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**Datasheet for the decision
of 10 March 2008**

Case Number: T 0013/06 - 3.2.02

Application Number: 99101348.3

Publication Number: 0914803

IPC: A61B 18/00

Language of the proceedings: EN

Title of invention:

Endovascular electrolytically detachable guidewire tip

Patentee:

The Regents of the University

Opponent:

EFMT Entwicklungs- und Forschungszentrum

Headword:

-

Relevant legal provisions:

EPC Art. 52(1)

Relevant legal provisions (EPC 1973):

EPC Art. 56, 100(a)

Keyword:

"Inventive step (yes)"

Decisions cited:

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Catchword:

-



Case Number: T 0013/06 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 10 March 2008

Appellant:
(Opponent) EFMT Entwicklungs- und Forschungszentrum
für Mikrotherapie GmbH
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Representative: Prins, Hendrik Willem
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Respondent:
(Patent Proprietor) The Regents of the University of California
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Representative: Price, Nigel John King
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 4 November 2005
rejecting the opposition filed against European
patent No. 0914803 pursuant to Article 102(2)
EPC 1973.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division relating to European patent No. 0 914 803, rejecting its opposition to the grant thereof. The decision was dispatched on 4 November 2005.

The appeal was received on 3 January 2006 and the fee for the appeal was paid on the same date. The statement setting out the grounds of appeal was received on 14 March 2006.

- II. The opposition was filed against the entire patent and based on Article 100(a) EPC 1973 (lack of novelty and inventive step) and Article 100(c) EPC 1973. The opposition division decided that the patent met the requirements of the EPC and rejected the opposition, accordingly.

During the oral proceedings, held before the Board on 12 December 2007, the appellant withdrew all its objections save that of lack of inventive step of the claimed subject-matter.

At the end of the oral proceedings the chairman closed the debate and stated that the Board would issue its decision in writing at a later date.

- III. The following documents were of particular interest in the appeal procedure:

E16: Piton et al., J. Radiology, 1979, p.799-808

E34: Philpott et al., Investigative Radiology, 18,
p.100-104, 1983.

- IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed, i.e. that the patent be maintained in the granted form.

- V. Independent claim 1 reads as follows: -

"A combination of a guidewire (10) and a voltage source, the guidewire being connected to the voltage source and being for use with a microcatheter, the guidewire being suitable for use in the initiation or formation of a thrombus due to the application of electric current to the guidewire by the voltage source, the guidewire (10) comprising: a core wire having a main body (12,16,32) and a distal portion (18,26,36), said distal portion (18,26,36) being susceptible to electrolytic disintegration in blood; and a tip portion (28) for endovascular insertion within a vascular cavity, said tip portion being coupled to said main body (12,16,32) via said distal portion, comprised of material not susceptible to electrolytic disintegration in blood, and comprising a coil (28) prebiased to a spiral or helical shape such that on its advancement out of the distal end of the microcatheter the coil is capable of changing from being straight to its prebiased spiral or helical shape; the guidewire being so constructed and arranged that, on the application of electric current to the guidewire (10) when said tip portion coil (28) is endovascularly disposed in the vascular cavity, at

least one portion of said distal portion (18,26,36) can be electrolytically disintegrated to detach said tip portion coil (28) from said main body (12,16,32) to enable the removal of the main body (12,16,32) of the core wire whilst leaving the detached tip portion coil (28) within the vascular cavity".

Claims 2 to 14 are dependent claims.

VI. The parties argued as follows:

Appellant

Although claim 1 defined a wire having a three-part structure, the claim also encompassed a wire having a two-part structure. The main body was not identified in respect of its structure or composition, and the claim merely stated that the distal portion was susceptible to electrolytic disintegration in blood. According to paragraph 33 of the patent the location where the disintegration occurred was indefinite, so there was no predictable or defined detachment.

E16 disclosed a stainless steel guidewire having a main body and an integral distal portion, and a tip portion which was detached at the immediate exit of a catheter by electrolytic disintegration, after which the main body was withdrawn leaving behind the tip portion (as shown in Figure 13). The left-behind tip portion had an irregular tip and this problem could be solved by using a material less susceptible to electrolytic disintegration such as platinum, as suggested by E34. A second problem was to improve the filling of an

aneurysm, which could be performed by using a coil instead of the curved wire of E16.

Respondent

Claim 1 clearly defined a three-part wire including a main body, a distal portion which was susceptible to electrolytic disintegration in blood, and a tip which was not susceptible to electrolytic disintegration in blood. The wire of E16 was made of a single material only and did not possess three distinct portions. Moreover, the detachment of the tip portion in E16 was merely an observation, not an aim, so there was no incentive to change this wire.

Reasons for the decision

1. The appeal is admissible.
2. The only point at issue is the question of inventive step of the claimed subject-matter, see point II above.
3. *Inventive step*
- 3.1 Construction of claim 1

An important feature of claim 1 is that the claimed guidewire has three distinct portions, a proximal portion, a corrodable intermediate distal portion, and a non-corrodable tip portion, whereby in use the distal portion disintegrates in blood leaving the detached tip in the thrombus. This ensures a controlled detachment of a predetermined length of the tip. The three

different parts are not just notionally different parts of a uniform wire, but physically different and distinct, by virtue of their construction and function.

Although paragraph [0033] of the patent in suit describes the use of the wire together with a catheter, the wire, nevertheless, possesses three distinct portions and corrosion occurs in the part of the wire exposed out of the catheter by virtue of its construction which is different to that of the main body portion or the tip portion.

3.2 Structure of the E16 wire

E16 discusses the use of a Pt wire for electrothrombosis, and is critical of Pt as the material in that it is somewhat rigid (page 800, right column, lines 6-10), and recommends instead the use of a stainless steel wire A 60 or A 90 (page 800, right column, 3rd paragraph). E16 suggests that if a wire (whose entire length is of the same material) gives problems, whether of corrosion or rigidity, then the material of the (entire) wire should be changed.

There is no suggestion whatsoever of using a composite wire in E16, and the person skilled in the art would not be incited to apply a Pt tip or coil at the end of a steel wire from the disclosure of E16 alone.

The wire of E16 requires the cooperation of a catheter to define the location of the region of disintegration whereas, by contrast, the claimed guidewire does not rely on cooperation with a catheter to define the point of rupture; it has defined within itself the location

of this region at the distal portion. The embodiment described in paragraph [0033] also corrodes away at the distal portion primarily because of the wire construction.

The wire of E16 disintegrates at the immediate exit of a catheter (page 800, right column, lines 16-19 and page 807, right column, second paragraph), and sometimes a tip portion is left captive in the thrombus when the main part of the wire is removed from the cavity.

- 3.3 The statement that sometimes a distal part of the wire becomes detached and is retained by the thrombus, means that the detachment is an uncontrolled process. Moreover, it is generally undesirable to leave behind detritus in the body and the tenor of E16, accordingly, is that it is not desirable for the guidewire to disintegrate and that the detachment of the wire is, if anything, not the goal but a problem.

By contrast, the patent in suit positively requires the controlled detachment of the tip so as to use the detached tip portion to stuff a cavity and also to form a thrombus therein and then allow the main body of the wire to be withdrawn. To this end the guidewire has, in addition to the tip portion, a main body and a distal portion which is susceptible to electrolytic disintegration in blood, i.e. it has a three-part form in the longitudinal direction, as discussed above.

- 3.4 The problems defined by the appellant, relating to E16, are not derivable from an objective reading thereof. Instead, having knowledge of the patent in suit and by

the use of hindsight, the appellant defines problems associated with the tip of the wire of E16, and then invokes solutions from other documents.

As demonstrated above, however, there is no suggestion in E16 that only part of the wire thereof should be modified so as to replace its distal part by a different material, let alone by a coil. No other prior art document cited by the appellant suggests the modification of guidewires described in E16, so as to give the claimed three-part structure.

In particular, E34 was cited by the appellant as complementary to E16 in its inventive step attack. This document discloses anodes of stainless steel or Pt, but in each case a homogeneous wire is disclosed. Although this document mentions some advantages of Pt over steel as the wire material, there is no suggestion of replacing only part of a steel wire by Pt to give a composite wire. There is, moreover, no reason to combine this document with E16 because no problem in either document points to the other.

3.5 For these reasons, the subject-matter of claim 1 as granted involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

V. Commare

T. Kriner