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Datasheet for the decision of 22 September 2025

Case Number: T 0931/23 - 3.2.01

Application Number: 12710104.6

Publication Number: 2689359

IPC: A61M5/31, G16H40/40, A61M5/315

Language of the proceedings: EN

Title of invention:
DEVICE AND METHOD FOR DETECTING AN ACTUATION ACTION PERFORMABLE WITH A MEDICAL DEVICE

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponent:
Herzog IP Patentanwalts GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 99(1), 100(a), 100(b), 100(c), 114(2)
EPC R. 115(2)
RPBA 2020 Art. 12(2), 12(3), 12(4), 12(5), 12(6), 15(3)

Keyword:
Grounds for opposition - added subject-matter (no) - insuffciency of disclosure (no) - lack of novelty (no) - lack of inventive step (no)
Admittance of document (no)

Decisions cited:
G 0007/93

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0931/23 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 22 September 2025

Appellant: (Opponent)	Herzog IP Patentanwalts GmbH Steinstraße 16-18 40212 Düsseldorf (DE)
Representative:	Herzog IP Patentanwalts GmbH Steinstraße 16-18 40212 Düsseldorf (DE)
Respondent: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)
Representative:	Schmidt, Christian ZSP Patentanwälte PartG mbB Hansastraße 32 80686 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 May 2023 rejecting the opposition filed against European patent No. 2689359 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	G. Pricolo
Members:	B. Spitzer
	A. Jimenez

Summary of Facts and Submissions

I. The opponent appealed the decision of the opposition division rejecting the opposition against the European patent No. 2 689 359 ("the patent").

II. The opposition was filed against the patent as a whole on the basis of the grounds for opposition under Article 100(a) together with Article 54 EPC (lack of novelty) and Article 56 EPC (lack of inventive step), Article 100(b) and (c) EPC.

III. The following documents filed in the opposition proceedings are relevant to this decision:

D1: WO 2010/098931 A1
D2: WO 2010/023303 A1
D6: EP 2 182 456 A1
D7: WO 2010/098927 A1
D15: US 2002/0188419 A1
D17: Pearson: "Practical Aspects of Insulin Pen Devices"; Journal of Diabetes Science and Technology; Vol. 4(3); May 2010; pages 522 to 531
D18: Instruction Manual for "NovoPen® 4" (Polish version), published in 2004
D19: Instruction Manual for "NovoPen® 4" (Danish version), published in 2004
D20: Manual "How to use NovoPen® 4"; no publication date

IV. In addition to the opponent's statement of grounds of appeal, it filed arguments with letter dated 29 May 2024.

V. In a communication dated 7 April 2025 in accordance with Article 15 (1) RPBA, the Board provided its preliminary opinion.

VI. Oral proceedings before the Board were held on 22 September 2025 by videoconference in the absence of the appellant (opponent), which had informed the Board by letter of 19 August 2025 that it withdrew its request for oral proceedings and that it would not attend the oral proceedings. According to Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued in its absence.

VII. Final requests

The appellant (opponent) requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed, or, alternatively, that the case be remitted to the opposition division for further prosecution. Further alternatively, it requested that the patent be maintained as amended on the basis of the claims of one of auxiliary requests 1, 2, 2a, 3, 3a, 4, 4a, 5, 5a, 6, 6a, 7 and 7a filed with their reply to the statement of grounds of appeal.

VIII. Granted independent claims 1, 14 and 15 have the following wording (with the parties' feature designations in square brackets):

"1.**[1.1]** An apparatus (2), comprising:
[1.2] - a detector unit (20, 21 , 22, 23) comprising a detector (21) configured to detect an actuation action performable via said detector unit (20, 21 , 22, 23) to

an actuation button (11) of a medical device (1) to cause said medical device (1) to eject at least a portion of a medicament comprised in said medical device (1), **[1.2.1]** wherein said detector (21) is configured to detect said actuation action based on a detection of a force and/or a touch applied to said detector unit (20, 21 , 22, 23) as part of said actuation action, **[1.2.2]** wherein said detector unit (20, 21 , 22, 23) is placeable on top of said actuation button (11) or forms an upper part of said actuation button (11) itself and
[1.3] -an electric unit (22) connected to said detector and configured to store and/or provide information related to said detected actuation action,
[1.3.1] wherein said electric unit (22) is configured to determine a length of time interval during which said actuation action is applied, and **[1.3.2]** to store and/or provide information related to said determined length of said time interval and/or to store and/or **[1.3.3]** provide said information related to said detected actuation action in dependence on said determined length of time interval."

"14. A method (400), comprising:
- detecting (401), with a detector (21), an actuation action performable via a detector unit (20, 21, 22, 23) that comprises said detector (21) to an actuation button (11) of a medical device (1) to cause said medical device (1) to eject at least a portion of a medicament comprised in said medical device (1), wherein said detector (21) is configured to detect said actuation action based on a detection of a force and/or a touch applied to said detector unit (20, 21, 22, 23) as part of said actuation action, wherein said detector unit (20, 21, 22, 23) is placed on top of said actuation button (11) or forms an upper part of said

actuation button (11) itself,
- determining a length of time interval during which said actuation action is applied and
- storing and/or providing information related to said determined length of said time interval and/or storing and/or providing (402) information related to said detected actuation action in dependence on said determined length of time interval."

"15. A computer program, comprising instructions operable to cause a processor to control the steps (401, 402) of the method (400) of claim 14 when said computer program is executed on said processor."

IX. In its statement of grounds of appeal, the appellant raised objections under

- Article 100(a) EPC together with Article 54 EPC (lack of novelty), in particular, that the subject-matter of the independent claims was not new over documents D6 or D7,
- Article 100(a) EPC together with Article 56 EPC (lack of inventive step), in particular, that the subject-matter of the independent claims was obvious starting from document D2 as closest prior art taking into account the common general knowledge or in combination with documents D1 or D7 and - if feature 1.3.1 of granted claim 1 was the sole distinguishing feature for document D6 - starting from document D6 as closest prior art taking into account the common general knowledge or in combination with documents D1 or D7,
- Article 100(b) EPC and
- Article 100(c) EPC.

It further requested to set aside the decision of the opposition division in so far it decided not to admit

document D17 into the proceedings. Documents D18 to D20 were addressed by the appellant in its statement of grounds of appeal in the context of document D6.

With its letter dated 29 May 2024, the appellant raised a further inventive-step objections starting from document D2 in combination with document D15.

Reasons for the Decision

Ground for opposition under Article 100(c) EPC

1. The subject-matter of the patent does not extend beyond the content of the application as filed.

1.1 The Board follows the opposition division's conclusion (see decision under appeal, Reasons, point 16.).

1.2 The appellant contested that the application as filed directly and unambiguously disclosed the combination of feature 1.2.2 defining the physical localisation of "detector unit (20, 21, 22, 23)" and feature 1.3.1 defining the kind of information detected by means of "electric unit (22)" of granted claim 1.

1.3 It was undisputed that feature 1.2.2 of claim 1 as granted is disclosed on page 6, lines 1 to 3 of the application as filed and feature 1.3.1 of claim 1 as granted in dependent claim 9 and on page 11, lines 4 to 7 of the application as filed.

1.4 Feature 1.2.2 further specifies the detector unit of originally filed claim 1 and its physical location, while feature 1.3.1 further specifies the electric unit of originally filed claim 1 and its operational purpose. The skilled person, when reading the passage

on page 11, lines 4 to 7, understands that the electric unit is configured to determine a length of a time interval during which the actuation action is applied. The last paragraph on page 6 of the application as filed informs the skilled person that the actuation action is detected by a detector. From these passages, the skilled person would directly and unambiguously infer that the electric unit is intended to be associated with the detector unit. This detector unit is exemplified on page 6, lines 1 to 3 of the application as filed, as being at least partially placed on top of the actuation button or forming an upper part of the actuation button itself. Accordingly, the application as filed provides a direct and unambiguous disclosure linking the electric unit with this specific detector arrangement.

1.5 The appellant's arguments do not convince the Board. The application has not been considered to be a reservoir from which features pertaining to separate embodiments of the application as filed were combined to artificially create a particular embodiment. Rather, as shown above, the combination of features 1.2.2 and 1.3.1 of granted claim 1 is directly and unambiguously disclosed based on the application as a whole and taking into account the common general knowledge of the skilled person.

Ground for opposition under Article 100(b) EPC

2. The patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2.1 The Board agrees with the opposition division (see decision under appeal, Reasons, point 17.)

In particular, the opposition division found that "*the skilled person would be capable of providing e.g. time measurement indicating the actuation of actuation button, and provide information affiliated therewith in dependence on the determined time length in principle by applying common general knowledge and standard electronic components, presumably relying on respective programming implementing the necessary data handling and processing.*"

2.2 The appellant contested this.

2.2.1 According to the appellant, features 1.3.1 and 1.3.2 of granted claim 1 were insufficiently disclosed. This was particularly evident in light of the opposition division's conclusion on inventive step, that modifying the microprocessor of document D2 to recognize the switch-closure duration did not belong to the common general knowledge of the skilled person. The patent did not teach the person skilled in the art how to implement an electric unit capable of determining the length of time interval during which the actuation action is performed and to provide and/or store such information. Reference was made to paragraph [0046] of the patent, which was the only passage in the description mentioning the measurement of a "length of time interval" as defined in feature 1.3.1 of granted claim 1. However, this paragraph contained no technical teaching as to how such a measurement could be carried out.

2.2.2 The appellant further argued that the patent did not disclose how a detector, as defined in feature 1.2, could be combined with an electric unit as claimed in feature 1.3.1 of granted claim 1. Figure 3 of the

patent did not remedy this issue, since it did not enable the detection that "switch S1" was reopened and, therefore, did not allow the implementation of feature 1.3.1 of granted claim 1. Reference was made to paragraphs [0090] and [0092] of the patent.

2.3 The appellant's arguments are not convincing for the following reasons.

2.3.1 The Board concurs with the respondent that paragraph [0046] of the patent discloses sufficient information, including examples, in relation to features 1.3.1 and 1.3.2 of granted claim 1. The Board considers their technical implementation to belong to the common general knowledge.

Regarding the appellant's alleged contradiction between the opposition division's conclusion on sufficiency of disclosure and inventive step, the Board refers to established case law. Although the same level of skill is applied for both sufficiency of disclosure and inventive step, the two starting points differ. For inventive step purposes, the skilled person knows only the prior art, while for sufficiency of disclosure, they know the prior art and the disclosed invention (see Case Law of the Boards of Appeal of the European Patent Office, 11th edition, July 2025, "Case Law", I.D.8.3.1).

2.3.2 As regards the alleged lack of disclosure regarding a combination of the claimed detector (feature 1.2) with the electric unit configured to determine a length of time interval (feature 1.3.1), the Board refers to paragraph [0033] of the patent, as cited by the respondent. This paragraph discloses that the electric unit is connected to the detector, for instance, by a

wired connection. Figure 3 of the patent, relied upon by the appellant, does not disclose an electric circuit for determining a length of time interval. However, as further noted by the respondent, and as disclosed in paragraph [0094] of the patent, Figure 3 discloses a timer circuit which switches a LED on for a predetermined time.

Admittance of documents D15 and D17 to D20 and of the inventive-step objection based on a combination of documents D2 and D15

3. Documents D15 and D17 are not admitted into the appeal proceedings in accordance with Article 12(6) RPBA. Consequently, also the inventive-step objection based on a combination of documents D2 and D15 is not admitted. Documents D18 to D20 are not admitted into the appeal proceedings in accordance with Article 12(2) and (4) RPBA.

3.1 Documents D15 and D17 to D20 have been filed after the expiry of the opposition period (Article 99(1) EPC). The opposition division did not admit documents D15 and D17 in accordance with Article 114(2) EPC since they were considered as not being *prima facie* relevant (see decision under appeal, Reasons, points 19.3 and 19.7).

Document D18 and D19 were addressed during the oral proceedings before the opposition division in the context of usual dispensing times (see minutes, point 64). Document D20 was not addressed by the appellant during those oral proceedings, and the admittance of documents D18 to D20 was not decided upon by the opposition division.

3.2 Document D15 is a US patent application which is related to dispensing times and the determination of dose amounts (see document D15, paragraph [0015]). Document D17 is a review article about insulin pen devices. Documents 18 and D19 are instruction manuals of NovoPen®4 and document D20 is an undated document concerning the use of NovoPen®4.

3.3 The appellant referred to documents D17 to D20 in its statement of grounds of appeal in the context of novelty over document D6. Document D17 is also referred to as common general knowledge in the course of its objection of lack of inventive step starting from document D2. The appellant requests to set aside the decision of the opposition division in so far as it had been decided not to admit document D17. In its letter dated 29 May 2024, the appellant further argued that the subject-matter of claim 1 as granted was not inventive over a combination of documents D2 and D15.

3.4 The respondent requests that documents D15 and D17 to D20 should not be admitted into the proceedings.

3.5 Non-admittance of documents D15 and D17 and of the inventive-step objection based on a combination of documents D2 and D15

3.5.1 In accordance with Article 12(6), first sentence, RPBA, the Board does not admit requests, facts, objections or evidence which were not admitted in the proceedings leading to the decision under appeal, unless the decision not to admit them suffered from an error in the use of discretion or unless the circumstances of the appeal case justify their admittance.

3.5.2 In the present case, the Board came to the conclusion that the opposition division exercised its discretion under Article 114(2) EPC not to admit documents D15 and D17 without any procedural or discretionary error. Their finding that documents D15 and D17 lacked *prima facie* relevance (see decision under appeal, Reasons, points 19.3 and 19.7) is a decisive criterion for admitting late-filed documents to opposition proceedings. The appellant's argument is not based on the opposition division having exercised its discretion in an impermissible manner, but on the appellant's disagreement with the opposition division's view on the *prima facie* relevance of documents D15 and D17. However, this is not usually relevant when reviewing discretionary decisions of the first instance. It is not the task of the Board of Appeal to re-examine the facts of the case as a first-instance body in order to decide whether it would have exercised its discretion in the same way. A Board of Appeal should only disregard the manner in which the first instance exercised its discretion in deciding a particular case if it concludes that the first instance exercised its discretion on the basis of incorrect criteria, failing to observe the correct criteria, or in an arbitrary or inappropriate manner, thereby exceeding the discretion granted to it (see G 7/93, OJ EPO 1994, 775, reasons, point 2.6). Since this is not the case here, the Board sees no reason to disregard the manner in which the opposition division exercised its discretion.

3.5.3 The appellant did not claim any circumstances of the appeal case justifying their admittance in accordance with Article 12(6) sentence 1 RPBA and the Board also does not see any.

3.6 Non-admittance of documents D18 to D20

3.6.1 Documents D18 to D20 were filed late before during the opposition proceedings and have not been addressed in the decision under appeal. Since the appellant did not demonstrate that they have been admissibly raised and maintained in the opposition proceedings, they are considered as an amendment to the appellant's appeal case (see Article 12(2) and (4) RPBA).

3.6.2 In accordance with Article 12(4) RPBA, second sentence, any such amendment may be admitted only at the discretion of the Board, which exercises its discretion in view of, *inter alia*, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal, and the need for procedural economy (see Article 12(4), fifth sentence, RPBA).

3.6.3 In the present case, documents D18 to D20, which relate to insulin pen, NovoPen®4, are referred to by the appellant in the context of document D6. Since document D6 does not cite NovoPen®4, irrespective of possible similarities, documents D18 to D20 are not suitable to address the issues of novelty vis-à-vis document D6. Therefore, documents D18 to D20 are not admitted in the appeal proceedings in accordance with Article 12(4) RPBA.

Interpretation of feature 1.3.1 of granted claim 1

4. The Board interprets feature 1.3.1 literally as claimed in feature 1.3.1 as "*a length of time interval during which said actuation action is applied*", i.e. it is not any time as argued by the appellant, but the time during which an actuation action to an actuation button

of a medical device (feature 1.2), detected by a force or a touch supplied to the detector unit (feature 1.2.1), is applied, irrespective whether an injection actually takes place.

Ground for opposition under Article 100(a) EPC in combination with Article 54 EPC - novelty of the subject-matter of claim 1 as granted over document D7

5. The subject-matter of the independent claims 1, 14 and 15 is new over document D7.

5.1 In the opposition division's view, document D7 did not disclose features 1.2, 1.2.1 and 1.2.2 of claim 1 as granted (see decision under appeal, Reasons, point 18.13.3). In the respondent's view, also features 1.3, 1.3.1 and 1.3.2 were not anticipated by the disclosure of document D7.

5.2 Mode of operation of the dosage sensing module 204 in document D7 - third type of module (see Figures 7 and 8; paragraphs [0064] to [0075], especially paragraphs [0072] and [0073])

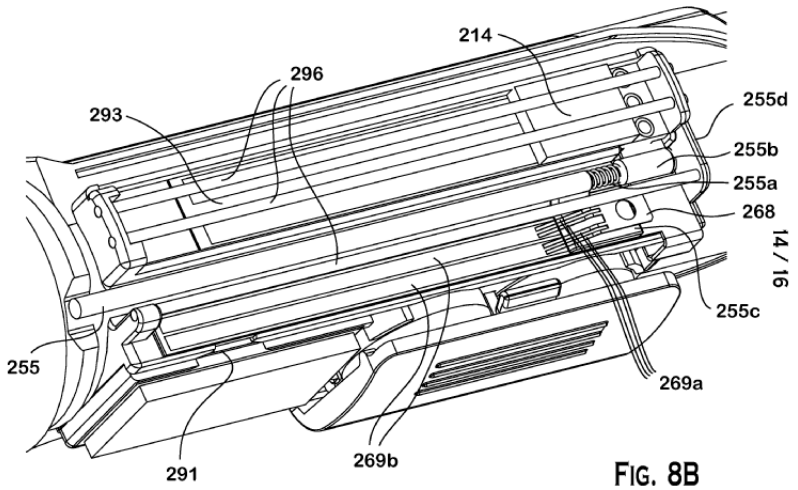


Figure 8B of document D7

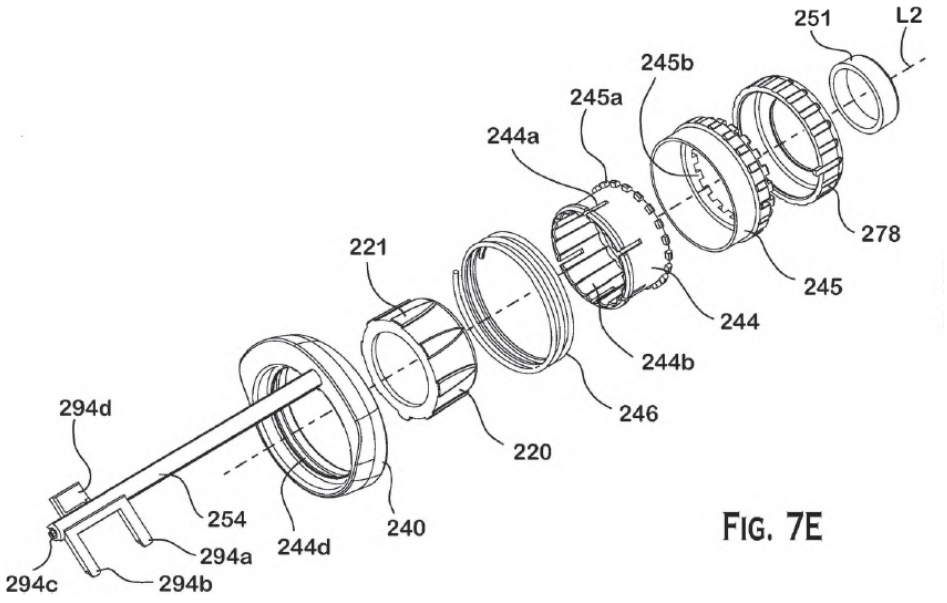


Figure 7E of document D7

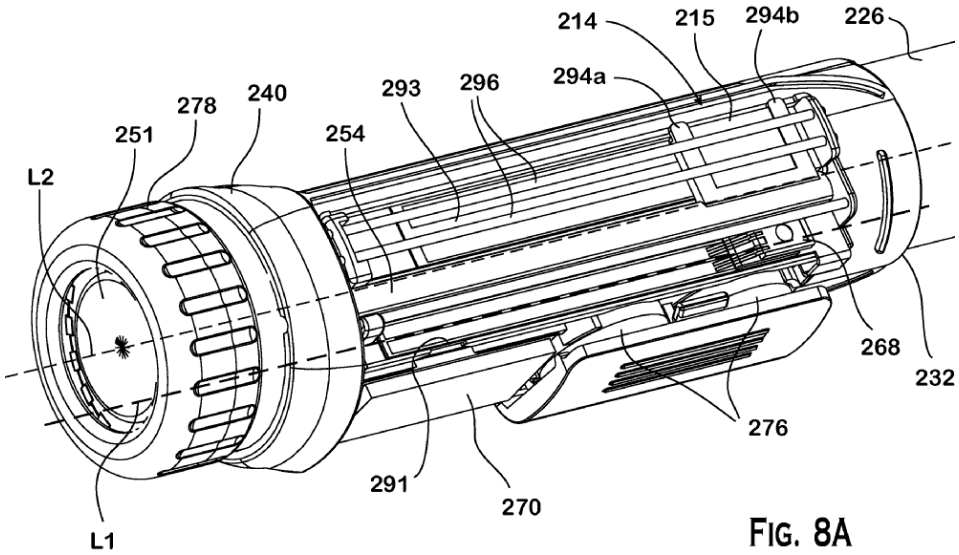


Figure 8A of document D7

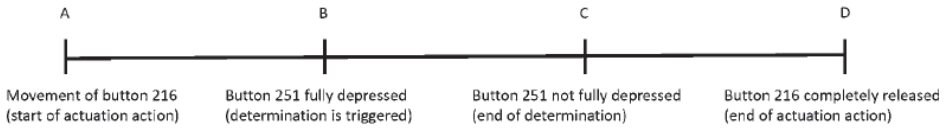
The Board shares the appellant's view on the mode of operation of the dosage sensing module 204 in document D7. As disclosed in Figure 8B and in the corresponding paragraph [0073], element 255, activation

shaft 297, that is located inside of longitudinal member 254 (shown in Figure 7E) is connected to a separator 255c. This separator, depending on its position, is able to prevent a contact between fingers 269a of micro-switch 268 and conductive tracks 269b and, thus, to change micro-switch 268 from a closed to an open circuit and *vice versa*. If a force is applied via button 251 of the dosage sensing module (shown in Figure 8A) onto the actuation button 216 of a drug delivery pen (shown in Figure 7D), longitudinal member 254, activation shaft 297 and separator 255c move along longitudinal axis L1 (shown in Figure 8A) until the setscrew 255b abuts against the retainer wall 255d. As setscrew 255b approaches retainer wall 255d, separator 255c lowers fingers 269a of micro switch 268 onto conductive tracks 269b, creating a closed circuit. If the force is released again, separator 255c, driven by the force of the tensioned setscrew 255b, is again pushed back between fingers 269a and conductive tracks 269b, creating an open circuit (see grounds of appeal, paragraph (30)).

5.3 Regarding the movement of the pen button 216 in document D7, it further discloses that the "*[a]ctuation button 251 is also coupled to knob 278 so that button 251 of module 202 is in contact with pen button 216 once both components are assembled together*" (see document D7, paragraph [0071]). Paragraph [0066] of document D7 discloses that the "*actuation button 216 of pen 224 abuts with button 251 of module 204*". Hence, as put forward by the respondent, a movement of the button 251 in the distal (depression) direction directly leads to a corresponding distal movement of the pen button 216, as there is no gap or clearance between the button 251 and the button 216 in the assembled state (see reply to the statement of grounds

of appeal, paragraph (64)).

Therefore, in document D7 the pen button 216 is moved as soon as the button 251 of the module 204 is depressed while the determination of the actuation action only starts when button 251 is fully depressed (see document D7, paragraph [0073] "*Because fingers 269a are normally out of contact with conductive tracks 269b, switch 268 is normally-open whenever button 251 is not depressed fully (e.g., during a dosage selection or adjustment).*"). The respondent illustrated this in its drawing reproduced below.



Respondent's drawing in its letter dated 4 November 2024, paragraph (37)

5.4 Difference between document D7 and the patent

The pen button 216 in document D7 corresponds to the actuation button 11 in the patent and the button 251 in document D7 corresponds to the snap disk 210 of the electric switch 21 in the patent.

As stated by the respondent, in document D7 the pen button 216 is moved as soon as the button 251 of the module is pressed, while determination of the actuation action is started with a short time delay, namely when the button 251 of the module is fully depressed.

In the patent, the activation action starts when the electric switch 21/snap disc 210 is fully depressed, i.e. contacts the contact areas, which also triggers the determination of the activation action.

Comparing now the disclosure of D7 with the claimed features, it derives from the above that feature 1.3.1 and consequently also feature 1.3.2 of claim 1 as granted are not disclosed in document D7. It can be left open whether document D7 discloses the remaining features of claim 1 as granted.

5.5 The appellant's arguments concerning the disclosure of feature 1.3.1 of claim 1 as granted are based, in particular, on paragraphs [0075] and [0088] of document D7, and hinge on the fact that document D7 allows tracking the start point and the end point of the injections. While this is correct, the Board draws attention to claim 1 as granted, which determines "*a length of time interval*" of "*an actuation action performable via said detector unit to an actuation button of a medical device*" (see features 1.3.1 and 1.2 of claim 1 as granted). Reference is made to the respondent's drawing in paragraph (37) of its letter dated 4 November 2024, reproduced above.

5.6 Conclusion on novelty over document D7

The subject-matter of claim 1 as granted is new vis-à-vis document D7. This applies *mutatis mutandis* to the subject-matter of claims 14 and 15 which are directed to a corresponding method and a computer program, comprising instructions operable to cause a processor to control the steps of the method of claim 14 when said computer program is executed on said processor.

Ground for opposition under Article 100(a) EPC in combination with Article 54 EPC - Novelty of the subject-matter of claim 1 as granted over document D6

6. The subject-matter of the independent claims 1, 14 and 15 is new over document D6.

6.1 The opposition division was of the view that document D6 did not disclose features 1.2, 1.2.1, 1.2.2, 1.3.1, 1.3.2 and 1.3.3, the latter was not a matter of dispute (see decision under appeal, Reasons, point 18.4).

6.2 The Board concurs with the oppositions division and the respondent that document D6 does not disclose an actuation button and, consequently, not a detector unit comprising a detector configured to detect an actuation action performable via said detector unit to an actuation button of a medical device to cause said medical device to eject at least a portion of a medicament comprised in said medical device (feature 1.2 of claim 1 as granted), nor the related features 1.2.1 to 1.3.3.

6.3 The Board is not persuaded by the appellant's arguments which are addressed below.

6.3.1 Contrary to the appellant's allegations, that the adjusting knob 4 in document D6 also functioned as actuation button, document D6 does not address the actuation at all. Paragraph [0031] of document D6, cited by the parties, does not disclose the manner in which the needle is pressed onto the injection site.

6.3.2 The appellant's allegation that "*a pressure on 'touch contact element 32' only occurs if the user applies a force on top of that module (which he would only do if 'adjustment knob 4' also serves as the actuation button used to trigger the ejection of insulin)*" has no basis in document D6. Paragraph [0044] of document D6, cited

by the appellant, discloses that, "*Upon operation of the medication delivery module in the medication delivery device as per Fig. 1, there is pressure on the touch contact element 32 whereupon the events of operation in its characteristic are registered.*" and does not directly and unambiguously support that the actuation action is detected as claimed in claim 1 as granted.

6.3.3 The appellant further referred to paragraphs [0010] and [0012] of document D6, which state that not only is the event of medication dispensing registered, but also that "*the time course and/or the waveforms of the signals measured can be analyzed.*" However, this does not disclose the detection of an actuation action based on identifying a force and/or a touch applied to a detector unit as claimed in claim 1 as granted. On the contrary, paragraphs [0014] and [0040] of document D6 disclose the further analysis of data, for instance, by detecting whether during a priming event or a drug delivery event air has been expelled - the flow resistance upon expulsion of air differs from the flow resistance upon expulsion of a liquid. Also in this context, there is no actuation action detected.

6.3.4 Concerning the appellant's allegation that "*[p]urely 'needle-triggered' medication delivery devices are not known in the prior art at all and they thus cannot represent a mechanical principle that was known for various medication delivery devices*" , the Board notes that neither the opposition division nor the respondent considered the medication delivery device in document D6 as a needle-triggered device.

6.3.5 According to the appellant, the module shown in Figures 3a to 3c of document D6 was placeable on

different medical delivery devices having an adjustment knob in addition or instead of an adjustment knob. The Board observes that although the activation button is not part of the claimed apparatus, the functionality of the claimed apparatus is based on the detection of an actuation action and the determining of a length of time internal during which said actuation action is applied. This is not disclosed in document D6.

6.4 Conclusion on novelty over document D6

The subject-matter of claim 1 as granted is new vis-à-vis document D6. This applies *mutatis mutandis* to the subject-matter of claims 14 and 15 which are directed to a corresponding method and a computer program, comprising instructions operable to cause a processor to control the steps of the method of claim 14 when said computer program is executed on said processor.

Ground for opposition under Article 100(a) EPC in combination with Article 56 EPC

7. The Board confirms the conclusion of the opposition division, that the subject-matter of claims 1, 14 and 15 as granted is not rendered obvious starting from document D2 as closest prior art taking into account the common general knowledge or in combination with documents D1 or D7.

7.1 In appeal, the appellant raised objections of lack of inventive step for the subject-matter of claim 1 as granted starting from document D2 based on common general knowledge or in combination with documents D1, D7 or D15. In its statement of grounds of appeal, the appellant further raised an inventive-step objection for the first time starting from document D6 as closest

prior art based on common general knowledge, or in combination with the disclosure of documents D1 or D7 - if the subject-matter of claim 1 as granted was novel over document D6 for the sole reasons that document D6 did not disclose feature 1.3.1. (see statement of grounds of appeal, point 5.6).

7.2 The inventive-step objection starting from document D6 as closest prior art was only raised if feature 1.3.1 of granted claim 1 was the sole distinguishing feature. This is not the case, as elaborated under point 6. above. Therefore, the inventive-step objection starting from document D6 is moot.

7.3 Document D15 is not admitted into the appeal proceedings (see point 3.). Consequently, the inventive-step objection based on document D2 in combination with document D15 is likewise not admitted and, therefore, not considered.

7.4 Document D2 as closest prior art - distinguishing features

Document D2 discloses a time delay indicator placeable on top of the actuation button of a medical injection device.

The switch in document D2 exhibits the same mechanical construction as the one claimed in the patent (see document D2, Figure 4 and patent, Figure 2; these figures are reproduced below). Since the snap disc 210 in the patent, functioning as a type of spring, corresponds to display 32 and spring 35 in document D2, the actuation action in document D2 is the same as in the patent, or as the appellant formulated (see statement of grounds of appeal, paragraph (118): "*This*

closing (activation) of the detector is then registered by an 'electric unit' in the sense of feature 1.3 (which in the assembly shown in Fig. 4 of D2 is 'microprocessor unit 34' comprising a timer function and in the apparatus shown in Fig. 2 of the patent in suit is 'electric circuit 22' also comprising a timer function)."

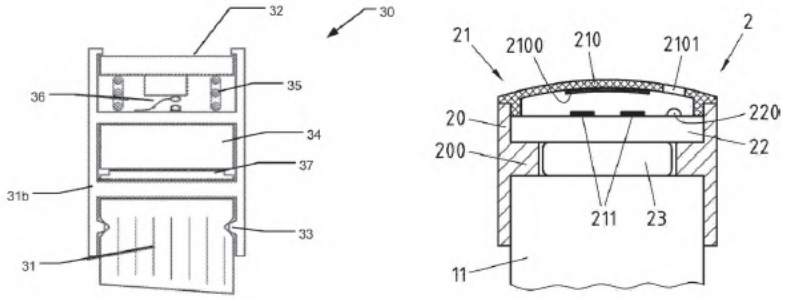


Fig. 4 in **D2** Fig. 2 in patent in suit

Figure 4 of document D2 (left side) and Figure 2 of the patent (right side)

During the oral proceedings before the Board, the respondent did not contest any more that feature 1.2.1 was disclosed by document D2. Thus, it is undisputed that the subject-matter of claim 1 as granted differs from document D2 in that the electric unit is configured to determine a length of time interval during which said actuation action is applied (feature 1.3.1) and to store and/or provide information related to said determined length of said time interval (feature 1.3.2) and/or to store and/or provide said information related to said detected actuation action in dependence on said determined length of time interval (feature 1.3.3, optional).

7.5 Technical effect and objective technical problem

7.5.1 According to the respondent, the technical effect of the distinguishing features, features 1.3.1 and 1.3.2, was to enable a distinction between different operations of the medical device (see patent, paragraphs [0010]). In more detail, the length of time interval may be indicative of the type of action that was performed with the medical device, for instance, an injection/infusion or priming operation (see patent, paragraph [0046]).

7.5.2 The respondent accordingly formulated the objective technical problem as the provision of an apparatus that can be placed on top of an actuator button, wherein also further information about the operation of the injection device can be provided. This formulation of the objective technical problem was endorsed by the opposition division and is confirmed by the Board.

7.5.3 The appellant formulated the objective technical problem in a slightly different way, especially "i*n the provision of an apparatus similar to the assembly shown in Fig. 4 of D2, but by means of which further information about the drug delivery event can be provided to enable monitoring of appropriate dosage delivery.*" (see statement of grounds of appeal, paragraph (121)).

7.5.4 While the Board considers that the "apparatus similar to the assembly shown in Figure 4 of document D2" corresponds to an "apparatus which can be placed on top of an actuator button", there is a difference between further information about the drug delivery event and further information about the operation of the injection device. In this regard, the Board does not agree with the appellant since the length of time interval during which said actuation action is applied

according to features 1.2 and 1.3.1 of granted claim 1 does not necessarily correspond to the drug delivery event. As stated by the appellant (see statement of grounds of appeal, paragraph (121)), "*[d]etermining the length of the time interval during which the switch is closed enables measuring the time during which the actuation action is performed.*", which, however, is not necessarily equal to the dispensing time.

7.5.5 Concerning the limitation of the objective technical problem "*to enable monitoring of appropriate dosage delivery*", the Board concurs with the respondent that this limitation concerns the interpretation of the information and is not appropriate in view of avoiding hindsight. Reference is made to established case law (see Case Law, I.D.4.2.1) according to which the technical problem addressed by an invention has to be formulated in such a way that it does not contain pointers to the solution or partially anticipate the solution, since including part of a solution offered by an invention in the statement of the problem necessarily results in an *ex post facto* view being taken of inventive step when the state of the art was assessed in terms of that problem.

7.6 Non-obviousness taking into account the common general knowledge

7.6.1 It undisputedly belongs to the common general knowledge that the dispensing time is an important information for a medical device and that the actuation button of a medical device has to be pressed for a certain time, usually 5 to 10 seconds to ensure a complete dosing takes place.

7.6.2 The Board agrees with the respondent that the skilled person could have determined, in addition to the closed state, also the open state of the mechanical switch 36. However, in the absence of any incentive and given the knowledge that the actuation time of the switch in document D2 does not necessarily correspond to the dispensing time, the skilled person would not have done so.

7.6.3 Furthermore, the gist of document D2 is to provide a simple and cost-effective solution so that the time delay indicator will be adaptable for inclusion as an integral part of a pre-filled device (see document D2, lines 22 to 23). The person skilled in the art would, thus, not have been prompted to look for further information.

7.7 Non-obviousness in view of document D1

7.7.1 Document D1 discloses a drug delivery pen. As stated by the appellant, document D1 shows a momentary switch 267 in Figure 7 which can be activated when knob 204 is depressed in axial direction. Pushing down knob 204 in axial direction in document D1 causes insulin to be dispensed (see document D1, paragraphs [0047] and [0048]). The point of time at which momentary switch 267 is closed in document D1 corresponds to the injection start point, however, contrary to the appellant's arguments and the preliminary opinion of the Board, not to the actuation of knob 204, i.e. the start of the actuation action in the sense of feature 1.2 of granted claim 1. This was explained in detail by the respondent during the oral proceedings. Document D1 discloses that the duration of a dosage delivery is determined and that the use of the momentary micro-switch 267 (or 167) enables tracking of the injection

start point and the injection end point (see document D1, paragraph [0045] and claim 2). The respondent further emphasises that in document D1, momentary switch 267 is activated only while knob 204 is pressed down (see document D1, paragraphs [0045] and [0068]).

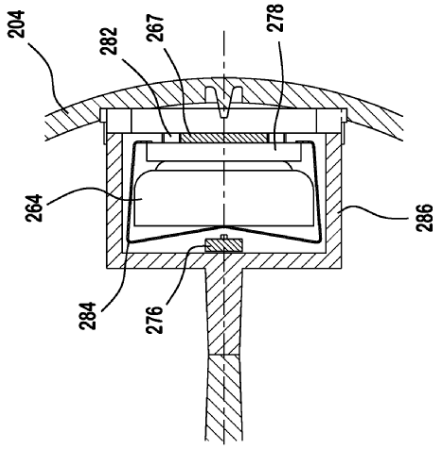


Figure 7 of document D1

7.7.2 Since, in document D1, the duration of the dosage injection event is determined using momentary switch 267, while in the patent the duration of the actuation action is determined using snap disk 210, document D1 does not disclose feature 1.3.1 of granted claim 1. Therefore, the skilled person would not have arrived at the claimed invention by combining documents D2 and D1.

7.8 Non-obviousness in view of document D7

Since document D7 does not disclose feature 1.3.1 (see point 5. above), the subject-matter of claim 1 as granted is not rendered obvious by a combination of documents D2 and D7. The considerations for a combination of documents D2 and D1 apply *mutatis mutandis*.

7.9 The appellant's arguments are not convincing for the following reasons.

7.9.1 The appellant's arguments do not take into account the difference between an actuation action detected by the detecting unit and an actuation action detected by the actuation button of the medical device. The first being detected slightly above the actuation button of the medical device (such as in Figure 2 of the patent and the start point in Figure 4 of document D2) and the latter being detected slightly below the actuation button of the medical device (such as, for instance, in Figure 7 of document D1). Therefore, contrary to the appellant's allegations (see statement of grounds of appeal, paragraph (184)), neither the prior art nor the common general knowledge provides any hint that the actuation action detected by a detector unit positioned above the actuation button of the medical device constitutes a (valuable) information for the person skilled in the art.

7.9.2 The appellant further argued that the skilled person would have simply reconfigured the "microprocessor unit 34" in "time delay assembly 30" shown in Figure 4 of document D2 to also detect when "switch 36" is opened again after the actuation action has ended. The Board acknowledges that the skilled person could have done so, but the question remains whether they would have actually done it.

7.9.3 The appellant referred to the common general knowledge that the skilled person knew that the actuation button of an insulin pen had to be pressed for a certain time, for instance, 5 to 10 seconds to ensure a complete dosing and that this was a valuable information (see statement of grounds of appeal, paragraphs (128) to

(131)). This is not disputed. However, the patent in suit determines the length of time interval of the actuation action performable via a detector to an actuation button of a medical device. The Board refers to its elaborations above where it pointed to the difference between the actuation of the detecting unit and the actuation of the actuation button of the medical device (see e.g. point 7.9.1).

7.9.4 While the Board concurs with the appellant that starting from document D2, no complex modifications to the configuration are required and that a momentary switch can detect only activation and deactivation, the core question remains why the skilled person would have determined not only the closing but also the opening of the switch, and why they would have reprogrammed the microprocessor unit. This issue was already been raised in point 13.5.3 in the Board's communication under Article 15(1) RPBA. It is not apparent, particularly in view of the fact that the skilled person is usually interested in retrieving the dispensing time (see point 7.9.1).

7.9.5 Although the general objective of document D2 is to ensure that a patient is always adequately supplied with insulin, document D2 focuses on the number of insulin injections, i.e. whether the patient skips a dose or takes it twice (see document D2, page 1, lines 15 to 16). Document D2 does not address individual insulin injections.

7.9.6 Regarding the appellant's argument in paragraph (145) of its statement of grounds of appeal, that the skilled person's common general knowledge was the same for evaluating sufficiency of disclosure and inventive

step, reference is made to point 2.3.1 above.

7.9.7 Furthermore, the appellant argued that replacing manual counting with an electronic timer lacked inventive step, referring to established case law (see statement of grounds of appeal, paragraphs (148) and (158) to (161); see Case Law, I.D.9.21.6). The Board notes, however, that while the replacement of counting for determining the dispensing time is generally known - e.g from document D1, where the injection start and the injection end points are determined (see document D1, paragraph [0045]) - the detection of the length of actuation action by the detecting unit according to feature 1.3.1. of claim 1 as granted is not (see point 7.9.1 above).

7.9.8 The appellant's reference in paragraph (162) of its statement of grounds of appeal, citing point 19.3.4 of the Reasons of the decision under appeal, cannot succeed. The opposition division did not hold that document D7 failed to determine the actuation action according to feature 1.3.1 of granted claim 1, but rather it relates to the dispensing action (see point 5.).

7.9.9 Although the construction of the mechanical switch 36 in document D2 and the momentary switch 267 in document D1 correspond to each other - as brought forward by the appellant - their physical location differs. The switch 36 in document D2 is on top of actuation button 31 of a medical device while the switch 267 in document D1 is below the actuation button/knob 204 of the medical device. This results in the difference as mentioned in point 7.9.1.
Document D1, in particular paragraphs [0045] and [0068], explicitly refers to the "*duration of such a*

dosage delivery".

7.9.10 The appellant argued that the closing of switch in document D2 was indicated as "a dosing takes place" (see document D2, page 14, lines 3 to 5). The Board notes that document D2 discloses on the one hand a closing of switch 36 and on the other hand a continued and increased force on the display part transferred to the injection pen's dosing button 31. Document D2 does only detect the closing of the switch 36 which starts the timer function. The length of the actuation action or the dispensing action is not addressed in document D2.

7.10 The above conclusion of lack of inventive step for the subject-matter of claim 1 as granted applies *mutatis mutandis* for the subject-matter of claims 14 and 15 as granted.

8. Overall conclusion

Since none of the grounds for opposition raised by the appellant prejudices the maintenance of the patent, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow G. Pricolo

Decision electronically authenticated