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**Datasheet for the decision
of 10 July 2025**

Case Number: T 0396/23 - 3.2.02

Application Number: 08835859.3

Publication Number: 2197518

IPC: A61M5/142, A61M37/00

Language of the proceedings: EN

Title of invention:

DISPOSABLE INFUSION DEVICE WITH REUSE LOCK-OUT

Patent Proprietor:

Ethicon, Inc.

Opponent:

Roche Diabetes Care GmbH

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83

RPBA Art. 13(2)

Keyword:

Novelty - main request (no) - auxiliary request 41 (yes)
Inventive step - auxiliary request 41 (yes)
Sufficiency of disclosure - main request and auxiliary
requests 1 to 40 (no) - auxiliary request 41 (yes)
Late-filed auxiliary request - admitted (yes)

Decisions cited:

T 2022/22

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0396/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 July 2025

Appellant: Ethicon, Inc.
(Patent Proprietor) 1000 Route 202
Raritan, NJ 08869 (US)

Representative: Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Appellant: Roche Diabetes Care GmbH
(Opponent) Sandhofer Strasse 116
68305 Mannheim (DE)

Representative: Altmann Stöbel Dick Patentanwälte PartG mbB
Theodor-Heuss-Anlage 2
68165 Mannheim (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
13 December 2022 concerning maintenance of the
European Patent No. 2197518 in amended form.

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Böttcher
C. Schmidt

Summary of Facts and Submissions

- I. Both the opponent and the patent proprietor filed an appeal against the interlocutory decision of the opposition division that the patent could be maintained on the basis of auxiliary request 5 as filed during the oral proceedings on 4 October 2022.
- II. Oral proceedings before the board took place on 10 July 2025.
- III. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of one of the 1st to 16th auxiliary requests as filed with the proprietor's letter setting out its grounds of appeal, dated 24 April 2023, or on the basis of one of the 17th to 20th auxiliary requests as filed with the proprietor's reply to the opponent's appeal, dated 8 September 2023, or on the basis of one of the 21st to 40th auxiliary requests as filed by letter dated 13 November 2023, or on the basis of the 41st or 42nd auxiliary request as filed by letter dated 27 June 2025.

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

- IV. Claim 1 of the main request reads as follows.

"A wearable infusion device (210) comprising: a reservoir (222) that holds a liquid medicament; an outlet port (50) that delivers the liquid medicament to a patient;

a pump (224) that displaces a volume of the liquid medicament to the outlet port when actuated;
a control (216, 218) that actuates the pump; and
a lock-out (420) that disables the control to disable the device when the medicament level in the reservoir is at a given level."

Claim 2 of the main request reads as follows.

"A wearable infusion device (210) comprising:
a reservoir (222) that holds a liquid medicament;
an outlet port (50) that delivers the liquid medicament to a patient;
a pump (224) that displaces a volume of the liquid medicament to the outlet port when actuated;
a control (216, 218) that actuates the pump;
a fill port (440) communicating with the reservoir to permit the reservoir to be filled with the liquid medicament; and
a lock-out that blocks the fill port to disable the device when the medicament level in the reservoir is at a given level."

Claim 3 of the main request reads as follows.

"A wearable infusion device (210) comprising:
a reservoir (222) that holds a liquid medicament;
an outlet port (50) that delivers the liquid medicament to a patient;
a pump (224) that displaces a volume of the liquid medicament to the outlet port when actuated;
a control (216, 218) that actuates the pump;
a fill port (440) communicating with the reservoir to permit the reservoir to be filled with the liquid medicament; and
a lock-out that blocks the fill port and disables the

control to disable the device when the medicament level in the reservoir is at a given level."

- V. The feature "a lock-out that blocks the fill port to disable the device" is present in an independent claim of each of auxiliary requests 1 to 16 and 18 to 40.

Claim 1 of auxiliary request 17 corresponds to claim 3 of the main request.

- VI. Claim 1 (the sole claim) of auxiliary request 41 reads as follows.

"A wearable infusion device (210) comprising:
a reservoir (222) that holds a liquid medicament;
an outlet port (50) that delivers the liquid medicament to a patient;
a pump (224) that displaces a volume of the liquid medicament to the outlet port when actuated;
a control (216, 218) that actuates the pump;
a fill port (440) communicating with the reservoir to permit the reservoir to be filled with the liquid medicament; and
a lock-out that blocks the fill port and disables the control to disable the device when the medicament level in the reservoir is at a given level, wherein the given level is empty."

- VII. Documents referred to in this decision

D1 ACCU-CHEK D-TRONplus Insulin Pump user manual

- VIII. The appellant-patent proprietor's arguments can be summarised as follows.

Main request - claim 1 - sufficiency of disclosure

Implementing a lock-out that is activated when there is more than one dose of medicament remaining in the reservoir was well within the capabilities of the person skilled in the art.

Paragraphs [0044], [0052] and [0056] of the description of the patent disclosed an embodiment with a last dose lock-out and a medicament level indicator since the rigid plate 310 formed a moveable wall that moved as the medicament volume increased and decreased within the flexible reservoir 222 (Figures 14 and 15). The person skilled in the art could easily implement some form of simple mechanical latching system attached to the rigid plate (or to the flexible reservoir itself) that disabled the control when the rigid plate reached a certain level. This was achievable without undue burden and without the need for inventive skill.

Hence, the subject-matter of claims 1, 2 and 3 was sufficiently disclosed for a person skilled in the art to carry out the invention.

Main request - claim 2 - sufficiency of disclosure

It was possible to implement a lock-out that disabled the device as a direct consequence of blocking the fill port. Blocking the fill port after the first dose would render the device disabled since a refill would not be possible. Hence, the device would ultimately be disabled, even if the disabling only came into effect once all the doses in the reservoir had been administered.

Hence, the subject-matter of claim 2 was sufficiently disclosed for a person skilled in the art to carry out

the invention.

Main request - claim 1 - novelty in view of D1

According to the plain English meaning of the term "lock-out", the disabling of the device was permanent, i.e. the device could not be reused. This was also made clear by the title of the patent, "Disposable infusion device with reuse lock-out", and by the last sentence of paragraph [0067] of the patent, which states "the device is now locked and cannot be reused".

D1 disclosed an insulin pump for injecting insulin from a cartridge. Insulin delivery was interrupted when the cartridge was empty (sections 7.2 and 7.2.1 of D1). However, the lock-out of D1 was not permanent since once the cartridge had been replaced the pump could be put into the RUN mode again.

Furthermore, claim 1 required the control to be disabled, i.e. to be stopped from working. In D1, when the device was in the STOP mode, the control was not disabled as the buttons could still be pressed and the processor was still enabled.

Moreover, D1 did not disclose a disablement of the device caused by the disablement of the control. As stated in section 2.3, in both the STOP and RUN modes, the insulin pump could still function.

Hence, D1 did not disclose a lock-out that disabled the control to disable the device when the medicament level in the reservoir was at a given level. The subject-matter of claim 1 was therefore novel in view of D1.

Auxiliary requests 1 to 40

The arguments presented on sufficiency of disclosure in connection with the main request also applied to auxiliary requests 1 to 40.

Auxiliary request 41 - admittance

Auxiliary request 41 comprised the claims of auxiliary request 18 but with independent claims 1 and 2 removed. This request addressed the objections made in the board's preliminary opinion.

Admitting auxiliary request 41 did not change the legal or factual framework of the case, and it improved procedural economy.

The objection regarding the "empty level" feature had first been addressed with auxiliary request 5 in the opposition proceedings, which corresponds to auxiliary request 8 in the appeal proceedings. The independent claims of this request included the features "mechanical lock-out" and "disable permanently". Since the opposition division had indicated that the introduction of the terms "mechanical" and "permanently" was allowable, there had at that time been no reason to file a request that included the "empty level" feature but not these terms.

Auxiliary request 18, which includes the "empty level" feature but leaves out the "mechanical" and "permanently" terms, had been filed with the reply to the opponent's statement of grounds of appeal. This had been the most procedurally efficient moment to file this request.

Admitting auxiliary request 41 did not require any new

substantive discussion since the "empty level" feature had been included in the independent claims since the reply to the notice of opposition and had been discussed in the written submissions. In addition, a claim including both blocking the fill port and disabling the control had also been on file since the reply to the notice of opposition and had also been discussed in the written proceedings. As such, the opponent would not be disadvantaged by the admission of this request and there was nothing that would prevent the board from reaching a decision on this request, were it to be admitted.

In summary, these were cogent reasons as to why there were exceptional circumstances justifying the admittance of this request at this stage of proceedings.

Auxiliary request 41 - novelty in view of D1

In D1, the chamber for the cartridge could not be regarded as a reservoir within the meaning of claim 1. Rather, the reservoir was the cartridge itself. It followed that the opening through which the cartridge was inserted into the device could not be regarded as a fill port since it was not "communicating with the reservoir [i.e. the cartridge] to permit the reservoir to be filled with the liquid medicament", as required by claim 1.

The presence of the adapter "blocking the fill port" could not be said to disable the device, as required by claim 1, since the adapter was intended to be removed and replaced in the process of replacing the cartridge, while the device remained working.

Hence, D1 disclosed neither a fill port nor a lock-out that blocked the fill port and disabled the control to disable the device.

The subject-matter of claim 1 of auxiliary request 41 was therefore novel over D1.

Auxiliary request 41 - inventive step starting from D1

The person skilled in the art would not have modified the device of D1 to provide a fill port and a lock-out that blocked this fill port and disabled the control to disable the device when the medicament was empty. This would have effectively transformed the device into a single-use device, which was contrary to the entire teaching of D1, which pertained to a reusable device.

Thus, the subject-matter of claim 1 was inventive starting from D1.

IX. The appellant-opponent's arguments can be summarised as follows.

Main request - claim 1 - sufficiency of disclosure

The patent did not disclose how to implement a lock-out triggered by any given medicament level (i.e. not just by the empty level). According to paragraph [0067] of the patent, the last dose lock-out was triggered by the negative pressure created in the diaphragm chamber 424 when the reservoir was (almost) empty. This negative pressure was only created in this case; it could not be present at any other given level (see paragraph [0065], last two sentences). At any other given level of medicament in the reservoir, the person skilled in the art would have to find a different mechanism involving

determining the actual level of medicament and finding a mechanical variable that was assigned to this level and could be used as a trigger for the lock-out.

Hence, the invention as defined in claims 1, 2 and 3 of the main request was not sufficiently disclosed.

Main request - claim 2 - sufficiency of disclosure

Furthermore, the patent did not disclose how the infusion device could be disabled by blocking only the fill port, as defined in claim 2. The skilled person was not taught how to build an infusion device that could be disabled by blocking the fill port. It was not technically possible to disable the main function of the device when the reservoir was still largely full simply by blocking the fill port of the reservoir.

Hence, the invention as defined in claim 2 of the main request was not sufficiently disclosed.

Main request - claim 1 - novelty in view of D1

D1 was a user manual for the ACCU-CHEK® D-TRONplus insulin pump. It described a lock-out that disabled the control to disable the device when the medicament level in the reservoir was at a given level. As described on page 154, section 7.2.1, of D1, when the cartridge was empty, an error message was displayed, the insulin pump was put into the STOP mode, and insulin delivery was prevented.

A lock-out did not necessarily have to result in a permanent disabling. Furthermore, the lock-out merely had to disable the main function of injecting medicament. Hence, the STOP mode of D1 could be

regarded as a lock-out according to claim 1 even if some functions of the device remained operational and unaffected.

Thus, the subject-matter of claim 1 lacked novelty in view of D1.

Auxiliary requests 1 to 40

The arguments presented on sufficiency of disclosure and novelty with respect to the main request also applied to auxiliary requests 1 to 40.

Auxiliary request 41 - admittance

The late filing of auxiliary request 41 constituted an abuse of procedure.

Auxiliary request 41 had not been obtained by deleting two out of the three independent claims of auxiliary request 18, since claim 3 of that request was a dependent claim. Rather, claim 1 of auxiliary request 41 was obtained by introducing features of a dependent claim into the independent claim. This was not permissible at this stage of the proceedings.

Auxiliary request 41 was to be considered an amendment within the meaning of Articles 12(4), 13(1) and 13(2) RPBA.

The opponent's grounds of appeal did not contain any new facts or evidence that had not already been on file in the first-instance proceedings. The fact that the preliminary opinion of the board deviated from the opinion of the opposition division as set out in the decision did not constitute exceptional circumstances,

either.

Thus, there was no valid justification for admitting auxiliary request 41 on appeal. This request could and should have been submitted in the first-instance proceedings.

Auxiliary request 41 should therefore not be admitted into the proceedings.

Auxiliary request 41 - novelty in view of D1

D1 disclosed an infusion device having a reservoir that held a liquid medicament, namely a cartridge compartment for receiving a cartridge filled with a liquid medicament (page 32). D1 also described a fill port via which the cartridge was filled into the cartridge compartment (page 84) and a lock-out ("adapter") that was inserted into the fill port and thus blocked the fill port (at any given medicament level) such that no further cartridges could be inserted into the fill port. When the medicament level within the reservoir was empty, the fill port remained blocked as long as the adapter was not removed, and therefore the device was disabled as the cartridge could not be replaced.

The lock-out of D1 also disabled the control to disable the device when the medicament level in the reservoir was empty. In that case, the insulin pump was in the STOP mode, and thus insulin delivery was prevented.

Hence, the subject-matter of claim 1 was not novel over D1.

Auxiliary request 41 - inventive step starting from D1

D1 disclosed a reusable device which could be reused when the reservoir was empty (the adapter could be removed and the cartridge replaced). Claim 1 of auxiliary request 41 required that the replacement of the cartridge was prevented. An unexpected technical advantage of transforming a reusable infusion device into a disposable infusion device could not be identified.

Starting from D1, the person skilled in the art could easily transform the reusable infusion device into a disposable device, by providing means for preventing the separation of the adapter and the cartridge, for example, such as a latching nose or a snap-fit connection. Such a modification was generally known to the person skilled the art.

The subject-matter of claim 1 therefore did not involve an inventive step.

Reasons for the Decision

1. Subject-matter of the patent

The patent relates to a wearable infusion device to enable liquid medicaments (e.g. insulin) to be self-administered by a patient. The device comprises a medicament reservoir, an outlet port, a pump, a control that actuates the pump, a fill port, and a lock-out that blocks the fill port and disables the control to disable the device when the medicament level in the reservoir is empty.

An example of a last dose lock-out mechanism is shown in Figures 23 to 26 and described in paragraphs [0064] to [0068]. When the reservoir has insufficient medicament to support delivery of a further dose of medicament, and during the return of the actuator button 218 after what will be the last dose delivered, a negative pressure is created in the diaphragm chamber 424. This causes the diaphragm 422 to be drawn into the chamber 424 and the pin 322 to be drawn upwards. Upon the next attempted actuation of the device, the actuator button 216 will be locked and cannot be returned to its first position. At the same time, the fill port 440 will be blocked by the extension 442 of the actuator button 216. The pump actuator button 218 will also be locked in its second position, as shown in Figure 26. Hence, the device 210 is locked and the reservoir cannot be refilled. Thus, the device cannot be reused.

2. Main request - sufficiency of disclosure with respect to "any given medicament level"
- 2.1 Claims 1, 2 and 3 of the main request specify a lock-out that disables the device when the medicament level in the reservoir is at a given level. The claims leave the possible values of the given level open. It is thus clear that different given levels are contemplated. However, the invention as defined in these claims is not sufficiently disclosed with respect to any given medicament level; it is only sufficiently disclosed with respect to the empty level.
- 2.2 In paragraph [0067] of the patent, a last dose lock-out is described. The last dose lock-out is triggered by the negative pressure created in the diaphragm chamber 424 when the reservoir is empty.

Paragraph [0065] states that as long as the reservoir contains medicament, the diaphragm is not affected. The patent does not describe any lock-out other than this specific last dose lock-out. Hence, for any other given level of medicament in the reservoir, the person skilled in the art would have to find a different lock-out mechanism. This would involve determining the actual level of medicament and finding a mechanical variable that is assigned to this level and can be used as a trigger for the lock-out.

- 2.3 Contrary to the patent proprietor's view, implementing such a lock-out would involve an undue burden and would require inventive skill. Although paragraphs [0056] and [0057] disclose a medicament level indicator, the person skilled in the art is not taught how the movement of the rigid plate 310 or the elongated web 316 to any given extent could be used to trigger a lock-out that disables the control (i.e. the buttons 16 and 18) and/or blocks the fill port.
- 2.4 Hence, claims 1, 2 and 3 do not meet the requirements of Article 83 EPC.
- 3. Main request - claim 2 - sufficiency of disclosure with respect to "a lock-out that blocks the fill port to disable the device"
- 3.1 The invention as defined in claim 2 of the main request is not sufficiently disclosed either, as the skilled person is not taught how to build an infusion device that can be disabled by blocking the fill port.
- 3.2 In paragraph [0068] of the patent, it is mentioned that it is the last dose lock-out that blocks the fill port 440 by keeping the actuator button 216 in its

fully actuated second position, thereby further rendering the device disabled. However, blocking the fill port as such does not disable the device. Rather, it can be derived from this paragraph that during use of the device, the fill port is covered by the extension 442 every time the actuator button is in the fully actuated second position (Figure 28), but the fill port is opened again when the button 216 is returned to its initial position (Figure 27).

3.3 Contrary to the patent proprietor's view, preventing a refill by blocking the fill port cannot be regarded as a way to disable the device. As long as there is medicament in the reservoir, the pump can be operated, regardless of whether or not the fill port is blocked. Even if the reservoir is empty and the fill port is blocked, the pump remains operational and will then deliver air to the outlet.

3.4 Hence, claim 2 does not meet the requirements of Article 83 EPC also for this reason.

4. Main request - claim 1 - novelty in view of D1

4.1 D1 is a user manual for the ACCU-CHEK® D-TRONplus insulin pump. The insulin is provided in a cartridge which is inserted into the device (section 4.3 on pages 83 and 84). As described on page 154, section 7.2.1, when the cartridge is empty, an error message is displayed, the insulin pump is put into the STOP mode, and insulin delivery is prevented.

4.2 Contrary to the patent proprietor's view, the claimed lock-out does not necessarily have to result in a permanent disabling of the device.

Hence, the STOP mode of D1 can be regarded as a lock-out that disables the control to disable the device when the medicament level in the reservoir is empty.

4.3 The board does not agree that "disabling the control" means that the buttons and the processor have to be disabled. In D1, the "control" amounts to the actual signals sent by the processor to the pump (in the RUN mode) to infuse a dose of insulin every three minutes (basal rate, mentioned in section 5.1). In the STOP mode, these control signals are not sent, i.e. the control is disabled.

4.4 The proprietor also argued that D1 did not disclose a disablement of the device caused by the disablement of the control since in both the STOP and RUN modes the insulin pump was still functioning (section 2.3).

However, the disabling of the control in the STOP mode results in a stopping of the pump motor, and hence in an interruption of the infusion. The disabling of the control signals therefore causes the disablement of the pump, although part of the infusion device might still be operative.

4.5 The subject-matter of claim 1 of the main request therefore lacks novelty in view of D1.

5. Auxiliary requests 1 to 40

5.1 An independent claim comprising the feature "a lock-out that blocks the fill port to disable the device" is present in all of the auxiliary requests except auxiliary request 17. Hence, auxiliary requests 1 to 16 and 18 to 40 do not meet the requirements of Article 83

EPC for the reasons given under point 3 above.

5.2 Claim 1 of auxiliary request 17 requires that the lock-out disables the device when the medicament level in the reservoir is at a given level (not necessarily the empty level), and therefore this claim does not meet the requirements of Article 83 EPC either, for the reasons given under point 2 above.

6. Auxiliary request 41 - admittance

6.1 Auxiliary request 41 was filed on 27 June 2025, after the board had issued a communication pursuant to Article 15(1) RPBA. Its admittance is thus subject to the provisions of Article 13(2) RPBA. In exercising its discretion according thereto, which is necessary given the circumstances of this particular case, the board may also rely on the criteria set out in Article 13(1) RPBA.

6.2 Auxiliary request 41 includes only one claim, which corresponds to independent claim 3 of auxiliary request 18, or to dependent claim 4 of the main request. It is undisputed that the sufficiency of disclosure objections against claims 1 to 3 of the main request are overcome with claim 1 of auxiliary request 41 since that claim specifies that the lock-out blocks the fill port and disables the control to disable the device and introduces the feature that the given level is empty.

6.3 With its reply to the notice of opposition, which contained a large number of objections, the patent proprietor filed auxiliary request 5. Claims 1 to 3 thereof contain the "empty level" feature, though also the terms "mechanical" and "permanent", which were

deemed necessary to overcome the novelty objection.

- 6.4 In its decision, the opposition division held that a lock-out that disabled the device when the medicament level in the reservoir was at any given level was sufficiently disclosed.
- 6.5 With its reply to the opponent's statement of grounds of appeal, the patent proprietor filed auxiliary request 18, which included the "empty level" feature but left out the terms "mechanical" and "permanently".
- 6.6 Auxiliary request 41 corresponds to auxiliary request 18 but with claims 1 and 2 removed. The remaining claim of auxiliary request 18, claim 3, is based on independent claim 16 as originally filed, i.e. it has been in the proceedings as an independent claim, although it comprises all of the features of another independent claim. By drafting claim 3 as one of three independent claims and by presenting arguments in respect of its patentability, the proprietor had clearly indicated its intention to defend this embodiment. Hence, the filing of auxiliary request 41 does not result in a situation for which the opponent or the board was unprepared.
- 6.7 Moreover, the admittance of auxiliary request 41 does not change the legal or factual framework of the case and does not require any new substantive discussion. A claim restricting the given level to the empty level has been included in the independent claims ever since the reply to the notice of opposition. A claim including both blocking the fill port and disabling the control has been on file since the reply to the notice of opposition and has been discussed in the written proceedings. Indeed, the submission of auxiliary

request 41 merely serves to remove some of the points of dispute, without introducing any new aspect to be discussed, thus improving procedural economy.

- 6.8 In summary, the admittance of auxiliary request 41 is compatible with the principles of both procedural economy and procedural fairness and does not change or add anything to the subject of the appeal proceedings. In other cases where new requests were filed that satisfy these conditions, a considerable amount of case law has concluded that there were exceptional circumstances within the meaning of Article 13(2) RPBA justifying the admittance of the new requests (see point 2. of decision T 2022/22 and the decisions cited therein, for example).

The board thus decided, in view of the circumstances above, to admit auxiliary request 41 into the appeal proceedings.

7. Auxiliary request 41 - novelty in view of D1

- 7.1 D1 does not disclose that the lock-out that disables the control to disable the device also blocks a fill port communicating with the reservoir when the medicament level in the reservoir is empty.

- 7.2 Contrary to the opponent's view, the cartridge compartment of D1 cannot be regarded as a reservoir within the meaning of claim 1 since this compartment is not filled with the liquid medicament, the level of which triggers the lock-out. On the contrary, when the medicament in the cartridge is empty, the compartment is still "filled" with the cartridge. Consequently, the opening of the compartment through which the cartridge is inserted into the device cannot be regarded as a

fill port.

- 7.3 Furthermore, the adapter, which the opponent considered to be a lock-out blocking a fill port, does not have any influence on the pumping function. Hence, it does not disable the control to disable the device. Moreover, the STOP mode, i.e. the lock-out that disables the control to disable the device when the reservoir is empty, does not block a fill port.
- 7.4 Hence, the subject-matter of claim 1 is novel over D1.
8. Auxiliary request 41 - inventive step starting from D1
- 8.1 The technical effect of providing a fill port that is blocked by the (same) lock-out that disables the control when the reservoir is empty is to further render the device disabled such that it cannot be refilled. The technical problem to be solved by this is to improve patient safety.
- 8.2 D1 discloses an electric infusion pump that can be reused several times by replacing the medicament cartridge (i.e. the reservoir) when it is empty. The device according to claim 1 has a reservoir that cannot be replaced and has to be filled with the medicament via a fill port before use. When the reservoir is empty, the reservoir is prevented from being refilled by the lock-out. Given these fundamental technical differences between the two devices, the person skilled in the art would not be motivated to modify the device of D1 to provide a fill port that permits the reservoir to be filled with the liquid medicament or to configure the lock-out such that it blocks this fill port.

8.3 The subject-matter of claim 1 therefore involves an inventive step.

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 on the basis of claim 1 of auxiliary request 41 as filed by letter dated 27 June 2025, and a description to be adapted thereto.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated