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D E C I S I O N
of 22 April 2004

Case Number: T 0152/03 - 3.2.2

Application Number: 97112837.6

Publication Number: 0803230

IPC: A61B 17/12

Language of the proceedings: EN

Title of invention:
Endovascular electrolytically detachable wire for thrombus formation

Patentee:
The Regents of the University of California

Opponent:
EFMT Entwicklungs- und Forschungszentrum für Mikrotherapie GmbH
Dendron GmbH
ev3 EUROPE SAS

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56

Keyword:
"Allegation of public prior use (inadmissible)"
"Novelty (yes), inventive step (yes)"

Decisions cited:
T 0017/91, T 0328/87

Catchword:
Evidence of prior use which is in the posession of an opponent should be submitted as soon as it is recognised as being highly relevant, particularly in cases where the evidence is likely to be contested, such as for deciding the question of confidentiality of the prior use.

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0152/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 22 April 2004

Appellant I: (Opponent)
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Representative:	Price, Nigel John King J.A. KEMP & CO. 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 27 November 2002 rejecting the opposition filed against European patent No. 0803230 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
U. J. Tronser

Summary of Facts and Submissions

I. European patent application 97 112 837.6, filed on 30 September 1992 with a priority date of 24 February 1992, matured into European patent No. 0 803 230.

The decision of the opposition division rejecting an opposition filed under Article 99 EPC and an opposition filed by an intervener under Article 105 EPC was dispatched on 27 November 2002.

II. On 27 January 2003 appellant I (Dendron GmbH) and on 28 January 2003 appellant II (EFMT Entwicklungs- und Forschungszentrum für Mikrotherapie GmbH) filed respective appeals against this decision and both paid the appeal fee on 28 January 2003. The statements of grounds of appeal were received on 12 March 2003.

On 17 April 2003 an intervener (eV3 EUROPE SAS) filed a notice of intervention/opposition under Article 105 EPC together with its reasons, referring to court proceedings before the Court of the Hague, Netherlands during which the patent proprietor started proceedings for infringement of the patent in suit against, inter alia, 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.

III. Claim 1 according to the opposition division's decision reads:

"A combination of a microcatheter (144) and a wire (10,56), the wire being for use in combination with the

microcatheter (144) to form an occlusion within a vascular cavity (64), the wire being for disposal within the microcatheter and comprising: a core wire (10); and a detachable elongate tip portion (56) coupled to a distal portion of the core wire (10), the tip portion extending the core wire for a predetermined lineal extent and being adapted to be deployed, in use, in the vascular cavity (64) to form an occlusion in the vascular cavity, whereby endovascular occlusion of the vascular cavity can be performed; characterised in that the core wire (10) has a radiopaque marker (112) disposed thereon and that the microcatheter has two radiopaque markers (108, 110) disposed thereon and spaced apart."

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

E1: WO-A-9113592
E2: EP-A-0 397 357
E3: US-A-4 554 929
E4: US-A-4 545 390
E5: US-A-4 838 879
E6: US-A-4 994 069
E7: US-A-3 605 750
E8: WO-A-9104716
E9: MDR Database, 28/01/92, Access No. M264109
E10: Target Therapeutics catalogue 1992
E11: Guglielmi et al, J. "Electrothrombosis of saccular aneurysms via endovascular approach", Neurosurgery, Vol. 75, July 1991, pages 1 to 14 (parts 1 and 2)
E12: Guglielmi et al, "Embolization of Intracranial Aneurysms with Detachable Coils and

Electrothrombosis", Interventional Neuradiology: Endovascular Therapy of the Central Nervous System, Vinuela et al, Raven Press, N. York, 1992

E13: US-A-4 739 768

E14: Historical note by Gido Guglielmi, ANJR Am. J. Neuroradiol., 23:342, Feb. 2002

E15: US-A-4 669 465

E16: MDR Database, 10/10/90, Access No. M220254

E17: MDR Database, 29/01/90, Access No. M183708

E18: MDR Database, 28/01/91, Access No. M235647

E19: MDR Database, 17/05/91, Access No. M231556

E20: MDR Database, 01/10/91, Access No. M246650

E21: Declaration of Guido Guglielmi dated 8 January, 2003

E22: Declaration of Alan G. Robinson dated 25 July, 2003

E23: Declaration of Gary Duckwiler dated 22 July, 2003

E24: Investigator's Agreement Letter of 15 June 1991 signed by Guglielmi and Vinuela

E25: Investigator's Agreement Letter of 1 July 1991 signed by Duckwiler

E26: Declaration of Roxane Baxter dated 11 April 2003

E27: Declaration of Cynthia D. Bellefeuille dated 11 April 2003

E28: Declaration of Patrick Burt dated 8 April 2003

Attachment 4: Statement of Dr. Henkes dated 18 March 2003

Attachment 5: Statement of Dr. Henkes dated 19 March 2004

Attachment 6: Letter from the US FDA dated 12 June 2003

Attachment 7: Prospectus of Target Therapeutics Common Stock dated January 1992

Attachment 8: Declaration of Dr. Shroff dated 19 March 2004
Attachment 9: Translation of the Decision of the District Court The Hague of 22 October 2003 re eV3/BSC
Attachment 10: Statement of Mr Truttman dated 4 July 2003
Attachment 11: Statement of Dr. Kendall dated 2 May 2003
Attachment 12: Statement of Dr. van Rooij dated 4 May 2003.

The intervener who entered the proceedings at the appeal stage and the patent proprietor referred to patent litigations pending in several countries, particularly in Germany, the Netherlands, and the United Kingdom. In some of the declarations and statements submitted by the parties reference is made to these litigations.

Oral proceedings (Article 116 EPC) took place on 22 April 2004.

V. Requests

The appellants and the intervener requested that the decision under appeal be set aside and that the European patent No. 0 803 230 be revoked. On an auxiliary basis the remittal of the case to the opposition division was requested.

The respondent requested that the appeal be dismissed (main request) or that the decision under appeal be set aside and the patent be maintained in amended form with

the claims according to one of the auxiliary requests as filed with the letter dated 19 March 2004, and that the new facts and evidences, which the appellants submitted despite the Board's comments of 5 March 2004, not be considered.

VI. The parties submitted the following arguments:

(i) Appellants and intervener

Remittal

Documents that were newly filed but relevant enough to prejudice the outcome of the case should be admitted, and if admitted then the case should be remitted so that the appellants and the intervener could have the benefit of a first instance procedure.

Novelty

The wire of document E8 was a filter for installation in the vena cava and was, therefore, automatically in the cardio-vascular field. The pusher wire of this document could be equated with the core wire of claim 1 of the patent in suit, and the filter with the radiopaque ends with the detachable wire portion, in which case E8 read on to claim 1 since, when the end of the filter sat in the endpiece of the pusher wire, the latter had a radiopaque marker disposed on it.

Inventive step

According to E11 the platinum/steel junction must be placed precisely 3 mm beyond the catheter tip, so the

technical problem of the opposed patent was to place the platinum/steel junction of the wire precisely at a given position beyond the distal end of the catheter, and this was achieved in the patent by indexing the wire using markers. However, the concept of marking and indexing catheters was commonplace in the art, this often being the only possibility of placing such devices. The person skilled in the art was a medical engineer and he would look to E15 for a solution to the problem of exact placement since E15 was in a similar field, and would immediately find the solution in the form of markers located away from the distal end.

However, if the hiding problem was considered as the relevant problem, this problem would occur to the person skilled in the art upon inspecting Figure 1 of E11, but in any case would become evident upon use of the device, specially if several wires were stuffed into an aneurysm, as in Case 14 of E11. The solution was given by E15 which provided indexing in a non-obscured region, so, as confirmed by the decision of the Dutch court, this solution was not inventive.

Prior use

According to the EPO case law, a document or evidence which was prima facie highly relevant should be admitted, even at a very late stage of the procedure. The "up to the hilt" test was based on two important considerations, firstly that the evidence was in the opponent's possession, and secondly that a statement concerning the circumstances of the prior use was unspecified. In the present case the evidence was in

the appellant 's possession, and the statement was specific.

In any case, the prior use case set out in paragraph 6(c) of the notice of intervention was made "up to the hilt". This prior use was even acknowledged by the respondent, only the question of confidentiality was contested. Henkes' statements, attachments 4 and 5, were not initially in the hands of the intervener, and, since the respondent was aware of them it should not be surprised. This evidence was submitted at the appeal stage to counter the respondent's claim that confidentiality had been imposed during the clinical procedures. Moreover, the onus to show that the acts of prior use would be subjected to a bar of confidentiality lay with the respondent, not with the appellants or intervener.

The evidence filed on 22 March 2004 was in response to the communication from the Board and as support for and corroboration of arguments presented in the notice of intervention. The evidence of Prof. Schumacher was specific and precise but the respondent was hindering its presentation to the EPO, which was accordingly requested to admit it into the EPO procedure so that the English judge would allow its release. This evidence was not late filed, it was filed as soon as it became available, given the complexity of the issue in various countries where litigation was taking place. It would be efficient to admit all this evidence and keep the procedure within the EPO rather than to have separate litigation in each individual country.

Other evidence, such as attachments 7, 8, 11 and 12 submitted on 22 March 2004 were filed in response to the communication from the Board or to counter the respondent's claim that confidentiality had been imposed during the clinical procedures.

The attachments 7 and 10 proved further commercial prior use and were highly relevant and thus should be admitted. These too were filed in response to respondent's argument that the device had only been tested but not commercially used.

Publication of documents E9 and E10

Attachment 8, a declaration by a former employee of the FDA, proved that E9 was published immediately upon receipt by the FDA, ie before the priority date.

(ii) Respondent

Novelty

Although document E8 disclosed a catheter, it did not disclose a microcatheter, which latter term implied certain properties that rendered it suitable for use in very tortuous vessels, for example in the brain. Nor was the device of E8 adapted to form an occlusion in a vascular cavity, instead it was the antithesis of the claimed device in that it was meant to obstruct blood flow as little as possible, since if the blood flow in the vena cava were to be interrupted the patient would suffer a stroke or die. Furthermore, E8 did not disclose any feature which was the equivalent of a core wire having a radiopaque marker disposed thereon.

Inventive step

The real problem of the patent was not the exact positioning of the wire since E11 clearly stated that this was not an issue. The real problem was the hiding problem, which was not disclosed in E11, and to say so was to use hindsight. Since E15 did not disclose a detachable end portion it was of no relevance to the hiding problem and the person skilled in the art would not consult this document.

However, even if E15 were to be invoked, this document did not disclose the present solution since if the more distal member of the catheter were to be radiographically hidden, then attempting to align a marker of the laser fibre with the more distal catheter marker would not overcome the hiding problem.

Prior use

The issue of confidentiality was crucial to the intervener's case but the notice of intervention contained a bare assertion in this respect, despite the fact that the statement of Dr. Henkes dated 18 March 2003 (Attachment 4) was in the possession of the intervener at the outset of its intervention. Instead, it was filed only much later to bolster its case and without any excuse for the late filing, except that it was in response to the Board's communication, but this was not true. Such filing in a piecemeal fashion should be deemed inadmissible.

The Schumacher statement was also available to the appellants and the intervener at the appeal stage much earlier than the date on which it was filed and this too should not be admitted.

Publication of documents E9 and E10

It took about three months to process an MDR by the FDA, so that E9 was published after the priority date of the patent. The printing date of E10 was unknown but it was most likely in the Spring of 1992, also after the priority date.

Reasons for the Decision

1. The appeals by appellants I and II are admissible.

2. The intervention filed on 17 April 2003 under Article 105 EPC.

The first sentence of Article 105(1) EPC states that "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 intervener stated (see the notice of intervention dated 17 April 2003)

– that amongst others, it initiated court proceedings before the Court of The Hague for a ruling that other patents (ie other than the patent in suit) are not infringed by certain products and that in these court proceedings the patent proprietor started, by counterclaim of 22 22 January 2003, proceedings for infringement of the patent in suit against, amongst others, the intervener, and

– that the present notice of intervention was given within three months of the date that the proceedings for infringement were instituted.

Thus the intervention is relying on the first sentence of Article 105(1) EPC, and is admissible.

3. Admissibility of grounds of opposition based on public prior use, and documents E9, E10, and E12

3.1 Public prior use

The intervener has made the following allegations of public prior use:

(a) On or about 1 February 1990 and thereafter on further occasions with further patients in the period before the priority date of EP ›230 the coils according to EP ›230 were used in the Millard Fillmore Hospital in Buffalo, New York.

(b) On or about 6 March 1990 and thereafter on further occasions with fourteen further patients during the period to 5 November 1990 and thereafter on

further occasions in the period before the priority date of EP ›230 the coils were used at the University of California, Los Angeles Medical Center, USA (UCLA). Reference in this respect is made to Guglielmi part 1&2 (Enclosure E3), the Historical Note (Enclosure E4) and Guglielmi 1992 (Enclosure E7). Page 9 of Guglielmi part 1&2 (E3) shows a chart of 15 patients treated with detachable coil embolization between 6 March and 5 November 1990. In the Historical Note Guglielmi claims that he put the first coil in a person on 6 March 1990 and he thanks the staff at the Medical Center of the University of California. Page 70-70, table 1 of Guglielmi 1992 (E7) shows a chart of 39 patients, the patients 1-15 being the same as on page 9 of Guglielmi part 1&2 (E3).

(c) Several procedures have been performed in August 1991 in which GDC-s were used in combination with Target Tracker 18 Dual Marker catheters. At the UCLA Neuroradiology Department live demonstrations of embolisation treatments of aneurysms with the Guglielmi Detachable Coils were given to visitors without any obligation to secrecy. In those demonstrations two spaced apart markers at the tip of the microcatheter were visible under fluoroscopy as well as a radiopaque marker on the core wire. Evidence by witnesses of those demonstrations is offered. One of these witnesses/visitors was Dr. Hans Henkes, Alfred-Krupp-Strasse 59, 45131 Essen, Germany, who was there from 5-10 August 1991. Dr. Henkes is offered as a witness.

(d) During a public conference of American Society for Neurology, Washington DC, USA, June 1991 Guglielmi gave a presentation explaining the dual marker catheter and GDC. Further evidence is offered.

3.2 As regards allegations of public prior use of an invention, it is well established jurisprudence of the Boards of Appeal that certain strict requirements must be met in order for the respective ground of opposition to be deemed admissible. The headnote of decision T 0328/87 reads: *"When an opposition is based on grounds of prior use, the requirements of Rule 55(c) EPC are only fulfilled if the notice of opposition indicates, within the opposition period, all the facts which make it possible to determine the date of prior use, what has been used, and the circumstances relating to the alleged use. The notice of opposition must also indicate the evidence and arguments presented in support of the grounds of opposition.".*

According to Point 3.3 of the Reasons of T 0328/87 the requirement 3 of Rule 55(c) EPC is satisfied if the Opposition Division (and the patent proprietor) are able to determine the following details:

(a) the date on which the alleged use occurred, i.e. whether there was any instance of use before the date on which the application for the relevant European patent was filed,

(b) what has been used, in order to determine whether the object in prior use is identical with or similar to the subject-matter of the contested patent,

(c) all the circumstances relating to the use, by which it was made available to the public, as for example the place of use and the form of use.

The same principles apply to an opposition based on an intervention, except that the indications must be made before the end of the intervention period.

3.3 The allegations (a), (b), and (d) in point 3.1 above are manifestly deficient in respect of each of the three issues. There are absolutely no details given of the construction of the device used, the statement that "coils according to EP '230 were used" not being adequate in this respect. Similarly no details as to the circumstances pertaining to the use are described, in particular whether there was any obligation of confidentiality imposed. Also, the date of use is stated in vague terms ("on or about ..... and thereafter").

In response to a communication from the Board to the effect that all the allegations (a), (b), (c), and (d) were deficient, the intervener accepted these criticisms in respect of the allegations (a), (b), and (d), but not in respect of the allegation (c), arguing that it did address all the issues adequately.

3.4 While section 6(c) of the notice of intervention dated 17 April 2003 does indeed address the three issues, it is fatally deficient in one crucial respect, that of the issue of the circumstances of the prior use, and more particularly the question of confidentiality.

In this field there is a prima facie assumption that any person involved in a medical process is obliged to confidentiality, given the need for patient confidentiality and the need to protect the development and testing of prototype devices. Therefore, any evidence proving the contrary would be important and must be produced as soon as possible. The appellant must also have been aware that its arguments on this issue would be challenged by the respondent, so that any evidence it had in support of this matter should have been submitted as soon as it was in its possession.

On the contrary, no evidence was initially provided to substantiate the allegation that Dr. Henkes did indeed witness any clinical procedure, nor was his statement, that no bar of confidentiality was imposed on him for the duration of the procedure, furnished. This despite the fact that this evidence had been in the possession of the intervener when the notice of intervention was filed.

3.5 Decision T 17/91 is firm in stating that any evidence should be submitted in the proceedings as soon as it is in the possession of the opponent and it is recognisable that it could be highly relevant to the validity of the patent it. It is not permissible to submit evidence and arguments piecemeal wise and to put forward statements about intentions to do something at a later stage when the need arises. If this has a dilatory effect on the procedure, the matter of alleged prior use should be rejected as not being submitted in due time under Article 114(2) EPC.

3.6 In the present case the evidence was supplied only after prompting from the Board. It was only in response to the Board's communication of 5 March 2004 that the intervener filed, on 22 March 2004, statements by Dr. Henkes (attachments 4 and 5) in further support of the allegation of public prior use (c) in point 3.1 above.

At the oral proceedings before the Board the intervener disputed that this evidence was in its possession early in the present proceedings. However, Attachment 9 indicates that it was a party to the Dutch case and must have been aware of the Henkes statement, filed in the Dutch proceedings on 16 May 2003 (see point 2.6 of this appellant's submission of 22 March 2004), quite early in the present proceedings.

Although these statements were in the possession of the intervener at the outset of its intervention, they were withheld up to the last day for making submissions before the oral proceedings without any explanation as to their late filing.

3.7 The delayed filing of evidence meant that if the matter of alleged prior use were to be admitted, the oral proceedings before the Board would have to be postponed, which is unfair to the respondent, who had requested an accelerated processing of the appeal at an early stage, and would also cause legal uncertainty for the interested public. For these reasons the allegations of public prior use (a) to (d) in point 3.1 are inadmissible.

4. *Further allegations of public prior use*

4.1 Prior uses disclosed by E9 to E12

E9 is a medical device report (MDR) of 28 January 1992 and was cited in the notice of intervention. This MDR purports to disclose an event in relation to the use of a Tracker 18 Dual Marker device before that date, and E10-E12 are cited to support the view that the device had the features of the characterising part of claim 1 of the patent in suit. Apart from the question of what exactly was used, this allegation is deficient in that the circumstances of the alleged prior use were not given in the notice of intervention. Bearing in mind that the device was allegedly used in a clinical study (see the words "prototype - for testing only" at the top left of E9), the issue of confidentiality, in particular, should have been addressed.

4.2 The testimony of a Prof. Schumacher was offered at a late stage of the procedure, ie in the intervener's letter of 27 February 2004, although it is dated 18 February 2003. A Medicor invoice purporting to prove public commercial prior use was also filed at this late stage although it is dated February 1992, and in each case no explanation was given for the late filing of this material.

These allegations of public prior use are also inadmissible.

5. *Publication dates of E9, E10, and E12*

The publication dates of E9 and E10 are disputed by the parties. They have submitted contradictory evidence in the form of affidavits (E26 to E28 by the respondent and Attachments 6 to 8 by the appellants) regarding the date when an MDR is available to the public. Also submitted are imprecise and contradictory indications about the regulations pertaining to the proceedings before the US Food and Drug Administration. Thus the Board is unable, given the present evidence, to resolve this dispute, so that it is not proven that E9 and E10 are pre-published documents forming part of the written state of the art. The appellants admit that E12 was published after the priority date of the patent in suit.

6. For the above reasons, all the arguments based on the allegations of public prior use must be disregarded, as must the documents E9, E10, and E12. The remainder of the decision will be devoted to the question of novelty and inventive step of the claimed subject-matter, having regard to the undisputed pre-published documents.

Main request

7. *Novelty*

7.1 The device disclosed in document E8 is neither intended for nor is it suitable for forming an occlusion within a vascular cavity. The device is an anti-pulmonary embolism filter for use in preventing existing blood clots from migrating from the lower limbs or pelvis to the heart via the vena cava. The purpose of the device

is to prevent an occlusion rather than causing one, which latter occurrence in the vena cava would endanger the patient's life by causing a stroke or heart attack. For this reason alone this device does not anticipate the claimed device.

Moreover, the wire has a remanent spring effect which makes it assume the shape shown in Figure 1 when released from a delivery catheter, the effect being to take up, in the vena cava, the configuration shown in Figures 5 and 6 and maintain patency for blood flow. This is the antithesis of the patent in suit since the effect and intention of E8 is to maintain blood flow. Blocking the flow of blood in the vena cava would soon be catastrophic for the patient.

If several of the coils of E8 were to be stuffed into the vena cava in an attempt to block it, in the manner of the GDCs of E11, this would be frustrated by the stiffness of the coils, in contrast to the coil of the patent in suit, which is suitable for this purpose (soft and deformable, see, for example, column 7, lines 31-43 of the patent in suit).

The patent in suit also calls for a radiopaque marker on the core wire. In the context this means a permanent marker on the core wire, so that when this is withdrawn after the tip portion is detached, the marker is withdrawn with it. No such marker is to be found on that part of the device of E8 which is equated with the core wire, ie the pusher cable 19. The temporary placement of the end 6 of the filter 1 in an endpiece 18 at the end of the cable 19 is not the equivalent of a (permanent) marker on the core wire.

The reference in E8 on page 6, lines 13 and 14, to the end of the sheath being radiopaque, is not relevant since it is not radiopaque by virtue of a marker disposed thereon and, moreover, it is the sheath that is radiopaque and not a part of the core wire. The statement in the patent in suit in column 6, paragraph 31 does not change this since this statement only makes clear where the core wire ends and the tip portion begins. This statement does not extend the scope of "tip" to include other structures such as a sheath.

At least for these reasons E8 does not anticipate the combination of claim 1 of the patent in suit.

8. *Inventive step*

8.1 Technical problem

The combination of the microcatheter and wire of claim 1 of the main request is characterised in that the core wire has a radiopaque marker disposed thereon and the microcatheter has two radiopaque markers disposed thereon and spaced apart. In order to derive the technical problem associated with these features, the actual achievement of these features must be evaluated in a realistic manner.

The purpose of this arrangement of markers is given in column 12, lines 11 to 15 of the patent in suit and it is that when the marker on the wire is approximately aligned with the more proximal marker on the microcatheter, the coil is fully deployed into the

aneurysm. Typically, full deployment will place the solder or connection point between the core wire and the tip portion of the order of 2-3 mm past the opening of the aneurysm. This ensures that the proximal end of the tip portion, after its detachment from the core wire, will not extend out of the opening of the aneurysm potentially to cause vascular thrombosis.

It is in such a situation, where the tip portion must be fully deployed and then detached so that further wire tips may be deployed, that the problem set out in the patent, at column 11, lines 47 to 55 (called the "hiding problem") arises. This problem is that there is some difficulty when manipulating the device under fluoroscopy to be able to determine the exact position or movement of the probe relative to the aneurysm. This is particularly true when a large number of coils is deployed and one coil then radiographically hides another.

According to the appellants the real technical problem is the correct and precise positioning of the wire since, as stated in E11 (page 10, right column), the platinum/steel junction must be positioned 3 mm beyond the tip of the microcatheter, otherwise either the aneurysm may be pierced by the wire or the electrolytic separation may not occur.

However, E11 says that platinum is radiopaque and allows fluoroscopic visualisation while it is being positioned within the aneurysm, beyond the tip of the microcatheter (page 2, right column), that the platinum component of the detachable coil is easy to see under fluoroscopy (page 3, left column), and that it was

possible to deliver up to 10 coils within sizeable aneurysms (page 3, right column). Furthermore it is said (page 10, right column) that "The intrinsic radiopacity of platinum delineates the position of the coil **very clearly**, allowing an **exact evaluation** of its location before electrical detachment occurs" [underlining added]. The Cases described in the following pages show that a plurality of coils was used, and the section "Conclusions" on page 6, reports successful operation of the device, with neither puncturing of the aneurysms nor unsuccessful detachment of the coils being reported. Therefore, exact positioning of the coil was clearly not an issue in E11, and this problem cannot be deduced from it.

8.2 The technical problem of the patent (the hiding problem) is not discussed in the prior art. The appellants argue that this problem becomes evident upon inspection of Figure 1 of E11, but this is hindsight since E11 is silent on this. The four drawings in Figure 1 are schematic and are scaled down in order to fit into a small space on the page, and they do not necessarily reflect the actual situation on a fluoroscopic screen since this would be larger and not necessarily show a crowded image.

The appellant's further argument is that the hiding problem would become evident upon use of the device. Be that as it may, the patentee was the first person to confront the hiding problem.

8.3 The solution

The solution proposed in the patent in suit, as defined by the characterising features of claim 1, enable the point of fluoroscopic observation to be removed from the distal tip of the catheter to a place adjacent to yet displaced from the distal tip, ie to a more proximal location where no radiographic hiding occurs.

8.4 The solution to the above problem is not suggested in the prior art. The main documents used by the appellants in arguing lack of inventive step were E11, which discloses the combination of features of the preamble of claim 1, in combination with E15.

E15 describes a laser-enhanced transluminal angioplasty catheter system in which a balloon catheter has a tip with a radiopaque marker, and two further, more proximal, radiopaque markers. The catheter guides a laser fibre with its own plurality of radiopaque markers along its distal end portion. This document relates to a different surgical operation (transluminal laser angioplasty) and the laser fibre has no detachable portion so that the hiding problem of the patent in suit does not arise here, so there was no need to seek a solution to this problem in E15. In the absence of a suitable nexus between E11 and E15 the person skilled in the art would not combine them.

Nevertheless, even if the appellant's argument is accepted, that the objective problem is the exact positioning of the coils, and that the radiopaque markers of document E15 would be used by the skilled person in order to position a catheter and whatever it

guides accurately, for example the device of E11, this would still not provide the essential teaching of the patent in suit.

Document E15 teaches only that the tip of the fibre is aligned with the tip of the catheter using the respective radiopaque markers (for example. column 3, lines 33-38) but the purpose of the other markers on the fibre is not stated clearly, nor is it stated that a marker other than the tip marker of the fibre may be used for aligning with either of the proximal markers on the catheter. At the oral proceedings the appellants confirmed that all observation in the E15 device is done at the distal tip of the catheter and beyond, but this is where the congestion occurs so this would not solve the hiding problem.

Moreover, the control of advance and positioning of the fibre beyond the catheter tip is not performed at the distal end of the system, but is done by the hand held unit at the proximal end of the system, outside the body and well away from the distal tip (column 3 lines 5-25, and column 12, lines 32-35 and 44-45), and only confirmation that the fibre is properly advanced is done fluoroscopically at the distal end (column 12, lines 46-50 and column 13, lines 32-36).

The argument, that once the hiding problem at the distal end is recognised, as it would be upon normal use of the GDC of E11, it would be obvious to place the markers so that the control of positioning and observations would be performed at a more proximal location, is not supported by the prior art. E15

teaches, for example, that the control of positioning is performed at the proximal end of the device.

By contrast, both the control of advance of the wire in the patent in suit as well as fluoroscopic observations are done adjacent to but displaced from the distal end of the catheter to a more proximal location.

9. The other cited and relevant documents are briefly reviewed below:

E6 discloses a vaso-occlusion coil wire which is pushed out of a catheter by a pusher wire, the coil wire and the pusher wire not being coupled together. The pusher wire has a radiopaque marker at its end, and the catheter may be of the type described in E13, which catheter has a single radiopaque marker adjacent its distal end for positioning the catheter. There is no disclosure of a second marker on the catheter or of any cooperation between the marker on the wire and that on the catheter.

E8, as shown above, relates to a different surgical device and it does not relate to the technical problem at hand and is also not capable of solving the problem of the patent. It is noted too that, although the catheter has two markers, these are not for the exact placing of the wire but for correcting distances as altered by the distortion due to X-rays.

The MDRs E16 to E20 do not of themselves disclose (despite the reference to a Target Therapeutics Tracker 18 catheter) a dual marker catheter.

Therefore, none of these documents is relevant to the question of inventive step.

9.1 For the reasons given above claim 1 involves an inventive step.

10. *Remittal to the first instance*

The appellants and the intervener requested remittal to the first instance in view of the new grounds of opposition and the new evidence submitted in the notice of intervention filed at the appeal stage. However, the respondent (patent proprietor) was desirous of an accelerated procedure and of an early decision in view of unresolved litigation between the patent proprietor and the appellants/intervener, and did not wish the case to be remitted.

In view of the respondent's request in this respect, and because of the the tardy and piecemeal filing of evidence by the appellants and the intervener, and also bearing in mind that an intervener must accept the status of the proceedings at the time of its entry thereto, the Board decided to make use of its power under Article 111(1) EPC to decide the case itself.

Order

For these reasons it is ordered that:

The appeal is dismissed.

The Registrar | The Chairman

V. Commare | W. D. Weiß