

Internal distribution code:

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

**Datasheet for the decision
of 12 July 2021**

Case Number: T 1462/16 - 3.2.02

Application Number: 03734294.6

Publication Number: 1565219

IPC: A61M1/00

Language of the proceedings: EN

Title of invention:
WOUND TREATMENT APPARATUS

Patent Proprietor:
KCI Licensing, Inc.

Opponent:
Smith and Nephew, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56
RPBA 2020 Art. 12(3)

Keyword:

Novelty - (yes)

Inventive step - (yes)

Reply to statement of grounds of appeal - reasons set out
clearly and concisely (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
Fax +49 (0)89 2399-4465

Case Number: T 1462/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 July 2021

Appellant: KCI Licensing, Inc.
(Patent Proprietor) 12930 W. Interstate 10
San Antonio, TX 78249 (US)

Representative: Simmons & Simmons
City Point
One Ropemaker Street
London EC2Y 9SS (GB)

Respondent: Smith and Nephew, Inc.
(Opponent) 1450 Brooks Road
Memphis, TN 38116 (US)

Representative: Appleyard Lees IP LLP
15 Clare Road
Halifax HX1 2HY (GB)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 30 May 2016
revoking European patent No. 1565219 pursuant to
Article 101(3)(b) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Böttcher
P. Schmitz

Summary of Facts and Submissions

- I. The patent proprietor filed an appeal against the decision of the opposition division to revoke the European patent No. EP 1 565 219.

In respect of the main request the opposition division found that it did not comprise added subject-matter, was sufficiently disclosed and that the subject-matter of claim 1 was novel in view of each of D2 to D5. However, the opposition division was of the view that the subject-matter of claim 1 of the main request did not involve an inventive step in view of D1 in combination with common general knowledge as evidenced by D6 and/or in combination with D5.

- II. The appellant (patent proprietor) requested to set aside the decision and to maintain the patent on the basis of one of the sets of claims of the main request or the first auxiliary request filed with the statement of grounds of appeal dated 29 September 2016.

The respondent (opponent) requested that the appeal be dismissed.

- III. In the communication dated 25 March 2021 the Board provided their provisional opinion and considered the objections of the respondent to the main request unconvincing.

In reply to the communication of the Board the respondent did not file any further arguments on the merit of the case but merely, with letter dated 23 April 2021, withdrew the request for oral proceedings

that had been submitted with the reply to the statement of grounds.

IV. The following documents are referred to by the parties:

- D1 WO 01/37922
- D2 US 3,831,588
- D3 US 4,342,218
- D4 US 4,886,070
- D5 DE 9105742 U1
- D5a English translation of D5
- D6 Instrument Engineer's Handbook, Fourth Edition, Process Measurement and Analysis, Volume 1, pages 108 to 113 (Liptak et al., 2003)

V. Claim 1 of the main request corresponds to the main request filed during the opposition proceedings and reads as follows:

"A method for calibrating a control unit adapter to provide a negative pressure through a vacuum wound bandage associated with a wound of a patient, the method comprising

positioning a first pressure sensor in communication with the control unit,

correlating a first output of a second pressure sensor of the control unit to a first calibration pressure when the first pressure sensor senses the first calibration pressure, and

correlating a second output of the second pressure sensor to a second calibration pressure when the first pressure sensor senses the second calibration pressure."

VI. The arguments of the appellant, as far as relevant for the decision, can be summarised as follows:

Main request - inventive step

Since D1 related to the provision of negative pressure to treat wounds, the objective technical problem should have been stated as "how to modify the teaching of D1 to achieve more accurate pressure readings and control of negative pressure".

The calibration method of claim 1 was in relation to negative pressures, not positive pressures.

The calibration techniques in the prior art were only applicable to positive pressures and there was no suggestion of any method of calibrating a negative pressure sensor.

D6, which was used by the opposition division to exhibit the common general knowledge, was directed to positive pressure sensors. Hence, D6 could not teach the person skilled in the art how to calibrate a negative pressure sensor.

D5 disclosed a very specific calibration technique for intracranial pressure sensors. Such a system would not be considered by the person skilled in the art to contain any disclosure of how to calibrate the pressure sensors of D1.

Therefore, the subject-matter of claim 1 did not lack an inventive step.

VII. The arguments of the respondent, as far as relevant for the decision, can be summarised as follows:

Main request - added subject-matter

Claim 1 had been amended during opposition proceedings to state that it was the first pressure sensor that sensed the second calibration pressure and not the second sensor. This amendment was not directly and unambiguously derivable from the passage referred to by the patent proprietor in making this amendment (page 29, lines 9 to 11). First, the omission of the features "user observation" and "user operated control" mentioned in that passage constituted an unallowable intermediate generalisation. Furthermore, the terms "first" and "second" pressure sensor were not used in the application as originally filed.

Main request - lack of novelty

The term "for" in claim 1 had to be interpreted as "suitable for". Hence, any method of calibrating a pressure sensor having the same method steps would anticipate the subject-matter of claim 1. Since each of D2 to D5 disclosed such a method, the subject-matter of claim 1 lacked novelty over D2 to D5.

Main request - lack of inventive step over the combination of D1 and the common general knowledge as described in D6

D1 represented the closest prior art since it related to the same technical field as the patent in suit, namely, wound treatment by applying negative pressure.

The subject-matter of claim 1 differed from D1 in that it defined a method of calibration using a further pressure sensor which sensed first and second calibration pressures.

The objective technical problem to be solved was how to achieve more accurate pressure readings and control of pressure.

It would be obvious to the person skilled in the art that machinery that measures pressure had to be calibrated to ensure that the readings given by the machinery were correct. Furthermore, the person skilled in the art would know that the term "calibration" indicated the steps as defined in claim 1, namely, to apply one or more known pressure values to the system, to compare the measured output from the system to the known values, and to adjust the system until the known values and the measured values match.

D6 described a method for calibrating pressure sensors comprising the same steps as those recited in claim 1 (page 111, column 1, paragraph 2; Figures 1.8g and 1.8h). Hence, the calibration steps of claim 1 belonged to the common general knowledge at the priority day of the patent.

Moreover, the disclosure of D6 would motivate the skilled person to apply calibration steps to pressure sensors, since it was mentioned that accuracy of a pressure sensor could be ensured by calibration (page 108, column 1). Hence, it would be obvious to the person skilled in the art to modify the method of D1 to use a further pressure sensor which senses first and second calibration pressures.

Hence, the subject-matter of claim 1 lacked an inventive step over the combination of D1 and the common general knowledge as described in D6.

Main request - lack of inventive step over the

combination of D1 and D5

D5 was from the same technical field of medical devices and related to a method for measuring and calibrating a pressure sensor using a first pressure and an atmospheric pressure. D5 disclosed the features which were missing from D1.

Since D5 also mentioned the necessity and the advantages of the calibration of a sensor (D5a, page 1, line 8; page 2, line 8, and page 2, line 18), the person skilled in the art would apply the teachings of D5 to the method of D1.

Hence, the subject-matter of claim 1 lacked an inventive step over the combination of D1 and D5.

Reasons for the Decision

1. The invention relates to a method for calibrating a control unit adapted to provide a negative pressure through a wound bandage.

Applying a negative pressure or vacuum to a wound may promote healing by drawing out exudate, which might contain dirt and bacteria, from the wound.

In a preferred embodiment, a negative pressure wound treatment apparatus comprises a waste canister 26 into which the wound exudate is drawn via an evacuating tube 20 (Figure 1). A vacuum pump 110 creates the negative pressure that is present through canister 26. A

pressure sensor 124 is arranged in line 128 extending from canister 26. This sensor measures the negative pressure that is present in the canister and provides feedback to the controller 50 (Figure 5).

In order to calibrate this pressure sensor, as described at page 28, line 3, to page 29, line 18 (reference is made to the application as published), two outputs of the sensor 124 are correlated to two calibration pressures which are measured by a further (reference) pressure sensor 1038. The further sensor 1038 is also positioned in communication with the interior of the canister. It is essential that both pressure sensors are exposed to the same calibration pressure. When the first calibration pressure (e.g. atmospheric pressure) is measured and indicated by pressure sensor 1038, the output of sensor 124 is stored and thereby correlated to the first calibration pressure. Then a second (different) calibration pressure is established in the canister and measured by sensor 1038. Again the respective output of sensor 124 is stored and correlated to the second calibration pressure. The calibration process is completed once the second calibration setting is obtained.

2. Main request - Interpretation of claim 1

In the communication dated 25 March 2021, point 3, the Board explained their interpretation of the claim. The parties did not dispute this interpretation.

Claim 1 obviously includes a typing error. The term "adapter" should read "adapted", as in claim 1 as originally filed and on page 1, line 32, of the description as originally filed.

Contrary to the description, which mentions the calibration of the pressure sensor 124 (column 22, lines 45 to 46, and lines 55 to 57), the claim mentions the calibration of a control unit. However, it is technically not feasible to calibrate a control unit, since only a device that delivers measurement values can be calibrated. Actually, the device which is calibrated in the present invention is the pressure sensor 124 which is connected and provides feedback to the control unit (column 9, lines 39 to 42). Hence, the person skilled in the art understands the claimed method as calibration of a pressure sensor of a control unit.

Consequently, claim 1 relates to a method for calibrating a pressure sensor of a control unit, wherein the control unit is adapted to provide a negative pressure to a wound.

3. Main request - added subject matter

In the communication dated 25 March 2021, point 2, the Board noted that the respondent's submission did not include any reference to the reasons given in the appealed decision, contrary to the requirements of Article 12(3) RPBA 2020. The respondent did not dispute this view.

In fact, in the reply to the statement setting out the grounds of appeal the respondent essentially repeated the arguments submitted in the first-instance proceedings, without submitting arguments as to why the reasons given by the examining division in respect of the objection raised under Article 123(2) EPC were wrong or not persuasive. The Board cannot see any such arguments either and, hence, there is no reason to

depart from the findings of the opposition division in respect of Article 123(2) EPC.

4. Main request - novelty

In the respondent's view, the term "for" in claim 1 has to be interpreted as "suitable for".

As already indicated in the communication dated 25 March 2021, point 4.1, the Board agrees with the opposition division, that the feature "for calibrating a [pressure sensor of a] control unit adapted to provide a negative pressure" is a functional method feature comparable in category with the other features (steps) of the method.

D2 to D5 all relate to methods for calibrating pressure sensors. The methods disclosed in D2 to D5 are based on the correlation of the output of a sensor with two (or more) reference values. However, the pressure sensors disclosed in D2 to D5 are not pressure sensors of a control unit adapted to provide a negative pressure to a wound. Hence, none of these documents discloses a method for calibrating a [pressure sensor of a] control unit adapted to provide a negative pressure.

Therefore, the subject-matter of claim 1 is novel over D2 to D5.

5. Main request - inventive step

5.1 The opposition division held that the subject-matter of claim 1 lacked an inventive step starting from D1 in combination with common general knowledge as evidenced by D6 or in combination with D5.

5.2 D1 is a patent application from the same inventors as in the present patent. It discloses a very similar negative pressure wound treatment apparatus with a pressure sensor 124, which is connected to a control unit 50 (Figure 5). However, it does not relate to possible problems concerning the accuracy of the sensor readings and it does not mention calibration of this pressure sensor. In fact, D1 does not disclose any of the method steps of claim 1.

Consequently, contrary to the respondent's view and as explained in the Board's communication dated 25 March 2021, point 5.1, there is nothing in D1 that would prompt the person skilled in the art to consider the technical problem of providing "more accurate pressure readings and control of pressure" (as defined by the opposition division in point 2.5.5 of the appealed decision). There is also nothing in the prior art referred to that would prompt the person skilled in the art to consider solving this problem by implementing a calibration method, and even less the specific calibration method of claim 1.

5.3 D6 is an excerpt from an engineer's handbook relating to calibration of pressure sensors. Firstly, as pointed out by the appellant, D6 concerns positive pressure sensors. Hence, D6 could not teach the person skilled in the art how to calibrate a negative pressure sensor.

Moreover, D6 discloses that the pressure sensor to be calibrated is connected to a calibration system that consists of a programmable pressure source and a computer (page 111, left hand column, 2nd paragraph; Figure 1.8g). The pressure source produces several known reference pressures that are applied to the sensor being calibrated. As pointed out by the Board in

the communication dated 25 March 2021, point 5.2, it cannot be derived that the calibration system comprises a reference pressure sensor (i.e. the first pressure sensor in the wording of claim 1).

Furthermore, as also explained in the communication of 25 March 2021, point 5.2, in D6, the control unit (computer) used for the calibration is part of the calibration system that is applied to the sensor to be calibrated, whereas in claim 1 the control unit used for the calibration belongs to the negative pressure treatment apparatus to which also the pressure sensor to be calibrated belongs.

It follows that D6 does not disclose the step "positioning a first pressure sensor in communication with the control unit".

- 5.4 The same applies to D5, which also discloses a calibration system for calibrating an external pressure sensor. This system comprises a reference sensor 19, a pump 21 and a control unit 37, and can be connected to an external pressure sensor 13 which is to be calibrated (Figure 3, page 4, lines 1 to 4 and lines 13 to 19; page 5, lines 1 to 5). Hence, as pointed out in the Board's communication, point 5.3, the calibration system of D5 also uses "its own" control unit (to which the reference sensor is already connected) and not the control unit of the negative pressure treatment apparatus to which also the pressure sensor to be calibrated belongs.

Hence, D5 does not disclose the step "positioning a first pressure sensor in communication with the control unit" either.

5.5 Hence, even if the person skilled in the art was prompted to implement a calibration method in the device of D1, neither the common general knowledge as exemplified in D6 nor the teaching of D5 would lead to the method of claim 1 because none of these documents discloses all the method steps of claim 1.

Consequently, the subject-matter of claim 1 involves an inventive step.

6. Amendment of the description

Paragraph [0004] of the description has been amended to align with claim 1 of the main request.

The Board does not have any objections against this amendment. The respondent did not raise any objections either.

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 as amended in the following version:

Claims:

No. 1 to 17 according to the main request filed with the letter of 29 September 2016

Description:

paragraphs [0001] to [0003] and [0005] to [0119] of the patent specification and paragraph [0004] filed with letter of 5 May 2021

Drawings:

Figures 1 to 48 of the patent specification.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated