(2004059515)
14/09/04

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 October 2004 (28.10.2004)

PCT

(10) International Publication Number
WO 2004/091631 A1

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

(21) International Application Number:
PCT/US2003/007910

(22) International Filing Date: 14 March 2003 (14.03.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/098,232	15 March 2002 (15.03.2002)	US
10/153,468	21 May 2002 (21.05.2002)	US

(71) Applicants: **UNIMED PHARMACEUTICALS, INC.** [US/US]; 901 Sawyer Road, Marietta, GA 30062 (US). **LABORATORIES BESINS INTERNATIONAL, S.A.** [FR/FR]; 5, rue du Bourg l'Abbe, F-75003 Paris (FR).

(72) Inventors: **DUDLEY, Robert, E.**; 636 Wayland Avenue, Kenilworth, IL 60042 (US). **KOTTAYIL, George, S.**; 8068 RFD, Long Grove, IL 60047 (US). **PALATCHI, Olivier**; 8 Villa Pierre Loti, 94240 L'Hay Les Rosses (FR).

(74) Agent: **MAHONEY, Joseph, A.**; Mayor Brown Rowe & Maw, P.O. Box 2828, Chicago, IL 60690-2828 (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, 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*

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.

162162

ACTION

WO 2004/091631 A1

(54) Title: ANDROGEN PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING DEPRESSION

(57) Abstract: The present invention relates to methods, kits, combinations, and compositions for treating, preventing or reducing the risk of developing a depressive disorder, or the symptoms associated with, or related to a depressive disorder in a subject in need thereof. The present invention also related to a method of administering a steroid in the testosterone synthetic pathway, for example testosterone, to a subject in need thereof. In addition, the methods, kits, combinations and compositions may be used in conjunction with other pharmaceutical agents including agents effective at treating, preventing, or reducing the risk of developing a depressive disorder in a subject.