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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/537,571	08/07/2009	Garry L. Myers	1199-82	5630

23869 7590 08/31/2011

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EXAMINER
EPPS -SMITH, JANET L

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/31/2011	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.	Applicant(s)	
	12/537,571	MYERS ET AL.	
	Examiner	Art Unit	
	JANET L. EPPS -SMITH	1633	

-- 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 _____.

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) 1-31 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) 1-31 is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

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).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9-3-09;3-15-11;6-21-11
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 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 –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 5, 7-10, 15, 17, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Oksche et al. WO2008/025791A1 (Citations are taken from US2010/0087470).

3. Instant claim 1 is drawn to the following: A film dosage composition comprising: a. A polymeric carrier matrix; b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and d. A **buffer in an amount to provide a local pH of said composition of a value sufficient to optimize absorption of said buprenorphine.**

4. See the following embodiments of Oksche et al. at the following paragraphs:

5. [0055] In one embodiment one may use non-gelatin film materials, e.g. films of modified cellulose materials as dosage forms. In this case, buprenorphine and optionally opioid antagonists such as naloxone are incorporated into the film matrix and films thus prepared may be administered orally.

6. [0046] The pharmaceutical dosage form in accordance with the invention will be administered such that the maximal dosage per day is 32 mg of buprenorphine. Once a

patient is enrolled in substitution therapy, the initial dosage will be typically between 2 mg to 4 mg of buprenorphine. The formulations may be administered once a day, every two days, preferably every three days or even less frequently.

7. [0072] Suitable pH modifiers include citric acid, tartaric acid, phosphoric acid, hydrochloric acid and maleic acid. Suitable sweeteners include aspartame and thaumatin. Suitable taste-masking agents include sodium bicarbonate, ion-exchange resins, cyclodextrin inclusion compounds, adsorbates or microencapsulated actives.

8. [0085] In order to allow absorption of buprenorphine over the mucosa of the mouth, and particularly sublingually, in one embodiment the dosage forms may additionally use agents that enhance absorption of the active agent, i.e. so-called permeation enhancers.

9. [0092] The polymer amount within the matrix may be between approximately 3% by weight and approximately 98% by weight and preferably between 7 and 80% by weight and even more preferably between 20 and 50% by weight, the weight percentages being based on the total weight of the dosage forms.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 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 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oksche et al. (as applied above).

12. Oksche et al. as describe above is incorporated here. However, the disclosure of this reference does not teach formulations buprenorphine and naloxone, where the buffer is present in an amount sufficient to inhibit the absorption of naloxone. Furthermore, the cited reference does not teach the specific range of pH recited in the instant claims.

13. According to the specification as filed, the buffer is present in such an amount so as to provide optimal release from the film and/or absorption into the body an amount of the agonist and the antagonist, see paragraph [0067]. Additionally, the reference specification as filed teaches that any buffer system may be used, as desired, however they preferably include sodium citrate, and citric acid. These features are already disclosed in Oksche et al., see ¶ [0072], which states that buprenorphine/naloxone formulations may comprise the citric acid as a pH modifier.

The following embodiments of Oksche et al. are also disclosed: [0012] Another buprenorphine preparation aimed at preventing this potential possibility of abuse has recently gained administrative approval in the United States (Suboxone.RTM.). The Suboxone.RTM. preparation comprises buprenorphine hydrochloride and the opioid antagonist naloxone hydrochloride dihydrate. The presence of naloxone is intended to prevent parenteral abuse of buprenorphine as parenteral co-administration of buprenorphine and naloxone in e.g. an opioid-dependent addict will lead to serious withdrawal symptoms.

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