Datasheet for the decision of 13 February 2019

Case Number: T 1025/14 - 3.2.02
Application Number: 06251331.2
Publication Number: 1702641
IPC: A61B5/03, A61B5/07, A61M27/00
Language of the proceedings: EN

Title of invention:
Pressure sensing devices

Patent Proprietor:
Codman & Shurtleff, Inc.

Opponent:
RAUMEDIC AG

Headword:

Relevant legal provisions:
EPC Art. 56, 111(1)

Keyword:
Admissibility of the second auxiliary request (yes)
Remittal (no)
Inventive step (yes)
Decisions cited:
T 0839/05, T 0745/03, T 0382/96

Catchword:
Case Number: T 1025/14 - 3.2.02

DECISION
of Technical Board of Appeal 3.2.02
of 13 February 2019

Appellant: RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts (DE)

(Opponent)

Representative: Rau, Schneck & Hübner
Patentanwälte Rechtsanwälte PartGmbB
Königstraße 2
90402 Nürnberg (DE)

Respondent: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham,
Massachusetts 02767 (US)

(Patent Proprietor)

Representative: Tunstall, Christopher Stephen
Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
24 February 2014 concerning maintenance of the
European Patent No. 1702641 in amended form.

Composition of the Board:
Chairman E. Dufrasne
Members: M. Stern
S. Böttcher
Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision, posted on 24 February 2014, concerning the maintenance of European patent No. 1 702 641 in amended form.

II. The following documents are relevant for the present decision:


III. Notice of appeal was filed on 5 May 2014, and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 26 June 2014.

IV. Oral proceedings were held on 13 February 2019.

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 decision under appeal be set aside and that the patent be maintained on the basis of the second auxiliary request filed with letter dated 19 January 2015. All other requests were withdrawn.

V. Claim 1 of the second auxiliary request reads as follows (amendments to claim 1 held allowable by the Opposition Division highlighted by the Board):
"A pressure sensing ventricular catheter (10) for measuring intra-ventricular pressure in a brain comprising:

an elongate body (12) having an inner lumen (12c) extending at least partially therethrough, a distal portion having a distal end having a pressure sensor (16), at least a portion of the pressure sensor (16) being exposed to an external environment surrounding the catheter (10) such that the pressure sensor (16) is effective to measure the pressure of the external environment, wherein the pressure sensor (16) is disposed within a recess formed in an external surface of the elongate body (12);

at least one fluid-entry port (14, 34) formed in the elongate body proximal to the pressure sensor and in fluid communication with the inner lumen (12c); and

an antenna (18) coupled to the pressure sensor (16) and adapted to communicate a measured pressure from the pressure sensor (16) to an external device; characterised in that:

wherein the antenna (18) comprises a coil coupled to the pressure sensor (16) by a connector, and the coil is either:

(a) disposed around the elongate body (12); or
(b) embedded within the elongate body (12)."

Independent claims 2 to 5 of the second auxiliary request read as claim 1, replacing the highlighted expression concerning the pressure sensor (16) by the following:

- Independent claim 2: "wherein the pressure sensor (16) is embedded within the elongate body (12), and wherein the elongate body (12) includes an opening formed therein for exposing at least a portion of the pressure sensor (16) to an external environment;"
- Independent claim 3: "wherein the pressure sensor (16) is embedded within a distal tip of the elongate body (12), and wherein the portion of the pressure sensor (16) protrudes beyond the distal tip of the elongate body (12) to measure a pressure of an external environment;"

- Independent claim 4: "wherein the pressure sensor (16) is disposed within the inner lumen (12c) of the elongate body (12) and wherein the elongate body (12) includes an opening formed therein for exposing at least a portion of the pressure sensor (16) to an external environment;"

- Independent claim 5: "wherein the elongate body (12) includes a second inner lumen extending therethrough, and wherein the pressure sensor (16) is disposed within the second inner lumen of the elongate body (12), the elongate body (12) including an opening formed therein and extending into the second inner lumen for exposing at least a portion of the pressure sensor (16) to an external environment;".

Claims 6 and 7 are dependent claims.

VI. The arguments of the appellant which are relevant for the present decision may be summarised as follows:

- Admissibility and remittal

The second auxiliary request should not be admitted into the proceedings since it no longer included the limitations of the first auxiliary request and was thus a non-converging formulation of the invention. The request involved, moreover, five independent claims,
which appeared to be a delaying tactic. The proprietor was thereby formulating its requests in an abusive way, similar to the cases underlying decisions T 745/03 and T 382/96.

However, if the Board admitted the second auxiliary request into the proceedings, the case should not be remitted to the department of first instance for procedural economy, as was requested by the respondent. According to established case law, there was no absolute right of a party to have every aspect of a case examined in two instances (T 839/05).

- Inventive step

The closest prior art was given by document D14a or D14. First, it was obvious to replace the coil of D14a by a coil embedded within the elongate catheter body, as D3 disclosed such a coil in a similar pressure sensing catheter. Second, the placement of the pressure sensor as defined in independent claims 1 to 5 was rendered obvious by D14a, in particular paragraphs [0023] and [0027]. D14a disclosed (paragraph [0023]) that the pressure sensor was disposed on an external surface of the catheter or embedded within the walls and/or the cap of the catheter such that it was effective to measure the pressure surrounding the catheter. Moreover, D14a disclosed in paragraph [0027] that the pressure sensor and its wires were coated to further protect them from coming into contact with fluids. In addition, the combination of D14a and D4 rendered obvious the placement of the pressure sensor according to claim 1. Moreover, the combination of D14a and D3 rendered obvious the placement of the pressure sensor according to claim 4.
VII. The arguments of the respondent which are relevant for the present decision may be summarised as follows:

- Admissibility and remittal

The second auxiliary request had been filed on time in response to the statement of grounds of appeal. It corresponded to the first auxiliary request submitted by the proprietor during the first-instance proceedings. It was therefore part of the respondent's case replying to the statement of grounds of appeal and therefore admissible. It was true that the first auxiliary request included a limitation (concerning the cylindrical shape of the coil) which was not present in the claims of the second auxiliary request. However, there was no legal requirement that the claims of the second auxiliary request had to include it as well.

The Board was requested to remit the case to the department of first instance since the subject-matter of the independent claims of the second auxiliary request had not yet been examined and the proprietor should have the right to two levels of jurisdiction.

- Inventive step

The respondent's arguments regarding inventive step which are relevant for the present decision are essentially those on which the reasons set out below are based. In particular, the placement of the pressure sensor on the catheter elongate body as defined in claims 1 to 5 was based on an inventive step. Moreover, it was not obvious to replace the antenna of D14a by a coil embedded within the elongate catheter body. D14a related to a trimmable catheter with a wire connected
to the antenna running along the length of the catheter which could be separated from the catheter body to allow the catheter body to be cut to a required length without severing the wire. Instead, in D3, the antenna and pressure sensors were built into the catheter body at fixed locations. Therefore, D14a and D3 related to fundamentally incompatible designs that could not have been combined.

**Reasons for the Decision**

1. The appeal is admissible.

2. **The invention**

The invention relates to a pressure sensing ventricular catheter (as depicted in Figure 2) for measuring intraventricular pressure in a brain comprising an elongate body (32) having at least one fluid entry port (34) in communication with an inner lumen (32c), a pressure sensor (36) exposed to an external environment surrounding the catheter, and an antenna (38) coupled to the pressure sensor adapted to communicate a measured pressure from the pressure sensor to an external device, the antenna comprising a coil which is either disposed around or embedded within the elongate body (32). The pressure sensor is disposed at various locations on the elongate body, as shown in Figures 4 to 6 and 7A and described in paragraph [0010] of the patent, for accurately measuring a patient's ventricular pressure (paragraph [0006]).
3. **Admissibility of the second auxiliary request**

3.1 The second auxiliary request (which corresponds to the first auxiliary request submitted by the respondent during the first-instance proceedings) had been filed in reply to the statement of grounds of appeal. Following Article 12(2) and (4) RPBA, the request is therefore part of the respondent's case which is to be taken into consideration in the appeal proceedings.

3.2 The claims of the second auxiliary request include limitations concerning the pressure sensor, but do not include the limitation of claim 1 of the first auxiliary request (concerning the shape of the antenna coil). In this, the appellant saw a "lack of convergence" which rendered the second auxiliary request inadmissible.

The Board disagrees. In the present case, the two mentioned auxiliary requests correspond to merely two alternative aspects of the invention. There is no valid justification for not examining both. Moreover, the Board finds it legitimate for the respondent to replace the single independent claim of the main request by multiple independent claims in the second auxiliary request in order to secure protection for all potentially inventive subject-matter contained in the patent. This is in line with the established case law (as cited in Case Law of the Boards of Appeal, 8th edition 2016, IV.D.4.1.4 (b) and (c)). The formulation of the second auxiliary request comprising five independent claims (corresponding to, respectively, dependent claims 10 to 14 of the withdrawn main request) is in response to the objection of lack of inventive step raised against the independent claim of the main request. The mere fact
that the presence of several independent claims increases the complexity of the proceedings to some degree is per se no reason to limit the number of independent claims. The present case is therefore far from involving any abusive usage of the proceedings or delaying tactics as the appellant argued with reference to the cases underlying decisions T 745/03 and T 382/96.

3.3 The second auxiliary request is thus admissible.

4. Remittal to the first instance

4.1 Since the Board was of the opinion that the request held allowable by the Opposition Division did not fulfil the requirements of an inventive step, the Board needs to consider the second auxiliary request, which was not decided upon by the Opposition Division.

4.2 It is established case law of the Boards of Appeal that there is no absolute right of a party to have every aspect of a case examined in two instances (T 839/05). Other criteria, e.g. the general interest that proceedings are brought to a close within an appropriate period of time, are also to be taken into account by the Board when deciding whether or not to remit a case. A possible consequence of remitting the present case to the Opposition Division could be further subsequent appeal proceedings, which would unduly lengthen the proceedings. Thus, with due consideration of the need for procedural economy and to avoid further delays, the Board decides not to remit the case but to decide on it itself in accordance with Article 111(1) EPC.
5. **Inventive step**

5.1 It is not in dispute that document D14a is the closest prior art. Document D14, which is cited in paragraph [0001] of the patent, is entirely similar to D14a, with the exception that its drawings fail to include several of the reference signs mentioned in its description.

The parties agree that D14a discloses a pressure sensing ventricular catheter for measuring intra-ventricular pressure in a brain, comprising an elongate body (12) having at least one fluid entry port (paragraph [0020], last sentence) in communication with an inner lumen (12c), a pressure sensor (14) exposed to an external environment surrounding the catheter, and an antenna (18) coupled to the pressure sensor adapted to communicate a measured pressure from the pressure sensor to an external device, the antenna (18) being attached to the catheter by a wire (16) and implanted under the patient's scalp, remote from the catheter (paragraph [0026]). It is obvious to the skilled person that the antenna depicted in Figure 1 of D14a is looped and consequently comprises a coil, a fact which was not contested by the respondent.

5.2 The catheter of independent claims 1 to 5 of the second auxiliary request differs from D14a, firstly, in that the coil is disposed around or embedded within the elongate body of the catheter.

Regarding these distinguishing features, the objective technical problem to be solved is to adapt the ventricle catheter of D14a to allow an easier implantation of the catheter in the patient's brain.
Contrary to the view expressed by the respondent, the Board considers that it is obvious to replace the coil of D14a by a coil embedded within the elongate catheter body. In fact, document D3 discloses (Figures 3 and 4) a ventricular catheter (column 4, lines 52 to 55) with a pressure sensor (112) at its distal end and an antenna coil (110) embedded within the elongate catheter body (column 7, lines 62 to 65). The skilled person attempting to modify the catheter of D14a to allow an easier implantation would readily replace the remote antenna of D14a by an antenna coil embedded within the elongate catheter body as disclosed in D3. When doing so, the skilled person would obviously embed the antenna at a position along the catheter body which is compatible with the general purposes of the catheter of D14a. In particular, for the catheter to retain the property of being trimmable to a desired length indicated in D14a (paragraph [0006]), the skilled person would obviously embed the coil in the vicinity of the pressure sensor so as to avoid cutting the wire connecting the coil to the pressure sensor when trimming the catheter to a desired length. The Board therefore sees no fundamental incompatibility for the skilled person to modify the catheter of D14a based on the teaching of D3, as argued by the respondent.

5.3 Secondly, the catheters defined in independent claims 1 to 5 of the second auxiliary request differ from the catheter of D14a in that the pressure sensor is disposed on the catheter elongate body in the following ways:

(a) according to claim 1, the pressure sensor is disposed within a recess formed in an external surface of the elongate body (Figure 4 of the patent);
(b) according to claim 2, the pressure sensor is embedded within the elongate body, wherein the elongate body includes an opening formed therein for exposing at least a portion of the pressure sensor to an external environment;

(c) according to claim 3, the pressure sensor is embedded within a distal tip of the elongate body, wherein the portion of the pressure sensor exposed to an external environment surrounding the catheter protrudes beyond the distal tip of the elongate body to measure a pressure of an external environment (Figure 7A of the patent);

(d) according to claim 4, the pressure sensor is disposed within the inner lumen of the elongate body, wherein the elongate body includes an opening formed therein for exposing at least a portion of the pressure sensor to an external environment (Figure 5 of the patent);

(e) according to claim 5, the elongate body includes a second inner lumen extending therethrough, wherein the pressure sensor is disposed within the second inner lumen of the elongate body, the elongate body including an opening formed therein and extending into the second inner lumen for exposing at least a portion of the pressure sensor to an external environment (Figure 6 of the patent).

5.4 For the reasons given hereinafter, these differentiating features are not rendered obvious by the cited prior art.

5.4.1 Regarding the positioning of the pressure sensor on the catheter elongate body, D14a discloses
(paragraph [0023], third sentence from the end) that the pressure sensor (14) may be disposed on an external surface of the catheter or may be embedded within the walls and/or the cap (20) of the catheter such that it is effective to measure the pressure surrounding the catheter. Moreover, in the sentence before last of paragraph [0027], D14a discloses that the pressure sensor (14) and its wires (16) may optionally be coated to further protect them from coming into contact with fluids.

5.4.2 A pressure sensor embedded within the walls of the elongate body as disclosed in D14a is not equivalent to the sensor being disposed in a recess formed in an external surface of the elongate body, as defined in claim 1 (and depicted in Figure 4 of the patent). A sensor which is embedded within the catheter wall, as in D14a, is entirely surrounded by the wall material, whilst the placement of the sensor in a recess as claimed rules this out. The claimed feature has the advantageous technical effect of increasing the sensor's pressure sensitivity (paragraph [0006] of the patent).

Moreover, when compared to a sensor being disposed on an external surface of the catheter, as alternatively disclosed in D14a, the claimed placement of the sensor in a recess has the technical effect of avoiding an increase of the catheter dimensions in a radial direction and creating a smooth outer surface.

Document D14a does not provide any hints or suggestions to modify the disclosed features in this way.

Document D4 discloses a catheter for use in magnetic resonance imaging comprising a microchip (11) at its
distal tip, the microchip comprising a pressure sensor integrated in the tip of the catheter, in particular in its sleeve 10a (paragraphs [0042], [0047] and [0058]; Figure 8). No further specific details regarding the placement of the pressure sensor are given in D4. Particularly, no mention is made of a recess formed in an external surface of the catheter elongate body.

The Board therefore concludes that aforementioned features (a) of claim 1 are not rendered obvious by D14a, nor by the combination of D14a with D4.

5.4.3 Whilst D14a discloses the pressure sensor to be embedded within the walls of the elongate body, there is no disclosure of an opening formed therein for exposing at least a portion of the pressure sensor to an external environment, as defined in claim 2. The openings disclosed at the end of paragraph [0020] of D14a are specifically devised to allow fluid to flow into the catheter; not to expose a portion of the pressure sensor to the external environment. The claimed opening has the advantageous technical effect of allowing an improved pressure measurement of the environment around the catheter (paragraph [0006] of the patent). There is nothing in D14a which suggests this feature.

As a consequence, aforementioned features (b) of claim 2 are not rendered obvious by D14a.

5.4.4 As indicated under point 5.4.1 above, D14a discloses in paragraph [0023], third sentence from the end, that the pressure sensor may be embedded within the cap (20) of the catheter. D14a fails, however, to disclose that a portion of the pressure sensor protrudes beyond the distal tip of the elongate body to measure the pressure
of an external environment surrounding the catheter (as shown in Figure 7A of the patent). This feature has the advantageous technical effect of increasing the sensor's pressure sensitivity (paragraph [0006] of the patent). There is nothing in D14a which suggests this feature.

As a consequence, aforementioned features (c) of claim 3 are not rendered obvious by D14a.

5.4.5 It is true that in paragraph [0023], second sentence, of D14a it is said that the "(pressure) sensor 14 can be disposed on any portion of the catheter 12". This general statement does not render obvious the placement of the sensor specifically within the inner lumen of the elongate body with an opening formed therein for exposing a portion of the pressure sensor to an external environment of the catheter (as in Figure 5 of the patent).

These features are not rendered obvious by D3 either. D3 discloses a catheter for measuring the pressure of cerebrospinal fluid flowing within a catheter placed in the ventricle of the brain (column 3, lines 33 to 39; column 4, lines 52 to 58) using pressure sensors placed within the inner lumen of the catheter (column 7, lines 49 to 53; Figure 3). As shown in Figure 2 of D3, the opening at the distal end of the catheter which allows the ingress of cerebrospinal fluid from the brain ventricle into the catheter lumen is located at a considerable distance from the pressure sensors 112 in the monitoring device 104 placed at the neck of the patient. Hence, in D3 the opening is not "for exposing a portion of the pressure sensor to an external environment of the catheter", in particular "such that the pressure sensor is effective to measure the
pressure of the external environment" as claimed. These features solve the problem of accurately measuring pressure within a patient's ventricle due to blockages of the catheter lumen in a device as that of D3, as mentioned in paragraph [0005] of the patent.

As a consequence, aforementioned features (d) of claim 4 are not rendered obvious by D14a or by D14a in combination with D3.

5.4.6 D14a discloses in paragraph [0019] and Figure 2 that wires 16 coupled to pressure sensor 14 are placed in what may be considered as a second inner lumen, additional to fluid lumen 12c. D14a does not disclose, however, to dispose the pressure sensor in said second inner lumen as well, and, a fortiori, there is no mention in D14a of an opening formed in the elongate body extending into the second inner lumen for exposing a portion of the pressure sensor to an external environment. This feature has the advantageous technical effect of increasing the sensor's pressure sensitivity (paragraph [0006] of the patent).

The appellant referred, moreover, to paragraph [0027] of D14a, where it is said that wire(s) and sensor may optionally be coated. However, in this embodiment involving a coating applied onto the wire(s) and sensor, the claimed second inner lumen is missing entirely.

There is, moreover, nothing in D14a which would suggest or render obvious aforementioned features (e) of claim 5.

5.4.7 The subject-matter of independent claims 1 to 5 is consequently based on an inventive step within the
meaning of Article 56 EPC. This applies, a fortiori, to the preferred embodiments of dependent claims 6 and 7.

5.5 As confirmed by the appellant during the oral proceedings, there are no further objections against the second auxiliary request. The Board therefore concludes that the raised objections do not prejudice the maintenance of the patent on the basis of this request.
Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance, with the order to maintain the patent on the basis of:

   - claims 1 to 7 of the second auxiliary request filed with letter dated 19 January 2015;
   
   - adapted description: columns 1 to 13 filed during oral proceedings; and
   
   - figures 1 to 11 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated