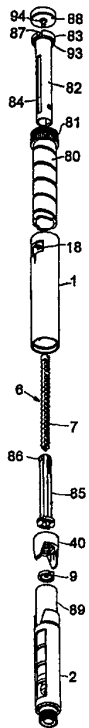




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61M 5/315, 5/24</p>	<p>A1</p>	<p>(11) International Publication Number: WO 99/38554 (43) International Publication Date: 5 August 1999 (05.08.99)</p>
<p>(21) International Application Number: PCT/DK99/00042 (22) International Filing Date: 28 January 1999 (28.01.99) (30) Priority Data: PA 1998 00130 30 January 1998 (30.01.98) DK (71) Applicant: NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK). (72) Inventors: STEENFELDT-JENSEN, Søren; Holmevænget 2B, DK-3100 Hornbæk (DK). HANSEN, Steffen; Gl. Frederiksborgvej 64A, DK-3400 Hillerød (DK). (74) Agent: NOVO NORDISK A/S; Corporate Patents, Novo Allé, DK-2880 Bagsværd (DK).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: AN INJECTION SYRINGE</p> <p>(57) Abstract</p> <p>In an injection syringe comprising a housing (1), a piston rod (6) with a not circular cross section and an outer thread (7), a piston rod drive comprising a piston rod guide (85) mating the cross section of the piston rod (6) and a nut (4) which is not axially displaceable and mates the thread (7) of the piston rod (6) to form a self locking thread connection, and a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element (81) is screwed out to project from the housing (1) and which thread connection by axial returning of the injection button (88) transforms this axial movement into a rotation of one of the piston drive elements (85) relative to the other one (4). A unidirectional coupling between the nut member (4) and the piston rod guide (85) allows rotation in one direction by which the piston rod (6) is transported in a distal direction. The coupling has an initial reluctance to be overcome before rotation takes place said reluctance being large enough to resist torques exerted during the dose setting.</p> <div style="text-align: right;">  </div>		

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An injection syringe

The invention relates to injection syringes of the kind apportioning set doses of a medicine
5 from a cartridge containing an amount of medicine sufficient for the preparation of a number
of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g.
diabetics. A number of demands are set to such syringes. The setting of a dose must be
10 easy and unambiguous and it must be easy to read the set dose. It must be possible with a
minimum of trouble to cancel or change a wrongly set dose and when the dose is injected
the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe
which is disposed of when the cartridge is empty, the syringe must further be cheap and
made of materials suited for recycling or burning without producing noxious gases. For these
15 purposes the number of parts from which the syringe is constructed and the number of dif-
ferent kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the
nut and the piston rod may be rotated relative to each other. The dose setting may be ob-
20 tained by screwing the nut away from a stop to which it is returned during the injection by
pressing the piston rod until the nut member abuts the stop. By other dose setting devices
one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to
rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance
through the nut.

25 In most syringes for apportioning set doses it is preferred that the piston rod is backing up
the piston upon which it works during the injection. To obtain this precaution is taken to pre-
vent the piston rod from moving in a proximal direction.

30 The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a
stop. During the setting of the dose the screwing may be performed in both direction so that
a too large set dose may be lowered just by rotating the nut in an opposite direction. Means
are provided preventing that negative doses are set. The mutual rotation of the piston rod
and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be

read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at
5 on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line
10 on a tubular extension of the nut so that these numbers may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user has to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

15 In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is pressed back to the end of the housing it will rotate
20 back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation
25 to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing. This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing. This pen fulfils all the
30 objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

5 This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

10

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

15 a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread
20 connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance deter-
25 mined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

which syringe according to the invention is characterised in that
30

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal di-

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