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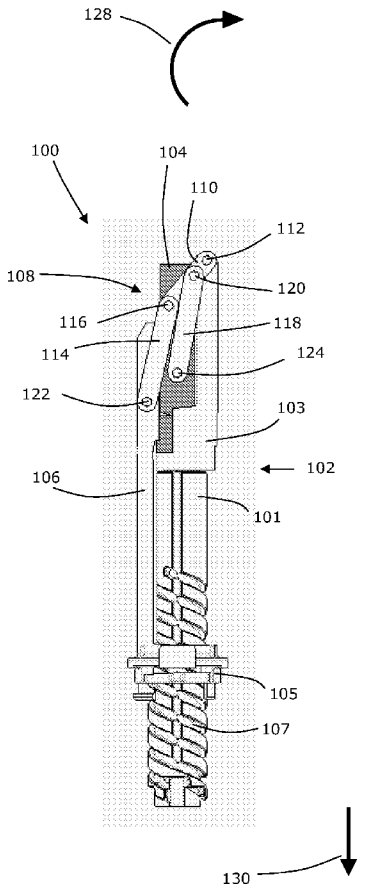
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(54) **Title:** A GEARING MECHANISM FOR AN INJECTION DEVICE



(57) **Abstract:** An injection device comprising: a base member (102); a plunger (104) for driving a piston in a distal direction; a driving member (106); and a gear mechanism (108) providing a gearing between the driving member (106) and the plunger (104) such that then the driving member (106) is moved at a first speed relative to the base member (102), the plunger (104) is moved at a second speed relative to the base member (102); wherein at least two of the base member (102), the plunger (104) and the driving member (106) are pivotally connected to the gear mechanism (108).

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A GEARING MECHANISM FOR AN INJECTION DEVICE

FIELD OF THE INVENTION

The present invention relates to a gear mechanism for an injection device, the gear mechanism comprising a lever mechanism for obtaining a gearing. In particular the present invention relates to a gear mechanism comprising a plurality of pivotally connected members.

BACKGROUND OF THE INVENTION

Syringe devices comprising a gear mechanism are known in the art and examples may be seen in WO 01/95959 and WO 03/080160. WO 01/95959 discloses an injection device for injection of set doses of medicine from a cartridge. The syringe device comprises a gearbox which provides a gearing between an axial movement of an injection button and a nut engaging a piston rod relative to a housing. A gear wheel transmission is established between the nut and the injection button.

It is an object of the present invention to provide a gearing mechanism which is more simple than prior art gear mechanisms. A further object of the invention is to provide a gear mechanism which enables a wider range of obtainable gear ratios as compared to prior art gear mechanisms.

BRIEF DESCRIPTION OF THE INVENTION

In a first aspect of the invention, the invention relates to an injection device for accommodation of a reservoir comprising a piston movable within the reservoir and a medicament to be injected, the injection device comprising:

- a base member;
- a plunger for driving the piston in a distal direction;
- a driving member movable in a proximal direction relative to an initial position so as to set a dose and movable in a distal direction towards the initial position so as to eject a dose of the medicament; and

- a gear mechanism providing a gearing between the driving member and the plunger such that when the driving member is moved at a first speed relative to the base member, the plunger is moved at a second speed relative to the base member;

wherein the gear mechanism comprises a lever mechanism coupling a distally directed movement of the driving member with a distally directed movement of the plunger.

In one embodiment, the gearing mechanism may be so arranged that at least two of the base member, the plunger and the driving member are pivotally connected to the gear mechanism.

In another embodiment, the gearing mechanism may be so arranged that both the base member, the plunger and the driving member are pivotally connected to the gear mechanism.

The injection device may be provided as a pen-injector for manually administering set doses of a medicament, where the piston of a reservoir accommodated in the device is axially moveable upon axially movement of the driving member. The driving member is axially movable in the distal direction responsive to a distally directed push-force exerted by the hand of a user. The push-force may be applied directly on the driving member or via one or more intermediate members.

The medicament containing reservoir may form an integral part of the injection device such that an emptied reservoir cannot be replaced, whereby a user will dispose off the injection device when the reservoir has been emptied. Alternatively, the device may allow replacement of a used reservoir by a new reservoir or allow the user to change between reservoirs containing different kinds of medication and/or the same type of medication at different concentrations.

The plunger and the piston of the reservoir may be interconnected by a piston rod, which may be locked for movement in the proximal direction such that when the plunger is moved in the proximal direction during dose setting, the piston rod remains in essentially the same position relative to the plunger. Moreover, the plunger may be adapted to move the piston rod in the distal direction during dose ejection, whereby a medicament contained in the reservoir is expelled.

Alternatively, the piston rod is adapted to retract a fixed distance in a proximal direction during an initial phase of a dose setting procedure, and adapted to move in a distal direction as a dose is being set.

The gear mechanism provides a gearing between the driving member and the plunger such that when the driving member is moved at a first speed relative to the base member, the plunger is moved at a second speed relative to the base member. Accordingly it will be appreciated, that when the driving member is moved a first distance, the plunger is moved a second distance.

In another embodiment the second speed is lower than the first speed, whereby the second distance is shorter than the first distance. This provides the advantage that the gear mechanism converts a relatively low force applied to the driving member to a relatively high force applied to the plunger.

In a further embodiment, the second speed is higher than the first speed, whereby the second distance is longer than the first distance.

The gear mechanism may comprise a first, second and third connecting member each of which is exclusively connected to one of the base member, the plunger and the driving member. In the context of the present invention the term "exclusively connected" shall be understood such that each of the first, second and third connecting member is directly connected to only one of the base member, the plunger and the driving member, but may be indirectly connected i.e. via one or more elements, to the another of the three elements. As an example, the first connecting member may be directly connected to the base member and indirectly connected to the driving member via the second connecting member.

The connecting members of the gear mechanism each operate in a corresponding plane, e.g. the first connecting member is adapted to rotate in a first plane perpendicular to a rotational axis of said first connecting member.

In one embodiment the three planes are spaced apart and do not coincide. This provides a gear mechanism wherein none of the connecting members limits the rotational movement of another connecting member. In another embodiment, two of said three planes coincide, whereby a compact configuration may be provided. However, as two of the connecting members operate in the same plane, each of said two connecting members is limited in its rotational movement by the other of the two connecting members.

In one embodiment the first connecting member is pivotally and directly connected to the base member, the second connecting member is pivotally and directly connected to the driving member, and the third connecting member is pivotally and directly connected to the plunger. Furthermore, at least one of the second and third connecting members is pivotally connected to the first connecting member.

As an example the first connecting member may be pivotally connected to the base member by means of a first pivotal connection, the second member may be pivotally connected to the first member by means of a second pivotal connection, and the third member may be pivotally connected to the first member by means of a third pivotal connection. As the each of the second and third connecting members may also be connected to one of plunger and the driving member, movement of the base member, the plunger and the driving member are interdependent.

In one embodiment the distance from the third pivotal connection to each of the first and the second pivotal connections is shorter than the distance between the first and the second pivotal connections.

By providing the first, the second and third pivotal connections on the first connecting member, said member serves as a moment arm. Thus, if the first connecting member is allowed to rotate about the first pivotal connection, a force applied to the second pivotal connection results in an even larger force acting on the third pivotal connection. Hence, if the distance between the third pivotal connection and each of the first and second pivotal connections is identical, a force of 1 Newton applied to the second pivotal connection results in a force of 2 Newton applied to the third pivotal connection.

From the above it will be appreciated, that the position of the third pivotal connection is decisive for the gearing of the injection device. Hence, in one embodiment the third pivotal connection is provided closer to the first pivotal connection than to the second pivotal connection, and in another embodiment the third pivotal connection is provided closer to the second pivotal connection than to the first pivotal connection.

It will be appreciated, that the relationship between the distance from the first pivotal connection and each of the second and third pivotal connections, corresponds to the gearing of the device. Hence, if the distance from the first pivotal connection to the second pivotal connection is three times the distance from the first pivotal connection to the third pivotal connection, a force of 1 Newton applied to the second pivotal connection results in a force of 3 Newton acting on the third pivotal connection.

In one embodiment the first, second and third connecting members have identical lengths. Alternatively, at least one of the second and the third connecting member may be at least 20 percent longer than the first connecting member, such as 50 percent longer, such as 100 percent, such as 150 percent. It will be appreciated, that the longer the second and third connecting member are relative to the first connecting member, the more linear the gear mechanism is.

In some embodiments the second and third connecting members have identical lengths. However it will be appreciated, that the non-linear properties of the gear mechanism may in some embodiments be reduced by providing the second and third connecting members at different lengths. As an example the difference in the length of the second and the third connecting member may be at least 20 percent, such as at least 50 percent, such as at least 100 percent, such as at least 150 percent.

In one special embodiment the gear mechanism comprises a first connecting member pivotally connected to at least two of the base member, the plunger and the driving member such as to each of the of said three elements. This provides a simplified solution comprising only one connecting member. The first connecting member may be arranged to interconnect both the base member, the plunger and the driving member, the latter three members each being pivotally connected to the first connecting member at respective specific locations along the extension of the first connecting member.

Moreover, at least one of the pivotal connections may be adapted to move along the first connecting member, e.g. by providing a groove in the first connecting member in which the pivotal connection is allowed to move. Thus, rotation of the first connecting member about one of the three pivotal connections does not force the slidable pivotal connection to follow an arc-shaped path. Thereby a mechanism is provided wherein each of the base member, the plunger and the driving member is moveable along respective rectilinear paths, the paths being mutually parallel. When the rotatable part of the base member, the plunger and the driving member are forced to rotate around the longitudinal axis of the device, their mutual spacing in directions normal to the longitudinal axis remains fixed.

Furthermore, the base member may comprise a fixed part and a rotatable part, the fixed part being rotationally and translationally retained in relation to a housing of the device, the rotatable part being adapted to rotate relative to the base member about a longitudinal axis of the base member, the rotatable part furthermore being translationally retained in relation to the fixed part.

In a still further embodiment, the driving member is rotatably mounted with respect to the fixed part of the base member, and hence, rotatably mounted relative to a housing of the device. The driving member may be adapted to be lifted in the proximal direction of the device as a function of its rotation, such as provided by a threaded coupling. In such an embodiment, the driving member is moved axially in the proximal direction in accordance with the size of the dose being set by rotating the driving member with respect to the housing.

Moreover, a clutch may be provided between the driving member and the fixed part, said clutch may be adapted to be changed between:

- a coupled position wherein a threaded inner surface of the clutch engages a threaded outer surface of the fixed part such that when the driving member is rotated, the threaded engagement causes the driving member to be moved in a proximal direction, and
- a decoupled position wherein the threaded inner surface of the clutch disengages the threaded outer surface of the fixed part, so as to allow translational and non-rotational movement between the driving member and fixed part.

In a still further embodiment, the driving member, and optionally, the plunger, is/are adapted to also rotate during their translational movement during injection.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1 and 2 disclose two extreme positions of a first embodiment of the gear mechanism according to the invention,

Fig. 3 discloses a second embodiment of the gear mechanism, and

Fig. 4 discloses a third embodiment of the gear mechanism.

Figs. 1 and 2 disclose a dosing assembly 100 for a syringe device, such as a pen based injector. The dosing assembly 100 described below is configured for inclusion in an injection pen having a dosing scheme of the kind disclosed in WO 01/95959, this reference hereby being incorporated by reference. The gear mechanism 108 described below substitutes the tooth and rack based gear-box arrangement of the embodiments shown in the figures of WO 01/95959.

Figs. 1 and 2 disclose two extreme positions of the gear mechanism. Fig. 1 illustrates the dosing assembly 100 in its initial position wherein no dose is set, and Fig. 2 illustrates the dosing assembly 100 when a maximum dose has been set.

The dosing assembly comprises a base member 102, a plunger 104 and a driving member 106. The plunger 104 and the driving member 106 are movable in an axial direction relative to the base member 102. Moreover, the distance between the base member 102, the plunger

104 and the driving member 106, remains essentially constant during dose setting and ejection of a dose. The base member comprises a fixed part 101 and a rotatable part 103.

The plunger 104 and the driving member 106 are pivotally connected to the base member 102 via a gear mechanism 108. The gear mechanism 108 comprises a first connecting member 110, which in a first end is pivotally connected to the base member 102 by means of a first pivotal connection 112 and in a second end is pivotally connected to a second connecting member 114 via a second pivotal connection 116. Moreover, the first connecting member 110 is pivotally connected to a third connecting member 118 via a third pivotal connection 120. Furthermore, the second connecting member 114 is pivotally connected to the driving member 106 via a fourth pivotal connection 122, and the third connecting member 118, is pivotally connected to the plunger 104 via a fifth pivotal connection 124.

The fixed part 101 is retained rotationally and translationally in relation to a housing of the device. Furthermore, the rotatable part 103 is adapted to be rotated about its longitudinal axis, while being retained translationally in relation to the fixed part 101. Moreover, a clutch 105 of the driving member is adapted to be changed between a coupled position wherein it engages a threaded outer surface 107 of the fixed part 101, and a decoupled position wherein it does not engage the threaded outer surface 107. When the clutch is in its decoupled position the driving member 106 is allowed to move in the distal direction 130 without rotating, as the clutch is disengaged from the threaded outer surface 107.

In order to set a dose, the driving member 106 is rotated about the longitudinal axis of the device. The rotational movement causes the driving member 106 to be moved in the proximal direction due to the engagement between the clutch 105 and the threaded outer surface 107.

As the second connecting member 114 is pivotally connected to the driving member 106, the proximal movement of the driving member 106 causes the first connecting member 110 to rotate about the first pivotal connection 112, as indicated by arrow 128. Due to the rotation, the third connecting member 118 is also forced in the proximal direction 126. As the third pivotal connection 120 is located closer to the first pivotal connection 112 than the second pivotal connection 116, the plunger 104 is moved at a slower speed relative to the base member 102 than the driving member 106. It will be appreciated that the closer the third pivotal connection 120 is to the first pivotal connection 112, the slower the speed of the plunger 104 is relative to the speed of the driving member 106.

In one embodiment the plunger 104 comprises a threaded inner surface (not shown) which is adapted to engage a threaded outer surface of the piston rod (not shown). Moreover,

rotational and translational movement of the driving member 106 during dose setting causes rotational and translational movement of the plunger 104. However as described in the aforementioned, the plunger 104 is moved at a slower translational speed, and, thus, in order to maintain the piston rod in substantially the same position during dose setting, the pitch of the thread of the piston rod must be decreased correspondingly relative to the pitch of the threaded outer surface 107.

Alternatively, the plunger 104 is arranged to cooperate with a pawl and ratchet mechanism (not shown) which provides for telescopically engagement between the plunger 104 and the piston.

In an embodiment, a dose setting drum (not shown) is operationally coupled to the driving member 106 for rotating the driving member 106 during dose setting. Additionally, an injection button (not shown) axially extending from the proximal end of the injection device is operationally coupled to the driving member 106 for axially moving the driving member 106 upon manually pushing of the injection button in the distal direction. Said dose setting drum and injection button may be provided as mutually separate members or alternatively, these elements form one unitary member.

Fig. 2 illustrates a situation wherein a dose is set and the device is ready for ejection of a dose. In order to eject a dose, the clutch is changed to its decoupled position, whereby the driving member is allowed to move in the distal direction without rotating, as the clutch does not engage the threaded outer surface. The plunger 104 cooperates with a piston rod (not shown) such that when the plunger is moved in the distal direction 130, the piston rod forces a piston (not shown) in a distal direction whereby a medicament contained in a reservoir (not shown) is expelled.

It will be appreciated that by using the driving member 106 to eject the medicament, the first connecting member 110 serves as a moment arm whereby a relatively small force need be applied to cause the plunger to move in the distal direction 130. Again it will be appreciated, that the closer the third pivotal connection 120 is to the first pivotal connection 112, the smaller a force need be applied to the driving member 106 in order to move the plunger 104. Moreover it will be appreciated, that due to the different speeds, the plunge 104 is moved a shorter distance relative to the base member than the driving member 106, for any angular movement of the first connecting member 110 about the first pivotal connection.

Additionally, it will be appreciated that the gearing between the plunger 104 and the driving member 106 is determined by the length of the first connecting member 110 and the relative

position of the first, second, and third pivotal connection 112,116,120 on said first connecting member 110.

Figs. 3 and 4 disclose a second and third embodiment of the gear mechanism 108. The two embodiments comprise a plunger 104 and a driving member 106 which are movable relative to a base member 102.

The gear mechanism 108 comprises a first connecting member 110, which is pivotally connected to the base member 102, the plunger 104 and the driving member 106, via a first pivotal connection 112, a fifth pivotal connection 124, and a fourth pivotal connection 122, respectively.

In Fig. 3, the first connecting member 110 comprises a first and second groove 132, 134 allowing the first pivotal connection 112 and the fourth pivotal connection 122 to move in a longitudinal direction of the first connecting member 110 between a first and second position 136,138. The fifth pivotal connection 124 is locked for longitudinal movement relative to the longitudinal direction of the first connecting member 110. All three pivotal connections allow the first connecting member 110 to rotate about each of the pivotal connections 112,122,124, such that the first connecting member 110 may pivot relative to the base member 102, the plunger 104 and the driving member 106.

In one embodiment the mutual distance between the base member 102, the plunger 104 and the driving member 106, in directions normal to the longitudinal axis, remains essentially constant during dose setting and ejection of a dose. Accordingly, it will be appreciated that when the driving member 106 is moved in the proximal direction 126, the fourth pivotal connection 122 is moved in the direction of the first position 136, until the first connecting member 110 is at right angle to the plunger 104. Upon further proximal movement of the driving member 106, the fourth pivotal connection 122 is moved away from the first position 136 and towards the second position 138. In order to reduce the friction between the pivotal connections 112,122 and the inner surfaces of the grooves 132,134, said inner surfaces may have a smooth surface with a low coefficient of friction. Alternatively, or as a supplement, bearings may be provided on the pivotal connections 112,122. In yet another alternative, the pivotal connections and the grooves are lubricated so as to reduce the friction between the engaging surfaces.

In Fig. 4 the grooves 132,134 are merged such that two pivotal connections 122,124 are allowed to move in the longitudinal direction of the first connecting member 110, whereas the first pivotal connection 112 is locked for longitudinal movement relative to the first

connecting member 110. It will be appreciated that in some embodiments the grooves 132,134 need not be merged in order to enable the gear mechanism to work.

It will be appreciated, that most of the description of the gear mechanism of Fig. 3 also applies to the gear mechanism of Fig. 4.

While the dosing assembly according to the above embodiments have been described with reference to the general dosing scheme of WO 01/95959, it should be stressed that the present invention is not limited to this particular dosing scheme. The gearing arrangement according to the present invention is further adoptable in pen-injectors having various kinds of dosing schemes, such as the ones described in WO9938554, WO2006114395, WO2006114396, US20040215152, US5584815 and US4883472, however, this list being non-exhaustive.

CLAIMS

1. A pen-injector for manually administering set doses of a medicament, the injector adapted for accommodating a reservoir comprising a piston movable along a first axis within the reservoir and a medicament to be injected, the pen-injector comprising:

- a base member (102);
- a plunger (104) for driving the piston axially in a distal direction;
- a driving member (106) axially movable relative to the base member (102), the driving member (106) movable in a proximal direction (126) relative to an initial position so as to set a dose and manually pushable in a distal direction (130) towards the initial position so as to eject a dose of the medicament; and
- a gear mechanism (108) providing a gearing between the driving member (106) and the plunger (104) such that when the driving member (106) is moved at a first speed relative to the base member (102), the plunger (104) is moved at a second speed relative to the base member (102);

wherein at least two of the base member (102), the plunger (104) and the driving member (106) are pivotally connected to the gear mechanism (108).

2. A pen-injector according to claim 1, wherein the gear mechanism (108) comprises a first, second and third connecting member (110,114,118) each of which is exclusively connected to one of the base member (102), the plunger (104) and the driving member (106).

3. A pen-injector according to claim 2, wherein the first connecting member (110) is pivotally connected to the base member (102), the second connecting member (114) is pivotally connected to the driving member (106), and the third connecting member (118) is pivotally connected to the plunger (104), and wherein at least one of the second and third connecting members (114,118) is pivotally connected to the first connecting member (110).

4. A pen-injector according to claim 3, wherein the first connecting member (110) is pivotally connected to the base member (102) by means of a first pivotal connection (112), the second member is pivotally connected to the first member by means of a second pivotal connection (116), and the third member is pivotally connected to the first member by means of a third pivotal connection (120).

5. A pen-injector according to claim 4, wherein the distance from the third pivotal connection (120) to each of the first and the second pivotal connections (112,116) is shorter than the distance between the first and the second pivotal connection (112,116).

6. A pen-injector according to claim 5, wherein the distance between the third pivotal connection (120) and the first pivotal connection (112) is shorter than the distance between the third pivotal connection (120) and the second pivotal connection (116).

7. A pen-injector according to claim 5, wherein the distance between the third pivotal connection (120) and the first pivotal connection (112) is longer than the distance between the third pivotal connection (120) and the second pivotal connection (116).

8. A pen-injector according to any of claims 2-7, wherein at least one of the second and the third connecting member (118) is at least 20 percent longer than the first connecting member (110), such as 50 percent longer.

9. A pen-injector according to any of claims 2-8, wherein the difference in the length of the second and the third connecting member (114,118) is at least 20 percent, such as 50 percent.

10. An pen-injector according to any of the preceding claims, wherein the second speed is lower than the first speed.

11. A pen-injector according to claim 1, wherein the gear mechanism comprises a first connecting member (110) pivotally connected to at least two of the base member (102), the plunger (104) and the driving member (106).

12. A pen-injector according to claim 11, wherein the first connecting member (110) is pivotally connected to the base member (102), the plunger (104) and the driving member (106).

13. A pen-injector according to any of the preceding claims, wherein the base member (102) comprises a fixed part (101) and a rotatable part (103), the fixed part being rotationally and translationally retained in relation to a housing of the device, the rotatable part (103) being adapted to rotate relative to the base member about a longitudinal axis of the base member, the rotatable part (103) furthermore being translationally retained in relation to the fixed part (101).

14. A pen-injector according to claim 13, further comprising a clutch (105) provided between the driving member (106) and the fixed part (101), said clutch being adapted to be changed between:

- a coupled position wherein a threaded inner surface of the clutch (105) engages a threaded outer surface (107) of the fixed part (101) such that when the driving member (106) is rotated, the threaded engagement causes the driving member (106) to be moved in a proximal direction (126), and

- a decoupled position wherein the threaded inner surface of the clutch (105) disengages the threaded outer surface (107) of the fixed part (101), so as to allow translational and non-rotational movement between the driving member (106) and fixed part (101).

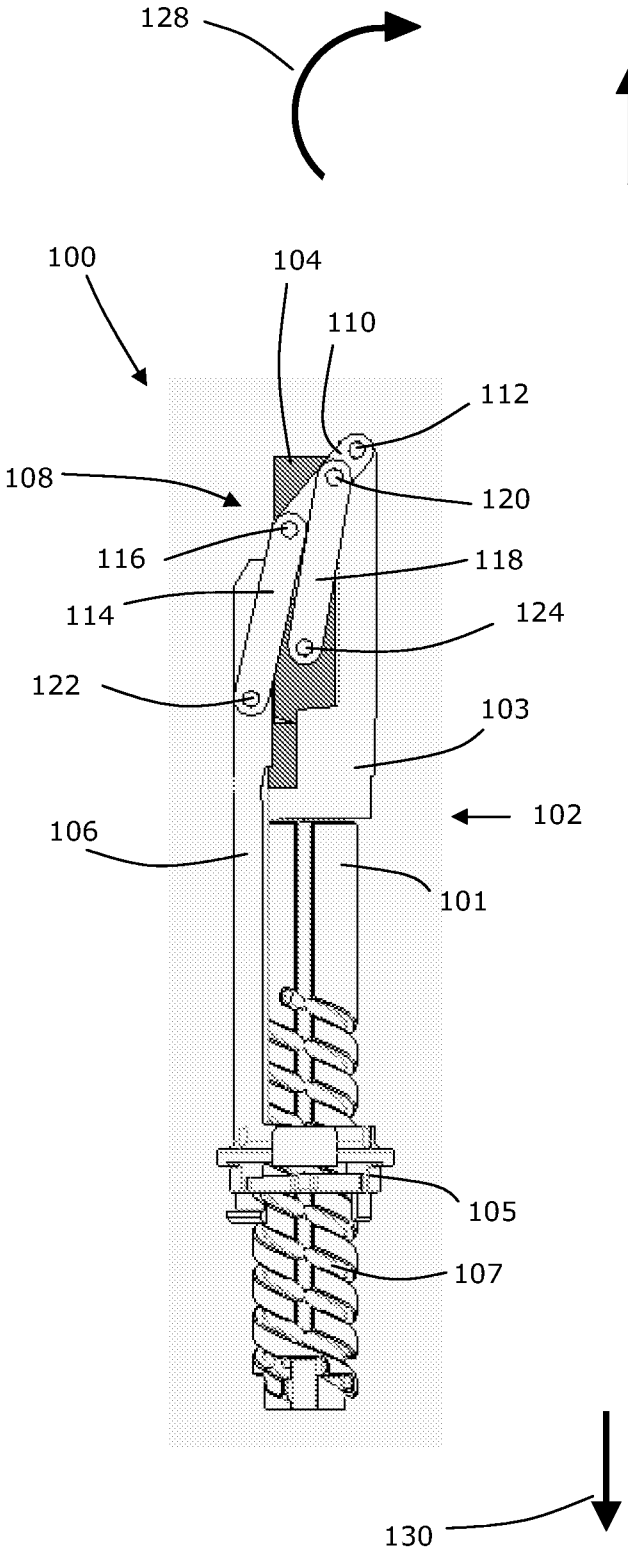

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Fig. 1

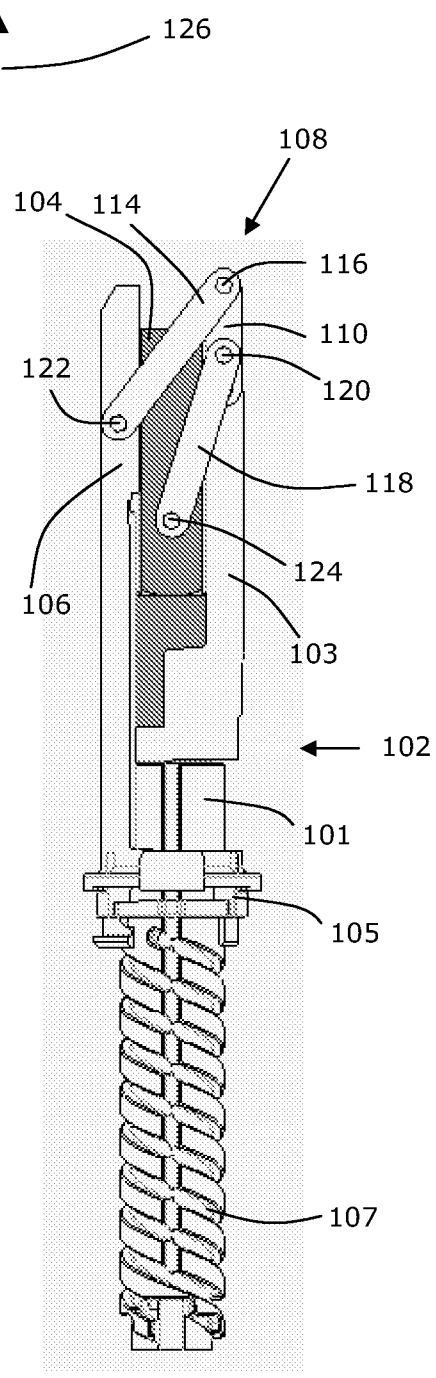

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Fig. 2

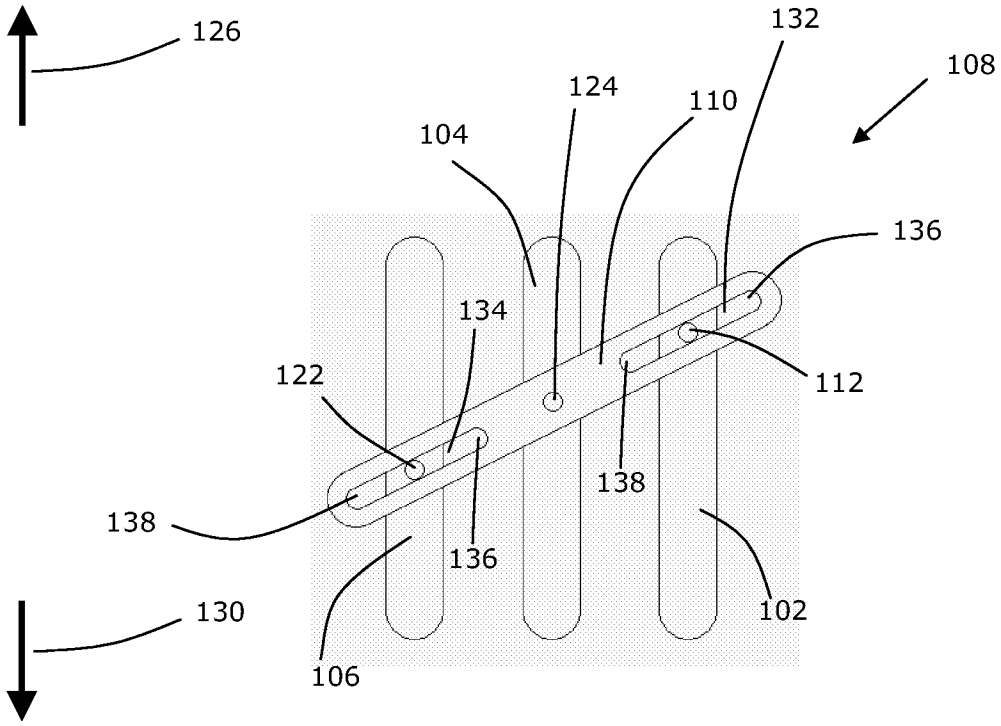

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Fig. 3

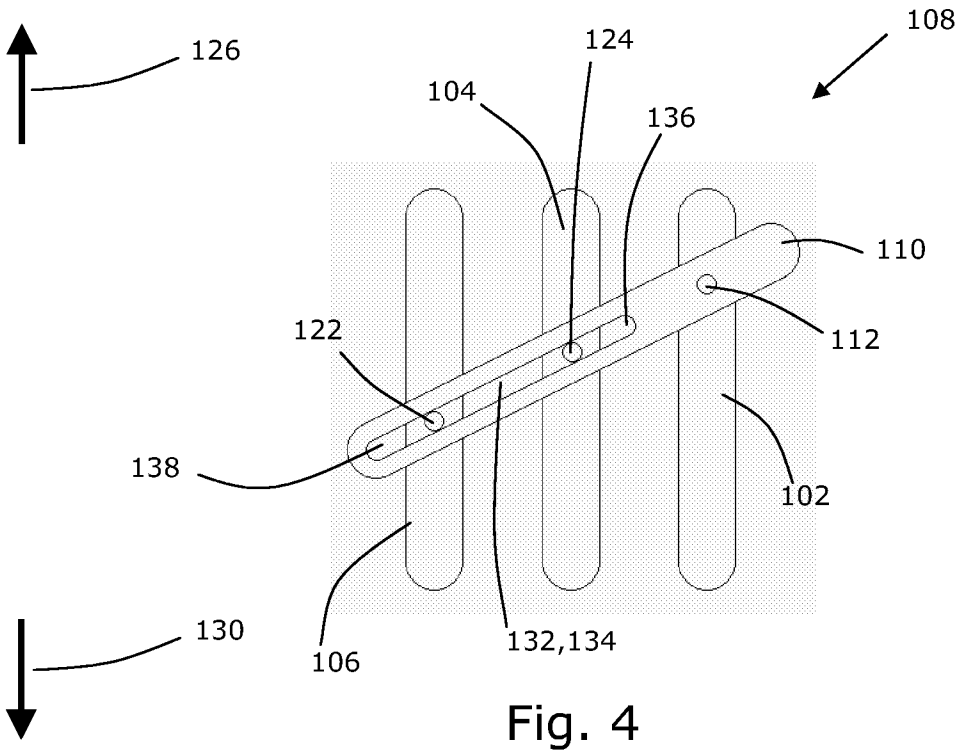

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Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/054796

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01/95959 A (NOVO NORDISK AS [DK]) 20 December 2001 (2001-12-20) cited in the application the whole document	1
A	WO 03/080160 A (LILLY CO ELI [US]; JUDSON JARED ALDEN [US]; STEWART WILLIAM CHARLES [U) 2 October 2003 (2003-10-02) cited in the application abstract	1
A	FR 2 767 479 A1 (AGUETTANT LAB [FR]) 26 February 1999 (1999-02-26) abstract	1
A	WO 02/076536 A (DCA DESIGN INT LTD [GB]; WOOLSTON ROBERT [GB]) 3 October 2002 (2002-10-03) abstract	1

☐ Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

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