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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
	7590 05/02/201 ⁻ & BARON, LLP	EXAMINER		
6900 JERICHO	TURNPIKE	EPPS -SMITH, JANET L		
SYOSSET, NY	11/91		ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			05/02/2012	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 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 29 February 2012.						
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 \boldsymbol{E}	<i>x parte Quayle</i> , 1935 C.D. 11, 45	3 O.G. 213.				
Disposition of Claims							
6)□ 7)⊠ 8)□	 ☐ Claim(s) 1 and 3-31 is/are pending in the application. ☐ Sa) Of the above claim(s) is/are withdrawn from consideration. ☐ Claim(s) is/are allowed. ☐ Claim(s) 1 and 3-31 is/are rejected. ☐ Claim(s) is/are objected to. ☐ 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)							
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <i>2-29-2012</i>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	ite				



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DETAILED ACTION

1. Claims 1 and 3-31 are presently pending for examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 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 1-10, 13-14, 16-23, 25-26 are rejected under 35 U.S.C. 112, 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(s), at the time the application was filed, had possession of the claimed invention. (New Matter).
- 5. Applicants have amended the claims to recite "a local pH....to optimize absorption of buprenorphine, wherein said local pH is from about 2 to about 3.5 in the presence of saliva." According to Applicants, support for this amendment could be found at paragraphs [0013-0017].
- 6. According to the specification as filed at ¶ [0016] pH 3-3.5 is the Cmax of naloxone. Moreover, the specification defines the Cmax as the mean maximum plasma concentration after administration of the composition to a human subject. The claims are drawn to a composition that produces a local pH of about 3.5, this pH represents the



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Cmax of naloxone. However, the claimed compositions are directed to inhibit the absorption of naloxone and optimize absorption of buprenorphine.

7. The specification does disclose a local pH of 2-4 as useful for optimizing the absorption of buprenorphine, paragraph [0013]. However, the disclosure of a local pH of 3.5 is clearly disclosed as related to the absorption of naloxone and is not disclosed as specifically related to the absorption of buprenorphine, paragraph [0016]. After reviewing the specification as filed for support for the limitation "about 3.5" as it relates to the absorption of buprenorphine, it is clear that the specification does not provide support for this limitation.

Response to Amendment/Arguments

Claim Rejections - 35 USC § 102

8. The rejection of claims 1, 4, 5, 7-10, 15, 17, and 20-24 under 35 U.S.C. 102(b) as being anticipated by Oksche et al. WO2008/025791A1 (Citations are taken from US2010/0087470) is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 103

- 9. Claims 1, and 3-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oksche et al. (as applied above).
- 10. Applicant's arguments filed 02/29/2012 have been fully considered but they are not persuasive.
- 11. Applicants traverse the instant rejection on the grounds that the buffering system used in the instant claims is sufficient to "optimize" the absorption of buprenorphine.



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Moreover, Applicants argue that a pH of about 5.5 may be useful for maximizing the absorption of buprenorphine, however not to "optimize" the absorption of buprenorphine (see 1st ¶ on page 9 of reply filed 2/29/2012). The use of the term "optimize" according to Applicants is based upon their definition of the term as set forth in the specification as filed at [0013]. However, contrary to Applicant's assertions, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the definition of the term "optimize") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's definition of the term "optimize" provided in the specification is not sufficiently precise and definite such that the ordinary skilled artisan would be able to adequately be apprised of the full scope of the claimed invention. For example, the specification as filed recites: "optimizing the absorption" does not refer to reaching the maximum absorption of the composition, and rather refers to reaching the optimum level of absorption at a pH of about 2 to about 4. Further, the specification teaches that "An 'optimum' Cmax of buprenorphine is **about** 0.67 to about 5.36 mg/ml at dosages of from 2-16 mg buprenorphine at a given pH. The definition here appears to provide an example of optimum buprenorphine (an optimum). Moreover, the use of the term "about" provides an open range (i.e. non-precise) regarding the level of buprenorphine concentration.



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