

US 20090041831A1

(19) United States

(12) Patent Application Publication Miller, II et al.

(10) **Pub. No.: US 2009/0041831 A1**(43) **Pub. Date: Feb. 12, 2009**

- (54) FENTANYL SUSPENSION-BASED SILICONE ADHESIVE FORMULATIONS AND DEVICES FOR TRANSDERMAL DELIVERY OF FENTANYL
- (75) Inventors: Kenneth J. Miller, II, St. Albans, VT (US); Sharad K. Govil, Essex, VT (US); Kuljit Singh Bhatia, Scottsdale, AZ (US)

Correspondence Address: DARBY & DARBY P.C. P.O. BOX 770, Church Street Station New York, NY 10008-0770 (US)

- (73) Assignee: **Mylan Laboratories**, Canonsburg, PA (US)
- (21) Appl. No.: 12/260,050
- (22) Filed: Oct. 28, 2008

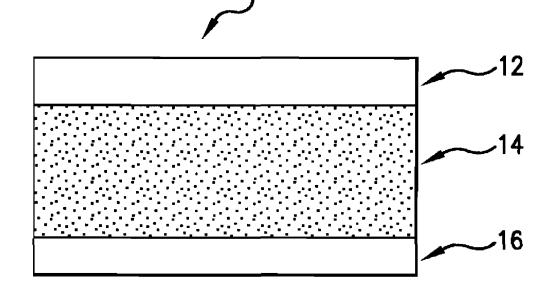
Related U.S. Application Data

(63) Continuation of application No. 11/743,411, filed on May 2, 2007, Continuation of application No. 11/723, 111, filed on Mar. 16, 2007, said application No. 11/743,411 is a continuation of application No. 11/438,391, filed on May 23, 2006, now abandoned, said application No. 11/723,111 is a continuation of application No. 11/438,391, filed on May 23, 2006, now abandoned, which is a continuation of application No. 10/283,355, filed on Oct. 30, 2002, now abandoned.

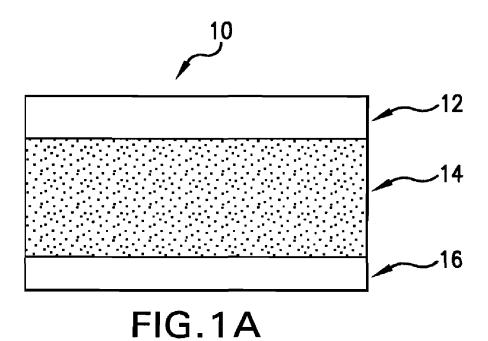
Publication Classification

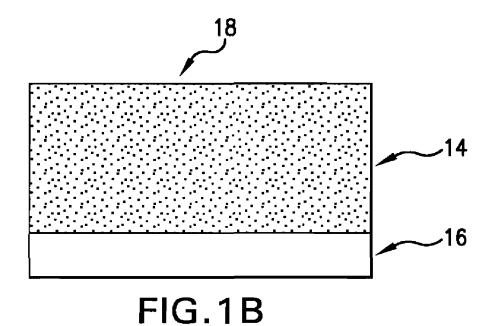
- (51) **Int. Cl. A61K 9/70** (2006.01) **A61K 31/445** (2006.01)
- (57) ABSTRACT

Silicone adhesive formulations are provided, in which fentanyl particles are suspended one or more a solvated silicone adhesives. The formulations can be used for manufacturing improved, matrix-type transdermal devices for administering fentanyl.











In vitro delivery of 3—day Clinical, 3—day Recrystallized, and Duragesic Patches (3 Donors, 2 to 6 Chambers per Donor)

-- Clinical lot-FIBJ10001 (Suspension Blend: 4% Fentanyl, 8.6% 360 Medical Fluid)

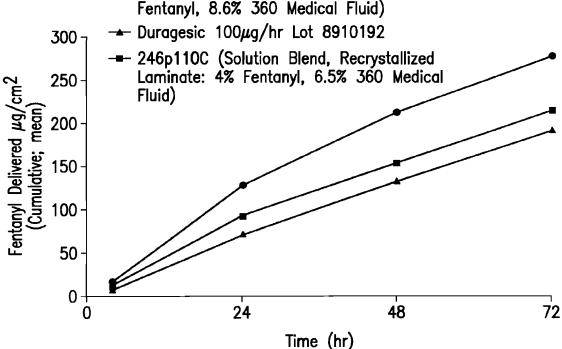


FIG.2

In vitro delivery of 7-day Suspension vs. 7-day Recrystallized (3 Donors, 6 Chambers/Donor)



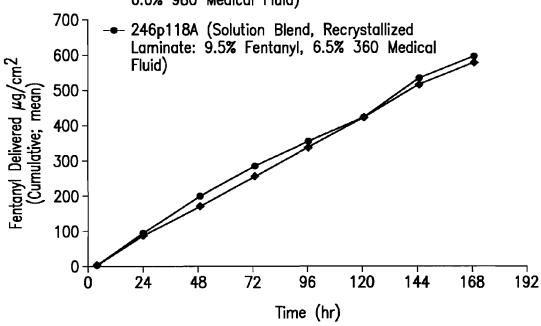


FIG.3

Fentanyl Rate of Release

- 246P110C (Solution Blend, Recrystallized Laminate: 4% Fentanyl, 6.5% 360 Medical Fluid)
- -- Clinical Lot FIBJ0001 (Suspension Blend: 4% Fentanyl, 8.5% 360 Medical Fluid) 140% 120% 100% Potency Claim 80% 60% 40% 20% 0% 2 3 5 6 7 8 4 0 1 9 Time (hr)

FIG.4

DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

