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**Datasheet for the decision
of 21 January 2022**

Case Number: T 0644/18 - 3.2.02

Application Number: 08725372.0

Publication Number: 2109472

IPC: A61M1/00

Language of the proceedings: EN

Title of invention:

SYSTEM FOR MANAGING REDUCED PRESSURE AT A TISSUE SITE

Patent Proprietor:

KCI Licensing, Inc.

Opponents:

Paul Hartmann AG
Smith & Nephew, Inc.

Headword:

Relevant legal provisions:

EPC Art. 123(2), 100(c), 56
RPBA Art. 12(2), 12(4)

Keyword:

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0644/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 January 2022

Appellant: KCI Licensing, Inc.
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Party as of right: Paul Hartmann AG
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 January 2018 concerning maintenance of the
European Patent No. 2109472 in amended form.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: A. Martinez Möller
 Y. Podbielski

Summary of Facts and Submissions

- I. The appeals lie from the decision of the Opposition Division concerning maintenance of European Patent No. 2 109 472 in amended form according to then second auxiliary request as filed during the oral proceedings before the Opposition Division.
- II. The patent proprietor and opponent 2 appealed against the decision.
- III. The Board summoned the parties to oral proceedings and sent a preliminary opinion in a communication dated 4 October 2021. Among other issues, that communication indicated that the submissions by opponent 1 on the lack of inventive step of the first auxiliary request did not seem to be substantiated and that the Board preliminarily agreed with the reasoning and conclusion in point 5.2.2.1 of the appealed decision as regards the subject-matter of claim 1 being inventive over O1 and O16.
- IV. Oral proceedings took place on 21 January 2022.

The patent proprietor (appellant 1) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, alternatively, on the basis of one of the first to third auxiliary requests, all filed with the statement of grounds of appeal. The first auxiliary request corresponds to the second auxiliary request before the Opposition Division.

Opponents 1 (party as of right) and 2 (appellant 2) requested that the decision under appeal be set aside and that the patent be revoked.

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

"An apparatus (100) for managing reduced pressure at a tissue site (105), the apparatus comprising:
a reduced pressure source (110) operable to generate reduced pressure- and deliver the reduced pressure to the tissue site via a delivery tube (135);
a single pressure sensor (155)
a control tube (160), wherein the single pressure sensor (155) detects the actual reduced pressure at the tissue site (105) via the control tube;
a controller (170) coupled to the single pressure sensor and the reduced pressure source, the controller configured to detect a change in an operating parameter of the reduced pressure source indicative of a change to reduced pressure generated by the reduced pressure source and to determine a responsiveness of the actual reduced pressure measured by the single pressure sensor to an increase in reduced pressure generated by the reduced pressure source; and
an indicator (180) operable to emit a signal when the controller determines that the actual reduced pressure measured by the single pressure sensor is nonresponsive to the increase in reduced pressure generated by the reduced pressure source."

Compared to claim 1 of the main request, claim 1 of the **first auxiliary request** further includes the following features added to the end of the claim:

"and

a control tube relief valve (165) coupled to the control tube that relieves reduced pressure in the control tube when a blockage is detected in the control tube, and
a manifold (120), wherein the single pressure sensor (155) is operable to detect the actual reduced pressure at the tissue site (105) through the control tube (160) via the manifold."

VI. The following documents are relevant for this decision:

O1 US2006/0025727 A1

O16 WO 2007/088530 A1

VII. The arguments of appellant 2 (opponent 2), as far as they are relevant for the decision, may be summarised as follows.

Main request - added subject-matter

The addition of the feature "control tube" to claim 1 without the feature "control tube valve" resulted in added subject-matter. The application as filed consistently presented the control tube together with the control tube valve. There was also a functional inter-relationship between both.

First auxiliary request - inventive step

The features distinguishing the subject-matter of claim 1 from O1 related to leak detection. The person skilled in the art starting from the apparatus of O1 would apply the teaching of O16 on page 23, lines 1 to 11 and reach the subject-matter of claim 1.

VIII. The arguments of the party as of right (opponent 1), as far as they are relevant for the decision, may be summarised as follows.

Main request - added subject-mater

The control tube was described throughout page 12 of the application as filed, which described the system as also having a control tube valve. The valve was also necessary to avoid blockage of the tube. Hence, it was not allowable to have the control tube without the control tube valve.

First auxiliary request - inventive step

The additional features of claim 1 of the first auxiliary request, namely the control tube relief valve and the manifold, did not have a synergistic effect and were known from the prior art.

IX. The arguments of appellant 1 (patent proprietor), as far as they are relevant for the decision, may be summarised as follows.

Main request - added subject-mater

The application as filed provided basis for the control tube on page 12, line 1. The wording "may be coupled to control tube 160" on page 12, line 31 indicated that the valve was optional. Moreover, the control tube and the control tube valve were not inextricably linked.

First auxiliary request - inventive step

The appealed decision correctly concluded that the subject-matter of claim 1 was inventive over O1

combined with O16. The technical problem solved was improved control of reduced pressure at the tissue site. Neither O1 nor O16 disclosed a controller and an indicator as defined by claim 1.

Reasons for the Decision

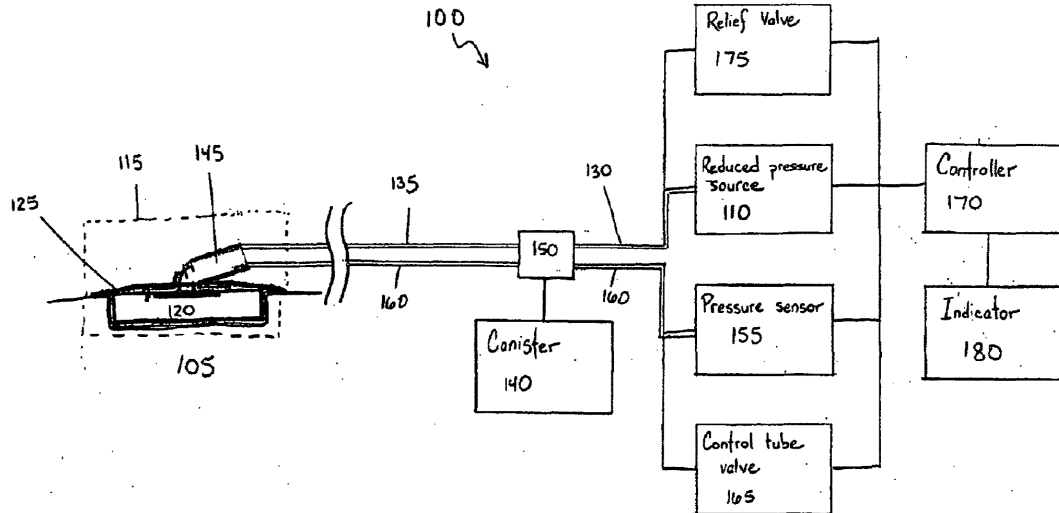
1. The invention

The invention is in the field of reduced pressure therapy. Subjecting a tissue site to reduced pressure augments and accelerates the growth of new tissue at the tissue site. This makes reduced pressure therapy helpful for treating wounds and promoting healing.

The claimed apparatus serves to manage the reduced pressure at the tissue site to maintain or increase the effectiveness of the treatment. The apparatus comprises a reduced pressure source, a single pressure sensor, a control tube, a controller and an indicator. The single pressure sensor detects the actual reduced pressure at the tissue site via the control tube. The controller is coupled to the sensor and the reduced pressure source and determines whether the measured reduced pressure is responsive to an increase in reduced pressure generated by the reduced pressure source. The indicator is operable to emit a signal when the controller determines that the measured reduced pressure is not responsive. Thus, detection of leaks and blockages in components of the system such as the tube that delivers the reduced pressure from the reduced pressure source to the tissue site may be facilitated.

Figure 1 of the contested patent, reproduced below and which also corresponds to Figure 1 of the application as filed, shows an apparatus 100 for managing reduced

pressure at a tissue site according to an embodiment of the invention.



2. Main request - added subject-matter

The application as filed consistently discloses the control tube in combination with a control tube valve (see Figure 1, claim 5 and page 12, line 30 to page 13, line 9 of the application as filed). The passage on page 12, lines 30 to 32 describes the system of Figure 1 to which page 12, line 1 also refers. According to this passage, the control tube valve is included in the system. The coupling of the control tube valve to the control tube is taught to be optional, but the presence of the control tube valve is not.

Moreover, the control tube and the control tube valve have a close functional relationship. The control tube valve serves to relieve the reduced pressure in the control tube and may be opened for example when a blockage is detected in the control tube (page 12, lines 31 to 32 and page 13, lines 3 to 9 of the application as filed).

There is thus no basis for the apparatus of claim 1 including the control tube without including the control tube valve. It follows that claim 1 comprises subject-matter extending beyond the content of the application as filed.

3. First auxiliary request - inventive step

3.1 Objections by the party as of right (opponent 1)

The party as of right submitted, in the letter of 9 October 2018, that no inventive step could be acknowledged for the first auxiliary request because the two additional features of claim 1 were known - pointing to two prior-art documents for each additional feature - and because there was no synergistic effect between them.

This submission does not reveal which apparatus from the prior art is to be regarded as the starting point for the subject-matter of claim 1, nor why the person skilled in the art would have carried out modifications to this apparatus which would result in an apparatus falling under the scope of claim 1. Hence, as pointed out in the communication dated 4 October 2021, the Board considers that these submissions are not substantiated within the meaning of Article 12(2) RPBA 2007 (referred to by Article 12(4) RPBA 2007). The party as of right did not argue against this view. The Board thus uses its discretion pursuant to Article 12(4) RPBA 2007 to not admit these submissions into the appeal proceedings.

3.2 Objections by appellant 2 (opponent 2)

The only objection against the first auxiliary request maintained by appellant 2 was the objection of inventive step over the teaching of documents O1 and O16. According to this objection, the apparatus disclosed by O1 did not comprise at least the following two features of claim 1:

"the controller configured ... to determine a responsiveness of the actual reduced pressure measured by the single pressure sensor to an increase in reduced pressure generated by the reduced pressure source"

"an indicator (180) operable to emit a signal when the controller determines that the actual reduced pressure measured by the single pressure sensor is nonresponsive to the increase in reduced pressure generated by the reduced pressure source."

These distinguishing features serve to detect and indicate that a component of the apparatus may be blocked or have a leak (see paragraphs [0059] and [0061] of the patent specification). The problem solved can thus be regarded as how to provide improved monitoring of the delivery of reduced pressure to the tissue site.

O16 deals with monitoring for leaks and/or blockages (see page 21, lines 25 to 27). To monitor for leaks and/or blockages, O16 teaches using a motor parameter and the actual pressure measurements at the chamber 54 obtained from the transducer 99 (see page 22, line 28 to page 23, line 11).

Incorporating the monitoring taught by O16 into the system of O1 would thus require, as argued in point 5.2.2.1 of the appealed decision, re-positioning the control tube and the relief valve in the system of O1. This is because the control tube of O16 (the tube connecting chamber 54 with transducer 99 in Figure 1, see also page 19, lines 6 to 9 and 24 to 29) is included in the main housing of the arrangement while in O1 the control tube (sensing conduit 16) and the associated relief valve (check valve in paragraph [0053], last sentence) are directly coupled to the tissue site.

Such fundamental modifications to the construction of the apparatus disclosed by O1 are beyond the type of modification that a person skilled in the art would contemplate without use of inventive skill. Hence, the objection of lack of inventive step over O1 and O16 is not convincing.

- 3.3 There were no further objections against the first auxiliary request. Since the first auxiliary request corresponds to the request found to meet the requirements of the EPC by the Opposition Division in the appealed decision, there is no reason to set aside that decision.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated