

Internal distribution code:

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

**Datasheet for the decision
of 17 May 2021**

Case Number: T 0325/17 - 3.4.01

Application Number: 05825356.8

Publication Number: 1814446

IPC: A61N1/00

Language of the proceedings: EN

Title of invention:

METHOD FOR LOW-VOLTAGE TERMINATION OF CARDIAC ARRHYTHMIAS BY
EFFECTIVELY UNPINNING ANATOMICAL REENTRIES

Applicant:

Washington University in St. Louis

Headword:

Unpinning anatomical reentries / WASHINGTON UNIVERSITY

Relevant legal provisions:

EPC Art. 84

Keyword:

Claims - clarity (no)



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 0325/17 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 17 May 2021

Appellant: Washington University in St. Louis
(Applicant) School of Medicine
Campus Box 1127
St. Louis, MO 63130 (US)

Representative: Copsey, Timothy Graham
Kilburn & Strode LLP
Lacon London
84 Theobalds Road
London WC1X 8NL (GB)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 28 June 2016
refusing European patent application No.
05825356.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair P. Scriven
Members: B. Noll
R. Winkelhofer

Summary of Facts and Submissions

- I. This appeal is of the Examining Division's decision to refuse European patent application 05825356.8.
- II. The application was refused for lack of clarity (Article 84 EPC) of claim 1 of the (then) main and second auxiliary requests. The first auxiliary request was held not to comply with Article 123(2) EPC.
- III. With the statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and a patent granted on the basis of a single request, which is still the appellant's sole request. The appellant also submitted a declaration by Dr. M. W. Kroll.
- IV. Claim 1 reads as follows:

An apparatus for treating cardiac arrhythmias, said apparatus including a pulse generator having programmably operable circuitry contained therein to detect a ventricular tachycardia event in a heart of a patient and to generate electrical shocks to be delivered to a plurality of electrodes in operable communication with the pulse generator, said apparatus being characterized in that :

in response to the ventricular tachycardia event, the programmably operable circuitry is programmed to automatically deliver at least one unpinning shock to the patient

configured to generate a voltage field that creates a depolarized region in the heart which destructively interferes with a reentry wave tip of an anatomical reentry associated with the cardiac arrhythmia that is passing through the depolarized region so as to effectively unpin the anatomical reentry,

wherein each of the at least one unpinning shocks has an energy that is higher than an anti-tachy pacing pulse and lower than a lower limit of vulnerability of the patient such that the voltage field created by the at least one unpinning shock is sufficient to unpin the anatomical reentry from a location in the heart at a core of the anatomical reentry without creating a risk of inducing ventricular fibrillation, and

wherein subsequent to delivering the at least one unpinning shock, the circuitry is programmed to deliver at least one anti-repinning pulse to the patient to extinguish the anatomical reentry that is unpinning from the location of the core, the at least one anti-repinning pulse having an energy that is less than the at least one unpinning shock.

- V. In a communication accompanying a summons to oral proceedings, the Board expressed its provisional view that *an energy higher than conventional anti-tachy pacing pulses* was indeed unclear, as the Examining Division had found, even in view of Dr. Kroll's declaration, from which the Board could not derive a

clear definition either; that the term *lower limit of vulnerability* was unclear; and that *creates a depolarized region ... which destructively interferes ... so as to effectively unpin the anatomical reentry* defined a desired therapeutic effect but did not clearly characterise the device itself.

- VI. In response to the summons, the appellant informed the Board that they would not attend oral proceedings and asked for "a decision on the written papers". Accordingly, the oral proceedings were cancelled.
- VII. The appellant submitted no further arguments, after the statement of grounds.

Reasons for the Decision

1. The feature that an unpinning shock has an energy higher than an anti-tachy pacing pulse is unclear, since the energy of an anti-tachy pacing pulse is not available as a specific value from the prior art.
2. Claim 1 is further unclear because it defines the energy of an unpinning shock as being less than an undefined lower limit of vulnerability LLV (for a defibrillation threshold) of a patient. The application does not provide any concrete LLV, or a clear definition of what is to be understood by the term. Further, LLV is not only dependent on the individual patient but also on additional parameters. It might be different for the right and left ventricles, for

example. The LLV is, therefore, unsuitable to serve as a reference for the energy of an unpinning shock.

3. Claim 1 is further unclear because of the definition that the voltage field creates a depolarized region in the heart which destructively interferes with a re-entry wave tip of an anatomical re-entry associated with the cardiac arrhythmia that is passing through the depolarized region so as to effectively unpin the anatomical re-entry. This feature only defines a desired therapeutic effect, which is, however, not suitable for defining the apparatus itself.
4. The appellant did not comment on these objections, which the Board had raised in its communication. No further issues have come to light which would call for their reconsideration.
5. To conclude, claim 1 fails to comply with Article 84 EPC as regards clarity.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



D. Meyfarth

P. Scriven

Decision electronically authenticated