

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 9 July 2025**

Case Number: T 0810/23 - 3.2.02

Application Number: 16882396.1

Publication Number: 3397142

IPC: A61B5/145, A61B5/1486

Language of the proceedings: EN

Title of invention:

TRANSCUTANEOUS ANALYTE SENSOR SYSTEMS

Patent Proprietor:

Dexcom, Inc.

Opponent:

Roche Diabetes Care GmbH

Headword:

Relevant legal provisions:

RPBA Art. 12(4)

Keyword:

Late-filed request - admitted (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0810/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 July 2025

Appellant: Dexcom, Inc.
(Patent Proprietor) 6340 Sequence Drive
San Diego, CA 92121 (US)

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

Appellant: Roche Diabetes Care GmbH
(Opponent) Sandhofer Strasse 116
68305 Mannheim (DE)

Representative: Simmons & Simmons LLP (Munich)
Lehel Carré
Gewürzmühlstraße 11
80538 Munich (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
24 February 2023 concerning the maintenance of
European Patent No. 3397142 in amended form**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor and the opponent appealed against the opposition division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings in accordance with auxiliary request 4, European patent 3 397 142 and the invention to which it related met the requirements of the EPC.

II. The board summoned the parties to oral proceedings and sent its preliminary opinion.

In that opinion it stated that the subject-matter of claim 1 of the patent as granted and of the then-pending auxiliary requests 1 to 4 was not novel over

E1: US 2016/0058470 A1,

which was prior art because the priority claim of the patent was not valid.

The board also stated that it did not intend to admit the further auxiliary requests into the appeal proceedings, because the proprietor had not explained how these requests would overcome the novelty objection. Moreover, *prima facie*, the subject-matter of their respective claims 1 did not appear patentable over E1.

III. Oral proceedings took place on 9 July 2025.

In the oral proceedings the patent proprietor withdrew its appeal, and its final requests were that the patent be maintained on the basis of one of auxiliary

requests 10 and 11, filed with the reply to the opponent's statement of grounds of appeal dated 24 November 2023.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

IV. **Claim 1 of auxiliary request 10** reads as follows (additions compared with claim 1 of the patent as granted underlined by the board):

"A sensor inserter assembly for applying an on-skin component (134, 134n, 134w, ...) to a skin (130) of a host, the sensor inserter assembly comprising:

an on-skin component (134, 134n, 134w, ...) being movable in at least a distal direction from a proximal position to a distal position,

a sensor (138) coupled to the on-skin component (134, 134n, 134w, ...),

a needle (156) configured to guide a sensor (138) into the skin of the host, wherein a distal portion of the sensor (138) is located in a channel of the needle (156),

a needle hub (162) that supports the needle (156),

a spring (234) configured to retract the needle hub (162) and the needle (156),

at least one distally-extending member (802),

a first securing feature (800, 800y, ...) configured to releasably secure the on-skin component (134, 134n, 134w, ...) in the proximal position,

wherein the first securing feature (800, 800y, ...) comprises a surface of the distally-extending member (802) configured to frictionally engage with a

corresponding structure of the on-skin component (134, 134n, 134w, ...),

a second securing feature configured to secure the

on-skin component (134, 134n, 134w, ...) in the distal position,

a telescoping assembly (132, ...) having a first portion (150, ...) configured to move distally relative to a second portion (152, ...), wherein, when the first portion (150, ...) is in a proximal starting position, the spring (234) is in a first compressed state,

wherein the first portion of the telescoping assembly (132, ...) is a pusher (150, ...) configured to move the on-skin component (134, 134n, 134w, ...) from the proximal position to the distal position, the needle hub (162) and the first securing feature (800, 800y, ...) being configured to retract in a proximal direction when the on-skin component (134, 134n, 134w, ...) has been moved to the distal position,

wherein, when the on-skin component (134) reaches the distal position, it is coupled to a base (128) and/or an adhesive patch, and

a first resistance feature (804, 804y, ...) configured to prevent movement of the on-skin component (134, 134n, 134w, ...) in a proximal direction at least when the on-skin component (134, 134n, 134w, ...) is in the distal position by creating a counterforce against the first securing feature (800, 800y, ...) as the needle hub retracts in the proximal direction, the counterforce allowing the first securing feature (800, 800y, ...) to separate from the on-skin component (134, 134n, 134w, ...),

wherein the first resistance feature (804, 804y, ...) comprises a distally-facing surface of the pusher (150, ...)".

Claim 1 of auxiliary request 11 is identical to claim 1 of auxiliary request 10 except that after the first occurrence of the expression "distally-extending" the term "member (802)" has been replaced by "leg (802)

that forms part of a securement member (800), wherein the securement member (800) is integrally formed with the needle hub (162)"; after the second occurrence of the expression "distally-extending" the term "member (802)" has been replaced by "leg (802)"; and after the first occurrence of the term "first securing feature" the expression "(800, 800y, ...)" has been deleted.

V. The proprietor's arguments, where relevant to this decision, can be summarised as follows.

Auxiliary requests 10 and 11 were to be regarded as an amendment of the proprietor's case and might be admitted only at the discretion of the board under Article 12(4) RPBA.

The board should admit these requests because the opponent had raised new objections of lack of clarity and added subject-matter during the oral proceedings before the opposition division and in its statement setting out the grounds of appeal. Auxiliary requests 10 and 11 had been filed as a reaction to these objections.

Moreover, the subject-matter of claim 1 of auxiliary requests 10 and 11 was novel and inventive over E1. This document had not been cited by the opponent against auxiliary requests 10 and 11.

Finally, the proprietor had explained that auxiliary requests 10 and 11 addressed the patentability requirements because the subject-matter of claim 1 of these requests was further restricted against the prior art. For example, as explained in the reply to the opponent's statement setting out the grounds of appeal (page 23, last sentence), the prior art did not

disclose a first securing feature which moved in a proximal direction after the on-skin component had been applied to the skin of a host, i.e. it had been moved to the distal position within the meaning of claim 1 of these auxiliary requests.

VI. The opponent's arguments, where relevant to this decision, can be summarised as follows.

The board should not admit auxiliary requests 10 and 11. In contravention of Article 12(4) RPBA, the proprietor had not provided reasons why the amendments in these requests overcame the objections raised. If the requests had been admitted, the opponent and the board would have been presented with such reasons for the first time during the oral proceedings. The opponent might have been faced with unexpected reasons and might have needed time for preparing a reaction. This would go against procedural economy.

Reasons for the Decision

1. Subject-matter of the patent

The claimed invention relates to a sensor inserter assembly for applying an on-skin component to a skin of a host.

The on-skin component is typically a glucose sensor for monitoring the blood glucose of a person (host) having diabetes mellitus.

The sensor inserter assembly comprises an on-skin component being movable in a distal direction from a proximal position to a distal position, and a pusher

configured to move the on-skin component from the proximal position to the distal position.

In the proximal position the on-skin component is typically housed in the inserter assembly, while in the distal position it is normally applied to the host's skin.

The sensor inserter assembly further comprises a first securing feature configured to releasably secure the on-skin component in the proximal position, a second securing feature configured to secure the on-skin component in the distal position and a first resistance feature configured to prevent movement of the on-skin component in a proximal direction when the on-skin component is in the distal position.

The patent generally states that the process of applying the on-skin component is important for obtaining a sensor system which is effective and user friendly (paragraph [0005]).

2. Admittance of auxiliary requests 10 and 11

Auxiliary requests 10 and 11 were first filed with the proprietor's reply to the opponent's statement setting out the grounds of appeal. Under Article 12(4) RPBA they are to be regarded as amendments to the proprietor's case and may be admitted only at the discretion of the board.

Article 12(4) RPBA requires the party submitting amendments to the patent to provide reasons why these amendments overcome the objections raised.

During the oral proceedings the proprietor withdrew all

the higher-ranking requests. Against several of these requests, however, the opponent had raised an objection of lack of novelty over E1, which the board had found convincing in its preliminary opinion and also after the discussion of these requests in the oral proceedings. This objection was first raised during the written proceedings before the opposition division.

Neither in the reply to the opponent's statement of grounds of appeal nor in any other submission prior to the oral proceedings before the board did the proprietor provide reasons why auxiliary requests 10 and 11 would overcome the objection of lack of novelty over E1. Whether the opponent had raised further objections of lack of clarity and added subject-matter during the oral proceedings before the opposition division and in its statement setting out the grounds of appeal, and whether auxiliary requests 10 and 11 had been filed as a reaction to these latter objections, is irrelevant in this respect. It is also irrelevant whether the opponent cited E1 against auxiliary requests 10 and 11. This could hardly have been done before these auxiliary requests had actually been filed.

The proprietor's argument that an explanation had been provided as to why auxiliary requests 10 and 11 addressed the patentability requirements is not convincing. The mere statement that "*this amendment further delimits the claimed subject-matter from the prior art*" in points IV-f and IV-g of the proprietor's reply to the opponent's statement setting out the grounds of appeal does not amount to reasons why auxiliary requests 10 and 11 would overcome the objection of lack of novelty over E1. The same holds true for the general statement that "*none of the*

entities identified by the OD or the Opponent in E1, E2, E3, or E9 as allegedly forming a 'first securing feature' in the sense of the granted claim 1 is disclosed to retract, i.e. move, in a proximal direction after the on-skin component has been applied to the skin of a host, i.e. has been moved to the distal position" (page 23, last sentence of the proprietor's reply to the opponent's statement setting out the grounds of appeal), especially because this was a matter of dispute between the parties and no reason was provided in support of this statement. It is also noted that the board stated, in its preliminary opinion, that the subject-matter of claim 1 of auxiliary requests 9 and 10 did not seem *prima facie* to involve an inventive step when starting from E1. The proprietor chose not to react to this assessment until the oral proceedings, i.e. the last possible occasion before a decision is normally issued.

As the opponent submitted, if auxiliary requests 10 and 11 had been admitted, the opponent and the board would have been presented for the first time during the oral proceedings with reasons why these requests met the patentability requirements over E1. This would have gone against procedural economy, the need for which is to be taken into account by the board in the exercise of its discretion whether to admit amendments under Article 12(4) RPBA. Moreover, these reasons would have constituted further amendments to the proprietor's appeal case submitted for the first time during the oral proceedings, the admittance of which would have had to be assessed under the stricter criteria of Article 13(2) RPBA.

For these reasons the board decided under Article 12(4) RPBA not to admit auxiliary requests 10 and 11 into the

appeal proceedings.

3. Since none of the proprietor's final requests is admitted into the appeal proceedings, the patent has to 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:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated