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Datasheet for the decision of 20 June 2013

Case Number: T 2039/12 - 3.2.06

Application Number: 02746951.9

Publication Number: 1406567

IPC: A61F13/02

Language of the proceedings: EN

Title of invention:
Control of vacuum rate of change

Patent Proprietor:
KCI Medical Resources

Opponents:
Paul Hartmann AG
VCS Medical Technology GmbH
Smith and Nephew, Inc.

Relevant legal provisions:
EPC Art. 123(2)
RPBA Art. 13(1)

Keyword:
Amendments - extension beyond the content of the application as filed (yes)

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Case Number: T 2039/12 - 3.2.06

D E C I S I O N
of Technical Board of Appeal 3.2.06
of 20 June 2013

Appellant: (Patent Proprietor)	KCI Medical Resources 122 Mary Street Zephyr House Grand Cayman (KY)
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Respondent: (Opponent 2)	VCS Medical Technology GmbH Sylvesterallee 2 22525 Hamburg (DE)
Representative:	RAe Schwierholz Jarchow Scholz Dr. Olaf Büchler Drehbahn 9 20354 Hamburg (DE)
Respondent: (Opponent 3)	Smith and Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 (US)
Representative:	Harrison Goddard Foote LLP Saviour House 9 St. Saviourgate York YO1 8NQ (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 19 July 2012 revoking European patent No. 1406567 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: M. Harrison
Members: G. de Crignis
K. Garnett

Summary of Facts and Submissions

I. European patent No. 1 406 567 was revoked by the opposition division by way of its decision posted on 19 July 2012.

The opposition division held that the subject-matter of claim 1 according to the main request (claim 1 as granted) did not meet the requirement of Article 123(2) EPC as no clear and unambiguous disclosure in the originally filed application could be identified for the addition of the word "time" before the wording "rate of change of negative pressure" or for the wording "predetermined maximum allowable rate".

Concerning claim 1 of the first auxiliary request, in which the term "time" was deleted in the expression "time rate of change of negative pressure" and the wording "predetermined maximum allowable rate" was replaced by the term "desired value", the opposition division considered that the term "desired value" encompassed a range of possibilities which might be different from the possibilities to be considered within the wording "rate of change of negative pressure" in combination with the wording "predetermined maximum allowable rate" whereby the European patent was amended in such a way as to extend the protection it confers, contrary to the requirement of Article 123(3) EPC.

II. On 18 September 2012 the appellant (patent proprietor) filed an appeal against this decision and paid the appeal fee. A statement setting out the grounds of appeal was received at the European Patent Office on 16 November 2012 together with the request to set aside the decision of the opposition division and to remit

the case to the opposition division for consideration of the remaining objections.

III. With its communication annexed to a summons to oral proceedings, the Board indicated that the addition of the term "time" to the wording of claim 1 did not appear to result in subject-matter extending beyond the content of the application as filed but that it might be a matter of discussion as to whether this applied with regard to the amendment concerning the wording of a "predetermined maximum allowable rate".

IV. With letter of 16 May 2013 the appellant filed amended claims as first and second auxiliary requests.

V. Oral proceedings were held on 20 June 2013.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted, alternatively on the basis of the first auxiliary request filed with the letter dated 16 May 2013, alternatively on the basis of the second auxiliary request filed during the oral proceedings and, if any of these requests were found not to infringe Articles 100(c), 123(2) or 84 EPC, that the case be remitted to the Opposition Division for further prosecution.

Respondents I and III (opponents I and III) both requested that the appeal be dismissed.

Respondent II (opponent II) did not attend the oral proceedings, as announced by telephone on 16 May 2013, nor did it make any written submissions during the appeal procedure.

VI. Claim 1 as granted (main request) reads:

"A vacuum wound therapy device (10) for providing a negative pressure at a wound bed (22), the vacuum wound therapy device comprising a controller (20), a vacuum bandage (28) configured to fluidly communicate with the wound bed (22), a vacuum source (110) fluidly coupled to the vacuum bandage (28) to provide negative pressure for presentation at the wound bed, characterized by the controller (20) controlling the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that its characterizing portion reads as follows:

"characterized by the controller (20) implementing a PID control algorithm (302) and a filter to limit the control signal generated by the PID control algorithm within bounds to control the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate."

Claim 1 of auxiliary request 2 reads as follows:

"A vacuum wound therapy device (10) for providing a negative pressure at a wound bed (22), the vacuum wound therapy device comprising a controller (20) implemented by a microcontroller, a vacuum bandage (28) configured to fluidly communicate with the wound bed (22), a vacuum source (110) fluidly coupled to the vacuum bandage (28) to provide negative pressure for presentation at the wound bed,

a pressure transducer (124) in fluid communication with the wound bed (22) and electrically coupled to the controller, and
an electrically actuated proportional valve electrically (130) coupled to the controller (20) and controlled by a PWM signal from the controller and fluidly coupled between the vacuum source (110) and the vacuum bandage (28)
characterized by the controller (20) implementing a PID control algorithm (302) and a filter to limit the control signal generated by the PID control algorithm within bounds to control the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate."

VII. The arguments of the appellant were essentially the following:

The addition of the word "time" to "rate of change" merely clarified the meaning of "rate of change" such as set out in various paragraphs in the description which justified such clarification. Such amendment did not result in an extension of subject-matter as no other rate of change was disclosed or plausible within the context of the claim.

The skilled person understood that the wording "desired value" had the meaning of "predetermined value" and of "maximum allowable rate" in the context of the claimed device. Such understanding resulted from various paragraphs in the originally filed application (page 3, lines 28/29, page 4, lines 5/6, page 16, lines 7/8, claim 7 of the application as filed). Although these citations did not use identical wording, they all had that meaning and were consistent with the wording of the claim.

The skilled person understood further that the disclosure of the "maximum allowable rate of change" was not restricted to the particular embodiment disclosed on page 16 but that any apparatus or method of implementation might be utilised to provide the required functionality. Such understanding resulted mainly from the aim of the invention to minimize pain due to too fast pressure changes. Thus the rate of change had to be limited.

The first and second auxiliary requests further specified the details of the embodiment disclosed in the paragraph bridging pages 15/16.

Claim 1 of the first auxiliary request included the features of originally filed claims 4 and 5 (which corresponded also to the granted claims) which were a PID control algorithm and the filter which limited the control signal, and all these features were linked to the rate of change defined in claim 1. The combination of such features was thus originally disclosed. The term "within bounds" had been present not only in originally filed claim 5, but also in granted claim 5 and thus should be considered as being clear.

Claim 1 of the second auxiliary request additionally included the feature that the controller was implemented by a microcontroller, the pressure transducer and the valve, and it was not necessary to insert further features into claim 1. The second auxiliary request - although only filed during the oral proceedings - was a reaction to the objections arising during the oral proceedings and should be admitted into the proceedings.

VIII. The arguments of the respondents (opponents) were essentially as follows:

The patent as granted disclosed subject-matter extending beyond the content of the application as originally filed.

The application as filed did not specify that the rate of change was with respect to time; it could be with respect to other parameters. The word "time" had apparently been added in claim 1 in order to confer clarity to the meaning of "rate of change"; however, there was no clear and unambiguous disclosure in the application as filed in this respect.

The amended wording in claim 1 allowed the rate of change of negative pressure to be varied over time, on the sole proviso that it did not exceed the "predetermined maximum allowable rate", whereas the disclosure in the application as filed only referred to a constant (= fixed) rate of change. There was also no disclosure at all of the word "predetermined" in the application as filed.

Claim 1 of auxiliary request 1 did not overcome the objections raised against claim 1 of the main request. In addition, it was not clear how to interpret the term "within bounds" in the context of the claim.

Claim 1 of auxiliary request 2 should not be admitted into the proceedings as it was not *prima facie* allowable. Claim 1 still included the situation that a variable rate of change below the maximum value was included although no disclosure of this was present. Additionally, the amendments led to further objections under Article 84 and 123(2) EPC, *inter alia* the

terminology "within bounds" was not clear in its meaning in relation to further features of the claim.

Reasons for the Decision

1. Main request - Claim 1 (as granted) - Article 123(2) EPC

1.1 Claim 1 was amended compared to claim 1 as originally filed during prosecution of the application by amending the terminology "controlling the rate of change of negative pressure presented at the wound bed" to "controlling the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate".

1.2 Insertion of the word "time" into the terminology "controlling the rate of change of negative pressure":

1.2.1 The insertion of the word "time" to read "time rate of change" is rather unconventional, since "rate of change" alone would normally be associated with a change of a parameter over time already. However, since the word "time" has been added it is necessary to consider whether any other interpretation is reasonable and whether such is disclosed. On proper interpretation by a skilled person, the Board concludes that this feature defines merely a change of the parameter specifically with respect to time, and that such subject-matter is therefore also disclosed unambiguously in the application as filed since the only change of pressure (i.e. the parameter in question) mentioned is one which is with respect to

time and this is also presented consistently throughout the application as being the case.

1.2.2 Disclosures concerning "time" being the only parameter with respect to which pressure is to be altered when considering the "rate of change" can be found for example on:
- page 15, line 23 to 26: "the PWM signal 306 induces the solenoid to open and close the valve rapidly and as a result of hysteresis and time averaging of the open periods an average position or constriction is approximated.";
- page 16, lines 1 to 3: "The rise (or fall) time of a system controlled using PID control of a PWM driving signal inherently includes some aspect of control over the rate of change of the controlled parameter. ... Thus, the actual negative pressure over the wound bed, ... is raised or lowered slowly to the set point.";
- page 17, lines 13 to 15: "the desired pressure .... slowly ramps up so as to avoid a sudden change .... The desired pressure is computed by determining the elapsed time since the pressure was set and computing a delta value such that the pressure changes no more than 7.5 mmHg per second.";
- page 18 to 21 disclosing the control algorithm including a delta t and related delta p (see e.g. page 18, lines 17 to 21).
From all these passages, the only logical and consistent conclusion that can be drawn as regards the operation of the system and the way in which pressure can vary is that all concern a rate of change referring to pressure change/time.

1.2.3 Hence, understanding that "time rate of change" must mean the change of a parameter with respect to time,

there is a clear and unambiguous disclosure of the feature "controlling the time rate of change of negative pressure" at least by implication and no extension beyond the content of the application as filed can be recognized in this respect since the insertion of the word "time" in claim 1 is consistent with the whole specification, albeit that insertion of the term "time" is essentially superfluous in the context of the claim.

1.2.4 The argument of the respondents that the rate of change need not be a change of pressure over time but that it could be a change of pressure with respect to other parameters such as flow rate or temperature, finds no support in the application at all. Thus, these are only theoretical possibilities which, in the context of the application for reducing patient discomfort whereby the rate of change of pressure over time is the relevant factor, are implausible when read by a skilled person. Likewise, the argument that the time rate of change could be the second derivative of change of pressure with respect to time also finds no support.

1.2.5 Thus, the insertion of the word "time" before the expression "rate of change of negative pressure" in claim 1 is allowable.

1.3 Insertion of the wording "controlling the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate":

1.3.1 As with the foregoing terminology "time rate of change", there is no literal disclosure of the wording "to not exceed a predetermined maximum allowable rate" in the application as filed. Accordingly, in order to decide on whether there is a clear and unambiguous

disclosure in the application as filed for the amended wording, and whether accordingly it is allowable to insert such wording into the claim, it has to be scrutinized what is disclosed in relation to this term.

1.3.2 The following passages of the application as filed were cited by the appellant as providing support therefor:

(a) page 3, lines 26 to 29: "the device ... limits the rate of change for the negative pressure applied to the wound. ... the device controls the rate of change of the negative pressure ...";

(b) page 4, lines 4 to 6; "... the controller limits the input to the variable flow orifice to produce the allowable rate of change of negative pressure as monitored by the pressure transducer.";

(c) page 16, lines 6 to 8; "...the disclosed controller further limits and controls the rate of change of negative pressure by filtering the control signal with a filter 308 implemented in the micro-controller 320 to ensure that the rate of change of negative pressure does not exceed a desired value.";

(d) page 17, lines 15 to 18:

- "The desired pressure is computed by determining the elapsed time since the pressure was set and computing a delta value such that the pressure changes no more than 7.5 mm Hg per second.";

(e) page 20, line 16:

- "#define PRESS_CHANGE 7 // max change .7 mmHg/100 msec => 7 mmHg/sec".

(f) claim 7; "... whereby the control circuitry generates the pressure regulation signal in response to the pressure signal and setpoint signal to limit the rate of change of negative pressure at the wound bed while adjusting the

negative pressure at the wound bed to the desired negative pressure.".

1.3.3 Citation (c) indicates to the user the logical conclusion that the rate of change of negative pressure is "limited ... to not exceed" a "desired value" in the sense of a fixed upper value. This citation is however the only disclosure including the wording "to not exceed" and where the Board can see at least an indication for the particular terminology chosen in the claim.

1.3.4 Moreover, citations (d) and (e) provide an example for such a predetermined maximum allowable rate as a fixed (= set = desired = preset) value of an upper limit for the pressure change of either 7 mmHg/sec or 7.5 mmHg/sec. Thus, these citations support clearly and unambiguously the presence of a fixed upper (maximum, desired and also predetermined) value for the rate of change set by the operator.

1.3.5 Accordingly, the wording "controlling the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate" can be clearly understood as having the meaning of referring to a fixed upper value to which the rate of change of the negative pressure is limited and on the basis of which the device is controlled. The remaining references also do not contradict such view.

1.3.6 However, as also argued by the respondents, the terminology in the claim encompasses the possibility that the rate of change could vary and thus include a rate (or rates) below the maximum allowable rate provided that it does not exceed the "predetermined maximum allowable rate" - even though no clear and

unambiguous disclosure is present for such an alternative. None of the above citations refers to the possibility of using a range below such rate or how to define, set, regulate and/or control a rate below such "predetermined maximum allowable rate". Here it should be noted that although citation (d) states "the pressure changes no more than 7.5 mmHg per second", which might perhaps (when read in isolation) be understood to allow other rates to occur below the maximum value, this citation is qualified by the next sentence in the paragraph which explains that the pressure changes no more than that rate due to the rate being fixed at a predetermined value.

1.3.7 The appellant referred additionally to the final paragraph starting on page 43, line 10 of the specification which, in the appellant's view, allowed for the inclusion of further values below the maximum allowable rate due to the disclosure of "variations and modifications of the device" which would also apply with regard to the maximum allowable rate. However, this paragraph contains general wording which the Board cannot understand as giving a clear and unambiguous disclosure of a specific variant of the device as claimed.

1.3.8 Thus, only a fixed maximum allowable rate is clearly and unambiguously disclosed. Consequently there is no clear and unambiguous disclosure in the application as filed of the more general feature, as claimed, "to not exceed a predetermined maximum allowable rate", something which also includes any value of rate in an unspecified range below an upper limiting value of the rate. Thus the main request is not allowable with respect to Article 100(c) EPC.

2. First auxiliary request

2.1 This request was filed in reply to the communication of the Board. According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA), it lies within the discretion of the Board to admit any amendment to a party's case after it has filed its grounds of appeal or reply, as to which it is stated that "the discretion shall be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy." Hence, such provisions apply to the first auxiliary request (and indeed also to the second since this was filed during the oral proceedings before the Board).

2.2 Claim 1 includes an amended characterizing portion which is worded to include additionally "the controller (20) implementing a PID control algorithm (302) and a filter to limit the control signal generated by the PID control algorithm within bounds".

2.3 The amendment relates to the embodiment disclosed in the paragraph bridging pages 15/16 of the application as filed, in which embodiment there are further features disclosed in combination which are however not present in claim 1. These features include *inter alia* the PWM driving signal and the filtering of the control signal with a filter. These features are disclosed in a functional and structural relationship with the final feature in claim 1 which is to control and ensure that the rate of change of negative pressure does not exceed a predetermined maximum allowable rate.

2.4 Thus, the mere addition of the PID control algorithm and the "filter to limit the control signal generated

by the PID control algorithm within bounds" does not correspond with all features disclosed in that particular embodiment. It accordingly results in an unallowable intermediate generalisation of the disclosed embodiment since a more general disclosure of the combination of features in claim 1 is not to be found elsewhere. It also does not overcome the objection set out above in relation to the main request with regard to the lack of a clear and unambiguous disclosure concerning the feature "controlling the time rate of change of negative pressure presented at the wound bed to not exceed a predetermined maximum allowable rate".

2.5 Since claim 1 of the first auxiliary request was filed in reply to the Board's communication with the intention of overcoming the specific objections set out therein, the Board exercised its discretion under Article 13(1) RPBA to admit the request into proceedings. However, the requirement of Article 123(2) EPC is not met since the objection set out above for the main request (in regard to the absence of features relating to a fixed rate) still applies. Hence, the first auxiliary request is not allowable.

3. Second auxiliary request

3.1 This request was submitted during the oral proceedings. As mentioned in item 2.1 above, the provisions of Article 13(1) RPBA apply.

3.2 Claim 1 has been further amended, whereby the appellant stated that it had incorporated the essential features of the embodiment disclosed in the paragraph bridging pages 15/16 and as far as possible the features of dependent claims 2 to 6 as filed. Due to the amendments

made, the objections set out above for the main and first auxiliary request concerning the broadness of the feature "to not exceed a predetermined maximum allowable rate" were said to have been overcome.

3.3 However, although further features from the paragraph bridging pages 15 and 16 have been included, it is noted that the disclosure in that paragraph itself does not clearly state in which way the "desired value" (corresponding to the "maximum allowable rate" defined in claim 1) is not exceeded. As has already been stated above (item 1.3.8), the only unambiguous disclosure in the application as filed is that the maximum allowable rate is not exceeded by virtue of the rate being set at a fixed value. However, none of the features introduced into claim 1 of the second auxiliary request appears to explicitly or implicitly overcome this particular objection.

3.4 Thus, the objection under Article 123(2) EPC - previously raised against the granted claim under Article 100(c) EPC - is at least *prima facie* not overcome by the amendments in the second auxiliary request and for this reason the Board exercised its discretion not to admit the second auxiliary request into the proceedings (Article 13(1) RPBA).

3.5 Since the request was not admitted into the proceedings, it is not necessary to consider the further objections of the respondents regarding the alleged lack of clarity of the term "within bounds" in claim 1 nor the objections under Article 123(2) EPC that still further features of the specific embodiment relied upon would have to be inserted into claim 1 in order to avoid additional objections under Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. H. A. Patin M. Harrison

Decision electronically authenticated