

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KING PHARMACEUTICALS, INC.
and MERIDIAN MEDICAL
TECHNOLOGIES, INC.,

Plaintiffs,

V.

TEVA PARENTERAL MEDICINES, INC., and
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs King Pharmaceuticals, Inc. (“King Pharmaceuticals”) and Meridian Medical Technologies, Inc. (“Meridian”) (collectively, “Plaintiffs”) bring this action for patent infringement against Defendants Teva Parenteral Medicines, Inc. (“TPM”) and Teva Pharmaceuticals USA, Inc. (“Teva USA”), (collectively, “Defendants” or “Teva”). Plaintiffs allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendant TPM's filing of Abbreviated New Drug Application ("ANDA") No. 90-589 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff Meridian's highly successful EpiPen® Auto-Injector prior to the expiration of U.S. Patent No. 7,449,012 B2, which expires on September 11, 2025.

THE PARTIES

2. Plaintiff King Pharmaceuticals is a Tennessee corporation with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. King Pharmaceuticals is in the business of developing, manufacturing, and bringing innovative medicines and technologies to market, primarily in specialty-driven markets including neuroscience, hospital and acute care medicines.

3. Plaintiff Meridian is a Delaware corporation with its principal place of business at 10240 Old Columbia Road, Columbia, Maryland 21046. Meridian is a wholly-owned subsidiary of King Pharmaceuticals.

4. Meridian is the holder of approved New Drug Application No. 019-430, which has the proprietary name EpiPen[®] (epinephrine) Auto-Injector 0.3/0.15 mg (“EpiPen[®] Auto-Injector”). On July 17, 2009, as required by the Federal Food, Drug, and Cosmetic Act and FDA regulations, Meridian submitted information concerning the ’012 patent for listing in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations*, a publication that is often referred to as the “Orange Book.” Meridian developed and manufactures the EpiPen[®] Auto-Injector, an easy-to-use, disposable drug delivery system featuring spring activation and a concealed needle. The EpiPen[®] Auto-Injector is sold throughout the United States and worldwide.

5. Upon information and belief, Defendant TPM is a Delaware corporation with its principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, TPM is a wholly-owned and directly controlled subsidiary of Defendant Teva USA. Upon information and belief, TPM acts as an agent of Defendant Teva USA and develops and markets

generic injectable drug products for sale and use throughout the United States, including this judicial district.

6. Upon information and belief, Defendant Teva USA is a Delaware corporation with its principal place of business at 1090 Harsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of Delaware. Teva USA specifically markets injectable drug products through, and in connection with, TPM, its wholly-owned subsidiary.

7. Upon information and belief, TPM's preparation and submission of ANDA No. No. 90-589 was completed in collaboration with, and oversight by, Teva USA and Teva Ltd.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over TPM and Teva USA because, among other things, each is a Delaware corporation. By virtue of their incorporation under Delaware law, TPM and Teva USA have submitted themselves to the personal jurisdiction of the courts in Delaware.

10. This Court also has personal jurisdiction over the Defendants by virtue of the fact that, among other things, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction

over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

BACKGROUND

12. The EpiPen[®] Auto-Injector is designed for self-administration of epinephrine in acute allergic emergencies (anaphylaxis), by providing a rapid, convenient dose of epinephrine for individuals needing protection from potentially fatal allergic reactions.

13. Meridian developed and manufactures the EpiPen[®] Auto-Injector pursuant to New Drug Application No. 019-430, which was approved by the FDA.

14. United States Patent No. 7,449,012 B2 (“the ’012 patent”), entitled “Automatic Injector” was duly and legally issued by the United States Patent and Trademark Office on November 11, 2008. The ’012 patent, owned by Meridian, will expire on September 11, 2025.

15. The EpiPen[®] Auto-Injector is covered by one or more claims of the ’012 patent, and as such, the ’012 patent was listed in connection with the EpiPen[®] Auto-Injector in the FDA’s Orange Book.

16. Upon information and belief, TPM submitted ANDA No. 90-589 under 21 U.S.C. § 355(j)(2) in order to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of the EpiPen[®] Auto-Injector prior to the expiration of Meridian’s ’012 patent.

17. By letter dated July 20, 2009, TPM, notified Plaintiffs that TPM submitted ANDA 90-589 concerning its proposed drug product epinephrine injectable, intramuscular (“Teva’s ANDA product”) as required by § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (“FDC Act”). *See* 21 U.S.C. § 355(j)(2)(B)(ii).

18. TPM's July 20 letter further notified Plaintiffs that TPM had filed with the FDA, pursuant to § 505(j)(2)(A)(vii)(IV), a certification with respect to the '012 patent ("Paragraph IV certification"), alleging, along with the letter, that the '012 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Teva's ANDA product.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,449,012 B2

19. Plaintiffs reallege and incorporate by reference paragraphs 1-18, above.

20. Meridian is the owner by assignment of the '012 patent and has the right to sue for infringement thereof. A true and correct copy of the '012 patent is attached as Exhibit A.

21. Upon information and belief, Teva's ANDA product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe one or more of the claims of the '012 patent.

22. Upon information and belief, TPM's submission of ANDA No. 90-589 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA product before the expiration of the '012 patent constitutes an act of infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA product would infringe one or more claims of the '012 patent.

24. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 90-589.

25. Upon information and belief, immediately upon approval of ANDA No. 90-589, Teva will infringe the '012 patent by making, using, offering to sell, selling, and/or importing Teva's ANDA product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 90-589 shall be no earlier than the expiration date of the '012 patent.

26. Upon information and belief, the use of Teva's ANDA product constitutes a material part of at least one or more claims of the '012 patent; Teva knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '012 patent; and Teva's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

27. Upon information and belief, the offering to sell, sale, and/or importation of Teva's ANDA product would contributorily infringe one or more claims of the '012 patent.

28. Upon information and belief, Teva had knowledge of the '012 patent and, by its promotional activities and package insert for Teva's ANDA product, knows or should know that it will actively aid and abet another's direct infringement of one or more claims of the '012 patent.

29. Upon information and belief, the offering to sell, sale, and/or importation of Teva's ANDA product would actively induce infringement of one or more claims of the '012 patent.

30. Unless Teva is enjoined from infringing the '012 patent, actively inducing infringement of the '012 patent, and/or contributing to the infringement by others of the '012

patent, Plaintiffs King Pharmaceuticals and Meridian will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT

31. Plaintiffs reallege and incorporate by reference paragraphs 1-30, above.

32. Upon information and belief, if ANDA No. 90-589 is approved, Teva's ANDA product will be distributed in the United States by or through TPM and/or Teva USA and their affiliates.

33. Upon information and belief, Defendants know that patients will use Teva's ANDA product in accordance with the labeling sought by ANDA No. 90-589 and Defendants will therefore infringe one or more claims of the '012 patent.

34. Upon information and belief, Defendants plan to begin marketing, selling, and offering to sell Teva's ANDA product immediately after the FDA approves ANDA No. 90-589. Such conduct will constitute infringement of one or more claims of the '012 patent under 35 U.S.C. § 271.

35. Upon information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Teva's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 90-589.

36. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs King Pharmaceuticals and Meridian, and Defendants TPM and Teva USA, concerning liability for the infringement of the '012 patent.

37. Plaintiffs Meridian and King Pharmaceuticals will be substantially and irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

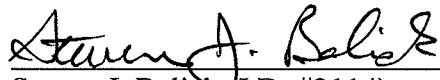
PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- (1) a declaratory judgment that, under 35 U.S.C. § 271(e)(2)(A), TPM's submission to the FDA of ANDA No. 90-589 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA product before the expiration of the '012 patent was an act of infringement of one or more claims of the '012 patent;
- (2) a declaratory judgment that Teva's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA product would constitute infringement of one or more claims of the '012 patent;
- (3) an order that the effective date of any FDA approval of Teva's ANDA product shall be no earlier than the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);
- (4) a permanent injunction enjoining Teva, its affiliates and subsidiaries, and all persons and entities acting in concert with Teva from commercially manufacturing, using, offering for sale, or selling Teva's ANDA product within the United States, or importing Teva's ANDA product into the United States, until the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);
- (5) an award of damages or other relief if Teva engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of Teva's ANDA product, or any product that infringes the '012 patent, prior to the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);
- (6) a declaration that this is an exceptional case, and an award of attorneys' fees to Plaintiffs, in accordance with 35 U.S.C. § 285;

- (7) an award to Plaintiffs of their costs and expenses in this action; and
- (8) such further and additional relief as this Court deems just and proper.

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Date: August 28, 2009

EXHIBIT A

(12) **United States Patent**
Young et al.

(10) **Patent No.:** **US 7,449,012 B2**
(45) **Date of Patent:** **Nov. 11, 2008**

(54) **AUTOMATIC INJECTOR**

(75) Inventors: **Matthew Egerton Young**, Over Cambs (GB); **Sophie Rebecca Raven**, Swavesey Cambs (GB); **Martin Joseph Murphy**, Letchworth Garden City Herts (GB); **Christopher John Hurlstone**, Newport Saffron Walden Essex (GB); **Joseph William Daintrey**, Royston Herts (GB); **Craig Malcolm Rochford**, Monxton Andover Hants (GB); **Stephen Philip Kirkwood**, Haynes Beds (GB); **Colin James Mathews**, Godmanchester Huntingdon (GB); **Robert L. Hill**, Abingdon, MD (US); **John Glyndwr Wilmot**, Mount Airy, MD (US)

(73) Assignee: **Meridian Medical Technologies, Inc.**, Columbia, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 163 days.

(21) Appl. No.: **11/095,664**

(22) Filed: **Apr. 1, 2005**

(65) **Prior Publication Data**

US 2006/0030819 A1 Feb. 9, 2006

Related U.S. Application Data

(60) Provisional application No. 60/599,054, filed on Aug. 6, 2004.

(51) **Int. Cl.**
A61M 6/32 (2006.01)

(52) **U.S. CL.** **604/192; 604/198**

(58) **Field of Classification Search** **604/187, 604/110, 198, 192**
See application file for complete search history.

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Primary Examiner—Kevin C. Sirmons

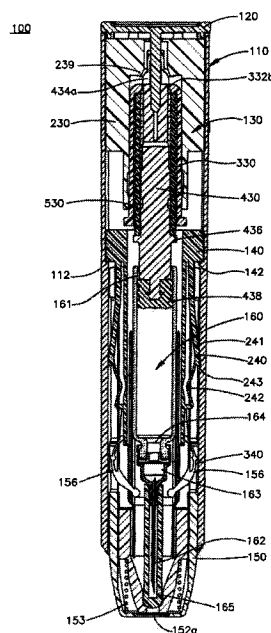
Assistant Examiner—Deanna K Hall

(74) *Attorney, Agent, or Firm*—Jones Day

(57) **ABSTRACT**

An auto-injector for dispensing a predetermined dose of medicament is disclosed. The auto-injector includes a needle cover that is configured to move from a retracted position to an extended locked position. The auto-injector includes a first locking assembly to hold the needle cover in a locked retracted position and a second locking assembly to hold the needle cover in a locked extended position.

124 Claims, 26 Drawing Sheets

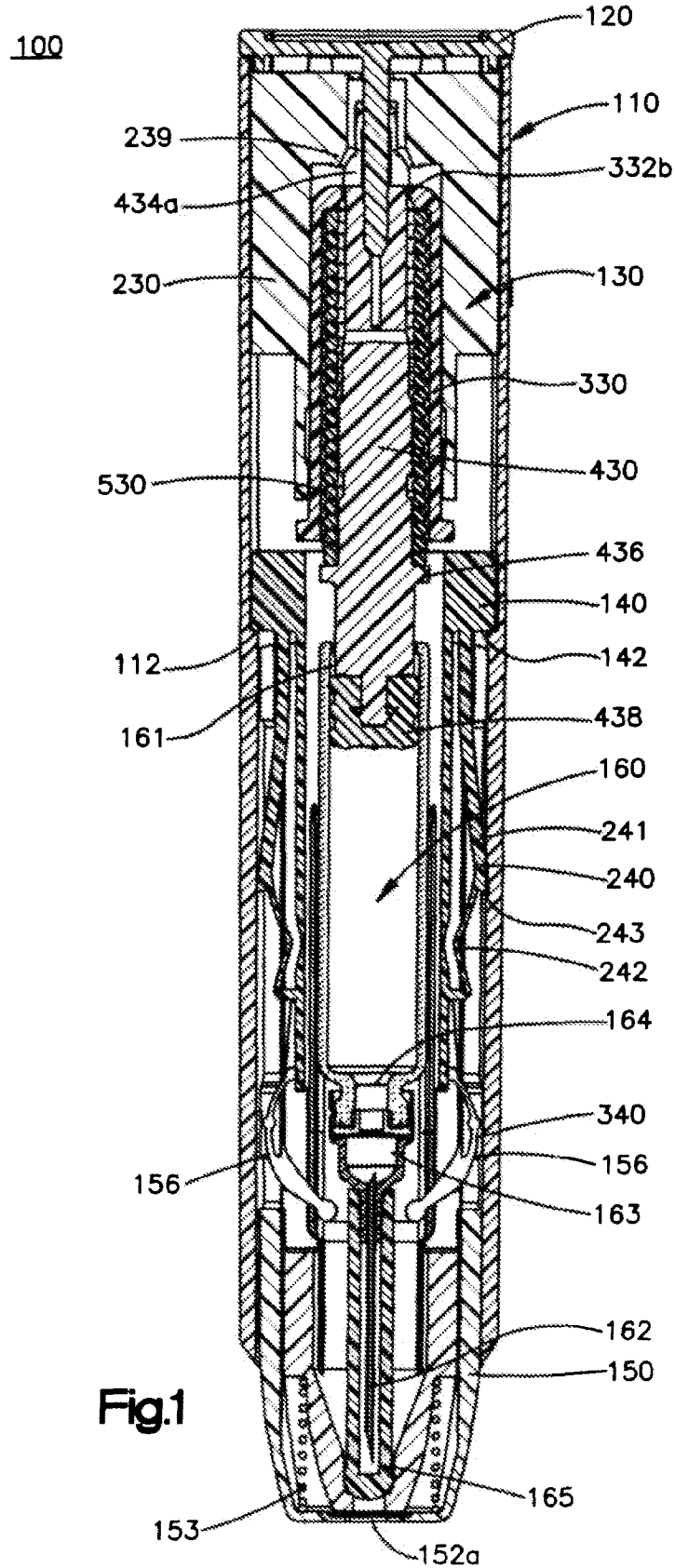


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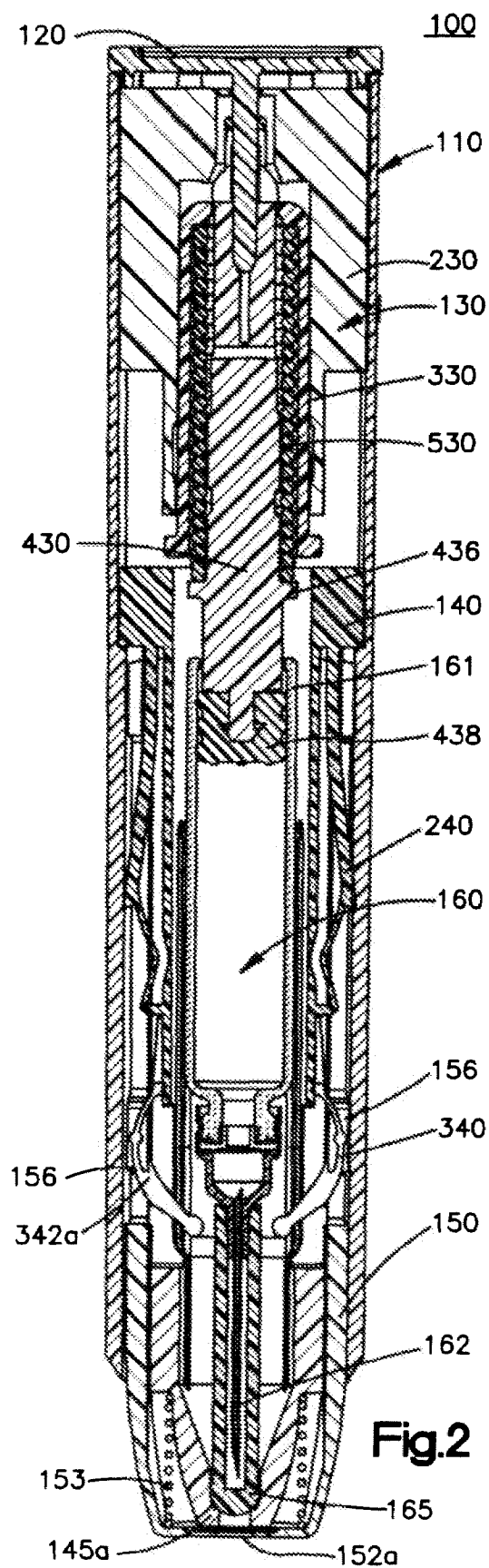


Fig.2

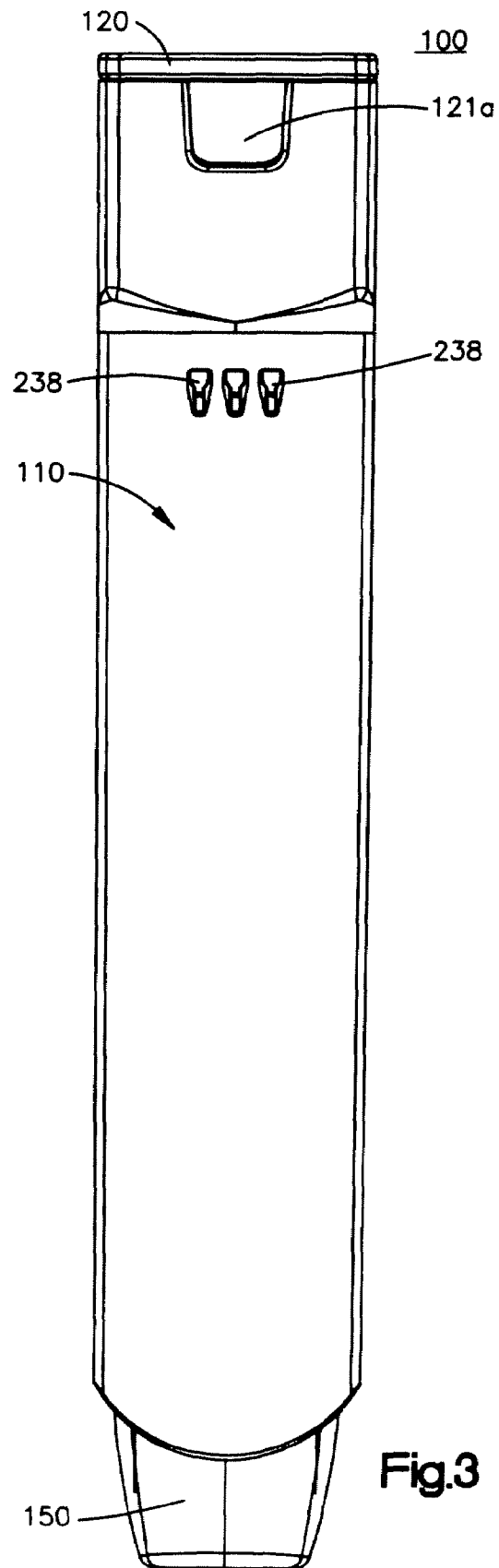


Fig.3

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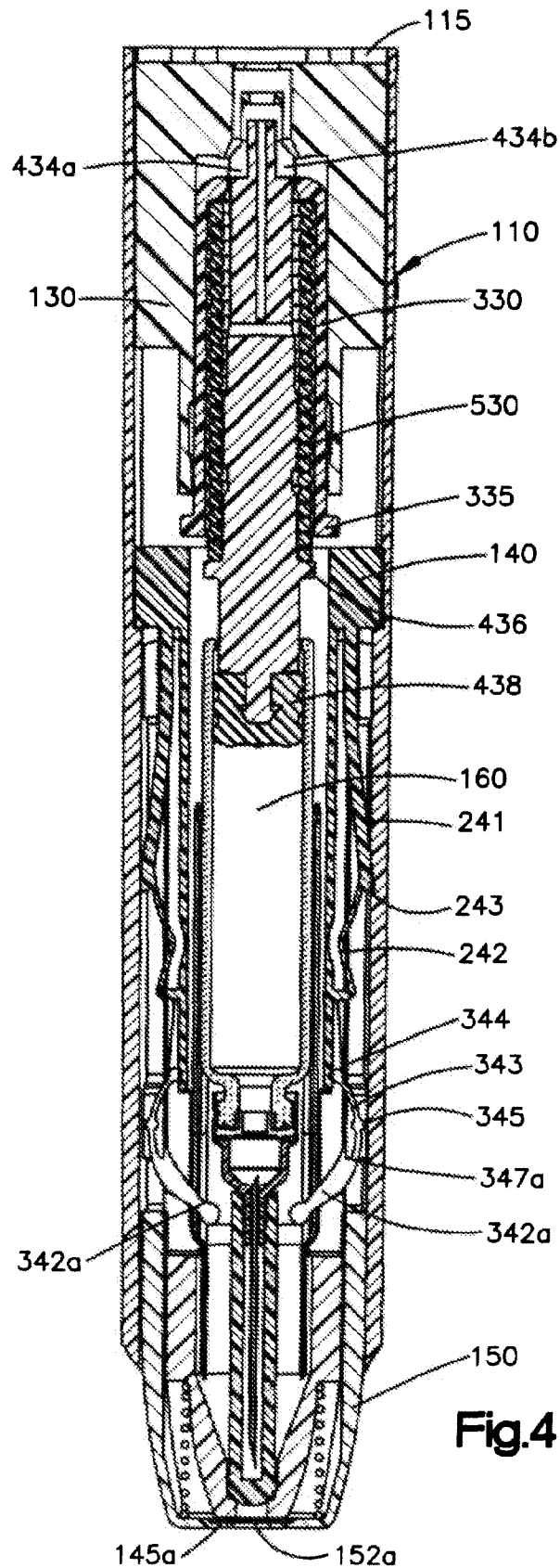


Fig.4

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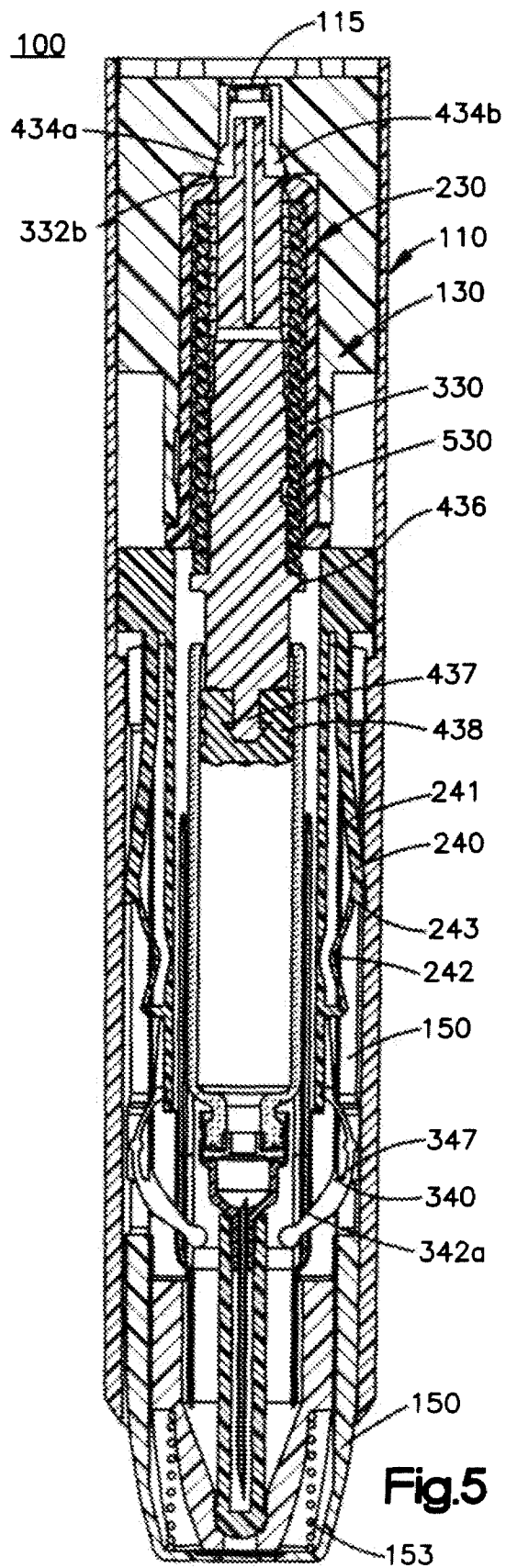


Fig. 5

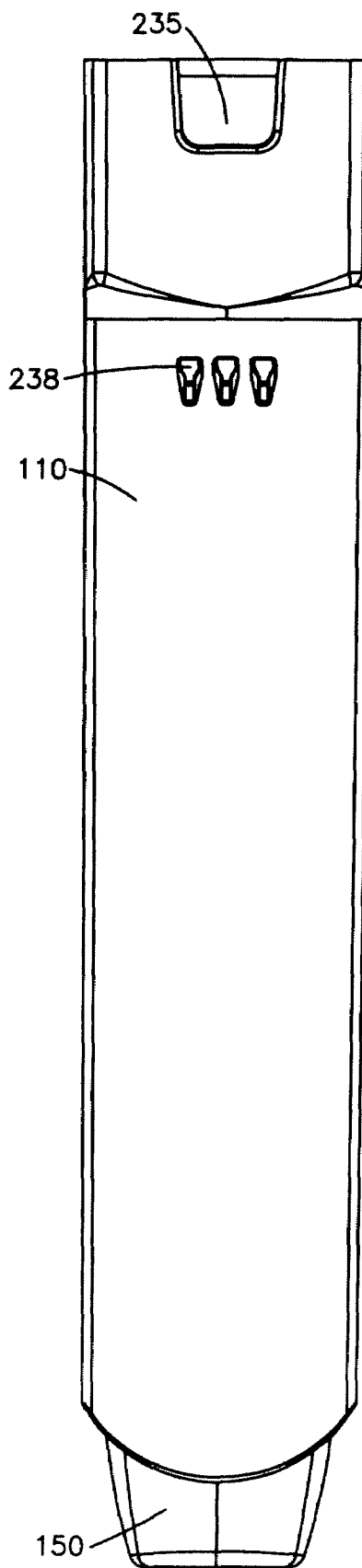
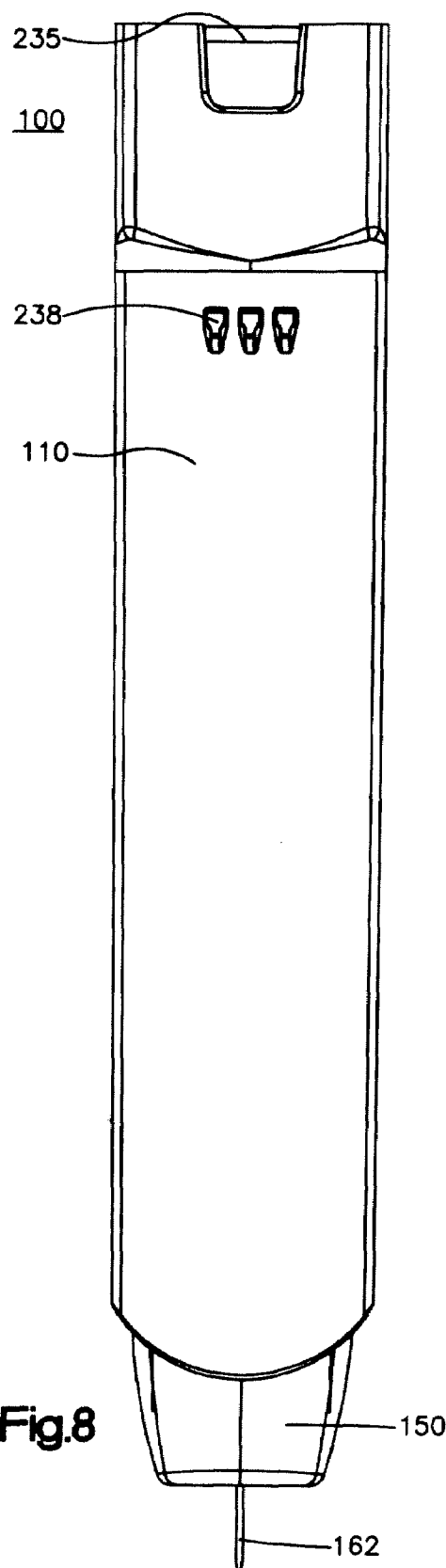
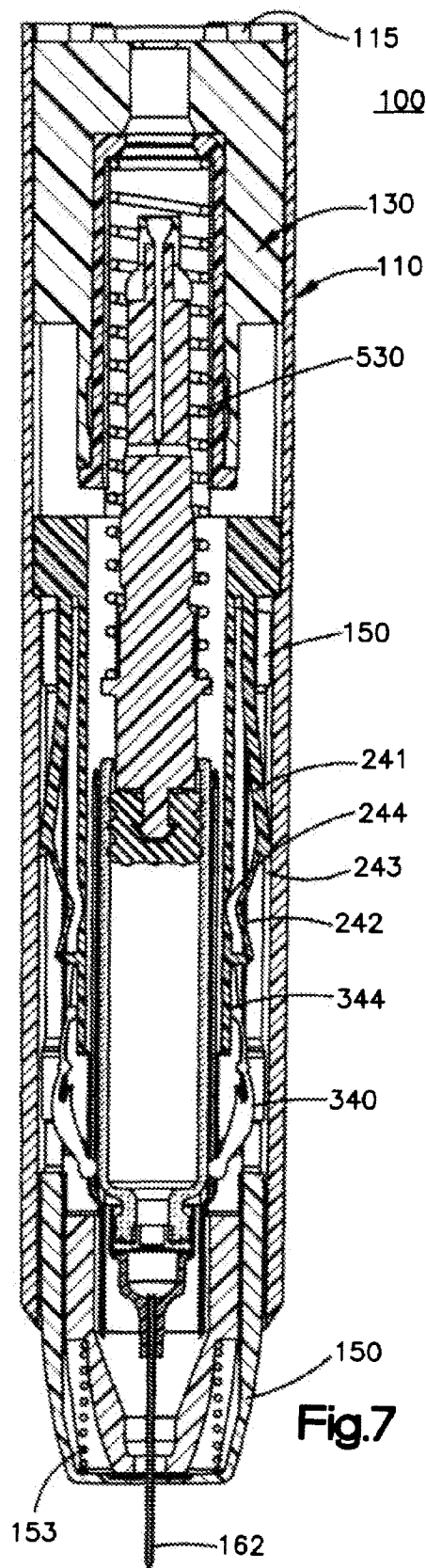


Fig. 6

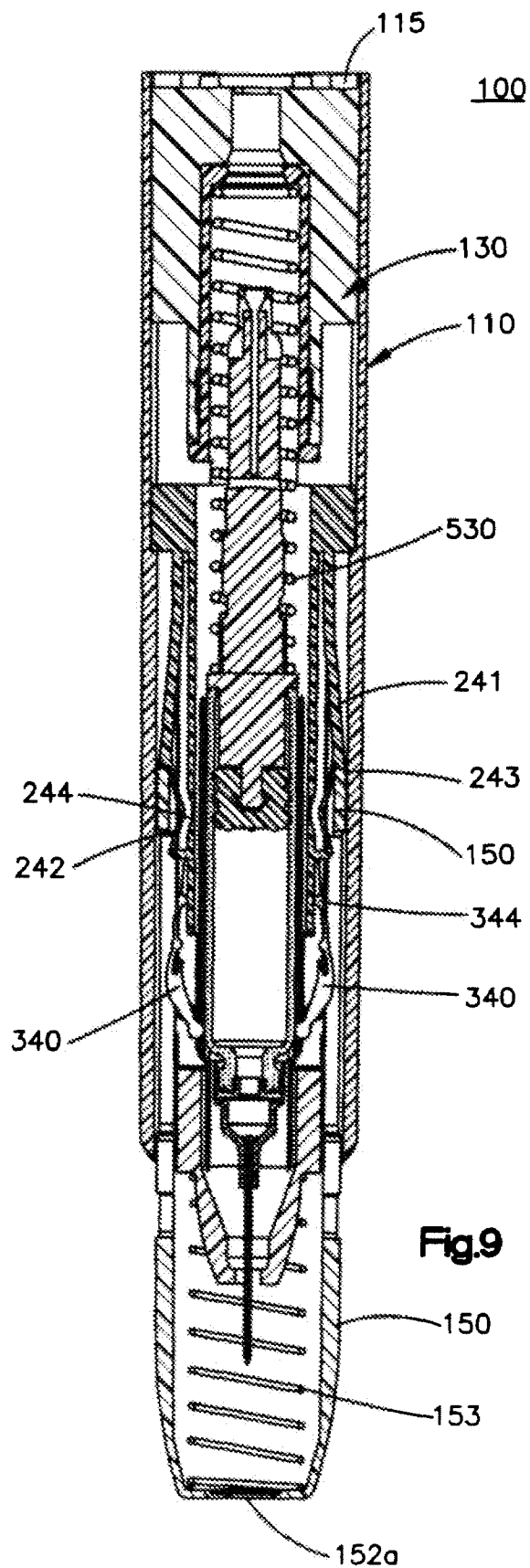


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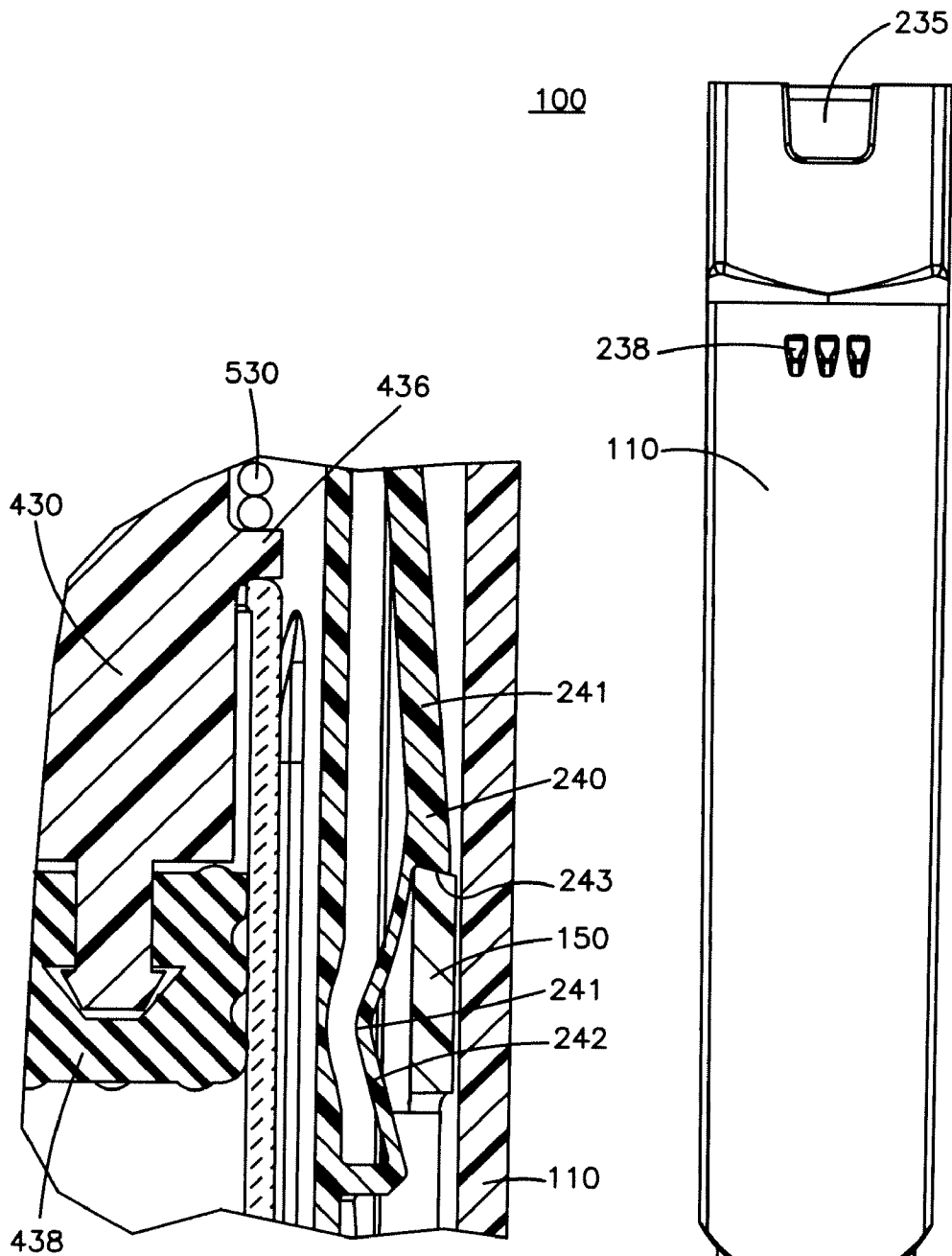
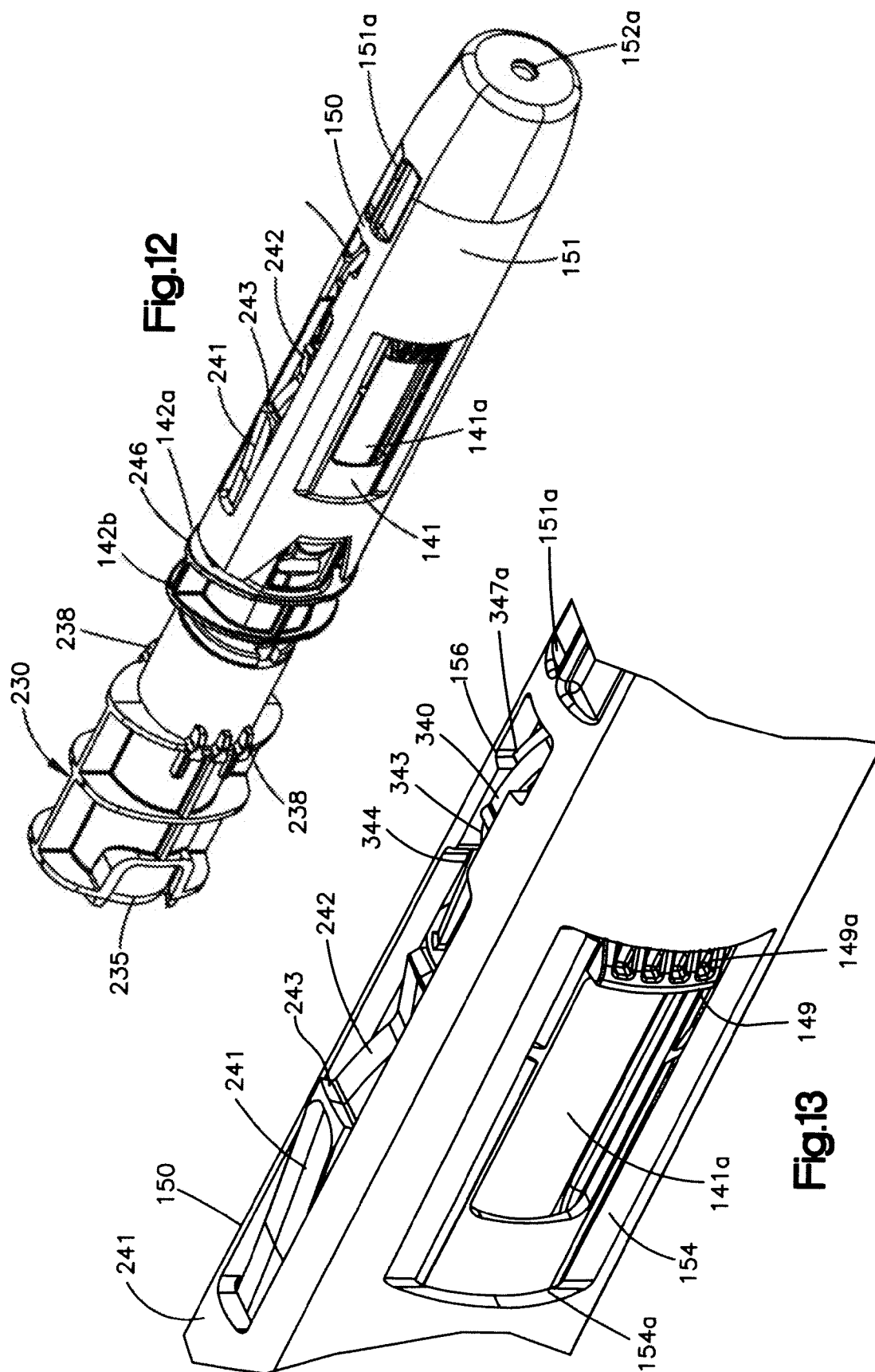


Fig.10

Fig.11



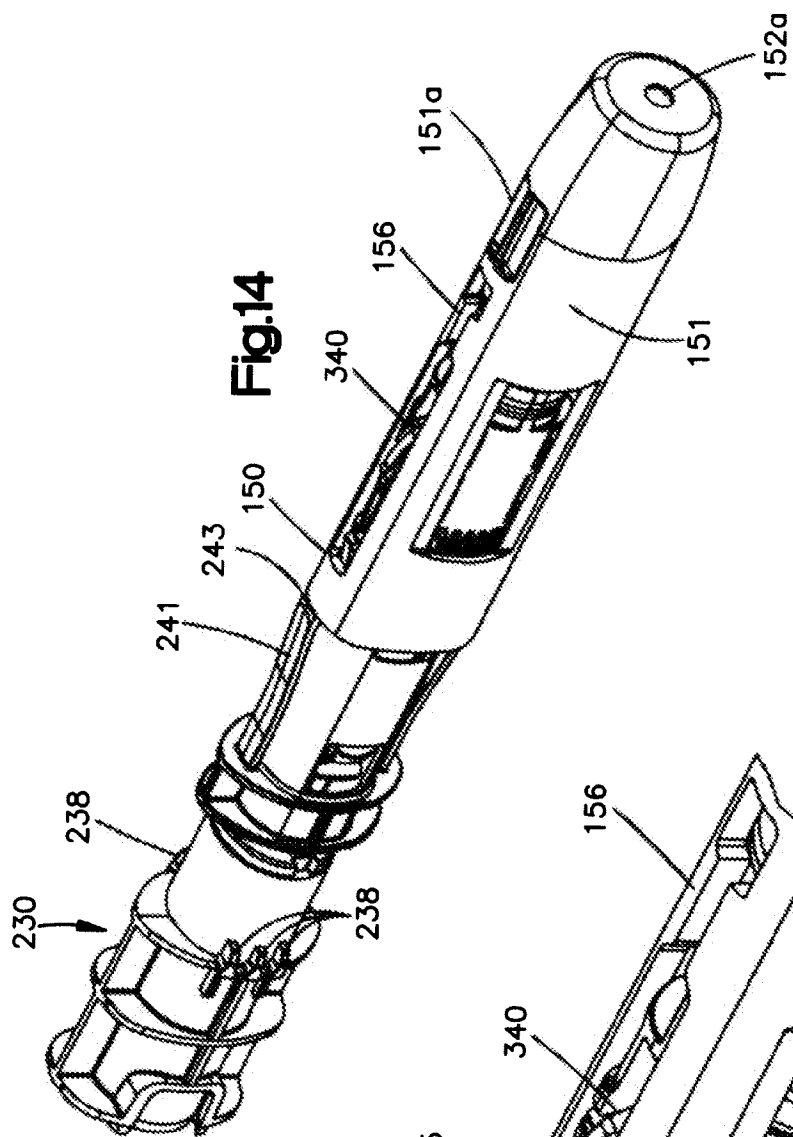


Fig. 14

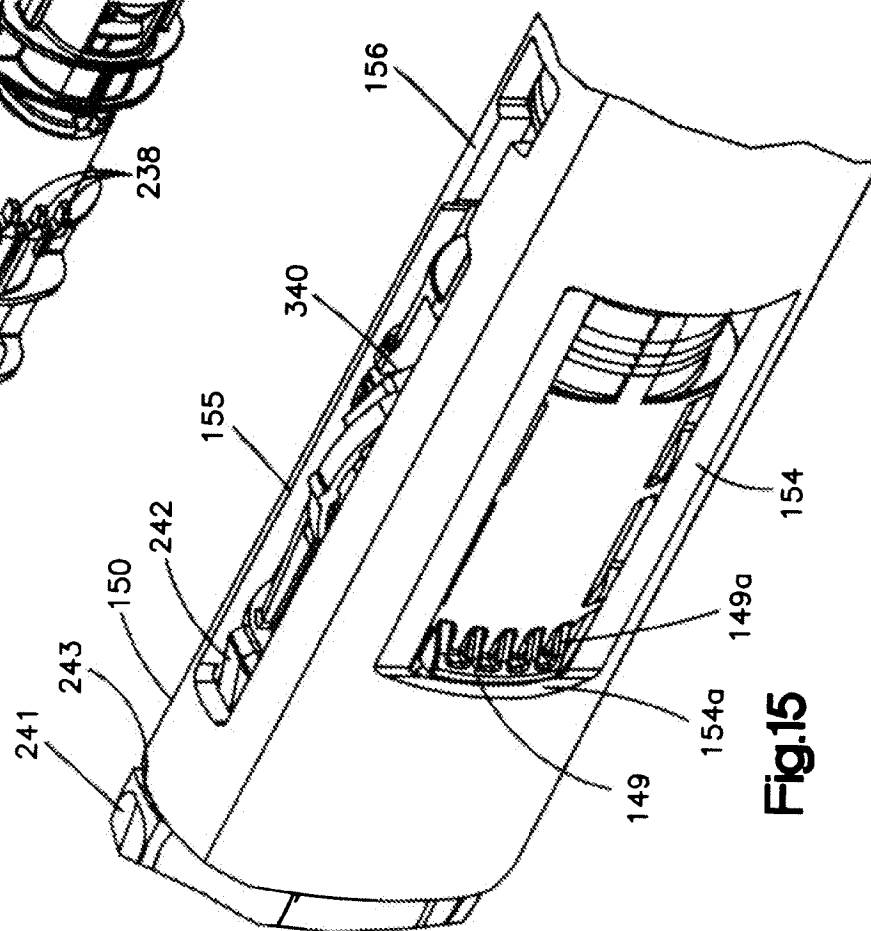


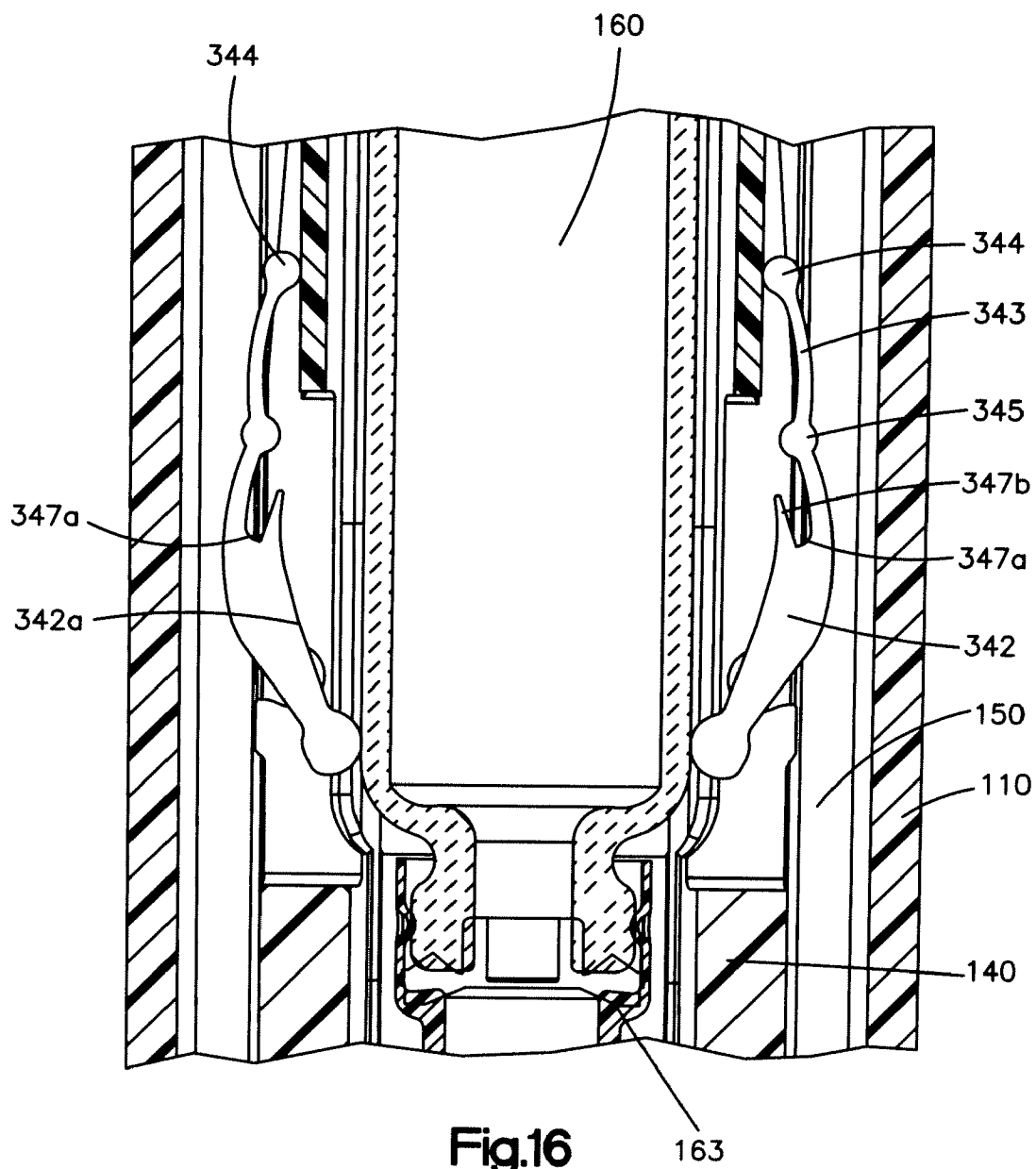
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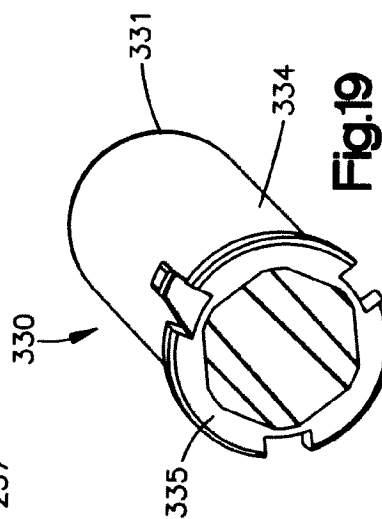
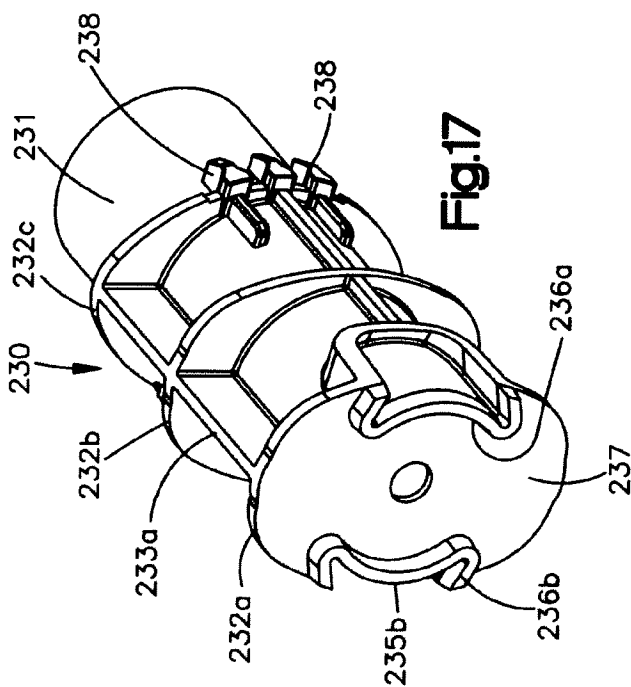
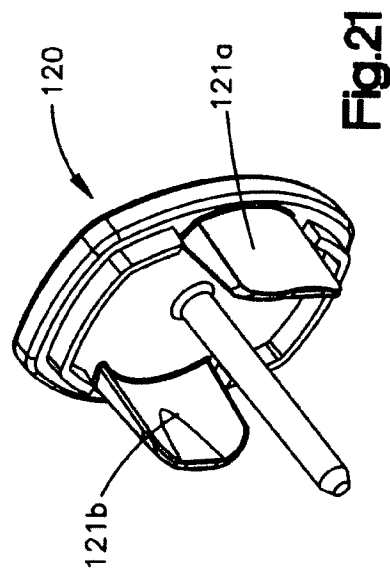
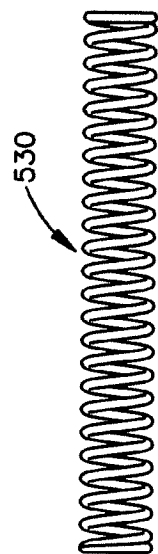
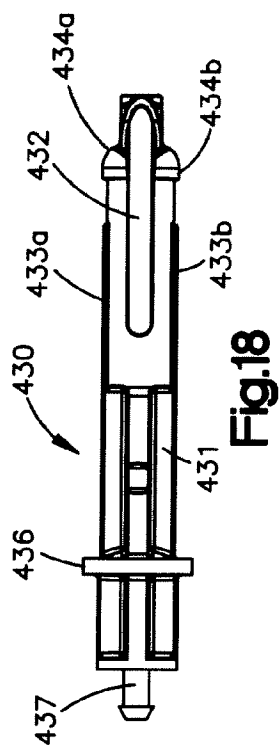
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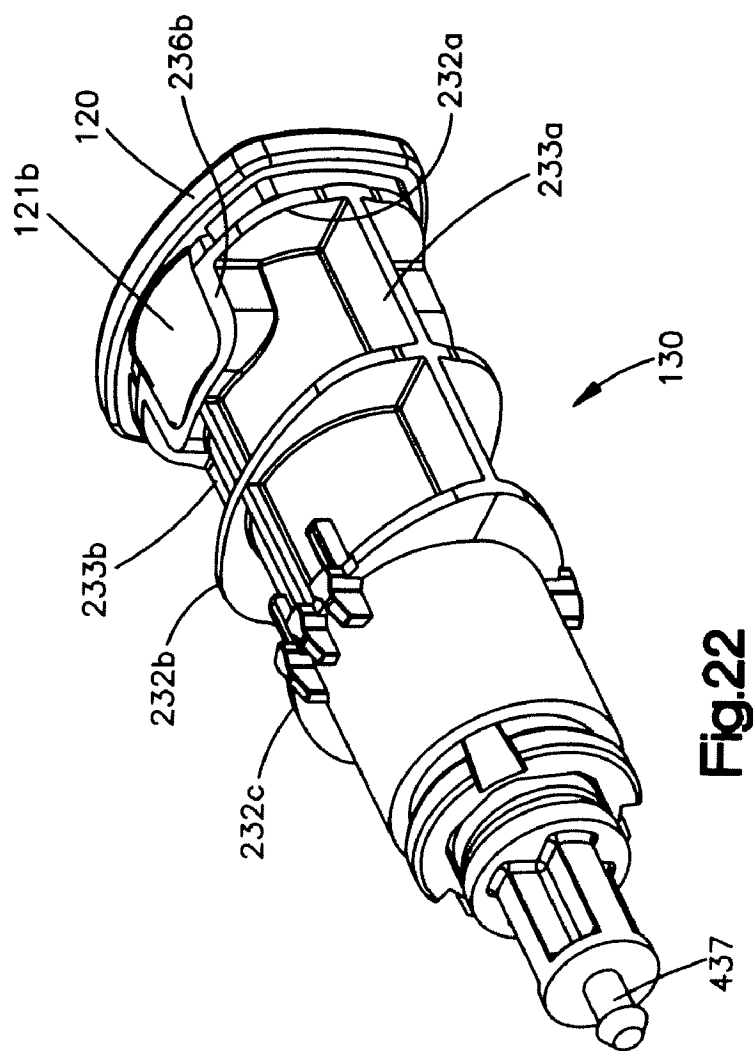
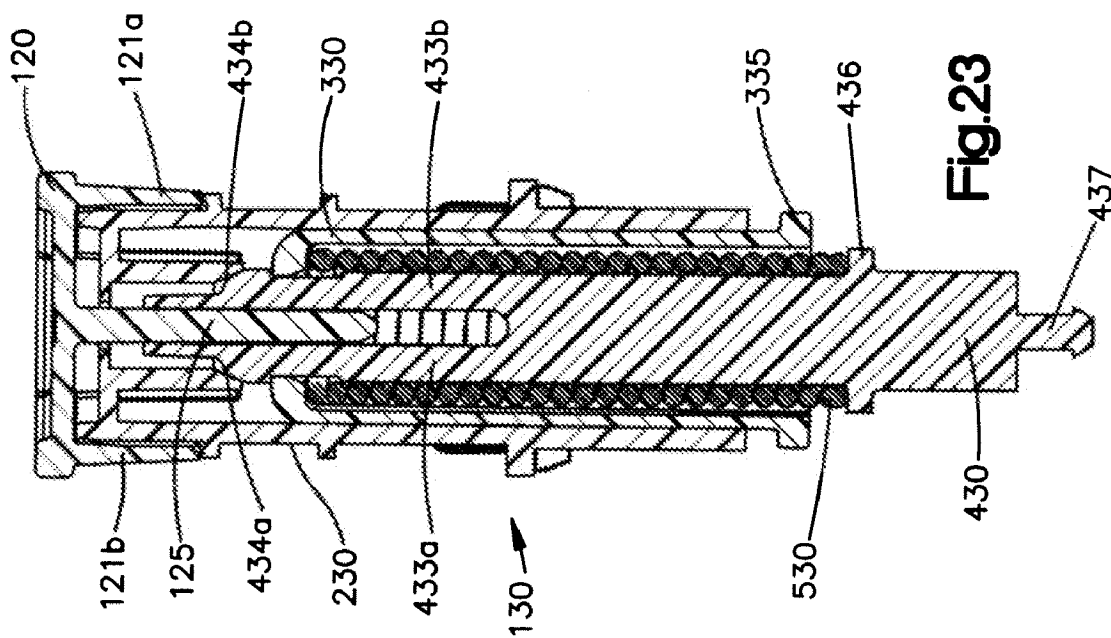
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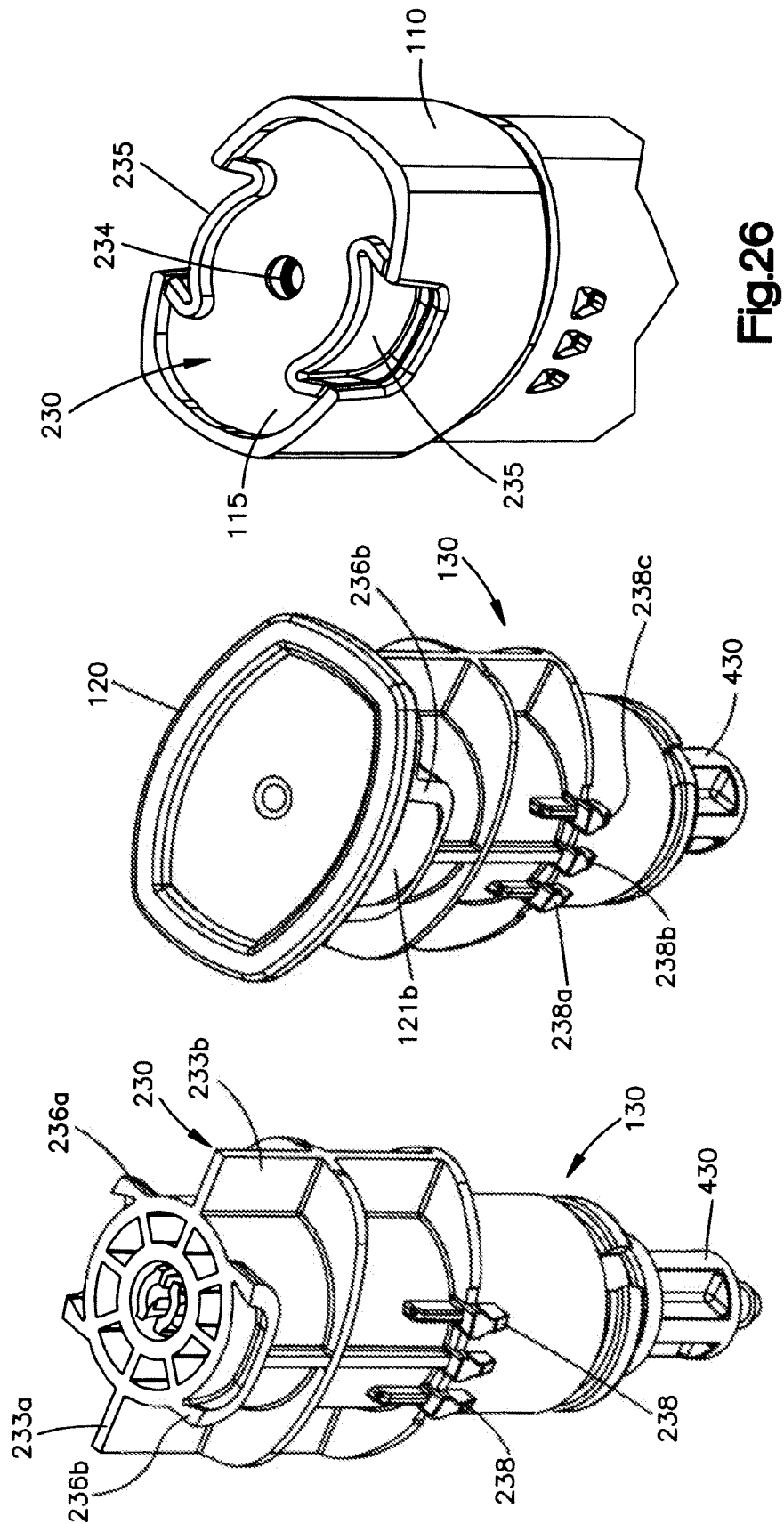
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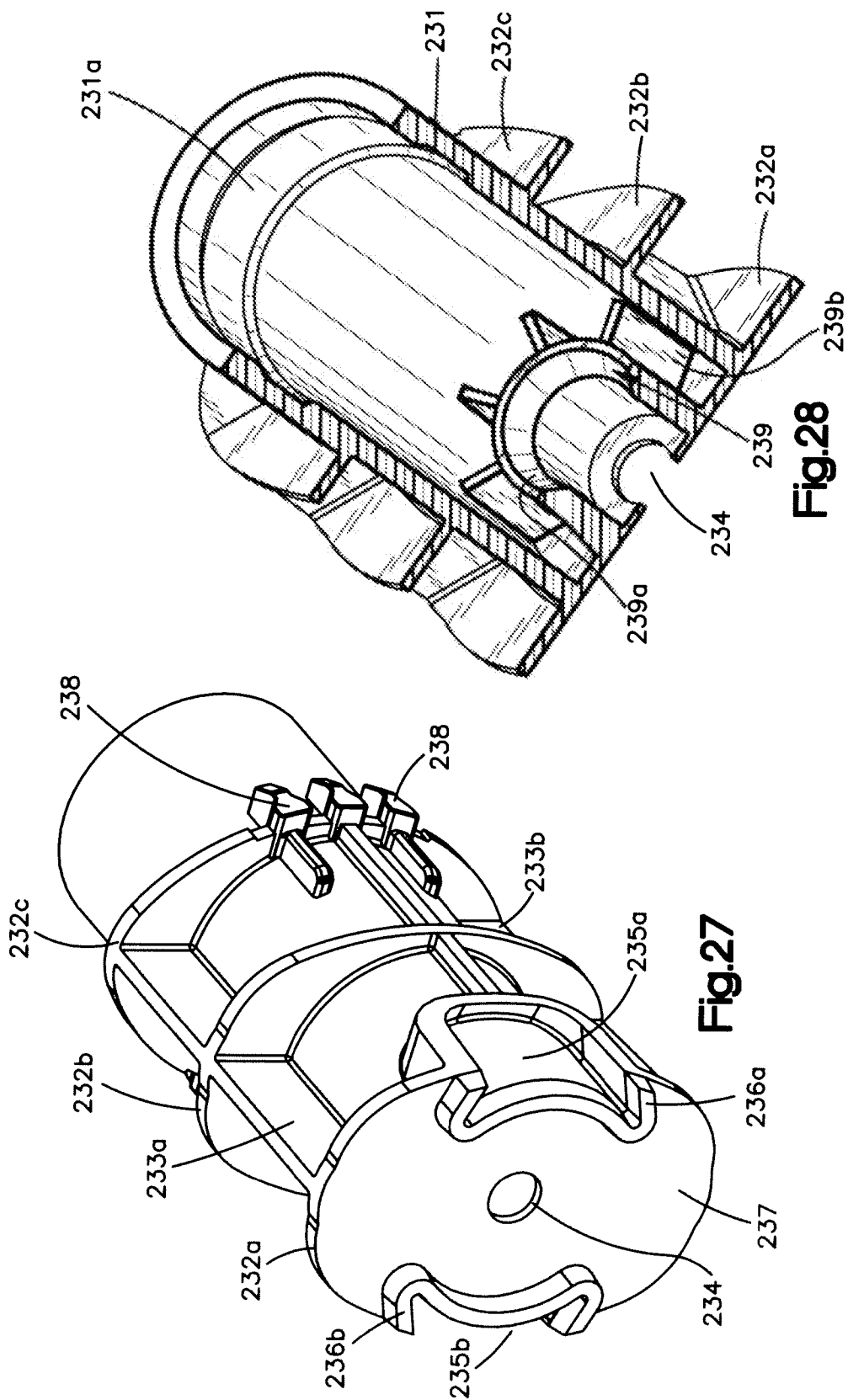
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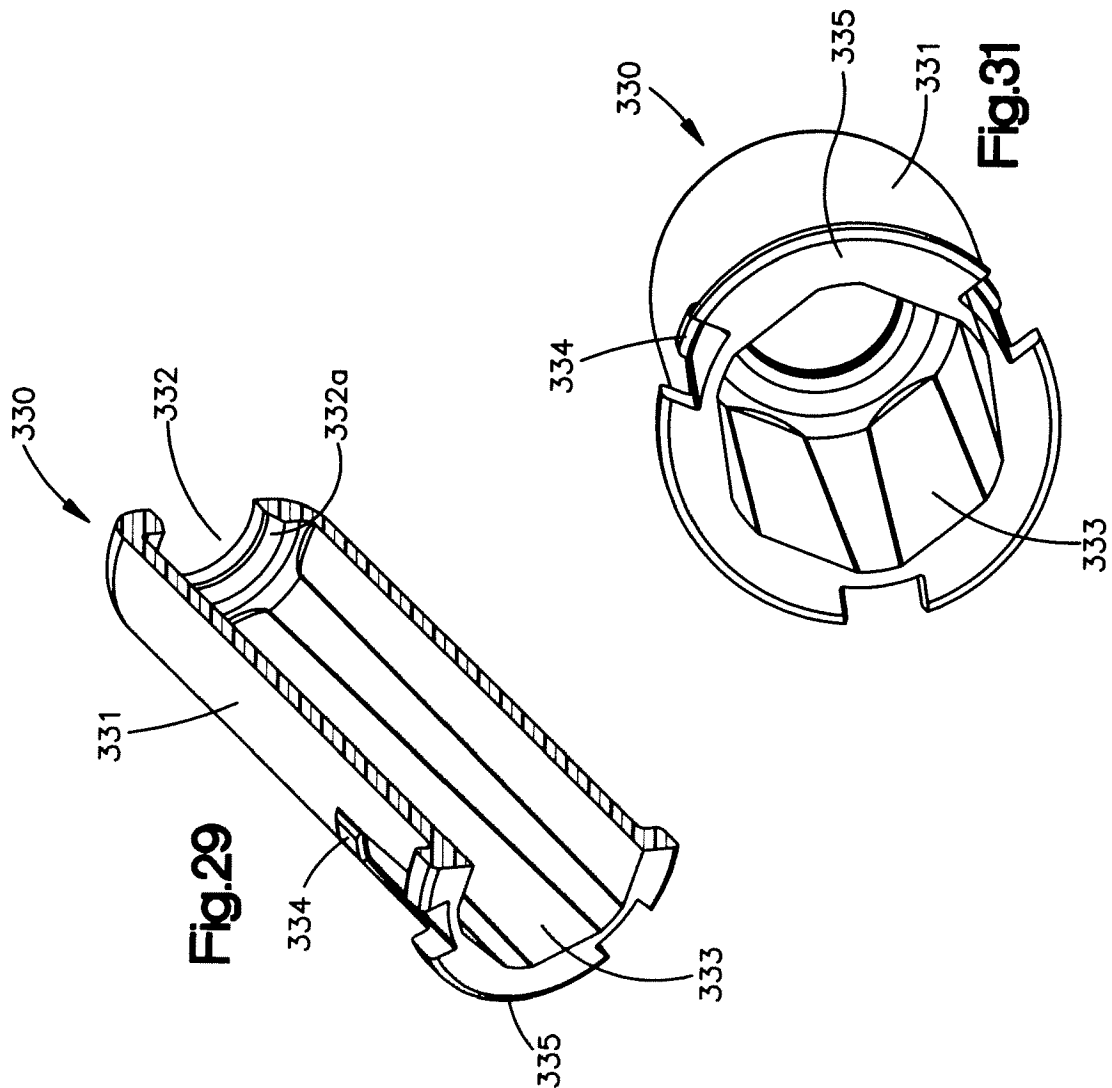
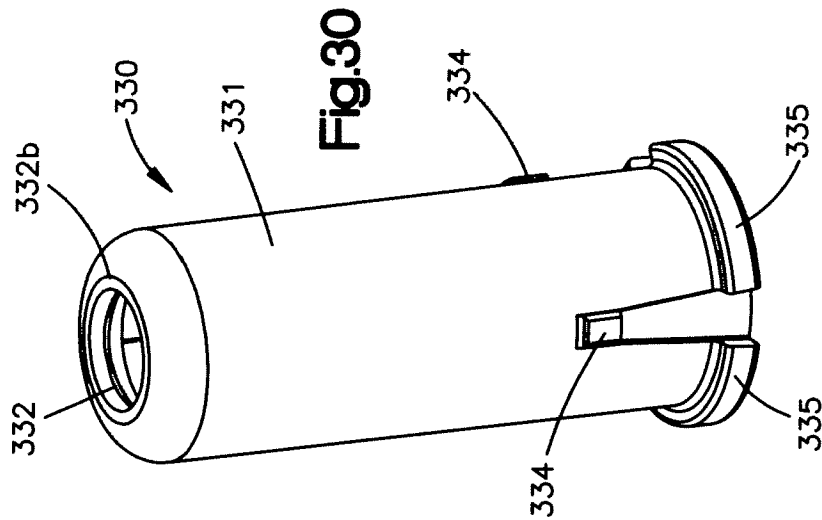












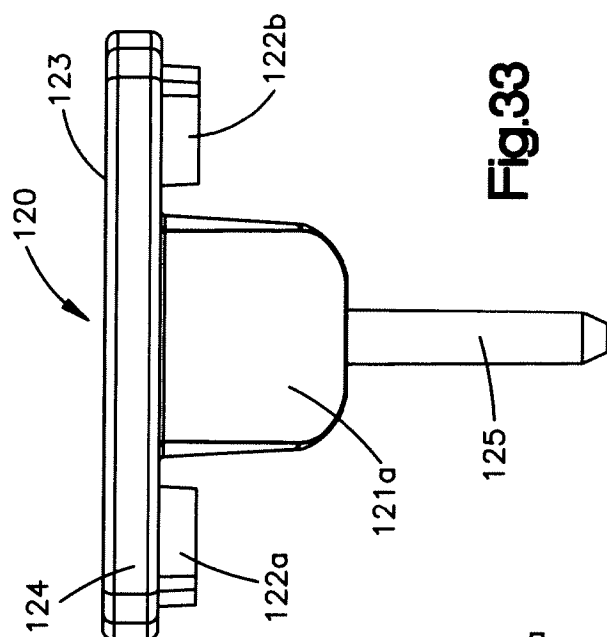


Fig. 32

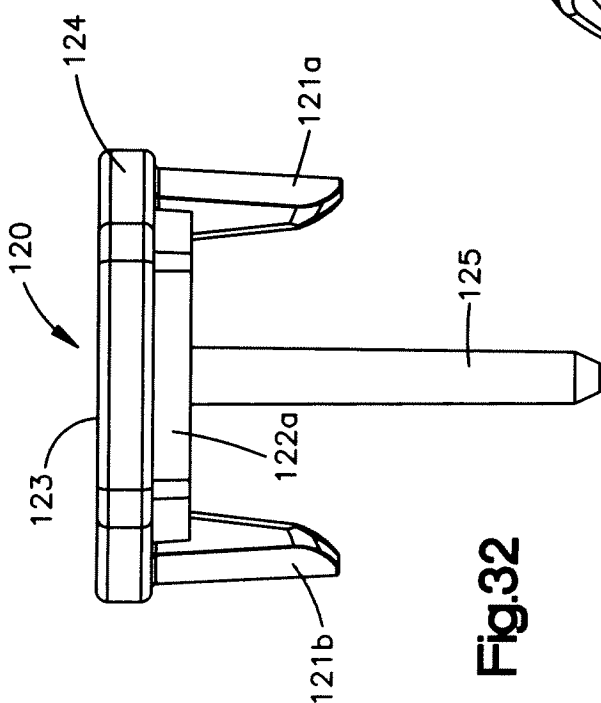


Fig. 33

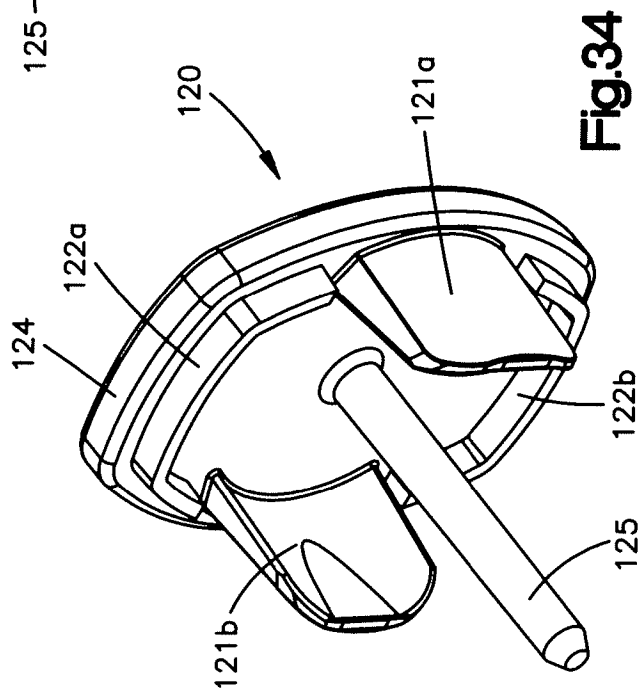


Fig. 34

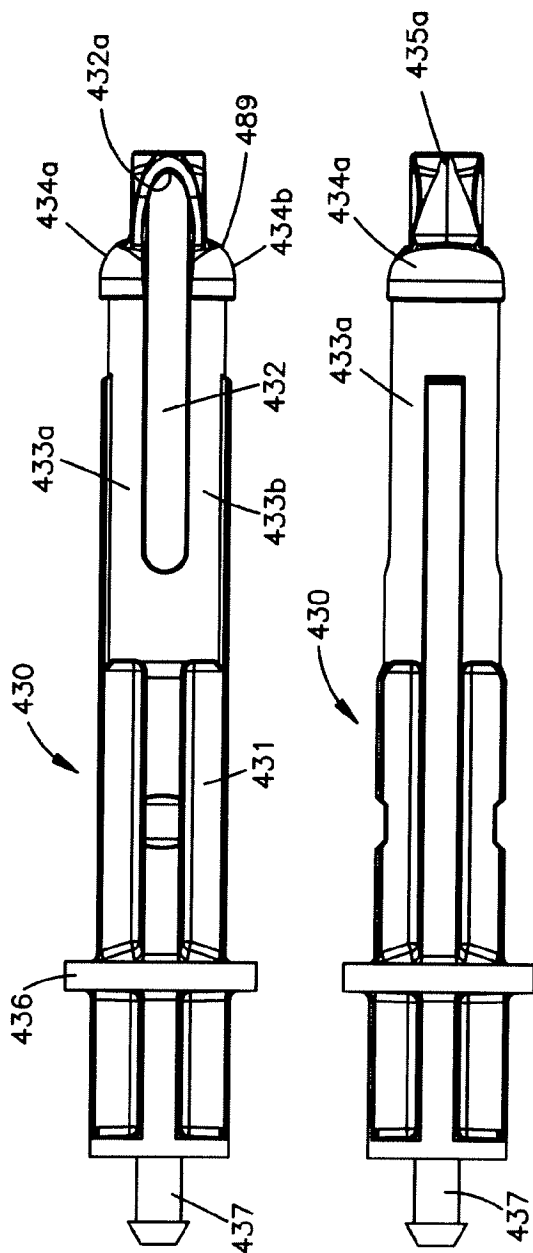


Fig.35

Fig.36

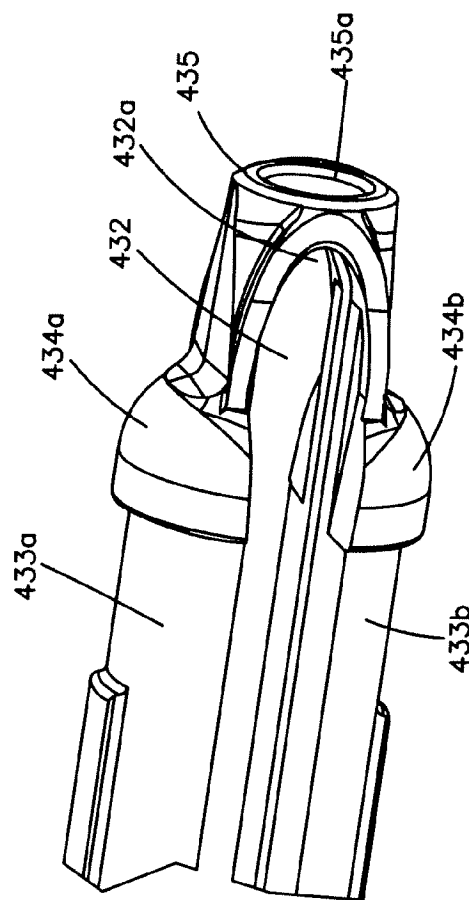


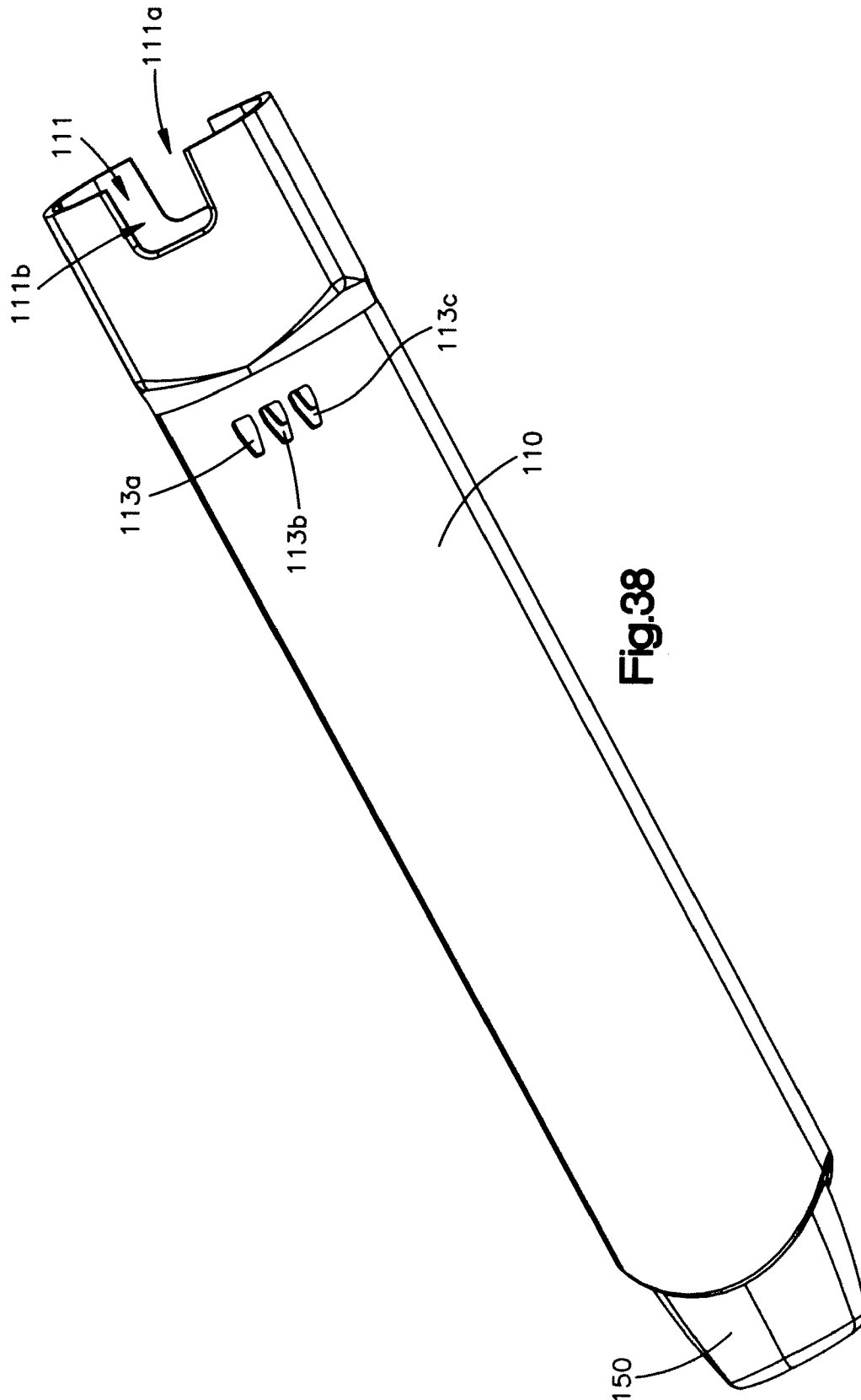
Fig.37

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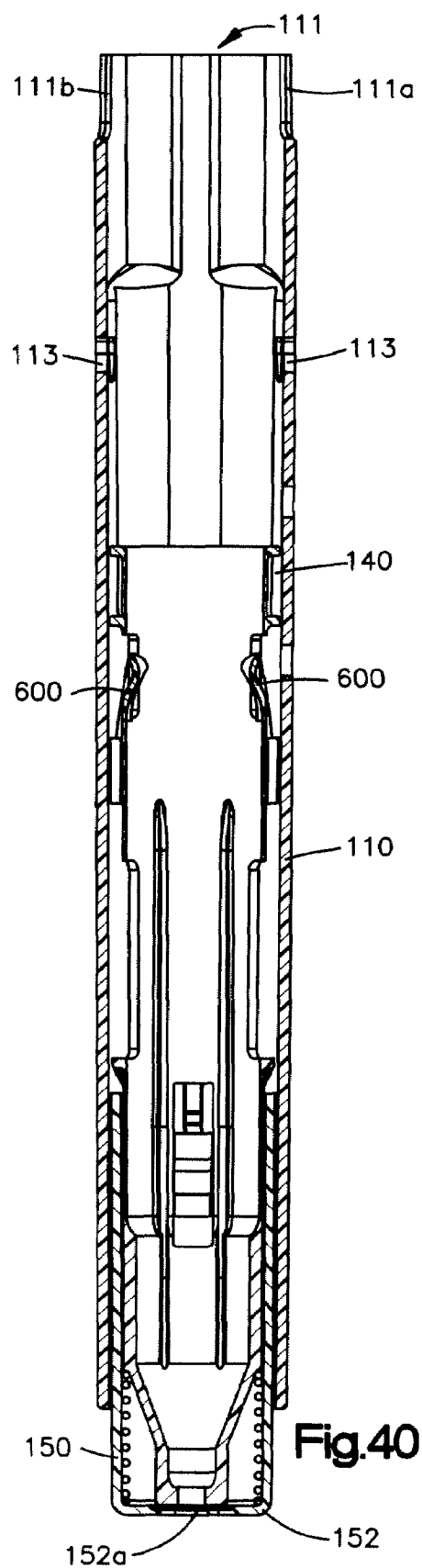
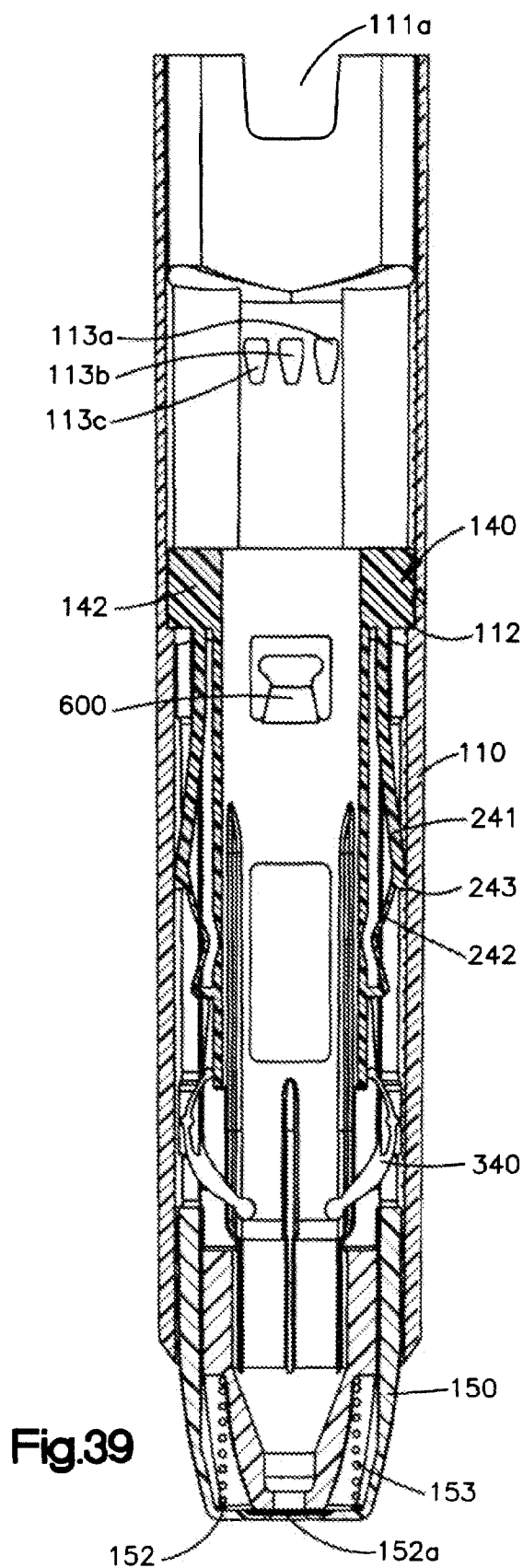


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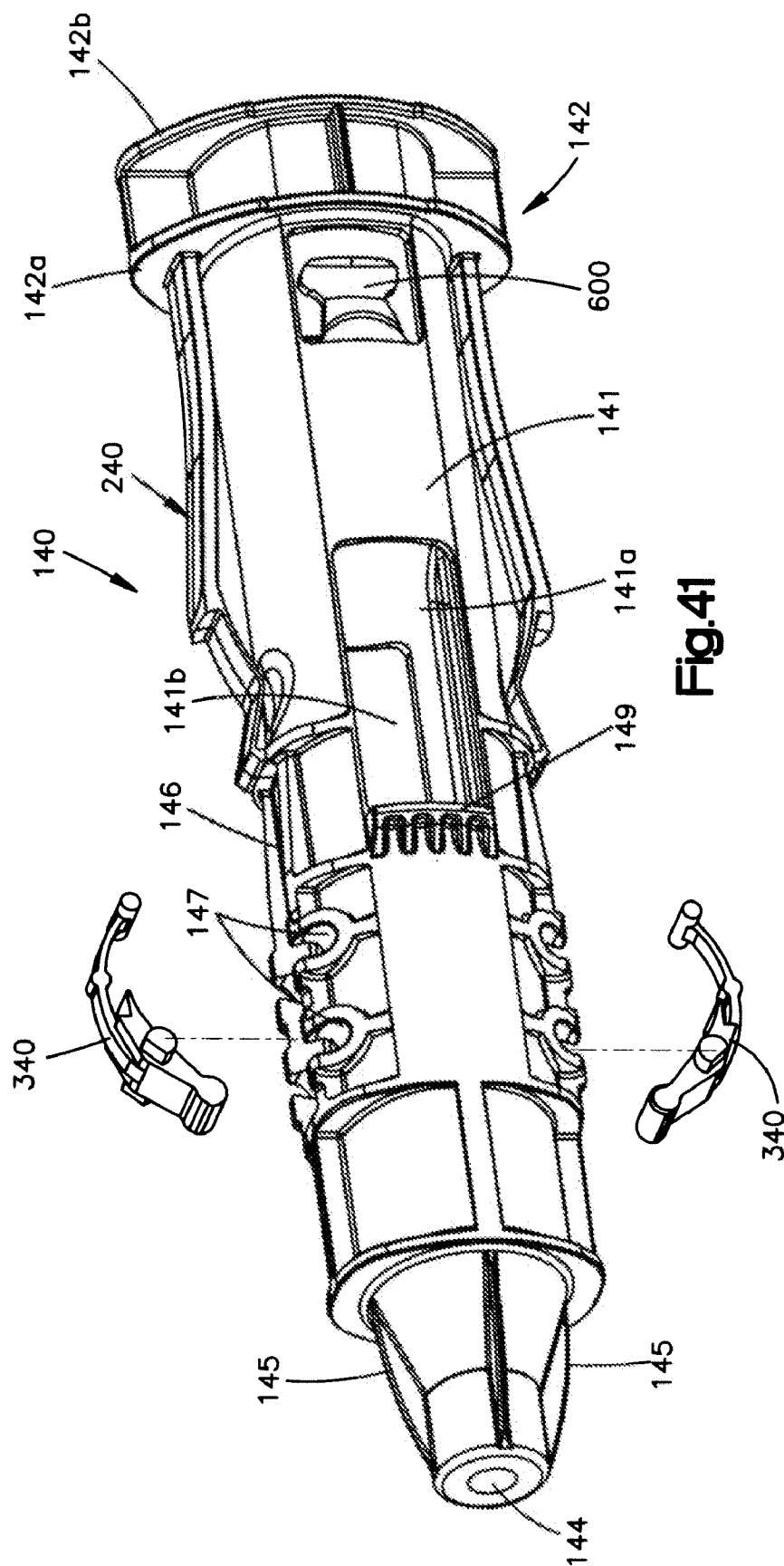


Fig. 41

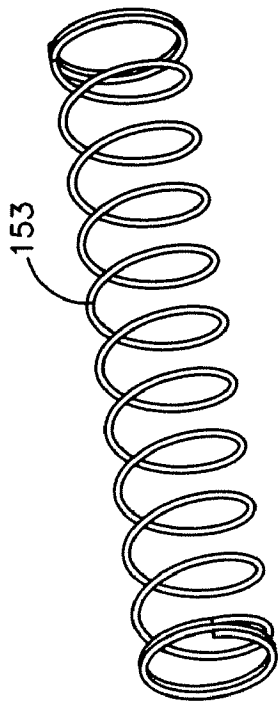


Fig. 42

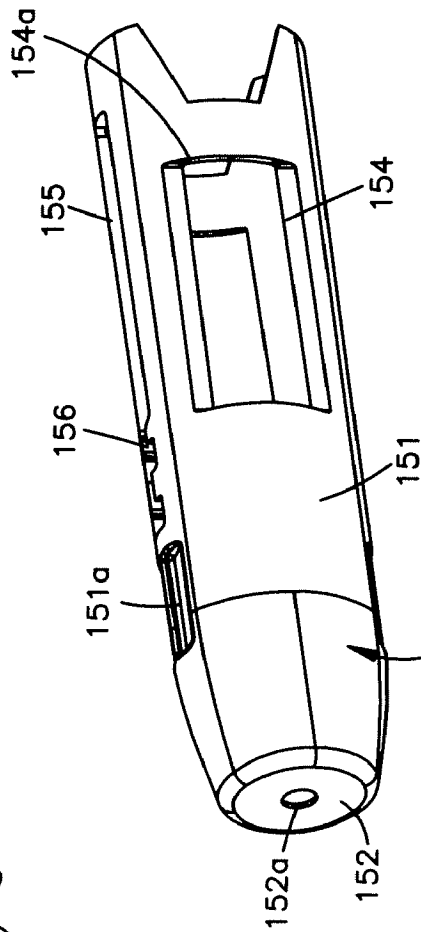


Fig. 43

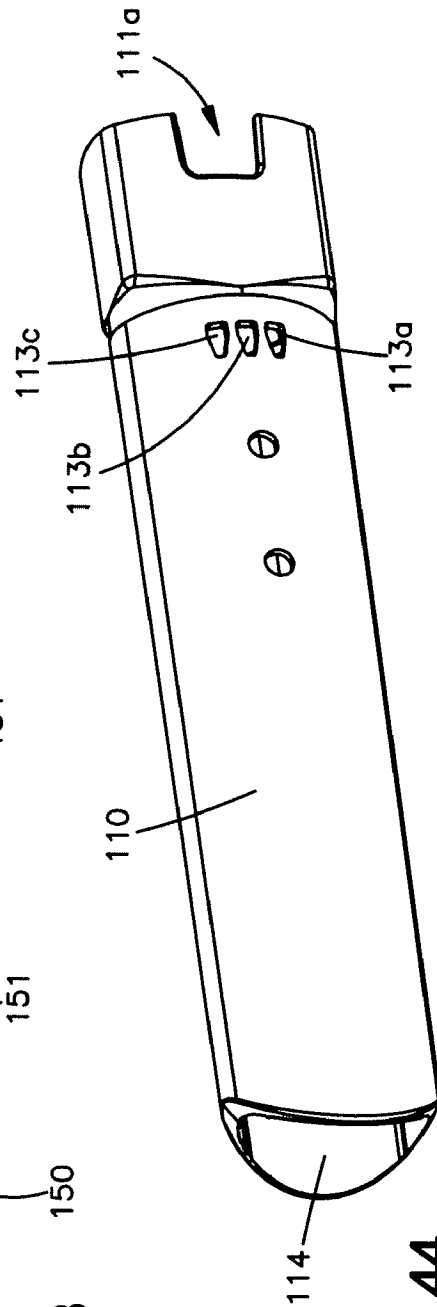


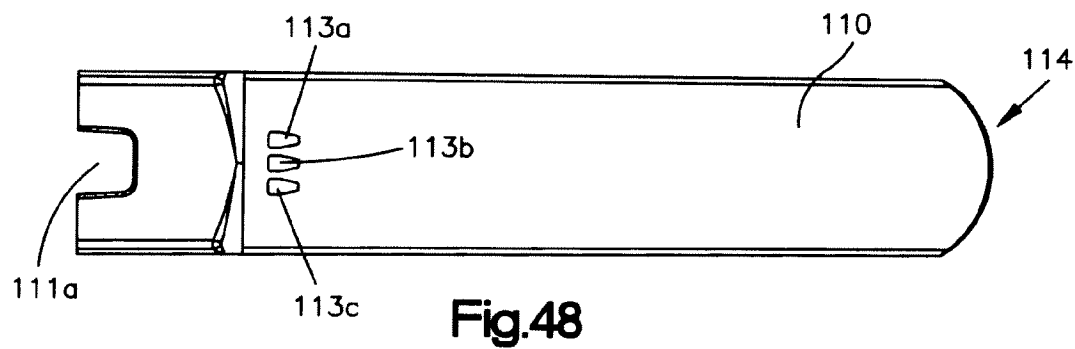
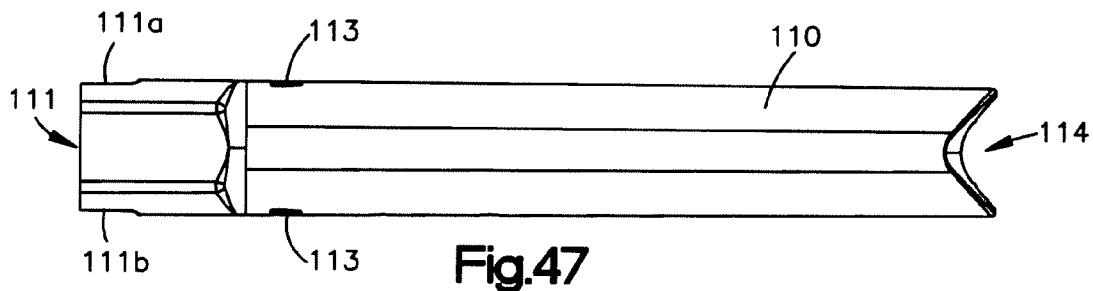
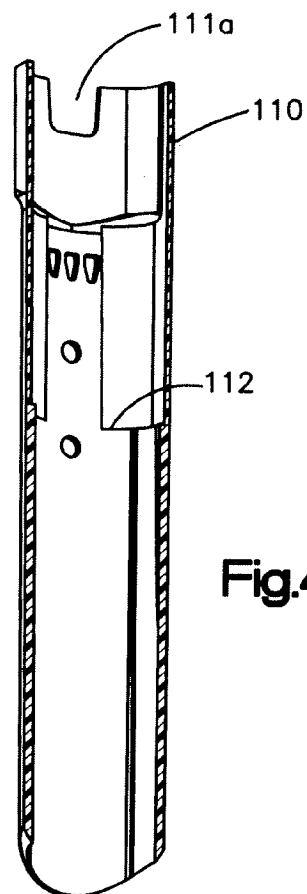
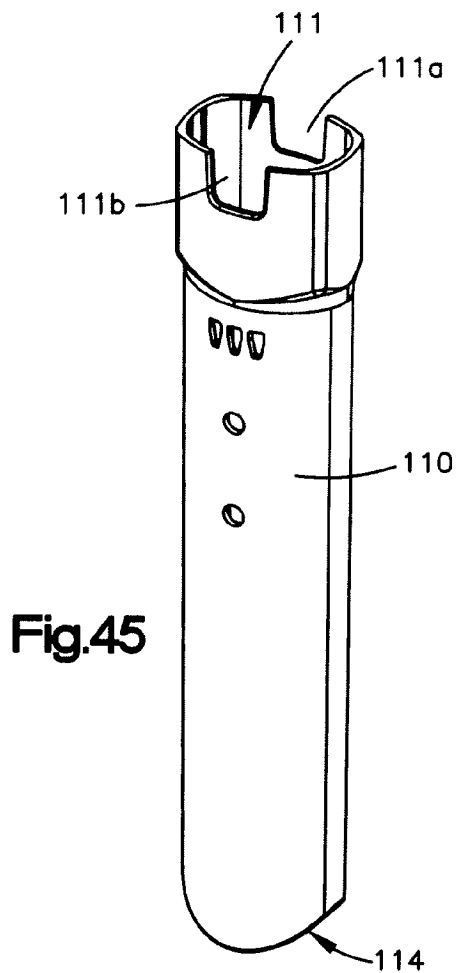
Fig. 44

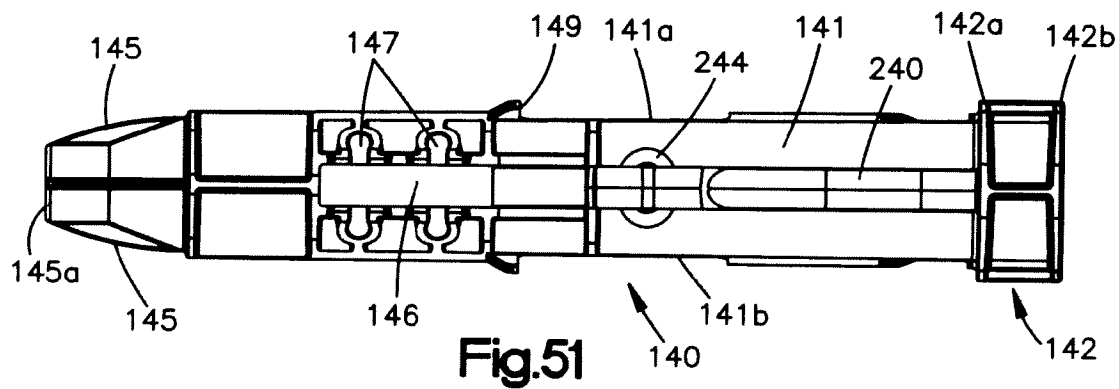
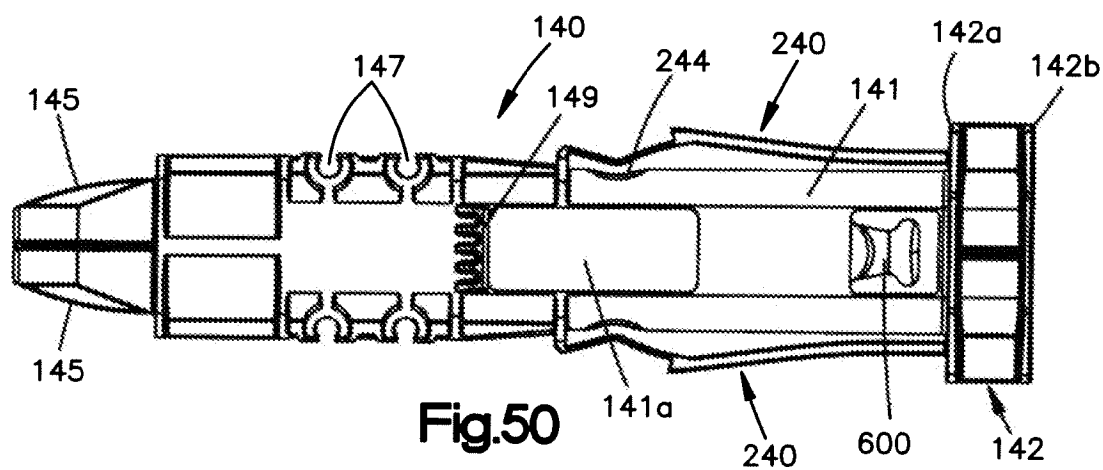
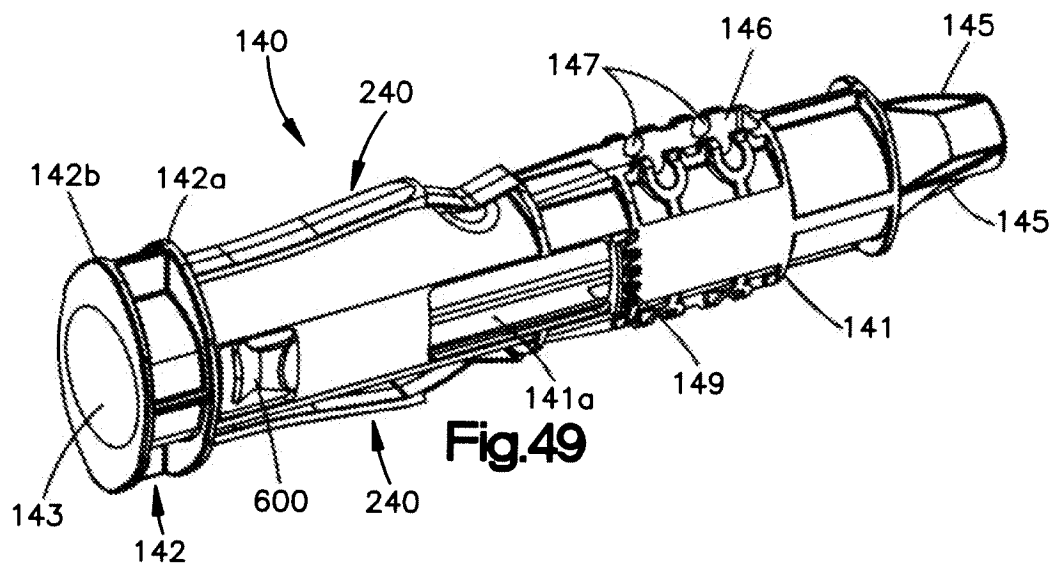
U.S. Patent

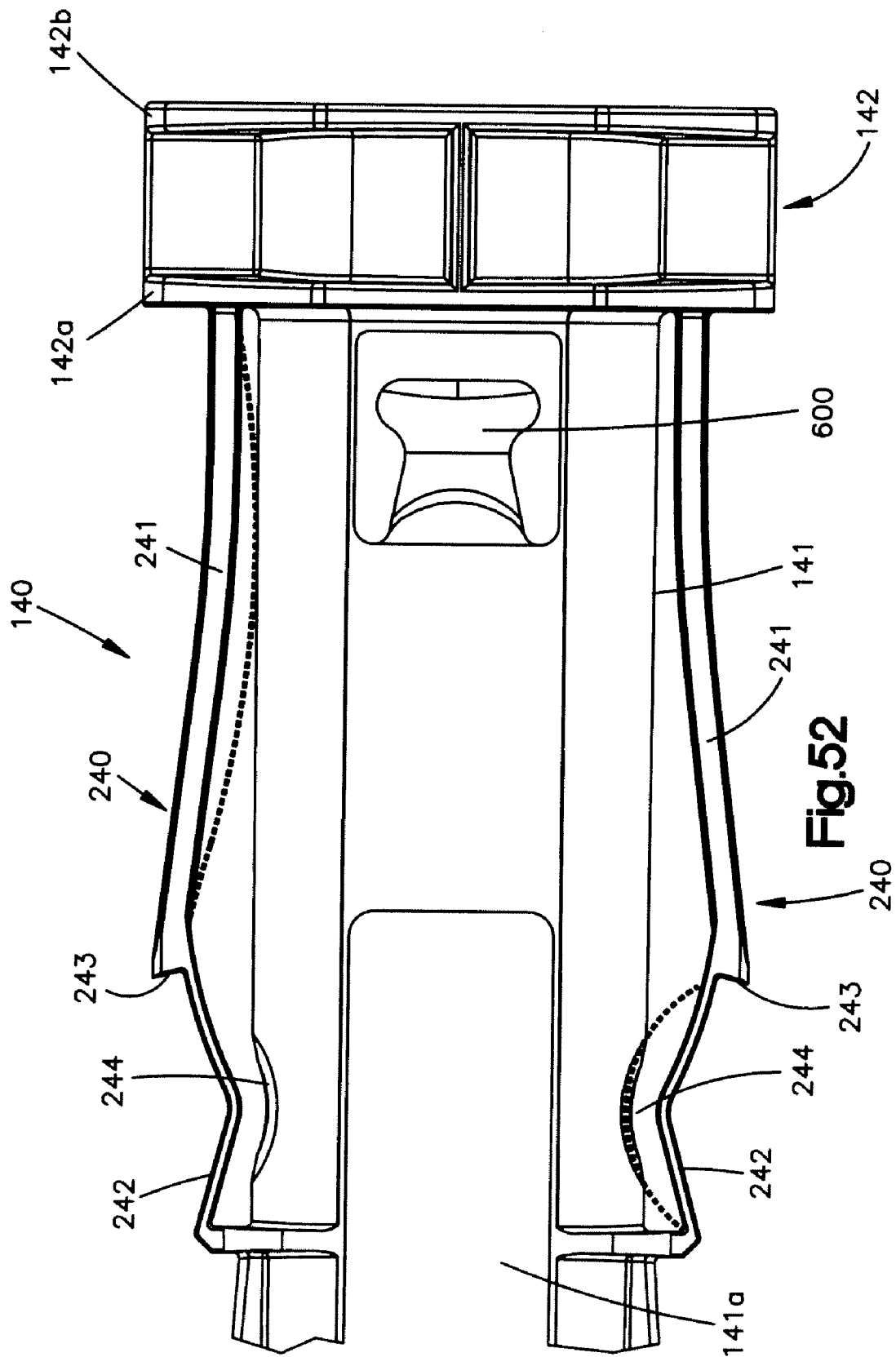
Nov. 11, 2008

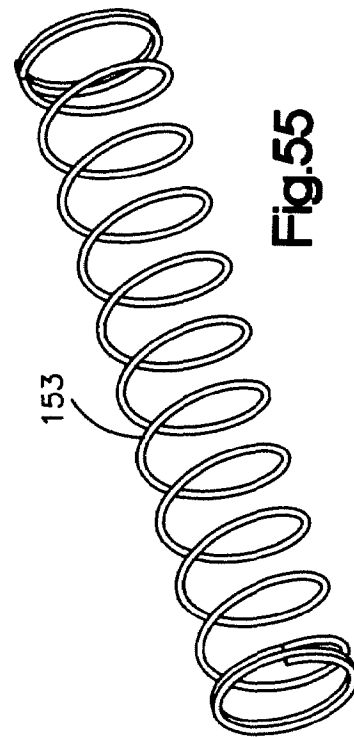
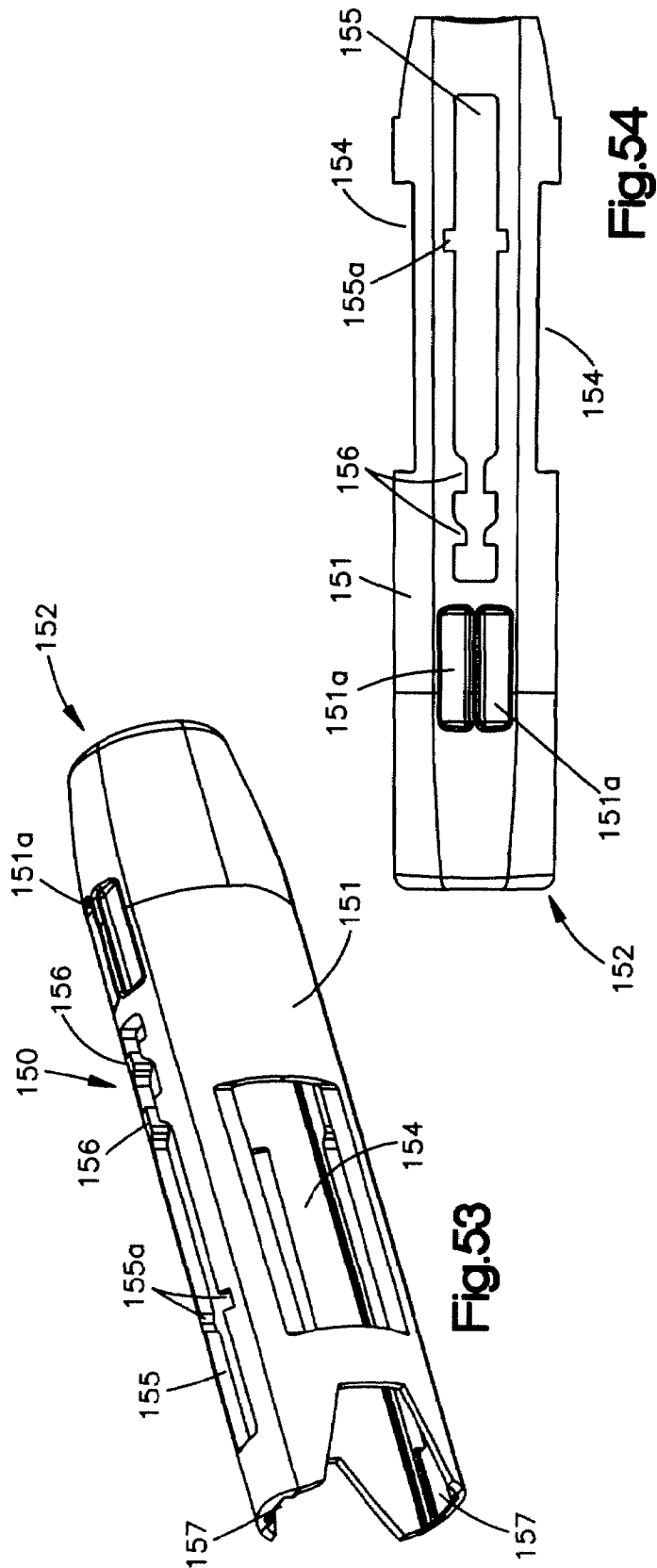
Sheet 22 of 26

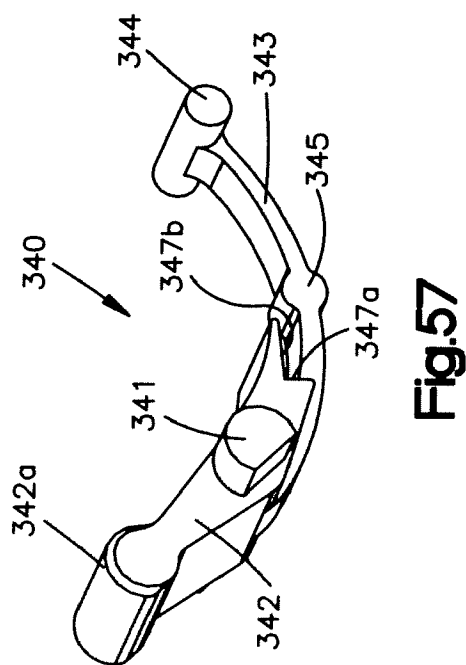
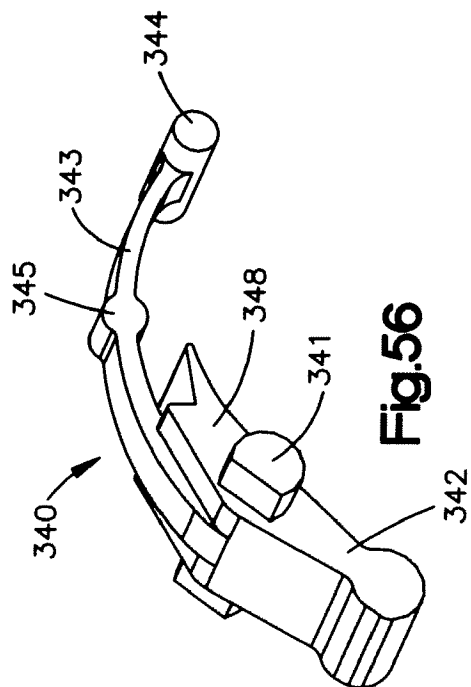
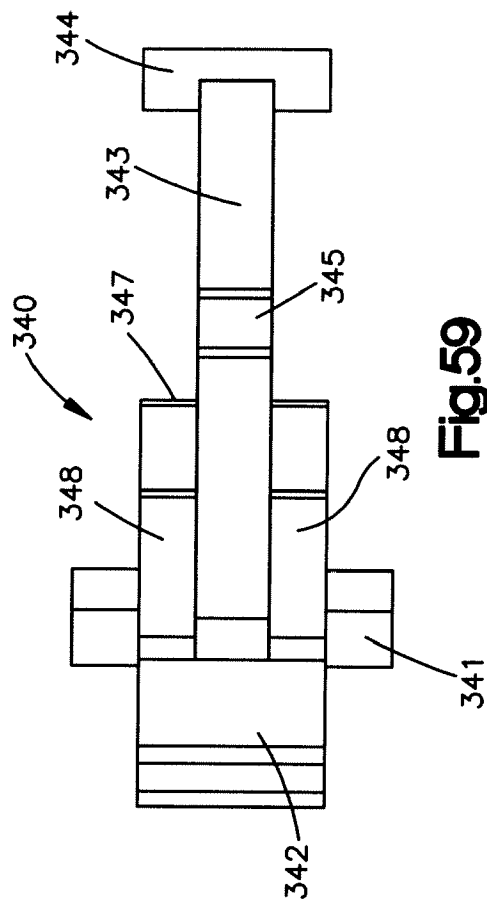
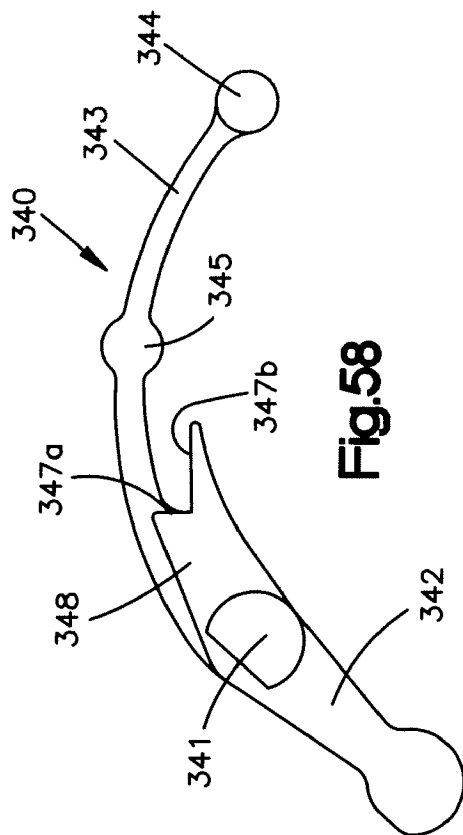
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AUTOMATIC INJECTOR**CROSS REFERENCE TO RELATED APPLICATION**

The application relates to and claims priority to U.S. Provisional Patent Application No. 60/599,054, filed on Aug. 6, 2004, which is incorporated herein in its entirety specifically by reference.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

The present invention relates to an automatic injector or auto-injector for delivering medicament to an injection site. In particular, the present invention is directed to an auto-injector having a needle cover mechanism to prevent a user from coming into contact with the needle of the auto-injector after use. The needle cover mechanism is held in a locked position prior to activation of the auto-injector. After injection, the needle cover mechanism is held in a locked deployed position such that the user cannot access the needle.

The present invention is also directed to an auto-injector having a power pack containing a one-piece molded collet. The molded collet reduces the overall number of manufactured components while increasing versatility. The molded collet can be used with cartridges of varying sizes, different sized needles and can be used to vary the amount of the delivered dosage of medicament.

2. Description of Related Art

An automatic injector or auto-injector is a device designed to allow a user to self-administer a pre-measured dose of a medicament composition subcutaneously or intramuscularly, usually in an emergency situation. Automatic injectors are used, for example, to treat anaphylactic (severe allergic) reactions and to administer antidotes for certain poisons, such as chemical nerve agents and various drug compositions such as diazepam.

A typical auto-injector has a housing, inside of which is a cartridge. The cartridge has one or several chambers containing medicament compositions or components thereof and is adapted to be attached to a needle assembly. The cartridge can hold either a pre-mixed liquid medicament or a solid medicament and a liquid that are mixed prior to injection. The housing carries an actuation assembly with a stored energy source, for example, a compressed spring. Activation of the actuation assembly causes a sequence of movements, whereby the needle extends from the auto-injector into the user so that the medicament compound is then forced through the needle and into the user. After delivery of the dose of medicament into the injection site, the needle remains in an extended position. If the auto-injector is of the type designed to carry plural components of the medicament composition in separate, sealed compartments, structure may be included that forces the components to mix when the actuation assembly is activated.

There is a need for an auto-injector having a cover that provides adequate protection from the needle both prior to and after operation of the auto-injector. U.S. Pat. No. 5,295,965 to Wilmot et al. discloses an external cover member providing sharps protection for an auto-injector after use. The cover member is deployed after actuation of the auto-injector such that the user does not view the needle after use. The position of the cover member with respect to the auto-injector body is offset after use such that the needle cannot be redeployed through an opening in the needle cover.

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U.S. Pat. No. 6,767,336 in Kaplan discloses a cover for an auto-injector. In an effort to reduce components, Kaplan eliminates an outer housing for the auto-injector. The cover is secured to the exterior of the cartridge holder sleeve. The cartridge holder sleeve includes several slots, which are sized to receive a latch on the cover. When the auto-injector is actuated, the cartridge within the cartridge holder sleeve causes the latch to be released from the recess such that the cover is free to travel under the bias of the spring. Since the cover disclosed by Kaplan is located on the exterior of the cartridge holder sleeve, it is possible for the user to grip the cover during operation of the auto-injector. As such, the user may prevent the latches from being released from the respective slots, which could prevent the cover from being properly deployed. This could impede the movement of the cartridge within the cartridge holder sleeve, which could result in the medicament being dispensed through the needle prior to the needle reaching the injection site. To overcome these deficiencies, higher trigger forces would be necessary. When the latches are released during the deployment of the cover, the latches are biased outwardly. It is possible for the user to be pinched or otherwise injured by this deployment.

If the cover deploys prior to delivery of the drug, a potentially life threatening event may arise because the user may not receive the proper dose of medicament. There is a need for a secured cover such that cannot be displaced prior to use of the auto-injector. There is also a need for a cover that does not impede or adversely impact the operation of the auto-injector in the event it is contacted by the user. It is also desirable that the cover be locked in an extended position after use of the auto-injector so that the needle is not exposed such that a person cannot be accidentally pricked by the needle. It is also desirable to have a cover member having locking and deployment mechanisms that are protected against contact from the operator to prevent improper deployment of the cover.

SUMMARY OF THE INVENTION

One aspect of the present invention relates to an auto-injector for dispensing a predetermined dosage of a medicament. The medicament may be either self administered or administered by a caregiver. The auto-injector includes a housing. The housing is preferably oval or elliptical in shape such that it is more ergonomic. The oval shape prevents the auto-injector from rolling off a table or flat surface, while providing a larger surface area for printing user instructions. A cartridge container is disposed within the housing. A cartridge is received within the cartridge container. The cartridge has at least one opening therein and contains a medicament. The medicament is rearwardly confined by a plunger. The cartridge includes a needle assembly to dispense the medicament therethrough. The cartridge is advanced within the cartridge container from a stored position to an operation position where the needle extends from the cartridge container such that the dose of medicament can be administered. An actuation assembly or power pack provides a stored energy source that is capable of being released to drive the plunger within the cartridge to dispense the medicament through the needle assembly into the user and allowing the needle to be accessible on activation.

Another aspect of the auto-injector is the provision of a needle cover received within the housing. The needle cover shields the user from inadvertent exposure to the needle after use of the auto-injector providing sharps protection. Theoretically, the operation of the needle cover is fail safe because the cover will not deploy until after the needle penetrates the user. During operation, the needle of the cartridge extends

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through an opening in the needle cover to permit the dispensing of a dose of medicament. After use of the auto-injector, the needle cover is held in a locked position to prevent the cover from being retracted to expose the needle. According to another aspect of the invention, the needle cover has a locked retracted position prior to activation of the auto-injector, thus maintaining a compact configuration of the device prior to use. According to another aspect of the invention, the actuation forces associated with the auto-injector are not imparted on the needle cover.

In accordance with another aspect of the present invention, the auto-injector has a first locking assembly that holds the needle cover in the first locked position. The first locking assembly may be located on the cartridge container. The first locking assembly may include at least one locking tooth pivotally connected to the cartridge container or the needle cover. Each locking tooth releasably engages the needle cover and includes a locking surface constructed and arranged to contact a surface on the needle cover or the cartridge container. Each locking tooth may be formed as a separate component that is connected to the container or cover. It is contemplated that the locking teeth may be formed as integral parts of the needle cover or cartridge. A spring force of the locking tooth biases the locking surface into contact with the needle cover. The spring force may be provided by a spring portion of the locking tooth. The spring force may also be provided by a separate spring assembly biasing the locking surface into contact with the needle cover. Each locking tooth is preferably pivotally connected to the cartridge container. Each locking tooth pivots in response to movement of the cartridge within the cartridge container. It is also contemplated that the locking teeth can pivot in response to movement of the collet or the power pack. Typically, the locking surface pivots out of contact with the needle cover when the locking tooth pivots in response to the movement of the cartridge. The spring force and the force exerted by the locking teeth on the cartridge are controlled such that they negligibly or minimally impede the motion of the cartridge during the injection operation to avoid any premature rupturing of the diaphragm within the cartridge and premature administering of the medicament.

The needle cover is spring biased so that the cover is biased outwardly from the housing to cover the exposed needle after the first locking assembly is released. In accordance with another aspect of the present invention, the auto-injector has a second locking assembly that holds the needle cover in the second locked position. The second locking assembly may be located on the cartridge container, the outer body or the cover member. The second locking assembly may include at least one locking arm or wing preferably connected to the cartridge container. Each locking arm is spaced from the cartridge container such that the locking arm can be temporarily compressed against the cartridge container as the needle cover moves from the first locked position to the second locked position. Each locking arm has a locking surface to engage the needle cover when the needle cover is in the locked extended position. Each locking arm has a thick strut portion and a thin strut portion, wherein the thick strut portion is outwardly curved and the thin strut portion is inwardly curved. This construction maintains the locking arm in a normal uncompressed state to reduce stress on the cartridge container. This also permits a smooth deployment of the cover member. Furthermore, this arrangement ensures that the thick strut portion will buckle into a stable condition. This creates a stronger lock to prevent the cover member from being moved rearwardly to a retracted position. The inwardly curved nature of the thin strut portion allows the thick portion

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to buckle in a controlled manner to a stable condition. Additionally, the outwardly curved shape of the thick strut portion provides for fail safe locking of the cover member in the extended position. In the event that the thin strut breaks, the thick strut portion will still engage the cover member to maintain it in an extended locked position.

The cartridge container may further include at least one ledge extending outwardly therefrom. Each ledge is constructed and arranged to engage an edge of an opening in the needle cover to limit the travel of the needle cover with the respect to the cartridge container when the needle cover is in the extended position. When the ledge on the cartridge container engages the edge of the opening, the outward travel of the needle cover is limited. The second locking assembly limits the inward travel of the needle cover. The needle cover and the cartridge container contain openings formed therein. When the openings are aligned prior to activation of the auto-injector, user can view the contents of the cartridge through the housing and the openings. The housing may be transparent or opaque. When opaque, the housing may contain an opening that can be aligned with the openings in the needle cover and cartridge container so that the color of the medicament may be checked to determine whether or not the medicament is suitable for injection. If the medicament is discolored, the user will know not to administer the medicament. When the openings are not aligned after operation of the auto-injector, the user is no longer able to view the contents of the cartridge through the openings providing a visual indication to the user that the auto-injector has been used.

Another aspect of the present invention is the construction and arrangement of the actuation assembly or power pack, which is mounted within the housing adjacent to an open end. A release pin or safe pin is removably attached to the actuation assembly to prevent inadvertent actuation of the auto-injector when the release pin is in place. A pin or stem on the release pin is received within an opening in the actuation assembly to prevent actuation of the auto-injector. This opening in the power pack is spaced from the open end of the housing such that the opening is less visible to a user prior to administering the drug. This arrangement is provided so that user will not orient the incorrect end of the auto-injector against the injection surface of the user. The power pack is recessed or spaced from the end of the housing, which provides an indication to the user that pressing the power pack will not operate the auto-injector. The recessed nature of the power pack serves to hide the release pin hole in the power pack when the user is viewing the instructions on the outer body such that the user does not confuse the release pin hole with the opening through which the needle passes for administering the medicament. The release pin includes at least one tab extending therefrom. The tab is compression fit into a complimentary recess formed in the actuation assembly to prevent the inadvertent removal of the release pin. The tabs also prevent rotation of the release pin such that the user easily recognizes that the release pin must be pulled in order to be removed.

The actuation assembly includes an outer body, which is configured to engage the release pin. The outer body is constructed to be connected to the housing. An inner body is operatively coupled to the outer body. At least one retention tab on the inner body secures the inner body to the outer body. The inner body is capable of limited movement with respect to the outer body. A collet is operatively coupled to the inner body. An energy source is operatively connected to the inner body and the collet. Unlike conventional collets, the collet in the present invention is molded as a single piece. No spacers or other components are provided between the collet and the

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plunger in the cartridge. This arrangement simplifies construction. Different sized collets can be produced and installed into the actuation assembly, such that only the collet needs to be altered when different sized cartridges are used or a different sized dosage of medicament is to be administered.

BRIEF DESCRIPTION OF THE DRAWINGS

An understanding of the various embodiments of the invention may be gained by virtue of the following figures, of which like elements in various figures will have common reference numbers, and wherein:

FIG. 1 is a side cross sectional view of the auto-injector according to an embodiment of the present invention;

FIG. 2 is a side cross sectional view of the auto-injector of FIG. 1 in an unactivated state having the release pin in place;

FIG. 3 is a side schematic view of the auto-injector in the unactivated state of FIG. 2;

FIG. 4 is a side cross sectional view of the auto-injector of FIG. 1 having the release pin removed in preparation for activation;

FIG. 5 is a side cross sectional view of the auto-injector of FIG. 1 wherein the needle cover spring is in a compressed state;

FIG. 6 is a side schematic view of the auto-injector of FIG. 5;

FIG. 7 is a side cross sectional view of the auto-injector in an actuated state with the needle in a drug delivery position;

FIG. 8 is a side schematic view of the auto-injector of FIG. 7;

FIG. 9 is a side cross sectional view of the auto-injector following delivery of the drug wherein the needle cover is in an extended protective state;

FIG. 10 is an enlarged view of the locking wings of the cartridge container when the needle cover is in the extended protective state, as shown in FIGS. 9 and 11;

FIG. 11 is a side schematic view of the auto-injector of FIG. 9;

FIG. 12 is a left front schematic view of the auto-injector of FIG. 1 having the outer body removed wherein the needle cover is located in a retracted position prior to activation of the auto-injector;

FIG. 13 is an enlarged view of FIG. 12 illustrating the position of the locking wings of the cartridge container and the locking teeth;

FIG. 14 is a left front schematic view of the auto-injector of FIG. 1 having the outer body removed when the needle cover is located in an extended protective position after use of the auto-injector;

FIG. 15 is an enlarged view of FIG. 14 illustrating the position of the locking wings of the cartridge container and the locking teeth;

FIG. 16 is an enlarged cross sectional view illustrating the position of the locking teeth when the needle cover is in the extended protective position;

FIG. 17 is a left rear perspective view of the power pack outer body for the power pack for the auto-injector according to the present invention;

FIG. 18 is a side perspective view of the collet for the power pack for the auto-injector according to the present invention;

FIG. 19 is a right front perspective view of the power pack inner body for the power pack for the auto-injector according to the present invention;

FIG. 20 is a side perspective view of the spring assembly for the power pack for the auto-injector according to the present invention;

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FIG. 21 is a left bottom perspective view of the release pin for the auto-injector according to the present invention;

FIG. 22 is a right bottom perspective view of the power pack of the auto-injector in an assembled state;

FIG. 23 is a side cross sectional view of the power pack of FIG. 22;

FIG. 24 is a top left perspective view of the power pack of FIG. 22 having the top portion of the release pin and a peripheral rib of the power pack outer body removed;

FIG. 25 is a top left perspective view of the power pack of FIG. 22;

FIG. 26 is a top left perspective view of the power pack positioned within the outer body having the safe pin removed;

FIG. 27 is left side perspective view of the power pack outer body

FIG. 28 is a partial cross sectional perspective view illustrating the interior of the power pack outer body;

FIG. 29 is a partial cross sectional perspective view illustrating the interior of the power pack inner body;

FIG. 30 is side perspective view of the power pack inner body;

FIG. 31 is a bottom perspective view of the power pack inner body;

FIG. 32 is a side view of the release pin;

FIG. 33 is another side view of the release pin of FIG. 32 rotated 90° about an axis;

FIG. 34 is a bottom perspective view of the safe pin of FIG. 32;

FIG. 35 is a side view of the collet of the power pack;

FIG. 36 is another side view of the collet of FIG. 35 rotated 90° about an axis;

FIG. 37 is an enlarged end view of the collet illustrating the stabilizing arch;

FIG. 38 is side perspective view of the needle cover located within the outer body of the auto-injector;

FIG. 39 is a cross sectional view of the cartridge container and needle cover located within the outer body with the power pack removed prior to final assembly of the auto-injector;

FIG. 40 is a cross sectional view of the cartridge container and needle cover located within the outer body of FIG. 39 rotated 90° about an axis with the power pack removed prior to final assembly of the auto-injector;

FIG. 41 is a front left side perspective view of the cartridge container of the auto-injector;

FIG. 42 is a perspective view of the needle cover spring;

FIG. 43 is a front left side perspective view of the needle cover of the auto-injector;

FIG. 44 is a front left side perspective view of the outer body of the auto-injector;

FIG. 45 is another left side perspective view of the outer body of FIG. 44;

FIG. 46 is a partial cross sectional perspective view illustrating the interior of the outer body;

FIG. 47 is a side view of the outer body;

FIG. 48 is another side view of the outer body of FIG. 47 rotated 90° about an axis;

FIG. 49 is a right rear side perspective view of the cartridge container of the auto-injector;

FIG. 50 is a side view of the cartridge container;

FIG. 51 is another side view of the cartridge container of FIG. 51 rotated 90° about an axis;

FIG. 52 is an enlarged side view of the cartridge container illustrated in FIG. 51, wherein the dotted lines illustrate the deflection path of the locking wings;

FIG. 53 is a right rear perspective view of the needle cover of the auto-injector;

FIG. 54 is a side view of the needle cover of FIG. 53;

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FIG. 55 is a perspective view of the needle cover spring;
 FIG. 56 is a right top perspective view of a locking tooth of
 the auto-injector in accordance with the present invention;
 FIG. 57 is a left bottom perspective view of the locking
 tooth of FIG. 55;
 FIG. 58 is a side view of the locking tooth; and
 FIG. 59 is a top view of the locking tooth.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

It should be appreciated that some of the components described herein are conventionally known in the broader aspects, as described in U.S. Pat. No. 4,031,893 ("the '893 patent") hereby incorporated by reference in its entirety, and thus not described in unnecessary detail here. It should also be appreciated that known modifications or variations to the '893 patent can apply equally to the auto-injector of the present invention as will be described below. These modifications or variations include embodiments described in U.S. Pat. Nos. 4,226,235; 4,329,988; 4,394,863; 4,723,937; and U.S. Ser. Nos. 09/985,466; 10/285,692, each of which is incorporated by reference in its entirety for the full teachings therein.

An auto-injector 100 of the present invention will now be described in greater detail in connection with FIGS. 1-59. The auto-injector 100 includes an outer body 110, a release pin 120, a power pack 130, a cartridge container 140, a needle cover 150 and a cartridge 160 housing a dose of medicament. The dose can be stored in liquid or solid form or as a combination of a liquid and a solid that is mixed prior to injection.

The auto-injector 100 includes an outer body 110 shown in FIGS. 38 and 44-48. The outer body 110 has a generally oval or elliptical shape, which is more ergonomic sized to permit easy grasping and use by the user or caregiver in comparison with a cylindrical body. The generally oval shape of the outer body 110 prevents the auto-injector 100 from inadvertently rolling or sliding off a flat surface. Furthermore, the oval shape provides a larger print surface for labeling the auto-injector 100 with instructions. The outer body 110 is preferably formed from a synthetic material such that it can be easily molded. The outer body 110 can be transparent such that the interior components can be easily viewed through the outer body 110. With such a construction, the user can view the contents of the cartridge 160 through windows 141a and 141b in the cartridge container 140 and the needle cover 150 at predetermined times. It is also contemplated that the outer body 110 can be opaque such that the interior components are not visible through the outer body 110. It is also contemplated that the outer body 110 has a window or windows that permit viewing of the components within the outer body 110. The outer body 110 has an opening 111 formed in one end that is sized to receive a release pin 120. When in place, the release pin 120 prevents inadvertent use or activation of the auto-injector 100. The release pin 120 is illustrated in FIGS. 32-34. It is contemplated that operating instructions may be printed directly onto the outer body 110. It is also contemplated that a label may be affixed to the outer body 110, which may increase the rigidity of the outer body 110. When the outer body 110 includes one or more apertures, the provision of a label increases the strength of the outer body 110, which makes the provision of additional structural reinforcements unnecessary.

The opening 111 includes side recesses 111a and 111b, which extend downwardly along opposing sides of the outer body 110, shown in FIGS. 45, 46 and 48. While two recesses are shown, it is contemplated that a single recess may be

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provided or more than two may be provided. The number of recesses will correspond to the number of tabs. The recesses 111a and 111b are sized so that they may receive downwardly extending tabs 121a and 121b on the release pin 120. The tabs 121a and 121b prevent rotation of the release pin 120 such that the user easily recognizes that the release pin 120 is to be pulled rather than rotated to permit removal of the release pin 120 in order to actuate the auto-injector 100. The tabs 121a and 121b are primarily received in retention recesses 235 located on opposing sides of the power pack 130, described in greater detail below. The recesses 111a and 111b provide access to the tabs 121 in the recesses 235. The tabs 121a and 121b are compression fit onto the power pack 130 to prevent inadvertent removal. To release the pin 120, the operator compresses or pinches the tabs 121 to dislodge the edges of the tabs 121 from the recesses 235 such that the pin 120 can then be pulled/removed from the power pack 130. As shown, the tabs 121 have a curvature which creates a chamfered edge that engages the edges of the recesses 235. The shape of the tabs 121 and the recesses 235 are full complimentary, which creates the friction or compressive retaining force between the pin 120 and power pack 130. The release pin 120 also includes downwardly projecting ribs 122a and 122b, which are adapted to be received on the top surface of the power pack 130. The ribs 122a and 122b increase the stability and rigidity of the release pin 120. It is contemplated that additional ribs may be provided. The release pin 120 includes an outwardly facing flat end 123 having a peripheral ledge 124. The peripheral ledge 124 permits grasping of the release pin 120 by the user. The ledge 124 is sized to rest on the end surface of the outer body 110 adjacent opening 111. The release pin 120 includes a downwardly extending pin 125, which engages the collet 430 of the power pack 130. When secured in place (i.e., prior to removal of the release pin 120 and prior to actuation of the auto-injector 100), the pin 125 prevents the end of the collet 430 from compressing, which prevents actuation of the auto-injector 100. The end 123 has a shape corresponding to the oval/elliptical shape of the outer body 110.

As shown in FIG. 46, the inner surface of the outer body 110 is contoured to receive the power pack 130, a cartridge container 140 and a needle cover therein 150. Unlike many prior art needle covers, the needle cover 150 is positioned between the container 140 and the outer body 110 such that the user does not contact the cover 150 during the operation, which could impede the deployment of the cover or cause a diaphragm within the cartridge to rupture prematurely. Additionally, the mechanisms for locking and deploying the cover member are located within the outer body 110 and are thus protected against tampering and dirt ingress. The outer body 110 includes a cartridge container retention step 112 formed on the inner surface near the end of the outer body 110 adjacent the opening 111. A ledge 142 of the cartridge container 140 abuts the retention step 112 to limit the downward movement of the cartridge container 140 within the outer body 110 once the auto-injector 100 has been assembled such that the container can not be moved out of opening 114. A plurality of power pack retention openings 113a, 113b and 113c are formed on at least one side of the outer body 110. Projections or teeth 238 on the power pack 130 are snap fit into the openings 113. This snap fit prevents the removal of the power pack 130 from the outer body 110 once installed in the outer body 110. The power pack outer body 230 is not movable with respect to the outer body 110. The ledge 142 of the cartridge container 140 is sandwiched between the retention step 112 and the power pack 130.

An opening 114 is formed in the outer body 110 on an end opposite the opening 111. The opening 114 is configured such

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that a portion of the cartridge container **140**, a portion of the needle cover **150** can extend therefrom. The step **112** limits the travel of the container **140** through opening **114**. The end of the outer body **110** is intended to be orientated adjacent the injection surface of the user such that end portion of the cover **100** contacts the injection surface.

The power pack **130** will now be described in greater detail in connection with FIGS. **17-20**, **22-31** and **35-37**. The power pack **130** includes a power pack outer body **230**, a power pack inner body **330**, a collet **430**, and a power pack spring assembly **530**. The activation force necessary to release the energy stored in the power pack is between 4 to 8 pounds. The activation force is the force required to release the collet **430** from the inner body **330** when the auto-injector **100** is pressed against the injection surface. The injection force provided by the spring assembly **530** is approximately 30 pounds. The injection force must be sufficient such that the cartridge **160** is advanced within the cartridge container **140** to drive the needle such that it pierces the sheath to permit injection of the medicament into the user. The power pack outer body **230** is a generally cylindrical elongated hollow body **231**. A plurality of outer peripheral ribs **232a**, **232b** and **232c** extend outwardly from an outer surface of the hollow body **231**. While these ribs **232** are shown, it is contemplated additional ribs may be provided. The ribs **232** are provided to prevent distortion of the outer body **110** of the auto-injector **100**. A plurality of outer longitudinal ribs **233a**, **233b** are spaced about the outer surface of the hollow body **231**. The ribs **233** cooperate with the ribs **232** to further strengthen the auto-injector **100** and prevent distortion of the outer body **110** when gripped and used by a user.

One of the peripheral ribs **232a** forms a top end surface **237** of the power pack outer body **230**. A hole **234** is provided in end surface which is sized to receive the downwardly extending pin **125** of the release pin **120**. Retention recesses **235a** and **235b** are formed on opposing sides of the hollow body **231** adjacent the top end surface. The recesses **235a** and **235b** are formed by walls **236a** and **236b** which extend outwardly from the hollow body **231** and upwardly from the top end surface **237** of the peripheral rib **232a**. The recesses **235a** and **235b** are aligned with the side recesses **111a** and **111b** of the outer body **110** such that when the release pin **120** is secured to the auto-injector **100**, the tabs **121a** and **121b** are received in both recesses **235a** and **235b**. The recesses **235a** and **235b** are sized to apply a compressive force on the tabs **121a** and **121b** to secure the release pin **120** in place to prevent inadvertent removal.

As shown in FIGS. **17**, **26** and **27**, the walls **236a** and **236b** extend upwardly from the end surface **237** of the peripheral rib **232a**. With such an arrangement, the end surface **237** is spaced or recessed below the end surface of the outer body **110**, as shown in FIG. **26**, forming a recess **115**. The recess **115** reduces and/or avoids the visual effect of a push button. As such, the user will not be inclined to press the end surface **237** to administer the medicament. Additionally, it provides a visual indication to the user that the recess **115** is located at the inoperative end of the auto-injector **100** such that the user is inclined to place the cover **150** against the injector surface not the opposite end of the auto-injector. The recess **115** also serves to space the hole **234** from the end of the auto-injector **100** to deemphasize the presence of the hole **234** such that it is hidden when the user reads the label on the outer body **110**. As such, the user is disinclined to position the hole **234** adjacent the injection site. This arrangement is just one countermeasure provided to insure against improper use of the auto-injector **100**. The ribs **122a** and **122b** of the release pin **120** are received within the recess **115**.

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A plurality of projections or teeth **238a**, **238b**, **238c** are formed on the outer surface of the hollow body **231**. The teeth **238a**, **238b**, **238c** are sized to be snap fit into the openings **113a**, **113b**, **113c** to secure the power pack **130** within the outer body **110**. This construction permits these components **110** and **130** to be secured together without the need of an adhesive or other form of bonding. A corresponding set of teeth **238** may be provided on the opposite side of the hollow body **230** to match the corresponding openings in the outer body **110**.

The interior of the hollow body **231** includes a recess **231a**, which is sized to receive a retention tab **334** on the power pack inner body **330**. The recess **231a** may be a groove, which extends about the inner periphery of the hollow body **231**. The recess **231a** is positioned in the hollow body **231** near an end opposite the end surface **237**. As seen in FIGS. **1** and **28**, a collet activation structure **239** extends into the interior of the hollow body **231** from the inner side of the end surface **237**. The collet activation structure **239** has a generally cylindrical shape with a sloped collet activation surface **239a** located on a free end. The activation surface **239a** is provided such that when the pin **120** is removed and the front end of the injector is forced into an injection site so that cartridge container **140** rearwardly moves to engage inner body **330**, this will rearwardly force the arrowheads **434** and particularly rearward surface **489** thereof (see FIG. **35**) into engagement with surface **239a** to force the arrowheads **434** of the collet **430** together to release the spring assembly **530** and thus release the necessary energy to inject the medicament into the user. Ribs **239b** may be provided to reinforce the collet activation structure **239**. It is contemplated that other means of releasing the collet **430** may be employed. A push button type actuation arrangement may be employed, which is described in greater detail in U.S. Pat. No. 4,031,893 and hereby incorporated in its entirety by reference.

The power pack inner body **330** is a generally cylindrical hollow inner body **331**. The hollow inner body **331** has an opening **332** formed in one end. The opening **332** has a collet assembly lead-in surface **332a** which is used to compress a portion of the collet assembly **430** during assembly of the auto-injector **100** such that it can be properly mounted within the power pack inner body **330**. The opening **332** also has a collet retention surface **332b** located on an opposite edge which support the opposing arrowheads **434** of the collet **430** prior to activation. The hollow inner body **331** has an opening **333** formed on an opposing end. Spaced from the opening **333** are a plurality of retention tabs **334** which are sized to be snapped into the retention recess **231a**. The recess **231** and tabs **334** permit limited movement between the power pack inner body **330** and the power pack outer body **230**. The arrangement is also beneficial for purposes of assembling the auto-injector **100**. The inner body **330** and the outer body **230** can be preassembled. The recess **231** and tabs **334** maintain the inner body **330** and the outer body **230** in proper alignment for assembly. Furthermore, this arrangement prevents the subassembly of the inner body **330** and the outer body **230** from separating prior to the final assembly in the auto-injector **100**. It is also contemplated that other means which permit limited movement between the outer power pack and the inner power pack, which secure the components together may be employed. A ledge **335** at least partially extends about the periphery of the opening **333**. The ledge **335** is sized to engage the cartridge container **140** and the power pack outer body **230** at certain times during the operation of the auto-injector **100**, described in greater detail below. A spacing exists between the inner power pack **330** and the cartridge container **140** after assembly and prior to activation of the

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auto-injector **100** to create a gap, which avoids permanently putting forces on the power pack and the spring **530**.

A collet **430** is received within the hollow interior of the power pack inner body **330**. The collet **430** preferably is a molded one piece construction. The collet **430** has an elongated body **431** having an opening **432** formed therein which forms a pair of side arms **433a** and **433b**. Each side arm **433a** and **433b** includes an arrowhead detail **434a** and **434b** respectively. One side of each arrowhead **434a** and **434b** is configured to contact and engage the collet retention surface **332b**. An opposite side of each arrowhead **434a** and **434b** is configured to engage the collet assembly lead-in surface **332a**, which permits the side arms **433a** and **433b** to be deflected inwardly to permit operation of the auto-injector **100**. The end **435** of the collet **430** adjacent the arrowheads **434a** and **434b** includes an opening **435a** sized to receive the pin **125** of the release pin **120**. The pin **125** prevents the side arms **433** from being deflected inwardly towards each other. When secured in place, the pin **125** prevents activation of the auto-injector **100**. The opening **432** has an arch **432a** formed on one end, as shown in FIG. 37. The arch **432a** helps stabilize the side arms **433** and assist them in springing apart when the arms have been compressed together. The arch **432a** reduces the amount of stress on the collet.

The collet **430** is positioned within the power pack spring assembly **530**. One end of the spring assembly **530** is supported on a flange **436** formed on the collet **430**. The flange **436** extends outwardly from the elongated body **431**. While the flange **436** supports one end of the spring assembly **530**, the location of the flange **436** on the body **431** can also serve to define the delivered dose volume of medicament injected into the user. In certain applications it is desirable to control the amount of medicament delivered through the needle such that a portion of the medicament remains in cartridge **160**. The flange **436** may limit the distance that the collet **430** can travel into the cartridge **160**, which contains the liquid medicament. As such, the amount of medicament delivered is controlled. In this arrangement, the flange **436** is sized to contact the end of the cartridge **160**. For larger diameter cartridges and for larger doses of medicament, it is contemplated that the flange **436** can travel within the cartridge **160**. The collet **430** further includes a projection **437**, which receives a plunger **438**. The plunger **438** is slidably received within the cartridge **160**. In other applications, it is desirable to dispense all of the medicament from the container **160**. A small residual amount of medicament remains in the needle **162** and the neck of the cartridge **160** adjacent the needle **162**. In these applications, the flange **436** travels within the interior of the cartridge **160** so that the plunger **438** travels the length of the interior of the cartridge **160** to dispense all of the medicament (except for the residual amounts mentioned above) through the needle **162**. It is contemplated that different sized collets **430** may be used in the present auto-injector **100**. As such, the collet **430** can be changed based upon cartridge size and desired dose.

The collet **430** is preferably formed as a single piece from a suitable plastic material. The one piece collet **430** simplifies manufacturing and lowers costs by reducing the number of components needed to form a collet. In conventional collets, multiple brass components may be used. In addition in other auto-injectors, a spacer has been required for use in conjunction with the collet **430** to accommodate different amounts of medicament for different auto-injectors. The collet **430** in accordance with the present invention eliminates the multi component construction and also advantageously eliminates the need for a spacer. The length of the collet can be selected based upon the desired dosage. This construction further per-

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mits the elimination of a metal insert typically found in the plunger and a firing seat above the power pack inner body. It is contemplated that the size and shape of the collet **430** itself may be varied to accommodate different sized cartridges **160**.

When the flange **436** does not contact the cartridge **160**, it is possible to dispense the entire contents of the cartridge **160** except for any residual amounts remaining in the needle or in the neck of the cartridge **160**. It is contemplated that a nipple plunger, as disclosed in U.S. Pat. No. 5,713,866 to Wilmot, the disclosure of which is hereby incorporated specifically herein by reference, may be employed to prevent any buildup of residual amounts of medicament in the neck of the cartridge **160**. The position of the flange **436** can be varied to control the amount of dosage injected into the user when the flange is positioned such that the collet and the plunger **438** travel a greater distance within the cartridge **160** before the flange **436** contacts the cartridge **160**, a larger dose is dispensed. The length of the collet **430** and the diameter of the cartridge **160** can be selected to control the flow of fluid through the needle **162** of the cartridge **160** so that a desired flow rate is obtained. The auto-injector **100** in accordance with the present invention is configured such that collets **430** of varying sizes can be used within the same outer body **110** and the power pack **430**.

An opposite end of the spring assembly **530** rests against an inner surface of the power pack inner body **330** against opening **332**.

The cartridge container **140** will now be described in greater detail in connection with FIGS. 41 and 49-52. The cartridge container **140** has a generally elongated hollow body **141** sized to be received within the outer body **110**. A ledge **142** is formed on one end of the elongated body **141**. The ledge **142** contacts the retention step **112** formed on the inner surface of the outer body **110**. The ledge **142** limits the downward movement of the cartridge container **140** within the outer body **110** such that it cannot be removed through opening **114**. The ledge **142** is formed by peripheral ribs **142a** and **142b**, which extend outwardly similar to the ribs **232a**, **232b** and **232c** on the power pack outer body **230**. The ribs **142a** and **142b** also prevent distortion of the outer body **110**.

The elongated hollow body **141** has a hollow interior sized to receive the cartridge **160** therein. The hollow body has an opening **143** such that the cartridge **160** can be located in the hollow interior and to permit the collet **430** to be slidably received within the cartridge **160**. The cartridge container **140** and the locking teeth **340** thereof are designed to accommodate various sized cartridges **160**, while maintaining full needle cover functionality. As such, a common design needle cover assembly (including the cartridge container and locking teeth) can be used for various different volumes of drugs and different sized needles. For longer and larger cartridges, it is desirable to provide additional support to prevent axial and radial movement, which could damage or fracture the cartridge **160**. A pair of tabs **600** are formed on the hollow body **141** to apply a compressive force on the cartridge **160** to hold and align the cartridge **160** in a proper orientation to prevent such axial and radial movement. The tabs **600** provide friction to prevent movement of the cartridge **160** within the hollow body **141** during shock loading to prevent the cartridge from being dislodged or moved forward with the cartridge holder **140** prior to the medicament dispensing sequence. Typically, the smaller cartridges do not contact the tabs **600**. The collet **430** and the needle and needle sheath provide sufficient support for the cartridge. The end of hollow body **141** has a tapered construction with an opening **144** sized to permit the passage therethrough of the needle **162** and protective sheath **165** of the cartridge **160**. A plurality of ribs

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145 are formed on the outer surface of the hollow body 141 on the tapered end. The ribs 145 help stabilize the needle cover spring 153 of the needle cover 150. The ribs 145 also serve as guides to aid in the assembly of the auto-injector 100.

The elongated hollow body 141 has at least one viewing window 141a and 141b formed therein. The viewing windows 141a and 141b permit the user to view the contents of the cartridge 160 before activation of the auto-injector 100 to insure that the medicament has not become contaminated or expired.

A pair of locking arms or wings 240 extend from the ledge 142 and are connected to a mid-portion of the hollow body 141, as shown in FIG. 52. Each locking wing 240 has a thickened strut 241 having a generally curved shape, as shown in FIG. 52. The thickened strut 241 is curved such that when a compressive load is applied to the locking wing 240 (e.g., when a user is attempted to push the needle cover 150 back into the outer body 110 after use of the auto-injector 100) the thickened strut 241 bends in the manner illustrated by the dashed lines in FIG. 52. With such a construction, the locking wings 240 are supported by the body 141 of the cartridge container 140, which increases the compressive strength of the locking wings 240. While not preferred, it is contemplated that a single locking wing 240 can be provided.

A thinner strut 242 extends from the free end of the strut 241 and is connected to the body 141 of the cartridge container 140. A locking surface 243 is formed at the intersection of struts 241 and 242. The locking surface 243 engages a surface on the cover 150 to limit the inward travel of the cover 150 after operation of the auto-injector 100, as shown in FIGS. 9 and 10. The thinner strut 242 provides a spring force to keep the thicker strut 241 biased in an outwardly direction. The thinner strut 242 also provides tensile strength under extreme loads and helps prevent the strut 241 from collapsing in a sideways direction because the thinner strut 242 remained retained in a guide groove in the needle cover 150 after the cover member 150 has moved to an extended position. The curved shape of the strut 242 permits the strut 242 to bend inwardly as shown in the dashed lines in FIG. 52. This prevents the entire wing 240 from forming a rigid arch. Thus allowing the thicker strut 241 to flex inwardly towards the body 141 without causing excessive compressive loads along the wing 240. It is contemplated that the locking arm 240 may be located on the outer body 110.

As shown in FIGS. 39, 41, 49, 50 and 52, the elongated body 141 of the cartridge container 140 includes a recess 244 located between the thinner strut 242. If the locking arms 240 are located on the outer body 110, the recess 244 could be formed in the outer body 110. Alternatively, an opening in the outer body 110 could also be provided. This recess 244 increases the distance that the thinner strut 242 travels inwardly toward the body 141, which increases the spring force provided to the thicker strut 241 to maintain the strut 241 in an outwardly biased position. The locking wings 240 are normally maintained in unstressed states. The locking wings 240 are compressed temporarily as the needle cover 150 passes over them. The locking wings 240 spring out such that the locking surface 243 engages the cover member 150 to prevent the needle cover 150 from being pushed backwards as shown in FIG. 10.

An elongated slot 146 is formed on each side of the elongated body 141. The slot 146 extends from the ends of the strut 242, as shown in FIGS. 49 and 51. Each slot 146 is sized to receive a locking tooth 340. As shown in FIGS. 1, 2, 4, 5, 7, 9, 16, 39 and 41, the locking teeth 340 are locked on opposing sides of the cartridge container 140. The locking teeth 340 are provided to hold back the needle cover 150 from deploying

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until after operation of the auto-injector 100. A pair of locking teeth 340 are provided. While not preferred, it is contemplated that a single locking tooth 340 can be employed.

Each locking tooth 340 is capable of pivoting about the bearing axle 341 within the axle slot 147. Multiple axle slots may be provided such that the position of the tooth 340 may be adjusted. As shown in FIGS. 56-59, each locking tooth 340 has a tab 342 having a bearing surface 342a. The tab 342 is positioned within the slot 146 such that it extends into the interior of the elongated body 141 and is capable of contacting the cartridge 160. As the cartridge 160 is advanced within the body 141 during operation of the auto-injector 100, the contact between the cartridge 160 and the bearing surface 342a causes the locking tooth 340 to rotate about the axle 341. While the surface 342a contacts the cartridge 160, the locking teeth 340 have minimal or negligible impact on the movement of the cartridge 160 within the container 140 during the injection operation. The low or minimal force applied by the locking teeth to the cartridge is advantageous in that it does not build pressure within the cartridge that could prematurely burst the diaphragm before the needle is fully extended. Furthermore, the movement of the cartridge 160 within the container 140 is not impeded or negligibly impeded by the locking teeth 340. The tab 342 extends from one side of the axle 341. A spring tail 343 extends from an opposing side of the axle 341. The spring tail 343 is positioned within the slot 146 and is designed to slide along the cartridge container 140. The spring tail 343 serves to bias the locking tooth 340 into a locked position such that the needle cover 150 is retained or locked in a retracted position prior to operation of the auto-injector 100. It is contemplated that the spring tail 343 may be replaced with a spring assembly. A bearing surface 344 is provided on one end of the tail 343 to permit the spring tail 343 to slide smoothly along the cartridge container 140 within slot 146. The bearing surface 344 and central body 345 provide a flat area for an ejector pin.

Formed below the spring tail 343 is a v-shaped notch 347. The notch 347 has a locking surface 347a on one side which holds the needle cover 150 before activation of the auto-injector 100. Another surface 347b limits the travel of the tooth 340 within the cartridge container 140 to limit its rotation. The notch 347 is formed as part of a tab 348, which extends on either side of the spring tail 343. The locking teeth 340 increase the flexibility of the auto-injector 100. Numerous cartridges of various lengths and diameters can be used without modifying the auto-injector 100. The spring action of the tails 343 adjust the position of the locking teeth 340 such that the surface 342a contacts the cartridge 160.

The cartridge container 140 further includes a pair of openings 141a and 141b, which are formed on opposing sides of the body 141. The openings 141a and 141b permit viewing of the contents of the cartridge 160 such that the user can visually inspect the medicament prior to operation of the auto-injector 100. Prior to use the openings 141a and 141b are aligned with corresponding openings in the needle cover 150 such that the user can view the contents of cartridge 160 through the outer body 110. A ledge 149 having a plurality of reinforcing ribs 149a is formed adjacent one end of the opening 141. The ledge 149 contacts the edge 154a of the opening 154 in the needle cover 150 to prevent the needle cover 150 from moving any further forward relative to the cartridge container 140 so that the needle cover 150 cannot be pulled out of the outer body 110. When in this position, the locking surface 243 of the locking wings 240 engages the end of needle cover 150 to prevent the needle cover 150 from being inserted back into the outer body 110. When the ledge 149 is in contact with the edge of the opening in the needle cover 150, the openings in

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the cartridge container and the needle cover are no longer aligned such that the user cannot view the cartridge 160 through the outer body 110. This provides a visual guide indicator to the user that the auto-injector 100 has been used.

The needle cover 150 will now be described in greater detail in connection with FIGS. 12-15, 38, 42, 43 and 53-54. The needle cover 150 has a generally elongated hollow body 151 having a shape that is complementary to the shape of outer body 110. The elongated body 151 is slidably received within the outer body 100. One end of the hollow body 151 is tapered having an enclosed end surface 152. The end surface 152 has an opening 152a sized to permit the passage of the needle of the cartridge 160 therethrough during an injection operation, as shown in FIGS. 7 and 8. The end surface 152 is intended to be placed on the injection surface of the user during operation of the auto-injector 100. A needle cover spring 153 is compressed between the end surface 152 of the needle cover 150 and the cartridge container 140, as shown in FIGS. 1, 2, 4, 5, 7, and 9. The auto-injector 100 with needle cover 150 in accordance with the present invention is designed to function like auto-injectors without needle covers in that a similar activation force is required to operate the auto-injector. As such, the spring 153 has a very low load. The biasing force for the cover 150 is less than the activating force of the auto-injector 100. The maximum load for the spring 153 is preferably 1.5 pounds. The load is lower than the activation force (1.5 versus 4-8) necessary to actuate the auto-injector 100 such that the needle cover 150 does not impact the operation of the auto-injector 100 when compared to injectors without covers such as disclosed in the '893 patent. The ribs 145 on the cartridge container 140 act to stabilize the spring 153 within the cover 150. The hollow body 151 may include indents 151a, shown in FIGS. 53 and 54. The indents 151a reduce the thickness of the plastic to conserve materials.

The hollow body 151 further includes a pair of openings 154 formed thereon. As discussed above, the openings 154 align with the openings 141a and 141b in the cartridge container 140 prior to activation to allow visibility of the medicament within the cartridge 160. Edge surface 154a of the opening 154 is designed to contact ledge 149 to prohibit further advancement of the needle cover 150.

Slots 155 are provided on opposing sides of the needle cover 150. The slots 155 are positioned to be aligned with the locking wings 240 and the locking teeth 340. The slots 155 guide and support the locking wings 240 prior to deployment of the needle cover 150. A cross slot 155a may be provided to aid in the assembly of the auto-injector 100 such that the locking teeth 340 can be inserted in place on the cartridge container 140 through slot 155 in the needle cover 150. Bearing surface 344 can be placed through the slot 155a. Locking projections 156 extend inwardly into the slot 155. The locking projections 156 are configured to engage the locking surface 347a on the locking teeth 340. Multiple projections 156 are provided to correspond to the multiple axle slots 147 in the cartridge container 140 for the bearing axle 341.

An interior groove 157 is provided within the interior of the hollow body 151. The interior groove 157 is axially aligned with the slots 155. A portion of the strut 241 is aligned in the groove 157 when the cover member 150 is in the position shown in FIGS. 12 and 13. The grooves are aligned with the locking wings 240 to provide support and prevent sideways collapsing of the locking wings 240.

The cartridge 160 includes a generally elongated glass tube having an opening 161 at one end sized to receive the plunger 438 and collet 430. The flange 436 on the collet 430 is designed to contact the end of the cartridge 160 to limit the

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inward travel of the plunger and collet into the cartridge 160 to control the dosage dispensed through the needle 162. The needle 162 is attached to a hub assembly 163 which is secured to another end of the cartridge 160. The hub assembly 163 may include a diaphragm 164 to prevent the passage of liquid medicament through the needle 162 prior to activation of the auto-injector. The needle 162 is encased in a protective sheath 165. The sheath 165 is secured to the hub assembly 163. The needle 162 pierces the sheath 165 during operation, when the needle 162 projects through the needle cover 150. The cartridge 160, as illustrated, provides a container for a dose of liquid medicament. It is not intended that the auto-injector 100 be limited solely to the use of a single liquid, rather, it is contemplated that one or more liquids may be stored in cartridge 160 that mix upon activation of the auto-injector 100. Furthermore, a solid medicament and a liquid can be separately stored in the cartridge 160 whereby the solid is dissolved in the liquid prior to dispensing.

The operation of the auto-injector 100 will now be described in greater detail. The auto-injector 100 is shown in an unactivated state in FIGS. 1, 2 and 3. The release pin 120 is secured in place such that the pin 125 is received within the hole 234 and the hole 435a in the collet 430 such that the side arms 433 can not be inwardly deflected. In this position, the needle cover 150 is held in a locked retracted position by the locking teeth 340. The locking surfaces 347a are biased by the spring tails 343 into alignment with the locking projections 156 on the needle cover member 150. In this position, the auto-injector 100 cannot be operated and the needle 162 is not exposed.

When operation of the auto-injector 100 is desired, the release pin 120 is grasped by the peripheral ledge 124 and pulled to remove the release pin 120 from the end of the auto-injector 100. This readies the auto-injector 100 for operation, as shown in FIG. 4. The arrowheads 434a and 434b and side arms 433a and 433b are now capable of being compressed together when the auto-injector 100 is activated. The locking wings 240 are not compressed or stressed at this time.

As shown in FIGS. 5 and 6, the user presses the end surface 152 of the needle cover 150 against the injection site. This causes the pre-compressed spring 153 to be slightly further compressed until the needle cover 150 moves and contacts the front end 145a of the cartridge container 140 (see FIG. 51), thus moving the ledge 142 of the cartridge container 140 rearwardly. The force of spring 153 is less than the force of spring 530. The needle cover 150, the cartridge container 140 and the cartridge 160 are then moved rearwardly into the outer body 110. The cartridge container 140 moves upward into the outer body 110 until the ledge 142 thereof contacts the ledge 335 of the power pack inner body 330. The power pack inner body 330, and the collet 430 and the spring assembly 530 are then pushed rearwardly into the auto-injector 100 into the power pack outer body 230. The collet 430 moves upwardly until it contacts the collet activation structure 239, shown in FIG. 28. The arrowheads 434a and 434b contact the sloped activation surface 239a. The arrowheads 434a and 434b are compressed together by the sloped surface 239 as the collet 430 moves rearwardly, such that the arrowheads 434a and 434b are released from the collet retention surface 332b. During this loading operation, the needle cover 150 is rearwardly pushed a small amount into outer body 110. When this occurs, the preload on the locking teeth 340 provided by the spring 153 is temporarily removed. As such, the v-shaped notch 347 temporarily disengages projection 156 formed on the needle cover 150. During this operation, the projection 156 no longer contacts either surface 347a or 347b, but remains in a space provided between the surfaces. As such,

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when pressure from the needle cover 150 is removed, the projection 156 will return into contact with the surfaces 347a or 347b. The locking teeth 340 will completely release the needle cover 150 only in response to movement of the cartridge 160 as it travels forwardly within the cartridge container 140. Accordingly, the needle cover 150 cannot deploy until the cartridge 160 moves.

The spring 530 and collet 430 simultaneously force the cartridge 160 and the cartridge container 140, forward toward the open front end of the outer body 110. Once the needle 162 has been extended through the needle cover 150, pressure of the medicament within the cartridge 160 causes the diaphragm 164 to burst permitting the flow of medicament into the user. The drug is forced through the needle 162 allowing the plunger 438 and collet 430 to move further into the cartridge 160. The cartridge container 140 retains the sheath 165 and also prevents the spring force of the spring 530 from being transferred through the cartridge 140 onto the needle cover 150 and the injection site. That is, the force from spring 530 that drives the cartridge 160 forward is opposed by the front end of the cartridge container 140, with the sheath 165 compressed therebetween, rather than force being received directly by the needle cover 150. In addition, the needle cover spring force is less than the activation force required to collapse the collet to release the collet during actuation. Preferably, the needle cover spring force is about 0.25 to 0.75 of the minimum activation force. The power pack residual spring force after activation is contained within the cartridge container 140, cartridge 160, the outer body 110 and the power pack outer body 230. This arrangement advantageously prevents a kick back effect from occurring. As such, the auto-injector is not pushed away from the injection site during activation to ensure that the proper dose of medicament is administered and the proper needle extended length or proper needle penetration is maintained. This effect would occur if the spring force from the spring 530 were transferred to the needle cover 150 and the injection site, whereby the auto-injector 100 could be pushed away from the injection site and alter the location of the needle 162 within the injection site. This has several negative impacts including startling the patient; changing the injection from an intramuscular to subcutaneous injection, which will affect pk levels. At the same time, the cartridge 160 is advanced within cartridge container 140 (i.e., when the needle 160 goes from a retracted position to extended position). The advancement of the cartridge 160 causes the locking tooth 340 to pivot about the axle 341. This is in response to cartridge 160 contacting bearing surface 342a and pushing the bearing surface 342a away from the main longitudinal axis of the needle 162. This rotation of the locking tooth 340 causes the locking surface 347a to disengage the locking projections 156. The surface 347b limits the rotation of the locking tooth 340. At this point, the cover member 150 is in an unlocked position such that it can move with respect to the cartridge container 140. The release of the collet 430 from the collet retention surface 332b forces the end of the power pack inner body 330 into contact with the power pack outer body 230.

Once the dose has been injected into the user, the user removes the auto-injector 100 from the injection surface. Since the needle cover 150 is not locked with respect to the cartridge container 140, the spring 153 forces the needle cover 150 out of the outer body 110 to cover the exposed needle 162, as shown in FIGS. 9 and 11. Since the slot 155 is aligned with groove 157 and a portion of the strut 241 is retained in the slot 157, the portion of the strut 241 moves into the groove 157 when the cover 150 moves outwardly. As the needle cover 150 slides outwardly, the locking wings 240 are

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temporarily compressed by the needle cover 150 as the thicker strut 241 slides through the groove 157. This compression occurs when the bottom surface of the groove 157 contacts the top surface of the strut 241. The wings 240 compress in the manner shown in the dashed lines in FIG. 52. Once the thicker strut 241 clears the groove 157 such that the wings 240 and needle cover 150 are in the position illustrated in FIGS. 10, 14 and 15, the locking surface 243 contacts the end of the needle cover 150 to prevent the needle cover from being reinserted into outer body 110. In the event that inward force is applied, the struts 241 and 242 compress such that the locking wing 240 is pressed against the body 141 of the cartridge container 140 such that the surface 243 remains engaged with the needle cover 150. This arrangement limits the inward travel of the needle cover 150. The ledge 149 engages the edge 154a of the opening 154 in the needle cover 150. The auto-injector 100 is now in an inoperable stored position.

The invention having been disclosed in connection with the foregoing embodiment and examples, additional variations will now be apparent to persons skilled in the art. Various modifications and variations to the above described auto-injector can be made without departing from the scope of the present invention. The invention is not intended to be limited to the embodiment specifically mentioned and accordingly reference should be made to the appended claims rather than the foregoing discussion of preferred embodiments and examples to assess the spirit and scope of the invention in which exclusive rights are claimed.

What is claimed is:

1. An auto-injector comprising:

a housing;

a cartridge container disposed within the housing;

a cartridge received within the cartridge container, the cartridge having at least one opening therein and containing a medicament, the medicament rearwardly confined by a plunger, wherein the cartridge includes a needle assembly to dispense the medicament there through, the needle assembly comprising a needle and a non-removable protective needle sheath;

an actuation assembly providing a stored energy source capable of being released to drive the needle through the protective needle sheath and to drive the plunger within the cartridge to dispense the medicament through the needle assembly;

a needle cover received within the housing, the needle cover having an opening formed therein to permit the passage of the needle assembly there through during a medicament dispensing operation, the needle cover having a first locked position whereby the needle cover is in a locked retracted position prior to activation of the auto-injector, the needle cover having a second locked position whereby the needle cover is in a locked extended position after operation of the auto-injector;

a first locking assembly that holds the needle cover in the first locked position; and

a second locking assembly that holds the needle cover in the second locked position.

2. The auto-injector according to claim 1, wherein the first locking assembly is connected to one of the cartridge container and the housing.

3. The auto-injector according to claim 2, wherein the first locking assembly includes at least one locking tooth that releasably engages the needle cover.

4. The auto-injector according to claim 3, wherein each locking tooth includes a locking surface constructed and arranged to contact a surface on the needle cover.

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5. The auto-injector according to claim 4, wherein the locking surface contacts the surface on the needle cover to prevent movement of the needle cover such that it is maintained in the first locked position prior to activation of the auto-injector.

6. The auto-injector according to claim 5, wherein the first locking assembly further includes a tab, wherein the tab is constructed and arranged to contact the cartridge.

7. The auto-injector according to claim 6, wherein the tab causes the first locking assembly to pivot in response to movement of the cartridge during a medicament dispensing sequence such that the locking surface pivots out of contact with the surface on the needle cover.

8. The auto-injector according to claim 6, wherein the tab is constructed and arranged to minimally impede the movement of the cartridge within the cartridge container during a medicament dispensing sequence.

9. The auto-injector according to claim 7, wherein the locking surface is formed by a notch formed in the first locking assembly.

10. The auto-injector according to claim 1, further comprising:

a needle cover spring assembly for moving the needle cover from the locked retracted position to the locked extended position, wherein:

the actuation assembly requires an activation force to release the stored energy source,

the needle cover spring assembly provides a biasing force, and

the activation force is greater than the biasing force.

11. The auto-injector according to claim 1, wherein the second locking assembly includes at least one locking arm connected to one of the housing, the cover member and the cartridge container.

12. The auto-injector according to claim 11, wherein at least a portion of the locking arm is received within an aperture when the needle cover is in the first locked position.

13. The auto-injector according to claim 12, wherein each locking arm has an exterior sliding surface formed on a strut, wherein the sliding surface is constructed and arranged to contact an edge of the aperture to temporarily compress the locking arm when the needle cover moves from the first retracted locked position to the second extended locked position.

14. The auto-injector according to claim 13, wherein each locking arm has a locking surface that is constructed and arranged to engage an outer edge of the needle cover when the needle cover is in an extended position to hold the needle cover in the second locked position.

15. The auto-injector according to claim 14, wherein each locking arm has a thick strut portion and a thin strut portion, wherein the thick strut portion is outwardly curved and the thin strut portion is inwardly curved, wherein the strut portions are constructed and arranged such that the locking arm cannot be compressed when the needle cover is in the second locked position such that the locking surface remains engaged with the outer edge of the needle cover.

16. The auto-injector according to claim 11, wherein each locking arm is connected to the cartridge container.

17. The auto-injector according to claim 16, wherein each locking arm is spaced from the cartridge container such that the locking arm can be temporarily compressed against the cartridge container as the needle cover moves from the first locked position to the second locked position.

18. The auto-injector according to claim 17, wherein each locking arm has a locking surface to engage the needle cover when the needle cover is in the locked extended position.

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19. The auto-injector according to claim 11, wherein each locking arm has a thick strut portion and a thin strut portion, wherein the thick strut portion is outwardly curved and the thin strut portion is inwardly curved.

20. The auto-injector according to claim 19, wherein the strut portions are constructed and arranged such that the locking arm can be temporarily compressed as the needle cover moves from the first locked position to the second locked position.

21. The auto-injector according to claim 1, wherein the cartridge container includes at least one ledge extending outwardly therefrom, wherein the at least one ledge is constructed and arranged to engage an edge of an opening in the needle cover to limit the travel of the needle cover with the respect to the cartridge container when the needle cover is in the extended position.

22. The auto-injector according to claim 1, wherein each of the needle cover and the cartridge container having an opening formed therein, wherein the openings are aligned prior to activation of the auto-injector such that a user can view the contents of the cartridge through the openings.

23. The auto-injector according to claim 21, wherein the cartridge container includes at least one ledge constructed and arranged to engage an edge in the opening in the needle cover to limit the travel of the needle cover with respect to the cartridge container.

24. The auto-injector according to claim 23, wherein the ledge engages one edge in the opening in the needle cover when the needle cover in the first locked position and the ledge engages another edge when the needle cover is in the second locked position.

25. The auto-injector according to claim 23, wherein the openings are not aligned after operation of the auto-injector such that the user cannot view the contents of the cartridge through the openings.

26. The auto-injector according to claim 1, wherein the housing has an oval cross section in a lateral direction.

27. The auto-injector according to claim 1, wherein the actuation assembly is mounted within the housing adjacent an open end.

28. The auto-injector according to claim 27, wherein the actuation assembly has a housing having at least one projection extending therefrom, the at least one projection located within a complimentary opening formed in the housing.

29. The auto-injector according to claim 28, wherein the actuation assembly housing is located within the housing adjacent to and spaced from one end of the housing such that a recess is formed adjacent the one end.

30. The auto-injector according to claim 29 further comprising a release pin removably connected to the actuation assembly, the release pin located in the recess.

31. The auto-injector according to claim 30, wherein the release pin has a pin removably recessing within an opening in the actuation assembly, wherein the auto-injector is not operable when the release pin is connected to the actuation assembly.

32. The auto-injector according to claim 31, wherein the release pin includes at least one tab extending therefrom, wherein the at least one tab is compression fit into a complimentary recess formed in the actuation assembly housing.

33. The auto-injector according to claim 27, further comprising a release pin removably attached to the actuation assembly, wherein the auto-injector is not operable when the release pin is connected to the actuation assembly.

34. The auto-injector according to claim 33, wherein a pin on the release pin is received within an opening in the actuation assembly to prevent actuation of the auto-injector.

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35. The auto-injector according to claim 34, wherein the opening is spaced from the open end of the housing.

36. The auto-injector according to claim 34, wherein the release pin includes at least one tab extending therefrom, wherein the at least one tab is compression fit into a complementary recess formed in the actuation assembly.

37. The auto-injector according to claim 1, wherein the actuation assembly comprises:

- an outer body;
- an inner body operatively coupled to the outer body;
- a collet operatively coupled to the inner body; and
- an energy source.

38. The auto-injector according to claim 37, wherein the collet is molded as a single piece.

39. The auto-injector according to claim 38, wherein the collet having an opening formed on one end, wherein the auto-injector further comprises a release pin removably attached to the actuation assembly, wherein the release pin is removably received in the opening in the collet to prevent operation of the actuation assembly.

40. The auto-injector according claim 39, wherein the collet is received within an opening in the inner body prior to medicament dispensing, wherein the collet is displaced from the opening at the initiation of the medicament dispensing sequence.

41. The auto-injector according to claim 40, wherein the collet has an elongated opening formed therein, wherein the release pin is received within the elongated opening.

42. The auto-injector according to claim 41, wherein the collet having at least one tapered portion, wherein the outer body having at least one surface constructed and arranged to contact the at least one tapered portion.

43. The auto-injector according to claim 42, wherein the at least one surface being constructed and arranged to contact the at least one tapered portion to compress the collet in an area around the elongated opening such that the collet is released from the inner body in response to application of an activation force.

44. The auto-injector according to claim 38, wherein the collet includes a flange, whereby the energy source is constructed and arranged to be positioned between the flange and an end of the inner body.

45. The auto-injector according to claim 44, wherein the flange is constructed and arranged to contact the cartridge to limit the travel of the plunger within the cartridge.

46. The auto-injector according to claim 44, wherein the flange is constructed and arranged to travel within the cartridge such that a full volume of medicament can be dispensed through the needle.

47. The auto-injector according to claim 37, wherein the collet is operatively coupled to the plunger.

48. The auto-injector according to claim 37, wherein the collet has an elongated opening formed therein, wherein one end of the opening has an arch construction.

49. The auto-injector according to claim 37, wherein the inner body is constructed and arranged to receive different sized collets.

50. The auto-injector according to claim 37, wherein the cartridge container is constructed and arranged such that the energy released from the stored energy source of the actuation assembly during the medicament dispensing operation is opposed by a front end of the cartridge container and is not transmitted to the needle cover.

51. The auto-injector according to claim 50, wherein the cartridge container, the cartridge, the housing, and the activation assembly outer body receive residual force from the

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energy source after activation of the medicament dispensing operation to prevent kick back of the auto-injector during the injection operation.

52. The auto-injector according to claim 37, wherein the cartridge container is constructed and arranged such that the energy released from the stored energy source to drive the needle and cartridge during the medicament dispensing operation is opposed by a front end of the cartridge container and is not transmitted to the needle cover.

53. The auto-injector according to claim 52, wherein the cartridge container, the cartridge, the housing, and the activation assembly outer body receive residual force from the energy source after activation of the medicament dispensing operation to prevent kick back of the auto-injector during the injection operation.

54. The auto-injector according to claim 1, wherein the cartridge container has at least one tab contacting the cartridge to orient and align the cartridge within the cartridge container.

55. An auto-injector comprising:

- a housing;
 - a cartridge container disposed within the housing;
 - a cartridge received within the cartridge container, the cartridge having at least one opening therein and containing a medicament, the medicament rearwardly confined by a plunger, wherein the cartridge includes a needle assembly to dispense the medicament there through, the needle assembly comprising a needle and a non-removable protective needle sheath;
 - an actuation assembly providing a stored energy source capable of being released to drive the needle through the protective needle sheath and to drive the plunger within the cartridge to dispense the medicament through the needle assembly;
 - a needle cover at least partially received within the housing, the needle cover having an opening formed therein sized to permit the passage of the needle assembly there through during a medicament dispensing operation, the needle cover having a first locked retracted position and a second locked extended position; and
 - a locking mechanism for selectively holding the needle cover in the first locked position and in the second locked position,
- wherein the locking mechanism is constructed and arranged to be protected against external contact by at least one of the needle cover and the housing.

56. The auto-injector according to claim 55, wherein the locking mechanism is concealed by at least one of the needle cover and the housing.

57. The auto-injector according to claim 56, wherein the locking mechanism comprises:

- a first locking assembly that holds the needle cover in the first locked position; and
- a second locking assembly that holds the needle cover in the second locked position.

58. The auto-injector according to claim 57, wherein the first locking assembly is connected to one of the cartridge container and the housing.

59. The auto-injector according to claim 58, wherein the first locking assembly includes at least one locking tooth that releasably engages the needle cover.

60. The auto-injector according to claim 59, wherein each locking tooth includes a locking surface constructed and arranged to contact a surface on the needle cover.

61. The auto-injector according to claim 60, wherein the locking surface contacts the surface on the needle cover to

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prevent movement of the needle cover such that it is maintained in the first locked position prior to activation of the auto-injector.

62. The auto-injector according to claim 61, wherein the first locking assembly further includes a tab, wherein the tab is constructed and arranged to contact the cartridge in response to movement of the cartridge.

63. The auto-injector according to claim 62, wherein the tab causes the first locking assembly to pivot in response to movement of the cartridge during the medicament dispensing operation such that the locking surface pivots out of contact with the surface on the needle cover.

64. The auto-injector according to claim 62, wherein the tab is constructed and arranged to minimally or negligibly impede the movement of the cartridge within the cartridge container during a medicament dispensing operation.

65. The auto-injector according to claim 63, wherein the locking surface is formed by a notch formed in the first locking assembly.

66. An auto-injector comprising:

a housing;

a cartridge container disposed within the housing;

a cartridge received within the cartridge container, the cartridge having at least one opening therein and containing a medicament, the medicament rearwardly confined by a plunger, the cartridge including a needle assembly to dispense the medicament there through;

an actuation assembly having a stored energy source capable of being released to drive the plunger within the cartridge to dispense the medicament through the needle assembly;

a needle cover at least partially received within the housing, the needle cover having an opening formed therein to permit passage of the needle assembly there through during a medicament dispensing operation, the needle cover having a first locked retracted position and a second locked extended position; and

a locking mechanism for selectively holding the needle cover in the first locked position and in the second locked position, wherein:

the locking mechanism comprises at least one locking tooth that releasably engages the needle cover;

each locking tooth has a spring action extension that adjusts the position of the locking tooth with respect to the cartridge to accommodate cartridges of different sizes and of different needle sizes received within the cartridge container; and

each locking tooth is pivotally connected to the cartridge container.

67. The auto-injector according to claim 66, wherein each locking tooth includes a bearing axle and a tab located on one side of the bearing axle, each locking tooth also including a locking surface located on an opposite side of the bearing axle, wherein the tab is constructed and arranged to contact the cartridge such that the locking tooth pivots about the bearing axle in response to movement of the cartridge within the cartridge container.

68. The auto-injector according to claim 67, wherein the locking surface is constructed and arranged to contact a surface of the needle cover to prevent movement of the needle cover.

69. The auto-injector according to claim 68, wherein the spring action extension biases the locking surface into alignment and contact with the needle-cover surface at predetermined times.

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70. The auto-injector according to claim 69, wherein the spring action extension is constructed and arranged to contact the cartridge container.

71. The auto-injector according to claim 66, wherein each locking tooth pivots in response to movement of the cartridge within the cartridge container, wherein each locking tooth includes a locking surface constructed and arranged to contact a surface on the needle cover, wherein the locking surface pivots out of contact with the surface when the locking tooth pivots in response to the movement of the cartridge.

72. The auto-injector according to claim 66, wherein each locking tooth includes a bearing surface formed thereon, wherein the bearing surface is constructed and arranged to contact the cartridge within the cartridge container during the medicament dispensing sequence.

73. The auto-injector according to claim 72, wherein the cartridge contacts the bearing surface as the cartridge moves during a medicament dispensing sequence causing the locking tooth to pivot, wherein each locking tooth includes a locking surface constructed and arranged to contact a surface on the needle cover, wherein the locking surface pivots out of contact with the surface when the locking tooth pivots in response to the movement of the cartridge.

74. The auto-injector according to claim 73, wherein the spring action extension biases the locking surface into alignment and contact with the needle-cover surface at predetermined times.

75. The auto-injector according to claim 74, wherein the pivoting of the locking tooth in response to the cartridge contacting the bearing surface disengages the locking tooth from the cover member.

76. The auto-injector according to claim 72, wherein each locking tooth minimally or negligibly impedes the movement of the cartridge within the cartridge container during the medicament dispensing sequence when the bearing surface contacts the cartridge.

77. The auto-injector according to claim 76, wherein the bearing surface is constructed and arranged to slide over the cartridge as the cartridge moves during the medicament dispensing sequence.

78. The auto-injector according to claim 55, further comprising:

a needle cover spring assembly for moving the needle cover from the locked retracted position to the locked extended position, wherein:

the actuation assembly requires an activation force to release the stored energy source,

the needle cover spring assembly provides a biasing force, and

the activation force is greater than the biasing force.

79. The auto-injector according to claim 57, wherein the second locking assembly includes at least one locking arm connected to one of the housing, the cover member and the cartridge container.

80. The auto-injector according to claim 79, wherein at least a portion of the locking arm is received within an aperture when the needle cover is in the first locked position.

81. The auto-injector according to claim 80, wherein each locking arm has an exterior sliding surface formed on a strut, wherein the sliding surface is constructed and arranged to contact an edge of the aperture to temporarily compress the locking arm when the needle cover moves from the first retracted locked position to the second extended locked position.

82. The auto-injector according to claim 81, wherein each locking arm has a locking surface that is constructed and arranged to engage an outer edge of the needle cover when the

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needle cover is in an extended position to hold the needle cover in the second locked position.

83. The auto-injector according to claim 82, wherein each locking arm has a thick strut portion and a thin strut portion, wherein the thick strut portion is outwardly curved and the thin strut portion is inwardly curved, wherein the strut portions are constructed and arranged such that the locking arm can not be collapsed when the needle cover is in the second locked position such that the locking surface remains engaged with the outer edge of the needle cover.

84. The auto-injector according to claim 83, wherein the thin strut portion is constructed and arranged to prevent the collapse of the locking arm.

85. The auto-injector according to claim 79, wherein each locking arm is connected to the cartridge container.

86. The auto-injector according to claim 85, wherein each locking arm is spaced from the cartridge container such that the locking arm can be temporarily compressed against the cartridge container as the needle cover moves from the first locked position to the second locked position.

87. The auto-injector according to claim 86, wherein each locking arm has a locking surface to engage the needle cover when the needle cover is in the locked extended position.

88. The auto-injector according to claim 80, wherein each locking arm has a thick strut portion and a thin strut portion, wherein the thick strut portion is outwardly curved and the thin strut portion is inwardly curved.

89. The auto-injector according to claim 88, wherein the strut portions are constructed and arranged such that the locking arm can be temporarily compressed as the needle cover moves from the first locked position to the second locked position.

90. The auto-injector according to claim 55, wherein the cartridge container includes at least one ledge extending outwardly therefrom, wherein the at least one ledge is constructed and arranged to engage an edge of an opening in the needle cover to limit the travel of the needle cover with the respect to the cartridge container when the needle cover is in the extended position.

91. The auto-injector according to claim 55, wherein each of the needle cover and the cartridge container having an opening formed therein, wherein the openings are aligned prior to activation of the auto-injector such that a user can view the contents of the cartridge through the openings.

92. The auto-injector according to claim 91, wherein the cartridge container includes at least one ledge constructed and arranged to engage an edge in the opening in the needle cover to limit the travel of the needle cover with respect to the cartridge container.

93. The auto-injector according to claim 92, wherein the ledge engages one edge in the opening in the needle cover when the needle cover in the first locked position and the ledge engages another edge when the needle cover is in the second locked position.

94. The auto-injector according to claim 92, wherein the openings are not aligned after operation of the auto-injector such that the user can not view the contents of the cartridge through the openings.

95. The auto-injector according to claim 55, wherein the housing has an oval cross section in a lateral direction.

96. The auto-injector according to claim 55, wherein the actuation assembly is mounted within the housing adjacent an open end.

97. The auto-injector according to claim 96, wherein the actuation assembly has an actuation assembly housing having

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at least one projection extending therefrom, the at least one projection located within a complimentary opening formed in the housing.

98. The auto-injector according to claim 97, wherein the actuation assembly housing is located within the housing adjacent to and spaced from one end of the housing such that the actuation assembly housing and the housing form a recess.

99. The auto-injector according to claim 98, further comprising a release pin removably connected to the actuation assembly, the release pin being located in the recess.

100. The auto-injector according to claim 99, wherein the release pin has a pin removably recessing within an opening in the actuation assembly, wherein the auto-injector is not operable when the release pin is connected to the actuation assembly.

101. The auto-injector according to claim 100, wherein the release pin includes at least one tab extending therefrom, wherein the at least one tab is compression fit into a complimentary recess formed in the actuation assembly housing.

102. The auto-injector according to claim 96, further comprising a release pin removably attached to the actuation assembly, wherein the auto-injector is not operable when the release pin is connected to the actuation assembly.

103. The auto-injector according to claim 102, wherein a pin on the release pin is received within an opening in the actuation assembly to prevent actuation of the auto-injector.

104. The auto-injector according to claim 103, wherein the opening is spaced from the open end of the housing.

105. The auto-injector according to claim 34, wherein the release pin includes at least one tab extending therefrom, wherein the at least one tab is compression fit into a complimentary recess formed in the actuation assembly.

106. The auto-injector according to claim 55, wherein the actuation assembly comprises:

- an outer body;
- an inner body operatively coupled to the outer body;
- a collet operatively coupled to the inner body; and
- an energy source.

107. The auto-injector according to claim 106, wherein the collet is molded as a single piece.

108. The auto-injector according to claim 107, wherein the collet having an opening formed on one end, wherein the auto-injector further comprises a release pin removably attached to the actuation assembly, wherein the release pin is removably received in the opening in the collet to prevent operation of the actuation assembly.

109. The auto-injector according claim 108, wherein the collet is received within an opening in the inner body prior to a medicament dispensing sequence, wherein the collet is displaced from the opening at the initiation of the medicament dispensing sequence.

110. The auto-injector according to claim 109, wherein the collet has an elongated opening formed therein, wherein the release pin is received within the elongated opening.

111. The auto-injector according to claim 110, wherein the collet having at least one tapered portion, wherein the outer body having at least one surface constructed and arranged to contact the at least one tapered portion.

112. The auto-injector according to claim 111, wherein the at least one surface being constructed and arranged to contact the at least one tapered portion to compress the collet in an area around the elongated opening such that the collet is released from the inner body in response to application of an activation force.

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113. The auto-injector according to claim **107**, wherein the collet includes a flange, whereby the energy source is constructed and arranged to be positioned between the flange and an end of the inner body.

114. The auto-injector according to claim **113**, wherein the flange is constructed and arranged to contact the cartridge to limit the travel of the plunger within the cartridge.

115. The auto-injector according to claim **113**, wherein the flange is constructed and arranged to travel within the cartridge such that a full volume of medicament can be dispensed through the needle.

116. The auto-injector according to claim **106**, wherein the collet is operatively coupled to the plunger.

117. The auto-injector according to claim **106**, wherein the collet has an elongated opening formed therein, wherein one end of the opening has an arch construction.

118. The auto-injector according to claim **106**, wherein the inner body is constructed and arranged to receive different sized collets.

119. The auto-injector according to claim **106**, wherein the auto-injector is constructed and arranged such that the energy released from the stored energy source of the actuation assembly during the medicament dispensing sequence is opposed by a front end of the cartridge container and is not transmitted to the needle cover.

120. The auto-injector according to claim **119**, wherein the cartridge container, the cartridge, the housing, and the acti-

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vation assembly outer body receive residual force from the energy source after activation of the medicament dispensing operation to prevent kick back of the auto-injector during the injection operation.

121. The auto-injector according to claim **106**, wherein the auto-injector is constructed and arranged such that the energy released from the stored energy source to drive the needle and cartridge during a medicament dispensing sequence is opposed by a front end of the cartridge container and is not transmitted to the needle cover.

122. The auto-injector according to claim **121**, wherein the cartridge container within the auto-injector, the cartridge, the housing, and the activation assembly outer body receive residual force from the energy source after activation of the medicament dispensing operation to prevent kick back of the auto-injector during the injection operation.

123. The auto-injector according to claim **121**, wherein the housing, cartridge container and actuation assembly are constructed and arranged such that the energy released from the stored energy source to drive the needle and cartridge during a medicament dispensing sequence is not transmitted to the needle cover.

124. The auto-injector according to claim **55**, wherein the cartridge container having at least one tab contacting the cartridge to orient and align the cartridge within the cartridge container.

* * * * *

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS KING PHARMACEUTICALS, INC. and MERIDIAN MEDICAL TECHNOLOGIES, INC.	DEFENDANTS TEVA PARENTERAL MEDICINES, INC., and TEVA PHARMACEUTICALS USA, INC.
(b) County of Residence of First Listed Plaintiff <u>Tennessee corporation</u> (EXCEPT IN U.S. PLAINTIFF CASES)	County of Residence of First Listed Defendant _____ (IN U.S. PLAINTIFF CASES ONLY)
(c) Attorney's (Firm Name, Address, and Telephone Number) Steven J. Balick, ASHBY & GEDDES, 500 Delaware Avenue, 8th Floor, P.O. Box 1150, Wilmington, DE 19899 (302) 654-1888	NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED. Attorneys (If Known) Unknown

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)	III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)																								
<input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	<table style="width:100%;"> <tr> <th></th> <th>PTF</th> <th>DEF</th> <th></th> <th>PTF</th> <th>DEF</th> </tr> <tr> <td>Citizen of This State</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td><input type="checkbox"/> 4</td> <td><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td><input type="checkbox"/> 5</td> <td><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

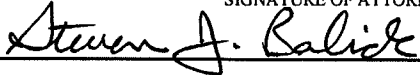
IV. NATURE OF SUIT (Place an "X" in One Box Only)					
CONTRACT <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	FORFEITURE/PENALTY <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	BANKRUPTCY <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	OTHER STATUTES <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

V. ORIGIN (Place an "X" in One Box Only)							
<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from another district (specify)	<input type="checkbox"/> 6 Multidistrict Litigation	<input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judgment	

VI. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): <u>Title 35 U.S. Code</u> Brief description of cause: <u>Action arising under the patent laws of the United States.</u>
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VII. REQUESTED IN COMPLAINT:	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$ <u>Declaratory & injunctive relief</u>	CHECK YES only if demanded in complaint: JURY DEMAND: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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VIII. RELATED CASE(S) IF ANY	(See instructions): JUDGE _____ DOCKET NUMBER _____
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DATE 08/28/2009	SIGNATURE OF ATTORNEY OF RECORD 
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RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____