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Datasheet for the decision of 16 September 2021

Case Number: T 0758/16 - 3.2.02

Application Number: 06736006.5

Publication Number: 1986543

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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. 56, 84, 123(2)
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - main request (no) - third auxiliary request (yes)
Claims - clarity - third auxiliary request (yes)
Amendments - third auxiliary request- added subject-matter (no)
Late-filed evidence - admitted (yes)
Amendment after summons - exceptional circumstances (no)

Decisions cited:

Catchword:

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Beschwerdekammern

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Case Number: T 0758/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 16 September 2021

Appellant: (Opponent)	Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502 (US)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Respondent: (Patent Proprietor)	DexCom, Inc. 5555 Oberlin Drive San Diego, California 92121 (US)
Representative:	Hill, Justin John Dentons UKMEA LLP One Fleet Place London EC4M 7WS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 January 2016 rejecting the opposition filed against European patent No. 1986543 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the Opposition Division to reject the opposition against European patent No. 1 986 543.

II. Oral proceedings before the Board were held on 16 September 2021.

III. The appellant (opponent) requests that the decision under appeal be set aside and that the patent be revoked.

IV. The respondent (patent proprietor) requests that the appeal be dismissed or that the patent be maintained on the basis of one of the third to sixth auxiliary requests filed with the reply to the grounds of appeal dated 16 December 2016.

V. Claim 1 of the main request reads as follows:

"A device (10) for measuring an analyte in a host, the device comprising:
a sensor (32) operably connected to sensor electronics (16), the sensor electronics configured for measuring an analyte in a host;
at least one electrical contact (28) configured to connect the sensor to the sensor electronics, wherein the at least one electrical contact comprises a material having a durometer hardness of from about 20 Shore A to about 80 Shore A; and
a sealing member (36), wherein the sealing member at least partially surrounds at least one of the sensor and the at least one electrical contact, wherein the

sealing member comprises a material having a durometer hardness of from about 10 Shore A to about 50 Shore A and wherein the durometer hardness of the at least one electrical contact (28) is higher than the durometer hardness of the sealing member (36)."

VI. Claim 1 of the third auxiliary request reads as follows:

"A device (10) for measuring an analyte in a host, the device comprising:
a sensor (32) operably connected to sensor electronics (16), the sensor electronics configured for measuring an analyte in a host;
at least one electrical contact (28) configured to connect the sensor to the sensor electronics, wherein the at least one electrical contact comprises a material having a durometer hardness of from about 20 Shore A to about 50 Shore A; and
a sealing member (36), wherein the sealing member at least partially surrounds at least one of the sensor and the electrical contact, wherein the sealing member comprises a material having a durometer hardness of from about 10 Shore A to about 50 Shore A and wherein the durometer hardness of the at least one electrical contact (28) is higher than the durometer hardness of the sealing member (36)."

VII. In the present decision, reference is made to the following documents:

D1: US-A-2006/0019327
D2: US-A-2004/0133164
D3: US-B-6,336,269
D6: US-B-5,823,802
D18: "ASTM D2240 - 05 - Standard Test Method for Rubber

Property - Durometer Hardness"
D19: US-A-5,770,028
D20: US-B-6,730,072
D21: US-A-2005/0267325
D22: EP-A-0 319 277
D24: US-B-6,180,221
D26: Declaration by Mr Louis Pace
D27: "Durometer Made Easy", Paramount PDS, 2008
D28: "Durometer Shore Hardness Scale", Smooth-On
D29: Internet site - The Wayback Machine, https://web.archive.org/web/20030701203253/http://www.applerubber.com/sdg/dguide/sec_1/start.cfm
D30: "Silastic® MDX4-4210 BioMedical Grade Elastomer", Product information, Dow Corning, 08/08/2005
D31: CV and declaration by Mr Damien Lacroix
D32: "Handbook of Biomaterial Properties", J. Black, G. Hastings (Eds.), XXIV, pp. 319-322, 1998

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

Admittance of documents D26 to D32

The Opposition Division incorrectly exercised its discretion not to admit D26 since it did not take the high relevance of the declarant's submissions into account. D26 had been filed after expiry of the opposition period because it had been a response to the respondent's filing of D18 with the reply to the notice of opposition.

D27 and D28 had been timely submitted with the grounds of appeal. They had been filed in response to arguments made by the respondent for the first time during oral proceedings before the Opposition Division. D27 and D28 evidenced that the claimed ranges covered most if not

all the workable range from which the person skilled in the art would select a material hardness.

D29 to D32 were highly relevant to issues considered important by the Board, in particular since no guidance on inventive step had been given by the Board in the preliminary opinion prior to the oral proceedings. D29 to D32 provided further evidence that the person skilled in the art would use materials having hardnesses within the claimed ranges for the sealing member and the contacts of the device of D1. D29 had only been found after continual, extensive efforts and research and could therefore not have been filed earlier. Likewise, D32 could not have been filed earlier since it had only been found after consultation with the expert who provided the declaration D31.

Hence, all these documents should be admitted into the appeal proceedings.

Main request - Added subject-matter

The combination of the claimed hardnesses while the contact had a greater hardness than the sealing member and the omission of the feature that the contacts were elastomeric involved added subject-matter.

These features were disclosed in different, unrelated parts of the application without clear and unambiguous teaching to combine them.

Paragraph [0404] mentioned a hardness of the contacts of about 50 Shore A and a hardness of the sealing member of about 20 Shore A. Thus, it was clear that a significant difference in the hardnesses was required. Furthermore, paragraph [0404] of the application as

filed did not provide a basis for the claimed ranges but instead required that the contacts were elastomeric.

Furthermore, claims 88 to 92 disclosed different ranges from the claimed ones.

Main request - Sufficiency of disclosure

Durometer hardness was an ill-defined parameter because it was ambiguous and unclear. Since it was relevant for solving the problem posed, the invention was insufficiently disclosed.

According to paragraph [0279] of the patent, it was necessary to report the time the measurement was made. However, the indentation time was not reported in conjunction with the claimed hardness ranges in claim 1.

Paragraph [0278] disclosed various standards by which hardness could be measured. It was not clear which standard should be used. The invention did not teach the skilled person how to measure the hardness for the many unspecified materials (e.g. noble metals) in a reproducible way. The durometer hardness testing according to ASTM D2240 (D18) referred to in paragraph [0278] merely related to the measurement of the hardness of various grades of polymers.

The standard ASTM D2240 did not allow the person skilled in the art to achieve reproducible results. D18 taught that the measurement results were influenced by various factors, such as details of the equipment and the environment and characteristics of the sample. However, none of these factors was addressed in the patent. Since the hardness could not be precisely

measured with this standard, it was not possible for the person skilled in the art to work within the claimed ranges and ensure that the contacts were harder than the sealing member.

Furthermore, the invention was not enabled over the entire claimed range since no information was given on how to:
a) achieve a better seal by partially surrounding only one of the sensor or the electrical contact
b) achieve the claimed benefits with non-elastomeric contacts
c) achieve the alleged improvements by selecting materials for the sealing member and the contacts at the lower or higher ends of the hardness ranges

Main request - Inventive step starting from D1

The subject-matter of claim 1 differed from the device of D1 only in that the seal and electrical contacts had a hardness falling within the claimed ranges and that the contact had a greater hardness than the seal.

The patent did not disclose any advantages of the respective claimed range over a hardness outside the range.

Thus, the objective technical problem to be solved by this was simply to select a sealing member and an electrical contact that each had an appropriate hardness.

Since the claimed ranges covered everything from soft to hard materials, as evidenced by D27 and D28, there was nothing inventive about them.

D2 disclosed a sensor for measuring an analyte having a silicone seal 442 having a durometer hardness of 30 Shore A (paragraphs 115 and 119). Hence, D2 taught that a silicone seal for use in a sensor for measuring an analyte would typically have a hardness around 30 Shore A, which was right in the middle of the claimed range.

Although D6 was not directed to an analyte sensor, the skilled person, when looking for teaching on suitable hardnesses for a sealing member and a contact that it may partially surround, would be taught by D6 to select materials having hardnesses falling within the claimed ranges and a higher hardness for the electrical contact.

Furthermore, sealing members having a durometer hardness falling within the claimed range were known from D19 (column 11, lines 47-60), D20 (column 8, lines 19-31), D21 (paragraph [0099]) and D22 (column 17, lines 36 to 45).

As to the electrical contacts, the skilled person would be aware from the common general knowledge that a material having a durometer hardness in the range of 20 to 80 Shore A would be sufficiently hard to ensure a good and stable contact.

Furthermore, the skilled person was provided with such teaching explicitly in D24 (column 4, lines 42 to 46) and D3 (column 50, line 59 to column 51, line 1), which disclosed electrically conductive contacts with a durometer hardness falling within the claimed range.

It was therefore obvious that the skilled person would choose a durometer hardness for the contact of D1 that fell within the claimed range.

Furthermore, it was a routine design choice for the skilled person to choose a higher durometer hardness for the electrical contact compared with the sealing member or the other way round since there was no particular advantage in the choice. This was supported by the application as filed, which disclosed some arrangements in which the sealing member was harder than the contacts (paragraph [0405]).

Third auxiliary request - Admittance

The third auxiliary request had been filed by the respondent to address an objection of added subject-matter, as indicated in the table on page 19 of the reply to the statement of grounds of appeal. The use of this request in an attempt to overcome an objection of lack of inventive step had to be considered late filed.

The request should therefore not be admitted into the appeal proceedings.

Third auxiliary request - Clarity

It was not clear how the sealing member could be made from a material having a durometer hardness of 50 Shore A and still have a lower hardness than the contact which could also have a maximum hardness of 50 Shore A.

Third auxiliary request - Added subject-matter

An embodiment in which both the material of the sealing member and the material of the contacts had a hardness of 50 Shore A with one being harder than the other could not be derived from the application as originally filed.

Third auxiliary request - Inventive step

The materials for the electrical contact mentioned in D1 fell within the hardness range of from about 20 to about 50 Shore A. Carbon black elastomers could have a hardness falling within this range.

Hence, the same arguments as for the main request applied to claim 1 of the third auxiliary request.

The patent did not mention any advantages of the claimed combination of hardness ranges. Paragraph [0281] only referred to the material of the sealing member, and paragraph [0405] mentioned a range of from 5 to 80 Shore A for the material of the contacts.

Furthermore, D27 and D28 disclosed that the hardness range of from about 20 to about 50 Shore A included materials which were not soft. In view of D24, which disclosed a hardness range of from about 40 to about 80 Shore A for an electrical contact, selecting a material having a hardness of about 40 to 45 Shore A would be obvious.

Selecting a hardness range of from about 20 to about 50 Shore A for the electrical contacts would therefore be obvious for the person skilled in the art. The subject-matter of claim 1 did not involve an inventive step.

IX. The arguments by the respondent can be summarised as follows.

Admittance of documents D26 to D32

D26 was late filed and should not be admitted.

D27 and D28 should have been filed during the opposition proceedings since no amendments were filed during the oral proceedings. Furthermore, their filing could not be regarded as a reaction to arguments made for the first time during opposition oral proceedings. These documents did not constitute prior art as they did not pre-date the application as filed and were not *prima facie* relevant.

D29 to D32 should also have been filed during the opposition proceedings since they did not provide a direct response to any issue raised during the oral proceedings or in the decision under appeal. The appellant did not provide cogent reasons that the submission of new documents resulted from exceptional circumstances.

Hence, none of these documents should be admitted into the appeal proceedings.

Main request - Added subject-matter

The sensor system was described in paragraphs 254 to 266, the monitoring unit was described in paragraphs 267 to 320, and the sensor insertion was described in paragraphs 397 to 427. Since these passages referred to the same drawings and features, it was clear that they did not relate to separate, distinct embodiments but provided details on the components of the sensor system.

The feature concerning the relative hardness was disclosed in claim 89, which did not require the contacts to be elastomeric. The claimed ranges were disclosed as preferred ranges in paragraphs [0280] and

[0403].

In paragraph [0404], the values "20" and "50" were mentioned as examples. A general requirement for a certain, significant difference in hardnesses could be derived neither from these examples nor from claim 89.

Main request - Sufficiency of disclosure

The parameters in claim 1 were not ambiguous or unclear.

Paragraph [0278] did not teach that it was necessary to report the time the measurement was made. It was merely stated that sometimes the indentation time was reported.

Durometer testing was a standardised procedure which allowed the person skilled in the art to achieve reproducible results. Since the person skilled in the art was aware of the tolerances of the testing standard, they would know how to measure the hardness with reasonable tolerances.

Claim 1 required the person skilled in the art to select a material which fell within the specified Shore A hardness range; not to manufacture such a material.

A partial seal around the sensor or the contacts would be better than no seal at all. Paragraph 403 did not require the contacts to be elastomeric. For the invention to be enabled, it was not necessary to provide the person skilled in the art with specific information on how the improvement was achievable by selecting a material at the ends of the range.

Main request - Inventive step

It was disclosed in D1 that silicone could be used for the sealing member as one option but not that this material must be used. Likewise, while in paragraph [0109] carbon black elastomer was mentioned as an example for the electrical contacts, paragraph [0110] disclosed the use of stiff plastic. Furthermore, D1 did not disclose the combination of silicone and carbon black elastomer in one embodiment.

The technical effect and advantage achieved by the claimed selection of materials was mentioned in paragraph [405] of the patent. Furthermore, paragraph [0281] referred to the advantages of the lower and upper ends of the durometer hardness range for the sealing material.

Therefore, the objective technical problem identified by the Opposition Division remained applicable.

It was not obvious for the person skilled in the art to select materials having the claimed hardnesses. The person skilled in the art could also choose a material with a lower hardness for the contacts, or the sealing member and contacts could be made from materials having the same hardness.

Hence, the subject-matter of claim 1 involved an inventive step.

Third auxiliary request - Admittance

The auxiliary requests had been filed with the respondent's reply to the appeal, together with reasoning for their filing. It was mentioned (page 18,

third last paragraph) that they were submitted to address the various objections raised by the opponent, including the objection to inventive step.

Third auxiliary request - Clarity

Claim 1 was a combination of granted claims 1 and 10. Therefore, clarity could not be an issue.

Third auxiliary request - Added subject-matter

The hardness range of from about 20 to about 50 Shore A for the electrical contact had a basis in paragraph [0403] of the application as filed. Its inclusion in claim 1 did not involve added subject-matter.

Third auxiliary request - Inventive step

D1 disclosed electrical contacts formed from carbon black elastomer (paragraph [0109]). According to D27 and D28, tyre treads, which were made from carbon black elastomers, had a durometer hardness of above 50 Shore A.

The selection of a material for the contacts having a hardness in the range of about 20 to about 50 Shore A, together with a sealing material having a hardness in the range of from about 10 to about 50 Shore A, made the whole system more compliant while improving the contact and the seal to the sensor. This synergistic effect could be derived from paragraphs [0281] and [0405] of the patent. A higher compliance was advantageous since the device had to be worn by a user.

Starting from the disclosure of D1, it would not be obvious for the person skilled in the art to form an

electrical contact with a material having a hardness in the range of about 20 to about 50 Shore A, which was in the soft range of the Shore A scale.

Thus, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to a device for measuring an analyte in a host, such as the transcutaneous measurement of glucose in a patient. The device comprises a sensor intended for insertion under a host's skin. The sensor is connected to sensor electronics by at least one electrical contact. The electrical contact comprises a material having a durometer hardness between 20 and 80 Shore A. At least one of the sensor and the electrical contact is at least partially surrounded by a sealing member. This can protect the electrodes from damage due to moisture, humidity or dirt. The sealing member comprises a material having a durometer hardness between 10 and 50 Shore A. The durometer hardness of the at least one electrical contact is higher than the durometer hardness of the sealing member.

Figure 4A shows the sensor 32, two electrical contacts 28 and the sealing member 36. Figures 4D to 4H show different configurations of these elements.

2. Admittance of documents D26 to D32

2.1 D26

The Opposition Division did not admit D26 since it considered it to not be *prima facie* relevant (point 3.1, last paragraph of the Reasons).

As D26 was filed after issue of the summons to oral proceedings and therefore late. The Opposition Division had discretion to not admit it.

A board should only overrule how a department of first instance exercised its discretion if the board concludes that it did so according to the wrong principles, without taking into account the right principles or in an unreasonable way.

The Board has no reason for overruling the decision of the Opposition Division. While the opponent challenges the Opposition Division's assessment that D26 is not *prima facie* relevant, the Board notes that the Opposition Division explained the reasons for this assessment.

Consequently, in accordance with Article 12(4) RPBA 2007, the Board decided not to admit D26 into the appeal proceedings.

2.2 D27 and D28

D27 and D28 disclose various Shore hardness scales, illustrating what kind of products are actually covered by the Shore A ranges mentioned in claim 1.

The documents were submitted with the statement of

grounds of appeal to address whether the claimed ranges were narrow and precise. This question was raised at the oral proceedings before the Opposition Division.

The Board used its discretion under Article 12(4) RPBA 2007 to admit these documents into the appeal proceedings.

2.3 D29 to D32

D29 to D32 were submitted after notification of the summons to oral proceedings. The filing of new documents constitutes an amendment to the party's appeal case. In accordance with Article 13(2) RPBA, such amendments shall not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.

In this case, the appellant did not provide cogent reasons for any exceptional circumstances that would justify the admittance of D29 to D32. Difficulties in obtaining a document does not amount to exceptional circumstances.

Hence, the Board decided not to admit D29 to D32 into the appeal proceedings.

3. Main request - Added subject-matter

Claim 1 of the main request is based on claims 88 and 89 as originally filed and paragraphs [0403] (for the narrower range of the hardness of the electrical contact) and [0280] (for the narrower range of the hardness of the sealing member).

Claims 88 and 89 and the passages to which paragraphs

[0403] and [0280] belong do not relate to different embodiments because, for instance, the same reference numerals are used. Furthermore, both paragraphs state that "it is generally preferred that...", which means that the ranges referred to in these paragraphs are valid for all embodiments.

As to the omission of the feature "elastomeric", neither in claims 88 and 89 nor in paragraphs [0403] and [0280] are the contacts referred to as elastomeric contacts. Hence, the omission of this feature does not constitute an unallowable intermediate generalisation.

Paragraph [0404] gives an example in which the hardness of the contacts is about 50 Shore A and the hardness of the sealing member is about 20 Shore A. However, from this example, it cannot be derived that the hardness of the contacts must differ from the hardness of the sealing member by a certain, significant amount.

Hence, claim 1 does not include added subject-matter.

4. Main request - Sufficiency of disclosure

4.1 Reproducibility of the parameter of durometer hardness

Durometer is an international standard for measuring the hardness of materials such as rubber and plastic. Hence, the parameter Shore A hardness mentioned in claim 1 is neither ill-defined nor ambiguous or unclear.

As stated in paragraph [0279] of the patent, the Shore hardness of a sample is obtained from the ASTM D2240 test method (described in D18), which is a standard test method for the Shore A durometer hardness. The

other standards referred to in paragraph [0278] do not concern the Shore A hardness. Hence, the person skilled in the art was clearly taught to use the ASTM D2240 standard for the claimed hardness.

The Board further agrees with the Opposition Division and the respondent that the durometer hardness testing according to ASTM D2240 is a standardised procedure which allows the person skilled in the art to achieve reproducible results to enable them to carry out the invention as claimed. Although different factors are mentioned in D18 which might influence the result of the hardness measurement, the results would not diverge so much that the disclosure would be considered insufficient. When selecting the materials for performing the invention, the person skilled in the art would take the uncertainty caused by the influencing factors into account.

The Board also agrees with the respondent that the indentation time mentioned in paragraph [0278] of the patent is not essential for the reproducibility of the hardness measurement.

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

4.2 Water tightness of the sealing member

The appellant did not provide any evidence that a sealing member that only partially surrounds the contacts or the sensor, or materials having a hardness in the lower or upper end of the claimed ranges, would not achieve a technical effect. Furthermore, paragraph [0404] does not teach that the contacts have to be elastomeric to achieve a better seal by means of the

sealing member.

Thus, the Board holds that the invention is sufficiently disclosed to be carried out over the entire range.

5. Main request - Inventive step starting from D1

D1 discloses a device for measuring an analyte in a host having the same configuration as the device of the patent (Figure 4 of D1 in comparison to Figure 4A of the patent). However, D1 is silent on the durometer hardness ranges of the materials used for the sealing member and the electrical contacts and on the relative hardness between the sealing member and the contacts. This is undisputed by the parties.

The sealing member of the device of D1 is formed by an elastomeric material such as silicone (paragraph [0106]). The text of this paragraph is also included in the patent at issue (paragraph [0277]). Hence, this material must provide the functions of a watertight seal as required for the sealing member of claim 1.

It is also disclosed in D1 that the electrical contacts are formed from a conductive elastomeric material, such as carbon black elastomer (paragraph [0109]). According to paragraph [0107], the contacts are designed to form a stable mechanical and electrical connection, as is also stated in the description of the patent at issue (paragraph [0286]).

Since both paragraphs [0106] and [0109] of D1 refer to the reference numerals used in Figure 4 to designate the sealing member and the contacts, it can be derived that the materials "silicone" and "carbon black

elastomer" are disclosed in the same embodiment.

Hence, the subject-matter of claim 1 differs from the device of D1 in that:
- the elastomeric material of the sealing member has a durometer hardness of between 10 and 50 Shore A
- the material of the electrical contacts has a hardness of between 20 and 80 Shore A
- the hardness of the contacts is higher than the hardness of the sealing member

The patent does not mention any advantage of selecting materials having a hardness within the claimed ranges.

It is acknowledged that paragraphs [0281] and [0282] of the patent refer to a sealing member with a durometer hardness of about 10 Shore A for increased conformance and a sealing member with a durometer hardness of about 50 Shore A for increased strength. However, the same paragraphs mention that a sealing material with higher or lower durometer hardness could be used. Hence, from these passages it cannot be derived which particular advantage can be achieved by selecting a range of from about 10 to about 50 Shore A for the sealing material.

Likewise, no advantages from selecting a durometer hardness range of from 20 to 80 Shore A for the material of the electrical contacts can be derived from the patent. Instead, this range is very broad and covers soft materials like a rubber band and hard materials like a shoe heel and an extension cord plug, as shown in the tables of D27 and D28, according to which such materials are in that hardness range. Whether D27 and D28 were published after the filing date of the patent is not decisive since the materials as such and the hardness scale were certainly known

before the filing date.

Furthermore, as to the relative hardnesses, paragraph [0404] of the application as filed discloses that the higher durometer hardness contacts provide greater stability while the lower durometer hardness sealing member provides a superior compression and/or seal. However, the following paragraph [0405] states that the same could be achieved with a sealing member having a higher durometer hardness than the contacts. Hence, it can also not be derived why selecting a harder material for the contact and a softer one for the sealing member is advantageous.

Therefore, the Board does not concur with the respondent and the Opposition Division that the objective technical problem is to improve stability and liquid tightness of the electrical contact. The objective technical problem is rather to select materials for the sealing member and the electrical contact having an appropriate hardness.

Although D1 does not refer to the hardness of the materials at all, it would be routine for the person skilled in the art to select a silicone for the sealing member having a durometer hardness within the claimed range, in particular since it is known that silicones having a hardness within this range can be used as sealing material in medical devices (D2: paragraphs [0115] and [0119]; D19: column 11, lines 47-60; D20: column 8, lines 19-31; D21: paragraph [0099]; and D22: column 17, lines 36 to 45).

Likewise, it would be obvious for the person skilled in the art to select a carbon black elastomer for the contact having a durometer hardness within the claimed

range, in particular since this range covers almost the entire available range and carbon black elastomers are known to be used in tyre treads, which have a hardness of about 60 or 70 Shore A (D27 and D28). Moreover, electrical contacts made of electrically conductive materials having a durometer hardness between 40 and 80 Shore A (column 4, lines 42 to 46) are known from D24.

It would also be a routine design choice for the person skilled in the art to select a higher durometer hardness for the electrical contact than for the sealing member, in particular since this is one of the only two possible options when different materials are concerned.

It follows that the subject-matter of claim 1 of the main request lacks an inventive step.

6. Third auxiliary request - Admittance

In claim 1 of the third auxiliary request, the durometer hardness of the electrical contact has been limited to a range of from about 20 to 50 Shore A.

The third auxiliary request was filed by the respondent with the reply to the appellant's statement of grounds of appeal to have a fallback position in case the Board should "find differently than the Opposition Division in respect of any of the grounds of opposition" (page 20, first paragraph of the respondent's reply). With the Board's finding that the subject-matter of claim 1 of the main request does not involve an inventive step, this has occurred.

Furthermore, the amendment made in claim 1 of the third auxiliary request clearly limits the scope of the claim

and can therefore be regarded as an attempt to overcome the lack of inventive step. It is irrelevant that the request might have been submitted with the primary intention to overcome a different objection, as the appellant argued.

Consequently, in accordance with Article 12(4) RPBA 2007, the third auxiliary request is admitted into the proceedings.

7. Third auxiliary request - Clarity

Claim 1 is based on a combination of claims 1 and 10 as granted. Since lack of clarity is not a ground for opposition, the clarity of claim 1 cannot be challenged.

8. Third auxiliary request - Added subject-matter

The claimed hardness range of the electrical contacts is disclosed in paragraph [0403] of the application as originally filed. Together with claims 88 and 89 and paragraph [0280] (for the range of the hardness of the sealing member) of the application as originally filed, this forms the basis for claim 1.

The person skilled in the art would understand that the sealing member could not be made of a material having a durometer hardness of exactly 50 Shore A since then the electrical contact could not have a higher hardness. In this regard, the wording of claim 1, defining the upper limit of the respective ranges as "about 50 Shore A", allows for a margin of the maximum hardness.

Hence, claim 1 of the third auxiliary request meets the

requirements of Article 123(2) EPC.

9. Third auxiliary request - Inventive step

It is undisputed that the subject-matter of claim 1 differs from the device of D1 in that:
- the elastomeric material of the sealing member has a durometer hardness of between 10 and 50 Shore A
- the material of the electrical contacts has a hardness of between 20 and 50 Shore A
- the hardness of the contacts is higher than the hardness of the sealing member

It can be plausibly derived from the patent that the combination of these features has the effect that the whole system is rendered softer and more compliant, while the stability and the seal around the sensor is not compromised. This is advantageous since the device has to be worn with the sensor inserted in the host's skin.

Hence, the objective technical problem can be regarded as to provide a device for measuring an analyte that is more comfortable to wear.

It is assumed that the carbon black elastomers mentioned in D1 as a material for the electrical contacts have a durometer hardness higher than 50 Shore A. Carbon black is mainly used in automobile tyres, which have a hardness of about 60 or 70 Shore A (D27 and D28).

Furthermore, document D24, disclosing a material having a hardness range of from 40 to 80 Shore A (column 4, lines 42 to 46), relates to electrical contacts on circuit boards and thus to a different field than the

current invention. The person skilled in the art would therefore not consult this document to solve the above-mentioned problem. Furthermore, this document does not motivate the person skilled in the art to select a material having a hardness of less than 50 Shore A.

Hence, there is nothing in the prior art that would prompt the person skilled in the art to select a material having a hardness in the range of from 20 to 50 Shore A for the electrical contacts. It would not be obvious for the person skilled in the art to choose two rather soft materials for the sealing member and the contacts where the hardness of the contact is higher than that of the sealing member.

It follows that the subject-matter of claim 1 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 in the following version:

   - claims 1 to 12 of the third auxiliary request, filed with the letter dated 16 December 2016

   - description and figures of the patent as granted

The Registrar: The Chairman:

D. Hampe D. Ceccarelli

Decision electronically authenticated