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D E C I S I O N
of 26 February 2004

Case Number: T 1235/01 - 3.4.1

Application Number: 93110531.6

Publication Number: 0633041

IPC: A61N 5/10

Language of the proceedings: EN

Title of invention:
Medical appliances for the treatment of blood vessels by means of ionizing radiation

Patentee:
Schneider (Europe) GmbH

Opponent:
Delft Instruments Intellectual Property B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 56, 104(1), 113(1), 114(1), 123(2)
EPC R. 67

Keyword:
"Inventive step (no) - main request"
"Added subject-matter - auxiliary request"
"Apportionment of costs, reimbursement of the appeal fee (no)"

Decisions cited:
G 0009/91, G 0010/91, T 1002/92

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1235/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 26 February 2004

Appellant: (Proprietor of the patent)	Schneider (Europe) GmbH Ackerstrasse 6 CH-8180 Bülach (CH)
Representative:	Kiliaridis, Constantin Bugnion S.A. 10, Route de Florissant Case Postale 375 CH-1211 Genève 12 (CH)
Respondent: (Opponent)	Delft Instruments Intellectual Property B.V. Röntgenweg 1 NL-2624 BD Delft (NL)
Representative:	van der Burg, Louis, Drs. Algemeen Octrooi- en Merkenbureau P.O. Box 645 NL-5600 AP Eindhoven (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 27 September 2001 revoking European patent No. 0633041 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
G. Assi

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal, received on 16 November 2001, against the decision of the Opposition Division, despatched on 27 September 2001, revoking the European patent No. 0 633 041 (application No. 93 110 531.6). The fee for the appeal was paid on 16 November 2001 and the statement setting out the grounds of appeal was received on 25 January 2002.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, *inter alia,* objections under Articles 52(1), 54 and 56 EPC.

III. In the decision under appeal, the Opposition Division held, *inter alia,* that the subject-matter of claim 1 filed on 3 August 2001 did not involve an inventive step with respect to the following documents:

D1: US-A-5 213 561

D7: EP-A-0 380 873

IV. In reply to a communication of the Board, summoning the parties to oral proceedings, the appellant, by letter dated 28 October 2003, withdrew its request for oral proceedings ("*second auxiliary request*") and requested that the appeal be decided on the basis of the documents on file.

By letter dated 17 November 2003, the respondent (opponent) withdrew its request for oral proceedings.

By notification dated 24 November 2003, the oral proceedings were cancelled.

V. The appellant requests that the decision under appeal be set aside and that:

Main request

– the patent be maintained on the basis of claim 1 filed on 3 August 2001;

– document D7 be withdrawn from the present proceedings;

– costs be apportioned under Article 104 EPC "because the EPO failed to take the necessary steps to notify the Parties [sic] the existence of an alleged relevant prior art and also violated the right to be heard of the Patentee, creating a substantial procedure [sic] violation. In particular the reimbursement of the appeal fee and also the cost incurred by the present appeal are requested for this reason."

Auxiliary request

– the patent be maintained on the basis of claim 1 filed on 25 January 2002;

– document D7 be withdrawn from the present proceedings;

– costs be apportioned under Article 104 EPC (see main request).

VI. The respondent requests that the appeal be dismissed.

VII. Claim 1 according to the **main request** reads as follows:

"*1. A medical appliance for the treatment of a portion of blood vessel (7) by means of ionizing radiation, comprising a catheter (1,10) for percutaneous transluminal treatment of the blood vessel, an inflatable dilatation balloon (5) surrounding a portion of the catheter, a radioactive radiation emitter (4, 40, 45) fitting in said portion of the catheter and being radially centered inside the balloon, and means (1,2,10) for advancing, resp. removing, the radioactive radiation emitter into, resp. from the portion of the catheter, said means comprising a wire in sliding fit in said catheter and said emitter being affixed to said wire characterised in that the catheter (1) is a two lumen catheter, the portion of the catheter surrounded by the balloon (5) is a single lumen catheter, and the dilatation balloon (5) is mounted coaxially on said portion of the catheter (1) for radially centering the radioactive radiation emitter inside the balloon at the location of dilatation thereof in the blood vessel.*"

Claim 1 according to the **auxiliary request** differs from claim 1 of the main request in that its characterising portion defines the catheter as "*a two lumen catheter along its entire length".*

VIII. The appellant's arguments may be summarized as follows:

The patent in suit was revoked on the ground that the subject-matter of claim 1 lacked an inventive step with

respect to D1 and D7. The latter document, which was filed by the Opposition Division during the oral proceedings, was not relevant even on a *prima facie* basis and should be disregarded. In fact, D7 concerned a "rapidly exchangeable, coronary catheter", whereas the present invention was about "medical appliances for the treatment of blood vessels by means of ionising radiation". Even if both fields were considered to be related, in the sense that they were both directed to balloon catheters, they referred to completely different technical problems. In fact, the teaching of D7 was about designing a catheter that could be rapidly exchanged using a guide wire lumen which extended over a relatively short length of the catheter. However, the radiation treatment of blood vessels addressed by the contested patent required a guide wire lumen along the entire length of the balloon catheter.

D1 related to a radiation guide wire which, in principle, could be used with any suitable catheter, since no specific catheter had been explicitly indicated. Starting from D1, the skilled person was faced with the problem of finding a catheter balloon which was suitable for the radiation treatment of blood vessels in combination with the known radioactive guide wire. The solution according to the present invention consisted in a medical appliance comprising a balloon catheter, as specified in claim 1 of the main request, which was inserted into a blood vessel along a conventional guide wire. After removing such a guide wire, while leaving the catheter in the blood vessel, another guide wire comprising a radioactive radiation emitter affixed to its distal portion was inserted into

the balloon catheter and slid to the location to be ionized.

The catheter known from D7 was not suitable for exchanging guide wires while keeping the catheter located inside a blood vessel, because the proximate entry of the guide wire lumen was approximately 17 to 80 cm inside the blood vessel and could not be reached for direct introduction of an exchange guide wire without pulling the catheter out of the blood vessel.

In conclusion, even it were assumed that D7 constituted relevant prior art, because it showed some features of the claimed invention, it would not have been obvious to a skilled person, dealing with the problem of designing a suitable balloon catheter for the guide wire shown in D1, to consider the teaching of D7. Thus, the cited prior art could not have led the skilled person to a medical appliance falling within the terms of claim 1 of the main request.

Claim 1 according to the auxiliary request contained the expression "*along its entire length*". The fact that the guide wires could be exchanged was only possible when the proximate entry of the guide wire lumen was directly accessible with the catheter in position. This implied that the guide wire lumen had to extend along the entire length of the catheter to be accessible on the proximate side of the catheter. The arguments relating to the inventive step of the subject-matter of claim 1 of the main request applied also to the subject-matter of claim 1 of the auxiliary request.

The opposition division made no serious effort to notify the parties of the existence of a new document D7 before the oral proceedings and, thus, took the parties by surprise. Furthermore, by citing an allegedly relevant document at a very late stage in the proceedings, the Opposition Division put itself into the role of an opponent filing new evidence at a very late stage in the proceedings and thus should bear the responsibility of such action. Since the attitude of the Opposition Division in the present case had increased the costs incurred by the patentee in an unfair manner, an apportionment of costs under Article 104 EPC was equitable, as indicated by the case law relating to a party waiting until oral proceedings before presenting new facts or evidence. Furthermore, the appeal fee should be reimbursed under Rule 67 EPC because the Opposition Division committed a serious procedural violation by failing to take the necessary steps to notify the parties of the existence of an allegedly relevant prior art and, thus, by not giving the patentee sufficient opportunity to comment, as required by Article 113(1) EPC.

IX. The respondent argued essentially as follows:

There was no reason for overturning the decision of the Opposition Division concerning the lack of inventive step of the subject-matter of claim 1 according to the main request.

On the other hand, the subject-matter of claim 1 of the auxiliary request found neither explicit nor implicit support in the application as originally filed.

As to the question of the Opposition Division's alleged procedural violation and partiality, reference was made to the minutes of the oral proceedings, which reflected the true course of the proceedings in connection with D7.

Reasons for the Decision

1. The appeal is admissible.

2. The contested patent relates to a medical appliance for the treatment of stenoses of blood vessels by means of ionising radiation. Such an appliance comprises a radioactive radiation emitter and a balloon catheter for positioning the radiation emitter inside the blood vessel. While the catheter is defined as a two-lumen catheter comprising a first lumen for receiving the guide wire and a second lumen for inflating the balloon, the portion surrounded by the balloon comprises only the first lumen.

Main request

Admissibility of D7 and alleged substantial procedural violation

3.1 The case law relating to the admissibility of late-filed documents concerns documents **submitted by a party** at a late stage in the opposition or appeal proceedings. In the present case, however, the Opposition Division drew the parties' attention to document D7 for the first time during the oral proceedings.

3.2 Thus, a first question to be considered in the present appeal is whether the Opposition Division had the right to introduce a new document at such a late stage in the opposition proceedings.

3.3 Article 114(1) EPC, which applies to all proceedings within the EPO, introduces the principle of investigation by the EPO itself, or inquisitorial proceedings, into all stages of its procedure. This means that the factual background is evaluated by the EPO itself, and it is not left entirely to the parties to establish the facts, on the basis of which a decision is to be reached.

T 1002/92 (OJ EPO 1995, 605) concerns the extent to which the principles set out in G **9/91** (OJ EPO 1993, 408) and **G 10/91** (OJ EPO 1993, 420) influence the admissibility of late-filed new "facts, evidence and arguments" in support of the grounds of opposition already contained in the notice of opposition. In T **1002/92** the board reached the following conclusion (see point 3.3, emphasis added)

– "Thus following the principles set out in Opinion G 10/91, as regards proceedings before the Opposition Divisions, late-filed facts, evidence and related arguments, which go beyond the "indication of the facts, evidence and arguments" presented in the notice of opposition pursuant to Rule 55(c) EPC in support of the grounds of opposition on which the opposition is based, should only exceptionally be admitted into the proceedings by the Opposition Division, if prima facie, there are clear reasons to suspect that

such late-filed material **would prejudice** the maintenance of the European patent in suit.

Such consideration of relevance as the principal factor governing the exceptional admissibility of late-filed new facts, evidence and related arguments in proceedings before the Opposition Division follows from the administrative character of such opposition proceedings."

3.4 Thus, in the light of **T 1002/92, G 9/91** and **G 10/91**, the Opposition Division acted in conformity with Article 114(1) when it decided to draw the parties' attention to a document, which, **in its view**, was of such relevance as to prejudice the maintenance of the contested patent.

4.1 According to the appellant, however, the fact that the Opposition Division introduced D7 at a very late stage during the oral proceedings without having informed the parties of its new assessment of the case effectively deprived the patent proprietor of any opportunity to comment on the new evidence before the decision was issued, as required by Article 113(1) EPC.

4.2 According to Article 113(1) EPC, the decision of the European Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments. Failure to comply with the requirement of Article 113(1) EPC is normally regarded as a substantial procedural violation which may entail reimbursement of the appeal fee.

4.3 As it appears from the minutes of the oral proceedings held before the Opposition Division on 4 September 2001, the chairman explained the Opposition Division's preliminary opinion concerning the relevance of D7 and pointed out why the subject-matter of claim 1 then on file would be rendered obvious by the combination of D1 and D7. The parties were requested to present their submissions once they considered that they had had enough time to prepare themselves (Article 113(1) EPC).

After an interruption of the proceedings, the parties expressly acknowledged that they had had enough time to prepare their submissions and responses, and presented their comments.

There is no indication in the minutes of the patentee's representative protesting against the introduction of D7 or requesting that the proceedings be suspended or continued in writing to comply with Article 113(1) EPC.

4.4 In summary, the behaviour of the Opposition Division during the oral proceedings of 4 September 2001, as reported in the minutes dated 27 September 2001, does not provide any evidence of a substantial procedural violation.

State of the art

5.1 It is undisputed that Figures 6 and 8 of D7 show the **distal** portion of a catheter comprising **two lumens** over a certain length and only **one lumen** in the portion on which a balloon is coaxially mounted. In fact, the lumen 40, which is used to inflate and deflate the balloon, terminates at a port 42 located inside the

balloon, while the guide wire lumen 44 extends to the distal end of the catheter (see column 6, lines 48 to 52 and column 7, lines 10 to 11).

5.2 According to the appellant, however, D7 was not relevant to the present case and should not have been introduced into the proceedings because it related to a rapidly exchangeable coronary catheter and thus had nothing to do with the treatment of blood vessels by ionizing radiation.

6.1 Figures 3 and 4 of D7 (column 5, lines 41 to 44) show "a conventional over-the-wire **balloon dilatation catheter** 10 and a **guidewire** 12 inserted into the patient's vasculature through a **guide catheter** 14" (emphasis added). The **guide catheter** is initially placed and lodged in the entrance to the right or left coronary artery (see Figure 4). When it is desired to exchange the **balloon catheter** to further dilate the patient's artery by using a catheter having a larger balloon, it is important to maintain the **guide wire** within the patient's artery so that it may guide the next catheter in the patient's vascular system (D7, column 5, line 55 to column 6, line 2).

6.2 The problem addressed in D7 consists in providing a catheter which can be withdrawn over the guide wire while holding the guide wire by its proximal end without the need to increase the guide wire's length (cf column 6, lines 13 to 25)

However, the solution to the above problem does not involve the **distal portion** of the catheter and, in effect, consists in providing a balloon catheter with a

proximal segment 28 which comprises only one inflation/deflation lumen. Since the guide wire lumen in the catheter "*extends only over a relatively short length of the catheter at the distal end of the catheter",* some part of the guide wire is always exposed and may be grasped to maintain the guide wire positioned inside the guide catheter (see column 6, lines 13 to 21)

6.3 Thus, the Board finds, in accordance with the Opposition Division's decision to introduce D7 into the proceeding, that this document is relevant to the present case as far as it covers the following aspects of the present invention:

- the catheter, which is inserted with the help of a guide wire (see D7, column 8, lines 35 to 42), comprises a balloon located at its distal end;

- the distal portion of this catheter has an opening for inflating the balloon and a lumen for the guide wire;

- the middle portion of the catheter has two lumens: one for inflating the balloon and another one for inserting the guide wire.

7. D1 is concerned with radiation treatment from within the vascular structure to reduce the incidence of restenosis (column 1, lines 54 to 56). One of the proposed solutions (see Figure 1) is a "*balloon catheter guidewire*" which comprises the features of the guide wire recited in claim 1. Such guide wire can be inserted through the centre of a balloon catheter for

steering the catheter to the site where angioplasty is to be performed (column 3, lines 12 to 16). Thus, the guide wire structure, which comprises an inner wire and an outer sleeve, is sized to fit within the balloon catheter tube to allow guidance or steering of the balloon catheter by manipulation of the guide wire (column 3, lines 17 to 20).

According to D1 (column 3, lines 44 to 46), *"Except for the radioactive source 9 and retractable shielding 11 at the tip, guidewire 11 may be generally conventional".*

Inventive step

8.1 Since D1 does not specify any particular balloon catheter to be used with the guide wire shown in Figure 1 and the **distal portion** of the catheter known from D7 shows all the features of the catheter specified in claim 1 of the contested patent, a further question to be considered in the present appeal is whether it would be obvious to a person skilled in the art to combine the guide wire of D1 with a balloon catheter according to D7 and, thus, arrive at the claimed invention.

8.2 According to the appellant, a skilled person would not have arrived at the claimed catheter by combining the teachings of D1 and D7 because the present invention required that the guide wire for inserting the balloon catheter along the guide catheter be easily replaced with a guide wire comprising an ionising element at its distal end. However, the balloon catheter of D7, with its guide wire lumen approximately 70 to 80 cm in the

blood vessel, did not allow an exchange of guide wires and thus could not be used to implement the teaching of the patent in suit.

8.3 As pointed out in the patent specification, "In all the embodiments shown only the portions which have to be located in a blood vessel stenosis have been depicted; the other portions of the embodiments shown may be devised as currently practised in the art" (column 9, lines 50 to 54). This implies that the present invention does not depend on how "the other portions" of the catheter are implemented.

Furthermore, it is specified that "*In all the embodiments shown, the guide wire and radioactive emitter may be fixed to the catheter instead of being movable within the catheter. As a further development, the catheter may comprise a guide wire for conventional entry into the blood vessel and the radioactive radiation emitter may be a filament affixed to or coiled around a wire intended to replace the said guide wire*" (see column 10, line 53 to column 11, line 2).

In other words, the guide wire with the radioactive emitter **may** be fixed to the catheter instead of being movable within it, and **may** be used to introduce the catheter into the patient's blood vessels.

Thus, the patent specification is not limited to embodiments whereby the balloon catheter is inserted into the blood vessel by means of a **conventional** guide wire which is to be replaced by a guide wire comprising a radioactive source once the balloon is properly positioned.

8.4 In the appellant's view, however, the fact that D1 did not attach any particular importance to the choice of the balloon catheter implied that the person skilled in the art starting from D1 would have had no reason to select the balloon catheter of D7 with its particular features directed to the solution of a different problem.

8.5 On the other hand, D1 clearly specifies that the guide wire with the radiation emitter shown in Figure 1 can be used as an **ordinary guide wire** for inserting a balloon catheter into the patient's blood vessels, whereas the balloon catheter of D7 gives the possibility of exchanging balloons easily and quickly, without the need to replace or extend the guide wire used for the insertion of the catheter, so as to allow a progressive dilatation of the artery by means of increasingly larger balloons.

Furthermore, the teachings of D1 and D7 belong in the same field of angioplasty and do not appear to be mutually exclusive.

8.6 Hence, in the Board's opinion, the person skilled in the art, starting from the guide wire of D1, which can be used not only for endovascular irradiation but also **to steer a balloon catheter** to a site where angioplasty is to be performed, and wishing to look for a suitable balloon catheter, would realize that a catheter designed according to the teaching of D7 would present no apparent drawback in conjunction with said guide wire, but, on the contrary, it would provide the additional advantage mentioned in D7 and consisting in

an easy replacement of the balloon without removing or extending the guide wire. As the combination of these two teachings would lead the skilled person to a medical appliance falling within the terms of claim 1 according to the main request, the subject-matter of this claim does not involve an inventive step within the meaning of Article 56 EPC.

First auxiliary request

9.1 Claim 1 according to the auxiliary request differs from claim 1 of the main request in that it is specified that the catheter is a two-lumen catheter *"along its entire length".*

According to the appellant, this feature solved the problem of replacing the conventional guide wire used for inserting the catheter with a radiation guide wire and distinguished the present invention from the monorail-type configuration shown in D7.

9.2 As pointed out above, all the embodiments of the invention are specified only as far as the distal portion of the corresponding balloon catheter is concerned, while "*the other portions of the embodiments shown may be devised as currently practised in the art*" (column 9, lines 52 to 54). In fact, the disclosure of the application as originally filed is essentially concerned with means for centering a radiation source in the portion of blood vessel to be treated, and not with a catheter which allows an easy replacement of guide wires.

9.3 In the opinion of the Board, the introduction into claim 1 of a feature which is not explicitly disclosed in the application as originally filed but appears to be essential for the solution of the new problem identified by the appellant, is not admissible under Article 123(2) EPC.

Apportionment of costs and reimbursement of the appeal fee

10.1 Article 104(1) EPC stipulates that a departure from the principle of each party to proceedings bearing his own costs requires special circumstances, such as improper behaviour, which makes it equitable to award costs **against one of the parties**. In the present case, such circumstances do not arise from the respondent's conduct in the opposition and appeal proceedings.

For the avoidance of doubt, it is noted that under Article 104(1) EPC no costs may be awarded against the EPO.

10.2 According to Rule 67 EPC, an order for reimbursement of the appeal fee is made contingent on the establishment of three facts:

- the appeal must be allowed;
- there must have been a "substantial procedural violation" by the first instance;
- reimbursement must be equitable in the circumstances of the case.

As in the present case none of the above conditions is fulfilled, the reimbursement of the appeal fee has to be refused.

11. In summary, the Board finds that none of the appellant's requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Davies