Exhibit 1024

Coalition For Affordable Drugs XI LLC

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	KOTTAYIL, S. George, et al.	Confirmation No.:	4756
Application No.:	11/698,739	Group Art Unit:	1646
Filed:	January 25, 2007	Examiner:	WEGERT, Sandra L.

FOR: **SUBLINGUAL FENTANYL SPRAY**

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

REPLY UNDER 37 C.F.R. § 1.111

SIR:

Responsive to the non-final Office Action mailed May 2, 2011, Applicants respectfully request reconsideration of the present application in view of the following remarks.

Remarks begin on page 2 of this paper.

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REMARKS

I. Status of the Claims

Claims 1-8, 10-29 and 31-143 are pending in the present application. Claims 5-8, 12-19, 24-29 and 33-138 are withdrawn.

II. Rejection Under 35 USC § 112, Second Paragraph

Claims 1-4, 10, 11, 20-23, 31, 32 and 139-143 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action at pp. 3-4. Applicants respectfully traverse on the ground that the present claims are in no way unclear or indefinite, and describe explicitly the metes and bounds of the claimed invention.

The Examiner alleges that "the independent claims recite that the discrete liquid droplets must have a mean diameter of at least about 10 microns. Additional claims recite '20 microns,' '5-500 microns,' or '10-200 microns.' The claims are indefinite in that it is unclear how to achieve that particle size using the formulation specified. Similarly, the claims are indefinite in that it is unclear how the recited particle size relates to the effective concentrations recited, or how a particular droplet size contributes to a particular recited Cmax." Office Action at p. 4.

With regard to the Examiner's assertion that "[t]he claims are indefinite in that it is unclear how to achieve [the recited] particle size using the formulation specified" (*supra*), Applicants respectfully submit that the present specification explicitly and exhaustively describes how to achieve the presently claimed droplets sizes, and provides examples of various droplet sizes, size distributions as a function of various parameters, and measurement and validation of the same, etc. See, *e.g.*, Examples 13 and 14 at paragraphs [0233]-[0243]; *see also* paragraphs [0266]-[0297]. Accordingly, it is not clear how the present claims can be construed as indefinite in view of the extensive disclosure of how to generate the claimed droplet sizes, explicit examples of generating the claimed droplet sizes, and development and validation of methods for measuring droplet sizes.

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With regard to the Examiner's assertion that "the claims are indefinite in that it is unclear how the recited particle size relates to the effective concentrations recited, or how a particular droplet size contributes to a particular recited Cmax," it is not clear how this rejection, or the proffered rationale for such a rejection relates to 35 U.S.C. § 112, second paragraph.

MPEP § 2171 instructs:

> "There are two separate requirements set forth in [35 U.S.C. § 112, second paragraph]:
>
> (A) the claims must set forth the subject matter that applicants regard as their invention; and
>
> (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.
>
> The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - *i.e.*, ***whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art***." Emphasis added.

Applicants submit that the present claims explicitly recite clear, well defined limitations which are measurable and readily appreciable by one of ordinary skill in the art, as required by 35 U.S.C. § 112, second paragraph. For example, the present claim 1 recites certain explicit limitations, namely:

> (i) ***discrete liquid droplets*** of…fentanyl…in a pharmaceutically acceptable liquid carrier; said droplets ***having a mean diameter of at least about 10 microns***; and
>
> (ii) wherein ***the sublingual fentanyl formulation provides a mean maximum plasma concentration (C_{max}) of fentanyl of about 127 pg/ml to about 213 pg/ml per 100 µg fentanyl*** after sublingual administration to humans. *See* claim 1 of the present application; emphasis added.

Each of limitations (i) and (ii) above are readily measurable, and accordingly, definite. Similarly, independent claims 20 and 139 each recite limitations which are both definite and

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readily ascertained by one skilled in the art. Accordingly, the present claims are definite, and the scope thereof is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art, as required by 35 U.S.C. § 112, second paragraph.

Furthermore, Applicants respectfully submit that the present specification contains explicit disclosure regarding the relationship between droplet size and drug absorption. *See*, *e.g.*, paragraph [0017] of the present specification ("[l]iquid droplets or particles having a diameter of less than about 5 microns have the potential to enter into the lungs of a human upon administration. Such entry into the lungs could lead to an increase in patient to patient variability in absorption of the fentanyl. Further, absorption of fentanyl in the lungs could lead to an increased absorption and increased side effects, including respiratory depression which may be fatal.). In addition, the present specification provides explicit Examples wherein the respirable amount of a dose of the presently claimed formulations was determined. *See*, *e.g.*, paragraphs [0298]-[0326] of the present specification. Furthermore, the present specification is replete with examples wherein the presently claimed formulations produce the presently claimed C_{max} values. *See*, *e.g.*, paragraphs [0183]-[0199] of the present specification.

Thus, Applicants respectfully submit that the present claims are clear, and each claimed limitation is not only definite and readily measurable, but also explicitly described and exemplified in the present specification. Accordingly, the metes and bounds of the present claims are readily ascertainable by one skilled in the art, as required by 35 U.S.C. § 112, second paragraph. As a result, the present rejection is improper, and should be withdrawn.

III. Rejection Under 35 USC §103

Claims 1-4, 10, 11, 20-23, 31, 32 and 139-143 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Pat. Appl. Pub. No. 2006/0062812 (*Ross*). Office Action at p. 5. Applicants traverse on the grounds that Ross fails to disclose or suggest all of the limitations of the present claims. As a result, the Examiner has failed to satisfy the requirements for establishing a finding of *prima facie* obviousness. Further, the Examiner's rationale for the present rejection ignores the plain language of the present claims, and contradicts the explicit teachings of *Ross*. Finally, it would not be obvious to modify the formulations of *Ross* to

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