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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 September 2004 (23.09.2004)

PCT

(10) International Publication Number
WO 2004/080383 A3

(51) International Patent Classification[7]: A61K 31/56, 31/565, 31/568, 47/14

(21) International Application Number: PCT/IB2004/000716

(22) International Filing Date: 15 March 2004 (15.03.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PA200300399 14 March 2003 (14.03.2003) DK

(71) Applicant *(for all designated States except US)*: **SCHERING AKTIENGESELLSCHAFT** [DE/DE]; Müllerstrasse 178, 13342 Berlin (DE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HÜBLER, Doris** [DE/DE]; Ortsstrasse 12, 07407 Schmieden (DE). **FRICKE, Sabine** [DE/DE]; An der Riese 1b, 07749 Jena (DE). **INGWERSEN, Jan-Peter** [DE/DE]; Im Amseltal 10, 13465 Berlin (DE). **KUHNZ, Wilhelm** [DE/DE]; Tegeler Weg 13, 13589 Berlin (DE).

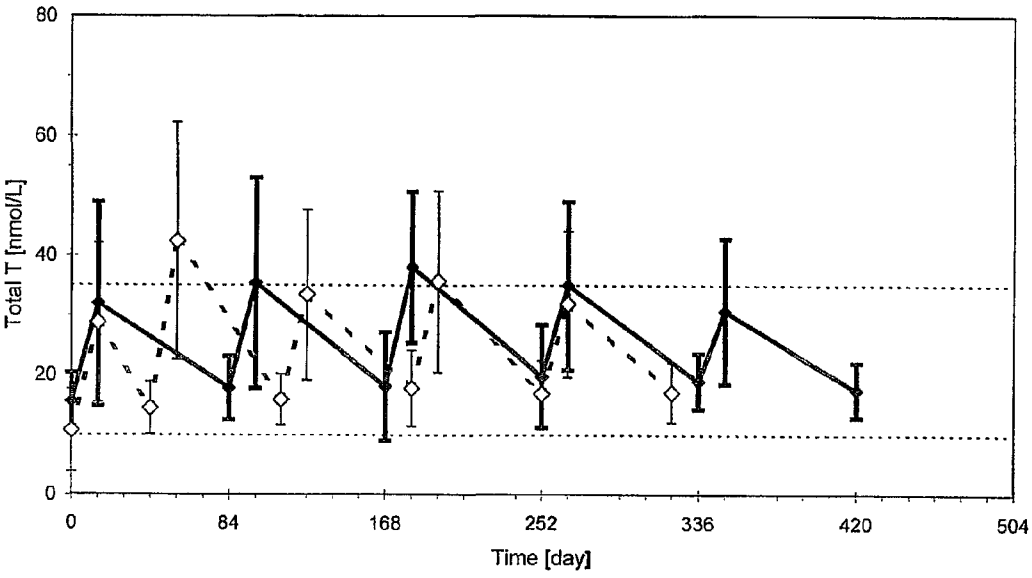
(74) Agent: **SCHOUBOE, Anne**; Plougmann & Vingtoft a/s, Sunkrogsgade 9, P.O. Box 831, DK-2100 Copenhagen Ø (DK).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, 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, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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

[Continued on next page]

(54) Title: METHODS AND PHARMACEUTICAL COMPOSITIONS FOR RELIABLE ACHIEVEMENT OF ACCEPTABLE SERUM TESTOSTERONE LEVELS



(57) Abstract: The present invention relates to pharmaceutical compositions, formulated for injectable administration, which comprises a testosterone ester, in particularly testosterone undecanoate, in a vehicle comprising castor oil and a co-solvent. Upon injecting the compositions according to a particular administration scheme, reliable levels of testosterone in serum in the normal physiological range is achieved for a long period. This allows for the use of the compositions in hormone replacement therapy and male contraception without concomitant monitoring of testosterone levels in serum by a physician.

WO 2004/080383 A3

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

(88) Date of publication of the international search report:
31 March 2005

Date of publication of the amended claims: 6 May 2005

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.