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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.

Art Unit: 1633

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 C_{max} of naloxone. Moreover, the specification defines the C_{max} 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

Art Unit: 1633

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.

Art Unit: 1633

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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