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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 November 2009 (19.11.2009)

PCT

(10) International Publication Number
WO 2009/139924 A3

(51) International Patent Classification:
A61K 9/06 (2006.01) *A61K 9/16* (2006.01)
A61P 27/16 (2006.01) *A61K 31/573* (2006.01)
A61K 9/14 (2006.01) *A61K 47/34* (2006.01)

(21) International Application Number:
PCT/US2009/003066

(22) International Filing Date:
14 May 2009 (14.05.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/127,713	14 May 2008 (14.05.2008)	US
61/060,425	10 June 2008 (10.06.2008)	US
61/074,583	20 June 2008 (20.06.2008)	US
61/082,450	21 July 2008 (21.07.2008)	US
61/087,940	11 August 2008 (11.08.2008)	US
61/094,384	4 September 2008 (04.09.2008)	US
61/095,248	8 September 2008 (08.09.2008)	US
61/101,112	29 September 2008 (29.09.2008)	US
61/140,033	22 December 2008 (22.12.2008)	US
0823378.5	22 December 2008 (22.12.2008)	GB

(71) Applicants *(for all designated States except US)*: **OTONOMY, INC.** [US/US]; 5626 Oberlin Drive, Suite 100, San Diego, California 92121 (US). **THE REGENTS OF THE UNIVERSITY OF CALIFORNIA** [US/US]; 1111 Franklin Street, 12th floor, Oakland, California 94607 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LICHTER, Jay** [US/US]; P.O. Box 676244, Rancho Santa Fe, California 92067 (US). **VOLLRATH, Benedikt** [DE/US]; 4704 Niagara Avenue, San Diego, California 92107 (US). **TRAMMEL, Andrew M.** [US/US]; 12485 South Alden Circle, Olathe, Kansas 66062 (US). **DURÓN, Sergio G.** [US/US]; 1605 Neale Street, San Diego, California 92103 (US). **PIU, Fabrice** [FR/US]; 11859 Stonedale Ct., San Diego, California 92131 (US). **DELLAMARY, Luis A.** [US/US]; 829 Quiet Hills Dr, San Marcos, California 92069 (US). **YE, Qiang** [US/US]; 7395 Mannix Court, San Diego, California 92129 (US). **LEBEL, Carl** [US/US]; 23256 Mariposa de Oro St., Malibu, California 90265 (US). **SCAIFE, Michael Christopher** [US/US]; 60 Marvin Avenue, Los Altos, California 94022 (US). **HARRIS, Jeffrey P.** [US/US]; 7717 Sierra Mar Drive, La Jolla, California 92037 (US).

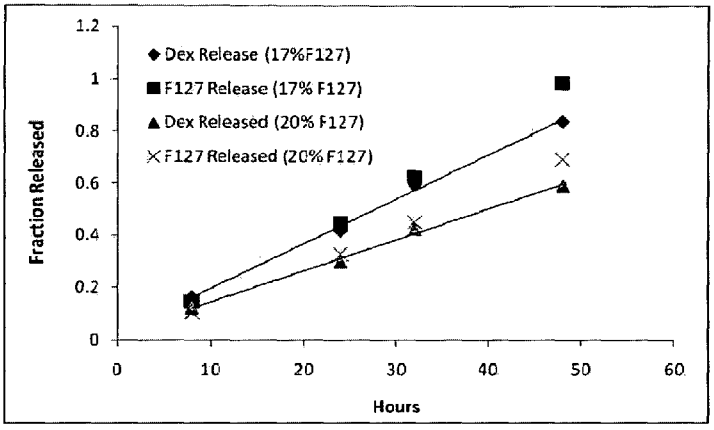
(74) Agents: **WILSON SONSINI GOODRICH & ROSATI** et al.; 650 Page Mill Road, Palo Alto, California 94304 (US).

(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, BR, BW, BY, BZ, CA, CH, 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, KM, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG,

[Continued on next page]

(54) Title: CONTROLLED RELEASE CORTICOSTEROID COMPOSITIONS AND METHODS FOR THE TREATMENT OF OTIC DISORDERS

FIGURE 1



(57) Abstract: Disclosed herein are compositions and methods for the treatment of otic disorders with steroid, NSAID, and/or adenosine triphosphatase ("ATPase") modulator agents. In these methods, the steroidal, NSAID, and/or ATPase compositions and formulations are administered locally to an individual afflicted with an otic disorder, through direct application of these compositions and formulations onto or via perfusion into the targeted auris structure(s).

WO 2009/139924 A3

SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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

(88) **Date of publication of the international search report**:
1 April 2010