



(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**

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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.

(21) Appl. No.: **09/434,878**

(22) Filed: **Nov. 5, 1999**

**Related U.S. Application Data**

(60) Provisional application No. 60/116,823, filed on Jan. 21, 1999.

(51) **Int. Cl.**<sup>7</sup> ..... **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

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(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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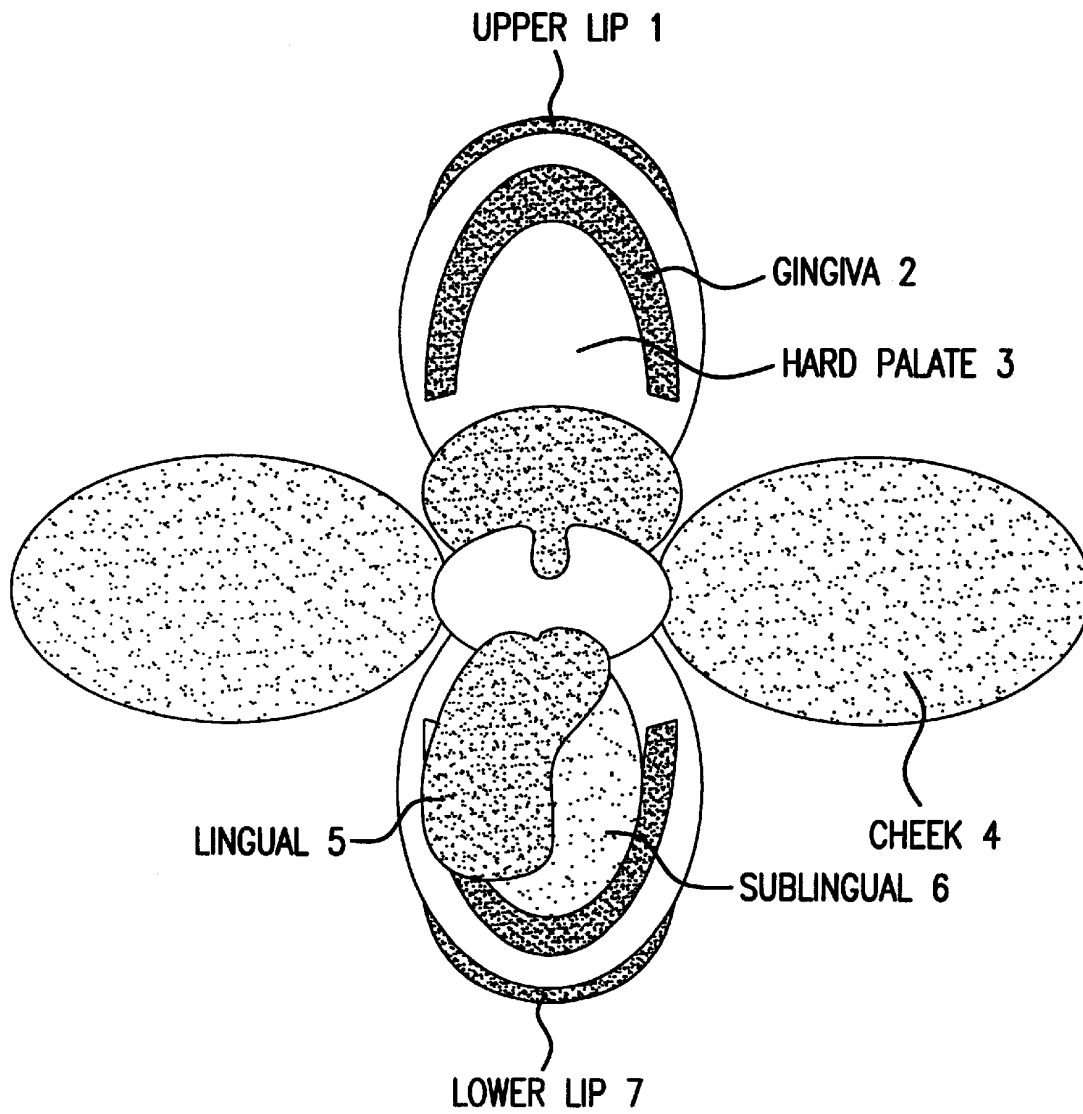


FIG.1

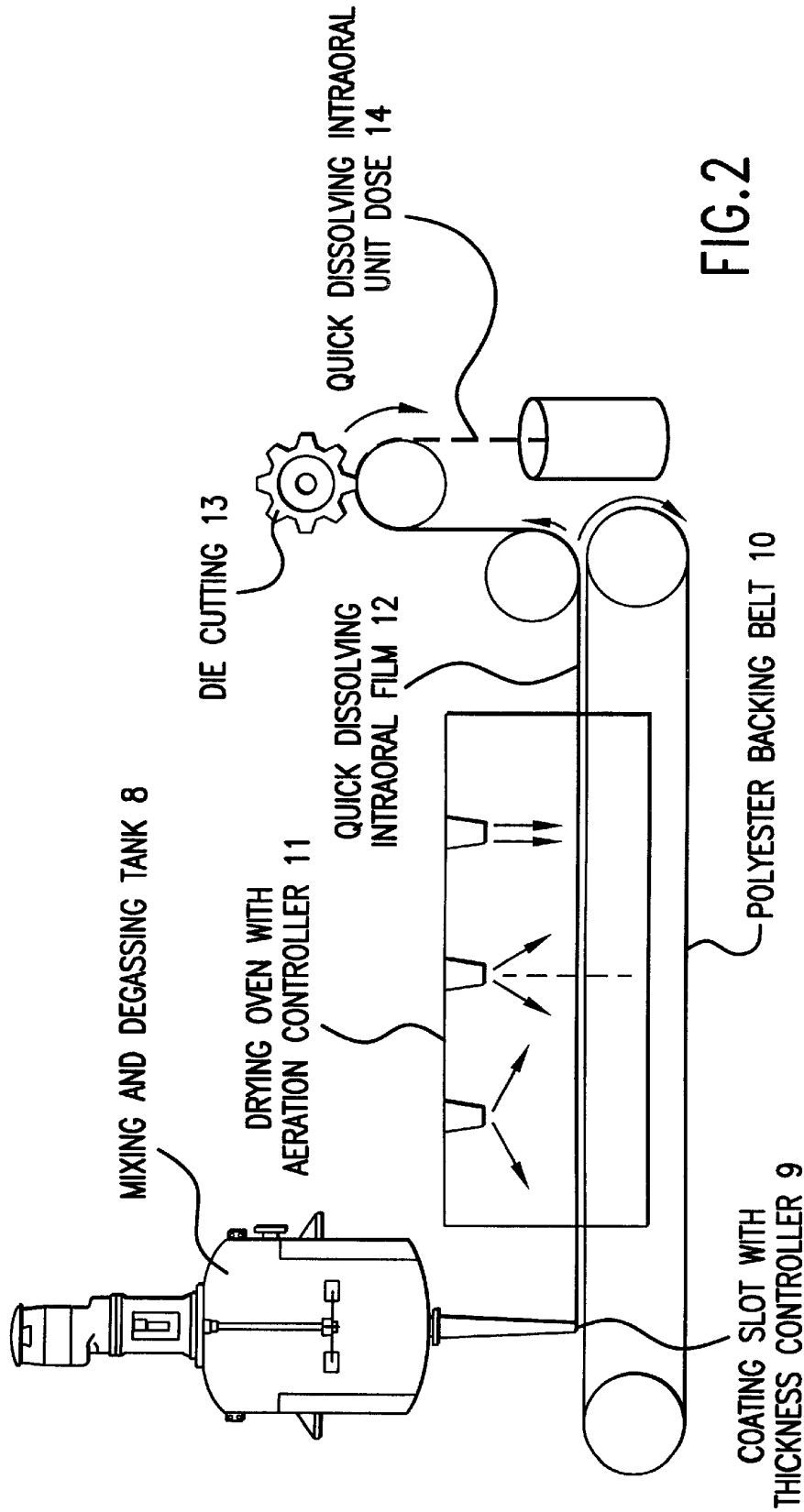


FIG. 2

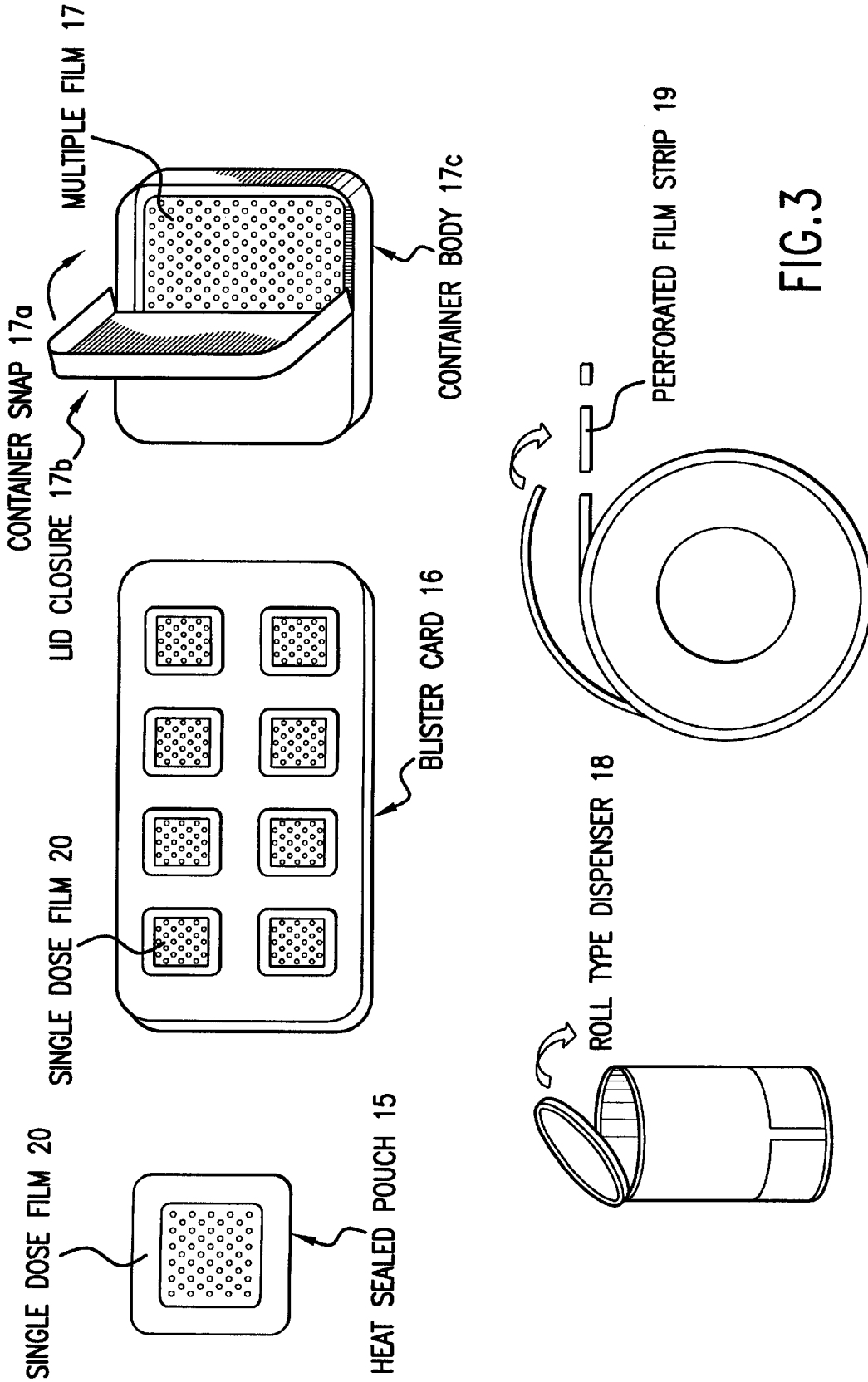


FIG.3

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