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(54) **SINGLE-USE NEEDLE-LESS HYPODERMIC JET INJECTION APPARATUS AND METHOD**

(75) Inventor: **Sergio Landau**, Laguna Niguel, CA (US)

(73) Assignee: **Bioject, Inc.**, Tualatin, OR (US)

(21) Appl. No.: **10/627,552**

(22) Filed: **Jul. 24, 2003**

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Reissue of:

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Issued: **Jul. 24, 2001**
Appl. No.: **09/252,131**
Filed: **Feb. 18, 1999**

U.S. Applications:

(63) Continuation-in-part of application No. 09/195,334, filed on Nov. 18, 1998, now Pat. No. 6,096,002.

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A61M 5/30 (2006.01)
A61M 37/00 (2006.01)

(52) **U.S. Cl.** **604/68**; 604/69; 604/143

(58) **Field of Classification Search** 604/68–72, 604/140, 141, 143, 148, 232, 131
See application file for complete search history.

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Primary Examiner — Kevin C Sirmons
Assistant Examiner — Andrew M Gilbert
(74) *Attorney, Agent, or Firm* — Schwabe, Williamson & Wyatt, P.C.

(57) **ABSTRACT**

A gas-powered, single-use, needle-less hypodermic jet injection device includes a hand-held injector, and a drug injection cartridge which provides a cylinder of liquid medication to be injected, an injection orifice, and an injection piston. Forceful movement of the injection piston in the cylinder causes an injection jet of medication to be expelled from the injection orifice. The injection device also includes a hermetically sealed gas pressure capsule which remains sealed until the moment of injection and powers the jet injection after opening of this cartridge.

35 Claims, 4 Drawing Sheets

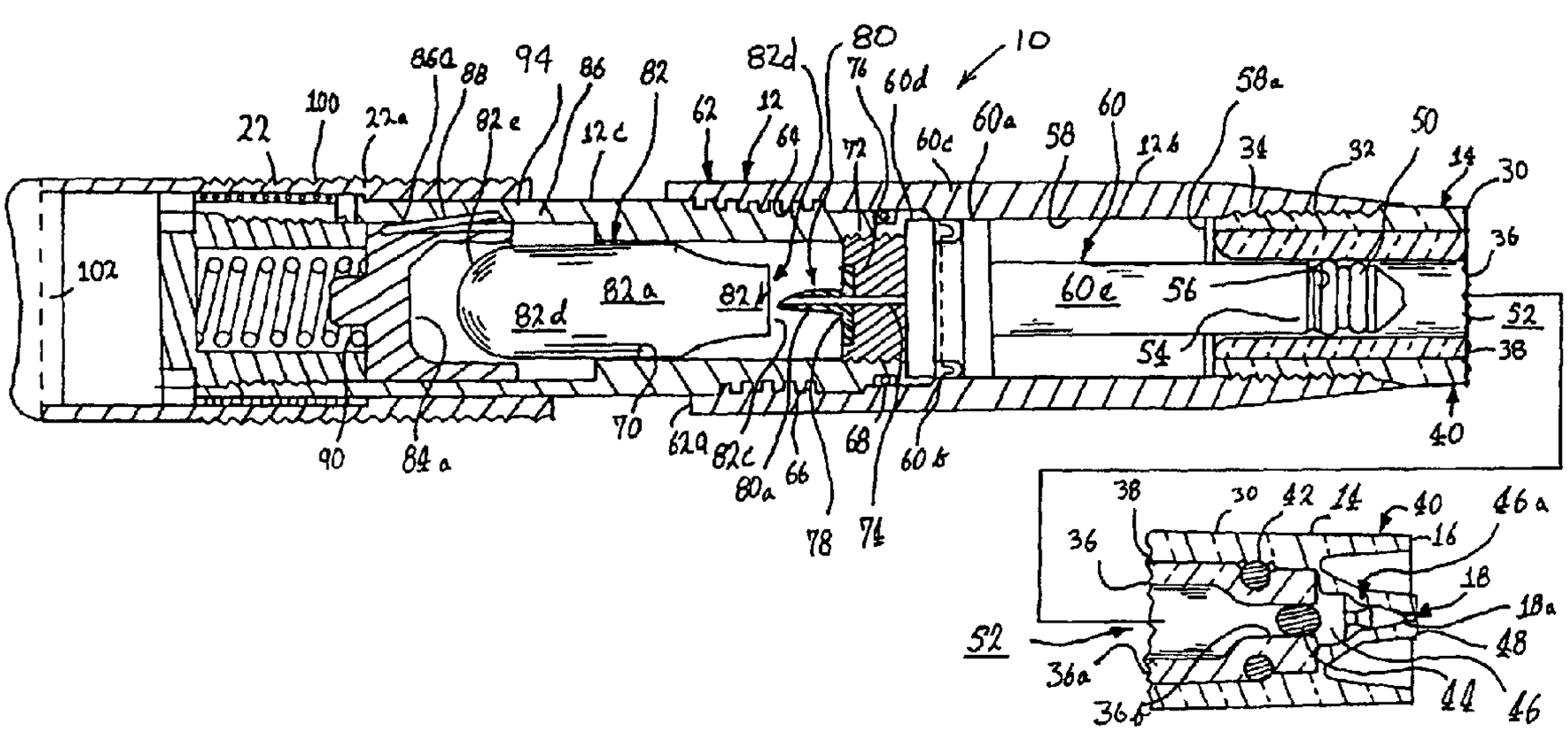


FIG. 1.

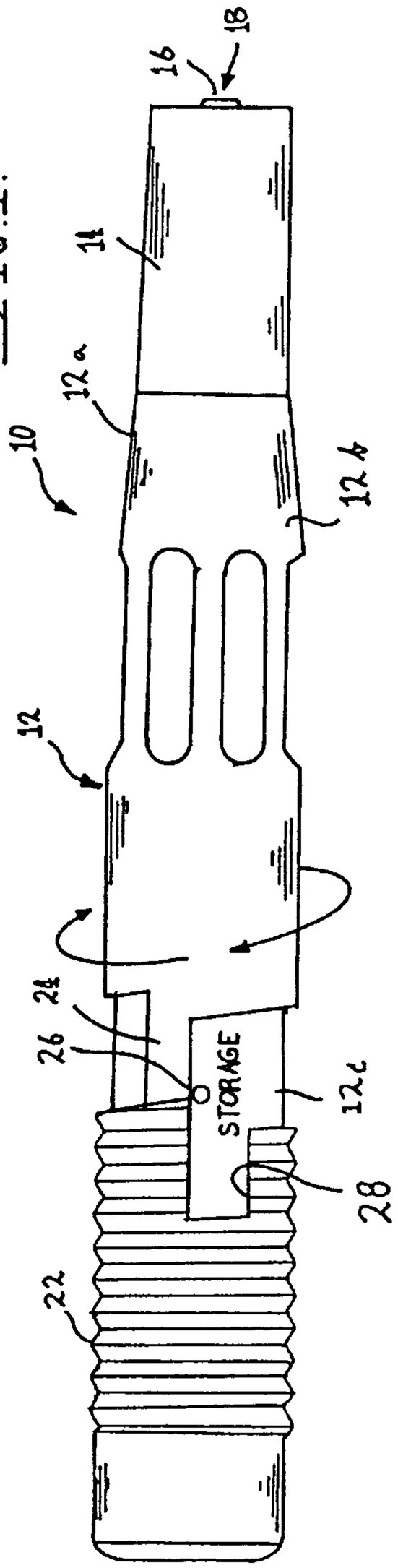

16
18
14
12a
10
12b
12
24
26
STORAGE
12c
28
22

FIG. 2.

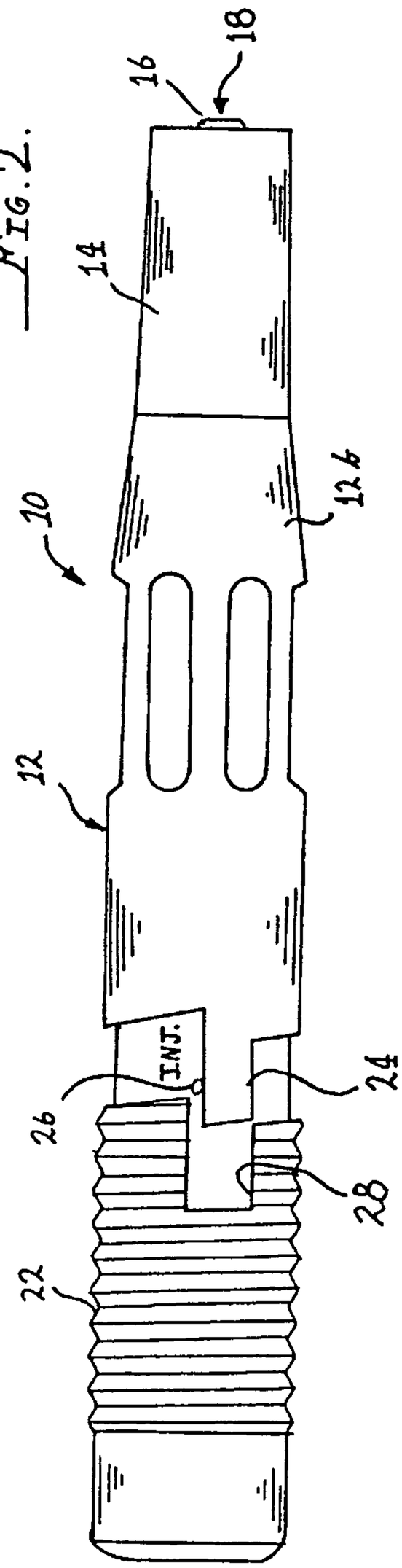
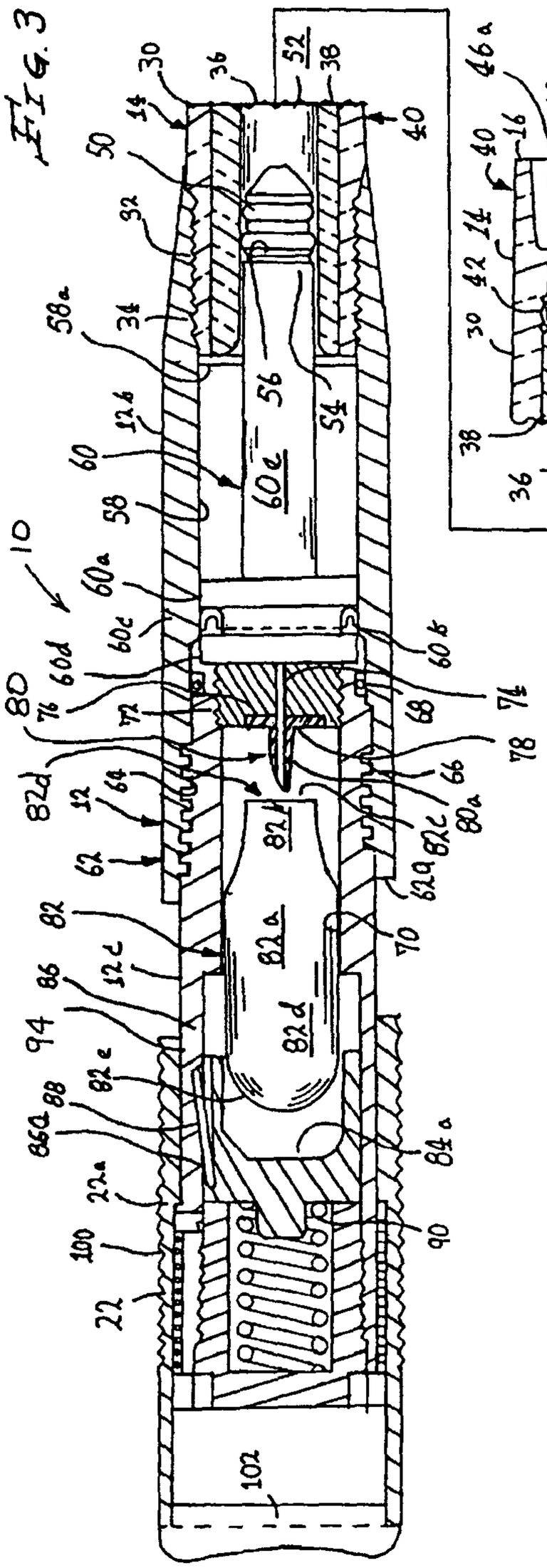

16
18
14
10
12b
12
INJ.
24
26
28
22

FIG. 3


10
12
12a
12b
12c
12d
14
16
18
18a
22
22a
30
32
34
36
36a
36b
38
40
42
44
46
46a
48
50
52
54
56
58
58a
60
60a
60b
60c
60d
62
64
66
68
70
72
74
76
78
80
80a
82
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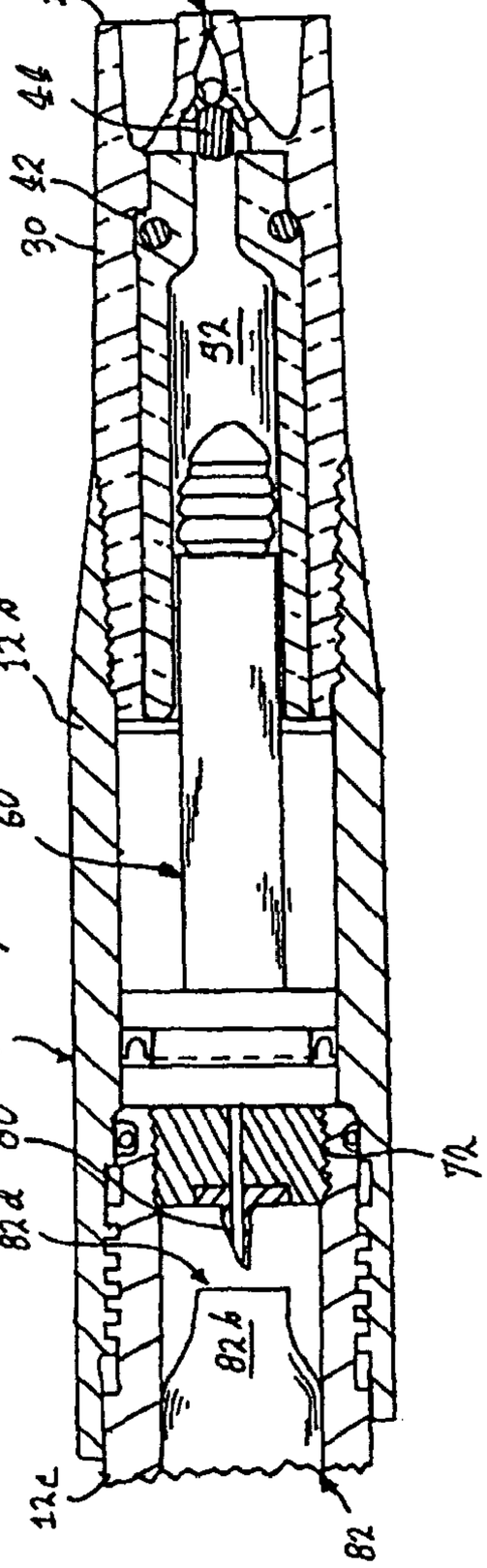
82b
82c
82d
84
84a
86
86a
88
90
94
100
102

FIG. 4.


10
12
12b
12c
16
18
30
32
42
44
52
60
72
80
82
82b

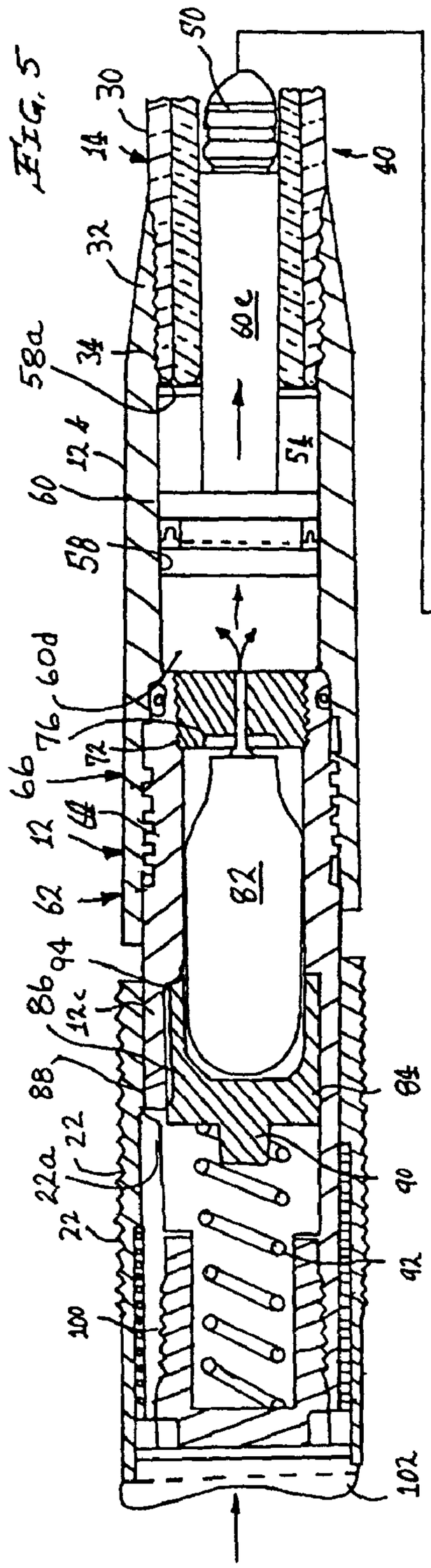


FIG. 5
50
30
14
40
32
40c
58a
34
54
60
12
58
60d
76
66
72
12
64
62
82
86
94
12c
88
84
22a
22
90
100
92
102

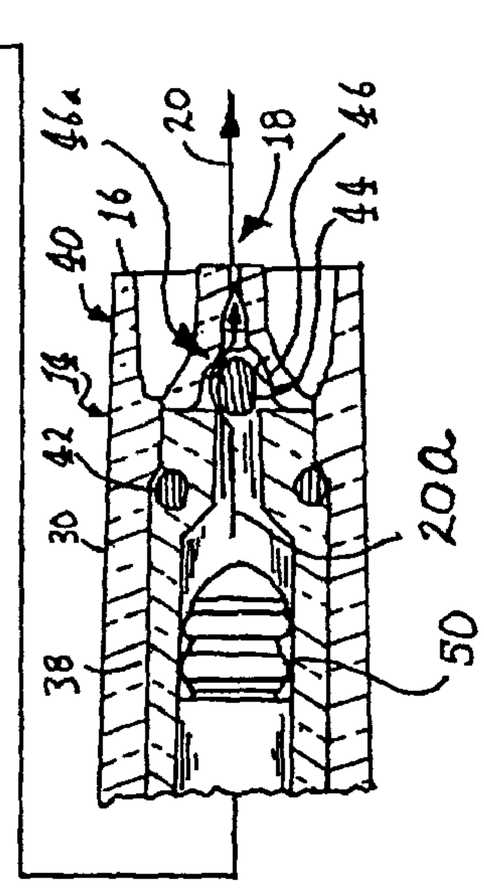
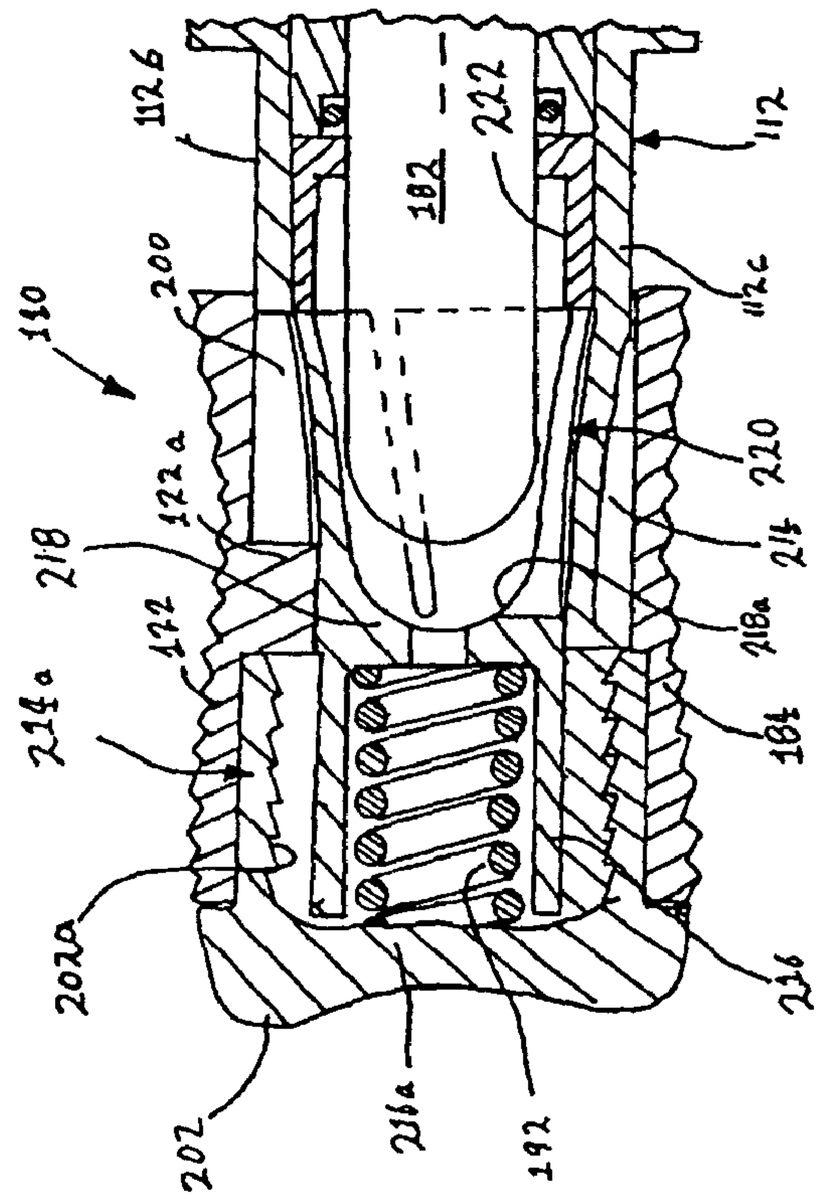

46a
20
18
46
16
40
44
14
42
30
202
38
50

FIG. 6.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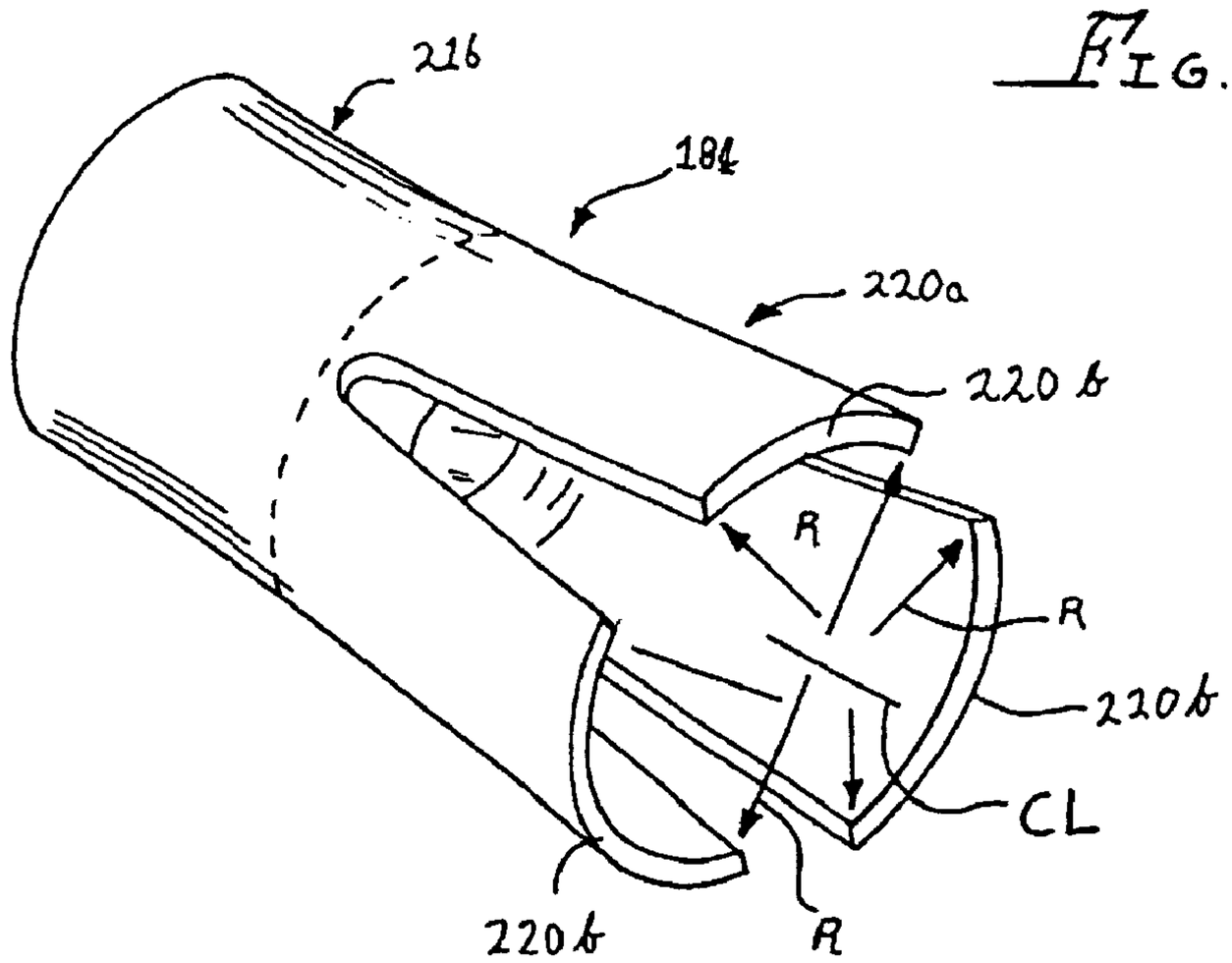
112b
222
112
182
200
112c
220
122a
218
214
218a
122
184
214a
202a
216
202
216a
192

FIG. 7.


216
184
220a
220b
R
R
220b
CL
220b
R

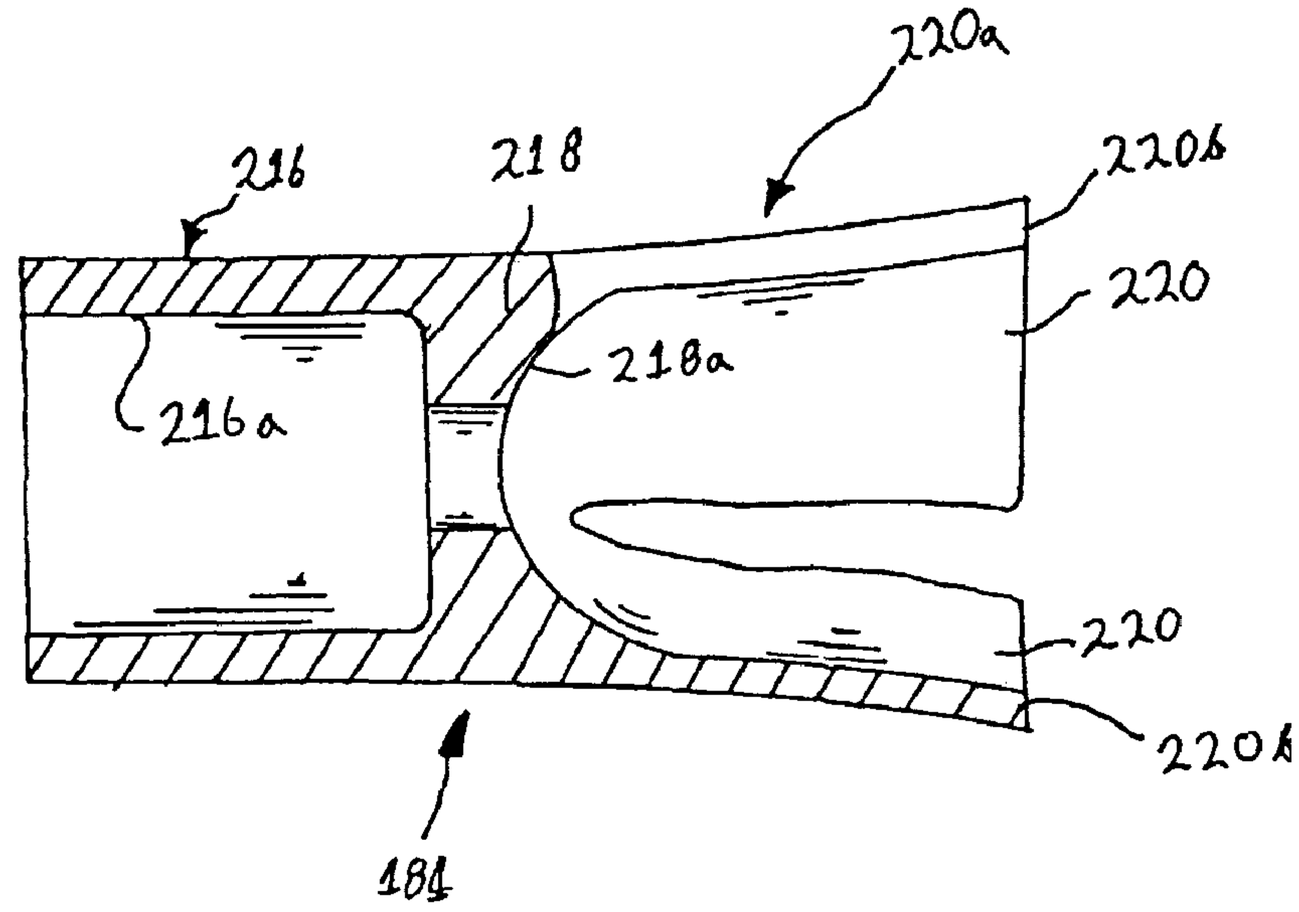

220a
216
218
220b
220
218a
216a
220
220b
184

FIG. 8.

SINGLE-USE NEEDLE-LESS HYPODERMIC JET INJECTION APPARATUS AND METHOD

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

CROSS REFERENCE TO RELATED APPLICATION

This application is a Continuation-in-Part of U.S. patent application Ser. No. 09/195,334, filed Nov. 18, 1998, now U.S. Pat. No. 6,096,002.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a single-use disposable needle-less (or needle-free) hypodermic jet injection device. Particularly, this invention relates to such a jet injection device which comprises a hand-held injector having a pre-filled drug cartridge sealingly carrying injectable medication, a sealed cylinder of pressurized gas, a pre-energized discharge mechanism for penetrating the gas cylinder, and a trigger device for releasing the discharge mechanism. Features are provided which simultaneously unseal the drug cartridge and prepare the device for performing a jet injection when a user of the device changes it from a storage configuration to a use configuration. When the user actuated the injection device, the trigger device releases the discharge mechanism to penetrate the gas cylinder, which drives a piston of the drug cartridge to effect a hypodermic jet injection.

2. Related Technology

Needle-less or needle-free hypodermic jet injection devices have been in commercial use for over 40 years. A number of these devices have used pressurized gas to power a hypodermic jet injection. The related technology includes a number of teachings for gas-powered injection devices, including: U.S. Pat. No. 4,596,556, issued Jun. 24, 1986 to J. Thomas Morrow, et al.; U.S. Pat. No. 4,913,699; issued Apr. 3, 1990 to James S. Parsons; and U.S. Pat. No. 5,730,723, issued Mar. 24, 1998, to Thomas P. Castellano, et al. WIPO publication WO 97/37705 also discloses a gas powered disposable needle-less hypodermic jet injector.

The Morrow, et. al. '556 patent is believed to teach a reusable hypodermic jet injection device in which a housing receives a shell or cartridge having a bore leading to a discharge aperture. Within the bore is received both a plunger sealingly engaging the bore, and a pressurized gas cylinder which rests against the plunger. The injection device includes a ram which has a penetrating tip confronting a penetrable wall section and seal of the gas cylinder, and a discharge mechanism for driving the ram through the penetrable wall section of the gas cylinder when a trigger device is released. Discharge of the pressurized gas from the cylinder drives the plunger to effect a jet injection, and also drives the seal of the gas cylinder to effect resetting of the discharge mechanism. The shell with its plunger, and spent gas cylinder, is discarded after an injection; and a new shell pre-filled with medication and with a new gas cylinder is used for each injection.

The Parsons '699 patent is believed to teach a single-use jet injector which is totally discarded after one use. This injector is believed to have a body with a pair of gas chambers separated by a breakable valve. One of the gas chambers contains a pressurized gas, while the other chamber is sealingly

bounded by a piston which drives a plunger. The plunger sealingly bounds a chamber into which a dose of medication is loaded by the user before the injection. This medication dose chamber leads to an injection orifice so that when the valve is broken, the piston and plunger are moved by pressurized gas communicated to the second chamber, and the plunger drives the medication forcefully out of the injection orifice to form an injection jet. After a single use, the device is discarded.

The Castellano '723 patent, which was issued in 1998 and which does not cite the earlier Parsons '699 patent, is believed to teach substantially the same subject matter as Parsons et al.

WIPO publication WO 97/37705 published pursuant to a Patent Cooperation Treaty (PCT) application for joint inventors Terence Weston and Pixey Thornlea, is believed to disclose a disposable hypodermic jet injector in which the device is powered by a gas pressure spring of the type common in the tool and die art as a substitute for the conventional metal spring-powered ejector pin. In the Weston device, the ram of the gas pressure spring is held in a contracted position by a trigger mechanism. When the trigger mechanism is released, the gas pressure spring is supposed to expand and drive a piston sealingly received in a bore and leading to a fine-dimension orifice in order to produce a jet hypodermic injection from liquid held in the bore ahead of the piston.

The Weston device is thought to have several deficiencies: such as difficult and costly manufacturing and sterilization processes, because pressurized gas and a drug dose need to be contained in the same package; and including a possible inability to endure long-term storage while still retaining the gas pressure in the gas spring to power an injection, and also maintaining the medication integrity. In other words, the gas pressure spring of the Weston device contains only a small quantity of gas, and depends upon the sealing relationship of the ram of this spring with a cylinder within which the ram is movably and sealingly received in order to retain this gas pressure. Even a small amount of gas leakage over time will be enough to render this injector inoperative.

SUMMARY OF THE INVENTION

In view of the above, it is desirable and is an object for this invention to provide a needle-less hypodermic jet injection device which reduces the severity of or avoids one or more of the limitations of the conventional technology.

Thus, it is an object of this invention to provide a single-use, disposable, needle-free gas-powered hypodermic jet injector utilizing a pressurized gas source which is hermetically sealed until the moment of injection.

Further, an object of this invention is to provide such a gas powered jet injector in which the device has a storage configuration and a use configuration. In the storage configuration, the device is safe, with the drug cartridge sealed closed, and is incapable of effecting a jet injection. In the use configuration, the device is prepared for making a jet injection, with the drug cartridge opened in preparation for this injection.

Additionally, an object for this invention is to provide such an injection device having a multi-function component which alternatively maintains the injector in a safe storage condition, and also allows a user to place the injection device into a use condition preparatory for performing a jet injection. When the user placed the device into the use configuration, the multi-function component prepares the jet injection device by effecting unsealing of the previously sealed drug cartridge, and also removes a safety block from an obstructing position relative to a trigger of the device. Thereafter, the

trigger of the injector can be manually activated by a user of the device to perform an injection.

Accordingly, a needle-less hypodermic jet injection system embodying this invention includes, for example: a hand piece assembly having a body including a drug injection cartridge with a medication cylinder pre-filled with substantially incompressible liquid medication such that substantially no ullage volume exists in said medication cylinder, said medication cylinder leading to an outlet orifice a plug-capture chamber and a drug injection nozzle, a sealing member sealingly and movably received in said outlet orifice, and a drug-injection piston; the hand piece assembly further defining a first bore within the body for movably receiving a gas-power piston, a gas power piston movably received in the first bore and having a ram portion extending into the drug injection cartridge to abut with the drug-injection piston, the body and gas-power piston cooperating to define a first variable-volume chamber in the first bore; the body also defining an elongate second bore in gas communication with the first bore and separated therefrom by a center wall portion of the body, a cylindrical gas capsule received into the second bore, the gas capsule having a penetrable wall section disposed toward the center wall, the center wall carrying a penetrator disposed toward the penetrable wall section of the gas capsule, and the hand piece assembly carrying a discharge mechanism including a trigger member outwardly disposed on the body and a hammer movable in the body in response to actuation of the trigger to forcefully move the gas capsule in the second bore so as to impale the gas capsule at the penetrable wall section thereof upon the penetrator and thus to communicate pressurized gas to the first chamber; whereby, the pressurized gas in the first chamber drives the gas-power piston to effect a hypodermic jet injection from the drug injection cartridge, and the body and trigger member cooperatively defining a first relative position in which said ram portion confronts but does not displace said injection piston so that said sealing member is disposed in said outlet orifice to maintain said drug injection cartridge sealingly closed, and said body and trigger member in a second relative position preparatory to effecting a jet injection causing said ram portion to abut and move said drug injection piston to a second position displacing said drug injection piston to a second position so that said sealing member is displaced from said outlet orifice into said plug-capture chamber by said liquid medication and unseals said drug injection cartridge.

Additional objects and advantages of this invention will appear from a reading of the following detailed description of a single exemplary preferred embodiment, taken in conjunction with the appended drawing Figures, in which the same reference numeral is used throughout the several views to indicate the same feature, or features which are analogous in structure or function.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

FIG. **1** provides an exterior side elevation view of a single-use, needle-less hypodermic jet injector device embodying the present invention, and in which the device is in a "storage" configuration;

FIG. **2** is an exterior side elevation view of the injector device seen in FIG. **1**, but with the device shown in an "inject" configuration preparatory to effecting a hypodermic jet injection;

FIG. **3** provides a longitudinal cross sectional view through the needle-less hypodermic jet injection device of FIG. **1**, and shows the device in the "storage" configuration;

FIG. **4** is a fragmentary cross sectional view similar to FIG. **3**, but shows the hypodermic jet injection device in the "inject" configuration;

FIG. **5** is also a fragmentary cross sectional similar to FIGS. **3** and **4**, but shows the hypodermic jet injection device during the process of effecting a jet injection;

FIG. **6** is a fragmentary cross sectional view similar to a portion of FIG. **4**, but shows a respective portion of an alternative embodiment of a single-use, needle-less hypodermic jet injection device according to the present invention;

FIG. **7** is a perspective view of a portion of the device seen in FIG. **6**; and

FIG. **8** provides a cross sectional view of the portion of the device seen in FIG. **7**.

DETAILED DESCRIPTION OF EXEMPLARY PREFERRED EMBODIMENTS OF THE INVENTION

Overview, Storage of the Device, and its Preparation for Effecting a Jet Injection

Viewing FIG. **1**, a needle-free, hypodermic jet injection device **10** is shown in a storage configuration in which it is maintained until it is prepared for its use in administering an injection. In this storage configuration, the device is incapable of effecting a jet injection, is safe, and can be stored for a comparatively long time while requiring only a moment of preparation before it can be used to make a jet injection of the medication within the device **10**.

The device **10** includes a hand piece assembly **12**, preferably fabricated principally of injection molded plastic polymers, and with a body **12**a including a pre-filled drug injection cartridge or medication cylinder **14**. The word "drug" as used herein is intended to encompass, for example, and without limitation, any medication, pharmaceutical, therapeutic, vaccine, or other material which can be administered by jet injection. Essentially, such an injectable medication is in the form of a substantially incompressible liquid, and as will be seen, this liquid substantially fills the drug injection cartridge so that no ullage volume of compressible gas is present in this cartridge.

The pre-filled drug injection cartridge **14** has an end surface **16** at which is defined a fine-dimension injection orifice or injection nozzle opening **18**. When the device **10** is used to effect an injection, a high velocity jet of liquid medication issues from this orifice (as is indicated by arrow **20** of FIG. **5**). To use the device **10**, it is first placed in an "inject" configuration, the end surface **16** is pressed against the skin of a patient who is to receive the jet injection, and then the device **10** is triggered so that the jet **20** issues out and penetrates the skin. Thus, the liquid medication enters the tissues of the patient without the use of a hypodermic needle.

Placing the device **10** in the "inject" configuration is effected manually by a user of the device **10** who rotates a first portion **12**b of the body **12**a relative to a second portion **12**c. As is seen in FIG. **1**, the body portion **12**c carries a trigger sleeve **22**, while the portion **12**b carries a projection **24** abutting this sleeve. The projection **24** and a blocking pin **26** cooperate to prevent the body portions **12**b and **12**c from being relatively rotated except in the direction of the arrow of FIG. **1**. When a user effects this relative rotation of the body portions **12**b and **12**c through a rotation of almost 360°, then this relative rotation aligns the projection **24** with a recess **28** on the trigger sleeve **22**, reveals the abbreviation of the word "inject" (indicated on FIG. **2** by the letters "INJ") on the body portion **12**c.

This relative rotation of the body portions **12**b and **12**c also effects a selected relative axial movement of these body portions toward one another (as will be further described below), and places the device **10** in the "inject" configuration seen in FIG. **2**. In this "inject" configuration, the device **10** is positioned with its surface **16** against the skin of the person who is to receive the injection, and an axial pressure is applied to the trigger sleeve **22**. The trigger sleeve **22** moves axially along the body portion **12**c, and this movement triggers the device **10** to effect injection jet **20** (recalling FIG. **5**).

Structure of the Device **10**

Turning now to FIGS. **3**, **4**, and **5**, in conjunction with one another, FIG. **3** shows the device **10** in the storage configuration of FIG. **1** preparatory to giving an injection. In FIG. **4** shows the device in the "inject" configuration, and FIG. **5** shows the device during the brief interval of an injection. In these Figures, it is seen that the drug cartridge **14** includes a cylindrical body **30** defining an external thread section **32**. This external thread **32** is threadably received by a matching internal thread section **34** of the body portion **12**b. Preferably, a thread locking compound, such as an anaerobic adhesive, is applied to the threads **32** of the cartridge **14** when it is assembled to the body portion **12**b during manufacture of the device **10**. Alternatively, a self-locking thread design or a thread-locking feature may be used on the device **10** to prevent the drug injection cartridge **14** from being removed from the device **10**. Thus, the cartridge is not removable from the device **10**, and the device **10** and cartridge **14** are disposed of after the first and only injection effected with the device **10**.

An advantageous feature of the device **10** embodying the present invention, and one which results from this construction of the device, is that the injection cartridge **14** may be manufactured and filled at a drug company (without the drug manufacture having to be concerned with handling capsules of pressurized gas), the gas pressure capsule of the device may be manufactured and filled at a factory devoted to this item (without this manufacturer having to handle drugs), and the hand piece assembly of the device may be manufactured at yet another location, if desired. Subsequently, completion of the device **10** requires merely the combining of the hand piece assembly, gas capsule, and drug injection cartridge.

The body **30** of cartridge **14** defines a stepped through bore **36** having a larger diameter portion **36**a which extends substantially the length of the body **26**. Adjacent to the forward end of the body **30** (i.e., adjacent to the end defining surface **16**), the bore **36** steps down and defines an outlet orifice **36**b. It is seen that the bore portion **36**a and outlet orifice **36**b are defined by a glass sleeve **38** which is received into a molded plastic body **40**. An O-ring type of seal member **42** prevents leakage between the glass sleeve **38** and the body **40**.

As those who are ordinarily skilled in the pertinent arts will understand, many medications are not suitable for long-term storage in contact with plastics, but will store satisfactorily in contact with glass. Thus, this construction of the cartridge **14** makes it suitable for long-term storage of even medications of this nature. However, for medications that will store satisfactorily in contact with plastic polymers, this construction detail is optional and the entire injection cartridge body **30** may be formed of a selected polymer.

In the embodiment of cartridge **14** having the glass sleeve **38**, the outlet orifice **36**b is sealingly closed in the storage configuration of the device **10** by a plug **44**. Importantly, viewing FIGS. **3**-**5**, it is seen that the cartridge **14** defines a plug-capture chamber **46** immediately outside of the outlet orifice **36**b (i.e., rightwardly of this outlet orifice, viewing FIGS. **3**-**5**). The plug capture chamber **46** includes a radial array **46**a of individual radially inwardly and axially extending ribs **48** disposed in a spaced relation to the outlet orifice **36**b. These ribs **48** are arrayed radially about and in a transition bore portion **18**a leading to the injection orifice **18**. Thus, as will be seen, the plug member **44** can be received into the plug-capture chamber **46** and be supported on the ribs **48** without it blocking the injection orifice **18**.

Sealingly and movably received in the bore section **36**a is a resilient piston member **50**. This piston member defines multiple circumferential grooves **50**a interdigitated with sealing ribs **50**b. The sealing ribs **50**b sealingly and movingly engages the bore **36**a of the injection cartridge (i.e., with the bore **36**a of glass sleeve **38** in this case). The piston member **50** and body **30** cooperatively define a medication chamber **52** communicating outwardly of the cartridge **14** via the injection orifice **18**. Prior to its use to effect an injection, the orifice **18** of each fresh and pre-filled device **10** will ordinarily also be sealed by an adhesively-applied, peel-off type of sealing membrane, which may be formed, for example, of foil or of a polymer/paper laminate. Such peel-off seals are conventional and well known, and for this reason, the seal formerly on cartridge **14** of device **10** as seen in FIG. **3** is not shown in the drawing Figures.

Further considering the cartridge **14**, it is seen that the piston member **50** defines an abutment surface **54** confronting the opening of bore **36** on body **30**. This surface **54** is abutted by an end surface **56** on an injection ram of the hand piece assembly **12** (which injection ram will be further described below). In the storage configuration of the device **10**, the end surface **56** confronts piston member **50**, but does not displace it from the position seen in FIG. **3**. In this storage configuration of the device **10**, the chamber **52** is sealed and is substantially full of incompressible liquid, without any substantial ullage volume of compressible gas being in the chamber **52**. The injection ram will be understood as effective during a jet injection to forcefully move the piston member **50** inwardly of the bore section **36**a toward the outlet orifice **36**b.

Hand Piece Assembly **12**

Considering now the hand piece assembly **12** in greater detail, as seen in FIGS. **1**-**5**, it is seen that the body **12**a generally is formed of two main cooperative tubular sections **12**b and **12**c, which are threadably engaged with one another to form the hand piece assembly **12**. Preferably both of the body sections **12**b and **12**c, as well as other components of the device **12** not otherwise identified as being made of some other material, are all formed of plastic polymers. Further, the preferred process for making the device **10** is by injection molding of the components formed of plastic polymer, so that manufacturing costs are very low. Materials utilization for the device **10** is very small as well, so that disposing of the device after a single injection does not cause a serious environmental concern.

The forward tubular body section **12**b defines a stepped through bore **58**, a forward portion **58**a of which opens at **58**b forwardly on the body **12**, and which inwardly of this bore opening **58**a defines the internal thread section **34** for threadably receiving the external threads **32** on the drug cartridge **14**. Sealingly and movably received in the bore portion **58**a is a stepped injection piston member **60**. A larger diameter portion **60**a of this piston member defines a groove **60**b carrying a seal member **60**c. The seal member **60**c movingly engages sealingly with the bore portion **58**a and bounds a gas pressure chamber **60**d, which is to the left of this piston member as seen in FIGS. **3**, **4**, and **5**. It is to be noted that in FIGS. **3** and **4**, this chamber **60**d is at a minimal volume, and so the lead line from reference numeral **60**d extends into the interface of the piston member **60** with the housing portion **12**c.

A smaller diameter portion **60**e of the piston member **60** is elongate and extends in the bore **58** to also be received into the bore portion **36**a of the drug cartridge **14**, as is seen in FIG. **3** in the storage configuration of the device **10**. The piston portion **60**e defines the end surface **56** which confronts and abuts the surface **54** of the piston member **50** of an drug cartridge **14**. Thus, the piston portion **60**e provides the injection ram of the device **10**.

Considering the forward body section **12**b in still greater detail, it is seen that this body section defines a tubular aft body section **62**. This aft body section includes an axially disposed end surface **62**a at which the stepped through bore **58** opens, and which defines an internal thread section **64** threadably engaging onto matching threads **66** of body section **12**c. For purposes of explanation, and without limitation of the present invention, the threads **64** and **66** may have a pitch of about **14** threads per inch.

As is seen comparing FIGS. **1** and **2**, the device **10** is converted from its storage to its "inject" configuration by rotating the body portions **12**b and **12**c in a relative rotational direction that threads these body portions together along threads **64** and **66**. As was explained above, this relative rotation of the body sections **12**b and **12**c brings projection **24** into alignment with recess **28** on trigger sleeve **22**, and makes possible the subsequent triggering of the device **10**.

Still considering FIGS. **2** and **3**, it is seen that the aft body portion **12**c outwardly defines the thread section **66** and slidably carries the trigger sleeve **22**. Adjacent to the thread section **66**, the body portion **12**c carries an O-ring type of sealing member **68** which sealingly engages the body portion **12**b both when the body portions are in their "storage" relative configuration of FIG. **3**, and also when these body portions are in their "inject" relative positions as is seen in FIGS. **4** and **5**.

Body portion **12**c defines a stepped through bore **70** which is substantially closed at the end of this bore adjacent to the forward body portion **12**b by a wall member **72**. This wall member **72** defines a stepped through bore **74** in a larger diameter part of which is seated a disk part **76** of a penetrator member **78**. This penetrator member **78** includes a hollow penetrator spike **80** which itself has a bore **80**a communicating through the wall member **72** via the smaller diameter portion of bore **74**. Thus, the bore **70** is communicated to the chamber **60**d adjacent to injection piston **60** in the body portion **12**b.

Slidably received in the bore **74** adjacent to and confronting the penetrator member **78** is a gas pressure capsule **82**. This gas pressure capsule **82** includes a body **82**a, having a cylindrical outer wall portion **82**a'. The capsule **82** is also necked down at a forward end to provide a reduced diameter portion **82**b leading to an axially disposed end surface **82**cdefined by a penetrable wall section **82**d (the wall section being indicated by the arrowed numeral in FIG. **3**). The gas capsule **82** is preferably formed of metal, and contains a supply of pressurized gas. Because the pressurized gas is contained in the capsule **82** until the moment of injection, the plastic parts of the device **10** are not exposed to or stressed by this pressurized gas until an injection is effected using the device **10**. For this reason, the device **10** is believed to have a much more reliable storage life then prior devices which attempt to contain pressurized gas in a plastic or plastic-composite containment.

The wall section **82**d confronts and is spaced slightly from the penetrator spike **80**. At an opposite or aft end of the capsule **82**, this capsule defines an outwardly rounded end wall **82**e.

Also slidably received into the bore **70** and confronting the end **82**e of capsule **82** is tubular and cylindrical hammer member **84**. This hammer member **84** defines an end surface **84**a which is engageable with the surface **82**e of capsule **82**, an axially extending groove **86** having an end wall at **86**a (into which a dowel pin **88** is received), and an axial protrusion at **90** which serves to center a spring **92**.

The dowel pin **88** is engaged in a first position (i.e., in the "storage" configuration of the device **10**) at end **86**a of groove **86**, and the other end of this pin rests upon a metal (i.e., preferably hardened steel) sear pin **94** carried by the body portion **12**c. Thus, as is seen in FIGS. **3** and **4**, the hammer **84** is maintained in a "cocked" position with the spring **92** preloaded between the hammer **84** and a spring seat member **96** threadably engaging into the end of body portion **12**c.

In order to provide for movement of the trigger sleeve **22** to effect release of the hammer **84**, the body portion **12**c defines an axially extending slot **100**, and the trigger sleeve **22** carries a radially inwardly extending trigger block **22**a, which is slidably received in this slot **100** and which confronts the dowel pin **88**, as is seen in FIG. **3**. Also, an end cap **102** is adhesively retained onto the trigger sleeve **22** and closes the end of this trigger sleeve so that a user's thumb, for example, may be used to effect forward movement of the trigger sleeve when an injection is to be effected. It will be understood that the trigger sleeve **22** may alternatively be grasped between the thumb and fingers, for example, to position the device **10** for making an injection, and then effecting forward movement of the trigger sleeve **22** to effect this injection.

However, as was pointed out above in connection to the comparison of FIGS. **1** and **2**, the device **10** is first placed by a user into its "inject" configuration before a jet injection can be effected. This conversion of the device **10** from its "storage" configuration to its inject configuration is effected by relative rotation of the body portions **12**b and **12**c, as is indicated by the arrow on FIG. **1**. As is seen in FIG. **2**, this relative rotation of the body portions **12**b and **12**c brings the projection **24** into engagement with blocking pin **26** and into alignment with recess **28**, so that the trigger sleeve **22** is movable in the axial direction toward body portion **12**b. However, viewing FIG. **4**, it is seen that this relative rotation of the body portions **12**b and **12**c also threads body portion **12**c by substantially one thread pitch dimension into the body portion **12**b.

Because the body portion **12**c and wall member **72** are abutting injection piston member **50**, this piston member **50** is moved rightwardly, viewing FIG. **4**, by substantially one thread pitch dimension. Consequently, the ram portion **60**e of the injection piston **60** moves forward and forces piston member **50** forwardly by a sufficient amount that plug member **44** is dislodged hydraulically (recalling that the liquid medication in chamber **52** is substantially incompressible) from the outlet orifice **36**b and into plug-capture chamber **46**. In this chamber **46**, the plug member **44** is retained an rests upon the ribs **48** while these rib provide a flow path leading (indicated by arrow **20**a in FIG. **5**) around the plug member **44** from the outlet orifice **36**b to the injection orifice **18**.

Although the conversion of device **10** from its "storage" configuration to its "inject" configuration unseals the injection cartridge **14**, this is not detrimental to the integrity of the medication in chamber **52** because it happens mere moments before the device **10** is used to inject the medication into a patient. This injection is effected by placement of the device **10** with its surface **16** against the skin at the intended location of injection, and sliding of trigger sleeve **22** forward (which also assists in seeing that the device **10** is held firmly to the

skin), so that the trigger block **102** slides along slot **100** to dislodge the dowel pin **88** from sear pin **94**, viewing FIG. **5**.

As is seen in FIG. **5**, the result is that the hammer member **84** is driven forward by spring **92**, impacts the capsule **82**, and impales this capsule at penetrable wall **82**d, as is seen in FIG. **5**. The result is the penetrator spike **80** penetrates the wall **82**c of the capsule **82**, and allows pressurized gas from this capsule to flow along the bores **80**a and **74** into the chamber **60**d. This pressurized gas in chamber **60**d drives piston member **60** forwardly, so that the piston member **50** in bore **36**a is also driven forwardly. Forward movement of piston member **50** drives the liquid medication out of chamber **52**, past the plug member **44** in plug-capture chamber **46**, and out of injection orifice **18**, forming injection jet **20**.

After the jet injection depicted in FIG. **5**, the device **10** is disposed of by the user of the device, and it is not again used. That is, the device **10** is a single-use device and is not designed or intended to be recharged or refilled. This design of the device **10** insures safety for those receiving an injection by use of the device **10** because they can be sure that only a new and never before used device is used to give them the injection. Further, the device **10** provides for long-term storage of the device and its pre-filled medication, so that devices **10** may be stockpiled in anticipation of such events as mass inoculations. The device **10** may be used under exigent circumstances as well, since it requires only a few seconds or less to convert it from its "storage" configuration to its "inject" configuration, after which the jet injection is immediately effected.

FIG. **6** provides a fragmentary view of an alternative embodiment of the jet injection device according to this invention. In FIG. **6**, only the aft or trigger assembly end of the device is illustrated. The forward end of the device and its pre-filled medication injection cartridge may be substantially as depicted and described above. Because the device illustrated in FIGS. **6-8** has many features that are the same as, or which are analogous in structure or function to those illustrated and described above, these features are indicated on FIGS. **6-8** using the same reference numeral used above, and increased by one-hundred (100).

Viewing FIGS. **6-8** in conjunction with one another, it is seen that the injection device **110** includes a body portion **112**c, which is necked to a slightly smaller diameter aft portion at **214**. This aft portion defines a plurality of circumferential barbs **214**a, and an end cap **202** is received on these barbs and is permanently engaged there by a matching set of inwardly extending barbs **202**a. Slidably received in this body portion **112**c is a one-piece molded hammer-and-sear member **184**.

Preferably, this member **184** is molded of plastic polymer. The hammer-and-sear member **184** is seen in perspective in FIGS. **7** and **8**. It is seen that this hammer-and-sear member **184** includes a cylindrical and tubular skirt section **216** defining a spring recess **216**a, into which the spring **192** is captively received and preloaded to make the device **110** ready for use. A center wall portion **218** of the member **184** provides a surface **218**a, which is engageable with the gas capsule **182** to move this capsule forward, and to impale the capsule on the penetrator spike (not seen in FIG. **6**, but recalling FIGS. **3-5** above). In order to hold the hammer-and-sear member against the pre-load of spring **192**, and to resist the pressure of this spring over a long term the member **184** includes three axially extending legs **220**.

Each of these legs **220** is a portion of a cone-shaped section **220**a, best seen in FIGS. **7** and **8**. The transition between the circular cylindrical section **216**, and the cone-shaped section **220**a is indicated with a dashed line circumscribing the member **184** in FIG. **7**. Forwardly of this transition, the legs **220** flare out by their own resilience. As is seen in FIG. **6**, these legs **220**, at an end surface **220**b of each one engage upon a ring-like abutment member or rear ring member **222** carried within the body portion **112**c. As is best appreciated by consideration of FIG. **7**, it is seen that the end surfaces **220**b of the legs **220** are not formed on the radius of the cone-shape at this end of the member **184** (i.e., at the cone diameter having a center line indicated as "CL" on FIG. **7**), but are formed at a smaller radius corresponding generally with the circular diameter of the section **216** (indicated by the radius lines and character "R" of FIG. **7**). During storage of the device **110**, these end surfaces **220**b rest upon the abutment member **222** and transfer the spring force from spring **192** to this abutment member on a long-term basis.

In order to prevent creep of the plastic polymer material from which the member **184** is formed, the surfaces **220**b define cooperatively, a contact area which corresponds substantially to that of the diameter **216** of the member **184** multiplied by the radial thickness of the legs **220**. This contact surface area is sufficient to prevent creeping of the polymer from which the member **184** is formed.

In order to effect release of the hammer-and-sear member **184** when it is desired to effect a jet injection with the device **110**, the body portion **112**c defines three axially extending slots **200** (only one of which is seen in FIG. **6**), each corresponding to a respective one of the legs **220**. As is seen in FIG. **6**, the trigger sleeve **122** carries three trigger blocks **122**a (again, only one of which is seen in FIG. **6**) which are slidably received in the slots **200**. When this trigger sleeve **122** is moved forward, the trigger blocks **122**a simultaneously force respective ones of the legs **220** radially inwardly and out of engagement with the abutment member **222**, overcoming both the inherent resilience of these legs and the component of spring force resulting from the radial flaring of these legs. It will be appreciated that in view of this combination of inherent resilience and outward flare of the legs **220**, there is virtually no risk that the device **110** will trigger except in response to deliberate forward movement of the trigger sleeve **122**.

Because the legs **220** are formed at a circular (rather than conical) radius, they nest together and are received into the ring-like abutment member **222**. Thus, the spring **192** forces the hammer-and-war member **184** forcefully forward, effecting a jet injection from device **110**, as was explained above.

While the invention has been depicted and described by reference to two particularly preferred embodiments of the invention, such reference does not imply a limitation on the invention, and no such limitation is to be inferred. The invention is capable of considerable variation and alteration in its embodiments without departing from the scope of this invention. Accordingly, the invention is intended to be limited only by the spirit and scope of the appended claims, giving cognizance to equivalents in all respects.

I claim:

1. A needle-less hypodermic jet injection device comprising:

a pre-filled drug injection cartridge including:

a medication cylinder having an outlet orifice,

an injection nozzle,

a flow path communicating the outlet orifice to said injection nozzle,

a drug-injection piston in a first position cooperating with said medication cylinder to define a variable-volume chamber of first selected size,

a dose of substantially incompressible liquid medication substantially filling said variable-volume chamber at said first size with substantially no ullage volume,

said drug-injection piston having a second position cooperating with said medication cylinder to define a variable-volume chamber of second selected size smaller than said first selected size;

a hand piece assembly having a body holding said drug injection cartridge, said hand piece assembly including a source of pressurized gas, and means for selectively applying force from said pressurized gas to said drug injection piston to move said drug injection piston from said second position to a third position substantially ejecting said dose of liquid medication via said injection nozzle;

said hand piece assembly including a first body portion holding said drug injection cartridge, and a second body portion manually movable relative to said first body portion, said second body portion including an abutment member selectively movable into engagement with said drug injection piston in response to manual relative movement of said first and second body portions to move said drug injection piston from said first position to said second position.

2. The device of claim **1**, wherein said hand piece assembly further includes a first bore within said first body portion, a gas power piston movably received in said bore and having a ram portion extending into said drug injection cartridge to abut with said drug-injection piston, said body and gas-power piston cooperating to define a first variable-volume gas-power chamber in said first bore;

said hand piece assembly further including a second body portion adjustably engaging with said first body portion, said second body portion defining an elongate second bore in gas flow communication with said first bore gas-power chamber and separated therefrom by a wall portion carried by said second body portion.

3. The device of claim **2** wherein said first body portion and said second body portion are threadably and adjustably engaged with one another, said second body portion carrying said abutment member.

4. The device of claim **3** wherein said wall portion includes said abutment member.

5. The device of claim **2** wherein said second body portion in said second bore further carries a cylindrical gas capsule, said cylindrical gas capsule providing said source of pressurized gas.

6. The device of claim **5** wherein said hand piece assembly second body portion is cylindrical, and a tubular trigger sleeve is movably carried by said second body portion to effect opening of said gas capsule.

7. A needle-less hypodermic jet injection device comprising:

a pre-filled drug injection cartridge including: a medication cylinder having an outlet orifice, a plug member in a first position sealingly closing the outlet orifice, an injection nozzle, a flow path communicating the outlet orifice to said injection nozzle and providing a chamber for capturing said plug member in a second position, a drug-injection piston in a first position cooperating with said medication cylinder to define a variable-volume chamber of first selected size, a dose of substantially incompressible liquid medication substantially filling said variable-volume chamber at said first size with substantially no ullage volume, said drug-injection piston having a second position cooperating with said medication cylinder to define a variable-volume chamber of second selected size sufficiently smaller than said first selected size that said plug member is hydraulically forced from said first position at said outlet orifice and to a second position in said chamber;

a hand piece assembly having a two-piece body having a first body portion holding said drug injection cartridge, and a second body portion providing an abutment movable relative to said first body portion to move said drug injection piston between said first and second positions;

a source of pressurized gas including a hermetically sealed metallic gas capsule;

trigger means for selectively penetrating said gas capsule and for applying force from said pressurized gas to said drug injection piston to move said drug injection piston from said second position to a third position substantially ejecting said dose of liquid medication via said injection nozzle.

8. The device of claim **7**, wherein said first body portion defines a first bore, a gas-power piston movably received in said first bore, said gas-power piston having a piston head and a ram portion extending into said drug injection cartridge to abut with said drug-injection piston, said first body portion and said gas-power piston cooperating to define a first variable-volume gas-power chamber in said first bore;

said second body portion sealingly and movably engaging with said first body portion to bound said gas-power chamber, said second body portion defining an elongate second bore in gas flow communication with said gas-power chamber, and said gas capsule being received into said second bore.

9. The device of claim **8** wherein said first body portion and said second body portion are threadably and adjustably engaged with one another, said second body portion including said abutment on a wall portion separating said second bore from said gas-power chamber.

10. A jet injection device comprising:

a drug cartridge having a cylinder in which is movable a piston to cooperatively define a variable-volume chamber for holding a dose of liquid medication;

a fine-dimension injection orifice in liquid flow communication with the variable-volume chamber to receive the liquid medication and discharge this medication as a high velocity forceful jet for hypodermic jet injection of the medication upon forceful movement of said piston in said cylinder;

a power source for forcefully moving said piston in said cylinder in response to triggering of said injection device, and

a trigger assembly for initiating forceful movement of said piston, said trigger assembly including a hammer member having a plurality of legs each having an end surface, a sear ring member upon which said end surfaces of said legs rests in a first position of the hammer member, means for urging said hammer member to a second position, and a trigger sleeve surrounding said hammer member and having a respective plurality of contact portions each engaging one of the plurality of legs to move said legs out of engagement with said sear ring upon axial movement of said trigger member.

11. The injection device of claim **10** wherein said hammer member includes a central wall portion from which extends in one axial direction a skirt defining a spring seat, said power source including a spring received into said skirt and into engagement with said central wall portion, said multitude of legs extending axially from said central wall portion in an opposite axial direction.

12. The injection device of claim 11 wherein said hammer member is a unitary molding of plastic polymer.

13. The injection device of claim 10 wherein said hammer member includes a first circular cylindrical portion and a second conically flaring portion axially arranged with one another.

14. The injection device of claim 13 wherein said first circularly cylindrical portion extends in one direction from said central wall portion, and said plurality of legs cooperatively define said second conically flaring portion and extend axially in said opposite axial direction from said central wall portion.

15. The injection device of claim 14 wherein said conically flaring portion has a conical diameter at an end of said hammer member, said plurality of legs are each part-circular segments having circular radii which are substantially equal to the radius of the circular cylindrical portion, whereby, said sear ring has an inner diameter substantially equal to said circular cylindrical portion of said hammer member and said plurality of legs in a second position are nested circumferentially adjacent to one another within said sear ring member.

16. A unitary elongate molded plastic polymer hammer member, said hammer member comprising:

a central wall portion extending radially;

a circular cylindrical portion extending axially in one direction from said central wall portion, said circular cylindrical portion including a tubular skirt and cooperating with said central wall portion to define a spring seat into which a spring may be received to engage upon said central wall portion;

a conically flaring portion extending in an opposite axial direction from said central wall portion, said conical portion including a plurality of circumferentially spaced apart resilient legs each extending axially to terminate in a respective axial end surface engageable with a sear ring in a first position of the legs to support said hammer member in opposition to force from the spring exerted on said central wall portion, said legs in said first position cooperatively defining a conical diameter at said end surfaces, and said legs at said end surfaces each also defining a circular radius which are substantially equal to the radius of said circular cylindrical portion;

whereby, said plurality of legs are movable to a second position in opposition to said resilience of said legs, in said second position said plurality of legs being circumferentially nested adjacent to one another and cooperatively defining a diameter substantially equal to that of said cylindrical portion.

17. A method of operating a needle-less hypodermic jet injection device using an injection cartridge having a cylinder receiving liquid medication, an orifice for forming the liquid into a high-velocity hypodermic injection jet, a plug member in a first position sealingly separating said medication from said orifice, and said plug member in a captive second position allowing communication of medication to said orifice, and an injection piston movable sealingly in said cylinder to displace said liquid medication via said orifice; said method including steps of:

providing said device with a two-piece body having a first body portion defining a first bore into which is received a gas-power piston, and a second body portion defining a second bore into which is sealingly and movably received a hermetically sealed pressurized gas capsule; utilizing said first and second body portions and said gas-power piston to cooperatively define a variable-volume chamber; and

first relatively moving said first and second body portions to forcefully move said plug member from said first position to said captive second position to unseal said injection cartridge, and then

utilizing communication of pressurized gas from said pressurized gas capsule into said variable-volume chamber to forcefully move said gas-power piston to displace said liquid medication from said cartridge via said orifice to effect a hypodermic jet injection.

18. The method of operating a needle-less injection device of claim 17 further including the step of utilizing a unitary molded plastic polymer hammer member to drive said gas capsule upon an impaling spike communicating pressurized gas to said variable-volume chamber.

19. A method of operating a needle-less hypodermic jet injection device using an injection cartridge having a cylinder receiving liquid medication, an orifice for forming the liquid into a high-velocity hypodermic injection jet, a plug member sealingly separating said medication from said orifice, and an injection piston movable sealingly in said cylinder to displace said liquid medication via said orifice; said method including steps of:

providing said device with a two-piece body having a first body portion defining a first bore into which is received a gas-power piston, and a second body portion defining a second bore into which is sealingly and movably received a hermetically sealed pressurized gas capsule; utilizing said first and second body portions and said gas-power piston to cooperatively define a variable-volume chamber; and

first relatively moving said first and second body portions to forcefully move said plug member to unseal said injection cartridge, and then

utilizing communication of pressurized gas from said pressurized gas capsule into said variable-volume chamber to forcefully move said gas-power piston to displace said liquid medication from said cartridge via said orifice to effect a hypodermic jet injection;

further including the step of providing said molded unitary plastic polymer hammer member with a plurality of axially extending legs each having an end surface engaging upon a sear ring surface to support said hammer member, and simultaneously slipping said plurality of legs off of said sear ring surface radially inwardly to be received in circumferentially adjacent nested position within said sear ring surface to allow axial movement of said hammer member.

20. A needle-free hypodermic jet injection device comprising:

a body substantially formed of plastic polymer;

a jet injection cartridge carried by said body and including a cylinder and piston cooperatively defining a variable-volume chamber receiving a dose of liquid medication, and a fine-dimension jet injection orifice in liquid flow communication with said variable volume chamber;

a metallic pre-filled hermetically-sealed single-use gas pressure cartridge axially movably disposed in said body, said gas pressure cartridge having a penetrable wall portion and said body including a penetrator axially spaced from and confronting said penetrable wall portion for penetrating said penetrable wall portion of said gas cartridge and releasing pressurized gas from said cartridge;

said device further including means responsive to pressurized gas released from said gas pressure cartridge for applying force to said liquid medication to eject said medication via said jet injection orifice;

said device further including means for selectively moving said gas pressure cartridge axially and impaling said gas pressure cartridge at said penetrable wall portion upon said penetrator in response to a singular user input so as to release pressurized gas from said gas pressure cartridge and to eject said medication via said jet injection orifice to effect a hypodermic jet injection.

21. A needle-less injection device, comprising:

a liquid container having an outlet orifice;

an injection orifice fluidly coupled with the outlet orifice and configured to inject liquid forwardly out of the needle-less injection device substantially along an injection axis into an injection site;

a plug member displaceable from a first position, in which it sealingly closes the outlet orifice, to a second position, in which liquid is permitted to flow out of the outlet orifice; and

plural bypass conduits defined between the outlet orifice of the liquid container and the injection orifice in a plug capture chamber when the plug member is in the second position, the plural bypass conduits being defined by walls of the plug capture chamber and the plug member such that the bypass conduits permit liquid to flow from the outlet orifice past the plug member to the injection orifice,

where a portion of the walls of the plug capture chamber extend at acute angles relative to a portion of the injection axis extending along the bypass conduits.

22. The device of claim 21, where the plug member moves forwardly along the injection axis when displaced from the first position to the second position.

23. The device of claim 21, where the bypass conduits converge forwardly of the plug member when the plug member is in the second position, such that streams of liquid flowing past the plug member through the bypass conduits converge into a single stream between the plug member and the injection orifice.

24. The device of claim 21, further comprising a plurality of ribs extending radially inward from the wall of the plug capture chamber.

25. The device of claim 24, where the bypass conduits are defined by the ribs, the wall of the plug capture chamber, and by the plug member when the plug member is in the second position.

26. The device of claim 25, where the plug member moves forward along the injection axis when displaced from the first position to the second position, and where the ribs are configured to block the plug member from further forward movement toward the injection orifice when the plug member is in the second position.

27. A needle-less injection device, comprising:

a liquid container having an outlet orifice;

an injection orifice fluidly coupled with the outlet orifice and configured to inject liquid forwardly out of the needle-less injection device substantially along an injection axis into an injection site;

a plug member displaceable from a first position, in which it sealingly closes the outlet orifice, to a second position, in which liquid is permitted to flow out of the outlet orifice; and

a plug capture chamber interposed between and fluidly coupling the outlet orifice with the injection orifice, the plug capture chamber being adapted to receive and hold the plug member when the plug member is displaced to the second position, so that the plug member does not prevent liquid from flowing from the outlet orifice to the injection orifice,

where plural bypass conduits are defined within the plug capture chamber such that, when the plug member is in the second position, the bypass conduits permit liquid to flow from the outlet orifice past the plug member to the injection orifice,

and where each bypass conduit is at least partially defined by a wall of the plug capture chamber that extends non-perpendicularly relative to the injection axis along the bypass conduit.

28. The device of claim 27, wherein a portion of the wall of the plug capture chamber that defines each bypass conduit extends at an acute angle relative to a portion of the injection axis extending along the bypass conduit.

29. The device of claim 27, where the plug member moves forwardly along the injection axis when displaced from the first position to the second position.

30. The device of claim 27, where the bypass conduits converge forwardly of the plug member when the plug member is in the second position, such that streams of liquid flowing past the plug member through the bypass conduits converge into a single stream between the plug member and the injection orifice.

31. The device of claim 28, where the plug capture chamber includes a plurality of ribs extending radially inward toward the injection axis.

32. The device of claim 31, where the bypass conduits extend between the ribs and are defined in part by the ribs.

33. The device of claim 32, where the plug member moves forward along the injection axis when displaced from the first position to the second position, and where the ribs are configured to block the plug member from further forward movement toward the injection orifice when the plug member is in the second position.

34. A needle-less injection device, comprising:

a liquid container having an outlet orifice;

an injection orifice fluidly coupled with the outlet orifice and configured to inject liquid forwardly out of the needle-less injection device substantially along an injection axis into an injection site; and

a plug member displaceable from a first position, in which it sealingly closes the outlet orifice, to a second position, in which liquid is permitted to flow out of the outlet orifice,

where the plug member contacts a plug capture structure within a plug capture chamber when in the second position, and where plural bypass conduits are formed in the plug capture structure to permit liquid to flow from the outlet orifice past the plug member to the injection orifice, and where the bypass conduits are defined at least partially by walls of the plug capture chamber and the plug member when in the second position, the walls extending at acute angles relative to a portion of the injection axis extending along the bypass conduits.

35. A needle-less injection device, comprising:

a container having an outlet orifice;

an injection orifice configured to inject liquid forwardly out of the needle-less injection device substantially along an injection axis into an injection site; and

a plug member displaceable from a first position, in which it sealingly closes the outlet orifice, to a second position, in which liquid is permitted to flow out of the outlet orifice and to the injection orifice,

where, in the second position, the plug member abuts a plug capture structure disposed between the outlet orifice and the injection orifice in a plug capture chamber, and

where a plurality of bypass conduits are formed in the plug capture structure by walls of the plug capture chamber and the plug member to permit liquid to flow from the outlet orifice around the plug member along the plurality of bypass conduits that converge forwardly of the plug member between the plug member and the injection orifice, each bypass conduit being shaped so that, liquid emerging from the bypass conduit into where the bypass conduits converge flows in an acute direction relative to a portion of the injection axis extending along the bypass conduits.

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