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**Datasheet for the decision
of 25 July 2022**

Case Number: T 0782/17 - 3.2.02

Application Number: 10195518.5

Publication Number: 2335587

IPC: A61B5/1495, A61B5/145,
A61B5/1486

Language of the proceedings: EN

Title of invention:
Transcutaneous analyte sensor

Patent Proprietor:
DexCom, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:

Relevant legal provisions:

EPC Art. 76(1)
EPC R. 139
RPBA 2020 Art. 13(2)

Keyword:

Divisional application - added subject-matter (yes)

Correction of error - (yes)

Amendment after summons - exceptional circumstances (no)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0782/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 July 2022

Appellant: DexCom, Inc.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
27 January 2017 concerning maintenance of the
European Patent No. 2335587 in amended form.

Composition of the Board:

Chairman D. Ceccarelli
Members: S. Böttcher
N. Obrovski

Summary of Facts and Submissions

- I. Both the patent proprietor and the opponent filed an appeal against the interlocutory decision of the opposition division to maintain the patent on the basis of auxiliary request 4.
- II. Oral proceedings before the board took place on 25 July 2022. During the oral proceedings, the patent proprietor withdrew their appeal.
- III. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed and the patent be maintained on the basis of auxiliary request 4 as maintained by the opposition division, filed with their statement of grounds of appeal and clarified in their submission dated 1 July 2022, or auxiliary request 5 filed during the oral proceedings before the board.

- IV. Claim 1 of auxiliary request 4 reads as follows.

"A single-use applicator system (10) for inserting a transcutaneous sensor into a host, the applicator system comprising:

a sensor (32) configured for transcutaneous placement through a skin of a host;

a needle (72) configured for inserting the sensor into the host, wherein the sensor is disposed within the needle prior to insertion into the host;

a housing (14) adapted for placement adjacent to the host's skin; and

an applicator (12) configured for inserting the needle and the sensor into the skin of the host, wherein the needle (72) and the sensor (32) are disposed within the applicator (12) prior to insertion of the sensor; wherein the applicator is configured to insert the needle and the sensor into the skin of the host, to leave the sensor transcutaneously placed within the host, and wherein the applicator is further configured to retract the needle from the skin of the host into the applicator, and wherein the applicator is configured to releasably mate with the housing, wherein the sensor comprises electrodes which share the same central axis or electrodes and membrane systems which all share the same central axis, wherein the central axis is the axis of insertion."

- V. Claim 1 of auxiliary request 5 corresponds to claim 1 of auxiliary request 4, in which the term "irreversibly" has been added before "retract the needle from the skin of the host into the applicator".
- VI. The arguments of the appellant may be summarized as follows.

Auxiliary request 4

The respondent, on appeal, had filed an auxiliary request 4 with submission dated 2 June 2017. This request was not identical to auxiliary request 4 found allowable by the opposition division. Dependent claim 4, which had been deleted during the oral proceedings before the opposition division (see point 6.3 of the minutes) had been reintroduced. Hence, neither this request nor any further auxiliary request 4 should be admitted as it was late filed and could have been filed already in the opposition proceedings.

Added subject-matter - Article 76(1) EPC

Claim 1 of auxiliary request 4 related to a single-use applicator system. In the parent application, claim 255 and paragraph [0258] were the only passages disclosing a single-use applicator system. It was clear from these passages that the system was rendered a single-use device only by the configuration of its applicator to irreversibly retract the needle into the applicator. Hence, in the context of the parent application, the feature "irreversibly", which had not been included in claim 1, was not an optional feature of a single-use device but a compulsory feature. Thus, the omission of this feature constituted an unallowable intermediate generalisation.

For the person skilled in the art it was clear that "single-use", in the context of the parent application, did not mean that the applicator system was disposable or cheap. The person skilled in the art rather derived that a "single-use" device was a device that could by no means be re-used, neither accidentally nor intentionally. Hence, there was a close functional link between the features "single-use applicator" and "irreversibly retract the needle". A device that was qualified as "single use", but not by an irreversibly retractable needle, represented new technical information which was not originally disclosed.

The feature "the applicator is configured to retract the needle into the applicator" provided protection against inadvertent injuries. However, this feature did not prevent the re-use of the device.

Consequently, the omission of the feature

"irreversibly" in claim 1 constituted an unallowable intermediate generalisation. Claim 1 did not meet the requirements of Article 76(1) EPC.

Admittance of auxiliary request 5

Pursuant to Article 13(2) RPBA, auxiliary request 5, presented during the oral proceedings before the board, should not be admitted into the proceedings. The fact that the board took a different view on the feature "irreversibly" than the opposition division did not amount to exceptional circumstances justifying the late filing.

Furthermore, since there had been only three objections as to added subject-matter, including the objection against the omission of the feature "irreversibly", the proprietor could have filed this request earlier in the proceedings.

VII. The arguments of the respondent may be summarized as follows.

Auxiliary request 4

With the submission of 2 June 2017 an erroneous version of auxiliary request 4 was filed, which included dependent claim 4. As mentioned in the last sentence on page 4 of that submission, the request was intended to be exactly the same as the claims which were maintained by the opposition division.

The filing of the set of claims (without dependent claim 4) with the letter dated 1 July 2022 was a correction under Rule 139 EPC and did not constitute an amendment of the appeal case within the meaning of the

RPBA.

Thus, auxiliary request 4 should be admitted into the proceedings.

Added subject-matter - Article 76(1) EPC

It was clear from paragraph [0536] of the patent, stating "In preferred embodiments,...", that the irreversible retraction of the needle was an optional feature which did not need to be incorporated into claim 1.

"Single-use" meant that the device was intended to be used once. This could be achieved by providing a low-cost device, as mentioned in the last sentence of paragraph [0445] or by other features rendering it suitable for a single use. In fact, the second sentence of paragraph [0536] mentioned a disposable device which had to be considered synonymous to a single-use device.

Hence, there was no direct link between the irreversible retraction and the single-use characteristics. The irreversible retraction rather was a feature which served to enhance the safety of the device.

Furthermore, according to claim 1 the applicator was configured to retract the needle into the applicator. Already this feature made the device a single-use device.

Hence, claim 1 did not contravene Article 76(1) EPC.

Admittance of auxiliary request 5

Claim 1 of auxiliary request 5 included only a minor amendment overcoming the added subject-matter issue which led to the non-allowance of auxiliary request 4.

Due to the high number of objections as to added subject-matter it would not have been appropriate/efficient to file a corresponding request to address each of the objections and all the possible combinations thereof.

The opposition division considered the omission of the term "irreversible" not problematic. Hence, it was only during the oral proceedings before the board that the patent proprietor became aware of the problem.

Furthermore, auxiliary request 5 seemed to be *prima facie* allowable. The dependent claims had been deleted to streamline the proceedings.

Hence, there were exceptional circumstances justifying the late filing of this request.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to a single-use applicator system for inserting a transcutaneous sensor for measuring an analyte (e.g. glucose) into a host. The applicator system comprises a sensor 32 which is disposed within a needle 72 to be inserted into the host, a housing 14 adapted for placement on the host's skin, and an applicator configured to releasably mate with the housing. The applicator is configured to insert the needle and the sensor into the skin. Prior to insertion, the needle and the sensor are disposed

within the applicator. After insertion of the sensor, the applicator retracts the needle from the skin into the applicator. The sensor comprises electrodes (44, 46) sharing the same central axis, which is the axis of the insertion (Figure 5b).

2. Auxiliary request 4

The last sentence in the patent proprietor's statement of grounds of appeal states that auxiliary request 4 corresponds to the request allowed in the decision under appeal. Hence, it is immediately apparent that the set of claims filed as auxiliary request 4 with the submission of 2 June 2017 erroneously included dependent claim 4 which was not present in the request found allowable by the opposition division.

Therefore, the board considered auxiliary request 4 filed with submission of 1 July 2022 to be a correction under Rule 139, first sentence, EPC which was filed without delay and which introduced what was originally intended. This version of auxiliary request 4 was therefore taken into account in the appeal proceedings.

3. Added subject-matter - Article 76(1) EPC

In the parent application as filed a single-use applicator system is mentioned only in claim 255 and paragraph [0258], both being of the same tenor. In paragraph [0258], the single-use applicator system is defined as having an applicator that is configured to insert the needle and the sensor into the skin of the host, to leave the sensor transcutaneously placed within the host, and to irreversibly retract the needle into the applicator.

The term "irreversibly" has been omitted from claim 1 of auxiliary request 4.

"Single-use" in the context of medical devices does not only mean that the device is intended to be used only once, e.g. by making it relatively inexpensive.

"Single-use" in the medical field normally requires the device to be configured such that it is impossible to use it a second time, either accidentally or intentionally. Hence, contrary to the respondent's view, "single-use" cannot be equated with "disposable" since a disposable device can be re-used, although it might not be recommended.

Consistently, according to paragraph [0258] and claim 255 of the parent application as filed re-use of the applicator system is prevented because the applicator is configured to irreversibly lock the needle within the applicator. Thus, according to the parent application as filed there is an inextricable link between the features "single-use" and "irreversible retraction".

Paragraph [0536], referred to by the respondent, states that "In preferred embodiments, retraction of the needle irreversibly locks the needle within the applicator so that it cannot be accidentally and/or intentionally released, reinserted, or re-used.". This means that the applicator system is preferably a single-use device, and that it is rendered "single-use" by the irreversible retraction of the needle. Thus, this sentence also supports the close link between "irreversible retraction" and "single-use". In any case, it cannot be derived from this sentence that a single-use device could be obtained by any other means than the irreversibly retractable needle.

Consequently, the omission of the term "irreversibly" in claim 1 constitutes an unallowable intermediate generalisation. Claim 1 of auxiliary request 4 does not meet the requirements of Article 76(1) EPC.

4. Admittance of auxiliary request 5

Auxiliary request 5 was filed during the oral proceedings before the board, and thus after notification of the summons to these oral proceedings. Claim 1 of this request has been amended in that the feature "irreversibly" has been introduced. It thus constitutes an amendment of the respondent's appeal case, and is subject to the provisions of Article 13(2) RPBA, according to which such amendments shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons.

With the introduction of the term "irreversibly" the respondent reacted to the objection under Article 76(1) EPC which led to the refusal of auxiliary request 4. This objection was one of only three objections as to added subject-matter that had already been raised by the opponent in the notice of opposition. Hence, the board does not concur with the respondent that there was a high number of objections which could not be dealt with efficiently.

It is correct that the opposition division had found that the omission of the term "irreversibly" did not introduce added subject-matter (point 2.1.2 of the decision). However, the appellant maintained and repeated their objection as to the omission of this term in the statement of grounds of appeal (point 3.1

a)). Furthermore, the board indicated in its communication under Article 15(1) RPBA that this objection would have to be discussed (point 5., first paragraph).

The respondent could and should have filed auxiliary request 5 earlier in the proceedings than only in the oral proceedings before the board, and there are no exceptional circumstances justifying its late filing, as required under Article 13(2) RPBA 2020. The fact that the board came to a different conclusion on the objection regarding added subject-matter than the opposition division does not amount to exceptional circumstances justifying the late filing. It is the board's primary task to review the decision under appeal.

The respondent's argument that auxiliary request 5 should be admitted since it was *prima facie* allowable and not detrimental to procedural economy does not convince the board. Firstly, even if the board considered that auxiliary request 5 were *prima facie* allowable, this would as such not automatically amount to a cogent reason justifying exceptional circumstances for taking an amendment into account under Article 13(2) RPBA 2020. Secondly, admitting auxiliary request 5 at such a late stage of the proceedings would have been detrimental to procedural economy.

Therefore, the board exercised its discretion under Article 13(2) RPBA 2020 not to admit auxiliary request 5 into the appeal proceedings.

5. In the absence of any request in the proceedings on the basis of which the patent can be maintained, the

impugned decision has to be set aside and the patent must be revoked.

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:



D. Hampe

D. Ceccarelli

Decision electronically authenticated