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**Datasheet for the decision
of 11 March 2019**

Case Number: T 0933/14 - 3.2.02

Application Number: 03776753.0

Publication Number: 1703922

IPC: A61M1/00

Language of the proceedings: EN

Title of invention:
DRAINAGE APPARATUS AND METHOD

Patent Proprietor:
Medela Holding AG

Opponents:
Gert Schmitt-Nilson/Stefan Weibel

Headword:

Relevant legal provisions:
EPC Art. 123(2), 54, 56

Keyword:
Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 0933/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 March 2019

Appellant:
(Opponents 02)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 14 February
2014 rejecting the opposition filed against
European patent No. 1703922 pursuant to Article
101(2) EPC**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The opponent lodged an appeal against the decision of the Opposition Division, dispatched on 14 February 2014, to reject the opposition against European patent No. EP 1 703 922.
- II. Opposition was filed against the patent as a whole and based on grounds for opposition under Articles 100(a) and (c) EPC.
- III. Notice of appeal was filed by the appellant/opponent on 17 April 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 24 June 2014.
- IV. The parties were summoned to oral proceedings by letter dated 21 December 2018.
- V. By letter dated 1 March 2019, the appellant announced that it would not be represented at the oral proceedings.
- VI. The following documents are referred to in this decision:

D9: US-A-5,738,656

D10: US-A-5,370,610

D11: US-A-4,735,606

D14: WO-A-97/18007

D16: US-A-3,982,540

D17: DE-B-1 148 709

D18: WO-A-03/103744

D19: US-A-4,573,965

VII. Oral proceedings took place on 11 March 2019.

The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the first to fifth auxiliary requests, filed with letter dated 29 December 2014, and the sixth auxiliary request, filed with letter dated 11 February 2019. The main request was withdrawn.

The respondent also withdrew its requests of remittal and of non-admission of D16 to D19 into the proceedings.

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

VIII. Claim 1 of the first auxiliary request reads as follows:

"An apparatus for removing body fluids from a body cavity (T) by suction, comprising
catheter means having a drainage lumen (3) and an auxiliary lumen (5) adapted for placement adjacent a wound in the body cavity (T) to be drained of body fluid, the drainage lumen (3) having a proximal end being in fluid communication with a proximal end of the auxiliary lumen (5);
a suction drainage collection means (2) for connection in fluid communication with the drainage lumen (3) and for receiving body drainage fluid from the body cavity (T);
a source of suction (1) for effecting negative pressure in the drainage lumen (3) and
means (7) for opening the auxiliary lumen (5) in order to supply air or gas to the body cavity (T)

characterized in that the apparatus comprises means for removing clots or plugs in the drainage lumen (3), these means comprising a first pressure sensor (6) for measuring the pressure in the auxiliary lumen (5) and a means (9) to increase the pressure difference between a pressure in the drainage lumen (3) and a pressure in the atmosphere when the auxiliary lumen (5) is open only when the pressure measured in the auxiliary lumen (5) corresponds at least to atmospheric pressure, wherein the first pressure sensor (6) is in communication with the means (9) for increasing the pressure difference."

IX. The appellant's arguments in so far as relevant to the present decision can be summarised as follows:

Claim 1 - lack of original disclosure (Article 123(2) EPC)

The original application documents did not disclose "means for removing clots or plugs in the drainage lumen", which were introduced as a subsystem comprising the "first pressure sensor" and the "means to increase the pressure difference".

Although the feature "a first pressure sensor measuring the pressure in the auxiliary lumen and being in communication with the means for increasing the pressure difference" was disclosed in original claim 3, its denotation as a "means for removing clots or plugs", together with the means to increase the pressure difference, could not be derived from the original application documents.

The passages of the description (page 2, lines 9 to 11 and lines 27 to 28, and page 5, lines 21 to 31)

referred to in the contested decision merely described the process of removing clots but did not disclose a subsystem specified as "means for removing clots or plugs".

Furthermore, the "means for removing clots or plugs" would have to include all elements mentioned in the description (page 5, lines 1 to 31) as being necessary for the removal of clots and for the return to normal operation. The omission of some of these elements, in particular the second pressure sensor 8, the valve 7 and the controller 9, constituted an unallowable intermediate generalisation.

Claim 1 - novelty with respect to D14

The feature "the means to increase the pressure difference increases the pressure difference only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure" did not imply any sort of hardware provision or pre-programming of the controller in order to carry out this functionality. The hardware components of claim 1 only had to be suitable for being programmed accordingly.

Hence, D14 had to be considered as novelty-destroying for the subject-matter of claim 1, since it disclosed an apparatus for removing body fluids from a body cavity by suction comprising all the structural features of claim 1 (page 5, paragraph 5 to page 6, paragraph 3; Figures 1, 4 and 6A to 6E). In particular, the microprocessor (4) (Figure 4) was suitable for an operation wherein the increase in pressure difference was effected when the auxiliary lumen was open and when there was atmospheric pressure in the auxiliary lumen.

The narrow interpretation of the claim implying a certain programming of the means to increase the pressure difference was not appropriate as it disregarded the fact that the claim was worded very broadly, using language such as "means for", and that the contested patent did not mention any programming of the controller.

Claim 1 - inventive step with respect to D9 in combination with any of D10, D11 and D16 or the common general knowledge

D9 disclosed a drainage device for removing fluids by suction from body cavities, from which the subject-matter of claim 1 differed in that the means for removing clots or plugs comprised "a means to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure" and in that "the first pressure sensor is in communication with the means for increasing the pressure difference".

The feature concerning the communication between the pressure sensor and the means for increasing the pressure was a mere implementation detail and could not involve an inventive step.

The objective technical problem solved by the differing features was to improve the removal of clots in the drainage lumen without increasing the danger of damaging the patient.

D10 related to a drainage tube system and addressed also the problem of blood clots in the drainage lumen,

which could lead to a stoppage of the apparatus (column 2, lines 27 to 30). Furthermore, D10 disclosed an auxiliary lumen for introducing vent air (column 5, lines 39 to 54; column 6, lines 46 to 49, Figure 4).

It was also known to the skilled person that the increase of suction pressure was a common measure for removing blood clots (column 2, lines 47 to 50 of D10). A clean-out procedure for dislodging and removing occlusions was described, during which a higher than normal pressure could be applied (column 8, lines 20 to 31 and column 9, lines 8 to 11).

When applying the teaching of D10 to the device of D9, it was obvious that the suction should be increased when the auxiliary lumen was open and when there was atmospheric pressure in the auxiliary lumen. Since D9 taught that it was advantageous to withdraw liquid when the auxiliary lumen was open (column 3, lines 45 to 48) and since the skilled person knew from D10 about the danger of applying too high a suction level (column 2, lines 44 to 46), it was obvious that the suction should be increased only when the auxiliary lumen was open, i.e. only when the pressure in the auxiliary lumen was atmospheric pressure. Consequently, the subject-matter of claim 1 lacked an inventive step in view of the combination of D9 and D10.

D11 also related to several measures for the removal of clogging in a drainage catheter with the aid of vent air, e.g. by increasing the flow rate in the vent lumen (column 6, lines 17 to 30), by otherwise increasing the pressure difference across the clogged matter (column 6, lines 17 to 30) or by hand stripping of the catheter, i.e. by manual squeezing of the catheter, which resulted in an increase in pressure difference

(column 6, lines 40 to 46). Since the hand stripping was done when the vent lumen was open, i.e. when the pressure in the cavity was close to atmospheric pressure (column 6, lines 46 to 55), D11 taught the increasing of the pressure only when the auxiliary lumen was open to atmosphere. It followed that the subject-matter of claim 1 was not inventive with respect to D9 and D11.

D16 disclosed a gastrointestinal aspirator pump with a double lumen tube having a negative pressure lumen and a positive pressure lumen (Figures 2 to 4; column 4, lines 17 to 37; column 3, lines 9 to 48). It also dealt with the loosening of a blockage by altering either the negative pressure or the positive pressure (column 8, lines 1 to 19). As an additional safety feature, D16 taught the provision of an air leakage input in the positive pressure lumen, to ensure that the pressure in that lumen could not drop below atmospheric pressure (column 1, line 65 to column 2, line 4). Hence, D16 taught to increase the pressure difference across the blockage only when the pressure in the auxiliary lumen corresponded at least to atmospheric pressure. Consequently, the combination of D9 and D16 would have led to the subject-matter of claim 1 in an obvious manner.

Starting from D9, the skilled person would also have arrived at the subject-matter of claim 1 by taking into account its common general knowledge. In particular, it would have been trivial and well known to the skilled person that the pressure difference across the clot should be increased in order to remove it (D17, column 1, lines 22 to 28) and to prevent the body tissue from damaging pressure (column 1, lines 20 to 22 of the contested patent; page 2, lines 6 to 8 of D18; column

1, lines 37 to 42 of D19; column 2, lines 44 to 46 of D10; and column 1, lines 54 to 59 of D11). Hence, the subject-matter was not inventive with respect to D9 and the skilled person's general knowledge.

Claim 1 - inventive step with respect to D11 in combination with D14 or D9

D11 taught the removal of clogging of drainage apparatus by hand stripping of the drain tube in the event that the increased vent air was not sufficient (column 6, lines 40 to 46). This hand stripping caused an increase in pressure difference in the drainage lumen. Hence, D11 described hand stripping as a manual measure to increase the negative pressure in the drainage lumen. Since this was done while the vent valve in the auxiliary lumen was open and the pressure in the cavity was atmospheric pressure (column 6, lines 46 to 55), tissue damage in the body cavity could be avoided.

The apparatus of D11 did not have a pressure sensor that was in communication with the means to increase the negative pressure.

Hence, the problem to be solved was the provision of an apparatus function to apply the increased negative pressure.

From D14 (page 6, lines 12 to 14, page 5, lines 24 to 26 and paragraph bridging pages 2 and 3) it was obvious that the hand stripping of D11 should be replaced by means to control the suction pump and a pressure sensor in the auxiliary lumen in order to increase the negative pressure when the pressure relief valve was open.

The automation of the hand stripping was also rendered obvious by D9, since it disclosed a pressure sensor in an auxiliary lumen that was coupled to a control device (column 6, lines 48 to 52).

Consequently, the subject-matter of claim 1 lacked inventive step with respect to the combination of D11 with either of D14 and D9.

According to the case law of the boards of appeal, a mere automation of method steps that were previously carried out manually, i.e. the automation of the hand stripping as claimed in claim 1, could not be considered inventive.

- X. The respondent's arguments are essentially those on which the present decision is based.

Reasons for the Decision

1. The appeal is admissible.
2. The invention relates to an apparatus for removing body fluids from a body cavity by suction. The apparatus comprises a catheter having a drainage lumen and an auxiliary lumen being in fluid communication at their proximal ends (i.e. the patient ends), fluid collection means and a source of suction in the drainage lumen, and a means for opening the auxiliary lumen to the atmosphere. The apparatus further comprises means for removing clots or plugs in the drainage lumen, these means comprising a pressure sensor for measuring the

pressure in the auxiliary lumen and a means to increase the pressure difference in the drainage lumen when the auxiliary lumen is open only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure. The pressure sensor is in communication with the means to increase the pressure difference.

Since the pressure difference is increased only when the pressure in the auxiliary lumen corresponds at least to atmospheric pressure, ill effects to the patient due to high negative pressure in the body cavity are prevented.

3. First auxiliary request - added subject-matter

Claim 1 of the first auxiliary request corresponds to claim 1 of the patent as granted. It is based on claims 1, 3 and 13 as originally filed, plus the following amendment:

- the apparatus comprises *means for removing clots or plugs* (...), these means comprising a first pressure sensor and a means to increase the pressure difference.

The Board holds that the amendment does not add subject-matter extending beyond the content of the application as originally filed, although "means for removing clots or plugs" were not mentioned in the application as originally filed. In the Board's view, the wording "means for removing clots or plugs" implies that the pressure sensor and the means to increase the pressure difference can be used in a method for removing clots and plugs in the drainage lumen. Such a method is described in the application as originally filed. In particular, it is mentioned (page 5, lines 21

to 25) that the auxiliary lumen is opened automatically and the pressure difference is increased automatically when the pressure sensor indicates a clot.

Moreover, the Board does not concur with the appellant in that the omission of the features "second pressure sensor", "valve" and "controller" constitutes an inadmissible intermediate generalisation. It is mentioned in the description (page 5, lines 25 to 26) that the second pressure sensor "can indicate the controller 9, that the clot C has been removed". Hence, the second pressure sensor is an optional feature which can show that the drainage lumen is open again and the suction power may be decreased. The Board acknowledges that the description refers to a valve (7) and a controller (9) in the context of means for removing clots or plugs. However, claim 1 as originally filed already included the more general features "means (7) for opening the auxiliary lumen (5)" and "means (9) to increase the pressure difference (...) when the auxiliary lumen (5) is open". Hence, claim 1 does not include any inadmissible intermediate generalisation.

It follows that the requirements of Article 123(2) EPC are met.

4. First auxiliary request - novelty

It is common ground that D14 discloses (Figures 1 and 4) an apparatus for removing body fluids from a body cavity comprising the features of the preamble of claim 1. The apparatus of D14 further includes a pressure sensor (108) for measuring the pressure in the auxiliary lumen (page 5, last three sentences).

However, the Board is of the opinion that D14 does not

disclose a "means to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure".

D14 relates to a portable wound treatment apparatus and addresses the issue of maintaining the pressure at the wound site within a predetermined range, irrespective of the movement of the patient. This can be achieved by measuring the pressure difference between the wound site and the pump, and by increasing or reducing the pump speed if the hydrostatic pressure increases or decreases (page 2, last paragraph to page 3, first paragraph). If it is intended to provide intermittent suction to be applied to the wound, the pressure relief valve (8) of the apparatus can be opened periodically (page 6, paragraph 3). During the application of constant suction, the valve remains closed. Thus, in D14 there is no link between a specific pressure value in the auxiliary lumen and the increase in pump speed. It follows that the apparatus of D14 is not suitable for increasing the pressure difference when the auxiliary lumen is open and only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure. To perform this function the controller of D14 would have to be reprogrammed.

In this regard, the Board does not concur with the appellant in that claim 1 has to be interpreted broadly in the sense that it only requires hardware components that can be programmed to carry out the function mentioned above. By the wording "means to (...) only when..." the claim defines the apparatus in terms of its function. Hence, only means suitable for performing this function without any further adaptation can be

considered as falling under the scope of the claim. Since D14 does not disclose such means, it can not anticipate the subject-matter of claim 1.

Moreover, the Board does not agree with the appellant in that the patent does not disclose any programming of the controller to perform the claimed functions. Since it is mentioned in paragraph [0022] that the opening of the valve and the increase of the suction power are done automatically, it is evident that the controller is programmed accordingly.

Consequently, the subject-matter of claim 1 of the first auxiliary request is novel over D14.

5. First auxiliary request - inventive step

5.1 Inventive step with respect to D9 in combination with D10, D11 or D16

D9 discloses (Figure 4) an apparatus for removing body fluids from a body cavity by suction, comprising the features of the preamble of claim 1. The Board further observes that the pressure in the auxiliary lumen (54) can be measured by a manometer (64). Hence, the manometer (64) is suitable to be used in a method of removing clots as described in the present patent and can therefore be regarded as part of a means for removing clots or plugs as defined in claim 1.

The subject-matter of claim 1 differs from the apparatus of D9 in that the means for removing clots or plugs further comprises "a means to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open only when the pressure measured

in the auxiliary lumen corresponds at least to atmospheric pressure" and in that "the first pressure sensor is in communication with the means for increasing the pressure difference".

The Board agrees with the appellant in that the problem to be solved can be regarded as the facilitation of the removal of clots in the drainage lumen while preventing ill effects to the patient.

Contrary to the appellant's assertion, the solution to this problem was not rendered obvious by the teaching of any of documents D10, D11 or D16. In particular, none of these documents discloses the measurement of the pressure in the auxiliary lumen and increasing the pressure difference only if the measured pressure corresponds at least to atmospheric pressure.

In detail, D10 teaches the removal of clots in the drainage lumen by introducing a separate clean-out apparatus into the lumen and applying repetitively a "higher than normal pressure". Although D10 mentions in the general part of the description the risk of high negative pressure to the patient (column 2, lines 44 to 46), it does not teach the avoidance of such risks during the clean-out procedure. In particular, D10 does not render obvious the measurement of the pressure in the auxiliary lumen and increasing the pressure difference only when the measured pressure is at least atmospheric pressure. Hence, contrary to the appellant's view, a combination of D9 and D10 would not lead to the subject-matter of claim 1.

In order to remove clots, D11 teaches increasing the flow of air to the cavity by opening the valve (66) in the vent lumen (22) (column 6, lines 17 to 30). In the

event that this is not successful, D11 further suggests hand stripping of the catheter (14), while the valve is open, i.e. while the pressure in the cavity is close to atmospheric pressure. However, although hand stripping might momentarily create a high negative pressure in the drainage lumen (column 6, lines 62 to 66), as pointed out by the appellant, the hand of the operator cannot be considered a component of the apparatus. Therefore, the apparatus of D11 does not include a "means to increase the pressure difference" as defined in claim 1. Moreover, D11 does not require the pressure in the vent lumen to be at least at atmospheric pressure. Thus, it does not disclose the measurement of the pressure in the vent lumen to ensure that this condition is fulfilled when performing the hand stripping.

Moreover, contrary to the appellant's assumption, D11 does not disclose increasing the negative pressure supplied by the vacuum regulator as a means of removing the clots. Instead, it mentions that a changing of the setting of the vacuum regulator is not necessary (column 6, lines 24 to 29 and lines 35 to 38).

It follows that the combination of D9 and D11 would not render the subject-matter of claim 1 obvious.

D16 teaches increasing and decreasing the negative pressure supplied by the vacuum pump (60) in order to dislodge a blockage in the drainage lumen (column 8, lines 8 to 19). The apparatus of D16 also includes a positive pressure lumen from which air under positive pressure is emitted in pulses during operation. In order to prevent the pressure in the positive pressure lumen dropping below atmospheric pressure, an air leakage device (82) is provided (column 3, lines 14 to

17). However, D16 does not disclose a pressure sensor for measuring the pressure in the positive pressure lumen. In fact, since it is ensured that the pressure in the positive pressure lumen does not drop below atmospheric level, as the appellant itself pointed out, it would be unnecessary to provide such a pressure sensor in the apparatus of D16. Hence, D16 even teaches away from measuring the pressure in the auxiliary lumen and using this measurement to increase the negative pressure only when the pressure corresponds to atmospheric pressure.

Hence, the combination of D9 and D16 would not lead to the subject-matter of claim 1 either.

5.2 Inventive step with respect to D9 and the skilled person's general knowledge.

The appellant alleged that the differing features of claim 1 are based on two entirely trivial considerations, the first being that a clot may be removed by increasing the pressure difference across the clot and the second being that damage to body tissue by high pressure must be prevented.

The Board observes that the second consideration merely describes the problem underlying the invention as claimed in claim 1, but not its solution. In the Board's view, it is irrelevant whether the problem belongs to the common general knowledge of the skilled person or whether the problem is known from D17 to D19. Rather, it is the solution that would have to be obvious in order to deny the existence of an inventive step. In the present case, the Board does not consider it obvious from the common general knowledge that means to increase the pressure difference should be provided

only when the measured pressure in the auxiliary lumen corresponds at least to atmospheric pressure, and the appellant did not submit any arguments to the contrary.

5.3 Inventive step with respect to D11 in combination with D14 or D9

D11 teaches the removal of clots from a drainage tube by opening the valve in the vent lumen, thereby increasing the flow of air to the cavity. If this fails, the drainage catheter can be stripped by hand to move the clogging material towards the collection chamber. Although hand stripping momentarily causes high pressure in the drainage lumen, in the Board's view, as explained above, it cannot be regarded as a means to increase the pressure difference as defined in claim 1. Furthermore, the apparatus of D11 does not include a pressure sensor for measuring the pressure in the vent lumen. Hence, D11 does not disclose the features of the characterising portion of claim 1.

The problem to be solved by these features can be regarded as the provision of an automatic means of removal of clots or plugs while protecting the patient from too high a level of suction in the body cavity.

The solution to this problem was not rendered obvious by any one of D14 and D9. Although both documents disclose a pressure sensor in the auxiliary lumen, the teaching does not include the use of the measurement from this sensor to control the means to increase the pressure difference, so as to increase the pressure difference only when the measured pressure corresponds at least to atmospheric pressure.

The Board does not concur with the appellant in that

the solution as defined in claim 1 is a mere automation of the manual method of hand stripping. If the skilled person had wished to automate the hand stripping, they would probably have provided instead an automated mechanical mechanism for performing the stripping. In contrast, claim 1 defines means to automatically increase the pressure difference by increasing the power of suction, depending on the measured pressure in the auxiliary lumen. Hence, hand stripping is not merely automated but replaced by another method that takes into account that measured pressure.

- 5.4 The Board concludes that the subject-matter of claim 1 of the first auxiliary request involves an inventive step.

6. Hence, none of the appellant's objections prejudices the maintenance of the patent on the basis of the first auxiliary request.

7. The description has been brought into conformity with the claims.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance, with the order to maintain the patent on the basis of:
 - claims 1 to 9 of the first auxiliary request filed with letter dated 29 December 2014;
 - adapted description, columns 1 to 4, filed during the oral proceedings;
 - figures 1 to 3 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated