

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
8 November 2001 (08.11.2001)

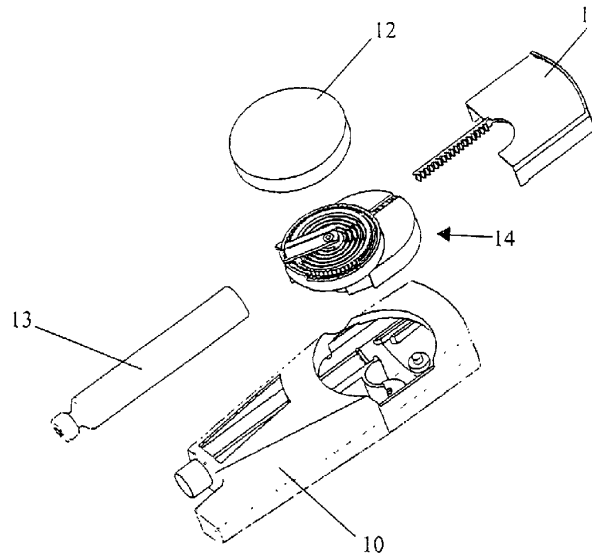
PCT

(10) International Publication Number
WO 01/83008 A1

- (51) International Patent Classification⁷: A61M 5/31 DE, DK, DM, DZ, 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, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (21) International Application Number: PCT/DK01/00281
- (22) International Filing Date: 27 April 2001 (27.04.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
PA 2000 00739 4 May 2000 (04.05.2000) DK
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, 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, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant: NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK). **Published:**
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (72) Inventors: HANSEN, Steffen; Gl. Frederiksborgvej 64A, DK-3400 Hillerød (DK). MILLER, Thomas, Dedenroth; Teglstrupvej 15, Emdrup, DK-2100 Copenhagen Ø (DK).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AN INJECTION DEVICE, A PREASSEMBLED DOSE SETTING AND INJECTION MECHANISM FOR AN INJECTION DEVICE, AND A METHOD OF ASSEMBLING AN INJECTION DEVICE



(57) Abstract: An injection device made up from a housing, a dose setting and injection mechanism, a dose setting member and an injection button is described. The dose setting and injection mechanism is made as a preassembled unit insertable into the housing. Both the dose setting member and the injection button is thereafter connected to the preassembled dose setting and injection mechanism inside the boundaries of the housing, while being accessible for a user from outside the housing. The same preassembled dose setting and injection mechanism can fit into a large variety of different houses making production of different variants of an injection device somewhat easier.



WO 01/83008 A1

An injection device, a preassembled dose setting and injection mechanism for an injection device, and a method of assembling an injection device.

The Technical Field of the Invention:

5

The invention relates to injection devices of the kind comprising a housing accommodating an cartridge, a dose setting and injection mechanism, a dose-setting member coupled to the dose setting and injection mechanism, and an injection button coupled to the dose setting and injection mechanism and by which a piston rod drive can be activated for advancing the piston rod forward to press out a set dose through a conduit connected to the cartridge.

10

The invention furthermore relates to a preassembled dose setting and injection mechanism for an injection device.

15

Finally the invention relates to a method of assembling an injection device.

Description of the Related Art:

20

A prior art injection device of this kind is shown in WO 98/56436, which injection device is also shown in figure 1 of this application. This device consists of three basic parts; a dose setting and injection mechanism, a dose-setting member and an injection button. The dose setting and injection mechanism contains a piston rod 1 and a piston rod drive comprising gear wheels 2 and 3, a coupling ring 4, and a driver 5. The coupling ring 4 and the driver 5 are connected through a unidirectional coupling. The dose-setting element 6 has a carrier 7 and a finger grip 8. The injection button 9 works a not shown gearwheel placed at the hub of the coupling ring 4.

25

30

In injection devices of this type the dose setting and injection mechanism is made as an integrated part of the housing. The outer shape of the housing has to facilitate the appearance of the dose setting and injection mechanism, and the housing is moulded with a number of protrusions supporting the various elements of the dose setting and injection mechanism.

35

Description of the Invention:

If for some reason an injection device with a different outer design is needed, it is necessary to reconstruct the entire dose setting and injection mechanism in order to fit it into the new redesigned housing. This takes a substantial amount of time, both to the reconstruction of the entire device, but also to get the proper approvals from the authorities. Therefore many manufactures of injection devices are very reluctance to market new injection devices, designed in accordance with the trends in the world of fashion.

Although a new type of injection devices are approved by the authorities prior to the marketing, there always persists a small risk of malfunction due to an erroneous construction of the dose setting and injection mechanism. Another safety disadvantage is that the function of the dose setting and injection mechanism cannot be tested once the injection device is assembled, while it is impossible to move the piston rod backwards once the injection device is assembled.

It is an object of the present invention to provide an injection device where the outer design of the housing can be altered without having to change the dose setting and injection mechanism. Further, it is an object to provide an injection device, which can be new in design but having a save and well-proven dose setting and injection mechanism, thereby minimizing the risk of malfunction. Finally it is an object of the present invention to provide an injection device where the function of the dose setting and injection device can be properly tested before the injection device is completely assembled.

This is obtained by an injection device having a housing accommodating an cartridge containing medicine sufficient for a number of dosed injections, which doses are injected by advancing a piston forward inside said cartridge, comprising:

A dose setting and injection mechanism comprising a piston rod abutting said piston and a piston rod drive for driving said piston rod,

A dose-setting member coupled to said dose setting and injection mechanism for setting up a dose, and

An injection button coupled to said dose setting and injection mechanism and by which said piston rod drive can be activated for advancing said piston rod and said piston forward to press out a set dose through a conduit connected to said cartridge,

5 Which injection device according to the invention is characterized in that

said dose setting mechanism is a preassembled unit insertable into said housing to form a complete assembly, and that said dose-setting member and said injection button, both being accessible for the user from outside said housing, is connected to said preassembled dose setting and injection mechanism inside the boundaries of said housing.

By making the dose setting and injection mechanism as a preassembled unit, this unit is independent of the housing, and if a new injection device with a new outer design is called for, it is fairly simple to redesign the housing and then insert the standardized dose setting and injection mechanism. From a manufacturing point of view production of a large variety of injection devices each carrying a different design is made very simple by using a preassembled dose setting and injection mechanism. But from a safety point of view it is certainly a great safety issue to be able to manufacture injection devices with a new outer design, but still containing the well proven standardized dose and injection mechanism of an earlier device.

It is also a particular advantage that the preassembled dose setting and injection mechanism permits a testing of the function of the mechanism before the complete assembly is done.

25 When, as disclosed in claim 2, the dose-setting member is provided with a number of carriers, which carriers is received in depressions in said preassembled dose setting and injection mechanism, it is in a very handy way ensured that the dose-setting member interfaces the preassembled dose setting and injection mechanism. The carriers could be provided with click-pawls, which would lock the dose-setting member to the preassembled dose setting and injection device in a inseparable way.

When, as disclosed in claim 3, the injection button is provided with a toothed rack, which toothed rack is received in a slot in said preassembled dose setting and injection mechanism, it is ensured that the longitudinal movement of the injection button is transferred to a rotational movement of the coupling ring. The injection button could be provided with a pro-

trusion, which fits into a longitudinal track in the housing, thereby locking the injection button to the housing.

It is also an object of the present invention to provide a preassembled dose setting and injection mechanism, which can be fitted into a large variety of different housings.

This is obtained by a preassembled dose setting and injection mechanism for an injection device according to the invention, which preassembled dose setting and injection mechanism is characterized in that said preassembled dose setting and injection mechanism comprises:

10

a coupling ring driven by said injection button,

a driver driving the piston rod through a suitable gearing, and

15 a unidirectional coupling connecting the coupling ring and the driver in a unidirectional manner.

By making the dose setting and injection mechanism as a single preassembled unit it will be possible to recycle the injection device. The recycled device can be disassembled, and the preassembled dose setting and injection mechanism can be reused after the piston rod has been moved backward to its original position. The other parts of the injection device can off

20 cause be recycled in the same manor. The various parts can either be recycled by using the same part again as described, or more likely, the various parts can be sorted into the different types of plastic and then granulated for recycling.

25

Finally it is an object of the invention to provide a method of assembling an injection device in a way, which is both easy and inexpensive.

This is obtained by a method of assembling an injection device according to the invention, which method is characterized in comprising the steps of:

30

a) Preassembling the dose setting and injection mechanism to provide a preassembled unit,

b) Placing the preassembled unit in the housing and connecting said preassembled unit to said housing,

35

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.