

Internal distribution code:

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

**Datasheet for the decision
of 19 June 2019**

Case Number: T 1843/14 - 3.2.02

Application Number: 10155630.6

Publication Number: 2204213

IPC: A61M27/00, A61M1/00

Language of the proceedings: EN

Title of invention:

Control of vacuum level rate of change

Patent Proprietor:

KCI Medical Resources Unlimited Company

Opponent:

Smith and Nephew, Inc.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 100(a), 100(c)

Keyword:

Grounds for opposition - subject-matter extends beyond content
of application or earlier application as filed (no)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

T 0304/08

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 1843/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 June 2019

Appellant: KCI Medical Resources Unlimited Company
(Patent Proprietor) Zephyr House
122 Mary Street
Grand Cayman (KY)

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: HGF Limited
Saviour House
9 St. Saviourgate
York YO1 8NQ (GB)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 26 June 2014
revoking European patent No. 2204213 pursuant to
Article 101(3) (b) EPC**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
S. Böttcher

Summary of Facts and Submissions

- I. The patent proprietor has appealed against the Opposition Division's decision, despatched on 26 June 2014, to revoke European patent No. 2 204 213. The main request was not allowed for lack of novelty of the subject-matter of claim 1.

- II. The patent in suit is derived from a divisional application of European patent application 02 746 951.9. The divisional application as originally filed comprises the description, claims and figures of the parent application as originally filed.

- III. The patent derived from the parent application was opposed and was the subject of appeal proceedings in case T 2039/12, which ended with its revocation.

- IV. Notice of appeal was filed on 21 August 2014. The appeal fee was paid on the same day. A statement setting out the grounds of appeal was received on 27 October 2014.

- V. Oral proceedings took place on 19 June 2019.

- VI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed with letter dated 24 October 2014.

- VII. The respondent requested that the appeal be dismissed.

The objection of insufficiency of disclosure, raised in a letter dated 20 February 2015, was withdrawn in the oral proceedings.

VIII. The following documents are mentioned in the present decision:

D1: WO-A-01/37922

D2: EP-A-0 880 953

IX. **Claim 1 of the main request** reads as follows:

"A controller (20) for regulating a negative pressure provided to a wound bed (22) of a patient through a vacuum bandage (28) fluidly coupled to a vacuum source (110), the controller (20) comprising:

a regulator configured to regulate the negative pressure provided at the wound bed (22) by the vacuum bandage (28) and vacuum source (110) in response to a pressure regulation signal,

a pressure transducer (124) positioned to detect the negative pressure at the wound bed (22) and provide a pressure signal indicative of the negative pressure at the wound bed (22),

setpoint (312) circuitry configured to provide a setpoint signal indicative of a desired negative pressure at the wound bed (22), and

control circuitry electrically coupled to the pressure transducer (124), the setpoint circuitry (312) and the regulator,

characterised in that the control circuitry generates the pressure regulation signal in response to the pressure signal and setpoint signal to control the rate of change of negative pressure at the wound bed (22) while adjusting the negative pressure at the wound bed (22) to the desired negative pressure, the regulator comprising an electrically actuated valve fluidly coupled to the bandage (28) and the vacuum source (110) and electrically coupled to the control circuitry, and the valve being a proportional valve."

Claim 2 is a dependent claim.

- X. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

Added subject-matter

The subject-matter of claim 1 of the main request was based on claims 7, 9 and 10, and claim 1 and page 3, lines 26 to 29 of the parent application as originally filed. Claim 1 and the passage in the description of the parent application provided a specific basis for introducing the feature of the control circuitry generating the pressure regulation signal to control the rate of change of the negative pressure at the wound bed.

Novelty

D1 did not disclose a controller that generated a signal to control the rate of change of negative pressure provided to a wound bed, as required by claim 1 of the main request. It was clear from page 10, lines 4 to 8 that the controller of D1 regulated the actual negative pressure but not its rate of change.

The same distinction was present over D2, which disclosed a controller opening a mechanical valve over a predetermined time (column 7, lines 42 to 47). This could have an impact on (in particular reduce) the rate of change of the negative pressure provided to a wound bed, but it did not amount to a control of that rate of change, which depended on further, non-monitored parameters. A control implied feedback, which was not present in D2.

Inventive step

A distinguishing feature of the subject-matter of claim 1 of the main request over each of D1 and D2 was the provision of the pressure regulation signal to control the rate of negative pressure at the wound bed. That feature was a solution to the problem of providing an improved system for controlling the negative pressure at the wound bed. Since none of the available prior art disclosed such a solution, the subject-matter of claim 1 of the main request was inventive.

- XI. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

Added subject-matter

Claim 1 of the main request included the term "control the rate of change" whereas claim 1 of the application as filed and claim 7 of the parent application as filed included "limit the rate of change". Control meant something different from limit. The thrust of the application as filed was to limit the rate of change so as to prevent pain to a patient. Page 3, lines 26 to 29 of the application and the parent application as filed disclosed a control to achieve the effect of reducing patient discomfort. That effect was only possible if the control was in respect of a maximum limit of the rate of change of the negative pressure. In omitting that necessary limit, claim 1 of the main request disclosed methods of control other than limiting and therefore added subject-matter compared with the application or the parent application as filed.

Novelty

D1 was novelty-destroying for the subject-matter of claim 1 of the main request. Specifically, the wording "to control the rate of change of negative pressure" in the claim was of much broader scope than the specific examples of the patent and could be interpreted in many ways. Controlling something did not mean that it had to be monitored or that an algorithm using additional parameters had to be provided. The wording could mean that the intention behind generating the pressure regulation signal was to control the rate of change. However, the reason the signal was generated was irrelevant in deciding whether the invention was novel over the prior art, as held in decision T 304/08. Alternatively, the wording could mean that the effect of generating the pressure regulation signal was to control the rate of change of the negative pressure. D1 disclosed a control system that used the same physical configuration as the controller of the patent. In particular, it disclosed a proportional valve of the same kind as the valve used in the control system of the patent to control negative pressure levels (page 10, lines 8 to 11 of D1). Since the physical configuration of the control system of the patent was the same as in D1, the effect would also be the same. It followed that the pressure regulation signal provided by the controller of D1 inevitably controlled the absolute negative pressure as well as - at least to some extent - the rate of change of the negative pressure at the wound bed by controlling the pressure at numerous moments in time.

D2 was also novelty-destroying for the subject-matter of claim 1 of the main request. In particular, D2 disclosed a programmable system (column 8, lines 29 to

37) for controlling the rate of change of negative pressure at a wound bed. The system used pressure valves to be opened slowly to avoid patient pain (column 7, lines 42 to 51 and Figure 3). This inevitably amounted to a control of the rate of change of the negative pressure as defined in claim 1 of the main request.

Inventive step

The skilled person would not have any difficulty in implementing the controller of D1 such that it controls the rate of change of negative pressure at the wound bed. The problem to be solved was reducing patient discomfort. Faced with that problem the skilled person would operate the proportional valve of D1 to ensure that the negative pressure value changed slowly, by providing a signal to control the rate of change. D2 started from the same observation as in the patent that a rapid change in pressure level caused discomfort to patients. The skilled person would implement the control of D2 in the apparatus of D1. Figure 3 of D2 disclosed a pressure control over time that came very close to the control of the rate of change of the negative pressure in the patent in suit. To provide a yet finer control, it would be obvious to the skilled person to monitor the rate of change of the negative pressure in order to reduce patient discomfort.

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention relates to vacuum wound therapy devices such as the one shown in Figure 1 of the patent, reproduced below. More particularly, the invention concerns a controller for regulating negative pressure applied to a wound bed through a vacuum bandage.

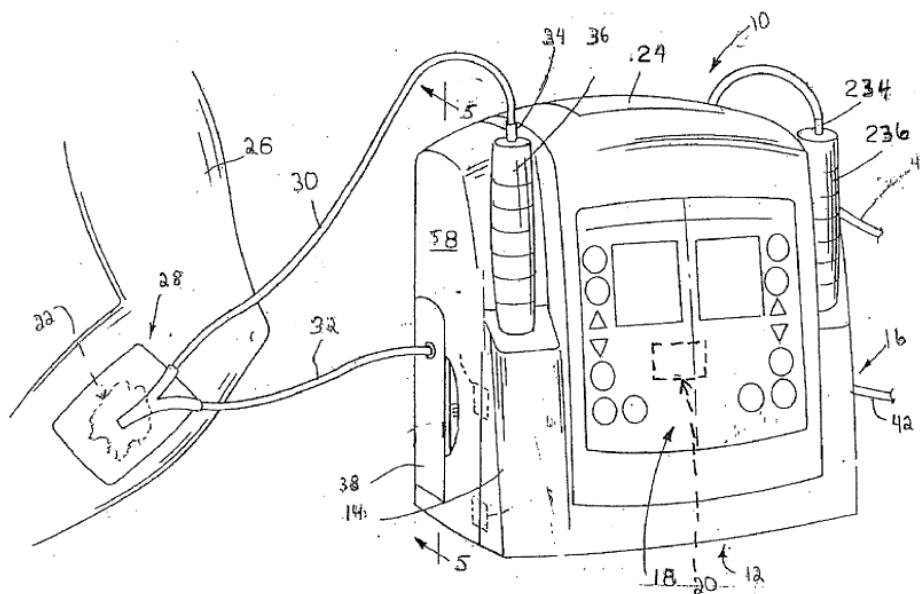


FIG 1

As explained in paragraph [0003] of the patent, the application of negative pressure to a wound draws out exudate, which might contain dirt and bacteria, to promote healing.

The invention focuses on the control of the rate of change of negative pressure at the wound bed, based on the observation that rapid changes in negative pressure levels applied to open wounds can cause discomfort to patients (paragraph [0003], last sentence).

3. Added subject-matter

Claim 1 of the main request corresponds to the combination of claims 7, 9 and 10 of the parent application as originally filed, with the only difference that, in the characterising portion, the control circuitry is specified as "control[ling]" the rate of change of negative pressure instead of limiting it.

The respondent argued that the difference added subject-matter.

The Board notes that claim 1 of the parent application as originally filed, directed to a vacuum wound therapy device, specifically features "a controller controlling the rate of change of negative pressure". That claim does not recite that the rate of change should be otherwise limited. Hence, the Board cannot accept the respondent's argument that it was necessary to define the limitation of the rate of change in claim 1 of the main request in view of the thrust of the application as originally filed; claim 1 of the parent application as originally filed provides a basis for that difference.

In conclusion, the subject-matter of claim 1 of the main request does not extend beyond the content of the parent application as originally filed.

Since the application as originally filed comprises the description, claims and figures of the parent application as originally filed, the subject-matter of claim 1 of the main request does not extend beyond the content of the application as originally filed either.

It follows that the ground for opposition under Article 100(c) EPC raised by the respondent does not prejudice the maintenance of the patent on the basis of the main request.

4. *Novelty*

4.1 The respondent argued that D1 was novelty-destroying for the subject-matter of claim 1 of the main request.

D1 concerns a controller for regulating negative pressure applied to a wound bed through a vacuum bandage of the same kind as the invention. It is common ground that D1 discloses all the features of the preamble of claim 1 of the main request, in particular in Figures 1 and 5 and on page 9, line 23 to page 10, line 26. D1 also discloses control circuitry that generates a signal for controlling a proportional valve (page 10, lines 4 to 7) for producing an appropriate level of negative pressure at the wound bed.

However, D1 does not disclose any control of the rate of change of negative pressure at the wound bed.

More precisely, in the present case the claimed control of the rate of change of negative pressure is not simply a wish or an "intention" as the respondent put it. Hence decision T 304/08 is not relevant. The claimed control is a generally accepted functional definition, which requires not only means for influencing the rate of change of the pressure, but also some monitoring of that rate of change to establish if and to what extent the rate of change should be influenced. If the control is to be carried out by a controller, as required by claim 1 of the main request, the controller must be suitable as is for

performing that control, i.e. it must be programmed and/or provided with suitable hardware which enables it to monitor and influence the rate of change as explained above.

D1 explains how the proportional valve is operated on page 9, lines 28 to 31 and page 10, lines 4 to 11: the controller monitors the negative pressure at the wound bed and provides a signal upon comparison of that pressure with a level defined by a caregiver. The signal provided by the controller simply opens the proportional valve, which applies negative pressure up to a maximum predetermined level. That maximum level is set by a vacuum regulator (134, Figure 3), which provides purely mechanical limitation (page 10, lines 12 to 15).

While the controller of D1 monitors the level of the negative pressure at the wound bed at numerous moments in time (in order to provide the signal to the proportional valve), there is no disclosure in D1 that it monitors the rate of change of that pressure. In other words, the speed with which the level defined by the caregiver is reached - within the mechanical limitation provided by the vacuum regulator - is not discussed in D1.

Hence, the subject-matter of claim 1 of the main request is novel (Article 54(1) and (2) EPC) over D1 by virtue of the feature that the control circuitry generates the pressure regulation signal to control the rate of change of negative pressure at the wound bed.

- 4.2 The respondent also argued that D2 was novelty-destroying for the subject-matter of claim 1 of the main request.

D2 concerns an apparatus for treating a wound by repeated application of an active agent to a wound and removal of the active agent by vacuum.

More specifically, D2 discloses a controller for regulating a negative pressure provided to a wound bed (Figure 3 shows pressure over time), comprising a regulator (tube clamp 34, Figure 2), a pressure transducer for detecting pressure at the wound site (38, Figure 1) and control circuitry (36, Figure 1).

While D2 teaches, as the respondent argued, that the regulator should be opened slowly so that the negative pressure at the wound bed is increased slowly (column 7, lines 42 to 47), there is no monitoring of the rate of change of the negative pressure as implied by a control of that rate of change. The slow opening of the regulator in D2 certainly influences the rate of change but does not result in a control of that rate of change by a controller. D2 does not teach different opening speeds of the regulator depending on the actual rate of change of the pressure at the wound bed, the rate of change being clearly influenced by factors other than the opening speed of the regulator.

Hence, the subject-matter of claim 1 of the main request is also novel (Article 54(1) and (2) EPC) over D2 by virtue of the feature that the control circuitry generates the pressure regulation signal to control the rate of change of negative pressure at the wound bed.

5. Inventive step

The respondent argued that the subject-matter of claim 1 was obvious in view of D1 and D2.

As explained above, neither D1 nor D2 discloses control circuitry that generates a pressure regulation signal to control the rate of change of negative pressure at the wound bed.

The Board concurs with the respondent that this distinguishing feature addresses the problem of reducing discomfort for a patient being treated, since this is also explicitly stated in the patent (paragraph [0003], last sentence).

It is true that D2 (column 7, lines 47 to 51) starts from the same observation as in the patent that a rapid change in pressure levels applied to open wounds could cause discomfort (or pain) to the patient. However, D2 merely teaches that the rate of change of the pressure should be reduced by opening a regulator slowly. Faced with the problem formulated above, the skilled person, when combining the teaching of D1 and D2, would have no reason to further modify the solution proposed by D2, no matter how difficult possible further modifications would be. Hence, the subject-matter of claim 1 of the main request is not obvious.

Consequently, the respondent's objections as to lack of inventive step (Article 56 EPC) of the subject-matter of claim 1 of the main request are without merit.

6. It follows that the ground for opposition under Article 100(a) EPC raised by the respondent does not prejudice the maintenance of the patent on the basis of the main request.

7. The respondent had no objections to the description.
The Board does not have any either.

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 and 2 of the main request filed with letter dated 24 October 2014; and
 - description and figures of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated