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Datasheet for the decision of 22 October 2009

Case Number: T 0144/08 - 3.2.02

Application Number: 98305273.9

Publication Number: 0894506

IPC: A61M 16/12

Language of the proceedings: EN

Title of invention:
On-line detection and correction in anesthesia delivery system

Patentee:
Datex-Ohmeda, Inc.

Opponent:
Drägerwerk AG & Co. KGaA

Headword:
-

Relevant legal provisions:
EPC Art. 52(1)

Relevant legal provisions (EPC 1973):
EPC Art. 54(1),(2), 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
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Catchword:
-

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Case Number: T 0144/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 22 October 2009

Appellant: (Opponent)
Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
D-23542 Lübeck (DE)

Representative:
Harbsmeier, Jörn Felix
Uexküll & Stolberg
Patentanwälte
Beselerstrasse 4
D-22607 Hamburg (DE)

Respondent: (Patent Proprietor)
Datex-Ohmeda, Inc.
3 Highwood Drive
Tewsbury
Massachusetts 01876 (US)

Representative:
Hedley, Nicholas James Matthew
Kilburn & Strode LLP
20 Red Lion Street
London WC1R 4PJ (GB)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 6 November 2007 rejecting the opposition filed against European patent No. 0894506 pursuant to Article 102(2) EPC 1973.

Composition of the Board:

Chairman: M. Noël
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division to reject its opposition to European patent No. 0 894 506.

The opposition was filed against the whole patent and based on Article 100 (a) EPC 1973 (lack of novelty and inventive step).

With its decision posted on 6 November 2007 the Opposition Division held that subject-matter of granted claim 1 was novel and involved an inventive step and rejected the opposition, accordingly.

II. A notice of appeal against this decision was filed by the opponent on 21 December 2007 and the appeal fee was paid on the same day. The statement of grounds was submitted on 19 February 2008.

III. The following documents are of interest in the appeal procedure:

D1: The user instruction book for a PhysioFlex Anaesthesia System Model number 54031001 V6.02 D03
D2: US-A-5 094 235
D4: EP-A-0 496 336
D5a: GB-A- 2 008 953
D6: WO-A-92/11887.

IV. Oral proceedings were held on 22 October 2009. The following requests were submitted:

The appellant requested that the decision under appeal be set aside and European Patent 0 894 506 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or that the patent be maintained on the basis of one of the sets of claims submitted as auxiliary requests 1 to 4 filed with the letter dated 19 August 2008.

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

"An anesthesia system for delivering a breathing gas containing a settable anesthetic concentration to a patient, said anesthesia system comprising: a patient circuit (14) for administering the breathing gas and anesthetic agent to the patient, said patient circuit having a wye connector (26) for connection to a patient through which inhaled and exhaled gases pass to and from a patient, a fresh gas supply (46,50) providing fresh gas to said patient circuit (14), said fresh gas supply comprising an electronic controlled gas mixer (46) for providing a mixture of gases at a settable proportion and an electronic controlled vaporizer (50) for introducing anesthetic vapor to the mixture of gases from said electronic controlled gas mixer, a CPU (48) controlling said electronic controlled vaporizer (50) and said electronic controlled mixer (46), a mixer setting device (54) operable by a user to input to said CPU the concentration of at least one component of the breathing gas desired to be administered to a patient through said patient circuit (14), a first gas monitor (56) for analyzing said at least one component and means to cause a flow of gas to enter said patient

circuit (14) from said fresh gas supply (46,50), the first gas monitor (56) is arranged for analyzing, said at least one component at or near said wye connector (26), the means to cause a flow of gas to enter said patient circuit (14) from said fresh gas supply (46,50) is such as to cause a high flow of gas to enter the patient circuit (14), characterized in that the system includes a second gas monitor (60) detecting the concentration of said at least one component in the gas circulating within said patient circuit (14), and said CPU (48) includes means to compare the concentration of said at least one component determined by said first gas monitor (56), said second gas monitor (60) and the concentration of said at least one component inputted by a user with said input device (54) when said high flow of gas is entering said patient circuit".

Claims 2-11 are dependent claims.

VI. The parties argued as follows:

Appellant

D1 disclosed an anaesthesia system having all the features of the preamble of claim 1. This system also had a second gas monitor for detecting the anaesthetic gas concentration, corresponding to feature 8, and a monitoring unit which examined whether a given value fell within a given range, which amounted to a comparison with the first gas monitor.

The first gas monitor helped to maintain the supply of fresh gas to the desired setting, and the second gas monitor associated with the monitoring unit gave an

alarm when the gas concentration exceed a given threshold. This construction took account of the fact that a faulty gas monitor could lead to a dangerous concentration of gas in the circuit, and thereby disclosed the feature that the monitors must themselves be monitored. The monitoring unit could be set at an alarm value which differed trivially from the desired setting, so that if an alarm was sounded, this meant that one of the monitors or the fresh gas supply was faulty. This was a 3-way comparison corresponding to feature 9 of claim 1. The subject-matter of claim 1 lacked novelty, accordingly.

D2 disclosed all the features of the preamble of claim 1, including a high gas flow mode because it disclosed flushing the system with anaesthetic gas. This fell within the term "high flow" since claim 1 did not define this term and did not compare this with the minute volume. Therefore, only the features 8 and 9 were not disclosed in D2. The corresponding objective problem was to provide an anaesthesia system in which the operation and precision of the gas monitors could be supervised.

D6 disclosed the concept of providing a second gas monitor for the same gas component as the first monitor, connected to a control unit, to detect discrepancies between the set and the actual values of gas concentration. Both gas monitors were connected to a control unit and D6 taught comparing the desired value of the anaesthetic concentration with the measured values in the two anaesthetic gas monitors. Faced with the problem posed upon consideration of D2, the person skilled in the art would invoke the solution suggested

by D6, thus leading to the claimed system in an obvious manner.

D5a dealt specifically with the need to calibrate gas monitors in a respiratory apparatus. In order to do so a calibration gas could be supplied to the inhalation line, or the mixer settings could provide the desired gas mixture. In the latter case the readings of the sensors would be compared with each other and inevitably with the settings of the mixer, which is the same 3-way comparison defined in feature 9 of claim 1. This claim only defined a 3-way comparison, it was not a method claim and did not define features relating to the detection of the location of the error.

Therefore, starting from D2 and given the above objective problem, the person skilled in the art would invoke the teaching of D5a, which would result in the claimed system in an obvious manner. The combination of the documents D2 and D5a was not precluded by the fact that they related to an anaesthesia system and a respiratory system, respectively, because the problem was one of checking proper operation of the apparatus, which was common to both types of apparatus. D4 disclosed an open circuit anaesthesia system similar to the system of D5a.

Respondent

Claim 1 defined a high gas flow, i.e. a high flow of the breathing gas as a whole and not a high flow of one component only of the gas. Moreover, by high flow in the patent was meant a flow rate above the minute volume of the patient.

The person skilled in the art would not combine the teachings of D2 and D5a because they related to different technical fields and purpose. But even if he did combine them some features of claim 1 would still be missing, such as the provision of the second sensor in the appropriate position, the change from low gas flow to high gas flow at which the sensor readings should agree, the need for a by-pass line, and a 3-way comparison.

Reasons for the decision

1. The appeal is admissible.

Main request

2. The parties used a feature breakdown of claim 1 as follows:

1. An anaesthesia system for delivering a breathing gas containing a settable anaesthetic concentration to a patient, said anaesthesia system comprising:
2. a patient circuit (14) for administering the breathing gas and anaesthetic agent to the patient,
2.1 said patient circuit having a wye connector (26) for connection to a patient through which inhaled and exhaled gases pass to and from a patient,
3. a fresh gas supply (46,50) providing fresh gas to said patient circuit (14), said fresh gas supply comprising

3.1 an electronic controlled gas mixer (46) for providing a mixture of gases at a settable proportion and

3.2 an electronic controlled vaporizer (50) for introducing anaesthetic vapor to the mixture of gases from said electronic controlled gas mixer,

4. a CPU (48) controlling said electronic controlled vaporizer (50) and said electronic controlled mixer (46),

5. a mixer setting device (54) operable by a user to input to said CPU the concentration of at least one component of the breathing gas desired to be administered to a patient through said patient circuit (14),

6. a first gas monitor (56) for analyzing said at least one component and

7. means to cause a flow of gas to enter said patient circuit (14) from said fresh gas supply (46,50), the first gas monitor (56) is arranged for analyzing, said at least one component at or near said wye connector (26), the means to cause a flow of gas to enter said patient circuit (14) from said fresh gas supply (46,50) is such as to cause a high flow of gas to enter the patient circuit (14), characterized in that

8. the system includes a second gas monitor (60) detecting the concentration of said at least one component in the gas circulating within said patient circuit (14), and

9. said CPU (48) includes means to compare the concentration of said at least one component determined by said first gas monitor (56), said second gas monitor (60) and the concentration of said at least one component inputted by a user with said input device (54)

when said high flow of gas is entering said patient circuit.

3. Novelty

Document D1 discloses a closed circuit ventilator comprising a T-connector with a patient tube, an inspiration limb having an O_2 sensor, and an expiration limb having an anaesthetic sensor. A single comparison of the sensor readings is made with corresponding set values, and a computer sets the desired O_2 and anaesthetic agent concentrations that are to be delivered to the patient.

A separate monitoring unit which works independently of the main system provides a safety check that the levels of gases are not too low or too high. The readings from the monitoring unit are used to trigger an alarm if, for the example, the oxygen level in the breathing gas falls to a dangerously low level, or if nitrogen build-up reaches an undesirable level the system is purged and filled at a high gas rate with a fixed composition of fresh gas.

While D1 discloses the comparison of a single measured concentration of one component with the concentration set by the user for that component, any difference between the measured concentration and the set concentration is used to control the inlet valves or the anaesthetic agent injector, there is no disclosure in Dl of a comparison between the three concentrations (for diagnostic or any other purpose), as required by Feature 9 of claim 1 of the patent.

For these reasons the subject-matter of claim 1 is novel.

4. Inventive step

4.1 It is agreed by the parties that D2 discloses an anaesthesia system comprising the features 1 to 6 of the preamble of claim 1. The appellant contends that feature 7 (the means to cause a flow of gas to enter said patient circuit from said fresh gas supply is such as to cause a high flow of gas to enter the patient circuit) is also disclosed in D2 because in this system it is possible to flush the system with the anaesthetic which involves increasing the concentration from say 0.5% to 5% by volume (D2: column 8, line 67 to column 9, line 3). The Board does not accept this argument.

Claim 1 of the patent in suit makes a distinction between the breathing gas and a component of the breathing gas, which are respectively defined in features 1 and 5, for example. The breathing gas is the whole gas mixture which is supplied to the patient circuit, and the gas sensors analyse only one component of the gas. This is consistent with the description of the patent according to which the breathing gas which is supplied by the mixer 46 and the agent vaporizer 50 enters the inspiratory limb 22, and the monitors 56 and 60 detect single components of the gas, which may be O_2 or CO_2, for example. By high gas flow, in feature 7 of claim 1 is meant that the flow of the whole breathing gas is increased and not just that of one component thereof. Therefore, D2 does not disclose a high flow rate mode in the sense of the patent in suit.

Moreover, it is necessary, according to the presently claimed invention, that the overall gas flow, in the high flow mode, be substantially higher than in the low flow mode, such that the gas composition at both gas monitors should be the same. As an example, the volumetric flow should be above the patient's minute volume. By contrast, a change of the anaesthetic concentration from 0.5% to 5% by volume in D2 will hardly affect the overall gas flow.

For these reasons a change of the anaesthetic level in the D2 system does not correspond to feature 7 of claim 1, and the system of claim 1 is distinguished over the system of D2 by the features 7 to 9.

4.2 The appellant has formulated a technical problem based on D2 as that of monitoring whether one of the gas sensors is faulty and requires calibration. This formulation does not correctly reflect the actual achievement of the claimed system over that of D2.

Firstly, feature 7 is based on the realisation that when the gas flow is high the gas composition should be identical at both the gas monitors 56 and 60 (see paragraph [0020] of the patent in suit). For this reason a second gas monitor is provided for the same component as the first monitor (feature 8), and the two monitors should give the same reading. Moreover, these readings should also agree with the setting made by the clinician and, accordingly, feature 9 defines a 3-way comparison of these readings and the setting in order to determine which of the three is the odd one out. This enables the location of the fault to be detected.

Therefore, a more realistic objective problem is how to determine quickly and accurately if one of the monitors is out of calibration or the gas delivery device is not delivering the set concentration (see paragraphs [0011] and [0012] of the patent in suit).

4.3 According to the patent in suit, in order to enable a direct 3-way comparison to be made, the two gas monitors must be exposed to gas having the same gas composition. In D6, however, the two gas monitors 8 and 11 cannot be exposed to the same gas composition since anaesthetic is supplied at an intermediate dosing point 30.

Moreover, the additional gas monitor 11 (Figure 2) is a safety device in that it guards against too high a discrepancy between the desired and the obtained concentration of a gas component, or it may form part of a feedback circuit for refining the control (D6: page 4, lines 3 to 10). There is no disclosure of a 3-way comparison for the purpose of quickly and accurately determining if one of the monitors is out of calibration or the gas delivery device is not delivering the set concentration.

For these reasons D6 does not suggest the present solution to the problem posed.

4.4 D5a also does not suggest the present solution to the problem posed. The Board does not accept the appellant's argument that with the second option for calibrating the sensors described on page 1, lines 89 to 94 of D5a, a 3-way comparison as defined in feature 9 of claim 1 results.

According to this option the gas mixer is set to give the desired gas properties and the sensor outputs are compared with each other. According to page 2, lines 53 to 64 of D5a, a calculator calculates a balancing factor for each sensor pair a-a', b-b', etc. and stores the values of these balancing factors. There is no disclosure in D5a of comparing the sensor outputs with numerical values of gas composition.

Nor is there any disclosure of comparing the sensor outputs with a value of the setting of the gas mixer. Not only is there no explicit or implicit disclosure of this feature in D5a, the Figure of this document supports the view that there is no data exchange between the gas mixer 2 and the CPU 7, as shown by the absence of a data line (a dot-dash line) therebetween.

To summarise, in D5a a comparison is made between the outputs of the sensors of the monitors 8 and 9, not in order to calibrate the sensors but to determine balancing factors. Nor is there a comparison made between the outputs of the sensors and the mixer setting. Thus, there is no suggestion of feature 9 of claim 1 and hence no suggestion of a solution to the presently defined technical problem.

4.5 For the above reasons the subject-matter of claim 1 of the main request involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Vottner M. Noël