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(54) **MICRODISPENSING OPHTHALMIC PUMP**

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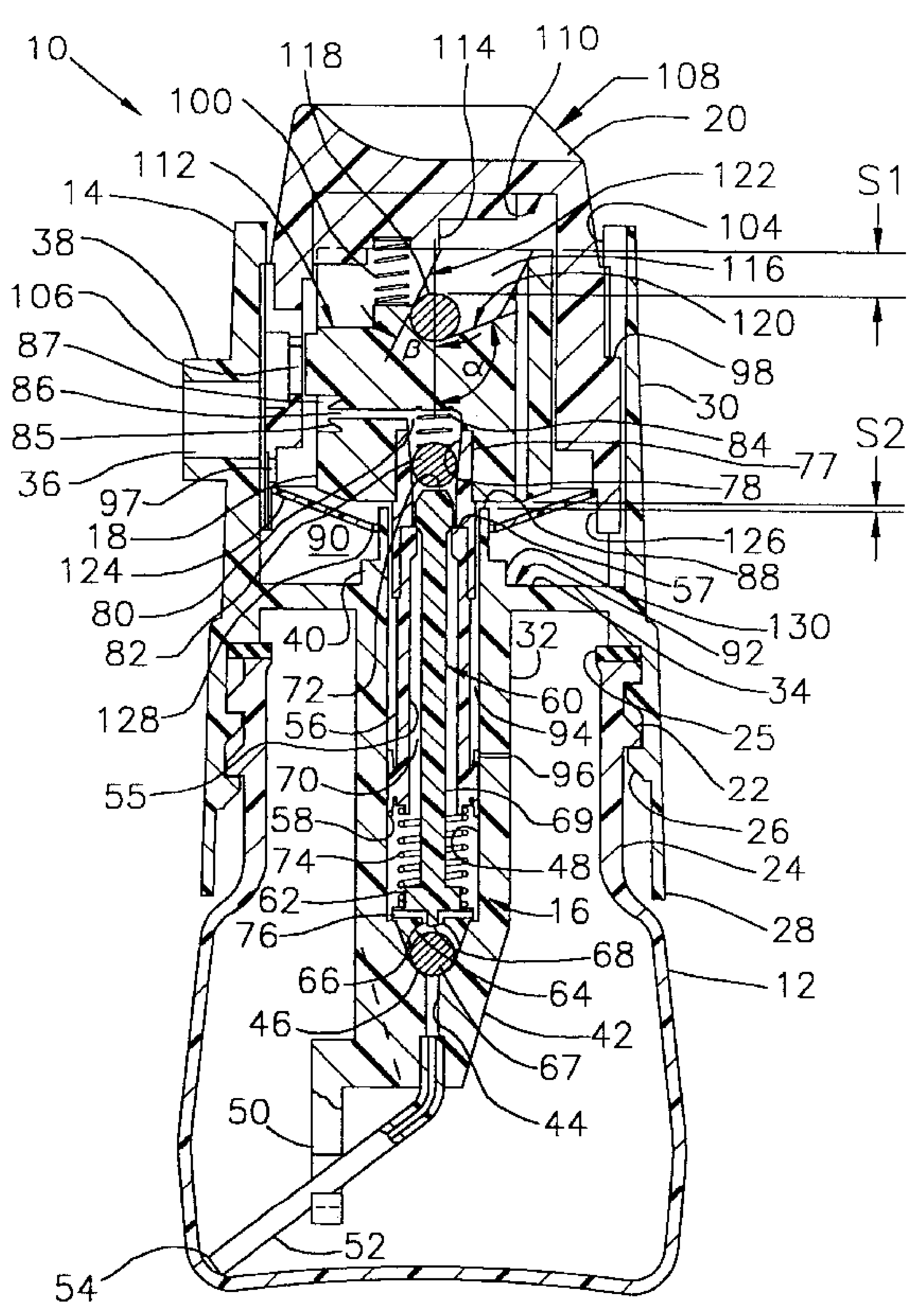
(57) **ABSTRACT**

A microdispensing ophthalmic pump is provided for repeatedly delivering doses as small as 5 microliters within an angular operating range. The pump basically comprises a reservoir, a dispensing cap, an actuator and a pump body with a pump mechanism disposed therein. The pump mechanism is regulated by a limited-travel inlet check valve and a biased-closed outlet check valve. A failsafe mechanism is formed between the actuator and dispensing cap to prevent operation of the pump outside the operating range.

40 Claims, 11 Drawing Sheets



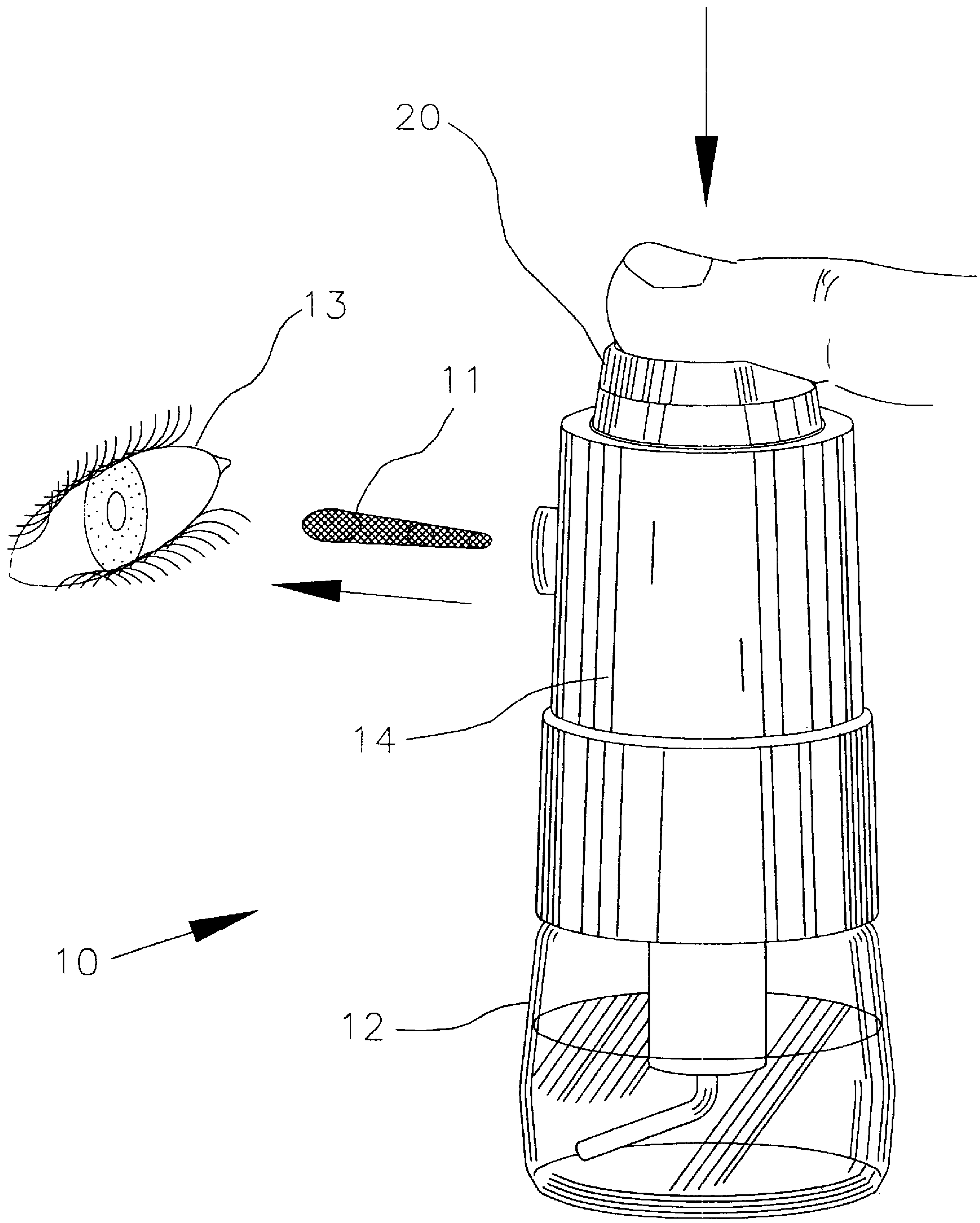


FIG. 1

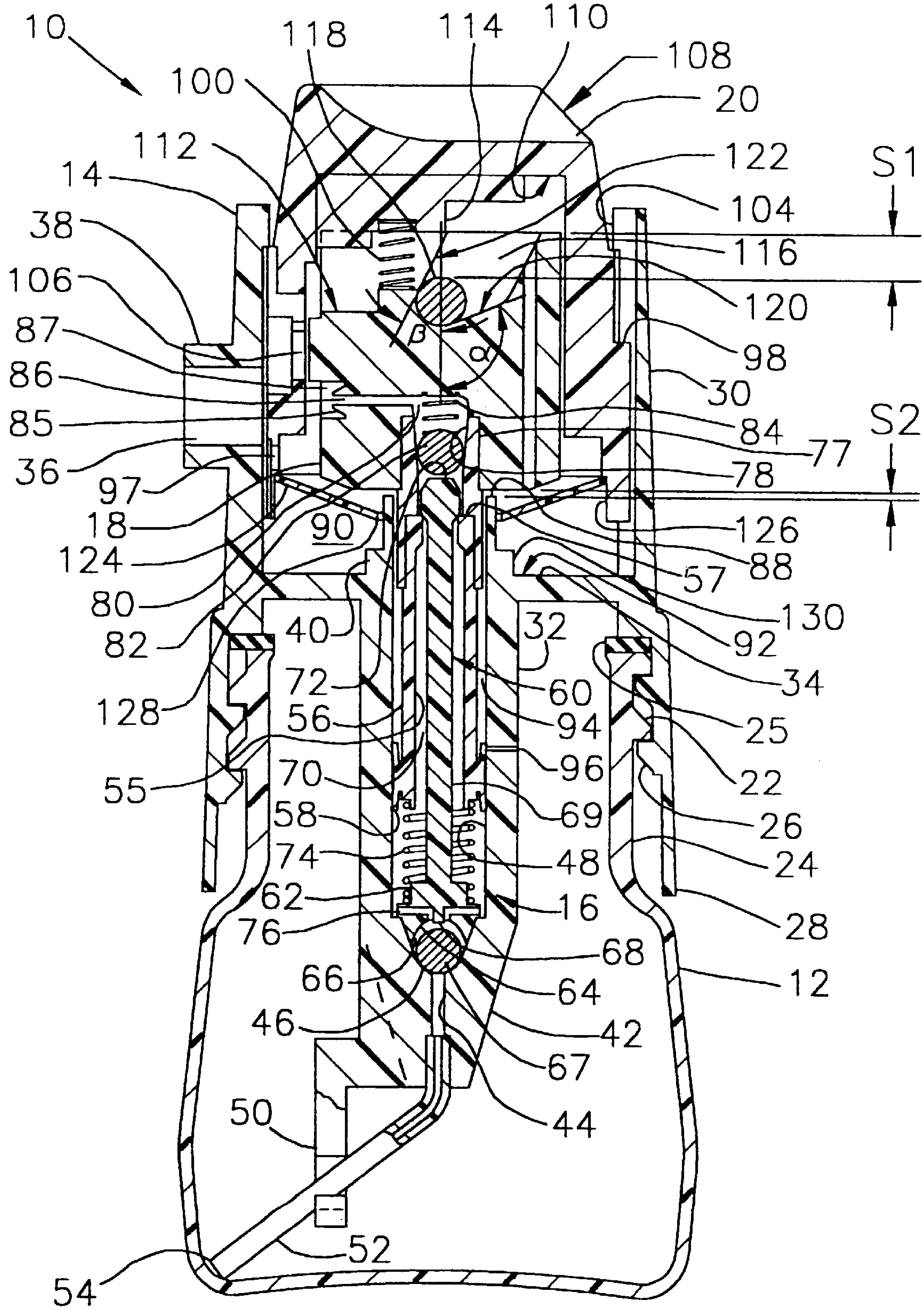

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FIG. 2

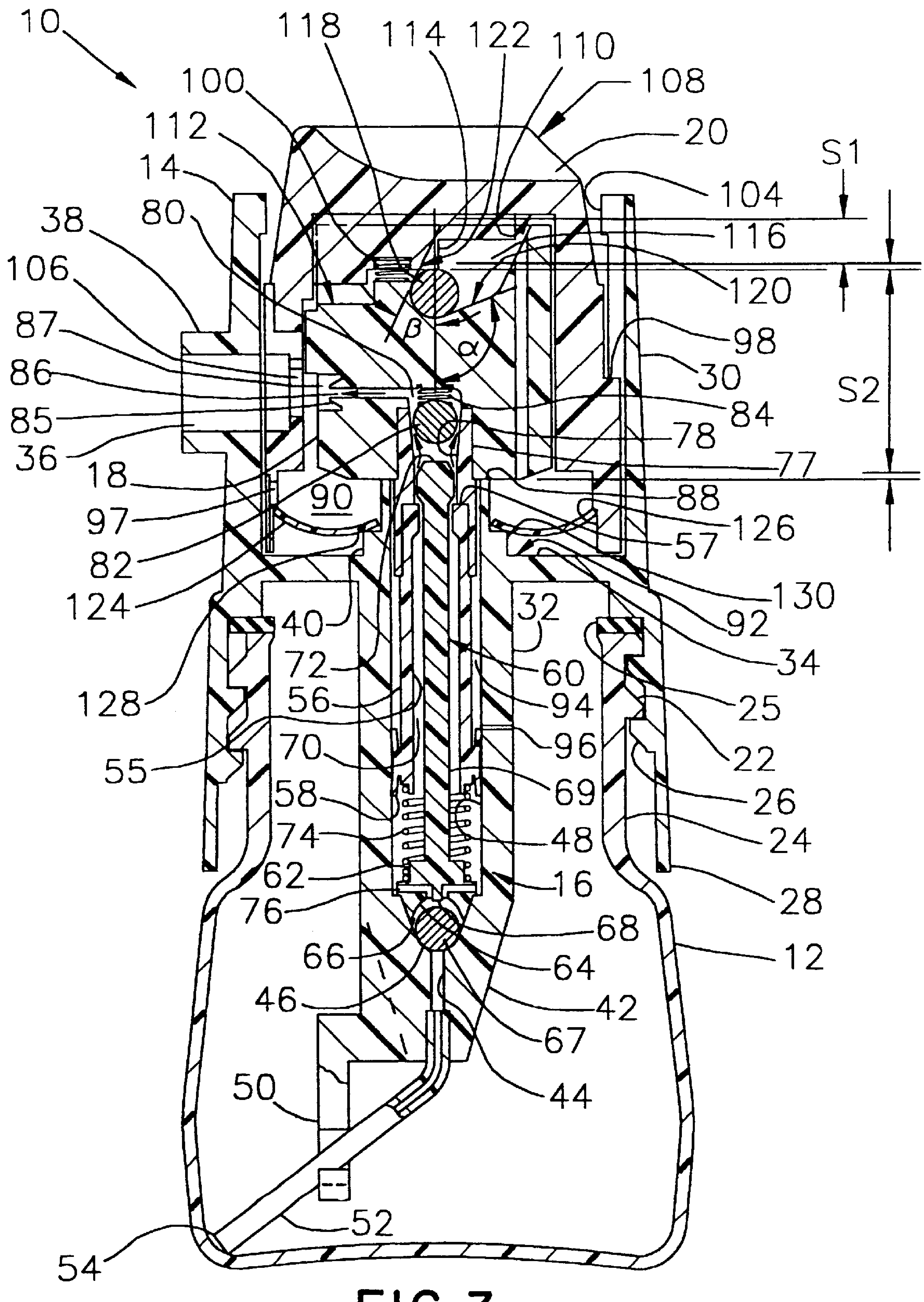
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FIG. 3

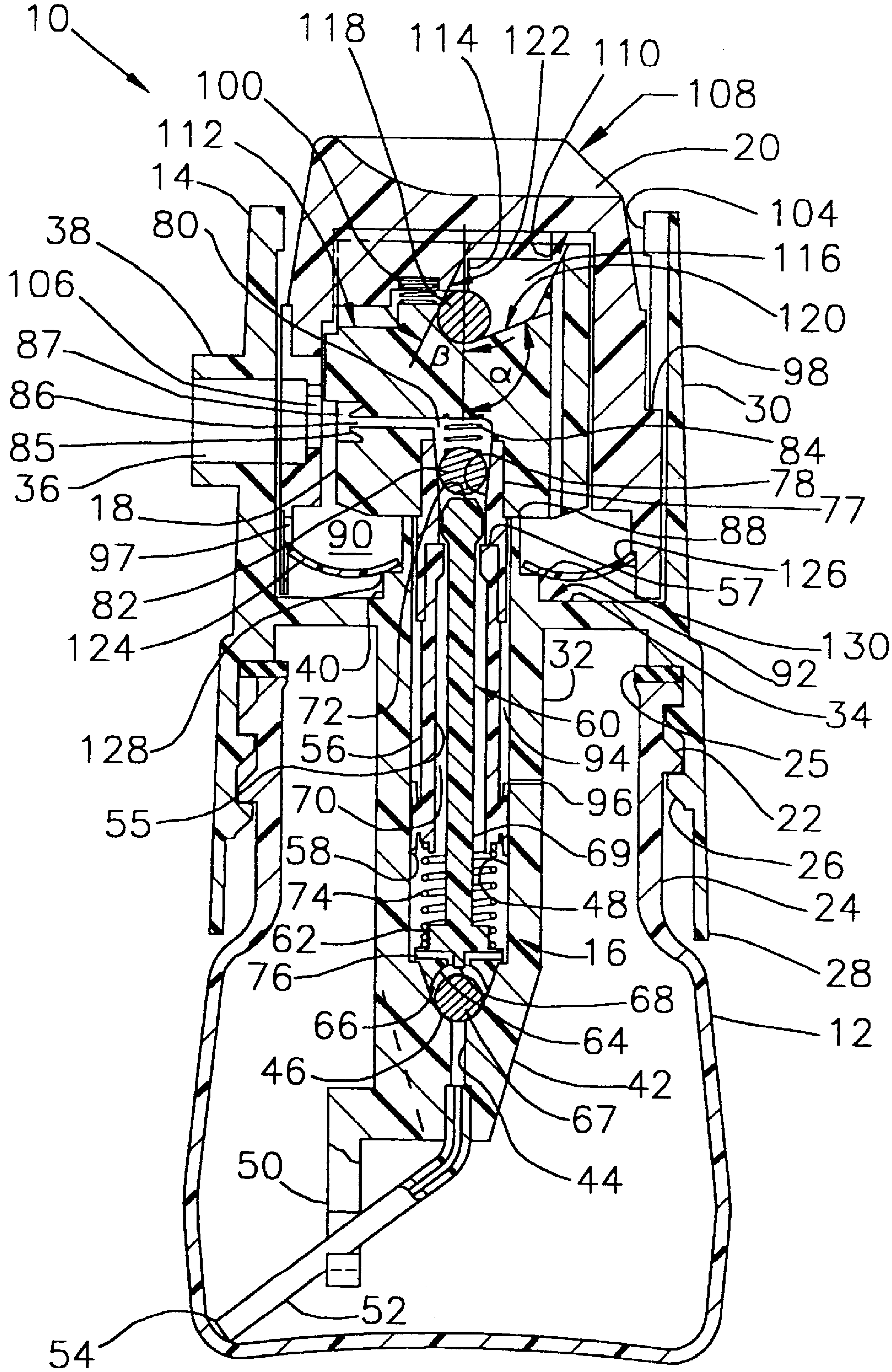
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FIG. 4

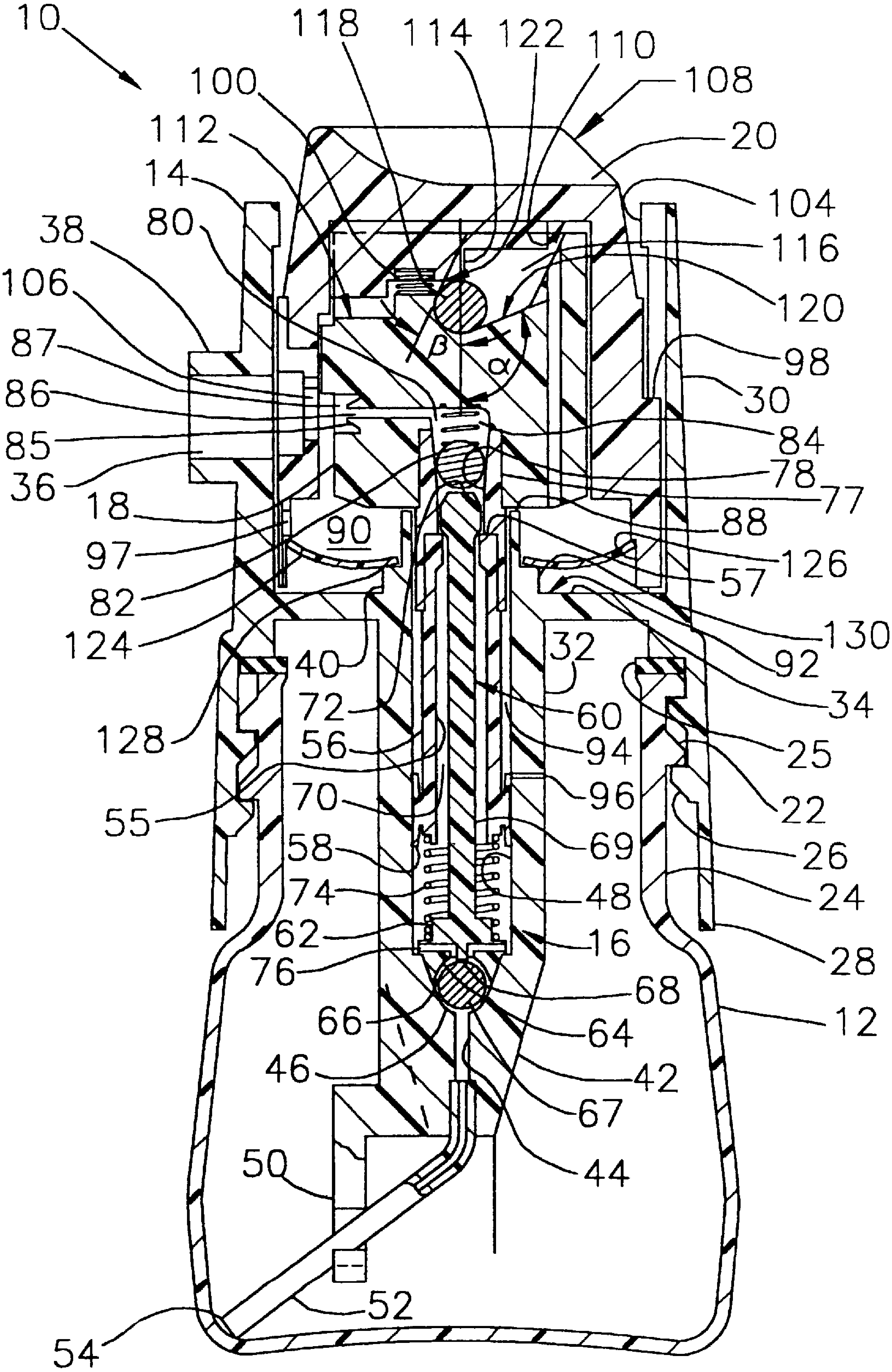
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FIG. 5

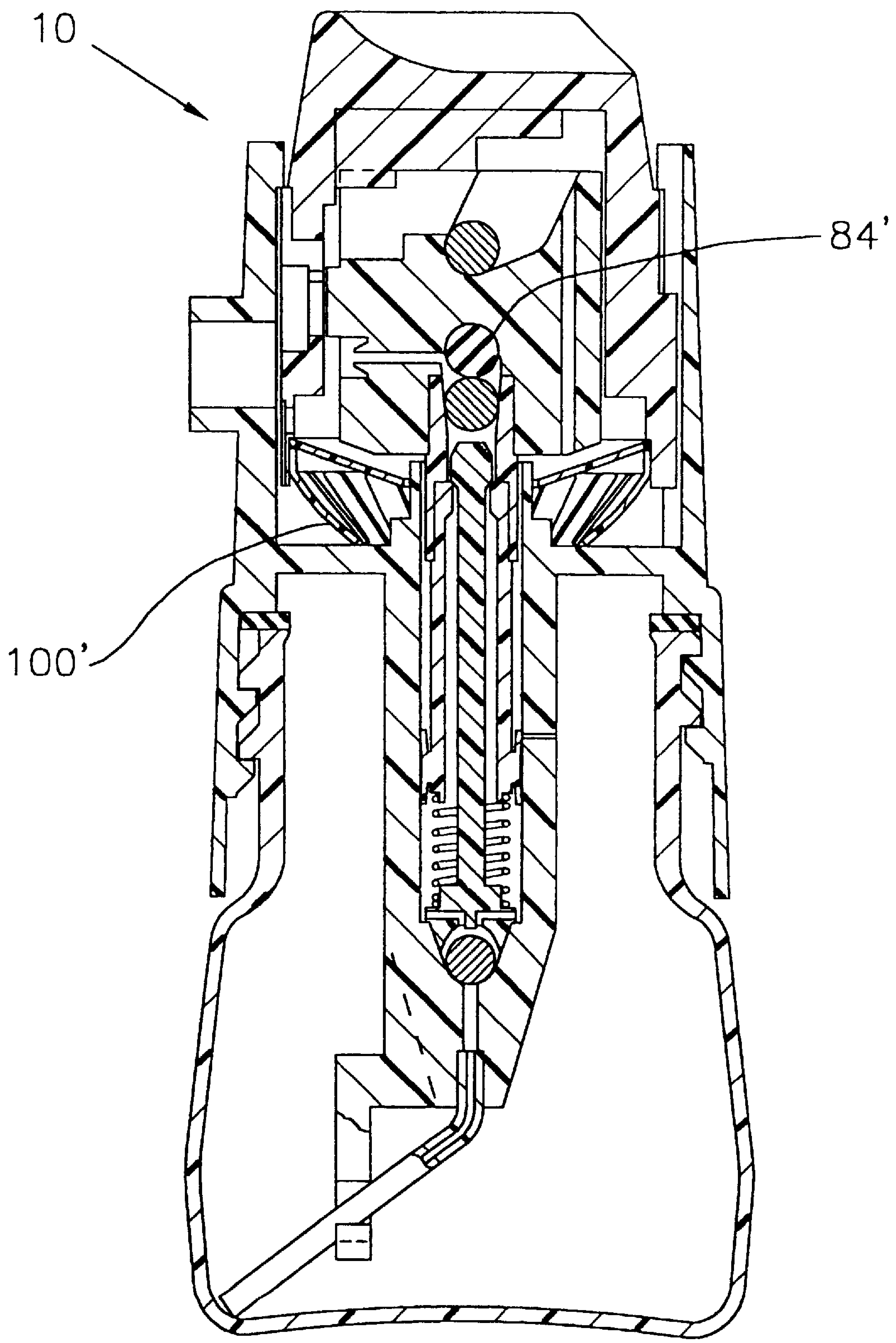

FIG. 6

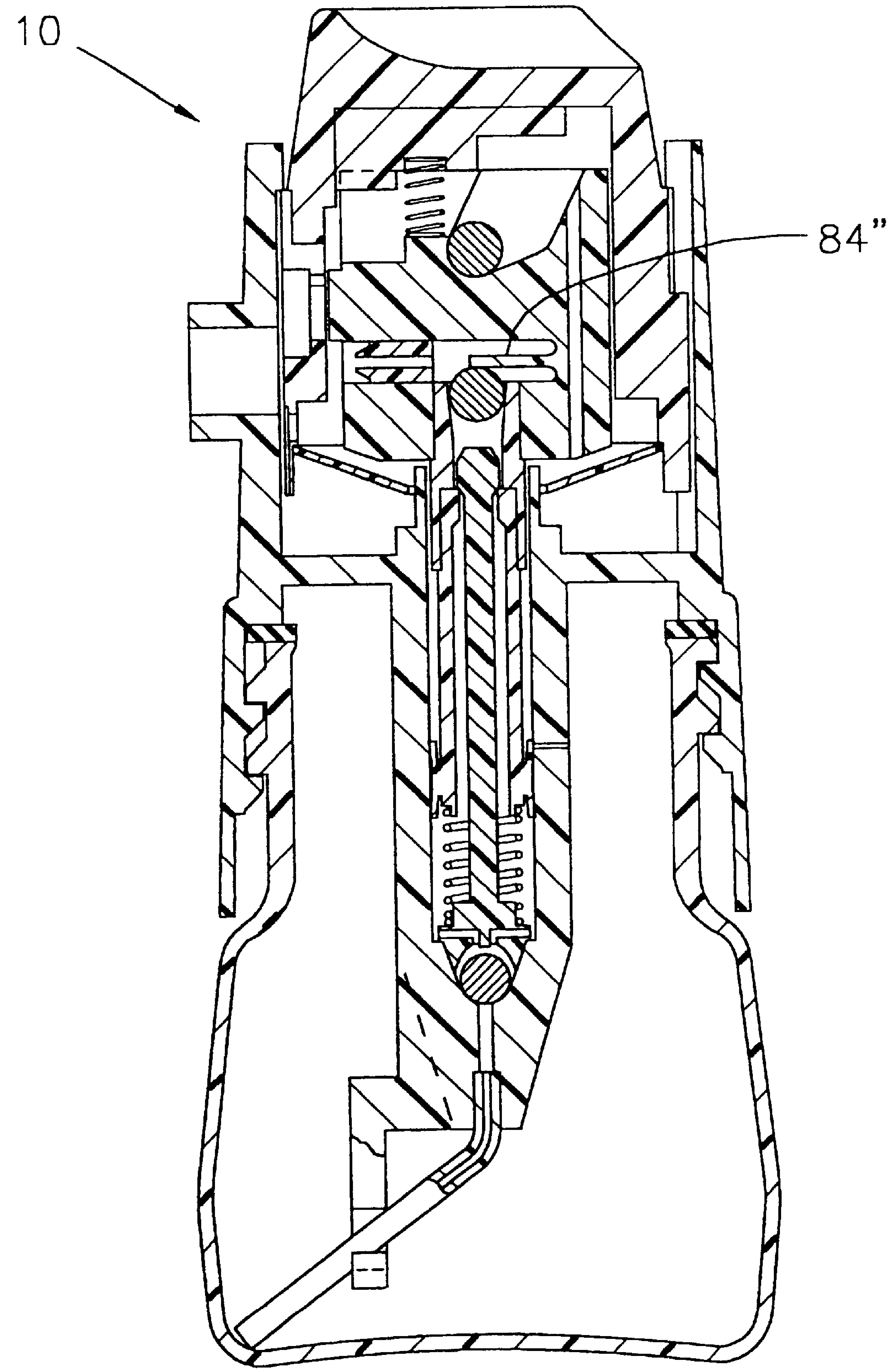

FIG. 7

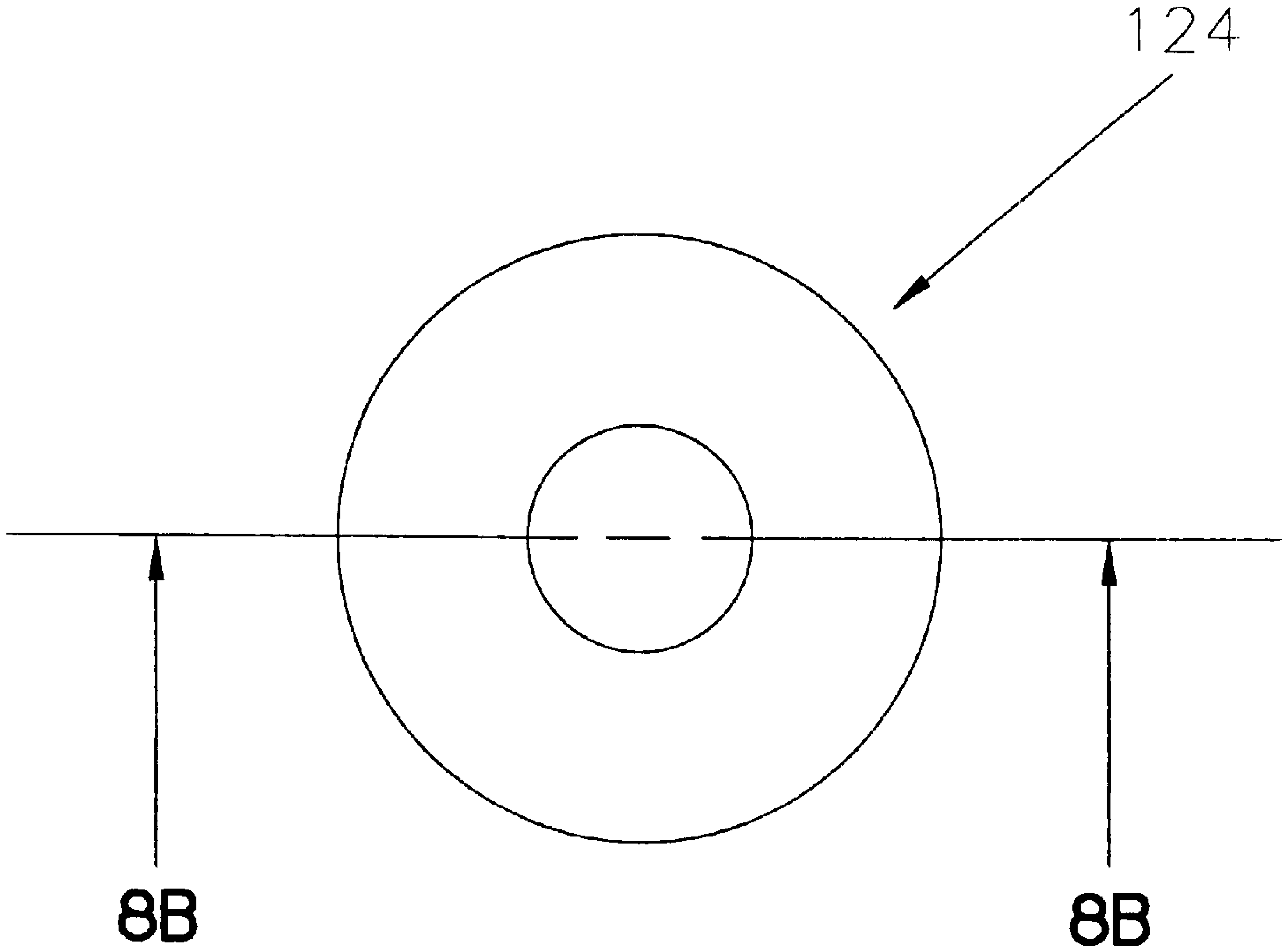

FIG. 8A

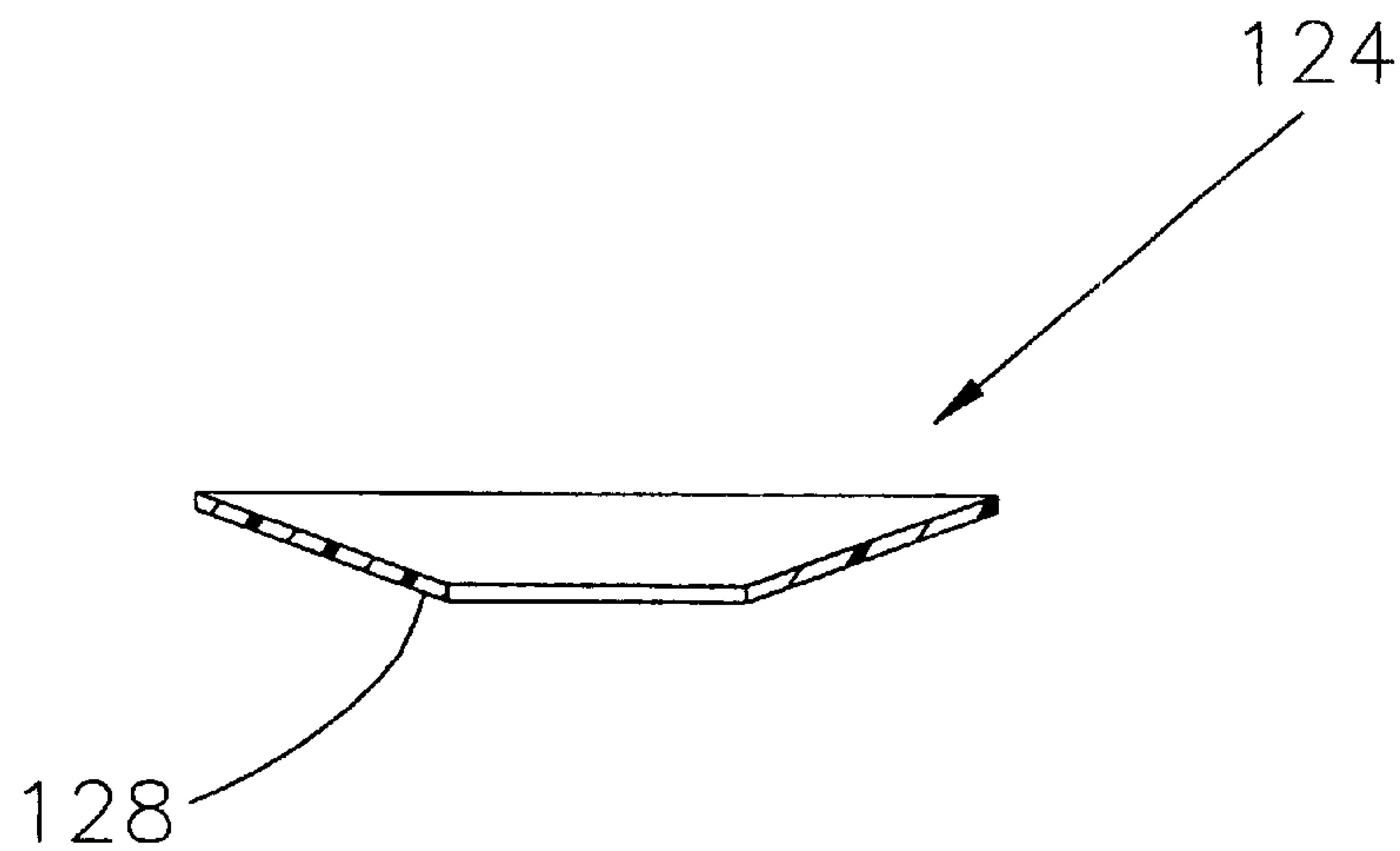

FIG. 8B

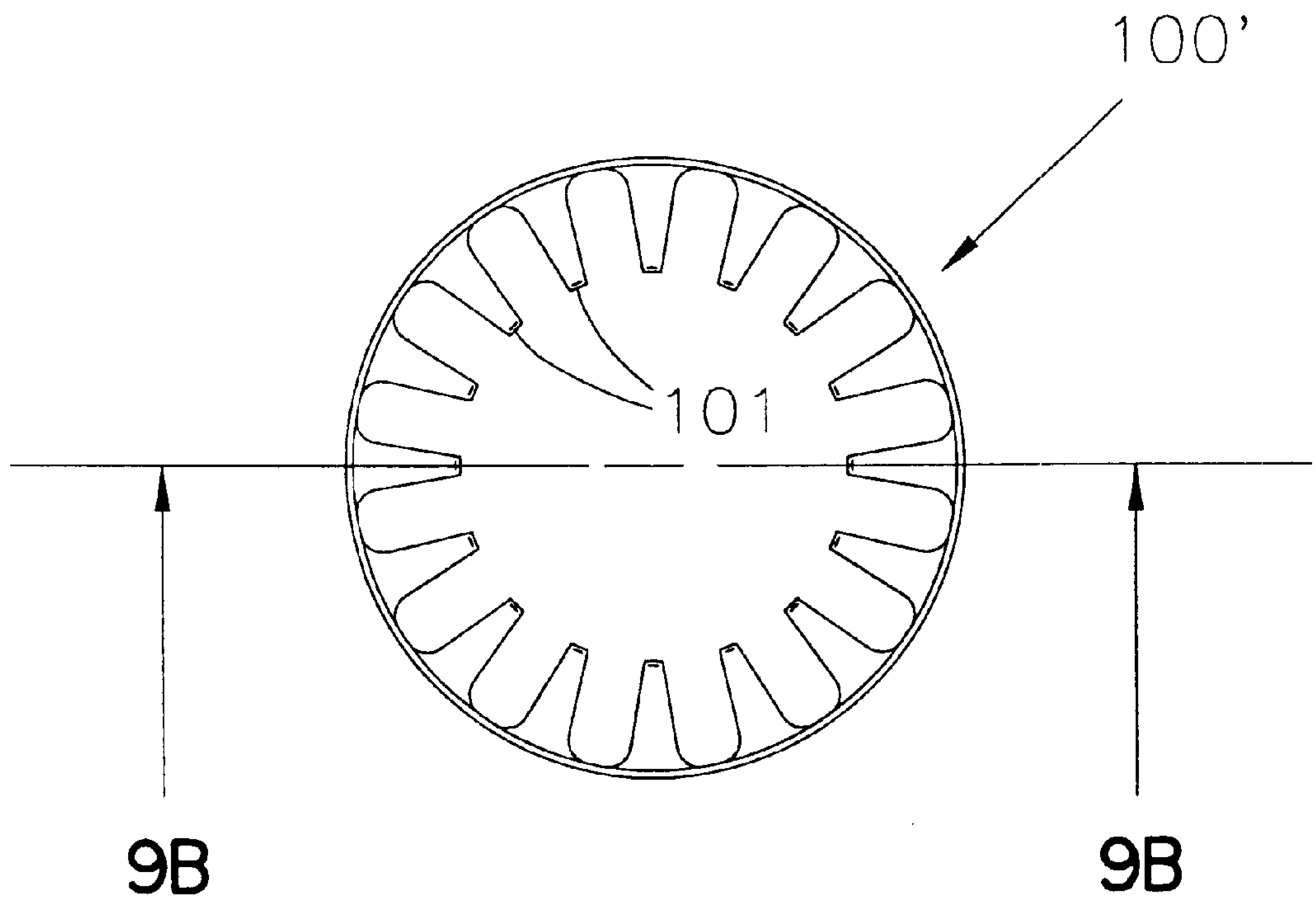

FIG. 9A

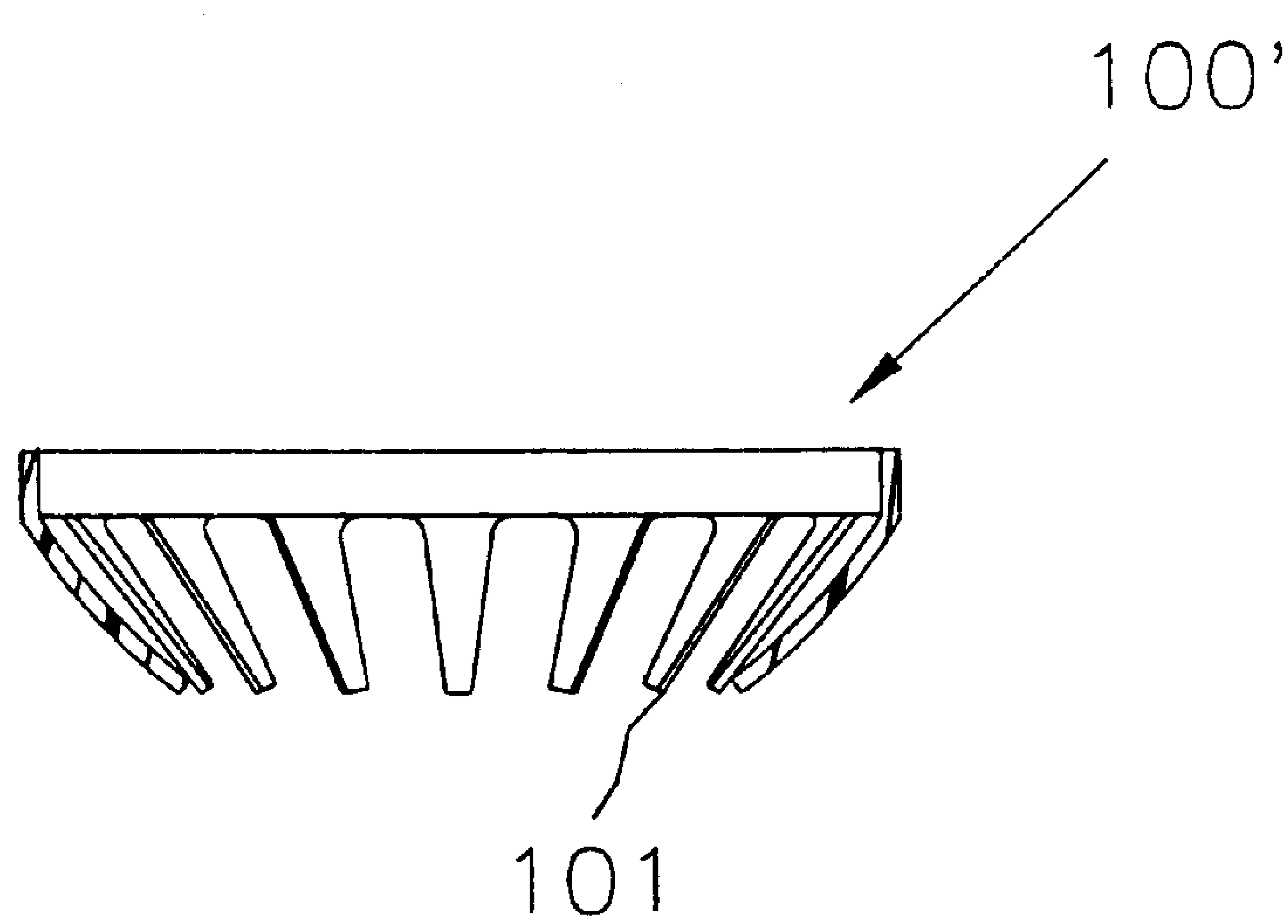

FIG. 9B

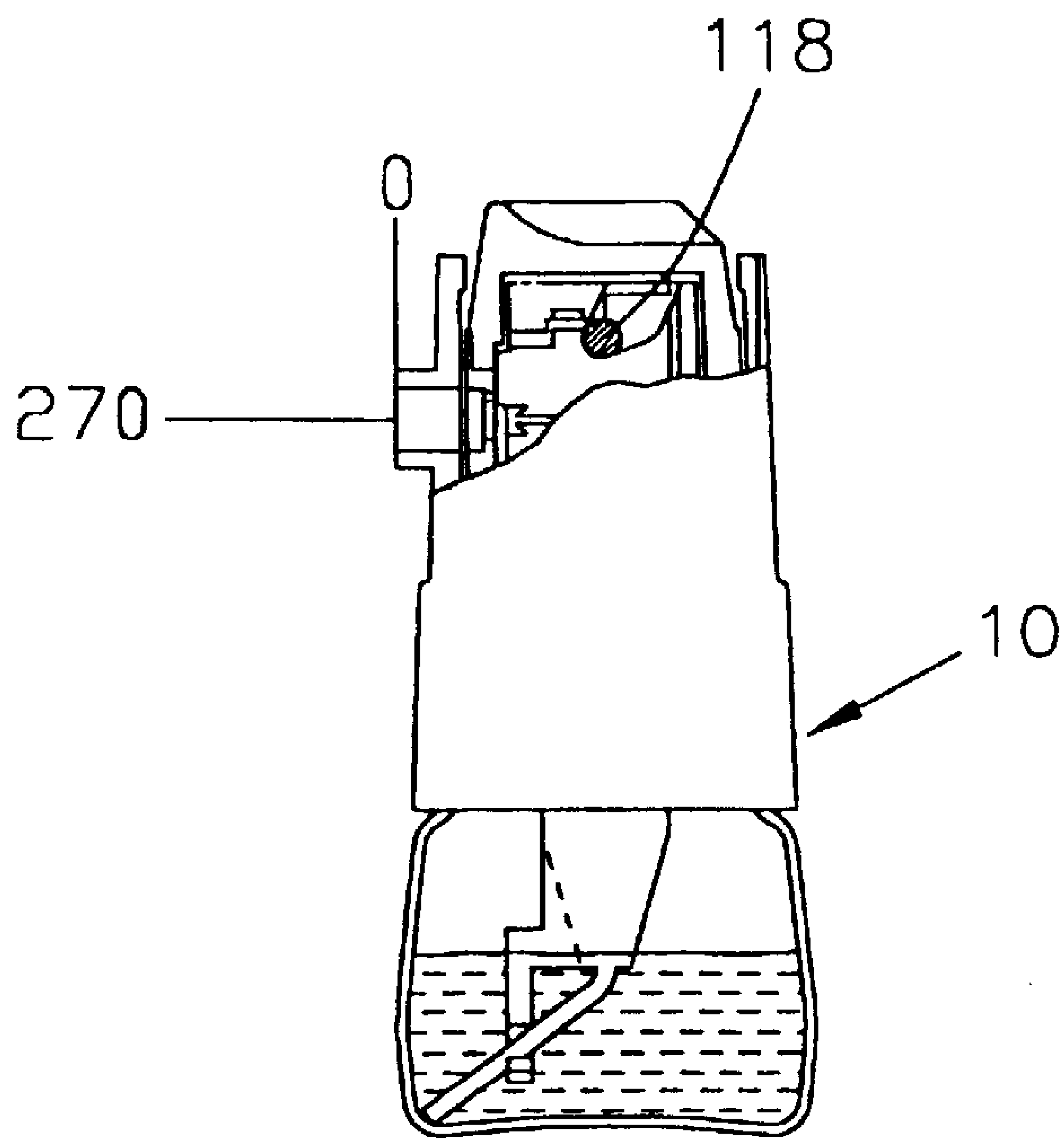

FIG. 10A

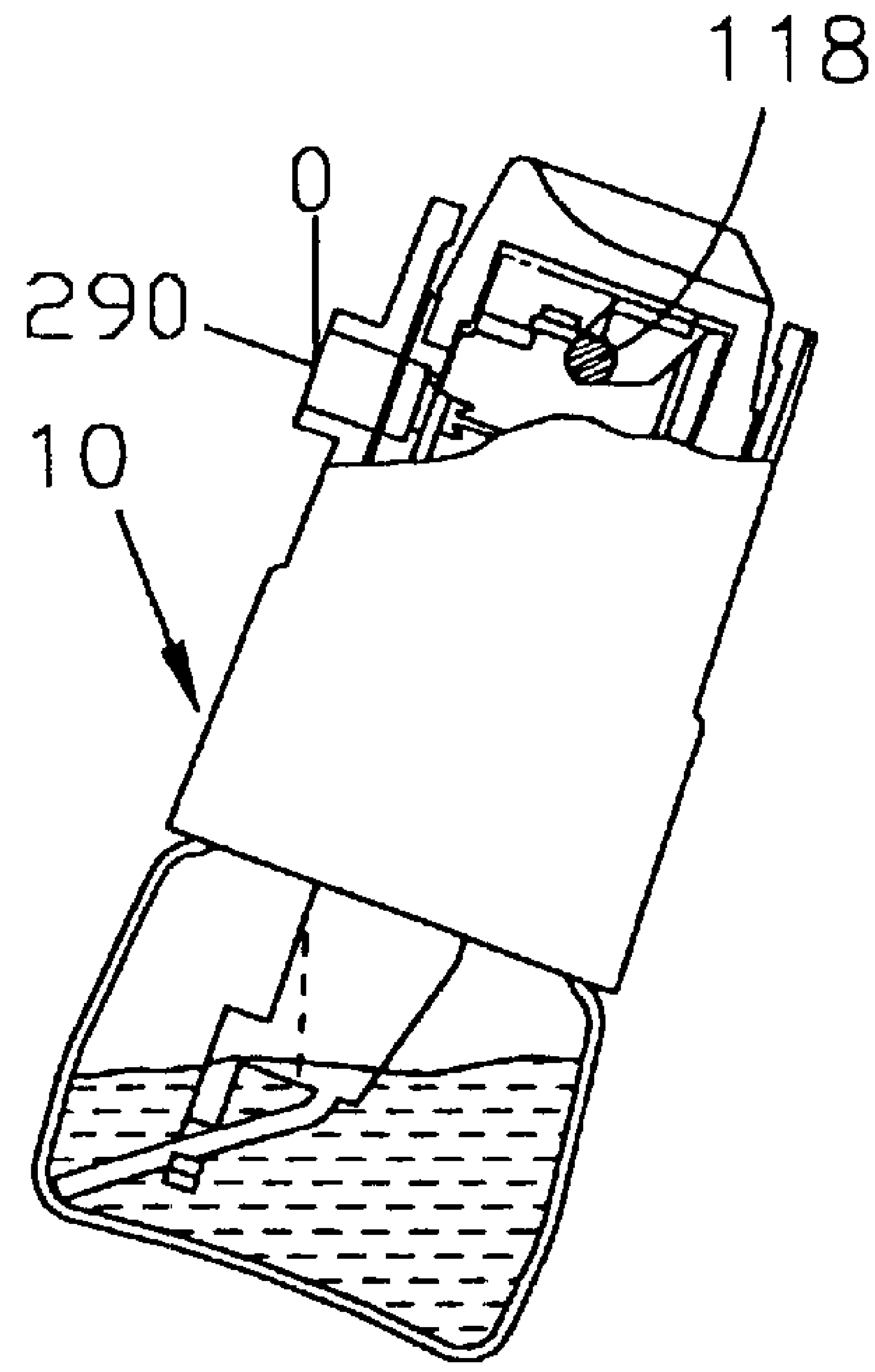

FIG. 10B

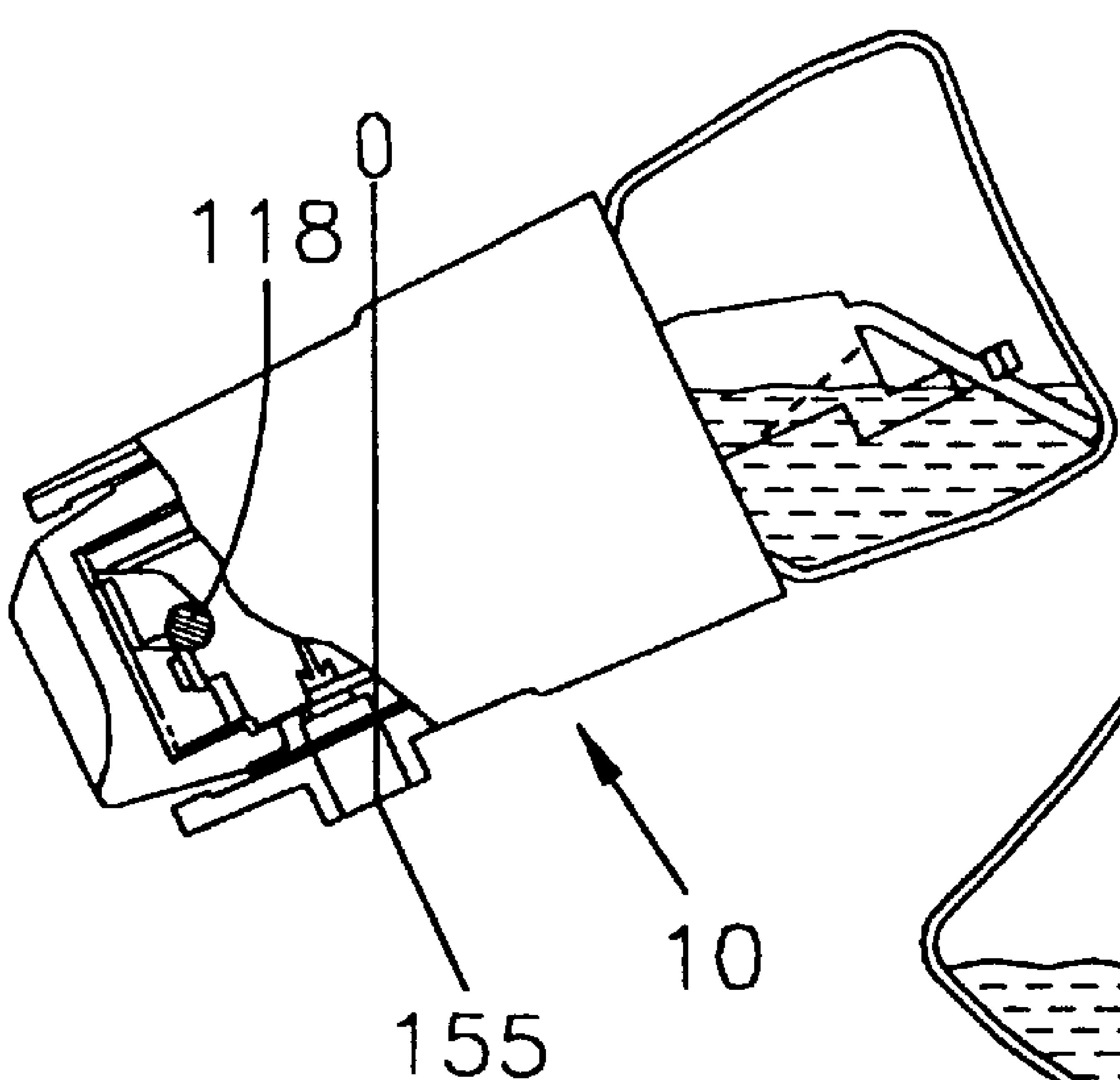

FIG. 10C

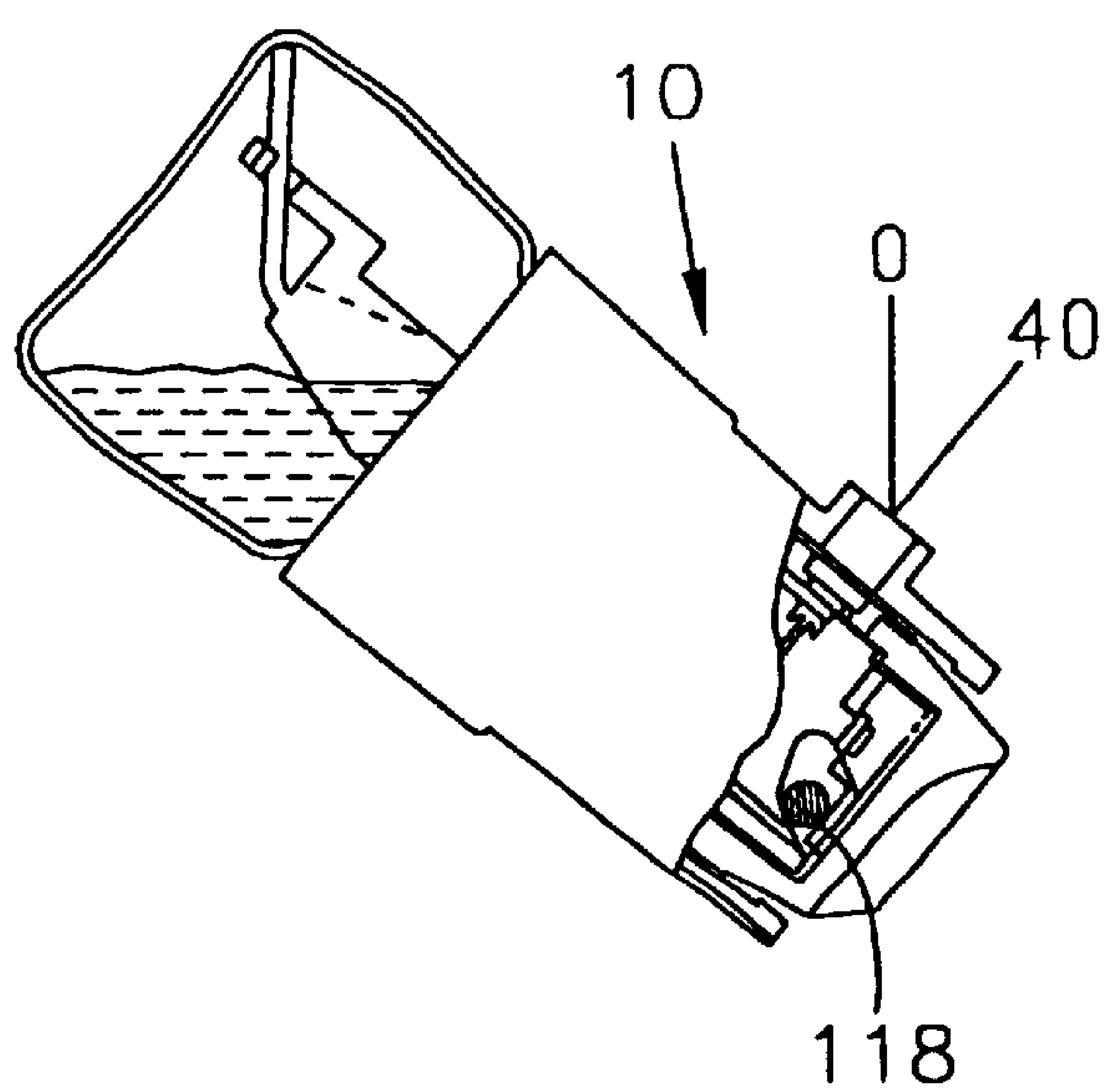

FIG. 10D

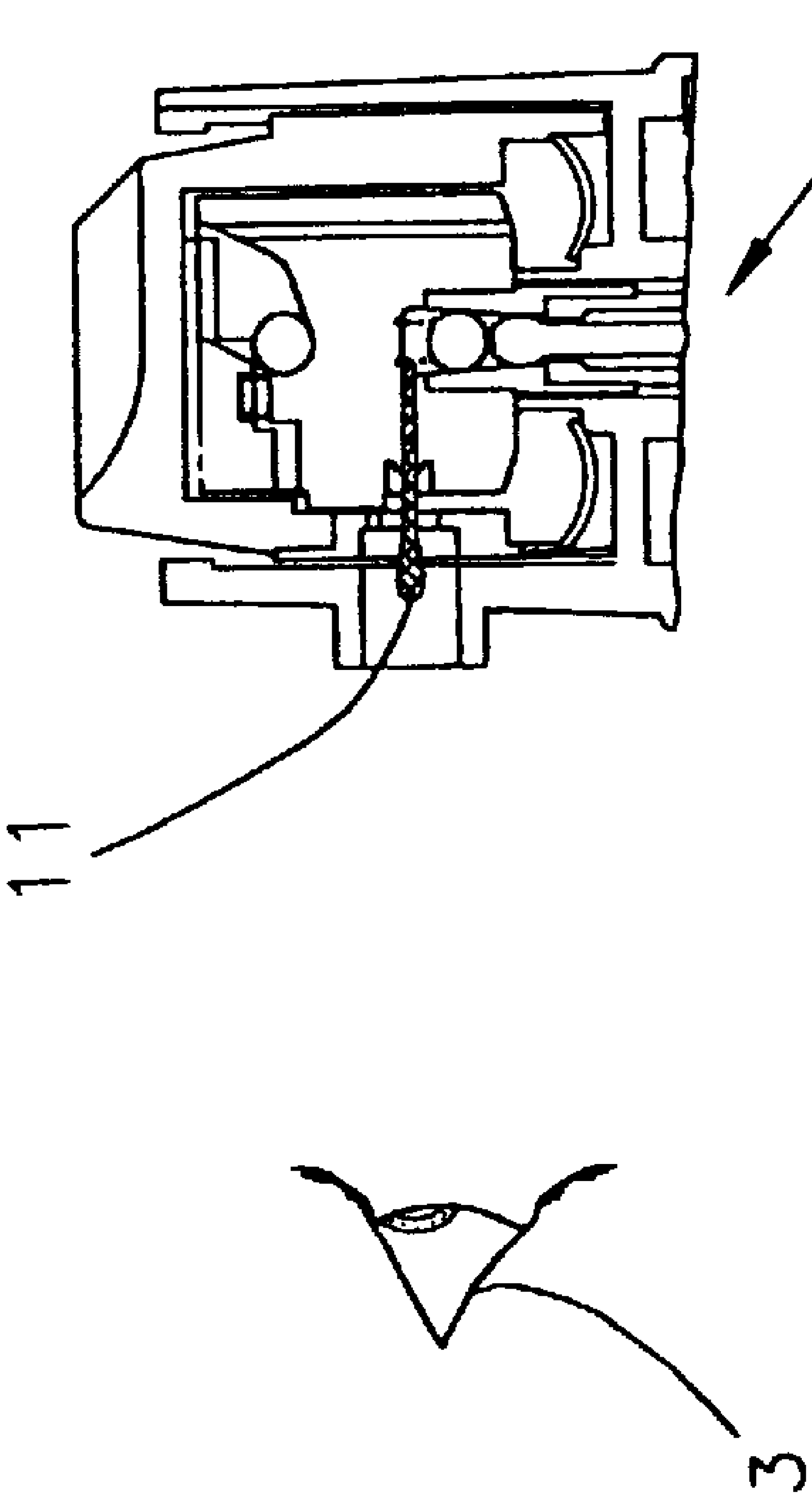

FIG. 11A

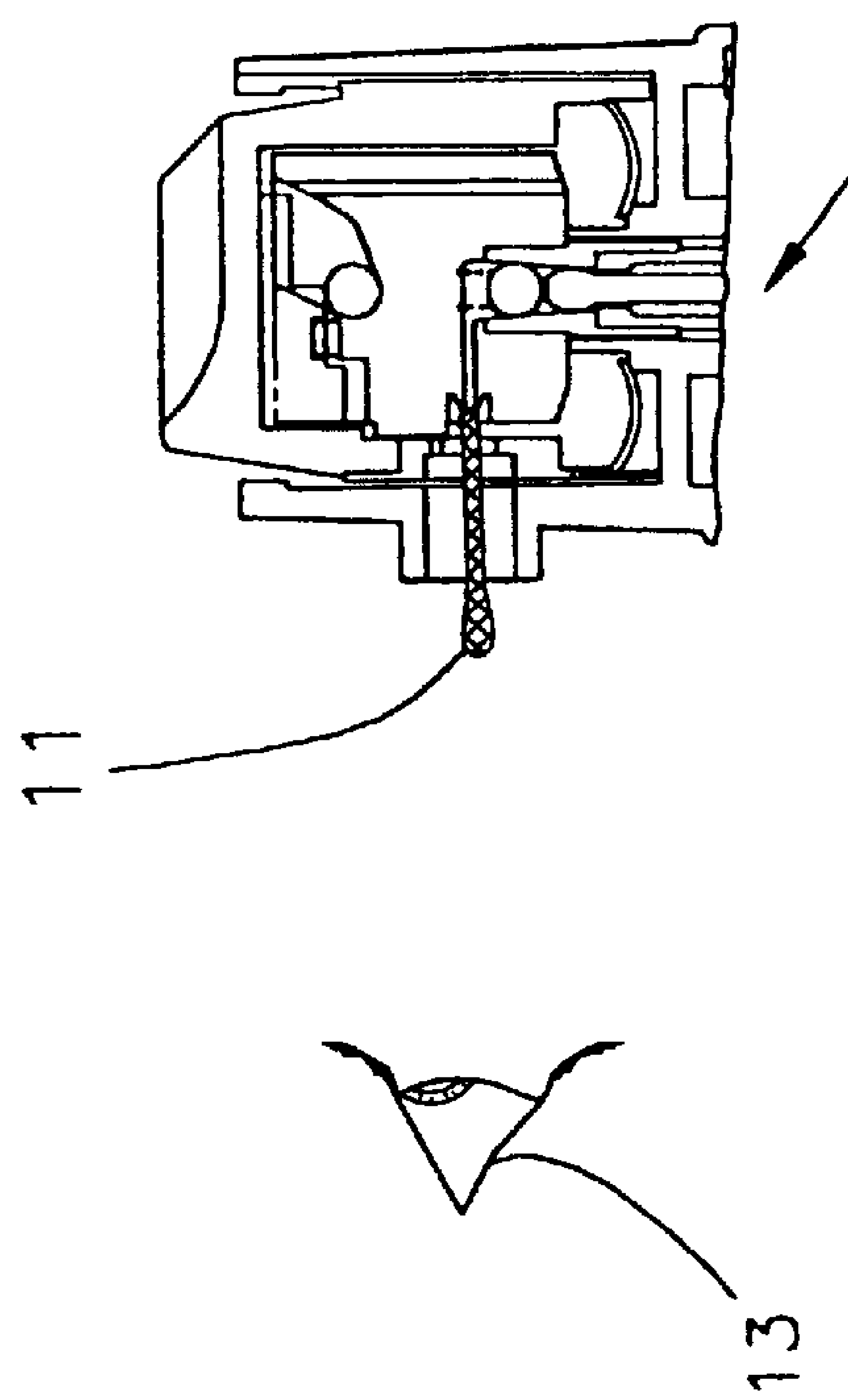

FIG. 11B

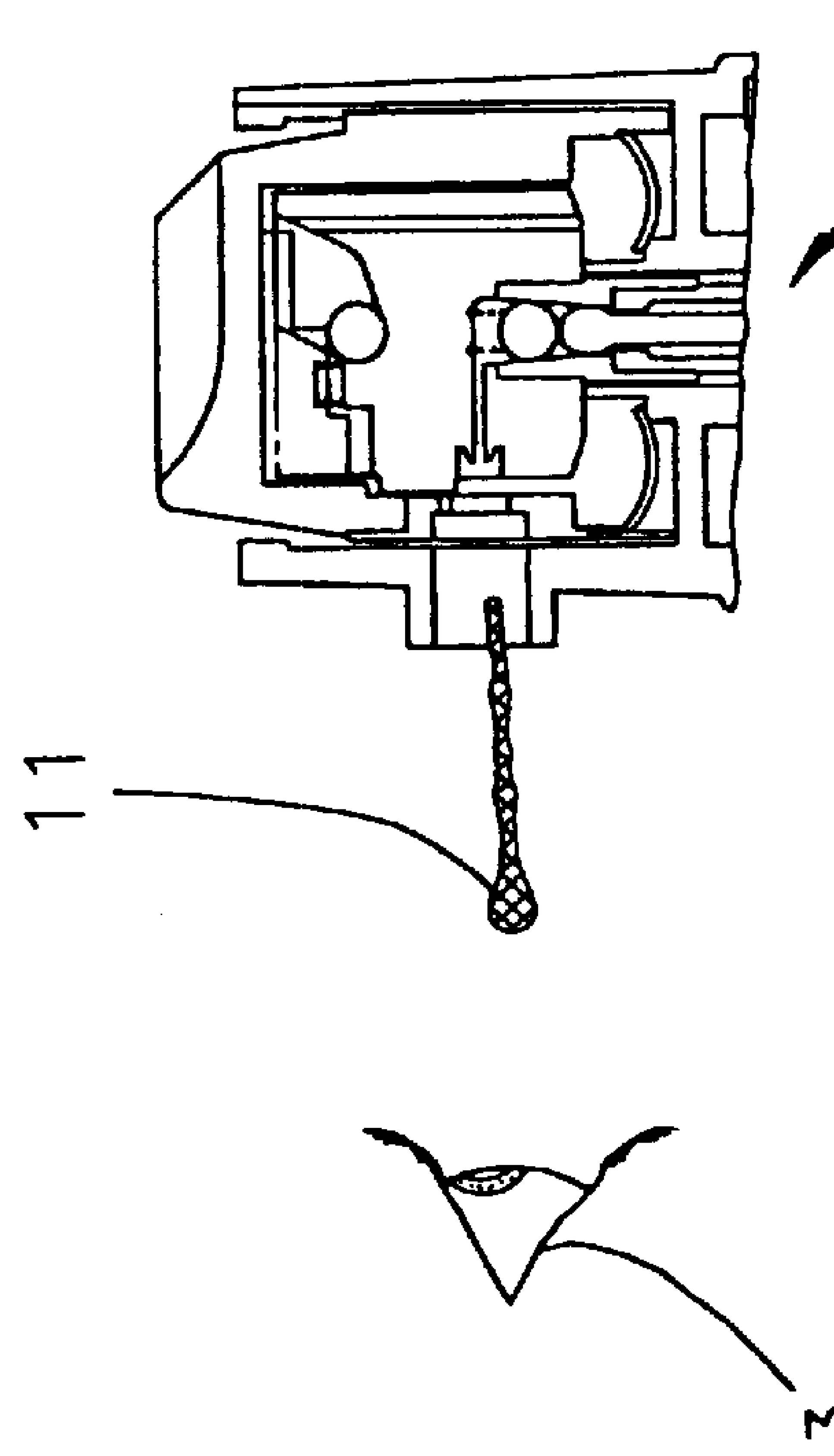

FIG. 11C

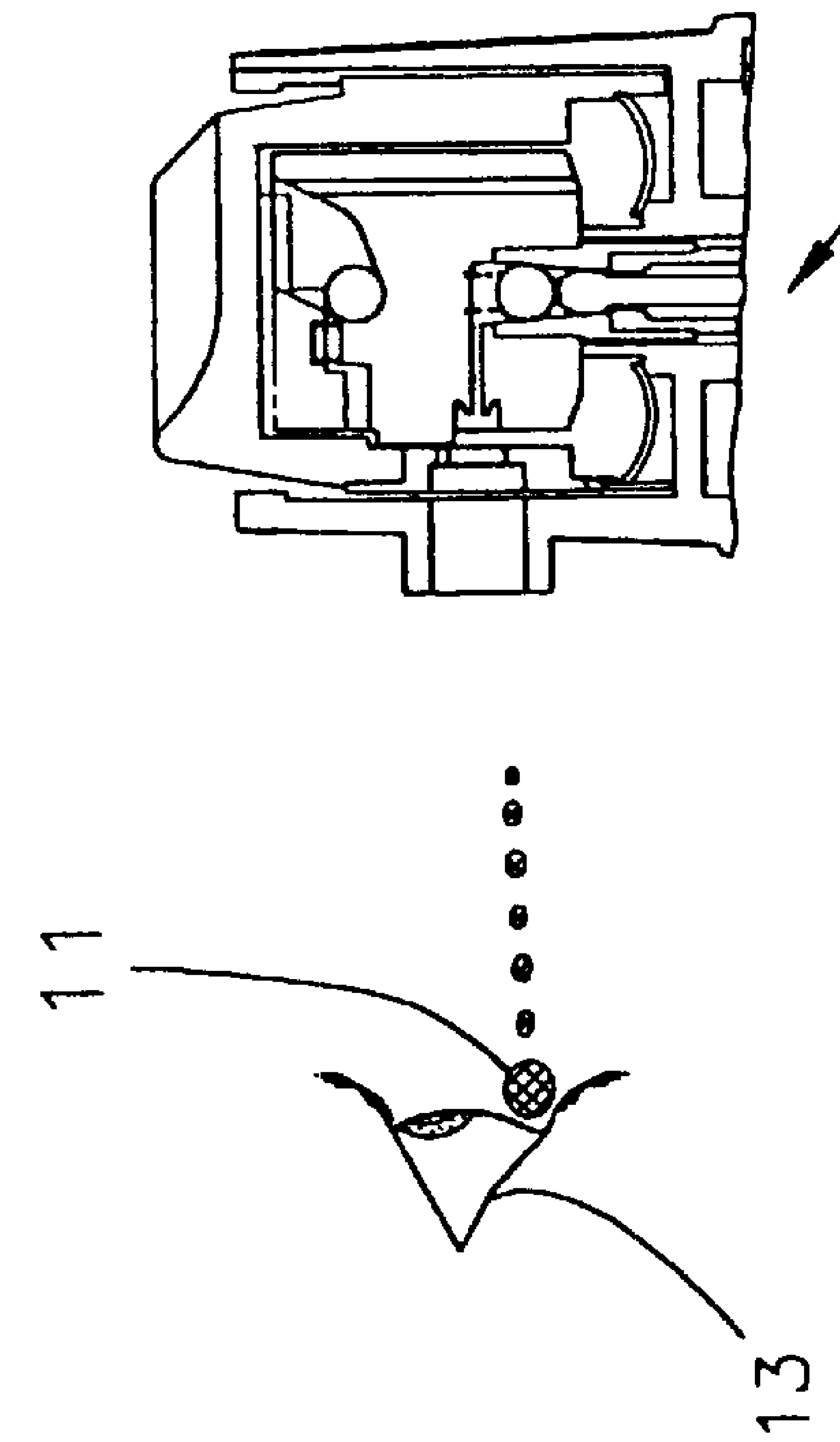

FIG. 11D

MICRODISPENSING OPHTHALMIC PUMP

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.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a fluid medicine delivery device, and, more particularly, the invention is directed to a microdispensing ophthalmic pump for delivering a microdose of ophthalmic fluid.

2. Description of the Prior Art

U.S. Pat. No. 5,152,435 (hereinafter "the '435 patent)", entitled "OPHTHALMIC DISPENSING PUMP", discloses a manually operated dispensing pump capable of delivering a precise quantity of ophthalmic solution to the surface of an eye in a desired spray pattern with an impact pressure on the eye that is comfortably tolerable by an individual and was issued to a co-inventor, Ben Z. Cohen, of this patent. The '435 patent is incorporated by reference herein, including the extensive discussion of the shortcomings of the prior art. The spray pump of the '435 patent is substantial improvement over the prior art, capable of delivering doses of ophthalmic fluid such as 50 microliters in the previously described manner. However, often a dose of much less than 50 microliters of ophthalmic fluid may be required to be delivered in the manner described above. Since a reduction in the size of a dosage inherently decreases the impact force exerted by the dose onto an eye, the administration of fluid by the '435 patent would be even more comfortably tolerable than that disclosed therein with a reduction in the size of the dose the '435 pump could deliver. Also, some medications can have toxic effects, even at doses as small as 50 microliters, and so doses of less than 50 microliters would be better tolerated.

It is a primary object of the subject invention to provide a manually operated microdispensing pump for delivering a microdose of ophthalmic solution as small as 5 microliters.

Also, it is an object of the subject invention to provide a manually operated microdispensing pump capable of repeatedly administering a full and proper microdose as small as 5 microliters.

SUMMARY OF THE INVENTION

The above-mentioned objects of the present invention are achieved by a new and improved manually operated microdispensing pump for delivering ophthalmic fluid. In particular, the new and improved manually operated microdispensing pump will enable an individual to repeatedly deliver a predetermined microdose of ophthalmic fluid.

In the preferred embodiment, the microdispensing pump of the subject invention is formed to be substantially cylindrical with one end being formed as a reservoir for storing the ophthalmic fluid intended to be dispensed. A pump body is threadedly secured to the reservoir with a cylindrical inner body formed therein which projects along a central axis into the reservoir. A dip tube is provided to communicate fluid from the reservoir to the inner body of the pump body. A pump mechanism is disposed within the inner body which urges fluid from the reservoir and through the pump of the subject invention. The pump mechanism comprises an inlet check valve element for regulating the flow of the fluid from the reservoir into the inner body, a cylindrical piston slidably disposed and sealingly supported within the inner body, an elongated poppet extending from the inner check valve element and through the inner body in a spatial relationship with the piston, an outlet check valve element for regulating flow of the fluid out of the inner body and a spring for urging the cylindrical piston into an upward position in contact with a head formed on the end of the support opposite the inlet check valve element.

The microdispensing pump of the subject invention further comprises a dispensing cap mounted onto the cylindrical piston and formed with an outlet chamber which communicates with the inner body, the communication therebetween being controlled by the outlet check valve element, and a slender discharge nozzle communicating the outlet chamber with the periphery of the dispensing cap. An actuator is slidably disposed adjacent the dispensing cap and substantially within the pump body.

Once primed with ophthalmic fluid within the inner body, the pump dispenses ophthalmic fluid with a downward translation of the actuator, the dispensing cap and the piston within the inner body. As the piston translates within the inner body, the volume therein is decreased with an accompanying increase in pressure of the ophthalmic fluid contained within the inner body. The check valve elements are both normally closed and contribute to the pressure build-up of the fluid. Eventually, the compressed ophthalmic solution will force the outlet check valve element open, thereby allowing fluid to enter the outlet chamber and the discharge nozzle and force out fluid previously drawn therein. The fluid is delivered in a non-aerosolized jet stream as a series of droplets. A spring is provided to urge the outlet check valve element into a closed position quickly after being forced open. The piston, having completed its downward translation, translates upward into contact with the head of the poppet due to the urging of the spring acting on the piston. As the piston comes into contact with the head of the poppet, the volume within the inner body is increased and the accompanying pressure decreased. The reduction of pressure within the inner body creates a suction effect which urges the inlet check valve element into an open position and draws fluid from the reservoir into the inner body. As pressure builds within the inner body due to the added fluid, the inlet check valve element will be urged into a closed position allowing the pump mechanism to be used again.

The new and improved manually operated microdispensing pump of the subject application uses a spring biased outlet check valve element and a limited-travel inlet check valve element to operate under the negligible pressures and strokes associated with the delivery of microdoses of fluid. In the preferred embodiment, a spring is applied to a stainless steel ball to form the outlet check valve, which is biased to a normally closed position. The suction created by the pump mechanism to draw fluid therein may affect the microdose of the pump if fluid disposed in the nozzle and the outlet chamber is drawn into the inner body due to the suction effect. During operation of the pump, the spring urges the outlet check valve element into a closed and seated position prior to suction being created in the inner body and ensures that a proper and full microdose of the ophthalmic fluid is maintained within the nozzle and the outlet chamber, unaffected by the suction effect.

An inlet check valve element is provided to regulate the flow of ophthalmic fluid into the pump of the subject invention. Since the delivery of microdoses as small as 5 microliters involves a negligible stroke of the inlet check valve element, a protrusion is disposed opposite the inlet check valve element which restricts the check valve element's range of motion and prevents the check valve element from simply shuttling during usage. The motion of the inlet check valve element is limited so that in an open position the volume displaced by the inlet check valve element in travelling from a closed position to an open position is less than the volume of the dose being dispensed by the pump. In the preferred embodiment, this volume is the swept volume of an inlet check valve ball and is calculated by taking the product of the clearance between the inlet check valve ball and the protrusion times the cross-sectional area of the inlet check valve ball: (clearance)×[π×(radius of the ball)^2]. Although a ball is preferred, any shape inlet check valve element may be used, such as a disk, with the swept volume being determined by the product of the clearance between the inlet check valve element and the protrusion times the largest cross-sectional area of the inlet check valve element measured in a plane perpendicular to the flow of fluid through the check valve. Thus, one feature of the new and improved manually operated microdispensing pump of the subject invention is a valve arrangement sensitive to the negligible strokes associated with microdosing.

Prior to initial use, the pump of the subject invention must be primed, wherein air is expelled from the pump mechanism. The pump is primed through the repeated actuation of the pump mechanism which draws fluid therein and forces air thereout. After priming, the re-introduction of air into the pump mechanism is undesired, since air pockets may be formed within the pump mechanism which may render the pump mechanism inoperative. To prevent the entrapment of air within the pump mechanism, the pump of the subject invention includes a failsafe device, a limited volume dip tube and a spherical inlet chamber which function to prevent the introduction and entrapment of air bubbles into the pump mechanism. The failsafe device comprises a ball disposed within an arcuate slotted track formed in the dispensing cap, which cooperates with an actuating block extending from the actuator. To operate the pump of the subject invention, the actuator is urged towards the dispensing cap with the actuating block coming into contact and pressing against the ball disposed within the track, which, under further urging, depresses the dispensing cap and activates the pump mechanism. If the pump were to be operated with the opening of the dip tube exposed to air entrapped within the reservoir, air could possibly be introduced into the pump mechanism. The slot of the failsafe device is formed to guide the ball out of alignment with the actuating block when the dip tube is positioned to be in communication with air trapped in the reservoir, with the ophthalmic fluid being within a predetermined range of fluid levels. Preferably, the slot is formed to allow the pump of the subject invention to operate with the nozzle discharge positioned in a range from approximately 155 to 290 degrees, going clockwise. Outside of this range, the ball will slide within the arcuate slot and prevent actuation of the subject invention pump.

To limit the entrapment of air in the pump during priming, the inlet chamber is formed to be substantially spherical to avoid the creation or entrapment of air bubbles therein. Also, during priming, as the pump is actuated with the inlet check valve element not being encompassed by ophthalmic fluid, the inlet check valve element will not provide an adequate seal against its seat and will allow fluid to freely pass the check valve element into the dip tube. This leakage, when the inlet check valve element is in a dry state, may cause an air pocket in the dip tube which prevents ophthalmic fluid from entering the pump mechanism. The air pocket will react to the actuation of the pump by rising and falling within the dip tube corresponding to the existence of suction within the pump mechanism. As a result, ophthalmic fluid is prevented from being drawn into the pump mechanism. To avoid such a problem, the dip tube of the pump of the subject invention is formed to encompass a volume less than the microdose intended to be dispensed by the pump to ensure that the inlet check valve element is submersed in ophthalmic fluid, since the inlet check valve element will not leak when encompassed by ophthalmic fluid. The dip tube has a hollow, substantially cylindric center which contains fluid from its free end to the seat of the inlet check valve element, which will be fully drawn into the pump upon a single actuation. Limiting the volume of the dip tube below the microdose of the pump ensures sufficient fluid will be drawn from the dip tube with a single actuation of the pump which will encompass the inlet check valve element and prevent the formation of an air pocket in the dip tube. Thus, another feature of the new and improved manually operated microdispensing pump of the subject invention prevents the entrapment of air within the pump mechanism.

To ensure proper operation of the pump, an annular tapered latch, formed from a resilient plastic, is provided at the base of the actuator and disposed about the inner body and pump mechanism. A corresponding annular shoulder is formed about the inner body with a top surface which comes into contact with the bottom surface of the latch with the downward translation of the actuator. The actuator can translate downward till the bottom surface of the latch is in contact with the annular shoulder without the pump dispensing any fluid. The actuator can further translate downwards, with the latch freely deforming. As the latch continues to deform, the latch generates resistance to further downward translation requiring increasing force to accomplish such translation. The increase in force will eventually build up and overcome a predetermined threshold force, which causes the latch to yield with a great reduction in resistance to even further downward translation.

To dispense fluid from the pump, a threshold force must be applied to deform the latch and exceed the yield point, thereby allowing the actuator translation into the pump body such that the pump mechanism is activated through the dispensing cap. The force needed to overcome the latch is much greater than that required to drive the piston a required stroke. Once the latch is overcome, the threshold force will cause the piston to rapidly travel its full stroke. A full and proper dose, as predetermined by the stroke of the pump mechanism, will be ensured through the elimination of a partial pump stroke. Therefore, another feature of the new and improved manually operated microdispensing pump of the subject invention is a latch for ensuring proper dosing.

Also, the translation of the dispensing cap into the pump body results in the compression of air trapped therebetween and resistance to downward translation. Vents may be provided to allow the compressed air to escape. The combination of the latch and the vents can be used to establish a threshold force needed to operate the subject invention. The quantity and the size of the vents can be manipulated to add or decrease the threshold force needed to overcome the latch.

The deformation of the latch converts the threshold force needed to deform the latch into a rapid actuation of the pump mechanism. An operator of the new and improved pump of the subject invention will not sense the point at which the latch will deform and will continue to apply the threshold force after deformation of the latch. Once deformed, the latch provides no resistance to further translation of the actuator and dispensing cap, which under the applied threshold force will rapidly move and activate the pump mechanism. This rapid activation will cause the pump mechanism to dispense fluid in a non-aerosolized jet stream as a series of droplets which will hit the desired target nearly simultaneously. As an additional feature, the rapid translation of the dispensing cap within the pump body causes the dispensing cap to strike the pump body, which limits the translation of the dispensing body, such that an audible click, tactile click, or any combination thereof, is generated. The audible or tactile click indicates to a user of the subject invention that a dose has been administered. The audible click can be avoided by padding the point of contact either on the dispensing cap or the pump body with a cushioning material, such as rubber or laminated paper.

The latch is not necessary to create a jet stream, if the pump can be actuated quickly without it. However, the latch ensures the pump mechanism will be activated with sufficient velocity to create a jet stream. Thus, yet another feature of the new and improved manually operated microdispensing pump of the subject invention is a deformable latch which ensures delivery of fluid from the pump in a jet stream.

As with all medical dispensers, precautions must be taken to prevent the introduction of foreign matter which could cause contamination of the dispenser. The spring acting against the outlet check valve element prevents the introduction of foreign matter into the pump mechanism. During fluid administration, the inner body draws fluid through the dip tube as fluid is dispensed. The drawing effect not only affects the inlet check valve element, but also the outlet check valve element. The spring urges the outlet check valve element into a seated position prior to suction being created within the inner body and prevents the drawing of contaminants into the pump through the nozzle.

Also, the dispensing cap, along with the discharge nozzle, is disposed within the actuator during non-use. In this position, the nozzle is protected from dirt and debris. The mouth of the discharge nozzle is provided with a conical rim which aids in the separation of the discharging fluid from the nozzle. The rim is encompassed by an annular depression which provides a pocket for collecting undispensed fluid. The annular depression is recessed within the dispensing cap and provides for separation of undispensed fluid from the nozzle, thereby avoiding possible blockage, and from the actuator, thereby avoiding possible gumming on the actuator of undispensed fluid which could contaminate future doses.

Although the discussion of the subject invention refers to ophthalmic solutions and administration to a person's eye, the new and improved manually operated microdispensing pump of the subject invention can be used with any type of fluid, such as lubricants, fragrances, medications and so on, for which a microdose as small as 5 microliters may be required.

These and other features of the invention will be better understood through a study of the following detailed description of the invention and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the new and improved pump of the subject invention.

FIG. **2** is a cross-sectional view of the new and improved pump of the subject invention in an unactuated position.

FIG. **3** is a cross-sectional view of the new and improved pump of the subject invention in a dispensing position.

FIG. **4** is a cross-sectional view of the new and improved pump of the subject invention returning to an unactuated position.

FIG. **5** is a cross-sectional view of the new and improved pump of the subject invention drawing fluid therein.

FIG. **6** is a cross-sectional view of an alternative embodiment of the new and improved pump of the subject invention.

FIG. **7** is a cross-sectional view of an alternative embodiment of the new and improved pump of the subject invention.

FIGS. **8**A–B are respectively is a plan and cross-sectional side view of the latch of the new and improved pump of the subject invention.

FIGS. **9**A–B are respectively is a plan and cross-sectional side view of the spring fingers of an alternative embodiment of the subject invention.

FIGS. **10**A–D are cross-sectional views of the operating range of the new and improved pump of the subject invention.

FIGS. **11**A–D are cross-sectional views of the jet stream dispensed by the new and improved pump of the subject invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. **1**, the new and improved manually operated microdispensing pump of the subject invention is generally indicated by reference numeral **10** and is capable of delivering a microdose of ophthalmic fluid **11** to a human eye **13**. Referring generally to FIGS. **1**–**5**, the pump **10** comprises a reservoir **12**, a pump body **14**, a pump mechanism **16**, a dispensing cap **18** and an actuator **20**.

The reservoir **12** is generally cup-shaped and formed to accommodate fluid. The pump body **14** is mounted onto the reservoir **12** and secured thereto through threaded engagement of threads **22**, formed on neck **24** of the reservoir **12**, and threads **26**, formed on a lower portion **28** of the pump body **14** which is disposed about the neck **24**. An annular seal **25** is disposed between the pump body **14** and the reservoir **12** which prevents fluid from leaking through the threads **22**, **26**. The pump body **14** comprises a substantially cylindrical outer shell **30**, a substantially cylindrical inner body **32** disposed co-axially within the outer shell **30**, and a transverse bulkhead **34** joining the two cylindrical elements. The outer shell **30** is formed to define a dispensing aperture **36** with sight **38** disposed thereabout. The sight **38** allows a user of the pump **10** to aim and direct the pump's discharge.

The inner body **32** extends from both sides of the bulkhead **34** with one end **40** being open, an opposed end **42** having an inlet channel **44** and an inlet check valve seat **46** formed therein, and a cylindrical inner chamber **48** extending between the two ends **40**, **42**. A hook-shaped guide **50** depends from the lower ends of the inner body **42** onto which dip tube **52** is mounted. The guide **50** directs the dip tube **52**, which encompasses a volume less than the microdose **11**, to the edge of the reservoir **12** in alignment with the sight **38**. The guide **50** and the dip tube **52** allow an individual to efficiently draw fluid from the reservoir **12**, since the dip tube **52** is fixed and formed to reach deep into the reservoir **12** and communicate with very low levels of fluid. Furthermore, an individual has a tendency to tilt a dispenser forward in administering a fluid; the guide **50** and an end of the dip tube **54** are aligned to consider this tendency.

A cylindrical piston **56** is slidably disposed within the inner chamber **48** with an annular seal **58** being in contact with the surface of the inner chamber **48**. The piston **56** is formed with a cylindrical inner chamber **55** having a constant cross-section and a top end **57** forming an opening smaller than the cross-section of the inner surface **55**. A poppet **60** is located within the piston **56** and extends throughout the inner chamber **48**. The poppet **60** is formed with a base **62** having a hemispherical lower surface **64**, which together with the inlet check valve seat **46** from a generally spherical inlet chamber **66**. The inlet channel **44** communicates with the inlet chamber **66** and together with the dip tube **52** form a passageway for fluid to pass into the pump body **14**. An inlet check valve element **67**, preferably a ball, is seated in the inlet check valve seat **46** within the inlet chamber **66**. A protrusion **68** extends from the lower surface **64** of the poppet **60** into close proximity with the inlet check valve element **67**. The protrusion **68** limits the travel of the inlet check valve element **67** within the inlet chamber **66** so that the swept volume of the inlet check valve element **67** is less than the microdose **11**, calculated in a manner previously described.

A stem **69** extends from the base **62** through the piston **56** in a spatial relationship, thereby forming an annular flow path **70** therebetween. A head **72** depends from the stem **69** and has a diameter greater than the inner diameter of the piston **56**. A spring **74** is disposed about the base **62** of the poppet **60**, and urges the top of the piston **57** into sealing contact with the head **72**. The inner chamber **48** and the annular flow path **70** receive fluid from the inlet chamber **66** through ports **76** formed in the base of the poppet **62**. An outlet check valve housing **77** is mounted to the piston **56** with a tapered portion **78** being formed therein. The poppet **60** is disposed within the piston **56** by forcing the head **72** through the piston **56**. The piston **56** is preferably made from low density polyethylene, which will allow the head **72**, preferably made from high density polyethylene, to pass through the piston **56** without permanent deformation.

The dispensing cap **18** is mounted onto the outlet check valve housing **77**. An outlet chamber **80** is formed within the dispensing cap **18** and communicates with the annular flow path **70** when the head **72** is not in contact with the piston **56**. An outlet check valve element **82**, preferably a ball, is located within the outlet chamber **80** and limits flow from the annular flow path **70** into the outlet chamber **80**. A quick return biasing means **84** urges the outlet check valve element **82** into sealing contact with the tapered portion **78**. Preferably, the quick return biasing means **84** is comprised of a conventional coil spring with a spring force of 2.9 lbs/in., as shown in FIG. **2**. Alternatively, a resilient rubber ball **84'** or cantilevered latch spring **84"** can also be used, as shown in FIGS. **6–7**.

A straight walled discharge nozzle **86** is formed to communicate the outlet chamber **80** with the periphery of the dispensing cap **18**. The discharge nozzle **86** is preferably formed to define a length to throat ratio of approximately 7 to 1. The design of the slender discharge nozzle **86** contributes to the formation of a jet stream which is dispensed therefrom. The nozzle **86** is formed with a conical rim **85** and an annular depression **87** about the discharge at the periphery of the dispensing cap **18**. The conical rim **85** aides in the formation of a jet stream which discharges from the nozzle **86** by causing separation of the fluid from the dispensing cap **18** since little surface area is provided about the discharge of the nozzle **86** to which fluid can adhere. If any fluid does adhere, the undispersed fluid collects in the annular depression **87**. The annular depression **87** allows undispensed fluid to collect which will not adhere to the discharge of the nozzle **86**, possibly causing blockage, or to the actuator **20**, possibly causing gumming and contamination of later doses.

An upper surface **88** of the inner body **32** and the head of the poppet **72** limit the stroke of the piston **56**. The upper surface **88** represents the lower limit of the stroke whereas the head **72** represents the upper limit. The amount of the microdose can be controlled through the establishment of these limits.

A void **90** exists between the upper surface **92** of the bulkhead **34** and the dispensing cap **18**. The void **90**, annular air chamber **94**, air vents **97** and vent **96**, formed within the wall of the inner body **32**, create an atmospheric flow path through which ambient pressure is exposed to the surface of the fluid when the piston **56** is not in contact with the head **72**. The introduction of ambient pressure into the reservoir **12** ensures the surface of the fluid will be under atmospheric pressure and drawn into the dip tube **52** due to a drop in pressure in the inlet chamber **66**, as described below. The reservoir **12** cannot be filled so that the vent **96** is covered by fluid, which would prevent the introduction of atmospheric pressure. The void **90** is vented to atmosphere by the air vents **96**. The air vents **97** also provide pathways for air to escape from the void **90** when the actuator **20** is depressed into the pump body **14** which compresses the air found in the void **90**.

The actuator **20** is formed with a skirt **98** disposed between the dispensing cap **18** and the outer shell **30**. Since the skirt **98** is not fixed to the dispensing cap **18** or the outer shell **30**, the actuator **20** is capable of translating therebetween. Normally, the actuator **20** is biased away from the dispensing cap **18** by biasing means **100**. Preferably, the biasing means **100** comprises a conventional coil spring but may also comprise spring member **100'** disposed about the lower edge of the actuator, as shown in FIGS. **6**, **9**A and **9**B. The spring member **100'** is formed with a plurality of inwardly extending resilient spring fingers **101** which urge the actuator **20** away from the dispensing cap **18** when the spring fingers **101** are deformed against the bulkhead **34**. Ridge **104** limits the upward travel of the actuator **20** and contains the actuator **20** within the pump body **14**. A discharge aperture **106** is formed in the skirt **98** which is aligned to be juxtaposed with the dispensing aperture **36** and the discharge nozzle **86** when the actuator **20** is forced into contact with the dispensing cap **18**, as shown in FIG. **3**. The top of the actuator **108** is conveniently formed with an arcuate surface which can comfortably accommodate the tip of a finger of a user of the pump **10**.

The inner surface of the actuator **110** and the upper surface of the dispensing cap **112** form a gravity sensitive failsafe mechanism for preventing the introduction of air into the inner chamber **48**. An actuating block **114** extends from the inner surface **110** towards the upper surface of the dispensing cap **112**. The upper surface **112** is formed with an arcuate slot **116** which accommodates ball **118**. The slot **116** is formed to seat the ball **118** below the actuating block **114** when the sight **38** is directed at an angle, rotating clockwise, from approximately 155 degrees to 290 degrees, as shown in FIGS. **10A–D**. Referring to FIG. **2**, the lower surface of the slot **120** is formed at an angle α, which is preferably 110°, and the upper surface **122** is formed at angle β, measuring 25°. As the pump **10** is turned counterclockwise beyond 155 degrees, the ball **118** will slide up the upper surface **122** and no longer be in alignment with the actuating block **114**. Similarly, if the pump **10** is rotated clockwise beyond 290 degrees, the ball **118** will roll up the lower surface **120** and out of alignment with the actuating block **114**. The range of angles from 155 degrees to 290 degrees was chosen to ensure submersion of the end of the dip tube **54** within the liquid found in the reservoir **12** with fluid being present therein with in predetermined levels.

An annular, tapered latch **124**, formed from a resilient plastic, preferably polypropylene, is disposed about the lower end of the actuator **126** about the inner body **32** and is shown in FIGS. **8**A and **8**B. The latch is formed with a bottom surface **128**. An annular shoulder **130** extends from the bulkhead **34** forming a diameter larger than the inner opening of the latch **124**. The actuator **20** is spaced from the dispensing cap **18** and may be pressed down without either the inner surface **110** or the actuating block **114** coming into contact with the dispensing cap **18**, or the bottom surface **128** of the latch **124** touching the annular shoulder **130**.

In operation, the reservoir **12** is filled with a fluid to a level below the vent **96** with the pump **10** being in a vertical position. Initially, the pump **10** must be primed with fluid being urged therethroughout. To do such priming, the pump **10** is activated several times using a normal pump operation. As fluid is drawn into the pump body **14**, air will be expelled, with the pump **10** being primed when no air is within the dip tube **52**, the pump body **14**, or the dispensing cap **18**. The pump process as described below is the same during priming, except the pump medium may include some air.

To dispense fluid from the pump **10**, the actuator **20** is depressed into the pump body **14** with the bottom surface **128** of the latch **124** coming into contact with the annular shoulder **130**, as shown in FIG. **3**. The latch **124** freely deforms with further downward translation of the actuator **20**. As the latch **124** continues to deform, the latch **124** generates resistance to further downward translation requiring increasing force to accomplish such translation. The force will eventually build up to a predetermined threshold force which overcomes the latch **124** and causes it to yield. As the threshold force is being reached, the actuating block **114** comes into contact with the ball **118**. The threshold force necessary to overcome the latch **124** ensures the piston **56** will rapidly translate its full stroke. The resistance against downward translation can also be regulated through the size and quantity of the air vents **97**. The depression of the actuator **20** causes the air in the void **90** to compress and requires additional force for further compression and further translation. Since the air vents **97** communicate with the atmosphere and the compressed air in the void **90** is bled thereto, having minimal or none of the air vents **97** results in a slow escape for the compressed air and resistance to translation of the actuator **20**. An increase in the number or size of the air vents **97** allows the compressed air to escape quicker from the void **90** and reduce the resistance against downward translation. The combination of the latch **124** and the vents **97** can be manipulated to establish a threshold force required to operate the pump **10**.

As shown in FIG. **3**, the actuator **20** must translate the distance S1 for the actuating block **114** to come into contact with the ball **118**. As the distance S1 is translated, the latch **124** and the air vents **97** offer resistance so that a threshold force must be applied to actuate the pump **10**. With the distance S1 translated, the latch **124** will be on the verge of yielding under the threshold force and the ball **118** will be in contact with the actuating block **114**. The distance S2 is equal to the stroke of the piston **56**, and the actuator **20** and the dispensing cap **18** can only travel the distance S2 by having the latch **124** yield and the air of the void **90** overcome. With the application of the threshold force, the latch **124** is quickly deformed with the threshold force continuously being applied thereafter, thereby causing the actuator **20**, along with the dispensing cap **18** and the piston **56**, to quickly travel the distance S2.

Referring to FIG. **3**, as the piston **56** travels downward the distance S2, fluid within the inner chamber **48** is compressed and forced through the annular flow path **70** about the head **72**, which through the downward travel of the piston **56** is separated from the top of the piston **57**. The fluid rushing past the head **72** will act against the outlet check valve element **82**, with the pressure of the fluid eventually overcoming the bias of the quick return biasing means **84** and causing the outlet check valve element **82** to separate from the tapered portion **78**. In turn, the fluid travelling past the outlet check valve element **82** will force fluid into the discharge nozzle **86** and the microdose **11** out of the nozzle **86**, which is aligned with the discharge aperture **106** and the dispensing aperture **36**. Due to the threshold force required to overcome the latch **124** and the air of the void **90**, the downward travel of the piston **56**, through the distance S2, is rapid, resulting in a rapid surge of fluid through the nozzle **86**. The microdose **11** exiting from the discharge nozzle **86** will from a non-aerosolized jet stream as shown in FIGS. **11**A–D. Due to the surface tension of fluid, as the microdose **11** travels away from the pump **10**, it will tend to break into a series of drops with a relatively large droplet and several smaller droplets, which will all hit the eye **13** nearly simultaneously.

The yielding of the latch **124** will cause the fluid to surge past the head **72** and the outlet check valve element **82**. As shown in FIG. **4**, the quick return biasing means **84** will urge the outlet check valve element **82** into contact with the tapered portion **78**, once the surge of fluid has bypassed the outlet check valve element **82**. The piston spring **74** will urge the piston **56**, the dispensing cap **18** and the actuator **20** upwards, with the biasing means **100** further urging the actuator **10** away from the dispensing cap **18**. Simultaneously, the latch **124** will separate from the annular shoulder **130** and resume its undeformed, annular tapered form. The upward travel of the piston **56** increases the volume of the inner chamber **48** and creates a suction effect. As a result, the inlet check valve element **67** is drawn towards the inner chamber **48** and into contact with the protrusion **68**, as depicted in FIG. **5**. Fluid is then drawn from the dip tube **52** through the inlet channel **44**, the inlet chamber **66** and the ports **76** into the inner chamber **48**. As the inner chamber **48** fills with the drawn fluid, pressure increases therein and the inlet check valve element **67** is forced into a seated position in the seat **46**.

The pump **10** can be manually actuated without the latch **124**. The latch **124**, however, ensures the application of the threshold force, which, in turn, ensures the application of a full dose in a jet stream, as described above.

Simultaneous to the pumping operation, the vent **96** is exposed to the annular air chamber **94** with the downward travel of the piston **56** and to ambient conditions. As such, the pressure on the surface of the fluid in the reservoir **12** is restored to atmospheric with each actuation of the pump **10**.

As is readily apparent, numerous modifications and changes may readily occur to those skilled in the art, and hence it is not desired to limit the invention to the exact construction and operation shown and described, and accordingly all suitable modification equivalents may be resorted to falling without the scope of the invention as claimed.

What is claimed is:

1. A microdispensing pump for administering minute doses of fluid, said pump comprising:

a pump body formed to define an inner chamber and an inlet chamber with a protrusion extending therein, said inner chamber being in communication with said inlet chamber;

a pump means for urging the fluid through said pump body, said pump means being disposed within said inner chamber; and

an inlet check valve element disposed within said inlet chamber opposite said protrusion, wherein said inlet check valve element regulates the flow of fluid into the inner chamber and wherein said protrusion limits the movement of said inlet check valve element within said inlet chamber such that a swept volume of said inlet check valve element is less than the volume of the minute dose of fluid.

2. A pump as in claim **1**, wherein said inlet chamber has an inner surface formed to substantially define a sphere.

3. A pump as in claim **1**, further comprising a dispensing cap extending from said pump means formed to define an outlet chamber with an inlet which communicates with said inner chamber and an outlet check valve element disposed within said outlet chamber which is urged into sealing contact with said inlet of said dispensing cap by a quick return biasing means selected from the group consisting of a resilient rubber ball, a coil spring, and a leaf spring.

4. A microdispensing pump for administering minute doses of fluid, said pump comprising:

a pump body formed to define a hollow inner chamber;

a pump means for drawing fluid into said pump body and urging the fluid therethrough, said pump means being disposed within said inner chamber;

a dispensing cap extending from said pump means formed to define an outlet chamber with an inlet which communicates with said inner chamber, said dispensing cap having an outer surface and a slender discharge nozzle communicating said outer surface with said outlet chamber;

an outlet check valve element disposed within said outlet chamber for controlling flow of the fluid into the outlet chamber; and

a quick return biasing means for urging said outlet check valve element into sealing contact with said inlet of said dispensing cap as the pump means draws the fluid into said pump body.

5. A pump as in claim **4**, wherein said quick return biasing means is selected from the group consisting of a resilient rubber ball, a coil spring, and a leaf spring.

6. A microdispensing pump for administering minute does of fluid, said pump comprising:

a pump body having an inner body being formed to defined a hollow inner chamber, an opened upper end and a lower end, with said lower end being formed to define an inlet aperture and inlet valve seat;

a pump mechanism disposed within said pump body having a cylindrical piston slidably and sealingly supported within said inner body, and elongated poppet with a base mounted over the inlet valve seat, a stem extending from said base through said piston in a spatial relationship and a head depending from said stem, said cylindrical piston having an inner surface defining a diameter, said head having a diameter greater than the diameter of said inner surface, and a biasing means for urging said piston into sealing contact with said head of said poppet, wherein the base forms a substantially spherical inlet chamber with the inlet valve seat, at least one port being formed in said base for communicating said inlet chamber with said inner chamber, and a protrusion extending from said base into said inlet chamber;

an inlet check valve element disposed within said inlet chamber for controlling flow of fluid into the inner chamber whereby said protrusion limits the movement of said inlet check valve element;

a dispensing cap extending from said piston and disposed within said pump body, said dispensing cap formed to define an outlet chamber with an inlet which communicates with said inner chamber when said poppet is not in sealing contact with said piston, and said dispensing cap having an outer surface and a slender discharge nozzle communicating said outer surface with said outlet chamber; and

an outlet check valve element disposed within said outlet chamber for controlling flow of the fluid into the outlet chamber, said outlet check valve element being urged into sealing contact with said inlet of said dispensing cap by a quick return means as the pump administers the minute does of fluid, whereby force applied to said dispensing cap causes said piston to slide within said cylinder and urge the fluid through said pump mechanism and said nozzle.

7. A pump as in claim **6**, further comprising an actuator slidably disposed in said pump body, said actuator having an annular deformable latch mounted thereto with the inner periphery of the latch being unfixed.

8. A pump as in claim **7**, further comprising an actuator biasing means for urging the actuator away from said dispensing cap.

9. A pump as in claim **6**, further comprising a dip tube for communicating fluid between the reservoir and the inlet aperture of the pump body, said dip tube formed to define a substantially cylindrical passageway which encompasses less volume than the minute dose of fluid.

10. A pump as in claim **9**, wherein said pump body further comprises a hook means for securing said dip tube in a predetermined position.

11. A pump as in claim **6**, wherein said quick return biasing means is selected from the group consisting of a resilient rubber ball, a coil spring, and a leaf spring.

12. A pump as in claim **6**, wherein said pump body includes a substantially cylindric outer shell formed to define a dispensing aperture juxtaposed with said nozzle.

13. A pump as in claim **12**, wherein a sight is formed about the dispensing aperture of said pump body.

14. A pump as in claim **6**, wherein said outer surface of said dispensing cap is formed to define a conical rim about said discharge nozzle.

15. A pump as in claim **13**, wherein said outer surface of said dispensing cap forms an annular depression about said conical rim.

16. A pump as in claim **6**, wherein said discharge nozzle has a length to throat ratio of approximately 7 to 1.

17. A pump as in claim **6**, wherein said protrusion is formed to define a swept volume of said inlet check valve element less than the volume of the minute dose of fluid.

18. A microdispensing pump with a discharge aperture for administering minute doses of fluid with the discharge aperture being oriented within an angular operating range, said pump comprising:

a dispensing cap formed about an axis having an outer surface formed to define the discharge aperture, said dispensing can also formed to define an outlet chamber and a discharge nozzle communicating said outlet chamber with the discharge aperture, and said outer surface also being formed to define a slot;

a pump means for delivering fluid to said dispensing cap, said pump means communicating with said outlet chamber;

an actuator disposed about said axis having an inner actuating surface facing said dispensing cap with an actuating member extending therefrom, said actuating member being aligned with at least a portion of said slot, said actuator capable of translation along said axis; and

a failsafe ball disposed within said slot, wherein said ball is aligned with said actuating member where the discharge charge aperture is oriented within the operating range.

19. A pump as in claim **18**, wherein said slot is formed with a first surface defining an acute angle of 25° relative to said axis and a second surface defining an obtuse angle of 110° relative to said axis.

20. A pump as in claim **18**, further comprising an annular deformable latch mounted to said actuator with an unfixed inner periphery.

21. A pump as in claim **18**, further comprising an actuator biasing means for urging said actuator from said dispensing cap.

22. A pump as in claim **18**, further comprising a dip tube for communicating the fluid to the pump means formed to define a substantially cylindrical passageway encompassing less volume than the minute dose of fluid.

23. A pump as in claim **18**, further comprising at least one check valve means for controlling the flow of the fluid through said pump means.

24. A microdispensing pump for administering minute doses of fluid within an angular operating range, said pump comprising:

a reservoir having a closed bottom for accommodating the fluid and an opened top defining a neck;

a pump body having a substantially cylindrical outer shell with an opened upper portion formed to define a dispensing aperture and a lower portion disposed about said neck, a substantially cylindric inner body disposed co-axially within said outer shell and a transverse annular bulkhead joining said outer shell and said inner body, said inner body being formed to define a hollow cylindrical inner chamber, an opened upper end and a lower end, with said lower end being formed to define an inlet aperture and inlet valve seat;

a pump mechanism disposed within said pump body having a cylindrical piston slidably and sealingly supported within said inner body, an elongated poppet with a base mounted over the inlet valve seat, a stem extending from said base through said piston in a spatial relationship and a head depending from said stem, said cylindrical piston having an inner surface defining a diameter, said head having a diameter greater than the diameter of said inner surface, and a biasing means provided to urge said piston into sealing contact with said head of said poppet, wherein the base forms a substantially spherical inlet chamber with the inlet valve seat, at least one port being formed in said base for communicating said inlet chamber with said inner chamber, and a protrusion extending from said base into said inlet chamber;

an inlet check valve element disposed within said inlet chamber for controlling flow of the fluid into the inner chamber whereby said protrusion limits the movement of said inlet check valve element;

an actuator slidably disposed in the upper portion of the outer shell, said actuator having an inner actuating surface facing said inner body with an actuating member extending therefrom;

a dispensing cap extending from said piston and disposed within said upper portion of said pump body between said actuator and said inner body, said dispensing cap formed to define an outlet chamber with an inlet which communicates with said inner chamber when said poppet is not in sealing contact with said piston, said dispensing cap having an outer surface and a slender discharge nozzle communicating said outer surface with said outlet chamber, said being juxtaposed with said dispensing aperture of said pump body, and said dispensing cap having an upper surface facing said inner actuating surface formed to define a slot, a portion of said slot being aligned with said actuating member;

a failsafe ball disposed within said slot, wherein said ball being aligned with said actuating member where the pump is oriented within the operating range; and

an outlet check valve element disposed within said outlet chamber for limiting flow of the fluid into the outlet chamber, said outlet check valve element being urged into sealing contact with said inlet of said dispensing cap by a quick return biasing means as the pump administers the minute dose of fluid, whereby force applied to said actuator is transferred to said dispensing cap through said actuating member and said failsafe ball with the pump being oriented within the operating range and whereby said dispensing cap causing said piston to slide within said cylinder and urge the fluid through said pump mechanism and said nozzle.

25. A pump as claim **24**, wherein said slot is formed with a first surface defining an acute angle of 25° relative to said axis of said pump body and a second surface defining an obtuse angle of 110° relative to said axis of said pump body.

26. A pump as in claim **24**, further comprising a dip tube for communicating the fluid between said reservoir and said inlet aperture of said inner body, said dip tube formed to define a substantially cylindrical passageway which encompasses less volume than the minute dose of fluid.

27. A pump as in claim **26**, wherein said pump body further comprises a hook means for securing said dip tube in a predetermined portion.

28. A pump as in claim **24**, wherein an annular deformable latch with an unfixed inner periphery is mounted to said actuator and disposed between said dispensing cap and said bulkhead.

29. A pump as in claim **24**, further comprising an actuator biasing means for urging said actuator from said dispensing cap.

30. A pump as in claim **24**, wherein said quick return biasing means is selected from the group consisting of a resilient rubber ball, a coil spring and a leaf spring.

31. A pump as in claim **24**, wherein said outer surface of said dispensing cap is formed to define a conical rim about said discharge nozzle.

32. A pump as in claim **31**, wherein said outer surface of said dispensing cap forms an annular depression about said conical rim.

33. A pump as in claim **24**, wherein said discharge nozzle has a length to throat ratio of 7 to 1.

34. A pump as in claim **24**, wherein said protrusion is formed to define a swept volume of said inlet check valve element less than the volume of the minute dose of fluid.

35. A microdispensing pump for repeatedly administering a predetermined minute dose of fluid, said pump comprising:

a pump body formed with a hollow inner chamber;

pump means for urging the predetermined dose of fluid through said pump body;

an actuator mounted on said pump means for actuating said pump means; and resistance means for creating a predetermined amount of resistance to the actuating of said pump means by said actuator, wherein said resistance means includes a deformable latch, whereby a force sufficient to administer the predetermined dose of fluid is required to overcome the predetermined amount of resistance.

36. A device for repeatedly administering non-aerosolized doses of ophthalmic fluid to an eye of a person, said device having a storage volume for storing a plurality of the doses of the ophthalmic fluid, and a pump for repeatedly forcibly ejecting and delivering at least one of the doses from said storage volume to the eye of the person, the doses being ejected and delivered in a non-diffuse and non-aerosolized form, wherein the delivery of the doses is unassisted by gravity.

37. A device as in claim 36 further comprising a nozzle, the non-aerosolized doses being forcibly ejected through said nozzle.

38. A method of administering doses of ophthalmic fluid to an eye of a person, said method comprising:

providing a closed, single storage volume containing a plurality of the doses of the ophthalmic fluid; and,

ejecting forcibly at least one of the doses from said storage volume so as to be delivered into the eye of the person, the doses being ejected and delivered in a non-diffuse and non-aerosolized form, wherein the delivery of the doses is unassisted by gravity.

39. A method as in claim 38, wherein a pump ejects forcibly the doses.

40. A method as in claim 39, wherein said supply is a reservoir formed on said pump.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE 38,077 E
DATED : April 15, 2003
INVENTOR(S) : Cohen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 2,
Line 7, delete "...the support opposite…" and insert -- the poppet opposite --.

Column 8,
Line 19, delete "...air vents 96…" and insert -- air vents 97 --.

Column 10,
Line 31, delete "...actuator 10…" and insert -- actuator 20 --.

Column 11,
Line 44, delete "...minute does…" and insert -- minute doses --.

Column 12,
Line 15, delete "...quick return means…" and insert -- quick return biasing means --.
Line 59, delete "...dispensing can…" and insert -- dispensing cap --.

Column 13,
Lines 6-7, delete "...discharge charge aperture.." and insert -- discharge aperture --.

Column 14,
Line 7, delete "...said being…" and insert -- said nozzle being --.

Column 16,
Line 15, delete "...wherein said supply is…" and insert -- wherein said storage volume is --.

Signed and Sealed this

Twenty-first Day of October, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office