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

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 December 2013 (19.12.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/188847 A8

(51) International Patent Classification:
A61K 31/135 (2006.01) *A61K 9/00* (2006.01)

(21) International Application Number:
PCT/US2013/046023

(22) International Filing Date:
14 June 2013 (14.06.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/660,593	15 June 2012 (15.06.2012)	US
61/667,774	3 July 2012 (03.07.2012)	US
61/725,402	12 November 2012 (12.11.2012)	US
61/792,900	15 March 2013 (15.03.2013)	US

(71) Applicant *(for all designated States except US)*: **TONIX PHARMACEUTICALS, INC.** [US/US]; 509 Madison Avenue, Suite 306, New York, New York 10022 (US).

(72) Inventors; and

(71) Applicants *(for US only)*: **LEDERMAN, Seth** [US/US]; 245 E. 93rd Street, Apt. 14E, New York, New York 10128 (US). **REINER, Giorgio** [IT/IT]; Via Rusconi 24, I-22 100 Como (IT). **BRITTAIN, Harry** [US/US]; 10 Charles Road, Milford, New Jersey 08848 (US).

(74) Agents: **HALEY, James F., Jr.** et al.; Ropes & Gray LLP, 1211 Avenue of the Americas, New York, New York 10036-8704 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

[Continued on next page]

(54) Title: COMPOSITIONS AND METHODS FOR TRANSMUCOSAL ABSORPTION

(57) Abstract: The invention provides compositions and methods for administering therapeutic compounds, specifically cyclobenzaprine or amitryptyline, for transmucosal absorption, wherein the compositions contain a basifying agent in addition to the therapeutic agent. The compositions and methods have a number of surprising pharmacokinetic benefits over oral administration. Methods of treating fibromyalgia in a human subject are also provided.

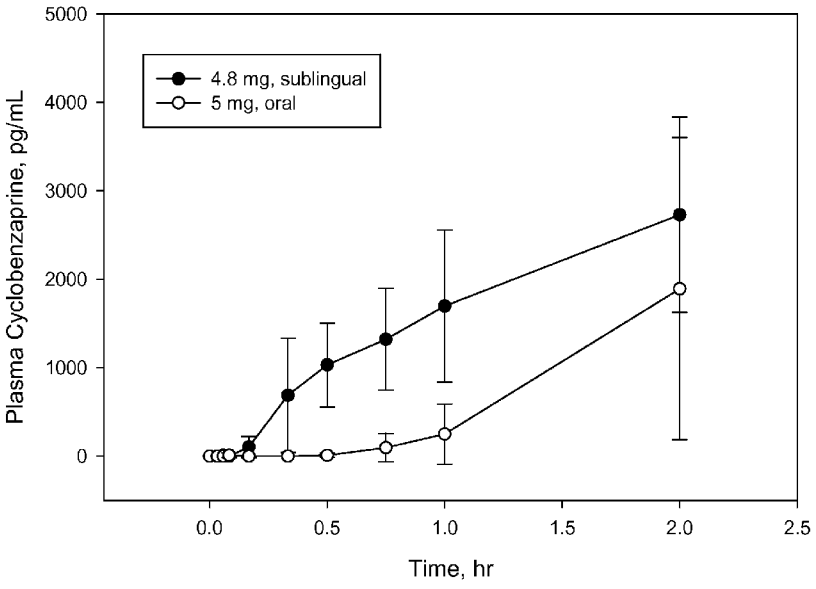


Figure 14b

WO 2013/188847 A8

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(48) **Date of publication of this corrected version**:
5 February 2015

(15) **Information about Correction**:
see Notice of 5 February 2015