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**Datasheet for the decision  
of 17 September 2021**

**Case Number:** T 0842/18 - 3.2.02

**Application Number:** 11182622.8

**Publication Number:** 2407094

**IPC:** A61B5/00, A61B5/05, C12M1/00,  
C12M1/40, C12M1/42, C25B9/00,  
G01N27/26, G01N33/52, G01N33/49

**Language of the proceedings:** EN

**Title of invention:**  
Analyte sensor

**Patent Proprietor:**  
DexCom, Inc.

**Opponent:**  
Abbott Diabetes Care Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 56, 83, 84, 123(2)

**Keyword:**

Novelty - (yes)

Inventive step - (yes)

Claims - clarity (yes)

Sufficiency of disclosure - (yes)

Amendments - allowable (yes)

Late-filed request - admitted in first-instance proceedings  
(yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

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**Chambres de recours**

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**Case Number: T 0842/18 - 3.2.02**

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 17 September 2021**

**Appellant:** DexCom, Inc.  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
19 January 2018 concerning maintenance of  
European Patent No. 2407094 in amended form**

**Composition of the Board:**

**Chairman** D. Ceccarelli  
**Members:** S. Böttcher  
C. Schmidt

## Summary of Facts and Submissions

- I. Both the opponent and the patent proprietor filed an appeal against the decision of the Opposition Division to maintain European patent No. 2407094 on the basis of auxiliary request 15.
- II. Oral proceedings before the Board were held on 17 September 2021.
- III. The appellant (opponent) requests that the decision under appeal be set aside and that the patent be revoked.
- IV. The appellant (patent proprietor) requests that the patent be maintained on the basis of auxiliary request 2, filed with its letter dated 29 May 2018.
- V. Claim 1 of auxiliary request 2 reads as follows:

" A device for use in measuring an analyte in a host, the device comprising:  
a transcutaneous analyte sensor (32) operably connected to sensor electronics (132), the sensor electronics (132) configured for measuring an analyte in a host;  
at least one electrical contact (28) configured to connect the sensor (32) to the sensor electronics (132);  
a housing; and  
a sealing member (36) having a durometer hardness of from about 20 Shore A to about 50 Shore A, said sealing member (36) at least partially surrounding at least one of the sensor (32) and the electrical contact (28), wherein the sealing member (36) is configured to be mechanically maintained on the housing (14, 314) by the

housing (14, 314) itself by means of male-female mechanical structures, without substantial translation, deformation and/or compression during insertion of the sensor (32) into subcutaneous tissue of the host using an applicator and wherein the sealing member (36) is configured to seal the electrical contact (28) from moisture when the sensor (32) is operably connected to the sensor electronics (132); wherein the sealing member is disposed on the housing."

VI. In the present decision, reference is made to the following document.

D2: US-A-2006/0019327

VII. The arguments by the appellant/opponent can be summarised as follows.

*Auxiliary request 2 - admittance*

Auxiliary request 2 was newly filed in the appeal proceedings. Whilst it bore some similarity to auxiliary request 8 of the opposition proceedings, it was not identical.

The request could have been presented in the opposition proceedings, since all the arguments in the opponent's statement of grounds of appeal were raised in writing in the opposition procedure before the oral proceedings took place.

Therefore, auxiliary request 2 should not be admitted.

*Auxiliary request 2 - added subject-matter*

The terms "hold" and "maintain" did not have the same

meaning. According to paragraph [0291], lines 5 to 7, of the application as filed, "maintained" was broader than "held substantially in place". Thus, there was no basis for the feature of the sealing member being configured to be mechanically maintained on the housing by the housing itself without substantial translation, deformation and/or compression.

Furthermore, there was no basis in the application as filed for the combination of the feature "without substantial translation, deformation and/or compression during insertion of the sensor" with the feature of the sealing member "having a durometer hardness of [...] 20 Shore A to [...] 50 Shore A". The person skilled in the art would not directly and unambiguously derive this combination of features, which have been taken from isolated paragraphs (paragraphs [0068], [0280] and [0291] of the application as filed).

Paragraph [0280] of the application as filed disclosed a sealing member with a durometer hardness of about 20-50 Shore A, and stated that a sealing member with a durometer hardness of about 50 Shore A had increased resistance to compression. Therefore, there was no reason to expect that the translation, deformation and/or compression issues discussed in paragraph [0291] would be a concern when using a sealing member with a hardness of 50 Shore A. Rather, the skilled person would understand paragraph [0291] to be concerned with sealing members with much lower durometer hardnesses, since it was mentioned that "a sealing member with a certain elasticity can be compressed or deformed".

Furthermore, the introduction of the feature "male-female mechanical structures" in claim 1 constituted an impermissible intermediate generalisation of the

disclosure of paragraph [0291]. This paragraph disclosed that depressions in the sealing member were configured to receive protrusions on the base. By contrast, claim 1 did not specify in any way where or on what the "male-female mechanical structures" could be provided.

Therefore, there was no basis in the application as filed for claim 1, for each of the above reasons.

*Auxiliary request 2 - clarity*

The feature "male-female mechanical structures" in claim 1 did not meet the requirements of Article 84 EPC, since it was not clear what structures were meant by this feature. In particular, it was not mentioned in the claim that the male-female structure was the same as a male-female connector.

*Auxiliary request 2 - sufficiency of disclosure*

The invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, since claim 1 did not specify how the durometer hardness of the sealing member was to be measured. The contested patent referred to several alternative standards by which hardness could be measured, such as ASTM, DIN, JIS, ISO and Rockwell hardness. Measuring any material by one of these standards would not produce a consistent and reliable result when compared with measurement by any of the others.

Additionally, the skilled person was provided with no teaching at all as to what "male-female mechanical structures" were, and could not carry out the claimed

subject-matter at all.

*Auxiliary request 2 - novelty and inventive step*

D2 disclosed all the features of claim 1, in particular the "male-female mechanical structures". The sealing member 36 of the device of Figure 4 could be regarded as the male part, and the elevated lip of the contact holder 34 could be regarded as the female part.

Alternatively, in accordance with the decision of the Opposition Division (point 7.2), the male-female structures could be represented by the contacts 28 and the sealing member 36, which surrounded the contacts to prevent sliding (paragraph [0107] of D2). It would be obvious to connect the contacts to the housing to provide the claimed function of preventing movement of the sealing member.

Even if it were concluded that the feature "male-female mechanical structures" was not disclosed in D2, the subject-matter of claim 1 lacked an inventive step for the following reasons.

The problem solved by the male-female mechanical structures was to prevent excessive movement of the seal during insertion of the sensor.

It was recognised in the contested patent itself (paragraph [0291]) that male-female mechanical structures were known to the person skilled in the art (i.e. were common general knowledge).

Therefore, there could be no inventive step in the claimed arrangement over D2, by itself or when seen in



light of the common general knowledge.

VIII. The arguments by the appellant/proprietor can be summarised as follows.

*Auxiliary request 2 - admittance*

Auxiliary request 2 was essentially the same as auxiliary request 8 from the opposition proceedings.

Since auxiliary request 8 was filed and admitted in the opposition proceedings, its admittance was not in question de novo.

*Auxiliary request 2 - added subject-matter*

In the context of the present patent, the terms "hold" and "maintain" were completely synonymous.

Paragraph [0280] referred to the Shore hardness of the sealing member as being in the range of 20-50 Shore A, and explained that this range allowed a good balance between the sealing properties and the ability to hold the sealing member in place.

Paragraph [0291] explained that the sealing member could be compressed or deformed during sensor insertion, because it had a certain elasticity. The person skilled in the art would understand this to mean "a certain elasticity in the preferred range", which was in line with the disclosure of paragraph [0280].

Thus, claim 1 did not contravene the requirements of Article 123(2) EPC.

*Auxiliary request 2 - clarity*

Male-female mechanical structures for providing a connection between two pieces were well known in mechanical engineering.

It was clear from the claim that, in order to prevent deformation and translation, the sealing member was maintained on the housing by such structures. This implied that the male-female mechanical structures provided a connection of the sealing member to the housing.

Therefore, claim 1 did not lack clarity.

*Auxiliary request 2 - sufficiency of disclosure*

The patent clearly stated that the hardness was to be measured using the Shore durometer test, and the range in claim 1 was a Shore hardness range, measured by the ASTM D2240 standard. The reference to other methods in the patent was therefore irrelevant.

The person skilled in the art would know how to use the ASTM D2240 method.

Hence, the invention was sufficiently disclosed to be carried out by the person skilled in the art.

*Auxiliary request 2 - novelty and inventive step*

D2 did not disclose the feature that the sealing member was mechanically maintained on the housing by means of male-female mechanical structures.

Simple placement of the entire sealing member in a base with an elevated lip (as shown in Figure 4 of D2) did

not amount to using a male-female mechanical structure as discussed for example in paragraph [0291] of the application as filed, and as shown in Fig. 4D.

Furthermore, contrary to the Opposition Division's view (point 7.2 of the contested decision), the contacts 28 extending into the sealing member could not be regarded as such structures. Since the contacts 28 were not connected to the housing, they could not hold the sealing member in place during insertion of the sensor.

The technical effect achieved by the male-female mechanical structures was a reduction of movement of the sealing member and sensor during insertion, which resulted in improved accuracy of sensor placement. The objective technical problem was therefore to design a device with improved sensor placement accuracy upon insertion.

The above-mentioned problem was solved by the above additional distinguishing feature.

The claimed solution is not obvious in view of the cited prior art. Neither D2 nor the remaining prior art said anything about the problem of sensor movement during the insertion.

For these reasons, the claimed subject-matter was novel and inventive in view of the cited prior art.

## Reasons for the Decision

### 1. Subject-matter of the invention

The invention relates to a device for transcutaneous measurement of glucose in a patient. The device comprises a housing and a sensor including a distal portion adapted to extend out of the mounting unit for insertion under the host's skin, and a proximal portion adapted to remain above the host's skin. The proximal portion of the sensor is connected to sensor electronics by at least one electrical contact.

According to claim 1 of auxiliary request 2, at least one of the sensor and the electrical contact is at least partially surrounded by a sealing member, which is disposed on the housing and has the following characteristics.

- It comprises a material having a durometer hardness between 20 Shore A and 50 Shore A.
- It is configured to be mechanically maintained on the housing by means of male-female mechanical structures, without substantial translation, deformation and/or compression during insertion of the sensor into subcutaneous tissue of the host using an applicator.
- It is configured to seal the electrical contact from moisture when the sensor is operably connected to the sensor electronics.

Figure 4A shows the contact subassembly 26 with sensor 32, two electrical contacts 28 and the sealing member

36. Figure 4D shows a sealing member 36 having depressions which are configured to receive mating protrusions on the housing to hold the sealing member in place during insertion of the sensor. By these or similar male-female mechanical structures, the sealing member is mechanically maintained on the housing (paragraph [0295] of the patent).

2. Auxiliary request 2 - admittance

Claim 1 corresponds to claim 1 of auxiliary request 8 filed during the opposition procedure. This request was admitted by the Opposition Division and dealt with in the impugned decision (point 7 of the grounds for the decision).

The opponent alleged that auxiliary request 2 was not identical to former auxiliary request 8. However, they did not point to any specific difference between these requests. The Board cannot find any significant difference.

Therefore, the request is likewise admitted in the appeal proceedings.

3. Auxiliary request 2 - added subject-matter

3.1 The use of the term "maintain" instead of "hold" in the feature of the sealing member being configured to be mechanically maintained on the housing in claim 1 does not contravene Article 123(2) EPC, in particular since both terms are used synonymously several times in paragraph [0291] of the application as filed (lines 5, 9, 13, 16, 17 and 21).

3.2 Combining features from paragraph [0280] (concerning the durometer hardness of the sealing member) with features from paragraph [0291] (concerning maintenance of the sealing member on the housing) of the application as filed does not contravene Article 123(2) EPC, either. The two paragraphs do not relate to different embodiments since, for example, the same reference numerals are used. Paragraph [0280] states that "[i]t is generally preferred that", which means that the range referred to in this paragraph is valid for all embodiments.

Furthermore, the reference to "a certain elasticity" in paragraph [0291] (line 2) does not mean that the problem of deformation during insertion of the sensor only occurs if the sealing member is very soft, and that only in this case is the sealing member configured to be maintained on the housing. Rather, paragraph [0291] explains why the male-female structures for holding the sealing member are to be provided. The person skilled in the art learns from this passage that these structures are advantageous irrespective of the hardness of the sealing member within the preferred range mentioned in paragraph [0280].

3.3 It can be inferred from paragraph [0291], lines 7 to 10, that depressions which are configured to receive mating protrusions are an example of male-female mechanical structures for holding the sealing member in place. Thus, the reference to such structures in claim 1 does not constitute an unallowable intermediate generalisation.

3.4 It follows that claim 1 does not include added subject-matter. Article 123(2) EPC is complied with.

4. Auxiliary request 2 - clarity

Paragraph [0291] mentions depressions on the sealing member which receive mating protrusions on the base of the contact subassembly in order to hold the sealing member in place. It is clear to the person skilled in the art that the depressions and the mating protrusions are the female and male parts of a connecting structure, and that other configurations of this male-female mating structure are conceivable. Hence, claim 1 does not lack clarity. Article 84 EPC is complied with.

5. Auxiliary request 2 - sufficiency of disclosure

From the reference to Shore A hardness in the claim, it is clear to the person skilled in the art that the hardness is to be measured by the ASTM D2240 test method referred to in the patent. Whether other methods could be used to measure hardness is therefore not decisive.

Furthermore, the patent discloses in paragraph [0291], lines 7 to 9 an example of the male-female mechanical structures, namely depressions and mating protrusions.

Hence, the invention is sufficiently disclosed to be carried out by the person skilled in the art. Article 83 EPC is complied with.

6. Auxiliary request 2 - novelty and inventive step

6.1 D2 discloses a device for use in measuring an analyte in a host, having the same configuration as the device of the patent (compare Figure 4 of D2 with Figure 4A of the patent).

D2 does not disclose male-female mechanical structures by means of which the sealing member is maintained on the housing, without substantial translation, deformation and/or compression during insertion of the sensor into subcutaneous tissue of the host using an applicator.

The Board does not share the opponent's view that the sealing member itself can be regarded as the male part of the male-female mechanical structure, given that it is received by the "cup" formed by the rim of the contact holder 34, which forms the female part (Figure 4 of D2). According to the claim wording, the sealing member is "configured to be [...] maintained on the housing [...] by means of male-female mechanical structures". This means that the corresponding elements are provided on the sealing member and the housing, for instance in the form of depressions and protrusions as explained in paragraph [0291] of the patent.

Moreover, the Board does not agree with the opponent's and the Opposition Division's view that the contacts 28 could be regarded as the male part of the male-female structures (point 7.2 of the contested decision). The contacts 28 are not connected to the housing and so cannot provide the effect of maintaining the sealing member on the housing. Connecting the contacts to the housing would be technically nonsensical, since the contact subassembly has to be pivotable from the insertion position (Figures 10A and 10B) to the functional position (Figures 11A and 11B).

It follows that the subject-matter of claim 1 differs from the device of D2 at least in that the sealing member is configured to be mechanically maintained on the housing by the housing itself by



means of male-female mechanical structures, without substantial translation, deformation and/or compression during insertion of the sensor into subcutaneous tissue of the host using an applicator.

- 6.2 In order to be applied to a host, the sensor has to be inserted through the sealing member, as described in paragraphs [0397] to [0401] with reference to Figures 7A to 7D. Due to its elasticity, the sealing member can be compressed or conformed by the insertion or retraction forces applied thereto. This can result in unwanted movement of the sensor relative to the host's skin and relative to the electrical contacts. When male-female mechanical structures are provided and used to maintain the sealing member in place, a reduction in movement of the sensor during the insertion process can be achieved. This allows more reliable and consistent placement of the sensor.

Hence, the objective technical problem solved by the present invention is to provide a device with improved sensor placement accuracy upon insertion.

- 6.3 Since neither this problem nor its solution is mentioned in the available prior art, it was not obvious to the person skilled in the art to modify the device of D2 in view of the objective technical problem such that it includes male-female mechanical structures. Whether male-female mechanical structures as such are within the common general knowledge of the person skilled in the art is irrelevant in this respect. Hence, the claimed subject-matter is novel (Article 54(1) and (2) EPC) and involves an inventive step (Article 56 EPC).

7. The proprietor filed an amended page 2a of the description to bring it into conformity with auxiliary request 2. The opponent had no objections to this. The Board does not have any either.

## **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 in the following version:
  - Claim 1 of auxiliary request 2, filed with the letter dated 29 May 2018,
  - description: pages 1 and 3 to 73 of the patent as granted, pages 2 and 74 as filed during the oral proceedings before the Opposition Division on 14 September 2017, and page 2a as filed during the oral proceedings before the Board,
  - Figures 1 to 27 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

D. Ceccarelli

Decision electronically authenticated