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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/964,975	08/12/2013	Garry L. Myers	2333-2 CON II	8904

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EXAMINER	
EPPS -SMITH, JANET L	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
11/07/2013	PAPER

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.

Office Action Summary	Application No. 13/964,975	Applicant(s) MYERS ET AL.	
	Examiner Janet Epps-Smith	Art Unit 1633	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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *9-27-2013*.

☐ 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) *1-24* 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) *1-24* 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/08)

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

DETAILED ACTION

1. The prior Office Action mailed 10/29/2013 is now vacated. The previous Office Action *improperly indicated* that the instant application was Under Accelerated Examination, and limited Applicants to a 1-month response time with no extensions of time available. The instant Office Action grants Applicants a 3-month response time with extensions of time available.

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

DETAILED ACTION

Claim Rejections - 35 USC § 103

3. 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.

4. Claims 1-24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Oksche et al. (US2010/0087470A1 or WO 2008025791 A1; citations given from the PGPUB).

5. Independent claims 1 and 7 recite the following:

1. An orally dissolving film formulation comprising from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.6 ng/ml and about 5.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 41 pg/ml to about 324 pg/ml for naloxone.

7. An orally dissolving film formulation comprising from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.7 ng/ml and about 6.9 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 40 pg/ml to about 405 pg/ml for naloxone.

6. Oksche et al. discloses the following embodiments, see the following paragraphs:

[0039] As regards the dosage amount, the pharmaceutical compositions in accordance with the present invention will typically comprise between approximately 0.1 mg and approximately 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof such as buprenorphine hydrochloride. Preferred dosage amounts will be in the range of between approximately 0.4 mg and approximately 12 mg or between approximately 2 mg and approximately 8 mg buprenorphine or a pharmaceutically acceptable salt thereof.

[0040] The oral pharmaceutical dosage forms in accordance with the invention may have the further characteristic of providing a C_{max} of approximately 1.5 to 2.5 ng/ml in the case of a dose of 4 mg buprenorphine hydrochloride being administered. A preferred C_{max} in the case of a dose of 4 mg of buprenorphine hydrochloride being administered may be approximately between 1.7 ng/ml to 2 ng/ml.

[0041] In the case of a dose of 8 mg buprenorphine hydrochloride being administered, the C_{max} may be approximately between 2.5 and 3.5 ng/ml. In a preferred embodiment the C_{max} may be approximately between 2.75 ng/ml and 3.25 ng/ml in the case of a dose of 8 mg buprenorphine hydrochloride being administered.

[0042] In case of a dose of 16 mg buprenorphine hydrochloride being administered, the C_{max} may preferably be in the range of approximately 5 to 7 ng/ml. In a preferred embodiment the C_{max} may be between 5.5 and 6.5 ng/ml if 16 mg of buprenorphine hydrochloride are administered.

[0043] The AUC_{0-48} (i.e. the Area under the Curve for 48 hours after administration) may in the case of administration of 4 mg of buprenorphine hydrochloride be in the range of approximately 10 to 15 hours.times.ng/ml. In a preferred embodiment the AUC_{0-48} may be approximately 12 to 13 hours.times.ng/ml. In the case of 8 mg buprenorphine hydrochloride being administered the AUC_{0-48} may be approximately in the range of 15 to 25 hours X ng/ml. In a preferred embodiment the AUC_{0-48} in this case may be between approximately 20 to 22 hours.times.ng/ml. In the case of 16 mg buprenorphine hydrochloride being administered, the AUC_{0-48} may be in the range of 25 to 40 hours X ng/ml. In a preferred embodiment the AUC_{0-48} in this case may be in the range of approximately 30 to 35 hours X ng/ml.

[0050] A particularly preferred antagonist is naloxone. Of the naloxone salts, naloxone hydrochloride dihydrate may be particularly preferable in combination with buprenorphine hydrochloride.

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