 21*.

Identification of prior art discussed: *N/A*.

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...)

On 5/8/15, the examiner left a message for applicant's representative proposing to: enter applicant's after final amendment of 4/28/15, allow claim 20, cancel claim 21, and amend the first paragraph of the specification (at line 2) to update the status of the parent application (which is now abandoned). (It is noted that new claim 20 was discussed as a draft claim in the interview of 4/16/15 and is allowable for the reasons indicated in the summary of that interview). The examiner indicated that she was not persuaded as to the patentability of proposed claim 21 (which recites ranges of dosages overlapping those taught in the art) for the reasons discussed in the prior interview (of 4/16/15). Applicant's representative authorized the proposed amendments by phone message on 5/11/15, but inquired as to why a further extension of time was needed; this was discussed briefly by phone on 5/12/15, and applicant's representative authorized the required one month extension of time (see also MPEP 706.07(f)).

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

/DIANA B JOHANNSEN/ Primary Examiner, Art Unit 1634	

WEST Search History for Application 14150575

Creation Date: 2015050813:11

Interference Searches

Query	DB	Op.	Plur.	Thes.	Date
vanda $.as.	UPAD	ADJ	YES		05-08-2015
(polymeropoulos-m $.in. or wolfgang-c $.in.)	UPAD	ADJ	YES		05-08-2015
(iloperidone or zomaril or ethanone)	UPAD	ADJ	YES		05-08-2015
(prozac or fluoxetine)	UPAD	ADJ	YES		05-08-2015
((prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone))	UPAD	ADJ	YES		05-08-2015

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
(polymeropoulos-m$.in. or wolfgang-c$.in.)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		07-07-2014

((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.))) and dos$4	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((qt or qtc)same(prolong$8 or interval))	PGPB, USPT, DWPI	ADJ	YES		07-07-2014
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or	PGPB, USPT, DWPI	ADJ	YES		07-07-2014

(polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))					
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
(polymeropoulos-m$.in. or wolfgang-c$.in.)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or	PGPB, USPT, DWPI	ADJ	YES		01-16-2015

zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))					
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((qt or qtc)same(prolong$8 or interval))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))	PGPB, USPT, DWPI	ADJ	YES		01-16-2015
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
(polymeropoulos-m$.in. or wolfgang-c$.in.)	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		04-16-2015

((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.))) and dos$4	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
		ADJ	YES		04-16-2015

((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((qt or qtc)same(prolong$8 or interval))	PGPB, USPT, DWPI				
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))	PGPB, USPT, DWPI	ADJ	YES		04-16-2015
vanda$.as.	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
(polymeropoulos-m$.in. or wolfgang-c$.in.)	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
(iloperidone or zomaril or ethanone)	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone)) and ((vanda$.as.) or ((polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone)) and (prozac or fluoxetine)	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and ((iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		05-08-2015

((iloperidone or zomaril or ethanone) and (prozac or fluoxetine)) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) and ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3)) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)))	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.))) and dos$4	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) and ((iloperidone or zomaril or ethanone)) .ab.	PGPB, USPT, DWPI	ADJ	YES		05-08-2015
((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4) not ((iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) not (iloperidone or zomaril or ethanone) and (prozac or fluoxetine) and (cyp2d6$3 or 2d6$3 or cypiid6$3 or iid6$3) and (iloperidone or zomaril or	PGPB, USPT, DWPI	ADJ	YES		05-08-2015

ethanone) and (prozac or fluoxetine) and (iloperidone or zomaril or ethanone) and (vanda$.as. or (polymeropoulos-m$.in. or wolfgang-c$.in.)) and dos$4 and ((qt or qtc)same(prolong$8 or interval)))					
8586610$.pn.	PGPB, USPT, DWPI	ADJ	YES		05-08-2015

AFCP 2.0 Decision	Application No.	Applicant(s)
	14/150,575	WOLFGANG ET AL.
	Examiner	Art Unit
	DIANA B. JOHANNSEN	1634

This is in response to the After Final Consideration Pilot request filed 28 April 2015.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☒ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ A proper AFCP 2.0 request was submitted in response to the most recent final rejection.

   ☐ Other:

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☐ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action. See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other:

   Examiner Note: Please attach an interview summary when necessary as described above.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	Art Unit
	DIANA B JOHANNSEN	1634

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM search; reviewed 14/060,978; 11/576,178; 60/614,798; 14/044,183; 12/301,675	7 July 2014	DBJ
STN search - see search history printout	7 July 2014	DBJ
WEST search - see search history printout	7 July 2014	DBJ
updated PALM search; updated WEST search - see search history printout	16 Jan 2015	DBJ
updated PALM search; updated WEST search - see search history printout	8 May 2015	DBJ

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	text interference search in WEST - see search history	8 May 2015	DBJ

	/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634

OK TO ENTER: /D.B.J./ 05/12/2015

REPLY UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
TECHNOLOGY CENTER 1600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Wolfgang, et al.	**Conf. No.**:	1033
Serial No.:	14/150,575	**Art Unit**:	1634
Filed:	01/08/2014	**Examiner**:	Johannsen, Diana B.
Docket. No.:	VAND-0002-US-CON2		
Title:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		

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

AMENDMENT AFTER FINAL

Sir:

I. INTRODUCTORY COMMENTS

This paper is being filed in response to the final Office Action dated January 28, 2015, and is submitted concurrently with a Certification and Request for Consideration under the AFCP 2.0 pilot program. Please amend the above-referenced patent application in accordance with the following:

Amendments to the Specification appear on page 2 of this paper;

A Listing of the Claims appears beginning on page 3 of this paper;

Applicant's summary of telephone interview with the Examiner appears on page 4 of this paper; and

Remarks begin on page 5 of this paper.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	**Art Unit**
	DIANA B JOHANNSEN	1634

CPC							
Symbol						**Type**	**Version**
A61K		31	/	454		F	2013-01-01
A61K		31	/	519		I	2013-01-01
C12Q		1	/	6883		I	2013-01-01
C12Q		2600	/	106		A	2013-01-01
C12Q		2600	/	156		A	2013-01-01
C12Q		2600	/	172		A	2013-01-01
			/				
			/				
			/				
			/				
			/				
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			/				
			/				
			/				

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	1	
/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634	05/12/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	**Art Unit**
	DIANA B JOHANNSEN	1634

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
		A	6	1	K	31 / 454 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 1	
/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634 05/12/2015 (Primary Examiner) (Date)	O.G. Print Claim(s) 1	O.G. Print Figure none

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	**Art Unit**
	DIANA B JOHANNSEN	1634

☒ 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

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 1	
/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634 (Primary Examiner)	05/12/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure none

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					
If you wish to add additional U.S. Published Application citation information please click the Add button.						Add

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NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

	1	Roden, "Drug-induced prolongation of the QT interval," N Engl J Med. 350(10):1013-22 (2004).	☐
	2	Office Action for Canadian Patent Application No. 2,582,022, dated April 28, 2015, Attorney Docket No. VAND-0002-CA (4 pages).	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Diana B. Johannsen/	Date Considered	05/26/2015

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	**Art Unit**
	DIANA B JOHANNSEN	1634

✓	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	05/12/2015								
	1	-								
	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
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	16	-								
	17	-								
	18	-								
	19	-								
	20	=								
	21	-								

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8586610	B2	2013-11-19	Wolfgang et al.	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add

U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					
If you wish to add additional U.S. Published Application citation information please click the Add button.						Add

FOREIGN PATENT DOCUMENTS							Remove	
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	02099118	WO	A2	2002-12-12	DNA Laboratories Sciences, Inc.		☐
	2	2004074456	WO	A2	2004-09-02	Mayo Foundation for Medical Education and Research		☐
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NON-PATENT LITERATURE DOCUMENTS	Remove

EFS Web 2.1.17

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14150575
	Filing Date	2014-01-08
	First Named Inventor	Curt Wolfgang
	Art Unit	1634
	Examiner Name	Diana B. Johannsen
	Attorney Docket Number	VAND-0002-US-CON2

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Diana B. Johannsen/	Date Considered	04/16/2015

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 07/22/2015

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
07/22/2015	ELECTRONIC

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

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

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

PTOCommunications@hoffmanwarnick.com

Applicant-Initiated Interview Summary	**Application No.** 14/150,575	**Applicant(s)** WOLFGANG ET AL.	
	Examiner DIANA B. JOHANNSEN	**Art Unit** 1634	

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

(1) *Diana Johannsen*. (3)_____.

(2) *Jayme Torelli*. (4)_____.

Date of Interview: *15 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: *20*.

Identification of prior art discussed: *NA*.

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...)

On 6/16/15, the possibility of a further amendment to the wording of allowed claim 20 was briefly discussed; applicant wishes to clarify the claimed invention by substituting "because" for "if" in each of the "administering" steps recited in the claim. The examiner indicated that she would need to review the file and get back to applicant's representative regarding whether such an amendment would be acceptable. On 7/6/15, the examiner left a message for applicant's representative indicating that the amendment proposed by applicant's representative would not clearly require that an "administering" actually be performed (and thus this amendment would not be acceptable); the examiner counter-proposed the language "if, and because," in lieu of "if" (as this language would both make clear that either one or the other 'administering" is to be performed, and also provide further clarification/explanation as to why such step is taken). On 7/9/15, applicant's representative contacted the examiner and agreed to the language proposed by the examiner. On 7/10/15, the manner of making the further amendment was briefly discussed; on 7/15/15 (after consultation with her SPE), the examiner requested that the amendment by made via a 312 amendment (it is noted that the issue fee has not yet been paid) .

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

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

☐ Attachment

/DIANA B JOHANNSEN/ Primary Examiner, Art Unit 1634	

Summary of Record of Interview Requirements

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

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

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

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

———

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

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

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

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

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

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

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

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

Examiner to Check for Accuracy

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14150575	WOLFGANG ET AL.
	Examiner	Art Unit
	DIANA B JOHANNSEN	1634

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
PALM search; reviewed 14/060,978; 11/576,178; 60/614,798; 14/044,183; 12/301,675	7 July 2014	DBJ
STN search - see search history printout	7 July 2014	DBJ
WEST search - see search history printout	7 July 2014	DBJ
updated PALM search; updated WEST search - see search history printout	16 Jan 2015	DBJ
updated PALM search; updated WEST search - see search history printout	8 May 2015	DBJ
consult with C. Myers regarding claim wording	6 July 2015	DBJ
consult with SPE D. Nguyen regarding post-allowance claim amendment	14 June 2015	DBJ

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	text interference search in WEST - see search history	8 May 2015	DBJ

	/DIANA B JOHANNSEN/ Primary Examiner.Art Unit 1634

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Wolfgang, et al.	**Conf. No.**:	1033
Serial No.:	14/150,575	**Art Unit**:	1634
Filed:	01/08/2014	**Examiner**:	Johannsen, Diana B.
Docket. No.:	VAND-0002-US-CON2		
Title:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE		

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR 1.312
AFTER NOTICE OF ALLOWANCE

Sir:

I. INTRODUCTORY COMMENTS

This paper is being filed subsequent to the Notice of Allowance (Form PTOL-85) dated June 2, 2015, and prior to payment of the issue fee. Please amend the above-referenced patent application in accordance with the following:

An amendment to the allowed claim appears on page 2 of this paper;

Applicant's summary of telephone interview with the Examiner appears on page 3 of this paper; and

Remarks begin on page 4 of this paper.

II. LISTING OF THE CLAIMS

The following listing replaces any and all prior listings of the claims:

1-19. (Canceled)

20. (Currently amended) A method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising:

administering to the patient a dose of iloperidone that is 24 mg/day if, and because, the patient is not being treated with fluoxetine; and

administering to the patient a dose of iloperidone that is 12 mg/day if, and because, the patient is being treated with fluoxetine.

21. (Canceled)

III. APPLICANT'S SUMMARY OF TELEPHONE INTERVIEW WITH EXAMINER

Initially, Applicants wish to thank Examiner Johannsen for the courtesies extended during the telephone discussions with Applicants' undersigned representative on June 16 and July 6, 9, 10, and 15, 2015. During these discussions, which Examiner Johannsen summarized in the Examiner's Applicant-Initiated Interview Summary dated July 22, 2015, Applicants' representative proposed the following amendment to allowed claim 20 to clarify the "administering" steps:

> "20. (Currently amended) A method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising:
> administering to the patient a dose of iloperidone that is 24 mg/day [[if]] <u>because</u> the patient is not being treated with fluoxetine; and
> administering to the patient a dose of iloperidone that is 12 mg/day [[if]] <u>because</u> the patient is being treated with fluoxetine."

During the interview, it was agreed that the counter-proposal made by Examiner Johannsen:

> "20. (Currently amended) A method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising:
> administering to the patient a dose of iloperidone that is 24 mg/day if<u>, and because,</u> the patient is not being treated with fluoxetine; and
> administering to the patient a dose of iloperidone that is 12 mg/day if<u>, and because,</u> the patient is being treated with fluoxetine."

would be acceptable to both the Examiner and Applicants, and could be made via amendment under 37 CFR 1.312 prior to issue fee payment. The agreed-upon language is embodied in the Amendment presented herewith.

The Amendment presented herewith is made without prejudice to any proposed or previously presented versions of the claims, and should not be construed as acquiescence in any interpretations or concerns noted by the Examiner in the Applicant-Initiated Interview Summary.

IV. REMARKS

Claim 20 is pending in the instant application. By this Amendment, claim 20 is amended after allowance and prior to payment of the issue fee. Claims 1-19 and 21 were previously canceled.

Entry of the amendment presented herein is respectfully requested. Applicants submit that no additional search or consideration is required, and that claim 20 as presented herein is allowable for at least the same reasons as previously determined (*see*, Notice of Allowability (June 2, 2015)).

Applicants submit that the Application as presented remains in condition for allowance. Should the Examiner believe that anything further is necessary, the Examiner is requested to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

/ /

Date: August 3, 2015

Jayme M. Torelli
Reg. No. 62,735

Hoffman Warnick LLC
540 Broadway, 4th Floor
Albany, New York 12207
Phone: (518) 449-0044
Fax: (518) 449-0047

Electronic Acknowledgement Receipt

EFS ID:	23091242
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	03-AUG-2015
Filing Date:	08-JAN-2014
Time Stamp:	09:36:14
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		VAND-0002-US-CON2_312Amendment_8-3-2015.pdf	114653 74fecbaa26e07045793f60f53456424867739b97	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Claims	2	2
	Applicant summary of interview with examiner	3	3
	Applicant Arguments/Remarks Made in an Amendment	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	114653	

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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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.

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

23550 7590 08/14/2015

HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
08/14/2015	ELECTRONIC

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

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PTOCommunications@hoffmanwarnick.com

Response to Rule 312 Communication	Application No.	Applicant(s)
	14/150,575	WOLFGANG ET AL.
	Examiner	Art Unit
	DIANA B. JOHANNSEN	1634

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

1. ☒ The amendment filed on *03 August 2015* under 37 CFR 1.312 has been considered, and has been:

a) ☐ entered.

b) ☒ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

It is noted that the amendment to the language of claim 20 further clarifies the claimed invention, and that the new claim language was previously agreed upon in an interview concluding 07/15/15 (see the Interview Summary mailed July 22, 2015).

/DIANA B JOHANNSEN/
Primary Examiner, Art Unit 1634

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)

23550 7590 06/02/2015
HOFFMAN WARNICK LLC
540 Broadway
4th Floor
ALBANY, NY 12207

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.
14/150,575	01/08/2014	Curt Wolfgang	VAND-0002-US-CON2	1033

TITLE OF INVENTION: METHODS FOR THE ADMINISTRATION OF ILOPERIDONE

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	09/02/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
JOHANNSEN, DIANA B	1634	435-006100

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 Hoffman Warnick LLC
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: Vanda Pharmaceuticals, Inc.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Washington, D.C.

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)
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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.
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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 /Jayme M. Torelli/ Date August 17, 2015
Typed or printed name Jayme M. Torelli Registration No. 62,735

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

Electronic Patent Application Fee Transmittal

Application Number:	14150575
Filing Date:	08-Jan-2014
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Filer:	Jayme M. Torelli
Attorney Docket Number:	VAND-0002-US-CON2

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

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

Electronic Acknowledgement Receipt

EFS ID:	23220643
Application Number:	14150575
International Application Number:	
Confirmation Number:	1033
Title of Invention:	METHODS FOR THE ADMINISTRATION OF ILOPERIDONE
First Named Inventor/Applicant Name:	Curt Wolfgang
Customer Number:	23550
Filer:	Jayme M. Torelli
Filer Authorized By:	
Attorney Docket Number:	VAND-0002-US-CON2
Receipt Date:	17-AUG-2015
Filing Date:	08-JAN-2014
Time Stamp:	15:11:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

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Payment was successfully received in RAM	$960
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	VAND-0002-US-CON2_IssueFeePayment_17AUG2015.pdf	86221 7209e8fc0ef6886f3594408c8baff9c02c2a051b	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30476 8eb5a0fe1904a7e994c93c6f991e1df27ba56b27	no	2
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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/150,575	09/22/2015	9138432	VAND-0002-US-CON2	1033

23550 7590 09/02/2015

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

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

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

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

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

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

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