

US010258631B2

(12) United States Patent Josephs et al.

(54) FORMULATIONS OF TESTOSTERONE AND METHODS OF TREATMENT THEREWITH

(71) Applicants: BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM, Austin, TX (US); MEDCARA PHARMACEUTICALS, LLC, Conrad, IA (US)

(72) Inventors: **Robert A. Josephs**, Austin, TX (US); **Craig Herman**, Cedar Rapids, IA (US)

(73) Assignees: BOARD OF REGENTS, THE
UNIVERSITY OF TEXAS SYSTEM,
Austin, TX (US); MEDCARA
PHARMACEUTICALS, LLC,
Conrad, IA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

(21) Appl. No.: 15/507,246

(22) PCT Filed: Aug. 28, 2015

(86) PCT No.: **PCT/US2015/047385**

§ 371 (c)(1),

(2) Date: Feb. 27, 2017

(87) PCT Pub. No.: WO2016/033430PCT Pub. Date: Mar. 3, 2016

(65) Prior Publication Data

US 2017/0281644 A1 Oct. 5, 2017

Related U.S. Application Data

(60) Provisional application No. 62/043,277, filed on Aug. 28, 2014. (10) Patent No.: US 10,258,631 B2

(45) **Date of Patent:**

Apr. 16, 2019

(51) **Int. Cl.** *A61K 31/5685* (2006.01)

A61K 45/06

(2006.01) (Continued)

(52) **U.S. Cl.** CPC *A61K 31/5685* (2013.01); *A61K 9/0043* (2013.01); *A61K 9/107* (2013.01);

(Continued)

(58) Field of Classification Search

None

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

5,756,071 A 5/1998 Mattern et al. 6,280,770 B1 * 8/2001 Pather A61K 9/0007 424/464

(Continued)

FOREIGN PATENT DOCUMENTS

WO WO 2006/113505 10/2006 WO 2011/129812 * 10/2011

OTHER PUBLICATIONS

Meng et al., International Journal of Nanomedicine 8 (2013): 3051 (Year: 2013).*

(Continued)

Primary Examiner — Karl J Puttlitz (74) Attorney, Agent, or Firm — Parker Highlander, PLLC

(57) ABSTRACT

The present disclosure relates to novel pharmaceutical composition for the administration of testosterone or testosterone derivatives. The present disclosure also provides methods of treatment of diseases and disorders associated with fear and anxiety, a decrease in libido, or hypogonadism.

15 Claims, 7 Drawing Sheets

