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**Datasheet for the decision
of 11 June 2018**

Case Number: T 1609/13 - 3.2.02

Application Number: 08708028.9

Publication Number: 2109474

IPC: A61M5/315

Language of the proceedings: EN

Title of invention:

INJECTION BUTTON

Patent Proprietor:

Novo Nordisk A/S

Opponent:

Bock Wolfgang

Headword:

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1609/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 June 2018

Appellant: Novo Nordisk A/S
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
2 May 2013 concerning the maintenance of
European patent No. 2109474 in amended form

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

- I. The patent proprietor and the opponent have appealed against the Opposition Division's decision, dispatched on 2 May 2013, that, taking into consideration the amendments according to the fourth auxiliary request made by the proprietor during the opposition proceedings, European patent No. 2 109 474 and the invention to which it related met the requirements of the EPC.
- II. The patent was opposed on the grounds of lack of novelty, lack of inventive step and insufficient disclosure.
- III. Notice of appeal was filed by the appellant/patent proprietor (hereinafter "the proprietor") on 12 July 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 August 2013.
- IV. Notice of appeal was filed by the appellant/opponent (hereinafter "the opponent") on 11 July 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 12 September 2013.
- V. Oral proceedings took place on 11 June 2018.

The proprietor requested that the opponent's appeal be dismissed or, in the alternative, that the patent be maintained on the basis of one of the fifth to eleventh auxiliary requests filed with letter dated 22 August 2013.

The main and the first to third auxiliary requests

filed with letter dated 22 August 2013 were withdrawn.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

VI. The following document is mentioned in the present decision:

D1: EP-B-1 003 581.

VII. Claim 1 of the request found allowable by the Opposition Division in the impugned decision reads as follows:

"A push button connection for an injection device comprising:

a push button (10) mountable on a driving part (20) being rotatable relatively to the push button (10) and which push button (10) further comprises a bore (12) with a bottom surface (17) and which bore (12) surrounds a protrusion (21) on the driving part (20) which protrusion (21) has a top surface (22) and wherein a pivot bearing (18, 22) is formed between the bottom surface (17) and the top surface (22),

wherein at least one radial bearing (13, 23; 14, 25) between the push button (10) and the driving part (20) is provided, and

wherein an upper radial bearing (13, 23) is provided at a top part (23) of the protrusion (21) and a lower radial bearing (14, 25) is provided at the bottom of the protrusion (21)."

Claims 2 to 5 are dependent claims.

VIII. The proprietor's arguments where relevant to the present decision may be summarised as follows:

The push button connection for an injection device according to claim 1 of the request found allowable by the Opposition Division comprised, in particular, a push button and a driving part. The definition of the push button as being "mountable on a driving part" did not mean that the driving part did not form part of the claim, in particular because the claim further specified that a pivot bearing was formed between a part of the push button and a part of the driving part. Since the driving part was a prerequisite for the forming of the pivot bearing, the claim required the provision of the driving part.

The push button connection disclosed in D1 comprised neither an upper nor a lower radial bearing between a push button and a driving part as required by claim 1. More specifically, the couplings between hooks 24 and bead 25, and between cap 23 and tubular extension 21 in the region of hooks 28, both shown in figure 2 of D1, did not provide any radial retention. On the contrary, radial clearance between the respective elements of the couplings was needed so as not to jeopardise other functions of the injection device. Hence, those couplings did not qualify as radial bearings. Instead, the bearings defined by the couplings between surfaces 12 and 23, and 14 and 25 in figure 1 of the patent, prevented relative radial movement even if, to a certain extent, push button 10 could tilt with respect to driving part 20, as explained in paragraph [0007] of the patent.

The upper and lower radial bearings defined in claim 1 had the technical effect of properly transferring tilting forces applied to the push button in an axial direction.

It followed that the problem solved over D1 was how to make more efficient use of the forces to be applied in order to inject a dose of medicament.

In the injection device shown in figure 2 of D1, radial forces applied to cap 23 were taken up by the coupling between the cap and tubular housing 1, provided outside the cap. Providing two bearings as claimed required a complete redesign of the injection device of D1, which was not obvious to the skilled person.

It followed that the subject-matter of claim 1 of the request found allowable by the Opposition Division was novel and inventive.

IX. The opponent's arguments where relevant to the present decision may be summarised as follows:

The use of the term "mountable" in claim 1 of the request found allowable by the Opposition Division made clear that the push button was part of the claim, but the driving part was not. Even the proprietor had admitted that such terminology was ordinarily used in connection with features not forming part of a claim. The reference to other components in the claim merely implied a requirement that the push button was suitable for interfacing with such components in a certain way.

As regards patentability, in the oral proceedings the opponent had stated that he only maintained objections to claim 1 based on D1 and the common general

knowledge.

The embodiment of the injection device depicted in figure 2 of D1 comprised a push button connection with an upper and a lower radial bearing as defined in claim 1. In particular, the coupling between hooks 24 and bead 25, described as forming a journal in paragraph [0030], was a lower radial bearing, analogous to the snap fit around radial extending track 15 shown in figure 1 of the patent. An upper radial bearing according to claim 1 was formed in the upper region of tubular extension 21, proximate to external hooks 28. These bearings could take up radial forces if a force in the direction of the axis of the injection device, but offset from it, was applied to cap 23.

In any event, starting from D1 the skilled person would provide radial bearings as claimed in order to improve the proper force transmission between cap 23 and the driving part of the injection device. The provision of radial bearings to support a shaft was generally known and was a straightforward measure for the skilled person. The proprietor's argument that, in the device of figure 2 of D1, radial forces applied to cap 23 were taken up by the coupling between the cap and tubular housing 1, provided outside the cap, was not correct. In particular, after having set a large dose and before injection, cap 23 would be fully extended above casing 1 in figure 2. In that configuration any lateral movement of the cap would be prevented by the provision of radial bearings as defined in claim 1.

It followed that the subject-matter of claim 1 of the request found allowable by the Opposition Division lacked an inventive step in view of D1 and the common

general knowledge.

Reasons for the Decision

1. The appeals are admissible.
2. The invention

The invention relates to a push button connection for an injection device such as a dosing injection pen.

With some dosing injection pens a dose of medicament to be injected may be set by rotating a scale drum axially out of a housing. The injection is then performed by axially pushing on a distal push button, so that a force is transmitted to the scale drum. During the injection the scale drum rotates back into the housing and acts on a piston which ejects the medicament. The force applied to the push button is therefore transferred to the piston to perform the injection.

Figures 1 and 2 of the patent, reproduced below, depict a push button connection in accordance with the invention comprising a push button (10) and a driving part (20) with a protrusion (21), wherein an upper radial bearing (13, 23 - force C) is provided at a top part of the protrusion and a lower radial bearing (14, 25 - force D) is provided at the bottom of the protrusion.

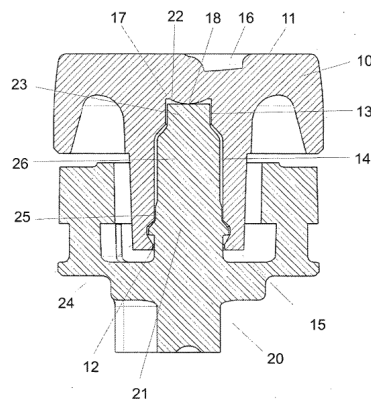


Fig. 1

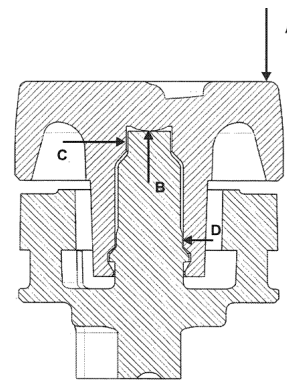


Fig. 2

The object of the invention as stated in paragraph [0004] of the patent is to provide a push button connection for an injection device which minimises the forces a user must apply to inject a dose. The radial bearings, in particular, are for securing the fit between the push button and the driving part and directing forces applied on the periphery of the push button to the driving part (paragraphs [0006] and [0007] and figure 2).

3. A matter of dispute between the parties is whether the subject-matter of claim 1 of the request found allowable by the Opposition Division comprises the driving part.

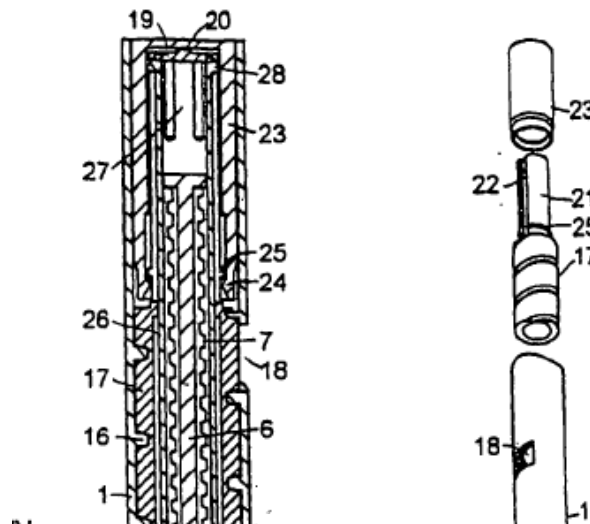
The opponent argued that since the claim defined "a push button (10) mountable on a driving part (20)", the latter was not part of the subject-matter claimed, but the reference to it simply defined certain features of the push button.

In the Board's view this argument ignores other features of the claim. More specifically, the claim further specifies that a bore of the push button **surrounds** a protrusion on the driving part, that a pivot bearing **is formed** between a bottom surface of the

push button and a top surface of the protrusion and that radial bearings **are provided** between the push button and the driving part. Since these features presuppose the presence of the driving part, the latter has to belong to the claimed subject-matter. In other words, according to the claim the push button is not only mountable but also inherently mounted on the driving part in order for the other defined features to be fulfilled.

4. The opponent only maintained objections to the patentability of the subject-matter of claim 1 of the request found allowable by the Opposition Division starting from D1.

D1 relates to dosing injection pens of the kind to which the present invention pertains. The most relevant embodiment, on which the opponent based his arguments, is depicted in figures 2 and 3, parts of which are reproduced below.



This embodiment of D1 comprises a push button connection for an injection device with a push button (cap 23), mountable on a driving part (dose scale drum

17 with its tubular extension 21 and end wall 19, described in paragraph [0030], first two sentences) being rotatable relative to the push button (paragraph [0030], last sentence); the push button further comprises a bore with a bottom surface (inner part of cap 23); the bore surrounds a protrusion (tubular extension 21) on the driving part; and the protrusion has a top surface (end wall 19). D1 further discloses a protrusion 20 on end wall 19 of tubular extension 17 which, together with the bottom surface of cap 23, forms a journal (paragraph [0030], last sentence).

In the Board's view, this push button connection comprises no radial bearings between the push button and the driving part as defined in claim 1.

More specifically, D1 does not disclose that the couplings identified as such bearings by the opponent could take up radial forces in a condition of use. Hence, they cannot qualify as radial bearings according to the generally accepted meaning of the term as also employed in the patent (paragraph [0007]).

In particular, the passage in paragraph [0030] of D1 describing the interaction between hooks 24 and circumferential bead 25 reads as follows:

"Internal hooks 24 at the open end of this cap snaps [sic] over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension."

While according to this passage a journal is formed and

the injection button cannot be axially displaced relative to extension 21 because of hooks 24 having snapped over bead 25, it cannot be inferred that any transfer of radial forces could take place between the hooks and the bead in a condition of use where a force in the direction of, but offset from, the axis of the injection device is applied on cap 23.

Under the same condition, no transfer of radial forces in the upper region of tubular extension 21, proximate to external hooks 28, is disclosed either.

As also explained in the impugned decision, from the mechanical design of the device of D1 it is apparent that radial forces would be taken up at a contact area between cap 23 and external housing 1. This would also be the case when, after setting a dose, cap 23 is lifted to protrude from the proximal end of housing 1 (column 8, lines 50 to 56), since a configuration with no radial overlapping at all between the cap and the external housing is not envisaged in D1.

For the sake of completeness, the opponent's argument that the coupling between hooks 24 and bead 25 was analogous to the snap fit around radial extending track 15 shown in figure 1 of the patent is flawed for the reason that the patent does not identify that snap fit as a radial bearing within the meaning of the claim.

5. As described in paragraph [0007] of the patent, if a tilting force is applied on a peripheral area of push button 10, a reaction torque will occur at the claimed upper and lower radial bearings. Compared with the situation where such a reaction torque has to occur at a continuous contact area, as is apparently the case in the device of D1, the technical effect of better

transferring that tilting force in an axial direction is achieved.

Consequently, the Board concurs with the proprietor that the objective technical problem solved by the claimed radial bearings over D1 is how to make more efficient use of the forces to be applied in order to inject a dose of medicament.

In view of the particular configuration of cap 23, external housing 1 and dose scale drum 17 in the device of D1, in which the housing contributes to the guiding of the cap when an injection is performed, it would not be obvious for the skilled person to provide radial bearings between cap 23 and dose scale drum 17. As convincingly argued by the proprietor, this would require a complete redesign of the device of D1. Thus, the opponent's argument that radial bearings to support a shaft are generally known as such is of little relevance.

It is therefore concluded that the subject-matter of claim 1 - and a fortiori of the dependent claims - of the request found allowable by the Opposition Division is novel and inventive.

6. It follows that the patent can be maintained in the version found allowable by the Opposition Division and that the lower-ranking requests submitted by the proprietor need not be considered by the Board.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated