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# Datasheet for the decision of 18 April 2018

**Case Number:** T 2286/12 - 3.4.01

**Application Number:** 06817232.9

**Publication Number:** 1933933

**IPC:** A61N1/00

**Language of the proceedings:** EN

**Title of invention:**
MRI-SAFE HIGH IMPEDANCE LEAD SYSTEMS

**Applicant:**
MRI Interventions, Inc.
Boston Scientific Neuromodulation Corporation

**Headword:**

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

**Keyword:**
Novelty - after amendment (yes)
Inventive step - (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 2286/12 - 3.4.01**

# D E C I S I O N
# of Technical Board of Appeal 3.4.01
# of 18 April 2018

| | |
|---|---|
| **Appellant:** (Applicant 1) | MRI Interventions, Inc.<br>1 Commerce Square, Suite 2550<br>Memphis, Tennessee 38103 (US) |
| **Appellant:** (Applicant 2) | Boston Scientific Neuromodulation Corporation<br>25155 Rye Canyon Loop<br>Valencia, CA 91355 (US) |
| **Representative:** | Vossius & Partner<br>Patentanwälte Rechtsanwälte mbB<br>Siebertstrasse 3<br>81675 München (DE) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 29 May 2012 refusing European patent application No. 06817232.9 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | P. Fontenay |
| **Members:** | F. Neumann |
| | R. Winkelhofer |

## Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division to refuse the European patent application number 06 817 232.9.

II. The application was refused because the subject-matter of claim 1 of each of the main request and the first to third auxiliary requests on file at that time was not new, the subject-matter of claim 1 of the fourth and fifth auxiliary requests lacked an inventive step, claim 1 of each of the sixth to ninth auxiliary requests contained added subject-matter and the tenth auxiliary request was not admitted into the procedure.

III. The following documents were referred to in the contested decision:

D1: WO-A-03/063946;
D3: US-B-6 284 971.

IV. The Appellants (Applicants) request that the decision under appeal be set aside and that a patent be granted on the basis of the documents making up the main request, i.e. claims 1-15, filed with submission of 16 April 2018, claims 16-18, filed with submission of 18 April 2018, description pages 2-4, 6, 7, 10-18, 20-30, filed with submission of 16 April 2018, description pages 5, 8, 9, 19, filed with submission of 18 April 2018 and drawing sheets 1/24-24/24, as published. Alternatively, the Appellants request that a patent be granted on the basis of one of the sets of claims filed as first to third auxiliary requests with the statement setting out the grounds of appeal.

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

"*An MRI/RF compatible medical device, comprising: an implantable lead system (20) elongate lead having at least a first and a second electrode ($100_1$, $100_2$), each associated with a respective first and second axially extending conductor (1,2), wherein, at each of a plurality of intermediate locations along at least a major portion of the length of the lead system (20), at least one of a plurality of spaced apart capacitors (3) is disposed between the first and second axially extending conductors (1,2) to define a plurality of high impedance circuit segments, each high impedance circuit segment comprising at least a portion of the first axially extending conductor (1), at least a portion of the second axially extending conductor (2), and at least one of the plurality of spaced apart capacitors (3), wherein each of the plurality of high impedance circuit segments is configured as an RF trap that inhibits flow of induced RF current at a target range of high frequencies to inhibit heating tissue adjacent to electrodes ($100_1$, $100_2$) of the lead system (20), wherein high frequencies are frequencies at or above 1 MHz, whereby the lead system (20) has a high impedance at the target range of high frequencies and a low impedance at low frequencies.*"

Claims 2-18 are dependent claims.

VI. The arguments of the Appellant, insofar as they are pertinent to the present decision, are set out below in the reasons for the decision.

## Reasons for the Decision

Main request

1. Novelty

1.1 It is not contested that D1 represents the closest prior art. D1 discloses an implantable medical device comprising an elongate lead extending between an active electronic device (AED) and a tip electrode (202, 502) and one or more ring electrodes (402,503) at the distal end of the lead. An axially extending tip conductor (404, 606) and an axially extending ring conductor (406, 608) extend through the lead to the tip and ring electrodes (202, 502; 402,503) respectively. The tip and ring electrodes serve as a cathode and an anode for pacing, stimulation or sensing operations controlled by the AED. The elongated conductors in D1 can act as linear antennas which couple with the external RF fields associated with MRI systems. This causes induced currents to flow through the conductors. When the induced current emerges from the tip electrode, it is concentrated and can cause unwanted heating and damage of the surrounding tissue. In the Figure 4 embodiment, a capacitor 408 (or a plurality of capacitive devices) is connected between the tip conductor 404 and the ring electrode 402. The value of the capacitor 408 is selected so as to divert a portion of any high frequency current induced in the conductor 404 to the shunting assemblies (208, 504) so as to spread the current between both the tip electrode 202 and the ring electrode 402. Thus, any induced high frequency current is dissipated over a larger portion of tissue resulting in a reduction of heat damage to the tissue.

1.2 At a purely structural level, the device of claim 1 is distinguished from the device of D1 in that a plurality of capacitors are disposed between the first and second axially extending conductors at a plurality of intermediate locations along at least a major portion of the length of the lead system.

1.3 In the contested decision, the Examining Division referred to Figure 7 of D1, arguing that two capacitors 712 and 714 were disposed between first and second axially extending conductors and were located along a major portion of "*a*" length of the lead system.

1.4 This argument relies on the interpretation that the tubular ring electrode 704 could be seen to be part of a second axially extending conductor and that the length of the lead system along which the capacitors were disposed was not defined.

1.5 However, in view of the amendments made to claim 1, this argument no longer holds. In particular, claim 1 now defines that the plurality of spaced apart capacitors are located at each of a plurality of intermediate locations along at least a major portion of "*the*" length of the lead system. Since the ring electrode only extends over a very minor portion of the lead system, the two capacitors 712, 714 located at either end of the ring electrode 704 in Figure 7 of D1 do not anticipate the claimed arrangement.

The third embodiment of D1, illustrated in Figures 5 and 6, employs two ring electrodes (503, 604). However, in this arrangement only a single capacitor is provided for redistributing the high frequency current on the tip conductor. This capacitor is arranged between the tip conductor and one of the ring electrodes. Thus even

this embodiment does not disclose a plurality of spaced apart capacitors disposed between the first and second axially extending conductors along a major portion of the length of the lead system.

1.6 The subject-matter of claim 1 is therefore new.

2. Inventive step

2.1 In contrast to the arrangement of D1, the present invention aims to provide a lead system which reduces or prevents the passage of RF currents induced during MRI, while allowing unimpeded passage of DC or low frequency signals essential for the active electronic device (AED) to perform its medical function. In other words, the idea behind the current invention as defined in claim 1 is to inhibit transmission of high frequency induced current along the lead system during exposure to RF and thus to **prevent** any heating of the tissue adjacent to the electrodes, as opposed to merely spreading the heat over a larger tissue area.

2.2 This aim is achieved by providing a plurality of capacitors along at least a major portion of the length of the lead system, thereby producing a plurality of spaced apart high impedance circuit segments which can reduce, block or inhibit induced current in the lead caused by RF signals present around the lead. These high impedance segments can be configured such that they do not tune to a range of RF frequencies, thus reducing the extent of coupling in the chosen frequency range.

2.3 D3 discloses a coaxial cable which reduces undesired induced RF currents, and hence the risk of excessive heating and burns, in uses involving an MRI scanner. In

particular, the coaxial cable of D3 is used to increase the safety of RF probes that are inserted into the body, e.g. endorectal, esophageal and intravascular probes.

The coaxial cable is made up of an elongated inner conductor and an outer shield conductor. The outer shield conductor is provided with two layers of shields: an annular inner shield portion and a segmented outer shield portion. One end of each of the segments of the outer shield portion is electrically connected to the inner shield portion.

Segmenting the outer shield portions means that from the perspective of external electromagnetic waves, the impedance is high and therefore undesired induced RF currents in the cable may be inhibited.
In one embodiment, a plurality of capacitors are distributed along the outer shield portion, the capacitors being connected between the annular inner shield portion and each segment of the outer shield portion. By appropriately selecting the value of the capacitors and the length of each of the segments, the impedance may be tuned to have the maximum possible value at the MRI operating frequency.

D3 makes no suggestion that the first and second axially extending conductors of an implantable lead system such as that disclosed in D1 could be connected by a plurality of capacitors at a plurality of locations along the length of the lead. D3 only teaches that the inner shield portion and the outer segmented shield portions of a coaxial cable should be connected by capacitors. There is nothing to suggest that this teaching could be applied to the two electrode conductors of D1.

None of the other prior art cited during the examining proceedings suggests such an arrangement.

Therefore, there is no incentive for the skilled person, starting from D1, to introduce a plurality of spaced apart capacitors disposed between the first and second axially extending conductors along a major portion of the length of the lead system.

The subject-matter of claim 1 is therefore inventive.

## Order

## For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division with the order to grant a patent in the following version:

Claims:
Nos. 1-15, filed with submission of 16 April 2018;
Nos. 16-18, filed with submission of 18 April 2018;

Description:
Pages 2-4, 6, 7, 10-18, 20-30, filed with submission of 16 April 2018;
Pages 5, 8, 9, 19, filed with submission of 18 April 2018;

Drawings:
Sheets 1/24-24/24, as published.

The Registrar: The Chairman:

R. Schumacher P. Fontenay

Decision electronically authenticated