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# Datasheet for the decision of 4 February 2025

**Case Number:** T 1305/22 - 3.2.02

**Application Number:** 14726183.8

**Publication Number:** 3010396

**IPC:** A61B5/00, A61M16/00

**Language of the proceedings:** EN

**Title of invention:**
RESPIRATORY THERAPY APPARATUS

**Patent Proprietor:**
Smiths Medical International Limited

**Opponent:**
Trudell Medical International

**Relevant legal provisions:**
EPC Art. 56, 84, 123(2)
RPBA 2020 Art. 13(2)

**Keyword:**
Amendment after notification of Art. 15(1) RPBA communication - taken into account (no)
Amendments - added subject-matter (no)
Claims - clarity (yes)
Inventive step - (yes) - problem and solution approach

**Decisions cited:**
T 0558/00

Europäisches Patentamt
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**Case Number: T 1305/22 - 3.2.02**

# D E C I S I O N
# of Technical Board of Appeal 3.2.02
# of 4 February 2025

| | |
|---|---|
| **Appellant:** (Opponent) | Trudell Medical International<br>725 Baransway Drive<br>London, Ontario N5V 5G4 (CA) |
| **Representative:** | Grünecker Patent- und Rechtsanwälte<br>PartG mbB<br>Leopoldstraße 4<br>80802 München (DE) |
| **Respondent:** (Patent Proprietor) | Smiths Medical International Limited<br>1500 Eureka Park<br>Lower Pemberton<br>Ashford, Kent TN25 4BF (GB) |
| **Representative:** | Charrier Rapp & Liebau<br>Patentanwälte PartG mbB<br>Fuggerstraße 20<br>86150 Augsburg (DE) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 March 2022 concerning maintenance of the European Patent No. 3010396 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chair** | M. Alvazzi Delfrate |
| **Members:** | A. Martinez Möller |
| | C. Schmidt |

## Summary of Facts and Submissions

I. In the decision despatched on 11 March 2022, the opposition division decided that, taking account of the amendments made by the patent proprietor during the opposition proceedings according to the then auxiliary request 13, European patent No. 3010396 and the invention to which it related met the requirements of the Convention.

II. An appeal was filed by the opponent. Oral proceedings before the Board took place on 4 February 2025.

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

The main request by the respondent (patent proprietor) was that the appeal be dismissed and that the patent be maintained on the basis of auxiliary request 13, which was the request found allowable in the decision under appeal. As an auxiliary measure the appellant requested that the patent be maintained on the basis of one of auxiliary requests 9 to 11 and 14 to 16, all filed with the letter setting out the grounds of appeal.

III. Claim 1 of the main request (i.e. of auxiliary request 13 in the decision under appeal) reads as follows:

"Respiratory therapy apparatus including a vibratory PEP therapy device (100) including a valve (11, 12) that is opened and closed by breathing through the device such as to produce an oscillating resistance to breathing through the device, the apparatus includes a

sensor (20) responsive to acoustic pressure waves transmitted through air caused by movement of the valve, the sensor (20) is arranged to provide a signal indicative of use of the device, and the sensor (20) is separate from the device (100) but placed close to it to receive the acoustic pressure waves transmitted from the device (100) through air to the sensor (20), characterised in that
the valve (11, 12) includes a valve element (11) on a rocker arm (12) that opens and closes an opening (10) during exhalation through the apparatus,
the oscillating movement of the rocker arm (12) producing an audible sound being transmitted through the surrounding air as the acoustic pressure waves,
the sensor (20) is arranged to provide a signal indicative of the frequency of oscillation,
the sensor (20) is contained in a unit including a display (24) on which is represented the frequency of oscillation detected by the sensor (20)."

IV. The following documents are relevant to the present decision:

D1 WO 2012/038903 A2
D5 Brigitte Bouzin, "La kiné sans accroc ou accro à la kiné", Article in Vaincre la Mucoviscidose, Feb. 2007, No 112
D10 US 2011/0125044 A1
D12 US 6,581,598 B1

V. The appellant's arguments relevant to the present decision can be summarised as follows.

*Added subject-matter*

Claim 1 of the main request comprised added subject-matter.

Claim 1 specified that the device included a valve that was opened and closed by breathing through the device. The application as filed only disclosed this feature in combination with other functionally linked features, in particular the shape of the opening and of the valve element and the rocker arm including an iron pin interacting with a magnetic field produced by a permanent magnet. Without the magnetic action, the rocker arm would move a single time into an open position and never move back, and it thus would not produce an oscillating movement or sound. The omission of these linked features when introducing the feature that the valve was opened and closed by breathing resulted in added subject-matter.

Claim 1 included the word "acoustic" in connection with the pressure waves. In the application as filed, the word "acoustic" was only disclosed in combination with the sensor being a microphone. The sensor in claim 1 was not explicitly or implicitly limited to a microphone, therefore resulting in added subject-matter.

*Clarity*

It was not clear in claim 1 if the valve element was the source for generating the acoustic pressure wave picked up by the sensor or if it was the rocker arm as such.

*Admittance of D1*

D1 was to be admitted into the appeal proceedings. D1 was part of the first-instance opposition proceedings and its discussion at the oral proceedings before the Board was merely a repetition of an argument raised in the first-instance proceedings without introducing new evidence or delaying the appeal proceedings. Moreover, there were exceptional circumstances as D1 addressed the indication in the Board's preliminary opinion that the location of the microphone was not considered to be trivial.

*Inventive step*

The subject-matter of claim 1 was not inventive starting from any of D1, D5 or D12.

Starting from D5, there were two distinguishing features: on one hand the construction of the valve with an oscillating rocker arm, and on the other hand the provision of the sensor in a unit including a display. There was no synergistic effect between these features, and therefore partial problems had to be used.

As compared with the respiratory apparatus disclosed in D5, the claimed construction of the valve had advantages in that it could be used in any orientation relative to gravity. The person skilled in the art would have replaced the construction in D5 (the "Flutter" device) with a construction with a magnetic mechanism as taught in D12 (the "Acapella" device).

As compared with the microphone attached to the respiratory apparatus disclosed in D5, the claimed provision of the sensor in a unit including a display was not associated with any advantage in the contested

patent (see paragraphs [0008] and [0019]), and merely represented an alternative. At best, the feature could be seen as improving the ergonomics. It would have been obvious, using common general knowledge, to use the built-in microphone of the laptop shown in D5 instead of a microphone attached to the respiratory apparatus. This modification would also have been obvious in view of either of D1 or D10. Paragraphs [0057] and [0058] of D10 disclosed that built-in microphones or external microphones could be used without any discernible difference.

Starting from D12, the person skilled in the art would have arrived at the subject-matter of claim 1 step by step, in a manner similar to that described in decision T 558/00. First, it would have been obvious to include a microphone as taught by D5. Second, it would have been an obvious alternative to use the built-in microphone of the laptop in D5 in order to improve ergonomics and avoid having any cables.

VI. The respondent's arguments relevant to the present decision can be summarised as follows.

*Added subject-matter*

Claim 1 of the main request did not comprise added subject-matter.

Claim 4 as originally filed disclosed a valve element as specified in claim 1 of the main request, without requiring the additional features mentioned by the appellant. Moreover, it was clear from the application as filed that the pressure waves to be detected were audible sound pressure waves, i.e. acoustic pressure waves. The sensor had to be responsive to acoustic

pressure waves, as specified in claim 1, without necessarily being limited to a microphone.

*Clarity*

The valve in claim 1 included a valve element on a rocker arm that opened and closed an opening. It was clear that the movement of the valve, i.e. of the movable part of the valve, caused the acoustic pressure waves.

*Admittance of D1*

D1 and the objections relying on it were not to be admitted into the appeal proceedings as they had been filed very late and there was no reason for not submitting them earlier.

*Inventive step*

The subject-matter of claim 1 involved an inventive step when starting from either of D5 or D12.

D5 taught the use of a microphone glued to the device for getting a suitable signal, i.e. teaching away from using a microphone built into a laptop, which would have resulted in poorer sensitivity. The location of the sensor specified in claim 1 was not a mere alternative to the attachment of the microphone disclosed in D5, but resulted in improved ergonomics. D10 described the use of a cell phone without teaching the solution in claim 1.

The two-step approach used by the appellant for the attack starting from D12 was not permissible and was based on hindsight.

## Reasons for the Decision

1. The patent

1.1 Positive expiratory pressure (PEP) devices are devices that present a resistance to expiration through the device. PEP devices are used to help treat patients suffering from a range of respiratory impairments. Vibratory devices that provide an oscillating resistance to flow are particularly effective.

1.2 To be effective, the devices must be used regularly at prescribed intervals. Users often neglect that, and it is difficult for the patient and the clinician to maintain a record of use. The invention addresses this problem by providing an apparatus including a vibratory PEP therapy device (such as the device shown in Figure 1 reproduced below) and a sensor. The sensor, which is responsive to acoustic pressure waves, is separate from the device and is arranged to provide a signal indicative of use of the device. It is contained in a unit including a display on which the frequency of oscillation detected by the sensor is represented.

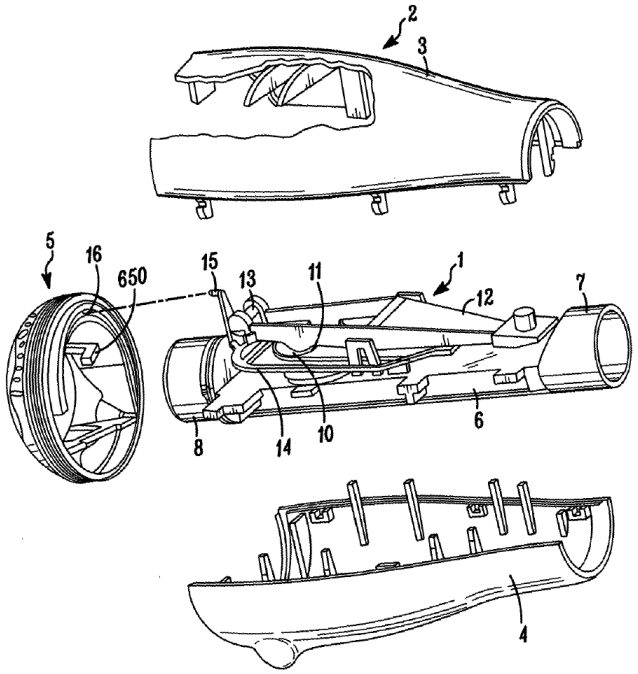


FIG. 1

2. Main request - added subject-matter

2.1 Claim 1 specifies the feature that the valve includes a valve element on a rocker arm that opens and closes an opening during exhalation through the apparatus. This feature adds details to the feature in the preamble of claim 1 that the valve is opened and closed by breathing through the device.

2.2 The feature was specified in claim 4 as originally filed and also disclosed on page 2, third paragraph, third sentence, in both cases independently of the features that have been omitted according to the appellant's submission (i.e. opening with non-linear profile, conical valve element, iron pin interacting with a permanent magnet). Hence, the alleged omissions do not lead to subject-matter which extends beyond the content of the application as filed.

2.3 The appellant puts forward that the use of the term "acoustic" to specify the pressure waves in claim 1 without also specifying that the sensor is a microphone results in added subject-matter. As set out in point 12.2 of the appealed decision, the term "acoustic" means relating to sound. It is clear from the application as filed (see for example page 2, third paragraph; page 3, fifth paragraph; page 6, second paragraph and penultimate sentence on the page) that the apparatus produces sound, thus implying that the pressure waves are "acoustic". Moreover, the original claim 1 does not explicitly specify that the sensor includes a microphone, a feature that is presented as optional (see the original claim 2). Hence, the amendment does not result in added subject-matter irrespective of whether or not the features of the sensor in claim 1 imply that the sensor is a microphone.

2.4 It follows that the main request complies with Article 123(2) EPC.

3. Main request - clarity

3.1 On one hand, claim 1 specifies that the valve includes a valve element on a rocker arm that opens and closes an opening during exhalation through the apparatus, and on the other hand it specifies that the sound waves are caused by the movement of the valve and produced by the oscillating movement of the rocker arm.

3.2 As pointed out by the Board in the communication under Article 15(1) RPBA, this does not give rise to a contradiction, since the rocker arm is part of the valve as specified in claim 1, and it does not result

in any doubt as to the scope of protection, either. The fact that claim 1 does not state whether or not the valve element is involved in generating sound and whether or not the sensor captures sound made by the valve element may result in a broad scope in this respect, but it does not give rise to any lack of clarity. Hence, the main request complies with Article 84 EPC.

4. Admittance of D1

4.1 D1 had been filed with the notice of opposition but not discussed in the appeal proceedings until the appellant indicated, at the oral proceedings before the Board, its intention to use it in two inventive-step objections (starting from D5 and starting from D1 itself).

4.2 The appellant argued that D1 was not new evidence, but that relying on it merely amounted to repeating an argument submitted in the first-instance proceedings, without delaying the appeal proceedings; however, D1 is new evidence as far as the appeal proceedings are concerned. Therefore, D1 and the objections relying on it constitute an amendment to the appellant's appeal case made after notification of a communication under Article 15(1) RPBA. According to Article 13(2) RPBA, such an amendment will, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

4.3 The appellant submitted that there were exceptional circumstances because the Board, in its communication under Article 15(1) RPBA, had considered that the location of the microphone was not trivial; however,

the same consideration was central to the finding that claim 1 was inventive in the decision under appeal (see last paragraph of page 37 and first paragraph of page 38 of the decision under appeal) and was also discussed by both parties in their written submissions during the appeal proceedings. Hence, the communication under Article 15(1) RPBA presented the Board's preliminary opinion on an issue under dispute without introducing a new issue into the appeal proceedings. It thus cannot justify the admittance of the intended amendment at such a late stage of the proceedings.

4.4 Therefore, the Board decided not to take D1 and the objections relying on it into account (Article 13(2) RPBA).

5. Main request - inventive step starting from D5

5.1 D5 discloses (see in particular the right-hand column of page 31) a vibratory PEP device (the "Flutter") with a microphone glued to it and plugged into a laptop. The microphone provides a signal indicative of the frequency of oscillation of the device. This frequency is then displayed on the screen of the laptop.

5.2 The Board agrees with the appellant that the features distinguishing the subject-matter of claim 1 from D5 (construction of the valve of the device on one hand and placement of the sensor on the other hand) have no synergistic effect and specify solutions to partial problems. The Board also agrees that the person skilled in the art starting from D5 would replace the "Flutter" device with the "Acapella" device from D12 (see e.g. Figure 2) without exercising inventive skill, as also acknowledged in section 42.1.3 of the decision under appeal.

5.3 With respect to the placement of the sensor, even if the appellant's submission that it merely specifies an alternative arrangement (rather than improving ergonomics) were to be followed, the Board is not convinced that the person skilled in the art would arrive at the claimed arrangement without exercising inventive skill. D5 teaches that the microphone is to be attached directly to the device ("il faut fixer un petit micro sur le couvercle du Flutter au moyen de pâte" on page 31, right-hand column, third paragraph), and it is not apparent why the person skilled in the art, using only common general knowledge, would go against this teaching. In addition, it is uncertain whether a built-in microphone provided in a laptop would have sufficient sensitivity in the relevant range of frequencies (see also paragraph [0018] of the contested patent). The greater distance between such a microphone and the therapy device could also result in poorer pickup of the sound generated during operation, further discouraging the person skilled in the art from this modification from D5.

5.4 The appellant put forward that the person skilled in the art would be prompted by D10 to use a built-in microphone. Paragraphs [0056] to [0060] of D10 disclose various embodiments for monitoring wheezing, coughing and activity data of an individual with asthma or other lung diseases (see also paragraph [0045]). In the embodiment in paragraph [0058], a computational module, a speaker, a microphone and an accelerometer are incorporated in a single device, giving the iPhone as an example; however, D10 does not prompt the person skilled in the art to use a microphone in a laptop to detect the frequency of the oscillation produced in a vibratory PEP therapy device. Instead, in paragraph

[0060], D10 explains the advantages of using a separate device that contains a microphone and is placed closer to the mouth to better detect sounds made by the user, teaching that is aligned with the use of a separate microphone in D5.

5.5 It follows that, starting from D5, the person skilled in the art would not arrive at an apparatus anticipating the subject-matter of claim 1 without exercising inventive skill.

6. Main request - inventive step starting from D12

6.1 D12 discloses a vibratory PEP therapy device including a valve as specified in claim 1. D12 does not disclose a sensor, and the features distinguishing the subject-matter of claim 1 from D12 are all features related to the sensor.

6.2 According to the appellant, the person skilled in the art starting from D12 would arrive at an apparatus anticipating the subject-matter of claim 1 using several obvious steps: in a first step, the person skilled in the art would follow the teaching of D5 to use a microphone to provide a signal indicative of the frequency of oscillation; in a second step, to improve ergonomics, it would be obvious to use the built-in microphone of the laptop rather than a microphone attached to the respiratory device. This approach using several obvious steps was acknowledged in the case law of the Boards of Appeal, for example in decision T 558/00.

6.3 In decision T 558/00, the document defining the starting point only incompletely disclosed implementation details of a printer (points 6 and 7 of

the Reasons), and neither that document nor the secondary document used in the inventive-step objection disclosed details of the carrier to be used in the printer (point 10 of the Reasons). The person skilled in the art had to fill in the informational gaps and, in particular, had to find a suitable carrier as a residual task. That situation does not apply to the present case, in which D5 clearly discloses that a separate microphone is to be attached directly to the respiratory device, without leaving a gap in this respect. The approach submitted by the appellant amounts to using the problem-solution approach starting from D12 and using it again starting from the result (i.e. from the combination of D12 with D5) in order to depart from an important element of the solution taught by D5. This approach is based on hindsight and is not a permissible way of assessing inventive step.

6.4 Moreover, for the reasons set out above when assessing inventive step starting from D5, the person skilled in the art would not be prompted to depart from the teaching of D5 and to instead use a built-in microphone provided in a laptop.

7. In summary, none of the objections prejudices the maintenance of the patent in the version found in the decision under appeal to meet the requirements of the EPC.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated