

Exhibit 16
IND 132,498
Regulatory Log

Date	Type	To/From or Serial No.	Description
13-16 Dec 2021	Email	TTaylor / PHirano PHirano / TTaylor	Notification of submission of response to IR. Offer to provide response by email. Confirmation that response was received. Expect preliminary meeting comments by 16 Dec.
14 Dec 2021	Submission	0075	DSUR (reporting period 10 Oct 2020-9 Oct 2021) Investigator's Brochure, Version 7, dated 13 December 2021 Information Amendment: CMC – updated CMC information
16 Dec 2021	Correspondence	From FDA	Preliminary meeting comments for 21 Dec 2021 meeting.
16-21 Dec 2021	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor PHirano / TTaylor	Courtesy copy of preliminary meeting comments. Request to focus discussion on questions 2, 3, and 5. Clarification if Dr Dunn would be attending the meeting. Request for slides prior to meeting. Notification that Dr. Dunn or Buracchio will attend the meeting. Slides and final list of Soleno attendees. Confirmation of receipt List of FDA attendees.
05 Jan 2022	Email	TTaylor / PHirano	Copy of Sponsor's minutes
20 Jan 2022	Correspondence	From FDA	Meeting minutes
20 Jan 2022	Email	PHirano / TTaylor TTaylor / PHirano	Courtesy copy of meeting minutes. Acknowledgment of receipt
28 Feb- 01 Mar 2022	Email	TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	Email re: upcoming meeting request and urgency of timing. Notification that meeting would be scheduled based on request. Request for clarity on meeting type Confirmation that Type C meeting is appropriate
03 Mar 2022	Submission	0076	Meeting Request – Type C Meeting

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09 – 10 Mar 2022	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano	Request to confirm availability for meeting on 27 th April Confirmation that meeting date/time is acceptable. Notification that review team members not available on 27 th April Acknowledgment of meeting date change Request to confirm availability for meeting on 11 th May Confirmation that meeting date/time acceptable
10 Mar 2022	Correspondence	From FDA	Meeting granted
14 Mar 2022	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	Request for tentative list of Soleno attendees at 11 th May meeting Tentative list provided. Acknowledgement of receipt.
21 Mar 2022	Submission	0077	Meeting Briefing Information; Meeting Correspondence Protocol Amendment: Change in Protocol Information Amendment: Clinical Pharmacology
21 Apr 2022	Email	PHirano / TTaylor TTaylor / PHirano	Request for tracked changes version of protocol. Acknowledgement of request
25 Apr 2022	Email	TTaylor / PHirano PHirano / TTaylor	Tracked changes version of protocol Confirmation of receipt.
10 May 2022	Email	TTaylor / PHirano	Copy of meeting slides
13 May 2022	Email	TTaylor / PHirano	Meeting follow-up.
19 May 2022	Email	TTaylor / PHirano	Meeting follow-up.
20-24 May 2022	Email	TTaylor / PHirano PHirano / TTaylor	Sponsor meeting summary and informed consent form with language discussed at meeting. Confirmation of receipt

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Date	Type	To/From or Serial No.	Description
20 May 2022	Email		Email to TTaylor Meeting follow-up – copy of Soleno meeting minutes; copy of informed consent for review
23 May 2022	Submission	0078	Correspondence regarding meeting – Soleno meeting minutes Protocol amendment – ICF for PA5 for review
27 – 31 May 2022	Email	PHirano / TTaylor TTaylor / PHirano	Request formal submission of C602 amendment to IND as protocol change Confirmation that this was submitted as a formal protocol change.
1 June 2022	Email		Courtesy copy of GST justification
2 June 2022	Submission	0079	Information Amendment – Clinical / Statistical -- Submission of GST justification
9 Jun 2022	Correspondence	From FDA	Meeting minutes
9-10 Jun 2022	Emails	PHirano / TTaylor TTaylor / PHirano	Email to TTaylor re: meeting minute omission. Email from TTaylor confirming receipt of email
23 Jun 2022	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor PHirano / TTaylor TTaylor / PHirano	Information request re: C602 PA5 and ICF Acknowledgement of receipt. Request for clarification of submission of redlines. Clarification of submission. Clarification of submission with an additional question.
27 Jun 2022	Submission	0080	FDA request for information: C602 amendment 5 – redline C602 patient information / informed consent form -- redline
27 Jun 2022	Submission	0081	Request for Deferral and Waivers for Carcinogenicity Studies

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15-22 Jul 2022	Email	TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano	Inquiry if comments on PIS/ICF expected. Notification that PIS/ICF still under review Re-iteration of urgency of reviews. Confirmation of understanding time constraints; continue to work diligently on PIS/ICF Request for clarification on RWP comment timing. Confirmation that both expected together. Confirming receipt.
05-10 Aug 2022	Email	TTaylor / PHirano PHirano / TTaylor	Request for info re: potential polygenic risk score meeting and status clarification for RWP/PIS/ICF Advice letter by 18 th Aug; premature to discuss polygenic risk score
18 Aug 2022	Correspondence	From FDA	Advice Letter re: C602 RWP; GST
19-23 Aug 2022	Email	TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano	Response to 18 Aug 2022 advice letter Acknowledgment of email Offer for a call
30 Aug 2022	Submission	0082	C602 protocol amendment 6 C602 patient information / sample informed consent form Clean and track changes copies
28 Oct 2022	Correspondence	From FDA	Advice letter re: C602 protocol amendment 6.
31 Oct 2022	Email	PHirano / TTaylor	Statistical comments re: C602 protocol amendment 6
14 Nov 2022	Submission	0083	C602 protocol amendment 7 with tracked changes Response to advice letter dated 28 October 2022 and statistical comments dated 31 October 2022 Guide for the Completion of the Clinical Global Impression Scales

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Date	Type	To/From or Serial No.	Description
9 Dec 2022	Submission	0084	Protocol amendment: New protocol Protocol C614
15 Dec 2022	Submission	0085	DSUR + IB version 8.0; CMC information update; new investigator info
16 Dec 2022	Submission	0086	Type C meeting request: CMC
23 Dec 2022	Submission	0087	New investigator information; revised investigator information; statistical analysis plan for C602; response to statistical comments
7 Feb 2023	Submission	0088	RPT-MG-010 C614, Protocol Amendment 1 New Investigator Information; Revised Investigator Information
09 Feb 2023	Email	TTaylor and TBouie / PHirano PHirano and TTaylor / TBouie	Follow-up on Type C meeting to discuss CMC related questions and one question for joint CMC and Clin Pharm questions. Meeting will be granted be need to be scheduled.
16-17 Feb 2023	Emails	PHirano / TBouie TBouie / PHirano PHirano / TBouie TBouie / PHirano PHirano / TBouie	Availability for meeting on 27 Mar 2023; timing of briefing document Confirmation of availability / timing of briefing document, Confirmation of proposed dates acceptable Request for clarification if meeting granted letter to be provided. Confirmation that meeting granted letter to be provided
17 Feb 2023	Email	TBouie / PHirano	Courtesy copy of CMC meeting briefing document to RPM
21 Feb 2023	Correspondence	From FDA	Meeting granted letter
21 Feb 2023	Submission	0089	CMC meeting briefing document
22 Mar 2023	Correspondence	From FDA	Preliminary meeting comments

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Date	Type	To/From or Serial No.	Description
22-23 Mar 2023	Email	TBouie / PHirano PHirano / TBouie	Confirmation to continue meeting; identification of questions for discussion. Confirmation of receipt
23-27 Mar 2023	Email	TBouie / PHirano PHirano / TBouie TBouie / PHirano PHirano / TBouie PHirano / TBouie TBouie / PHirano	Meeting slides and list of attendees Acknowledgment of receipt. Corrected slide deck Acknowledgement of receipt Notification that DS reviewer has a conflict at the beginning of the meeting; request to begin with DP Notification that one attendee will not be able to attend due to jury duty
24 May 2023	Submission	0090	TQT waiver
24 May 2023	Email	PHirano / TTaylor TTaylor / PHirano	Request for information regarding C614; recommendation for episodic on-site visits
31 May 2023	Submission	0091	Response to FDA Request for Information regarding C614
31 May 2023	Submission	0092	C602 RWP: New and Revised Investigator Information C602 OLE: Revised Investigator Information C614: Form FDA 3674 Information Amendment: Clinical – C614 Label Text and C614 Protocol Clarification Letter
16 Jun 2023	Email	PHirano / TTaylor TTaylor / PHirano	No additional studies needed to evaluate QT/QTc interval for diazoxide choline. Confirmation of receipt. Request for clarification if this is the only notification or if a separate letter will be provided. Confirmation that email is only communication. Acknowledgment of confirmation.
22 Jun 2023	Submission	0093	C614 New Investigator Information
14 July 2023	Submission	0094	SAP version 1; response to emailed statistical questions

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Date	Type	To/From or Serial No.	Description
8 Aug 2023	Submission	0095	Type C Meeting Request -Clinical Pharm / Biopharm
9 Aug 2023	Submission	0096	Errata Sheet for C602 RW Period SAP version 1.0 submitted in SN0094
14 Aug 2023	Submission	0097	Request for SPA: Carc Study, includes draft protocol PRT-PT-003
15 Aug 2023	Correspondence	From FDA	Meeting Granted / WRO – clin pharm / biopharm
15 Aug 2023	Email	PHirano / TTaylor	Request to complete clin pharm summary table and submit to IND as a separate pdf.
16 Aug 2023	Email	PHirano / TTaylor	Request to resubmit carc study waiver request including weight of evidence assessment.
28 Aug 2023	Submission	0098	Information Amendment: Clin Pharm / Biopharm (CMC) C614 New Investigator Information
5 Sep 2023	Submission	0099	Type C Meeting Background Materials (WRO) Information Amendment: Clin Pharm - updated Clinical Pharmacology Summary Table
15 Sep 2023	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	C602 RWP SAP comments Acknowledgement of receipt. Notification to clarify half-life of diazoxide in patients with PWS. Confirmation of receipt
2 Oct 2023	Submission	0100	Request for Type B Pre-NDA Meetings: Clinical, Nonclinical and CMC
6-13 Oct 2023	Email	TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	Working on scheduling meeting; confirm availability for 30 th Nov 2023 meeting Confirming availability Scheduling conflict means rescheduling meeting to 17 th Jan Confirming availability Clarification of meeting time

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Date	Type	To/From or Serial No.	Description
13 Oct 2023	Email	PHirano / TBouie	Type B CMC meeting to be granted
13 Oct 2023	Correspondence	From FDA	Meeting Granted letter
20 Oct 2023	Correspondence	From FDA	Clin Pharm Type C WRO responses
31 Oct 2023	Submission	0101	Type B Pre-NDA (CMC) Meeting Background Materials
14 Nov 2023	Submission	0102	C602 RWP Revised Investigator Information C614 New Investigator Information
20 Nov 2023	Correspondence	From FDA	Preliminary comments – pre-NDA CMC meeting
20-24 Nov 2023	Email	PHirano / TBouie TBouie / PHirano PHirano / TBouie	Courtesy copy of preliminary comments Confirmation that meeting will proceed; focus on DP question 2 Acknowledgment
28-29 Nov 2023	Email	TBouie / PHirano PHirano / TBouie	Meeting slides and list of attendees Confirmation of receipt
28 Nov 2023	Submission	0103	Request for Clarification to a Type C WRO for Clin Pharm
30 Nov 2023	Submission	0104	Request for a Full Waiver of Carc Studies
04 Dec 2023	Email	TTaylor / PHirano	Request to confirm that briefing document can be submitted on 18 th Dec since 17 th Dec is a Sunday.
05 Dec 2023	Submission	0105	New Protocol: C617; Form FDA 1572 and CV
06 Dec 2023	Submission	0106	Information Amendment: Clinical – C614 Case Report
08-19 Dec 2023	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor PHirano / TTaylor TTaylor / PHirano	Responses to clarifications requested in 28 Nov 2023 submission Request for clarification of responses Confirmation of receipt of request additional clarifications Responses to request for additional clarifications Confirmation of receipt; notification that protocol was submitted.

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11 Dec 2023	Submission	0107	DSUR (for reporting period 10 Oct 2022 – 9 October 2023)
12 Dec 2023	Submission	0108	Investigator's Brochure, Version 9.0 (dated 11 Dec 2023)
14 Dec 2023	Submission	0109	Information Amendment: CMC – update CMC information
15 Dec 2023	Submission	0110	Updated clin pharm summary table
18 Dec 2023	Submission	0111	Pre-NDA Meeting Briefing Document for 17 Jan 2024 meeting
28 Dec 2023	Email	PHirano / TTaylor TTaylor / PHirano	Information request in follow-up to safety event. Confirmation of receipt of IR
28 Dec 2023	Submission	0112	New Protocol: C618
04 Jan 2024	Submission	0113	Information Amendment: Response to FDA Request for Information regarding C614 SAE
04-08 Jan 2024	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	Comments regarding Protocol C617 Acknowledgement of receipt. Confirming question 1; applicability of comments for protocol C618 Confirmation of receipt
12 Jan 2024	Submission	0114	Protocol Amendment: C617 Amendment 2 C618 New Investigator Information C614 Revised Investigator Information
13 Jan 2024	Email	TTaylor / PHirano	Clinical and COA comments re: C602 PA7
13 Jan 2024	Correspondence	From FDA	Preliminary Comments

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16 Jan 2024	Email	TTaylor / PHirano PHirano / TTaylor PHirano / TTaylor TTaylor / PHirano	Responses are complete; since milestone meeting, if Agency believes Sponsor would benefit from the meeting, then proceed; if not, then meeting cancelled and preliminary comments become final. Acknowledgement of receipt; waiting to hear from Division Management Confirmation from Division management that meeting can be cancelled. Confirmation that meeting date was scheduled from 17 Jan 2024, not 2023. Confirmation
17 Jan 2024	Correspondence	From FDA	Meeting Cancelled Letter
2 Feb 2024	Submission	0115	C618 Protocol Amendment 1
15-16 Feb 2024	Email	TTaylor / PHirano PHirano / TTaylor PHirano / TTaylor TTaylor / PHirano	Follow-up to carcinogenicity study waiver request resubmission. Current timeline is 3-5 mos from date of submission. ECAC confirmed submission still under review Acknowledging updates Confirmed
23 Feb 2024	Submission	0116	Request for Breakthrough Therapy Designation
23 Feb 2024	Submission	0117	Request for SPA: Carc Study Protocol, includes draft protocol PRT-PT-005
27 Feb 2024	Correspondence	From FDA	Acknowledgement of breakthrough designation request
14 Mar 2024	Submission	0118	Revised Investigator Information for Studies C614, C617, C618
05 Apr 2024	Submission	0119	Request for Waiver for Gastric pH-Adjusting Drug Interaction Study
08 Apr 2024	Correspondence (Fax)	From FDA	Exec CAC comments regarding SPA submission.

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10 Apr 2024	Submission	0120	Request for Waiver in Patients with Renal Impairment Request for Deferral in Patients with Hepatic Impairment
10 Apr 2024	Email	PHirano / TTaylor	Request for completion of clinical pharmacology summary table
10 Apr 2024	Email	RAziz and TTaylor / PHirano	Request for telecon to clarify dosing related questions based on ECAC comments
17 Apr 2024	Submission	0121	Change in Protocol – C614 Amendment 2 (clean and redlined) Revised investigator Information – C618 Clinical Pharmacology Summary Table
18-23 Apr 2024	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano	6-mo carc study necessary, but can be deferred to post-approval Request for clarification re: 24-mo carcinogenicity study Weight of evidence submission being reviewed. Confirming receipt
26 April 2024	Correspondence	From FDA	Breakthrough designation granted
26 Apr 2024	Submission	0122	New Protocol: Expanded Access Program Treatment Protocol EAP-001
1 May 2024	Submission	0123	Investigator's Brochure, version 10, dated 25 April 2024
7 May 2024	Submission	0124	Investigator's Brochure, version 10, dated 25 April 2024 (redlined)
22 May 2024	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano	Request for clarifications regarding EAP / potential hold comments Response to comment Request to submit request to withdraw EAP protocol Confirmed
23 May 2024	Submission	0125	Withdrawal of Protocol EAP-001 (originally submitted 25 Apr 2024, SN0122)

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10-12 Jun 2024	Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	Notification that ECAC agreed that based on WoE, 2-year rat carc study would not add value to the overall assessment of carc potential. Agency still considers 6-mo mouse carc study and can be conducted post approval Confirmation of receipt. Reiteration that 6-mo study will be conducted once an additional dose range finding study can be conducted.
28 Jun 2024	Submission	0126	C614 Revised Investigator Information Withdrawal of Proprietary Name
02 Aug 2024	Submission	0127	Information Amendment: Clinical – C614 Case Report
22 Aug 2024	Submission	0128	Investigator's Brochure, version 11, dated 20 August 2024 (clean and tracked changes versions)
25 Nov 2024	Submission	0129	Investigator's Brochure, version 12 (clean and tracked changes versions)
06 Dec 2024	Submission	0130	Development Safety Update Report
06 Jan 2025	Submission	0131	CMC amendment: updated to include additional information regarding CMC information that are applicable for forthcoming batches of drug substance and drug product that may be used in nonclinical and/or clinical studies conducted under this IND. Information that is no longer relevant to clinical trial batches to be manufactured have been removed. C614 New investigator information (Zaman [supercedes Holland] and Kim [supercedes Salehi]) C614 Revised investigator information (Mejia-Corletto)
20 March 2025	Submission	0132	Information Amendment: Pharmacology/Toxicology – 28-day dose-range finding study (31977982 / RPT-PT-031) and SEND datasets

Docket No.: SLNO-034/04US 333072-2375
PTE Application for U.S. Pat. No. 9,757,384
VYKAT™ XR

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NDA Communication Log
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- Date Format: YYYY-MM-DD

Date	Type / Serial No.	From / To	Description
2024-06-27	Submission 00001	Soleno / FDA (DP)	Original NDA Submission
2024-07-08	Correspondence / Letter	From FDA	NDA acknowledgement letter
2024-07-12	Correspondence / Email	TTaylor / PHirano	Information Request: Regulatory Request to withdraw request for Pediatric Exclusivity determination since no written request from FDA received.
2024-07-15	Serial No. 00002	Submission	Response to 2024-07-12 Information Request: Regulatory 1.9.3, withdrawal of request for pediatric exclusivity determination
2024-07-15	Correspondence / Email	TBoie / PHirano	Information Request: CMC Request for executed batch records, including packaging records, for 3 lots each of 25 mg, 75 mg, and 150 mg tablets
2024-07-15	Call (VM)	PHirano / TTaylor	Left voice mail to offer an application orientation meeting
2024-07-16	Correspondence / Email	TTaylor / PHirano	Email acknowledging 2024-07-15 voicemail and note that this will be discussed with the review team and management.
2024-07-17	Correspondence / Email	TTaylor / PHirano	Information Request: Regulatory Request for each efficacy study, provide list of IND submissions for protocols, SAPs, amendments, and relevant meetings.
2024-07-17	Serial No. 00003	Submission	Response to CMC IR dated 2014-07-15 Requested executed manufacturing and packaging batch records
2024-07-18	Correspondence / Email	TTaylor / PHirano	Information Request: Labeling, Clinical Request for review and summary of available clinical data to support content of Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling

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Date	Type / Serial No.	From / To	Description
2024-07-22	Serial No. 00004	Submission	Response to 2024-07-17 Information Request: Clinical 1.11.3, Tabular summary of IND submissions with serial numbers and submission dates for protocols, SAPs, amendments, and any relevant meetings for efficacy studies in application (C602-RWP, C610, C601, C609, PC025), C602-OLE, CAS-SOL-001-01
2024-07-24	Correspondence / Email	TBouie / PHirano	Information Request: Biopharmaceutics Request to reinvestigate discriminatory power of proposed dissolution method. Request to provide supportive information regarding proposed ER claim
2024-07-25	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical Pharmacology Clarify nonclinical safety information for LD on which Sponsor is relying; request for PK simulation of divided dose of LD vs single dose of DCCR
2024-07-30	Correspondence / Email	TTaylor / PHirano	Information Request: Nonclinical Safety information to support maximum level of a polyox in children down to age 4 years
2024-08-05	Serial No. 00005	Submission	Response to 2024-07-30 Information Request: Nonclinical 1.11.2, Summary of safety information regarding polyox in children as young as 4 years
2024-08-06	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical (COA) Request for COA reviewers guide for HQ-CT and PWSP; clarify how each COA is administered, scored, and used; clarify if same caregiver reported all timepoints and location in submission
2024-08-08	Correspondence / Email	ASohn / PHirano and TTaylor	Information Request: CMC Request for 6-mo stability data Swallowability study with simulated saliva; analytical procedure requests associated with content uniformity; HPLC suitability parameters; justification of sum of the peak area responses of all peaks; add expiry info of standard and sample solutions; HPLC assay validation data for linearity; concentration, number of replicates; supporting information for drug product formulation experiments; tables for forced degradation studies, content uniformity, disso method

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2024-08-08	Serial No. 00006	Submission	Response to 2024-07-25 Information Request: Clinical Pharmacology 1.11.4, Tabular summary of LD information to be relied on; PK simulations for DCCR 150 mg vs equivalent dose of LD as divided dose (3/day)
2024-08-08-13	Correspondence / Email	PHirano / ASohn, TTaylor, and JKalsi TBouie / PHirano, TTaylor, JKalsi	Request for clarification to 2024-08-08 CMC IR – offer to submit 6-month stability data before responses to other IRs would be available; clarification for preference for stability data submission; request for clarification re: CU for 75 mg and 150 mg since drug loading is above 25% Submit stability data as soon as possible; clarification for rationale for CU data request
2024-08-12	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Clarify MedDRA version of ADaM Datasets; which datasets used to generate AE tables, updated adae.xpt file that includes AELLT and AEHLT variables
2024-08-13	Correspondence / Email	JKalsi / PHirano, TTaylor, PSingh	Information Request: Clin pharm / Stat All PBPK dataset and modeling files or ID location in submission
2024-08-14	Serial No. 00007	Submission	Response to 2024-08-06 Information Request: Clinical 1.2 (COA reviewers guide); 1.11.3 tabular summaries of location of validity, reliability, sensitivity, interpretability of HQ-CT and PWSP; information on how each was administered, scored, used to support efficacy; 5.3.5.1 training materials to support how each was administered/scored.
2024-08-15	Correspondence / Email	JKalsi / PHirano, TTaylor, PSingh	Information Request: Clinical – submit table for each phase 3 study that includes list of delegated responsibilities, locations of study related documentation; resubmit BIMO line listings; describe how HQ-CT data were collected; ID primary source of raw data for key endpoints; sample copy of DXA report
2024-08-19	Serial No. 00008	Submission	Response to 2024-08-12 Information Request: Clinical/Stat 1.11.3, Clarifications for MedDRA version of ADaM Datasets; which datasets used to generate AE tables, updated adae.xpt file that includes
2024-08-19	Serial No. 00009	Submission	Response to 2024-08-13 Information Request: Clinical 1.11.3 PBPK dataset and modeling files directory aligning file name referenced in report with finale name in submission; summary of model risk characterization and model validation plan for PBPK report SOL/1/B.

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Date	Type / Serial No.	From / To	Description
2024-08-20	Serial No. 00010	Submission	Partial Response to 2024-08-08 Information Request: CMC 6-month data provided in advance of remainder of IR.
2024-08-21	Correspondence / Email	PSingh / PHirano, TTaylor	Information request: Clinical Clarify same birthdates of UK patients
2024-08-21	Serial No. 00011	Submission	Response to 2024-08-15 Information Request – Clinical/BIMO Information regarding CRO's, delegated authority, locations of study documents Request for updated BIMO files for C601 and C602-RWP.
2024-08-21	Serial No. 00012	Submission	Response to 2024-07-18 Information Request – Labeling / Clinical Revised draft label with language added consistent with PLLR; associated literature review and review of relevant PV cases
2024-08-27	Correspondence / Letter	TFarchione / Soleno	Priority Review Designation Application sufficiently complete to permit a substantive review; user fee goal date.
2024-08-28	Serial No. 00013	Submission	Response to 2024-08-28 Information Request: Clinical Clarification request for UK birthdates since all have 1 July as date. Was required to conform to GDPR/data privacy rules in UK/Europe (pre-Brexit)
2024-08-29	Correspondence / Email	TTaylor / PHirano	Information Request: Clin Pharm Provide Vss values / additional information regarding PBPK report
2024-09-03	Correspondence / Memorandum	LTBonner / PHirano, YWaples	Memorandum notifying Soleno of tentatively scheduled Psychopharm Drugs Advisory Committee meeting
2024-09-05	Correspondence / Email	TTaylor / PHirano	Information request: Clinical Clarify if CAS-SOL001-01 caregivers remained blinded to C601 assignment when interviewed for meaningfulness of change
2024-09-06	Correspondence / Letter	TFarchione / Soleno	Filing Communication / Filing issues identified Review classification is Priority User fee goal date
2024-09-06	Correspondence / Email	TTaylor / PHirano	Information request: Stat Submit all stat programs for tables included in C602-RWP production run tables. If already submitted, specify location within NDA

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Date	Type / Serial No.	From / To	Description
2024-09-06	Correspondence / Email	TTaylor / PHirano	Information request: Clinical / Stat C602-OLE-CSR update body composition figures to show C601+C602 data over time by age group and by C601 randomized treatment group; similar figures for waist circumference and height change; complete table for RWP. For C601 justify ITT population vs mITT population; request for RWP forest plots by BMI categories; characterize food controls in OLE vs NIH NHS
2024-09-06	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical / Stat: Justification for applicability of foreign data
2024-09-08	Serial No. 00014	Submission	Response to IR Request dated 2024-09-05 – Clinical Clarification if CAS-SOL001-01 caregivers in C602 remained blinded to C601 treatment assignment.
2024-09-10	Serial No. 00015	Submission	Response to IR Request dated 2024-09-05 – Clinical Clarification if CAS-SOL001-01 caregivers in C602 remained blinded to C601 treatment assignment.
2024-09-12	Correspondence / Email	TTaylor / PHirano	Information request: Clinical / Stat Executable SAS codes and indicate datasets for specific OLE tablets.
2024-09-16	Correspondence / Email	TBouie / PHirano	Information request: Biopharm New dissolution data from debossed and non-debossed
2024-09-19	Serial No. 00016	Submission	Response to 2024-08-29 Information Request – Clinical PBPK/SOL/1/B report related questions regarding Vss, CL value estimation, % renal excretion, Fu,mic value in liver microsomes, estimated fmCYP1A2 and variability
2024-09-18	Serial No. 00017	Submission	Response to 2024-09-06 Information Request – Clinical C602-OLE CSR – body composition figures and height by age groupings; forest plots of weight and BMI changes for C602-RWP subgroups; characterize food controls for C602-OLE
2024-09-19	Correspondence / Email	TBouie / PHirano	Information Request: CMC Question re: 32P41, 21P54, 32P83, 32P22
2024-09-19	Serial No. 00018	Submission	Response to 2024-09-12 Information Request – Clinical SAS code and datasets for OLE tables 35-37 and table 16.
2024-09-20	Serial No. 00019	Submission	Response to 2024-07-24 Information Request – Biopharm Reevaluate discriminatory power of method; justification for extended-release claim

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2024-09-24	Correspondence / Email	TBouie / PHirano	Information Request: CMC 32P22 and DP IPCs
2024-09-27	Correspondence / Email	TTaylor / PHirano	Information Request: Labeling Request for carton labels
2024-09-27-30	Correspondence / Email	PHirano / TTaylor	Follow-up to telephone call on 27 Sep. Request for information regarding rejection of PPN.
		TTaylor / PHirano	Copy of PNR Unacceptable letter
	Letter	MMistry / Soleno	25 Sep 2024 letter noting similarity of Kabrey to Qelbree as the primary reason Kabrey concluded to be unacceptable
2024-09-30	Serial No. 00020	Submission	Response to 2024-09-06 Information Request – Clinical Justification for applicability of submitted foreign data to US population.
2024-09-30	Serial No. 00021	Submission	Response to 2024-08-08 Information Request – CMC Swallowability study information; analytical procedure requests associated with content uniformity; HPLC suitability parameters; justification of sum of the peak area responses of all peaks; add expiry info of standard and sample solutions; HPLC assay validation data for linearity; concentration, number of replicates; supporting information for drug product formulation experiments; tables for forced degradation studies, content uniformity, disso method 6-mo stability data provided previously. (Serial No. 00010)
2024-10-01	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical / Clin Pharm / Stat Request for assays used / validation for cardiometabolic markers; evaluate AUC vs safety events ; submit all datasets/programs
2024-10-01	Serial No. 00022	Submission	Request for Proprietary Name Review
2024-10-02	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical / Stat ADaM datasets and stat programs for C-SSRS data as requested.
2024-10-02	Correspondence / Email	TBouie / PHirano	Information Request: CMC Test available batches for content uniformity and submit data
2024-10-02	Serial No. 00023	Submission	Response to 2024-09-27 information request – carton labeling

Exhibit 17
NDA Communication Log
NDA 216665

Date	Type / Serial No.	From / To	Description
2024-10-03	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical / Stat COA Administration; CAS-SOL001-01 demographics and updated tables; summarize linguistic validation and cultural adaptation work to support use in study
2024-10-03	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical / Stat Correlations between HQ-CT and CGI-S; Change from baseline in HQ-CT and CGI-S non food related; anchor-based meaningful change analysis; requests for additional tables related to anchors/HQ-CT
2024-10-03	Serial No. 00024	Submission	Response to 2024-09-16 information request – Biopharm Newly generated dissolution data from Batches M12394 (25 mg) and M12396 (150 mg)
2024-10-07	Serial No. 00025	Submission	Response to 2024-09-19 information request – CMC Opadry CoA with data; Batch analysis table ques stability related questions.
2024-10-07	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical / Stat Data collection process for PATH; subject disposition tables for PATH and NIH NHS, clarify differences between 2 C610 ADaM datasets; explanation for why unstructured covariance not used for all mixed effects models stated in SAP
2024-10-08	Correspondence / Email	TTaylor / PHirano	Information Request: Clin Pharm Related to PBPK report – additional simulations
2024-10-08	Correspondence / Email	TBouie / PHirano	Information Request: CMC Clarification of units for high level linearity; provide precision and intermediate precision data with placebo spiked with diazoxide choline
2024-10-08	Serial No. 00026	Submission	Response to 2024-09-24 Information Request: CMC 32P22 and DP IPCs
2024-10-10	Correspondence / Email	TBouie / PHirano	Information Request: CMC Proposed dissolution specifications
2024-10-10	Serial No. 00027	Submission	Response to 2024-10-03 Information Request: Clinical Correlations between HQ-CT and CGI-S; Change from baseline in HQ-CT and CGI-S non food related; anchor-based meaningful change analysis; requests for 2tables related to anchors/HQ-CT
2024-10-11	Serial No. 00028	Submission	Response to 2024-10-03 Information Request: Clinical ADaM datasets and stat programs for C-SSRS data

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Date	Type / Serial No.	From / To	Description
2024-10-11	Serial No. 00029	Submission	Response to 2024-10-03 Information Request: Clinical Correlations between HQ-CT and CGI-S; Change from baseline in HQ-CT and CGI-S non food related; anchor-based meaningful change analysis; requests for additional tables related to anchors/HQ-CT
2024-10-15	Correspondence / Email	TBouie / PHirano	Information Request: CMC Moisture specification
2024-10-15	Serial No. 00030	Submission	Response to 2024-10-01 Information Request – Clinical Pharmacology Assays used / validation for cardiometabolic markers; evaluate AUC vs safety events ; submit all datasets/programs
2024-10-16	Serial No. 00031	Submission	Response to 2024-10-08 Information Request – Clinical Related to PBPK report – additional simulations
2024-10-17	Serial No. 00032	Submission	Response to 2024-10-10 Information Request – CMC Proposed dissolution specifications
2024-10-21	Serial No. 0033	Submission	Response to 2024-10-02 Information Request – CMC Content uniformity data for available batches of 75 mg and 150 mg tablets
2024-10-21	Serial No. 0034	Submission	Response to 2024-10-07 Information Request – Clinical Data collection process for PATH; subject disposition tables for PATH and NIH NHS, clarify differences between 2 C610 ADaM datasets; explanation for why unstructured covariance not used for all mixed effects models stated in SAP
2024-10-22	Correspondence / Email	TTaylor / PHirano	Patent statement certifications have not been included in emails
2024-10-23	Serial No. 00035	Submission	Response to 2024-10-15 Information Request – CMC Moisture specification
2024-10-25	Serial No. 00036	Submission	120-Day Safety Update Report
2024-10-29	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Clarify if TEAE event rates were estimated using AUC or Cmin as exposure metric
2024-10-30	Serial No. 00037	Submission	Response to 2024-10-08 Information Request – CMC Clarification of units for high level linearity; provide precision and intermediate precision data with placebo spiked with diazoxide choline
2024-10-31	Correspondence / Email	TBouie / Phirano Hirano / Tbouie TBouie / PHirano	Request for courtesy copy of 2024-10-08 CMC IR when submitted Email copy of files submitted as serial no. 0037 Confirmation of receipt

Exhibit 17
NDA Communication Log
NDA 216665

Date	Type / Serial No.	From / To	Description
2024-10-31	Correspondence / Email	TBouie / PHirano	Information Request: CMC Request for updated draft labeling, batch records, composition tables to comply with salt policy
2024-11-01	Serial No. 00038	Submission	Response to 2024-10-29 Information Request – Clinical Pharmacology Clarification TEAE event rates in the absence and presence of strong CYP1A2 inhibitor and of exposure metric used
2024-11-04	Correspondence / Email	TTaylor / PHirano PHirano / TTaylor	Information Request: Clin Pharm Provide Simcyp modeling file and simulations / summary of DDI similar results for PBPK report Confirmation of IR receipt. Request for confirmation that the workspace files submitted on 16 th October (Serial No. 00031) are the files that were expected.
2024-11-04	Correspondence / Email	PHirano / TBui Nguyen TBui Nguyen / PHirano	Follow-up to telephone conversation regarding PNR request goal date after NDA user fee goal date and importance of the PNR. Confirmation of receipt of communication
2024-11-04	Serial No. 00039	Submission	Response to 2024-10-31 Information Request – CMC Updated draft labeling, batch records, composition tables to comply with salt policy
2024-11-05-06	Correspondence / Email	TTaylor / PHirano PHirano / TTaylor TBouie / PHirano PHirano / TBouie TBouie / PHirano PHirano / TBouie TBouie / PHirano PHirano / TTaylor	Information Request: CMC Disagree with exception rationale; request to submit adjusted records Acknowledge receipt of email; request for telecon with OPQ Notification of OPQ availability at 3:30 PM Eastern Confirmation that Soleno team is available Zoom dial-in information List of attendees from Soleno List of attendees for call Courtesy copy of response to IR
2024-11-06	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Subgroup analyses for treatment differences in change in HQ-CT by baseline weight, BMI category, change in BMI for each study; plot mean weight, BMI change, and %BMI change versus mean HQ-CT change over time
2024-11-06	Serial No. 00040	Submission	Response to Information Request: CMC / Labeling

Exhibit 17
NDA Communication Log
NDA 216665

Date	Type / Serial No.	From / To	Description
2024-11-07-08	Correspondence / Email	CELee / PHirano, TTaylor	Information Request: Clinical/Stat Request for listings/ shift tables for BP, HR changes Request for clarification on 07 Nov IR
2024-11-08	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat AE tables by age; submit datafiles and executable SAS programs.
2024-11-12	Correspondence / Email	TTaylor / PHirano	Information Request: Clin Pharm Provide simulated box plots for weight ranges for proposed dosing regimen.
2024-11-12	Correspondence / Email	TBui Nguyen / PHirano, TTaylor, DLyons	PNR amendment needed based on 6 November CMC IR regarding revised tablet strengths.
2024-11-13-14	Correspondence / Email	TTaylor / PHirano PHirano / TTaylor	Request for clarification for what information from NDA 017425 that is not used in NDA 017453 is being used to support findings of safety. Confirmation that the listed drug in NDA 017453, but that the reviews were combined.
2024-11-13	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Summarize information related to risk of hypersensitivity reactions
2024-11-14	Serial No. 00041	Submission	Response to 2024-11-06 Information Request – Clinical Subgroup analyses for treatment differences in change in HQ-CT by baseline weight, BMI category, change in BMI for each study; plot mean weight, BMI change, and %BMI change versus mean HQ-CT change over time
2024-11-14	Serial No. 00042	Submission	Response to 2024-11-13 Information Request – Regulatory NDA 017425 that is not used in NDA 017453 is being used to support findings of safety. Confirmation that the listed drug in NDA 017453, but that the reviews were combined.
2024-11-15	Correspondence / Letter	MSolages / PHirano	6-Week Post marketing requirement (PMR) communication letter and most Marketing Commitments (PMC). None identified at this time; subsequent communications may be needed during remainder of review.
2024-11-15	Serial No. 00043	Submission	Response to 2024-11-08 Information Request – Clinical Clarification on 07 Nov IR
2024-11-15	Serial No. 00044	Submission	Response to 2024-11-08 Information Request – Clinical AE tables by age for C602 and C602-RWP with executable SAS programs and datafiles

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NDA Communication Log
NDA 216665

Date	Type / Serial No.	From / To	Description
2024-11-15	Serial No. 00045	Submission	Response to 2024-11-07 Information Request – Clinical ADaM vital signs dataset, executable SAS programs, reference range data, all datafiles for C601, c602-OLE, C602-RWP. Subject level listings for BP (hypertension, hypotension) and HR and shifts in BP and HR in format requested.
2024-11-18	Correspondence / Email	TTaylor / PHirano	Information Request: Clin Pharm Provide tabular summary of PK parameters in healthy subjects and patients with PWS after a single dose and at steady state at each dose level
2024-11-18	Correspondence / Email	TTaylor / PHirano	Information Request: Clin / Stat Provide reasons for treatment continuation of 14 subjects who discontinued prior to 26 weeks; include program code and datasets
2024-11-18	Serial No. 00046	Submission	Response to 2024-11-04 Information Request – Clinical Pharmacology Simcyp modeling file from (Serial No. 00031); additional simulations including DDI simulations assuming renal excretion of 40% of total clearance value.
2024-11-18	Serial No. 00047	Submission	Response to 2024-10-22 and 2024-11-14 Info Requests – Patent Certification / Re-certification Statements Patent certification / re-certification statements for Srial no. 00002 through 00013
2024-11-19	Serial No. 00048	Submission	Response to 2024-11-13 Information Requests – Clinical Patent certification / re-certification statements for Srial no. 00002 through 00013
2024-11-19	Serial No. 00049	Submission	Response to 2024-11-12 Information Request – Clinical Pharmacology Box plots for simulated Cmax and AUC for weight ranges in dosing table at C601 Visits; include PK profiles, summary statistics, simulated datasets, codes, and corresponding data definition files.
2024-11-19	Serial No. 00050	Submission	Response to 2024-11-13 Information Request – Clinical Safety data relevant to risk of hypersensitivity reactions from Phase 3 studies, including data suggestive of hypersensitivity reactions.
2024-11-21-25	Correspondence – General Advice Letter	TBouie / PHirano PHirano / TBouie TBouie / PHirano	Agreement to exception to salt policy. Provide all revised labeling, batch records, etc. Clarification to submit what's available sooner or submit together Request that all is submitted together

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Date	Type / Serial No.	From / To	Description
2024-11-22	Correspondence / Email	TBui Nguyen / PHirano PHirano / TBui Nguyen TBui Nguyen / PHirano	Information Request: PNR Request for amendment to PNR with revised tablet strengths Confirmation of info request and estimated time to submit response Confirmation of request of response re timing
2024-11-22	Serial No. 00051	Submission	Response to 2024-11-21 advice letter regarding agreement to exception to salt policy. Modules 32P33, 32P34, 32P51, 32R
2024-11-25	Correspondence / Letter	TFarchione / Soleno	Review extension – Major amendments (0044, 0045, 0049, 0050)
2024-11-25	Serial No. 00052	Submission	Response to 2024-11-13 Information Request – Clinical Reasons for patient discontinuation for patients who discontinued prior to Week 26.
2024-11-25	Serial No. 00053	Submission	Response to 2024-11-18 Information Request – Clinical Pharmacology Comparison of PK parameters in healthy subjects and patients with PWS after single dose and at steady state for each dose level.
2024-11-26	Correspondence / Email	TTaylor / PHirano	Information Request: Labeling Confirmation desiccant labeled as “Do not eat”; additional container label recommendations
2024-11-27	Correspondence / Email	PHirano / TTaylor	Request to consider a late cycle meeting or other meeting to better understand review progress.
2024-11-27	Serial No. 00054	Submission	Response to 2024-11-22 Email Exchange - Amendment to Proprietary Name Request to revert back to diazoxide choline doses.
2024-11-27	Serial No. 00055	Submission	Response to 2024-11-26 Information Request – CMC and Labeling Revised container label to update strength based on diazoxide choline strength and additional comments.
2024-12-03	Correspondence / Letter	MMistry / Soleno	Proprietary Name Request Conditionally Acceptable; recommendation to add a modifier to convey extended release properties.
2024-12-05	Correspondence / Email	PHirano / TBui Nguyen	Email follow-up to telephone conversation and voicemail. Question regarding the handling of adding the modifier.
2024-12-09	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Submit requested tables associated blood pressure and heart rate by age groupings; provided programs and datasets

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NDA 216665

Date	Type / Serial No.	From / To	Description
2024-12-11	Correspondence / Email	TBui Nguyen / PHirano, DLyons, TTaylor	Follow-up to 05 Dec 2024 email from PHirano to TBui Nguyen providing instructions on submitting/withdrawing name.
2024-12-11	Correspondence / Email	TTaylor / PHirano	PI labeling comments with instructions for handling.
2024-12-12-13	Correspondence / Email	PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	Voicemail follow-up regarding acceptability to use 'extended release' modifier for our dosage form. Confirmation that Agency has determined that use of the phrase "extended-release" would be appropriate if the product is approved. Confirmation of receipt
2024-12-13	Correspondence / Email	PHirano / TBui Nguyen, TTaylor, DLyons TBui Nguyen / PHirano, DLyons, TTaylor	Follow-up to 11 Dec 2024 email confirming that a DSI report has been request for name with modifier. Confirming receipt of proposed plan.
2024-12-13	Serial No. 00056	Submission	Response to 2024-12-09 Information Request – Clinical Pharmacology Accuracy data from validation documents for cardiometabolic markers
2024-12-17-18	Correspondence / Email	PHirano / TTaylor TTaylor / PHirano	Draft PI submitted to NDA with changes tracked Confirmation of receipt of tracked label
2024-12-17	Serial No. 00057	Submission	Response to 2024-12-11 Information Request – Labeling Commnets Revised draft USPI
2024-12-19	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Tabular summary of shifts in Blood pressure and in heart rate groups by age group and by Visit
2025-01-03	Correspondence / Email	PHirano / TTaylor TTaylor / PHirano	Request for timing update for label changes and communicating PMRs/PMCs Meeting internally this week; more info towards the end of the week
2025-01-06	Serial No. n 00058	Submission	Response to 2024-12-19 Information Request: Clinical Tabular summary of shifts in Blood pressure and in heart rate groups by age group and by Visit; datasets and executable SAS program
2025-01-15	Correspondence / Email	PHirano / TTaylor	Follow-up to 03 Jan 2025 request for timing update for label changes and communicating PMRs/PMCs
2025-01-27	Serial No. 00059	Submission	Request for withdrawal of Vykate as proposed proprietary name Request for proprietary name review: Vykate XR

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Date	Type / Serial No.	From / To	Description
2025-02-07	Correspondence / Email	TTaylor / PHirano	Information Request: Clinical/Stat Questions regarding how BP was measured at visits; rationale for wide range of absolute changes
2025-02-03-11	Correspondence / Email	TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano PHirano / TTaylor	List of PMRs Request for clarifications on PMRs Response to list of clarifications requested Confirming acceptance of PMRs
2025-02-12	Serial No. 00060	Submission	Response to 2025-02-07 Information Request – Clinical Module 1.11.3; Response to BP measurement questions.
2025-02-19	Correspondence / Email	TTaylor / PHirano	Information Request: Labeling Comments on primary container label
2025-02-18	Telephone call	PHirano / TTaylor	Telephone to discuss status of draft label, any additional PMRs/PMCs
2025-02-27	Serial No. 00061	Submission	Response to 2025-02-19 primary container label 1.11.4 summary of changes; 1.14.1.1 draft container labels (revised)
2025-03-03	Telephone call	PHirano / TTaylor	Telephone call to discuss status of label.
2025-03-07	Correspondence / Email	TTaylor / PHirano	Hoping to have labeling at end of day or Monday at the latest.
2025-03-07	Correspondence / Email	TTaylor / PHirano	Draft PI to applicant
2025-03-12	Serial No. 00062	Submission	Response to 2025-03-07 draft PI to applicant. 1.14.1.3 draft labeling text (TRADENAME and with proposed proprietary name 1.12.5.1 request for waiver from half-page requirement for Highlights of Prescribing Information
2025-03-12	Correspondence / Email	PHirano / TTaylor, TBui Nguyen TTaylor / PHirano, TBui Nguyen	Courtesy copy of draft PI with TRADENAME and proposed proprietary name. Confirmation of receipt
2025-03-13	Correspondence / Letter	MMistry / Soleno	Proposed proprietary name is acceptable.
2025-03-18	Correspondence / Email	TTaylor / PHirano	Comments regarding primary container label
2025-03-18	Correspondence / Email	TTaylor / PHirano	Anticipate that next round of labeling comments later that day or following day.
2025-03-19	Correspondence / Email	TTaylor / PHirano PHirano / TTaylor TTaylor / PHirano	Label comments being checked; hoping to provide label comments later in the day Confirmation of message; asked if comments on Medication Guide would also be coming Confirmation that Medication Guide comments would be included

Exhibit 17
NDA Communication Log
NDA 216665

Date	Type / Serial No.	From / To	Description
2025-03-19	Serial No. 00063	Submission	Response to 2025-03-18 Information Request – draft labeling Updated primary container labels
2025-03-19	Correspondence / Email	PHirano / TTaylor PHirano / TTaylor	Courtesy copy of draft labels. Notification that the submission would have to be withdrawn since tablet images were not consistent with actual size. Updated labels to be provided before COB on 20 th March.
2025-03-20	Serial no. 00064	Submission	Withdrawal of Serial No. 00063 and replacement primary container label drafts submitted.
2025-03-23	Serial No. 00065	Submission	Response to 2025-03-21 labeling comments Revised draft USPI and Medication Guide
2025-03-24	Serial No. 00066	Submission	Draft USPI intended to be submitted on Serial No. 00065 submitted.
2025-03-25	Correspondence / Email	TTaylor / PHirano	Request for labeling changes and comments regarding draft label and medication guide, both dated 25 March 2025
2025-03-25	Serial No. 00067	Submission	Response to 2025-03-25 request for labeling changes and comments regarding draft label and medication guide.
2025-03-26	Correspondence / Email	TTaylor / PHirano	Final labeling – request to confirm agreement of final labeling.
2025-03-26	Telephone Call	PHirano / TTaylor	Request for clarification if numbered bullets in section 3, 6 (on page 6) and 8.4 were intentional or if a formatting error on the version opened by Soleno. Confirmation that this was an error and that a revised label would be provided.
2025-03-26	Correspondence / Email	TTaylor / PHirano PHirano / TTaylor PHirano / TTaylor	Revised final PI with corrected formatting. Confirmation of agreement with final Medication Guide and Container Labels Confirmation of agreement with correct final PI
2025-03-26	Correspondence / Letter	TFarchione / Soleno	Final Approval Letter (provided by Email from TTaylor to PHirano)



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Alexandria, VA 22314-1450
www.uspto.gov

June 2, 2025

Food and Drug Administration
CDER, Office of Regulatory Policy
10903 New Hampshire Avenue
Bldg. 51, Room 6250
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension (PTE) of U.S. Patent No. 9,757,384 was filed on May 14, 2025 under 35 U.S.C. 156, based on the Food and Drug Administration's approval of NDA 216665 for the human drug product known by the tradename VYKAT™ XR (diazoxide choline). Please note that PTE applications for U.S. Patent Nos. 7,572,789; 7,799,777; and 12,178,823, also based on the approval of VYKAT™ XR (diazoxide choline), were filed concurrently pursuant to the provisions of 37 CFR 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, VYKAT™ XR (diazoxide choline), has been subject to a regulatory review period within the meaning of 35 U.S.C. 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7754 or kathleen.fonda@uspto.gov.

/Kathleen Kahler Fonda/
Kathleen Kahler Fonda
Senior Legal Advisor
Office of Patent Legal Administration

cc: Dr. Kimberly A. Bolin
Cooley LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue NW
Suite 700
Washington, DC 20004



U.S. FOOD & DRUG
ADMINISTRATION

Re: VYKAT

Patent Nos.	Docket Nos.
7,572,789	FDA-2025-E-1675
7,799,777	FDA-2025-E-1676
9,757,384	FDA-2025-E-1677
12,178,823	FDA-2025-E-1678

The Honorable John A. Squires
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

OCT 15 2025

Dear Director Squires

This letter is in response to the applications for patent term extension for U.S. Patent Nos. 7,572,789; 7,799,777; 9,757,384; and 12,178,823 filed by Essentialis, Inc., under 35 U.S.C. 156. The human drug product claimed by the patents is VYKAT (diazoxide choline), which was assigned new drug application (NDA) No. 216665.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records indicate that VYKAT represents the first permitted commercial marketing or use of the product or the individual active ingredients, as outlined under 35 U.S.C. sections 156(a)(5) and 156(f)(1).

NDA 216665 was approved on March 26, 2025, which makes the submission of the patent term extension applications on May 14, 2025, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
WO Building 51, Room 6200
Silver Spring, MD 20993-0002
www.fda.gov

USPTO - VYKAT

Patent Nos. 7,572,789; 7,799,777; 9,757,384;
12,178,823

Essentialis, Inc.

Page 2

Please let me know if we can be of further assistance.

Sincerely,



George F. Tidmarsh, M.D., Ph.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

cc: Kimberly A. Bolin, D.Phil.
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22314-1450
www.uspto.gov

October 29, 2025

Food and Drug Administration
CDER, Office of Regulatory Policy
10903 New Hampshire Avenue
Bldg. 51, Room 6250
Silver Spring, MD 20993-0002

Attention: Jack Dan

We transmitted a copy of an application for patent term extension (PTE) of U.S. Patent No. 9,757,384 to your office by our letter dated June 2, 2025. The application was filed on May 14, 2025 under 35 U.S.C. 156. Claims of the 9,757,384 patent cover the method of use of the human drug product known by the tradename VYKAT™ XR (diazoxide choline), which, as your office informed us by letter dated October 15, 2025, has been subject to a regulatory review period (RRP) before its commercial marketing or use as required under 35 U.S.C. 156(a)(4).

Please note that PTE applications for U.S. Patent Nos. 7,572,789; 7,799,777; and 12,178,823 based on the same RRP for VYKAT™ XR (diazoxide choline) were filed concurrently, pursuant to the provisions of 37 CFR 1.785.

Subject to final review, the 9,757,384 patent is considered to be eligible for PTE. Thus, a determination by your office of the applicable RRP is necessary. Accordingly, notice is provided pursuant to 35 U.S.C. 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at 571-272-7754 or kathleen.fonda@uspto.gov.

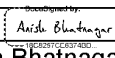
/Kathleen Kahler Fonda/
Kathleen Kahler Fonda
Senior Legal Advisor
Office of Patent Legal Administration

cc: Dr. Kimberly A. Bolin
Cooley LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue NW
Suite 700
Washington, DC 20004

re: VYKAT™ XR (diazoxide choline)

Docket No. FDA-2025-E-1677

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

PATENT - POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Patent Number		9,757,384	
	Issue Date		September 12, 2017	
	First Named Inventor		Neil M. Cowen	
	Title	METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME		
	Attorney Docket No.	SLNO-034/04US 333072-2375		
I hereby revoke all previous powers of attorney given in the above-identified patent.				
☐ A Power of Attorney is submitted herewith. OR ☒ I hereby appoint Practitioner(s) associated with the Customer Number identified in the box at right as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 58249				
OR ☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:				
Practitioner(s) Name		Registration Number	Practitioner(s) Name	Registration Number
Please recognize or change the correspondence address for the above-identified patent to:				
☒ The address associated with the above-identified Customer Number. OR ☐ The address associated with the Customer Number identified in the box at right:				
OR				
☐ Firm or Individual Name				
Address				
City		State		Zip
Country				
Telephone		Email		
I am the:				
☐ Applicant OR ☒ Patent owner. Statement under 37 CFR 3.73(c) (Form PTO/AIA/96) submitted herewith or filed on _____:				
SIGNATURE of Applicant or Patent Owner				
The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant or patent owner if the applicant or patent owner is a juristic entity (e.g., corporation, university).				
Signature	/ 	Date	12/3/2025 6:41:39 AM PST	
Name	Anish Bhatnagar	Telephone		
Title and Company	CEO, Soleno Therapeutics, Inc.			
NOTE: Signatures of all the applicants or patent owners of the entire interest or their representative(s) are required. If more than one signature is required, submit multiple forms, check the box below, and identify the total number of forms submitted in the blank below.				
☒ A total of <u>1</u> forms are submitted.				

STATEMENT UNDER 37 CFR 3.73(c)

First Named Inventor/Patent Owner: Neil M. Cowen

Application No./Patent No.: 9,757,384 Filed/Issue Date: September 12, 2017

Titled: **METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME**

Soleno Therapeutics, Inc., a Corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____ %. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached*.

- B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Neil M. Cowen To: Essentialis, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 37039, Frame 0755, or for which a copy thereof is attached*.

2. From: Essentialis, Inc. To: Soleno Therapeutics, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached*.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached*.

4. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached*.

5. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached*.

6. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached*.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ *As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature /John Kozlowski/

Date December 30, 2025

Printed or Typed Name John Kozlowski

Title or Registration Number 82,124

Attorney Docket No. SLNO 333072-2000

**ASSIGNMENT OF PATENT RIGHTS
(Company to Company)**

Essentialis, Inc., a Delaware corporation, having its principal place of business at 100 Marine Parkway, Suite 400, Redwood City, CA 94065 (herein referred to as “Assignor”) owns the entire right, title and interest in any Letters Patent(s) (“said patent(s)”) and any Patent application(s) (“said application(s)”) set forth in the attached **Schedule A**, as well as any invention(s) (“said invention(s)”) disclosed in said application(s) and said patent(s).

WHEREAS, Soleno Therapeutics, Inc., a Delaware corporation, having its principal place of business at 100 Marine Parkway, Suite 400, Redwood City, CA 94065 (the “Assignee”), its successors, legal representatives, and assigns, is desirous of acquiring the Assignor’s entire right, title, and interest in and to said invention(s), said application(s) for patent and/or registered design, and said patent(s); the right to file applications for patent and/or registered design of the United States or other countries on said invention(s); the entire right, title and interest in and to any application(s) for patent and/or registered design, and patent(s) of the United States or other countries claiming priority to, and/or benefit of, these applications and patents; the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) for patent and/or registered design and said patent(s); and the entire right, title, and interest in and to any and all Letters Patent or Patents and/or registered design(s), United States or foreign, to be obtained for said invention(s) and said application(s);

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, and to the extent that the Assignor has not done so already via a prior agreement with the Assignee or a predecessor in interest of the Assignee, or if the Assignor has already done so via a prior agreement with the Assignee or a predecessor in interest of the Assignee then in confirmation of said prior agreement, the Assignor has sold, assigned, transferred, and set over, and by these presents does sell, assign, transfer, and set over, unto the Assignee, its successors, legal representatives, and assigns Assignor’s right, title, and interest in and to:

- (a) said invention(s);
- (b) said application(s) for patent and/or registered design;
- (c) said patent(s);
- (d) the right to file applications for patent and/or registered design of the United States or other countries on said invention(s), including all rights under the Hague Convention, the Paris Convention for the

Protection of Industrial Property, and under the Patent Cooperation Treaty, and all rights of claiming priority in any country of the world;

- (e) any application(s) for patent and/or registered design of the United States or other countries claiming the invention(s);
- (f) any application(s) for patent and/or registered design of the United States or other countries claiming priority to, and/or the benefit of, at least one of the application(s) for patent and/or registered design identified above or any application(s) for patent claiming the invention(s), including any priority application(s), substitute application(s), division(s), continuation(s), and continuation(s)-in-part;
- (g) the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) for patent and/or registered design and said patent(s) identified in the preceding paragraphs (b)-(f) and of any and all patent(s) and/or registered design(s) granted based thereon in the United States and in all other countries; and
- (h) any and all Letters Patent or Patents and/or registered design(s), United States or foreign, to be obtained for said invention(s), said application(s) for patent and/or registered design, and said patent(s), including any reissue(s), reexamination(s), revival(s), renewal(s) and extension(s) of said patent(s).

The above-granted rights, titles, and interests are to be held and enjoyed by the Assignee, for its own use and behalf and the use and behalf of its successors, legal representatives, and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted as fully and entirely as the same would have been held and enjoyed by the Assignor had this sale and assignment not been made;

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns, that, at the time of execution and delivery of these presents, or if applicable, at such time said prior agreement was executed, the Assignor is the sole and lawful owner of Assignor's entire right, title and interest in and to said invention(s), said application(s), and said patent(s), and that the same are unencumbered, and that the Assignor has good and full right and lawful authority to sell and convey the same in the manner herein set forth;

AND for the same consideration, the Assignor also hereby represents that, except for said prior agreement, if applicable, the Assignor has not previously sold, transferred, or encumbered any part of Assignor's right, title, and interest in the Invention(s);

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns that the Assignor will, whenever counsel of the Assignee, or the counsel of its successors, legal representatives, and assigns, shall advise that any proceeding in connection with said invention(s), said application(s), said registered design(s), said patent(s), any application claiming priority to said application(s), any reissue or extension of said patent(s), and any United States or foreign Letters Patent or Patents for said invention(s) or said application(s), including interference and derivation proceedings, and any post-grant proceedings (e.g., opposition proceedings, post-grant reviews, *Inter partes* reviews, supplemental examinations, etc.), is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent or Patents for said invention(s), without charge to the Assignee, its successors, legal representatives, and assigns, but at the cost and expense of the Assignee, its successors, legal representatives, and assigns;

AND the Assignor waives all rights to challenge the validity of said invention(s) in the United States and its territorial possessions and in all foreign countries and of all Letters Patent or similar legal protection in the United States and its territorial possessions and in any and all foreign countries to be obtained for said invention(s) by said application or any continuation, continuation-in-part, divisional, renewal, substitute, or reissue thereof or any legal equivalent thereof in a foreign country for the full term or terms for which the same may be granted;

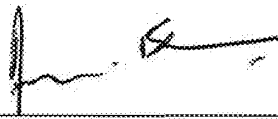
AND the Assignor hereby authorizes and requests the attorneys of COOLEY LLP to insert in the spaces provided the title, application number, filing date, attorney docket number, assignment recordation date, and Reel/Frame No(s). of the Patent Application(s) and/or Letters Patent(s) identified herein when known;

AND the Assignor hereby requests the Commissioner of Patents to issue any and all aforementioned patent(s) of the United States to the Assignee, as the Assignee of said invention(s) and the Letters Patent to be issued thereon, for the use of and on behalf of the Assignee, its successors, legal representatives, and assigns;

AND Assignor(s) and Assignee(s) understand that electronic signatures are acceptable and that, by signing electronically, signatories agree to the use of electronic signatures.

For and on behalf of ASSIGNOR:

Date: 11/25/2025

By: 
Name: ANISH BHATTACHAR
Title: CEO
Company: Essentialis, Inc.

By signing, I confirm that I am entitled to sign legally binding acts on behalf of
Essentialis, Inc.

My position in Essentialis, Inc. is: CEO

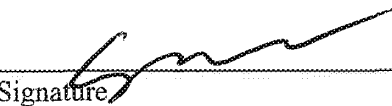
Witness:


Signature

11/25/2025
Date

Kartlyn Birsen
Printed Name

Witness:


Signature

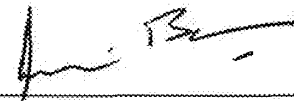
11/25/2025
Date

ANNIE GRAVES
Printed Name

For and on behalf of ASSIGNEE:

Date: 11/25/2025

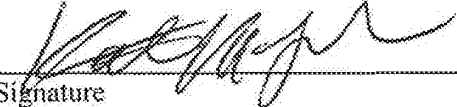
By:


Name: ANISH BHATNAGAR
Title: CEO
Company: Soleno Therapeutics, Inc.

By signing, I confirm that I am entitled to sign legally binding acts on behalf of Soleno Therapeutics, Inc.

My position in Soleno Therapeutics, Inc. is: CEO

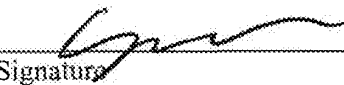
Witness:


Signature

Kaitlyn Johnson
Printed Name

11/25/2025
Date

Witness:


Signature

ANNIE BARNES
Printed Name

11/25/2025
Date

SCHEDULE A

Title	Application No.	Application Date	Registration No.	Registration Date	Country
USE OF DIAZOXIDE OR ITS DERIVATIVES IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMANS AND ANIMALS	60/604,085	8/25/2004			United States of America
THERAPEUTIC OUTCOMES FROM THE USE OF DIAZOXIDE OR ITS DERIVATIVES IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMAN AND ANIMALS	60/624,219	11/3/2004			United States of America
USE OF DIAZOXIDE OR ITS DERIVATIVES AND CO-FORMULATIONS IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMANS	60/654,571	2/22/2005			United States of America
CONTROLLED RELEASE FORMULATIONS AND CO-FORMULATIONS OF DIAZOXIDE AND DERIVATIVES THEREOF WITH IMPROVED BIOAVAILABILITY, SAFETY AND THERAPEUTIC EFFICACY	60/668,912	4/6/2005			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2005280058	8/25/2005	2005280058	12/16/2010	Australia
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Belgium
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2578224	8/25/2005			Canada
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Switzerland
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200580035520.5	8/25/2005			China
PHARMACEUTICAL FORMULATIONS OF POTASSIUM	05791600.9	8/25/2005	1781265	4/7/2010	Germany

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Title	Application No.	Application Date	Registration No.	Registration Date	Country
ATP CHANNEL OPENERS AND USES THEREOF					
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Denmark
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	European Patent Office
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Spain
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	France
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	United Kingdom
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08101936.7	8/25/2005			Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Ireland
A DELAYED RELEASE PHARMACEUTICAL FORMULATION COMPRISNG KATP CHANNEL OPENERS	1314/DELNP/2007	8/25/2005	284890	7/3/2017	India
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Italy
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2007-530177	8/25/2005			Japan
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Netherlands

Title	Application No.	Application Date	Registration No.	Registration Date	Country
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Sweden
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11/212,130	8/25/2005			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2005/030481	8/25/2005			Patent Cooperation Treaty
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2010246520	8/25/2005	2010246520	2/16/2012	Australia
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	201510404296.8	8/25/2005			China
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	10159141.0	8/25/2005			European Patent Office
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11100582.1	8/25/2005			Hong Kong
A DELAYED RELEASE PHARMACEUTICAL FORMULATION COMPRISING KATP CHANNEL OPENERS	201718019829	8/25/2005			India
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/368,215	2/9/2009			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Switzerland
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Germany
PHARMACEUTICAL FORMULATIONS OF POTASSIUM	11184285.2	8/25/2005	2404605	4/22/2015	European Patent Office

326784900

Title	Application No.	Application Date	Registration No.	Registration Date	Country
ATP CHANNEL OPENERS AND USES THEREOF					
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Spain
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	France
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	United Kingdom
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12101988.8	8/25/2005	1161133	3/11/2016	Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Italy
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/370,456	2/12/2009			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16102894.5	8/25/2005			Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	14/458,032	8/12/2014	9,782,416	10/10/2017	United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/683,516	8/22/2017			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/937,594	3/27/2018			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/692,852	11/22/2019			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/545,764	12/19/2023			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/792,416	8/1/2024			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/756,941	1/5/2006			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/854,740	10/27/2006			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Austria
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2006335153	12/20/2006	2006335153	6/28/2012	Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2636274	12/20/2006	2636274	5/26/2015	Canada
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200680050425.7	12/20/2006	200680050425.7	6/10/2015	China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Denmark
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Spain

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Greece
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08112056.8	12/20/2006	1117078	2/17/2012	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Croatia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	4890/DELNP/2008	12/20/2006	280967	3/3/2017	India
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2008-549491	12/20/2006	5543110	5/16/2014	Japan
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Luxembourg
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Netherlands
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Poland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Sweden
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Turkey

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11/614,044	12/20/2006	7,799,777	9/21/2010	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2006/048711	12/20/2006			Patent Cooperation Treaty
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2012203517	12/20/2006	2012203517	8/7/2014	Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	201310041514.7	12/20/2006	201310041514.7	1/6/2016	China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60 2006 057 398.7	12/20/2006	2404604	2/6/2019	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12101989.7	12/20/2006	HK1161134	11/15/2019	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/391,990	2/24/2009	7,572,789	8/11/2009	United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Spain
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	42020002856.1	12/20/2006	HK40013034	2/14/2025	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Liechtenstein
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/534,018	7/31/2009			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/819,155	6/18/2010			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/671,418	11/7/2012			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/846,542	3/18/2013	9,381,202	7/5/2016	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/195,826	6/28/2016	10,085,998	10/2/2018	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/110,621	8/23/2018			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/680,093	11/11/2019	11,045,478	6/29/2021	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	17/332,878	5/27/2021	11,786,536	10/17/2023	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/454,595	8/23/2023			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/947,628	7/2/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/949,207	7/11/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/950,854	7/19/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/986,251	11/7/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2008272923	7/1/2008			Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2692160	7/1/2008			Canada
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200880105223.7	7/1/2008			China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08772317.7	7/1/2008			European Patent Office

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	10109409.4	7/1/2008			Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2010-515241	7/1/2008			Japan
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/166,251	7/1/2008			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2008/068936	7/1/2008			Patent Cooperation Treaty
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/406,482	2/27/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/543,665	7/6/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	61/603,923	2/27/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13754866.5	2/25/2013			European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	14/466,852	8/22/2014	9,765,043	9/19/2017	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2013/027676	2/25/2013			Patent Cooperation Treaty
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/080,150	11/14/2014			United States of America
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/138,245	3/25/2015			United States of America
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/170,035	6/2/2015			United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	62/221,359	9/21/2015			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Armenia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Austria
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2015346196	11/12/2015	2015346196	5/16/2019	Australia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Azerbaijan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Belgium
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	BR1120170099861	11/12/2015			Brazil
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Belarus
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2966907	11/12/2015	2966907	9/7/2021	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Switzerland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201580072525.9	11/12/2015	201580072525.9	7/30/2021	China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Germany
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Denmark

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Eurasian Patent Organization
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	European Patent Office
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Spain
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Finland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	France
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	United Kingdom
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Greece
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18103580.0	11/12/2015	1243954	3/19/2021	Hong Kong
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Hungary
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00-2017-03651	11/12/2015	IDP000075724	4/1/2021	Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Ireland

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	252111	11/12/2015	252111	12/31/2021	Israel
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201717020516	11/12/2015			India
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Italy
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2017-544842	11/12/2015	6709226	5/26/2020	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Kyrgyzstan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10-2017-7016089	11/12/2015	10-2323613	11/2/2021	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Kazakhstan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	J/005421	11/12/2015	J/005421	1/24/2022	Macao
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	MX/A/2017/006244	11/12/2015	381305	4/8/2021	Mexico
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PI 2017701659	11/12/2015	MY-187610-A	10/4/2021	Malaysia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Netherlands
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Norway

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	731565	11/12/2015	731565	9/28/2021	New Zealand
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Poland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Russian Federation
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Sweden
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	11201703721S	11/12/2015	11201703721S	12/9/2019	Singapore
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Tajikistan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Turkmenistan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Turkey
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	14/940,018	11/12/2015	9,757,384	9/12/2017	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PCT/US2015/060455	11/12/2015			Patent Cooperation Treaty
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2017/04056	11/12/2015			South Africa

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2019202906	11/12/2015	2019202906	9/3/2020	Australia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	BR 122023002893-7	11/12/2015			Brazil
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3125839	11/12/2015	3125839	10/24/2023	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	202110786768.6	11/12/2015			China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00201909107	11/12/2015	IDP000093460	5/8/2024	Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2020-002555	11/12/2015	6955039	10/4/2021	Japan
METHODS FOR TREATING SUBJECTS WITH SMITH-MAGENIS SYNDROME	10-2021-7035884	11/12/2015	10-2452254	10/4/2022	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	MX/A/2021/003982	11/12/2015	393030	6/9/2022	Mexico
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PI2021000027	11/12/2015	MY-205748-A	11/11/2024	Malaysia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	768958	11/12/2015	768958	11/2/2021	New Zealand
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10201910108T	11/12/2015	10201910108T	9/14/2020	Singapore
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI	15/671,792	8/8/2017	10,058,557	8/28/2018	United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3125835	11/12/2015	3125835	1/3/2023	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	202511504739.0	11/12/2015			China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00202101729	11/12/2015			Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2021-160423	11/12/2015	7232300	2/21/2023	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME	10-2022-7029800	11/12/2015	10-2517840	3/30/2023	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	16/041,237	7/20/2018	10,456,408	10/29/2019	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3210794	11/12/2015			Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2023-023047	11/12/2015	7645913	3/6/2025	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10-2023-7010935	11/12/2015	10-2598666	11/1/2023	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	16/573,965	9/17/2019	10,874,676	12/29/2020	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	17/104,433	11/25/2020			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/421,914	1/24/2024	12,109,216	10/8/2024	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/824,811	9/4/2024	12,178,823	12/31/2024	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/988,636	12/19/2024	12,343,348	7/1/2025	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME	19/224,580	5/30/2025	12,419,895	9/23/2025	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	19/329,408	9/15/2025			United States of America



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
14/940,018	12/30/2025 07:23:55 PM Z ET	SLNO-034/04US 333072-2375

Title of Invention

METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	9757384
CONFIRMATION #	6992	FILED BY	Diana Sciamanna
PATENT CENTER #	73799239	FILING DATE	11/12/2015
CUSTOMER #	58249	FIRST NAMED INVENTOR	Neil M. Cowen
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	JOHN KOZLOWSKI

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
SLNO-034_04US_POA.pdf	1	Power of Attorney	279 KB
SLNO-034_04US_Statement.pdf	24	Assignee showing of ownership per 37 CFR 3.73	365 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
SLNO-034_04US_POA.pdf	C86CC558652DB24D35C2D9A83699BB461A8C092493E4745B3 E1F78AF3FC681E859EE638EDB6CDF4DEDD8BEF8B67F30DB 3883F4A2FC767A2446963BBF71758DE6
SLNO-	F31F29FF1BF03120FC9A0EB1F4096A210011CE8D5ED6C53DF

034_04US_Statement.pdf

1BC4EC0B8FCA5CB5AA9237CBD2817EAA21C0EA15F6253368
AFE190EFB6ABDC17CA12EAE88CFC4CC

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Communication for Application for Extension of United States Patent No.
9,757,384 under 35 U.S.C. §156
From Application No. 14/940,018
VYKAT™ XR
Atty Dkt. No. SLNO-034/04US 333072-2375
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Neil M. COWEN	Confirmation No.:	6992
Patent No.:	9,757,384	Group Art Unit:	1625
Issued:	September 12, 2017	Examiner:	Taylor V. Oh
For:	METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME – Application for § 156 Patent Term Extension		

**37 C.F.R. § 1.765 COMMUNICATION
FOR APPLICATION FOR EXTENSION OF PATENT TERM UNDER
35 U.S.C. § 156 FOR U.S. PATENT NO. 9,757,384 (VYKAT™ XR)**

Mail Stop Hatch-Waxman PTE
Office of Patent Legal Administration
Room MDW 7D55
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Alexandria, VA 22314

This submission under 37 C.F.R. § 1.765 is filed in connection with the Application for Extension of Patent Term under 35 U.S.C. § 156 (hereafter “the PTE application”), based on the above-referenced patent pursuant to the FDA approval of VYKAT™ XR (Atty Docket Ref.: SLNO-034/04US 333072-2375).

Applicant hereby notifies the Office that Essentialis, Inc. has assigned the above-referenced patent to Soleno Therapeutics, Inc., the NDA holder for VYKAT™ XR. The change of Assignee took place after the time of filing the PTE application.

A copy of Applicant's submission requesting the recordation of the executed Assignment from Essentialis, Inc. to Soleno Therapeutics, Inc. is included herewith as Exhibit A. This Assignment was submitted to the USPTO for recordation on December 3, 2025, however Applicant has not yet received a Notice of Recordation.

A new Power of Attorney from Soleno Therapeutics, Inc, including a Statement under 3.73(c) and copy of the executed assignment, was submitted to the Office on December 30, 2025.

Applicant respectfully requests that any Certificate of Extension issued in connection with the PTE application be issued with Soleno Therapeutics, Inc. as the Assignee.

Conclusion:

Should the USPTO have any questions regarding the information provided in this communication, please contact the undersigned at (650) 843-5387.

Communication for Application for Extension of United States Patent No.
9,757,384 under 35 U.S.C. §156
From Application No. 14/940,018
VYKAT™ XR
Atty Dkt. No. SLNO-034/04US 333072-2375
(PATENT)

Applicant believes that no fees are due in connection with the submission of this communication. However, should any fee be due, the Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283 referencing Docket No. SLNO-034/04US 333072-2375.

Dated: January 16, 2026

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004

Electronic signature: /Kimberly A. Bolin/
Kimberly A. Bolin
Reg. No. 44,546
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Tel: (650) 843-5387
Fax: (202) 842-7899

Docket No.: SLNO-034/04US 333072-2375
PTE Application for U.S. Pat. No. 9,757,384
VYKAT™ XR

EXHIBIT A

PATENT ASSIGNMENT COVER SHEET

Assignment ID: 1449015

Electronic Version v1.1
Stylesheet Version v1.2

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT
CONVEYING PARTY DATA	
Name	Execution Date
Essentialis, Inc.	11/25/2025
RECEIVING PARTY DATA	
Name:	Soleno Therapeutics , Inc.
Street Address:	100 Marine Parkway, Suite 400
City:	Redwood City
State/Country:	CALIFORNIA UNITED STATES
Postal Code:	94065
PROPERTY NUMBERS Total:54	
Property Type	Number
Application Number:	60604085
Application Number:	60624219
Application Number:	60654571
Application Number:	60668912
Application Number:	11212130
Application Number:	12368215
Application Number:	12370456
Application Number:	15683516
Application Number:	15937594
Application Number:	16692852
Application Number:	18545764
Application Number:	18792416
Application Number:	60756941
Application Number:	60854740
Application Number:	12534018
Application Number:	12819155

Application Number:	13671418
Application Number:	16110621
Application Number:	18454595
Application Number:	60947628
Application Number:	60949207
Application Number:	60950854
Application Number:	60986251
Application Number:	12166251
Application Number:	13406482
Application Number:	13543665
Application Number:	61603923
Application Number:	62080150
Application Number:	62138245
Application Number:	62170035
Application Number:	62221359
Application Number:	17104433
Application Number:	19329408
Patent Number:	9782416
Patent Number:	7799777
Patent Number:	7572789
Patent Number:	9381202
Patent Number:	10085998
Patent Number:	11045478
Patent Number:	11786536
Patent Number:	9765043
Patent Number:	9757384
Patent Number:	10058557
Patent Number:	10456408
Patent Number:	10874676
Patent Number:	12109216
Patent Number:	12178823
Patent Number:	12343348
Patent Number:	12419895
PCT Number:	US0530481
PCT Number:	US0648711
PCT Number:	US0868936
PCT Number:	US1327676
PCT Number:	US1560455

CORRESPONDENCE DATA

Fax Number: 2028427899
Phone: (650)843-5762
Email: dsciamanna@cooley.com

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Correspondent Name: COOLEY LLP
Address Line 1: ATTN: IP DOCKETING DEPARTMENT
Address Line 2: 1299 PENNSYLVANIA AVENUE NW, SUITE 700
Address Line 4: WASHINGTON , DISTRICT OF COLUMBIA 20004

ATTORNEY DOCKET NUMBER:	SLNO 333072-2000
NAME OF SUBMITTER:	Diana Sciamanna
Signature:	/Diana Sciamanna/
Date:	12/03/2025
TOTAL ATTACHMENTS: 1 source= Assignment.pdf	

Attorney Docket No. SLNO 333072-2000

**ASSIGNMENT OF PATENT RIGHTS
(Company to Company)**

Essentialis, Inc., a Delaware corporation, having its principal place of business at 100 Marine Parkway, Suite 400, Redwood City, CA 94065 (herein referred to as “Assignor”) owns the entire right, title and interest in any Letters Patent(s) (“said patent(s)”) and any Patent application(s) (“said application(s)”) set forth in the attached **Schedule A**, as well as any invention(s) (“said invention(s)”) disclosed in said application(s) and said patent(s).

WHEREAS, Soleno Therapeutics, Inc., a Delaware corporation, having its principal place of business at 100 Marine Parkway, Suite 400, Redwood City, CA 94065 (the “Assignee”), its successors, legal representatives, and assigns, is desirous of acquiring the Assignor’s entire right, title, and interest in and to said invention(s), said application(s) for patent and/or registered design, and said patent(s); the right to file applications for patent and/or registered design of the United States or other countries on said invention(s); the entire right, title and interest in and to any application(s) for patent and/or registered design, and patent(s) of the United States or other countries claiming priority to, and/or benefit of, these applications and patents; the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) for patent and/or registered design and said patent(s); and the entire right, title, and interest in and to any and all Letters Patent or Patents and/or registered design(s), United States or foreign, to be obtained for said invention(s) and said application(s);

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, and to the extent that the Assignor has not done so already via a prior agreement with the Assignee or a predecessor in interest of the Assignee, or if the Assignor has already done so via a prior agreement with the Assignee or a predecessor in interest of the Assignee then in confirmation of said prior agreement, the Assignor has sold, assigned, transferred, and set over, and by these presents does sell, assign, transfer, and set over, unto the Assignee, its successors, legal representatives, and assigns Assignor’s right, title, and interest in and to:

- (a) said invention(s);
- (b) said application(s) for patent and/or registered design;
- (c) said patent(s);
- (d) the right to file applications for patent and/or registered design of the United States or other countries on said invention(s), including all rights under the Hague Convention, the Paris Convention for the

Protection of Industrial Property, and under the Patent Cooperation Treaty, and all rights of claiming priority in any country of the world;

- (e) any application(s) for patent and/or registered design of the United States or other countries claiming the invention(s);
- (f) any application(s) for patent and/or registered design of the United States or other countries claiming priority to, and/or the benefit of, at least one of the application(s) for patent and/or registered design identified above or any application(s) for patent claiming the invention(s), including any priority application(s), substitute application(s), division(s), continuation(s), and continuation(s)-in-part;
- (g) the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) for patent and/or registered design and said patent(s) identified in the preceding paragraphs (b)-(f) and of any and all patent(s) and/or registered design(s) granted based thereon in the United States and in all other countries; and
- (h) any and all Letters Patent or Patents and/or registered design(s), United States or foreign, to be obtained for said invention(s), said application(s) for patent and/or registered design, and said patent(s), including any reissue(s), reexamination(s), revival(s), renewal(s) and extension(s) of said patent(s).

The above-granted rights, titles, and interests are to be held and enjoyed by the Assignee, for its own use and behalf and the use and behalf of its successors, legal representatives, and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted as fully and entirely as the same would have been held and enjoyed by the Assignor had this sale and assignment not been made;

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns, that, at the time of execution and delivery of these presents, or if applicable, at such time said prior agreement was executed, the Assignor is the sole and lawful owner of Assignor's entire right, title and interest in and to said invention(s), said application(s), and said patent(s), and that the same are unencumbered, and that the Assignor has good and full right and lawful authority to sell and convey the same in the manner herein set forth;

AND for the same consideration, the Assignor also hereby represents that, except for said prior agreement, if applicable, the Assignor has not previously sold, transferred, or encumbered any part of Assignor's right, title, and interest in the Invention(s);

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns that the Assignor will, whenever counsel of the Assignee, or the counsel of its successors, legal representatives, and assigns, shall advise that any proceeding in connection with said invention(s), said application(s), said registered design(s), said patent(s), any application claiming priority to said application(s), any reissue or extension of said patent(s), and any United States or foreign Letters Patent or Patents for said invention(s) or said application(s), including interference and derivation proceedings, and any post-grant proceedings (e.g., opposition proceedings, post-grant reviews, *Inter partes* reviews, supplemental examinations, etc.), is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent or Patents for said invention(s), without charge to the Assignee, its successors, legal representatives, and assigns, but at the cost and expense of the Assignee, its successors, legal representatives, and assigns;

AND the Assignor waives all rights to challenge the validity of said invention(s) in the United States and its territorial possessions and in all foreign countries and of all Letters Patent or similar legal protection in the United States and its territorial possessions and in any and all foreign countries to be obtained for said invention(s) by said application or any continuation, continuation-in-part, divisional, renewal, substitute, or reissue thereof or any legal equivalent thereof in a foreign country for the full term or terms for which the same may be granted;

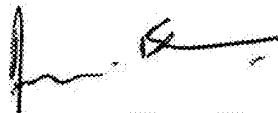
AND the Assignor hereby authorizes and requests the attorneys of COOLEY LLP to insert in the spaces provided the title, application number, filing date, attorney docket number, assignment recordation date, and Reel/Frame No(s). of the Patent Application(s) and/or Letters Patent(s) identified herein when known;

AND the Assignor hereby requests the Commissioner of Patents to issue any and all aforementioned patent(s) of the United States to the Assignee, as the Assignee of said invention(s) and the Letters Patent to be issued thereon, for the use of and on behalf of the Assignee, its successors, legal representatives, and assigns;

AND Assignor(s) and Assignee(s) understand that electronic signatures are acceptable and that, by signing electronically, signatories agree to the use of electronic signatures.

For and on behalf of ASSIGNOR:

Date: 11/25/2025

By: 

Name: ANISH BHATTACHARYA

Title: CEO

Company: Essentialis, Inc.

By signing, I confirm that I am entitled to sign legally binding acts on behalf of
Essentialis, Inc.

My position in Essentialis, Inc. is: CEO

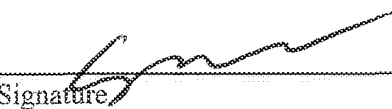
Witness:


Signature

11/25/2025
Date

Kartlyn Bhattacharya
Printed Name

Witness:


Signature

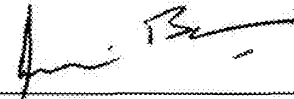
11/25/2025
Date

ANNIE GRAVES
Printed Name

For and on behalf of ASSIGNEE:

Date: 11/25/2025

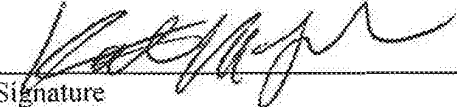
By:


Name: ANISH BHATTACHARYA
Title: CEO
Company: Soleno Therapeutics, Inc.

By signing, I confirm that I am entitled to sign legally binding acts on behalf of Soleno Therapeutics, Inc.

My position in Soleno Therapeutics, Inc. is: CEO

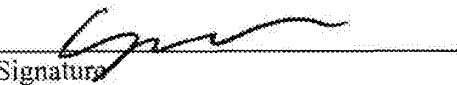
Witness:


Signature

Kaitlyn Johnson
Printed Name

11/25/2025
Date

Witness:


Signature

ANNIE GRIMES
Printed Name

11/25/2025
Date

SCHEDULE A

Title	Application No.	Application Date	Registration No.	Registration Date	Country
USE OF DIAZOXIDE OR ITS DERIVATIVES IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMANS AND ANIMALS	60/604,085	8/25/2004			United States of America
THERAPEUTIC OUTCOMES FROM THE USE OF DIAZOXIDE OR ITS DERIVATIVES IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMAN AND ANIMALS	60/624,219	11/3/2004			United States of America
USE OF DIAZOXIDE OR ITS DERIVATIVES AND CO-FORMULATIONS IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMANS	60/654,571	2/22/2005			United States of America
CONTROLLED RELEASE FORMULATIONS AND CO-FORMULATIONS OF DIAZOXIDE AND DERIVATIVES THEREOF WITH IMPROVED BIOAVAILABILITY, SAFETY AND THERAPEUTIC EFFICACY	60/668,912	4/6/2005			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2005280058	8/25/2005	2005280058	12/16/2010	Australia
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Belgium
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2578224	8/25/2005			Canada
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Switzerland
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200580035520.5	8/25/2005			China
PHARMACEUTICAL FORMULATIONS OF POTASSIUM	05791600.9	8/25/2005	1781265	4/7/2010	Germany

326784900

Title	Application No.	Application Date	Registration No.	Registration Date	Country
ATP CHANNEL OPENERS AND USES THEREOF					
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Denmark
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	European Patent Office
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Spain
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	France
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	United Kingdom
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08101936.7	8/25/2005			Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Ireland
A DELAYED RELEASE PHARMACEUTICAL FORMULATION COMPRISNG KATP CHANNEL OPENERS	1314/DELNP/2007	8/25/2005	284890	7/3/2017	India
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Italy
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2007-530177	8/25/2005			Japan
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Netherlands

Title	Application No.	Application Date	Registration No.	Registration Date	Country
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Sweden
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11/212,130	8/25/2005			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2005/030481	8/25/2005			Patent Cooperation Treaty
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2010246520	8/25/2005	2010246520	2/16/2012	Australia
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	201510404296.8	8/25/2005			China
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	10159141.0	8/25/2005			European Patent Office
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11100582.1	8/25/2005			Hong Kong
A DELAYED RELEASE PHARMACEUTICAL FORMULATION COMPRISING KATP CHANNEL OPENERS	201718019829	8/25/2005			India
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/368,215	2/9/2009			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Switzerland
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Germany
PHARMACEUTICAL FORMULATIONS OF POTASSIUM	11184285.2	8/25/2005	2404605	4/22/2015	European Patent Office

Title	Application No.	Application Date	Registration No.	Registration Date	Country
ATP CHANNEL OPENERS AND USES THEREOF					
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Spain
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	France
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	United Kingdom
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12101988.8	8/25/2005	1161133	3/11/2016	Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Italy
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/370,456	2/12/2009			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16102894.5	8/25/2005			Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	14/458,032	8/12/2014	9,782,416	10/10/2017	United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/683,516	8/22/2017			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/937,594	3/27/2018			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/692,852	11/22/2019			United States of America

326784900

Title	Application No.	Application Date	Registration No.	Registration Date	Country
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/545,764	12/19/2023			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/792,416	8/1/2024			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/756,941	1/5/2006			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/854,740	10/27/2006			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Austria
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2006335153	12/20/2006	2006335153	6/28/2012	Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2636274	12/20/2006	2636274	5/26/2015	Canada
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200680050425.7	12/20/2006	200680050425.7	6/10/2015	China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Denmark
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Spain

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Greece
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08112056.8	12/20/2006	1117078	2/17/2012	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Croatia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	4890/DELNP/2008	12/20/2006	280967	3/3/2017	India
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2008-549491	12/20/2006	5543110	5/16/2014	Japan
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Luxembourg
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Netherlands
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Poland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Sweden
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Turkey

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11/614,044	12/20/2006	7,799,777	9/21/2010	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2006/048711	12/20/2006			Patent Cooperation Treaty
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2012203517	12/20/2006	2012203517	8/7/2014	Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	201310041514.7	12/20/2006	201310041514.7	1/6/2016	China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60 2006 057 398.7	12/20/2006	2404604	2/6/2019	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12101989.7	12/20/2006	HK1161134	11/15/2019	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/391,990	2/24/2009	7,572,789	8/11/2009	United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Spain
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	42020002856.1	12/20/2006	HK40013034	2/14/2025	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Liechtenstein
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/534,018	7/31/2009			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/819,155	6/18/2010			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/671,418	11/7/2012			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/846,542	3/18/2013	9,381,202	7/5/2016	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/195,826	6/28/2016	10,085,998	10/2/2018	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/110,621	8/23/2018			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/680,093	11/11/2019	11,045,478	6/29/2021	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	17/332,878	5/27/2021	11,786,536	10/17/2023	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/454,595	8/23/2023			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/947,628	7/2/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/949,207	7/11/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/950,854	7/19/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/986,251	11/7/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2008272923	7/1/2008			Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2692160	7/1/2008			Canada
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200880105223.7	7/1/2008			China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08772317.7	7/1/2008			European Patent Office

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	10109409.4	7/1/2008			Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2010-515241	7/1/2008			Japan
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/166,251	7/1/2008			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2008/068936	7/1/2008			Patent Cooperation Treaty
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/406,482	2/27/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/543,665	7/6/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	61/603,923	2/27/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13754866.5	2/25/2013			European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	14/466,852	8/22/2014	9,765,043	9/19/2017	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2013/027676	2/25/2013			Patent Cooperation Treaty
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/080,150	11/14/2014			United States of America
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/138,245	3/25/2015			United States of America
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/170,035	6/2/2015			United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	62/221,359	9/21/2015			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Armenia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Austria
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2015346196	11/12/2015	2015346196	5/16/2019	Australia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Azerbaijan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Belgium
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	BR1120170099861	11/12/2015			Brazil
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Belarus
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2966907	11/12/2015	2966907	9/7/2021	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Switzerland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201580072525.9	11/12/2015	201580072525.9	7/30/2021	China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Germany
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Denmark

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Eurasian Patent Organization
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	European Patent Office
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Spain
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Finland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	France
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	United Kingdom
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Greece
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18103580.0	11/12/2015	1243954	3/19/2021	Hong Kong
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Hungary
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00-2017-03651	11/12/2015	IDP000075724	4/1/2021	Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Ireland

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	252111	11/12/2015	252111	12/31/2021	Israel
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201717020516	11/12/2015			India
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Italy
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2017-544842	11/12/2015	6709226	5/26/2020	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Kyrgyzstan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10-2017-7016089	11/12/2015	10-2323613	11/2/2021	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Kazakhstan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	J/005421	11/12/2015	J/005421	1/24/2022	Macao
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	MX/A/2017/006244	11/12/2015	381305	4/8/2021	Mexico
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PI 2017701659	11/12/2015	MY-187610-A	10/4/2021	Malaysia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Netherlands
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Norway

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	731565	11/12/2015	731565	9/28/2021	New Zealand
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Poland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Russian Federation
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Sweden
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	11201703721S	11/12/2015	11201703721S	12/9/2019	Singapore
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Tajikistan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Turkmenistan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Turkey
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	14/940,018	11/12/2015	9,757,384	9/12/2017	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PCT/US2015/060455	11/12/2015			Patent Cooperation Treaty
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2017/04056	11/12/2015			South Africa

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2019202906	11/12/2015	2019202906	9/3/2020	Australia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	BR 122023002893-7	11/12/2015			Brazil
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3125839	11/12/2015	3125839	10/24/2023	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	202110786768.6	11/12/2015			China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00201909107	11/12/2015	IDP000093460	5/8/2024	Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2020-002555	11/12/2015	6955039	10/4/2021	Japan
METHODS FOR TREATING SUBJECTS WITH SMITH-MAGENIS SYNDROME	10-2021-7035884	11/12/2015	10-2452254	10/4/2022	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	MX/A/2021/003982	11/12/2015	393030	6/9/2022	Mexico
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PI2021000027	11/12/2015	MY-205748-A	11/11/2024	Malaysia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	768958	11/12/2015	768958	11/2/2021	New Zealand
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10201910108T	11/12/2015	10201910108T	9/14/2020	Singapore
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI	15/671,792	8/8/2017	10,058,557	8/28/2018	United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3125835	11/12/2015	3125835	1/3/2023	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	202511504739.0	11/12/2015			China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00202101729	11/12/2015			Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2021-160423	11/12/2015	7232300	2/21/2023	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME	10-2022-7029800	11/12/2015	10-2517840	3/30/2023	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	16/041,237	7/20/2018	10,456,408	10/29/2019	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3210794	11/12/2015			Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2023-023047	11/12/2015	7645913	3/6/2025	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10-2023-7010935	11/12/2015	10-2598666	11/1/2023	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	16/573,965	9/17/2019	10,874,676	12/29/2020	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	17/104,433	11/25/2020			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/421,914	1/24/2024	12,109,216	10/8/2024	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/824,811	9/4/2024	12,178,823	12/31/2024	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/988,636	12/19/2024	12,343,348	7/1/2025	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME	19/224,580	5/30/2025	12,419,895	9/23/2025	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	19/329,408	9/15/2025			United States of America



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
14/940,018	01/16/2026 06:04:14 PM Z ET	SLNO-034/04US 333072-2375

Title of Invention

METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	9757384
CONFIRMATION #	6992	FILED BY	Diana Sciamanna
PATENT CENTER #	74026703	FILING DATE	11/12/2015
CUSTOMER #	58249	FIRST NAMED INVENTOR	Neil M. Cowen
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Kimberly Bolin

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
SLNO-034_04US Communication.pdf	29	Disclosure Under 37 CFR 1.765 in a Patent Term Extension Application	678 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
SLNO-034_04US Communication.pdf	A1C19BEF59574773CE45FE7D0E03CC9028DBAAD452CE8F72 E1CAAF0975C1AB148F739ED4119B0AA5B639555F730FF589F EC6EA7D99A1E606CDBDFCE06FA9095D

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as

described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
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14/940,018

11/12/2015

Neil M. Cowen

SLNO-034/04US

333072-2375

CONFIRMATION NO. 6992

58249

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POA ACCEPTANCE LETTER



OC000000102900097

Date Mailed: 03/17/2026

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/30/2025.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/ctuazon/

Communication for Application for Extension of United States Patent No.
9,757,384 under 35 U.S.C. §156
From Application No. 14/940,018
VYKAT™ XR
Atty Dkt. No. SLNO-034/04US 333072-2375
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Neil M. COWEN	Confirmation No.:	6992
Patent No.:	9,757,384	Group Art Unit:	1625
Issued:	September 12, 2017	Examiner:	Taylor V. Oh
For:	METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME – Application for § 156 Patent Term Extension		

**37 C.F.R. § 1.765 COMMUNICATION
FOR APPLICATION FOR EXTENSION OF PATENT TERM UNDER
35 U.S.C. § 156 FOR U.S. PATENT NO. 9,757,384 (VYKAT™ XR)**

Mail Stop Hatch-Waxman PTE
Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

This submission under 37 C.F.R. § 1.765 is filed in connection with the Application for Extension of Patent Term under 35 U.S.C. § 156 (hereafter “the PTE application”), based on the above-referenced patent pursuant to the FDA approval of VYKAT™ XR (Atty Docket Ref.: SLNO-034/04US 333072-2375).

Patentee hereby notifies the Office that a Notice of Recordation has been issued for the Assignment that was previously submitted in order to change the Assignee to Soleno Therapeutics, Inc. (attached as Exhibit A in the Communication under 37 C.F.R. § 1.765 filed on January 16, 2026). At the time of filing the prior Communication, the Notice of Recordation was not yet

available. Now that the Notice has been issued, Patentee is including a copy as Exhibit A to make it of record and notes that the Assignment was recorded at reel/frame 73832/0312. For completeness, Exhibit A included herewith also includes a copy of the underlying Assignment that was recorded at reel/frame 73832/0312, in addition to the Notice.

Patentee respectfully requests that any Certificate of Extension issued in connection with the PTE application be issued with Soleno Therapeutics, Inc. as the Assignee.

Conclusion:

Should the USPTO have any questions regarding the information provided in this communication, please contact the undersigned at (650) 843-5387.

Communication for Application for Extension of United States Patent No.
9,757,384 under 35 U.S.C. §156
From Application No. 14/940,018
VYKATTM XR
Atty Dkt. No. SLNO-034/04US 333072-2375
(PATENT)

Patentee believes that no fees are due in connection with the submission of this communication. However, should any fee be due, the Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283 referencing Docket No. SLNO-034/04US 333072-2375.

Dated: April 16, 2026

Respectfully submitted,
COOLEY LLP

USPTO CUSTOMER NO. 58249

COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004

Electronic signature: /Kimberly A. Bolin/
Kimberly A. Bolin
Reg. No. 44,546
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Fax: (202) 842-7899

Docket No.: SLNO-034/04US 333072-2375
PTE Application for U.S. Pat. No. 9,757,384
VYKAT™ XR

EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

FEBRUARY 23, 2026

PTAS

COOLEY LLP
ATTN: IP DOCKETING DEPARTMENT
1299 PENNSYLVANIA AVENUE NW, SUITE 700
WASHINGTON, DC 20004

509540667

UNITED STATES PATENT AND TRADEMARK OFFICE NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT RECORDATION BRANCH OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE ASSIGNMENT RECORDATION BRANCH AT 571-272-3350. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, MAIL STOP: ASSIGNMENT RECORDATION BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313.

RECORDATION DATE: 12/03/2025

REEL/FRAME: 73832/0312
NUMBER OF PAGES: 25

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST

DOCKET NUMBER: SLNO 333072-2000

ASSIGNOR:
ESSENTIALIS, INC.

DOC DATE: 11/25/2025

ASSIGNEE:
SOLENO THERAPEUTICS, INC.
100 MARINE PARKWAY, SUITE 400
REDWOOD CITY, CALIFORNIA, 94065

APPLICATION NUMBER: 60604085 FILING DATE: 08/25/2004
PATENT NUMBER: ISSUE DATE:
TITLE: Use of diazoxide or its derivatives in the treatment of
obesity and other diseases of humans and animals

APPLICATION NUMBER: 60624219 FILING DATE: 11/03/2004
PATENT NUMBER: ISSUE DATE:
TITLE: Therapeutic outcomes from the use of diazoxide or its
derivatives in the treatment of obesity and other diseases
of human and animals

APPLICATION NUMBER: 60654571 FILING DATE: 02/22/2005
PATENT NUMBER: ISSUE DATE:
TITLE: Use of diazoxide or its derivatives and co-formulations in
the treatment of obesity and other diseases of humans

APPLICATION NUMBER: 60668912 FILING DATE: 04/06/2005
PATENT NUMBER: ISSUE DATE:
TITLE: Controlled release formulations and co-formulations of
diazoxide and derivatives thereof with improved
bioavailability, safety and therapeutic efficacy

APPLICATION NUMBER: 11212130 FILING DATE: 08/25/2005
PATENT NUMBER: ISSUE DATE:
TITLE: Pharmaceutical formulations of potassium ATP channel
openers and uses thereof

APPLICATION NUMBER: 12368215 FILING DATE: 02/09/2009
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 12370456 FILING DATE: 02/12/2009
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 15683516 FILING DATE: 08/22/2017
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 15937594 FILING DATE: 03/27/2018
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 16692852 FILING DATE: 11/22/2019
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 18545764 FILING DATE: 12/19/2023
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 18792416 FILING DATE: 08/01/2024
PATENT NUMBER: ISSUE DATE:
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 60756941 FILING DATE: 01/05/2006
PATENT NUMBER: ISSUE DATE:
TITLE: Salts of potassium ATP channel openers and uses thereof

APPLICATION NUMBER: 60854740 FILING DATE: 10/27/2006
PATENT NUMBER: ISSUE DATE:
TITLE: Salts of potassium ATP channel openers and uses thereof

APPLICATION NUMBER: 12534018 FILING DATE: 07/31/2009
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 12819155 FILING DATE: 06/18/2010
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 13671418 FILING DATE: 11/07/2012
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 16110621 FILING DATE: 08/23/2018
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 18454595 FILING DATE: 08/23/2023
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 60947628 FILING DATE: 07/02/2007
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 60949207 FILING DATE: 07/11/2007
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 60950854 FILING DATE: 07/19/2007
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 60986251 FILING DATE: 11/07/2007
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 12166251 FILING DATE: 07/01/2008
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 13406482 FILING DATE: 02/27/2012
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 13543665 FILING DATE: 07/06/2012
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 61603923 FILING DATE: 02/27/2012
PATENT NUMBER: ISSUE DATE:
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 62080150 FILING DATE: 11/14/2014
PATENT NUMBER: ISSUE DATE:
TITLE: METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH
PRADER-WILLI SYNDROME

APPLICATION NUMBER: 62138245 FILING DATE: 03/25/2015
PATENT NUMBER: ISSUE DATE:
TITLE: METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH
PRADER-WILLI SYNDROME

APPLICATION NUMBER: 62170035 FILING DATE: 06/02/2015
PATENT NUMBER: ISSUE DATE:
TITLE: METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH
PRADER-WILLI SYNDROME

APPLICATION NUMBER: 62221359 FILING DATE: 09/21/2015
PATENT NUMBER: ISSUE DATE:
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 17104433 FILING DATE: 11/25/2020
PATENT NUMBER: ISSUE DATE:
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 19329408 FILING DATE: 09/15/2025
PATENT NUMBER: ISSUE DATE:
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 14458032 FILING DATE: 08/12/2014
PATENT NUMBER: 9782416 ISSUE DATE: 10/10/2017
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: 11614044 FILING DATE: 12/20/2006
PATENT NUMBER: 7799777 ISSUE DATE: 09/21/2010
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 12391990 FILING DATE: 02/24/2009
PATENT NUMBER: 7572789 ISSUE DATE: 08/11/2009
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 13846542 FILING DATE: 03/18/2013
PATENT NUMBER: 9381202 ISSUE DATE: 07/05/2016
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 15195826 FILING DATE: 06/28/2016
PATENT NUMBER: 10085998 ISSUE DATE: 10/02/2018
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 16680093 FILING DATE: 11/11/2019
PATENT NUMBER: 11045478 ISSUE DATE: 06/29/2021
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 17332878 FILING DATE: 05/27/2021
PATENT NUMBER: 11786536 ISSUE DATE: 10/17/2023
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 14466852 FILING DATE: 08/22/2014
PATENT NUMBER: 9765043 ISSUE DATE: 09/19/2017
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: 14940018 FILING DATE: 11/12/2015
PATENT NUMBER: 9757384 ISSUE DATE: 09/12/2017
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 15671792 FILING DATE: 08/08/2017
PATENT NUMBER: 10058557 ISSUE DATE: 08/28/2018
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 16041237 FILING DATE: 07/20/2018
PATENT NUMBER: 10456408 ISSUE DATE: 10/29/2019
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 16573965 FILING DATE: 09/17/2019
PATENT NUMBER: 10874676 ISSUE DATE: 12/29/2020
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 18421914 FILING DATE: 01/24/2024
PATENT NUMBER: 12109216 ISSUE DATE: 10/08/2024
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 18824811 FILING DATE: 09/04/2024
PATENT NUMBER: 12178823 ISSUE DATE: 12/31/2024
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 18988636 FILING DATE: 12/19/2024
PATENT NUMBER: 12343348 ISSUE DATE: 07/01/2025
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
 OR SMITH-MAGENIS SYNDROME

APPLICATION NUMBER: 19224580 FILING DATE: 05/30/2025
PATENT NUMBER: 12419895 ISSUE DATE: 09/23/2025
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME

APPLICATION NUMBER: FILING DATE: 08/25/2005
PATENT NUMBER: ISSUE DATE:
PCT NUMBER: US0530481
TITLE: PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL
OPENERS AND USES THEREOF

APPLICATION NUMBER: FILING DATE: 12/20/2006
PATENT NUMBER: ISSUE DATE:
PCT NUMBER: US0648711
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: FILING DATE: 07/01/2008
PATENT NUMBER: ISSUE DATE:
PCT NUMBER: US0868936
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: FILING DATE: 02/25/2013
PATENT NUMBER: ISSUE DATE:
PCT NUMBER: US1327676
TITLE: SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF

APPLICATION NUMBER: FILING DATE: 11/12/2015
PATENT NUMBER: ISSUE DATE:
PCT NUMBER: US1560455
TITLE: METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME
OR SMITH-MAGENIS SYNDROME

ASSIGNMENT RECORDATION BRANCH
PUBLIC RECORDS DIVISION

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

Assignment ID: PAT11449015

SUBMISSION TYPE:	NEW ASSIGNMENT	
NATURE OF CONVEYANCE:	ASSIGNMENT	
CONVEYING PARTY DATA		
Name		Execution Date
Essentialis, Inc.		11/25/2025
RECEIVING PARTY DATA		
Company Name:	Solenio Therapeutics, Inc.	
Street Address:	100 Marine Parkway, Suite 400	
City:	Redwood City	
State/Country:	CALIFORNIA	
Postal Code:	94065	
PROPERTY NUMBERS Total: 54		
Property Type	Number	
Application Number:	60604085	
Application Number:	60624219	
Application Number:	60654571	
Application Number:	60668912	
Application Number:	11212130	
Application Number:	12368215	
Application Number:	12370456	
Application Number:	15683516	
Application Number:	15937594	
Application Number:	16692852	
Application Number:	18545764	
Application Number:	18792416	
Application Number:	60756941	
Application Number:	60854740	
Application Number:	12534018	
Application Number:	12819155	
Application Number:	13671418	
Application Number:	16110621	
Application Number:	18454595	
Application Number:	60947628	

Attorney Docket No. SLNO 333072-2000

**ASSIGNMENT OF PATENT RIGHTS
(Company to Company)**

Essentialis, Inc., a Delaware corporation, having its principal place of business at 100 Marine Parkway, Suite 400, Redwood City, CA 94065 (herein referred to as "Assignor") owns the entire right, title and interest in any Letters Patent(s) ("said patent(s)") and any Patent application(s) ("said application(s)") set forth in the attached **Schedule A**, as well as any invention(s) ("said invention(s)") disclosed in said application(s) and said patent(s).

WHEREAS, Soleno Therapeutics, Inc., a Delaware corporation, having its principal place of business at 100 Marine Parkway, Suite 400, Redwood City, CA 94065 (the "Assignee"), its successors, legal representatives, and assigns, is desirous of acquiring the Assignor's entire right, title, and interest in and to said invention(s), said application(s) for patent and/or registered design, and said patent(s); the right to file applications for patent and/or registered design of the United States or other countries on said invention(s); the entire right, title and interest in and to any application(s) for patent and/or registered design, and patent(s) of the United States or other countries claiming priority to, and/or benefit of, these applications and patents; the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) for patent and/or registered design and said patent(s); and the entire right, title, and interest in and to any and all Letters Patent or Patents and/or registered design(s), United States or foreign, to be obtained for said invention(s) and said application(s);

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, and to the extent that the Assignor has not done so already via a prior agreement with the Assignee or a predecessor in interest of the Assignee, or if the Assignor has already done so via a prior agreement with the Assignee or a predecessor in interest of the Assignee then in confirmation of said prior agreement, the Assignor has sold, assigned, transferred, and set over, and by these presents does sell, assign, transfer, and set over, unto the Assignee, its successors, legal representatives, and assigns Assignor's right, title, and interest in and to:

- (a) said invention(s);
- (b) said application(s) for patent and/or registered design;
- (c) said patent(s);
- (d) the right to file applications for patent and/or registered design of the United States or other countries on said invention(s), including all rights under the Hague Convention, the Paris Convention for the

Protection of Industrial Property, and under the Patent Cooperation Treaty, and all rights of claiming priority in any country of the world;

- (e) any application(s) for patent and/or registered design of the United States or other countries claiming the invention(s);
- (f) any application(s) for patent and/or registered design of the United States or other countries claiming priority to, and/or the benefit of, at least one of the application(s) for patent and/or registered design identified above or any application(s) for patent claiming the invention(s), including any priority application(s), substitute application(s), division(s), continuation(s), and continuation(s)-in-part;
- (g) the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) for patent and/or registered design and said patent(s) identified in the preceding paragraphs (b)-(f) and of any and all patent(s) and/or registered design(s) granted based thereon in the United States and in all other countries; and
- (h) any and all Letters Patent or Patents and/or registered design(s), United States or foreign, to be obtained for said invention(s), said application(s) for patent and/or registered design, and said patent(s), including any reissue(s), reexamination(s), revival(s), renewal(s) and extension(s) of said patent(s).

The above-granted rights, titles, and interests are to be held and enjoyed by the Assignee, for its own use and behalf and the use and behalf of its successors, legal representatives, and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted as fully and entirely as the same would have been held and enjoyed by the Assignor had this sale and assignment not been made;

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns, that, at the time of execution and delivery of these presents, or if applicable, at such time said prior agreement was executed, the Assignor is the sole and lawful owner of Assignor's entire right, title and interest in and to said invention(s), said application(s), and said patent(s), and that the same are unencumbered, and that the Assignor has good and full right and lawful authority to sell and convey the same in the manner herein set forth;

AND for the same consideration, the Assignor also hereby represents that, except for said prior agreement, if applicable, the Assignor has not previously sold, transferred, or encumbered any part of Assignor's right, title, and interest in the Invention(s);

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns that the Assignor will, whenever counsel of the Assignee, or the counsel of its successors, legal representatives, and assigns, shall advise that any proceeding in connection with said invention(s), said application(s), said registered design(s), said patent(s), any application claiming priority to said application(s), any reissue or extension of said patent(s), and any United States or foreign Letters Patent or Patents for said invention(s) or said application(s), including interference and derivation proceedings, and any post-grant proceedings (e.g., opposition proceedings, post-grant reviews, *Inter partes* reviews, supplemental examinations, etc.), is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent or Patents for said invention(s), without charge to the Assignee, its successors, legal representatives, and assigns, but at the cost and expense of the Assignee, its successors, legal representatives, and assigns;

AND the Assignor waives all rights to challenge the validity of said invention(s) in the United States and its territorial possessions and in all foreign countries and of all Letters Patent or similar legal protection in the United States and its territorial possessions and in any and all foreign countries to be obtained for said invention(s) by said application or any continuation, continuation-in-part, divisional, renewal, substitute, or reissue thereof or any legal equivalent thereof in a foreign country for the full term or terms for which the same may be granted;

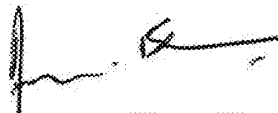
AND the Assignor hereby authorizes and requests the attorneys of COOLEY LLP to insert in the spaces provided the title, application number, filing date, attorney docket number, assignment recordation date, and Reel/Frame No(s). of the Patent Application(s) and/or Letters Patent(s) identified herein when known;

AND the Assignor hereby requests the Commissioner of Patents to issue any and all aforementioned patent(s) of the United States to the Assignee, as the Assignee of said invention(s) and the Letters Patent to be issued thereon, for the use of and on behalf of the Assignee, its successors, legal representatives, and assigns;

AND Assignor(s) and Assignee(s) understand that electronic signatures are acceptable and that, by signing electronically, signatories agree to the use of electronic signatures.

For and on behalf of ASSIGNOR:

Date: 11/25/2025

By: 

Name: ANISH BHATTACHARYA

Title: CEO

Company: Essentialis, Inc.

By signing, I confirm that I am entitled to sign legally binding acts on behalf of
Essentialis, Inc.

My position in Essentialis, Inc. is: CEO

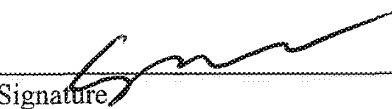
Witness:


Signature

11/25/2025
Date

Kartlyn Bhattacharya
Printed Name

Witness:


Signature

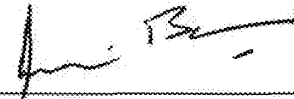
11/25/2025
Date

ANNIE GRAVES
Printed Name

For and on behalf of ASSIGNEE:

Date: 11/25/2025

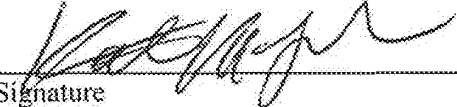
By:


Name: ANISH BHATNAGAR
Title: CEO
Company: Soleno Therapeutics, Inc.

By signing, I confirm that I am entitled to sign legally binding acts on behalf of Soleno Therapeutics, Inc.

My position in Soleno Therapeutics, Inc. is: CEO

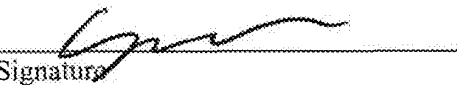
Witness:


Signature

Kaitlyn Johnson
Printed Name

11/25/2025
Date

Witness:


Signature

ANNIE GRIMES
Printed Name

11/25/2025
Date

SCHEDULE A

Title	Application No.	Application Date	Registration No.	Registration Date	Country
USE OF DIAZOXIDE OR ITS DERIVATIVES IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMANS AND ANIMALS	60/604,085	8/25/2004			United States of America
THERAPEUTIC OUTCOMES FROM THE USE OF DIAZOXIDE OR ITS DERIVATIVES IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMAN AND ANIMALS	60/624,219	11/3/2004			United States of America
USE OF DIAZOXIDE OR ITS DERIVATIVES AND CO-FORMULATIONS IN THE TREATMENT OF OBESITY AND OTHER DISEASES OF HUMANS	60/654,571	2/22/2005			United States of America
CONTROLLED RELEASE FORMULATIONS AND CO-FORMULATIONS OF DIAZOXIDE AND DERIVATIVES THEREOF WITH IMPROVED BIOAVAILABILITY, SAFETY AND THERAPEUTIC EFFICACY	60/668,912	4/6/2005			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2005280058	8/25/2005	2005280058	12/16/2010	Australia
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Belgium
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2578224	8/25/2005			Canada
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Switzerland
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200580035520.5	8/25/2005			China
PHARMACEUTICAL FORMULATIONS OF POTASSIUM	05791600.9	8/25/2005	1781265	4/7/2010	Germany

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Title	Application No.	Application Date	Registration No.	Registration Date	Country
ATP CHANNEL OPENERS AND USES THEREOF					
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Denmark
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	European Patent Office
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Spain
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	France
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	United Kingdom
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08101936.7	8/25/2005			Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Ireland
A DELAYED RELEASE PHARMACEUTICAL FORMULATION COMPRISNG KATP CHANNEL OPENERS	1314/DELNP/2007	8/25/2005	284890	7/3/2017	India
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Italy
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2007-530177	8/25/2005			Japan
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Netherlands

Title	Application No.	Application Date	Registration No.	Registration Date	Country
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	05791600.9	8/25/2005	1781265	4/7/2010	Sweden
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11/212,130	8/25/2005			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2005/030481	8/25/2005			Patent Cooperation Treaty
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2010246520	8/25/2005	2010246520	2/16/2012	Australia
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	201510404296.8	8/25/2005			China
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	10159141.0	8/25/2005			European Patent Office
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11100582.1	8/25/2005			Hong Kong
A DELAYED RELEASE PHARMACEUTICAL FORMULATION COMPRISING KATP CHANNEL OPENERS	201718019829	8/25/2005			India
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/368,215	2/9/2009			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Switzerland
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Germany
PHARMACEUTICAL FORMULATIONS OF POTASSIUM	11184285.2	8/25/2005	2404605	4/22/2015	European Patent Office

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Title	Application No.	Application Date	Registration No.	Registration Date	Country
ATP CHANNEL OPENERS AND USES THEREOF					
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Spain
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	France
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	United Kingdom
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12101988.8	8/25/2005	1161133	3/11/2016	Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184285.2	8/25/2005	2404605	4/22/2015	Italy
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/370,456	2/12/2009			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16102894.5	8/25/2005			Hong Kong
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	14/458,032	8/12/2014	9,782,416	10/10/2017	United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/683,516	8/22/2017			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/937,594	3/27/2018			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/692,852	11/22/2019			United States of America

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Title	Application No.	Application Date	Registration No.	Registration Date	Country
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/545,764	12/19/2023			United States of America
PHARMACEUTICAL FORMULATIONS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/792,416	8/1/2024			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/756,941	1/5/2006			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/854,740	10/27/2006			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Austria
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2006335153	12/20/2006	2006335153	6/28/2012	Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2636274	12/20/2006	2636274	5/26/2015	Canada
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200680050425.7	12/20/2006	200680050425.7	6/10/2015	China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Denmark
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Spain

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Greece
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08112056.8	12/20/2006	1117078	2/17/2012	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Croatia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	4890/DELNP/2008	12/20/2006	280967	3/3/2017	India
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2008-549491	12/20/2006	5543110	5/16/2014	Japan
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Luxembourg
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Netherlands
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Poland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Sweden
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	06847875.9	12/20/2006	1968601	10/19/2011	Turkey

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11/614,044	12/20/2006	7,799,777	9/21/2010	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2006/048711	12/20/2006			Patent Cooperation Treaty
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2012203517	12/20/2006	2012203517	8/7/2014	Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	201310041514.7	12/20/2006	201310041514.7	1/6/2016	China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60 2006 057 398.7	12/20/2006	2404604	2/6/2019	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12101989.7	12/20/2006	HK1161134	11/15/2019	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	11184345.4	12/20/2006	2404604	2/6/2019	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/391,990	2/24/2009	7,572,789	8/11/2009	United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Belgium
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Switzerland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Germany
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Spain
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	France
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	United Kingdom
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	42020002856.1	12/20/2006	HK40013034	2/14/2025	Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Ireland
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Italy
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	19154788.4	12/20/2006	3545958	7/10/2024	Liechtenstein
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/534,018	7/31/2009			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/819,155	6/18/2010			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/671,418	11/7/2012			United States of America

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SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/846,542	3/18/2013	9,381,202	7/5/2016	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	15/195,826	6/28/2016	10,085,998	10/2/2018	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/110,621	8/23/2018			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	16/680,093	11/11/2019	11,045,478	6/29/2021	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	17/332,878	5/27/2021	11,786,536	10/17/2023	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	18/454,595	8/23/2023			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/947,628	7/2/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/949,207	7/11/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/950,854	7/19/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	60/986,251	11/7/2007			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2008272923	7/1/2008			Australia
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2692160	7/1/2008			Canada
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	200880105223.7	7/1/2008			China
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	08772317.7	7/1/2008			European Patent Office

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	10109409.4	7/1/2008			Hong Kong
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	2010-515241	7/1/2008			Japan
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	12/166,251	7/1/2008			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2008/068936	7/1/2008			Patent Cooperation Treaty
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/406,482	2/27/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13/543,665	7/6/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	61/603,923	2/27/2012			United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	13754866.5	2/25/2013			European Patent Office
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	14/466,852	8/22/2014	9,765,043	9/19/2017	United States of America
SALTS OF POTASSIUM ATP CHANNEL OPENERS AND USES THEREOF	PCT/US2013/027676	2/25/2013			Patent Cooperation Treaty
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/080,150	11/14/2014			United States of America
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/138,245	3/25/2015			United States of America
METHODS TO INCREASE LEAN BODY MASS IN SUBJECTS WITH PRADER-WILLI SYNDROME	62/170,035	6/2/2015			United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	62/221,359	9/21/2015			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Armenia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Austria
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2015346196	11/12/2015	2015346196	5/16/2019	Australia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Azerbaijan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Belgium
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	BR1120170099861	11/12/2015			Brazil
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Belarus
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2966907	11/12/2015	2966907	9/7/2021	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Switzerland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201580072525.9	11/12/2015	201580072525.9	7/30/2021	China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Germany
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Denmark

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Eurasian Patent Organization
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	European Patent Office
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Spain
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Finland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	France
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	United Kingdom
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Greece
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18103580.0	11/12/2015	1243954	3/19/2021	Hong Kong
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Hungary
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00-2017-03651	11/12/2015	IDP000075724	4/1/2021	Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Ireland

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METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	252111	11/12/2015	252111	12/31/2021	Israel
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201717020516	11/12/2015			India
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Italy
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2017-544842	11/12/2015	6709226	5/26/2020	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Kyrgyzstan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10-2017-7016089	11/12/2015	10-2323613	11/2/2021	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Kazakhstan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	J/005421	11/12/2015	J/005421	1/24/2022	Macao
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	MX/A/2017/006244	11/12/2015	381305	4/8/2021	Mexico
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PI 2017701659	11/12/2015	MY-187610-A	10/4/2021	Malaysia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Netherlands
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Norway

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	731565	11/12/2015	731565	9/28/2021	New Zealand
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Poland
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Russian Federation
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Sweden
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	11201703721S	11/12/2015	11201703721S	12/9/2019	Singapore
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Tajikistan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	201791067	11/12/2015	036103	9/29/2020	Turkmenistan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	15859169.3	11/12/2015	3217963	5/20/2020	Turkey
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	14/940,018	11/12/2015	9,757,384	9/12/2017	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PCT/US2015/060455	11/12/2015			Patent Cooperation Treaty
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2017/04056	11/12/2015			South Africa

Title	Application No.	Application Date	Registration No.	Registration Date	Country
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2019202906	11/12/2015	2019202906	9/3/2020	Australia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	BR 122023002893-7	11/12/2015			Brazil
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3125839	11/12/2015	3125839	10/24/2023	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	202110786768.6	11/12/2015			China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00201909107	11/12/2015	IDP000093460	5/8/2024	Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2020-002555	11/12/2015	6955039	10/4/2021	Japan
METHODS FOR TREATING SUBJECTS WITH SMITH-MAGENIS SYNDROME	10-2021-7035884	11/12/2015	10-2452254	10/4/2022	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	MX/A/2021/003982	11/12/2015	393030	6/9/2022	Mexico
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	PI2021000027	11/12/2015	MY-205748-A	11/11/2024	Malaysia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	768958	11/12/2015	768958	11/2/2021	New Zealand
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10201910108T	11/12/2015	10201910108T	9/14/2020	Singapore
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI	15/671,792	8/8/2017	10,058,557	8/28/2018	United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
SYNDROME OR SMITH-MAGENIS SYNDROME					
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3125835	11/12/2015	3125835	1/3/2023	Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	202511504739.0	11/12/2015			China
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	P00202101729	11/12/2015			Indonesia
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2021-160423	11/12/2015	7232300	2/21/2023	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME	10-2022-7029800	11/12/2015	10-2517840	3/30/2023	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	16/041,237	7/20/2018	10,456,408	10/29/2019	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	3210794	11/12/2015			Canada
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	2023-023047	11/12/2015	7645913	3/6/2025	Japan
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	10-2023-7010935	11/12/2015	10-2598666	11/1/2023	Republic of Korea
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	16/573,965	9/17/2019	10,874,676	12/29/2020	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	17/104,433	11/25/2020			United States of America

Title	Application No.	Application Date	Registration No.	Registration Date	Country
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/421,914	1/24/2024	12,109,216	10/8/2024	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/824,811	9/4/2024	12,178,823	12/31/2024	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	18/988,636	12/19/2024	12,343,348	7/1/2025	United States of America
(Track One) METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME	19/224,580	5/30/2025	12,419,895	9/23/2025	United States of America
METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME	19/329,408	9/15/2025			United States of America



ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
14/940,018	04/16/2026 06:28:38 PM Z ET	SLNO-034/04US 333072-2375

Title of Invention

METHODS FOR TREATING SUBJECTS WITH PRADER-WILLI SYNDROME OR SMITH-MAGENIS SYNDROME

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	9757384
CONFIRMATION #	6992	FILED BY	Diana Sciamanna
PATENT CENTER #	75318356	FILING DATE	11/12/2015
CUSTOMER #	58249	FIRST NAMED INVENTOR	Neil M. Cowen
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Kimberly Bolin

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
SLNO-034_04US_Communication.pdf	34	Disclosure Under 37 CFR 1.765 in a Patent Term Extension Application	705 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
SLNO-034_04US_Communication.pdf	6236594812DE1E5E9B6382BB518F441D1CDD28D25A1B30490A062C1564859914A59532C53E510348EF691402C91EE440FFD58BB338ADD6907F38AE19F713533C

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.