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**Datasheet for the decision  
of 19 September 2018**

**Case Number:** T 1615/13 - 3.2.02

**Application Number:** 07007698.9

**Publication Number:** 1852137

**IPC:** A61M16/00

**Language of the proceedings:** EN

**Title of invention:**

Apparatus for administering oxygen or air with added oxygen,  
for respiratory therapies

**Patent Proprietor:**

Intersurgical S.P.A.

**Opponent:**

BOTTI & FERRARI S.R.L.

**Headword:**

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 1615/13 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 19 September 2018**

**Appellant:** BOTTI & FERRARI S.R.L.  
(Opponent) Via Cappellini, 11  
I-20124 Milano (IT)

**Representative:** Paglia, Pietro  
BOTTI & FERRARI S.R.L.  
Via Montebello, 2  
40121 Bologna (IT)

**Respondent:** Intersurgical S.P.A.  
(Patent Proprietor) 12, Via Morandi  
41037 Mirandola, Modena (IT)

**Representative:** Corradini, Cesare  
Ing. C. Corradini & C. S.r.l.  
Via Dante Alighieri, 4  
42121 Reggio Emilia (IT)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 8 May 2013  
rejecting the opposition filed against European  
patent No. 1852137 pursuant to Article 101(2)  
EPC**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** D. Ceccarelli  
P. L. P. Weber

### **Summary of Facts and Submissions**

- I. The opponent has appealed against the Opposition Division's decision, dispatched on 8 May 2013, rejecting the opposition against European patent No. 1 852 137.
- II. The patent was opposed on the sole ground of lack of inventive step.
- III. Notice of appeal was received on 4 July 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 29 August 2013.
- IV. The Board summoned the parties to oral proceedings. In the communication accompanying the summons, the Board expressed its preliminary opinion that document:  
  
A5: "GUIDA ILLUSTRATA DELLE EMERGENZE", second edition 2005, M. Chiaranda, Piccin Nuova Libreria s.p.a., pages 288 to 298  
  
was the closest prior art.
- V. Oral proceedings took place on 19 September 2018.  
  
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 to fourth auxiliary requests, all filed with letter dated 10 August 2018.

VI. The following documents are also mentioned in the present decision:

A5a: partial English translation of A5;

A2: US-A-3,913,607.

VII. Claim 1 of the patent as granted reads as follows:

"An apparatus for administering oxygen or air with added oxygen, for respiratory therapies, characterized in that it comprises a a [sic] Venturi meter (2) which is connected to an oxygen source (15), an air intake (16) which can be controlled by a flow control element (17) being provided on said Venturi meter (2), characterized in that said Venturi meter is directly connected to a respirator hood (1), and in that said Venturi meter (2) is connected to said oxygen source by means of a first flowmeter (14)."

VIII. The appellant's arguments where relevant to the present decision may be summarised as follows:

A2, as an alternative to A5, could be considered the closest prior art for the subject-matter of claim 1 of the patent as granted. Although A2 did not disclose a respiratory hood, it related to the same technical field and was concerned with the same problem, i.e. providing a versatile oxygen diluter (second paragraph of A2). The diluter disclosed in A2 was also suitable for administering oxygen to a respiratory hood. Although the oxygen flow rates mentioned in column 4, lines 35 to 40, were not suitable for CPAP (Continuous Positive Airway Pressure) therapy using a respiratory hood, the patent did not mention CPAP therapy at all. The range of flow rates disclosed in A2 partly overlapped with the range of flow rates suitable for

effectively providing oxygen to a patient by means of a respiratory hood. Moreover, those disclosed flow rates were only exemplary: A2 did not mention a maximum flow rate beyond which the diluter could not function properly. If the diluter of A2 had to be used with a hood, the oxygen flow rate could simply be set for that use. At the filing date of A2, CPAP therapy was not common practice. It was, however, at the filing date of the patent. Since the filing date of the patent was the relevant date for assessing inventive step, the skilled person would know how to set up the diluter of A2 for CPAP therapy with a hood. Hence, A2 could be considered the closest prior art.

Starting from A5 as the closest prior art, the subject-matter of claim 1 of the patent as granted was not inventive over a combination with the common general knowledge or with A2.

A5 disclosed an apparatus for administering oxygen comprising a Venturi meter and a respiratory hood. Compared with the subject-matter of claim 1 of the patent as granted, it did not disclose that the Venturi meter was directly connected to the hood. This distinguishing feature addressed the problem of simplifying the device of A5.

A2 disclosed a Venturi meter directly connected to an oxygen mask or tubing for such a mask (column 4, lines 54 to 60) and was concerned with the provision of a simple device (column 4, lines 41 to 46). The skilled person would, therefore, provide a Venturi meter directly connected to the respiratory hood in the apparatus of A5 in an obvious way. Providing a Venturi meter directly connected to an oxygen delivery device was also part of the common general knowledge. Whether

other features of the apparatus of A5 had to be modified or dispensed with because of the provision of the Venturi meter directly connected to the respiratory hood was a matter which the skilled person would be able to deal with on the basis of obvious technical considerations. More particularly an analyser for monitoring the oxygen concentration administered to a patient, present in the oxygen circuit of the apparatus of A5, would be dispensed with by the skilled person since it would be rendered superfluous by the presence of the Venturi meter, allowing the oxygen flow to be set directly.

IX. The respondent's arguments where relevant to the present decision may be summarised as follows:

Claim 1 of the patent as granted defined an apparatus for administering oxygen comprising a respiratory hood. Such an apparatus necessitated particular pressure and flow conditions of the oxygen. It was not automatic that those conditions could be obtained in apparatuses employing respiratory masks such as the one disclosed in A2. A5, which was the only document disclosing an apparatus for administering oxygen comprising a respiratory hood, disclosed that the pressure and flow conditions required for the use of respiratory hoods (page 298, first and second paragraphs, of A5a) were different from those typically employed for the use of respiratory masks. It followed that A5 was the closest prior art.

The feature of claim 1 of the patent as granted whereby the Venturi meter was directly connected to the respiratory hood solved the problem of making the respiratory apparatus safer and simpler, as described in paragraph [0021] of the patent.

The skilled person would not provide the apparatus of A5 with a Venturi meter directly connected to the respiratory hood, because that could only be done at the expense of other features. For example, the analyser for monitoring the oxygen concentration administered to a patient, present in the oxygen circuit of the apparatus of A5, would have to be placed downstream of the Venturi meter, which was not technically feasible or at least not obvious.

It followed that the subject-matter of claim 1 of the patent as granted was inventive.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *The invention*

The invention relates to an apparatus for administering oxygen, or air with added oxygen, for respiratory therapy. The therapy is to be performed, in particular, in case of emergencies (paragraph [0002] of the patent).

Such apparatuses normally employ nasal cannulas, nasal or facial masks, or respiratory hoods for delivering oxygen-enriched air to a patient.

The apparatus of the invention is of the kind employing a respiratory hood, and comprises a Venturi meter connected to an oxygen source, and an air intake controllable by a flow control element. The Venturi meter is directly connected to the respiratory hood and



is connected to the oxygen source by means of a flowmeter.

According to the patent (paragraph [0006]) the aim of the invention is to simplify known respiratory apparatuses for treating emergencies, by providing a portable device for "the most disparate types of use".

3. *The closest prior art*

It is the established jurisprudence of the boards of appeal (as cited in "Case Law of the Boards of Appeal of the European Patent Office", 8th edition 2016, I.D.2) that the problem and solution approach is applied for the assessment of inventive step, which is the only ground for opposition raised by the appellant.

According to the problem and solution approach the closest prior art is to be identified first.

The closest prior art should provide the most promising springboard to the invention. This implies that if an invention is not obvious starting from the closest prior art, it will not be obvious starting from other prior art either.

The closest prior art should be directed to the same purpose or effect as the invention. As the appellant pointed out, it should be assessed from the skilled person's point of view on the day before the valid priority date of the patent in order to represent a situation as close as possible in reality to that encountered by the inventor (jurisprudence cited in "Case Law of the Boards of Appeal of the European Patent Office", 8th edition 2016, I.D.3.1 and I.D.3.2).

The appellant argued that either of A2 and A5 could be considered the closest prior art.

A2 concerns an oxygen diluter for delivering oxygen-enriched air to patients, which can be adjusted to achieve different oxygen concentrations (column 1, lines 4 to 9 and 41 to 43). According to A2, such a diluter is usually employed in combination "with oxygen masks of various type" (column 1, lines 4 to 7). More particularly, it has one end "attached directly to an oxygen mask or large bore tubing for such a mask" (column 1, lines 54 to 60). The diluter disclosed in A2 eliminates the disadvantages of requiring separate diluter units for achieving different oxygen concentrations and "is relatively simple, easy to manufacture and assemble" (column 1, lines 41 to 46). Further, it makes it possible to significantly reduce noise in operation (column 1, lines 51 to 53, and column 2, lines 6 to 11).

A5 discloses an apparatus for administering oxygen or air with added oxygen to a patient by means of a respiratory hood for providing CPAP therapy (page 296, first and last paragraphs, of A5a). It describes the advantages and the peculiarities of employing a respiratory hood instead of facial or nasal masks (page 296, last paragraph, and page 298, second and third paragraphs, of A5a). It further discloses that by using specific devices employing the Venturi effect, adjustable by the operator, the high flow rates and the oxygen concentrations needed for CPAP therapy with a hood can be maintained (page 298, first paragraph, of A5a).

It is the Board's view that the most promising starting point towards the invention as defined in claim 1 of

the patent as granted is A5 since, similarly to the invention, it concerns specific respiratory apparatuses comprising a hood in which the oxygen concentration can be adjusted by means of the Venturi effect. A2 discloses the use of an oxygen diluter in apparatuses comprising respiratory masks, which are of a different kind. The use of masks involves different technical considerations, for example in relation to the air losses at the mask periphery and the smaller air volume inside the mask, which may require oxygen flow rates different from those present in apparatuses employing respiratory hoods.

The appellant's argument that A2 related to the same technical field and was concerned with the same technical problem as the claimed invention is not accepted. Providing a more versatile oxygen diluter in the context of A2 starts from the assumption that, when the diluter of A2 was devised, the known diluters necessitated a plurality of separate units to achieve different oxygen concentrations (column 1, lines 25 to 29 and 41 to 43). This has little to do with the problem of simplifying an apparatus for providing respiratory therapies by means of a hood, the apparatus already presenting a Venturi meter that makes it possible to adjust the oxygen concentration at will, as described in the patent (paragraphs [0017] and [0021]). In this context of establishing the closest prior art, in addition to being a mere assertion not supported by any evidence, the appellant's argument that the device of A2 was suitable for effectively administering oxygen to a respiratory hood is also irrelevant in substance. The same applies to the assertion that the skilled person would know how to set up the diluter of A2 for CPAP therapy with a hood.

It follows that A5 is the closest prior art.

4. *The objective technical problem and its solution*

It is common ground that A5 does not disclose a Venturi meter directly connected to the respiratory hood.

A5 generally teaches that the oxygen concentration in the air delivered to the patient may be adjusted by means of a flow control element based on the Venturi effect (page 298, first paragraph, of A5a). It is, however, silent about the position of the flow control element in the apparatus for administering oxygen, or air with added oxygen. Based on figure 5B-23 on page 298 of A5, which depicts such an apparatus comprising a respiratory mask, but also usable with respiratory hoods (page 298, second paragraph of A5a), it can be inferred that the flow control element is within the device for supplying high flow rates ("erogatore d'alti flussi" in the figure), connected to an air filter ("filtro" in the figure) as explained on page 298, first paragraph of A5a, upstream of an analyser ("cella O2" in the figure) for monitoring the oxygen concentration administered to the patient (page 298, first paragraph, of A5a).

Providing a Venturi meter directly connected to the respiratory hood makes it possible to easily adjust the oxygen concentration at the patient with only the need for a connection with a suitable oxygen source.

As also explained in the patent (paragraph [0021]), the objective technical problem of simplifying the construction and the use of the apparatus for administering oxygen, or air with added oxygen, is addressed.

A5 teaches a specific respiratory apparatus for providing CPAP therapy, the quality of operation of which should be ensured and closely monitored. This is apparent from the provision of an air filter, upstream of the flow control element, and of the analyser, downstream of the flow control element, for monitoring the effective oxygen concentration of the air administered to the patient (page 298, first paragraph). Moreover, in figure 5B-23 a further monitoring device ("ossimetro") is visible proximate to the device for supplying high flow rates ("erogatore d'alti flussi").

Providing a Venturi meter directly connected to the respiratory hood in the apparatus of A5 would require several modifications of other elements of the apparatus for preserving its operation as taught in A5. For example, some means for filtering the air drawn in through the Venturi meter should be provided in close proximity or even attached to it, and some means for monitoring the effective oxygen concentration of the air administered to the patient should be envisaged downstream of the Venturi meter. Moreover, all these elements would be close to or on the respiratory hood, thus increasing its weight, affecting the patient's comfort and impairing the view of the patient's face, which would be detrimental in the specific technical context of A5 as explained above. Globally, the implementation of the distinguishing feature of the subject-matter of claim 1 of the patent as granted would require a substantial redesign of the closest prior art, which goes beyond the normal activities the person skilled in the art would undertake without inventive step.

The appellant's argument that the skilled person would simply do away with the analyser for monitoring the oxygen concentration administered to the patient, in view of the presence of a Venturi meter directly connected to the hood and allowing a direct setting of the oxygen flow, is not convincing. The mere setting of the oxygen concentration by a Venturi meter is inherently less accurate than a constant monitoring of that concentration in the air delivered to the patient. The acceptance of such accuracy loss is neither taught in nor derivable from A5. On the contrary, its specific technical context rather dictates the opposite. It follows that even if a Venturi meter directly connected to a respiratory hood was generally known or taught by A2, the skilled person would still not implement it in the apparatus of A5 in an obvious way.

Moreover, as far as concerns the appellant's argument that A2 disclosed a Venturi meter directly connected to a respiratory mask or tubing for such a mask, the Board explained in point 3 above that the position of the Venturi meter in the apparatus of A2 bears no relation to the problem of simplifying an apparatus for providing respiratory therapies of the kind disclosed in A5.

For these reasons, the subject-matter of claim 1 of the patent as granted involves an inventive step (Article 56 EPC) in view of the cited prior art.

5. It follows that the ground for opposition under Article 100(a) EPC raised by the appellant does not prejudice the maintenance of the patent as granted. Hence, under Article 101(2) EPC, the opposition is to be rejected.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated