Exhibit 1017

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-- PATENT --

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	S. George Kottayil et al.	Docket No.:	50695.0100
Serial No.:	11/698,739	Confirmation No.:	4756
Filing Date:	January 25, 2007	Examiner:	Sandra L. Wegert
Title:	SUBLINGUAL FENTANYL SPRAY	Art Unit:	1646

RESPONSE TO RESTRICTION REQUIREMENT AND PRELIMINARY AMENDMENT

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

Sir:

In response to the Examiner's Restriction Requirement dated March 10, 2010, please accept the following Response to the restriction requirement entered pursuant to 35 U.S.C. § 121 for the above-referenced application.

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks directed to Applicants' election begin on page 20 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended): A sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl, a pharmaceutically acceptable salt thereof, or derivative thereof; in a pharmaceutically acceptable liquid carrier; said droplets having a mean diameter of at least about 10 microns[[.]] wherein said 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.

2. (Original): The sublingual fentanyl formulation of claim 1, wherein said liquid droplets have a mean diameter of at least about 20 microns.

3. (Original): The sublingual fentanyl formulation of claim 1, wherein said liquid droplets have a size distribution of from about 5 microns to about 500 microns.

4. (Original): The sublingual fentanyl formulation of claim 1, wherein said liquid droplets have a size distribution of from about 10 microns to about 200 microns.

5. (Withdrawn): The sublingual fentanyl formulation of claim 1, wherein said fentanyl, pharmaceutically acceptable salt thereof, or derivative thereof is included in said formulation in a concentration of from about 0.05 mg/ml to about 15 mg/ml.

6. (Withdrawn): The sublingual fentanyl formulation of claim 1 which provides a mean time to maximum plasma concentration (T_{max}) of fentanyl at from about 5 minutes to about 120 minutes, after sublingual administration to humans.

7. (Withdrawn): The sublingual fentanyl formulation of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) of fentanyl at from about 10 to about 60 minutes, after sublingual administration to humans.

8. (Withdrawn): The sublingual fentanyl formulation of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) of fentanyl at from about 15 to about 35 minutes after sublingual administration to humans.

9. (Cancelled): The sublingual fentanyl formulation of claim 1, which 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.

10. (Original): The sublingual fentanyl formulation of claim 1, which provides a mean maximum plasma concentration (C_{max}) of fentanyl of about 142 pg/ml to about 195 pg/ml per 100 μg fentanyl after sublingual administration to humans.

11. (Original): The sublingual fentanyl formulation of claim 1, which provides a mean maximum plasma concentration (C_{max}) of fentanyl of about 158 pg/ml to about 177 pg/ml per 100 μg fentanyl after sublingual administration to humans.

12. (Withdrawn): The sublingual fentanyl formulation of claim 1, further comprising an organic solvent.

13. (Withdrawn): The sublingual fentanyl formulation of claim 12, wherein said fentanyl, pharmaceutically acceptable salt thereof, or derivative thereof is dissolved in said organic solvent.

14. (Withdrawn): The sublingual fentanyl formulation of claim 1, wherein said fentanyl, pharmaceutically acceptable salt thereof, or derivative thereof is dispersed in said pharmaceutically acceptable liquid carrier.

15. (Withdrawn): The sublingual fentanyl formulation of claim 1, further comprising an absorption enhancer.

16. (Withdrawn): The sublingual fentanyl formulation of claim 15, wherein said absorption enhancer is triacetin.

17. (Withdrawn): The sublingual fentanyl formulation of claim 15 or 16, wherein said absorption enhancer is in an amount of from about 0.001 % to about 10 % by weight of the formulation.

18. (Withdrawn): The sublingual fentanyl formulation of claim 1, which is a non-propellant formulation.

19. (Withdrawn): The sublingual fentanyl formulation of claim 1, wherein the fentanyl, pharmaceutically acceptable salt thereof, or derivative thereof does not or substantially does not enter the lungs of a human patient after sublingual administration.

20. (Currently Amended): A unit dose of a sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl, a pharmaceutically acceptable salt thereof, or derivative thereof; in a pharmaceutically acceptable liquid carrier suitable for sublingual spray administration; said droplets having a mean diameter of at least about 10 microns[[.]], wherein said unit dose of said 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.

21. (Original): The unit dose of claim 20, wherein said liquid spray formulation comprises droplet particles having a mean diameter of at least about 20 microns.

22. (Original): The unit dose of claim 20, wherein said liquid spray formulation comprises droplet particles having a size distribution of from about 5 microns to about 500 microns.

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