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(71) Applicant: **AMGEN INC.** [US/US]; One Amgen Center Drive, Thousand Oaks, CA 91320-1799 (US).

(72) Inventors: **KELLY, Ron, Christopher**; c/o Amgen Inc., One Amgen Center Drive, Mail Stop 28-5-A, Thousand Oaks, CA 91320-1799 (US). **CHAVES, Mary**; c/o Amgen Inc., One Amgen Center Drive, Mail Stop 28-5-A, Thousand Oaks, CA 91320-1799 (US). **CAPORINI, Marc, A.**;

c/o Amgen Inc., One Amgen Center Drive, Mail Stop 28-5-A, Thousand Oaks, CA 91320-1799 (US). **SCHLEGEL, Fabrice**; c/o Amgen Inc., One Amgen Center Drive, Mail Stop 28-5-A, Thousand Oaks, CA 91320-1799 (US).

(74) Agent: **BATEMAN, Andrew, W.**; Marshall, Gerstein & Borun LLP, 233 S. Wacker Drive, 6300 Willis Tower, Chicago, IL 60606-6357 (US).

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(54) Title: PREDICTING SHELF LIFE STABILITY OF LYOPHILIZED DRUG PRODUCTS

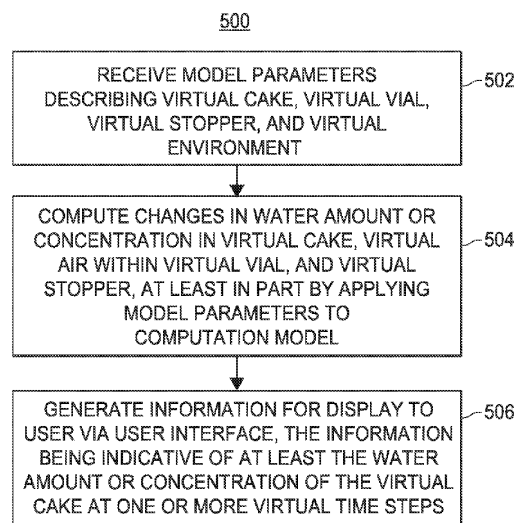


FIG. 5

(57) Abstract: A method of computational modeling to predict stability of a lyophilized drug product includes receiving model parameters describing a virtual cake, a virtual vial, a virtual stopper, and a virtual ambient environment. The method also includes computing, by implementing a computational model and at each of a plurality of virtual time steps, a change in water amount or concentration in the virtual cake, virtual air within the virtual vial, and the virtual stopper, in part by applying the model parameters to the computational model. The method also includes generating information for display to a user via a user interface.

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