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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 October 2003 (30.10.2003)

PCT

(10) International Publication Number
WO 03/088974 A1

(51) International Patent Classification[7]: A61K 31/56

(21) International Application Number: PCT/US03/12235

(22) International Filing Date: 21 April 2003 (21.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/374,103 19 April 2002 (19.04.2002) US

(71) Applicant *(for all designated States except US)*: **BENTLEY PHARMACEUTICALS, INC.** [US/US]; Bentley Park, 2 Holland Way, Exeter, NH 03833 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **GYURIK, Robert** [US/US]; 12 Ashbrook Road, Exeter, NH 03833 (US).

(74) Agent: **YAO, Gene**; Synnestvedt & Lechner LLP, 2600 Aramark Tower, 1101 Market Street, Philadelphia, PA 19107-2950 (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).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *with international search report*
— *with amended claims*

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 03/088974 A1

(54) Title: PHARMACEUTICAL COMPOSITION

(57) Abstract: A pharmaceutical composition comprising: (A) androgen; (B) a cyclic enhancer of the type used in the compositions and methods claimed by U.S. Patent No. 5,023,252 to Hsieh; and (C) a thickening agent; including, for example, a composition in which the cyclic enhancer is a macrocyclic ester or a macrocyclic ketone; the use of the composition to treat a condition, for example, male hypogonadism, in a patient by applying the composition to the membrane of the patient; and a method for making the composition.