

Exhibit 1001



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**(12) United States Patent
Kottayil et al.****(10) Patent No.: US 8,486,972 B2
(45) Date of Patent: Jul. 16, 2013****(54) SUBLINGUAL FENTANYL SPRAY****(75) Inventors: S. George Kottayil**, Long Grove, IL (US); **Venkat R. Goskonda**, Gurnee, IL (US); **Zhongyuan Zhu**, Vernon Hills, IL (US); **Neha Parikh**, Chicago, IL (US); **Linet Kattookaran**, Mount Prospect, IL (US)**(73) Assignee: Insys Therapeutics, Inc.**, Phoenix, AZ (US)**(*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1188 days.**(21) Appl. No.: 11/698,739****(22) Filed: Jan. 25, 2007****(65) Prior Publication Data**

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A61K 31/445 (2006.01)
A61K 31/21 (2006.01)
A61M 11/00 (2006.01)
A61K 9/00 (2006.01)
A61B 19/00 (2006.01)**(52) U.S. Cl.**
USPC **514/329**; 128/200.14; 424/400; 514/506; 604/407**(58) Field of Classification Search**
USPC 514/329
See application file for complete search history.**(56) References Cited**

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Primary Examiner — Robert Landsman
(74) Attorney, Agent, or Firm — Wood, Phillips, Katz, Clark & Mortimer**(57) ABSTRACT**

The present invention is directed to sublingual formulations containing fentanyl, a pharmaceutically acceptable salt thereof, or derivative thereof, suitable for administration to a patient, and methods for treatment with the formulations.

3 Claims, 7 Drawing Sheets

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Lejus, et al., "Fentanyl versus sufentanil: plasma concentrations during continuous epidural postoperative infusion in children," British Journal of Anaesthesia, vol. 85, Issue 4, Oct. 2000, pp. 615-617.
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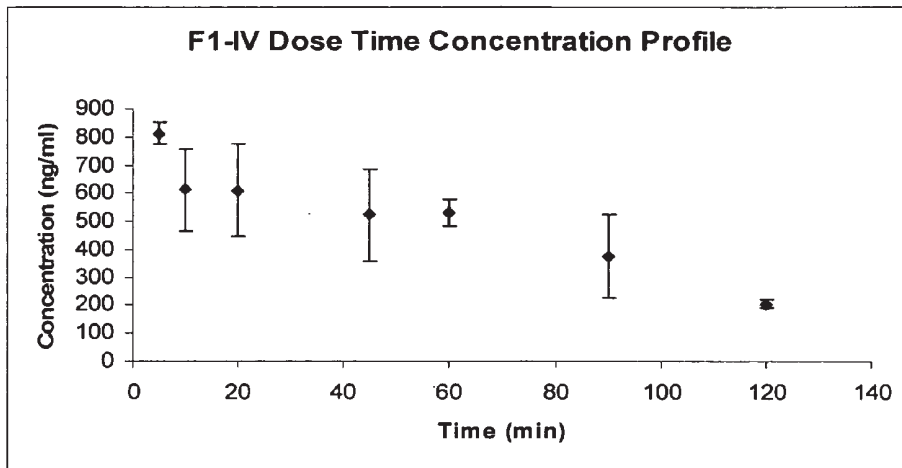
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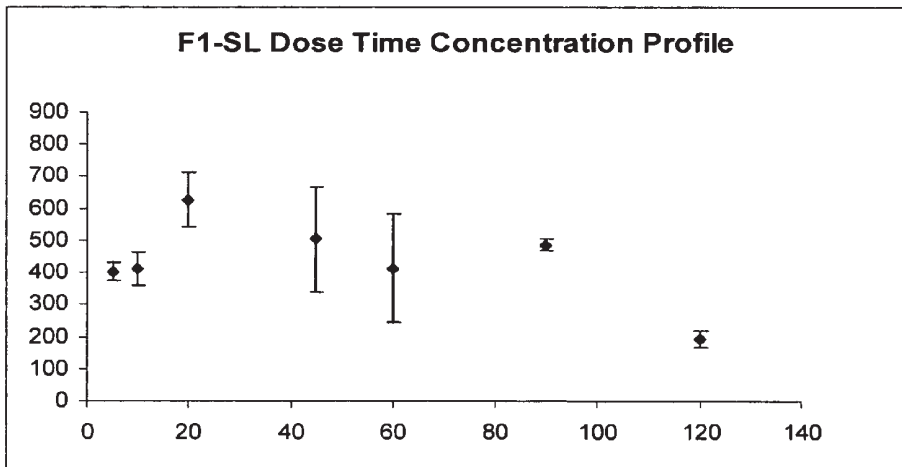
Plasma concentration-time curves after IV & SL doses of Fentanyl

Figure 1: Formula of Example 1, 50 µg IV dose



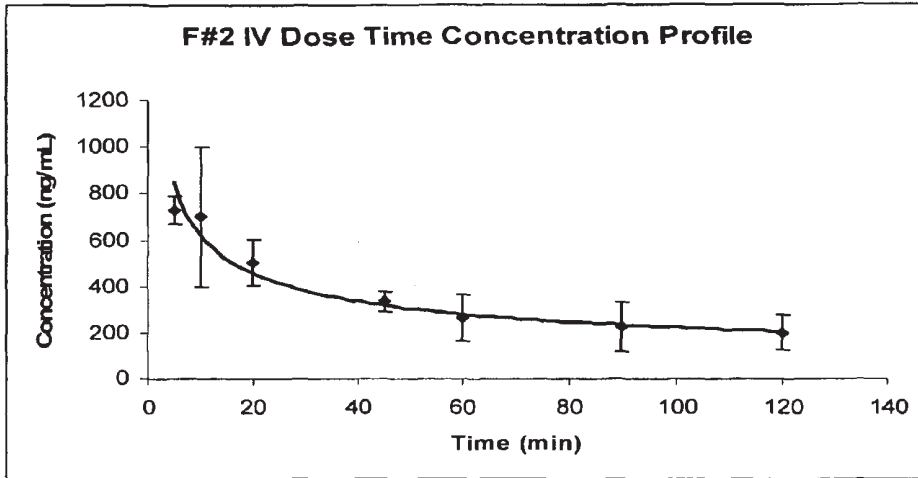
Mean (±S.E.) plasma concentration–time profiles following intravenous administration of Fentanyl (n=3).

Figure 2: Formula of Example 1, 50 µg Sublingual dose



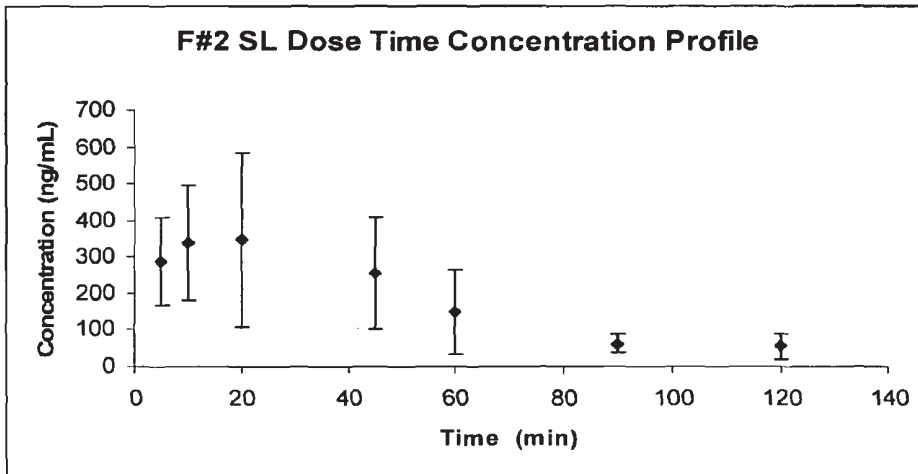
Mean (±S.E.) plasma concentration–time profiles following sublingual administration of Fentanyl (n=3)

Figure 3: Formula of Example 2, 80 µg IV dose



Mean (±S.E.) plasma concentration–time profiles following intravenous administration of Fentanyl (*n*=3).

Figure 4: Formula of Example 2, 80 µg SL dose



Mean (±S.E.) plasma concentration–time profiles following sublingual administration of Fentanyl (*n*=3)

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