



US 20080274194A1

(19) **United States**

(12) **Patent Application Publication**

Miller et al.

(10) **Pub. No.: US 2008/0274194 A1**

(43) **Pub. Date: Nov. 6, 2008**

(54) **STABILIZED HME COMPOSITION WITH SMALL DRUG PARTICLES**

(75) Inventors: **Dave A. Miller**, Austin, TX (US); **Jason T. McConville**, Austin, TX (US); **James W. McGinity**, Austin, TX (US); **Robert O. Williams**, Austin, TX (US)

Correspondence Address:
CHALKER FLORES, LLP
2711 LBJ FRWY, Suite 1036
DALLAS, TX 75234 (US)

(73) Assignee: **BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM**, Austin, TX (US)

(21) Appl. No.: **11/718,620**

(22) PCT Filed: **Nov. 9, 2005**

(86) PCT No.: **PCT/US05/40535**

§ 371 (c)(1),
(2), (4) Date: **Nov. 19, 2007**

Related U.S. Application Data

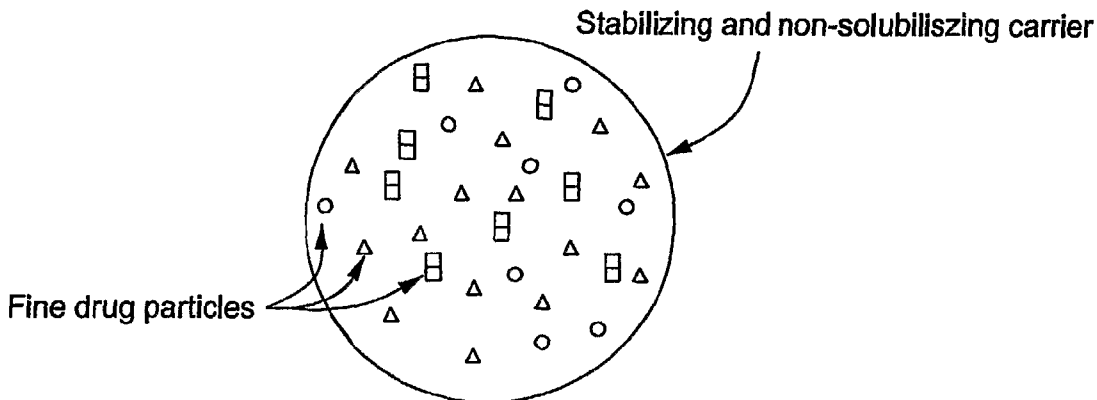
(60) Provisional application No. 60/626,400, filed on Nov. 9, 2004, provisional application No. 60/681,279, filed on May 16, 2005.

Publication Classification

(51) **Int. Cl.**
A61K 9/14 (2006.01)
A61P 43/00 (2006.01)
(52) **U.S. Cl.** **424/489**

(57) **ABSTRACT**

A hot-melt extruded composition having finely divided drug-containing particles dispersed within a polymeric and/or lipophillic carrier matrix is provided. The carrier softens or melts during hot-melt extrusion but it does not dissolve the drug-containing particles during extrusion. As a result, a majority or at least 90% wt. of the drug-containing particles in the extrudate are deaggregated during extrusion into essentially primary crystalline and/or amorphous particles. PEO is a suitable carrier material for drugs insoluble in the solid state in this carrier. Various functional excipients can be included in the carrier system to stabilize the particle size and physical state of the drug substance in either a crystalline and/or amorphous state. The carrier system is comprised of at least one thermal binder, and may also contain various functional excipients, such as: super-disintegrants, antioxidants, surfactants, wetting agents, stabilizing agents, retardants, or similar functional excipients. A hydrophilic polymer, such as hydroxypropyl methylcellulose (HPMC E15), polyvinyl alcohol (PVA), or poloxamer, and/or a surfactant, such as sodium lauryl sulfate (SLS), can be included in the composition. A process for preparing the extrudate is conducted at a temperature approximating or above the softening or melting temperature of the matrix and below the point of solubilization of drug-containing particles in the carrier system, and below the recrystallization point in the case of amorphous fine drug particles.



Petitioner InnoPharma EX 1069

IPR2015-00902

IPR2015-00903

Page 1

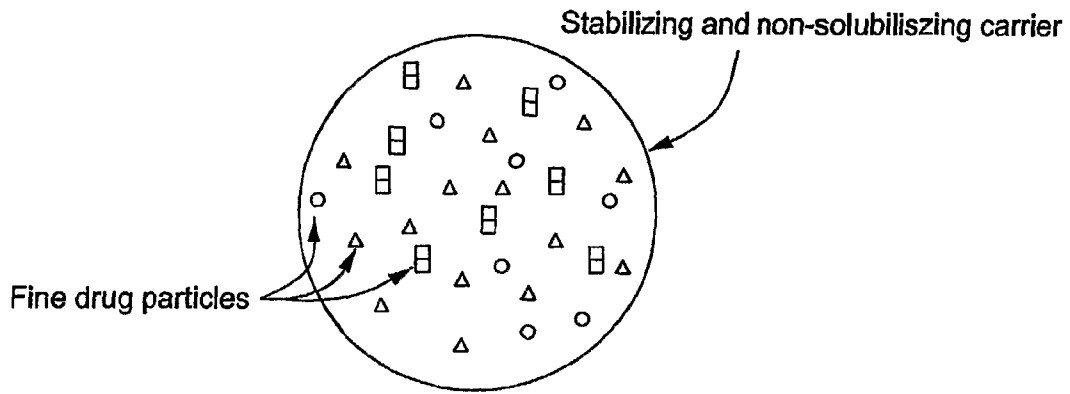


FIG. 1A

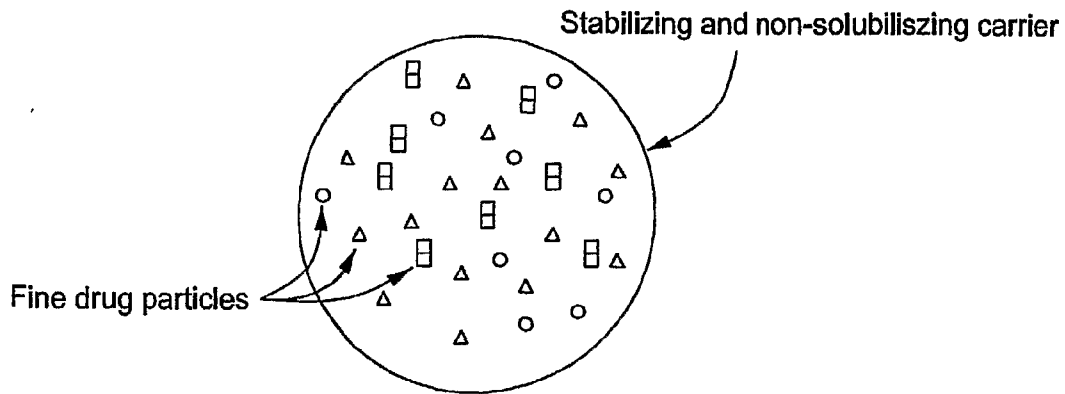


FIG. 1B

FIG. 2A

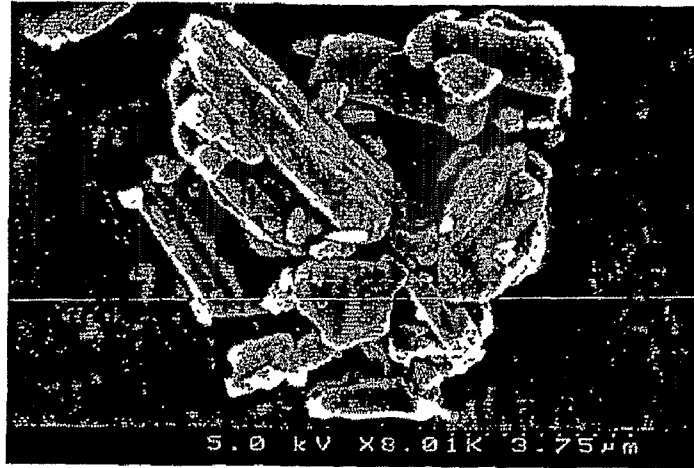


FIG. 2B

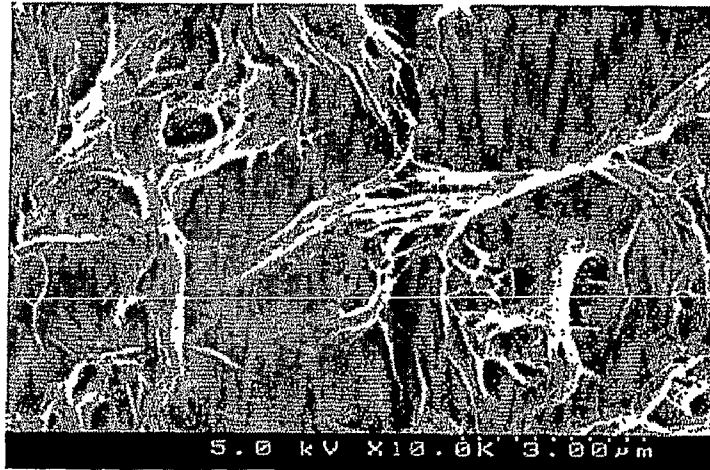
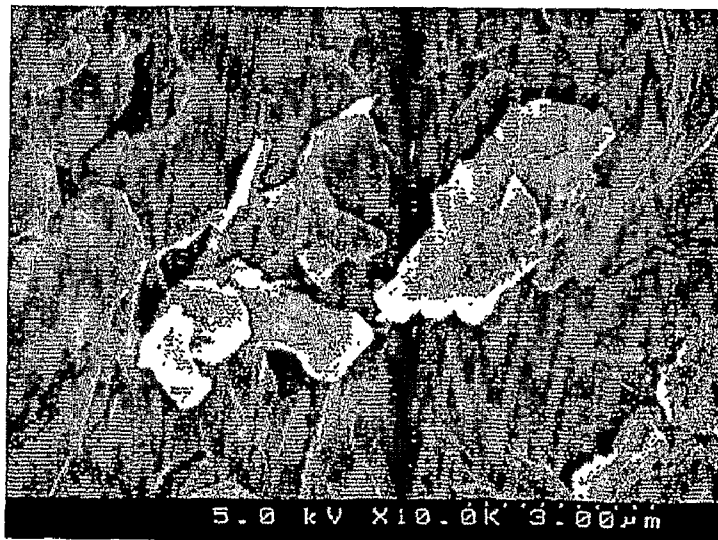


FIG. 2C



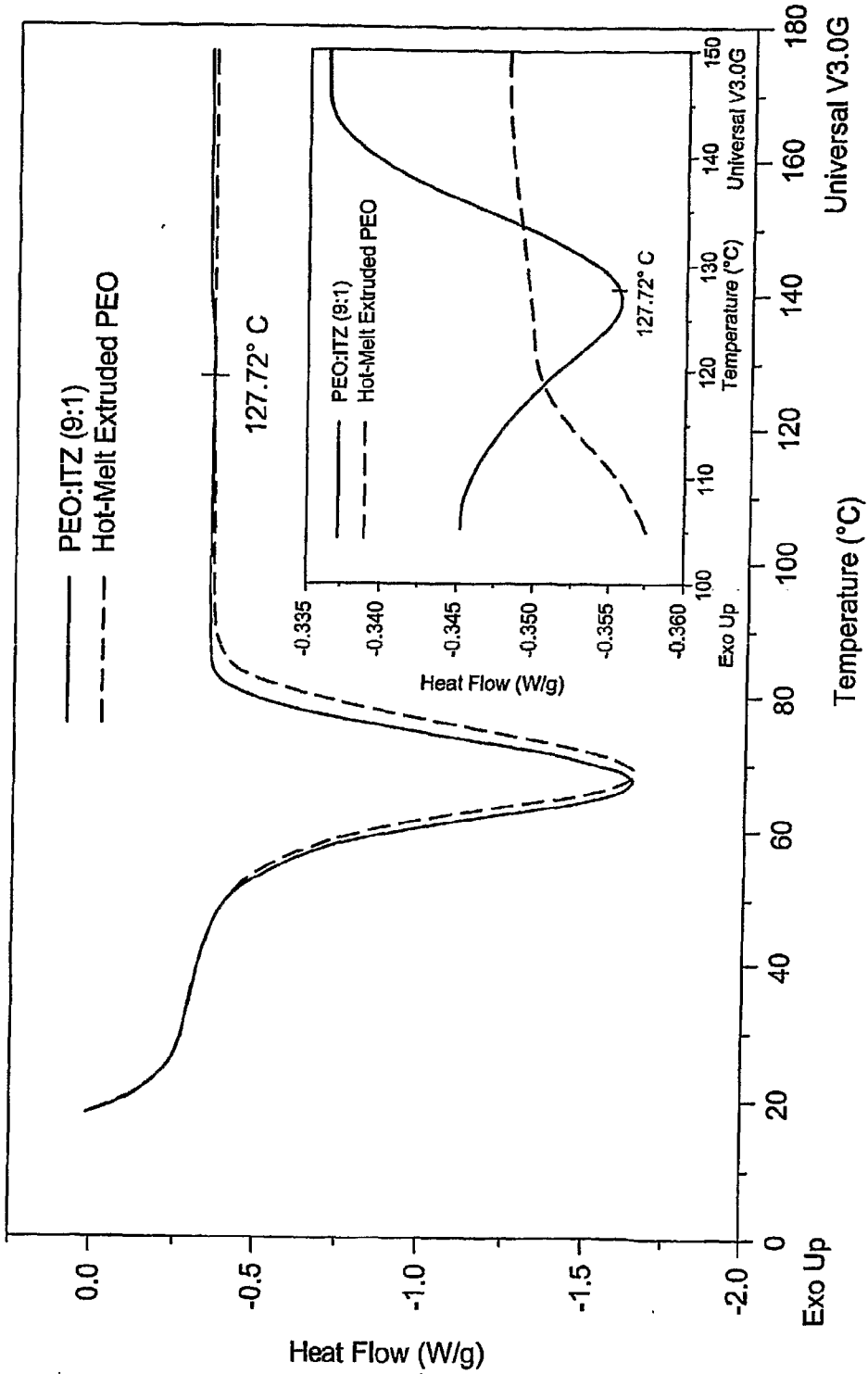


FIG. 2D

FIG. 3A

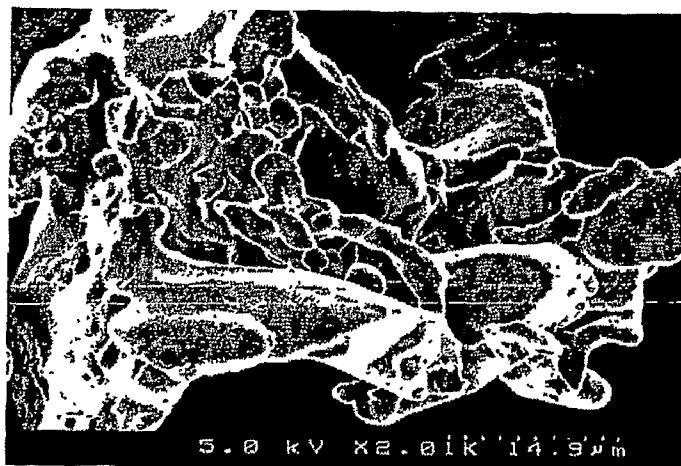


FIG. 3B



FIG. 3C



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.