(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 October 2003 (23.10.2003)

PCT

(10) International Publication Number
WO 03/086367 A1

(51) International Patent Classification[7]: A61K 9/36, 9/48

(21) International Application Number: PCT/US03/10371

(22) International Filing Date: 3 April 2003 (03.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/370,674 8 April 2002 (08.04.2002) US

(71) Applicant *(for all designated States except US)*: **BRISTOL-MYERS SQUIBB COMPANY** [US/US]; P. O. Box 4000, Route 206 and Provinceline Road, Princeton, NJ 08543-4000 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **DESAI, Divyakant** [US/US]; 19 Greenfield Dr., North, West Windsor, NJ 08550 (US). **LI, Danping** [US/US]; 10 Bearsley Dr., East Brunswick, NJ 08816 (US).

(74) Agents: **DAVIS, Stephen, B.** et al.; Bristol-Myers Squibb Company, P.O. Box 4000, Princeton, NJ 08543-4000 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/086367 A1

(54) Title: LOW DOSE LIQUID ENTECAVIR FORMULATIONS AND USE

(57) Abstract: Liquid pharmaceutical compositions are provided having a low dose of entecavir. In one embodiment of the present invention, the liquid entecavir composition is a ready-to-use composition that is formulated to be both stable and palatable. In a second embodiment of the present invention, the liquid entecavir composition is formulated from a powder composition at the time of use. The low dose entecavir compositions may also include at least one component selected from sweetener, preservative, flavoring agent, buffering agent, or combinations thereof. The liquid entecavir compositions may also be formulated in combination with other pharmaceutically active agents.