

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. §1.53(c)

Assistant Commissioner for Patents  
Washington, DC 20231

Express Mail Label No. EL021373705US  
Date of Deposit February 5, 1998

Sir:

This is a request for filing a provisional application under 37 C.F.R. §1.53(c),  
of the inventors:

Steenfeldt-Jensen, Søren, a citizen of Denmark, residing at Holmevænget 2B,  
DK-3100 Hornbæk; and

Hansen, Steffen, a citizen of Denmark, residing at Gl. Frederiksborgvej 64A,  
DK-3400 Hillerød, Denmark for application entitled An Injection Syringe.

The provisional application contains:

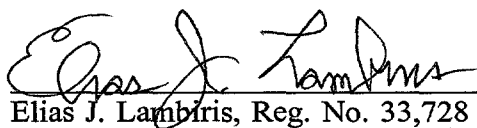
15 pages of specification

2 sheets of drawings

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of  
North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be \$150, to Novo Nordisk of North  
America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,



Elias J. Lambiris, Reg. No. 33,728  
Novo Nordisk of North America, Inc.  
405 Lexington Avenue, Suite 6400  
New York, NY 10174-6401  
(212) 867-0123

Date: February 5, 1998

Sanofi Exhibit 2127.001

## An injection syringe

The invention relates to injection syringes of the kind apportioning set doses of a medicine 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 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 purposes the number of parts from which the syringe is constructed and the number of different 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 obtained 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.

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 prevent the piston rod from moving in a proximal direction.

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

5472.000-DK,EIT/PGy

Sanofi Exhibit 2127.002

5472.000-DK, EIT/PGy

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 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 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.

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 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 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 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

5472.000-DK,EIT/PGy

screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

5 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.

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

10

a housing

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

15

a piston rod drive comprising two elements

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

20

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 connection,

25

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 determined 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,

30

which syringe according to the invention is characterised in that

5472.000-DK,EIT/PGy

Sanofi Exhibit 2127.004

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 direction in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod).

When the button is pressed hard enough the initial reluctance is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

5472.000-DK,EIT/PGy

Sanofi Exhibit 2127.005

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.