Exhibit 1020

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/895,124	05/15/2013	S. George Kottayil	INS10763P00091US	3808

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 1130
CHICAGO, IL 60661

EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
03/21/2014	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. 13/895,124	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) *1-4* is/are pending in the application.

5a) Of the above claim(s) *2 and 3* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1 and 4* 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 _____.

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

4) ☐ Other: _____.

DETAILED ACTION

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

1. Formal Matters

A. Claims 1 and 4 are the subject of this Office Action.

2. Specification

A. The objection to the specification has been withdrawn in view of Applicants' amendments regarding trademarks.

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

A. Claim 1 remains rejected for the reasons already of record on pages 2-3 of the Office Action dated 1/10/14. Applicants' argue that paragraph [0043] limits the derivatives. This argument has been considered, but is not deemed persuasive. The paragraph does not limit the compounds. It only states that the derivatives include (i.e. comprises) these. Applicants argue that each of the analogues possess the same backbone. While the Examiner will not extend the rejection to these compounds, it is not predictable, nor is there guidance or working examples that derivatives other than non-fentanyl analogues of paragraph [0043], or similarly structured compounds, would use the same backbone to achieve a size of at least about 10 microns.

B. Applicants addressed the potential rejection under 35 USC 112, first paragraph, regarding being enabled only for various formulations. Since the claims are drawn only to compositions and not to methods of treating, no rejection is being made. The issue would arise regarding methods of treating. It appears from the specification that only certain concentrations of ETOH and PG would result in the desired activity - in other words, altering these concentration/volumes, or substituting other compounds for these, may result in an ineffective formulation (ETOH and PG can be considered "result-effective variables"). Therefore, given the limited working examples, it may not be predictable to a PHOSITA how to make and use the claimed formulations.

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

A. Claim 1 remains rejected for the reasons already of record on pages 3-4 of the Office Action dated 1/10/14. Applicants' arguments and the Examiner's response is identical to that above regarding enablement.

B. Applicants addressed the potential rejection under 35 USC 112, first paragraph, regarding being enabled only for various formulations. Their arguments, as well as the Examiner's response, is identical to that above regarding enablement.

5. Claim Rejections - 35 USC § 112, second paragraph

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.

A. Claim 1 is confusing since it is drawn to a fentanyl formulation. However, the claim allows for derivatives (including those of paragraph [0043]), which include compounds which are not fentanyl (e.g. paragraph [0043] of the specification).

6. Claim Rejections - 35 USC § 102/103

A. Claims 1 and 4 remain rejected under 35 USC 102/103 for the reasons already of record on page 8 of the Office Action dated 1/10/14. Applicants argue that the compositions of McCarty would not necessarily form droplets with a mean diameter of at least about 10 microns. This argument has been considered, but is not deemed persuasive. Regarding the teaching of the nasal spray formulations, Applicants argue that theses sprays are likely to have a smaller droplet size than those of the instant invention. However, it is noted that it is possible for these sprays to contain droplets of at least about 10 microns. It is also noted that the claims recite "about 10 microns", which means that the droplet size could

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