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# D E C I S I O N
# of 5 October 2001

**Case Number:** T 0592/98 - 3.2.2

**Application Number:** 91302754.6

**Publication Number:** 0452001

**IPC:** A61M 16/00

**Language of the proceedings:** EN

**Title of invention:**
Lung ventilator device

**Applicant:**
UNIVERSITY OF MANITOBA

**Opponent:**
-

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 52(4), 54, 56

**Keyword:**
"Publication date of a document"
"Evaluation of evidence"
"Standard of proof"
"Medical treatment (yes)"
"Novelty and inventive step (no)"

**Decisions cited:**
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**Catchword:**
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**Case Number:** T 0592/98 - 3.2.2

**D E C I S I O N**
**of the Technical Board of Appeal 3.2.2**
**of 5 October 2001**

**Appellant:** UNIVERSITY OF MANITOBA
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**Representative:** Lawrence, Malcolm Graham
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 14 January 1998 refusing European patent application No. 91 302 754.6 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** W. D. Weiß
**Members:** D. Valle
M. B. Günzel

## Summary of Facts and Submissions

I. The applicant filed an appeal on 12 March 1998 against the decision of the Examining Division to reject the application posted on 14 January 1998. The appeal fee was paid on 13 March 1998 and the grounds for appeal were filed on 22 May 1998.

II. The Examining Division held that claim 1 of the main request did not meet the requirements of Article 52(4) EPC (medical treatment) and that claim 1 of the auxiliary request was not novel over:

D1: A microprocessor-based servo respirator, by Kuo-An Huang, Fargo, North Dakota, 1985.

Parts of this document (the front page and pages 55 and 56) were first submitted by a third party which filed observations with letter of 21 December 1995.

With communication dated 9 February 1996 the Examining Division introduced the document into the procedure and stated that the independent apparatus claim was not inventive having regard to the above cited document (point IV) and that due to document D1 the claims had obviously to be radically reformulated (point VI).

With letter of 26 December 1996, pages 6 to 8, the appellant replied to these objections and stated that pages 55 and 56 were taken out of context as regards the whole document: "The overall document demonstrates that, indeed, it is possible to deliver volume assist and flow assist and that these gains can be made to change automatically in response to the partial pressure of $CO_2$ in an effort to control the partial

pressure of $CO_2$. However, nowhere does this reference describe a method of use of volume assist and flow assist...". The letter goes to cite page 39, paragraph 2 of document D1; page 28, paragraph 2; page 129, bottom; Table 6.1, page 130; page 15, line 9; page 28, item 2; page 38, last sentence; page 39, item 1; page 80, lines 8 and 9; page 81, last sentence; page 82, last sentence, page 94, last sentence; page 128, last sentence; page 129, last sentence and Table 6.1, page 130 (see pages 6 and 7 of the letter of responses). Furthermore the applicant stated in the above cited letter that there was already in the specification of the patent in suit, page 5, an acknowledgment of an article by Poon et al which was in essence the same disclosure as was contained in document D1 (page 8 of the response).

With communication of 7 August 1997 the Examining Division pointed out that in its opinion the Poon article did not disclose the same respiratory assisting method as document D1 (page 4 of the communication). The Examining Division further suggested that - in order to facilitate the consideration of its arguments - the applicant should file the missing pages of document D1, because the file still contained only pages 1 (front page), 55 and 56 filed by a third party. In any case pages 55 and 56 were considered by the Examining Division sufficient for destroying the inventive step of the patent in suit (pages 5 to 8 of the communication).

With letter of 20 November 1997 the appellant filed a complete copy of document D1.

On 26 November 1997 oral proceedings were held before

the Examining Division. In the minutes of the oral proceedings, page 2, point 6, it is stated that document D1 was accepted by the appellant as being representative of the closest state of the art. The discussion regarding novelty was based only on document D1 and "the representative of the applicant had to acknowledge...that this [i.e. the difference between the claimed invention and the teaching of document D1] was not any constructional difference, but just a different use of the same apparatus, i.e. that the claimed apparatus was not novel over the prior art within the meaning of Article 54 EPC" (page 3 of the minutes). The following written decision to refuse the application was based on lack of novelty having regard to document D1.

In the statement of grounds of appeal filed with letter of 22 May 1998 the appellant brought forward arguments to support the novelty and the inventive step of the patent in suit in relation with document D1 (points 3 and 4). With letter of 6 February 2001 the appellant presented new arguments against the relevance of document D1 (pages 6 to 8). Upon request of the appellant, the Board held oral proceedings on 23 February 2001. In these oral proceedings the appellant for the first time challenged the publication date of document D1. The oral proceedings terminated with the declaration that the Board would further investigate whether or not document D1 had been made publicly available before the priority date of the application in suit. With respect to all other issues the debate was closed.

On 26 February 2001 an enquiry was sent by telefax on behalf of the Board to North Dakota State University

requesting information about the exact date on which document D1 was first made available to the public. On 2 March 2001 a reply was received by e-mail containing a declaration that document D1 was published and placed on the shelves of North Dakota State University Library in May 1985. In reply to the communication by the Board of the Board's above cited enquiry, and of the declaration received as reply, the appellant expressed doubts as to whether document D1 formed part of the state of the art. Furthermore, for the first time the appellant stated that the inventor of the application in suit first learned of the thesis (document D1) from Dr Poon, Major Advisor and a signatory to sheet ii of the thesis, in 1991, but that at that time Dr Poon refused his request for a copy. Finally, the appellant expressed his wish to file sworn evidence in support of his assertion that document D1 was not published before the claimed priority.

III. The final requests of the appellant as formulated on 23 February 2001 at the end of the oral proceedings were as follows:

As main request he requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request indicated in point 5 of the Facts and Submissions of the decision under appeal. As first auxiliary request he requested that a patent be granted on the basis of the auxiliary request indicated in said point 5. As second auxiliary request he requested that a patent be granted on the basis of the auxiliary request submitted by telecopy on 22 May 1998. As third auxiliary request he requested that the patent be granted on the basis of the auxiliary request filed on 6 February 2001.

IV. Claim 1 of the main request filed on 26 November 1997 reads as follows:

"A method for controlling gas flow of an apparatus for delivering pressure assist ventilation to a patient, which feeds assist gas in response to respiratory effort of the patient, characterized by the steps of:
a) providing a free flow of gas from a gas delivering system into a pipe;
b) determining the rate and volume of flow of said gas through said pipe;
c) independently amplifying signals corresponding to said determined rate and volume flow;
d) determining assist pressure from said signals by the equation:

$P_{vent} = K_1V + K_2V'$,

where $P_{vent}$ is the magnitude of the pressure assist, $K_1$ is a gain factor applicable to a continuous varying volume signal V which is a fraction of the elastance of the respiratory system, and $K_2$ is a gain factor applicable to a continuously variable flow rate signal V' which is smaller than the resistance at the respiratory system; and
e) sending a command signal to the gas delivery system to generate said assist pressure."

V. Claim 1 of the first auxiliary request filed on 26 November 1997 reads as follows:

"Apparatus for delivering proportional assist ventilation to a patient, comprising
a) means (202) for delivering a free flow of gas to a patient in response to patient inhalatory effort;

b) means (205) operatively connected to said gas delivery means (202) for generating pressure in said free flow of gas in response to an electrical command signal (207);
c) detection means (209) for detecting the instantaneous volume and flow of gas to the patient and for generating a separate electrical signal corresponding in magnitude to each of said detected values (V and V' respectively);
d) externally actionable gain control means (212, 215) for selectively applying amplification to each of said electrical signals; and
e) means (218) for generating said electrical command signal (207) to said pressure generating means (205) in proportion to the sum of said amplified electrical signals corresponding in magnitude to said instantaneous flow and volume in accordance with the equation:

$$P_{vent} = K_1V + K_2V',$$

where $P_{vent}$ is the magnitude of the variable assist, $K_1$ is a gain factor applied to said electrical signal by gain control means (215) corresponding to volume V and is a fraction of the respiratory elastance of the patient and $K_2$ is a gain factor applied to said electrical signal by gain control means (212) corresponding to flow V' and is a fraction of the respiratory resistance of the patient."

VI. Claim 1 of the second auxiliary request filed on 22 May 1998 reads as follows:

"Use of apparatus for delivering proportional assist ventilation to a patient, the apparatus comprising

a) means (202) for delivering a free flow of gas to a patient in response to patient inhalatory effort;
b) means (205) operatively connected to said gas delivery means (202) for generating pressure in said free flow of gas in response to an electrical command signal (207);
c) detection means (209) for detecting the instantaneous volume and flow of gas to the patient and for generating a separate electrical signal corresponding in magnitude to each of said detected values (V and V' respectively);
d) externally actionable gain control means (212, 215) for selectively applying amplification to each of said electrical signals; and
e) means (218) for generating said electrical command signal (207) to said pressure generating means (205), wherein said signal is generated in proportion to the sum of said amplified electrical signals corresponding in magnitude to said instantaneous flow and volume in accordance with the equation:

$$P_{vent} = K_1V + K_2V',$$

where $P_{vent}$ is the magnitude of the variable assist, $K_1$ is a gain factor applied to said electrical signal by gain control means (215) corresponding to volume V and is a fraction of the respiratory elastance of the patient and $K_2$ is a gain factor applied to said electrical signal by gain control means (212) corresponding to flow V' and is a fraction of the respiratory resistance of the patient,
characterized in that the apparatus further comprises:
a) means for inputting data representative of the elastance of the patient;
b) means for inputting data representative of the

resistance of the patient; and
c) means for inputting a value corresponding to the fraction of total pressure required to be supplied by the apparatus,
whereby $K_1$ is the product of input a) and input c), and $K_2$ is the product of input b) and input c)."

VII. Claim 1 of the third auxiliary request filed on 6 February 2001 reads as follows:

"Ventilator apparatus for delivering pressure assists to a patient in proportion to the instantaneous inhalatory effort $P_{mus}$ of the patient, the apparatus comprising:
a) means (202) for delivering a free flow of gas to a patient in response to patient inhalatory effort delivering pressure $P_{mus}$;
b) means (205) operatively connected to said gas delivery means (202) for generating a pressure $P_{vent}$ in said free flow of gas in response to an electrical pressure command signal (207);
c) detection means (209) for detecting the instantaneous volume (V) and flow (v) of gas to the patient and for generating respective separate electrical signals corresponding in magnitude to the detected values V and v respectively;
d) command signal generating means (212, 215, 218) comprising;
(i) adjustable gain control means (212, 215) for applying respective amplification to each of said electrical signals according to selected gain factors; and
(ii) final command signal generating means (218) disposed to receive said amplified electrical signals, to generate a final electrical command signal and to

apply said final electrical command signal as said electrical pressure command signal (207) to said pressure generating means (205);
Characterized in that:
(A) the apparatus includes governing means configured to provide that, in use of the apparatus , said final command signal is a signal, representative of a value of $P_{vent}$, determined by said gain factors and generated in accordance with the equation:

$$P_{vent} = (A/(1+A))E_{rs}V + (A/(1+A))R_{rs}v,$$

wherein:
A is the proportionality constant between $P_{vent}$ and $P_{mus}$ in the equation: $P_{vent} = P_{mus}A$,
$A/(_1+A))E_{rs}$ and $A/(1+A)R_{rs}$ are the values of the gain factors,
$E_{rs}$ is the elastance of the patient and
$R_{rs}$ is the respiratory resistance of the patient,
(B) the apparatus includes means for storing data representative of the elastance of the patient;
(C) that the apparatus includes means for storing data representative of the resistance of the patient.

VIII. The appellant argued as follows.

(a) Regarding the question whether document D1 belongs to the state of the art the appellant essentially submitted the following:

The communication of North Dakota state University was unsatisfactory. The statement that the document was placed on the library shelves on May 1985 appeared to be a slavish repetition of what the front page of the document said. No reference

was made to any internal catalogue or any other reference. Usually library records were as demonstrated by those which featured in decision T 381/87 (precise date of publication supported by library record extract). One would expect a specific date to be mentioned and not simply the month concerned. Furthermore it was not sure whether the date on the front page of D1 was the completion date of the thesis, its release date, or the starting date of the research or other work. The typed date could have been a misprint or even a falsehood. A typed date had none of the hallmarks of authenticity of a printed document and it should have been corroborated by external evidence. According to decision T 750/94 the evidence concerning alleged prior publications must be critically and strictly examined and a European patent should not be refused or revoked unless the grounds for refusal were fully and properly proved. The statement of North Dakota State University added nothing to the document which was under suspicion. The inventor, after the filing of Article 115 EPC observations, was unable to obtain a copy of document D1 other than by way of personal visit. In 1991 he was refused his request to Dr Poon for a copy. Guidelines C-IV 5.2 (60) state that "if the applicant shows sound reasons for doubting whether the document forms part of the "state of the art" in relation to his application and any further investigation does not produce evidence sufficient to remove that doubt the examiner should not pursue the matter further".

(b) Regarding Article 52(4) EPC, the invention did not

claim a method of ventilation as such.

(c) Regarding novelty and inventive step in relation with document D1, said document did not disclose the proportionality factors $K_1$ and $K_2$. Pressure, flow and volume in document D1 were all controlled (see page 128 and Table 6.1). This was possible only in paralysed and apneic patients. When the patient was making an effort, one could either control flow and volume or pressure, but not both. See also page 15, line 9; page 28, item 2; page 38, last sentence; page 39, item 1; page 80, lines 8, 9; page 81, last sentence; page 82, last sentence; page 94, first sentence; page 128, last sentence; page 129, last sentence; page 130, Table 6.1.

Referring in particular to the third auxiliary request, the special notation: A/(1+A) which for every A gives a result less than one, made it explicit that the gain factor K was always a fraction of the elastance/resistance in order to prevent runaway. The coefficient A was input manually by the operator. Document D1 did not disclose such restriction.

## Reasons for the Decision

1. The appeal is admissible.

2. *Article 52(4) EPC (medical treatment)*

The main request and the second auxiliary request do not comply with Article 52(4) EPC.

Claim 1 of the main request concerns a method for delivering pressure assist ventilation to a patient in response to respiratory efforts of the patient.

Claim 1 of the second auxiliary request concerns the use of the apparatus for delivering proportional assisted ventilation to a patient.

Both claims involve a therapeutical method within the meaning of Article 52(4) EPC. The "use" claim concerns the method of using an apparatus in assisting the breathing of a patient.

The term "therapy" within the meaning of Article 52(4) EPC is not restricted to curing a disease or to removing its causes but it covers also any treatment designed to alleviate or reduce the symptoms of any malfunction of the human body. This is the case here: The claimed method and use are designed to alleviate breathing insufficiency by providing pressure ventilation proportional to the ongoing effort of the patient throughout inspiration.

The purpose of Article 52(4) EPC is to prevent any obstacle to the freedom to choose the best medical treatment to be applied to a patient and to avoid any delay in the application of such medical treatment. Such obstacles or delays could arise if a medical treatment were the subject of an exclusive patent right.

Accordingly the main request and the second auxiliary request are not allowable under Article 52(4) EPC.

3. *Novelty and inventive step of the first and the third*

*auxiliary requests*

3.1 Document D1 belongs to the prior art to be considered for assessing novelty and inventive step of the application in suit.

Neither in the EPC nor in the case-law of the Board of Appeal are there formal rules laid down for the evaluation of evidence. Rather the Board has to decide on the basis of all of the evidence available in the proceedings, and in the light of its conviction arrived at on the evaluation of the evidence whether an alleged fact has occurred or not (principle of unfettered consideration of the evidence). The standard of proof in the case of an alleged prior publication which might result in refusal or revocation of the patent is however such that the facts underlying the grounds for refusal have to be fully and properly proved (T 590/94).

In the present case the Board has reached the conviction that it is fully and properly proved that the document D1 was published in May 1985. Its conviction is based on the following facts and considerations:

- The document contains on the front page the date May 1985 and the place (Fargo, North Dakota) where it was written together with the author (Kuo-An Huang), the title, the type of document (thesis), the purpose (in partial fulfillment of the Requirements for the Degree of Master of Sciences), and the institution to which it was submitted (Graduate Faculty of the North Dakota State University of Agriculture and Applied

Sciences), as well as the Department in which it was completed (Electrical and Electronics Engineering). Page ii contains furthermore the declaration that such publication, submitted by Kuo-An Huang in partial fulfillment of the requirements for the Degree of Master of Science from North Dakota State University, was thereby approved by the Faculty Advisory Committee under whom the work had been done. The declaration has been signed by the Chairman of the department of Electrical and Electronics Engineering and by the Major Advisor (Dr Poon).

- In his letters filed on 18 July 2001 and 14 September 2001 after the oral proceedings before the Board, as a reaction to the result communicated by the Board of the enquiries made with respect to the date on which D1 was available at the State University of North Dakota, the appellant, for the first time, doubted the authenticity of D1 and the date of May 1985 on its front page. However, no concrete indications were made by the appellant as to why precisely the date on the front page of D1 should be a misprint or even a falsification. In this respect, the appellant relied solely on the assertion that such indications in typed documents generally had none of the "hallmarks of authenticity" of printed documents.

  It is the position of the Board that the consideration of the document itself does not give rise to any reasonable ground to doubt its authenticity.

The indications on the front page of D1 mentioned above are the quite normal indications to be found on the front of papers which are submitted in order to obtain a University degree. As regards the date on it, there is no trace that a later change could have been effected nor is there any hint that the date would have been wrongly indicated from the beginning, nor has this specifically and concretely been contended by the appellant. The date May 1985 is corroborated by the declaration of Kris Dinusson Shenk of the Graduate School of North Dakota State University who declared on 2 March 2001 that the thesis titled "A Microcomputer-based Servo-Respirator with synchronized Airflow Pattern" (document D1) by Kuo-An Huang was published and placed on the North Dakota State University library shelves in May 1985. Placing a document on the shelves of a library is a fact which means that the document has thereby become accessible for third persons and thus available to the public within the meaning of Article 54(2) EPC. There are no apparent reasons to doubt that the official declaration of the North Dakota State University concerning the date of publication of document D1 has been given with full regard as to the potential serious nature of their contents. In the present case this is all the more so since the Board in its request for information had explicitly drawn attention to the legal significance of the question and its answer.

On the other hand, the priority date of the application in suit being 30 March 1990, i.e. a date long after May 1985, the exact day on which

D1 was put on the shelves of the University library in May 1985 is not relevant for the present case. Therefore, the Board saw no need to further investigate on which documentary basis this declaration has been made, i.e. in particular whether or not it is corroborated by special records in a journal, or why only the month of publication is given and not the day. The Board sees these matters as part of the administrative procedure of the University of North Dakota which are not directly relevant for the question to be answered in the present case.

- The appellant himself filed on 20 December 1997 a copy of D1. That means that even in 1997 the document was available to the public. There are no reasons to doubt that the document was available also starting from the publication date in May 1985.

  The fact that D1 may not have been distributed but only handed out on a personal visit - as the appellant also alleged for the first time in its reply as a result of enquires made by the Board after the oral proceedings - is irrelevant for the question of availability to the public within the meaning of Article 54(2) EPC as is the fact that the Major Advisor for paper D1, Dr Poon, would have refused to furnish a copy of D1 to the inventor of the application in suit. Moreover, both assertions of the appellant have remained totally unsupported. No proof whatsoever has been offered for these facts alleged only at a very late stage of proceedings. They need therefore not be further considered here.

In conclusion, there is no basis to doubt that the identification data contained in document D1 and in particular that the confirmed date of its placement on the library shelves does not correspond to the typed data appearing on the document or that the creation of this document did not follow the normal course of events. In the letter of 14 September 2001 the appellant expressed the wish to file sworn evidence in further support of his assertion that document D1 was not published before the claimed priority. However, the term "publication" is as such not the allegation of a fact but is a legal term. The appellant did not state which concrete facts he would want to prove nor which new elements (if any) relevant for the decision would be submitted. Under these circumstances the request for the hearing of witnesses was not to be furher pursued by the Board. Accordingly document D1 belongs to the state of the art for the application in suit.

3.2 The first auxiliary request contains the apparatus claim 1.

Document D1 deals with the techniques for improving serve respiration. On pages 42 to 45 the Siemens servo ventilator 900c is described, which was selected as study object. On pages 55 and 56 the serve equations are presented which govern the operations of the serve ventilation. On pages 57 to 59 the differential method of Figure 3.9, page 64, is finally described.

In particular from the passages cited above it can be seen that document D1 discloses an apparatus for delivering proportional assist ventilation to a

patient, comprising
a) means for delivering a free flow of gas to a patient in response to patient inhalatory effort (inhalation tube, air bellow, Figure 3.5, page 45);
b) means operatively connected to said gas delivery means for generating pressure in said free flow of gas in response to an electrical command signal (air bellow and control valve, Figure 3.5, page 45);
c) detection means for detecting the instantaneous volume and flow of gas to the patient and for generating a separate electrical signal corresponding in magnitude to each of said detected values (V and V'=dV/dt respectively, Figure 3.9, page 64, whereby the value of V' is detected and the value of V is derived through integration in the amplifier 4, see also page 44, lines 12 and 13, and page 53, last paragraph);
d) externally actionable gain control means for selectively applying amplification to each of said electrical signals (see paragraph bridging pages 57 and 58); and
e) means (amplifier 5, Figure 3.9) which can generate said electrical command signal to said pressure generating means in proportion to the sum of said amplified electrical signals corresponding in magnitude to said instantaneous flow and volume in accordance with the equation:

$$P_{vent} = K_1V + K_2V'$$

where $P_{vent}$ is the magnitude of the variable assist, $K_1$ is a gain factor applied to said electrical signal by gain control means corresponding to volume V and is a fraction of the respiratory elastance of the patient and $K_2$ is a gain factor applied to said electrical signal by gain control means corresponding to flow V'

and is a fraction of the respiratory resistance of the patient. See equation 3.6.c, page 56, and pages 57 to 59, whereby $P_{vent}$ = Pa, $K_1$ = Ea and $K_2$ = Ra.

Accordingly the subject-matter of claim 1 is not novel.

Contrary to the argument of the appellant document D1 discloses the proportionality factors $K_1$ and $K_2$, see description of D1, pages 55 to 59. Furthermore,,the apparatus of document D1 is also designed to unload the respiratory work of the patient and not only to substitute it, see the statement of purpose at page 2, from line 17, and page 3, from line 3. See also page 59, first paragraph. The passages cited by the appellant relate either to embodiments which are different from that of the invention or they have nothing to do with the problem at issue.

3.3 The third auxiliary request is distinguished from the above essentially by the features A), B) and C) (characterizing part). Features B) and C) are already implicitly known from document D1 since - in order to generate the required pressure - the apparatus should contain (i.e. it should have been stored in memory) the relevant values of the resistance and of the elastance.

The remaining feature A)is distinguished from the corresponding feature of the first auxiliary request in that:

- $k_1$, which - according to claim 1 of the first auxiliary request - was a fraction of the respiratory elastance $E_{rs}$, is now made explicit as $A/(1+A)E_{rs}$, where A, and therefore A/(1+A), is a constant.

- the same for $k_2$.

It is hard to see in this difference something more than a notation difference. However, even if novelty is accepted, the subject-matter of claim 1 does not involve an inventive step because the notational substitution is obvious.

The appellant maintains that introducing the constant A - which is manually input by the operator and which always gives a coefficient less than 1 - prevents runaway. However, preventing runaway is - if not implicitly disclosed - at least rendered obvious also by the apparatus of document D1 and achieved by the constructional limits necessarily present in the variation range of the regulators $R_a$ and $E_a$ in Figure 3.9. The particular embodiment disclosed in the application in suit, Figure 8, reference numbers 212 and 215, does not differ from the above embodiment of document D1.

Accordingly, the subject-matter of claim 1 of the third auxiliary request does not involve an inventive step.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß