

EXHIBIT 1016



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/895,111	05/15/2013	S. George Kottayil	INS10763P00101US	1050
32116	7590	03/24/2014	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 1130 CHICAGO, IL 60661			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER
			1647	
			NOTIFICATION DATE	DELIVERY MODE
			03/24/2014	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):

docketing@woodphillips.com

Office Action Summary	Application No. 13/895,111	Applicant(s) KOTTAYIL ET AL.	
	Examiner Robert Landsman	Art Unit 1647	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 3/6/14.
 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) 1-6 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) 1-6 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)
- 3) Interview Summary (PTO-413) _____
Paper No(s)/Mail Date. _____

DETAILED ACTION

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

1. Formal Matters

A. Claims 1-6 are pending and are the subject of this Office Action.

2. Specification

A. The amendment to the specification has been withdrawn in view of Applicants' amendments.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claims 1-3 under 35 USC 112, first paragraph, has been withdrawn. It appears that Treatment A (Table 52) is the only one meeting the claimed limitations. However, though Examples 1-6 do not appear to meet the claimed limitations, Applicants' argument that a PHOSITA would be able to produce such a formulation is persuasive.

The claims are not limited to liquid formulations. However, in view of the rejections below under 35 USC 102 and 103, this enablement rejection is being withdrawn. **However, if Applicants are able to overcome the prior art rejections, this enablement rejection may be reinstated.**

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 1-3 under 35 USC 112, first paragraph, has been withdrawn. The reasoning is seen above regarding scope of enablement.

5. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1647

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1 and 2 are rejected under pre-AIA 35 U.S.C. 102a as being anticipated by Ross et al. (US2006/0062812 – reference 27 on the 1449 dated 7/22/13). The claims have been discussed previously. Regarding claim 1, Ross teaches a sublingual fentanyl formulation which has a Tmax of either 2 hrs (Patient 2 of Table 1) or 1.5 hrs (Patient 5 of Table 1). This meets the limitations of "about 1.28 +/- 0.60 hrs). The Examiner has determined that 1.28 hrs +/- 0.60 hrs is equal to "about" 76 minutes +/- 36 minutes, which is a range of "about" 40 minutes to 112 minutes.

Regarding claim 2, Ross teaches that plasma concentrations start to fall just 30 minutes after administration (paragraph [0126]). Therefore, given that the maximum concentration in some cases would occur at 30 minutes, it would be expected that the levels would be approximately 60% of Cmax in 10 minutes and 86% of Cmax in 20 minutes.

B. Claim 1 is rejected under pre-AIA 35 U.S.C. 102a as being anticipated by Palmer et al. (US2012/0035216). The claims have been discussed previously. It is noted that the claims are not limited to liquid preparations.

Palmer teaches formulations #59 and #62, which are sublingual tablets, have a Tmax of 45 minutes and 50 minutes, respectively. Again, the Examiner has determined that 1.28 hrs +/- 0.60 hrs is equal to "about" 76 minutes +/- 36 minutes, which is a range of "about" 40 minutes to 112 minutes. Though Figure 6 appears to show a very rapid rise to Cmax, this is for sufentanyl. A case cannot be made that fentanyl will produce the same results.

6. Claim Rejections - 35 USC § 103 (previously 102/103)

A. Claims 1-3 remain rejected under 35 USC 103 for the reasons already of record on page 6 of the Office Action dated 11/21/13. Applicants argue that McCarty does not teach the claimed Tmax, Cmax and AUC values, nor would it have been obvious to have produced such formulations.

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