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**Datasheet for the decision
of 18 November 2019**

Case Number: T 0757/15 - 3.2.02

Application Number: 08396014.6

Publication Number: 2168623

IPC: A61M16/00, A61M16/10

Language of the proceedings: EN

Title of invention:

Arrangement for detecting a leak in anesthesia system

Patent Proprietor:

General Electric Company

Opponent:

Maquet Critical Care AB

Headword:

Relevant legal provisions:

EPC Art. 54, 100(a)

RPBA Art. 12(4), 13(1)

Keyword:

Admittance of a document filed with the statement of grounds
of appeal (yes)

Novelty - main request (no)

Admittance of first auxiliary request (no)

Decisions cited:

Catchword:



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Case Number: T 0757/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 November 2019

Appellant: Maquet Critical Care AB
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Representative: Schaumburg und Partner Patentanwälte mbB
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Respondent: General Electric Company
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Representative: TBK
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 12 February
2015 rejecting the opposition filed against
European patent No. 2168623 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman W. Sekretaruk
Members: M. Stern
S. Böttcher

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the Opposition Division, posted on 12 February 2015, rejecting the opposition against European patent No. 2 168 623.

II. Notice of appeal was filed on 13 April 2015, and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 19 June 2016.

III. The following documents are cited in the present decision:

E1: US-A-5 161 525

E9: US-A-2005/0087190

IV. Oral proceedings were held on 18 November 2019.

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

The respondent (patent proprietor) requested that the appeal be dismissed or the European patent be maintained on the basis of the first auxiliary request, filed 18 November 2019.

V. Claim 1 of the **main request** (patent as granted) reads as follows:

"1. An arrangement for detecting a leak in an anesthesia system comprising:
a ventilator (1) configured to control respiratory movements, including at least one flow sensor

(8,10,12,42) for measuring a ventilator gas flow added for an inspiration and removed for an expiration; a gas mixer (3) for supplying a fresh gas flow for a respiration, including at least one flow sensor (38,35,36) for measuring the fresh gas flow added; and a breathing circuit (2) for conducting an expiration gas flow to said ventilator (1) and for conducting the fresh gas flow from said gas mixer (3) for the respiration and for conducting the ventilator gas flow added for the inspiration, characterized in that said arrangement further comprising a leak analyzer (40) for receiving information indicative of the measured gas flows of said flow sensors and which leak analyzer (40) is configured to determine based on said information both the gas volume added and the gas volume removed and to compare these gas volumes to each other and to determine the anesthesia system leakage."

VI. Claim 1 of the **first auxiliary request** reads as follows (amendments to claim 1 of the main request highlighted by the Board):

"1. An arrangement for detecting a leak in an anesthesia system comprising:
a ventilator (1) configured to control respiratory movements, including at least one flow sensor (8,10,12,42) for measuring a ventilator gas flow added for an inspiration and removed for an expiration;
a gas mixer (3) for supplying a fresh gas flow for a respiration, including at least one flow sensor (38,35,36) for measuring the fresh gas flow added,
wherein the gas mixer (3) includes an anesthetic agent supply (37) for vaporizing an anesthetic agent into the fresh gas flow; and

a re-breathing circuit (2) for conducting an expiration gas flow to said ventilator (1) and for conducting the fresh gas flow from said gas mixer (3) for the respiration and for conducting the ventilator gas flow added for the inspiration, wherein the re-breathing circuit returns the expiration gas flow to next inspiration; and
~~characterized in that said arrangement further comprising a leak analyzer (40) for receiving information indicative of the measured gas flows of said flow sensors and which leak analyzer (40) is configured to determine based on said information both the gas volume added and the gas volume removed and to compare these gas volumes to each other and to determine the anesthesia system leakage, wherein the leak analyzer is configured to determine that the anesthesia system is leaking in case the gas volume added is substantially larger than the gas volume removed compared to the change in the amount of gas stored in the anesthesia system and the anesthesia system is tight in case the difference in the gas volume added and the gas volume removed are substantially equal compared to the change in the amount of gas stored in the anesthesia system."~~

VII. The arguments of the respondent which are relevant for the present decision may be summarised as follows:

Main request

Document E9 was filed late in the sense that it had been filed only with the statement of grounds of appeal and, therefore, should not be admitted into the proceedings. E9 did not provide information concerning novelty of the subject-matter of claim 1 of the granted patent which went beyond document E1.

Document E9 was concerned with a ventilator to support or substitute the patient's own ventilatory effort without reference to an anesthesia system as claimed. Moreover, the anesthesia system of claim 1 comprised a ventilator including sensors for gas flow added to the breathing circuit and gas flow removed from the breathing circuit, a gas mixer and the breathing circuit, i.e. a rebreathing circuit, in which the ventilator and the gas mixer served the breathing circuit. In contrast, the ventilating system 30 of E9 served a non-rebreathing system. The exhaust flow sensor 62 was not part of a component of the ventilating system 30. E9 did not show a breathing circuit according to claim 1 as granted. Hence, E9 did not disclose a sensor for measuring ventilator gas flow added for an inspiration and ventilator gas flow removed for an expiration. It was clear from the wording of claim 1 that it defined a closed breathing circuit. Furthermore, the secondary gas delivery system 66 in E9 could not be considered as a gas mixer as claimed, since it only delivered one gas from a single source G, rather than a mixture of gases from different gas supplies (30, 31) as in the patent. Hence, the secondary flow sensor (70) did not measure the flow added by a separate gas mixer but one component of the gas delivered by the whole ventilator system.

First auxiliary request

The first auxiliary request was admissible since it was filed in response of appellant's change in the identification of certain features in E9. The amended claim included additional features extracted from dependent claims 3 and 7 of the patent, as well as from

column 5, lines 35 to 37 and column 1, lines 16 and 17 of the description of the patent. The features taken from the description referred to a re-breathing circuit in which the expired gas is returned for the next inspiration.

VIII. The arguments of the appellant that are relevant for the present decision are essentially those on which the reasons set out below are based.

Reasons for the Decision

1. The appeal is admissible.
2. The invention relates to an arrangement for detecting a leak in an anesthesia system comprising, in essence, a ventilator for controlling respiratory movements including flow sensors for measuring a ventilator gas flow added for an inspiration and removed for an expiration, a gas mixer for supplying a fresh gas flow including a flow sensor for measuring the fresh gas flow added, a breathing circuit for conducting said gas flows, and a leak analyser for receiving information indicative of the measured gas flows of said flow sensors and configured to determine, based on said information, the gas volume added for an inspiration and the gas volume removed for an expiration, to compare these gas volumes to each other and to determine the anesthesia system leakage.
3. *Admittance of E9*

In the appealed decision, the Opposition Division reached the conclusion that the subject-matter claimed was novel over E1. Document E9 was filed by the

appellant together with the statement setting out the grounds of appeal as a highly relevant document for assessing the requirement of novelty of claim 1 of the granted patent. In a prima-facie consideration, the Board agrees with the appellant's view regarding the relevance of this document which discloses further aspects which are not directly and unambiguously derivable from E1, such as the claimed determination of the gas volumes. (The Board eventually held E9 to be indeed novelty-destroying, as indicated below.)

Since E9 was filed at the earliest possible stage in the appeal and addresses the issue of novelty which was decided upon in the impugned decision and is relevant for the present proceedings, the Board sees no reason not to admit this document into the appeal proceedings (Article 12(4) RPBA).

4. *Main request - novelty*

- 4.1 Document E9 discloses a ventilator system 30 that comprises a primary gas flow delivery system 32 which includes a pressure generator 34, a pressure/flow control element 36 and a flow sensor 38 (paragraph [0023]; Figure 1). The primary gas is breathing gas, indicated in Figure 1 with arrow A. The system comprises, moreover, an exhaust assembly 56 that monitors and/or controls the venting of exhaust fluids to atmosphere, as indicated by arrow E, and includes a pressure sensor 60, an exhaust flow sensor 62 and an exhaust flow control element 64 (paragraph [0028]).

The mentioned gas flow delivery system 32 and the exhaust assembly 56 constitute therefore a ventilator as claimed, which is configured to control respiratory movements and includes flow sensors (38, 62) for

measuring a ventilator gas flow added to the patient for an inspiration (breathing gas indicated with arrow A) and for measuring a gas flow removed from the patient for an expiration (exhaust gases indicated with arrow E).

- 4.2 The system of E9 comprises, furthermore, an oxygen or secondary gas delivery system 66 for delivering, from a source indicated by arrow G, a supplemental or secondary gas flow, concomitantly with the primary gas flow (paragraph [0031]). The secondary gas delivery system 66 comprises a secondary gas flow control element 68 and a secondary flow sensor 70. The secondary gas flow is provided to inhalation manifold 48 where it is introduced or mixed with the primary gas flow, which together form the flow of breathing gas delivered to the patient (paragraph [0031]).

The secondary gas delivery system 66 with its secondary flow sensor 70 anticipates the gas mixer as claimed, which is just defined to include a flow sensor for measuring the gas flow added to the primary gas flow.

The respondent argued that the gas added by the secondary gas delivery system 66 was not a mixture of gases and therefore the secondary gas delivery system 66 could not be equated to a gas mixer. This argument is not convincing, however, since also the patent describes an embodiment of a gas mixer where only one gas supply is connected to the gas mixer (column 7, lines 4 to 7).

- 4.3 E9 discloses, moreover, a breathing circuit 50 having an inspiratory limb 52 for carrying gas to the patient and an expiratory limb 54 for carrying gas from the

patient (paragraph [0027]). The gas flowing through the inspiratory limb 52 is the mixture of the primary and secondary gases.

That is, the inspiratory limb 52 has the functions of "conducting the fresh gas flow from said gas mixer (secondary gas delivery system 66) for the respiration" and of "conducting the ventilator gas flow added (breathing gas indicated with arrow A carried by the primary gas flow delivery system 32) for the inspiration" recited in claim 1. The expiratory limb 54 has the function of "conducting an expiration gas flow to said ventilator" recited in claim 1.

Contrary to the respondent's view, claim 1 does not define any feature limiting the breathing circuit to a re-breathing circuit in which the expired gas is returned for the next inspiration, as mentioned in the description of the patent (paragraphs [0002] and [0021]) and depicted in the figures. Incidentally, the description makes it clear that a re-breathing circuit is just an optional embodiment of the claimed breathing circuit (column 5, lines 35 to 37).

4.4 The system of E9 includes a processor 46 which is configured to detect leaks in the system by determining the leak volume during a breathing cycle using equation (9) disclosed in paragraph [0065]:

$$V_{loss} = T_s \sum_{i=0}^n (Q_{primary} + Q_{secondary} - Q_{exhaust})$$

where $Q_{primary}$ and $Q_{secondary}$ are, respectively, the flows of the primary gas and the secondary gas measured by flow sensors 38 and 70, and $Q_{exhaust}$ is the exhaust gas flow measured by flow sensor 62 (paragraph [0052]). The sum of the flows $Q_{primary}$ and $Q_{secondary}$ multiplied by the

sampling period T_s represents the volume added, and flow Q_{exhaust} multiplied by T_s represents the gas volume removed.

Hence, the processor 46 in E9 is a leak analyser which receives information indicative of the measured gas flows of the flow sensors 38, 70 and 62, determines based on this information both the gas volume added and the gas volume removed, compares these gas volumes to each other and determines (on this basis) the system leakage.

- 4.5 The respondent argued, moreover, that E9 was concerned with a ventilator to support or substitute the patient's own ventilatory effort, without referring to an anesthesia system as claimed.

This argument is not convincing as the claim is not directed to an anesthesia system. The claim defines, instead, "an arrangement for detecting a leak in an anesthesia system", that is, an arrangement that is *suitable for* detecting a leak in an anesthesia system. It is (undisputed) common general knowledge that a ventilator system (as that of E9) is a component of an anesthesia system. As a consequence, the ventilator system of E9 with its leak detection system is suitable for detecting a leak in an anesthesia system.

- 4.6 The Board therefore concludes that the subject-matter of claim 1 lacks novelty within the meaning of Article 54 EPC.

- 4.7 As a consequence, the grounds for opposition of Article 100(a) EPC prejudice the maintenance of the patent as granted.

5. *First auxiliary request - admittance*

5.1 The respondent filed the first auxiliary request only at the end of the oral proceedings, after the Board had announced its conclusion that the subject-matter of claim 1 of the patent as granted did not fulfil the requirement of novelty over E9.

5.2 It is the established jurisprudence of the boards of appeal that the appeal procedure is designed to ensure that the proceedings are as brief and concentrated as possible and ready for decision at the conclusion of oral proceedings. Therefore, amendments to the claims should be filed at the earliest possible moment and the Board has discretion under Article 13(1) RPBA to disregard amended claims if they are not filed at the earliest possible moment, and in particular if they are not filed in good time prior to oral proceedings. The Board must exercise that discretion in view inter alia of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

5.3 In the present case, the Board sees no justifiable reason for the respondent to have waited until the end of the oral proceedings before filing the first auxiliary request.

The only justification given by the respondent was that it was responding to the appellant's changed identification of certain features in E9 during the oral proceedings. The respondent did not explain, however, which arguments were novel, and the Board does not recognise any either. At the oral proceedings there were no new, let alone unforeseeable, developments

concerning the novelty objection regarding E9 raised throughout the appeal proceedings.

Moreover, the Board's communication annexed to the summons to oral proceedings included an explicit caveat regarding late filings, citing the provisions of Article 114(2) EPC and Articles 12 and 13 RPBA.

- 5.4 As explained by the respondent, claim 1 of the first auxiliary request amends claim 1 of the granted patent to include additional features extracted from dependent claims 3 and 7 of the patent, as well as from column 5, lines 35 to 37 and column 1, lines 16 and 17 of the description of the patent. In particular, the features taken from the description limit the breathing circuit to a re-breathing circuit in which the expired gas is returned for the next inspiration.

The Board shares the appellant's view that this novel subject-matter has not yet been examined during the appeal proceedings and may require, moreover, an additional search. It is hence difficult, if not impossible, for the appellant and the Board to appropriately deal with the modified subject-matter for the first time during the oral proceedings. The filing of the first auxiliary request is therefore contrary to the need of procedural economy.

- 5.5 As a consequence, the Board does not admit the first auxiliary request under Article 13(1) RPBA.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The European patent is revoked.

The Registrar:

The Chairman:



D. Hampe

W. Sekretaruk

Decision electronically authenticated