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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 11/06/2012

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EXAMINER
EPPS -SMITH, JANET L

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
11/06/2012	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.

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 rejection of claims 1-10, 13-14, 16-23, 25-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's argument.

Response to Amendment/Arguments

Claim Rejections - 35 USC § 103

4. Claims 1, and 3-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oksche et al. (as applied above).

5. Applicant's arguments filed 10/22/2012 have been fully considered but they are not persuasive.

6. Applicants traversed the instant rejection on the grounds that Oksche et al. does not disclose the pH range recited in the instant claims, and does not provide any direction that one of ordinary skill in the art could follow and come up with the claimed invention. Moreover, Applicants traversed that they have discovered that a desirable local pH of a composition including buprenorphine and naloxone is ***between* about 2 to about 3.5** (page 9, 2nd ¶ of the response filed 10/22/2012). Applicants then argued that their Examples show significant benefits when a pH of about 3.5 is used as compared to a pH or 6.5 and 5.5, Example 8 tested products at a pH of ***from 3.0-3.5*** (page 10, 3rd ¶).

Applicants then concluded that: “The present inventors have discovered ***that at a pH of about 2-3.5***, the relative absorptions can be controlled effectively.”

7. Moreover, Applicants argued that their definition of the term “optimize” is expressly an unequivocally defined in the specification. Applicant’s definition appears at ¶ [0013] of the specification as filed. It is noted that Applicant’s definition states that the "optimum" absorption of the instant invention provides “bioequivalent ***absorption as administration of the currently available Suboxone(R) tablet."***

8. Contrary to Applicant’s assertions, Oksche et al. discloses the *Suboxone® tablet* which Applicants assert that the presently claimed invention provides an optimized absorption of buprenorphine, see ¶ [0012] of Oksche et al. which teaches: "[A]nother buprenorphine preparation aimed at preventing this potential possibility of abuse has recently gained administrative approval in the United States (Suboxone®). The Suboxone® 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.”

9. Applicant’s argument that the Examples show significant benefits when a pH of about 3.5 is used as compared to a pH or 6.5 and 5.5, Example 8 tested products at a pH of ***from 3.0-3.5,*** is not sufficient to provide evidence of unexpected or significant benefits associated with the full scope of the claimed invention, which recites a “local pH

of ***about 2 to about 3.5 in the presence of saliva."*** Applicant's showing is not commensurate in scope with the claimed invention.

10. As stated in the prior Office Action, contrary to Applicant's assertions, and in light of the open range of pH recited in the instant claims (i.e. as it relates to the use of the term "about" to define the claimed pH range), it is clear that the sublingual film formulations of Oksche et al. are designed so as to prevent development of dependency. Thus, it would have been obvious to the ordinary skilled artisan, at the time of the instant invention, to modify their teachings so as to identify the optimal range of pH/dosage in an effort to identify formulations that would provide optimal absorption of both agonist and antagonist. As per MPEP 2144.05 [R-5], since the general conditions of the instantly claimed invention are disclosed in the prior art, identification of the optimal pH/dosage appears to be a matter of routine experimentation.

11. Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Epps-Smith whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L. EPPS -SMITH/
Primary Examiner, Art Unit 1633

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