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**Datasheet for the decision
of 6 August 2019**

Case Number: T 1306/14 - 3.2.02

Application Number: 06707250.4

Publication Number: 1855743

IPC: A61M5/315

Language of the proceedings: EN

Title of invention:

DOSE SETTING MECHANISM FOR AN INJECTION DEVICE CAPABLE OF
PRESETTING A MAXIMUM DOSE

Patent Proprietor:

NOVO NORDISK A/S

Opponents:

Ypsomed AG
PFIZER LIMITED (withdrawn)
Sanofi-Aventis Deutschland GmbH
Medbay Co. Ltd.

Headword:

Relevant legal provisions:

EPC Art. 54(1), 54(2), 56, 84, 100(b), 123(2)

EPC R. 80, 124(1)

RPBA Art. 12(4), 13(1), 13(3)

Keyword:

Amendments - added subject-matter - main request (yes), sixth auxiliary request (no)

Grounds for opposition - insufficiency of disclosure - sixth auxiliary request (no)

Claims - clarity - sixth auxiliary request (yes)

Novelty - sixth auxiliary request (yes)

Inventive step - sixth auxiliary request (yes)

Late-filed document - admitted (yes)

Late-filed request - submitted during oral proceedings
- admitted (yes)

Minutes of oral proceedings - essentials of oral proceedings

Decisions cited:

T 0169/83, T 0311/93, T 0523/00, T 0629/05, T 0079/08,

T 0556/11

Catchword:



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Case Number: T 1306/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 August 2019

Appellant:
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Representative: -

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 9 April 2014
revoking European patent No. 1855743 pursuant to
Article 101(3) (b) EPC**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
P. L. P. Weber

Summary of Facts and Submissions

- I. The patent proprietor has appealed against the Opposition Division's decision, despatched on 9 April 2014, to revoke European patent No. 1 855 743.

The patent was opposed on the grounds of insufficient disclosure, lack of novelty and lack of inventive step.

- II. Notice of appeal was filed on 5 June 2014. The appeal fee was paid on the same day. A statement setting out the grounds of appeal was received on 14 August 2014.
- III. The Board summoned the parties to oral proceedings and provided its provisional opinion by a communication dated 20 March 2019.
- IV. By letter dated 16 April 2019, respondent/opponent 4, who submitted no requests in appeal, announced that it would not be present at the oral proceedings.
- V. Oral proceedings took place on 6 August 2019 in the absence of respondent/opponent 4.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request filed with letter dated 1 June 2015, the sixth auxiliary request and auxiliary requests 7 to 11 filed during the oral proceedings. Auxiliary requests 1 to 5 were withdrawn.

Respondent/opponent 1 requested that the appeal be dismissed.

Respondent/opponent 3 requested that the appeal be

dismissed.

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

D1: EP-A-0 937 471;

D2: WO-A-99/64092;

D3: US-A-5,308,340;

D9: US-A-5,827,232;

D23: WO-A-99/38554.

VII. Claim 1 of the **main request** reads as follows:

"A dose setting mechanism for an injection device, the dose setting mechanism comprising:

a dose setting member being rotatably operable by a user to set a desired dose whereby the dose setting member performs a translational movement, the resulting movement of the dose setting member thereby being a spiral movement

a presetting member being operable to limit the maximum dose settable by the dose setting member,

a first stopping member being operatively connected to the presetting member in such a manner that the position of the first stopping member is changed when the presetting member is operated, the position of the first stopping member thereby being indicative of the preset maximum settable dose

a second stopping member being adapted to engage with the first stopping member in such a way that when the first stopping member and the second stopping member engage, the dose setting member cannot be operated to

set a further dose

wherein either the first or the second stopping member is movable along with the dose setting member during setting of a dose, and wherein the first and the second stopping member each comprises one or more teeth,

said movement causing the first and the second stopping member to perform a rotational movement relatively to each other, such that an angular distance between the first stopping member and the second stopping member decreases,

said relative rotational movement causing the teeth of the first and the second stopping member to engage when the maximum settable dose has been set, thereby preventing further setting of a dose."

Claim 1 of the **sixth auxiliary request** reads as follows (amendments over claim 1 of the main request highlighted by the Board):

"A dose setting mechanism for an injection device, the dose setting mechanism comprising:

a dose setting member being rotatably operable by a user to set a desired dose whereby the dose setting member performs a translational movement, the resulting movement of the dose setting member thereby being a spiral movement

a presetting member being operable to limit the maximum dose settable by the dose setting member,

a first stopping member being operatively connected to the presetting member in such a manner that the

position of the first stopping member is changed when the presetting member is operated, the position of the first stopping member thereby being indicative of the preset maximum settable dose

a second stopping member being adapted to engage with the first stopping member in such a way that when the first stopping member and the second stopping member engage, the dose setting member cannot be operated to set a further dose

wherein either the first or the second stopping member is movable along with the dose setting member during setting of a dose, and wherein the first and the second stopping member each comprises **only one tooth** ~~one or more teeth,~~

said movement causing the first and the second stopping member to perform a rotational movement relatively to each other, such that an angular distance between the first stopping member and the second stopping member decreases,

said relative rotational movement causing the teeth of the first and the second stopping member to engage when the maximum settable dose has been set, thereby preventing further setting of a dose."

Claims 2 to 4 of the sixth auxiliary request are dependent claims.

VIII. The arguments of the appellant, where relevant to the present decision, may be summarised as follows:

Main request - added subject-matter

The feature in claim 1 according to which the first and the second stopping member each comprised one or more teeth was disclosed on page 8, lines 9 to 13, Figure 6 and claims 4 and 5 of the application as originally filed. Although claim 5 specified that the number of teeth on each stopping member corresponded to the number of unit doses being set when the dose setting member was rotated through one revolution, it was not necessary to introduce this limitation in the claim, since page 8, lines 10 to 13, presented it as optional.

Sixth auxiliary request - admissibility

Although having only been submitted during the oral proceedings, the sixth auxiliary request was based on the main request, which was submitted with the statement of grounds, and limited to one of the possible alternative configurations already claimed in that request. Only in the oral proceedings did the appellant receive a clear indication by the Board that claiming those alternative configurations added subject-matter. The nature of the amendment was not detrimental to procedural economy and could not come as a surprise to the respondents. Hence, the sixth auxiliary request had to be admitted into the proceedings.

Sixth auxiliary request - basis in the application as originally filed

The provision of only one tooth in the first and the second stopping member was disclosed on page 8, lines 9 to 10, and in claim 4 of the application as originally filed. The "at least one stopping surface" mentioned in

claim 4 was to be understood as the tooth on each of the stopping members.

The feature in claim 1 referring to the dose setting member performing a translational movement, the resulting movement of the dose setting member thereby being a spiral movement, was literally disclosed on page 3, lines 20 to 22, of the application as originally filed. Since claim 1 defined a dose setting mechanism with a dose setting member, there was no need to also define the injection process in the claim.

The feature in claim 1 according to which a relative movement of the first and the second stopping member was such that an angular distance between the first stopping member and the second stopping member decreased was disclosed on page 4, lines 10 to 15, and page 5, lines 5 to 6, of the application as originally filed. Its introduction in the claim did not represent any intermediate generalisation, since the feature was technically linked to the teeth, which had been introduced in the claim too.

Sixth auxiliary request - sufficiency of disclosure

According to claim 1 of the sixth auxiliary request, either the first or the second stopping member was movable along with the dose setting member during setting of a dose. The claim wording excluded that both stopping members were so movable.

The embodiment of the invention, described in detail with reference to the figures, clearly disclosed a dose setting mechanism as claimed, with the first stopping member being movable along with the dose setting member during setting of a dose. Paragraph [0020] of the

patent expressly taught an alternative mechanism in which the second stopping member was movable along with the dose setting member during setting of a dose.

Based on this teaching and on the detailed disclosure of the embodiment of the invention, the person skilled in the art would devise such an alternative mechanism without undue burden or inventive step. The adaptations needed were a matter of routine design practice.

Sixth auxiliary request - clarity

In claim 1 the reference to "said movement", which caused the first and the second stopping member to perform a relative rotational movement relatively to each other, was not unclear, as the movement meant could only be the one taking place during setting of a dose, defined just before in the claim. Other movements mentioned in the claim were not defined in relation to the first or the second stopping member.

What had to be understood under the term "spiral" in claim 1 was derivable from the definition of that term in the patent, which was consistent with the description of the embodiment of the invention. The patent document was its own dictionary (T 523/00 and T 311/93).

In the patent, a threaded coupling was nothing but one possible implementation for the functional requirement in claim 1 of transforming a translational movement into a rotational movement. It was not an essential feature to be introduced in the claim.

The reference to the engagement of the teeth of the first and the second stopping member in claim 1 was

clear, as the one claimed tooth of the first stopping member and the one claimed tooth of the second stopping member, which defined an angular distance, were collectively meant.

Sixth auxiliary request - novelty

The subject-matter of claim 1 was novel over D3. D3 did not disclose a first and a second stopping member each comprising only one tooth, or a relative rotational movement of the first and the second stopping member causing an angular distance between the first and the second stopping member to decrease, or the teeth of the first and the second stopping member to engage when a maximum settable dose had been set. Moreover, D3 did not disclose a presetting member separate from the first stopping member.

Sixth auxiliary request - inventive step

The subject-matter of claim 1 was inventive.

Starting from D3, the objective technical problem solved by the distinguishing features was to obtain a dose setting mechanism which provided a more accurate definition of the point where the maximum settable dose had been reached, hence a higher dose accuracy. There was nothing in the cited prior art hinting that a first stopping member separate from the presetting member should be implemented in the dose setting mechanism of D3.

Respondent/opponent 1 and respondent/opponent 3 had argued against inventive step starting from any of D1, D9 and D23 in combination with D2.

D23 was not to be admitted into the appeal proceedings, since it had been filed late and, *prima facie*, was not more relevant than D1 or D9 already in the proceedings.

While D1, D9 and D23 disclosed injection devices each having a dose setting member rotated out of the injection device to set the dose, D2 concerned a different kind of injection device, with a dose setting member which remained at the same axial position during the dose setting. The person skilled in the art, in the absence of any specific teaching, would not even consider the combination of D2 with any of D1, D9 and D23, as a complete restructuring of the injection devices of these three last documents would be required.

Starting from D2, the person skilled in the art would have no motivation to provide a dose setting member that performed a spiral movement within the meaning of claim 1 when a dose was set. The provision of such a dose setting member would also require a complete restructuring of the injection device of D2.

The argument of respondent/opponent 1 and respondent/opponent 3 that the level of skill of the person skilled in the art had to be the same when assessing sufficiency of disclosure and inventive step was beside the point, since the situations were different. While the description of the patent directly hinted at implementing the second stopping member movable along with the dose setting member during setting of a dose, neither pointers nor teachings were provided by the cited prior art regarding the implementation of the distinguishing features of claim 1 in the dose setting mechanisms of the documents identified as starting points in the respondents' objections.

Sixth auxiliary request - other matter

Paragraph [0013] of the patent as granted did not need to be amended, since it did not introduce any lack of clarity of the claims of the sixth auxiliary request, compared with the claims of the patent as granted.

- IX. The arguments of the respondent/opponent 1 and respondent/opponent 3, where relevant to the present decision, may be summarised as follows:

Main request - added subject-matter

The feature in claim 1 according to which the first and the second stopping member each comprised one or more teeth left open the possibility that one stopping member comprised one tooth and the other more teeth. This possibility was not disclosed in the application as originally filed and amounted to a non-allowable intermediate generalisation.

Sixth auxiliary request - admissibility

The sixth auxiliary request should not be admitted into the proceedings. There had been no reason for the appellant to submit it at such late stage, since the arguments of the respondents against the allowability of the main request had been known since March 2015, and the appellant had already submitted counter arguments in June 2015. Moreover, the sixth auxiliary request was not *prima facie* allowable in view of the other objections raised by the respondents.

Sixth auxiliary request - basis in the application as originally filed

According to page 8, lines 9 to 13, of the application as originally filed, one tooth on each stopping member was shown in Figure 6 for the sake of clarity. That did not amount to a direct and unambiguous disclosure that the first and the second stopping member could each comprise only one tooth. In order for the dose setting mechanism as claimed to properly work, more teeth on each stopping member were required. In the application as originally filed, there was no disclosure either that the teeth on the stopping member engaged when the maximum settable dose had been set. According to claim 4 as originally filed, stopping surfaces - not teeth - engaged. Moreover, the passage on page 8, lines 9 to 13, only related to the embodiment of the invention according to which the first stopping member was movable along with the dose setting member during setting of a dose. There was no disclosure in the application as originally filed of the provision of only one tooth in the first and the second stopping member for the claimed alternative, according to which the second stopping member was movable along with the dose setting member during setting of a dose. For these reasons the subject-matter of claim 1 of the sixth auxiliary request extended beyond the content of the application as originally filed.

The feature in claim 1 referring to the dose setting member performing a translational movement, the resulting movement of the dose setting member thereby being a spiral movement, was not literally disclosed on page 3, lines 20 to 22, of the application as originally filed. That passage referred to a rotational movement defined in relation to an injection device of

the kind where the setting of a dose as well as the injection were performed by means of combined rotational and translational movements. Omitting the definition of the injection performed by means of such a combined movement amounted to a non-allowable intermediate generalisation. Moreover, due to the use of the term "whereby", the claim required that the rotational movement caused the translational movement of the dose setting member, that the two movements occurred simultaneously, and that the term "spiral" had a special meaning, namely "helical". Those requirements had no basis in the application as originally filed.

The feature in claim 1 according to which a relative movement of the first and the second stopping member was such that an angular distance between the first stopping member and the second stopping member decreased was not literally disclosed in the application as originally filed. The passage on page 4 cited by the appellant did not mention any angular distance. In addition, the decreasing distance in that passage was only disclosed in combination with further features which had been omitted in the claim. Hence, a further non-allowable intermediate generalisation had been introduced.

Sixth auxiliary request - sufficiency of disclosure

According to claim 1 of the sixth auxiliary request, either the first or the second stopping member was movable along with the dose setting member during setting of a dose. Also, in view of claim 2, this wording did not exclude that both the first and the second stopping members were movable along with the dose setting member; as such it was not sufficiently disclosed in the patent.

The patent did not disclose in a sufficient manner the working principle of a dose setting mechanism, with the first stopping member being movable along with the dose setting member during setting of a dose. Claim 1 mentioned four component parts, namely the dose setting member, the presetting member, the first stopping member and the second stopping member, which were defined by desired functions without indicating how they could be performed. The components could be floating in space. The patent did not disclose any interaction between the housing of the dose setting mechanism and the presetting member in the axial direction, or the friction between the presetting member and other component parts, or how the first and second stopping member could be brought into engagement during setting of a dose. According to the detailed disclosure of the patent, if the first and the second stopping member each comprised only one tooth, the teeth would not engage when a "desired" maximum settable dose had been set, since their engagement was possible only at one rotational position of the dose setting member with respect to the housing. This was a further reason why the subject-matter of claim 1 was not sufficiently disclosed.

The patent did not disclose either that the second stopping member could be movable along with the dose setting member during setting of a dose. The embodiment of the invention described with reference to the figures concerned a dose setting mechanism, with the first stopping member being movable along with the dose setting member during setting of a dose. Starting from that embodiment, the person skilled in the art would have had to become inventive in order to obtain an alternative mechanism in which the second stopping

member was movable along with the dose setting member during setting of a dose. Several modifications, involving a complex redesign of the dose setting mechanism, would be required in order for the mechanism to be assemblable and to properly function. It followed that, also in view of the case law of the boards of appeal (T 629/05, T 79/08 and T 169/83, for example), the subject-matter of claim 1 of the sixth auxiliary request was not sufficiently disclosed.

Sixth auxiliary request - clarity

Claim 1 was unclear.

The reference to "said movement", which caused the first and the second stopping member to perform a rotational movement relatively to each other, was ambiguous. While in claim 1 as granted that expression directly followed and could only refer to the movement of the first or the second stopping member along with the dose setting member during setting of a dose, claim 1 of the sixth auxiliary request had been amended by introducing the teeth of the first and second stopping member, a "translational movement" and a "resulting movement" of the dose setting member, and a "spiral movement". It was therefore unclear to which of the movements previously defined in the claim the expression "said movement" referred.

The expression "spiral movement", referring to the dose setting member, was unclear too. "Spiral" literally meant a curve on a plane that wound around a fixed centre point at a continuously increasing or decreasing distance from the point. However, in contradiction with claim 1, Figure 6 of the patent showed that the dose setting member performed a helical movement. Since both

a spiral movement according to its literal meaning and the helical movement as disclosed in Figure 6 were possible technical interpretations of the claim language (also because the description did not define the term "spiral" beyond any doubts), the expression "spiral movement" was ambiguous and, in accordance with the findings in T 556/11, should be held to lack clarity.

The definition of the "spiral movement" of the dose setting member also introduced a result to be achieved, for which the patent only taught a threaded coupling between a scale drum and a housing. The housing and the threaded coupling were therefore essential features that had to be defined in the claim.

The claim recited that an angular distance between the first and the second stopping member decreased. However, what decreased was the angular distance between the respective teeth of the stopping members. Moreover, "the teeth of the first and the second stopping member" referred to at the end of the claim lacked an antecedent basis, since, according to the claim, each of those members comprised "only one tooth".

Sixth auxiliary request - novelty

The subject-matter of claim 1 was not novel over D3. More particularly, distal edge 120 of barrier element 108 of the dose setting mechanism of D3 inherently had a surface roughness. The highest of the protrusions making up the surface roughness was technically equivalent to an extremely shallow tooth as covered by the claim language. Moreover, a single member, having the functions of the presetting member and the first

stopping member as claimed, was technically equivalent to two separate members having those functions.

If the Board held that D3 did not disclose a first stopping member operatively connected to the presetting member according to the claim language, then this distinguishing feature, in particular, had to be mentioned in the decision and in the minutes of the oral proceedings.

Sixth auxiliary request - inventive step

The subject-matter of claim 1 was not inventive.

Starting from D3, the provision of a first stopping member separate from follower 104 (the presetting member within the claim language) was a matter of design, as it was technically equivalent to follower 104 of D3 as such, which also performed the claimed functions of the first stopping member. Moreover, column 5, lines 33 to 40 of D3 disclosed methods of fixing together elements of the dose setting mechanism which rendered such provision obvious.

D23 had to be admitted into the proceedings. It had been submitted with a reply to the statement of grounds of the appellant and was *prima facie* very relevant; it could be considered as the closest prior art for the subject-matter of claim 1 and was more illustrative than D1 and D9.

Starting from D1, D9 or D23, the objective technical problem was to modify their device such that repeatedly setting the same dose could be easily performed. This problem was addressed in D2 (page 1, lines 14 to 22) by the provision of a presetting member and first and

second stopping members on a dose setting mechanism, as defined in claim 1. Although it did not involve any helical movement, the mechanism of D2 was compatible and easy to be adapted to the dose setting mechanisms of D1, D9 and D23.

Starting from D2, which concerned a spring-powered injector, the person skilled in the art faced with the objective technical problem of making the mechanism of D2 also available for manually driven injection devices would have arrived at the subject-matter of claim 1 in an obvious way. Such devices, known from D1, D9 and D23, normally had a dose knob which could be screwed out of the housing of an injection device, thereby performing a spiral movement within the meaning of claim 1.

In general, according to established case law of the boards of appeal, the same level of skill had to be applied when, for the same invention, the two questions of sufficiency of disclosure and inventive step were to be considered.

Sixth auxiliary request - other matter

The objection under Rule 43(7) EPC raised in the written proceedings was withdrawn during the oral proceedings.

Paragraph [0013] of the patent as granted had to be amended, since it contemplated the possibility that the first stopping member could be part of the presetting member, which was in contradiction with claim 1.

Reasons for the Decision

1. The appeal is admissible.
2. Although having been duly summoned by communication dated 20 March 2019, respondent/opponent 4 was not present at the oral proceedings, as announced by letter dated 16 April 2019. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party.
3. The invention

The invention relates to a dose setting mechanism for an injection device. The description discloses such a dose setting mechanism in a pen-type injection device for self-medication by repetitive injections of insulin or growth hormone. Figure 6 of the patent, reproduced below, is an exploded view of an injection device with a dose setting mechanism according to the invention.

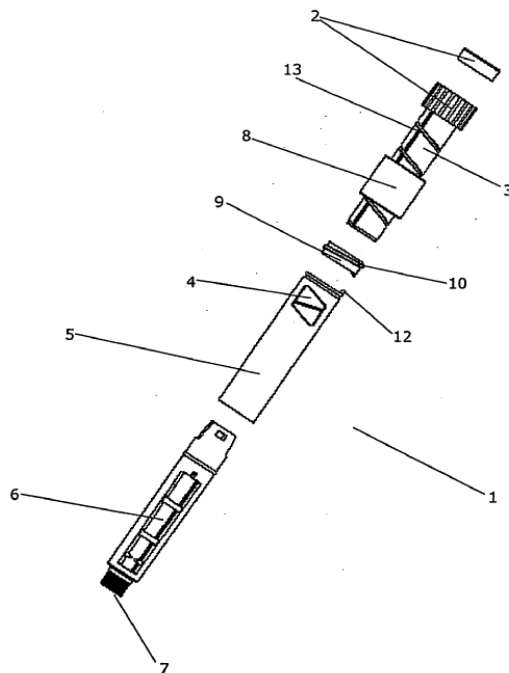


Fig. 6

The dose setting mechanism of that injection device comprises a dose setting member (2) for setting a dose by rotation, a presetting member (8) for limiting the maximum dose settable by the dose setting member, and a first (9) and a second (12) stopping member comprising teeth and together preventing operation of the dose setting member for setting a further dose when their teeth engage with each other.

During setting of a dose, the dose setting member performs, in addition to a rotational movement, a translational movement out of housing 5, and the first and the second stopping member perform a rotational movement relatively to each other, this movement causing their teeth to engage when the maximum settable dose has been set.

According to the patent, in particular paragraph [0016], the engagement, which takes place following a rotational movement, permits a more accurate definition of the point where the maximum settable dose has been reached.

4. Main request - added subject-matter

According to claim 1 of the main request, "the first and the second stopping member each comprises one or more teeth". This feature was not present in claim 1 of the application as originally filed. Claims 4 and 5 as originally filed, indicated by the appellant as a basis for the feature, respectively disclose the first and the second stopping member each with at least one stopping surface and each with a plurality of teeth, the number of teeth on each stopping member corresponding to the number of unit doses being set when the dose setting member is rotated through one

revolution.

A similar disclosure is provided on page 8, lines 9 to 13, of the application as originally filed:

"It should be noted that, for the sake of clarity, only one tooth is shown on first stopping member 9 and on the second stopping member 12. However, it should be understood that additional teeth may be present on the respective stopping members 9, 12, preferably the number of teeth on each stopping member 9, 12 corresponds to the number of unit doses being set when the dose setting member 2 is rotated through one revolution."

As regards Figure 6 of the application as originally filed, only one tooth is shown on each stopping member.

In the Board's view, while the provision of a plurality of teeth on each member, corresponding to the number of unit doses being set when the dose setting member is rotated through one revolution, is disclosed as optional, there is no disclosure in the application as originally filed that the first and the second stopping member may be provided with a different number of teeth. More importantly, the way of functioning of the embodiment depicted in the figures appears to technically exclude such an option; upon setting a maximum settable dose, some teeth on one stopping member would not engage with a respective one on the other stopping member. In contrast, this last option is left open by the wording of claim 1, which provides the person skilled in the art with information not directly and unambiguously derivable from the application as originally filed.

It follows that the main request is not allowable for lack of compliance with Article 123(2) EPC.

5. Sixth auxiliary request - admissibility

The sixth auxiliary request, filed during the oral proceedings, is an amendment to the appellant's case, the admission of which is at the Board's discretion under Article 13(1) and (3) RPBA. The discretion is to be exercised in view of, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. The amendment is not to be admitted if it raises issues which the Board and the respondents cannot reasonably be expected to deal with without adjournment of the oral proceedings. A further relevant criterion, according to the established case law of the boards of appeal, is the *prima-facie* relevance of the amendment.

Compared with the main request, the only amendment in claim 1 of the sixth auxiliary request was the deletion of the alternative that the first and the second stopping member could each comprise more than one tooth. The subject-matter of the claim was therefore merely limited to one of the previously defined alternatives, with no shift in scope of the claim. Hence, no new complex issues are introduced by the amendment, and the parties can be expected to be able to deal with it expediently during the oral proceedings. Moreover, from a *prima-facie* analysis, the sixth auxiliary request overcomes the non-compliance with Article 123(2) EPC on the basis of which the main request cannot be allowed, as it excludes the option that the first and the second stopping member may be provided with a different number of teeth. Whether other objections of the respondents could still be

relevant is not decisive, as they would apply to the main request too. Although the respondents rightly argued that the objection under Article 123(2) EPC which prejudices the maintenance of the patent on the basis of the main request was known to the appellant long before the oral proceedings, it also has to be considered that the particular relevance of this specific objection, amongst the many objections raised by the respondents, only emerged during the oral proceedings and was addressed expediently by the appellant by means of a simple amendment.

For these reasons the Board, in the exercise of its discretion under Article 13(1) and (3) RPBA, admits the sixth auxiliary request into the proceedings.

6. Sixth auxiliary request - basis in the application as originally filed

The subject-matter of claim 1 of the sixth auxiliary request is based on claims 1, 4 and 5; page 3, lines 20 to 22; page 4, lines 10 to 15; page 5, lines 5 to 6; page 8, lines 9 to 13; and Figure 6 of the application as originally filed.

- 6.1 The respondents argued that on the basis of page 8, lines 9 to 13, of the application as originally filed, Figure 6 showed one tooth on each stopping member only for sake of clarity, without any direct and unambiguous disclosure of such a configuration. The Board does not share this view, in particular because that passage on page 8 specifically states that "*additional teeth **may be present on the respective stopping members***" (highlighted by the Board), which inherently discloses a configuration without those additional teeth. The argument of the respondents that more teeth would be

required for the dose setting mechanism to properly work is not convincing either, as the presence of only one tooth limits, but still permits, a choice of the maximum settable dose between multiples of the doses corresponding to a full revolution of the first stopping member relative to the second stopping member.

The claimed engagement between the teeth of the first and the second stopping member is not only implied by claims 4 and 5 as originally filed, which respectively define abutting stopping surfaces and teeth on the stopping members, but also clearly derivable from Figure 6, showing that the teeth are the parts of the stopping members which, in operation, come into engagement. The Board accepts the respondents' argument that the passage on page 8, lines 9 to 13, of the application as originally filed specifically relates to an embodiment according to which the first stopping member is movable along with the dose setting member during setting of a dose. However, there is no reason for the person skilled in the art to assume that the alternative embodiment within the scope of claim 1, in which the second stopping member is movable along with the dose setting member during setting of a dose, should differ from the other embodiment in the claimed features of the teeth. The teeth are in no relation with a coupling between the one or the other stopping member and the dose setting member. Moreover, in the application as originally filed, claims 4 and 5 refer back to claim 1, the scope of which included both embodiments mentioned above.

- 6.2 The feature in claim 1 of the dose setting member performing a translational movement, the resulting movement of the dose setting member thereby being a spiral movement, is based in particular on page 3,

lines 20 to 22, of the application as originally filed. The respondents' argument that, to avoid a non-allowable intermediate generalisation, the claim should also specify that the injection is performed by a rotational movement, is not persuasive. First of all, even if according to page 3, lines 11 to 16, of the application as originally filed, dose setting as well as the injection are performed by rotating movements, claim 1 as originally filed only defined a dose setting mechanism. Hence, it did not require the injection to be performed by a rotational movement. It did not refer to injection at all. Moreover, for improving the accuracy of dose setting, the rotational movement for setting the dose is of technical importance. How the injection is subsequently performed is of no relevance in this respect.

In the Board's view, the term "whereby" in claim 1, from a contextual and technical point of view, does not imply more than what is specifically disclosed on page 3, lines 20 to 23 of the application as originally filed, i.e. that the resulting movement of a rotation and a translation of the dose setting member is a spiral movement within the meaning of the application. The respondents did not submit any arguments why, due to that term, claim 1 should additionally specify that the rotational and the translational movements should be simultaneous and should employ the term "helical", which never occurs in the application as originally filed.

6.3 The feature in claim 1 according to which a relative movement of the first and the second stopping member is such that an angular distance between the first stopping member and the second stopping member decreases is based on page 4, lines 10 to 15, together

with page 5, lines 5 to 6, of the application as originally filed. The respondents' argument that page 4, lines 10 to 15, did not provide a literal basis for that feature is accepted, since that passage does not disclose a decreasing angular distance but, more generally, a decreasing distance. However, the passage on page 5 qualifies the term "distance" employed in the passage on page 4: *"in the present context the term 'distance' should be broadly interpreted. Thus, the distance could, e.g., be an angular and/or an axial distance"*. Pages 4 and 5 belong to a section with the heading "Summary of the invention" and define the invention in general terms. In contrast to the respondents' view, the original disclosure does not inextricably link other features to the claimed feature in question. The respondents did not specifically mention any of such features either.

6.4 In conclusion, the sixth auxiliary request complies with Article 123(2) EPC.

7. Sixth auxiliary request - sufficiency of disclosure

7.1 In the respondents' view, the wording "either the first or the second stopping member is movable along with the dose setting member during setting of a dose" in claim 1 of the sixth auxiliary request did not exclude that both stopping members were movable.

The Board does not share this view. A patent document, including the claims, is directed to the person skilled in the art. It is not to be equated to a treatise on mathematics. The person skilled in the art would interpret the wording in question as an exclusive alternative, because that is the common meaning of such language. Only if the disclosure as a whole pointed to

the special and uncommon interpretation put forward by the respondents could the person skilled in the art adopt such an interpretation. However, the patent does not teach anything special in that respect. As explained above, the only embodiment described in detail comprises only one of the stopping members that moves along with the dose setting member during setting of a dose. For the same reasons claim 2, referred to by the respondents and employing similar wording to define an alternative ("...either the first or the second stopping member rotate(s) along with the dose setting member..."), does not cast doubts on the contextual interpretation of claim 1 for the purposes of sufficiency of disclosure.

- 7.2 The subject-matter of claim 1 of the sixth auxiliary request is disclosed in the description and the figures, in particular in relation to an embodiment of a dose setting mechanism as claimed in which the first stopping member is movable along the dose setting member during setting of a dose.

As disclosed in particular in paragraphs [0032] and [0033] of the patent, the maximum settable dose is preset by bringing the tooth of first stopping member 9 into engagement with second stopping member 12 as presetting member 8 is rotated, when that dose has previously been set by the rotation of dose setting member 2 (in the configuration of Figure 4 reproduced below). Subsequently, when a further dose is to be set after an injection - with the injection device in the configuration of Figure 3 reproduced below - dose setting member 2 is rotated again. By virtue of its engagement with outer groove 13 of dose setting member 2 and inner threads 11 of presetting member 8, first stopping member 9 rotates within the presetting

member and translates distally until, at the maximum dose, its tooth engages second stopping member 12 on the housing.

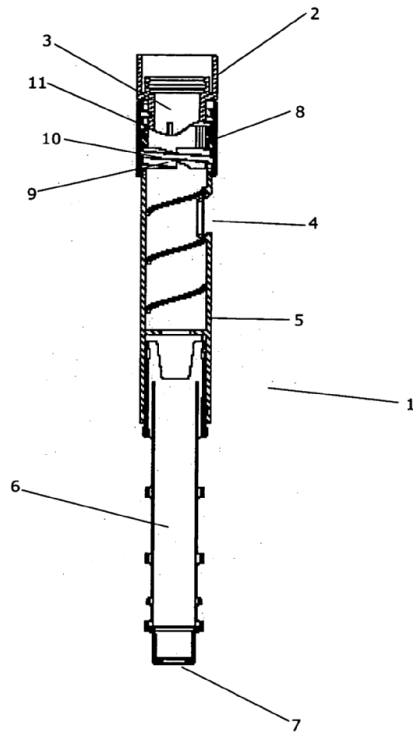


Fig. 3

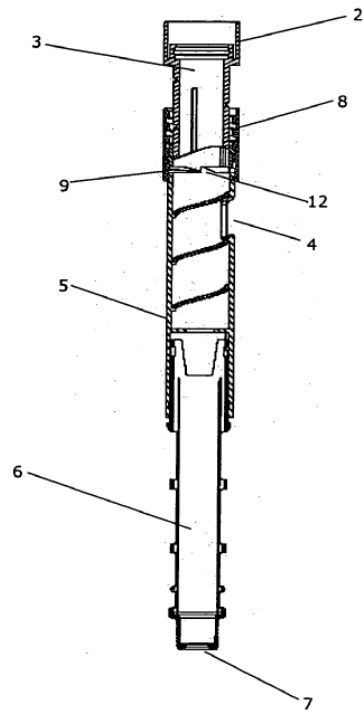


Fig. 4

As regards the respondents' arguments that the components defined in claim 1 could be floating in space and that the patent did not disclose the necessary interactions between various components of the injection device, the Board notes that sufficiency of disclosure has to be assessed on the basis of the teaching of the patent as a whole, taking into account the general knowledge of the person skilled in the art. A certain generalisation of that teaching, such as defining only the components needed for a certain technical effect, is the very purpose of the claims and is not objectionable in the present case, since the interrelationship between those components is further

explained or derivable on the basis of the description and drawings. Similarly, interactions between various components do not need to be explained in detail as long as they can be inferred, on the basis of common general knowledge, from the disclosure of the patent as a whole. The disclosure of the relative movement between those various components, provided in the figures and the description as summarised above, is sufficient for the person skilled in the art to understand and reproduce the necessary friction and engagement between those components.

As the respondents submitted, with only one tooth on the first and the second stopping member, not all possible doses can be set as the maximum settable dose, but only those corresponding to a whole number of revolutions of the first stopping member relative to the second stopping member. However, the choice between a plurality of possible maximum doses is still possible, which amounts to an enabling disclosure of the claimed limitation of the maximum dose settable, as desired dose, by the dose setting member.

- 7.3 The Board agrees with the respondents that the patent does not disclose in detail an embodiment in which the second stopping member is movable along with the dose setting member during setting of a dose. This is however not decisive. First of all, the Board notes that at least one way of carrying out the claimed invention is described in detail in relation to the embodiment illustrated in the figures of the patent. What may have to be established is whether the person skilled in the art, on the basis of the teaching of the patent as a whole and common general knowledge, could perform the task of devising an alternative embodiment in which the second - not the first - stopping member

is movable along with the dose setting member during setting of a dose, without undue burden or the need for inventive skill. This is in accordance with established case law of the boards of appeal, in particular T 629/05, point 4 of the Reasons, and T 79/08, point 3.3 of the Reasons, referred to by the respondents.

The Board notes that the patent provides a specific teaching towards such an alternative embodiment not only in claim 1 as such, but also in paragraph [0020]. From the disclosure of the patent, the person skilled in the art is therefore prompted to carry out the task mentioned above. In the Board's view, in the field of mechanics, such a task is normal design practice. For example, in a configuration similar to the one disclosed in detail in the patent, the first stopping member could be provided movable along the housing by operating the presetting member, and the second stopping member could be provided in a fixed relationship with the dose setting member. Clearly, some minor structural modifications would be needed for the dose setting mechanism to be assemblable and to work properly. However, it is the Board's view that such modifications are also within the competence of the person skilled in the art. As a consequence, the scope of claim 1 is not incommensurate with the disclosure of the patent as a whole (T 169/83, point 3.1 of the Reasons, cited by the respondents).

7.4 In conclusion, the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of the sixth auxiliary request.

8. Sixth auxiliary request - clarity

- 8.1 The respondents argued that the reference to "said movement", which caused the first and the second stopping member to perform a rotational movement relatively to each other, rendered the subject-matter of claim 1 unclear.

The Board notes that the claim, in the paragraph just above, specifies that either the first or the second stopping member is movable with the dose setting member. This definition makes clear that the movement in question causes a displacement of the stopping members relative to one another. The definitions of the other movements in the claim are not only further away from the reference in question, but also in no direct relation with a displacement of the stopping members relative to each other. Hence, the person skilled in the art has no doubts that "said movement" refers to the movement defined just above. This is fully in conformity with what is explained in the description.

- 8.2 As regards the expression "spiral movement" in claim 1, the Board agrees with the respondents that it is mathematically inaccurate. However, it is stressed again that a patent document is directed to the person skilled in the art, and the interpretation of the claim wording cannot take place outside the technical context and terminology set out in the description and drawings. This is in line with the findings in T 523/00 and T 311/93, cited by the appellant. The description clearly discloses a helical movement of the dose setting member while a dose is being set (derivable from Figures 3 and 4). Such a movement is referred to as a "spiral movement" (paragraph [0027]), while the term "helical" never occurs in the patent. On that

basis, on a contextual technical reading, the person skilled in the art has no doubts that the "spiral movement" defined in claim 1 has to be interpreted as a helical movement such as the one disclosed in relation to Figures 3 and 4. Hence, no ambiguity is present in the claim and the respondents' reference to T 556/11 is of no relevance.

8.3 The definition of the "spiral movement" of the dose setting member is a functional definition, which leaves open which structural means should be implemented for achieving the function. Functional definitions are usually employed in the claims and are not objectionable as such. The patent specifically teaches a threaded coupling between the dose setting member and the housing of the injection device. However, it is within the competence of the person skilled in the art to devise analogous couplings for performing the same claimed function. Hence, the definition of a threaded coupling is not essential in the claim. Rather, the functional definition is perfectly understandable by the person skilled in the art and does not introduce any non-allowable result to be achieved as the respondents put it.

8.4 The respondents' objection to the definition of the decreasing angular distance in claim 1 is not convincing either. A decrease in angular distance between two members in the presence of a relative rotational movement can only be interpreted as a decrease of the angle defined by two respective points on each member and the axis of rotation. If, as the claim requires, those members comprise one tooth each, the decrease in angular distance is necessarily that of the angular distance between those teeth. It is also clear that the reference to "the teeth of the first and

the second stopping member" at the end of the claim applies to the tooth of the first stopping member and the tooth of the second stopping member collectively. No other teeth are defined in the claims.

8.5 In conclusion, the subject-matter of claim 1 is clear, and the respondent's objections under Article 84 EPC do not prejudice the maintenance of the patent on the basis of the sixth auxiliary request.

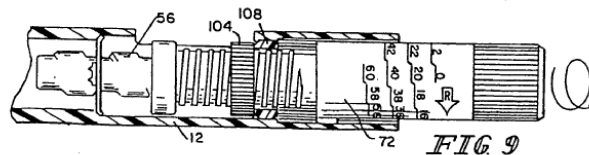
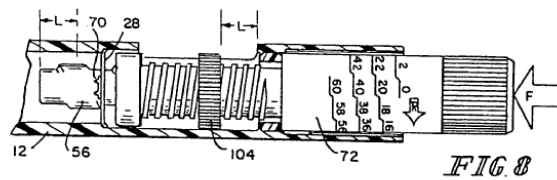
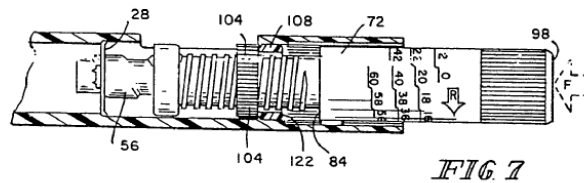
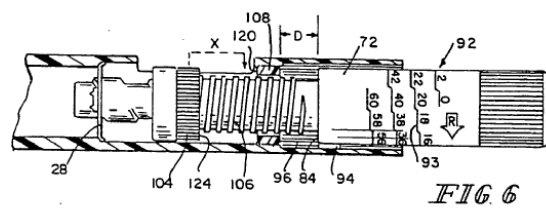
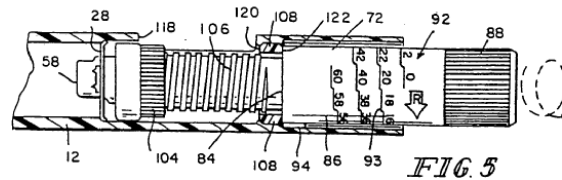
9. Sixth auxiliary request - novelty

The respondents argued that the subject-matter of claim 1 was not novel over D3.

D3 concerns a pen-type syringe for multiple measured injections of medicament such as insulin or growth hormone (column 1, lines 10 to 16).

With reference to Figures 5 to 9 reproduced below, D3 discloses such a syringe comprising a dose setting mechanism with a dose setting member (72) rotatably operable by a user to set a desired dose, the dose setting member performing a spiral movement (column 6, lines 1 to 6), a presetting member (follower 104) operable to limit the maximum dose settable by the dose setting member (column 6, lines 22 to 27) and having a surface (124) for engaging a surface of a second stopping member (barrier element 108) such that, upon engagement, the dose setting member cannot be operated to set a further dose (column 6, lines 61 to 68), the presetting member being movable along with the dose setting member during setting of a dose (for example from the configuration of Figure 8 to the configuration of Figure 9), this movement causing the presetting member and the second stopping member to perform a

rotational movement relatively to each other such that an angular distance between those members decreases, the relative rotational movement causing corresponding surfaces of those members to engage when the maximum settable dose has been set.



As the appellant argued, D3 does not disclose stopping members each comprising only one tooth.

The respondents' argument that the surface roughness on a surface may amount to only one tooth is not accepted, as it is clearly based on an uncommon interpretation of the claim language which could only be justified if it was specifically taught in the patent. However, no such teaching is present in the patent in suit.

Nor does D3 disclose a first stopping member operatively connected to the presetting member within the meaning of claim 1.

The claim requires four distinct members which, based on a normal technical interpretation, are to be considered as different physical elements. Furthermore, the claim specifies that the first stopping member is "operatively connected to the presetting member in such a manner that the position of the first stopping member is changed when the presetting member is operated". A surface or part of follower 104 - the presetting member in the claim language - cannot fulfil this feature, as its integrity with the stopping member technically excludes such an operative connection. The parties pointed to paragraph [0013] of the patent, in which it can be read: "*the first stopping member may be or form part of the presetting member*". However, the patent does not mention that such an option is in accordance with the claimed invention. It is the Board's view that an alternative is defined, which is not within the scope of claim 1 according to the sixth auxiliary request. The Board further notes that technical equivalence is not enough to establish a direct and unambiguous disclosure.

As regards the respondents' request that the distinguishing features as explained above should be mentioned in the minutes of the oral proceedings, the Board notes that under Rule 124(1) EPC the minutes are to contain the essentials of the oral proceedings. It is the Board's responsibility, when drafting the minutes, to decide what is necessary to be recorded. In the Board's view, the distinguishing features of the subject-matter of claim 1 over D3 do not need to be

mentioned in the minutes, but they are specifically reported and considered in the present decision.

In conclusion, the subject-matter of claim 1 is novel (Article 54(1) and (2) EPC) over D3.

10. Sixth auxiliary request - inventive step

10.1 The respondents argued that the subject-matter of claim 1 of the sixth auxiliary request was not inventive when starting from D3.

The distinguishing feature of the first stopping member operatively connected to the presetting member as claimed has the technical effect that the change of position of the first stopping member for changing the preset maximum settable dose does not have to be obtained by a movement being the same as the movement performed by the presetting member to obtain that change. In the embodiment of the patent, a rotational movement of the presetting member is transformed into a linear movement of the first stopping member along the dose setting member. This ensures that the corresponding teeth on the stopping members correctly engage when the maximum settable dose has been set.

It follows that, as the appellant submitted, the objective technical problem solved is not the simple provision of a design alternative providing the same technical effect, but how to obtain a more accurate definition of the point where the maximum settable dose has been reached.

For solving the objective technical problem, there is no teaching in the cited prior art suggesting the provision of a first stopping member separate from

follower 104 in D3,. Hence, the person skilled in the art would not implement that distinguishing feature in the dose setting mechanism of D3 in an obvious way.

It follows that the subject-matter of claim 1 is inventive when starting from D3.

- 10.2 The appellant argued that D23, starting from which the respondents had raised an objection of lack of inventive step, should not be admitted into the proceedings.

The Board notes that D23, used in an inventive-step attack, was filed by respondent/opponent 1 with its reply to the appellant's statement of grounds. Hence, it meets the requirements of Article 12(2) RPBA. Under Article 12(4) RPBA, its admission, which remains at the Board's discretion, should be more the rule than the exception. The Board is satisfied with the respondents' explanations why this document could be considered a promising starting point for the subject-matter of claim 1 of the sixth auxiliary request and, in the exercise of its discretion under Article 12(4) RPBA, admits D23 into the proceedings.

- 10.3 The respondents raised objections of lack of inventive step starting from D1, D9 or D23, in combination with D2.

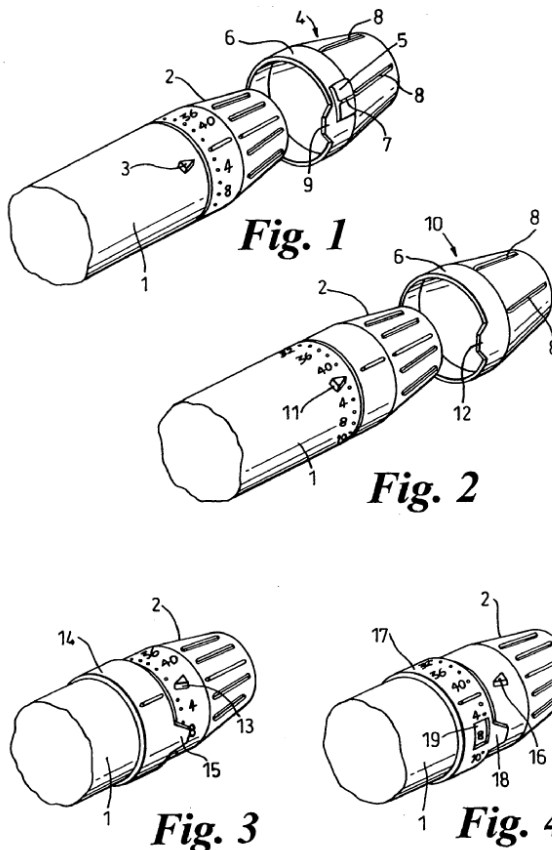
It is common ground that each of D1, D9 and D23 discloses a dose setting mechanism for an injection device comprising a dose setting member rotatably operable by a user to set a desired dose, with the dose setting member performing a spiral movement.

None of D1, D9 and D23 disclose a first and a second

stopping member each comprising only one tooth, as defined in claim 1 of the sixth auxiliary request.

The respondents argued that the objective technical problem was to provide a device such that repeatedly setting the same dose could be easily done. That problem was solved by D2.

However, as the appellant submitted, D2 does not disclose a dose setting mechanism with a dose setting member that performs a spiral movement as claimed (figures of D2 reproduced below).



D2 discloses projections (3, 11, 13 and 16) of a barrel (1) or of a dose setting member in the form of a dosing knob (2) which engage with respective projections (9, 12, 15 and 18) of an annular member (6, 14 and 17) on

the dosing knob or on the barrel, when the barrel and the dosing knob rotate relatively to one another. There is no obvious reason why the person skilled in the art would consider D2 when starting from a document with a dose setting member that performs a different movement, i.e. the spiral movement as claimed. The fact that some adaptations, albeit easy in the respondents' view, would be needed to make some elements of the dose setting mechanism of D2 compatible with the devices disclosed in D1, D9 or D23 confirms that the person skilled in the art would avoid the combination unless a specific teaching in that direction was present. Such a teaching is simply not provided by the cited prior art.

It follows that the subject-matter of claim 1 is inventive when starting from D1, D9 or D23.

- 10.4 As regards the respondents' attack starting from D2, the Board notes that the same difficulty arises. Even in view of the technical problem formulated by the respondents, i.e. making the mechanism of D3 available for manually driven injection devices, there is no reason why the person skilled in the art would turn to a device with a dose setting member that performs a spiral movement, such as the devices of D1, D9 and D23. Dose setting in D2 takes place with the dose setting member performing a purely rotational movement, and, clearly, not all manually driven injection devices have a dose setting member that performs a spiral movement.

Hence, the subject-matter of claim 1 is inventive also when starting from D2.

- 10.5 The Board shares the respondents' view that the same level of skill has to be applied when, for the same invention, the two questions of sufficiency of

disclosure and inventive step have to be considered. However, as the appellant submitted, the two questions involve fundamentally different situations in the present case. While the description of the patent provides direct pointers to the implementation of the second stopping member movable along with the dose setting member during setting of a dose, pointers or teachings are not provided by the cited prior art for the implementation of the distinguishing features of claim 1 in the dose setting mechanism of the documents identified as starting points in the respondents' objections.

10.6 In conclusion, the objections of lack of inventive step (Article 56 EPC) do not prejudice the maintenance of the patent on the basis of the sixth auxiliary request.

11. Sixth auxiliary request - other matter

The respondents argued that paragraph [0013] of the patent as granted had to be amended, since it was in contradiction with claim 1. However, the Board notes that the same alleged contradiction, which could result in a lack of clarity of the claim, was present in relation to claim 1 of the patent as granted. Since clarity is not a ground for opposition, the amendment is neither justified nor even possible (Rule 80 EPC).

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, with the order to maintain the patent on the basis of:
 - claims 1 to 4 of the sixth auxiliary request filed during the oral proceedings;
 - columns 1 to 8 of the adapted description filed during the oral proceedings; and
 - Figures 1 to 6 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated