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Datasheet for the decision of 24 May 2018

Case Number: T 0251/14 - 3.2.02

Application Number: 04257498.8

Publication Number: 1537886

IPC: A61M5/36

Language of the proceedings: EN

Title of invention:
Air-bubble-monitoring medication assembly

Patent Proprietor:
ETHICON ENDO-SURGERY, INC.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(a)
EPC R. 115(2)
RPBA Art. 15(3)

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

Decisions cited:
T 0190/90

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 0251/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 May 2018

Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Nordmeyer, Philipp Werner df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Respondent: (Patent Proprietor)	ETHICON ENDO-SURGERY, INC. 4545 Creek Road Cincinnati, Ohio 45242 (US)
Representative:	Tunstall, Christopher Stephen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 29 November 2013 rejecting the opposition filed against European patent No. 1537886 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	S. Böttcher

Summary of Facts and Submissions

I. The appeal of the opponent is against the decision of the Opposition Division posted on 29 November 2013 to reject the opposition.

The notice of appeal was filed on 29 January 2014 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 28 March 2014.

II. Oral proceedings were held on 24 May 2018.

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

The respondent-patent proprietor requested in writing that the appeal be dismissed.

Duly summoned by communication dated 9 March 2018, the respondent-patent proprietor did not attend the oral proceedings, as communicated by letter dated 23 April 2018. The proceedings were held in its absence in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

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

D1: US-A-4564500
D2: EP-A-0416911
D3: WO-A-98/14234
D9: EP-A-0643301
D12: IEC 60601-2-24, Ed.1: Medical electrical equipment - Part 2: Particular requirements for the safety of

infusion pumps and controllers (circulated on 1997-09-26).

IV. Claim 1 reads as follows:

An air-bubble-monitoring medication assembly (10) comprising:

a) a drug infusion subassembly (12) having a tube (18) for administering therein a liquid (20) to a patient (22);

b) a bubble-size determinator (14) which is disposed to sense an air bubble (24) above a minimum size entrained in the liquid in the tube and which determines the volume of the sensed air bubble; and

c) an analyzer (16) which logs the time the bubble-size determinator senses an air bubble and the volume of the sensed air bubble, which calculates a first running sum of a total air volume of all air bubbles sensed over a first time interval, which compares the first running sum with a first preselected limit, and which generates an output when the first running sum exceeds the first preselected limit, and which further calculates a second running sum of a total air volume of all air bubbles sensed over a second time interval; compares the second running sum with a second preselected limit; and generates the output when the second running sum exceeds the second preselected limit,

characterised in that

the second time interval is longer than the first time interval, wherein the second preselected limit equals the first preselected limit times a multiplier, and

wherein the second time interval does not equal the first time interval times the multiplier.

V. The arguments of the appellant-opponent relevant for the decision are summarised more precisely in the corresponding parts of the reasons for the decision. It essentially considered that the subject-matter according to claim 1 was not novel in view of D3 and/or not inventive in view of D3 and common general knowledge; D3 and common general knowledge and D12; D1 and D12; D1 and D3; D3 and D1, D2 or D9.

VI. The respondent-patent proprietor's arguments are essentially those on which the following reasons of this decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention is about detecting air bubbles and their volume in an infusion line, and calculating the total volume of air over a period of time in order to generate an output signal such as an alarm when a certain critical volume is reached. Two time intervals are used, the first one being shorter than the second one. Each time interval is associated with a preselected air volume limit for triggering an alarm. The second preselected air volume limit equals the first preselected air volume limit times a multiplier, but the second time interval does not equal the first time interval times the same multiplier.

3. Novelty

The appellant-opponent considered that the subject-matter of claim 1 lacked novelty over D3 for essentially three reasons. In relation to the respective critical feature, the appellant-opponent held the following:
i) the claim wording was very general when it came to calculate "*a first running sum of a total air volume of all air bubbles sensed over a first time interval*". This wording had also to cover the case of a single-bubble air volume not being added to anything else. Since this was what was done in the first embodiment disclosed in D3, this feature was anticipated by said document.
ii) In the second embodiment disclosed in D3, an option was presented in which accumulated air volumes over a time interval of 15 min and a time interval of 16 min were compared to a limit volume for a 15 min time interval. These time intervals were not alternative but cumulative because a safety norm required that there be a 15 min time interval check. The fact that for both the 15 min time interval and the 16 min time interval the accumulated air volume was compared with the same limit volume meant that the definition given in claim 1 with a multiplier of 1 applied.
iii) During the time interval of 15 min (or 16 min), the aim was to trigger an alarm when the accumulated air volume exceeded a certain limit. This meant that after every minute the accumulated volume was compared to the limit volume, such that after two minutes and then every minute the requirement of the claim was satisfied.

3.1 D3 discloses "a safety monitoring apparatus for a patient care system", more specifically adapted for use with infusion pump units (e.g. page 1, lines 15 to 32).

This apparatus can monitor a number of dangerous situations including air-in-line (page 2, line 37 to page 3, line 7). More specifically the air-in-line (AIL) detecting system is described starting page 11, and is said to be able to detect whether "a single air bolus exceeds a predetermined volume or whether the accumulated air within a particular time period exceeds a predetermined volume" (page 11, lines 18 to 31).

3.2 i) How the single air bolus is determined is essentially explained on page 12. At appropriate intervals (Tn) which may be prescribed by the set infusion rate, the AIL sensor is enabled. The AIL sensor signal can only assume one of two states based on whether the AIL sensor detects air or fluid in the line at that particular moment (page 12 lines 2 to 4). If air is detected at a moment T1, another timer is started, and if the AIL sensor still detects air at time T2, it will be assumed that the air was present between T1 and T2 and the volume will be calculated on the basis of the infusion rate and the time interval between T1 and T2. If the volume so detected is above a predetermined limit, an alarm signal is triggered.

In parallel or additionally the volumes detected are added together over a longer period of time and the total volume compared to a limit value. If the total exceeds a predetermined value, an alarm signal is triggered.

From the above, it follows that if no air is detected (yes-no sensor) at the time T2, the bubble and its volume are ignored, and so this bubble volume is not added to anything, or in other words, the first alarm is only triggered when a single bubble is too big, and

any bubble smaller than the predetermined limit is not considered at all.

In any case, and whatever other differences may exist, it follows from the above that D3 does not disclose an analyser which is suitable for calculating *a running sum of a total air volume of all air bubbles sensed over a first time interval* as required by claim 1. The device of D3 is only able to calculate a total air volume of a single bubble but not of a series of bubbles.

The appellant-opponent considered that this was enough to anticipate the said feature. However, the claim is an apparatus claim, and even though the functionalities of the analyser are mentioned in the claim wording in the form of functional features, this means that the apparatus must include the means to fulfil these functions. In other words, when it is said that the analyser "*calculates a first running sum of a total air volume of all air bubbles sensed over a first time interval*", this means that the analyser must have the technical means to be able to calculate the above, namely the sum of the volumes of several bubbles. Such technical means can therefore not be anticipated by means which are only able to calculate the volume of a single bubble as in D3, even though both systems will react the same way when a big enough single bubble is present.

For this reason alone the subject-matter of claim 1 is novel in view of the first embodiment of D3.

3.3 ii) The second embodiment (page 13, line 15 to page 14, line 25) which is basically an implementation of the

aforementioned general principles does not anticipate the said feature either.

The whole reasoning presented by the appellant-opponent in this respect is based on the concept that the 15 min time interval and the 16 min time interval mentioned on page 13, lines 29 to 31 (*The ring buffer may also advantageously include an additional element (in this case a sixteenth element)*) would imply two simultaneously running calculations.

The Board does not share this interpretation since it is explicitly mentioned in the following sentence that this is done to increase safety (*With this additional element, a 16 element ring buffer representing a 16 minute accumulation period may then be checked against a maximum limit for a 15 minute accumulation period, creating a one minute margin of error and thus an increased margin of safety*). This is a clear statement that if more safety is desired, the 16 min interval is better, but otherwise the 15 min interval is good enough, in both cases the accumulated volume being compared to the limit value for the 15 min interval. There is no direct and unambiguous indication in D3 that both results (of the adding together of the 15 minutes and the 16 minutes) are checked in parallel in the apparatus.

Moreover, since the totals obtained for the 15 min and the 16 min time interval are compared to the same limit value for the 15 min time interval, the second preselected limit does not equal the first preselected limit times a multiplier. This is contrary to the requirement of the claim.

The appellant-opponent argued that a multiplier equal to "1" was also a multiplier.

In the Board's opinion such a mathematical reading of the term "multiplier" in claim 1 does not correspond to a common sense technical reading the person skilled in the art would make (T 190/90) in the context of the present invention. When a technically skilled person uses the word "multiplier", this means that it addresses a number different (usually greater) than "1". There is no indication in the description of the patent that something else, e.g. a value of "1" for this multiplier could be envisaged.

Hence, the subject-matter of claim 1 is also novel in view of this embodiment of D3.

3.4 iii) This objection is deficient in at least the same way as explained in ii) above, namely that the same limit (multiplier equal to "1") is used each time, meaning that novelty is given at least for the same reason as under ii).

3.5 Hence, the subject-matter of claim 1 is novel in view of D3. Consequently, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

4. Inventive step

The appellant-opponent raised several lines of argument in relation to inventive step. It considered that the subject-matter of claim 1 was not inventive in view of the following combinations:
D3 and common general knowledge
D3 and common general knowledge and D12

D1 and D12
D1 and D3
D3 and D1, D2 or D9

4.1 Closest prior art

In D1 an air-bubble-determining arrangement 12 is described that is able to distinguish between "nuisance bubbles" and "problem bubbles". Only in the latter case is an alarm triggered (column 4, lines 8 to 13). The problem bubbles are defined as having a volume above a certain limit. The volume is measured by measuring the length of the bubble, because it is assumed that the bubble has the diameter of the tubing. The critical volume is checked by counting the number of steps of the stepping motor 20 forming part of the peristaltic pump, the counting being started when a bubble is detected. If the relevant number of steps is achieved and the bubble is still present, an alarm signal is triggered (column 4, line 48 to column 5, line 12). Otherwise nothing happens.

This means that when only a nuisance bubble is detected its length is not detected, or stored, or indeed stored to be added to some other detected bubbles. Basically the system according to D1 only detects the presence of a bubble of a critical size by determining its length with the aid of a stepping motor. However, it is unable to add bubbles for a first interval of time and to add bubbles for a second interval of time; it basically never adds bubble volumes.

The disclosure of D3 has been analysed in the context of the objection of lack of novelty.

Therefore, in the Board's opinion, from D1 and D3, D3 is the closest prior art, because in D3 there is at least one means of adding up values over a particular time period.

4.2 The appellant-opponent considered that given that D3 explicitly mentioned on the top of page 11 that the level of danger of the presence of air in the circulatory system depended on several conditions specific to the patient concerned, this would prompt the person skilled in the art to set several volume limits for the triggering of an alarm signal in order to take account of these different patient-specific conditions. Therefore, the subject-matter of claim 1 was obvious, because several different limit values would be checked over several different time intervals.

Independently of how exactly the above suggested idea would be applied to the system disclosed in D3, the Board does not see how it could lead to the subject-matter of claim 1. Indeed, if the limit values for the different air volumes checked were adapted to the connected patient, the respective values for the specific patient connected would be the sole values used by the system. The system would obviously not simultaneously check different limit values for different patients when the aim is to check the risk for the one specific patient connected to it. This does not make any technical sense. Such a system is conceived to monitor the risk for the connected patient. Or to put it differently, there is no point in monitoring the critical value for one patient and checking it against the limit value of another patient, the first patient possibly being at a dangerous level before the second.

Hence, this line of argument cannot lead to the subject-matter of claim 1.

4.3 The appellant-opponent further considered that the subject-matter of claim 1 was not inventive because, in order to increase the safety, it was obvious to the person skilled in the art to integrate the bubble detecting system of D9 into the system of D3.

D9 is about improving ultrasonic micro air bubble detectors so they are less sensitive to detection environment change over time during a given procedure (column 2, lines 46 to 54; column 3, lines 49 to 53), in particular when such a detector is used in acute care dialysis on the blood line to the patient connected for a longer time to an artificial kidney. Owing to the lower blood flow rate in such a case, the usual drip chamber cannot be used because the risk of blood clot formation and the risk of a cumulative effect of the microbubbles may be higher (column 2, lines 1 to 7; column 2, lines 20 to 23).

The system of D3 is meant for use with an infusion pump or infusion pump unit (e.g. page 1, lines 15 to 32). Even if the person skilled in the art wished to improve the safety of the system disclosed in D3, as alleged by the appellant-opponent, the Board fails to see why the person skilled in the art would seek a solution in a field as specific as that of the invention disclosed in D9, namely intended to increase the reliability of a microbubble sensor placed in the blood line of an artificial kidney during an acute care dialysis. And all the more so since D9 also explains that under normal infusion conditions (i.e. with infusion pumps) fairly large bubbles can result in injury or death of the patient, whereas the effects of a small number of

microbubbles are less serious (column 1, lines 38 to 43). In any case, D9 leads away from checking the total air volume over two time intervals of different lengths and towards the use of respective limit values which do not have the same multiplier (different from 1) as the time intervals.

In the Board's opinion the combination of D3 with D9 can only be the result of hindsight. Hence, this line of argument cannot lead to the subject-matter of claim 1 either.

4.4 Nor do the other documents suggest integrating means for calculating a first running total air volume in respect of all air bubbles sensed over a first time interval into the device according to D3.

As already indicated above, D1 does not disclose any means for adding bubble volumes together.

D2 only discloses a self-test procedure for an ultrasonic air-in-line detector.

Document D12 is a final draft for an international standard. Point 51.104 on page 50 states the following:

"*Infusion of 1 ml of air within 15 min is not considered to be a SAFETY HASARD. Bubbles of less than 50 µl of air each are omitted in summing up the 1 ml.*"

This document hence discloses no more than the second running sum already present in D3, it does not even indicate that even a single bolus could be hazardous.

4.5 Hence, none of the cited combination of documents can render the subject-matter of claim 1 obvious, with the

result that the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated