DTO

29-01-09
pedido

Industria y Comercio
SUPERINTENDENCIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-088001- -00005-0000

Fecha: 2008-12-30 15:37:24 Dep. 2020 NUECREACIONE
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 400 OPOSIOBSERVTER Folios: 38

FORMULARIO ÚNICO DE OPOSICIÓN

① **OPOSICIÓN A:**

- [X] Patente de Invención.
- [ ] Patente de Modelo de Utilidad.
- [ ] Diseño Industrial.
- [ ] Esquema de Trazado para Circuitos Integrados.
- [ ] Marcas de Productos o Servicios.
- [ ] Marca Colectiva.
- [ ] Marca de Certificación.
- [ ] Lema Comercial.

② **SOLICITUD PUBLICADA**

Número del expediente: 07-88001
Solicitante: ALLERGAN, INC.
Apoderado: JERÓNIMO CASTILLO BONILLA
Título de la nueva creación o denominación del signo: "MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR."
Gaceta: 597

③ **OPOSICIÓN PRESENTADA POR:**

SOLICITANTE	Nombre: PROCAPS S.A Dirección: CALLE 80 No. 78B -201 Nacionalidad o Domicilio: COLOMBIA Lugar de Constitución: BARRANQUILLA Teléfono: (571)3719900 Fax: (571)3730818 E-mail:	**IDENTIFICACIÓN** C.C. [ ] NIT [X] C.E. [ ] Otro [ ] Cual Número: 890.106.527-5
REPRESENTANTE O APODERADO	Nombre: ELIANA ISAURA MORENO BOHORQUEZ Dirección: CARRERA 13 No. 119-95 OF 104 Teléfono: (571)213/213 Fax: (571)6121979 E-mail: negocios@optimum-co.com	**IDENTIFICACIÓN** C.C. [X] NIT [ ] C.E. [ ] Otro [ ] Cual Número 51.975.664 TP 83823

④ **FUNDAMENTOS DE LA OPOSICIÓN:**

Art.14, 16, 18, 20 y 30 de la Decisión 486 de la CAN

Causal: No cumple con los requisitos de patentabilidad.

Signo opositor:

Justificación:

La presente solicitud no cumple con los requisitos de patentabilidad dado que lo revelado, ya se encontraba en el estado de la técnica o es posible derivarlo de la misma tal y como se demostrará en el capítulo "Fundamento de Hechos".

2000 FUA

⑤ **Comprobante de pago No.** _____ **Fecha** _____

⑥ **ANEXOS**

- [x] Comprobante de pago de la tasa.
- [x] Poderes, si fuere el caso.
- [x] Pruebas de los fundamentos de la oposición.
- [ ] Documentos que acrediten el legítimo interes, si fuere el caso.
- [x] Documento que acredita la existencia y representación legal de las partes, cuando sean personas jurídicas.

⑦

NOMBRE: **ELIANA ISAURA MORENO B.**

FIRMA:

C.C. **51975664** **TP.** **83823 CSJ**

Instrucciones para el diligenciamiento del presente formulario, ver reverso de esta página.

PROCAPS

PODER ESPECIAL

Yo, **WALTER TANAKA TATEKAWA,** mayor de edad y vecino de la ciudad de Barranquilla (Colombia), identificado como aparece al pie de mi firma, quien en el presente documento actúa en calidad de Representante Legal de la sociedad **PROCAPS S.A.** sociedad legalmente constituida y domiciliada en la ciudad de Barranquilla (Colombia), por el presente documento otorgo a la doctora **ELIANA ISAURA MORENO BOHORQUEZ**, abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 83823 **del C.S. de la J.**, poder especial, amplio y suficiente, para formular oposiciones u observaciones a la solicitud de patente No. 07 088.001, titulada **"MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR",** cuyo titular es **ALLERGAN, INC.,** Publicada en la gaceta No. 597 del 31 de octubre de 2008.

Nuestro apoderado queda facultado, de manera expresa, para realizar todo tipo de actos necesarios para llevar a cabo el trámite de la oposición, incluyendo, sin limitación, preparar y presentar solicitudes, hacer declaraciones, pagar tasas, contribuciones e impuestos, recabar los títulos o certificados. Asimismo quedan autorizados para impugnar administrativa y judicialmente todo lo que fuere resuelto en el expediente a que se hace expresa referencia en el presente poder, con todas las facultades generales y específicas que fuera requerido para ella.

De la misma manera, además de las facultades que le confiere la naturaleza del presente mandato, se encuentran facultados para recibir, desistir, transigir, sustituir, y reasumir el presente poder, incoar acciones, interponer recursos y demás facultades conferidas por la ley.

Dado y Firmado en Barranquilla (Colombia) a los 9 días del mes de Diciembre de 2008.

PROCAPS S.A.

C.C. N° 16'251.923
NIT: 890.106.527-5
Representante Legal

Acepto:

ELIANA ISAURA MORENO BOHORQUEZ
C.C. 51'975.664 de Bogotá
T.P.A. 83823 del C.S. de la J.

NOTARIA PRIMERA DEL CIRCULO
DE BARRANQUILLA
DILIGENCIA DE RECONOCIMIENTO

LA PRESENTE DILIGENCIA SE PRACTICA A PETICION DE PARTE INTERESADA

Ante el Notario Primero de Barranquilla Compareció:
Walter Pineda Tarazona
Identificado con C.C. 72.162.1923 de Soledad (Atlántico)
y declaro que es cierto el contenido del documento anterior y suya la firma.
Barranquilla. 09 DIC. 2008

El suscrito Notario Primero del Circulo de Barranquilla, hace constar que la Huella: Declarar que aquí aparece, fué impresa por

REPUBLICA DE COLOMBIA
Carlos J. Pulido Escallón
NOTARIO
NOTARIA 1ra. DE BARRANQUILLA

NOTARIA PRIMERA DE CHIA
PRESENTACION PERSONAL

Este memorial dirigido a Transnovustria y Cia.
fué presentado personalmente ante el suscrito notario por Eliana Isaura Moreno Bohorquez
Identificado C.C. 51.925.664 de
T.P. de Abogado No. 83.823 C.S.J.
Chia 09 DIC 2008

REPUBLICA DE COLOMBIA
M. DEL PILAR HERRERA VERGARA
NOTARIA PRIMERA DE CHIA

No. 13035449

4

CAMARA DE COMERCIO DE BARRANQUILLA

C A M A R A D E C O M E R C I O
D E B A R R A N Q U I L L A

11***

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.
PROCAPS S.A.---
NIT: 890.106.527-5.

EL SUSCRITO SECRETARIO DE LA CAMARA DE COMERCIO DE BARRANQUILLA, CON FUNDAMENTO EN LAS INSCRIPCIONES DEL REGISTRO MERCANTIL:

C E R T I F I C A

Que por Escritura Pública No. 1,190 del 22 de Julio de 1976, otorgada en la Notaria Tercera de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 28 de Julio de 1976 bajo el No. 6,070 del libro respectivo, fue constituida la sociedad-------------------- limitada denominada "PRODUCTORA DE CAPSULAS DE GELATINAS LIMITADA "PROCAPS LIMITADA".---

C E R T I F I C A

Que por Escritura Pública No. 1,307 del 28 de Junio de 1979, otorgada en la Notaria Tercera de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 23 de Julio de 1979 bajo el No. 10,039 del libro respectivo, la sociedad antes mencionada------------------- se transformo en sociedad anonima bajo la denominacion social de "PRODUCTORA DE CAPSULAS DE GELATINA S.A." PROCAPS S.A.".------------

C E R T I F I C A

Que por Escritura Pública No. 3,810 del 31 de Dic/bre de 1980, otorgada en la Notaria Primera de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 30 de Enero de 1981 bajo el No. 12,705 del libro respectivo, la sociedad antes mencionada------------------- se transformo en sociedad de responsabilidad limitada bajo al razon social de "PRODUCTORA DE CAPSULAS DE GELATINA LIMITADA "PROCAPS LI - MITADA".--

C E R T I F I C A

Que por Escritura Pública No. 3,755 del 10 de Nov/bre de 1983, otorgada en la Notaria Unica de Soledad, inscrito(as) en esta Cámara de Comercio, el 22 de Nov/bre de 1983 bajo el No. 17,922 del libro respectivo, la sociedad antes mencionada---------------------- se transformo en sociedad anonima bajo la denominacion social de "PRODUCTORA DE CAPSULAS DE GELATINA S.A. "PROCAPS S.A.".------------

C E R T I F I C A

Que por Escritura Pública No. 3,615 del 06 de Dic/bre de 1996, otorgada en la Notaria 2a. de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 20 de Dic/bre de 1996 bajo el No. 67,218 del

********** C O N T I N U A **********

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.

NIT: 890.106.527-5.

libro respectivo, la sociedad antes mencionada----------
cambio de razon social, por la denominacion LABORATORIOS PROCAPS S.A
. ----------

C E R T I F I C A

Que por Escritura Pública No. 3,775 del 18 de Dic/bre de 1996, otorgada en la Notaria 2a. de Barranquilla, inscrito(as) en esta Cámara de Comercio, el 23 de Enero de 1997 bajo el No. 67,704 del libro respectivo, la sociedad antes mencionada----------
cambio de razon social, por la denominacion PROCAPS S.A. ----------

C E R T I F I C A

Que dicha sociedad ha sido reformada por las siguientes escrituras y/o documentos privados:

Numero	aaaa/mm/dd	Notaria	No. Insc o Reg	aaaa/mm/dd
39	1979/01/18	Notaria 3a. de Barranquilla.	9,452	1979/01/24
992	1981/04/30	Notaria 1a. de Barranquilla.	13,112	1981/05/06
1,464	1982/08/27	Notaria Unica de Soledad	15,533	1982/09/08
2,744	1983/08/18	Notaria Unica de Soledad	17,416	1983/08/26
3,826	1984/07/16	Notaria Unica de Soledad	19,554	1984/07/27
3,835	1985/08/26	Notaria Unica de Soledad	22,230	1985/09/04
2,260	1986/09/10	Notaria Unica de Soledad.	24,995	1986/09/15
1,849	1989/07/11	Notaria 2a. de Barranquilla.	33,909	1989/07/13
444	1990/02/21	Notaria 2a. de Barranquilla.	36,101	1990/03/16
3,090	1991/12/17	Notaria 2a. de Barranquilla	43,993	1992/01/28
269	1993/02/01	Notaria 2a. de Barranquilla	48,428	1993/02/16
2,342	1993/07/28	Notaria 2a. de Barranquilla	50,582	1993/08/10
3,652	1993/11/09	Notaria 2a. de Barranquilla	51,798	1993/11/22
3,615	1996/12/06	Notaria 2a. de Barranquilla	67,218	1996/12/20
89	1997/01/16	Notaria 2a. de Barranquilla	67,704	1997/01/23
2,070	1997/07/17	Notaria 2a. de Barranquilla	70,627	1997/07/31
2,281	1997/08/04	Notaria 2a. de Barranquilla	70,813	1997/08/14
765	1999/04/22	Notaria 3a. de Barranquilla	80,628	1999/04/23
459	2001/02/21	Notaria 2a. de Barranquilla	91,502	2001/02/23
2,608	2001/10/05	Notaria 2a. de Barranquilla	95,771	2001/11/08
1,730	2004/07/29	Notaria 2. de Barranquilla	112,999	2004/08/26
416	2005/03/03	Notaria 2. de Barranquilla	116,364	2005/03/10
1,613	2005/07/28	Notaria 2. de Barranquilla	119,322	2005/08/18

C E R T I F I C A

Que de acuerdo con la(s) escritura(s) arriba citada(s), la sociedad se rige por las siguientes disposiciones:
DENOMINACION O RAZON SOCIAL:
PROCAPS S.A.----------
SIGLA: PROCAPS.
DOMICILIO PRINCIPAL: Barranquilla.
NIT No: 890.106.527-5.
MATRICULA MERCANTIL: 24,802.

C E R T I F I C A

********** C O N T I N U A **********

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.
PROCAPS S.A.----------
NIT: 890.106.527-5.

Direccion para notificaciones judiciales:
CL 80 No 78 B - 201.
De la ciudad de Barranquilla.

C E R T I F I C A

DURACION: El término de duración de la sociedad se fijó hasta el 18 de Agosto de 2073.

C E R T I F I C A

OBJETO SOCIAL: El objeto principal de la sociedad sera: a)-La fabricacion de capsulas y otros productos similares a partir de materiales tales como gelatinas u otros de distinta naturaleza, que puedan ser utilizados como envases o recipientes de productos y sustancias quimicas, farmaceuticas y cosmeticas, para uso y consumo humano y veterinario; b)-La investigacion, desarrollo y fabricacion de toda clase de productos y sustancias quimicas, farmaceuticas y cosmeticas para uso y consumo humano, animal y vegetal; c)-La compra y venta de materias primas, insumos y productos intermedios necesarios para los procesos de fabricacion de sustancias quimicas, farmaceuticas,alimenticias y cosmeticas, asi como la comercializacion interna y externa de los productos terminados, d) La compra, venta, importacion, exportacion y distribucion de toda clase de elementos instrumentales y equipos medicos,quirurgicos,odontologicos,y hospitalarios para la salud humana y animal. e)La compra,venta,exportacion y disdistribucion de dulces, confites, galletas y todo tipo de golosinas o alimentos para el consumo humano. f) Actuar como representante o agente de personas naturales y juridicas, nacionacionales y extranjeras en la realizacion de operaciones o transacciones relacionadas con la industria farmaceutica y en especial con cualquiera de las actividades descritas en los literales a), b), c). d) y e) antes descritos; g) Prestar los servicios de asesoria y consultoria en las areas administrativas, de mercadeo, analisis clinico, asistencia tecnica, investigacion, costos y produccion, exportaciones, importaciones, ventas, relacionadas con iguales o similares actividades a las que constituyen el objeto de PROCAPS S.A., asi como los de publicidad y promocion de productos quimicos, cosmeticos y farmaceuticos para uso humano, animal o industrial; h)-Adquirir, operar, administrar y explotar, a cualquier titulo, empresa o establecimientos dedicados a la investigacion, desarrollo, fabricacion o comercializacion de productos quimicos, farmaceuticos, hospitalarios o cosmeticos. En desarrollo de su objeto principal, la sociedad podra tomar interes social como accionista,

********** C O N T I N U A **********

socio o fundador de empresas que tengan igual o similar objeto, comprar, vender, importar y exportar maquinarias, insumos y repuestos requeridos para el desarrollo de sus actividades; tomar dinero en prestamo, financiar y garantizar las operaciones comerciales que celebre con terceros relativas a su objeto; celebrar y ejecutar todo tipo de actos y contratos necesarios para desarrollar sus operaciones; girar, aceptar, otorgar y protestar todo tipo de titulos valores e instrumentos negociables; comprar, vender y constituir gravamenes sobre bienes muebles e inmuebles; designar representantes o apoderados en el pais y en el exterior y, en general, realizar cualquier acto o negocio que sea necesario o conveniente para el desarrollo de su objeto social y para la mejor proteccion de sus intereses corporativos o la de sus socios. La sociedad podra garantizar el cumplimiento de obligaciones adquiridas por terceros o por sus socios, para lo cual podra inclusive constituir gravamenes reales sobre sus bienes de cualquier naturaleza.----------

C E R T I F I C A

CAPITAL	Nro Acciones	Valor Acción
Autorizado		
$**********2,000,000,000	**********2,000,000	**********1,000
Suscrito		
$**********1,229,071,000	**********1,229,071	**********1,000
Pagado		
$**********1,229,071,000	**********1,229,071	**********1,000

C E R T I F I C A

ADMINISTRACION: La direccion y administracion de la sociedad corresponderа a la Asamblea General de Accionistas, a la Junta Directiva, al Presidente, al Vicepresidente y a un Gerente General. Corresponde a la Junta Directiva las siguientes funciones y atribuciones entre otras: Autorizar cualquier acto o contrato cuya cuantia sea superior al equivalente en pesos Colombianos a doscientos cincuenta mil dolares de los Estados Unidos de America (US$250.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la transacion. Cuando se trate de operaciones en virtud de las cuales la sociedad garantice obligaciones de terceros o de los socios, se requerira que la operacion sea aprobada con el voto de por lo menos 2/3 partes de los integrantes de la Junta Directiva.
La sociedad tendra un Presidente , quien ejercera la representacion legal de la sociedad y tendra las siguientes atribuciones entre otras: Ejecutar las decisiones de la Asamblea General de Accionistas y de la Junta Directiva. Ejercer la Representacion Legal de la sociedad en todos los actos y contratos que se requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Constituir apoderados judiciales y extrajudiciales, recibir notificaciones, absolver interrogatorios de parte, confesar obligaciones de la sociedad, transigir, disistir y allanar a la sociedad en cualquier asunto judicial. Aprobar y celebrar en nombre de la socieda todo acto o contrato cuya cuantia sea igual o inferior al equivalente

********** C O N T I N U A **********

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.
PROCAPS S.A.----------
NIT: 890.106.527-5.

en pesos colombianos a doscientos cincuenta mil dolares de los Estados Unidos de America (US$250.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la transacion o celebracion del acto. Las demas funciones que le correspondan como Representante Legal por disposicion de la ley, de estos estatutos o de la Junta Directiva. El Presidente tendra un suplente, designado por la Junta Directiva, quien reemplazara al Presidente en sus faltas temporales, absolutas o meramente accidentales, con entidades facultades y sin que sea necesario para ello acreditar la ausencia del principal. La sociedad tendra un Vicepresidente designado por la Junta Directiva, quien tambien ejercera la representacion legal de la sociedad, pudiendo ejercerla conjunta o separadamente con el Presidente. El vicepresidente tendra las siguentes facultades entre otras. Ejecutar dentro de su competencia las decisiones de la Asamblea General de Accionistas, de la Junta Directiva y del Presidente. Ejercer la representacion legal de la sociedad en todos los actos y contratos que se requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Constituir apoderados judiciales y extrajudiciales, recibir notificaciones, absolver interrogatorios de parte, confesar obligaciones de la sociedad, transigir, desistir y allanar a la sociedad en cualquier asunto judicial. Aprobar y celebrar en nombre de la sociedad todo acto o contrato cuya cuantia sea igual o inferior al equivalente en pesos colombianos a ciento cincuenta mil dolares de los Estados Unidos de America (US$150.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la aprobacion o celebracion del acto, siempre que no se trate de enajenar bienes inmuebles o cualquier otro activo fijo de la sociedad, inclusive de naturaleza muebles, acciones, cuotas o partes de interes inversiones y todo tipo de derechos de la sociedad, o de constituir gravamenes sobre cualquiera de los anteriores, facultades que radican exclusiva y privativamente en cabeza del Presidente. Las demas funciones que le corresponda como Representante legal por disposicion de la ley, de estos estatutos o de la Junta Directiva. El Vicepresidente tendra (1) suplente, designado por la Junra Directiva, quien lo reemplazara conjunta o separadamente en sus faltas temporales, absolutas o meramente accidentales, con identicas facultades y sin que sea necesario para ello acreditar la ausencia del principal. La sociedad tendra un (1) Gerente General, con su respectivo Suplente, designados por la Junta Directiva. El Suplente reemplazara al Gerente General, en sus faltas temporales, absolutas o meramente accidentales, quien junto con el gerente general, llevaran la representacion legal de la sociedad, con identicas facultades, pudiendolas ejercer conjunta o separadamente con el Presidente y Vicepresidente, con identicas facultades

Impreso por deposcales.com 97302

que el Gerente General y sin que sea necesario para ello acreditar la ausencia del titular. El Gerente General tendra las siguientes facultades entre otras: Ejercer la representacion legal de la sociedad, en todos los actos y contratos que se requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Aprobar y celebrar en nombre de la sociedad todo acto o contrato cuya cuantia sea igual o inferior al equivalente en pesos Colombianos a Cincuenta Mil dolares de los Estados Unidos de America (US$50.000), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la aprobacion o celebracion del acto, siempre que no se trate de enajenar a cualquier titulo bienes inmuebles o cualquier otro activo fijo de la sociedad, inclusive de naturaleza mueble, acciones, cuotas o partes de interes, inversiones y todo tipo de derechos de la sociedad o de constituir gravamenes sobre cualquiera de las anteriores facultades que radican exclusiva y privativamente en cabeza del Presidente. ----------

C E R T I F I C A

Que según Acta No. 116 del 27 de Junio de 1997 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad:
PROCAPS S.A.----------
cuya parte pertinente se inscribió en esta Cámara de Comercio, el 15 de Agosto de 1997 bajo el No. 70,838 del libro respectivo, y según Acta No. 127 del 22 de Marzo de 2000 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad:
PROCAPS S.A.----------
cuya parte pertinente se inscribió en esta Cámara de Comercio, el 29 de Mayo de 2000 bajo el No. 87,250 del libro respectivo, fueron hechos los siguientes nombramientos:

CLASE: JUNTA DIRECTIVA

Principales

1. Minski Gontovnik Ruben	CC.*******7,463,982
2. Minski Gontovnik Meyer	CC.*******7,461,324
3. Minski Gontovnik Jose	CC.*******8,671,834

Suplentes

1. Minski Zilberblum Elliot	CC.******72,219,541
2. Minski Deitel Daniel	.***************
3. Minski Sharon	PA.*990,212,082,805

C E R T I F I C A

Que según Acta No. 116 del 27 de Junio de 1997 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 15 de Agosto de 1997 bajo el No. 70,838 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre	Identificación
Presidente.	

********** C O N T I N U A **********

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.
PROCAPS S.A.---
NIT: 890.106.527-5.

Minski Gontovnik Ruben CC.*******7,463,982
Suplente del Presidente
Minski Minski Abraham CC.*********802,575
Vicepresidente
Minski Gontovnik Meyer CC.*******7,461,324
Suplente del vicepresidente
Minski Gontovnik Jose CC.*******8,671,834

C E R T I F I C A

Que según Acta No. 11 del 01 de Febrero de 2001 correspondiente a la Junta Directiva en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 12 de Febrero de 2001 bajo el No. 91,273 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre Identificación
Gerente General.
Uribe Ochoa Guillermo Luis CC.******70,073,754

C E R T I F I C A

Que según Acta No. 406 del 02 de Sep/bre de 2004 correspondiente a la Junta Directiva en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 09 de Sep/bre de 2004 bajo el No. 113,263 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre Identificación
Suplente del Gerente.
Tanaka Tatekawa Walter CC.******16,251,923

C E R T I F I C A

Que según Acta No. 124 del 29 de Marzo de 1999 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: PROCAPS S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 04 de Agosto de 1999 bajo el No. 82,226 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre Identificación
Revisor Fiscal Ppal.
Vargas Pertuz Ana Isabel CC.******32,696,645

C E R T I F I C A

Que según Acta No. 127 del 22 de Marzo de 2000 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: PROCAPS

********** C O N T I N U A **********

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S A

NIT: 890.106.527-5.

S.A. cuya parte pertinente se inscribió en esta Cámara de Comercio, el 29 de Mayo de 2000 bajo el No. 87,250 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre	Identificación
Suplente del Revisor Fiscal.	
Lozada Villareal Milena	CC.******32,748,111

C E R T I F I C A

Que por Escritura Pública No. 2,784 del 07 de Dic/bre de 2007, otorgada en la Notaria 2 a. de Barranquilla cuya parte pertinente se inscribió en esta Cámara de Comercio, el 20 de Dic/bre de 2007 bajo el No. 3,492 del libro respectivo,---------- y las inscripciones 3.492-1, 3.493, 3.494, 3.495, 3.496, 3.497, ---- 3.498, 3.499, 3.500, 3.501, 3.502, 3.503, 3.504, 3.505, 3.506, ----- 3.507, Consta que RUBEN MINSKI GONTOVNIK, C.C. No. 7.463.982, ------ obrando como Presidente y Representante Legal de la sociedad C.I. NATURMEGA S.A., que obrando en su condicion de Presidente y ------- Representante Legaql de la sociedad PROCAPS S.A., el presidente ---- debidamente facultado por los Estatutos Sociales y por el Maximo Organo Social, otorga los siguientes poderes: Otorgar poder -------- general, amplio y suficiente a los doctores JOSEFINA DEL CARMEN ---- MIELES BUELVAS CC.No.33.138.497; a MARCELA CARVAJALINO PAGANO ------ CC.No.22.579.748; CRISTINA VIOLI FRANCESCHINI CC.No.22.463.716, con las facultades que se transcriben a continuacion: a.- Para que ----- representen a la sociedad PROCAPS S.A, ante todo tipo de ---------- autoridades administrativas y jurisdiccionales, en asuntos de ------ naturaleza civil, laboral, comercial, penal, aduanera, cambiaria, tributaria, policiva, administrativa y fiscal. b.- Contestar y ----- presentar demandas, requerimientos, recursos, pedir y aportar ------ pruebas, recibir, notificarse, ejercer la accion de tutela, -------- tramitar incidente de desacato, comparecer en los procesos que ----- cursen contra la sociedad, allanarse en nombre de la sociedad en los asuntos que sean necesarios, transigir, desistir, sustituir, renunciar y reasumir el poder. c.- La facultad expresa de ---------- conciliar, por tanto pueden llegar a acuerdos conciliatorios, ------ transaccionales, judiciales o extrajudiciales o extrajudiciales, cualquiera que sea su cuantia, para lo cual las apoderadas deben aportar la autorizacion simple y escrita del Representante legal de la sociedad. d.- Podran presentar solicitudes de devolucion y/o compensacion de impuestos, ventas y rentas, recibir los pagos por las devoluciones y adelantar todo tramite o proceso administrativo ante la DIAN, de tal forma que en ningun momento quede sin --------- representacion legal de la sociedad. PODERES ESPECIALES: a.- Se ---- confiere poder especial amplio y suficiente a las personas que se determinan seguidamente, que conformen el grupo A y B, para, para que conjuntamente suscriban contratos de suministros de mercancias y servicios con entidades oficiales, hasta la suma de OCHOCIENTOS MIL DOLARES DE LOS ESTADOS UNIDOS DE AMERICA (US800.000.00), ------- liquidados a la tasa representativa del mercado vigente en el dia que se realice la respectiva transaccion. Grupo A. WALTER NANAKA TATEKAWA CC.No.16.251.923, CLAUDIA TANGARIFE CASTILLO ---------- CC.No.41.660.293, CARMEN ALICIA FLOREZ CC.No.22.434.044, IVAN ------

********** C O N T I N U A **********

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.
PROCAPS S.A.----------
NIT: 890.106.527-5.

VILLAREAL CAMACHO CC.No.91.201.749, CARMEN ALICIA HERRERA ----------
DIAZGRANADOS CC.No.22.377.540, DAVID ANTONIO CHARRIS GIRALDO -------
CC.No.19.341.274, RICARDO DORADO HURTADO CC.No.79.715.772, JAIME FORERO LLINAS CC.No.19.300.593. b.- Se confiere poder especial -----
amplio y suficiente al senor WILLIAM ALBERTO BARROS CERRA ----------
CC.No.8.715.941, para que en nombre y representacion de PROCAPS ----
S.A., suscriban declaraciones cambiarias, aduaneras y tributarias a que este obligada la sociedad, en el giro normal de sus negocios y operaciones sociales, por tanto quedan facultados para firmarlas, como tambien los demas documentos relacionados con ellas, ----------
notificarse, aportar y solicitar las pruebas que sean necesarias.
c.-Otorgar poder especial amplio y suficiente al senor MARLON -----
TATIS PAREDES CC.No.72.176.874 y al senor WILLIAM ALBERTO BARROS CERRA CC.No.8.715.941, para que en nombre y representacion de ------
PROCANPS S.A., suscriban las declaraciones, reportes y cualquier documento relacionado con los tramites o registros de Comercio -----
Exterior y o cualquier entidad del Estado que haga sus veces: d) Otorgar poder especial amplio y suficiente a la doctora CARMEN -----
ALICIA HERRERA DIAZGRANADOS, CC.No.22.377.540 y al doctor WALTER TANAKA TATEKAWA, CC.No.16.251.923, para que en nombre y ----------
representacion de PROCAPS S.A.; endosen los titulos valores de la sociedad hasta por la suma de UN MIL MILLONES DE PESOS ----------
(1.000.000.000.00) M.L. CUARTO: EI representante legal de la -------
sociedad PROCAPS S.A.; doctor RUBEN MINSKI GONTOVNIK, manifiesta que la presente reforma fue aprobada por la Asamblea General -------
Extraordinaria de Accionista de PROCAPS S.A., con observancia de las disposiciones legales y estatutarias.----------

C E R T I F I C A

Que por Escritura Pública No. 1,933 del 16 de Sep/bre de 2008, otorgada en la Notaria 2 a. de Barranquilla cuya parte pertinente se inscribió en esta Cámara de Comercio, el 06 de Octubre de 2008 bajo el No. 3,748 del libro respectivo,----------
Consta que el señor RUBEN MINSKI GONTOVNIK, C.C. No. 7.463.982, que comparece en su condicion de Presidente y Representante Legal de la Sociedad PROCAPS S.A., confiere por medio de este instrumento ------
publico Poder especial Amplio y Suficiente a la doctora MILENA -----
ESCAFFI PARDO, C.C. No. 32.758.420, para que en nombre y ----------
representacion de PROCAPS S.A., suscriba declaraciones cambiarias, aduaneras y tributarias a que este obligada la sociedad en el giro normal de sus negocios y operaciones sociales, por tanto queda -----
facultada para firmar, como tambien los demas documentos ----------
relacionados con ellas, notificarse, aportar y solicitar las -------
pruebas que sean necesarias.----------

Impreso por Decisiones S.A. NIT: 860.029.586-2 www.decisiones.com 97302

CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.

PROCAPS S.A.

NIT: 890.106.527-5.

C E R T I F I C A

Que en esta Cámara de Comercio no aparecen inscripciones posteriores de documentos referentes a reforma, disolución, liquidación o nombramientos de representantes legales de la expresada sociedad.

C E R T I F I C A

Que su última Renovación fue el: 19 de Marzo de 2008.

La información sobre embargos de establecimiento se suministra en Certificados de Matrícula, la de contratos sujetos a registro, en Certificados Especiales.

Optimum

Derecho de la Competencia, Propiedad Industrial y Comercio Exterior

Señora Jefe,

DIVISIÓN DE NUEVAS CREACIONES

Superintendencia de Industria y Comercio

E. S. D.

Referencia	: Expediente N° 07 088001
Asunto	: Oposición a la solicitud de patente de Invención titulada *"MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR"*
Solicitante	: *ALLERGAN*
Opositora	: PROCAPS S.A.

Publicada en la Gaceta de la Propiedad Industrial

N° 597 del 31 de Octubre de 2008

Yo, *ELIANA ISAURA MORENO BOHORQUEZ,* abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 83823 del Consejo Superior de la Judicatura, en mi condición de apoderada de la sociedad *PROCAPS S.A.* conformada bajo las leyes de la República de Colombia y domiciliada en la ciudad de Barranquilla, Colombia, atentamente manifiesto que estando dentro del término de ley y por orden expresa de mi representada, presento oposición a la concesión del registro de la Patente de Invención titulada "*MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR*" cuyo titular es *ALLERGAN,* y pido a Usted declarar fundada esta oposición y en consecuencia negar el registro de la patente solicitada.

1. INTERÉS PARA ACTUAR

Conforme a lo dispuesto en el artículo 42 de la Decisión 486 de 2000 de la CAN, estando dentro del término estipulado por la ley, manifiesto el legitimo interés de nuestra representada para oponerse al registro de la patente de la referencia, atendiendo a que la solicitud pretendida no cumple con los requisitos dispuestos en la ley como se analizará más adelante y de ser concedida afectaría directamente la comercialización de algunos productos de mi representada, que contienen, en particular polímeros bioerosionables, cortisona, dexametasona, hidrocortisona, metilprednisolona, prednisolona, prednisona, y triamcinolona. Por lo tanto, solicito respetuosamente a ese Despacho se sirva tener en cuenta la presente oposición dentro del trámite administrativo que se surte en esta Superintendencia.

2. FUNDAMENTOS DE HECHOS

2.1. La solicitud objeto de la presente fue presentada el 28 de agosto de 2007 reivindicando prioridad bajo la solicitud US20050070158 del 2005-03-01; y fue publicada en Colombia, en la Gaceta de la Propiedad Industrial **N° 597 del 31 de Octubre de 2008**, cuya publicación internacional corresponde a la WO2006093758 del 2006-09-08.

2.2. La solicitud colombiana **07 088001** objeto de la presente oposición, se refiere a un microimplante ocular para implante en el ojo, que comprende: una mezcla homogénea de uno o más ingredientes activos y uno o más polímeros bioerosionables, en donde dicho microimplante tiene un diámetro de 482,6 µm o menos; donde dicho microimplante tiene un diámetro de 381 µm o menos; donde

dicho microimplante tiene una longitud de 10 milímetros o menos; donde dicho microimplante tiene una longitud de 7 milímetros o menos; donde dicho microimplante tiene una longitud de 1 milímetro o menos; donde dicho uno o más polímeros bioerosionables es copolímero de ácido poliláctico y ácido poliglicálico (PLGA); donde dicho ingrediente activo es un agente anti-inflamatorio; en donde dicho agente antiinflamatorio es un agente anti-inflamatorio seleccionado del grupo conformado por cortisona, dexametasona, hidrocortisona, metilprednisolona, prednisolona, prednisona, y triamcinolona; y en donde dicho agente antiinflamatorio es dexametasona.

2.3. Ahora bien, con base en el artículo 14 de la Decisión 486 de la CAN consagra lo siguiente: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*. Así las cosas, las invenciones objeto de patente deben ser nuevas y tener nivel inventivo. Bien, pues antes de la fecha de prioridad de esta solicitud se encuentran los siguientes documentos que afecta la patentabilidad de la presente solicitud:

- D1: US2004054374 publicada el 18 de marzo de 2004.

2.4. Ahora bien, el documento D1, particularmente en la descripción revela un aparato y métodos para entregar implantaciones oculares o microimplantaciones. El aparato es ergonómico diseñado para facilidad de empleo, que incluye una depresión simple manual de un actuador que produce el movimiento proporcional de un acoplamiento que causa la implantación o la microimplantación ser expulsado por una cánula dispuesta en la posición deseada en el ojo. Como tal esta anterioridad proporciona pequeñas cánulas de medida para los métodos autoadhesivos de entrega. Particularmente en los párrafos 0001, 0003, 0006, 0008, 0012, 0058, 0067

y 0079 revela un microimplante ocular para implantación en el ojo que comprende un mezcla homogénea de uno o más activos y uno o más polímeros bioerodibles donde el microimplante tiene un diámetro de 0,019 pulgadas o menos conforme se indica en el párrafo 58. Por lo tanto, como se prevé en la anterioridad, la presente solicitud no aporta ninguna novedad al estado de la técnica por que igualmente comprende las mismas características que incluye un microimplante ocular para implante en el ojo, que comprende: una mezcla homogénea de uno o más ingredientes activos y uno o más polímeros bioerosionables, en donde dicho microimplante tiene un diámetro de 482,6 µm o menos. Así las cosas, como lo evidencia dicho documento D1, la presente solicitud no es novedosa pues lo revelado ya se encontraba en el estado de la técnica.

2.5. Por lo tanto, este documento objeto de oposición a la luz del documento D1 carece evidentemente de NOVEDAD.

2.6. En consecuencia y de acuerdo a lo descrito anteriormente, se deriva que la solicitud colombiana **07 088001** no puede pretender un monopolio por patente toda vez que lo que pretende no cumple con uno de los tres requisitos necesarios para su protección.

2.7. Que por consiguiente, respecto a la solicitud pretendida se tiene que:

2.7.1. <u>CARECE DE NOVEDAD</u>: Según la decisión 486 de la Comunidad Andina de Naciones, Artículo 16.- *"Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.".* A la fecha de prioridad, 1° de marzo de 2005 ya era conocido, pues como se demostró, era parte del arte

anterior con base en el documento D1, un microimplante ocular para implante en el ojo, que comprende: una mezcla homogénea de uno o más ingredientes activos y uno o más polímeros bioerosionables, en donde dicho microimplante tiene un diámetro de 482,6 µm o menos, sobre el cual busca protección en el capítulo reivindicatorio.

2.8. Dado lo anterior, es posible deducir que la solicitud y lo reivindicado no es objeto de patentabilidad pues es contrario a lo que dicta la Decisión 486 de la Comunidad Andina de Naciones, Artículo 14.- *"Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial."*. La solicitud pretendida no cumple con uno de los tres requisitos de patentabilidad.

2.9. Por todo lo anterior, atentamente solicito a usted que se sirva declarar fundada la presente oposición y negar el registro Patente de invención denominada "***MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR***" cuyo titular es ***ALLERGAN,*** solicitud Colombiana que apareció publicada en la Gaceta de la Propiedad Industrial **N° 597 del 31 de Octubre de 2008.**

3. PRUEBAS

De conformidad con lo dispuesto por las normas vigentes, solicito a usted tener como prueba en este asunto los siguientes:

- D1: US2004054374 publicada el 18 de marzo de 2004.

4. FUNDAMENTO DE DERECHO

Fundamento esta observación en las normas legales siguientes:

4.1. Numeral 1 del artículo 586 del Código de Comercio.

4.2. Artículo 42 de la Decisión 486 de la Comisión del Acuerdo de Cartagena.

4.3. En las demás normas concordantes.

5. ANEXOS

Para los efectos correspondientes anexo al presente escrito los siguientes documentos:

1. Poder para actuar en el presente.
2. Documento que acredita al representante legal de **PROCAPS S.A.**
3. Recibo de caja del respectivo pago de tasa.
4. Copias de los documentos:

- D1: US2004054374 publicada el 18 de marzo de 2004.

Optimum

Derecho de la Competencia, Propiedad Industrial y Comercio Exterior

6. NOTIFICACIONES

Para efectos de notificaciones que por disposición del artículo 50 del Decreto 01 de 1984 debe hacer su Despacho, informo que mi representada y la suscrita recibiremos notificaciones en la Secretaría de su Despacho o en mis oficinas situadas en la Carrera 13 N° 119-95, Of. 104 de esta ciudad de Bogotá.

Señor Superintendente,

ELIANA ISAURA MORENO BOHORQUEZ
C.C. 51'975.664 de Bogotá
T.P.A. 83823 del C.S. de la J.

US 20040054374A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0054374 A1**

Weber et al. (43) **Pub. Date: Mar. 18, 2004**

(54) **METHODS AND APPARATUS FOR DELIVERY OF OCULAR IMPLANTS**

(76) Inventors: **David Weber**, Danville, CA (US); **Ingrid Kane**, Los Altos, CA (US); **Mike Rehal**, Boulder Creek, CA (US); **Robert L. Lathrop III**, Santa Clara, CA (US); **Kenny Aptekarev**, Santa Cruz, CA (US)

Correspondence Address:
Cameron A. King
Morrison & Foerster LLP
425 Market Street
San Francisco, CA 94105-2482 (US)

(21) Appl. No.: **10/246,884**

(22) Filed: **Sep. 18, 2002**

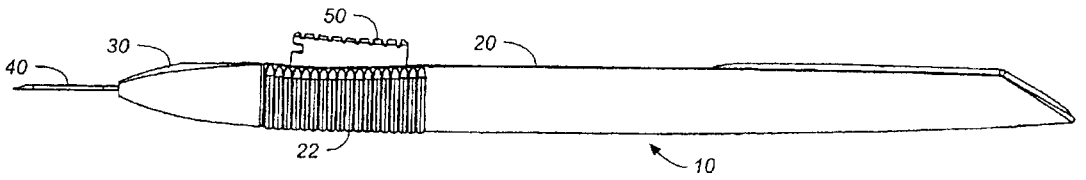
Publication Classification

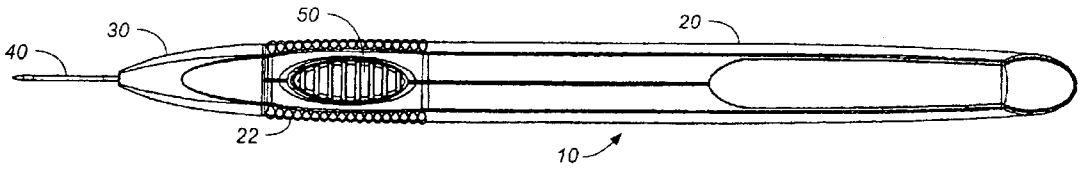
(51) **Int. Cl.**[7] **A61F 9/00**

(52) **U.S. Cl.** **606/107**

(57) **ABSTRACT**

An apparatus and methods for delivering ocular implants or microimplants. The apparatus is ergonomically designed for ease of use, and a simple manual depression of an actuator produces proportional movement of a linkage causing the implant or microimplant to be ejected through a cannula disposed at the desired location in the eye. Small gauge cannulas are provided for self-sealing methods of delivery.





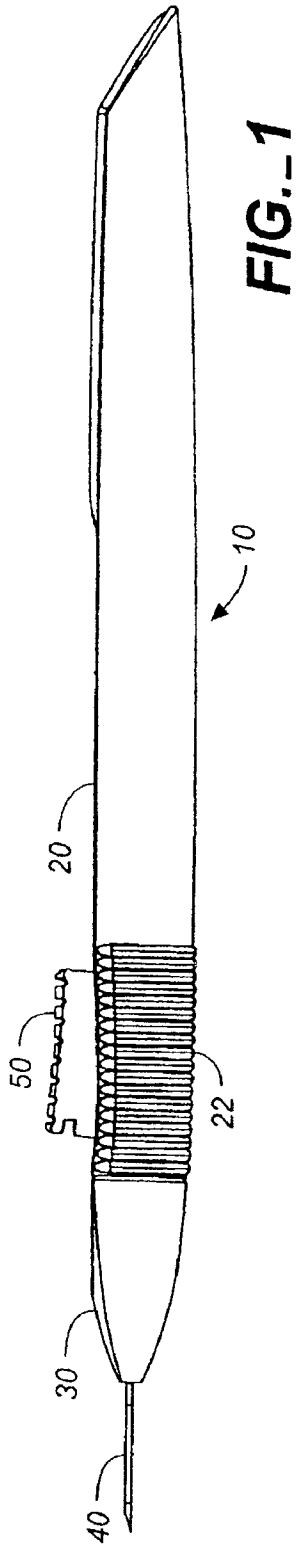


FIG._1

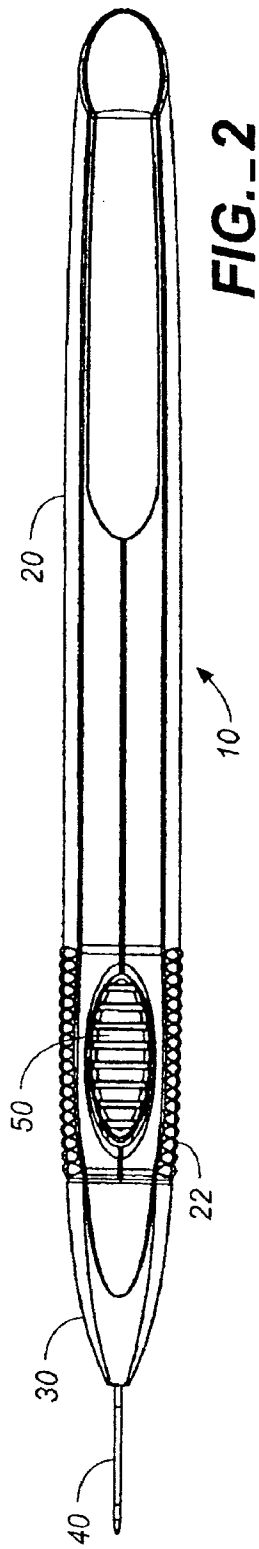


FIG._2

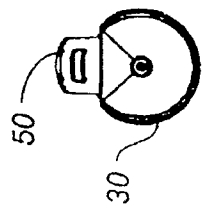


FIG._3

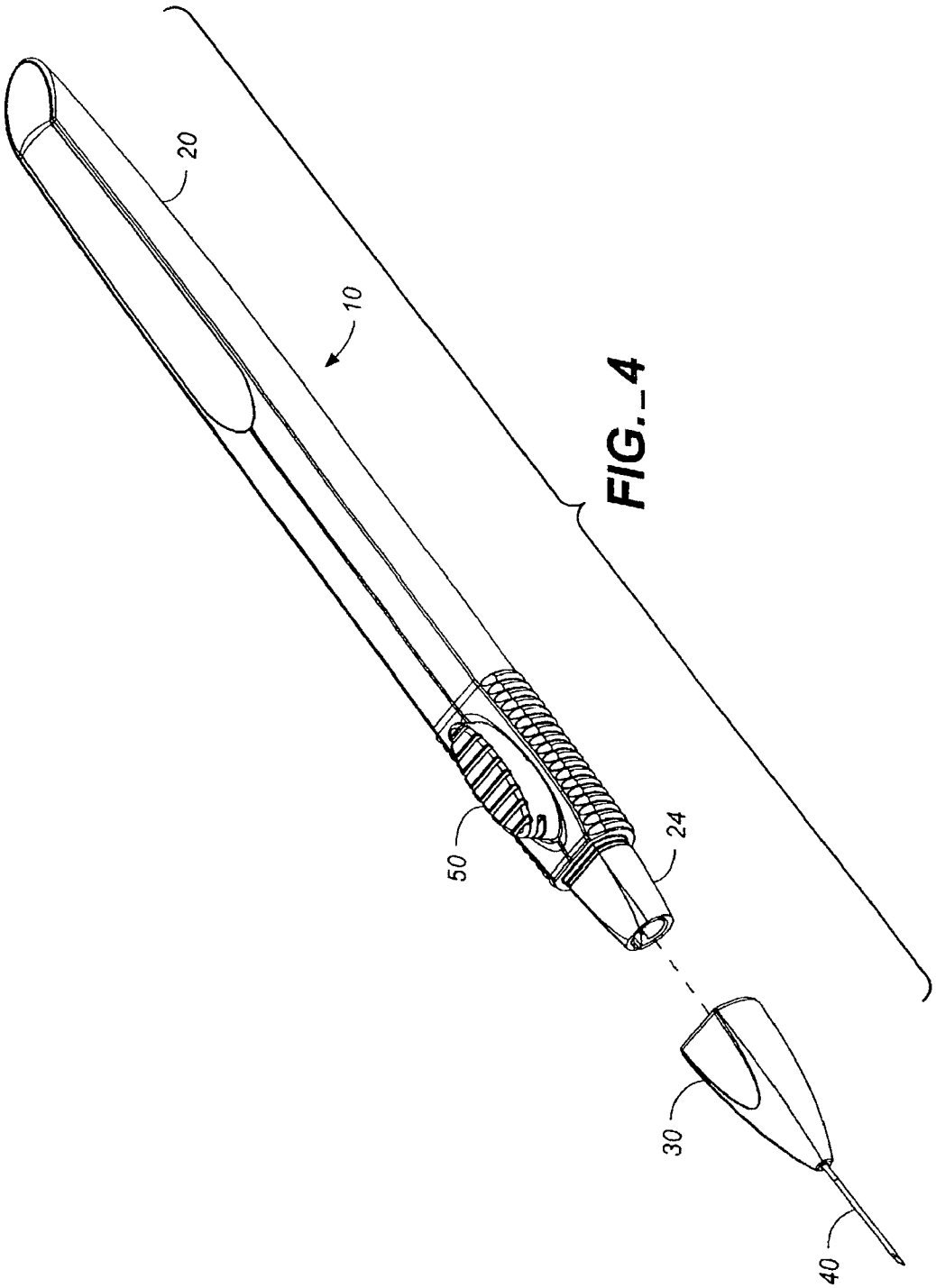


FIG._4

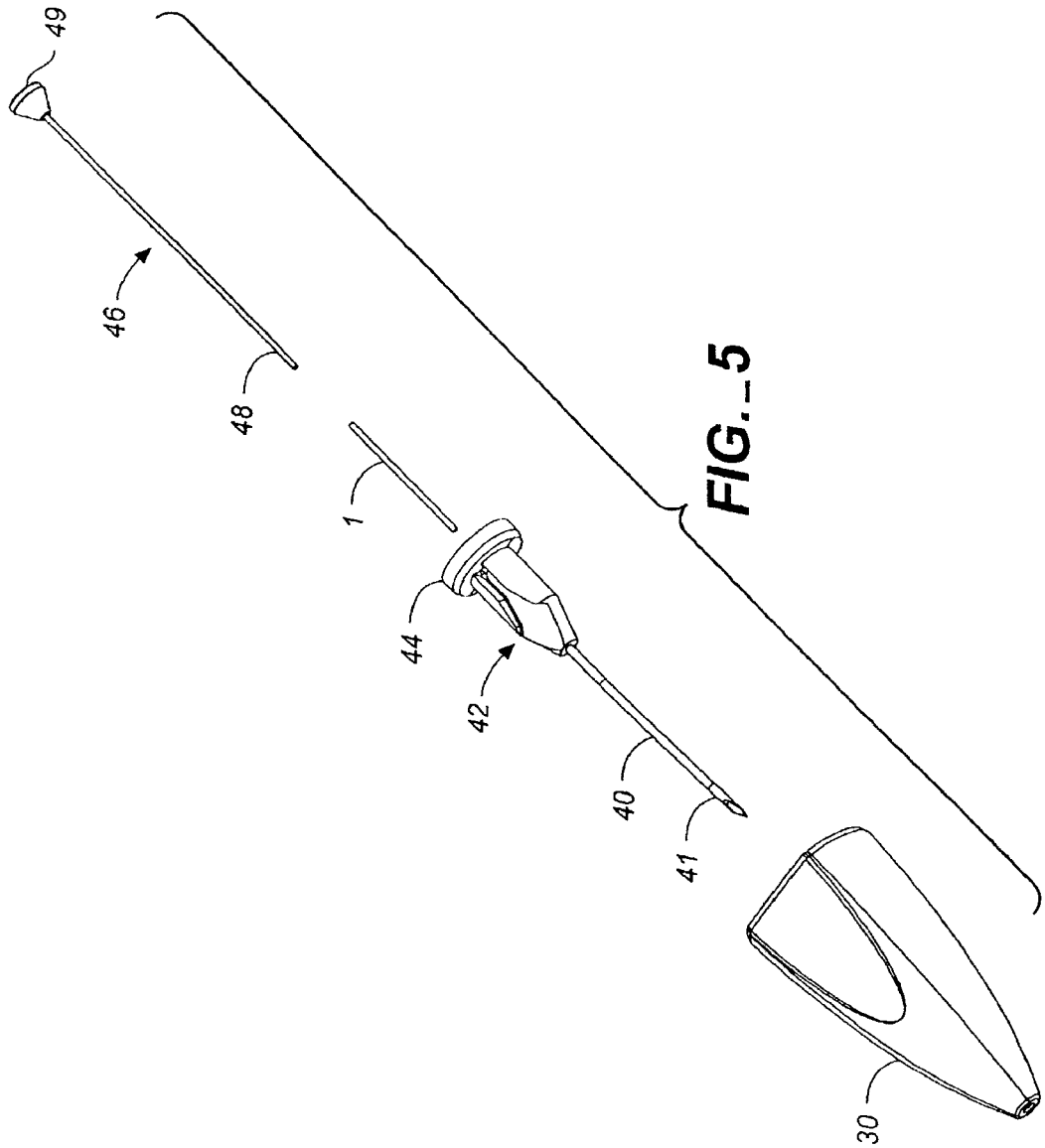


FIG._5

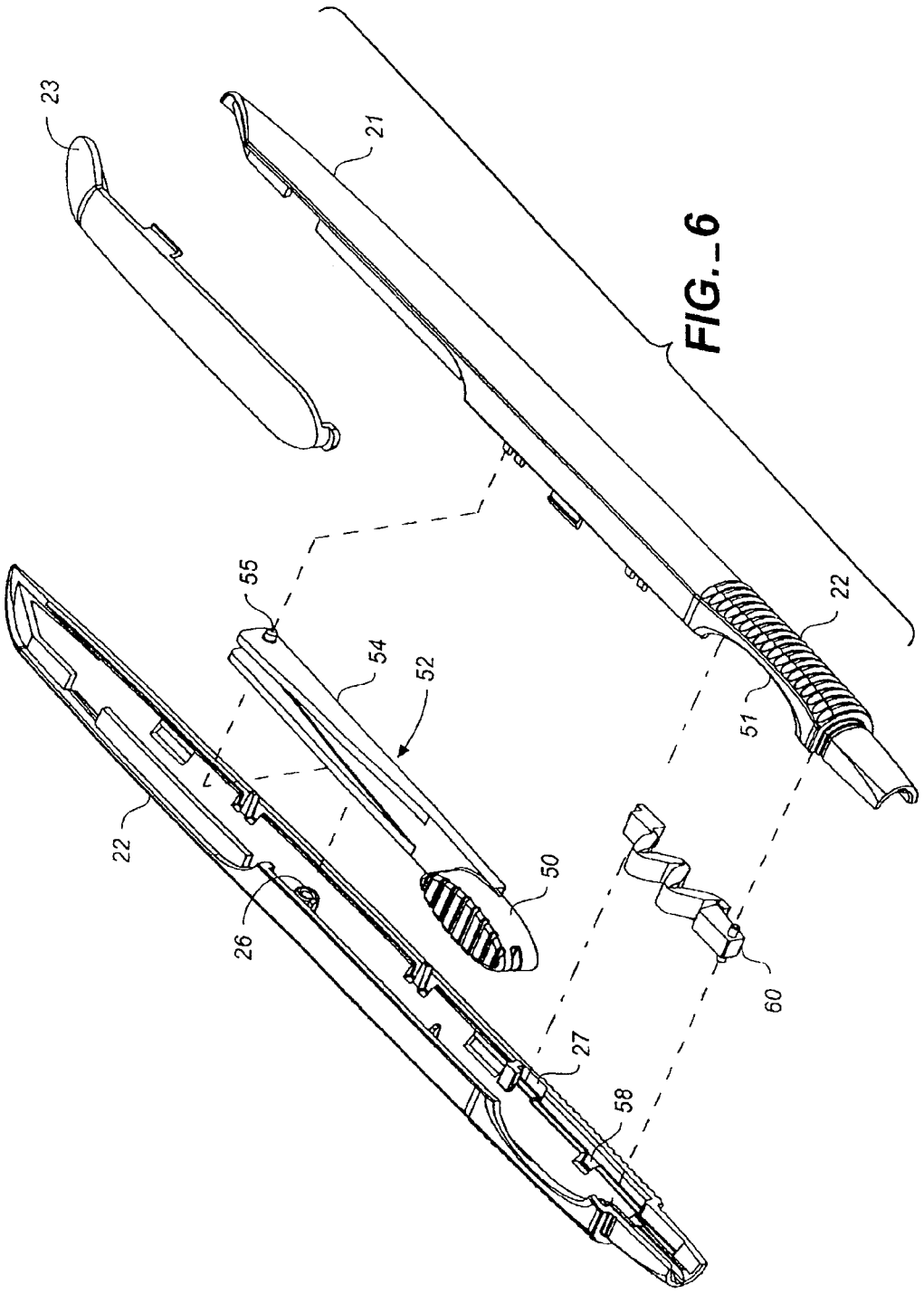


FIG._6

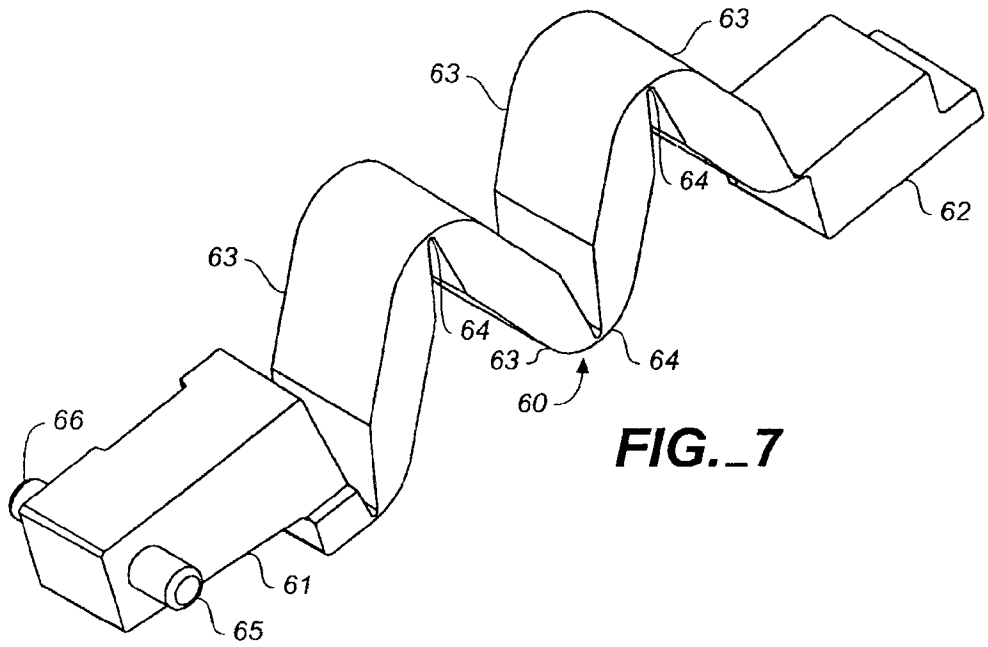


FIG._7

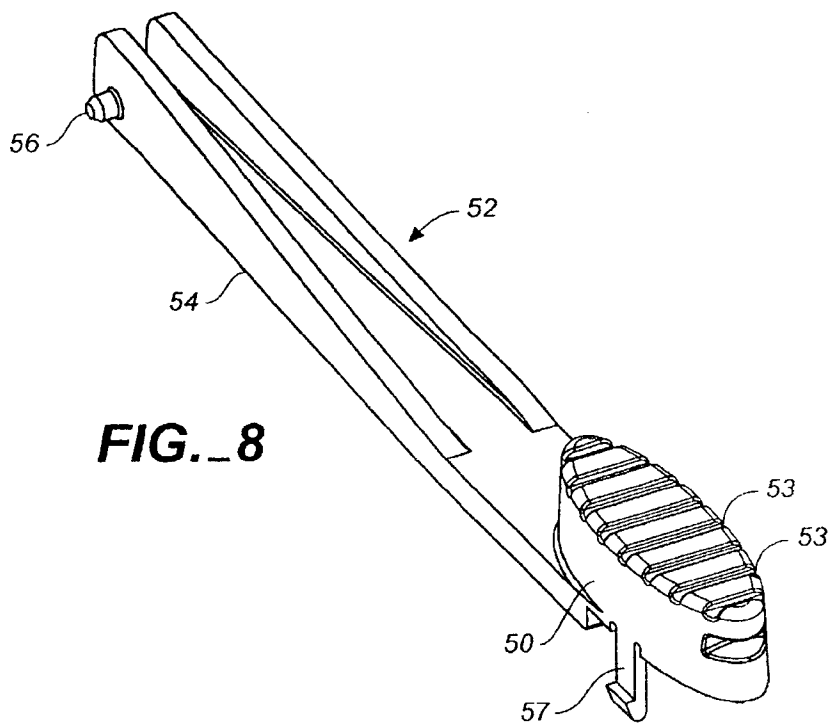


FIG._8

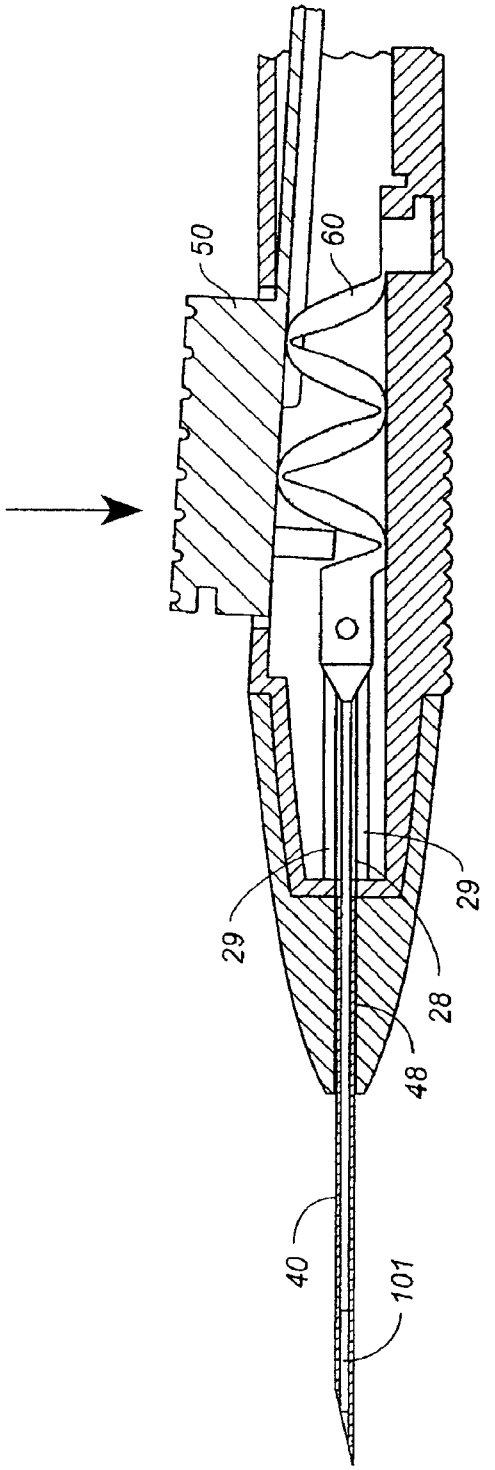


FIG._9A

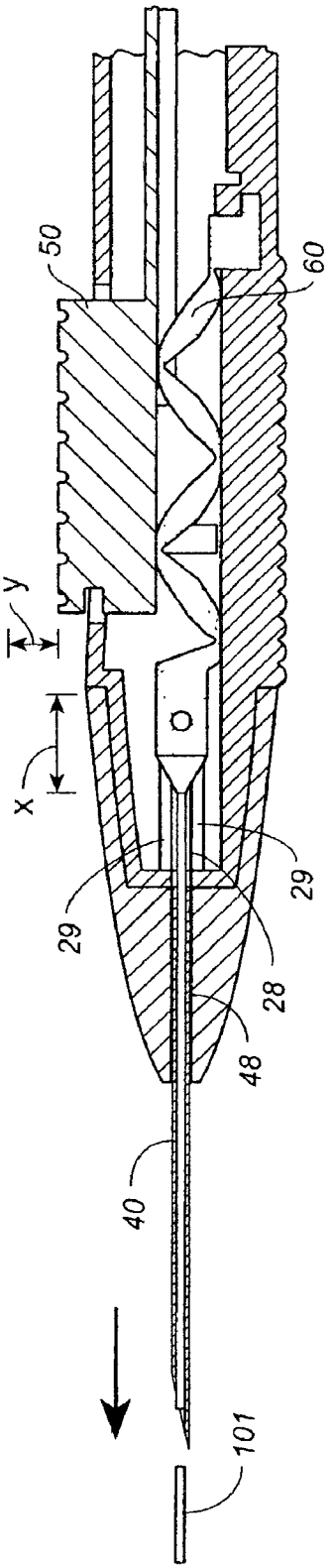


FIG._9B

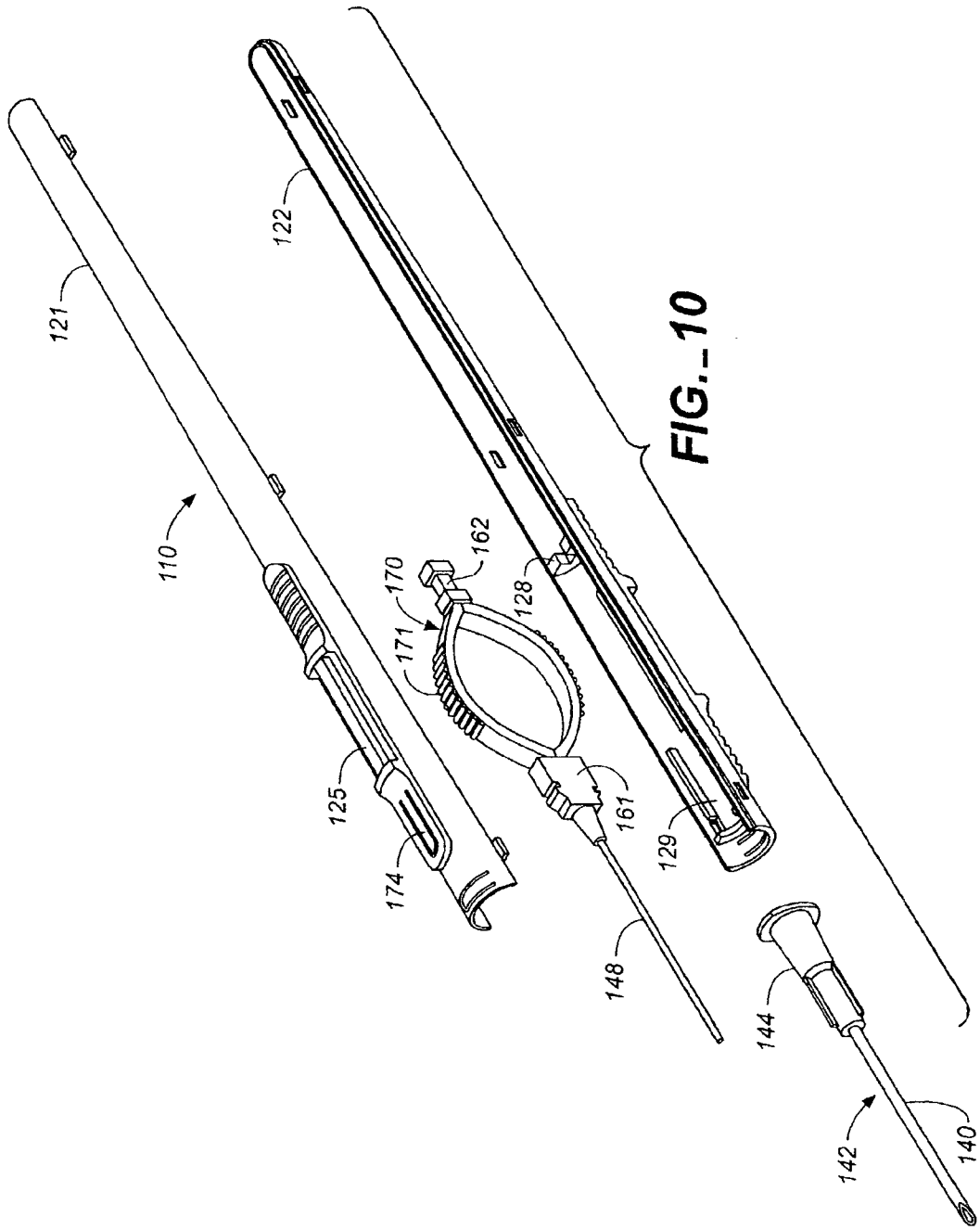


FIG._10

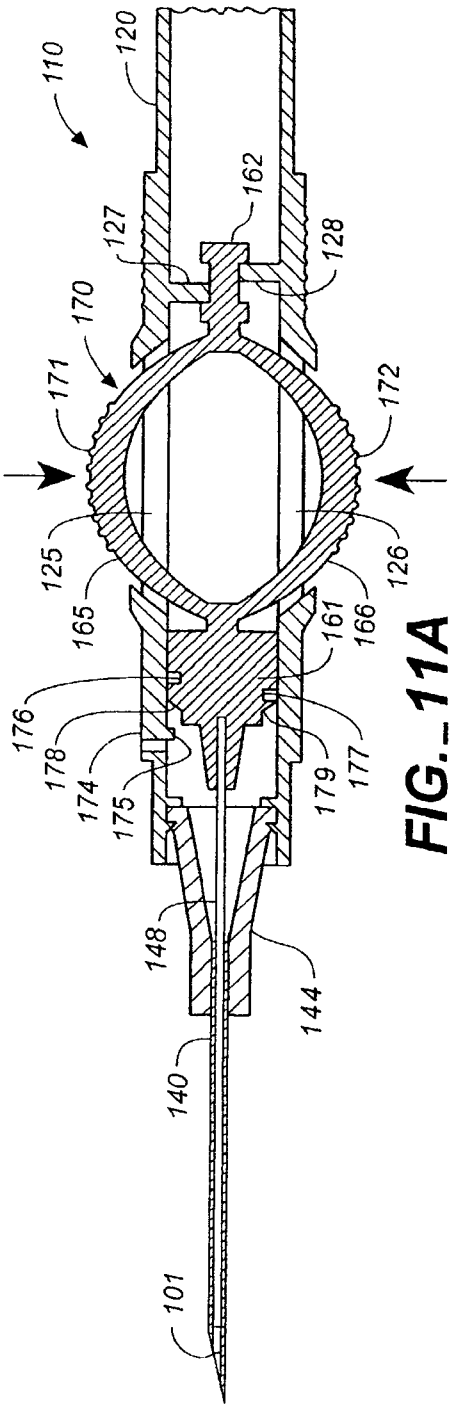


FIG._11A

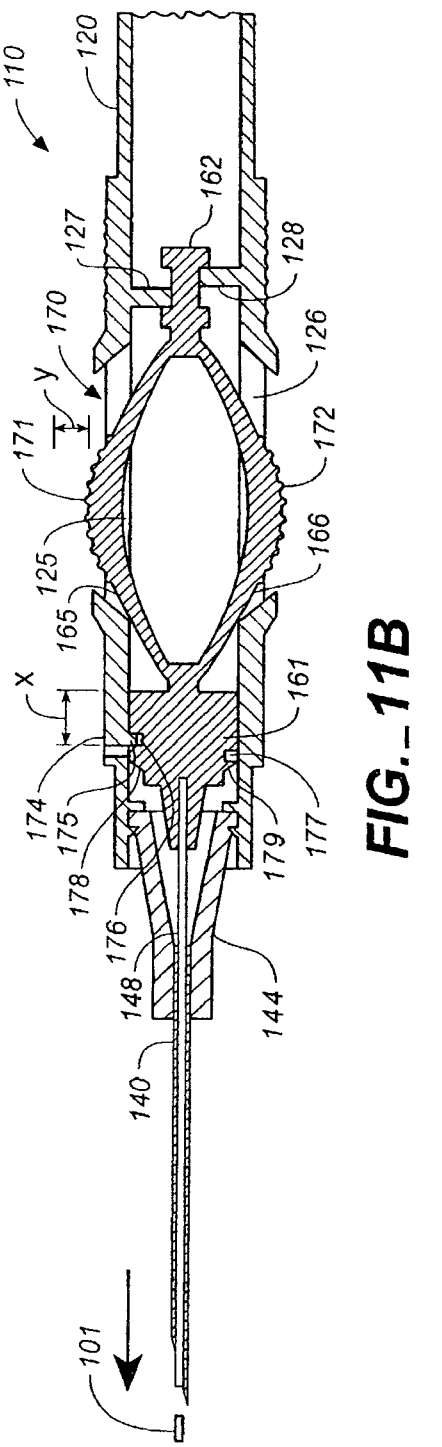


FIG._11B

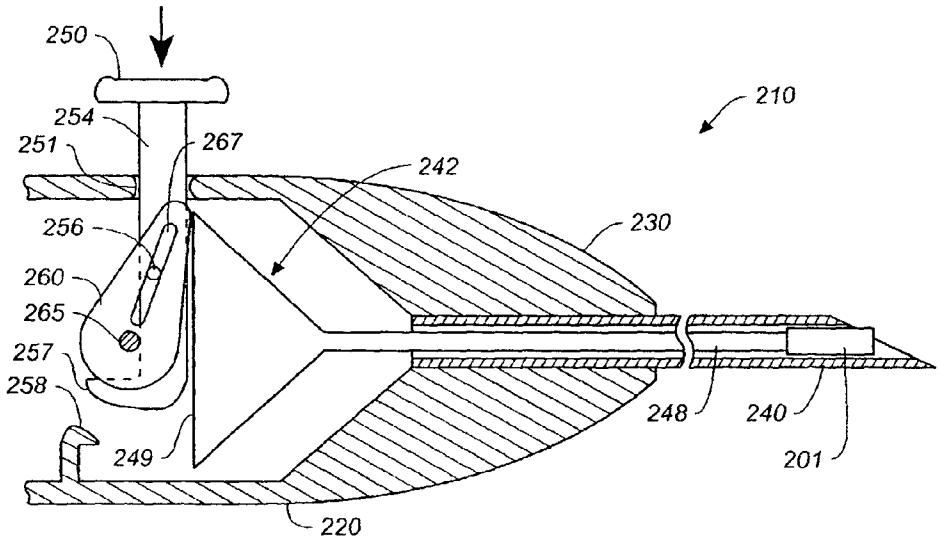


FIG._12A

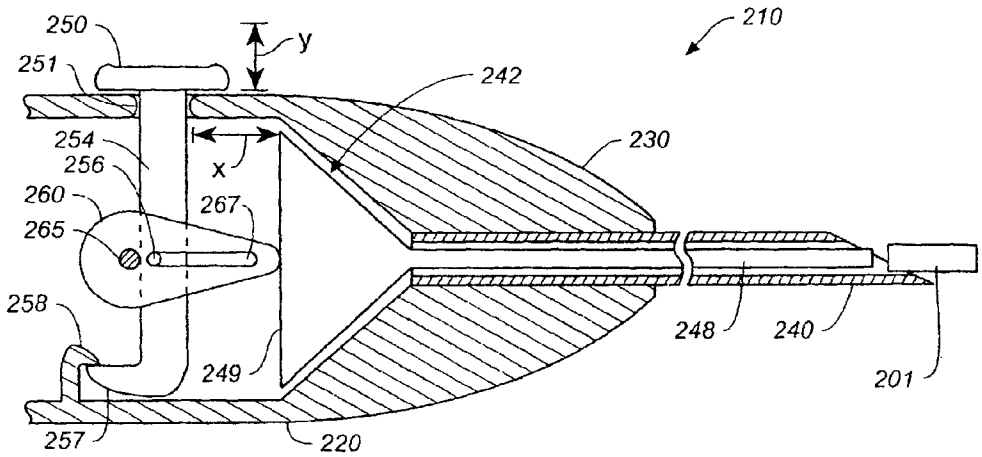


FIG._12B

FIG._13A

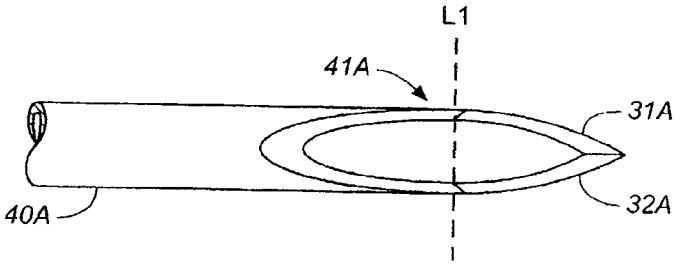


FIG._13B

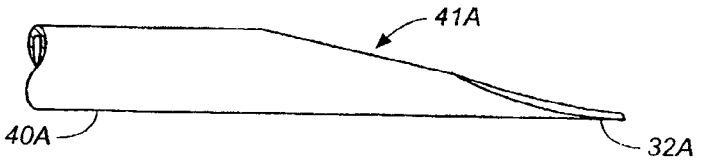


FIG._14A

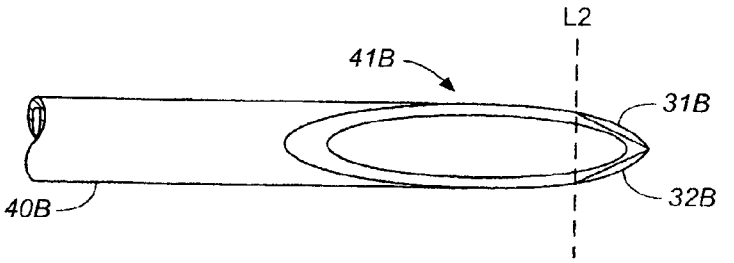
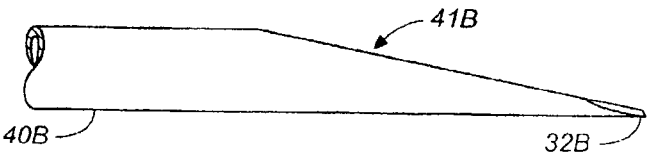


FIG._14B



METHODS AND APPARATUS FOR DELIVERY OF OCULAR IMPLANTS

TECHNICAL FIELD

[0001] The present invention relates to methods and apparatus for delivering solid or semi-solid materials into the eye. Specifically, the methods and apparatus can be used to introduce implants containing therapeutic or active agents, including bioerodible implants, into various locations within the eye, including the vitreous of the eye.

BACKGROUND ART

[0002] A primary difficulty in treating diseases of the eye is the inability to introduce drugs or therapeutic agents into the eye and maintain these drugs or agents at a therapeutically effective concentration in the eye for the necessary duration. Systemic administration may not be an ideal solution because, often, unacceptably high levels of systemic dosing is needed to achieve effective intraocular concentrations, with the increased incidence of unacceptable side effects of the drugs. Simple ocular instillation or application is not an acceptable alternative in many cases because the drug may be quickly washed out by tear-action or is otherwise depleted from within the eye into the general circulation. Suprachoroidal injections of drug solutions have also been performed, but again the drug availability is short-lived. Such methods make it difficult to maintain therapeutic levels of drug for adequate time periods.

[0003] Efforts to address this problem have lead to the development of drug delivery devices, or implants, which can be implanted into the eye such that a controlled amount of desired drug can be released constantly over a period of several days, or weeks, or even months. Many such devices have been previously reported. See, for example, U.S. Pat. No. 4,853,224, which discloses biocompatible implants for introduction into an anterior segment or posterior segment of an eye for the treatment of an ocular condition. U.S. Pat. No. 5,164,188 discloses a method of treating an ocular condition by introduction of a biodegradable implant comprising drugs of interest into the suprachoroidal space or pars plana of the eye. See also U.S. Pat. Nos. 5,824,072, 5,476,511, 4,997,652, 4,959,217, 4,668,506, and 4,144,317. Other methods include anchoring a plug or tack containing a drug into the sclera of the eye (see, e.g., U.S. Pat. No. 5,466,233).

[0004] Various sites exist in the eye for implantation of a drug delivery device or implant, such as the vitreous of the eye, anterior or posterior chambers of the eye, or other areas of the eye including intraretinal, subretinal, intrachoroidal, suprachoroidal, intrascleral, episcleral, subconjunctival, intracorneal or epicorneal spaces. Wherever the desired location of implantation, typical methods of implantation all require relatively invasive surgical procedures, pose a risk of excessive trauma to the eye, and require excessive handling of the implant. For example, in a typical method for placement in the vitreous, an incision is made through the sclera, and the implant is inserted into and deposited at the desired location in the vitreous, using forceps or other like manual grasping device. Once deposited, the forceps (or grasping device) is removed, and the incision is sutured closed. Alternatively, an incision can be made through the sclera, a trocar can be advanced through the incision and then the implant can be delivered through the trocar. Similar methods can be employed to deliver implants to other locations, e.g., implantation in the anterior chamber of the eye through an incision in the cornea.

[0005] The drawbacks of such techniques for implant delivery are many-fold. Extensive handling of the implant is necessitated in these techniques, creating a risk that the implant will be damaged in the process. Many such implants are polymer-based and are relatively fragile. If portions of such implants are damaged and broken-off, the effective therapeutic dose delivered by the implant once placed will be significantly altered. In addition, it becomes inherently difficult using these methods to achieve reproducible placement from patient to patient. Also of import is that fact that all such techniques require an incision or puncture in the eye large enough to require suturing. Thus such techniques are typically performed in a surgical setting.

[0006] There thus remains a need for a more facile, convenient, less invasive, and less traumatic means for delivering implants into the eye. There also remains a need for a more controlled means of delivering implants into the eye.

SUMMARY OF THE INVENTION

[0007] The present invention meets these and other needs and provides methods and apparatus for easily, safely, and more precisely delivering an implant into the eye.

[0008] In one aspect of the invention, an apparatus is provided having an elongate housing with a cannula extending longitudinally from the housing. The cannula includes a lumen extending through the length of the cannula, such that an ocular implant can be received within the cannula lumen. A plunger having a push rod is also received within the cannula lumen and is capable of movement from a first to second position within the lumen. A linkage is provided having a moveable end engageable with the plunger, and a fixed end secured to the housing. The moveable end of the linkage is capable of movement from a first to second position relative to the housing upon application to the linkage of a force normal to the housing axis. When such a force is applied the plunger moves from the first to the second position within the cannula, forcing an implant retained within the cannula to be ejected.

[0009] In one embodiment, the apparatus further includes an actuating lever with one end pivotally mounted within mounted the housing and the other end of the lever engaged with the linkage. The actuating lever can further be configured for manual accession, such that manual depression of the lever against the linkage provides the force normal to the housing axis which causes translational motion of the moveable end of the linkage along the housing axis and subsequent movement of the plunger and ejection of the implant. The linkage itself can further include a series of flexibly joined segments.

[0010] In another embodiment, the apparatus includes a linkage that includes one or more flexible bow elements. The bow element or elements can further include a portion or portions that extend from the housing for manual accession, such that manual depression of the portion or portions provides the normal force to the housing axis to cause translational motion of the linkage.

[0011] In a further embodiment, the apparatus includes an actuating lever operably linked to a linkage comprising a

cam assembly. The actuating lever can be oriented for movement in a direction normal to the housing axis and can be further configured for manual accession. Manual depression of the lever causes rotation of the cam assembly about a fixed pivot point resulting in engagement of the cam assembly with the plunger and subsequent movement of the plunger to eject the implant.

[0012] In yet another embodiment, the cannula is further configured to have an outer diameter of 0.032 inches or less. In further embodiments, the cannula is configured to have an outer diameter of 0.028 inches or less or 0.025 inches or less. Alternatively, in cases where the cannula has a non-circular cross-section, the cannula can have a cross-sectional area of up to 0.0008 square inches or more, depending on the particular cross-sectional geometry. Cannulas having such configurations are able to receive and deliver smaller ocular implants, i.e., so-called microimplants.

[0013] The invention also provides methods of delivery of an implant into a location of the eye. In one aspect of the invention, a cannula is used having an outer diameter of 0.032 inches or less. In other aspects of the invention, a cannula is used having an outer diameter of 0.028 inches or less or 0.025 inches or less. In yet another aspect of the invention, in cases where the cannula has a non-circular cross-section, the cannula has a cross-sectional area of up to 0.0008 square inches or more, depending on the particular cross-sectional geometry. The use of cannulas having such cross-sectional dimensions allows for self-sealing methods of implant delivery.

[0014] Accordingly, in one embodiment, a method of delivering an ocular microimplant into a patient's eye is provided which involves providing a cannula having a distal sharpened tip, lumen extending through the cannula, a microimplant retained within the lumen, and a push rod received through a proximal end of the cannula. The cannula is then used to puncture through the outer layer of a patient's eye with the cannula and inserted to a desired location within the patient's eye to a desired location. Once the cannula is positioned, the push rod is moved from the proximal end of the cannula toward the distal end of the cannula, thereby ejecting the microimplant from the cannula. After ejection, the cannula and push rod are removed from the patient's eye, and the puncture created by the insertion of the cannula into the patient's eye is self-sealing upon the removal of the cannula. Particular orientations of the cannula during insertion can aid in self-sealing. The cannula tip can further be configured to have particular beveled designs which further aid in the self-sealing method.

[0015] While the delivery apparatus according to the invention facilitates the inventive method of delivering an ocular microimplant, it is not necessary to the practice of inventive method. For example, one skilled in the art can also use a needle and plunger assembly, where the needle has dimensions corresponding to the described cannula.

[0016] The methods and apparatus of the invention provide numerous advantages, not least of which is providing for an easier, convenient, and less traumatic means for delivering implants into the eye. In certain embodiments, the self-sealing means of implant delivery can be achieved, which in addition to being less invasive and traumatic, offers less costly treatment by obviating the need for performing the procedure in a surgical setting.

[0017] The methods and apparatus of the invention also provide for a more controlled means of delivering implants into the eye. In particular, embodiments of the inventive apparatus are designed to provide a smooth, controlled delivery of the implant. Additional embodiments provide for safety features which include, among other things, user feedback upon the ejection of an implant and locking mechanisms which prevent backflow of eye fluid after ejection and/or which also prevent reuse of the applicator. Another advantage of the inventive apparatus is ease and flexibility of manufacture and assembly of apparatuses for delivery of different implants.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] **FIG. 1** depicts a side view of an implant delivery apparatus according to one embodiment of the present invention;

[0019] **FIG. 2** depicts a top view of the apparatus of **FIG. 1**;

[0020] **FIG. 3** depicts a front view of the apparatus of **FIG. 1**;

[0021] **FIG. 4** depicts a perspective exploded view of the apparatus of **FIG. 1**, showing the nose cone disengaged from the housing;

[0022] **FIG. 5** depicts a perspective exploded view of the nose cone and cannula assembly of the apparatus of **FIG. 1**;

[0023] **FIG. 6** depicts a perspective exploded view of the housing, linkage, and actuating lever of the apparatus of **FIG. 1**;

[0024] **FIG. 7** depicts an enlarged perspective view of the linkage of the apparatus of **FIG. 1**;

[0025] **FIG. 8** depicts an enlarged perspective view of the actuating lever of the apparatus of **FIG. 1**;

[0026] **FIG. 9A** depicts a side elevated view in section of the apparatus of **FIG. 1**, showing the linkage, actuating lever and cannula assembly prior to ejection of an implant from the apparatus;

[0027] **FIG. 9B** depicts a side elevated view in section of the apparatus of **FIG. 1**, showing the linkage, actuating lever and cannula assembly after ejection of an implant from the apparatus;

[0028] **FIG. 10** depicts a perspective exploded view of an implant delivery apparatus according to another embodiment of the invention, showing different housing, linkage and cannula assemblies;

[0029] **FIG. 11A** depicts a side elevated view in section of the apparatus of **FIG. 10**, showing the linkage and cannula assembly prior to ejection of an implant from the apparatus;

[0030] **FIG. 11B** depicts a side elevated view in section of the apparatus of **FIG. 10**, showing the linkage and cannula assembly after ejection of an implant from the apparatus;

[0031] **FIG. 12A** depicts a side elevated view in section, with parts broken away, of an implant delivery apparatus according to yet another embodiment of the invention, showing yet another linkage mechanism and cannula assembly prior to ejection;

[0032] **FIG. 12B** depicts a side elevated view in section of the apparatus of **FIG. 12A**, with parts broken away, showing the linkage and cannula assembly after ejection of an implant from the apparatus;

[0033] FIGS. **13A-B** depict top and side views, with parts broken away, of a cannula tip according to one embodiment of the invention; and

[0034] FIGS. **14A-B** depict top and side views, with parts broken away, of a cannula tip according to another embodiment of the invention.

DETAILED DESCRIPTION

[0035] An embodiment of an implant delivery apparatus according to the present invention is depicted in FIGS. **1-9**. As shown, implant delivery apparatus **10** includes external housing **20** with nose cone **30** attached to and extending from the housing. Cannula **40**, having beveled tip **41**, extends from the nose cone. Ejector button **50** extends through opening **52** of the housing. As described further herein, an implant can be loaded into the cannula and the apparatus can be readily manipulated to introduce the cannula into a patient's eye at a desired location. Depression of the ejector button actuates the apparatus, and causes the ejection of the implant into the patient's eye.

[0036] As used herein, "implants" refers to ocular implants or drug delivery devices which can be implanted into any number of locations in the eye, and which are designed such that a controlled amount of desired drug or therapeutic can be released over time. Such implants are biocompatible, and in many but not all cases are formed of a bioerodible substance, such as a bioerodible polymer. "Microimplants" refers to implants having a sufficiently small cross-sectional area that they can be delivered by methods and/or apparatus according to the invention that result in self-sealing of the eye at the puncture site associated with the delivery. In particular, such microimplants have dimensions such that they are deliverable through 21 gauge or 22 gauge or smaller gauge cannulas. Thin wall versions of 21 gauge needles can be manufactured having inner diameters of up to 0.028 inches, thus cylindrical microimplants deliverable through such sized cannulas will have outer diameters of less than 0.028 inches. Thin wall versions of 22 gauge needles can have inner diameters of up to 0.023 inches, and thus cylindrical microimplants with diameters of less than 0.023 inches will be deliverable through such sized cannulas. Microimplants can also have non-circular cross-sectional geometries for delivery through cannulas having corresponding cross-sectional geometries. Where the microimplant has non-circular cross-section, the cross-sectional area may be up to 0.00025 square inches or more, depending on the particular cross-sectional geometry.

[0037] As used herein, "self sealing" methods of delivering microimplants into the eye refers to methods of introducing microimplants through a cannula and into desired locations of a patient's eye without the need for a suture, or other like closure means, at the cannula puncture site. Such "self sealing" methods do not require that the puncture site completely seal immediately upon withdrawal of the cannula, but rather that any initial leakage is minimum and dissipates in short order such that a surgeon or another equally skilled in the art, in his or her good clinical judgment, would not be compelled to suture or otherwise provide other like closure means to the puncture site.

[0038] The apparatus is ergonomically configured for easy gripping and manipulation, and has a general overall shape similar to a conventional pen or other writing instrument. The apparatus will typically be grasped by the user between the thumb and the middle finger. Tactile ridges **22** are provided on the housing, in the areas around the ejector button where the thumb and middle finger of the user are contact the apparatus, to provide a more secure grip and feel to the user. Ejector button **50** itself is provided with tactile grooves **53** on the button surface where the index finger typically contacts the button, also providing for a more secure grip and feel for the user.

[0039] As shown more clearly in **FIG. 4**, nose cone **30** can be manufactured as a separate piece that is then secured to the housing. Specifically, collar **24** extends from the housing as shown. Nose cone **30** is configured for receipt over and attachment to the collar.

[0040] As seen in **FIG. 5**, nose cone **30** receives cannula assembly **42** which consists of cannula **40** and cannula hub **44**. The hub is configured for receipt and securement within nose cone **30**, with cannula **40** extending through nose cone hole **32**. The cannula lumen is in communication with inner passageway **43** of the hub, such that implant **1** can be passed through the inner passageway of the hub and loaded into the cannula lumen. Plunger **46** includes push rod **48** and cone **49**. Push rod **48** is configured for slidable receipt within the cannula lumen, and is of sufficient length to displace a loaded implant retained with the cannula lumen and eject it from the cannula tip.

[0041] Referring to **FIG. 6**, it can be seen that housing **20** is formed of two half sections **21** and **22**. These sections are preferably configured to snap-fit together, although other known methods of attaching the two halves together are contemplated, including, e.g., gluing, welding, fusing, etc. Alternatively, the housing could be singularly molded. Label plate **23** is also provided, which likewise can be snapped onto or otherwise secured to, the housing. Nose cone **30** can be secured to collar **24** of housing **20** by similar means.

[0042] Actuating lever **52** and linkage **60** are retained within housing **20**. As seen in **FIGS. 6 and 8**, actuating lever **52** consists of elongate member **54** having pins **55**, **56** extending from the member at one end and ejector button **50** extending from the other end. Pins **55**, **56** extend along a common axis and are received in corresponding pivot holes **26** of the housing sections, such that when assembled, the lever can pivot about the pins in a restricted range of motion within the housing.

[0043] Linkage **60**, as seen more clearly seen in **FIG. 7**, consists of front and rear blocks **61** and **62**, with a plurality of joined segments **63** extending therebetween. The segments are sequentially joined to one another. Flexible joints **64** connect the segments to each other and to the front and rear blocks. The linkage is flexible yet resilient, and preferably formed of a contiguous, moldable plastic piece. Portions of the linkage having a relatively thin cross-sectional area of material form flexible joints **64**, and disposed between thicker, less flexible segments **63**. This allows for flexure of the linkage at the joint locations when a force is applied to the linkage. Other known materials are

also suitable for the linkage, including e.g. shape memory alloys, provided the resultant linkage is capable of lengthwise extension when a force normal to or perpendicular to the length of the linkage is applied.

[0044] When assembled, rear block **62** is fixedly secured into slot **27** of the housing, as shown in **FIG. 6**, and more clearly in **FIGS. 9 and 10**. Guide pins **65**, **66** extend from front block **61** and are received in guide track **28**. Guide track **28** is defined by guide ribs **29**, **29** that extend inwardly from collar **24**. Cone **49** of plunger **46** abuts against front block **61** of the linkage. The linkage, guide track, plunger, cannula, and implant (if loaded within the cannula) are all aligned along the longitudinal axis of the apparatus.

[0045] As can be seen, the underside of button **50** of actuating lever **52** is in contact with the linkage (**FIG. 9A**). In operation, depression of button **50** by the user transmits force against the linkage through underside of button **50** in a direction generally normal to the longitudinal axis of the apparatus. This force is transmitted through the linkage, and is converted into a longitudinal force along the longitudinal axis of the apparatus, through flexure of the linkage joints. Because the rear block end of the linkage remains fixed to the housing, this action results in translational motion of the free, front block end of the linkage in the direction away from the fixed rear block of the linkage. This translational movement of the front block of the linkage in turn pushes push rod **46** through the lumen of cannula **40**. Where an implant is loaded and retained within the cannula lumen, the motion of the push rod in turn ejects the implant from the cannula tip (**FIG. 9B**).

[0046] Button **50** also includes tab **57**, which is engageable with tab slot **58** of the housing. The tab includes a detent which, when engaged in slot **58** will provide an audible click, signaling the user that the implant has been deployed, and will also retain the actuating lever in a locked, depressed condition, after deployment of the implant.

[0047] A second embodiment of an implant delivery apparatus according to the present invention is depicted in FIGS. **10-11**. In this embodiment, implant delivery apparatus **110** includes housing **120** with actuator **170** disposed within the housing. The actuator includes linkage **160** formed of two opposing flexible bowing elements **165** and **166**. Ridges **171** and **172** are provided on the apexes of the bowing elements, and portions of the bowing elements that include ridges **171** and **172**, extend through openings **124** and **125** of the housing. Cannula assembly **142** is secured to the housing. As with the previous embodiment, an implant can be likewise loaded into the cannula. Depression of bowing elements **165** or **166** actuates the apparatus, causing the ejection of the implant from the cannula, as will be further detailed.

[0048] Housing **120** is formed of two sections, upper and lower housing sections **121** and **122**, that can be assembled as previously described above with respect to the embodiment of FIGS. **1-9**. Similarly, apparatus **110** is also ergonomically configured for easy gripping, and will likewise typically be grasped by the user between the thumb and the middle finger. Ridges **171** or **172** include tactile grooves or are otherwise textured to provide for a more secure grip and feel for the user. Additional tactile ridges can be provided on the housing itself in proximity to openings **125** and **126**.

[0049] Linkage **160** further includes front and rear blocks **161** and **162**, and push rod **148** extending from the front block **161**. The ends of bowing elements **165** and **166** coincide at front and rear blocks **161** and **162**. Suitable materials for linkage **160** are the same as those describe above with respect to linkage **60** of the embodiment of FIGS. **1-9**. When assembled, rear block **162** is secured to the housing and retained in a fixed position relative to the housing by tabs **127** and **128**. Front block **161** is received and slidable within track **129** on lower housing section **122**. Push rod **148** extends from front block **161** and is axially aligned with cannula **140**. The push rod can be formed of wire, and in one method of manufacture, the linkage can be molded directly onto a wire and then the wire can be cut to the desired dimensions to form the push rod.

[0050] In the undeployed condition, depicted in **FIG. 11A**, implant **101** is retained in the cannula, distal to the push rod. Manual pressure on bowing element **165** or **166** supplies a normal force to longitudinal axis of the apparatus. This force is transmitted, via flexing of the bowing elements, into a longitudinal force along the longitudinal axis, which in turn causes movement of the free, front block **161** of the linkage away from the fixed, rear block **162**. This in turn pushes push rod **146** through the cannula, which in turn ejects a loaded implant from the cannula, as shown in **FIG. 11B**.

[0051] Lock tab **174** is provided on upper housing section **121** and further includes lock stop **175** that is engageable with notch **176** on front block **161**. The lock tab itself can be integrally formed with upper housing section **121**, and configured such that the lock stop snap-fits into the notch when positioned properly. In operation, as front block **161** moves forward in relation to the housing, angled face **178** engages lock stop **175** and deflects the lock tab upward. The lock tab remains deflected upward until movement of the front block brings notch **176** into position such that lock stop engages the notch. As can be appreciated, the location of the notch relative to the front block length will govern the distance traveled by the push rod in ejecting the implant. In the embodiment shown, the actuator can be inserted into the housing in two different orientations to provide for two different ejection distances for the push rod. As seen, a similar angled face **179** and notch **177** are provided on block **161** opposite face **178** and notch **176**, with notch **176** being offset from notch **177** relative to housing longitudinal axis. Therefore, the same actuator can be rotated **180** degrees upon assembly of the apparatus such that lock stop **175** instead engages notch **177**, thereby allowing for the push rod to travel an alternate distance govenrned instead by the location of notch **177** relative to the front block length. In the embodiment shown, notch **177** provides for a **1** mm displacement and notch **176** provides for a **2** mm displacement.

[0052] A third embodiment of an implant delivery apparatus according to the present invention is depicted in FIGS. **12A-12B**. In this embodiment, implant delivery apparatus **210** includes housing **220** and cannula assembly **242**. Cannula assembly **242** includes cannula **240** disposed within and extending from nose portion **230**, and push rod **248** that is slidably received with the cannula and terminates at its proximal end in cone **249** which is disposed in the interior of the housing. Lever **254** is mounted for movement normal to the longitudinal axis of the apparatus. One end of the lever extends from the apparatus through opening **251** and terminates in button **250**. The other end of the lever includes tab **257** which is engageable with latch **258** on housing **220**. The tab and latch can be configured to engage in a snap-fit

relationship. Cam **260** is disposed within housing **220** and is pivotally mounted to the housing about pivot **265** which is located distally relative to lever **254**. Slot **267** is provided on cam **260**. Pin **256** on lever **254** is slidably retained within slot **267**. The end of cam **260** is located proximal to the cone **249** and push rod **248** assembly.

[0053] In the undeployed condition depicted in **FIG. 12A**, implant **201** is retained in the cannula distal to the push rod. Manual depression of button **250** causes downward movement of lever **254** normal to the longitudinal axis of the apparatus. This movement exerts a force onto cam **260** which is transmitted by way of pin **256** of the lever to slot **267** of the cam, causing rotational movement of cam about pivot **265**. With the end of cam **260** in approximation to cone **249**, such rotation of the cam causes the end of the cam to engage cone **249**, causing translational movement of cone **249** and plunger **248** relative to the housing. This translational movement of the plunger, in turn, ejects the implant from the cannula, as depicted in **FIG. 12B**. When the lever is fully depressed and the implant ejected, tab **257** engages latch **258**, thereby locking the assembly into a depressed, post-ejection, condition.

[0054] An advantage of an implant delivery apparatus according to the invention is that it provides for a very smooth, controlled ejection of the implant. By "controlled" it is meant that the force applied to the implant for ejection is proportional to the force applied by the user to actuate the apparatus. The user has direct feedback as to the rate of ejection and can dynamically adjust the force being delivered to the linkage to obtain the desired ejection rate. In addition, depending in particular linkage configurations and dimensions, the apparatus can be configured such that the range of translational movement of the plunger along the longitudinal, or "x" axis, of the housing can be significantly longer, although still proportional to, the range of movement of the actuator along the normal or "y" axis. In such situations, relatively long implants can be effectively delivered by an apparatus that is actuated by a comparatively short actuating stroke. The embodiment of FIGS. **9A** & **9B** depicts such a situation, where the displacement y of button **50** results in a larger displacement x of plunger **48**.

[0055] The controlled delivery that can be achieved by the inventive apparatus has additional advantages as well. For example, the controlled delivery provides a more predictable and reproducible placement of the implant, i.e., the implant will tend to be placed at a location very near the cannula tip, and not be projected to a more distant location as may potentially occur with the use of, e.g., a spring-loaded device where a sudden force is instantaneously applied to the implant. The inclusion of locking mechanisms, such as tab **57** and slot **58** locking mechanism of the apparatus of FIGS. **1-9**, or the lock tab mechanism of the apparatus of FIGS. **10-11**, or the tab-latch mechanism of the apparatus of FIGS. **12A-12B**, guards against backflow of eye fluid into the cannula after deployment of the implant. These locking mechanisms can further be configured such that the engagement between the two is irreversible, which prevents reuse of the apparatus. This is advantageous, e.g., if a single-use apparatus is desired.

[0056] The combination of the overall housing shape, together with the particular positioning of the tactile ridges in approximation with the actuator position also provides for additional safety advantages. In particular, the design allows the user to control the positioning of the cannula and maintain its stability primarily through manipulation of the thumb and middle finger. The index finger meanwhile controls actuation of the apparatus, and thus the ejection of the implant from the cannula at the desired location. This design effectively separates positioning control from actuation control, and reduces the risk that the step of ejecting the implant will inadvertently cause movement of the device such that the actual placement of the implant is not at the intended location.

[0057] The cannulas themselves are in many respects is similar to standard surgical needles, and can be formed of stainless steel in a variety of gauges. The gauge will be chosen such that the inner diameter of the cannula lumen, or bore, will correspond to the outer diameter of the chosen implant, with enough tolerance such that the implant can be received into and subsequently ejected from the cannula lumen. In the embodiment of **FIGS. 10 and 11**, cannula 140 can be a standard surgical needle having luer lock fitting on its hub, which can be received and secured to a corresponding luer fitting provided on the end of housing 120.

[0058] It is desirable, although not necessary, to use a cannula that corresponds in dimensions to a 21 or 22 gauge needle or smaller. Such a small cannula has the important advantage that punctures made by such small bore needle or cannula according to techniques described herein are self-sealing. In the present application, this becomes advantageous in that the implant delivery into the eye can be accomplished without the need for suturing the puncture site, as would be necessary were a larger gauge needle used. We have determined that by using a 21 or 22 gauge cannula or smaller, the implant can be placed and the cannula withdrawn without excessive fluid leakage from the eye, despite the normal fluid pressures within the eye, and stitching of the puncture site can be avoided. 21 gauge needles have outer diameters of approximately 0.032 inches. Thin wall or extra thin wall versions of 21 gauge needles can have inner diameters of approximately 0.023 to 0.026 inches. 22 gauge needles have outer diameters of approximately 0.028 inches, and thin wall or extra thin wall versions of 22 gauge needles have inner diameters of approximately 0.019 to 0.023 inches. Ideally a cannula corresponding in dimensions up to those of 22 or 23 gauge, thin wall needles are used. Microimplants are dimensioned to have outer diameters to be received within the needle cannulaes with sufficient tolerances to be readily pushed through the cannula. For example and without being so limited, microimplants with a diameter of 0.018 inches can be easily delivered through a 22 gauge thin wall needle, and a microimplant with a diameter of 0.015 inches is easily deliverable through a 23 gauge thin wall needle. The invention further contemplates the use of cannulas having non-circular cross-sections, including oval or elliptical cross-sections. For such non-circular cross-sectional cannulas, it is desirable that the cross-sectional area correspond to that of a circular cannula having up to a 0.032 inch diameter, that is, a cross-sectional area up to 0.0008 square inches or more, depending on the particular cross-sectional geometry.

[0059] In addition to cannula dimensions, additional modifications to both the cannula tip and in particular methods of insertion can further aid successful self-sealing methods of implantation. A typical problem when inserting

a cannula into any tissue is the phenomena of "coring" of the tissue, where the insertion actually cuts a cylindrical section of tissue that enters the cannula lumen. Such coring when it occurs in the eye can exacerbate leakage of eye fluid through the injection site. By approaching the eye tissue at more of an angle relative to normal, there is a better opportunity for the cannula tip penetrate and separate through the tissue layers and reduce coring of the tissue. Additional techniques to further reducing coring and/or excessive leakage are further described herein.

[0060] The cannula tip itself also can be configured to reduce coring phenomena, for instance, by sharpening certain portions of the bevel tip and dulling others. **FIGS. 12A and 12B** depict one such embodiment, where cannula tip **40***a* includes side bevels **31***a*, **32***a* that extend distally of designated line L1 and constitute approximately one half of the bevel tip and dulled area **33***a* extending proximally of line L1, constituting the other half of the bevel tip. The dulled area **33***a* can be created through conventional polishing techniques known in the art. **FIGS. 13A and 13B** depict another such embodiment, where cannula tip **40***b* that also includes side bevels **31***b* and **32***b* extending distally of designated line L2 and dulled area **33***b* extending proximally of line L2. However, in this embodiment, the side bevels **31***b*, **32***b* constitute only about one quarter or less of the bevel tip. In each of these embodiments, the sharp side bevels allow for an initial piercing of tissue, but as the tip is further inserted the tissue encounters the dulled areas of the bevel tip, which do not have sharp cutting edges, thus promoting separation of tissue layers as the cannula is advanced and mitigating against further cutting and possible coring of the tissue. In addition to these designs, conventional needle tips have also proven satisfactory.

[0061] One skilled in the art will appreciate that the particular site of entry and the distance the cannula is inserted will depend on the particular application and the desired final location of the implant. As can also be appreciated, the ability provided herein to provide for a self-sealing method for delivering implants, has enormous impact on the ability of physicians and healthcare workers to treat diseases of the eye, because it obviates in most situations the necessity of surgery facilities, and accompanying surgical support, currently required by conventional methods.

[0062] To administer an implant using, e.g., the implant delivery apparatus of FIGS. **1-9**, the user can grasp apparatus **10** between the thumb and middle finger along tactile ridges **22**, and position the apparatus near the desired point of entry into the patient's eye. The patient typically will be under a topical or local anesthetic. The user can then advance cannula **40** into the patient's eye to the desired depth, and depress ejector button **50** to eject the implant at the desired location. The cannula **40** is then withdrawn. Specific techniques for cannula advancement, including angles of orientation of the cannula and the bevel are further discussed herein. Where cannula **40** is dimensioned to receive and retain a microimplant, as previously discussed, the resultant puncture site can self-seal upon withdrawal of the cannula. Otherwise, in situations where a larger cannula and implant are used, the puncture site can be closed up by known methods, such as suturing.

[0063] Self-sealing methods can also be performed without the inventive apparatus, albeit less conveniently. In such a method, a cannula having dimensions corresponding to those described above can be provided attached to a suitable holder, such as, e.g., a typical needle and syringe assembly. The microimplant is loaded and retained within the cannula lumen, and a push rod is further provided with the distal end received through the proximal end of the cannula lumen and positioned adjacent the microimplant. The distal end of the push rod remains outside the cannula and manually accessible. This assembly is then brought into position near the patient's eye, and the cannula is then used to puncture through the outer layer of a patient's eye and the cannula is further advanced a desired location within the patient's eye for deposition of the microimplant. Once the cannula is positioned, the push rod is moved from the proximal end of the cannula toward the distal end of the cannula, thereby ejecting the microimplant from the cannula. After ejection, the cannula and push rod are withdrawn from the patient's eye, and the puncture created by the insertion of the cannula into the patient's eye is self-sealing upon the removal of the cannula.

[0064] For placement e.g. in the vitreous cavity of the eye, useful implantation methods include advancing the needle through the pars plana at a location approximately 3.5-4 mm from the limbus of the eye. For smaller diameter needles, e.g., 25 gauge or smaller, the needle can be inserted from any angle relative to the eye and still produce acceptable self-sealing results. For larger gauge needles, e.g., 23 gauge and above, self-sealing results can be enhanced by inserting the needle at angle relative to the eye surface. For example, good results are achieved by inserting the angle at an angle of 45° or less relative to the eye surface. Also, slightly improved results can be seen in some cases by orienting the bevel of the needle downward with respect to the eye surface. Another advantageous method involves a so-called "tunnel technique" approach. In this technique, the patient's eye is restrained from moving using e.g. a cotton swab or forceps, and the needle is advanced into the sclera at an angle approaching parallel relative to the eye surface. In this technique, the bevel will usually be oriented upward with respect to the eye surface. Once the tip is advanced sufficiently far enough into the scleral layer, usually such that the bevel portion is at least disposed within the scleral layer, the angle of the needle is adjusted to a more downward angle into the eye, and the needle is further advanced. Using such methods, with the shallower angle of insertion, yields wound edges that close up and seal more readily. Without being bound by theory, it is believed that insertion of the needle by this technique creates a scleral "flap" that, under intraocular pressure of the eye, is forced upward and pressed against the wound path to more effectively close up the wound.

[0065] In addition, the direction of insertion of the needle relative to the limbus of eye can have further implications upon the deposition of the implant in the vitreous cavity. For example, advancement of the needle posteriorally of the limbus or even circumferentially relative to the limbus usually provides for a suitable and acceptable location for deposition of the implant. On the other hand, advancement of the needle anteriorally of the limbus requires some caution, as it can lead to placement of the implant close to the lens of the eye, which may cause some complications.

[0066] Implants that are compatible with loading and ejection from apparatus according to the present invention can be formed by a number of known methods, including

phase separation methods, interfacial methods, extrusion methods, compression methods, molding methods, injection molding methods, heat press methods and the like. Particular methods used can be chosen, and technique parameters varied, based on desired implant size and drug release characteristics. For microimplants described herein, which can be delivered through cannulas corresponding to a 21 gauge needle or smaller, and which therefore have cross-sectional diameters of 0.026 inches or less, or similar cross-sectional areas, extrusion methods are particularly useful. Extrusion methods, as well as injection molding, compression molding, and tableting methods, can all achieve the small cross-sectional diameters or areas required of microimplants. Extrusion methods also may result in more homogenous dispersion of drug within polymer, which can be important given the small dimensions of microimplants.

[0067] As previously mentioned, microimplants that have diameters of 0.018 inches or less are deliverable through 22 gauge thin-walled cannulaes, and microimplants with diameters of 0.015 inches or less are deliverable through 23 gauge thin-walled cannulaes. Because of the extremely small cross-sectional diameters or areas of these microimplants, the corresponding length will need to proportionally larger to provide desired therapeutic dosages of many active agents. Typically, the microimplants can be manufactured so as to extend up to about 6 or 7 mm in length or longer. A microimplant of 7 mm or less in length may be preferable, at least for placement in the vitreous, as implants of greater length may interfere with a patient's vision.

[0068] In manufacturing an implant delivery apparatus according to the invention, it may be desirable to pre-load the implant into the cannula. Pre-loaded apparatus provide added convenience for the user and avoid unnecessary handling of implants. Further, such loading can be done under sterile conditions, thereby ensuring delivery of a sterilized implant. For the embodiment of FIGS. **1-9**, the implant can be pre-loaded into the cannula assembly and the loaded cannula assembly incorporate into the nose cone. In this fashion, loaded nose cone/cannula assemblies can be pre-assembled, for later incorporation with the housing assembly. Similarly, for the embodiment of FIGS. **10-11**, the implant can be preloaded in the cannula and then later assembled onto the housing assembly. In an alternative variation on this embodiment, the cannula can have two separate parts, with one part of the cannula retained within the housing that then communicates with the other external portion of the cannula that is subsequently connected to the housing. In such a variation, an implant can further be preloaded in the cannula part retained within the housing. In any case, push rods and linkages of the appropriate lengths are provided dependent on the length of the particular loaded implant, such that complete ejection of the particular implant can be assured.

[0069] Label plates, or other locations on the housing, can include the appropriate information relative to particular implant loaded. Given this interchangeability, unique apparatus for the delivery of selected implants can be easily manufactured, simply by providing the particular cannula, plunger, and linkage system for the selected implant. The remaining components of the apparatus remain the same. The name plate or housing itself can be labeled to correspond to the selected implant, thus identifying the apparatus with the loaded implant.

[0070] When the apparatus is assembled with the implant pre-loaded, it may further be desirable that the implant be positioned just proximal of the opening at the cannula tip. In this fashion, the introduction of air into the eye can be avoided when the implant is ejected, as could otherwise occur were the implant located further within the cannula lumen and an air bubble or air pocket allowed to exist between the cannula tip and the implant and ejection of the implant were to force the air bubble or air pocket into the eye. One method to accomplish this is to load the implant distally into the cannula followed by the plunger, with the plunger length designed to push the implant to the desired pre-actuation position. When the cannula assembly is then installed onto the housing, the plunger and thus the implant is advanced to the desired position. To guard against inadvertent premature release of the implant, the cannula can have a slight bend incorporated into the tip such that enough friction exists between the inner wall of the cannula and the implant to hold the implant in place, but at the same time, the frictional force is easily overcome by action of the plunger to eject the implant upon actuation of the apparatus.

[0071] Other cannula designs can likewise achieve the desired effect of avoiding the introduction of air into the eye upon ejection of the implant. For example, the implant can be positioned proximally of the cannula tip but with sufficient tolerance between the implant and cannula wall to provide for air exhaust past the implant as it is moved through the cannula. Adequate tolerances are those that retain air in front of the implant at close to ambient pressure as the implant is moved along the cannula. Because fluid pressure within the eye is typically slightly positive relative to ambient pressure, air at ambient pressure will not enter the eye.

[0072] Loaded apparatus according to the invention can be packaged to include a safety cap extending over the cannula and securing to the housing. This will provide a measure of safety during handling of the apparatus. The button or other depression mechanism of the apparatus can also include a notch which receives the rim of the safety cap. In this configuration, the safety cap will then also operate to guard against unintentional depression of the button or other depression mechanism and ejection of the implant.

[0073] As can be appreciated, an implant delivery apparatus according to the invention that is provided loaded with the desired implant is of great benefit to the physician user. Such apparatus can be provided sterile packaged for a single use application. The user need not ever handle the implant itself. As previously mentioned, the apparatus provides for a controlled ejection of the implant. The configuration and design of the apparatus also helps to achieve uniform placement of implants from patient to patient. Further, when the apparatus is configured to deliver a micro-implant, the apparatus provides a self-sealing method for delivery, as previously discussed. This has enormous benefit to the physician and patient in that the entire implant procedure can safely, easily, and economically be performed in a physician's office, without the need for more costly surgical support currently required for implant delivery.

[0074] The invention is further illustrated by the following non-limiting examples.

EXAMPLES

Example 1

Effects of Needle Size and Technique on Vitreous Leakage

[0075] Different gauge needles together with various insertion techniques were pursued to determine the maximum size needle gauge and optimum insertion technique for mimimum vitreous leakage and "self-sealing" wounds.

[0076] Eight rabbits were anaesthetized with a Ketamine/Xylazine cocktail. Drops of a 0.5% Opthaine solution were delivered to each eye of the rabbit as a local anaesthetic. 16 g, 20 g, 22 g, 23 g, 25 g needles (Beckton-Dickinson, Franklin Lakes, N.J.) were attached to syringes and inserted into the vitreous cavities of the rabbits' eyes, through the pars plana (2-3 mm from the limbus) according to varying techniques. For each needle size, the needles were inserted at either angles of 90° or 45° relative to the pars plana of the eye, or according to the following "tunnel" technique. In the "tunnel" technique, the needle is initially advanced into the first scleral layer of the eye tissue at a very shallow angle, almost parallel, to the sclera. Once the needle has penetrated sufficiently, usually to a position whereby the bevel has passed into the scleral layer, the orientation of the needle is adjusted and further advanced at a sharper angle of attack, for example, typically anywhere up to 45°. Table 1A below details the needle gauge and insertion technique for each animal.

TABLE 1A

STUDY DESIGN

Animal	Eye	Needle size	Bevel position, insertion orientation
1	OD	16 g	Up, 90°
	OS	16 g	Down, 90°
2	OD	20 g	Up, 90°
	OS	20 g	Down, 90°
3	OD	22 g	Up, 90°
	OS	22 g	Down, 90°
4	OD	23 g	Up, 90°
	OS	23 g	Down, 90°
5	OD	25 g	Up, 90°
	OS	25 g	Down, 90°
6	OD	23 g	Up, 45°
	OS	23 g	Down, 45°
7	OD	23 g	Tunnel technique
	OS	23 g	Tunnel technique
8	OD	22 g	Tunnel technique
	OS	22 g	Tunnel technique

OD - right eye, OS - left eye

[0077] Upon removal of each needle from the eye, the resulting wounds were examined and observations of wound shape and characteristics and amount of vitreous were recorded. The results are tabulated in Table 1B below.

TABLE 1B

OBSERVATIONS

Animal	Eye	Needle size (gauge)	Bevel position, orientation	Observed Leakage	Wound description and characterization
1	OD	16	Up, 90°	+++	Big, round, not sealing after swab, suture needed
	OS	16	Down, 90°	+++	Big, round, not sealing after swab, suture needed
2	OD	20	Up, 90°	+++	Big, round, not sealing after swab
	OS	20	Down, 90°	+++	Big, round, not sealing after swab
3	OD	22	Up, 90°	+++	Round, not sealing after swab
	OS	22	Down, 90°	+	Round, not sealing after swab
4	OD	23	Up, 90°	++	Round, not sealing after swab
	OS	23	Down, 90°	+	Round, not sealing after swab
5	OD	25 g	Up, 90°	no leakage	Very small, round, sealed after swab
	OS	25 g	Down, 90°	Minimum ±	Very small round, not sealed after swab
6	OD	23 g	Up, 45°	Minimum ±	Almost sealed, edges close
	OS	23 g	Down, 45°	no leakage –	Almost sealed, edges close
7	OD	23 g	Tunnel technique	no leakage –	perfectly sealed
	OS	23 g	Tunnel technique	no leakage –	perfectly sealed
8	OD	22 g	Tunnel technique	Minimum ±	sealed

TABLE 1B-continued

		OBSERVATIONS			
Animal	Eye	Needle size (gauge)	Bevel position, orientation	Observed Leakage	Wound description and characterization
	OS	22 g	Tunnel technique	Minimum ±	sealed

OD - right eye, OS - left eye
+++ = severe leakage
++ = substantial leakage
+ = some amount of leakage
+/− = minimum amount of leakage
− = no leakage

[0078] Based on the above and additional observations, it can be concluded that insertion technique as well as needle size are important factors in determining wound characteristics and subsequent wound leakage. For the 25 gauge needles, the angle or technique of insertion was less important, with the would be being relatively small, sealed, and demonstrating minimal to no leakage. For larger gauge needles, insertion techniques become more important, insertion of the needle at angles less than normal, i.e., less than 90°, dramatically reduced the amount of leakage and the ability of the wound to sealf seal was enhanced. Insertion by the above-described tunnel technique gave the most promising results, but even a direct approach at an angle under 45° provides very good results. Additionally, slightly better results were obtained with the bevel facing downward relative to the eye tissue upon insertion. Thus it is expected that self-sealing is achievable with 23 gauge or larger needles, including 22 and 21 gauge needles, using the described techniques.

Example 2

Delivery of Microimplants

[0079] Cylindrical microimplants having dimensions of 0.015 inches diameter and 6 mm length were delivered into posterior segments of rabbits' eyes using a 23 gauge thin wall needle and according to insertion techniques described above in Example 1.

[0080] Four rabbits were anaesthetized as before with a Ketamine/Xylazine cocktail and with drops of a 0.5% Opthaine solution administered to each eye of the rabbit as a local anaesthetic. 23 g thin wall needles (BD, Franklin Lakes, N.J.) were attached to syringes and the needle cannulaes were loaded with the microimplants. The needles were inserted into the vitreous cavities of the rabbits' eyes, according to varying techniques detailed in Example 1 and as further described herein. Table 2A below details the needle gauge and insertion technique for each animal.

TABLE 2A

	STUDY DESIGN	
Animal	Eye	Bevel position, orientation of needle
1	OD	Up, 90°
	OS	Down, 90°
2	OD	Up, 45°
	OS	Down, 45°
3	OD	Up, 45°
	OS	Down, 45°
4	OD	Tunnel technique
	OS	Tunnel technique

OD - right eye, OS - left eye

[0081] In addition to the angle of insertion and the bevel orientation, different orientations of the needles relative to the limbus of the eye were also examined for situations where the needle was inserted at an angle other than normal, i.e., 90°. More specifically, the needles advanced into the eye in (1) a circumferential fashion, that is, along a direction generally tangential to the limbus, (2) a posterior manner, that is, the needle is advanced generally towards the posterior of the eye, and (3) in an anterior manner where the needle advanced toward the anterior of the eye.

[0082] Upon insertion of the needle, the microimplants were delivered into the vitreous cavity of the posterior segment by advancing a push wire through the needle cannula to push the microimplants through the needle cannula. The needle was then removed and the resulting wound was examined and observations of wound shape and characteristics and amount of vitreous leakage were recorded. The results are tabulated in Table 2B below. Observations were also made as to location and condition of the delivered implant.

TABLE 2B

		OBSERVATIONS			
Animal	Eye	Bevel position, orientation, direction	Leakage	Wound description	DDS disposition
1	OD	Up, 90°	+	Round, not quite sealed after swab	Adequate
	OS	Down, 90°	+	Round, not quite sealed after swab	Adequate
2	OD	Up, 45° circumferentially	±	Almost sealed	Adequate
	OS	Down, 45° circumferentially	–	DDS in the wound, after removing almost sealed	Small piece in the wound
3	OD	Up, 45° posteriorly	–	Almost sealed, edges close	DDS broken into 2 pieces
	OS	Up, 45° anteriorly	–	Almost sealed, edges close	DDS touch the lens
4	OD	Tunnel Technique circumferentially	–	Sealed	Very close to pars plana and anterior vitreous
	OS	Tunnel Technique circumferentially	–	Sealed	Very close to pars plana and anterior vitreous

+/– = minimum amount of leakage
– = no leakage

[0083] From the above and additional observations it can be expected that insertion of the needle at an angle of 45, or less gave satisfactory results with respect to self-sealing and likewise resulted in satisfactory placement of the implant. While the previously described tunnel technique provides for the best self-sealing results, the positioning of the implant was slightly less controllable than that observed by a methods where the needle was advanced along a single path. Also, the orientation of the needle relative to the limbus can be important. For example, needles advanced into the eye circumferentially or posteriorly provide for a more advantageous deposition of the implant, whereas needles advanced anteriorly can result in placement of the implant close to the lens which may cause complications. Other difficulties observed in placement of the implants were caused in one instance by breakage of implants during loading such that small pieces of implant were located in the wound. Such occurrences are easily alleviated through increased care in loading the implant and ensuring that the push wire is long enough to completely eject the implant.

[0084] While preferred apparatus and methods have been described, the skilled artisan will appreciate that obvious modifications can be made that are within the scope of the invention, as defined in the appended claims.

We claim:

1. An apparatus for injecting an ocular implant into a patient's eye, comprising:

an elongate housing having a longitudinal axis;

a cannula extending longitudinally from the housing, the cannula having a lumen extending therethrough and being configured to receive an ocular implant within the cannula lumen;

a plunger having a push rod receivable within the cannula lumen and moveable from a first to second position; and

a linkage operably linked to said plunger, the linkage having a moveable end engageable with the plunger, and a fixed end secured to the housing, the moveable end of the linkage being capable of movement from a first to a second position relative to the housing upon application to the linkage of a force normal to the housing axis, thereby moving the plunger from the first to the second position.

2. The apparatus of claim 1 wherein the moveable end of the linkage is capable of translational motion along the housing axis.

3. The apparatus of claim 1 further comprising an ocular implant located within the lumen cannula.

4. The apparatus of claim 3 wherein said implant is a microimplant.

5. The apparatus of claim 1 further comprising an actuating lever engageable with said linkage.

6. The apparatus of claim 5 wherein the actuating lever is pivotally mounted within said housing.

7. The apparatus of claim 5 wherein said actuating lever further includes a button extending from the housing for manual depression of the lever.

8. The apparatus of claim 1 wherein said linkage further comprises a plurality of flexibly joined segments.

9. The appartus of claim 1 wherein said linkage further comprises one or more flexible bow elements.

10. The apparatus of claim 9 wherein a portion of at least one of the flexible bow elements extends from the housing for manual depression.

11. The apparatus of claim 1 wherein said linkage further comprises a cam assembly.

12. The apparatus of claim 1 wherein the cannula has an outer diameter of approximately 0.032 inches or less.

13. The apparatus of claim 1 wherein the cannula has an outer diameter of approximately 0.028 inches or less.

14. The apparatus of claim 1 wherein the cannula has a cross-sectional area of approximately 0.0008 square inches or less.

15. An apparatus for injecting an ocular implant into a patient's eye, comprising:

an elongate housing having a longitudinal axis;

a cannula extending longitudinally from the housing, the cannula having a lumen extending therethrough;

a plunger having a push rod received within the cannula lumen and in engagement with the implant, the plunger moveable from a first to second position; and

a linkage having a moveable end connected to the plunger, and a fixed end secured to the housing,

an actuating lever having a first end pivotally mounted within the housing, and a second end in engagement with the linkage,

wherein movement of the second end of the actuating lever against the linkage in a direction normal to the housing axis causes translational movement of the moveable end of the linkage from a first to second position parallel to the housing axis, thereby moving the plunger from the first to the second position and ejecting the implant from the cannula.

16. The apparatus of claim 15 further comprising an ocular implant located within the lumen cannula.

17. The apparatus of claim 16 wherein said implant is a microimplant.

18. The apparatus of claim 15 wherein said actuating lever further comprises a button extending from the housing for manual depression of the lever.

19. The apparatus of claim 15 wherein the cannula has an outer diameter of 0.032 inches or less.

20. The apparatus of claim 15 wherein the cannula has an outer diameter of approximately 0.028 inches or less.

21. The apparatus of claim 15 wherein the cannula lumen has a cross-sectional area of 0.0008 square inches or less.

22. A method of delivering an ocular implant into a patient's eye using the apparatus of claim 1 or **15**.

23. A method of delivering an ocular microimplant into a patient's eye using the apparatus of claim 12 or **19**.

24. A method of delivering an ocular microimplant into a patient's eye comprising the steps of:

(a) providing

a cannula having a proximal end, a distal sharp end, and a lumen extending therethrough,

a microimplant retained within the lumen, and

a push rod received through the proximal end of the cannula;

(b) puncturing the outer layer of a patient's eye with the cannula and inserting the cannula into a patient's eye to a desired location;

(c) moving the push rod from the proximal end of the cannula toward the distal end of the cannula, thereby ejecting the microimplant from the cannula; and

(d) removing the cannula and push rod from the patient's eye;

wherein the puncture in the patient's eye created by the insertion of the cannula in step (c) is self-sealing upon the removal of the cannula in step (d).

25. The method of claim 24 wherein the providing step (a) further comprises providing a cannula having an outer diameter of 0.032 inches or less.

26. The method of claim 24 wherein the providing step (a) further comprises providing a cannula having an outer diameter of approximately 0.028 inches or less.

27. The method of claim 24 wherein the providing step (a) further comprises providing a cannula wherein the cannula lumen has a cross-sectional area of 0.0008 square inches or less.

28. The method of any one of claims **24-27** wherein the puncturing step (b) further comprises inserting the cannula into the patient's eye at an angle of 45° or less relative to the eye surface.

* * * * *

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-088001- -00005-0000

Fecha: 2008-12-30 15:37:24 Dep. 2020 NUECREACIONI
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 400 OPOSIOBSERVTER Folios: 38

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 101,493
FECHA : DICIEMBRE 30 DE 2008

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
LAB. PROCAPS	CONSIGNACION	BANCO DE BOGOTA	062754387	14727985	18/12/2008	1,064,000.00
LAB. PROCAPS	CONSIGNACION	BANCO DE BOGOTA	062754387	96103313	28/11/2008	1,064,000.00
GYNOPHARM S.A.	CONSIGNACION	BANCO DE BOGOTA	062754387	105711141	26/12/2008	1,330,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-04 PRESENTACION DE OBSERVACIONES	12 MARCAS Y LEMAS COMERCIALES	266,000.00
		TOTAL : $	266,000.00

SON: DOSCIENTOS SESENTA Y SEIS MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

COP 99

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 07-088001- -00005-0000
Fecha: 2008-12-30 15:37:24 Dep. 2020 NUECREACIONI
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 400 OPOSIOBSERVTER Folios: 38

Señora Jefe,

DIVISIÓN DE NUEVAS CREACION

Superintendencia de Industria y Comei

E. S. D.

Referencia : Expediente N° 07 088001

Asunto : Oposición a la solicitud de patente de Invención titulada *"MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR"*

Solicitante : *ALLERGAN*

Opositora : PROCAPS S.A.

Publicada en la Gaceta de la Propiedad Industrial

N° 597 del 31 de Octubre de 2008

Yo, *ELIANA ISAURA MORENO BOHORQUEZ,* abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 83823 del Consejo Superior de la Judicatura, en mi condición de apoderada de la sociedad *PROCAPS S.A.* conformada bajo las leyes de la República de Colombia y domiciliada en la ciudad de Barranquilla, Colombia, atentamente manifiesto que estando dentro del término de ley y por orden expresa de mi representada, presento oposición a la concesión del registro de la Patente de Invención titulada "*MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR*" cuyo titular es *ALLERGAN,* y pido a Usted declarar fundada esta oposición y en consecuencia negar el registro de la patente solicitada.

Carrera 13 N° 119-95, Of. 104 Tel. (571) 2 13 12 13 - 6 20 50 21 - Fax. (571) 6 12 19 79
E-mail: negocios@optimum-co.com - www.optimum-co.com
Bogotá Colombia

1. INTERÉS PARA ACTUAR

Conforme a lo dispuesto en el artículo 42 de la Decisión 486 de 2000 de la CAN, estando dentro del término estipulado por la ley, manifiesto el legitimo interés de nuestra representada para oponerse al registro de la patente de la referencia, atendiendo a que la solicitud pretendida no cumple con los requisitos dispuestos en la ley como se analizará más adelante y de ser concedida afectaría directamente la comercialización de algunos productos de mi representada, que contienen, en particular polímeros bioerosionables, cortisona, dexametasona, hidrocortisona, metilprednisolona, prednisolona, prednisona, y triamcinolona. Por lo tanto, solicito respetuosamente a ese Despacho se sirva tener en cuenta la presente oposición dentro del trámite administrativo que se surte en esta Superintendencia.

2. FUNDAMENTOS DE HECHOS

2.1. La solicitud objeto de la presente fue presentada el 28 de agosto de 2007 reivindicando prioridad bajo la solicitud US20050070158 del 2005-03-01; y fue publicada en Colombia, en la Gaceta de la Propiedad Industrial **N° 597 del 31 de Octubre de 2008**, cuya publicación internacional corresponde a la WO2006093758 del 2006-09-08.

2.2. La solicitud colombiana **07 088001** objeto de la presente oposición, se refiere a un microimplante ocular para implante en el ojo, que comprende: una mezcla homogénea de uno o más ingredientes activos y uno o más polímeros bioerosionables, en donde dicho microimplante tiene un diámetro de 482,6 µm o menos; donde dicho microimplante tiene un diámetro de 381 µm o menos; donde

dicho microimplante tiene una longitud de 10 milímetros o menos; donde dicho microimplante tiene una longitud de 7 milímetros o menos; donde dicho microimplante tiene una longitud de 1 milímetro o menos; donde dicho uno o más polímeros bioerosionables es copolímero de ácido poliláctico y ácido poliglicálico (PLGA); donde dicho ingrediente activo es un agente anti-inflamatorio; en donde dicho agente antiinflamatorio es un agente anti-inflamatorio seleccionado del grupo conformado por cortisona, dexametasona, hidrocortisona, metilprednisolona, prednisolona, prednisona, y triamcinolona; y en donde dicho agente antiinflamatorio es dexametasona.

2.3. Ahora bien, con base en el artículo 14 de la Decisión 486 de la CAN consagra lo siguiente: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*. Así las cosas, las invenciones objeto de patente deben ser nuevas y tener nivel inventivo. Bien, pues antes de la fecha de prioridad de esta solicitud se encuentran los siguientes documentos que afecta la patentabilidad de la presente solicitud:

- D1: US2004054374 publicada el 18 de marzo de 2004.

2.4. Ahora bien, el documento D1, particularmente en la descripción revela un aparato y métodos para entregar implantaciones oculares o microimplantaciones. El aparato es ergonómico diseñado para facilidad de empleo, que incluye una depresión simple manual de un actuador que produce el movimiento proporcional de un acoplamiento que causa la implantación o la microimplantación ser expulsado por una cánula dispuesta en la posición deseada en el ojo. Como tal esta anterioridad proporciona pequeñas cánulas de medida para los métodos autoadhesivos de entrega. Particularmente en los párrafos 0001, 0003, 0006, 0008, 0012, 0058, 0067

y 0079 revela un microimplante ocular para implantación en el ojo que comprende un mezcla homogénea de uno o más activos y uno o más polímeros bioerodibles donde el microimplante tiene un diámetro de 0,019 pulgadas o menos conforme se indica en el párrafo 58. Por lo tanto, como se prevé en la anterioridad, la presente solicitud no aporta ninguna novedad al estado de la técnica por que igualmente comprende las mismas características que incluye un microimplante ocular para implante en el ojo, que comprende: una mezcla homogénea de uno o más ingredientes activos y uno o más polímeros bioerosionables, en donde dicho microimplante tiene un diámetro de 482,6 µm o menos. Así las cosas, como lo evidencia dicho documento D1, la presente solicitud no es novedosa pues lo revelado ya se encontraba en el estado de la técnica.

2.5. Por lo tanto, este documento objeto de oposición a la luz del documento D1 carece evidentemente de NOVEDAD.

2.6. En consecuencia y de acuerdo a lo descrito anteriormente, se deriva que la solicitud colombiana **07 088001** no puede pretender un monopolio por patente toda vez que lo que pretende no cumple con uno de los tres requisitos necesarios para su protección.

2.7. Que por consiguiente, respecto a la solicitud pretendida se tiene que:

2.7.1. **CARECE DE NOVEDAD**: Según la decisión 486 de la Comunidad Andina de Naciones, Artículo 16.- *"Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.".* A la fecha de prioridad, 1° de marzo de 2005 ya era conocido, pues como se demostró, era parte del arte

anterior con base en el documento D1, un microimplante ocular para implante en el ojo, que comprende: una mezcla homogénea de uno o más ingredientes activos y uno o más polímeros bioerosionables, en donde dicho microimplante tiene un diámetro de 482,6 µm o menos, sobre el cual busca protección en el capítulo reivindicatorio.

2.8. Dado lo anterior, es posible deducir que la solicitud y lo reivindicado no es objeto de patentabilidad pues es contrario a lo que dicta la Decisión 486 de la Comunidad Andina de Naciones, Artículo 14.- *"Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial."*. La solicitud pretendida no cumple con uno de los tres requisitos de patentabilidad.

2.9. Por todo lo anterior, atentamente solicito a usted que se sirva declarar fundada la presente oposición y negar el registro Patente de invención denominada "***MICROIMPLANTES PARA ADMINISTRACIÓN OCULAR***" cuyo titular es ***ALLERGAN,*** solicitud Colombiana que apareció publicada en la Gaceta de la Propiedad Industrial **N° 597 del 31 de Octubre de 2008.**

3. PRUEBAS

De conformidad con lo dispuesto por las normas vigentes, solicito a usted tener como prueba en este asunto los siguientes:

- D1: US2004054374 publicada el 18 de marzo de 2004.

4. FUNDAMENTO DE DERECHO

Fundamento esta observación en las normas legales siguientes:

4.1. Numeral 1 del artículo 586 del Código de Comercio.

4.2. Artículo 42 de la Decisión 486 de la Comisión del Acuerdo de Cartagena.

4.3. En las demás normas concordantes.

5. ANEXOS

Para los efectos correspondientes anexo al presente escrito los siguientes documentos:

1. Poder para actuar en el presente.
2. Documento que acredita al representante legal de **PROCAPS S.A.**
3. Recibo de caja del respectivo pago de tasa.
4. Copias de los documentos:

- D1: US2004054374 publicada el 18 de marzo de 2004.

6. NOTIFICACIONES

Para efectos de notificaciones que por disposición del artículo 50 del Decreto 01 de 1984 debe hacer su Despacho, informo que mi representada y la suscrita recibiremos notificaciones en la Secretaría de su Despacho o en mis oficinas situadas en la Carrera 13 N° 119-95, Of. 104 de esta ciudad de Bogotá.

Señor Superintendente,

ELIANA ISAURA MORENO BOHORQUEZ

C.C. 51'975.664 de Bogotá

T.P.A. 83823 del C.S. de la J.

Industria y Comercio
SUPERINTENDENCIA

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No.07-088001

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCIÓN**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **597** DE

FECHA **31** DE **OCTUBRE DE 2008** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **02** DE **FEBRERO** DEL **2009**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI __X___ NO__ ___ _____