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Datasheet for the decision of 19 August 2021

Case Number: T 1804/16 - 3.2.02

Application Number: 09792808.9

Publication Number: 2331162

IPC: A61M1/00

Language of the proceedings: EN

Title of invention:
SYSTEM FOR USING MICRO-ELECTRO-MECHANICAL SYSTEMS (MEMS) TO HEAL WOUNDS

Patent Proprietor:
KCI Licensing, Inc.

Opponent:
Smith and Nephew, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56, 83, 123(2)

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It can be changed at any time and without notic

Keyword:
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - extension beyond the content of the application as filed (no)

Decisions cited:

Catchword:

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Case Number: T 1804/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 August 2021

Appellant: (Opponent)	Smith and Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	Appleyard Lees IP LLP 15 Clare Road Halifax HX1 2HY (GB)
Respondent: (Patent Proprietor)	KCI Licensing, Inc. P.O. Box 659508 San Antonio, TX 78265 (US)
Representative:	Simmons & Simmons City Point One Ropemaker Street London EC2Y 9SS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 May 2016 rejecting the opposition filed against European patent No. 2331162 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	W. Sekretaruk

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the opposition division to reject the opposition against European patent number 2 331 162.

The opposition division decided that the subject-matter of the claims as granted did not extend beyond the content of the application as filed, that the invention was sufficiently disclosed and that the subject-matter of the claims as granted involved an inventive step.

II. Oral proceedings before the Board were held on 19 August 2021.

III. The appellant (opponent) requests that the decision under appeal be set aside and that the patent be revoked.

IV. The respondent (patent proprietor) requests, as a main request, that the appeal be dismissed, or, alternatively, that the patent be maintained in amended form on the basis of any of the first or second auxiliary requests as filed with the submission dated 8 March 2016.

V. Claim 1 of the main request reads as follows:

" A reduced pressure delivery system for treating a tissue site of a patient, comprising:
a reduced pressure dressing (110), the reduced pressure dressing including a manifold and a drape (112);
electromechanical components configured to apply a treatment to the tissue site of the patient;
a processing unit (406) in communication with said

electromechanical components, and configured to cause said electromechanical components to activate to apply or alter the treatment to the tissue site;
at least one conduit (204) configured to deliver the treatment to the tissue site;
a micro-electro-mechanical system (MEMS) device (216) configured to sense one or more characteristics of exudate fluid from the tissue site, and further configured to communicate data indicative of the sensed one or more exudate fluid characteristics, said processing unit (406) further configured to receive the data from said MEMS device (216) and cause said electromechanical components to apply the treatment to the tissue site of the patient via said at least one conduit (204); and
an electronic display (312) in communication with said processing unit (406), said processing unit further configured to generate and display a graphical user interface (GUI) on said electronic display (312), the GUI including an indicia representative of a characteristic level of the exudate fluid from the tissue site;
said processing unit further being configured to (i) determine whether the one or more characteristics of the exudate fluid crosses a minimum or maximum threshold value and (ii) generate an alarm signal in response to determining that the one or more characteristics of the exudate fluid crosses a minimum or maximum threshold value;
said processing unit (406) further being configured to store a preset value for at least one of the minimum and maximum threshold values; and
said processing unit (406) further being configured to alter at least one of the minimum and maximum threshold values from the preset value in response to receiving

input from a caregiver via the GUI."

VI. In the present decision, reference is made to the following documents:

D1: WO 2008/040020
D5: Extract from Wikipedia, "Microelectromechanical systems" published 28 September 2008
D7: WO 2004/071279

VII. The arguments by the appellant can be summarised as follows:

Main request - Sufficiency of disclosure

The patent did not enable the person skilled in the art to carry out the invention since none of the embodiments described in the patent exemplified the subject-matter of claim 1. In particular, the paragraphs referred to by the opposition division in point 2.1 of the decision related to different embodiments of the invention.

Furthermore, the electromechanical components were not sufficiently disclosed since paragraphs [0033] and [0044] did not describe which of the components were required and how they should be arranged or controlled.

Main request - Added subject-matter

According to paragraph [0042] of the application as filed, only the alarm module, which was executed by the processing unit, and not the processing unit itself was able to perform the function of features (i), (ii) and (iii) (mentioned in point 1.1 of the decision). Hence, the feature "the processing unit being configured to

generate an alarm signal..." of claim 1 included added subject-matter.

According to paragraph [0047] of the application as filed, the processing unit was configured with threshold values. From this it could not be derived that the processing unit was configured to store these values. The application as originally filed only disclosed a storage unit for storing data (paragraph [0033]). Hence, the feature that the processing unit was configured to store a preset value for the threshold values could not be derived from the application as originally filed.

Paragraph [0047] in the application as filed only disclosed receiving input via a menu on the graphical user interface (GUI), not via the GUI itself. Hence, the feature "receiving input (...) via the GUI" of claim 1 constituted an unallowable intermediate generalisation.

Paragraphs [0025], [0031] and [0032], referred to in the decision as providing basis for the amendments of claims 10 and 11, described different embodiments. Paragraph [0025] related to the embodiment shown in Figure 2, whereas paragraphs [0031] and [0032] related to the embodiment shown in Figure 3. Thus, the subject-matter of claims 10 and 11 could not be derived directly and unambiguously from the application as filed.

Main request - Inventive step

D1 could be considered to represent the closest prior art.

From the three distinguishing features mentioned at point 5.3 of the decision the first one, concerning the MEMS-device, was known from D5.

The second feature, relating to the generation of an alarm signal, was also disclosed in D1. At page 34, first paragraph, it was mentioned that it was possible to adjust the amount of flow or the pH of the solution. This required implicitly a signal to indicate that something wasn't correct. Such a signal could be considered as an alarm signal.

The third feature, concerning the adjustment of the threshold values, was known from D7. In paragraph [0090] it was mentioned that the threshold could be preset manually. Hence, the thresholds could be altered. Since D1 disclosed a GUI, it was implicit that this was done via input from a GUI.

Furthermore, the fourth distinguishing feature mentioned by the patent proprietor (page 3 of the reply to the statement of grounds of appeal, third paragraph), i.e. the display of an indicia representative of the characteristic value on the GUI, was obvious from D1. Since in D1 the pH of the solution at the wound dressing was measured, and since the device of D1 included a GUI, the display of this value on the GUI suggested itself.

The distinguishing features related to two partial problems. The first problem, the provision of a more compact system, was solved by using a MEMS device in an obvious way, in view of the common general knowledge and D5.

The second to fourth features could be considered to

solve the problem of providing personalized monitoring of the performance of the reduced pressure system.

The parameter to be monitored was not necessarily a chemical characteristic, but could as well be a physical characteristic of the fluid, e.g. the pressure or the flow rate. Hence, the problem to be solved did not relate to the healing process.

The solution to the second problem was obvious in view of D1 and D7, since D7 disclosed to alter the threshold values, and the generation of an alarm signal and the display of the characteristic value on the GUI was suggested by D1.

Thus, the subject-matter of claim 1 lacked an inventive step.

VIII. The arguments by the respondent can be summarised as follows:

Sufficiency of disclosure

The allegation that the features of claim 1 were not disclosed in a single embodiment did not amount to a valid objection under Article 83 EPC.

With regard to the electromechanical components, the description provided sufficient disclosure, particularly in combination with the common general knowledge of the person skilled in the art, to implement the claimed invention.

Added subject-matter

Paragraph [0042] of the application as filed set out

that the alarm module was part of the processing unit, rather than a separate distinct entity.

Paragraph [0047] gave basis for the feature that the processing unit was configured to store a preset value, since "configured to" meant the same as "stored". Furthermore, "configured to store" covered storing in a storage unit.

The feature concerning user input via a GUI found basis in the disclosure of a GUI which could be combined with the set characteristics module 450.

Hence, claim 1 did not include added subject-matter.

Claims 10 and 11 found basis in paragraphs [0025], [0031] and [0032]. Figures 2 and 3, referred to in these paragraphs, did not relate to separate embodiments.

Hence, claims 10 and 11 did not include added subject-matter, either.

Inventive step

In addition to the three distinguishing features mentioned in the decision, D1 did not disclose the feature "the GUI including an indicia representative of a characteristic level of the exudate fluid from the tissue site".

The objective technical problem to be solved by the distinguishing features was to facilitate personalised monitoring of the healing process of a wound under reduced pressure treatment.

None of the distinguishing features was disclosed or rendered obvious by D1. In fact, D1 related to a system for use at the patient's home, which was supervised by a caregiver via a processing unit that was situated at a remote location. Furthermore, the GUI mentioned in D1 was arranged on the solution generator and not on the treatment device. Hence, the person skilled in the art would not use the GUI of D1 to display a characteristic value of the wound exudate.

Starting from the remote controlled system of D1, the person skilled in the art would not consult D7, since D7 related to a system with controls at the treatment device. Furthermore, D7 did not disclose the feature concerning the altering of the threshold values, but mentioned only the manual preset of the alarm threshold (paragraph [0090], last sentence).

Therefore, the subject-matter of claim 1 involved an inventive step over a combination of D1 and D7.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to a reduced pressure delivery system for treating a tissue site (e.g. a wound) of a patient. In addition to the usual components (wound dressing, electromechanical components (e.g. reduced pressure pump), reduced pressure conduit) the system

includes a MEMS (micro-electro-mechanical system) device for sensing one or more characteristics of the fluid aspirated from the wound. The sensed data is transmitted to a processing unit which displays the measured characteristic of the exudate fluid on a graphical user interface and determines whether the measured characteristic crosses a minimum or maximum threshold value. If so, an alarm is generated. The preset threshold values are stored by the processing unit and can be altered by a caregiver via the graphical user interface (GUI).

2. Main request - Sufficiency of disclosure

The Board agrees with the opposition division that the patent provides several examples which enable the person skilled in the art to carry out the claimed invention without undue burden.

It is noted that the disclosure of features of the invention in (possibly) different embodiments does not render the invention insufficiently disclosed, in particular since the embodiments are not mutually exclusive.

The electromechanical components for applying reduced pressure treatment are mentioned in paragraphs [0033] and [0044] of the patent. Based on this teaching, it is within the common general knowledge of the person skilled in the art to select the appropriate components for the negative pressure delivery.

Consequently, the invention is sufficiently disclosed to be carried out by a person skilled in the art.

3. Main request - Added subject-matter

3.1 Claim 1

According to paragraphs [0042] and [0047] of the application as filed, the alarm module is software that is executed by the processing unit. Hence, it is directly and unambiguously disclosed in the application as originally filed that the processing unit itself is configured to perform the functions of features (i), (ii) and (iii) mentioned in the appealed decision (point 1.1), namely:

"(i) said processing unit further being configured to store a preset value for at least one of the minimum and maximum threshold values;
(ii) said processing unit further being configured to determine whether the one or more characteristics of the exudate fluid crosses a minimum or maximum threshold value;
(iii) said processing unit further being configured to alter at least one of the minimum and maximum values from the preset value in response to receiving input from a caregiver".

The Board agrees with the Opposition Division that "configured with thresholds" (paragraph [0047]) means that the threshold values have to be stored by the processing unit. Even if the threshold values are stored in a storage unit, the corresponding commands are given by the processing unit, which is therefore "configured to store" them.

The omission of the feature "menu" (mentioned in paragraph [0047]) in feature (iii) does not add subject-matter because this feature is not inextricably

linked to the processing unit being configured to alter the threshold values upon input by a caregiver. It is explicitly disclosed at page 15, first sentence, that in setting the thresholds the module may provide a menu. Hence, the thresholds could as well be set by alternative means, e.g. by direct input.

Hence, claim 1 meets the requirements of Article 123(2) EPC.

3.2 Claims 10 and 11

It is true that paragraphs [0025] (relating to the position of the MEMS device) and [0031] to [0032] (relating to the kind of characteristic measured) refer to different figures (Figures 2 and 3). However, contrary to the appellant's submissions, there is no indication that these figures, which show different views of a dressing, and the corresponding paragraphs in the description relate to different embodiments. Hence, the disclosure of these paragraphs in combination can be regarded as a basis for claim 10.

Claim 11 finds basis in paragraph [0032] alone (lines 25 to 28).

Therefore, claims 10 and 11 do not contain subject-matter extending beyond the content of the application as originally filed.

4. Main request - Inventive step

4.1 It is undisputed that D1 represents the closest prior art.

D1 relates to a system for infusing a wound with a

wound treatment solution and for optionally applying negative pressure to a wound. Both treatments may be applied simultaneously but they may also be applied independently. The wound treatment solution can be prepared by an electrochemical generator.

4.2 D1 does not disclose the following features of claim 1:

(i) a MEMS device configured to sense one or more characteristics of exudate fluid from the tissue site;

(ii) the processing unit configured to generate an alarm signal in response to determining that the one or more characteristics of the exudate fluid crosses a minimum or maximum threshold value;

(iii) the processing unit configured to alter at least one of the minimum or maximum threshold values from the preset value in response to receiving input from a caregiver via the GUI;

(iv) the GUI including an indicia representative of a characteristic level of the exudate fluid from the tissue site.

4.3 As to feature (ii), the Board does not share the appellant's view that the instructions to adjust parameters of the electrolysed solution mentioned at page 34, first paragraph, imply the generation of an alarm signal. Said instructions, generated by a remote computer and directed to the controller, do not require an interaction with the user and the generation of the alarm directed to said user.

4.4 All the distinguishing features contribute to provide for the effect that the infection status and the healing of the wound can be assessed continuously and in a personalised way by a caregiver. This applies also to feature (i), since the MEMS device is configured to sense one or more characteristics of the exudate fluid.

Hence, the objective technical problem to be solved may be regarded as to allow for personalised monitoring of the healing process of a wound under reduced pressure treatment.

Since the distinguishing features relate to a characteristic of the exudate fluid from the tissue site, the Board does not concur with the appellant's view that the problem to be solved concerns the monitoring of the performance of the system.

4.5 The objective technical problem is not addressed in D1, which rather relates to controlling the irrigation treatment.

4.6 Contrary to the appellant's view feature (iv) is not rendered obvious by D1. The passage at page 44, 1st paragraph, of D1 does not refer to the pH of the exudate fluid, but rather to the pH of the electrolyzed solution that is prepared by the generator and delivered to the wound. Hence, the target value of the pH is displayed (and can be changed by the user), and not the actual value. This target value cannot be regarded as a "characteristic level of the exudate". Thus, D1 does not prompt the person skilled in the art to modify the device of D1 such that the actual value of a characteristic level of the exudate fluid is displayed on the GUI, in particular since the GUI is

arranged on the electrolysed solution generator and displays controls relating to the production of the solution.

4.7 D7 relates to a surgical drain having at least one sensor for monitoring the condition of the anatomical site or fluid emitted from the site (abstract). The sensed parameter is shown on a display (GUI) (paragraph [0100]). From the sensed physiological condition (e.g. color, temperature) of the tissue the physician can determine the general health of the tissue (paragraphs [0076] to [0081]). The system may include an alarm which is triggered when an abnormality is detected. A manual preset of the alarm threshold (paragraph [0090], last two sentences) is possible.

Since D7 does not relate to personalised monitoring of the healing of a wound, the person skilled in the art would not turn to D7 in order to solve the problem posed. Moreover, even if they did so, they would not arrive at a system according to the invention. The fact that the alarm threshold of D7 can be manually preset does not imply that the processing unit is configured to alter at least one of the alarm threshold values from the preset values in response to receiving input from the caregiver via the GUI, as stipulated by distinguishing feature (iii).

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

5. From the above it follows that none of the objections raised prejudices the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated