

(12) **United States Patent**
Chen et al.(10) **Patent No.:** **US 6,552,024 B1**
(45) **Date of Patent:** **Apr. 22, 2003**(54) **COMPOSITIONS AND METHODS FOR
MUCOSAL DELIVERY**5,166,202 A 11/1992 Schweizer 514/220
5,166,233 A 11/1992 Kuroya et al. 524/37
5,198,436 A 3/1993 Ellinwood, Jr. et al. 514/221(75) Inventors: **Li-Lan H. Chen**, Edison; **William R. Pfister**, Robbinsville, both of NJ (US); **Donald W. Renn**, Glen Cove, ME (US); **Thitiwan Buranachokpaisan**, Milltown, NJ (US); **James Osborne**, Princeton Junction, NJ (US); **Hock Seng Tan**, Old Bridge, NJ (US); **Li Tao**, Edison, NJ (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(21) Appl. No.: **09/434,878**(22) Filed: **Nov. 5, 1999****Related U.S. Application Data**

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(51) **Int. Cl.**⁷ **A61K 31/495**; A61K 9/00; A61K 9/14; A61K 9/70; A61K 31/24; A61K 31/44; A61K 31/50; A61K 31/505; A61K 31/56(52) **U.S. Cl.** **514/252.16**; 424/400; 424/443; 424/444; 424/484; 424/485; 424/486; 424/487; 424/488; 514/182; 514/258; 514/289; 514/343; 514/534(58) **Field of Search** 424/400, 443, 424/444, 484, 485, 486, 487, 488; 514/182, 252.16, 258, 289, 343, 534(56) **References Cited**

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Primary Examiner—Jose' G. Dees*Assistant Examiner*—Frank Choi(74) *Attorney, Agent, or Firm*—Dechert; Thomas S. Deibert(57) **ABSTRACT**

Mucosal surface-coat-forming film dosage units containing a water-soluble hydrocolloid, an effective dose of an active agent and a mucosal adhesion enhancer; wherein the active agent is encapsulated within a polymer which is chemically or physically distinct from the hydrocolloid; wherein the mucosal adhesion enhancer is a starch graft copolymer; wherein the film exhibits a dry tack value of less than 3.5 g, a wet tack of greater than 35 g, a gelation temperature that is greater than 70° C. for a 2% polymer solution, a dry film thickness of less than 20 mil, a water content of 0.5 to 10%, a tensile strength greater than 1500 psi, a modulus in the range of 35,000 to 300,000 psi, a % elongation of less than 20%, a tear propagation resistance of 0.001 to 1 N, and a dissolution time in the range of 1 to 600 seconds upon application to an oral mucosal surface.

51 Claims, 6 Drawing Sheets

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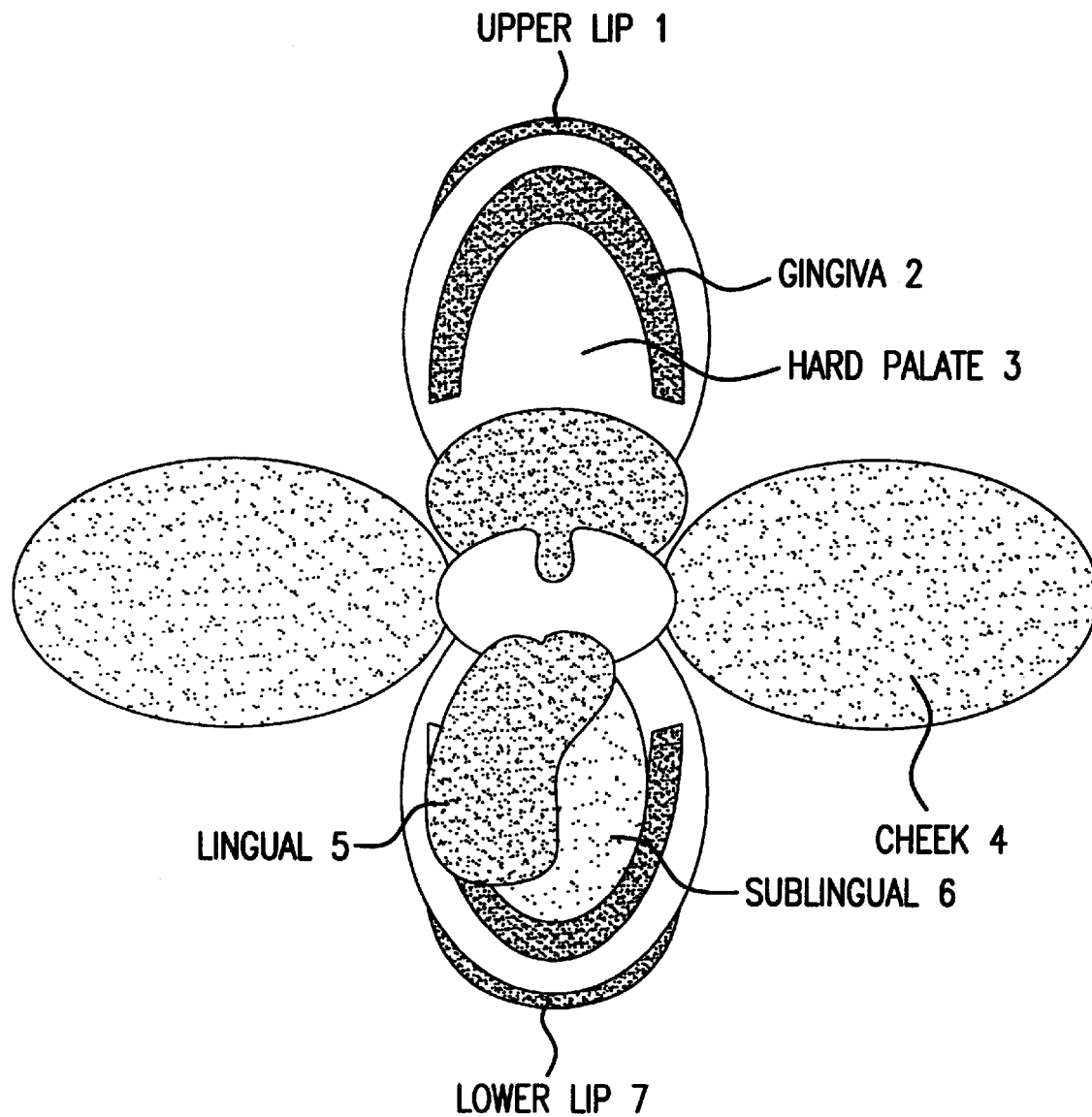


FIG. 1

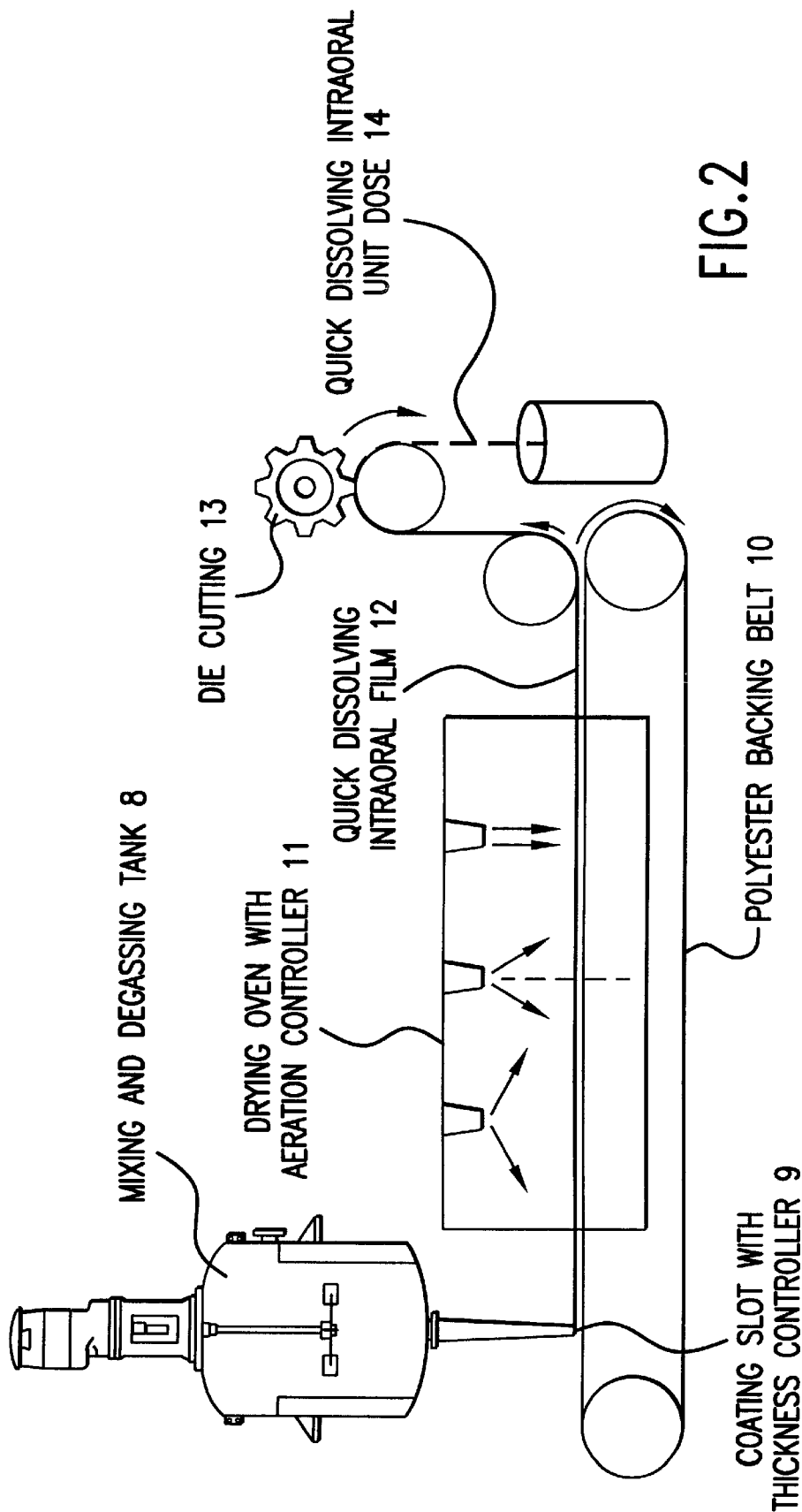


FIG.2

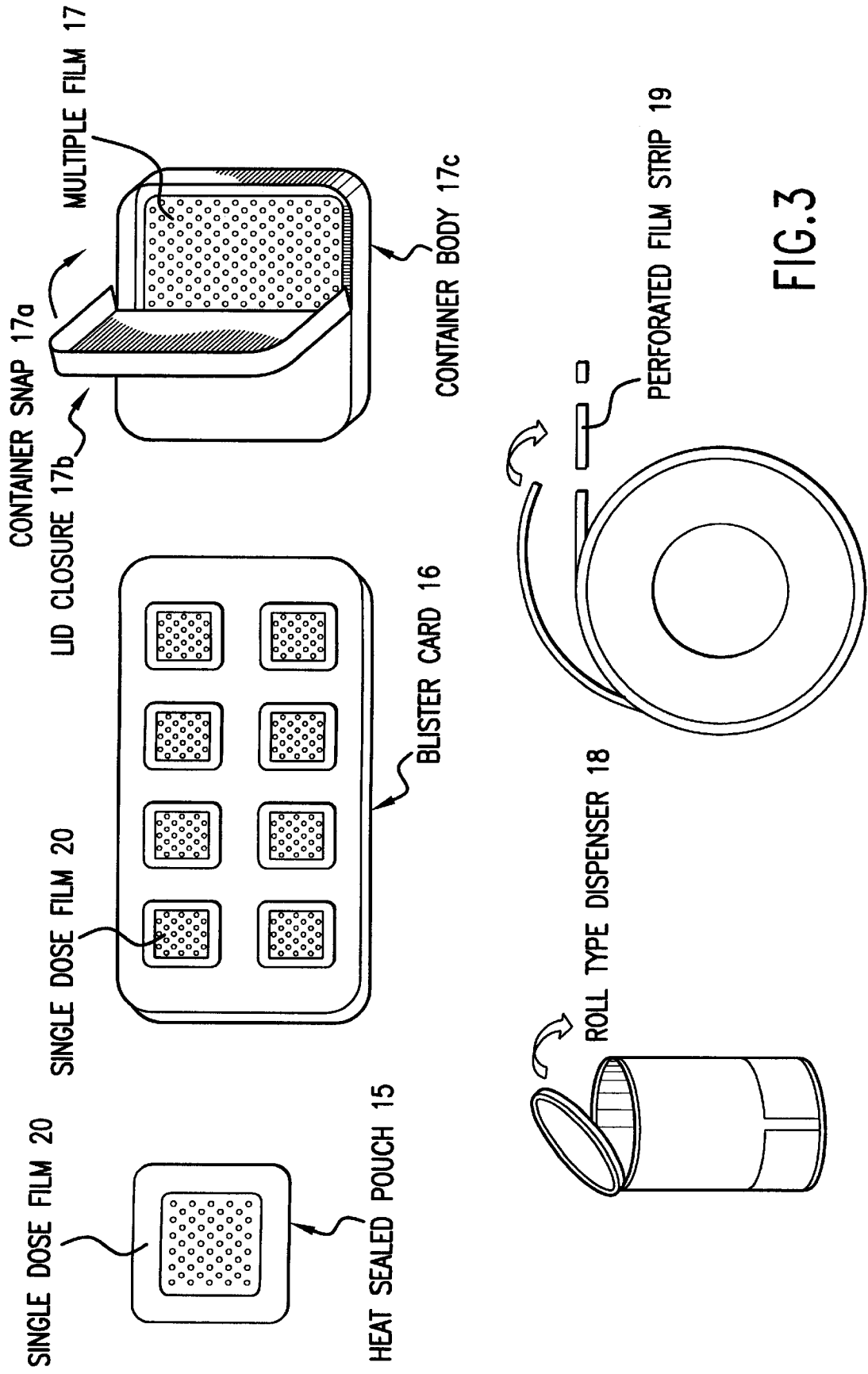


FIG. 3

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