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Datasheet for the decision of 30 May 2018

Case Number: T 1415/13 - 3.2.02

Application Number: 00986240.0

Publication Number: 1237472

IPC: A61B5/04, A61B5/05

Language of the proceedings: EN

Title of invention:
ELECTROMYOGRAPHY SYSTEM

Applicant:
Nuvasive Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 115(2)
RPBA Art. 15(3)

Keyword:
Oral proceedings - held in absence of appellant
Amendments - intermediate generalisation - extension beyond the content of the application as filed (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1415/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 30 May 2018

Appellant: (Applicant)	Nuvasive Inc. 7475 Lusk Boulevard San Diego, CA 92121 (US)
Representative:	Harding, Andrew Philip Forresters IP LLP Skygarden Erika-Mann-Strasse 11 80636 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 January 2013 refusing European patent application No. 00986240.0 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	P. L. P. Weber

Summary of Facts and Submissions

I. The applicant has appealed against the Examining Division's decision, dispatched on 4 January 2013, to refuse European patent application No. 00 986 240.0.

The impugned decision refers to a communication dated 20 June 2012 in which the appellant was informed, in particular, of the Examining Division's view that the only request on file did not comply with Article 123(2) EPC.

II. Notice of appeal was received on 13 March 2013. The appeal fee was paid the same day. The statement setting out the grounds of appeal was received on 14 May 2013.

III. On 14 February 2018 the Board summoned the appellant to oral proceedings. In the communication accompanying the summons it expressed its preliminary view that the subject-matter of claim 1 of the main request appeared to infringe Article 123(2) EPC. It also observed that although a number of auxiliary requests were referred to in the appellant's letter dated 14 May 2013, none of them had been formally filed in writing, and so their scope could not be established with certitude.

IV. By letter dated 24 May 2018 the appellant informed the Board that it would not attend the oral proceedings.

V. Oral proceedings took place on 30 May 2018 in the appellant's absence.

VI. The appellant had requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter dated 14 May 2013.

The appellant had also requested consideration of a number of auxiliary requests contained in its letter dated 14 May 2013.

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

"A system for detecting a crack in a pedicle wall within the spine of a patient, said patient having a spinal nerve lying adjacent to said pedicle, said system comprising:

a probe having an electrode to transmit stimulus pulses to a pedicle;

a pulse generator (100), amplitude modulator (102), patient return electrode (13), impedance monitor (104), and output stage (103) to output a stimulus pulse to the probe;

a controller (118) connected to the pulse generator and amplitude modulator, the controller configured to automatically incrementally increase the intensity of the stimulus pulse in rapid step-by-step succession, at least until an onset neuro-muscular response is detected;

electrodes (128-138) configured to electrically monitor a muscle myotome associated with said spinal nerve to detect if an onset neuro-muscular response occurs in response to the transmission of said electrical stimulus to said pedicle; and

a display to visually communicate to the operator the intensity level of the stimulus pulse at which the neuro-muscular response is first detected."

VIII. The appellant has provided no arguments against the objections on which the present decision is based. These objections were set out in the Board's

communication dated 14 February 2018.

Reasons for the Decision

1. The appeal is admissible.

2. Although having been duly summoned in the communication dated 14 February 2018, the appellant was not present at the oral proceedings, as announced by letter dated 24 May 2018. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without the appellant, which is treated as relying only on its written case.

3. The application generally concerns the detection of a dangerous proximity of a surgical instrument to a nerve, particularly during a minimally invasive surgical procedure. The invention as claimed relates more specifically to a system for detecting a crack in a pedicle wall within the spine of a subject, possibly caused by a wrongly placed pedicle screw.

The system comprises a probe with an electrode to transmit stimulus pulses through the pedicle to a patient return electrode, a controller to automatically incrementally increase the intensity of the pulses in a step-by-step succession, and electrodes to electrically monitor a muscle myotome associated with a spinal nerve adjacent to the pedicle, to detect if an onset neuro-muscular response occurs in response to the transmitted pulses.

If the pedicle wall is cracked, the pulses transmitted to the patient return electrode provide an electric stimulus to the spinal nerves in proximity to the

pedicle, sufficient to generate a neuro-muscular response at the muscle myotome (for example of a leg as illustrated in figure 5 of the application) associated with the nerves. The detection of such a response, depending also on the intensity of the pulse at which it is detected, provides information about the presence and extent of the crack.

According to the description (page 7, lines 24 to 27), incrementally increasing the level of the stimulus pulses may avoid overstimulating or causing other damage to a nerve, since it is possible to stop pulse transmission at the lowest intensity causing a neuro-muscular response.

4. The application as originally filed comprises no claims directed to a device or a system, but only method claims. It follows that claim 1 of the main request could only have a basis in the description and drawings of the application as originally filed. More particularly, the "optional preferred aspect" on page 8, lines 23 to 29, which discloses the detection of a crack in a pedicle wall, together with the "particular exemplary embodiment" described in relation to figure 6 on page 23, line 10, to page 24, line 21, which discloses details of the pulse generator, the controller, the electrodes and the display, concern a system of the kind defined in claim 1.

The Board, however, sees no basis for a probe having an electrode to transmit stimulus pulses to a pedicle, as generically defined in claim 1. The "optional preferred aspect" disclosed on page 8, lines 23 to 29, comprises a more specific "screw test" probe, with an electrode that may be placed in **contact with a pedicle screw**, thereby electrifying the pedicle screw. Omitting the

particular transmission capability of the pulses by electrification of the pedicle screw provides the technical information, not disclosed in the application as originally filed, that according to that "optional preferred aspect" the crack in the pedicle wall might be detected without any pedicle screw. This is however in contradiction with the explicit teaching that the crack is detected by the stimulus pulse passing from an electrified pedicle screw to a nerve adjacent to the screw.

Moreover, the Board sees no basis in the application as originally filed for the introduction of the "impedance monitor" at the claimed general level. More particularly, the claim does not specify any relation between the impedance monitor and the other elements. In the original application, however, it is specified that the impedance monitor is **for sensing the voltage and current characteristics of the output pulses**, which are then fed to the controller (page 23, lines 24 to 26). Hence, according to the application as originally filed, this function of the impedance monitor is essential for - and thus technically inextricably linked with - the detection and communication to the operator of the intensity level of the stimulus pulse causing the first neuro-muscular response, as defined in claim 1. Omission of the specification that the impedance monitor is for sensing the voltage and current characteristics of the output pulses means that the skilled person is presented with the fresh information that this function is merely optional.

At least for these reasons, claim 1 of the main request contains subject-matter which extends beyond the content of the application as originally filed, in violation of Article 123(2) EPC.

Hence, the main request is not allowable.

5. In its statement of grounds the appellant referred to a number of auxiliary requests, contingent upon the Board's view on particular issues. However, as pointed out by the Board in the communication accompanying the summons to oral proceedings, those auxiliary requests were not submitted formally, i.e. no claims containing the intended amendments were formulated. Since the scope and validity of such hypothetical requests cannot be established with certitude, the Board cannot examine them.

For the sake of completeness, however, it is apparent from the statement of grounds that none of those auxiliary requests was intended to comprise amendments overcoming the deficiencies under Article 123(2) EPC as explained above.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated