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**Datasheet for the decision
of 24 October 2012**

Case Number: T 1845/07 - 3.2.02
Application Number: 02726984.4
Publication Number: 1351732
IPC: A61M 5/315, A61M 5/24
Language of the proceedings: EN

Title of invention:
Automatic injection device with reset feature

Patent Proprietor:
NOVO NORDISK A/S

Opponents:
OWEN MUMFORD LIMITED
Genentech, Inc.
TecPharma Licensing AG

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c), 101(3), 83, 84, 123(2), 54,
EPC R. 100(1)

Keyword:
"Added subject-matter (no, after amendment)"
"Novelty (yes, after amendment)"
"Remittal (yes)"

Decisions cited:
G 0010/91

Catchword:
-



Case Number: T 1845/07 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 24 October 2012

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 27 September 2007
revoking European patent No. 1351732 pursuant
to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: E. Dufrasne
Members: P. L. P. Weber
 M. Stern

Summary of Facts and Submissions

- I. The appeal by the proprietor is against the decision of the Opposition Division posted 27 September 2007 to revoke the European patent n° 1351732.

In its decision the Opposition Division considered that the subject-matter of claim 1 was not novel over E1, E2, E3 and E14, and considered that the auxiliary requests (first to fourth) contravened Article 123(2) EPC.

Notice of appeal was filed on 2 November 2007 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 5 February 2008.

- II. Oral proceedings were held on 24 October 2012.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the first to sixth auxiliary requests filed with letter dated 4 February 2008, one of the seventh and eighth auxiliary requests filed with letter dated 21 September 2012, or the ninth auxiliary request filed during the oral proceedings of 24 October 2012.

The appellant further requested the remittal of the case to the department of first instance for further prosecution if the Board considered the subject-matter of claim 1 of one of the requests to satisfy the novelty requirement.

All three respondents requested that the appeal be dismissed.

III. The following documents are mentioned in the present decision:

E1: WO-A-01/72361
E2: US-A-5320609
E3: CA-A-2359375
E14: DE-U-29513214.

IV. The different versions of claim 1 are the following:

Claim 1 of the patent as granted reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10),
- a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
- a spring means (70) mounted in the housing,
- a dose setting assembly (40, 50, 60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, wherein movement of the dose setting member is accompanied by straining of the spring,
- a releasable latch means (80, 90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring

means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, characterized in that the dose setting member is moveable in a second direction to selectively adjust the set position."

Claim 1 according to first auxiliary request reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10),
- a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
- a spring means (70) mounted in the housing,
- a dose setting assembly (40,50,60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position, wherein movement of the dose setting member is accompanied by straining of the spring,
- a releasable latch means (80,90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring means, wherein release of the latch means causes the

dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member so that the numbers pass a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir."

Claim 1 according to the second auxiliary request reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10),
- a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
- a spring means (70) mounted in the housing,
- a dose setting assembly (40,50,60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position, wherein movement of the dose setting member is accompanied by straining of the spring,
- a releasable latch means (80,90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring

means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member, the skirt rotating and moving axially relative to a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir so that the numbers pass the window (17)."

Claim 1 according to the third auxiliary request reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10),
- a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
- a spring means (70) mounted in the housing,
- a dose setting assembly (40,50,60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position, wherein movement of the dose setting member is accompanied by straining of the spring,

- a releasable latch means (80,90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member, the skirt rotating and moving axially relative to a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir so that the numbers pass the window (17) and are returned to "0" following expulsion of the dose from the fluid-filled reservoir."

Claim 1 of the fourth to the sixth auxiliary requests corresponds respectively to claim 1 of the first to third auxiliary requests, with the addition of the following feature:

"that the dose setting device further comprises a threaded member (20) fixed in the housing and comprising a first internal thread, the drive member being a longitudinal piston drive member (30) having an external thread (31) corresponding to the first internal thread, the threads being non-locking having a pitch angle whereby axial movement of the piston drive member is obtained by an axial force applied to the piston drive member by the spring means."

Claim 1 according to the seventh auxiliary request reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10)
 - a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
 - a spring means (70), mounted in the housing,
 - a dose setting assembly (40,50,60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position, wherein movement of the dose setting member is accompanied by straining of the spring,
- a releasable latch means (80,90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means,
- wherein the dose setting assembly further comprises a coupling member (60) in displaceable engagement with the dose setting member, the spring means acting on the coupling member, the coupling member acting on the dose setting member (50), the dose setting member (50) and

the coupling member (60) comprise mutually cooperating surfaces (54, 62) providing a coupling therebetween such that movement of the dose setting member in order to set a dose results in straining of the spring means, and the dose setting member (50) is rotationally mounted on the drive member, the coupling member (60) being arranged in sliding, non-rotational engagement with the drive member, and further comprising a threaded member (20) with a first internal thread, the drive member being a longitudinal drive member (30) having an external thread (31) corresponding to the first internal thread, the threads being non-locking having a pitch angle whereby axial movement of the drive member is obtained by an axial force applied to the drive member by the spring means, characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member, the skirt rotating and moving axially relative to a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir so that the numbers pass the window (17) and are returned to "0" following expulsion of the dose from the fluid-filled reservoir."

Claim 1 according to the eighth auxiliary request reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10)

- a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
- a spring means (70), mounted in the housing,
- a dose setting assembly (40,50,60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position wherein movement of the dose setting member is accompanied by straining of the spring,
a releasable latch means (80,90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means,
wherein the dose setting assembly further comprises a coupling member (60) in displaceable engagement with the dose setting member, the spring means acting on the coupling member, the coupling member acting on the dose setting member (50), the dose setting member (50) and the coupling member (60) comprise mutually cooperating surfaces (54, 62) providing a coupling therebetween such that movement of the dose setting member in order to set a dose results in straining of the spring means, one of the dose setting member (50) and the coupling member (60) is rotationally mounted on the drive member, the other being arranged in sliding, non-rotational engagement with the drive member, and

the dose setting member (50) is rotationally mounted on a threaded portion of the drive member whereby selectively setting a dose results in an axial movement of the dose setting member relative to the drive member, and the coupling member (60) is arranged in sliding, non-rotational engagement with the drive member, the spring means acting on the coupling member in a direction corresponding to a longitudinal axis of the drive member, and further comprising a threaded member (20) with a first internal thread, the drive member being a longitudinal drive member (30) having an external thread (31) corresponding to the first internal thread, the threads being non-locking having a pitch angle whereby axial movement of the drive member is obtained by an axial force applied to the drive member by the spring means, characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member, the skirt rotating and moving axially relative to a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir so that the numbers pass the window (17) and are returned to "0" following expulsion of the dose from the fluid-filled reservoir."

Claim 1 according to the ninth auxiliary request reads as follows:

"1. A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- a housing (10)

- a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,
- a spring means (70), mounted in the housing,
- a dose setting assembly (40,50,60) mounted in the housing and connected to the spring means, the dose setting assembly composing [sic] a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, wherein movement of the dose setting member is accompanied by straining of the spring, and in a second direction to selectively adjust the set position, a releasable latch means (80,90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, wherein the dose setting assembly further comprises a coupling member (60) in displaceable engagement with the dose setting member, the spring means acting on the coupling member, the coupling member acting on the dose setting member (50), the dose setting member (50) and the coupling member (60) comprise mutually cooperating surfaces (54, 62) providing a coupling therebetween such that movement of the dose setting member in order to set a dose results in straining of the spring means, one of the dose setting member (50) and the coupling member (60) is rotationally mounted on the drive member, the other being arranged in sliding, non-rotational engagement with the drive member, and

the dose setting member (50) is rotationally mounted on a threaded portion of the drive member whereby selectively setting a dose results in an axial movement of the dose setting member relative to the drive member, and the coupling member (60) is arranged in sliding, non-rotational engagement with the drive member, the spring means acting on the coupling member in a direction corresponding to a longitudinal axis of the drive member, and further comprising a threaded member (20) with a first internal thread, the drive member being a longitudinal drive member (30) having an external thread (31) corresponding to the first internal thread, the threads being non-locking having a pitch angle whereby axial movement of the drive member is obtained by an axial force applied to the drive member by the spring means, characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member, the skirt rotating and moving axially relative to a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir so that the numbers pass the window (17) and are returned to "0" following expulsion of the dose from the fluid-filled reservoir."

V. The arguments of the appellant can be summarised as follows:

Main request

Added subject-matter

The appellant agrees with the opinion of the Opposition Division expressed in the impugned decision that there

is no added subject-matter beyond the content of the application as originally filed.

Novelty

Document E1 only discloses an automatic-type injection device in the Figures 11 to 13, and in relation to the embodiment shown in these Figures there is no direct and unambiguous disclosure that the clutch mechanism allowing the adjustment of the dose in both directions is identical to that used in the manual injection embodiment of the other Figures. There is thus no disclosure of the dose setting member moveable in a second direction as required by the wording of claim 1 of the patent in suit.

Neither E2 nor E3 explicitly discloses that the dose setting member can be moved in a second direction in order to selectively adjust the set position, so that this feature must be considered undisclosed and examined for inventive step.

E14 does not anticipate the subject-matter of claim 1. In particular, nut 6 is retained in its "set position" on the spindle 5 by means of the screw thread provided on the spindle and not by an associated latch means which retains the dose setting member against the bias of the spring means. In E14, upward movement of the spindle 5 and nut 6 against the bias of the spring 7 does not set the dose but simply prepares the mechanism for an injection.

First to sixth auxiliary requests

Added subject-matter

In the paragraph bridging page 7 and 8 of the originally filed application documents, where a basis for the amendment introduced in the first auxiliary request can be found, there is no mention of any non-locking thread, so that the decision of the Opposition Division, relying only on the specific embodiment, is not justified. A general teaching at the beginning of a description should be combinable with any other general teaching also present in the description. In particular the person skilled in the art does not need an indication of the use of threads to achieve the desired result; he knows that the same result could be obtained for example with an electro-magnetic system. Further, it is established case law that functional features are accepted in claims, so that the generalisations in these requests should be allowable. In any case, the wording of a claim has to be read with a mind willing to understand, so that, for instance, the skilled reader will understand that for the present invention a skirt (as claimed) is the same element as the sleeve mentioned on page 7.

The second auxiliary request is based on the same paragraph bridging page 7 and 8. In claim 1 the further constructional limitation that the skirt rotates and moves axially has been introduced. The simultaneity of the two movements is implicit from the fact that the numbers are on a helical line and shown in the window.

The additional feature of the third auxiliary request is based on the last paragraph of page 8 of the originally filed application documents.

In claim 1 according to any of the fourth to sixth auxiliary requests, the subject-matter of granted claim 9 has been added which makes it clear that there is a first internal thread and that this thread is non-locking. Granted claim 9 corresponds to original claim 8.

It should further be noted that the word "*straining*" is unspecific and that it can be used to describe a compression or a release of the spring.

The seventh and eighth auxiliary requests should be admitted into the proceedings as they were filed in response to the summons, they are based on auxiliary request 3 and the amendments consist of combinations with granted dependent claims. For these reasons they must be considered a bona fide attempt by the appellant to address the outstanding issues.

The ninth auxiliary request should be admitted into the proceedings because it is an attempt to answer an objection only raised during the oral proceedings.

In claim 1 of the seventh and eighth auxiliary requests the constructional relationship between the dose setting member and the plunger or drive member is further specified, so that the objection of added subject-matter is overcome.

The appellant does not agree to the introduction of the new ground of opposition under Article 100(b) EPC raised by the respondents.

VI. The arguments of the respondents can be summarised as follows:

Main request

Added subject-matter

Claim 1 contains subject-matter extending beyond the application as filed for the following two reasons:

- the word "*apparatus*" has been replaced by "*dose setting member*" in the feature "*a releasable latch means (80, 90) associated with the housing and adapted to retain the dose setting member in the set position*",
- the word "*dose*" has been replaced by "*position*" in the feature "*the dose setting member is moveable in a second direction to selectively adjust the set position.*"

In particular this last amendment means that the dose setting member could be moved to adjust the set position without changing the set dose.

Novelty

Documents E1, E2, E3 and E14 disclose dose setting devices which anticipate the subject-matter of claim 1 according to the main request.

In E1 the paragraph on page 14, lines 12 to 15 explicitly states in relation to the embodiment shown in Figures 11 to 13 that apart from the changes which give the automatic injection the mechanism is similar to the previous embodiment, so there can be no doubt

that the dose setting member is adjustable in both directions.

Concerning E2 and E3 the respondents share the opinion of the Opposition Division.

Concerning E14, the proprietor's arguments are not supported by the wording of the claim since the claim only requires that the dose setting member is movable to a selected set position and not to set a dose. According to the wording of the claim it is actually irrelevant whether this set position defines a set dose. Additionally the nut can still be adjusted when it is in the position shown in Figure 2.

First to sixth auxiliary requests

The missing preposition "through" in the term "*so that the numbers pass a window in the housing*" adds embodiments, since the numbers can now pass by the side of the window without being seen, which was not originally disclosed. In the application as originally filed the only way described (e.g. page 14) to obtain a helical movement is by the use of several interrelated threads, namely on the plunger, on the dose setting member, and on the partition member, and the use of tongues as described on pages 17 and 18. A more general statement cannot be found in the application as originally filed. In addition, the general statements present at the beginning of the description, in particular the helical line feature and the resetting feature, cannot be combined as easily as the appellant asserts because the appellant combines general features of paragraphs introduced by the statement "*according to*

a first aspect of the invention" with paragraphs introduced by the statement "*according to the second aspect*" of the invention, and no general statement links the two aspects.

Although in claim 1 according to any of the fourth to the ninth auxiliary requests additional constructional features have been added, these added features are still not sufficient to avoid an objection of added subject-matter beyond the only specific embodiment originally disclosed, which is the only possible basis for claim 1 of any of the above-mentioned requests.

Additionally to the several threaded connections existing between the dose setting member, the partition member and the piston drive member, it was never disclosed that the so-called movement in the second direction is accompanied by a straining of the spring, so that also for this reason claim 1 according to any of the requests mentioned contravenes Article 123(2) EPC.

Moreover, the seventh to the ninth auxiliary requests should not be admitted into the appeal proceedings. Since filing the notice of appeal, the appellant has had enough time to formulate proper auxiliary requests. It was not necessary to wait till such a late stage of the proceedings to file such complicated auxiliary requests. They do not, *prima facie*, solve the existing problems, because, in particular, the threaded connection between the drive member and the dose setting member is not present, and/or the correspondence of the threads and the partition wall is absent from the claim wording.

Claim 1 according to the ninth auxiliary request further violates Articles 83, 84, 100(c) and 123(2) EPC, because the unclear, unsupported and insufficiently disclosed concept of straining the spring when the dose is adjusted is still present in the claim in the feature "*that movement of the dose setting member in order to set the dose results in straining of the spring means*", the setting of the dose implying a movement of the dose setting member in both directions.

The novelty of the subject-matter of claim 1 of the ninth auxiliary request is not questioned.

The respondents have no objection against a remittal to the department of first instance for further prosecution, as long as the examination of inventive step is based on claim 1 according to the ninth auxiliary request.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Added subject-matter

The respondents considered that claim 1 as granted extends beyond the application as filed for the following two reasons:

- the word "apparatus" has been replaced by "dose setting member" in the feature "a releasable latch means (80, 90) associated with the housing and adapted to retain the dose setting member in the set position",
- the word "dose" has been replaced by "position" in the feature "the dose setting member is moveable in a second direction to selectively adjust the set position."

In particular this last amendment would mean that the dose setting member could be moved to adjust the set position without changing the set dose.

In the Board's opinion the replacement of the word "apparatus" was simply necessary for consistency of the vocabulary used, as this word did not appear elsewhere in the claim. Further, although in the specific embodiment presented in the description the latch means actually acts on the drive member and not directly on the dose setting member, in the Board's opinion the wording "a releasable latch means associated with the housing and adapted to retain the dose setting member in a set position..." is acceptable under Article 123(2) EPC as it is clear throughout the patent specification and from the function of the latch means that it is there to keep the set position of the dose setting member. Such a general wording was also already present in claim 1 as originally filed, which generally mentioned that the dose setting device comprised "a latch means (80,90) associated with the housing to retain the apparatus in the set position against the bias of the spring means."

Concerning the second objection, by definition "*dose setting member*" appears to designate the member which is used to set the dose. In other words, when it is written that "*the dose setting member is moveable in a first direction to a selected set position*" it is clear that the set position corresponds to the position defining the desired dose to be set, e.g. to be injected. In the same and consistent way, when in the characterising portion it is written that "*the dose setting member is moveable in a second direction to selectively adjust the set position*" this can only mean that the set dose is adjusted.

Hence, in the Board's opinion the objection under Article 100(c) EPC does not hold against claim 1 of the main request.

3. Novelty

The Board agrees with the respondents and the Opposition Division that all four documents E1, E2, E3, E14 are novelty-destroying for the subject-matter of claim 1 of the main request.

3.1 All the requirements for E1 to be a document pursuant to Article 54(3) EPC are fulfilled, which has not been challenged by the appellant.

The first embodiment shown in Figures 1 to 7 of E1 is not novelty-destroying because the dose is injected manually by pressing on the end cap 14 (page 10, lines 3 to 5) and not automatically as required by the wording of claim 1.

The same is true for the second embodiment.

However, the third embodiment shown in Figures 11, 12 and 13 is novelty-destroying. In particular, there is an automatic injection of the dose (page 14, lines 8 to 12, page 15, lines 11 to 14) and the feature of the characterising portion of the claim is present as well. It is clearly expressed on page 14 that "*Apart from the changes required to the mechanism to give the above functionality, the mechanism is similar to the previous embodiments...*" and for the first embodiment it is explicitly mentioned on page 10, lines 22 to 26 that: "*This also has the action of freeing the clutch between the set doses and thus there is no penalty in overshooting the required dose and then winding the end-cap 14 in the opposite sense, from a larger dose to a lesser dose, since this will not significantly drive the rod 12 forwardly.*" Thus, this also applies to the third embodiment. The disclosure of the other features was not disputed.

The appellant submitted that because there is no explicit mention of this functionality in relation to the third embodiment the criterion "directly and unambiguously derivable" used for novelty examination was not met.

The Board cannot share this opinion. There is a rotational connection between the end cap 90 and the track member 93 (external spines 91 and internal spines 92) on which there is the helix 94 in which the tooth 95 is engaged to set the dose. There is no indication that this tooth could slide only in one direction in the helix, nor is there any indication that the tooth on the cone member 23 and the pressure component 25 are different from those in the first embodiment and do not

allow a rotation of the track member 93 to diminish the dose set.

Hence E1 is novelty-destroying for the subject-matter of claim 1 according to the main request.

- 3.2 Document E2 discloses a dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir.

Although this feature is not explicitly mentioned in the document, it is implicit from the intended use of the device (diabetic patients, introductory part of the document) and is quite clear from the constructive features of the device. To set the dose the cap or knob 60 is rotated. This rotation is transmitted to the dose adjusting screw 158 which will thereby be displaced in the piston driver 140 comprising an inner thread. This displacement compresses injection spring 174. During this compression of the spring the piston drive is retained by brake pads 194 (column 6, lines 51 to 61). The connection between the cap and the dose adjusting screw being through a vertical slot in the screw and two drive lugs, the cap can rotate the screw in either direction. The screw thread being engaged in a normal inner thread of the piston drive 140, the screw can be moved in either direction along the inner thread. Hence, the dose can be adjusted in both directions. When the dose is set a latch is released which will free the insertion phase (insertion spring 106 pushes main barrel 4 in the distal direction so that the needle penetrates the patient's skin). Once that penetration has occurred, the windows 128 become

aligned with the windows 198 so that the brake pads are released and the injection spring 174 can inject the set dose.

The subject-matter of claim 1 of the main request is thus anticipated by E2 as well.

- 3.3 Document E3 discloses a device similar to that of E2. The dose is set as in E2 with a screw system (explanations starting page 16, lines 38), so that there is no technical reason why such a system is not reversible. The injection is also started by pressing a latch means 64.

The subject-matter of claim 1 according to the main request is thus also anticipated by E3.

In relation to both documents E2 and E3 the appellant submitted that they did not explicitly disclose that the dose setting member could be moved in a second direction in order to selectively adjust the set position, so that this feature had to be considered undisclosed and examined for inventive step.

The Board does not share the opinion of the appellant. As explained above, in both documents there is a screw-nut connection between the knob rotated when setting the dose and the element actually displaced in order to mechanically fix it. A screw-nut connection is a simple mechanical connection in which the nut and the screw can be rotated either to unscrew or to screw the screw into the nut. In the absence of any indication to the contrary, this cannot be interpreted differently and must be considered as inherently disclosed technical

information. Neither in E2 nor in E3 is there any indication to the contrary, so that the movement in the second direction in order to adjust the set dose is inherently disclosed.

- 3.4 Document E14 discloses a device different from the devices disclosed in E1, E2, or E3 in that it is not for injecting several individual doses from a reservoir containing all the doses and integrated in the syringe but to draw an individual dose into a reservoir of the syringe from a separate container and then inject it into the patient (page 1, first paragraph). However, given the general wording of claim 1 of the main request, this document also anticipates its subject-matter.

The appellant submitted that the latch means did not retain the dose setting member (nut 6) in the set position against the bias of the spring means, as required by the wording of claim 1 according to the main request.

According to the understanding of the Board, the wording of the claim does not include the concept implied by the appellant that the dose setting member cannot be brought into the set position without there being a latch means to retain it against the bias of spring means. The wording of the claim requires only that the dose setting member is moveable in a set position against the bias of a spring means. This is the case of nut 6 which is moveable against the bias of spring 12. The wording of claim 1 further requires that the dose setting member be retained by the latch means against the bias of a spring means when it is in the

set position, which is also the case when the nut is in the position shown in Figure 2 of E14.

- 3.5 Thus, for the reasons above, the subject-matter of claim 1 of the main request is not novel within the meaning of Article 54 EPC.

First to third auxiliary requests

4. Added subject-matter

- 4.1 According to the first auxiliary request the subject-matter is *characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member so that the numbers pass a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir.*

According to the second auxiliary request the subject-matter is *characterized in that numbers are printed along a helical line on an external surface of a skirt (52) of the dose setting member, the skirt rotating and moving axially relative to a window (17) in the housing during the setting and expulsion of a dose from the fluid-filled reservoir so that the numbers pass the window (17).*

According to the third auxiliary request the subject-matter is further *characterized in that ... the numbers ... are returned to "0" following expulsion of the dose from the fluid-filled reservoir.*

- 4.2 The appellant considered that a basis for these amendments could be found in the paragraph bridging

page 7 and page 8, in the last paragraph of page 8, and on pages 14, 18 and 19 of the originally filed application.

In the Board's opinion, claim 1 of each of the first to third auxiliary requests contravenes Article 123(2) EPC for at least the following reasons:

The paragraph bridging pages 7 and 8 of the originally filed application clearly states that the numbers printed on the helical line can be inspected through an opening, or window, and that when the sleeve is rotated and simultaneously axially displaced along the opening a number indicating the actually set dose can be inspected through the opening.

No claim 1 of any of the first to the third auxiliary requests stipulates that the skirt is rotated and simultaneously axially displaced and that this double simultaneous movement allows the numbers to be seen in the window. In other words, the wording of claim 1 of any of the three auxiliary requests covers movements of the skirt which are different from a simultaneous axial and rotational movement. Such different movements made in order to show the numbers printed along a helical line in the window are not disclosed in the originally filed application. As mentioned above, the general statement in the paragraph bridging pages 7 and 8 requires a simultaneous rotational and axial movement. Moreover, the specific embodiment described in the description which allows such movement works with several threads, as will be explained further below, so that there is no general disclosure of any combined rotational and axial movements in order to show the

number in the window. The passages mentioned on pages 14, 18 and 19 do not support the arguments of the appellant because they belong to the description of the specific embodiment.

The second reason is that the wording of all three auxiliary requests requires the numbers also to pass the window when the dose is expelled. The paragraphs of pages 7 and 8 mentioned above, however, do not disclose any general teaching along that line. It is only in the context of the specific embodiment, which works with threads on the plunger, the dose setting member and the partition member, that such a movement of the numbers through the window and back to zero, when the dose is expelled, was disclosed. In claim 1 of any of the three auxiliary requests none of the threads is mentioned, so that the present wording of claim 1 of any of these auxiliary requests encompasses embodiments which were not originally disclosed.

The appellant considered that the mentioning of the numbers as being on a helical line, and the mentioning of the resetting of the dose in the last paragraph of page 8 were a sufficient indication for the person skilled in the art to understand that both when setting the dose and when expelling the dose the numbers pass the window.

The Board does not share this opinion. In the passage cited by the appellant on page 8, no link is made between the resetting of the dose and any passing of the numbers through the window. This paragraph leaves it open how the resetting is done. It merely states

that when the dose is expelled the dose setting member finally returns to "0".

- 4.3 Hence, claim 1 of the first to the third auxiliary requests does not fulfil the requirements of Article 123(2) EPC.

Fourth to sixth auxiliary requests

5. Added subject-matter

- 5.1 Claim 1 of the fourth to the sixth auxiliary requests corresponds respectively to claim 1 of the first to third auxiliary requests, with the addition of the following feature:

"that the dose setting device further comprises a threaded member (20) fixed in the housing and comprising a first internal thread, the drive member being a longitudinal piston drive member (30) having an external thread (31) corresponding to the first internal thread, the threads being non-locking having a pitch angle whereby axial movement of the piston drive member is obtained by an axial force applied to the piston drive member by the spring means."

- 5.2 This additional feature cannot change anything as regards the above objections because it does not define any further mechanical means which would cause the numbers to pass through the window when the dose is expelled, nor does it define that the movement of the skirt is simultaneously rotational and axial, so that these requests have to be rejected for the same reasons as the first three auxiliary requests.

Seventh and eighth auxiliary requests

6. Claim 1 of the seventh auxiliary request corresponds to claim 1 of the third auxiliary request, with the addition of the features of claims 3, 4, 5 and 9 of the granted patent. Claim 1 of the eighth auxiliary request is distinguished by the inclusion of the second embodiment of claim 5 of the granted patent and additionally includes the features of claim 6 of the granted patent.

- 6.1 Admission into the proceedings

These two requests were filed after the summons to oral proceedings. They are based on the third auxiliary request and on dependent claims of the granted patent, so that they do not create a new case as a result of substantive amendment. They constitute an attempt to deal with the objections of added subject-matter addressed in the annex to the Board's summons. The introduction into claim 1 of subject-matter taken from dependent claims of the granted patent also cannot be considered as raising new complex issues which the respondents cannot be expected to deal with, because these dependent claims must also have been considered by the respondents. Finally, the added features anyway belong to the only embodiment extensively described in the patent in suit.

For the reasons above the Board decided to admit the seventh and eighth auxiliary requests into the proceedings.

- 6.2 Added subject-matter

In claim 1 of the seventh auxiliary request the threaded link between the dose setting member and the drive member is missing, which is, however, the only disclosed connection which allows the number to pass the window also when the dose is expelled. At least for this reason the seventh auxiliary request also contravenes Article 123(2) EPC.

In claim 1 of the eighth auxiliary request this problem is solved because the features of claim 6 of the granted patent (corresponding to original claim 5) have been introduced.

However, in claim 1 of the eighth auxiliary request, the wording "*a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position wherein movement of the dose setting member is accompanied by straining of the spring*" implies that the movement of the dose setting member in the second direction also strains the spring. However, a mechanism allowing a straining of the spring both when the dose setting member is moved in the first direction to set the dose and when the dose setting member is moved in the second direction (normally opposite to the first) when adjusting the dose is not disclosed in the application as originally filed. The only embodiment disclosed therein has a threaded connection which strains the spring when the dose setting member is rotated in the first direction and "unstrains" the spring when the dose setting member is rotated in the second direction.

For this reason claim 1 of the eighth auxiliary request also does not fulfil the requirements of Article 123(2) EPC.

Ninth auxiliary request

7. In claim 1 of the ninth auxiliary request the feature "*...a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, and in a second direction to selectively adjust the set position, wherein movement of the dose setting member is accompanied by straining of the spring,...*" present in claim 1 of the eighth auxiliary request has been changed into "*...a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, wherein movement of the dose setting member is accompanied by straining of the spring, and in a second direction to selectively adjust the set position,...*" so that it is now clear from the wording of this feature that the movement of the dose setting member in the second direction does not strain the spring.

7.1 Admission into the proceedings

In the opinion of the Board the admissibility of this request cannot be challenged, because the objection mentioned above was only raised by the respondents during the oral proceedings. In such a case an opportunity must be given to the appellant to reply to the new objection, in particular by a simple amendment.

7.2 Added subject-matter

In claim 1 according to the ninth auxiliary request the wording of the eighth auxiliary request has been amended to avoid the above-mentioned objection against claim 1 of the eighth auxiliary request. The feature at stake now makes it clear that the movement in the second direction does not strain the spring, which is in conformity with the embodiment described in the description of the application as originally filed, working with threads.

For this reason, the subject-matter of claim 1 according to the ninth auxiliary request does not extend beyond the content of the application as filed, and this claim complies with the requirements of Article 123(2) EPC.

7.3 Further objections

The respondents also objected to claim 1 of the ninth auxiliary request on the grounds that the feature that *"the dose setting member (50) and the coupling member (60) comprise mutually cooperating surfaces (54, 62) providing a coupling therebetween such that movement of the dose setting member in order to set a dose results in straining of the spring means"* still comprises the problem mentioned in relation to claim 1 of the eighth auxiliary request, namely that the second movement of the dose setting member strains the spring means, because the wording *"the movement of the dose setting member in order to set the dose results in straining of the spring means"* implies that any movement to set the dose strains the spring means. For this reason they felt that this feature of claim 1 according to the

ninth auxiliary request could be objected to under any of the Articles 123(2), 100(b), 100(c), 83 or 84 EPC.

The Board does not share the opinion of the respondents.

Since the feature objected to was present in claim 4 of the granted patent, it is not open for objections under Articles 83, 84 or 123(2) EPC, because the objection does not result from an amendment of the claims of the granted patent introduced during the opposition proceedings, in particular during the opposition-appeal proceedings (Article 101(3) EPC, Rule 100(1) EPC, G 10/91 (OJ EPO, 1993, 420, point 19 of the reasons)).

Moreover an objection under Article 100(c) EPC cannot hold against the added feature because the wording of claim 4 of the granted patent is identical to the wording of original claim 3.

Finally, the ground for opposition under Article 100(b) EPC constitutes a fresh ground for opposition within the meaning of point 18 of the reasons of G 10/91 because this ground was not considered in the opposition proceedings. According to the same point of the reasons of G 10/91, such fresh grounds for opposition should not be introduced into the appeal proceedings unless the patent proprietor agrees to that. However, in the present case the patent proprietor did not agree.

Therefore, the further objections raised by the respondents against claim 1 of the ninth auxiliary request do not hold.

7.4 Novelty

None of the respondents had any objection as regards the novelty of the subject-matter of claim 1 of the ninth auxiliary request, and the Board has none either.

Hence, the subject-matter of claim 1 according to the ninth auxiliary request is novel within the meaning of Article 54 EPC.

8. Since the objections upon which the impugned decision is based have been removed and the remaining ground of opposition, lack of inventive step, has not yet been decided upon by the Opposition Division, remittal of the case to the department of first instance for further prosecution pursuant to Article 111(1) EPC, as requested by the appellant, is justified.

The respondents had no objections to remittal of the case on the basis of the ninth auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of claims 1 to 5 of the ninth auxiliary request filed during the oral proceedings of 24 October 2012.

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne