

US005656286A

United States Patent [19]

Miranda et al.

[11] Patent Number:

5,656,286

[45] Date of Patent:

Aug. 12, 1997

[54] SOLUBILITY PARAMETER BASED DRUG DELIVERY SYSTEM AND METHOD FOR ALTERING DRUG SATURATION CONCENTRATION

[75] Inventors: Jesus Miranda; Steven Sablotsky,

both of Miami, Fla.

[73] Assignee: Noven Pharmaceuticals, Inc., Miami,

Fla.

[21] Appl. No.: 178,558

[22] Filed: Jan. 7, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 722,342, Jun. 27, 1991, Pat. No. 5,474,783, which is a continuation-in-part of PCT/US90/01750, Mar. 28, 1990, which is a continuation-in-part of Ser. No. 671,709, Apr. 2, 1991, Pat. No. 5,300,291, which is a continuation-in-part of Ser. No. 295,847, Jan. 11, 1989, Pat. No. 4,994,267, which is a continuation-in-part of Ser. No. 164,482, Mar. 4, 1988, Pat. No. 4,814,168.

[51]	Int. Cl	A61F 13/02
[52]	U.S. Cl	424/449 ; 424/448
[58]	Field of Search	424/448, 449

[56] References Cited

U.S. PATENT DOCUMENTS

3,969,308	7/1976	Penneck 260/37 SB
3,972,995	8/1976	Tsuk et al 424/28
4,291,015	9/1981	Keith et al 424/28
4,292,301	9/1981	Keith et al 424/28
4,390,520	6/1983	Nagai et al 424/28
4,438,139	3/1984	Keith et al 424/28
4,542,013	9/1985	Keith 424/28
4,585,452	4/1986	Sablotsky 604/896
4,593,053	6/1986	Jevne et al 523/111
4,668,232	5/1987	Cordes et al 604/897
4,690,683	9/1987	Chien et al 604/896
4,693,887	9/1987	Shah 424/19
4,696,821	9/1987	Belsole 424/448
4,699,146	10/1987	Sieverding 128/640
4,750,482	6/1988	Sieverding 128/156

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

2027053	4/1991	Canada .
0201828	11/1986	European Pat. Off
208395	1/1987	European Pat. Off
0272045	6/1988	European Pat. Off
0343807	11/1989	European Pat. Off
0 371 496	6/1990	European Pat. Off
0416842	3/1991	European Pat. Off
0529123	3/1993	European Pat. Off
54-89017	7/1979	Japan .
58-225010	12/1983	Japan .
2 105 990	4/1983	United Kingdom .
91/05529	5/1991	WIPO .
93/08795	5/1993	WIPO .

OTHER PUBLICATIONS

Yu et al., "Transdermal Dual-Controlled Delivery of Testosterone and Estradiol: (I) Impact of System Design," *Drug Devel. Indust. Pharm.* 17(14): 1883–1904 (1991).

Ziller et al., "Control of Crystal Growth in Drug Suspensions," *Pharm. Ind.* 52(8):1017-1022 (1990).

English translation of Japanese patent application No. 2-48859, filed Feb. 27, 1990.

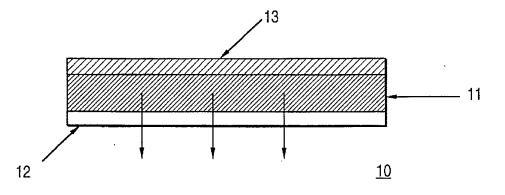
Sloan, K. B. et al., "Use of Solubility Parameters of Drug and Vehicle to Predict Flux Through Skin", *The Journal of Investigative Dermatology*, vol. 87 (No. 2) pp. 244–252 (Aug. 1986).

Primary Examiner—Jyothsna Venkat Attorney, Agent, or Firm—Foley & Lardner

57] ABSTRACT

A blend of at least two polymers, or at least one polymer and a soluble polyvinylpyrrolidone, in combination with a drug provides a pressure-sensitive adhesive composition for a transdermal drug delivery system in which the drug is delivered from the pressure-sensitive adhesive composition and through dermis when the pressure-sensitive adhesive composition is in contact with human skin. According to the invention, soluble polyvinylpyrrolidone can be used to prevent crystallization of the drug, without affecting the rate of drug delivery from the pressure-sensitive adhesive composition.

73 Claims, 19 Drawing Sheets





5,656,286Page 2

U.S. PATENT DOCUMENTS			5,122,543	6/1992	Khanna 514/772.5
			5,128,138	7/1992	Blank 424/449
4,769,013		Lorenz et al 604/265	5,141,750	8/1992	Lee et al 424/448
4,814,168		Sablotsky et al 424/78	5,151,271	9/1992	Otsuka et al 424/443
.,,		Sloan 514/232.2	5.154.922	10/1992	Govil et al 424/448
4,883,669		Chien et al 424/448	- , ,-		Yeh et al 424/443
4,906,169		Chien et al 424/448	., , .		Horstmann et al 424/449
4,911,916		Cleary 424/449	, , , , , ,		Pfister et al
4,931,281		Kim et al 424/448	, ,		Blank
4,987,893	1/1991	Salamone et al 128/156	, ,		
4.994.267	2/1991	Sablotsky 424/78			Chiang et al 424/448
5,032,403		Sinnreich	5,260,064	11/1993	Nakagawa et al 424/448
		Cilento et al 604/307	5,262,165	11/1993	Govil et al 424/448
		Lee et al 424/448	5,393,529	2/1995	Hoffmann et al 424/445



FIG. 1

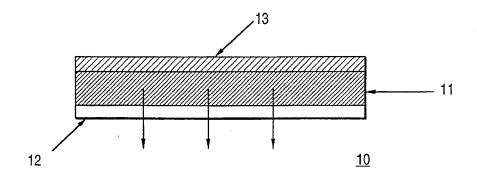
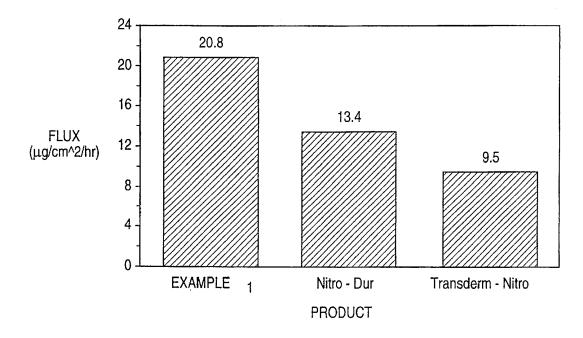
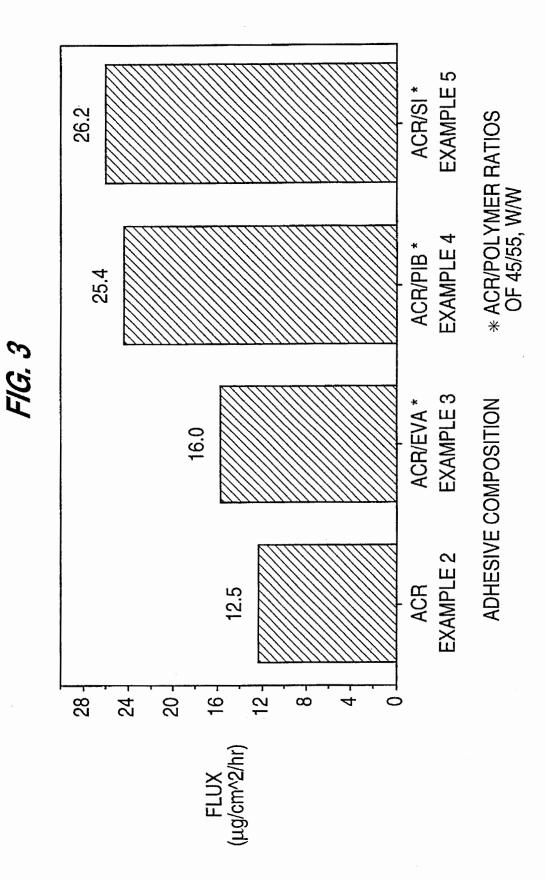


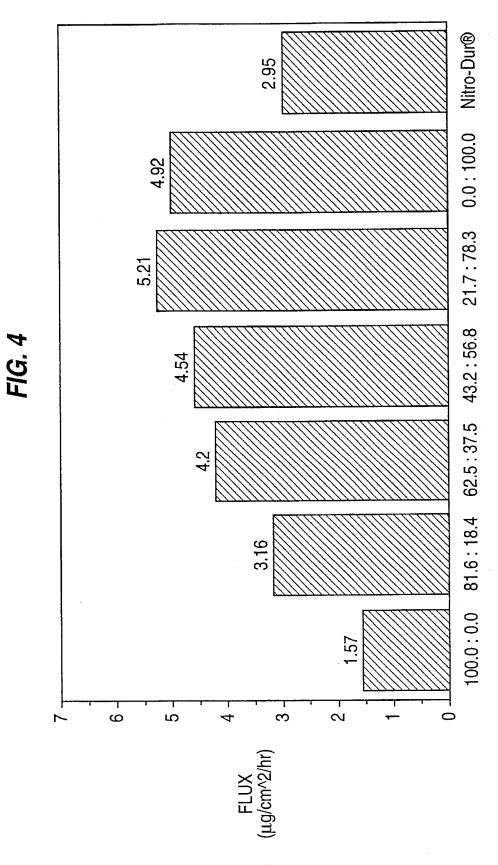
FIG. 2







ACRYLIC: SILOXANE POLYMER RATIO (W / W)





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.

