

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 24 March 2016**

Case Number: T 1840/12 - 3.2.02

Application Number: 03746093.8

Publication Number: 1489964

IPC: A61B5/0285

Language of the proceedings: EN

Title of invention:

SYSTEM AND METHOD OF ASSESSMENT OF AROUSAL, PAIN AND STRESS
DURING ANESTHESIA AND SEDATION

Applicant:

Covidien LP

Headword:

Relevant legal provisions:

EPC Art. 123(2), 54, 56

Keyword:

Added subject-matter (no)
Right to priority (yes)
Novelty and inventive step (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent
Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89
2399-4465

Case Number: T 1840/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 March 2016

Appellant: Covidien LP
(Applicant) 15 Hampshire Street
Mansfield, MA 02048 (US)

Representative: Kinsler, Maureen Catherine
Marks & Clerk LLP
Atholl Exchange
6 Canning Street
Edinburgh EH3 8EG (GB)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 2 March 2012
refusing European patent application No.
03746093.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: M. Stern
D. Ceccarelli

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division refusing European application No. 03 746 093.8. The Examining Division found that the then claimed subject-matter did not fulfil the requirement of novelty in view of document

D2: S. Greenwald et al.: "Pulse Transit Time (PTT) Reflects Changes in Anesthetic State during Sevoflurane/N₂O Anesthesia", *Anesthesiology* 2002; 96, page A544, published 12 October 2002.

In an additional remark at the end of the appealed decision, the Examining Division stated that it appeared impossible to draft a claim for which the priority document of the present application could be considered as the first application filed in respect of the same invention, without violating Article 123(2) EPC.

II. Notice of appeal was filed on 23 April 2012 and the fee for appeal was paid on 19 April 2012. A statement setting out the grounds of appeal was received on 10 July 2012.

III. The Board presented its provisional opinion in a communication dated 8 January 2016.

IV. With its letters dated 23 February 2016 and 1 March 2016, the appellant filed amended application documents. It requested that a patent be granted on the basis of: claim 1 of the main request filed on 23 February 2016; description pages 2, 5 and 7 as originally filed, page 6 filed on 23 February 2016 and pages 1, 3 and 4 filed on 1 March 2016; and figure sheets 1/4 to 4/4 as originally filed. It also requested that the requests filed with

the statement of grounds of appeal be treated as first to fourth auxiliary requests, respectively.

V. The following documents are also cited in the present decision:

D1: WO-A-02/100267

D3: A. Babchenko et al.: "Increase in pulse transit time to the foot after epidural anaesthesia treatment", Medical & Biological Engineering & Computing, 2000, Vol. 38, pages 674-679.

VI. Claim 1 of the main request reads as follows:

"A method of noninvasively monitoring stress, pain or arousal states of a patient during anesthesia, wherein the anesthesia consists of sevoflurane/N₂O, the method comprising:
acquiring at least one EGG signal from a subject being analysed;
using a finger photoplethysmograph to acquire a photoplethysmograph waveform;
processing the ECG signal to identify a peak of an EGG R-wave;
processing said photoplethysmograph waveform to identify a point of steepest ascent;
calculating a time difference between the peak of the EGG R-wave and the point of steepest ascent of the photoplethysmograph waveform;
estimating a pulse transit time from a plurality of the time differences, and
using rapid decreases in the pulse transit time to identify painful stimulation or recovery from anesthesia."

The main request contains no dependent claims.

VII. The arguments of the appellant relevant for the present decision are summarised as follows:

The Examining Division was of the opinion that the passage on page 6, third paragraph of the original application referred only to the publication D2 and did not form part of the description of the invention. This was disputed. The cited passage clearly described that the method of the present invention was used in D2, in particular during sevoflurane/N₂O anesthesia, to calculate the pulse transit time (PTT). Therefore, claim 1 of the main request complied with the requirements of Article 123(2) EPC.

The subject-matter of claim 1 of the main request could be fully derived from the priority application, and consequently claim 1 was entitled to the claimed priority date. As acknowledged during the examination proceedings, if the priority claim was valid, then D2 was not citable and D1 was citable only for the purposes of assessing novelty. D1 was entirely devoid of information on identifying rapid decreases in the pulse transit time to identify a change in anesthesia state.

Reasons for the Decision

1. The appeal is admissible.
2. *Article 123(2) EPC*
 - 2.1 The method of claim 1 relates, in essence, to a method of monitoring pain or recovery of a patient during sevoflurane/N₂O anesthesia by detecting rapid decreases in the pulse transit time (PTT), where the PTT is

estimated from the time difference between the peak of the ECG R-wave and the point of steepest ascent of the finger photoplethysmograph (PPG) waveform.

2.2 The claimed method finds a basis in the original application in original claim 1 in combination with the following passages of the description:

- page 4, last paragraph which discloses that the PPG is a finger PPG;
- page 2, paragraph 2 which discloses PTT as the time difference between the peak of the ECG R-wave and the point of steepest ascent of the finger PPG;
- page 7, lines 1 to 2 which discloses the use of rapid decreases in PTT to identify painful stimulation or recovery from anesthesia;
- finally, in the third paragraph on page 6 it is first explained that "an example of such a system [i.e. a system as presented in the present application] for performing PTT estimation is described in ... [D2]". It is then explained that in D2 PTT was calculated for patients undergoing sevoflurane/N₂O anesthesia and that for this PTT calculation "the method of the present invention was used". Thus, in the Board's opinion, this is an unambiguous and direct disclosure of the method of the present invention being performed on patients undergoing sevoflurane/N₂O anesthesia.

2.3 Therefore, claim 1 of the main request satisfies the requirements of Article 123(2) EPC.

3. *Novelty*

3.1 In the appealed decision, the then claimed method was found not to enjoy the claimed priority date of 1 April 2002, so that document D2 - co-authored by the

present inventors and published on 12 October 2002, before the international filing of the application on 1 April 2003 - was state of the art under Article 54(2) EPC. It was not contested that D2 anticipated the claimed method on which the appealed decision was taken.

3.2 However, the method of claim 1 of the present main request includes the additional limitation of being carried out during an anesthesia consisting of sevoflurane/N₂O, which corresponds to what is specifically disclosed in the priority application US-60/369,142 of the present application. Hence, the claimed method enjoys the claimed priority date of 1 April 2002, so that D2 no longer constitutes state of the art.

3.3 Apart from the novelty objection in view of D2, the appealed decision contains no further patentability objections. The Board does not see any further objections either, particularly none involving the other documents cited in examination proceedings against the method claims then on file, namely documents D1 and D3.

Document D1 (assuming validity of its priority) pertains to the state of the art under Article 54(3) EPC. As such, it is relevant only as far as the novelty of the claimed method is concerned. D1 discloses a method of monitoring arousal states during anesthesia by measuring PTT between an electrocardiograph (ECG) waveform and the pulse waveform from a finger plethysmograph pulse (page 42, lines 8 to 28).

Several features of the method of claim 1 are however absent from the disclosure of D1. For example, D1 is not concerned with sevoflurane/N₂O anesthesia, and there is no mention in D1 of PTT being determined from the time

difference between the *peak* of the ECG *R-wave* and the point of *steepest ascent* of the finger PPG, or *rapid decreases in PTT* being used to identify painful stimulation or recovery from anesthesia.

Consequently, the Board is satisfied that the method of claim 1 is novel over D1 too.

4. Of the state of the art under Article 54(2) EPC identified during the examination proceedings, the closest prior art seems to be given by D3, which discloses the effect of epidural anesthesia on PTT. D3 is however not related to *sevoflurane/NO₂ anesthesia* as in claim 1, and in D3, PTT is determined by measuring the transit time of pulses between the toe and the finger PPG (first seven lines of the abstract), rather than the time difference between the *peak of the ECG R-wave* and the point of *steepest ascent* of the finger PPG, as in claim 1. In the absence of any other relevant prior art on file, these differentiating features of the subject-matter of claim 1 do not appear to be rendered obvious to the skilled person.

Thus, the method of claim 1 of the main request is considered to be inventive within the meaning of Article 56 EPC.

5. In view of the above, the Board comes to the conclusion that the method of claim 1 of the main request is patentable under Article 52(1) EPC.
6. Since the main request is found to be allowable, there is no need for the Board to consider the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to grant a patent on the basis of:
 - claim 1 of the main request filed on 23 February 2016;
 - description pages 2, 5 and 7 as originally filed, page 6 filed on 23 February 2016 and pages 1, 3 and 4 filed on 1 March 2016; and
 - figure sheets 1/4 to 4/4 as originally filed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated