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Kanios

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(54) **COMPOSITIONS AND METHODS TO EFFECT THE RELEASE PROFILE IN THE TRANSDERMAL ADMINISTRATION OF ACTIVE AGENTS**

FOREIGN PATENT DOCUMENTS

(75) **Inventor:** **David Kanios**, Miami, FL (US)
(73) **Assignee:** **Noven Pharmaceuticals, Inc.**, Miami, FL (US)
(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

EP	0 224 981	6/1987
EP	0 697 860	4/1994
EP	913 158	6/1999
WO	WO94/06436	3/1994
WO	WO94/26257	11/1994
WO	WO95/22322	8/1995
WO	WO95/31188	11/1995
WO	WO96/21433	7/1996
WO	WO98/17263	4/1998
WO	WO98/31349	7/1998
WO	WO98/39042	9/1998
WO	WO99/55286	11/1999
WO	WO00/59483	10/2000
WO	WO00/74661	12/2000
WO	PCT/US01/01999	8/2001

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Related U.S. Application Data

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(60) Provisional application No. 60/177,103, filed on Jan. 20, 2000.
(51) **Int. Cl.⁷** **A61K 9/70; A61K 13/00**
(52) **U.S. Cl.** **424/449; 424/448; 424/443; 424/484**
(58) **Field of Search** **424/448, 449, 424/484, 487, 488, 443**

OTHER PUBLICATIONS

Dow Chemical Company, "Product Specification Sheet for Ethocel FP Polymers," Oct. 1998, U.S.A.
Dow Chemical Company, "Bibliography: ETHOCEL Ethylcellulose in Pharmaceuticals," Jun. 1996, U.S.A.

(List continued on next page.)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,584,355 A	4/1986	Blizzard et al.
4,585,836 A	4/1986	Homan et al.
4,591,622 A	5/1986	Blizzard et al.
4,638,043 A	1/1987	Szycher et al.
4,655,767 A	4/1987	Woodard et al.
4,746,509 A	5/1988	Haggiage et al.
4,839,174 A	6/1989	Baker et al.
4,840,796 A	6/1989	Sweet et al.
4,842,864 A	6/1989	Guillemet et al.
RE32,991 E	7/1989	Szycher et al.
4,883,669 A	11/1989	Chien et al.
4,900,554 A	2/1990	Yanagibashi et al.
4,994,267 A	2/1991	Sablotsky

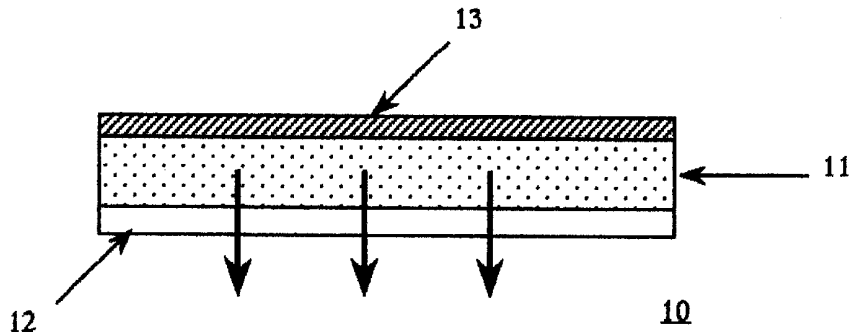
(List continued on next page.)

Primary Examiner—Thurman K. Page
Assistant Examiner—Robert M. Joynes
(74) *Attorney, Agent, or Firm*—Jay G. Kolman, Esq.

(57) **ABSTRACT**

Compositions and methods for the transdermal delivery of active agents up to a period of seven days or more at substantially a zero-order release rate comprising a pharmaceutically acceptable adhesive matrix and a polymeric plastic material that provides a release rate regulating effect on the active agents.

6 Claims, 6 Drawing Sheets



U.S. PATENT DOCUMENTS

5,118,779 A 6/1992 Szycher
 5,176,915 A 1/1993 Hoffmann
 5,232,702 A 8/1993 Pfister et al.
 5,446,070 A 8/1995 Mantelle
 5,474,783 A 12/1995 Miranda et al.
 5,523,095 A 6/1996 Wison et al.
 5,556,635 A 9/1996 Istin et al.
 5,656,286 A 8/1997 Miranda et al.
 5,662,923 A 9/1997 Roreger
 5,662,926 A 9/1997 Wick et al.
 5,676,969 A 10/1997 Wick et al.
 5,679,373 A 10/1997 Wick et al.
 5,716,609 A 2/1998 Jain et al.
 5,810,786 A 9/1998 Jackson et al.
 5,885,612 A 3/1999 Meconi et al.
 5,904,931 A 5/1999 Lipp et al.
 5,906,814 A 5/1999 Epstein
 6,010,715 A 1/2000 Wick et al.
 6,024,974 A * 2/2000 Li 424/448
 6,143,319 A 11/2000 Meconi et al.
 6,190,689 B1 2/2001 Hoffmann et al.
 6,231,885 B1 5/2001 Carrara
 6,274,165 B1 8/2001 Meconi et al.

OTHER PUBLICATIONS

Dow Chemical Company, "Ethocel Polymers for General Applications," Mar. 1998, U.S.A.
 Dow Chemical Company, "Ethocel Premium Polymers for Pharmaceutical Applications," May 1996, U.S.A.
 Dow Chemical Company, "Ethocel Premium Ethylcellulose in Pharmaceutical Applications," Dec. 1991, U.S.A.
 Wiley-Interscience/John Wiley & Sons, March, Jerry, *Advanced Organic Chemistry: Reactions, Mechanisms, and Structure, 4th Ed.*, 1992.
 BASF Aktiengesellschaft, Buhler, *Kollidon® Polyvinylpyrrolidone for the Pharmaceutical Industry, 2nd Ed.*, Aug. 1993.
 Van Nostrand Reinhold, New York, Satas, Donatas, "Acrylic Adhesives," pp. 396-456, 1989, *Handbook of Pressure-Sensitive Adhesive Technology, 2nd Edition*.
 Van Nostrand Reinhold, New York, Sobieski, Loretta, et al., "Silicone Pressure Sensitive Adhesives," pp. 508-517; 1989, *Handbook of Pressure Sensitive Adhesive Technology, 2nd Ed.*

* cited by examiner

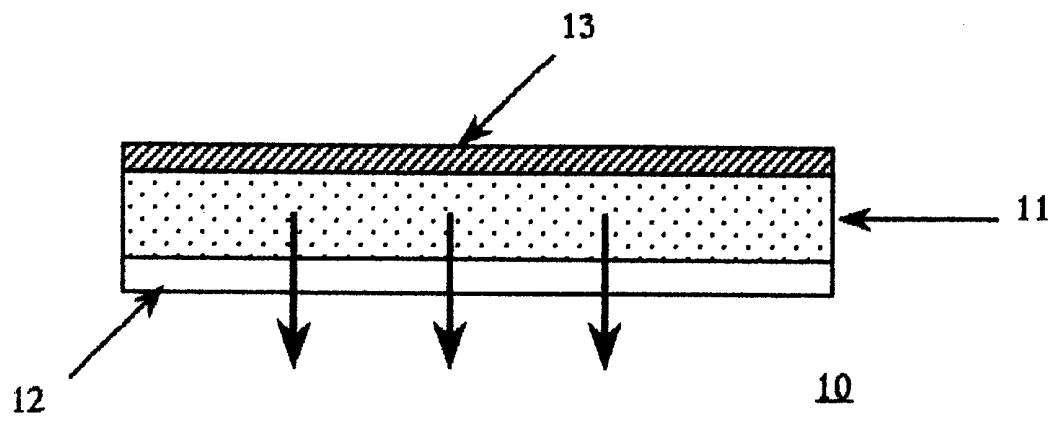


FIG. 1

FIGURE 2

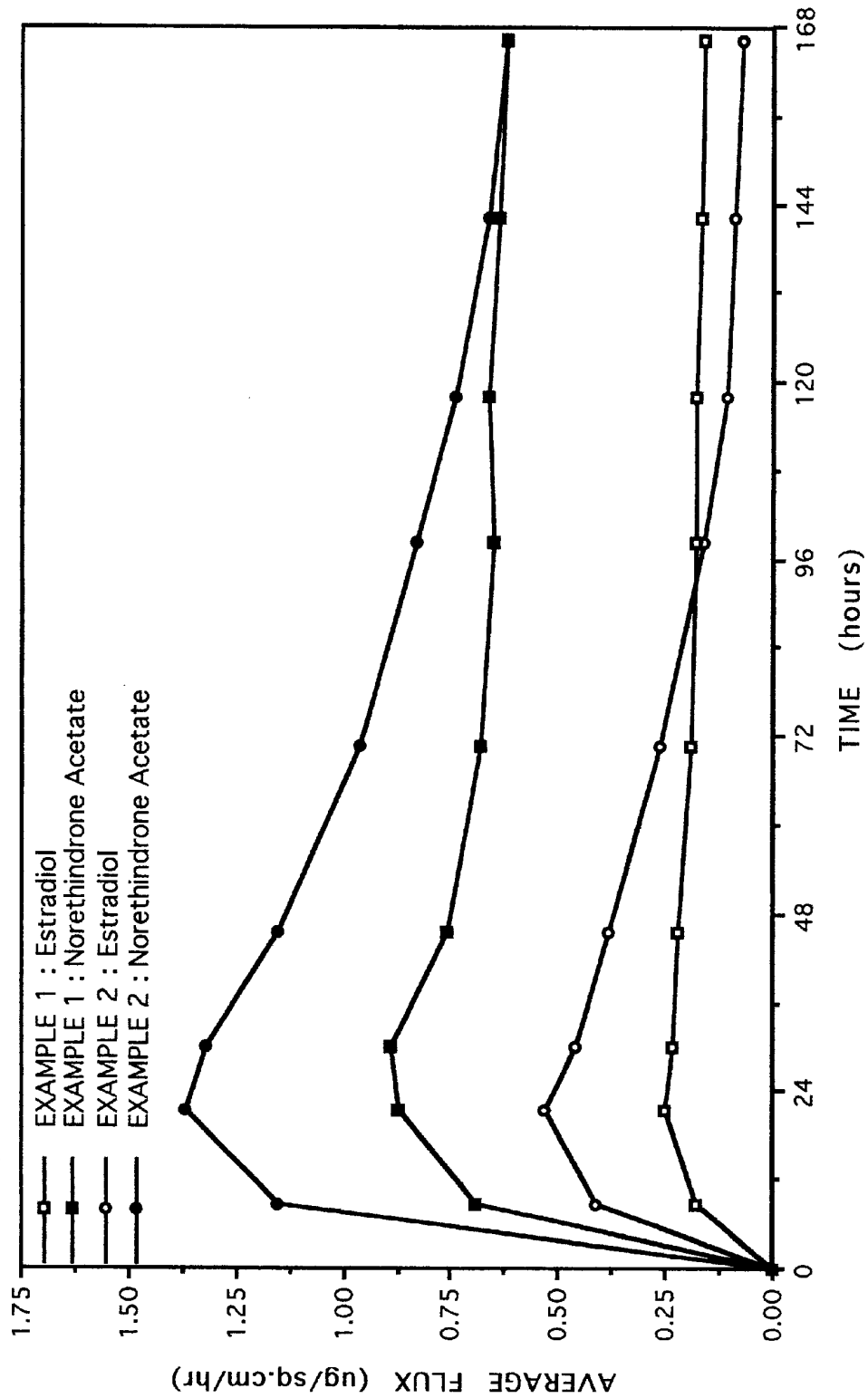
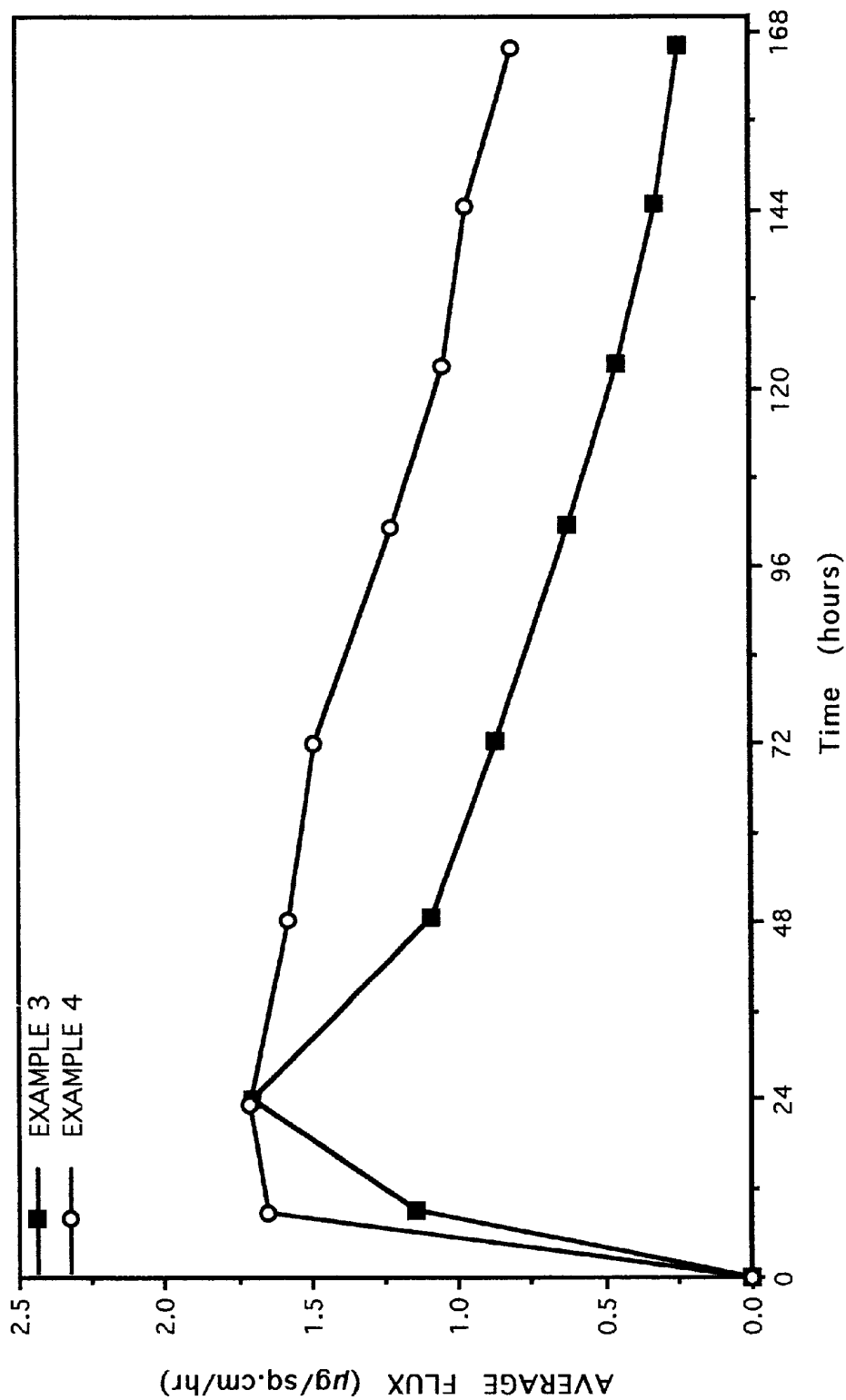


FIGURE 3



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