

Notice of Allowability	Application No. 11/576,178	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA 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 the Supplemental Amendment filed 6/10/13 and interview of 7/19/13.
 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 63-73,76-79 and 82. 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/oph/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. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>0313; 0613; 0713</u> | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>part of 20130718</u> . | |

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634

Examiner-Initiated Interview Summary	Application No. 11/576,178	Applicant(s) WOLFGANG ET AL.	
	Examiner DIANA JOHANNSEN	Art Unit 1634	

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

- (1) Diana Johannsen. (3)_____.
- (2) Jayme Torelli. (4)_____.

Date of Interview: 19 July 2013.

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: 64 and 79.

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...)

The examiner contacted applicant's representative on 7/18/13 to discuss minor clarifying amendments to claims 64 and 79. Agreement was reached and an examiner's amendment was authorized on 7/19/13.

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

EXAMINER'S AMENDMENT

1. This action is responsive to the amendment filed June 10, 2013 and the interview concluding July 19, 2013. Claims 63-73, 76-79, and 82 are now allowed, subject to the examiner's amendment set forth below. In accordance with 37 CFR 1.126, claims 63-73, 76-79, and 82 will be renumbered as claims 1-16 in the issued patent; original claim numbering is employed in the examiner's amendment.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jayme M. Torelli on July 19, 2013.

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3. The application has been amended as follows:

In claim 64, at line 7, after “extracted genomic DNA” insert—~~or mRNA--~~.

In claim 64, at line 9, after “having sequenced the” delete “amplified CYP2D6 DNA” and insert therefore—DNA sample--.

In claim 64, at line 10, delete “amplified DNA” and insert therefore—DNA sample--.

In claim 79, at line 2, after “metabolizer” delete “, therefore”.

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4. **The following is an examiner's statement of reasons for allowance.** All of the claims as amended June 10, 2013 now require steps in which the CYP2D6 genotype of a particular type of patient is assayed or has been assayed in a biological sample from the patient, and in which particular dosages of iloperidone are internally administered based on the genotype determined. As noted in the interview summary mailed April 17, 2013, applicant's arguments of March 20, 2013 were found persuasive with respect to the fact that prior art did not teach or suggest methods in which the dosages specified in the claims are administered based on a determination of the presence or absence of a CYP2D6 poor metabolizer genotype. Particularly, the teachings of the prior art are not sufficient to suggest that which is claimed in view of: (a) the teachings of the prior art as exemplified by Bertilsson et al (Br. J. Clin. Pharmacol. 53:111 [2002]; cited in IDS) regarding the need to establish for each type of substrate the effect of CYP2D6 genotype on drug metabolism, and the fact that the actual effect of a CYP2D6 poor metabolizer genotype on iloperidone metabolism was unknown at the time the invention was made; and (b) the unexpected benefit of reducing the risk of QTc prolongation by administering the specified reduced dosages of iloperidone to those with a CYP2D6 poor metabolizer genotype (as disclosed in the specification and discussed in the arguments of March 13, 2013).

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

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