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**Datasheet for the decision  
of 3 July 2020**

**Case Number:** T 1168/15 - 3.2.02

**Application Number:** 05799659.7

**Publication Number:** 1804868

**IPC:** A61M5/32, A61M5/315, A61M5/145

**Language of the proceedings:** EN

**Title of invention:**  
INJECTION DEVICE WITH A PROCESSOR FOR COLLECTING EJECTION  
INFORMATION

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

**Opponent:**  
Sanofi-Aventis Deutschland GmbH

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(a), 56  
RPBA 2020 Art. 13(2)

**Keyword:**

Inventive step - (no)

Late-filed auxiliary requests - admitted (no)

**Decisions cited:**

**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  
Fax +49 (0)89 2399-4465

Case Number: T 1168/15 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 3 July 2020**

**Appellant:**  
(Patent Proprietor)  
NOVO NORDISK A/S  
Corporate Patents  
Novo Allé  
P.O. Box 3000  
2880 Bagsvaerd (DK)

**Representative:**  
Hoffmann Eitle  
Patent- und Rechtsanwälte PartmbB  
Arabellastraße 30  
81925 München (DE)

**Appellant:**  
(Opponent)  
Sanofi-Aventis Deutschland GmbH  
Brüningstrasse 50  
65929 Frankfurt am Main (DE)

**Representative:**  
Keil & Schaafhausen Patentanwälte PartGmbH  
Friedrichstraße 2-6  
60323 Frankfurt am Main (DE)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
7 April 2015 concerning the maintenance of  
European Patent No. 1804868 in amended form**

**Composition of the Board:**

**Chairman** M. Alvazzi Delfrate  
**Members:** D. Ceccarelli  
C. Schmidt

## **Summary of Facts and Submissions**

I. The patent proprietor and the opponent have appealed against the Opposition Division's decision, posted on 7 April 2015, that, account being taken of the amendments according to the fourth auxiliary request then on file, European patent No. 1 804 868 and the invention to which it related met the requirements of the EPC. *Inter alia*, novelty and inventive step were raised as grounds for opposition.

II. Oral proceedings took place on 3 July 2020.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the first to tenth auxiliary requests filed with letter dated 3 June 2020.

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

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

D2: WO-A-03/005891

D6: WO-A-02/064196

IV. **Claim 1 of the patent as granted** reads as follows:

"A medication delivery device (100) comprising:

a prefilled injection device (100) having a reservoir comprising a medicament to be ejected, the medication

delivery device further comprising:

a sensor arranged to detect an ejection of the medicament from the injection device, the sensor being arranged to output a signal comprising ejecting information, and a processor for collecting and storing the ejection information,

characterized in that,

the medication delivery device further comprises an communication means (162, 164) arranged to transmit the ejecting information to an external data receiving device (108), and

that the sensor comprises a movable part (200, 210) adapted to rotate relative to a stationary part during ejection."

**Claim 1 of the first auxiliary request** reads as claim 1 of the patent as granted except that the medication delivery device is qualified as "prefilled".

**Claim 1 of the second auxiliary request** reads as claim 1 of the patent as granted with the addition of the following wording at the end of the claim:

"and at least two conductors which are arranged such that an electrical characteristic is defined by the mutual position of the movable and the stationary part".

**Claim 1 of the third auxiliary request** reads as claim 1 of the second auxiliary request except that the medication delivery device is qualified as "prefilled".

**Claim 1 of the fourth auxiliary request** reads as claim 1 of the second auxiliary request with the addition of the following wording after the expression "medicament to be ejected":

"the reservoir being an integral part of said prefilled injection device (100),".

**Claim 1 of the fifth auxiliary request** reads as claim 1 of the fourth auxiliary request except that the medication delivery device is qualified as "prefilled".

**Claim 1 of the sixth auxiliary request** reads as claim 1 of the fourth auxiliary request with the addition of the following wording after the expression "external data receiving device (108)":

"said communication means (162, 164) comprising a wireless data transmission device based on RF-technology,".

**Claim 1 of the seventh auxiliary request** reads as claim 1 of the sixth auxiliary request except that the medication delivery device is qualified as "prefilled".

**Claim 1 of the eighth auxiliary request** reads as claim 1 of the patent as granted with the addition of the following wording after the expression "external data receiving device (108)":

"said communication means (162, 164) comprising a wireless data transmission device,"

and the following wording at the end of the claim:

"and during setting of a dose to be ejected and at

least two conductors which are arranged such that an electrical characteristic is defined by the mutual position of the movable and the stationary part."

**Claim 1 of the ninth auxiliary request** reads as claim 1 of the eighth auxiliary request except that the medication delivery device is qualified as "prefilled".

**Claim 1 of the tenth auxiliary request** reads as claim 1 of the ninth auxiliary request with the addition of the following wording after the expression "medicament to be ejected":

"the reservoir being an integral part of said prefilled injection device (100),".

- V. The proprietor's arguments, where relevant to the present decision, may be summarised as follows:

*Main request*

The meaning of the term "prefilled" in claim 1 of the patent as granted played a central role in these proceedings. A prefilled injection device as claimed was not merely a device which could be filled prior to some time, as held by the Opposition Division in the impugned decision. On the contrary, the description of the patent as granted implied that a prefilled injection device was a device which could not be refilled for further use and, consequently, needed to be disposed of after use. By the same token, a disposable injection device had to be prefilled within the meaning of claim 1.

Although the term "prefilled" appeared in the claim explicitly only in conjunction with the injection

device, it actually implied that the entirety of the claimed medication delivery device had to be prefilled with all the corresponding implications. Other constructions would deviate from the definitions provided in paragraphs [0008] and [0009] of the description of the patent.

D6 disclosed a combination of a disposable part - an injection device - and a reusable part - an injection button. It followed that D6 did not disclose a medication delivery device disposable in its entirety, as implied by claim 1.

As regards inventive step, starting from D2 as the closest prior art, this document neither disclosed a prefilled injection device nor a sensor comprising a movable part adapted to rotate relative to a stationary part during ejection.

The entire teaching of D2 was specifically directed to an injection device in the form of a doser in which a patient could insert/exchange a cartridge when needed (page 18, lines 26 to 30). Although D2 also disclosed other types of drug administration devices, there was no reason why the skilled person would consider using a disposable injection device as defined in claim 1.

Moreover, D2 was silent about the kind of sensor employed in its medication delivery device. There was no reason why the skilled person would have implemented a sensor as taught in D6. Neither D2 nor D6 were concerned with problems associated with the components of a medication delivery device being too expensive and too complex for providing a disposable device with log functions.



Even if the teaching of D2 and D6 were combined, D6 disclosed different kinds of sensors, such as a linear sensor (page 7, lines 8 to 12). There was no reason why the skilled person would have picked specifically the rotational sensor disclosed in D6.

It followed that the subject-matter of claim 1 of the patent as granted was inventive over the combination of D2 with D6.

*First, third, fifth, seventh, ninth and tenth auxiliary requests*

The first, third, fifth, seventh, ninth and tenth auxiliary requests had been submitted as an immediate reaction to the Board's preliminary opinion attached to the summons to oral proceedings. The Board had not provided a precise interpretation of the term "prefilled". These requests should be admitted into the proceedings.

*Second and fourth auxiliary requests*

Claim 1 of the second auxiliary request comprised the additional feature of the conductors arranged to define an electrical characteristic by the mutual position of the movable part and the stationary part.

The sensor disclosed in D6 was a Hall sensor, which comprised sensing means in the form of Hall elements made of semiconductors, contacted by wires. In contrast to the sensor of the patent, the Hall sensor required current to be applied to several Hall elements to define an electrical characteristic. Moreover, no electrical characteristic was defined by a mutual position of the movable and the stationary part. Only a

change of position could define the electrical characteristic. Finally, if the necessary wiring of the sensor were to be interpreted as the conductors defined in the claim, these conductors would not be arranged to define the electrical characteristic within the meaning of claim 1. Due to the claim term "arranged", the change of the electrical characteristic had to be a consequence of a change in the configuration of the conductors. In a Hall sensor, the configuration of the wiring had no effect whatsoever in the definition of an electrical characteristic.

The additional feature of claim 1 of the fourth auxiliary request - the reservoir being an integral part of the prefilled injection device - further distinguished the claim from D2, which concerned reusable injection devices.

*Sixth auxiliary request*

D2 did not disclose a wireless data transmission device specifically based on RF-technology, as defined in claim 1 of the sixth auxiliary request. This feature further contributed to the achievement of the object of the invention, which was the provision of a simple and inexpensive disposable device with log functions.

*Eighth auxiliary request*

The main embodiment of D6, in relation to which the Hall sensor was described in detail, did not comprise a movable part and a stationary part of the sensor adapted to rotate relative to each other also during setting of a dose to be ejected. Although D6 might hint at an injection device comprising a movable part and a stationary part adapted to rotate relative to each

other also during setting of a dose, there was no reason why the skilled person would have departed from the main teaching of D6 when wanting to combine D6 with the closest prior art D2. The relative rotation of the movable and the stationary part of the sensor during setting of a dose permitted to additionally detect the dose set. This made it possible to compare the dose intended for ejection with the dose actually ejected to establish possible discrepancies. Hence the problem of ensuring a safe and correct drug administration was solved. The fact that the patent did not expressly discuss this problem was of little relevance since the problem could be derived from a technical reading of the patent as a whole.

Moreover, the claim feature in question was a further difference over the disclosure of D2. There were so many differences between the subject-matter of claim 1 of the eighth auxiliary request and the closest prior art that the claimed invention could only be arrived at with hindsight.

VI. The opponent's arguments, where relevant to the present decision, may be summarised as follows:

*Main request*

The term "prefilled" in claim 1 of the patent as granted merely meant that the medicament was provided in the injection device.

In any case, D6 expressly disclosed a disposable injection device (page 7, lines 20 to 24), which was a "prefilled" injection device within the meaning of the claim.

An interpretation of the claim according to which the whole medicament delivery device had to be disposable was not correct since the claim only defined the injection device as "prefilled". Moreover such an interpretation had no basis in the patent as a whole.

Starting from D2 as the closest prior art, the only difference of the subject-matter of claim 1 of the patent as granted over the disclosure of this document was the feature of the sensor provided with a movable part adapted to rotate relative to a stationary part during ejection. D2 disclosed a prefilled injection device on page 18, lines 18 to 19.

The medication delivery device disclosed in D2 comprised a sensor. However, the document was silent about its structure. Starting from D2 the objective technical problem would therefore be how to provide a suitable sensor.

D6 provided a solution to this problem as it disclosed in detail a sensor as claimed, suitable for being employed in the medication delivery device of D2. Hence, the skilled person would have combined the teaching of D2 and D6 and arrived at the subject-matter of claim 1 of the patent as granted in an obvious way.

Whether D6 also disclosed other embodiments of sensors which did not comprise the features of the sensor defined in claim 1 was of little relevance as the main embodiment concerned a sensor comprising those features.

*First, third, fifth, seventh, ninth and tenth auxiliary requests*

The first, third, fifth, seventh, ninth and tenth auxiliary requests had been only submitted after notification of the summons to oral proceedings, without any cogent reason. The meaning to be attributed to the term "prefilled" had been intensively discussed in the first instance proceedings, and it had been a matter of dispute since the beginning of the appeal proceedings. Under Article 13(2) RPBA 2020, these requests should not be admitted into the proceedings.

*Second and fourth auxiliary requests*

The general definition of the conductors in claim 1 of the second auxiliary request was anticipated by the Hall sensor disclosed in D6. In particular, such a sensor necessarily comprised two conductors in order to transmit the electrical signal generated by the sensor.

The additional feature of claim 1 of the fourth auxiliary request - the reservoir being an integral part of the prefilled injection device - was also known from D6.

It followed that the combination of D2 with D6 rendered obvious the subject-matter of those claims too.

*Sixth auxiliary request*

D2 disclosed a data transmission device generally employing wireless technology (page 7, lines 26 to 33). The specific definition of RF-technology would have been a mere design option for the skilled person.

*Eighth auxiliary request*

The feature of claim 1 of the eighth auxiliary request, according to which a movable part and a stationary part of the sensor were adapted to rotate relative to each other also during setting of a dose was not necessarily concerned with the problem of establishing possible discrepancies between the dose intended to be ejected and the dose actually ejected. The patent as a whole did not mention any comparison in this respect. Starting from D2, the objective technical problem was rather the provision of a sensor which could reliably work with a variety of different injection devices.

D6 disclosed an embodiment in which an injection button always followed the rotation of a dose setting drum. In such a case, a sensor could measure the relative rotation between a finger pad (of the button) and the dose setting drum to measure the size of an injected dose. D6 also explained how, with this embodiment, the ejected dose could be reliably detected (page 7, lines 12 to 17). In view of this teaching, working with a sensor that could detect dose setting as well as ejection would have been an obvious possibility for the person skilled in the art.

**Reasons for the Decision**

1. The invention

The invention relates to a medication delivery device comprising a prefilled injection device, a sensor arranged to detect an ejection of medicament from the injection device, and a processor for collecting and storing ejection information.

Medication delivery devices of the kind of the invention are typically employed for injecting insulin for the treatment of diabetes. In such treatment, it is important to keep a log of the size and time of each injection to ensure compliance with a specified regimen to closely control the level of glucose in the patient's blood.

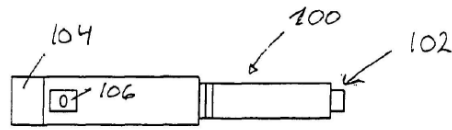
Typically, the log is kept by the patient in a handwritten notebook. There is a risk of having an incomplete log if the patient forgets to enter some injections or makes mistakes about the size and the time of the injections. Since patients with diabetes are frequently elderly and with co-morbidities, this risk is relatively high.

By providing the sensor and the processor as defined in claim 1 of the patent as granted, a reliable logbook can be kept.

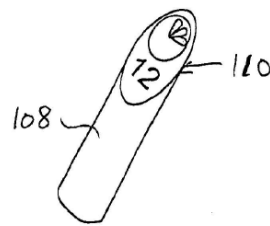
According to the claim, the medication delivery device further comprises communication means arranged to transmit ejecting information to an external data receiving device.

Such an external data receiving device can be part of a cover of a needle of the injection device (claim 2 of the patent as granted).

Figures 1 and 2 of the patent as granted, reproduced below, depict a medication delivery device in the form of a pen (100) with a cover (108). The cover comprises a display (110) for displaying ejection information.



**Fig. 1**



**Fig. 2**

Paragraph [0009] of the patent describes that the prefilled injection device defines a reservoir forming an integral part of the device such that the device may be regarded as disposable. Accordingly, it may be desirable to have few and inexpensive electronic components. For example, no electronic display need be provided on the device.

To detect an ejection of the medicament from the injection device, the sensor comprises a movable part adapted to rotate relative to a stationary part.

2. Main request

2.1 A crucial point to be considered is the meaning attributed to the term "prefilled" in claim 1 of the patent as granted.

According to established case law, a term in a patent claim must be interpreted in a technically sensible manner, taking into account the context, which includes



the general knowledge of the skilled person in the technical field of the patent as well as the disclosure of the patent as a whole (Case Law of the Boards of Appeal, 9th edition 2019, Chapter II.A.6.1).

The Board agrees with the proprietor that in the field of medicament delivery devices, a "prefilled" injection device does not simply mean that the injection device could be filled prior to use. If that were the case, the term would be meaningless from a technical point of view since every injection device must be filled prior to using it for delivering an injection.

The patent provides a definition of what has to be understood as a "pre-filled device" in paragraphs [0008] and [0009]:

*"[0008] It will thus be appreciated that the present device is a pre-filled device, i.e. a device in which it is not possible to exchange the drug reservoir [...]"*

*"[0009] Since the injection device defines a reservoir forming an integral part of the device, the device may be regarded as a disposable device. Accordingly, it may be desirable from a manufacturing point of view that the electronic components are as few and as inexpensive as possible. For example, in preferred embodiments of the invention, no electronic display is provided in the device."*

Accordingly, a prefilled injection device within the meaning of claim 1 has to be understood as an injection device with an integral, non-replaceable reservoir making the device disposable in the sense that it has

to be discarded once the reservoir is empty.

In turn, as also argued by the proprietor, a disposable injection device as normally meant in the technical field of the patent is a prefilled injection device within the meaning of claim 1.

In the proprietor's view, the patent as a whole implied that the medication delivery device in its entirety, as defined in claim 1, had to be prefilled within the meaning specified above.

The Board does not share this view.

While paragraphs [0008] and [0009] generally refer to *"a pre-filled device"* and a *"device [that] may be regarded as a disposable device"*, other passages of the description and the figures make it clear that the device referred to is only the injection device part of the claimed medication delivery device.

The patent discloses a cover for the injection device. The cover is reusable and may comprise several electronic components (in particular, a display). Due to the presence of the display on the cover, no display is needed on the disposable injection device. This is desirable from a manufacturing point of view as the injection device can be produced cheaply (paragraph [0009] reproduced above and paragraph [0027]).

The patent goes on to explain (in particular, paragraph [0057]) that the medication delivery device may comprise such a cover:

*"[0057] Figs. 4-6 show three different medication delivery devices 120, 130, and 140, each comprising*

a cover 122, 132, and 142 with a display portion 124, 134, 144."

It follows that the medication delivery device comprises a reusable part. Hence, it cannot be considered to be disposable as a whole. By way of analogy, a prefilled disposable cartridge, to be used with a reusable doser of an injection device, does not make that injection device disposable as a whole either.

2.2 It is common ground that D2 can be considered the closest prior art for the subject-matter of claim 1 of the patent as granted.

D2 discloses a medication delivery device as depicted in Figures 1a and 1b reproduced below.

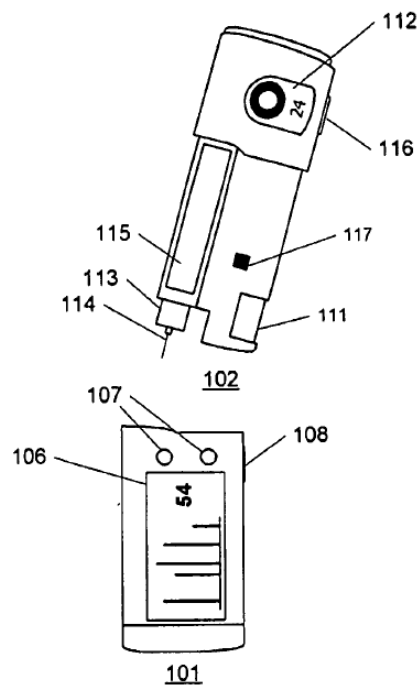


Figure 1a

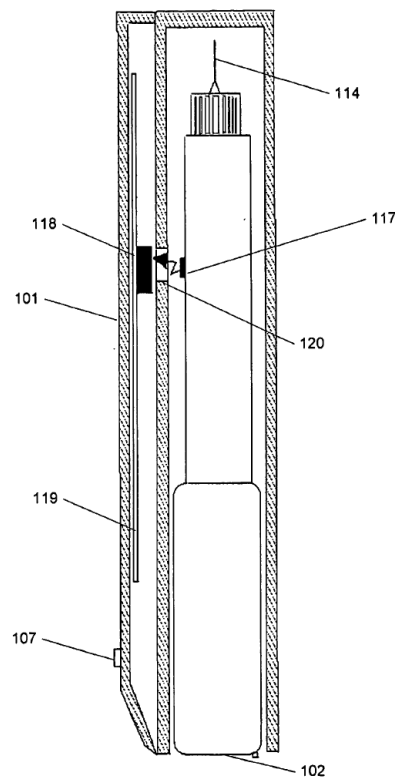


Figure 1b

The medication delivery device comprises an injection device (second apparatus 102 as described on page 16, lines 14 to 24) having a reservoir (cartridge 113) comprising a medicament to be ejected.

The medication delivery device further comprises a sensor arranged to detect an ejection of the medicament from the injection device, the sensor being arranged to output a signal comprising ejecting information, and a processor for collecting and storing the ejection information (page 18, lines 1 to 13). Finally, the medication delivery device comprises a communication means arranged to transmit ejecting information to an external data receiving device (short-range communication means 117 in Figure 1a as explained on page 21, lines 17 to 21).

The Board agrees with the proprietor that D2 does not directly and unambiguously disclose a prefilled injection device within the meaning of claim 1 of the patent as granted.

D2 also fails to disclose a specific sensor which comprises a movable part adapted to rotate relative to a stationary part during ejection.

In the Board's view, these distinguishing features address the objective technical problem of providing a suitable injection device with a sensor to be used in the medication delivery device of D2 since this document provides few details of the injection device, in particular with respect to the sensor to be employed.

The Board sees no relation, and the proprietor has not

explained any either, between the movable and the stationary part of the sensor as such and problems associated with the cost and complexity of the injection device. In this respect, claim 1 does not require the sensor to be part of the injection device. Thus, the sensor as such does not have to be disposable.

Although D2 does not directly and unambiguously disclose a prefilled injection device, the proprietor's argument that the entire teaching of D2 was specifically directed to an injection device in the form of a reusable doser is not accepted. While page 18, lines 26 to 30, briefly describes the injection device as a doser in which a cartridge can be inserted by the patient, page 16, lines 26 to 29, explains that the injection device may also be "another type of drug administration device like a pen, syringe, inhaler, tablet dispenser, etc. or in general any medication administration device". Injection pens and syringes are frequently of the disposable kind, i.e. prefilled within the meaning of claim 1.

D6 discloses a medication delivery device (page 1, lines 4 and 5) comprising an injection device having a reservoir comprising a medicament to be ejected.

Figures 1 and 2 of D6, reproduced below, disclose a sensor for use with the medication delivery device. The sensor may be in the form of a Hall sensor (page 6, lines 23 and 24) comprising a movable part (magnet ring 7) adapted, during ejection, to rotate relative to a stationary part (Hall element 17) located in an injection button (1). As shown in Figure 2, the stationary part may comprise several Hall elements 21, 22, 23 and 24.

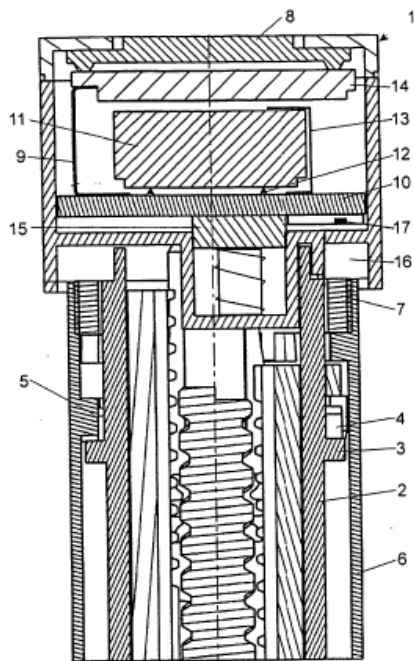


Fig. 1

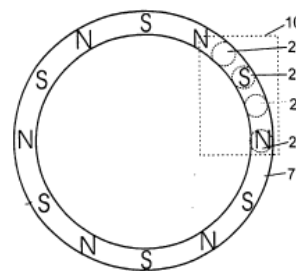


Fig. 2

D6 expressly teaches that this sensor is not only suitable for detecting ejection of a medicament expressed from an injection device. It can also be adapted to transmit data to an integrated circuit block with storage capability (page 8, lines 22 to 26). The injection button can equally be applied to a disposable and a reusable injection device (page 7, lines 20 to 25).

The skilled person, faced with the objective technical problem defined above, would therefore have turned to the teaching of D6 and provided the medication delivery device of D2 with an injection device of the disposable kind including an injection button as disclosed in D6. By doing so he or she would have arrived at the subject-matter of claim 1 of the patent as granted in an obvious way.

The proprietor's argument that D6 disclosed other kinds of sensors, such as a linear sensor (page 7, lines 8 to 12), and that there was no reason why the skilled person would have picked specifically the rotational sensor disclosed in D6 in conjunction with a disposable injection device is not convincing. The rotational sensor as part of a disposable injection device is described in detail in this document. Such an injection device is suitably applicable to the medication delivery device of D2. The implementation of other injection devices with other sensors may at most be as obvious, but this is irrelevant as far as inventive step of the subject-matter claimed is concerned.

2.3 It follows that the ground for opposition of lack of inventive step (Article 100(a) EPC) prejudices the maintenance of the patent as granted. Hence, the main request cannot be allowed.

3. First, third, fifth, seventh, ninth and tenth auxiliary requests

The first, third, fifth, seventh, ninth and tenth auxiliary requests were only submitted after notification of the summons to oral proceedings. They constitute amendments to the proprietor's case, the admission of which is at the Board's discretion under Article 13(2) RPBA 2020.

According to this article, such amendments "shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned".

As the opponent pointed out, the meaning to be attributed to the term "prefilled" was intensively

discussed in the first-instance proceedings and has been a matter of dispute since the beginning of the appeal proceedings. In this context, the Board sees no exceptional circumstances which may justify the admission of these requests.

The proprietor's argument that the filing had been triggered by the Board's preliminary opinion is not convincing. The expression of a preliminary opinion by the Board on disputed issues should help concentration on essentials during the oral proceedings (Article 15(1) RPBA 2020) rather than give the parties a further unconditional opportunity to file amendments.

The first, third, fifth, seventh, ninth and tenth auxiliary requests are therefore not admitted into the proceedings pursuant to Article 13(2) RPBA 2020.

4. Second and fourth auxiliary requests

- 4.1 Compared with claim 1 of the patent as granted, claim 1 of the second auxiliary request additionally defines two conductors of the sensor, arranged such that an electrical characteristic is defined by the mutual position of the movable part and the stationary part.

However, the Hall sensor disclosed in D6 necessarily comprises conductors coupled to each of the Hall elements for energising the elements and transferring an output signal to a differential operational amplifier (page 8, lines 1 to 6). These conductors - not the Hall elements as such - are considered to be the conductors defined in claim 1 of the second auxiliary request. Whether a plurality of Hall elements in the form of semiconductors energised by current are needed, as argued by the proprietor, is of little



relevance since the claim does not exclude this possibility.

The conductors are also arranged such that an electrical characteristic, i.e. the output of each Hall element, is defined by the mutual position of the movable part, i.e. magnet ring 7, with respect to the stationary part where the Hall elements are located.

The proprietor's argument that the electrical characteristic was not defined by a mutual position but rather by a change of position between the movable and the stationary part is not convincing. In a Hall sensor, the output of the Hall elements depends on the magnitude of the magnetic field where the elements are positioned. This, in the configuration of the sensor of document D6 described above, depends on the position of the magnets on magnetic ring 7 with respect to the Hall elements.

The proprietor also argued that the term "arranged" in the claim implied that the change of the electrical characteristic had to be a consequence of a change in the configuration of the conductors.

The Board does not share this view. The claim specifies that the electrical characteristic is defined by the mutual position of the movable and the stationary part. As regards the conductors, the claim defines them in broad terms. For example, neither their position nor the elements to which they are connected are defined. Under these conditions, a claim interpretation that the arrangement of the conductors merely plays the role of conveying the (change of) the electrical characteristic to the processor cannot be excluded. This is also the case with the Hall sensor of D6.

As a consequence, the obvious application of the teaching of D6 to the medication delivery device of D2 deprives the subject-matter of claim 1 of the second auxiliary request of an inventive step.

- 4.2 Claim 1 of the fourth auxiliary request additionally defines a reservoir being an integral part of the prefilled injection device. In view of the interpretation of the term "prefilled" given above, this additional feature is already implied by that term.

It follows that the subject-matter of claim 1 of the fourth auxiliary request is not inventive for the same reasons as those given in relation to the second auxiliary request.

- 4.3 Hence, the patent cannot be maintained on the basis of either the second or the fourth auxiliary request for lack of inventive step of the subject-matter of claim 1 of each of them (Article 56 EPC).

#### 5. Sixth auxiliary request

- 5.1 Compared with claim 1 of the fourth auxiliary request, claim 1 of the sixth auxiliary request further defines that the communication means comprise a wireless data transmission device based on RF-technology.

D2 generally discloses short-range communication means, for example based on optical or inductive wireless technology (page 7, lines 26 to 33). The Board sees no relation between the implementation of RF-technology as a specific wireless technology and the provision of a simple and inexpensive disposable injection device with

log functions. For example, there is no reason to believe - and the proprietor has not explained any either - that communication means involving RF-technology would be simpler and cheaper than communication means involving optical or inductive wireless technology. Implementing the specific RF-technology, undisputedly known as such, is no more than an obvious design alternative to the wireless technology specifically mentioned in D2.

5.2 It follows that the patent cannot be maintained on the basis of the sixth auxiliary request for lack of inventive step of the subject-matter of claim 1 (Article 56 EPC).

6. Eighth auxiliary request

6.1 Compared with claim 1 of the second auxiliary request, claim 1 of the eighth auxiliary request further specifies that the communication means comprise a wireless data transmission device and that the movable part is adapted to rotate relative to a stationary part also during setting of a dose to be ejected.

As explained in relation to the sixth auxiliary request, D2 discloses communication means comprising a wireless data transmission device.

As regards the relative rotation of the movable part with respect to the stationary part of the sensor during setting of a dose, D6 discloses the details of the Hall sensor in relation to an embodiment in which the movable part rotates relative to the stationary part only during ejection.

The proprietor argued that the relative rotation of the

movable part with respect to the stationary part of the sensor during setting of a dose made it possible to compare the dose intended for ejection with the dose actually ejected, in order to establish possible discrepancies. Hence, the problem of ensuring a safe and correct drug administration was solved.

However, as the opponent pointed out, the patent does not disclose that such a comparison should be made or that discrepancies between a dose set and a dose subsequently ejected may be of concern. What should be reliably recorded is the ejected dose (paragraphs [0004], [0025], [0039] and [0040]).

According to established case law (Case Law of the Boards of Appeal, 9th edition 2019, I.D.4.3.2), the objective definition of the problem to be solved by the invention should normally start from the problem described in the contested patent. At the same time, the problem should be one which the skilled person knowing only the prior art would wish to solve.

In this context, the problem formulated by the opponent, i.e. providing a sensor which could reliably work with a variety of different injection devices, has to be considered the objective technical problem since it can immediately be derived from the patent in suit. This applies even if the problem formulated by the proprietor could be derived from a technical reading of the patent as a whole as well. It also follows that the claimed relative rotation of the movable part with respect to the stationary part of the sensor during setting of a dose is not synergistic for the solution of a common problem with the other distinguishing features of the claim but solves a different partial problem.

D6 discloses on page 7, lines 12 to 17, that the Hall sensor may be applied to injection devices comprising an injection button which rotates relative to a stationary part also during setting of a dose. According to this passage on page 7, the sensor may be configured to detect the rotation of a movable part in the form of a finger pad which follows the button during the dose setting, but relative to which the button is rotated during injection. The passage also comprises the more general teaching that a circuit may be programmed such that the relative movement is only taken as an indication of an injection when the injection button is pressed. When the circuit is programmed in such a way, it is irrelevant whether the movable part of the sensor rotates during dose setting or not, as long as the injection button is not pressed.

Hence, D6 generally teaches a configuration in which the sensor may comprise a movable part which rotates relative to a stationary part also during setting of a dose to be ejected. Such an application of the Hall sensor disclosed in D6 is apparently also suitable for the known injection devices in which relative rotation between a dose setting drum and a stationary part takes place both during dose setting and injection. Hence, it addresses the objective technical problem formulated above.

This leads to the conclusion that the skilled person, applying the general teaching of D6 to the medicament delivery device disclosed in D2, would have provided the medicament delivery device of D2 with an injection device in which relative rotation between a dose setting drum and a stationary part also takes place during dose setting as a further straightforward

option, thus arriving at the subject-matter of claim 1 of the eighth auxiliary request in an obvious way.

It follows that the subject-matter of claim 1 of the eighth auxiliary request is not inventive over the combination of D2 with D6. It is irrelevant how many distinguishing features over the closest prior art are defined in the claim if these features do not provide any synergistic effect in the solution of a common objective technical problem, but rather address different independent problems.

6.2 It follows that the patent cannot be maintained on the basis of the eighth auxiliary request for lack of inventive step of the subject-matter of claim 1 (Article 56 EPC).

7. In view of the conclusions on inventive step, it is not necessary to additionally consider novelty, although this was discussed during the oral proceedings.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



G. Magouliotis

M. Alvazzi Delfrate

Decision electronically authenticated