EXHIBIT 1017

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Sublingual Fentanyl Spray
	)	
S. George Kottayil	)	Examiner: Robert S Landsman
	)	
Serial No.: 13/895,111	)	Group Art Unit: 1647
	)	
Filed: May 15, 2013	)	Confirmation No.: 1050

AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

Responsive to the Office Action mailed March 24, 2014, please amend the above-identified application as indicated below.

If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account No. 23-0785.

Amendment of the Claims begin on page **2** of this paper.

Remarks begin on page **3** of this paper.

Amendment to the Claims

1. (Currently amended) A sublingual formulation comprising from about 0.001% to about 15% by weight ~~an effective amount of~~ fentanyl, from about 20% to about 60% by weight ethanol, and from about 4% to about 6% by weight propylene glycol, ~~at least one pharmaceutically acceptable excipient~~, the formulation providing a mean T_{max} of about 1.28+/-0.60 hours when a dose is administered sublingually to humans.

2. (Currently amended) A ~~The~~ sublingual formulation ~~of claim 1,~~ comprising from about 0.001% to about 15% by weight fentanyl, from about 50% to about 60% by weight ethanol, and from about 4% to about 6% by weight propylene glycol, which provides a plasma concentration after administration to humans selected from the group consisting of: about 60% of the mean C_{max} in about 10 minutes, about 86% of the mean C_{max} by about 20 minutes and a combination thereof.

3. (Original)The sublingual formulation of claim 1, that when administered to humans provides a plasma concentration that is greater than about 80% of the mean C_{max} for about 2 hours.

4. (Previously presented) A sublingual spray formulation comprising 400 mcg dose of fentanyl which provides one or more mean pharmacokinetic values selected from the group consisting of: AUC_{last} 4.863 +/-1.70821 hr*ng/mL, AUC_{inf} 5.761 +/- 1.916 hr*ng/mL, and AUC_{extrap} 10.26 +/- 5.66%, when administered to humans.

5. (Previously presented) A sublingual spray formulation comprising a dose of fentanyl which provides a substantially dose proportional mean AUC_{last} based on a mean AUC_{last} of about 4.863 +/-1.70821 hr*ng/mL for a 400 mcg fentanyl dose when administered to humans.

6. (Previously presented) A sublingual spray formulation comprising a 400 mcg dose of fentanyl which provides a mean F(AUC_{last}) of about 0.721 +/- 0.199 ng/mL when administered to humans.

REMARKS

Claims 1-6 are pending. Claims 1 and 2 have been amended. Support for the amendments to claim 1 and 2 can be found in paragraphs [00122] and [00124] and table 50 and 52 of the specification.

35 U.S.C. § 112 Rejections

The rejection under 35 U.S.C. § 112, first paragraph, for claims 1-3 failing to comply with the enablement requirement or the written description requirement because the specification does not reasonably provide enablement for or description of all sublingual formulations "(1) which are formulated for a spray and (2) which have the desired properties" has been withdrawn. The Office Action asserts that this rejection may be reinstated if Applicants overcome the prior art rejections.

Applicants anticipatorily and respectfully traverse the reinstatement of these rejections. Claims 1 and 2 have been amended to include specific concentration ranges for the components of the composition. The formulations disclosed in the instant specification (Table 50 and Table 52) fully enable and disclose compositions comprising fentanyl, ETOH and PG within the specific claimed concentration ranges that provide the claimed Tmax and Cmax values. Paragraphs [00122] and [00124] of the instant specification describe the claimed concentration ranges and paragraphs [0048], [0049] and [0057] describe the claimed Tmax and Cmax values in general. Thus, applicants respectfully request that these rejections be withdrawn.

35 U.S.C. § 102 Rejection

Ross

Claims 1-3 stand rejected under 102(a) as anticipated by or Ross et al. U.S. 2006/0062812. Regarding claim 1, the Office Action asserts that Ross teaches a sublingual fentanyl formulation having a Tmax of either 2 hours or 1.5 hours. Regarding claim 2, the Office Action asserts that Ross teaches that plasma concentrations start to fall just 30 minutes after administration, therefore, it would be expected that the levels would be approximately 60% of Cmax in 10 minutes and 86% of Cmax in 20 minutes.

Applicants respectfully traverse this rejection. Amended claims 1 and 2 comprise a specific concentration of fentanyl, ethanol ("ETOH") and propylene glycol ("PG") that are not taught in Ross and thus, Ross does not anticipate instant claims 1-3. Accordingly, Applicants request withdrawal of this rejection.

Palmer

Claim 1 stands rejected under 102(a) as being anticipated by Palmer et al. U.S. 2012/0035216. The Office Action asserts that Palmer teaches formulations #59 and #62 which are sublingual tablets that have a Tmax of 45 minutes and 50 minutes, respectively.

Applicants respectfully traverse this rejection. The instant application claims priority to U.S. application No. 11/698,739 which was filed on 1/25/2007 and U.S. Provisional Application No. 60/762,057. Palmer was not published until 2/9/2012 and thus is not prior art under 102(a). Assuming for the sake of argument that Palmer was 102(a) prior art, amended claim 1 comprises a specific concentration of fentanyl, ETOH and PG that are not taught in Palmer and thus, Palmer does not anticipate instant claim 1. Accordingly, Applicants request withdrawal of this rejection.

35 U.S.C. § 103

Claims 1-3 remain rejected under 35 U.S.C. § 103 for being obvious over McCarty U.S. 2007/0071806 or Ross. The Office Action asserts that if view of Applicant's argument that a person having ordinary skill in the art ("PHOSITA") would have been able to routinely produce formulations meeting the instant claims, even though only one is disclosed, it would have also been obvious to vary the formulas taught in McCarty or Ross to reach the claimed formulations.

Applicants respectfully traverse this rejection. The formulations disclosed in the instant specification (Table 50 and Table 52) fully enable and disclose compositions comprising fentanyl, ETOH and PG within the specific claimed concentration ranges that provide the claimed Tmax and Cmax values. Paragraphs [00122] and [00124] of the instant specification describe the claimed concentration ranges and paragraphs [0048], [0049] and [0057] describe the claimed Tmax and Cmax values in general. Thus, a PHOSITA, in light of the instant specification, would not have to endure undue experimentation to enable the claims. No

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