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**Datasheet for the decision  
of 10 January 2018**

**Case Number:** T 0484/12 - 3.2.02

**Application Number:** 04731882.9

**Publication Number:** 1624914

**IPC:** A61M5/142

**Language of the proceedings:** EN

**Title of invention:**  
INTERNAL NEEDLE INSERTER

**Patent Proprietor:**  
NOVO NORDISK A/S

**Opponent:**  
Sanofi-Aventis Deutschland GmbH

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(a), 111(1)  
EPC R. 115(2)  
RPBA Art. 12(2), 12(4), 15(3)

**Keyword:**

Oral proceedings - held in absence of appellant  
New document filed with statement setting out the grounds of  
appeal - admitted (yes)  
Auxiliary requests filed with reply - admitted (yes)  
Novelty - main, first and second auxiliary requests (no)  
Third auxiliary request - allowable (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 0484/12 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 10 January 2018**

**Appellant:** Sanofi-Aventis Deutschland GmbH  
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**Respondent:** NOVO NORDISK A/S  
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**Representative:** Kristoffersen, Bo  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 23 December  
2011 rejecting the opposition filed against  
European patent No. 1624914 pursuant to Article  
101(2) EPC.**

**Composition of the Board:**

**Chairman**            L. Bühler  
**Members:**            P. L. P. Weber  
                             M. Stern

## **Summary of Facts and Submissions**

- I. The appeal of the opponent (appellant) is against the decision of the Opposition Division posted on 23 December 2011 to reject the opposition.
- II. The notice of appeal was filed on 27 February 2012 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 27 April 2012.
- III. A summons to oral proceedings was issued on 27 September 2017.
- IV. By letter dated 10 October 2017, the respondent-patent proprietor announced that it would not attend the scheduled oral proceedings.
- V. In a submission dated 20 November 2017, the appellant-opponent raised, among other points, a lack-of-novelty objection based on E9 to the subject-matter of claim 1 according to the first and the second auxiliary requests.
- VI. Oral proceedings were held on 10 January 2018.

The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked. It further requested that auxiliary requests 1 to 6 not be admitted into the appeal proceedings.

The respondent-patent proprietor had requested in writing that the appeal be dismissed (main request), or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 6 filed with the letter dated 14 September 2012. It also had

requested that document E9 not be admitted into the appeal proceedings.

Duly summoned, the respondent-patent proprietor did not attend the oral proceedings, as announced by letter dated 10 October 2017, such that the proceedings continued in its absence in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

Asked by the Chairman, the appellant-opponent confirmed that it had no objections to the maintenance of the patent according to auxiliary request 3.

VII. The following documents are cited in this decision:

E2: WO 99/33504

E9: WO 92/19296

VIII. The independent claims relevant to the decision read as follows:

(a) Claim 1 of the patent as granted:

"A medical device (100, 400) comprising:

a housing (110, 120) having a mounting surface (121) adapted for application to the skin of a subject,

a transcutaneous device with a distal pointed end portion (151, 451, 461) adapted to penetrate the skin of the subject,

the transcutaneous device having a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface,

user actuatable driving means (137, 454, 464) disposed within the housing and adapted to move the transcutaneous device from the first position to the second position when the driving means is actuated, characterized in that

the driving means, with the transcutaneous device arranged in the first position, is actuatable from a first state through an intermediate state to a second state,

whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the transcutaneous device from the first position to the second position."

(b) Claim 1 of auxiliary request 1 (new feature over claim 1 of the patent as granted in italics):

"A medical device (100, 400) comprising:

a housing (110, 120) having a mounting surface (121) adapted for application to the skin of a subject,

a transcutaneous device with a distal pointed end portion (151, 451, 461) adapted to penetrate the skin of the subject,

*the transcutaneous device being in the form of a pointed hollow infusion needle, a micro needle array, a pointed needle sensor, or a combination of a relatively*

*flexible cannula, the cannula per se being blunt, with a pointed insertion needle, and*

the transcutaneous device having a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface, and

user actuatable driving means (137, 454, 464) disposed within the housing and adapted to move the transcutaneous device from the first position to the second position when the driving means is actuated,

characterized in that

the driving means, with the transcutaneous device arranged in the first position, is actuatable from a first state through an intermediate state to a second state,

whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the transcutaneous device from the first position to the second position."

(c) Claim 1 of auxiliary request 2 (new feature over claim 1 of the patent as granted in italics):

"A medical device (100, 400) comprising:

a housing (110, 120) having a mounting surface (121) adapted for application to the skin of a subject,



a transcutaneous device with a distal pointed end portion (151, 451, 461) adapted to penetrate the skin of the subject,

the transcutaneous device having a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface, and

user actuatable driving means (137, 454, 464) disposed within the housing and adapted to move the transcutaneous device from the first position to the second position when the driving means is actuated,

characterized in that

the driving means, with the transcutaneous device arranged in the first position, is actuatable from a first state through an intermediate state to a second state,

whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the transcutaneous device from the first position to the second position, and

*the transcutaneous device is a hollow infusion needle comprising a proximal end (152) and the distal pointed end portion (151)."*

(d) Claim 1 of auxiliary request 3 (new feature over claim 1 of the patent as granted in italics):

"A medical device (100, 400) comprising:

a housing (110, 120) having a mounting surface (121) adapted for application to the skin of a subject,

a transcutaneous device with a distal pointed end portion (151, 451, 461) adapted to penetrate the skin of the subject,

the transcutaneous device having a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface,

*wherein the transcutaneous device is a cannula (351, 451) in combination with a pointed insertion needle (361, 461) accommodated at least partially within the cannula, the cannula having a distal opening, and wherein the insertion needle is arranged to be moveable away from the distal opening when the cannula and the insertion needle have been moved to their second position, and*

user actuatable driving means (137, 454, 464) disposed within the housing and adapted to move the transcutaneous device from the first position to the second position when the driving means is actuated,

*wherein the cannula and insertion needle are arranged to be simultaneously moved by the driving means from their respective first position to their respective second position when the driving means is actuated,*

characterized in that

the driving means, with the transcutaneous device arranged in the first position, is actuatable from a first state through an intermediate state to a second state,

whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the transcutaneous device from the first position to the second position."

- IX. The arguments of the respondent-patent proprietor can be summarised as follows (more details are presented in the reasons for the decision):

At least one essential feature is not disclosed in E9, such that it is not *prima facie* relevant for claim 1, and should therefore not be admitted into the appeal proceedings.

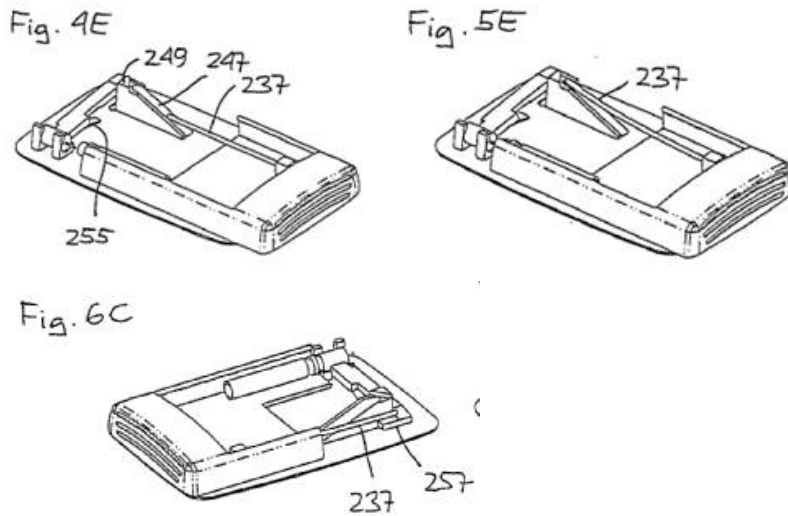
The subject-matter of claim 1 of the patent as granted and of claim 1 according to the first and the second auxiliary requests is new in view of E2.

- X. The appellant-opponent's arguments are essentially those underlying the reasons for the present decision as set out below.

## **Reasons for the Decision**

1. The appeal is admissible.
2. Duly summoned, the respondent-patent proprietor did not attend the oral proceedings, as announced by letter dated 10 October 2017, such that the proceedings continued in its absence in accordance with Rule 115(2) EPC and Article 15(3) RPBA.
3. The invention

The invention is an injection device for applying to the surface of the skin (normally adhesively) which has an actuatable injection needle or cannula-injection needle combination. The aim is to create a functioning but cost-effective device, in particular for injection of insulin. The needle is normally within the housing of the device until a drive means introduces the needle into the skin. The drive means is armed or activated and then triggered or released. In the embodiments described, this is done with a leaf spring (Figures 1 to 3) or rod spring (Figures 4 to 6 and 9). In a first position the leaf spring is in a rest position, in an intermediate position it is "armed", and then it is "fired" and goes to the second position. The needle can be combined with a cannula (Figures 9 and 10).



4. Main request - Interpretation of claim 1
- 4.1 The features of the characterising portion of claim 1 read as follows:
- *the driving means, with the transcutaneous device arranged in the first position, is actuatable from a first state through an intermediate state to a second state,*
  - *whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the transcutaneous device from the first position to the second position.*

This claim wording requires three "states" of the driving means - a first, an intermediate and a second - and it further requires that the driving means be actuated to go from the first to the intermediate state and be actuated again to go from the intermediate to the second state. The term "state" might suggest that the three states mentioned are stable states, and that

an action is necessary on the drive means to go from one state to the next.

4.2 However, as convincingly argued by the appellant-opponent, the author of the patent in suit did not limit the meaning of this term to stable states, but wished to include transient states too in which the user maintains its holding force. Such interpretation is confirmed by the description of the patent.

Paragraph [0024] makes it clear that the term "state" does not necessarily imply stable states:

*"It should be emphasized that the activated state not necessarily is a stable state in which the spring means can be left, but a state which may require that an actuation input (e.g. a force applied by the user) is upheld, i.e. the spring means may resume an initial state if the actuation input is removed."*

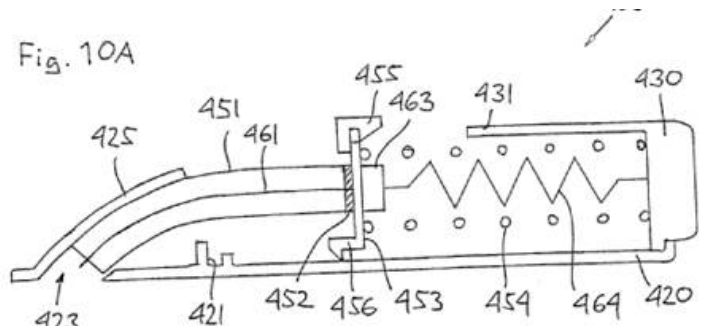
In addition, the disclosed embodiments do not work with a stable intermediate state. As regards the first embodiment (Figures 1A to 3E), the leaf spring 137 is activated by movement on an inclined ramp surface 147 terminating in an upper free edge 148. It is technically self-evident that, as long as the leaf spring is on the ramp surface 147, it can resume its initial state if the actuation input on the actuation member 130 is removed, as explained in paragraph [0024]. A stable intermediate state is therefore not recognisable.

The same is true for the second embodiment - which works basically according to the same principle as the first embodiment, the leaf spring 137 being replaced by

a rod spring 237 - and for the third embodiment shown in Figures 9A to 9C.

Finally, the embodiment according to Figures 10A to 10D also does not have a stable intermediate state, since in paragraph [0063] the intermediate state is said to correspond to a compressed state of the springs 454 and 464.

Paragraph [0063] states: *"When a user actuates the actuation member the two springs are compressed corresponding to an intermediate state, however, as the actuation member reaches its fully actuated position the release member 431 releases the catch 455 (see fig. 10B ) which allows the two compressed springs to expand and thereby move the cannula and the insertion needle to their respective extended and downwardly deflected positions whereby the locking catch 456 engages a corresponding catch 421 in the housing as shown in fig.*



10C."

4.3 From the above it follows that the intermediate state mentioned in claim 1 does not have to be a stable state, but can be a state in which the user maintains its actuation input.

5. Admissibility of E9

The appellant-opponent filed document E9 with the statement setting out the grounds of appeal,

substantiating why it anticipated the subject-matter of claim 1. It follows that the condition of Article 12(2) RPBA is fulfilled such that, pursuant to Article 12(4) RPBA, second part, the document is in the proceedings unless an exception according to Article 12(4) RPBA, first part, applies.

The respondent-patent proprietor considered that E9 was not *prima facie* relevant to claim 1, and should therefore not be admitted. According to the respondent-patent proprietor, in the injection device of E9 the release of the activated driving means is not caused by actuation of the driving means (the spring 34), but only by pushing the outer housing part 22 sufficiently far about the main housing 16 so as to accommodate the balls 44 in the groove 46. The compression of the spring 34 does not constitute the cause of the spring 34 actually being released.

In the opinion of the Board, this is, however, analogous to the embodiments according to the invention. As can be seen, for instance in the embodiment according to Figures 10A to 10D, it is not the compression of the springs 454 and 464 which is the cause of their release, but the pushing of the housing 430 and the release member 431 against the releasable catch member 455. Therefore, in the Board's opinion, also according to the patent, actuation of the driving means does not necessarily mean that the driving means *per se* is the cause of the release.

Moreover, as the appellant-opponent argued, E9 was filed in response to arguments developed in the impugned decision in favour of novelty in view of E2. And, as will be seen below, E9 is highly relevant in



the sense that it will change the outcome of the proceedings.

Therefore, E9 is admitted into the proceedings.

6. Main request - Novelty in view of E9

6.1 E9 discloses an automated device for rapid vascular drug delivery. The device is placed against a patient's skin. The needle 14 connected to a syringe body 12 remains in a housing 16 while a main spring 34, for driving the plunger 26 of the syringe, is loaded by pressing on the actuation handle 22. The plunger 26 is held in place relative to the syringe body 12 by lock balls 44 until the lock balls go into an annular "trip pocket 46" in the actuation handle 22 and free the plunger which then pushes the syringe body 12 along the inside walls of the housing 16 and at the same time the needle out of the housing 16 into the patient's body and the drug out of the syringe.

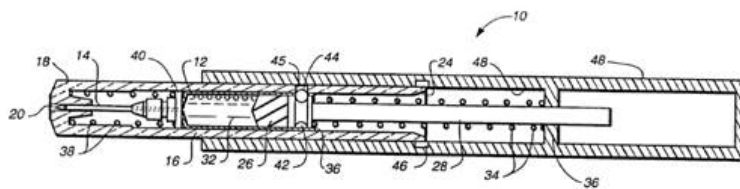


FIG. 1

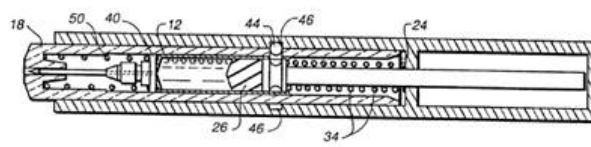


FIG. 2

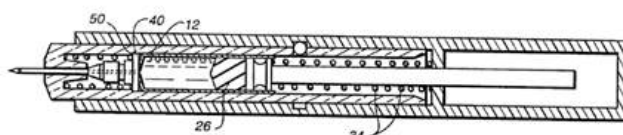


FIG. 3

6.2 In the terms of the claim, E9 discloses:

A medical device 10 comprising:

a housing (main housing 16) having a mounting surface (front barrel 18 with orifice 20) adapted for application to the skin of a subject,

a transcutaneous device with a distal pointed end portion (needle 14) adapted to penetrate the skin of the subject,

the transcutaneous device having a first position in which the distal end portion is retracted within the housing (Figure 1), and a second position in which the distal end portion projects relative to the mounting surface (Figure 3),

user actuatable driving means 34 disposed within the housing 16 and adapted to move the transcutaneous device from the first position to the second position when the driving means is actuated.

The features of the first part of claim 1 are thus disclosed in E9.

The Board notes that, even though the spring 34 might be considered to be only partially positioned within the housing 16, such a construction falls under the wording of claim 1. Moreover, in the Board's opinion, the cylindrical handle 22 fitted over the end 24 of the main housing 16 corresponds, for instance, to the actuation member 430 with the release member 431 of the embodiment according to Figures 10A to 10D of the patent.

As explained above under point 2, since the intermediate state does not have to be a stable state but can be a state maintained by the user, the intermediate state in the device according to E9 is when the spring 34 is compressed but not yet so far as to free the balls 44 into groove 46. This is a comparable intermediate state to that in the embodiment according to Figures 10A to 10D and paragraph [0063] of the patent.

Therefore, the features of the characterising portion of claim 1 that

*"the driving means, with the transcutaneous device arranged in the first position, is actuatable from a first state through an intermediate state to a second state,*

*whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the transcutaneous device from the first position to the second position"*

are also disclosed in E9, such that the subject-matter of claim 1 is not new in view of E9.

6.3 Hence, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC prejudices the maintenance of the patent as granted.

7. Admissibility of auxiliary requests 1 to 6

The appellant-opponent requested that

- the auxiliary requests not be admitted into the proceedings because they were not examined during the first-instance opposition proceedings, and

- the second to sixth auxiliary requests not be admitted into the proceedings because they were directed to subject-matter which did not converge with the line of development defined by the subject-matter of the main request and first auxiliary request.

These requests were already filed (but not examined) during first instance opposition proceedings and filed again during appeal proceedings with the respondent-patent proprietor's reply to the statement setting out the grounds of appeal.

The auxiliary requests were thus filed at the earliest possible moment in the appeal proceedings since the respondent-patent proprietor filed them immediately with the reply to the statement setting out the grounds of appeal. Since they are the same as those filed in the opposition proceedings the appellant-opponent already knew them, and, hence, had no additional difficulties for examining these requests in the appeal proceedings. Moreover, since the main claims of these requests are essentially combinations of granted claims, the appellant-opponent already examined them when filing the notice of opposition.

These auxiliary requests, therefore, form part of the appeal proceedings pursuant to Article 12 RPBA.

8. First auxiliary request - Novelty in view of E9

In the first part of claim 1 according to this request the feature *the transcutaneous device being in the form of a pointed hollow infusion needle, a micro needle array, a pointed needle sensor, or a combination of a relatively flexible cannula, the cannula per se being blunt, with a pointed insertion needle*, has been added.

In its reply dated 20 November 2017, the appellant-opponent raised a lack of novelty objection based on E9 against the subject-matter of claim 1 according to this request. No counter-arguments were filed by the respondent-patent proprietor.

In the device according to E9 a pencil point needle 14 is said to be used to inject the liquid medication 32 into the patient body (see page 7, lines 16 to 18), so that the above feature is anticipated.

Hence, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC prejudices the maintenance of the patent on the basis of the first auxiliary request.

9. Second auxiliary request - Novelty in view of E9

In the characterising part of claim 1 according to this request the feature *the transcutaneous device is a hollow infusion needle comprising a proximal end (152) and the distal pointed end portion (151)* has been added.

In its reply dated 20 November 2017, the appellant-opponent also raised a lack of novelty objection based on E9 against the subject-matter of claim 1 according to this request. Again no counter-arguments were filed by the respondent-patent proprietor.

As already mentioned, in the device according to E9 a pencil point needle 14 is said to be used to inject the liquid medication 32 into the patient body (see page 7, lines 16 to 18), so that the above feature is anticipated.

Hence, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC prejudices the maintenance of the patent on the basis of the second auxiliary request.

10. Auxiliary request 3

In the oral proceedings the appellant-opponent declared that it had no objections against this request.

The Board does not have any either.

11. Considering that the respondent-patent proprietor was not present at the oral proceedings and that it had not filed any adapted description and/or drawings in the written proceedings, the Board decided to remit the case to the first-instance department for such adaptation pursuant to Article 111(1) EPC.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent with the following claims and the description and drawings to be adapted thereto:

Claims 1 to 16 of the auxiliary request 3 filed with letter dated 14 September 2012.

The Registrar:

The Chairman:



D. Hampe

L. Bühler

Decision electronically authenticated