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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4680.32US07
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mark	E.	Deem	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

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Postal Code	94025	Country i	US

Inventor 2 Remove

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Prefix	Given Name	Middle Name	Family Name	Suffix
	Hanson	S.	Gifford	III

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

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☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	24113		
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Application Information:

Title of the Invention	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT		
Attorney Docket Number	4680.32US07	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter			
Total Number of Drawing Sheets (if any)	14	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
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Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	14/601529	2015-01-21

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14/601529	Continuation of	13/660629	2012-10-25	8961391	2015-02-24

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13/660629	Continuation of	13/253595	2011-10-05	8338164	2012-12-25

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13/253595	Continuation of	12/559278	2009-09-14	8133497	2012-03-13

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12/559278	Division of	11/459090	2006-07-21	7608275	2009-10-27

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
11/459090	Claims benefit of provisional	60/702077	2005-07-22

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4680.32US07
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4680.32US07
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4680.32US07
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section. Clear

Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
● Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	The Foundry, LLC		
Mailing Address Information For Applicant:			
Address 1	199 Jefferson Drive		
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City	Menlo Park	**State/Province**	CA
Country	US	Postal Code	94025
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4680.32US07
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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

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Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
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Signature:

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This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Daidre L. Burgess/			Date (YYYY-MM-DD)	2016-11-21
First Name	Daidre	Last Name	Burgess	Registration Number	60389

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4680.32US07
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

RELATED APPLICATIONS

This application is a continuation of Application No. 14/601,529 filed January 21, 2015, which in turn is a continuation of Application No. 13/660,629 filed October 25, 2012, now U.S. Patent No. 8,961,391 issued February 24, 2015, in turn which is a continuation of Application No. 13/253,595 filed October 5, 2011, now U.S. Patent No. 8,338,164 issued December 25, 2012, which in turn is a continuation of Application No. 12/559,278 filed September 14, 2009, now U.S. Patent No. 8,133,497 issued March 13, 2012, which in turn is a divisional of Application No. 11/459,090 filed July 21, 2006, now U.S. Patent No. 7,608,275 issued October 27, 2009, which claims the benefit of U.S. Provisional Application No. 60/702,077 filed July 22, 2005, each of which is hereby fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to methods and apparatus for the control of autonomic nerve function comprising delivery via permeabilization of targeted cell membranes a therapeutically effective amount of a portion or fragment of a neurotoxin such as botulinum toxin (BoNT), the active portion known as the light chain (LC), to cause a clinical benefit in various regions within the body.

First used for medical purposes over 20 years ago for treatment of blepharospasm and strabismus and other skeletal muscle abnormalities, certain neurotoxins have found widespread use in millions of patients worldwide for a variety of conditions.

Controlled injection of neurotoxins has become a common procedure to control skeletal muscle spasms. While the primary application of neurotoxins such as BOTOX®, commercially sold by Allergan, Inc. (Irvine, Calif.), has been focused on cosmetic applications, such as treatment of facial wrinkles, other uses for the compound are now common. Certain applications include treatment of cervical dystonia, tremor, headache (migraine), spasticity, torticollis, hemifacial spasm, blepharospasm, meige syndrome, spastic dysphonia, writers cramp, hyperhydrosis, hypersalivation, bladder dysfunction multiple sclerosis, spinal cord injury, cystic fibrosis, stroke paralysis, stuttering, and all types of pain.

Clostridium botulinum neurotoxins (BoNTs) block the release of acetylcholine from peripheral cholinergic nerve endings thereby disabling the release of neurotransmitters from the cells (Bigalke, H. and Shoer, L. F. (1999) Clostridial Neurotoxins in Handbook of Experimental Pharmacology 45, 407-443). This mechanism of action is well defined. Seven immunologically distinct serotypes of neurotoxin, designated types A through G, have been identified as discussed by Simpson, L. L., Schmidt, J. J. and Middlebrook, J. L. (1988) in Methods Enzymol. 165, 76-85. There are general structural and functional similarities among the various types of neurotoxins, but they all have preferred recipients, for example some favor use in humans and other in non-human species.

A frequently used neurotoxin for many applications in the human body is Botulinum Toxin Type A (BoNT\A), a protein produced by the bacterium Clostridium botulinum and sold commercially by Allergan, inc., as BOTOX®. Botulinum toxin blocks the release of neurotransmitter from the nerves that control the contraction of the target muscles. When used in medical settings, small doses of the toxin are injected into the affected muscles and block the

release of a chemical acetylcholine that signals the muscle to contract. The toxin thus paralyzes or weakens the injected muscle.

In addition, use of neurotoxin for control of the following conditions has been proposed in U.S. Patent No. 6,063,768 to First, and U.S. Patent No. 5,766,605 to Sanders, including: rhinorrhea, asthma, COPD, excessive stomach acid secretion, spastic colitis, otitus media, arthritis, tensoynovitis, lupus, connective tissue disease, inflammatory bowel disease, gout, tumors, musculo-skeletal abnormalities, reflex sympathetic dystrophies, tendonitis, bursitis, and peripheral neuropathy. Various other patents contemplate the use of a neurotoxin for additional applications such as, neuromuscular disorders (U.S. Patent No. 6,872,397), essential tremor (U.S. Patent No. 6,861,058), pancreatitis (U.S. Patent No. 6,843,998), muscle spasm (U.S. Patent No. 6,841,156), sinus headache (U.S. Patent No. 6,838,434), endocrine disorders (U.S. Patent No. 6,827,931), priapism (U.S. Patent No. 6,776,991), thyroiditis (U.S. Patent No. 6,773,711), cardiovascular disease (U.S. Patent No. 6,767,544), thyroid disorders (U.S. Patent No. 6,740,321), hypocalcemia (U.S. Patent No. 6,649,161), hypercalcemia (U.S. Patent No. 6,447,785), tardive dyskenesia (U.S. Patent No. 6,645,496), fibromyalgia (U.S. Patent No. 6,623,742), Parkinson's Disease (U.S. Patent No. 6,620,415) cerebral palsy (U.S. Patent No. 6,448,231), inner ear disorders (U.S. Patent No. 6,358,926), cancers (U.S. Patent No. 6,139,845), otic disorders (U.S. Patent No. 6,265,379), appetite reduction (US2004/0253274), compulsive disorders (US2004/0213814, US2004/0213813), uterine disorders (US2004/0175399), neuropsychiatric disorders (US2003/0211121), dermatological or transdermal applications (US2004/00091880), focal epilepsy (US2003/0202990) the contents of which are expressly incorporated herein by reference in their entirety.

The patent authors have further detailed devices and methods for treating asthma with local delivery of the intact botulinum toxin in U.S. Patent Application No. 10/437,882, filed on May 13, 2003, the contents of which are expressly incorporated by reference herein in its entirety.

Due to their extreme toxicity, neurotoxins are highly controlled and can have disastrous consequences if not used and controlled properly, especially when used *in vivo*. In addition, due to their toxicity, the body tends to build up a resistance to their use, resulting in lower efficacy, the need for increased treatments, or the need to discontinue their use all together in certain patients.

In light of the foregoing, it would be desirable to provide methods and apparatus for delivering neurotoxins such as botulinum toxins non-toxically.

It would also be desirable to provide methods and apparatus for treating various conditions with a neurotoxin such as botulinum toxin fragments via *in vivo* cell permeabilization.

In would also be desirable to provide a system of devices, including catheters, trocars, needles, endoscopes, inhalers, nebulizers and aerosolizers and other mechanisms to deliver fragmented neurotoxins non-toxically.

Further, it would be desirable to couple energy delivery devices with the delivery of fragmented neurotoxins to deliver active neurotoxins, non-toxically, including catheter based energy systems, and non-invasive energy systems.

All publications and patents or patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent or patent application was specifically and individually so incorporated by reference.

BRIEF SUMMARY OF THE INVENTION

According to the present invention, an active fragment (sometimes referred to as a catalytic portion) of a neurotoxin such as the botulinum neurotoxin (BoNT), preferably the light chain (LC) portion of BoNT, is delivered to target cells via cell membrane permeabilization. Such delivery provides a non-toxic delivery scheme for deriving a variety of clinical benefits. Although botulinum toxins are used broadly for a variety of clinical applications, the present invention provides enhanced methods of delivery and use of the isolated active fragments or portions of the toxin. Other neurotoxins which may be used in the methods and systems of the present invention include ricin and its active fragments, exotoxin A and its active fragments, diphtheria toxin and its active fragments, cholera toxin and its active fragments, tetanus toxin and its active fragments, and the like.

The present invention contemplates application to all of the conditions listed herein, collectively defined as "therapeutic target conditions", and any other conditions for which BoNT and other neurotoxins are known to or can be shown to provide a therapeutic benefit. Certain examples have been detailed below for specific applications, but it is within the scope of the present invention that the methods and devices detailed herein have specific applications to many or all of the conditions wherein the intact neurotoxins have shown or proposed to show a therapeutic benefit or effect.

In one aspect of the present invention, BoNT-LC or other active neurotoxin fragment is delivered with the application of energy to achieve cell membrane permeabilization.

In another aspect of the present invention methods and apparatus are provided for altering autonomic nerve function by utilizing an electric field or ultrasonic energy generated by a pulse or pulses of a designated duration and amplitude to alter tissue at the cellular level via permeabilization of the cell membrane to facilitate the translocation of the BoNT-LC or other active neurotoxin fragment to the cell cytosol.

A further aspect of the invention is to provide methods and apparatus for treating or inhibiting a variety of diseases or syndromes that have an underlying neurogenic component, by disrupting the neurogenic activities of the promoters or mediators of the disease or syndrome. Such disruption is facilitated by delivering an active fragment of botulinum toxin, such as the light chain portion of botulinum toxin serotype A (BoNT-LC/A), in the presence of an electric field or ultrasonic energy applied to permeabilize the wall of targeted cell under conditions which induce reversible poration of the cellular membrane and efficient passage of the BoNT-LC fragment to the cell cytosol, its catalytic environment.

In addition to the methods described thus far, the present invention further provides systems for delivering toxins to target cells in a mammalian host. The target cells may be in any of the target regions described above or in any other target region which may benefit from the specific and enhanced delivery of a neurotoxin to cells within the region. Systems comprise catheter or other structure adapted to introduce the toxin or toxin fragment to a region adjacent the target cells. The systems further comprise an energy applicator for applying energy to the target cells under condition which cause poration of the cell membranes to enhance delivery of the toxins and/or their active fragments. The systems still further comprise a source of the toxin or active fragments suitable for introduction from the catheter or other delivery structure.

The energy applicator will typically be adapted to selectively apply energy to target cells within the region where the toxin is to be introduced, e.g., by focusing energy distribution to the particular target cells or regions which are rich with the target cells. Alternatively, the energy applicator may be adapted to apply energy non-selectively within the target region where both target cells and other cell types may receive the energy.

In some instances, the toxin may comprise an intact toxin, but more usually will comprise an active toxin fragment as defined elsewhere in this application. In the exemplary embodiments, the active toxin fragment is the light chain fragment of the botulinum toxin (BoNT-LC). The light chain fragment may be derived from any one of at least botulinum toxins A, B, C, D, E, F, and G.

The energy applicators of the systems of the present invention may be adapted to apply electric energy, typically pulses between 1 V and 500 V to the targeted region. The electric energy may be radiofrequency (RF) energy, where the energy may be pulsed for durations between 5 microseconds to 100 milliseconds. Alternatively, the electrical energy can be direct current (DC), alternating current (AC), or combinations thereof.

`In addition to electrical energy, the energy applicator may be adapted to deliver ultrasonic energy, X-ray beam energy, microwave energy, or any other energy type which can achieve a reversible poration of the target cell walls.

There are at least two general power categories of medical ultrasound waves which may be utilized in the present invention. One category of medical ultrasound wave is high acoustic pressure ultrasound. Another category of medical ultrasound wave is low acoustic pressure ultrasound. Acoustic power is expressed in a variety of ways by those skilled in the art. One

method of estimating the acoustic power of an acoustic wave on tissue is the Mechanical Index. The Mechanical Index (MI) is a standard measure of the acoustic output in an ultrasound system. High acoustic pressure ultrasound systems generally have a Ml greater than 10. Low acoustic pressure systems generally have a MI lower than 5. For example, diagnostic ultrasound systems are limited by law to a Mechanical Index not to exceed 1.9. Another measurement used by those skilled in the art is the spatial peak, peak average intensity (Isppa). The intensity of an ultrasound beam is greater at the center of its cross section than at the periphery. Similarly, the intensity varies over a given pulse of ultrasound energy. Isppa is measured at the location where intensity is maximum averaged over the pulse duration. Isppa for high acoustic pressure or high intensity focused ultrasound (HIFU) applications ranges from approximately 1500 W/cm^2 to 9000 W/cm^2. Diagnostic ultrasound equipment, for instance, will generally have, and an Isppa less than 700 W/cm^2. Yet another way in which ultrasound waves can be characterized is by the amplitude of their peak negative pressure. High acoustic pressure or HIFU applications employ waves with peak amplitudes in excess of 10 MPa. Low acoustic pressure ultrasound will generally have peak negative pressures in the range of 0.01 to 5.0 MPa. Diagnostic ultrasound equipment, for example, will generally have a peak amplitude less than 3.0 MPa. Both high and low acoustic pressure ultrasound systems generally operate within the frequency range of 20 KHz-10.0 MHz Interventional applications (such as in blood vessels) operate clinically up to about 50 MHz. Also opthalmologic applications up to about 15 MHz. Diagnostic imaging typically uses frequencies of about 3 to about 10 MHz. Physical therapy ultrasound systems generally operate at frequencies of either 1.0 MHz or 3.3 MHz. High acoustic pressure ultrasound or high intensity focused ultrasound has been used for tissue disruption, for example

for direct tumor destruction. High intensity focused ultrasound using high acoustic pressure ultrasound is most commonly focused at a point in order to concentrate the energy from the generated acoustic waves in a relatively small focus of tissue.

Systems and methods for permeabilization of target tissue cell membranes according to the present invention may employ either high acoustic pressure or low acoustic pressure ultrasound. Some embodiments may preferably employ relatively low acoustic pressure, for example the systems described herein where the transducers are mounted on the delivery devices and operate inside the body. Other systems may operate at interim acoustic pressure ranges. For example, systems described herein which employ an external ultrasound generator and transducer and which conduct the ultrasound to the target tissues through the use of a wave guide. In these systems, losses due to transduction through the wave guide can be compensated for by increasing the input power to the wave guide until adequate power is delivered to the target tissue. Finally, some systems described herein may employ focused or partially focused higher pressure ultrasound, for example the systems which employ an external mask to conduct the ultrasonic power through the tissues to the target tissues. It should be appreciated that combinations of high and low acoustic pressure systems may also be employed.

The catheter or other structure may be adapted to introduce the toxin to the target cells in a variety of ways. For example, catheters may comprise a needle for injecting the toxin, optionally a needle which is deployable axially or radially from the catheter body. Alternatively or additionally, catheters may be provided with nozzles or other ports for aerosolizing the toxin, particularly within regions of the lung as described herein. Still further alternatively or additionally, the catheters may comprise balloons or other expandable elements for deflecting an

end of the catheter to engage one or more ports on the catheter against the tissue where the toxin fragments are released through the port(s). In a specific embodiment, the ports may be in the balloon itself where the toxin fragments are released through the ports in the balloon as the balloon is inflated with the medium containing the fragments. With such balloon embodiments, the electrodes or other energy transducers will typically be located within the balloon for applying the poration energy to the target tissue. Further optionally, the energy applicators may be mounted directly on the catheters, for example in the form of acoustic transducers, RF or other electrical electrodes, or the like. Alternatively, the energy applicator may be provided separately from the toxin delivery catheter or other source, typically being an external source, such as an external high intensity focused ultrasound (HIFU) source or an external electrode array for delivering radiofrequency or other electroporation energy.

In a further aspect of the invention, it may be desirable to provide methods and devices that utilize a non-toxic delivery mechanism to target cells to reduce the potential for an immunogenic response to the delivered toxin over time.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment and energy via a catheter.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment via an aerosolizer or nebulizer.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment via an inhaler.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment and membrane transport energy transdermally.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment via a catheter, or aerosolizer or inhaler, and the energy via a catheter placed in the vicinity of the targeted cell.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment and the membrane transport energy via an implantable generator and drug delivery pump.

In a further aspect of the invention, it may be desirable to deliver the therapeutic neurotoxin fragment via a catheter, or aerosolizer (nebulizer) or inhaler, and the energy via an external energy source adapted to target the applied energy in the vicinity of the targeted cell.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description, in which:

FIG. 1 - depicts a schematic of the creation of neurotoxin Botulinum Toxin Type A (BoNT/A), including the light chain (LC) fragment or portion.

FIG. 2A - depicts a schematic of a target cell, including the cell membrane, and inner cellular matrices.

FIG. 2B - depicts a schematic of the target cell wherein LC molecule has been introduced.

FIG. 3A-3B - depicts a the target cell of FIG. 2 showing application of an energy field (EF) to produce permeabilization or pores (P) in the cell membrane, and introduction of the LC fragment therethrough.

FIG. 4 - depicts a schematic of a cell wherein the energy field has been discontinued, and neurotransmission of the cell has been effectively blocked.

FIGS. 5, 5A-5B - depicts various embodiments of a delivery device of the present invention utilizing multiple energy transmission elements and an energy transmission system.

FIGS. 6A-D, 6AA, and 6CC - depict various electrode catheter configurations adapted to deliver energy or energy and therapeutic agents to target tissue.

FIG. 7 - depicts an alternative embodiment of the present invention wherein one of the multiple energy transmission elements is placed at the targeted cell site, and the other in a location remote therefrom.

FIG. 8 - depicts an embodiment of the present invention utilizing an ultrasound element on a catheter device.

FIG. 9 - depicts an embodiment of the present invention utilizing an inhaler with an in vivo energy delivery source.

FIG. 10 - depicts an interstitial method of use of the present invention.

FIG. 11 - depicts an embodiment of the present invention utilizing an aerosolizing element.

FIG. 12 - depicts a fully implantable pulse generator, lead and agent delivery pump of the present invention.

FIG. 13 - depicts an embodiment of the present invention utilizing an external energy delivery source applied to the therapeutic agent applied in the vicinity of a targeted cell.

FIG. 14 - depicts an embodiment of the present invention wherein the energy and therapeutic agent are delivered transdermally.

FIG. 15 - depicts a method of use of a noninvasive agent delivery device coupled with a non-invasive energy source for treating a lumen or tract of the respiratory system.

FIGS. 15A and 15B - depict use of a balloon for delivering toxin fragments in a lung.

FIGS. 16A and 16B - depict use of a deflected catheter tip for delivering toxin fragments in a lung.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to methods and apparatus for targeting the non toxic delivery of a fragment of a neurotoxin, while still maintaining the catalytic or toxic effect of the neurotoxin fragment once it is non-toxically delivered to its targeted cell. For purposes of this specification, the term "non-toxic", "non-toxically" and the like refer to the state of the fragment molecule prior to delivery to a target location. In this description, the fragment neurotoxin is intended to retain its toxic effect once delivered to its catalytic environment; the intracellular matrix or cytosol of the targeted cell.

Devices and methods of the present invention may be directed to suitable "targeted regions" such as muscle cells in various regions of the body related to the various "therapeutic target conditions" or syndromes to be treated, as detailed in this specification above. Some particular examples include targeting mucosal and muscular lining of the lung, cholinergic cells in the region of tumors, myofacial regions, vascular smooth muscle cells, musculoskeletal regions and the like.

According to the present invention, energy fields (EF) may be applied to target regions in conjunction with the delivery of a fragmented neurotoxin such as BoNT-LC to facilitate the

transfer of the neurotoxin fragment into the targeted cell, non-toxically via in vivo target cell permeabilization.

Use of Isolated Light Chain of Botulinum Neurotoxins

Generally, the BoNT molecule is synthesized as a single polypeptide chain of 150 kD molecular weight. The neurotoxin is then exposed to enzymes, either during cultivation of the *Clostridium botulinum* organism or subsequent to purification of the toxin, wherein specific peptide bonds are cleaved or "nicked" resulting in the formation of a dichain molecule referred to as BoNT. As shown in FIG. 1, dichain neurotoxin is composed of a light chain (LC) region 50 kD molecular weight linked by disulfide bonds to a heavy chain (HC) 100 kD molecular weight (Kistner, A., Habermann, E. (1992) *Naunyn Schmiedebergs Arch. Pharmacol.* 345, 227-334). When the light chain is separated from the heavy chains of botulinum toxin, neither chain is capable of blocking neurotransmitter release, however, the light chain alone is capable of blocking acetylcholine release if transported directly into the cell cytosol. (Ahnert-Hilger, G., Bader, M. F., Bhakdi, S., Gratzl, M. (1989) *J. Neurochem.* 52, 1751-1758 and Simpson, L. L. (1981) *Pharmacol. Rev.* 33, 155-188.) Focusing on the light chain, the isolation or separation process essentially renders the light chain "non-toxic" in a general environment, while still maintaining its effect or toxicity, once it is transported through the target cell membrane.

Over the past several years, the separation and purification of the light chain and heavy chain of BoNT has seen significant development activity. In the case of the heavy chain (HC), researchers are interested in its ability to bond with a target cell and deliver certain molecules into that cell. For example, various drug delivery applications have been suggested, for example,

using the HC to bind to tPA so that a patient could inhale the HC bound tPA allowing it to cross the membrane of the lungs and be transported into the bloodstream for anticoagulation. Of particular interest to the present invention are the efforts to isolate and purify the light chain (LC) of the botulinum molecule. In its isolated and purified form, all HC elements are removed, rendering the LC incapable of crossing the cell membrane without assistance. Thus, the LC is non-toxic until delivered to the target cell cytosol by the delivery protocols of the present invention.

Various groups have been active in the area of isolation and purification. For example, companies such as Metabiologics, a group affiliated with the University of Wisconsin, the Center for Applied Microbiology and Research (CAMR), a division of the UK Health Protection Agency, List Biological Laboratories, Inc. of California, and other research groups throughout the world. Many of these companies provide purified preparations of botulinum neurotoxins from *Clostridium botulinum* types A and B. List Laboratories in particular provides recombinantly produced light chains from both types A, B, C, D and E.

According to the present invention, the therapeutic use and delivery of the light chain only may significantly improve the safety profile of certain applications of therapies utilizing BoNT. BoNT are some of the most lethal toxins known to man. All concerns about migration of the neurotoxin into unintended regions, and harm or toxicity to the patient or physician are eliminated by storing, handling, injecting and metabolizing the light chain only. In the absence of a specific membrane binding technology, the LC is completely non-toxic. In certain applications, such as the treatment of asthma, this is of critical import. In using BoNT to treat asthma, a large quantity of the purified LC substance may be introduced directly into the lung,

and then specifically transported to target cells in the exact location and only during the period of use of application of the membrane transport technology, such as cell membrane permeabilization by energy. Once the membrane transport technology has been removed, turned off or otherwise inactivated, the remaining LC which has not been transported into target cells can simply be removed from the body by standard biologic processes for expelling foreign materials, e.g. coughing, immune system or lymphatic system transport and the like.

In addition, therapeutic use of only the LC of the neurotoxin BoNT may reduce the likelihood of the body developing an immunogenic response to the therapy that is seen with delivery of the intact toxin. This could be a major advantage in light of the repetitive application or injection of the toxin that is required to maintain a therapeutic effect.

Non-Toxic Membrane Transport Mechanisms

To date, the main application of purified or isolated light chain has been the study of its mechanism of action. To further this research, literature has reported the use of certain detergent based permeabilization techniques to deliver fragment BoNT (Bittner M A, DasGupta B R, Holz R W. Isolated light chains of botulinum neurotoxins inhibit exocytosis. Studies in digitonin-permeabilized chromaffin cells. J Biol Chem 1989 June 25; 264(18):10354-10360.) Further reference to the mechanism of permeability of cell membranes to deliver botulinum toxin are mentioned in U.S. Patent No. 6,063,768 to First, and U.S. Patent No. 6,632,440 to Quinn, Chaddock, et al "Expression and Purification of Catalytically Active Non-Toxic Endopeptidase Derivatives of Clostridium botulinum toxin type A", *Protein Expression and Purification*, 25 (2002) 219-228, contemplating the insertion of the light chain of BoNT into a target cell without

the heavy chain for purposes of deriving vaccines or in bench top studies of cell mechanisms of action. The contents of these references are expressly incorporated by reference in their entirety. None of the teachings contemplate a delivery of a fragment of neurotoxin using a clinically acceptable permeabilization technique in vivo for therapeutic uses as is contemplated by the present invention.

For purposes of this specification, the term "poration" includes various forms of electroporation, such as the use of pulsed electric fields (PEFs), nanosecond pulsed electric fields (nsPEFs), ionophoreseis, electrophoresis, electropermeabilization, as well as other energy mediated permeabilization, including sonoporation (mediated by ultrasonic or other acoustic energy), and/or combinations thereof, to create temporary pores in a targeted cell membrane. Similarly, the term "electrode" or "energy source" used herein, encompasses the use of various types of energy producing devices, including x-ray, radiofrequency (RF), DC current, AC current, microwave, ultrasound, adapted and applied in ranges to produce membrane permeabilization in the targeted cell.

Reversible electroporation, first observed in the early 1970's, has been used extensively in medicine and biology to transfer chemicals, drugs, genes and other molecules into targeted cells for a variety of purposes such as electrochemotherapy, gene transfer, transdermal drug delivery, vaccines, and the like.

In general, electroporation may be achieved utilizing a device adapted to activate an electrode set or series of electrodes to produce an electric field. Such a field can be generated in a bipolar or monopolar electrode configuration. When applied to cells, depending on the duration and strength of the applied pulses, this field operates to increase the permeabilization of

the cell membrane and reversibly open the cell membrane for a short period of time by causing pores to form in the cell lipid bilayer allowing entry of various therapeutic elements or molecules, after which, when energy application ceases, the pores spontaneously close without killing the cell after a certain time delay. As characterized by Weaver, *Electroporation: A General Phenomenon for Manipulating Cells and Tissues* Journal of Cellular Biochemistry, 51:426-435 (1993), short (1-100 .mu.s) and longer (1-10 ms) pulses have induced electroporation in a variety of cell types. In a single cell model, most cells will exhibit electroporation in the range of 1-1.5V applied across the cell (membrane potential).

In addition, it is known in the art that macromolecules can be made to cross reversibly created pores at voltages of 120V or less applied to cells for durations of 20 microseconds to many milliseconds. For applications of electroporation to cell volumes, ranges of 10 V/cm to 10,000 V/cm and pulse durations ranging from 1 nanosecond to 0.1 seconds can be applied. In one example, a relatively narrow (pee) high voltage (200V) pulse can be followed by a longer (>msec) lower voltage pulse (<100V). The first pulse or series of pulses open the pores and the second pulse or series of pulses assist in the movement of the BoNT-LC across the cell membrane and into the cell.

Certain factors affect how a delivered electric field will affect a targeted cell, including cell size, cell shape, cell orientation with respect to the applied electric field, cell temperature, distance between cells (cell-cell separation), cell type, tissue heterogeneity, properties of the cellular membrane and the like.

Various waveforms or shapes of pulses may be applied to achieve electroporation, including sinusoidal AC pulses, DC pulses, square wave pulses, exponentially decaying

waveforms or other pulse shapes such as combined AC/DC pulses, or DC shifted RF signals such as those described by *Chang in Cell Potation and Cell Fusion using and Oscillating Electric Field*, Biophysical Journal October 1989, Volume 56 pgs 641-652, depending on the pulse generator used or the effect desired. The parameters of applied energy may be varied, including all or some of the following: waveform shape, amplitude, pulse duration, interval between pulses, number of pulses, combination of waveforms and the like.

A schematic example of the methods of the present invention are shown in FIGS. 2-4 in a simplified single cell model. A targeted cell 10 is shown in FIG. 2A. Fragmented neurotoxin such as BoNT-LC (LC) is introduced into the vicinity of the targeted cell as depicted in FIG. 2B. An energy field (EF) is applied in accordance with the present invention resulting in the transfer of the BoNT-LC through pores P to the intracellular matrix (cytosol) as shown in FIGS. 3A and 3B. Once this transfer has occurred, the release of neurotransmitters of the target cell are then blocked or disrupted, and once energy application is discontinued, the pores P in the cell membrane recover or close as depicted in FIG. 4.

Of particular interest for application in certain therapeutic target conditions is the developing field of sonoporation. Just as pulses of high voltage electricity can open transient pores in the cell membrane, ultrasonic energy can do the same. See for example Guzman et al. "Equilibrium Loading of Cells with Macromolecules by Ultrasound: Effects of Molecular Sizing and Acoustic Energy," Journal of Pharmaceutical Sciences, 91:7, 1693-1701, which examines the viability of ultrasound to deliver molecules of a variety of sizes into target cells. In addition, techniques for nebulizing fluids and aqueous drugs are well known in the art, and as such, devices of the present invention may be adapted to introduce a BoNT-LC solution to a target

region, such as the lung and then effect selective membrane transport of the BoNT-LC into the cell using sonoporation.

For example, U.S. Patent No. 6,601,581 to Babaev, hereby incorporated by reference in its entirety, describes certain techniques for delivering therapeutic agents using ultrasound for pulmonary delivery via an aerosolizing technique. Further, Guzman, et al, depicts delivery of molecules from a low of 62 Da up to 464 kDa (a range of 0.6-18.5 nm radius). Since the LC of the botulinum toxin is in the 50 kDa range, the LC would be very susceptible to sonoporetic delivery. Furthermore, Guzman, et al also showed that for all size ranges tested, levels of macromolecule within the cell reached thermodynamic equilibrium with the extracellular environment, and the cell uptake also depended on the energy delivered, as expressed in J/cm2. As such, the sonoporetic delivery of LC to the targeted regions may be controlled by adjusting the concentration of the LC exposed to the target region (e.g. wall or membrane of the lung), the energy delivered to the target region, or both.

Catheter Devices

To achieve the goals of the present invention, it may be desirable to employ methods and apparatus for achieving cell membrane permeabilization via the application of an energy source, either from a catheter located directly in the vicinity of the targeted cells, or an externally focused energy system. For purposes of this specification, the term "catheter" may be used to refer to an elongate element, hollow or solid, flexible or rigid and capable of percutaneous introduction to a body (either by itself, or through a separately created incision or puncture), such as a sheath, a trocar, a needle, a lead. Further descriptions of certain electroporation catheters are

described in U.S. Patent Application 60/701,747 (Attorney Docket No. 020979-003500US), filed on July 22, 2005, the full disclosure of which is expressly incorporated herein by reference.

FIGS. 5 and 5A-5B depict a system 20 utilizing an electroporation catheter 22 for selective electroporation of targeted cells. In certain configurations of the present invention, voltages may be applied via the electroporation catheter 22 to induce reversible electroporation at the same time as the catheter delivers the fragmented neurotoxin to the targeted region.

Referring to FIG. 5, electroporation catheter system 20 further comprises a pulse generator 24 such as those generators available from Cytopulse Sciences, Inc. (Columbia, Md.) or the Gene Pulser Xcell (Bio-Rad, Inc.), or IGEA (Carpi, Italy), electrically connected to a catheter having a proximal end and a distal end and adapted for minimally invasive insertion into the desired region of the body as described herein. The catheter further comprises an electroporation element 26 at a distal 28 end thereof The electroporation element may include for example a first and second electrode 30 and 32 operatively connected to the pulse generator for delivering the desired number, duration, amplitude and frequency of pulses to affect the targeted cells. These parameters can be modified either by the system or the user, depending on the location of the catheter within the body (intervening tissues or structures), and the timing and duration of reversible cell poration desired. FIG. 5A depicts an arrangement of electrodes 30 and 32 that produces an electric field concentrated in a lateral direction from the catheter body whereas, FIG. 5B shows a device constructed to create a more uniform electric field about the shaft of the catheter body.

Further catheter device and electrode configurations are shown in FIGS. 6A-6D. FIG. 6A depicts an elongate catheter 40 having first and second electrodes 42 and 44 near the distal tip

thereof, and including a monitoring or stimulation electrode 46 in the vicinity of the active porating electrodes for localizing the treatment area. In some embodiments, the monitoring or stimulating function may be performed by one or more of the treatment electrodes. The catheter device may have an optional sharp tip 48 to facilitate percutaneous introduction. Cross-sectional view FIG. 6A A shows various lumens provided for neurotoxin fragment delivery and other purposes.

FIG. 6B is a similar catheter device 50 having electrodes 52, 54, and 56, but is further adapted to be steerable, or articulate at a region 53 near the distal end of the device, e.g., including a pull wire for deflecting the tip. Such steering ability enables the operator to introduce the device into tight or tortuous spaces (such as the bronchial passages or cardiovascular vessels) so that optimal placement of the device at the target location may be achieved.

FIG. 6C depicts a catheter device 60 having a needle 62 or other injection element to allow for the injection of a therapeutic agent such as a fragmented neurotoxin before, during or after the application of the pulsed energy or electroporation. The catheter 60 further includes electrodes 64 and 66 or other poration components as discussed herein. The injection element may be a needle 62 as shown in FIG. 6C, an infusion port, or other infusion means. Needle 62 may also be used as an electrode in addition to an injection port. Electrode 68 comprises a monitoring or stimulating electrode. FIG. 10 depicts the use of a catheter of FIG. 6C to treat bronchial tissue in the lung for a variety of respiratory ailments such as asthma. FIG. 6CC is a cross-sectional view taken along line 6CC-6CC in FIG. 6, showing a co-axial sleeve design.

FIG. 6D depicts a catheter device 70 having electrode elements 72 and 74 that are adapted to extend laterally from the main catheter body, and in some cases, penetrate the surrounding tissue prior to application of energy. In doing so the depth and direction of the energy field created by the electroporative process, may be further controlled. A monitoring/stimulating electrode 76 will usually also be provided. Elements 72 and 74 may also be used as injection ports for introduction of toxin or toxin fragments.

FIG. 7 depicts the use of a catheter device 80 of the present invention for treatment of a respiratory tract, by positioning at least one electrode (82) at the target region, and a second electrode (84) remote from the target region, the target region being positioned between 82 and 84, such that activation of the electrodes produces an energy field (EF) therebetween, the size and intensity of which can be controlled by the placement of the electrodes relative to each other and the targeted region.

FIG. 8 depicts catheter 90 constructed in accordance with the principles of the present invention utilizing an ultrasonic element 92 that may be particularly useful in delivery of the BoNT-LC to bronchial tissue (lung) that provides a broad but targeted transport of the LC across the target cell walls, for example, epithelial and goblet cell walls. In this device, ultrasound energy is delivered to the distal end of the catheter device via an ultrasonic waveguide 94 that is operatively connected to an ultrasound energy source (U/SES). The LC fragment would be delivered from a receptacle 96 via the same lumen as the waveguide via a lumen provided the distal tip of the device. In operation, the ultrasonic energy would cause the LC solution to be nebulized, forming a mist or aerosol 98 within the lung, as shown in FIG. 11. The aerosol 98 itself, in the appropriate concentrations, may act as an ultrasound coupler, conveying the

ultrasonic energy to the wall of the lung or other targeted cellular structures, causing sonoporation of the targeted cells whereby the LC fragment is transmitted across the cell membranes to become an effective neurotransmitter blocker. In an alternative embodiment, an ultrasonic transducer may be located directly at the tip of the delivery device, eliminating the need for a wave guide. Various catheters useful for delivering vibrational energy to tissue are described in U.S. Patent Nos. 6,361,554 and 6,464,680 to Brisken, the contents of which are expressly incorporated herein by reference in their entirety, for various therapeutic effects, such as enhancing cellular absorption of a substance.

Since air is a very effective insulator against transmission of ultrasonic energy, the treatment area in the lung may be more precisely controlled by the concentration of the LC mist and the intensity of the ultrasonic energy. A fairly steep drop off in energy delivery would occur as mist concentration diffused, effectively protecting areas outside the predetermined radius surrounding the distal end of the delivery device. According to the present invention, since no functional neurotoxin exists without an effective membrane transport technology, terminating the energy application leaves a harmless mist that is then coughed up (if resident in the lungs) or otherwise metabolized and excreted by the body.

Any of the catheter devices described herein, or described in the contemporaneously filed U.S. Patent Application 60/701,747 (Attorney Docket No. 020979-003500US), previously incorporated by reference in its entirety, may be adapted to include an energy delivery element such as those described herein for purposes of providing a membrane transport system for delivery of a fragment of neurotoxin. In addition, certain catheter devices and methods such as those set forth in U.S. Patent Nos. 5,964,223 and 6,526,976 to Baran may be adapted to include

energy transmission elements capable of producing a porative effect at the cellular level, including electrodes, ultrasonic elements and the like, for treatment in the respiratory tract.

Furthermore, any of the foregoing systems may include electrodes or other monitoring systems either located on the treatment catheter, or external to the patient, to determine the degree of treatment to the region, including, thermocouple, ultrasound transducers, fiberoptics, sensing or stimulating electrodes. Further, it may be desirable to incorporate multiple pairs of electrodes that may be activated in pairs, in groups, or in a sequential manner in order to maximize the desired shape of the energy field (EF) while minimizing the field strength requirements.

Implantable Devices

Just as energy may be delivered to a targeted region to facilitate the delivery of fragmented neurotoxin via a catheter system, it is also within the scope of the present invention to deliver neurotoxins via an implantable system, including a pulse generator, lead and drug pump as depicted in FIGS. 12. A neuromodulation system 200 may be fully implantable, having a pulse generator and a power supply or battery and be operatively connected to a programmable drug delivery pump all housed within a module 202, including a reservoir in which the BoNT-LC is stored for delivery over time using the principles of the present invention and technology of the programmable drug pump. A catheter 204 can be adapted to deliver the drug and poration energy to a desired target location in the patient's body.

Examples of useful implantable devices of the present invention arc, devices such as those set forth in U.S. Patent No. 5,820,589 to Torgerson et al, the entire contents of which are

hereby incorporated by reference, the SynchroMed® programmable pump available from Medtronic, Inc. (Minneapolis, Minn.), and the neurostimulation units such as the RESTORE* or SynergyPlus® available from Medtronic, Inc., modified if necessary to deliver the desired voltage range for cell membrane permeabilization. Implantation of the neurostimulation device is further described in U.S. Patent No. 6,847,849, incorporated herein by reference in its entirety.

The non-toxic nature of the BoNT in the absence of applied energy makes it possible to contemplate placing a bolus of neurotoxin in the body of a patient in what might otherwise be a toxic amount. This is particularly advantageous, since the traditional treatment regime using neurotoxins, is typically repeat injections of the toxins every 3 to 6 months and sometimes more frequently depending on the application. Certainly in more chronic conditions such as chronic pain, tremor, spasm, palsy and the like, such a fully implantable system may be highly desirable.

Non-Invasive Devices

It is within the scope of the invention to deliver either the energy or the therapeutic BoNT-LC non-invasively, or both. For example, FIG. 13 depicts delivery of the BoNT-LC via a catheter 100 placed in the bronchial passageway with the energy field (EF) delivered from outside the patient in the form of an energy system 102 such as focused ultrasound (HIFU), stereotactic x-ray beams, magnetic resonance transmission, and the like. As detailed in U.S. Patent Nos. 6,626,855 and 6,719,694 to Weng, the contents of which are expressly incorporated herein by reference in their entirety, an ultrasound beam can be controlled from outside the patient to focus the ultrasound beam in the desired location and intensity. For use in the present invention, it may be desirable to pulse or otherwise attenuate the ultrasound beam to achieve

reversible cellular poration at the targeted site. Further, due to its non-toxic state, the BoNT-LC may be inhaled by the patient using a standard inhaler device such as those using pressurized aerosols known as metered dose inhalers (MDI) available from Cardinal Health (Somerset, N.J.), the OPTIHALER® available from National Allergy Supply Incorporated (Georgia, USA), or a nebulizer breathing machine such as a Pari DURANEB 3000 portable nebulizer available from Medinfinity, Co. (Fountain Valley, Calif.). In addition, certain technology currently under development employing thermal aerosols, such as a the STACCATO.TM. vaporization technology from Alexza Molecular Delivery (Palo Alto, Calif.) may also be useful within the scope of the present invention. Such devices 110 may be used as depicted in FIG. 9 for treating a respiratory ailment such as asthma. Optionally, the drug can be delivered with the catheter 22 (as shown) or with the external sources of FIG. 13.

A combination of these non-invasive approaches may also be advantageous as shown in FIG. 15, wherein an non-invasive inhaler 110 is used to deliver the BoNT-LC to the target region (such as the lung), and the energy is delivered to the target region by the non-invasive source 102 such as the focused ultrasound (HIFU), stereotactic x-ray, or magnetic resonance transmission as previously described. Due to its non-invasive technique, this approach may have broad appeal to a large patient population, including pediatric use, on an outpatient basis in a clinic designated for the treatment of specific respiratory ailments.

In a further aspect of the present invention, the fragmented molecule BoNT-LC may be delivered intravenously to a patient to achieve a systemic affect. A non-invasive energy application device, such as those described above, may then be targeted at the area of interest to

porate the target area, thereby locally delivering the BoNT-LC to the region sufficiently porated by the applied energy.

Cosmetic and Myofacial Applications. For some conditions, it may be desirable to apply the energy field from the surface of the skin to produce a porative effect, while injecting the BoNT-LC fragment into the targeted facial muscles as shown in FIG. 14. In operation, an injection device 220 places the BoNT-LC in the muscle to be treated (target region), and an energy transmission device such as an ultrasonic pen 222 with a single, or a series of ultrasonic elements located on the distal end and coupled to an energy transmission system 224, follows along the target region to controllably discharge the BoNT-LC fragments to the targeted cells leaving a highly controlled treated region. In some instances for treatments around the eye, it may be desirable to limit the penetration of the BoNT-LC to dermal or subdermal layers. In these applications, BoNT-LC may be applied transdermally with ultrasound assistance using techniques similar to those set forth in U.S. Patent No. 4,767,402 to Kost the contents of which is expressly incorporated herein in its entirety or through transdermal electroporation.

Intraluminal Devices

It may further be advantageous to position catheters of the present invention through vessels in the body to direct them to various regions to affect neurotransmitters in the cardiovascular system. Intraluminal catheters such as those shown in United States Patent Applications 2001/0044596 to Jaafar and 2002/0198512 to Seward, hereby incorporated by reference in their entirety, may be used in this application of the present invention.

Treatment Enhancements

In some applications of the present invention, it may be desirable to assess the appropriate location for the therapy prior to treatment, the therapeutic effect as it is delivered, and ultimately the resulting effect. To achieve this, once the treatment device is in place adjacent the tissue to be treated, the energy generator may be activated, causing an energized field to be generated in the target area. Prior to activation of therapeutic voltages and agent, stimulation using one or more electrodes may be used to elicit a nerve response or reflex. By observing the nerve response, a target treatment location can be confirmed. Similarly, once the therapy has been delivered, a similar stimulation response may be sought, to determine presence or lack of neurogenic response.

In operation, effects of electroporation and delivery of a therapeutic dose of BoNT LC may be selective due to the cellular structure and orientation of the targeted cells. For example, targeted cells may be preferentially affected due to size, avoiding smaller or cross-oriented tissue cells.

In a further aspect of the present invention, the method of delivering the LC fragment of the BoNT molecule may include the use of a media that contains microspheres or microbubbles, such as Optison.TM. sold by GE Healthcare (www.amershamhealth-us.com/optison/). Delivery of an ultrasound energy (or other form of energy, for example, laser, RF, thermal, energy) to the media causes the microspheres to rupture, which causes a release of energy toward the targeted region. Such a technique may assist in the desired porative effect by reducing the amount of applied energy required to create poration in the targeted cell membrane. *Bioeffects Caused by Changes in Acoustic Cavitation Bubble Density and Cell Concentration: A Unified Explanation*

Based on Cell-to-Bubble Ratio and Blast Radius, Guzman, et al. Ultrasound in Med. & Biol., Vol. 29, No. 8, pp. 1211-1222 (2003). In an alternative embodiment, the LC fragment may actually be contained or encapsulated within a microsphere to assist in delivery. Such enhancing elements may be delivered prior to energy application or during energy application.

In a further aspect of the present invention, it may be advantageous to heat the targeted cells or surrounding tissue by either applying thermal energy directly to the region, or directing a heated fluid, such as saline to the region through an injection element, to aid the cell poration process. Other substances may also be injected to aid in the transmission of the BoNT-LC into the intracellular membrane, such as amino acids, detergents or other agents that may facilitate the catalytic activity of the LC, in addition to the applied energy.

Referring now to FIGS. 15A and 15B, a balloon catheter 300 may be delivered to a target site in the bronchus B of a lung (FIG. 15B). Typically, the catheter 300 will be delivered through an endoscope E, and the shaft 302 of the catheter will comprise at least one lumen for inflating the balloon 304. The inflation medium may carry the toxin fragment which is released through ports 306 formed in the balloon itself. Thus, inflation of the balloon both engages the ports against the wall of the bronchus B and provides the pressure necessary to infuse the neurotoxin fragments into the wall of the bronchus B. Usually, energy will be applied from electrodes 308 or other transducers located within the balloon 304.

Referring now FIGS. 16A and 16B, the catheter 400 may also be delivered to a bronchus B of a lung through an endoscope E. Catheter shaft 402 terminates with a delivery port 404 near its distal end. A deflection balloon 406 (or other expandable element capable of pressing against the wall of the bronchus B to engage the port 404 against target tissue) is provided on a side of

the catheter shaft 402 which is opposite to that of the port 404. Electrodes 408 are provided on either side of the port 404 in order to deliver the poration energy into the target tissue.

Although various illustrative embodiments of the present invention are described above, it will be evident to one skilled in the art that various changes and modifications may be made without departing from the scope of the invention. It will also be apparent that various changes and modifications may be made herein without departing from the invention. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A nerve modification device for altering nerve function in a bronchial airway of a patient, the nerve modification device comprising:

a main catheter body configured to extend though a trachea into the bronchial airway;

at least one energy applicator having at least one energy emitter configured to emit energy laterally relative to the main catheter body; and

a movable mechanism to move the at least one energy applicator laterally within the bronchial airway such that the at least one energy emitter contacts a first portion of a circumference of the airway wall,

wherein the nerve modification device is adapted to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in the wall of the bronchial airway in a first lateral direction from the catheter body to alter nerve cells within the target region.

2. The nerve modification device of claim 1, wherein the energy is at least one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

3. The nerve modification device of claim 1, wherein the at least one energy emitter comprises at least one electrode.

4. The nerve modification device of claim 3, wherein the energy is RF energy.

5. The nerve modification device of claim 1, wherein the at least one energy emitter comprises at least one ultrasound transducer.

6. The nerve modification device of claim 5, wherein the energy is ultrasound energy.

7. The nerve modification device of claim 1, wherein the movable mechanism comprises an expandable member coupled to the main catheter body, the expandable member being configured to expand to move the at least one energy emitter into contact with the first portion of the circumference of the wall.

8. The nerve modification device of claim 8, wherein the expandable member is further configured to expand such that the expandable member engages a second portion of the circumference of the airway wall.

9. The nerve modification device of claim 8, wherein the expandable member is expanded laterally in a second lateral direction from the catheter body opposite the first lateral direction.

10. A system for altering nerve function in a bronchial airway of a patient, the system comprising:

an intraluminal catheter configured to be positioned within a bronchial airway of a patient, the intraluminal catheter including

a main catheter body, and

a first energy emitter configured to emit energy laterally relative to the main catheter body;

a movable mechanism coupled to a distal end of the main catheter body, and configured to move the first energy emitter laterally within the bronchial airway such that the first energy emitter contacts a first portion of a circumference of the airway wall; and

an energy generator operably coupled to the first energy emitter and configured to activate the first energy emitter, thereby causing an energy field to be generated in a target region in the airway wall to alter nerve cells within the target region.

11. The system of claim 10, wherein the first energy emitter is coupled to the movable mechanism, the system further comprising:

a second energy emitter operably coupled to the energy generator, the second energy emitter being configured to be positioned outside of the airway and remote from the target region, the target region being positioned between the first and second energy emitters such that activation of the first and second energy emitters by the energy generator produces the energy field between the first and second emitters and within the target region.

12. The system of claim 11, wherein a placement of the first and second energy emitters relative to each other controls the size and/or intensity of the energy field.

13. The system of claim 10, the system further comprising:

a second energy emitter operably coupled to the energy generator, and coupled to the movable mechanism relative to the first energy emitter such that an arrangement of the first and second energy emitters causes the energy field produced therefrom to be concentrated in a lateral direction from the main catheter body.

14. The system of claim 10, a second energy emitter operably coupled to the energy generator, and coupled to the movable mechanism relative to the first energy emitter such that an arrangement of the first and second energy emitters causes the energy field produced therefrom to comprise a uniform energy field about the main catheter body.

15. The system of claim 10, wherein the movable mechanism comprises an expandable member coupled to the main catheter body, the expandable member being configured to expand to move the first energy emitter into contact with a first portion of a circumference of the airway wall.

16. The system of claim 15, wherein the expandable member is further configured to expand such that the expandable member engages a second portion of the circumference of the airway wall.

17. The system of claim 10, wherein the energy is at least one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

18. The system of claim 10, wherein the first energy emitter comprises an electrode.

19. The system of claim 18, wherein the energy is RF energy.

20. The system of claim 10, wherein the first energy emitter comprises an ultrasound transducer.

ABSTRACT

Methods and apparatus are provided for applying an fragment of a neurotoxin such as the active light chain (LC) of the botulinum toxin (BoNT), such as one of the serotype A, B, C, D, E, F or G botulinum toxins, via permeabilization of targeted cell membranes to enable translocation of the botulinum neurotoxin light chain (BoNT-LC) molecule across the targeted cell membrane to the cell cytosol where a therapeutic response is produced in a mammalian system. The methods and apparatus include use of catheter based delivery systems, non-invasive delivery systems, and transdermal delivery systems.

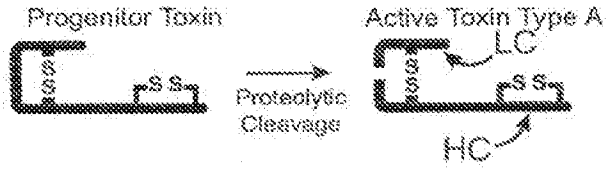
Progenitor Toxin
S S
S S
Proteolytic
Cleavage
Active Toxin Type A
LC
S S
S S
HC

FIG. 1

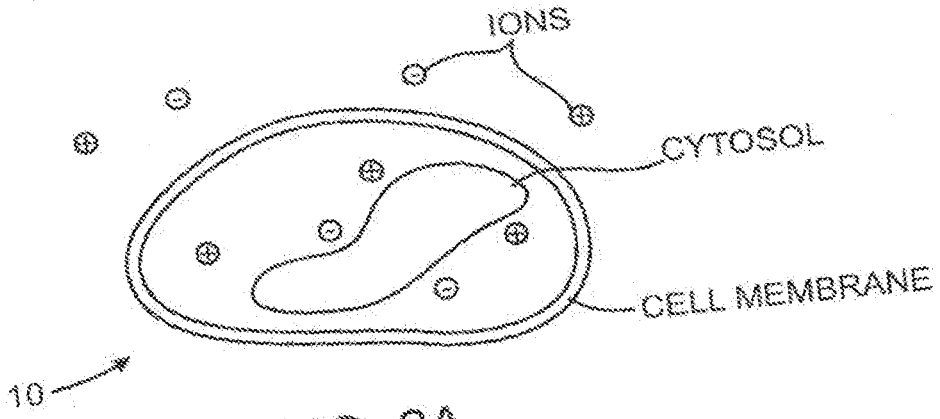

FIG. 2A

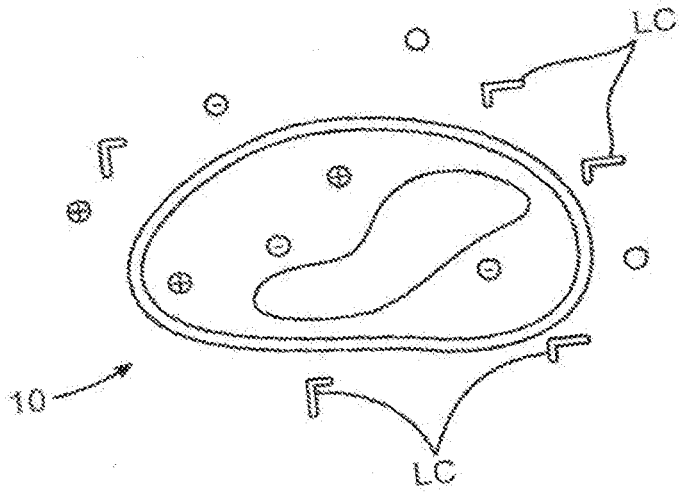

FIG. 2B

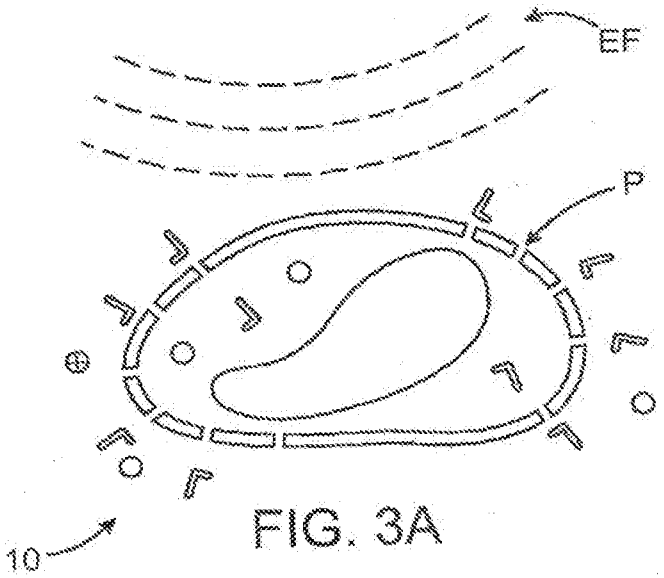

FIG. 3A

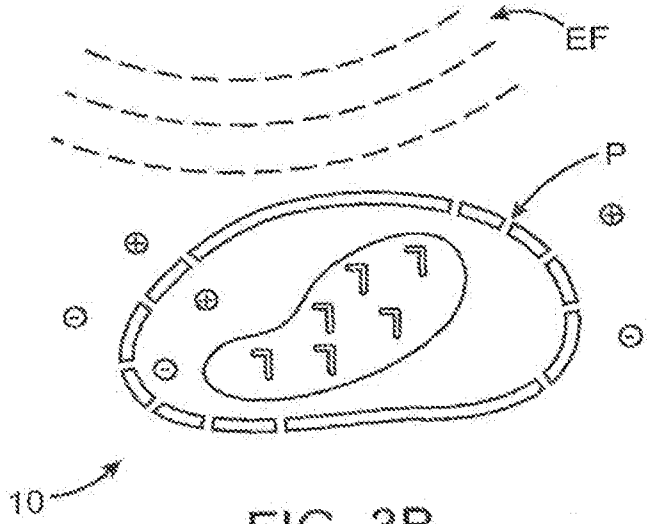

FIG. 3B

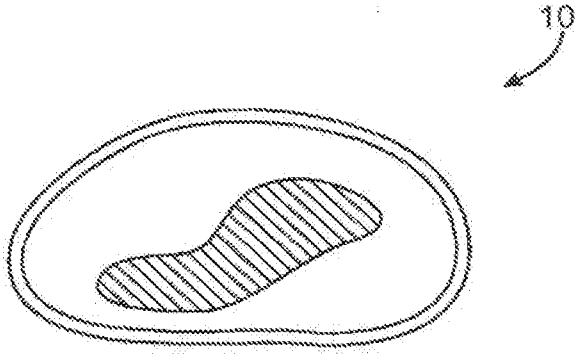

FIG. 4

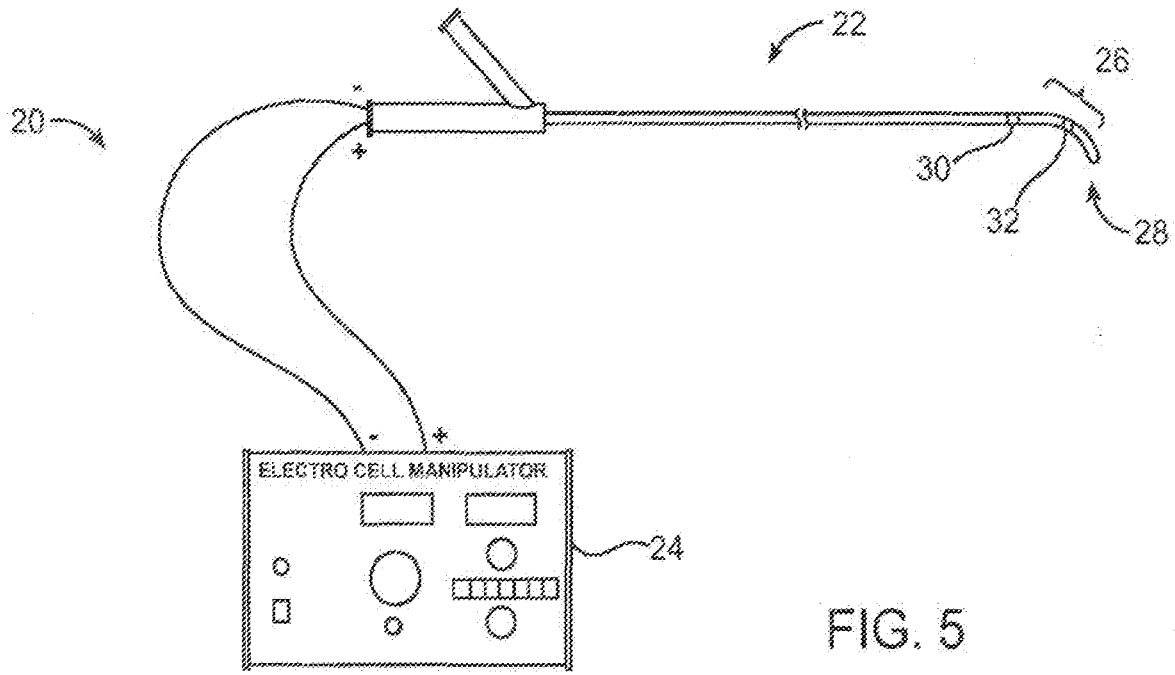

FIG. 5

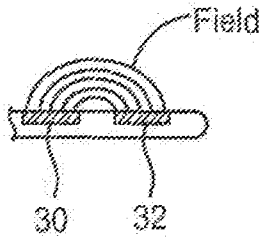

FIG. 5A

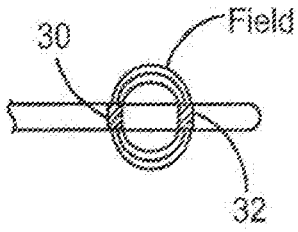

FIG. 5B

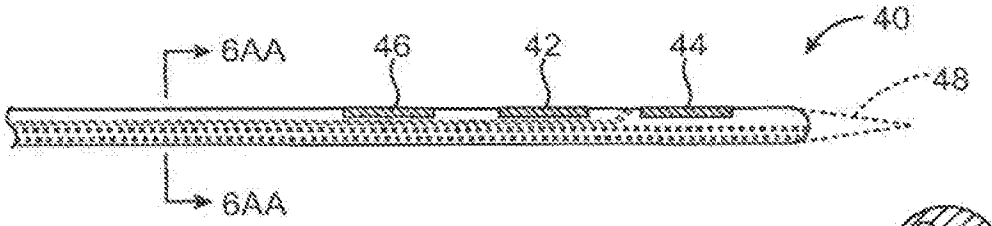

FIG. 6A

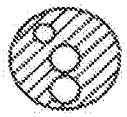

FIG. 6AA

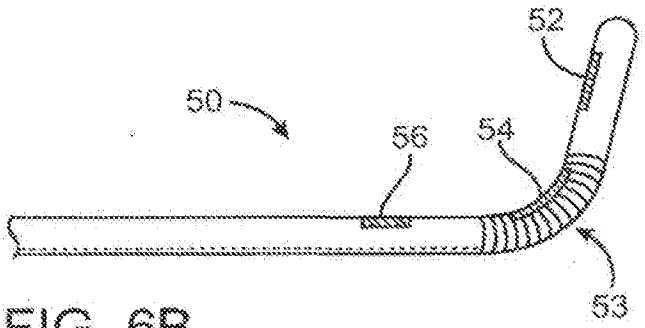

FIG. 6B

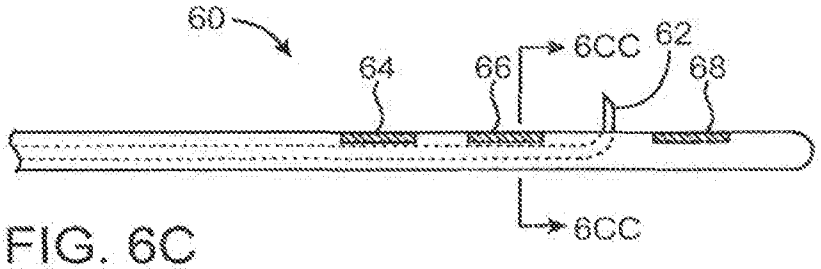

FIG. 6C

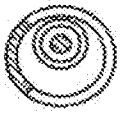

FIG. 6CC

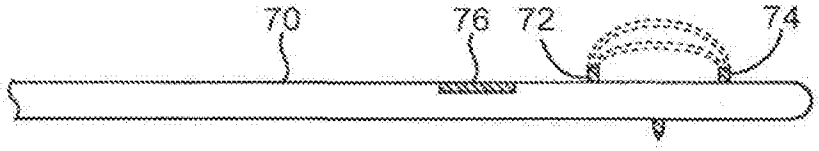

FIG. 6D

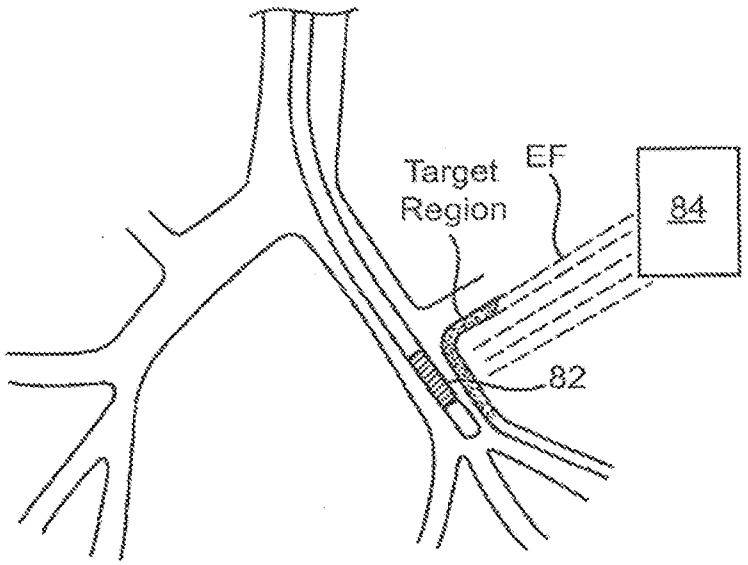

FIG. 7

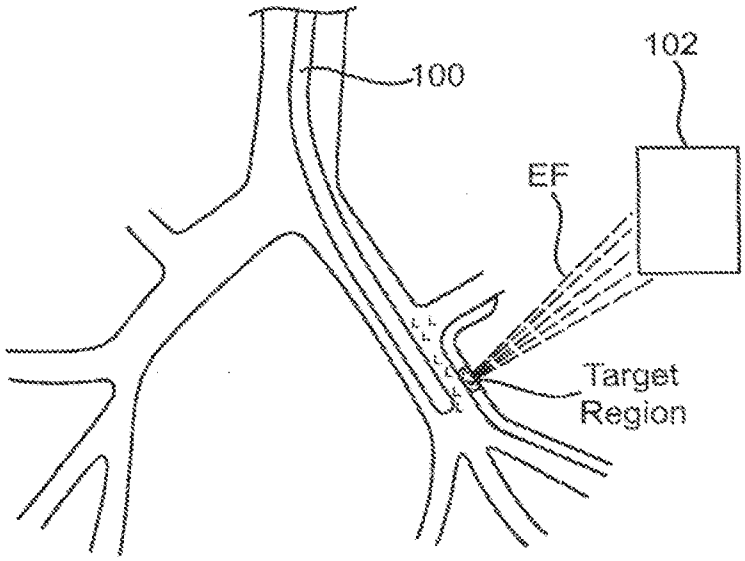

FIG. 13

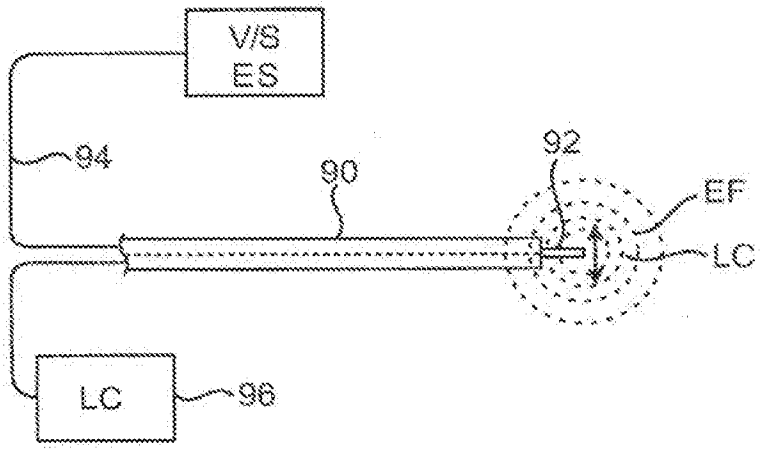

FIG. 8

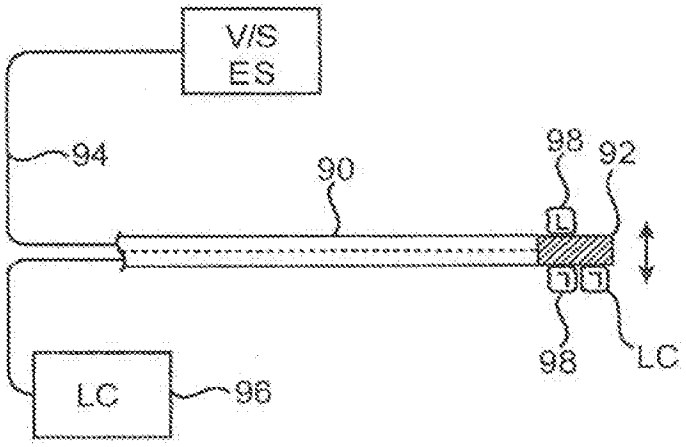

FIG. 11

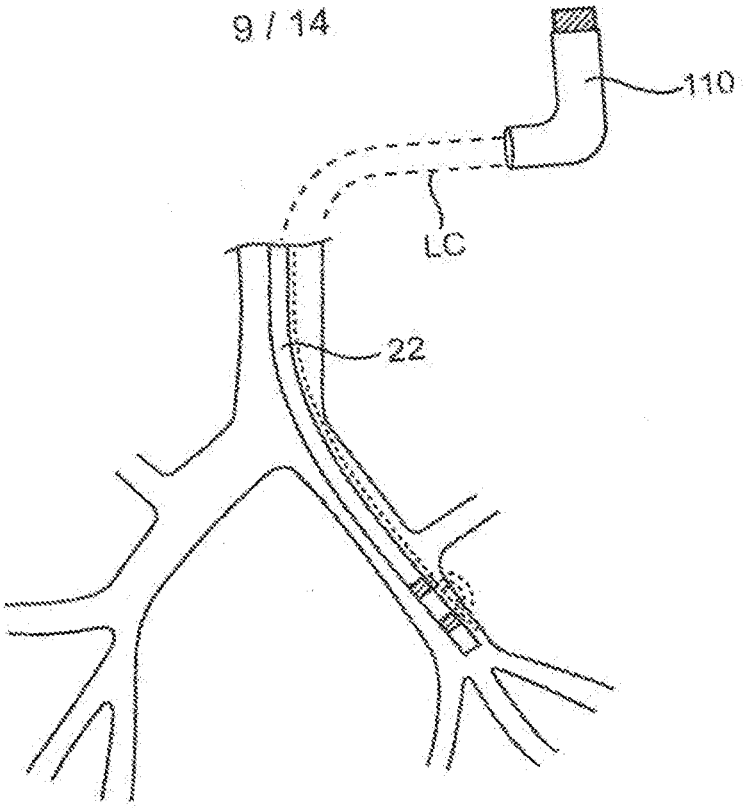

FIG. 9

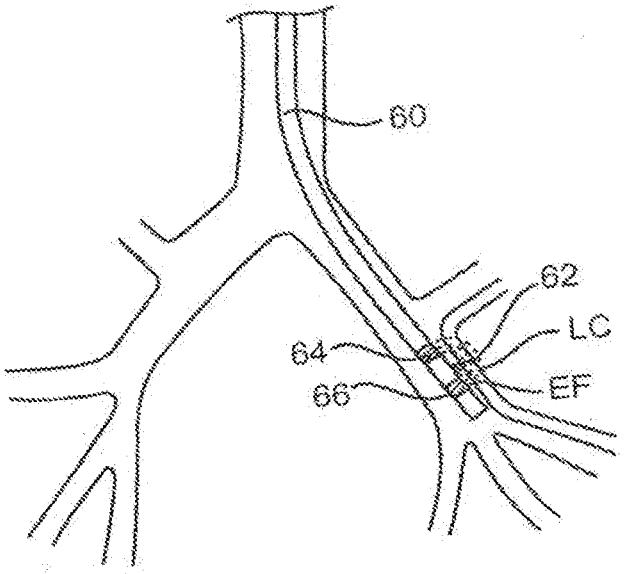

FIG. 10

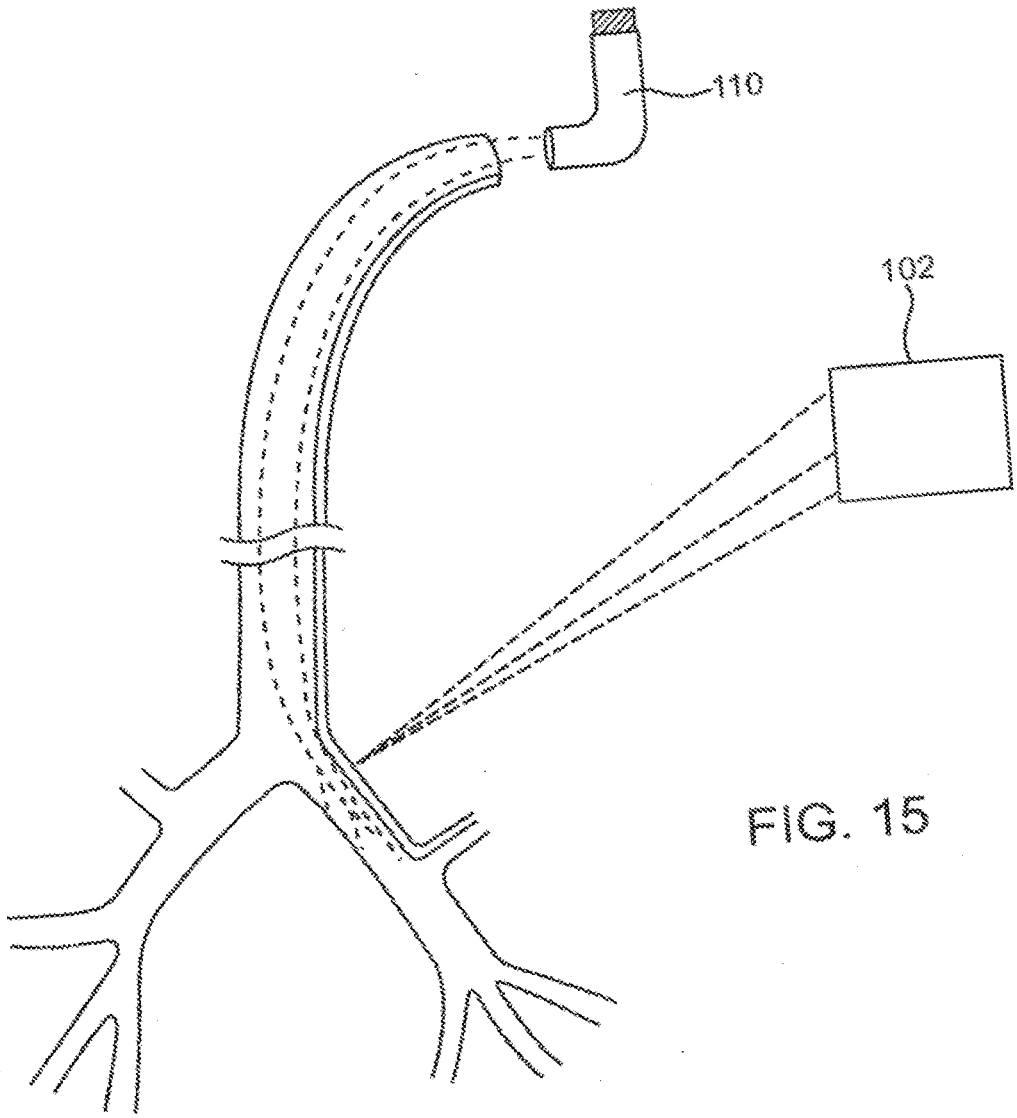

FIG. 15

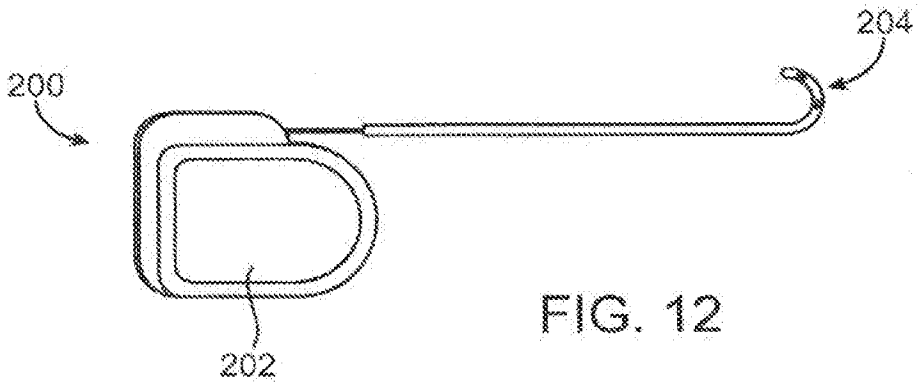

FIG. 12

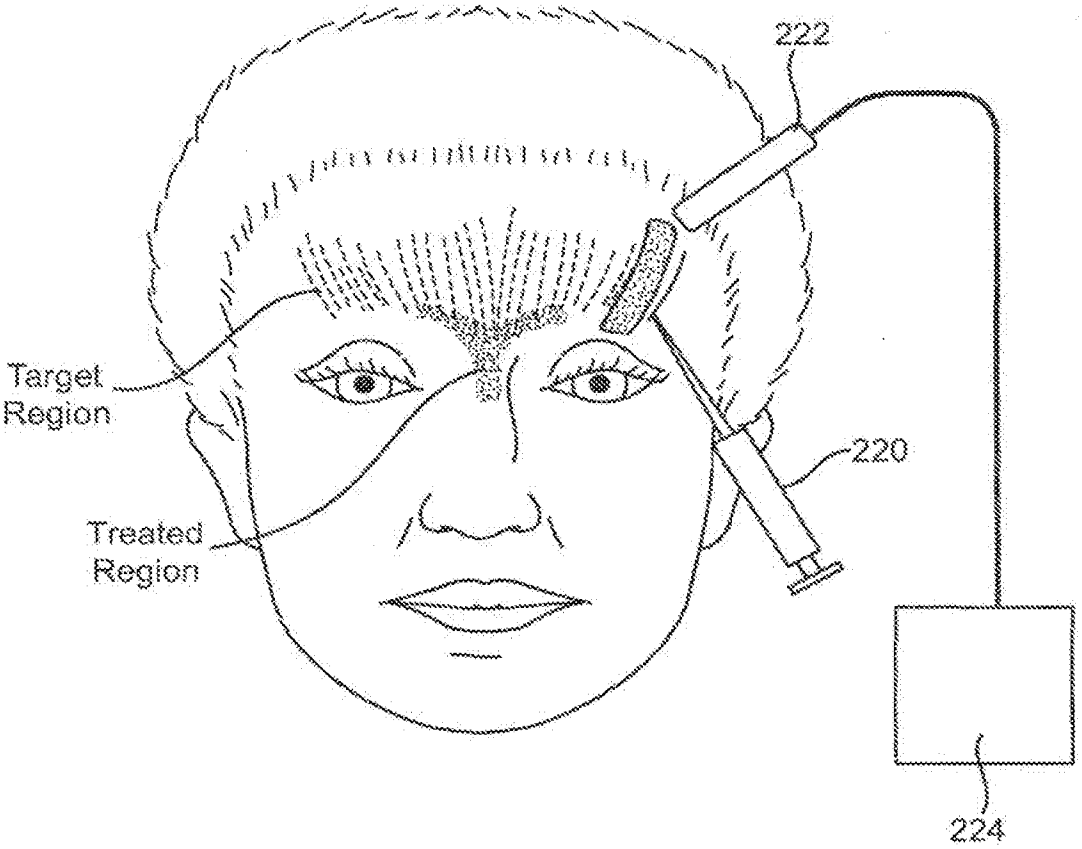

FIG. 14

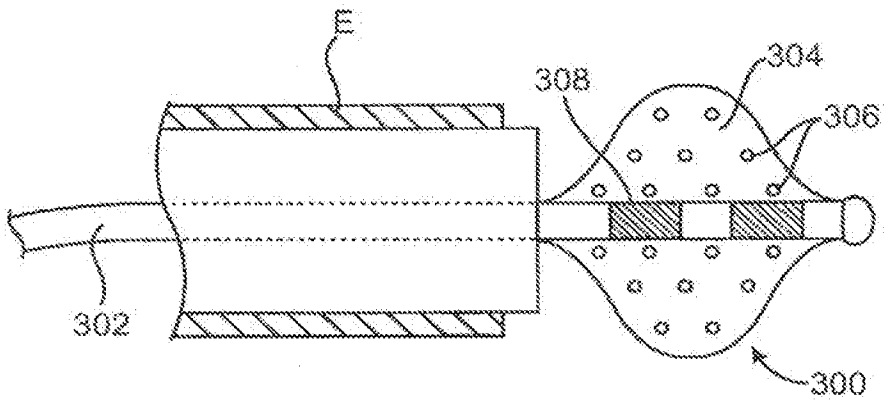

FIG. 15A

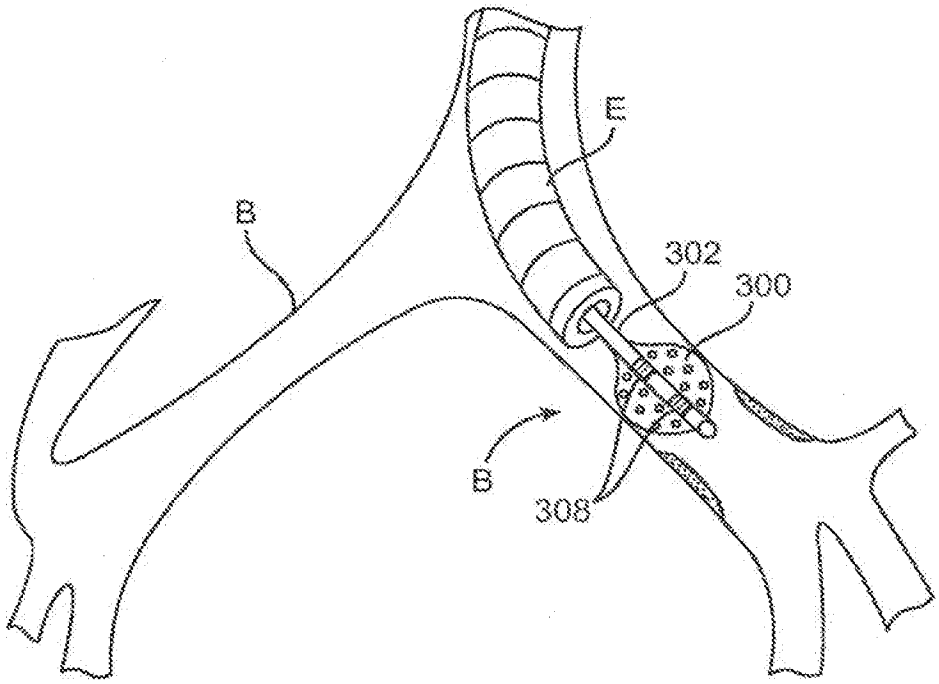

FIG. 15B

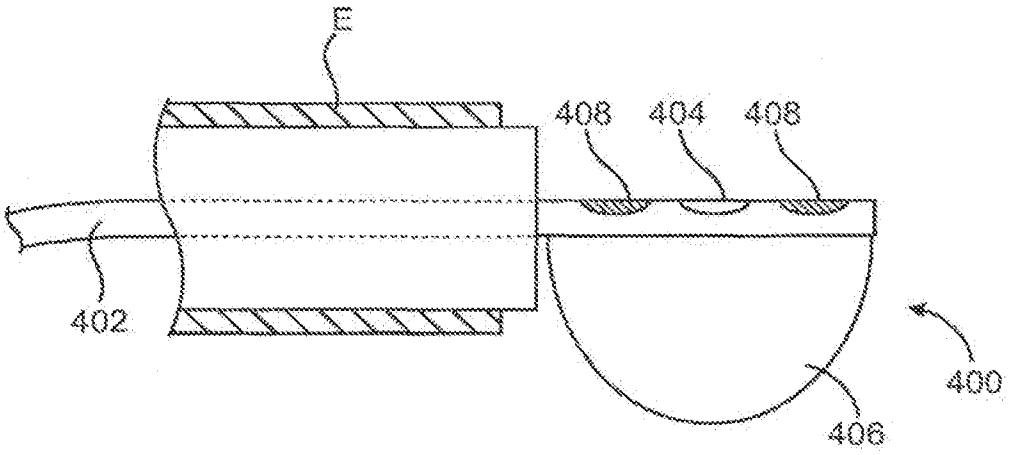

FIG. 16A

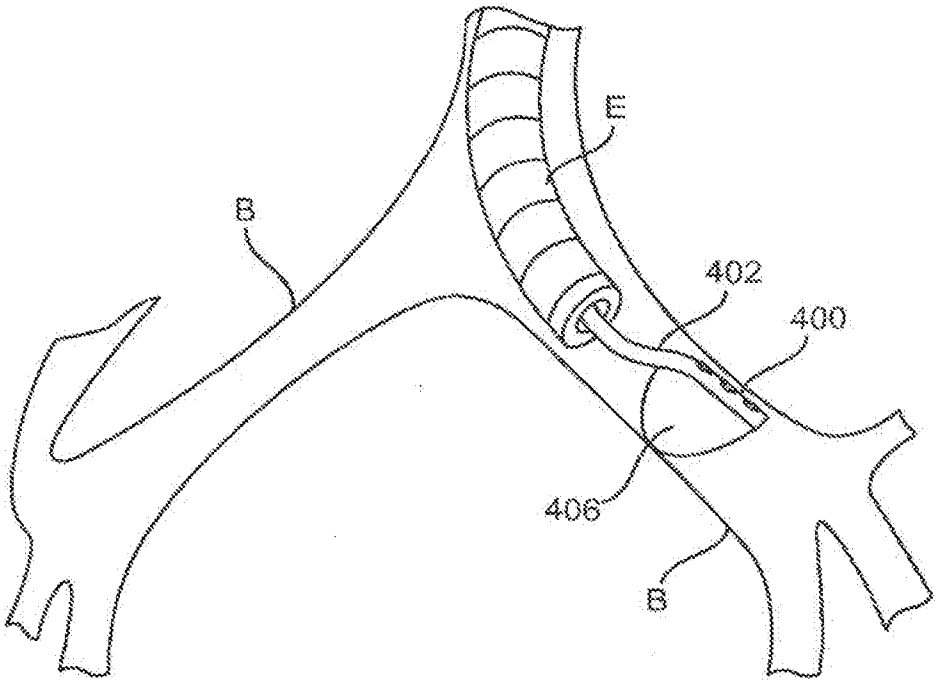

FIG. 16B

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Filer:	Daidre L. Burgess/Valerie Mitchell
Attorney Docket Number:	4680.32US07

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	70	70
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**800**

Electronic Acknowledgement Receipt

EFS ID:	27581945
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	22-NOV-2016
Filing Date:	
Time Stamp:	09:34:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$800
RAM confirmation Number	112216INTEFSW09353800
Deposit Account	160631
Authorized User	Daidre Burgess

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	4680_32US07_ADS.pdf	1823684 829411855410f43916aa710b55e9c59c893bc0a9	no	9
Warnings:					
Information:					
2		4680_32US07_APP.pdf	150579 41f6ee6b5285c6a446d6b20ac5e2d2ed6407fbf2	yes	37

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	31
Claims	32	36
Abstract	37	37

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
Warnings:					
Information:					
3	Drawings-only black and white line drawings	4680_32US07_DRW.pdf	1177609 87ef2d3cef20e5ac34b606f9bc3b66f7fdd328d2	no	14
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Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	36843 80ce3e4d344a59a412d1ada387f7222807350c3b	no	2
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Information:					
			Total Files Size (in bytes):	3188715	

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 a 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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
15/358,187

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
AMENDMENT A	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
AMENDMENT A	Application Size Fee (37 CFR 1.16(s))									
AMENDMENT A	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
AMENDMENT B	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
AMENDMENT B	Application Size Fee (37 CFR 1.16(s))									
AMENDMENT B	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/358,187	11/22/2016	1645	800	4680.32US07	20	2

CONFIRMATION NO. 6425

FILING RECEIPT

24113
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

OC000000087550108

Date Mailed: 12/02/2016

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Mark E. Deem, Mountain View, CA;
Hanson S. Gifford III, Woodside, CA;

Applicant(s)

The Foundry, LLC, Menlo Park, CA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 14/601,529 01/21/2015 PAT 9498283
which is a CON of 13/660,629 10/25/2012 PAT 8961391
which is a CON of 13/253,595 10/05/2011 PAT 8338164
which is a CON of 12/559,278 09/14/2009 PAT 8133497
which is a DIV of 11/459,090 07/21/2006 PAT 7608275
which claims benefit of 60/702,077 07/22/2005

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 11/30/2016

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/358,187**

Projected Publication Date: 03/16/2017

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/358,187	11/22/2016	Mark E. Deem	4680.32US07

CONFIRMATION NO. 6425

INFORMAL NOTICE

24113
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

OC000000087550109

Date Mailed: 12/02/2016

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Mark E. Deem
  Hanson S. Gifford III

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**.

/zmoguss/

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 4680.32US07

Deem et al. Confirmation No.: 6425

Application No.: 15/358,187 Examiner: Unknown

Filed: November 22, 2016 Group Art Unit: 1645

For: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

TRANSMITTAL OF DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Enclosed are the Declarations. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 16-0631.

Respectfully submitted,

/Daidre L. Burgess/

Daidre L. Burgess
Registration No. 60389

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.252.1558

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

This application, entitled: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT, the specification of which ___ is attached hereto or XX was filed on October 25, 2012, as Application No. 13/660,629 and was amended on _____ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

Full Name of Inventor 1:	Last Name: DEEM	Suffix:	First Name: Mark	Middle Name or Initial: E.	
Residence & Citizenship:	City: Mountain View		State/Foreign Country: CA	Country of Citizenship: US	
Post Office Address:	Post Office Address: 685 Sierra Avenue		City: Mountain View	State/Country: CA/USA	Postal Code: 94041
Full Name of Inventor 2:	Last Name: GIFFORD	Suffix:	First Name: Hanson	Middle Name or Initial:	
Residence & Citizenship:	City: Woodside		State/Foreign Country: CA	Country of Citizenship: US	
Post Office Address:	Post Office Address: 3180 Woodside Road		City: Woodside	State/Country: CA/USA	Postal Code: 94062

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this declaration (or oath) is punishable under 18 U.S.C. §1001 by fine or imprisonment of not more than five (5) years, or both.

Signature of Inventor 1	Signature of Inventor 2
Mark E. Deem	Hanson Gifford
Date 12-15-14	Date Dec. 15, 2014

Electronic Acknowledgement Receipt

EFS ID:	28167977
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	25-JAN-2017
Filing Date:	22-NOV-2016
Time Stamp:	17:05:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4680_32US07_Declarations.pdf	353414 484fbba2c7a5b220a9c341e5bace4db27be080a1	yes	2

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	1
	Oath or Declaration filed	2	2
Warnings:			
Information:			
	Total Files Size (in bytes):	353414	

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 a 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.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 4680.32US07

Deem et al. Confirmation No.: 6425

Application No.: 15/358,187 Examiner: Unknown

Filed: November 22, 2016 Group Art Unit: Unknown

For: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

PRELIMINARY AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

INTRODUCTORY COMMENTS

Prior to examination, please amend the above-identified application as follows:

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

Electronic Acknowledgement Receipt

EFS ID:	28310492
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	09-FEB-2017
Filing Date:	22-NOV-2016
Time Stamp:	12:52:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4680_32US07_PREL_AMEND.pdf	74227 1c94ac5bf705be45aff95c5262e5071427f3fe57	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	8	8
	Claims	2	7
	Preliminary Amendment	1	1

Warnings:	
Information:	
Total Files Size (in bytes):	74227

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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 a 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.

REMARKS

Claims 1-20 are pending. By this Amendment, claims 1-20 are cancelled, no claims are amended and new claims 21-40 are added. Support for the amendments can be found throughout the specification and figures as originally filed.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Daidre L. Burgess/

Daidre L. Burgess
Registration No. 60389

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.252.1558

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remain(s) under examination in the application is presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or fewer characters; and 2. added matter is shown by underlining.

1-20. (Cancelled)

Please add new claims 21-40 as follows:

21. (New) A nerve modification device for altering nerve function in a bronchial airway of a patient, the nerve modification device comprising:

a main catheter body configured to extend though a trachea into the bronchial airway; and

at least one energy applicator having at least one energy emitter configured to emit energy laterally relative to the main catheter body,

wherein the nerve modification device is adapted to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in the wall of the bronchial airway in a first lateral direction from the main catheter body to alter nerve cells within the target region.

22. (New) The nerve modification device of claim 21, wherein the energy is at least one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

23. (New) The nerve modification device of claim 21, wherein the at least one energy emitter comprises at least one electrode.

24. (New) The nerve modification device of claim 23, wherein the energy is RF energy.

25. (New) The nerve modification device of claim 21, wherein the at least one energy emitter comprises at least one ultrasound transducer.

26. (New) The nerve modification device of claim 25, wherein the energy is ultrasound energy.

27. (New) The nerve modification device of claim 21, wherein the energy applicator is configured to be positionable in contact with a first portion of a circumference of the airway wall.

28. (New) A system for altering nerve function in a bronchial airway of a patient, the system comprising:

an intraluminal catheter configured to be positioned within a bronchial airway of a patient, the intraluminal catheter including:

a main catheter body, and

a first energy emitter configured to emit energy laterally relative to the main catheter body; and

an energy generator operably coupled to the first energy emitter and configured to activate the first energy emitter, thereby causing an energy field to be generated in a target region in the airway wall to alter nerve cells within the target region.

29. (New) The system of claim 28, wherein the main catheter body is configured to be positionable such that the first energy emitter is in contact with a first portion of a circumference of the airway wall.

30. (New) The system of claim 28, further comprising:

a second energy emitter operably coupled to the energy generator, the second energy emitter being configured to be positioned outside of the airway and remote from the target region, the target region being positioned between the first and second energy emitters such that activation of the first and second energy emitters by the energy generator produces the energy field between the first and second emitters and within the target region.

31. (New) The system of claim 30, wherein a placement of the first and second energy emitters relative to each other controls the size and/or intensity of the energy field.

32. (New) The system of claim 28, the system further comprising:

a second energy emitter operably coupled to the energy generator, such that an arrangement of the first and second energy emitters causes the energy field produced therefrom to be concentrated in a lateral direction from the main catheter body.

33. (New) The system of claim 28, a second energy emitter operably coupled to the energy generator, such that an arrangement of the first and second energy emitters causes the energy field produced therefrom to comprise a uniform energy field about the main catheter body.

34. (New) The system of claim 28, wherein the energy is at least one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

35. (New) The system of claim 28, wherein the first energy emitter comprises an electrode.

36. (New) The system of claim 38, wherein the energy is RF energy.

37. (New) The system of claim 28, wherein the first energy emitter comprises an ultrasound transducer.

38. (New) A method, comprising:

causing a nerve modification device to be manufactured and made available to a user, the nerve modification device including a main catheter body and at least one energy applicator having at least one energy emitter; and

providing instructions to the user for use of the nerve modification device, the instructions recorded on a tangible or non-transitory computer-readable medium and including:

positioning the nerve modification device at a treatment site in a bronchial airway of a patient; and

causing the nerve modification device to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in the wall of the

bronchial airway in a first lateral direction from the main catheter body to alter nerve cells within the target region.

39. (New) The method of claim 38, wherein causing the nerve modification device to deliver energy from the at least one energy emitter comprises causing the nerve modification device to deliver a pulse of radio frequency energy.

40. (New) The method of claim 38, wherein causing the nerve modification device to deliver energy from the at least one energy emitter comprises causing the nerve modification device to deliver one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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 APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	
15/358,187	11/22/2016	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	x $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	x $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT

02/09/2017	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x $40 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LDRC
ADRIANE WINSTON

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 24113

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

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OR

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OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

The Foundry, LLC

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	[signature]	Date (Optional)	2/17/17
Name	Hanson S. Clifford III		
Title	Managing member		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	15/358,187
Filing Date	November 22, 2016
First Named Inventor	Mark E. Deem
Title	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
Art Unit	1645
Examiner Name	
Attorney Docket Number	4680.32US07

SIGNATURE of Applicant or Patent Practitioner

Signature	/Daidre L. Burgess/	Date (Optional)	02/27/2017
Name	Daidre L. Burgess	Registration Number	60389
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

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Electronic Acknowledgement Receipt

EFS ID:	28473704
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	27-FEB-2017
Filing Date:	22-NOV-2016
Time Stamp:	16:56:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4680_32US07_Power_of_Atty.pdf	165445 202a16f36745d6b39c3471e6e7fdf8edcd0b97f3	yes	2

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Power of Attorney	2	2
	Transmittal Letter	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	165445	

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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 a 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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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/358,187	11/22/2016	Mark E. Deem	4680.32US07

CONFIRMATION NO. 6425

POA ACCEPTANCE LETTER

24113
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

OC000000089550894

Date Mailed: 03/01/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/27/2017.

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**.

/hsarwari/

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/358,187	11/22/2016	Mark E. Deem	4680.32US07

CONFIRMATION NO. 6425

PUBLICATION NOTICE

OC000000089938997

24113
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

Title:SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

Publication No.US-2017-0072176-A1
Publication Date:03/16/2017

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Substitute for form 1449/PTO	Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	15/358,187
	Filing Date	November 22, 2016
	First Named Inventor	Deem et al.
	Art Unit	1645
	Examiner Name	Albert Mark Navarro
Sheet 1 of 17	Attorney Docket Number	4680.32US07

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2001/0044596 A1	11-22-2001	Jaafar
		US-2002/0013581 A1	01-31-2002	Edwards et al.
		US-2002/0082197 A1	06-27-2002	Aoki et al.
		US-2002/0087208 A1	07-04-2002	Koblish et al.
		US-2002/0111620 A1	08-15-2002	Cooper et al.
		US-2002/0143302 A1	10-03-2002	Hinchliffe et al.
		US-2002/0198512 A1	12-26-2002	Seward
		US-2003/0018344 A1	01-23-2003	Kaji et al.
		US-2003/0023287 A1	01-30-2003	Edwards et al.
		US-2003/0036755 A1	02-20-2003	Ginn et al.
		US-2003/0050591 A1	03-13-2003	McHale
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		US-2003/0159700 A1	08-28-2003	Laufer et al.
		US-2003/0202990 A1	10-30-2003	Donovan et al.
		US-2003/0211121 A1	11-13-2003	Donovan
		US-2003/0233099 A1	12-18-2003	Danaek et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		CA 2,152,002	12-18-1995	Trudell Medical Limited	
		JP 2002-145784	05-22-2002	Morishita et al.	X (Abstract Only)
		WO 95/19805 A1	07-27-1995	Hofmann et al.	

EXAMINER SIGNATURE		DATE CONSIDERED	

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	2	of	17	Attorney Docket Number	4680.32US07

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number / Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2004/0009180 A1	01-15-2004	Donovan
		US-2004/0010290 A1	01-15-2004	Schroeppel et al.
		US-2004/0028676 A1	02-12-2004	Klein et al.
		US-2004/0086531 A1	05-06-2004	Barron
		US-2004/0091880 A1	05-13-2004	Wiebusch et al.
		US-2004/0142005 A1	07-22-2004	Brooks et al.
		US-2004/0151741 A1	08-05-2004	Borodic
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		US-2004/0186435 A1	09-23-2004	Seward
		US-2004/0213813 A1	10-28-2004	Ackerman
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		US-2004/0220562 A1	11-04-2004	Garabedian et al.
		US-2004/0226556 A1	11-18-2004	Deem et al.
		US-2004/0226556 A1	11-28-2004	Deem et al.
		US-2004/0248188 A1	12-09-2004	Sanders
		US-2004/0253274 A1	12-16-2004	Voet
		US-2005/0019346 A1	01-27-2005	Boulis

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document / Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 99/34831 A1	07-15-1999	Hoffman et al.	
		WO 00/62699	10-26-2000	Danek et al.	
		WO 2004/006954 A2	01-22-2004	Donovan	
		WO 2004/101028 A2	11-25-2004	Deem et al.	
		WO 2005/032646 A2	04-14-2005	Beebe et al.	

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	3	of	17	Attorney Docket Number	4680.32US07

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2005/0065575 A1	03-24-2005	Dobak
		US-2005/0074461 A1	04-07-2005	Donovan
		US-2005/0107853 A1	05-19-2005	Krespi et al.
		US-2005/0152924 A1	07-14-2005	Voet
		US-2005/0182393 A1	08-18-2005	Abboud et al.
		US-2005/0183732 A1	08-25-2005	Edwards
		US-2005/0245926 A1	11-03-2005	Edwards et al.
		US-2006/0084966 A1	04-20-2006	Maguire et al.
		US-2006/0106361 A1	05-18-2006	Muni et al.
		US-2006/0153876 A1	07-13-2006	Sanders
		US-2006/0222667 A1	10-05-2006	Deem et al.
		US-2006/0225742 A1	10-12-2006	Deem et al.
		US-2006/0254600 A1	11-16-2006	Danek et al.
		US-2007/0021803 A1	01-25-2007	Deem et al.
		US-2007/0025919 A1	02-01-2007	Deem et al.
		US-2007/0043350 A1	02-22-2007	Soltesz et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 2005/048988 A1	06-02-2005	Scott et al.	
		WO 2004/101028 A2	11-25-2004	Deem et al.	
		WO 2004/101028 A3	12-14-2006	Deem et al.	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	4	of	17	Attorney Docket Number	4680.32US07

U.S. PATENT DOCUMENTS

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	5	of	17	Attorney Docket Number	4680.32US07

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Sheet	6	of	17	Attorney Docket Number	4680.32US07

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				Art Unit	1645
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Sheet	7	of	17	Attorney Docket Number	4680.32US07

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Sheet	8	of	17	Attorney Docket Number	4680.32US07

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Sheet	9	of	17	Attorney Docket Number	4680.32US07

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[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	12	of	17	Attorney Docket Number	4680.32US07

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-7,027,869 B2	04-11-2006	Danek et al.
		US-7,184,811 B2	02-27-2007	Phan et al.
		US-7,371,231 B2	05-13-2008	Rioux et al.
		US-7,462,179 B2	12-09-2008	Edwards et al.
		US-7,608,275 B2	10-27-2009	Deem et al.
		US-7,628,789 B2	12-08-2009	Soltesz et al.
		US-7,747,324 B2	06-29-2010	Errico et al.
		US-7,853,331 B2	12-14-2010	Kaplan et al.
		US-8,007,495 B2	08-30-2011	McDaniel et al.
		US-8,088,127 B2	01-03-2012	Mayse et al.
		US-8,105,817 B2	01-31-2012	Deem et al.
		US-8,133,497 B2	03-13-2012	Deem et al.
		US-8,172,827 B2	05-08-2012	Deem et al.
		US-8,226,638 B2	07-24-2012	Mayse et al.
		US-8,338,164 B2	12-25-2012	Deem et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

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		US-8,483,831 B1	07-09-2013	Hlavka et al.
		US-8,489,192 B1	07-16-2013	Hlavka et al.
		US-8,731,672 B2	05-20-2014	Hlavka et al.
		US-8,740,895 B2	06-03-2014	Mayse et al.
		US-8,777,943 B2	07-15-2014	Mayse et al.
		US-8,808,280 B2	08-19-2014	Mayse et al.
		US-8,821,489 B2	09-02-2014	Mayse et al.
		US-8,911,439 B2	12-16-2014	Mayse et al.
		US-8,932,289 B2	01-13-2015	Mayse et al.
		US-8,961,391 B2	02-24-2015	Deem et al.
		US-8,961,507 B2	02-24-2015	Mayse et al.
		US-8,961,508 B2	02-24-2015	Mayse et al.
		US-9,005,195 B2	04-14-2015	Mayse et al.
		US-9,017,324 B2	04-28-2015	Mayse et al.
		US-9,125,643 B2	09-08-2015	Hlavka et al.
		US-9,149,328 B2	10-06-2015	Dimmer et al.
		US-9,339,618 B2	05-17-2016	Deem et al.
		US-9,498,283 B2	11-22-2016	Deem et al.

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		AHNERT-HILGER, et al. Introduction of macromolecules into bovine adrenal medullary chromaffin cells and rat pheochromocytoma cells (PC12) by permeabilization with streptolysin O: inhibitory effect of tetanus toxin on catecholamine secretion. J Neurochem. 1989 Jun;52(6):1751-8.	
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		CHANG. Cell poration and cell fusion using an oscillating electric field. Biophys J. 1989 Oct;56(4):64152.	
		DE PAIVA, et al. Light chain of botulinum neurotoxin is active in mammalian motor nerve terminals when delivered via liposomes. FEBS Lett. 1990 Dec 17;277(1-2):171-4.	
		European search report and search opinion dated 01/07/2014 for EP Application No. 6788062.5.	

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Sheet	15	of	17	Attorney Docket Number	4680.32US07

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		GUZMAN, et al. Bioeffects caused by changes in acoustic cavitation bubble density and cell concentration: a unified explanation based on cell-to-bubble ratio and blast radius. Ultrasound Med Biol. 2003 Aug;29(8):1211-22. Anonymous: "Neurotoxin (from Wikipedia)", internet citation, Retrieved from the Internet: URL:http://en.wikipedia.org/w/index.php?title=Neurotoxin&printable=yes [retrieved on 2015-04-02].	
		International search report and written opinion dated 08/08/2007 for PCT/US2006/028310.	
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		RAJ. Editorial, Pain Practice. 2004; 4(1S):S1-S3.	
		SCHMITT, et al. Indwelling transbronchial catheter drainage of pulmonary abscess. Ann Thorac Surg. 1988 Jan;45(1):43-7	
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		SIMPSON, et al. Isolation and characterization of the Botulinum neurotoxins. Methods Enzymol. 1988;165:76-85.	

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Sheet	16	of	17	Attorney Docket Number	4680.32US07

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		SUNDARAM, et al. An experimental and theoretical analysis of ultrasound-induced permeabilization of cell membranes. Biophys J. 2003 May;84(5):3087-101.	
		TSUJI, et al. Biodegradable stents as a platform to drug loading. Int J Cardiovasc Intervent. 2003;5(1):13-6.	
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		SIMPSON. The origin, structure, and pharmacological activity of botulinum toxin. Pharmacol Rev. 1981 Sep;33(3):155-88	
		Office Action dated May 24, 2016 for Japanese Application No. 2015-120827, 7 pages.	
		Application and File history for U.S. Patent Application No.: 11/459,090, filed July 21, 2006. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	
		Application and File history for U.S. Patent Application No.: 12/559,278, filed September 14, 2009. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	

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		Application and File history for U.S. Patent Application No.: 13/253,595, filed October 5, 2011. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	
		Application and File history for U.S. Patent Application No.: 13/660,629, filed October 25, 2012. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	
		Application and File history for U.S. Patent Application No.: 14/601,529, filed January 21, 2015. Inventors: Deem et al. *as available on PAIR at www.uspto.gov*	

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Electronic Acknowledgement Receipt

EFS ID:	30810002
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	31-OCT-2017
Filing Date:	22-NOV-2016
Time Stamp:	11:56:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4680_32US07_IDS.pdf	240008 00612b9fe45fcbfd90df7b502b86a8f9819b996b	yes	20

	Multipart Description/PDF files in .zip description		
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	Transmittal Letter	1	3
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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a 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.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
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.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 4680.32US07

Deem et al. Confirmation No.: 6425

Application No.: 15/358,187 Examiner: Albert Mark Navarro

Filed: November 22, 2016 Group Art Unit: 1645

For: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of the above-referenced application, and be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information may not be prior art, and/or prove that this information may not be enabling for any aspect of the information provided herewith.

This Information Disclosure Statement is being filed without a certification or fee because this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR § 1.97(b)(3).

The Examiner's attention is directed to the applications or patents, if any, to which priority is claimed, as well as to any continuing applications which claim priority to the above-referenced application, and to applications, if any, that may be related by virtue of similar claimed subject matter as the above-referenced application (collectively, the "Related Case(s)"). The Related Case(s), or documents associated with the Related Case(s), are identified on the attached form PTO-1449 by serial number, publication number and/or patent number, along with a copy of the current prosecution history, downloaded from PAIR where available. The current prosecution history for the Related Case(s) is submitted as an NPL document for the convenience of the Examiner.

The prosecution history for any and all of these Related Case(s) may include information material to patentability of the above-referenced application including Office Actions, Responses, Office Communications or Notices of Allowance, all of which are readily accessible to the Examiner via PAIR/PALM. To promote consistency and full disclosure during the prosecution of the above-referenced application together with the prosecution of any of the Related Case(s) and to assist the Examiner in complying with the obligations of MPEP 609.02 and/or 2001.06(b), the Examiner is respectfully requested to review the prosecution history of each of the Related Case(s). **This request for review should be considered ongoing throughout the prosecution of the above-referenced application with an updated review via PAIR/PALM of the prosecution histories of any Related Case(s) being made prior to**

issuance of any Notice of Allowance for the above-referenced application. The identification of any of the Related Case(s) for purposes of this Information Disclosure Statement should not be construed as a waiver of secrecy, if applicable, as to such applications now or upon issuance of the above-referenced application as a patent. For purposes of the Related Case(s), it should be noted that all of the Related Case(s) are published or otherwise publicly available on PAIR.

Please note that copies of the references that were cited by or submitted to the Office in applications which are relied upon for an earlier filing date under 35 U.S.C. § 120 may be found in the appropriate records via PAIR/PALM. 37 CFR § 1.98(d).

Respectfully submitted,

/Daidre L. Burgess/

Daidre L. Burgess
Registration No. 60389

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.252.1558

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*	Application Number	15/358,187
	Filing Date	November 22, 2016
	First Named Inventor	Deem et al.
	Art Unit	1645
	Examiner Name	Albert Mark Navarro
Sheet 1 of 17	Attorney Docket Number	4680.32US07

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Sheet	2	of	17	Attorney Docket Number	4680.32US07

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Sheet	3	of	17	Attorney Docket Number	4680.32US07

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				Examiner Name	Albert Mark Navarro
Sheet	4	of	17	Attorney Docket Number	4680.32US07

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Sheet	5	of	17	Attorney Docket Number	4680.32US07

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Sheet	6	of	17	Attorney Docket Number	4680.32US07

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	9	of	17	Attorney Docket Number	4680.32US07

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Sheet	12	of	17	Attorney Docket Number	4680.32US07

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		SIMPSON, et al. Isolation and characterization of the Botulinum neurotoxins. Methods Enzymol. 1988;165:76-85.	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.M.N/

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	16	of	17	Attorney Docket Number	4680.32US07

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		SUNDARAM, et al. An experimental and theoretical analysis of ultrasound-induced permeabilization of cell membranes. Biophys J. 2003 May;84(5):3087-101.	
		TSUJI, et al. Biodegradable stents as a platform to drug loading. Int J Cardiovasc Intervent. 2003;5(1):13-6.	
		UNAL, et al. Effect of botulinum toxin type A on nasal symptoms in patients with allergic rhinitis: a double-blind, placebo-controlled clinical trial. Acta Otolaryngol. 2003 Dec;123(9):1060-3.	
		WEAVER, et al. Electroporation: a general phenomenon for manipulating cells and tissues. J Cell Biochem. 1993 Apr;51(4):426-35.	
		GUZMAN, et al. Equilibrium loading of cells with macromolecules by ultrasound: effects of molecular size and acoustic energy. J Pharm Sci. 2002 Jul;91(7):1693-701.	
		SIMPSON. The origin, structure, and pharmacological activity of botulinum toxin. Pharmacol Rev. 1981 Sep;33(3):155-88	
		Office Action dated May 24, 2016 for Japanese Application No. 2015-120827, 7 pages.	
		Application and File history for U.S. Patent Application No.: 11/459,090, filed July 21, 2006. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	
		Application and File history for U.S. Patent Application No.: 12/559,278, filed September 14, 2009. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	

EXAMINER SIGNATURE		DATE CONSIDERED	

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	17	of	17	Attorney Docket Number	4680.32US07

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Application and File history for U.S. Patent Application No.: 13/253,595, filed October 5, 2011. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	
		Application and File history for U.S. Patent Application No.: 13/660,629, filed October 25, 2012. Inventors: Deem et al. *as available on PAIR at www.uspto.gov.*	
		Application and File history for U.S. Patent Application No.: 14/601,529, filed January 21, 2015. Inventors: Deem et al. *as available on PAIR at www.uspto.gov*	

EXAMINER SIGNATURE	/ALBERT M NAVARRO/	DATE CONSIDERED	11/02/2017

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/358,187	11/22/2016	Mark E. Deem	4680.32US07	6425

24113 7590 11/09/2017
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/09/2017	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 15/358,187	Applicant(s) Deem et al.	
	Examiner Mark NAVARRO	Art Unit 1645	AIA Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____ .

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☑ Claim(s) 21-40 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☑ Claim(s) 21-40 is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____ .

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____ .

4) ☐ Other: _____ .

DETAILED CORRESPONDENCE

Applicants preliminary amendment filed February 9, 2017 has been received and entered. Claims 1-20 have been cancelled, and new claims 21-40 have been added. Consequently, claims 21-40 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. Claim 36 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 36 recites the "system of claim 38." However, claim 38 is directed to a method, not to a system. Accordingly, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46

USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

2. Claims 21-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,498,283. Although the claims at issue are not identical, they are not patentably distinct from each other because each set of claims encompasses nerve modification devices for altering nerve function in a bronchial airway comprising a main catheter body and at least one energy applicator having at least one energy emitter configured to emit energy laterally relative to the main catheter body.

3. Claims 21-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 8,961,391. Although the claims at issue are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of using nerve modification devices for altering nerve function in a bronchial airway comprising a main catheter body and at least one energy applicator having at least one energy emitter configured to emit energy laterally relative to the main catheter body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark NAVARRO whose telephone number is (571)272-0861.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ALBERT M NAVARRO/
Primary Examiner, Art Unit 1645
November 2, 2017

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BIB DATA SHEET

CONFIRMATION NO. 6425

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/358,187	11/22/2016 RULE	435	1645	4680.32US07

APPLICANTS
The Foundry, LLC, Menlo Park, CA

INVENTORS
Mark E. Deem, Mountain View, CA;
Hanson S. Gifford III, Woodside, CA;

**** CONTINUING DATA ***************************
This application is a CON of 14/601,529 01/21/2015 PAT 9498283
which is a CON of 13/660,629 10/25/2012 PAT 8961391
which is a CON of 13/253,595 10/05/2011 PAT 8338164
which is a CON of 12/559,278 09/14/2009 PAT 8133497
which is a DIV of 11/459,090 07/21/2006 PAT 7608275
which claims benefit of 60/702,077 07/22/2005

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
11/30/2016

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ALBERT MARK NAVARRO/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	14	20	2

ADDRESS
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100
UNITED STATES

TITLE
SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

FILING FEE RECEIVED		
800	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/358,187	Deem et al.
	Examiner	**Art Unit**
	Mark NAVARRO	1645

CPC - Searched*		
Symbol	**Date**	**Examiner**

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
Medline, Biosis, Ca, Caplus, Embase, USPatfull, terms: update search history 14/601,529, 13/660,629, 13/253,595, 12/559,278, 11/459,090	11/02/2017	MN

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	1	of	1	Attorney Docket Number	4680.32US07

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Office Action dated August 21, 2017 for Japanese Application No. 2016-227703, 4 pages.	X

EXAMINER SIGNATURE		DATE CONSIDERED	

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 4680.32US07

Deem et al. Confirmation No.: 6425

Application No.: 15/358,187 Examiner: Albert Mark Navarro

Filed: November 22, 2016 Group Art Unit: 1645

For: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 CFR § 1.56, and in addition to information disclosed in any previously filed prior Information Disclosure Statements, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of the above-referenced application, and be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information may not be prior art, and/or prove that this information may not be enabling for any aspect of the information provided herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing of a Final Action or Notice of Allowance. This Information Disclosure Statement is being filed without a fee, but with a certification pursuant to 37 CFR § 1.97(c)(1).

I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR § 1.97(e)(1). An English language translation of the communication from the foreign patent office is enclosed for the Examiner's convenience.

Respectfully submitted,

/Daidre L. Burgess/

Daidre L. Burgess
Registration No. 60389

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.252.1558

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

Electronic Acknowledgement Receipt

EFS ID:	30903866
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	09-NOV-2017
Filing Date:	22-NOV-2016
Time Stamp:	14:25:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	4680_32US07_NPL_JP_Office_Action_08_21_2017.pdf	114832 2d84fa3e45372f2e3def43b09aef72317cf629cc	no	4

Warnings:

Information:					
2		4680_32US07_SUPP_IDS.pdf	177908 1f78fe4595ae5c4e63c61e82051bb9c8c3a9e187	yes	3

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Information Disclosure Statement (IDS) Form (SB08)	3	3
Transmittal Letter	1	2

Warnings:	
Information:	
Total Files Size (in bytes):	292740

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 a 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.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 4680.32US07

Deem et al. Confirmation No.: 6425

Application No.: 15/358,187 Examiner: Albert Mark Navarro

Filed: November 22, 2016 Group Art Unit: 1645

For: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

INTRODUCTORY COMMENTS

In response to the Office Action of November 9, 2017, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remain(s) under examination in the application is presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or fewer characters; and 2. added matter is shown by underlining.

1-20. (Cancelled)

21. (Previously Presented) A nerve modification device for altering nerve function in a bronchial airway of a patient, the nerve modification device comprising:

a main catheter body configured to extend though a trachea into the bronchial airway; and

at least one energy applicator having at least one energy emitter configured to emit energy laterally relative to the main catheter body,

wherein the nerve modification device is adapted to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in the wall of the bronchial airway in a first lateral direction from the main catheter body to alter nerve cells within the target region.

22. (Previously Presented) The nerve modification device of claim 21, wherein the energy is at least one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

23. (Previously Presented) The nerve modification device of claim 21, wherein the at least one energy emitter comprises at least one electrode.

24. (Previously Presented) The nerve modification device of claim 23, wherein the energy is RF energy.

25. (Previously Presented) The nerve modification device of claim 21, wherein the at least one energy emitter comprises at least one ultrasound transducer.

26. (Previously Presented) The nerve modification device of claim 25, wherein the energy is ultrasound energy.

27. (Previously Presented) The nerve modification device of claim 21, wherein the energy applicator is configured to be positionable in contact with a first portion of a circumference of the airway wall.

28. (Previously Presented) A system for altering nerve function in a bronchial airway of a patient, the system comprising:

an intraluminal catheter configured to be positioned within a bronchial airway of a patient, the intraluminal catheter including:

a main catheter body, and

a first energy emitter configured to emit energy laterally relative to the main catheter body; and

an energy generator operably coupled to the first energy emitter and configured to activate the first energy emitter, thereby causing an energy field to be generated in a target region in the airway wall to alter nerve cells within the target region.

29. (Previously Presented) The system of claim 28, wherein the main catheter body is configured to be positionable such that the first energy emitter is in contact with a first portion of a circumference of the airway wall.

30. (Previously Presented) The system of claim 28, further comprising:

a second energy emitter operably coupled to the energy generator, the second energy emitter being configured to be positioned outside of the airway and remote from the target region, the target region being positioned between the first and second energy emitters such that activation of the first and second energy emitters by the energy generator produces the energy field between the first and second emitters and within the target region.

31. (Previously Presented) The system of claim 30, wherein a placement of the first and second energy emitters relative to each other controls the size and/or intensity of the energy field.

32. (Previously Presented) The system of claim 28, the system further comprising:

a second energy emitter operably coupled to the energy generator, such that an arrangement of the first and second energy emitters causes the energy field produced therefrom to be concentrated in a lateral direction from the main catheter body.

33. (Previously Presented) The system of claim 28, a second energy emitter operably coupled to the energy generator, such that an arrangement of the first and second energy emitters causes

the energy field produced therefrom to comprise a uniform energy field about the main catheter body.

34. (Previously Presented) The system of claim 28, wherein the energy is at least one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

35. (Previously Presented) The system of claim 28, wherein the first energy emitter comprises an electrode.

36. (Currently Amended) The system of claim [[38]] 35, wherein the energy is RF energy.

37. (Previously Presented) The system of claim 28, wherein the first energy emitter comprises an ultrasound transducer.

38. (Previously Presented) A method, comprising:

causing a nerve modification device to be manufactured and made available to a user, the nerve modification device including a main catheter body and at least one energy applicator having at least one energy emitter; and

providing instructions to the user for use of the nerve modification device, the instructions recorded on a tangible or non-transitory computer-readable medium and including:

positioning the nerve modification device at a treatment site in a bronchial airway of a patient; and

causing the nerve modification device to deliver energy from the at least one energy emitter to produce an energy field concentrated in a target region in the wall of the bronchial airway in a first lateral direction from the main catheter body to alter nerve cells within the target region.

39. (Previously Presented) The method of claim 38, wherein causing the nerve modification device to deliver energy from the at least one energy emitter comprises causing the nerve modification device to deliver a pulse of radio frequency energy.

40. (Previously Presented) The method of claim 38, wherein causing the nerve modification device to deliver energy from the at least one energy emitter comprises causing the nerve modification device to deliver one of x-ray energy, radiofrequency energy, DC current, AC current, microwave energy, and ultrasound energy.

REMARKS

Claims 21-40 are pending. By this Amendment, no claims are cancelled, claim 36 is amended and no new claims are added.

Claim Rejections – 35 U.S.C. § 112

Claim 36 stands rejected under pre-AIA 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claim 36 has been amended to depend from system claim 35, and withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 21-40 stand rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,498,283 and claims 1-9 of U.S. Patent No. 8,961,391. A Terminal Disclaimer is filed herewith, rendering the rejection moot.

The Terminal Disclaimer filed herewith is not intended, and shall not be construed under any circumstances, as an admission that any invention claimed in a patent granted on the instant application is obvious in view of the prior patent or that the prior patent constitutes prior art to the instant application. See MPEP 801.02(II) (citing Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d. 870, 874 (Fed. Cir. 1991)).

The Terminal Disclaimer filed herewith does not disclaim any patent term extension under 35 U.S.C. § 156 of any patent granted on the instant application that may extend beyond the expiration date of the full statutory term defined in 35 U.S.C. § 154, as presently shortened

by any terminal disclaimer, of prior U.S. Patent Nos. 9,498,283 or 8,961,391. See Merck & Co. v Hi-Tech Pharmacal Co., 482 F.3d 1317 (Fed. Cir. 2007). The Terminal Disclaimer filed herewith also does not disclaim any patent term adjustment that may be permitted under 35 U.S.C. § 154.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Daidre L. Burgess/

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PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

Docket Number (Optional)
4680.32US07

In re Application of: Mark E. Deem

Application No.: 15/358,187

Filed: November 22, 2016

For: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

The applicant, The Foundry, LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 9498283, 8961391 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
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Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 60389

/Daidre L. Syverson/	02/07/2018
Signature	Date

Daidre L. Burgess
Typed or printed name

Attorney of Record	612-252-1558
Title	Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Electronic Patent Application Fee Transmittal

Application Number:	15358187
Filing Date:	22-Nov-2016
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Filer:	Daidre L. Burgess/Valerie Mitchell
Attorney Docket Number:	4680.32US07

Filed as Small Entity

Filing Fees for **Utility under 35 USC 111(a)**

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	160	160
		Total in USD ($)		**160**

Electronic Acknowledgement Receipt

EFS ID:	31728021
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	07-FEB-2018
Filing Date:	22-NOV-2016
Time Stamp:	15:23:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$160
RAM confirmation Number	020818INTEFSW15244900
Deposit Account	160631
Authorized User	Daidre Burgess

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37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4680_32US07_AMEND.pdf	100509 e6894aa19f64185400befadb5d30df780d5035f7	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	7
Applicant Arguments/Remarks Made in an Amendment	8	9

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Information:

2	Terminal Disclaimer Filed	4680_32US07_Terminal_Disclaimer.pdf	160353 3cca004ef715e7cda36e4036bb0929347485a612	no	2

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	30562 c356808b680cd002c0b5650f7d47d5a8b07f0b2c	no	2

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	
15/358,187	11/22/2016	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	x $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	x $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT

02/07/2018	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x $50 =	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x $230 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
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VICTOR BARLOW

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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination
	15/358,187	DEEM ET AL.

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 07 February, 2018	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

PAMELA YOUNG

Technology Center: PLRC

Telephone: _____

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/358,187	Deem et al.
	Examiner	**Art Unit**
	Mark NAVARRO	1645

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61M 37/00	03/06/2018	MN

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
Medline, Biosis, Ca, Caplus, Embase, USPatfull, terms: update search history 14/601,529, 13/660,629, 13/253,595, 12/559,278, 11/459,090	03/06/2018	MN

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61M	37/00	03/06/2018	MN

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/358,187	Deem et al.
	Examiner	**Art Unit**
	Mark NAVARRO	1645

CPC						
Symbol					**Type**	**Version**
A61M	/	37	/	00	F	2013-01-01
A61K	/	38	/	164	I	2013-01-01
A61K	/	38	/	168	I	2013-01-01
A61K	/	38	/	4893	I	2013-01-01
A61K	/	41	/	00	I	2013-01-01
A61K	/	41	/	0028	I	2013-01-01
A61N	/	1	/	08	I	2013-01-01
A61N	/	1	/	327	I	2013-01-01
A61N	/	1	/	303	I	2013-01-01
A61N	/	7	/	00	I	2013-01-01
A61K	/	9	/	0021	I	2013-01-01
A61K	/	9	/	0078	I	2013-01-01
A61B	/	18	/	1492	I	2013-01-01
A61B	/	18	/	1815	I	2013-01-01
A61N	/	5	/	10	I	2013-01-01
A61K	/	41	/	0047	I	2013-01-01
A61M	/	37	/	0092	I	2013-01-01
C12Y	/	304	/	24069	I	2013-01-01
A61B	/	2018	/	0016	A	2013-01-01
A61B	/	2018	/	00214	A	2013-01-01
A61B	/	2018	/	00434	A	2013-01-01
A61B	/	2018	/	1861	A	2013-01-01
A61N	/	2007	/	003	A	2013-01-01
A61M	/	2210	/	1035	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	38	/	4893	I	1	1	2013-01-01
A61K	/	2300	/	00	A	1	2	2013-01-01

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/ALBERT M NAVARRO/ Primary Examiner, Art Unit 1645 (Primary Examiner)	06 March 2018 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/358,187	Deem et al.
	Examiner	**Art Unit**
	Mark NAVARRO	1645

INTERNATIONAL CLASSIFICATION				
CLAIMED				
C12M	/	1	/	00

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
435	283.1

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/ALBERT M NAVARRO/ Primary Examiner, Art Unit 1645 (Primary Examiner)	06 March 2018 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office

Part of Paper No.: 20180306B

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/358,187	Deem et al.
	Examiner	**Art Unit**
	Mark NAVARRO	1645

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 20	
/ALBERT M NAVARRO/ 06 March 2018 Primary Examiner, Art Unit 1645 (Primary Examiner) (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

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PATTERSON THUENTE PEDERSEN, P.A.
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4800 IDS CENTER
MINNEAPOLIS, MINNESOTA 55402-2100

EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/13/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/358,187	11/22/2016	Mark E. Deem	4680.32US07	6425

TITLE OF INVENTION: SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
REGULAR	SMALL	$500	$0.00	$0.00	$500	06/13/2018

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7590 03/13/2018
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MINNESOTA 55402-2100

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/358,187	11/22/2016	Mark E. Deem	4680.32US07	6425

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REGULAR	SMALL	$500	$0.00	$0.00	$500	06/13/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
NAVARRO, ALBERT MARK	1645	435-283100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

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15/358,187	11/22/2016	Mark E. Deem	4680.32US07	6425

24113 7590 03/13/2018
PATTERSON THUENTE PEDERSEN, P.A.
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MINNEAPOLIS, MINNESOTA 55402-2100

EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/13/2018

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. 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.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 15/358,187	Applicant(s) Deem et al.	
	Examiner Mark NAVARRO	Art Unit 1645	AIA Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the amendment filed February 7, 2018 .
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____ .

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file areply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____ .

/ALBERT M NAVARRO/
Primary Examiner, Art Unit 1645

Continuation of 3. The allowed claim(s) is/are: 21-40, renumbered as 1-20, respectively

UNITED STATES PATENT AND TRADEMARK OFFICE
COMMISSIONER FOR PATENTS
P.O.BOX 1450
ALEXANDRIA VA 22313-1451

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PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

Courtesy Reminder for
Application Serial No: 15/358,187

Attorney Docket No: 4680.32US07
Customer Number: 24113
Date of Electronic Notification: 03/13/2018

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:

To view your correspondence online or update your email addresses, please visit us anytime at **https://sportal.uspto.gov/secure/myportal/privatepair.** If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	15/358,187
				Filing Date	November 22, 2016
				First Named Inventor	Deem et al.
				Art Unit	1645
				Examiner Name	Albert Mark Navarro
Sheet	1	of	1	Attorney Docket Number	4680.32US07

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Office Action dated August 21, 2017 for Japanese Application No. 2016-227703, 4 pages.	X

EXAMINER SIGNATURE	/ALBERT M NAVARRO/	DATE CONSIDERED	03/06/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.M.N/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

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15/358,187	11/22/2016	Mark E. Deem	4680.32US07	6425

24113 7590 03/21/2018
PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MINNESOTA 55402-2100
UNITED STATES OF AMERICA

EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
03/21/2018	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
15/358,187	11/22/2016	Deem et al.	4680.32US07

		EXAMINER	
PATTERSON THUENTE PEDERSEN, P.A. 80 SOUTH 8TH STREET 4800 IDS CENTER MINNEAPOLIS, MN 55402-2100		Mark NAVARRO	
		ART UNIT	PAPER
		1645	20180318

DATE MAILED: _____

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Applicant's IDS filed November 9, 2017 was previously considered, however it appears to have been separated. Accordingly, a signed copy is enclosed to make clear that it was considered.

/ALBERT M NAVARRO/
Primary Examiner, Art Unit 1645

PTO-90C (Rev.04-03)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7890 03/13/2018
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80 SOUTH 8TH STREET
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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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(Depositor's name)
(Signature)
(Date)

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EXAMINER	ART UNIT	CLASS-SUBCLASS
NAVARRO, ALBERT MARK	1645	435-283100

Patterson Thuente Pedersen, P.A.

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: The Foundry, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Menlo Park, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.

☒ Payment by credit card.

☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 16806.11 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature: Daidre Burgess Date: 6/13/18

Typed or printed name: Daidre L. Burgess Registration No. 60389

Electronic Patent Application Fee Transmittal

Application Number:	15358187
Filing Date:	22-Nov-2016
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Filer:	Daidre L. Burgess/Valerie Mitchell
Attorney Docket Number:	4680.32US07

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt

EFS ID:	32888040
Application Number:	15358187
International Application Number:	
Confirmation Number:	6425
Title of Invention:	SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT
First Named Inventor/Applicant Name:	Mark E. Deem
Customer Number:	24113
Filer:	Daidre L. Burgess/Valerie Mitchell
Filer Authorized By:	Daidre L. Burgess
Attorney Docket Number:	4680.32US07
Receipt Date:	13-JUN-2018
Filing Date:	22-NOV-2016
Time Stamp:	15:21:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$500
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1	Issue Fee Payment (PTO-85B)	4680_32US07_ISSUE_FEE.pdf	422356 47d5d1607f92f5a8fe50dba44144639756e2cec0	no	1
Warnings:					
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2	Fee Worksheet (SB06)	fee-info.pdf	30445 aa54f207834575b79bb46116c98a447c4e32a17e	no	2
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Substitute for form 1449/PTO	Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	15/358,187
	Filing Date	November 22, 2016
	First Named Inventor	Deem et al.
	Art Unit	1645
	Examiner Name	Albert Mark Navarro
Sheet 8 of 17	Attorney Docket Number	4680.32US07

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-5,409,483	04-25-1995	Campbell et al.
		US-5,432,092	07-11-1995	Bailey et al.
Change(s) applied		US-5,496,304 03/1996	~~10-06-1998~~	~~Krespi~~ Chasan
to document,		US-5,562,608	10-08-1996	Sekins et al.
/C.C.B./		US-5,766,605	06-16-1998	Sanders et al.
3/23/2018		US-5,817,073	10-06-1998	Krespi
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		US-5,972,026	10-26-1999	Laufer et al.
		US-6,033,397	03-07-2000	Laufer et al.
		US-6,056,744	05-02-2000	Edwards
		US-6,063,768	05-16-2000	First

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.M.N/

Substitute for form 1449/PTO	Complete if Known	
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2009/0043301 A1	02-12-2009	Jarrard et al.
		US-2009/0177192 A1	07-09-2009	Rioux et al.
		US-2009/0221997 A1	09-03-2009	Arnold et al.
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		US-2011/0301587 A1	12-08-2011	Deem et al.
		US-2012/0016363 A1	01-19-2012	Mayse et al.
Change(s) applied		US-2012/0016364 A1	01-19-2012	Mayse et al.
to document,		US-2012/0029261 A1	~~02-02-2011~~	Deem et al. 02/2012
/C.C.B./		US-2012/0158101 A1	06-21-2012	Stone et al.
3/23/2018		US-2012/0203216 A1	08-09-2012	Mayse et al.
		US-2012/0203222 A1	08-09-2012	Mayse et al.
		US-2012/0209261 A1	08-16-2012	Mayse et al.

FOREIGN PATENT DOCUMENTS

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EXAMINER SIGNATURE		DATE CONSIDERED	

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/358,187	07/17/2018	10022529	4680.32US07	6425

24113 7590 06/27/2018

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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The Foundry, LLC, Menlo Park, CA
Hanson S. Gifford III, Woodside, CA;

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