US008338395B2

(12) **United States Patent**
Hubler et al.

(10) **Patent No.: US 8,338,395 B2**
(45) **Date of Patent: Dec. 25, 2012**

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

(75) Inventors: **Doris Hubler**, Jena (DE); **Sabine Fricke**, Jena (DE); **Jan-Peter Ingwersen**, Berlin (DE); **Wilheim Kuhnz**, Berlin (DE)

(73) Assignee: **Bayer Intellectual Property GmbH**, Monheim (DE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 717 days.

(21) Appl. No.: **12/391,655**

(22) Filed: **Feb. 24, 2009**

(65) **Prior Publication Data**

US 2009/0156564 A1 Jun. 18, 2009

Related U.S. Application Data

(62) Division of application No. 10/798,780, filed on Mar. 12, 2004, now Pat. No. 7,718,640.

(60) Provisional application No. 60/454,312, filed on Mar. 14, 2003.

(51) **Int. Cl.**
A61K 31/56 (2006.01)

(52) **U.S. Cl.** **514/170**; 514/182

(58) **Field of Classification Search** 514/170, 514/182

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,164,520	A *	1/1965	Huber	514/174
4,181,721	A	1/1980	Speck et al.	
4,212,863	A	7/1980	Cornelius	
5,364,632	A	11/1994	Benita et al.	
6,274,582	B1	8/2001	Marin	

FOREIGN PATENT DOCUMENTS

DE	25 48 413	4/1977
EP	0 001 851 A1	5/1976
EP	1 313 511	11/2005
GB	1 567 515 A1	5/1980
GB	1 569 286	6/1980
WF	WO 97/40823	11/1997
WO	WO 95/12383	5/1995
WO	WO 95/18603	7/1995
WO	WO 98/36770	8/1998
WO	WO 99/67270	12/1999
WO	WO 99/67271	12/1999
WO	WO 00/59512	10/2000

OTHER PUBLICATIONS

Database WPI, Section Ch, Week 199524, Derwent Publications Ltd. London, GB, AN 1995-185577 XP002264337, 1995.

Wang Lie-zhen, Wang et al., The Therapeutic Effect of Domestically Produced Testosterone Undecanoate in Klinefelt Syndrome (Abstract), 1991.

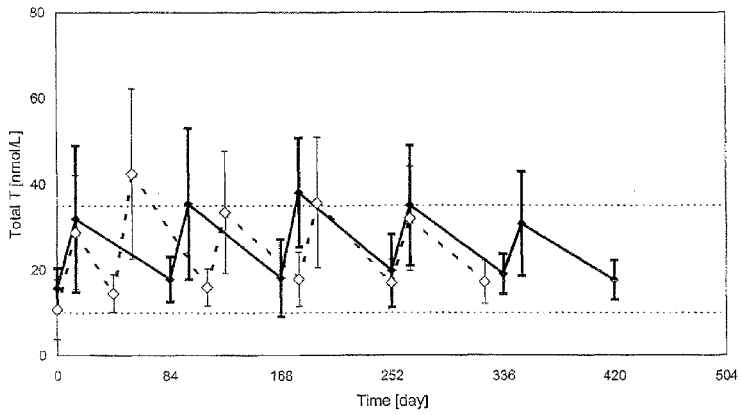
Zhao-dian, Chen et al., "Clinical Study of Testosterone Undecanoat Compound on Male Contraception", First Affiliated Hospital of Zhejiang Medical University, (Abstract), 1993.

(Continued)

Primary Examiner — San-Ming Hui

(74) *Attorney, Agent, or Firm* — Millen, White, Zelano & Branigan, P.C.

(57) **ABSTRACT**

Described are methods for providing prolonged physiologically acceptable steady state serum testosterone levels in a patient deficient in endogenous testosterone levels, methods for male contraception and methods for treating a disease or symptom associated with deficient endogenous levels of testosterone in a man, by intramuscularly administering testosterone esters in a vehicle.

27 Claims, 1 Drawing Sheet