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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**
03/07/2014	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 *01/02/2014*.

☐ 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) *1-28* 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) *1-28* 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. _____ .

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

2. Claims 1-28 are presently pending for examination.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

3. 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.

4. Claims 1-28 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. (New Matter).

5. Instant claim 1 was amended as follows:

1. (Currently Amended) 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; wherein said film formulation further comprises one or more polymers and the ratio of a free base equivalent amount of said buprenorphine to the total amount of said one or more polymers is from about 1:0.6 to about 1:25 by weight.

6. The specification as filed does not provide any express support for the phrase "free base equivalent amount of said buprenorphine." Additionally, the specification as filed does not provide any support for the range of 1:0.6 to about 1:25 by weight of free base equivalent amount of buprenorphine to polymer.

7. Applicants have made reference to paragraphs [0066] and [0067] as support for this amendment. However, paragraph [0066] makes reference only to "self-supporting film forming polymers..." The instant claims broadly refer to any form of polymer.

8. Moreover, Table 1 and Table 5 are referenced as support for the newly added limitations. Table 1 recites specific polymers in combination with buprenorphine and naloxone. However, the instant claims are generically drawn to any form of polymer and are not limited to the specific polymers recited in Table 1. Table 5 describes formulations of buprenorphine/naloxone with and without buffer and at specific pH levels. Again, the instant claims make no reference to pH or the presence and/or absence of buffer. Therefore, the broad range of buprenorphine to polymer of "***from about*** 1:.06 ***to about*** 1:25 by weight," as recited in the instant claims is not supported by the specification as filed.

9. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

10. 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.

11. Claims 1-28 stand 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) in view of US Patent No. 7,357,891, and Merriam Webster definition of “bioequivalence.”

12. Applicant's arguments filed 01/02/2014 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the Oksche et al. reference “does not teach or suggest how to achieve the claimed Cmax values for buprenorphine and naloxone alone or in combination in a film composition. In addition Oksche does not provide any direction as to how to achieve a non-divertible film that produces optimized buprenorphine release while simultaneously producing a Cmax for naloxone that is within the claimed invention.”

13. Contrary to Applicant’s assertions, Oksche et al. clearly describe Suboxone preparations, see ¶[0012]:

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