Exhibit 1019

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 January 10, 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.

Amendments to the Specification begin on page **2** of this paper.

Listing of the Claims begin on page **8** of this paper.

Remarks begin on page **9** of this paper.

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AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0005] with the following paragraph:

[0005] Fentanyl is currently available in injectable form, as a lozenge (e.g. Actiq®; fentanyl citrate; Actiq is a registered trademark of Anesta, LLC), and as a transdermal patch (e.g. Duragesic® 25, 50, 75, and 100 µg of fentanyl per hour; Duragesic is a registered trademark of Johnson & Johnson Corporation). Duragesic® provides continuous systemic delivery of fentanyl for approximately 72 hours. Duragesic® is indicated in the management of chronic pain in patients requiring continuous opioid analgesia for pain that is not optimally managed with lesser means such as acetaminophen-opioid combinations, non-steroidal analgesics, or *prn* (as needed) dosing with short-acting opioids. Duragesic® is typically not suitable for patients experiencing acute pain due to the delay in absorption of the fentanyl through the patch, or postoperative pain because serious or life-threatening hypoventilation could result.

Please replace paragraph [0094] with the following paragraph:

[0094] In certain embodiments, the compositions comprise a C_{2-8} alcohol such as propylene glycol, or a polyethylene glycol and/or polypropylene glycol of an average molar weight of 200 to 4000, or a mixture thereof, in addition to the organic solvent described above. The C_{2-8} alcohol may act as a cosolvent in combination with the organic solvent. Polyethylene glycols commercially available as Carbowax®~~®~~(Carbowax is a registered trademark of Union Carbide Corporation; e.g., Carbowax® 300 of a molar weight of 300), can be used.

Please replace paragraph [00134] with the following paragraph:

[00134] Droplet size distribution can be determined by utilizing any reliable method known to one of skill in the art. One such method uses laser diffraction devices, such as, for example, the Malvern® (Malvern is a registered trademark of Malvern Instruments Limited) Spraytec® with RT Sizer Software. A Malvern® Mastersizer® (Mastersizer is a registered trademark of Malvern Instruments Limited) S, by Malvern® Instruments Limited (U.K.), device may also be used to determine size distribution. A Malvern® ~~Mastersize~~Mastersizer® S is a modular particle size analyzer offering measurement versatility. It can measure spray droplet size as well as wet and

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dry samples. Particles from sub-micron to a few millimeters may be measured with the Malvern® Mastersizer® S.

Please replace paragraph [00135] with the following paragraph:

[00135] Further, automated actuation stations for comparative *in vitro* bioequivalence tests or other testing to decrease the variability associated with manual actuation may also be used when determining the droplet size distribution. Any such automated actuation stations known to one of skill may be applicable in practicing the present invention. An example of one such device is the MightyRunt Actuation Station by Innova Systems, Inc. In a preferred embodiment, a MightyRunt is equipped with an exhaust fan attachment. In a further embodiment, the MightyRunt is further equipped with a Mettler Toledo® (Mettler Toledo is a registered trademark of Mettler-Toledo AG) balance Model AT201.

Please replace the paragraph titled Preparation of Formulations (Examples 1 - 5) which follows Table 5 with the following paragraph:

Preparation of Formulations (Examples 1-5)

1. Calculated amount of Fentanyl base or Fentanyl citrate was weighed in a tared glass container.
2. Calculated amount of alcohol was added to the container and mixed to dissolve fentanyl.
3. Propylene glycol was weighed and added to the fentanyl solution.
4. Water or Buffer or Miglyol® (Miglyol is a registered trademark of Cremer Oleo GmbH & Co. KG Limited Liability Partnership) was weighed, added to the fentanyl solution and mixed for 2 mm.
5. Inactive ingredients (Mannitol, Triacetin, or TW80) were added at the end and mixed well.
6. The final solution was vortexed for 3 min. After mixing, the formulations were stored in refrigerator for further studies.

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Please replace paragraph [00188] with the following paragraph:

[00188] The EpiOral tissues, grown on cell culture inserts with Teflon® (Teflon is a registered trademark of E.I. Du Pont De Nemours and Company) backing membrane, were shipped by MatTek Corp on Monday for delivery on Tuesday morning. All the tissues were used in the permeability experiments within 72 hours of shipment. The inserts containing the tissues were rinsed with distilled water before the start of permeation experiments. The tissue area for the ORL-100 is 0.6 cm2.

Please replace Table 20 with the following table:

	EXAMPLE #*	**CONC. OF FENTANYL BASE**	**ALCOHOL %(V)**	**PG %(V)**	**MIGLYOL® %(V)**	**% PERMEATED IN 2 HOURS**
Fentanyl Base	8-a (b)	1 mg/ml	20	5	-	17.33
Fentanyl Base	8-b (w)	1 mg/ml	20	5	-	17.18
Fentanyl Citrate	8-c (b)	0.646 mg/ml	20	5	-	1.81
Fentanyl Citrate	8-d	1 mg/ml	20	5	79.3	1.64

(b)-buffer, (w)-water

Please replace paragraph [00195] with the following paragraph:

[00195] In Example 12, several ingredients including hydroxypropyl beta cyclodextrin (HPBCD), mannitol, polyvinyl pyrrolidone (PVP), propylene carbonate (PC), sodium glycocholate (SG), sodium lauryl sulphate (SLS), triacetin, triethyl citrate and ~~tween~~ Tween® 80 (Tween is a registered trademark of Uniqema Americas LLC; TW 80) were added to the formulations either individually or in combination and studied for their effect on permeability and solution stability. Table 24 to 36 summarizes the formulations and permeation results of buffered and water formulations containing the above excipients.

Please replace paragraph [00196] with the following paragraph:

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