

EXHIBIT 1001



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(12) **United States Patent**
Kottayil et al.(10) **Patent No.:** **US 8,835,459 B2**
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(21) Appl. No.: **13/895,111** 2007/0261695 A1 11/2007 Kottayil et al.
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(51) **Int. Cl.**
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A61M 11/00 (2006.01)
A61K 31/435 (2006.01)
A61K 31/4468 (2006.01)
A61K 9/00 (2006.01)

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CPC **A61K 31/4468** (2013.01); **A61K 31/435** (2013.01); **A61M 11/00** (2013.01); **A61K 31/445** (2013.01); **A61K 9/006** (2013.01); **A61K 9/0056** (2013.01)
USPC **514/329**; 128/200.14

(58) **Field of Classification Search**
None
See application file for complete search history.

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(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.

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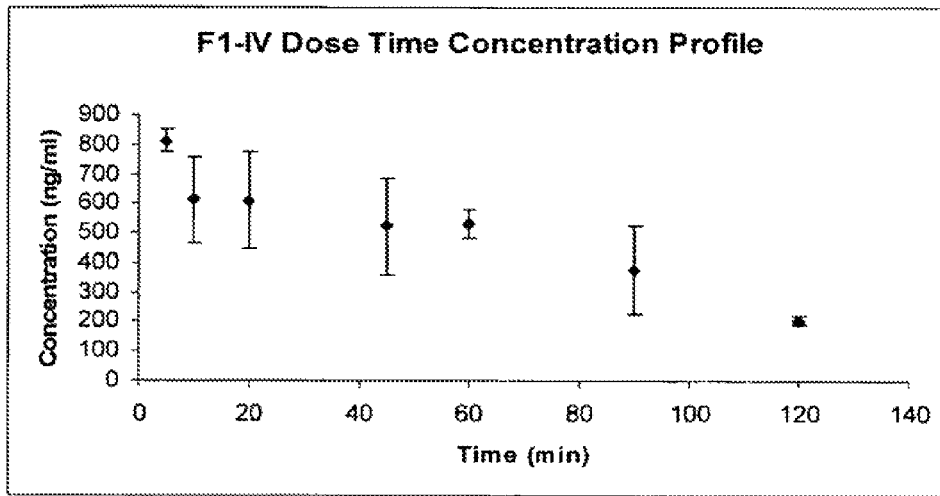
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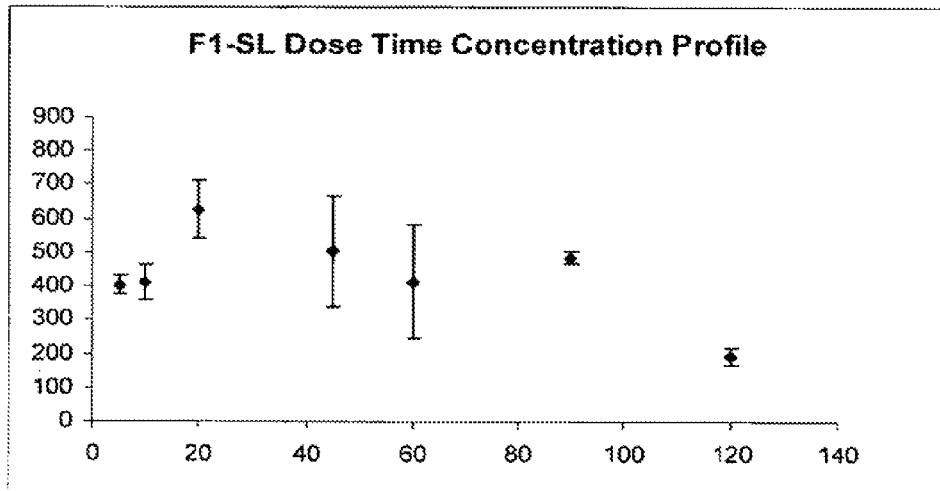
Plasma concentration-time curves after IV & SL doses of Fentanyl

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



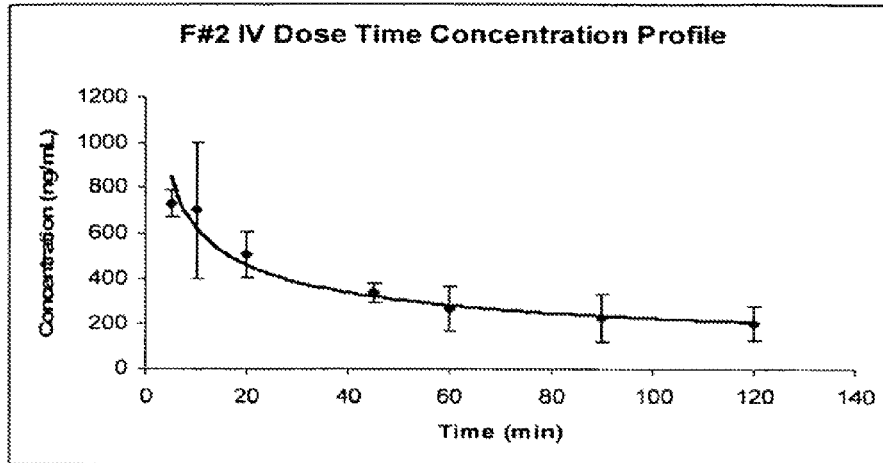
Mean (\pm S.E.) plasma concentration-time profiles following intravenous administration of Fentanyl ($n=3$).

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



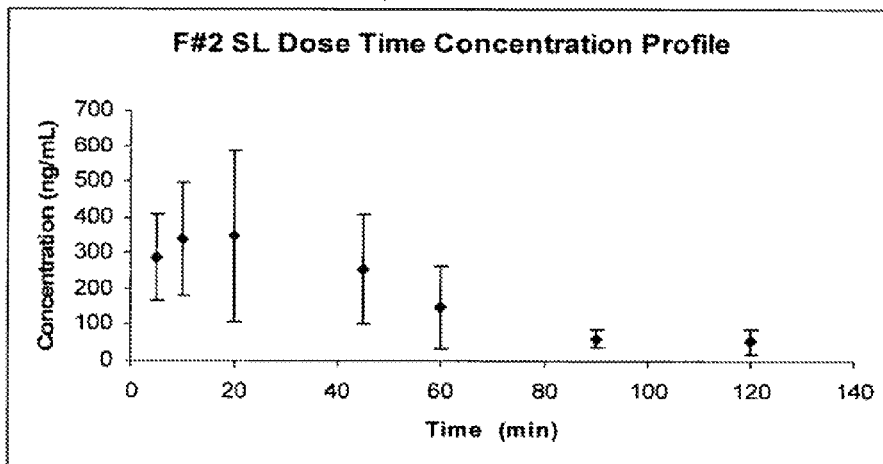
Mean (\pm S.E.) plasma concentration-time profiles following sublingual administration of Fentanyl ($n=3$)

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



Mean (\pm S.E.) plasma concentration-time profiles following intravenous administration of Fentanyl ($n=3$).

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



Mean (\pm S.E.) plasma concentration-time profiles following sublingual administration of Fentanyl ($n=3$).

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