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**Datasheet for the decision
of 29 April 2024**

Case Number: T 1297/21 - 3.2.02

Application Number: 10739031.2

Publication Number: 2393418

IPC: A61B5/00, A61B5/145,
A61B5/1486, A61M5/158

Language of the proceedings: EN

Title of invention:

COMPACT ON-BODY PHYSIOLOGICAL MONITORING DEVICES

Patent Proprietor:

Abbott Diabetes Care Inc.

Opponent:

Dexcom, Inc.

Headword:

Relevant legal provisions:

EPC Art. 100(c)
RPBA 2020 Art. 13(2)

Keyword:

Amendments - added subject-matter (yes)

Amendment after summons - exceptional circumstances (no) -
taken into account (no)

Decisions cited:

G 0001/93, G 0001/16, T 1779/09, T 0518/99

Catchword:



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Case Number: T 1297/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 29 April 2024

Appellant: Abbott Diabetes Care Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 9 June 2021
revoking European patent No. 2393418 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chair M. Alvazzi Delfrate
Members: A. Martinez Möller
C. Schmidt

Summary of Facts and Submissions

- I. The appeal is against the opposition division's decision revoking European patent No. 2393418.
- II. Oral proceedings before the board took place on 29 April 2024.
- III. At the end of the oral proceedings the requests were as follows.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted. In the alternative, it requested that the patent be maintained on the basis of auxiliary request AR1, filed at the oral proceedings before the board, on the basis of auxiliary requests Aux2 to Aux33 or appeal auxiliary requests 1 to 12, all filed with the statement of grounds of appeal, or on the basis of appeal auxiliary requests 5a, 6a and 7a filed by letter of 29 July 2022.

The respondent requested that the appeal be dismissed.

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

"An integrated analyte monitoring device assembly (110, 211), comprising:

an analyte sensor (101, 250, 540, 1020) for transcutaneous positioning through a skin layer (210) and maintained in fluid contact with an interstitial fluid under the skin layer during a predetermined time

period, the analyte sensor having a proximal portion and a distal portion; and
sensor electronics (102, 1030) coupled to the analyte sensor, the sensor electronics comprising:
a circuit board (1310) having a conductive layer (801) and a sensor antenna disposed on the conductive layer;
one or more electrical contacts (1360) provided on the circuit board and coupled with the proximal portion of the analyte sensor to maintain continuous electrical communication;
and
a data processing component (610, 950) including an application specific integrated circuit (ASIC) provided on the circuit board and in signal communication with the analyte sensor, the data processing component configured to execute one or more routines for processing analyte related signals received from the analyte sensor, the data processing component configured to control the transmission of the data associated with the analyte related signals received from the analyte sensor to a remote location (220) using the sensor antenna only in response to a request signal received from the remote location; characterised in that the analyte sensor is coupled with the sensor electronics and provided to the user within a housing (1010) prior to positioning the analyte sensor through the skin layer.

V. Claim 1 of auxiliary request AR1 includes the following amendments compared with claim 1 of the main request:

"a data processing component (610, 950) including an application specific integrated circuit (ASIC) provided on the circuit board and in signal communication with the analyte sensor, the ASIC of the data processing component configured to execute one or more routines

for processing analyte related signals received from the analyte sensor, wherein the sensor electronics is configured to receive a request signal and RF power from a remote location (220) to perform transmission of data associated with the analyte related signals and the data processing component is configured to control the transmission of the data associated with the analyte related signals received from the analyte sensor to thea remote location (220) using the sensor antenna only in response to thea request signal and the RF power received from the remote location;"

- VI. For the other auxiliary requests, reference is made to the electronic file.
- VII. The appellant's arguments relevant to the present decision can be summarised as follows.

Main request - added subject-matter

The decision under appeal wrongly held that claim 1 as granted contained added subject-matter.

Original claim 1 included the transmission of data only in response to a request signal and also by other means, e.g. automatically. The word "only" in claim 1 as granted limited the transmission of data to only in response to a request signal and excluded transmission at any other time, without introducing new subject-matter. This was not altered by the wording "control the transmission".

The "request signal" in claim 1 as granted could be any signal, including radio frequency (RF) power. Hence, claim 1 encompassed transmission "on demand" and "upon request". The original application presented these two

options as discrete monitoring, in contrast to continuous monitoring of real-time data. The first sentence of paragraph [0059] disclosed continuous and discrete monitoring as or-alternatives, unambiguously disclosing operation only as a discrete monitoring system.

A basis for transmitting data only in response to a request signal could be found in paragraph [0051] of the original application. This paragraph disclosed transmission in response to a request as an alternative to transmission under the control of the data processing unit itself. Even if paragraph [0051] did disclose data storage, paragraph [0068] disclosed transmission of real-time data or stored historical data, and the transmission was not linked to the type of data being transmitted, so there was no need to limit the assembly of claim 1 to store any data.

Passages related to specific embodiments also showed transmission only in response to a request. Paragraphs [0158], [0160] and [0161] described data transmission upon request without any other means for initiating data transmission. Paragraph [0076] disclosed transmission in response to a request as an alternative to automatic transmission. Paragraph [0115] disclosed that transmission could only occur when RF power was provided, with the subsequent paragraphs describing that data were sent in response to an RF control signal. Transmission in response to an RF control signal was also disclosed in paragraph [0078]. Paragraph [0047], when read with paragraph [0035] or any of the other paragraphs, also provided a basis. Other paragraphs such as [0074], [0107], [0108], [0109], [0069], [0080], [0103] and [0121] provided a basis too.

Moreover, the situation was the same as in T 1779/09: the addition of the term "only" excluded protection for part of the subject-matter, did not influence the solution of the technical problem and did not provide a technical contribution. It was thus allowable in accordance with G 1/93.

A basis for the feature whereby the data processing component included an ASIC was provided in original claim 13. The feature of original claim 13 whereby the ASIC was configured to process signals from the analyte sensor could be omitted in view of paragraphs [0103], [0162], [0164] and [0226] of the original application.

Auxiliary request AR1 - admittance

Auxiliary request AR1 was a combination of auxiliary requests Aux8 and Aux14. Exceptional circumstances within the meaning of Article 13(2) RPBA were present because there was a change of opinion regarding the feature of the ASIC as compared with the opposition division.

A basis for claim 1 of auxiliary request AR1 was provided in paragraphs [0068] (last two sentences), [0108], [0115] and [0121], without relying on paragraph [0051]. A basis for the ASIC was provided in original claim 13.

VIII. The respondent's arguments relevant to the present decision can be summarised as follows.

Main request - added subject-matter

Claim 1 comprised added subject-matter.

There was no basis for data transmission "only" in response to a request signal. The application as filed presented continuous and discrete monitoring as alternatives, and within discrete monitoring transmission "on demand" and "upon request" were also presented as alternatives (paragraphs [0051], [0080] and [0157]). Transmission on demand upon receiving RF power was not upon request because the RF power was not a request.

The application disclosed that for continuous transmission, on-demand transmission and upon-request transmission, the data could be transmitted in real-time or later using a storage device. This resulted in six combinations.

In claim 1 as granted, transmission was limited to upon request, encompassing transmission of real-time data or stored data. However, the fifth sentence of paragraph [0051] only provided a basis for transmission of stored data upon request. Moreover, it was disclosed as an alternative to continuous transmission of real-time data, so it did not provide a basis for excluding other modes of transmission such as on demand.

The other paragraphs referred to by the appellant did not provide a basis for adding the word "only". Paragraphs [0158], [0160] and [0161] did not exclude transmission without a request signal, and they disclosed other related features which were absent from claim 1. Paragraph [0076] concerned transmission on demand, not in response to a request signal. Paragraph [0047] was a general boilerplate paragraph; it did not identify any specific feature that could be separated and it could not serve to separate features in

paragraph [0035]. None of the other paragraphs provided a basis for transmission only in response to a request either.

The "only" limitation did provide a technical contribution, distinguishing it from the situation in T 1779/09. Hence, also in view of G 1/93, adding the undisclosed feature was not allowable.

Claim 1 also contained added subject-matter because of the feature whereby the data processing component included an ASIC. Original claim 13 required the ASIC to be configured to process signals from the analyte sensor - a feature absent from claim 1. The paragraphs cited by the appellant as a basis concerned specific embodiments which were different from claim 1 and included further features related to the ASIC which were absent from claim 1.

Auxiliary request AR1 - admittance

The request should not be admitted because there were no exceptional circumstances. Both added-matter objections ("only" and ASIC) were already present in the notice of opposition.

Moreover, the request was *prima facie* not allowable because it did not remedy the issues of added subject-matter and introduced new added-matter issues.

Reasons for the Decision

1. The patent

- 1.1 The patent relates to the transcutaneous detection of the level of analytes such as glucose in interstitial fluid. An important aspect is the transmission of data associated with the analyte-related signals from the sensor electronics to a remote location, such as a reader device or a receiver unit.
- 1.2 Claim 1 is directed to an integrated analyte monitoring device assembly comprising an analyte sensor and sensor electronics coupled to the analyte sensor. The sensor electronics comprise a circuit board having a conductive layer, a sensor antenna, electrical contacts and a data processing component. The data processing component is configured, *inter alia*, to control the transmission of the data associated with the analyte-related signals received from the analyte sensor to a remote location using the sensor antenna only in response to a request signal received from the remote location.

2. Main request - added subject-matter (Article 100(c) EPC)

- 2.1 Addition of the word "only"
- 2.1.1 It is common ground that owing to the word "only", claim 1 as granted limits the transmission of data to only in response to a signal received from a remote location, excluding transmission at any other time.

- 2.1.2 The parties disagree on how the term "request signal" is to be construed in claim 1.

Throughout the specification of the contested patent, data transmission "on demand" and "upon request" are presented as two different modes of transmitting the data (see for example paragraphs [0007], [0012] and [0028]).

According to the specification, transmission "on demand" occurs once the claimed assembly is in close proximity to the "remote location" such as a reader device, in particular within its RF power range (see for example the last sentence of paragraph [0029], the last two sentences of paragraph [0045] and the last three sentences of paragraph [0138] of the patent specification). In contrast, in data transmission "upon request", the data are sent in response to a request to send the data (see for example the last-but-one sentence of paragraph [0012], the fifth sentence of paragraph [0028], paragraph [0046], and the first sentence of paragraph [0057]). It is also clear from the first sentence of paragraph [0057] that providing RF power is not the same as a request to send analyte data.

Hence, the wording in claim 1 "in response to a request signal" is construed as relating to the transmission "upon request" and thus as requiring a signal with a request, i.e. it does not encompass transmission "on demand" triggered by RF power without any request.

- 2.1.3 Paragraph [0051] of the original application has been extensively discussed by the parties as a possible

basis for the amendment, in particular its fifth sentence starting "Alternatively".

That sentence presents an alternative to transmission "in real time to the receiver/data unit at the time of data sampling and processing" (previous sentence in paragraph [0051]). In line with the appellant's argument that an alternative is exclusionary, what is excluded is transmission in real time at the time of data sampling and processing. Hence, the word "Alternatively" in this sentence does not exclude the possibility that stored data are also transmitted without a request for that data in addition to the transmission explicitly described in that sentence ("sampled analyte data and processed analyte related signals ... stored and transmitted to a remote location ... in response to a request for such information"). For this reason alone, the fourth and fifth sentences of paragraph [0051] cannot provide a basis for excluding transmission which is not "in response to a request signal".

Moreover, the fifth sentence of paragraph [0051] discloses that "continuously sampled analyte data and processed analyte related signals may be stored and transmitted to a remote location ... in response to a request for such information from the remote location". The alternative of the fifth sentence of paragraph [0051] thus comprises the closely related features of storing and transmitting the sampled data and processed signals - features not present in claim 1 as granted. The appellant referred to the last-but-one sentence of paragraph [0068] as supporting the omission of those features. However, that sentence relates to on-demand transmission and cannot be used to generalise the disclosure of transmission in response to a request in

paragraph [0051]. It follows that for this reason too, paragraph [0051] does not provide a basis for the amendment in connection with the word "only" in claim 1.

- 2.1.4 The appellant referred to the first sentence of paragraph [0059], which discloses that "[t]he analyte monitoring system 100 may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system".

This passage refers to the system 100 shown in Figure 1, which comprises additional elements such as receiver units. Whether the system as a whole is continuous or discrete does not determine if the claimed assembly is configured to transmit only in response to a request signal. Moreover, the word "only" in claim 1 excludes any transmission which is not in response to a request signal, with no direct correspondence to any of the three options disclosed in the first sentence of paragraph [0059]. Hence, even if the three options were to be understood as mutually exclusive, the passage would still not provide a basis for the disputed amendment.

- 2.1.5 The appellant referred to paragraphs [0158], [0160] and [0161] as describing data transmission in response to a request signal.

However, none of these paragraphs implicitly or explicitly discloses transmission *only* in response to a request signal. For this reason alone, they do not provide a basis for excluding data transmission without a request signal. Moreover, paragraph [0160] refers to "on demand" transmission without mentioning any request signal. Paragraphs [0158] and [0161] disclose

transmission together with the closely related feature whereby continuously or intermittently monitored data are stored and may be retrieved at a later time - a feature absent from claim 1.

- 2.1.6 The appellant further referred to paragraph [0076], in particular to its second sentence.

Said sentence relates to user activation in the reader device (i.e. the remote location in claim 1). It does not mention any request signal being received by the sensor electronics, let alone transmission only in response to such a request signal.

- 2.1.7 The appellant referred to paragraph [0047] in combination with [0035] or any other paragraph.

The general statement in paragraph [0047] that features may be readily separated does not imply that any feature can be isolated from an embodiment even if closely related features are present in that embodiment. The appellant's reference to "any other paragraph" thus cannot provide a basis for the disputed amendment.

Paragraph [0035] relates to embodiments in which analyte data are acquired in real time and stored in a memory or storage unit (see the first sentence of paragraph [0035]) - features not present in claim 1. The second sentence of paragraph [0035] discloses that in those embodiments the *reader device* can acquire the data in real time and/or on demand or upon request. However, it does not deal with whether the *data processing component* is configured to control the transmission of data only in response to a request signal, as defined in claim 1. For these reasons,

paragraphs [0047] and [0035] in combination cannot provide a basis for the disputed feature.

2.1.8 The appellant refers to many other paragraphs of the original application as providing a basis.

Paragraphs [0069] and [0080] mention a request signal but do not indicate that data are only transmitted in response to the request signal.

Paragraphs [0074] and [0107] disclose transmission when RF power is provided, without mentioning any request signal. Paragraph [0078] relates to RF power and does not mention any request signal either.

Paragraph [0103] discloses storing processed sensor data for subsequent transmission when prompted by the reader device to transmit the stored data in addition to the real-time data. It does not exclude the possibility of data being transmitted without a request signal.

Paragraphs [0108] and [0109] disclose an RF interrogation signal in the specific context of communication using RFID over an RF communication link.

Paragraphs [0114] and [0115] describe an embodiment that uses a carrier signal to carry a control signal to request transmission while simultaneously providing RF power. In response, as explained in paragraphs [0117]-[0120], the on-body patch device sends a backscatter signal with data associated with the monitored glucose level.

The appellant mentioned paragraphs [0069], [0080], [0103] and [0121] but without any supporting argument

as to why they would provide a basis. None of them provides a basis for excluding transmission which is not "in response to a request signal".

2.1.9 In summary, the original application does not provide a basis for the subject-matter resulting from the addition of the word "only".

2.1.10 The appellant argued that the addition of "only" was allowable in accordance with G 1/93 and T 1779/09, and in particular that it did not provide a technical contribution.

The feature of the data processing component being configured to control the transmission *only* in response to a request signal received from the remote location excludes such options as the data processing component being able to transmit the data periodically or according to a programmable schedule without any prior request. This limitation has an impact on the possible uses of the claimed assembly as well as on its power management, which the application as filed recognises in paragraph [0004] as an important aspect of devices for monitoring analytes. It is therefore clear that the feature provides a technical contribution to the subject-matter of the claimed invention. The feature may also be or become relevant to the assessment of inventive step, an aspect that is incompatible with a feature that does not provide a technical contribution (see G 1/16, point 49.1 of the Reasons). Hence, one of the conditions set out in point 2 of the order of G 1/93 for an undisclosed feature not to be considered subject-matter which extends beyond the content of the application as filed is not fulfilled.

The situation in the case in hand is different from the situation in T 1779/09, which dealt with the identification of only a name and/or address (specific non-technical content) from text typed by a user for their subsequent use as search terms. Moreover, the case law referred to by the appellant emphasises that the assessment of whether or not a feature has a technical contribution should not be dependent on the prior art available at the particular time, meaning - in agreement with G 1/16, point 49.1 of the Reasons - that it must be assessed not only if the feature is relevant for inventive step in view of the prior art at hand but also if it may become relevant for inventive step (comment on T 518/99, section II.E.3.2.4 of the Case Law of the Boards of Appeal, 10th edition, 2022).

- 2.1.11 It follows from the above that claim 1 of the main request comprises added subject-matter in connection with the word "only".

- 2.2 Feature "including an application specific integrated circuit (ASIC)"
 - 2.2.1 Claim 1 as granted specifies that the data processing component is configured to execute routines for processing analyte-related signals and that the data processing component includes an ASIC, without specifying what the ASIC is configured to do. By contrast, original claim 13 disclosed that the ASIC is configured to process signals from the analyte sensor. The originally filed application provides no basis for omitting said configuration.

 - 2.2.2 The appellant referred to several passages as providing a basis for said omission.

Paragraph [0103], second sentence, discloses that the control unit in the diagram of Figure 6 may be an ASIC, adding that it is coupled to analogue front-end circuitry to process signals received from the sensor. Therefore, it cannot provide a basis for omitting the fact that the ASIC is configured to process signals from the sensor.

Paragraphs [0162] and [0164] mention an ASIC. However, they do not disclose that the ASIC is included in the data processing component as required by claim 1.

Paragraph [0226] is part of a list of claim-like statements and corresponds to original claim 52. It discloses that the controller unit may include an ASIC. This paragraph cannot be read in isolation since it is not clear which controller unit is meant. The controller unit in paragraph [0226] must be read as referring to the controller unit in paragraph [0211], which corresponds to original claim 37. The combination of paragraphs [0211] and [0226] relates to an embodiment with very different features from claim 1 as granted, e.g. an activation switch, a power supply and an insertion device. Hence, this paragraph cannot provide a basis for the ASIC as recited in claim 1 either.

2.3 In summary, the subject-matter of claim 1 extends beyond the content of the application as filed due to the addition of the word "only" and the feature of the ASIC. Hence, Article 100(c) EPC prejudices maintenance of the patent as granted.

3. Auxiliary request AR1 - admittance

- 3.1 The appellant filed auxiliary request AR1 at the oral proceedings before the board. This request constitutes an amendment to the appellant's appeal case after notification of a communication under Article 15(1) RPBA. Under Article 13(2) RPBA, this request must, in principle, not be taken into account unless there are exceptional circumstances justified with cogent reasons by the appellant.
- 3.2 The appellant argued that there were exceptional circumstances because the board had a different opinion regarding the ASIC as compared with the opposition division. However, it is inherent to appeal proceedings that a board may reach a different conclusion from the department of first instance on an issue under dispute. Hence, the fact that the board is convinced by an objection that did not convince the opposition division does not represent exceptional circumstances.
- 3.3 Moreover, the appellant did not convincingly demonstrate that auxiliary request AR1 *prima facie* overcame the added-matter issue in relation to the word "only" without giving rise to new objections. In particular, the appellant argued that instead of paragraph [0051], a basis for the new request was provided in paragraphs [0068] (last two sentences), [0108], [0115] and [0121]. However, the last two sentences of paragraph [0068] relate to "on demand" transmission and do not mention any request. Paragraph [0108] relies on RF identification, which is not present in claim 1. Paragraph [0115] includes many related features of the communication protocol that are not present in claim 1, and paragraph [0121] also

includes related features not present in claim 1 (e.g. power supply, sensor always turned on). Hence, the request does not *prima facie* overcome the finding that claim 1 comprises added subject-matter.

3.4 The board thus decided not to admit auxiliary request AR1 into the proceedings.

4. Further auxiliary requests

4.1 The appellant conceded at the oral proceedings that none of the further auxiliary requests overcame the added-matter issues found to be present in the main request.

4.2 It follows that the patent cannot be maintained on the basis of any of auxiliary requests Aux2 to Aux33, appeal auxiliary requests 1 to 12 or appeal auxiliary requests 5a, 6a and 7a.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated