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23869	7590	11/07/2013	EXAMINER	
Hoffmann & Baron LLP 6900 Jericho Turnpike Syosset, NY 11791			EPPS -SMITH, JANET L	
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**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.



### 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 negated 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.

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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.

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[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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