

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
23 March 2023 (23.03.2023)



(10) International Publication Number
WO 2023/044319 A1

(51) International Patent Classification:
A61K 31/343 (2006.01) *A61P 25/00* (2006.01)

Published:

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

(21) International Application Number:
PCT/US2022/076393

(22) International Filing Date:
14 September 2022 (14.09.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/243,918 14 September 2021 (14.09.2021) US
63/268,430 23 February 2022 (23.02.2022) US
63/269,137 10 March 2022 (10.03.2022) US

(71) Applicant: **VANDA PHARMACEUTICALS INC.**
[US/US]; 2200 Pennsylvania Ave. NW, Suite 300E, Wash-
ington, District of Columbia 20037 (US).

(72) Inventors: **POLYMEROPOULOS, Mihael**; 2200 Penn-
sylvania Ave. NW, Suite 300E, Washington, District of
Columbia 20037 (US). **POLYMEROPOULOS, Christos**;
2200 Pennsylvania Ave. NW, Suite 300E, Washington, Dis-
trict of Columbia 20037 (US). **SMIESZEK, Sandra**; 2200
Pennsylvania Ave NW, Suite 300E, Washington, District of
Columbia 20037 (US).

(74) Agent: **SWINTON, Stephen**; 540 Broadway, 4th Floor,
Albany, New York 12207 (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, CV, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE,
KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, 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, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,
ZA, ZM, ZW.

(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, ST, 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).

(54) Title: TREATMENT OF SLEEP DISTURBANCES IN AUTISM SPECTRUM DISORDER PATIENTS

(57) Abstract: The invention relates generally to the treatment of autism spectrum disorder (ASD) and sleep disturbances and, more particularly, to the treatment of sleep disorders and/or the improvement of daytime functioning in ASD patients using tasimelteon.

