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**D E C I S I O N**  
**of 14 June 2005**

**Case Number:** T 0228/03 - 3.2.2

**Application Number:** 91905194.6

**Publication Number:** 0484468

**IPC:** A61B 17/36

**Language of the proceedings:** EN

**Title of invention:**

Endovascular electrolytically detachable guidewire tip

**Patentee:**

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

**Opponents:**

EFMT Entwicklungs- und Forschungszentrum für Mikrotherapie  
GmbH  
Dendron gmbH  
Micro Therapeutics Inc.  
ev3 EUROPE SAS

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 100(a), (b), (c), 105(1), 114(2)

**Keyword:**

"Admissibility of interventions, late-filed documents (not admitted), sufficiency (yes), novelty (yes), inventive step (yes) "

**Decisions cited:**

T 0392/97

**Catchword:**

-



Case Number: T 0228/03 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 14 June 2005**

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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
24 October 2002 concerning maintenance of the  
European patent No. 0484468 in amended form.

**Composition of the Board:**

**Chairman:** T. K. H. Kriner  
**Members:** S. S. Chowdhury  
U. J. Tronser

## Summary of Facts and Submissions

I. European patent application 91 905 194.6, filed on 3 January 1991 with a priority date of 13 March 1990, matured into European patent No. 0 484 468.

Following an opposition filed under Article 99 EPC and an intervention under Article 105 EPC, the interlocutory decision of the opposition division was dispatched on 24 October 2002.

On 23 December 2002 appellant I (the patent proprietor, Regents of the University of California) filed an appeal against this decision and paid the appeal fee on the same day. The statement of grounds of appeal was received on 28 February 2003.

On 20 December 2002 appellant II (opponent EFMT Entwicklungs- und Forschungszentrum für Mikrotherapie GmbH) and appellant III (opponent/intervener Dendron GmbH) filed respective appeals against this decision and both paid the appeal fee on 21 December 2002. The statements of grounds of appeal of these appellants were received on 1 March 2003.

On 27 December 2002 an intervener appellant IV (Micro Therapeutics, Inc.) filed a notice of intervention under Article 105 EPC together with its reasons, referring to court proceedings before the Court of the Hague, Netherlands which were started by itself (amongst others) on 27 September 2002 in order to request a declaration of non-infringement of the patent in suit. It filed facts and arguments for the opposition and

paid the opposition fee and the fee for appeal on the same day.

On 22 April 2003 a further intervener (eV3 EUROPE SAS) filed a notice of intervention/opposition under Article 105 EPC together with its reasons, referring to the aforementioned court proceedings before the Court of The Hague, Netherlands during which the patent proprietor started proceedings for infringement of the patent in suit against the intervener by counterclaim of 22 January 2003. It filed facts and arguments for the opposition and paid the opposition fee and the fee for appeal on the same day.

The oppositions and interventions are based on Article 100(a), (b), and (c) EPC.

II. The following documents were principally relied upon during the appeal proceedings:

- E1: "Transcatheter Electrocoagulation: Experimental Evaluation of the Anode"; Thompson et al; Invest. Radiol., Vol. 14; pages 41 to 47; 1979
- Int5: Philpott et al., Investigative Radiology, Vol. 18, No. 1, 1983
- Int6: Piton et al., Neuroradiology 16, pages 385 to 388, 1978
- Int7: Piton et al., J. Radiology, 1979, pages 779 to 808
- Int8: EP-A-0 040 138
- Int9: ZA-A-81-2814
- Int15: US-A-4 884 579.

In its notice of intervention the intervener eV3 EUROPE SAS had made allegations of public prior use of the claimed device, but at the oral proceedings before the Board it withdrew this allegation.

Oral proceedings took place on 14 June 2005.

III. Requests

Appellant I requests that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 27, description columns 1 to 11, and Figures 1, 1A, 3, 4, and 5 as submitted at the oral proceedings.

The further appellants and opponents I to IV requested that the decision under appeal be set aside and that the European patent No. 0 484 468 be revoked.

IV. Claim 1 according to appellant I's request (claim 1 of the patent as granted) reads as follows:

"A combination of a guidewire (10,42) and a voltage source (70), the guidewire (10,42) being connected to the voltage source (70) and being for use with a microcatheter (44) in endovascular electrothrombosis, the guidewire (10,42) comprising: a core wire having a main body (12,16;32) and a distal portion (18,26;36,46); and a tip portion (28,56) for endovascular insertion within a vascular cavity, said tip portion being coupled to said main body (12,16,32) via said distal portion(18,26,36,46) and comprised of material not susceptible to electrolytic disintegration in blood; wherein said distal portion (18,26,36,46) is

susceptible to electrolytic disintegration in blood whereby, on the application of current to the guidewire(10,42) by the voltage source when said tip portion (28,56) is disposed in the vascular cavity, endovascular electrothrombosis can be performed and at least one portion of said distal portion (18,26,36,46) electrolytically disintegrated to detach said tip portion (28,56) from said main body (12,16,32)."

V. The parties submitted the following arguments:

(i) Appellant opponents

Article 100(b) EPC

For electrothrombosis and electrolytic disintegration to occur in blood the distal portion of the guidewire must be exposed to blood, and since claim 1 was silent about this feature it was unworkable. Claim 1 only required that the tip portion be comprised of a material not susceptible to electrolytic disintegration, so that it could be made of Teflon which was not a conductor.

Article 100(c) EPC

The Pt coil was originally disclosed as not being prebiased only in combination with having no internal reinforcement. Similarly, the long and pliable property was disclosed only in combination with a metal not being susceptible to electrolytic disintegration (original claims 17 and 19 and page 11), so that claims 10 and 15 were unjustifiably broader than the original disclosure.

The application only disclosed the situation in which when a current was applied to the guidewire it corroded. The wording of claim 1 (endovascular electrothrombosis can be performed) suggested this property was optional and, accordingly, the claim was thus unjustifiably broader than the original disclosure.

Article 100(a) EPC

Novelty:

Although claim 1 defined a main body, a distal portion, and a tip portion, it did not define the boundaries between the various portions.

Int7 described a guidewire for inducing arterial thrombosis, which had a main portion which, when a current was passed through it, reliably and controllably separated where it exited the catheter. Moreover, the electrode ruptured at its distal end, so that this wire anticipated the guidewire of claim 1. For the same reasons Int8 also destroyed the novelty of claim 1.

E1 disclosed a guidewire made of stainless steel, which had a Pt wire soldered to its distal end. Figure 1 showed a tapering solder joint between the two wires which was susceptible to electrolytic disintegration and formed a region of weakness where preferential corrosion would occur. This part corresponded to the distal portion of the guidewire of claim 1 whose subject-matter was, therefore, not novel.



In order to establish novelty of the claimed subject-matter, it was important to demonstrate which feature of claim 1 differed from the prior art wires known from these documents.

Inventive step

Page 807 of Int7 stated that detachment of the tip was desired since it reinforced the thrombosis. Although electrolysis occurred over the entire exposed part of the wire it was most intense at the exit of the catheter, so the disintegration could be controlled. This document suggested (page 800, second paragraph in the right column) the use of a Pt tip at the end of a stainless steel wire. This modification was also obvious because some material was lost by electrolysis at the end of a steel wire. However, Pt was known to be rigid and to solve the problem of rigidity the person skilled in the art would turn to Int8 and Int15 which suggested the use of a coil to restore flexibility. The resulting guidewire would have the three-part form of the wire of claim 1.

(ii) Appellant patentee

Article 100(b) EPC

It was incorrect to use claim 1 as the basis for this objection, instead the patent specification should be consulted for sufficiency of the disclosure, and this was satisfactory in this respect. It was implicit for the person skilled in the art that the tip must be conducting.

Article 100(c) EPC

Two features must be defined in combination only if they are technically related, which was not the case with the long and pliable feature and the susceptible to electrolytic disintegration feature. The same applied to the pre-biased and susceptible to electrolytic disintegration features. Moreover, in each case, each feature had been originally disclosed independently of the other.

Article 100(a) EPC

Novelty

Claim 1 of the patent in suit clearly defined a guidewire having three distinct parts as constructional features, which contrasted with the wires of the Piton documents (Int6 to Int9) which were always made of a single material and had no parts differing in shape or size. In the patent the tip was characterised by its material which must be preferentially susceptible to electrolytic disintegration, and this was not the case with the Piton wires.

The steel/Pt wires of E1 did not disintegrate since this document was concerned with the problem of the destruction of the steel wire, and the steel/Pt wires were said to solve this problem. The Tables of E1 also showed that even after 40 minutes of use for thrombosis formation no destruction of the steel/Pt wires occurred.

### Inventive step

Each of the Piton documents always disclosed wires of a single material only for the entire length of wire, and there was no incentive for making wires of different materials, in particular for making the end part of a material susceptible to electrolytic disintegration. The flexibility of the tip was spoken of with hindsight, it had no bearing on the problem which the patent addressed.

### Reasons for the Decision

1. The appeals by appellants I, II, and III are admissible.
2. *Admissibility of the interventions under Article 105 EPC*
  - 2.1 According to Article 105(1) EPC, in the event of an opposition to a European patent being filed, any third party who proves that proceedings for infringement of the same patent have been instituted against him may, after the opposition period has expired, intervene in the opposition proceedings, if he gives notice of intervention within three months of the date on which the infringement proceedings were instituted. The same shall apply in respect of any third party who proves both that the proprietor of the patent has requested that he cease alleged infringement of the patent and that he has instituted proceedings for a court ruling that he is not infringing the patent.

2.2 The intervener Micro Therapeutics, Inc. stated in its notice of intervention dated 27 December 2002

- that on 27 September 2002 it initiated court proceedings before the Court of The Hague for a ruling declaring non-infringement of EP-B-0 484 468 by specified products. It thereby fulfilled the requirements of Article 105(1) second sentence EPC.
  
- that these court proceedings were started because, through its subsidiary Dendron GmbH, it was requested to halt alleged infringement by the proprietor of EP-B-0 484 468 in an infringement claim submitted by the patent proprietor in German Court proceedings on 26 March 2002. While the infringement claim relates to the infringement of EP-B-0 804 905 of the same proprietor, the allegations made in those proceedings include allegations of infringement of EP-B-0 484 468. Thus, Micro Therapeutics, Inc. also fulfilled the requirements of Article 105(1) first sentence EPC.

The intervention of Micro Therapeutics, Inc. is inadmissible since the proceedings for a court ruling, which were instituted by Micro Therapeutics, Inc were not preceded by a request by the patent proprietor and addressed to Micro Therapeutics, Inc. to cease the alleged infringement of the patent in suit, that is to say EP-B-0 484 468. Thus, on 27 December 2002 neither the requirements of Article 105(1) EPC first sentence nor those of the second sentence were fulfilled.

2.3 The intervener ev 3 EUROPE SAS has proven that the designation "ev 3 EUROPE SA" in the list of assumed

infringers in the counterclaim of 22 January 2003 instituted by the patent proprietor was a clerical error and the correct designation is "ev 3 EUROPE SAS". This intervener declared its intervention on 22 April 2003. The time limit for this intervention was, according to the first sentence of Article 105(1) EPC, triggered by the initiation of the counterclaim by the patent proprietor on 22 January 2003, and not on 27 September 2002 with the institution of proceedings for a court ruling that the interveners, amongst others, were not infringing the patent. The reason for this is that the court proceedings were not preceded by a request by the patent proprietor to ev 3 EUROPE SAS to cease the alleged infringement, as required by the second sentence of Article 105(1) EPC so that a time limit for intervention according to the second sentence of Article 105(1) may be triggered (see T 392/97).

The intervention of ev 3 EUROPE SAS meets the requirements of Article 105(1) EPC and is admissible.

3. *Late filed submissions*

With its letters dated 22 September 2004 and 20 January 2005, that is, almost five years after the initial opposition and about two and a half years after the beginning of the appeal procedure, Appellant II filed new documents to support its arguments under Article 100(a) EPC. The Board has examined these documents and finds them to be no more relevant than those already on file and does not admit them in accordance with Article 114(2) EPC.

4. *Amendments*

4.1 At the oral proceedings the Board came to the conclusion that claim 23 of the patent was objectionable under Article 123(2) EPC in response to which the patentee cancelled this claim.

4.2 During the debate as to the novelty of the claimed subject-matter there was some discussion regarding the expression "a tip portion (28, 56) ..... comprised of material not susceptible to electrolytic disintegration in blood" in claim 1 of the patent in suit. The Board was of the opinion that the scope of claim 1 was confined to a tip made entirely of a material not susceptible to electrolytic disintegration in blood, and that the embodiments such as that of Figure 2 were not consistent with the claim.

This embodiment, together with paragraph 37 of the patent, was cancelled accordingly, and consequential amendment was carried out. Since these amendments arose during the discussion of novelty, they are allowable under Rule 57a EPC.

5. *Article 100(b) EPC*

The description, particularly with reference to Figures 4 and 5, describes in detail and adequately how the claimed device is used. It is not necessary to include this explanation in claim 1, the more so since this would involve inserting use features in a device claim. For the person skilled in the art, who must be presumed to have knowledge of electrolysis and electrothrombosis, it is clear that those parts

involved in conducting a current for electrothrombosis and electrolysis must be conducting, it is also not necessary to spell this out in claim 1. The objections under Article 100(b) EPC are not well founded, accordingly.

6. *Article 100(c) EPC*

Although two different features were originally disclosed in combination in claim 17, this alone is not a bar to their later being separated if they are not technically related. The properties of the coil: "long and pliable", and "not being susceptible to electrolytic disintegration", are not technically related and need not always go together, and for this reason alone the separation of the features of original claim 17 is allowable. This also applies to the properties: "not being prebiased", and "having no internal reinforcement".

In the present case, moreover, there was an original disclosure of each of the features of granted claims 10 and 15 separately and independently of the other feature. Original page 9, lines 8 to 11, for example, discloses the use of a long and pliable length of the distal tip without the requirement that this not be susceptible to electrolytic disintegration. Also, Figures 1 and 3, respectively, show a tip portion with a coil and no internal reinforcement, and being prebiased and not being prebiased, respectively. The objections under Article 100(c) EPC are not well founded, accordingly.

*Article 100(a) EPC*

7. *Construction of the wording of claim 1*

Claim 1 of the patent in suit defines a guidewire having three distinct portions, a main body, a distal portion, and a tip portion whereby, in use, the distal portion disintegrates upon passage of a current through the wire leaving the detached tip, which is comprised of material not susceptible to electrolytic disintegration in blood, in the thrombus. The distal portion ensures a controlled and predictable detachment of a predetermined length of the tip since the distal portion may be preferentially corroded because the main body is covered in insulation and the tip is made of a non-corrodable material (Pt). Alternatively, the wire of the main body has a diameter of 0.254-0.508 mm (see column 6, line 25 of the patent) and the wire of the coil 26 has a diameter of 0.025-0.127 mm (column 7, lines 4 to 6) which means that the latter corrodes preferentially by electrolysis.

These properties of the guidewire are expressed in claim 1 by the features "wherein said distal portion is susceptible to electrolytic disintegration in blood", "the tip being comprised of material not susceptible to electrolytic disintegration in blood" and "at least one portion of said distal portion electrolytically disintegrates to detach said tip portion from said main body". The preferential corrosion of the distal portion ensures that this portion disintegrates first.

Therefore, the Board is satisfied that claim 1 defines three distinct parts of the guidewire, which parts are



distinct by virtue of constructional features, and not only on a notional basis, as the appellant opponents suggest. Moreover, when exposed to blood and a current passed through it a part of the distal portion will be corroded away to leave the two other parts substantially unaffected. The appellant opponents/intervenors objected that claim 1 did not define the boundary between the three parts, but this is not necessary, a guidewire would fall under the scope of the claim if it clearly possessed the three parts as defined in claim 1.

8. *Novelty*

8.1 The appellant has argued that the various Piton documents, Int6 to Int9 anticipate the subject-matter of claim 1.

As indicated above, a guidewire will fall under the scope of claim 1 only if it clearly and unambiguously possesses all the three different sections as constructional features. The Piton wires are all constructed along their entire length from a single material only, and it is the manner of their use rather than their construction which causes a part of thereof to disintegrate when conducting a current in blood.

Int7 describes the use of a stainless steel wire A 60 or A 90, which disintegrates at the immediate exit from a catheter. However, this 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 an external agent, it has

defined within it the location of this region, ie the distal portion.

Insofar as the wire of Int7 does not clearly and unambiguously possess the three portions as defined in claim 1 it does not anticipate its subject-matter. The same goes for all the other Piton documents.

- 8.2 Document E1 describes guidewires for use in electrocoagulation induced electrothrombosis. Two different wires are described, one of stainless steel and another of stainless steel with a Pt tip soldered at its end. The document says that a problem with the steel wires was the electrolysis and destruction of the tip, and says further that Pt is resistant to electrolysis (page 41, right column, last two paragraphs) and would solve the problem of the destruction of the tip (page 45, left column, second paragraph).

According to the appellant opponent/intervener, a tapered solder portion joins the steel and Pt sections together and would corrode preferentially in blood and therefore corresponds to the distal portion of claim 1, so that this wire has the three-part structure of claim 1.

This argument is not acceptable for the following reasons: It is not clear from Figure 1 of E1 that there is indeed a distinct tapered connecting portion between the steel and Pt sections. If there were such a solder connecting portion (which is not clear from the Figure), however, it is not clear that this would necessarily disintegrate in blood since this would depend, *inter*

*alia*, on the configuration and composition of the solder.

However, the purpose of such wires generally is to introduce them into the body for thrombus formation and then remove them in their entirety since it may be assumed that it is undesirable to leave pieces thereof behind. The steel wire of E1 was found to be unsatisfactory in this respect, for which reason the steel/Pt wire was investigated, and it is inconceivable that this wire would be reported as performing satisfactorily if the tip had become detached. In fact currents were passed through it for up to 60 minutes (see Tables 1 and 2) and no rupture of the wire was reported.

As for the experimental results provided by the opponents/interveners in this respect, it is not clear that they were performed under the same conditions as those used in E1, in particular that the same solder was used to join the steel and Pt parts together and the configuration of the joint was the same, this latter also being an important factor regarding its disintegration. It is always possible to set up an experiment to produce the required result on an ex post facto basis. Instead, the Board is guided by E1 which reports no rupture of the steel/Pt wires.

Thus the steel/Pt wire of E1 does not clearly and unambiguously possess the three-part structure required by claim 1 and does not anticipate the guidewire thereof.

8.3 Document Int9

A bipolar probe for coagulation of blood vessels has a distal anode and a more proximal cathode covered by a flexible sheath, for introducing into an angiography catheter. The electrodes may be made of steel, Pt, Ag, etc (page 4, lines 19 to 23). In the paragraph linking pages 7 and 8 it is stated that there may occur partial or total electrolysis of the anode, causing more or less complete corrosion of the anode and even, sometimes, release of the distal fragment thereof in the embolized artery, where this fragment will remain caught in the thrombus and consolidate the thrombus.

Here too the wire does not have three physically distinct parts, and the wire may corrode anywhere and uncontrollably along its exposed (to blood) portion. This uncontrollable corrosion is indicated by the fact that release of the distal fragment occurs sometimes (page 7, last paragraph).

The construction of this wire is different to that claimed, and its suitability for the controlled detachment of the tip to promote thrombus formation appears doubtful for the same reasons as given with respect to E1.

8.4 To summarise, it is the three-part form of the claimed guidewire which is the feature that distinguishes the claimed guidewire from the prior art guidewires. For the above reasons the guidewire combination of claim 1 is novel.

9. *Inventive step*

9.1 The patent in suit relates to the field of electrothrombosis as described in the Piton documents and in E1. These documents report problems with the use of Pt guidewires (lack of flexibility) and stainless steel wires (destruction of the distal tip) when used for this purpose. One solution to these problems which is given in E1 is the use of a composite steel/Pt wire.

In carrying out the method a thrombus is created by applying a positive voltage to a guidewire in a blood vessel and then withdrawing the guidewire in its entirety leaving behind a thrombus as indicated in E1, page 46, left column, second sentence of the second paragraph. It is generally undesirable to leave behind detritus in the body and the tenor of E1 and the Piton documents, accordingly, is that it is not desirable for the guidewire to disintegrate (see E1, page 41, right column, lines 22 to 24). To overcome this problem Int6 suggests using a thin wire since this detaches itself more easily (page 387, right column, lines 13 to 15). Thus, the detachment of the wire is not the goal but a problem.

The fact that there are statements to the effect that this could be used to advantage (eg Int6, page 386, last complete paragraph of the left column and Int9, the paragraph linking pages 7 and 8) does not alter the fact that this phenomena is not only seen as being problematic in the prior art but also somewhat uncontrolled. These documents appear to suggest that while being problematic one can live with the tip

- disintegrating, rather than suggesting that this is desirable.
- 9.2 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 allowing 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, ie it has a three-part form in the longitudinal direction, as discussed above.
- 9.3 None of the prior art documents suggests such a modification of the Piton or E1 guidewires.
- 9.4 The Piton documents suggest 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, and the opponents/intervenors argument that a person skilled in the art would be incited to apply a Pt tip or coil at the end of a steel wire is made with hindsight since there is no indication of this in any of the documents.
- 9.5 The steel/Pt wire of E1 was found to be satisfactory as regards the disintegration behaviour, and the person skilled in the art would not be incited to improve this wire in respect of this property.
- 9.6 Therefore, the guidewire combination of claim 1 involves an inventive step.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the following documents:
  - claims 1 to 27
  - description pages 1 to 7 (columns 1 to 11) and
  - Figures 1, 1A, 3, 4, and 5
  - all as submitted at the oral proceedings.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner



Case Number: T 0228/03 - 3.2.02

**D E C I S I O N**  
**of 4 January 2006**  
**correcting errors in the decision**  
**of the Technical Board of Appeal 3.2.02**  
**of 14 June 2005**

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**Composition of the Board:**

**Chairman:** T. K. H. Kriner  
**Members:** S. S. Chowdhury  
U. J. Tronser

In application of Rule 89 EPC, the decision given on 14 June 2005 is hereby corrected as follows:

In the Summary of Facts and Submissions on page 7, under Novelty replace the second sentence:

"In the patent the tip was characterised by its material which must be preferentially susceptible to electrolytic disintegration, and this was not the case with the Piton wires"

by

"In the patent the tip was characterised by its material which was not susceptible to electrolytic disintegration, and this was not the case with the Piton wires".

On page 8, under Inventive step insert

"not"

before

"susceptible to electrolytic disintegration".

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner