Exhibit 1012

Coalition For Affordable Drugs XI LLC

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Sublingual Fentanyl Spray
S. George Kottayil	)	Examiner: Robert S Landsman
Serial No.: 13/895,124	)	Group Art Unit: 1647
Filed: May 15, 2013	)	Confirmation No.: 3808

AMENDMENT

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

Madam:

Responsive to the Office Action mailed March 21, 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 to the Claims begin on page **2** of this paper.

Remarks begin on page **4** of this paper.

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Amendment to the Claims

1. (Currently amended) A sublingual ~~fentanyl~~ formulation comprising discrete liquid droplets of an effective amount of fentanyl or a fentanyl derivative selected from the group consisting of sufentanil, carfentanil, lofentanil and alfatenil, a free base or a pharmaceutically acceptable salt thereof~~, or derivative thereof~~, in a pharmaceutically acceptable liquid carrier; said droplets having a mean diameter of from ~~at least~~ about 30 to about 70 ~~10~~ microns.

2. (Withdrawn) A method of treating pain comprising sublingually administering a liquid spray formulation in the form of discrete liquid droplets having a mean diameter of at least about 10 microns to a human patient experiencing pain, said liquid spray formulation comprising an effective amount of fentanyl, a free base or a pharmaceutically acceptable salt thereof, or derivative thereof, dispersed in a pharmaceutically acceptable liquid carrier.

3. (Withdrawn) A multi-dose device for sublingual administration of a drug comprising:

a reservoir containing a liquid formulation comprising fentanyl, a free base or a pharmaceutically acceptable salt thereof, or derivative thereof in a pharmaceutically acceptable liquid carrier; and

the device having an actuator which when actuated delivers a therapeutically effective dose of the liquid formulation in the form of liquid droplets having a mean diameter of at least about 10 microns.

4. (Currently amended) A non-propellant sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl in a pharmaceutically acceptable liquid carrier, wherein the sublingual fentanyl formulation comprises:

from about 0.001% to about 15% by weight fentanyl free base;

from about 50% to about 60% by weight of ethanol; and

from about ~~0.1%~~ 4% to about ~~40%~~ 6% by weight of propylene glycol;

said droplets having a mean diameter of at least about 10 microns.

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5. (New) A non-propellant sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl in a pharmaceutically acceptable liquid carrier, wherein the sublingual fentanyl formulation consists essentially of:

from about 0.001% to about 15% by weight fentanyl free base;

from about 50% to about 60% by weight of ethanol; and

from about 1% to about 30% by weight of propylene glycol;

said droplets having a mean diameter of at least about 10 microns.

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REMARKS

Claims 1, 4 and 5 are pending. Claims 1 and 4 are currently amended. Support for the amendment to claim 1 regarding specific fentanyl derivatives can be found in paragraph [0043] of the specification. Support for the amendment to claim 1 regarding droplet diameter can be found in paragraph [0020] of the specification. Support for the amendment to claim 4 can be found in paragraph [0099] of the specification. Claim 5 is new.

35 U.S.C. § 112 rejections

Claim 1 remains rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement and written description. The Office Action maintains that the specification "does not reasonably provide enablement for sublingual formulations comprising 'derivatives thereof'". Applicants respectfully traverse this rejection. Amended claim 1 is limited only to fentanyl and those derivatives disclosed in paragraph [0043] of the specification (i.e. sufentanil, carfentanil, lofentanil, alfentanil). Each of these analogues possesses the same N-Phenyl-N-(4-piperidinyl)propanamide backbone as fentanyl and differ only slightly in the substituents of that backbone. All of these analogues and their effective amounts are well known in the art. What is not well known in the art are sublingual formulations of fentanyl or these analogues that have discrete liquid droplets having a mean diameter of from about 30 to about 70 microns. This slight variation in the identity of the substituents that are attached to the backbone should have little to no effect on the ability to form these discrete liquid droplets. Thus, taking any of the sublingual fentanyl formulations from the specification, which the Office Action admits are enabling, and replacing an effective amount of fentanyl with an effective amount of one of these analogues would not impose undue experimentation on a person having ordinary skill in the art ("PHOSITA"). Thus, applicants respectfully request withdrawal of this rejection.

Claim1 is rejected under 35 U.S.C. § 112, second paragraph, for lack of definiteness. The Office Action asserts that the claim is confusing because it is drawn to a fentanyl formulation, however, allows for derivatives which are not fentanyl. Claim 1 has been amended to be drawn to a sublingual formulation. Thus, applicants respectfully request withdrawal of this rejection.

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