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**Datasheet for the decision
of 31 May 2016**

Case Number: T 2253/12 - 3.2.02

Application Number: 07117289.4

Publication Number: 1897569

IPC: A61M1/00, A61M27/00

Language of the proceedings: EN

Title of invention:

Vacuum assisted tissue treatment system

Patent Proprietor:

KCI Licensing, Inc.

Opponent:

Smith and Nephew, Inc.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 76(1), 84, 100(a), 100(b), 100(c), 111(1),
123(2)

RPBA Art. 12(4)

Keyword:

Subject-matter extends beyond content of earlier application -
main request (no)
Insufficiency of disclosure - main request (no)
Novelty - (yes)
Inventive step - main and first auxiliary request (no)
- second auxiliary request (yes)
Added subject-matter - second auxiliary request (no)

Decisions cited:

T 1574/07, T 1808/10

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 2253/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 31 May 2016

Appellant: Smith and Nephew, Inc.
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 August 2012 concerning maintenance of the
European Patent No. 1897569 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
C. Körber

Summary of Facts and Submissions

- I. The opponent has appealed the Opposition Division's decision, dispatched on 23 August 2012, that European patent No. 1 897 569 as amended according to the then pending auxiliary request 1 complied with the EPC.
- II. The patent, which is derived from a divisional application of parent application No. 02 766 098.4, was opposed on the grounds of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step.
- III. The notice of appeal was received on 23 October 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 14 December 2012.
- IV. The respondent (patent proprietor) replied to the statement of grounds by letter dated 15 April 2013.
- V. The appellant filed further written submissions by letter dated 17 April 2015.
- VI. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 25 February 2016.
- VII. The appellant and the respondent filed further written submissions by letters dated 27 April 2016 and 29 April 2016 respectively.
- VIII. Oral proceedings took place on 31 May 2016.

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the first auxiliary request filed with letter dated 29 April 2016, the second auxiliary request filed during the oral proceedings, and the third to the fifth auxiliary requests filed with letter dated 29 April 2016.

IX. The following documents are referred to in the present decision:

P1: WO-A-01/37922;
P2: US-A-4,710,165;
P3: WO-A-96/05873.

X. Claim 1 of the request found allowable by the Opposition Division, which constitutes the main request, reads as follows:

"A system (10) for stimulating the healing of tissue, comprising:

a porous pad (11);
an airtight dressing (13);
a means for connecting a distal end (16b) of a conduit (16) through the dressing (13);
a canister (18) removably connected to a proximal end (16a) of the conduit (16);
means (14) for applying negative pressure to a wound site;
a first filter (20) positioned between said canister (18) and said means (14) for applying negative pressure;
a second filter (22) positioned between said first filter (20) and said means (14) for applying

negative pressure; and
a means for varying said negative pressure over a
time interval comprising means for adjusting actual
pressure to meet a varying target pressure,
characterised in that said varying target pressure
oscillates between a set target maximum and a set
target minimum pressure."

XI. Claim 1 of the first auxiliary request differs from
claim 1 of the main request only in its characterising
portion, which reads:

"characterised in that the system oscillates the
varying target pressure between a set target
maximum and a set target minimum pressure".

XII. Claim 1 of the second auxiliary request reads as
follows (deletions and underlining as in the text filed
by the respondent):

"A system (10) for stimulating the healing of
tissue, comprising:
a porous pad (11);
an airtight dressing (13);
a means for connecting a distal end (16b) of a
conduit (16) through the dressing (13);
a canister (18) removably connected to a proximal
and (16a) of the conduit (16);
means (14) for applying negative pressure to a
wound site;
a first filter (20) positioned between said
canister (18) and said means (14) for applying
negative pressure;
~~a second filter (22) positioned between said first
filter (20) and said means (14) for applying
negative pressure;~~ and

a means for varying said negative pressure over a time interval comprising means for adjusting actual pressure to meet a varying target pressure, characterised in that wherein said varying target pressure oscillates between a set target maximum and a set target minimum pressure-;

characterised in that

the system further comprises a second filter (22) positioned between said first filter (20) and said means (14) for applying negative pressure; and in that

the system is adapted to control the negative pressure according to the following process

if the pressure is increasing the system ascertains whether the varying target pressure is less than the target maximum pressure and if so determines whether the actual pressure has equalled the varying target pressure and if so increases the varying target pressure by an interval, if the varying target pressure has reached the maximum target pressure, the pressure direction is set to decreasing,

if the pressure is decreasing the system ascertains whether the varying target pressure is greater than the minimum target pressure and if so determines whether the actual pressure has attained the varying target pressure and if so decrements the varying target pressure by one interval, if the varying target pressure has reached the minimum target pressure, the pressure direction is set to increasing."

The second auxiliary request includes only one claim.

XIII. The appellant's arguments may be summarised as follows:

(a) Main request

Added subject-matter

The patent was opposed inter alia on the ground under Article 100(c) EPC and the Opposition Division took a decision on this ground. The arguments regarding added matter of claim 1 of the main request were introduced in the statement of grounds of appeal and were therefore admissible.

The features of claim 1 of the main request were derived from a combination of features of the different independent claims 1 and 31, and of dependent claims 32 and 33 of the parent application as originally filed.

However, independent claims were directed to different, discrete embodiments of an invention, which were independent from each other as they related to separate independent ideas and different partial problems. In the absence of a suggestion or teaching in the parent application as originally filed that the features of these discrete embodiments could be combined, such a combination would come up against a prejudice of the skilled person. By the presence of the separate independent claims the skilled person was clearly induced to think that their combination was not envisaged. It followed that the subject-matter of claim 1 of the main request was not directly and unambiguously derivable from the parent application as filed. More specifically, on page 10, lines 18 et seq. referred to by the respondent, only control aspects

in relation to the embodiment of figure 5 were disclosed. There was no suggestion that these aspects could be implemented in the embodiment of figure 1, to which claim 1 related. The direct combination of independent claims and claims without the correct original dependencies was also contrary to case law, since decisions T 1574/07 and T 1808/10 stated that combining claims without the correct dependencies added matter to an application.

A combination of one of the independent claims with features of the description or simply a combination of features from the description could not provide a basis for the subject-matter of claim 1 either. The various features of the description were only ever disclosed in combination with various other features, such as an access port or a pressure sensor, not included in claim 1 of the main request. There was no teaching in the parent application as originally filed to leave out some of the features of the disclosed combinations and only "cherry pick" others in order to arrive at the claimed subject-matter. Accordingly, such subject-matter represented an intermediate generalisation not directly and unambiguously derivable from the parent application as originally filed.

Sufficiency of disclosure

The appellant's arguments in the statement of grounds of appeal that the invention as defined in claim 1 of the main request was not sufficiently disclosed were in response to the Opposition Division's decision on sufficiency affecting the appellant. The appellant had the right to appeal

such a decision merely on the basis of the arguments submitted in written opposition proceedings. There was no need for further submissions during the oral proceedings before the Opposition Division, in order to have those arguments considered in the appeal proceedings.

It was of utmost importance to the invention as defined in claim 1 of the main request that the pressure within the claimed system should be finely controllable. However, the patent did not disclose and the claim did not define any specific means making possible such a fine control. The respondent's assertion that realising them was part of the common general knowledge and could be achieved for example by making a small hole or relying on inadequacies of the pump system was unsubstantiated. Moreover, such exemplary means were rudimentary and would not allow the careful control of pressure that the invention required. In any case, those means were required in order to put the invention into effect but were not included in claim 1.

Furthermore, the claim required "means for adjusting actual pressure to meet a varying target pressure". However, the claimed invention did not include any means for monitoring pressure at the wound site. Such a means for monitoring pressure was an essential feature for working the invention and had to be included in the claim pursuant to Rule 45 EPC.

Accordingly, the patent did not disclose the invention as defined in claim 1 of the main request in a manner sufficiently clear and complete for it

to be carried out by a person skilled in the art as required under Article 83 EPC.

Novelty

P1 disclosed a system as defined in claim 1 of the main request. More particularly, the finding of the Opposition Division that there were two points of novelty of claim 1 over P1 was not correct.

The first point concerned the definition of "a second filter positioned between said first filter and said means for applying negative pressure". The system disclosed in P1 with reference to figure 2 included a canister (26), a filter (108), a vacuum pump (110) and a further filter (137). This latter filter was situated "between the first filter", i.e. filter 108, and the "means for applying negative pressure", i.e. vacuum pump 110. Firstly, there was no requirement in claim 1 that the second filter had to be positioned within the same fluid flow path as the first filter, as argued by the respondent. Rather, the term "between" had to be interpreted as simply referring to the physical position of the elements concerned. In any case, at least when pump 110 was turned off, fluid flowing between filter 108 and vacuum pump 110 was free to flow through (in a first direction) and back through (in a second opposite direction) filter 137. Hence, filter 137 was in the fluid flow path between filter 108 and vacuum pump 110. Moreover, by comparing the technical functions of filter 137 of P1 and that of the patent, the skilled person would find that filter 137 in P1 acted to prevent contamination of the pump in P1 (page 10, lines 21 to 23), which was the same technical effect as the

second filter defined in claim 1 of the main request of the patent. Alternatively, sound chamber 140, which acted as a filter for sound and heat and was situated between first filter 108 and vacuum pump 110, also fell within the scope of the claimed "second filter", especially because the claim made no reference whatsoever to any technical feature or purpose of the second filter. It followed that P1 disclosed the feature of the second filter positioned between the first filter and the means for applying negative pressure.

The second novelty point concerned the definition of "a varying target pressure that oscillates between a set target maximum and a set target minimum pressure". Such a definition included the situation where a varying target pressure simply changed from the set target maximum to the set target minimum and back. It was not required that the varying target pressure was a dynamic target generated by the system and altered in increments between the set target maximum and the set target minimum, and that the actual pressure was controlled to follow the varying target pressure as it oscillated between the two set pressures, as argued by the respondent. P1 disclosed on page 16, lines 20 to 25, that the system could be set up to provide different levels of vacuum at various times or an intermittent pressure profile. An intermittent pressure had to oscillate and if there were various levels of pressure to be provided then there had to be at least a maximum and a minimum pressure. Furthermore, the fact that providing intermittent pressure was described as a profile mode implied that target pressure values were set at various levels. It followed that P1 disclosed

also the feature of "a varying target pressure that oscillates between a set target maximum and a set target minimum pressure".

Accordingly, the subject-matter of claim 1 of the main request lacked novelty over P1.

Inventive step

P1 should be considered the closest prior art.

Providing the system of P1 with a "second filter positioned between said first filter and said means for applying negative pressure" was rendered obvious by the disclosure of P3.

The nature of the second filter was not defined in claim 1. The patent itself disclosed two different kinds of second filters in the description: a "second hydrophobic filter" and a "second odour filter". It followed that the provision of the second filter as claimed did not address any problem specifically related to the inhibition of contamination of the means for applying negative pressure by wound exudates, as held by the Opposition Division in the impugned decision. Such an effect might be obtained by a second hydrophobic filter, but not by an odour filter.

P3 described the use of two filters in a wound therapy system of the kind defined in claim 1. More particularly, with reference to figures 1, 6 and 9, the system of P3 comprised a vacuum pump (84), located in a housing (11, 12) having a chamber or recess (18) for receiving a removable and disposable canister (19). A hydrophobic filter (46)

was placed over an outlet (44) of the canister to prevent fluid flow from the canister to the vacuum pump (page 10, lines 8 to 15). A further filter (85) was shown in a position between a connector (45) to be joined to the canister and the vacuum pump. On page 16, lines 17 to 18 it was stated that *"filter 85 is similar to filter 46 and thus ensures no wound fluids contaminate vacuum pump 84"*. This made it clear that filter 85 was intended to be used in addition to filter 46 mounted over the canister outlet. Thus, filter 85 constituted a second filter positioned between the first filter and the means for applying negative pressure, as required by claim 1 of the main request.

The second filter of P3 had the function of preventing contamination of the vacuum source, as disclosed on page 10, lines 10 to 12 in specific relation to first filter 46. Moreover, the presence of a second filter inevitably resulted in a possible separation of functions of the two filters, which could be separately engineered. Hence, even in view of the alleged advantages and the inappropriate formulation of the problem by the Opposition Division in the impugned decision, i.e. how to enhance the protection of the vacuum pump against contaminants, the provision in the system of P1 of a second filter as claimed was rendered obvious by document P3.

(b) First auxiliary request

The amendments made to claim 1 of the first auxiliary request with respect to claim 1 of the main request did not change the meaning of of the subject-matter claimed. Hence the objections to the

main request applied equally to the first auxiliary request.

Furthermore, those amendments introduced a further non-compliance with Article 123(2) EPC and did not render the first auxiliary request clearly allowable. For this reason and since it had only been filed in the appeal proceedings, the first auxiliary request should not be admitted into the proceedings in accordance with Rule 12(4) RPBA.

(c) Second auxiliary request

The appellant stated during the oral proceedings that it had no objections to admitting the second auxiliary request into the proceedings. Moreover, the case should not be remitted to the department of first instance for further prosecution based on the second auxiliary request, since there was no absolute right for the parties to have their requests considered at two instances and, anyway, the second auxiliary request had already been presented before the Opposition Division.

The objections as to added matter and insufficiency of disclosure raised with respect to the main request applied equally to the second auxiliary request.

Moreover, the second auxiliary request introduced further non-compliance with the EPC.

Clarity

In the last two paragraphs of claim 1 of the second auxiliary request a process was defined, according to which different settings were carried out depending if "the pressure is increasing" or if "the pressure is decreasing". However, in the preceding paragraphs of the claim a "negative pressure", an "actual pressure", a "varying target pressure", a "set maximum pressure" and a "set minimum pressure" had been introduced. Hence, it was not clear which of the previously introduced pressures was meant in the definition of the process.

Furthermore, the defined process required the system to ascertain whether the varying target pressure was lower (greater) than the target maximum (minimum) pressure and, depending on the result, increase (decrease) the varying target pressure by an interval or set the pressure direction to decreasing (increasing). However, in the claim no means were defined to achieve these functions. Moreover, the amplitude of the interval and the pressure direction lacked a meaningful definition.

It followed that the added features regarding the definition of the process rendered the claim completely unclear.

Added subject-matter

Claim 1 required that the system be adapted to control the negative pressure according to a specific process. Such a control could find a basis

in the specific embodiment described on page 10, line 18 to page 11, line 4 of the parent application as filed. However, in this embodiment the control was carried out specifically by a software program. Claiming a general control carried out by the system included the situation in which that control was carried out by hardware, for example. This had no basis in the parent application as filed. Moreover, several essential features of the embodiment in addition to the software program had been omitted from the claim, such as a computer processing unit, the fact that the program was initialised by a user who also set target pressures, and the performance of a control loop. This constituted an unallowable intermediate generalisation that added subject-matter to the content of the parent application as filed.

Inventive step

Compared with claim 1 of the main request, claim 1 of the second auxiliary request further defined a control of the negative pressure according to a specific process. This process constituted a further distinguishing feature over the disclosure of P1. However, it did not address the same problem as the presence of the second filter. The obviousness of the proposed solutions to these two partial problems had to be assessed independently, possibly considering the closest prior art in combination with different prior art.

More particularly, the claimed process was obvious when starting from P1 as the closest prior art and further considering common general knowledge or P2.

According to the claim there was no requirement that the varying target pressure assumed any value between the set target minimum and the set target maximum pressure. It could simply switch between the two extremes. The resulting process represented a mere alternative to the application of pressure profiles as disclosed in P1 since it was technically equivalent to the latter, without any advantages for the wound treatment. Thus, implementing the claimed process in the system of P1 was within the competence of the person skilled in the art based on common general knowledge.

P2 disclosed a suction and collection device for controlling the application of negative pressure to a wound site, the negative pressure being maintained in a dead band above a set negative pressure. Such a control implied an oscillation of the pressure between the set negative pressure and the highest pressure in the dead band. The claimed process had no advantages for the wound treatment over the control of P2 either. It followed that the combination of P2 with the closest prior art likewise rendered the claimed process obvious.

XIV. The respondent's arguments may be summarised as follows:

(a) Main request

Added subject-matter

The appellant had not objected to claim 1 of the main request under Article 100(c) EPC before the department of first instance. Therefore, there was no decision of the Opposition Division in this

respect, against which the appellant could appeal. For this reason the ground for opposition under Article 100(c) EPC should not be admitted into the appeal proceedings against claim 1. If the Board intended to consider an objection under Article 100(c) EPC to claim 1, the matter had to be remitted to the Opposition Division to ensure the respondent was not deprived of a right to be heard by two instances on this matter.

Claim 1 found a basis in claims 1 and 31 to 33 of the parent application as originally filed. These claims were directed to different, but overlapping, subsets of features of the same system, which related to filtration aspects and pressure control aspects. These aspects were not mutually exclusive, but rather disclosed in the description as forming part of a single system. More particularly, the filtration aspects were described on page 6, line 30 to page 7, line 7, whereas the control aspects were described starting from page 10, line 18, with reference to figure 5. The algorithm shown in figure 5 was a way to operate the system as described throughout the parent application as originally filed.

There was no general principle that features of different independent claims could not be combined. The skilled person would assess the disclosure of a document from a technical standpoint, deriving no prejudice from the way claims were drafted. What had to be assessed was whether the reader would derive the subject-matter of the claim from the parent application as originally filed. This was the case under the present circumstances.

Since claim 1 of the main request was derived from a direct combination of original claims it did not constitute an intermediate generalisation either.

Sufficiency of disclosure

The appellant had not provided any arguments in addition to those presented before the department of first instance as to why the invention as defined in claim 1 of the main request was not sufficiently disclosed. There was therefore no reason for the Board to alter the Opposition Division's decision in this regard.

The appellant, who bore the burden of proof, had not explained at all why the skilled person, using his common general knowledge, would be unable to carry out the invention as claimed. According to the latter, air needed to be allowed into the system. However, the skilled person knew a range of techniques to make this possible, for example by designing imperfectly sealed systems. The system could have an inherent air inlet, e.g. a small hole, or utilise natural leakage paths that inherently existed in all systems, e.g. through the pump. The skilled person was also fully aware how to monitor pressure at a wound site.

Accordingly, the main request was in conformity with Article 83 EPC.

Novelty

The respondent agreed with the Opposition Division's findings in the impugned decision that there were two differences between the

subject-matter of claim 1 of the main request and P1.

More particularly, the claim required "a second filter positioned between said first filter and said means for applying negative pressure". Such a filter was not disclosed in P1. It was clear from figure 2 that there was only one filter (108) between a canister (26) and a pump (110). Filter 137 was not positioned between filter 108 and pump 110, as required by the claim. The skilled person would understand the term "between", from a technical standpoint, as meaning "fluidly between", not simply "physically between". In the system of P1 filter 137 was only used to allow the pump to draw atmospheric air into the system. No fluid flow to the exterior took place. In any case, due to the schematic nature of figure 2, P1 did not even disclose that filter 137 was located physically between filter 108 and pump 110. Sound chamber 140 was not a filter within the meaning of the claim. It was not even physically - and clearly not fluidly - between filter 108 and pump 110.

P1 did not disclose a "means for varying said negative pressure over a time interval comprising means for adjusting actual pressure to meet a varying target pressure" or that "said varying target pressure oscillates between a set target maximum and a set target minimum pressure", as defined in claim 1.

The claim actually required four distinct parameters:

- 1) the actual negative pressure in the system;
- 2) the minimum set target, set by the user;
- 3) the maximum set target, set by the user;
- 4) the varying target pressure, oscillated by the system.

The claimed system was therefore controlled by a two-step process, with the system generating the varying target pressure and then controlling the actual pressure in response to that varying target pressure, as explained with reference to figure 5 in the patent.

In contrast, P1 merely disclosed that a number of pressures could be entered by the user such that the pump controlled the negative pressure to attain those pressures over time. This did not amount to any oscillation. It followed that those entered pressures were not maximum or minimum set points within the meaning of the claim. There was no varying target pressure either. With regard to the disclosure on page 16, lines 23 to 24 that the user could choose a continuous and an intermittent pressure mode, the continuous mode clearly provided no oscillation of pressure either, whereas the intermittent mode was simply an on-off cycle with no minimum set, no maximum set and no varying target pressures coded out.

Inventive step

The respondent clarified during the oral proceedings that it had no objections to the admissibility of the appellant's line of arguments starting from P1 as the closest prior art in combination with P3 or common general knowledge.

P1, which was the closest prior art, did not disclose a "second filter positioned between said first filter and said means for applying negative pressure". It was immediately evident to the reader that the second filter according to the claim could not be an odour filter, since the described second odour filter in the patent was on the outlet of the pump and not between the first filter and the pump.

A second filter solved the problem of ensuring that no fluid from the wound site contaminated the vacuum pump.

P3 or common general knowledge gave the skilled person no reason to consider a second filter as a solution to that problem. It followed that the subject-matter of claim 1 of the main request was inventive.

(b) First auxiliary request

The argumentation in respect of the main request applied equally to the first auxiliary request as far as inventive step was concerned.

(c) Second auxiliary request

The case should be remitted to the department of first instance for further prosecution based on the second auxiliary request, since the appellant's objections to the second auxiliary request had not been heard before. The parties should be given the opportunity to have their requests considered by two instances.

Clarity

According to claim 1 of the second auxiliary request, the system was adapted to control the negative pressure according to a process in which the system ascertained whether the pressure was increasing or decreasing. From a technical point of view it was clear from the claim wording that this latter pressure could only be the actual negative pressure in the system.

The claimed control process was defined in terms of functional features. There was no need to define specific structural means for carrying out the functions, since the skilled person knew how to implement them. Similarly, the amplitude of the interval and the pressure direction did not have to be more specifically defined, as they depended on the circumstances.

Read in context the claim was clear to a person willing to understand.

Added subject-matter

In claim 1 the essential features of the control system as disclosed on page 10, line 18 to page 11, line 18 and figure 5 of the parent application as originally filed had been incorporated. The language used in the claim did not reproduce verbatim the corresponding passages of the original description, but captured the essential features of the algorithm on which the control system was based. In particular, the feature mentioned in the description according to which the algorithm was carried out by software was not essential, since the skilled person would understand that the control could be carried out by something else, e.g. specific hardware.

Inventive step

P1 did not disclose a system controlling the negative pressure according to the process defined in claim 1 of the second auxiliary request. In particular, it was plausible that the system of P1 controlled the pressure variation based on time, and not on the instant values reached by the negative pressure in its oscillation between the set target maximum and the set target minimum pressure.

The claimed process provided an improved control of the varying negative pressure at the wound site, which resulted in an improved healing process.

Common general knowledge and P2 provided no hint to implement in P1 the specific process as claimed. In particular, P2 aimed to keep the pressure at the

wound site as constant as possible, while preventing a continuous on-off cycle (paragraph bridging columns 8 and 9). The skilled person would not consider its teaching for a control process of a varying negative pressure.

It followed that the subject-matter of claim 1 of the second auxiliary request was inventive over the cited prior art.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The patent in suit is derived from a divisional application. The description and the figures of the parent and the divisional applications as originally filed are identical.

The invention relates to a system for stimulating the healing of tissue at a wound site of a patient by applying negative pressure.

As shown in figure 1 of the patent, reproduced on the following page, such systems generally comprise a foam pad (11) to be inserted into the wound site (12), a wound drape (13) for sealing the wound site over the foam pad, a conduit (16) for connecting the sealed wound site to a source of negative pressure, and the source of negative pressure (14). The claimed system also includes a canister (18) in fluid communication with the conduit and two filters (20 and 22) disposed

between the canister and the source of negative pressure. Wound exudates sucked through the conduit are directed and kept in the canister. They should not reach the source of negative pressure.

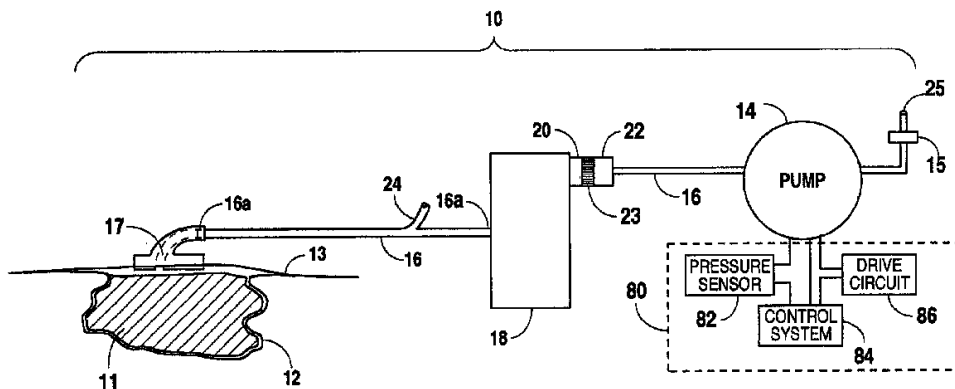


Fig. 1

The invention focuses on the provision of particular means for varying the negative pressure applied to the wound site, such that, in use, it oscillates between a set target maximum and a set target minimum pressure. According to the patent (paragraph [0036]), with such means the source of negative pressure, typically in the form of a portable vacuum pump, can be of reduced size or weight and suitably battery-operated, thereby giving the user greater mobility by not having to be tethered to a stationary power source.

3. Main request

3.1 *Added subject-matter*

3.1.1 The respondent requested that the appellant's objection to claim 1 of the main request under Article 100(c) EPC not be admitted into the proceedings.

According to Article 12(4) RPBA, while the Board retains discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings, everything presented by the appellant in the statement of grounds should be taken into account if it relates to the case under appeal. The Board notes that the ground for opposition according to Article 100(c) EPC was raised in the notice of opposition and was decided upon by the Opposition Division. While the specific objection to claim 1 under that ground was not raised in the first-instance proceedings, it was presented by the appellant in the statement of grounds as a reason why the Opposition Division's decision should be reversed. Under these circumstances the Board sees no reasons why the appellant's objection should be held inadmissible and concludes that it is part of the appeal proceedings.

The respondent also requested that, if the appellant's objection was admitted, the case be remitted to the Opposition Division for further prosecution.

According to Article 111(1) EPC the Board has the discretion to exercise any power within the competence of the department responsible for the decision appealed or to remit the case to that department for further prosecution. In exercising its discretion, the Board should consider several factors, including procedural efficiency and the overall length of the first-instance and appeal proceedings. Another factor is the opportunity of a party to have its case heard by two levels of jurisdiction. However, the EPC does not foresee an absolute right of a party to have this opportunity. In the present case, the Opposition Division's opinion on the subject-matter of claim 1 of

the main request, albeit without consideration of the specific objection raised by the appellant in the appeal proceedings and the counter-arguments of the respondent, is known to the parties and the Board. In the impugned decision, point 3.1, it was concluded that the subject-matter of claim 1 of the present main request did not extend beyond the content of the parent application as originally filed. In view of this conclusion and for reasons of procedural efficiency, the Board decides not to remit the case to the Opposition Division for consideration of this objection made by the appellant.

- 3.1.2 The parties did not dispute that the subject-matter of claim 1 of the main request is derived from a combination of features of claims 1 and 31 to 33 of the parent application as originally filed.

Claims 1 and 31 are independent claims. The appellant argued that the presence of separate independent claims induced the skilled person to think that the combination of their features was not envisaged. However, the Board notes that a sensible assessment of the technical disclosure of a patent document requires the consideration of the claims together with - and not in isolation from - the description and the drawings. The appellant further argued that independent claims 1 and 31 related to different discrete embodiments respectively described with reference to figures 1 and 5 and that, in the absence of a suggestion or teaching in the parent application as originally filed that the features of these discrete embodiments could be combined, such a combination would come up against a prejudice of the skilled person. However, both independent claims 1 and 31 relate to a system for stimulating the healing of tissue comprising a porous

pad, an airtight dressing, and means for applying negative pressure to a wound site, as generally disclosed on page 5, line 27 to page 6, line 26, and more specifically page 6, lines 19 to 26 of the description of the parent application as filed. The subject-matter of those independent claims focuses on different aspects of the system. Claim 1, defining in particular a means for connecting a distal end of a conduit through the dressing, a canister removably connected to a proximal end of the conduit, a first filter positioned between the canister and the means for applying negative pressure and a second filter positioned between the first filter and the means for applying negative pressure, focuses on elements permitting the suitable collection of exudate from a wound site. Claim 31, defining in particular a means for varying said negative pressure over a time interval, focuses on elements for suitably applying a variable negative pressure to the wound site. The Board accepts that since these aspects were originally claimed in different independent claims, the skilled person would understand that they were disclosed as being not necessarily linked to one another. However, there is no disclosure in the parent application as originally filed that these aspects should be considered incompatible with each other. On the contrary, the detailed description of the parent application as filed refers to a single embodiment of the invention (page 5, lines 23 to 26) and encompasses both aspects on page 6, line 27 to page 7, line 22 and page 9, line 31 to page 10, line 27, respectively. These aspects are described in detail with reference to different figures, but this does not mean that the figures relate to different, incompatible embodiments. Thus, the skilled person directly and unambiguously understands that these aspects are not only perfectly

compatible but even, preferably, to be combined. Hence, the combination of the features of independent claims 1 and 31 had a basis in the parent application as originally filed.

In claim 1 of the main request no features of the combination of claims 1 and 31 to 33 of the parent application as originally filed are missing. Hence, contrary to the appellant's arguments, no intermediate generalisation can arise.

As regards the appellant's arguments based on decisions T 1574/07 and T 1808/10, the Board notes that the conclusions drawn in the respective Reasons were based not only on the fact that claims without the correct dependencies had been combined, but also on the fact that the remaining application documents as originally filed did not provide any basis for such combinations either. The Board has shown that this is not the case for the subject-matter of claim 1 of the present main request.

3.1.3 For these reasons it is concluded that the subject-matter of claim 1 of the main request does not extend beyond the content of the parent or the original application as filed. It follows that the ground for opposition under Article 100(c) EPC does not prejudice the maintenance of the patent on the basis of the main request.

3.2 *Sufficiency of disclosure*

3.2.1 In the statement of grounds the appellant argued against the Opposition Division's decision that the invention as defined in claim 1 of the main request was sufficiently disclosed. The fact that these arguments,

substantiated under point 4 of that statement, were already presented at first instance is not, as such, a bar to their consideration by the Board, which has the competence to review the Opposition Division's decision. Pursuant to Article 12(4) RPBA the Board concludes that the appellant's objection that the invention as defined in claim 1 of the main request was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art is part of the appeal proceedings.

- 3.2.2 The appellant objected that the claimed invention was not sufficiently disclosed because the patent did not disclose how the pressure within the claimed system could be appropriately controlled and/or monitored.

The Board notes that, in order to assess whether the patent discloses the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, the common general knowledge of the skilled person is to be duly taken into account. There is no need for an exhaustive description of generally known technical details to be implemented according to the invention, if such an implementation does not require any undue burden because it is well within the competence of the skilled person. On the contrary, such a description may dilute the inventive teaching of a patent, making it more cumbersome for the skilled person to readily grasp the important technical points.

In the present case the skilled person, based on the common general knowledge in the art, can carry out the claimed invention without any undue burden. As the respondent and the Opposition Division observed, there are several known straight-forward possibilities of

finely varying the pressure in a system for stimulating the healing of tissue in a wound site as claimed. This could easily be done, for example, via the means for applying the negative pressure itself. If a vacuum pump is used, the pump could be reversible or, when idle, not sealed, thereby permitting a decrease of suction. Monitoring the actual pressure at the wound site can easily be done by providing a suitable pressure sensor, as generally known to the skilled person.

3.2.3 For these reasons the patent discloses the invention as defined in claim 1 of the main request in a manner sufficiently clear and complete to be carried out by a person skilled in the art. It follows that the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of the main request.

3.3 *Novelty*

The sole outstanding novelty objection to the subject-matter of claim 1 of the main request is based on P1.

P1 discloses a system for stimulating the healing of tissue by applying negative pressure to a wound site (abstract and figure 1).

The system comprises a porous pad (302, figure 3), an airtight dressing (covering bandage 314, figure 3), a conduit (20, figures 1 and 3), a canister (26, figures 3 and 6), a means for applying negative pressure to the wound site (vacuum pump 110, figures 3 and 6) and a first filter (108, figure 6) disposed between the canister and the means for applying

negative pressure.

- 3.3.1 In the Board's view, contrary to the conclusion reached by the Opposition Division in the impugned decision, P1 also discloses "a means for varying said negative pressure over a time interval comprising means for adjusting actual pressure to meet a varying target pressure, [...] [wherein] said varying target pressure oscillates between a set target maximum and a set target minimum pressure", as defined in claim 1.

In particular, on page 16, lines 23 to 28 of P1 it is disclosed that:

"the caregiver can choose between continuous, intermittent (profile) and no negative pressure modes. It will be appreciated that the apparatus 2 may be set up to provide various levels of vacuum at various times."

An apparatus functioning according to the disclosed intermittent (profile) pressure mode, for which various levels of vacuum can be provided at various times, does not work according to an on-off cycle, contrary to the respondent's arguments. Rather, as indicated by the use of the term "profile", the negative pressure in the system will necessarily vary from one level to a second level and back. These levels correspond to a set maximum and a set minimum target pressure to be reached at the wound site. Accordingly, the target pressure will vary between these two extremes too. Such a variation amounts to an oscillation of the target pressure within the meaning of the claim. It follows that the four parameters required by the claim, as argued by the respondent, are disclosed in P1. Moreover, the Board does not share the Opposition

Division's view that "in order to oscillate between a maximum and a minimum the target pressure has to take at least one value in between the maximum and the minimum values". Nothing in the claim prescribes this and even the description of the patent leaves it open, noting that the flow chart of figure 5 represents a preferred embodiment.

- 3.3.2 P1, however, does not disclose "a second filter positioned between said first filter and said means for applying negative pressure".

First of all, it is the established jurisprudence of the boards of appeal that claims should be construed from a technical point of view, trying to make technical sense of the features defined. In view of this, the appellant's argument that the term "between" referring to the position of the second filter had to be interpreted as merely relating to a physical position of the latter is not convincing. If a system is the subject-matter of the claim, its features are to be interpreted in the light of the way the system normally functions. In the present case the use of the claimed system presupposes a flow of fluid from a wound site to a means for applying negative pressure to the wound site. Consequently, from a technical point of view, it only makes technical sense to interpret the defined positions of the filters with respect to this flow of fluid.

As the appellant submitted, the system of P1 comprises a further filter in the form of air filter 137 associated with port 136 of a vacuum regulator, the latter being for mechanically establishing a maximum level of negative pressure that may be present in the system (page 10, lines 12 to 26 and figures 2 and 5).

However, as submitted by the respondent and held by the Opposition Division in the impugned decision, this filter is not between the first filter and the means for applying negative pressure within the meaning of the claim. Filter 137 is for filtering particles from air drawn into the system when pressure regulator 134 opens port 136. In normal operation, filter 137 cannot be used to filter fluid coming from the first filter (108). Hence, it cannot be considered to be functionally "between" the first filter and the means for applying negative pressure within the technical meaning of the term.

As regards the appellant's argument that sound chamber 140 housing the vacuum pump (page 11, lines 6 to 11 and figure 2) of P1 could be considered the second filter within the meaning of claim 1 of the main request, such a construction is excluded by a sensible technical reading of the claim. The skilled person would construe the claimed filters as adapted to filter out something from a fluid. A sound chamber is simply not intended for such a purpose.

It follows that P1 does not disclose a second filter disposed between the first filter and the means for applying negative pressure as required by claim 1 of the main request.

- 3.3.3 As a consequence, the subject-matter of claim 1 of the main request is novel over P1 within the meaning of Article 54 EPC. Therefore, the ground for opposition under Article 100(a) EPC in relation to novelty does not prejudice the maintenance of the patent on the basis of the main request.

3.4 *Inventive step*

- 3.4.1 It is undisputed by the parties that P1 could be considered the closest prior art.
- 3.4.2 As explained above, the subject-matter of claim 1 of the main request differs from the disclosure of P1 in the presence of a second filter disposed between the first filter and the means for applying negative pressure.
- 3.4.3 The technical effect of this differentiating feature may be derived from the patent, in particular paragraph [0027], and P1 itself. In systems for stimulating the healing of tissue of the kind disclosed in these documents, a first filter after the canister is normally a hydrophobic filter having the function of blocking liquid wound exudates so that they are captured in the canister. Such a filter may also have the function of acting as a fill sensor of the canister, by blocking the conduit connecting the vacuum pump with the wound site when the canister is full of liquid (P1, page 9, lines 18 to 22). Under these conditions all the suction of the pump is applied to the liquid in the canister. There is therefore a risk that the filter may be damaged and part of the fluid may pass through it. A second hydrophobic filter would therefore further inhibit contamination of the vacuum source with liquid wound exudates (column 6, lines 25 to 30 of the patent). However, as the appellant submitted, according to the patent the claimed system may comprise a different kind of "second filter", in the form of an odour vapour filter (column 6, lines 33 to 39). In this respect the Board notes that claim 1 of the main request does not specify the nature of the filters defined. Accordingly, the technical effect of a

second filter as claimed is to make it possible to separate functions otherwise to be performed by a single filter, or to provide for additional functions, allowing each filter to be independently engineered and optimised for its specific function (column 6, lines 30 to 32 of the patent).

3.4.4 The objective technical problem may therefore be regarded as how to reliably prevent unwanted fluids from reaching the means for applying negative pressure.

3.4.5 Like P1, P3 relates to a system for stimulating the healing of tissue in a wound site of a user by applying negative pressure (page 2, last paragraph). In particular, P3 discloses a system comprising means for applying negative pressure to the wound site (vacuum pump 84, figure 9, connected to line 62, figure 6), a canister for receiving wound exudates (19, figure 6), and a filter (46, figure 6 and page 10, second paragraph) disposed between the canister and the means for applying negative pressure.

In P3 it is expressly stated that "*a major safety concern is preventing wound fluids from contaminating the vacuum pump*" (page 10, second paragraph). Moreover, P3 discloses a second filter between the first filter and the means for applying negative pressure (filter 85, figure 9 and page 16, last paragraph), the presence of which "*ensures no wound fluids contaminate vacuum pump 84*".

As a consequence, P3 discloses the claimed distinguishing feature of the subject-matter of claim 1 of the main request over P1, addressing the objective technical problem.

Hence, contrary to the respondent's arguments, the disclosure of P3 would motivate the skilled person to modify the system of P1, thus arriving at the subject-matter of claim 1 of the main request in an obvious way.

- 3.4.6 As a consequence, the subject-matter of claim 1 of the main request lacks inventive step over the combination of P1 and P3. Therefore, the ground for opposition under Article 100(a) EPC in relation to inventive step prejudices the maintenance of the patent on the basis of the main request.

4. First auxiliary request

In comparison with claim 1 of the main request, claim 1 of the first auxiliary request defines that it is the system that oscillates the varying target pressure. However, this is also the case for the system of P1 functioning in intermittent (profile) mode. On page 16, lines 24 to 25 it is specified that "*the apparatus 2 may be set up to provide various levels of vacuum*".

It follows that the subject-matter of claim 1 of the first auxiliary request lacks inventive step for the same reasons as those given in relation to the subject-matter of claim 1 of the main request.

Hence, the patent cannot be maintained on the basis of the first auxiliary request pursuant to Article 52(1) in conjunction with Article 56 EPC.

Under these circumstances it is not necessary for the Board to formally decide on the admissibility of the first auxiliary request, objected to by the appellant.

5. Second auxiliary request

The respondent requested that the case be remitted to the department of first instance for further prosecution based on the second auxiliary request, since the appellant's objections to the second auxiliary request had not been heard before. The Board however notes that the subject-matter of claim 1 of the second auxiliary request was already presented before the Opposition Division as a fourth auxiliary request with letter dated 23 July 2010. The Opposition Division did not decide on that request only because it held allowable a higher-ranking request. In view of these circumstances and for reasons of procedural efficiency, the Board, making use of the discretion conferred on it by Article 111(1) EPC, decides not to remit the case to the Opposition Division for further prosecution based on this request.

5.1 *Clarity*

The appellant argued that in the definition of the process in the characterising portion of claim 1 it was not clear which pressure was meant in the expressions "if the pressure is increasing" and "if the pressure is decreasing", introduced into the claim during the opposition proceedings.

However, as the respondent observed, the claim specifies that "the system is adapted to control the negative pressure according to the [...] [defined] process". It follows that, for the skilled person, the pressure referred to in those expressions can only be the pressure to be controlled, i.e. the actual negative pressure in the system. As a result, those expressions

do not introduce any ambiguity into the claim.

As regards the fact that the claim does not define any structural means for checking and varying the pressure to be controlled, the Board notes that, in a claim directed to a system, defining a control process in terms of functional features is quite common and acceptable in claim drafting, as long as the skilled person knows how to implement those features. In the present case the Board does not see any difficulty for the skilled person in providing those features, for example in the form of appropriate sensors and a processing unit. Further, the amplitude of the interval and the pressure direction defined in the process depend on the circumstances of the specific application and can clearly be set or identified by the skilled person according to those circumstances.

It follows that the subject-matter of claim 1 of the second auxiliary request is clear and complies with Article 84 EPC.

5.2 *Added subject-matter*

The process defined in claim 1 of the second auxiliary request is additionally based on page 10, line 18 to page 11, line 4 and on figure 5 of the parent application as originally filed.

The appellant argued that the claim did not specify several features mentioned in those passages of the description, in particular that the process was carried out by a software program. Omitting these features constituted a non-allowable intermediate generalisation. However, the Board notes that the process defined in the claim is not technically linked

as such with the particular software or hardware means with which it can be performed. Rather, its essential features are represented by the steps required for achieving its technical effect. The Board is satisfied that claim 1 of the second auxiliary request encompasses all these steps. Hence, the subject-matter of claim 1 of the second auxiliary request does not extend beyond the content of the parent application as originally filed.

It follows that Articles 76(1) and 123(2) EPC are complied with.

5.3 *Inventive step*

5.3.1 Compared with claim 1 of the main request, claim 1 of the second auxiliary request further defines a control of the negative pressure according to a specific process. The parties did not dispute that this process constitutes a distinguishing feature over the disclosure of P1.

5.3.2 The fact that the pressure direction is changed from increasing to decreasing - or vice versa - upon reaching the maximum - or minimum - target pressure results in the actual pressure in the system never keeping a constant value, but continuously varying between the maximum and the minimum target pressures. This is not necessarily the case with the system disclosed in P1. According to the patent, such a variation increases the stimulation of cellular growth (paragraph [0037]).

5.3.3 The problem solved may therefore be regarded as a way to provide a system for improving the healing process

of a wound.

- 5.3.4 P1 and common general knowledge do not hint at the claimed distinguishing feature as a solution to this problem.

P2 discloses a suction and collection device for controlling the application of negative pressure to a wound site, the negative pressure being maintained in a dead band above a set negative pressure. As the respondent argued, such a control aims to keep the pressure at the wound site as constant as possible, while preventing a continuous on-off cycling (paragraph bridging columns 8 and 9 of P2). Since a major concern of P2 is to keep a constant pressure at the wound site, the skilled person would not consider it to improve a system applying varying negative pressure. As a consequence, a combination of P1 and P2 is not obvious.

For these reasons the Board concludes that the subject-matter of claim 1 of the second auxiliary request involves an inventive step. Thus, Article 52(1) in conjunction with Article 56 EPC is complied with.

6. The description has been brought into conformity with the claim of the second auxiliary request.
7. As the second auxiliary request is allowable, there is no need for the Board to consider the respondent's lower-ranking requests.

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:
 - claim 1 of the second auxiliary request;
 - adapted description (columns 1 to 10); and
 - figures 1 to 5,all filed during the oral proceedings.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated