**BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS**

**BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE**

**CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS**

**Internal distribution code:**
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

# Datasheet for the decision of 9 December 2009

**Case Number:** T 2026/07 - 3.2.02

**Application Number:** 96106578.6

**Publication Number:** 0803264

**IPC:** A61M 25/00

**Language of the proceedings:** EN

**Title of invention:**
Interventional catheter

**Patentee:**
Schneider (Europe) GmbH

**Opponent:**
Terumo Kabushiki Kaisha Head Office

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 56

**Relevant legal provisions (EPC 1973):**
-

**Keyword:**
"Inventive step (yes, after amendments)"

**Decisions cited:**
-

**Catchword:**
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 2026/07 - 3.2.02

# D E C I S I O N
**of the Technical Board of Appeal 3.2.02**
**of 9 December 2009**

| | |
|---|---|
| **Appellant**: (Patentee) | Schneider (Europe) GmbH<br>Ackerstrasse 6<br>CH-8180 Bülach (CH) |
| **Representative**: | Peterreins, Frank<br>Fish & Richardson P.C.<br>Highlight BusinessTowers<br>Mies-van-der-Rohe-Strasse 8<br>D-80807 München (DE) |
| **Respondent**: (Opponent) | Terumo Kabushiki Kaisha Head Office<br>44-1, 2-chome Hatagaya, Shibuya-ku<br>Tokyo<br>Japan (DE) |
| **Representative**: | Hofer, Dorothea<br>Prüfer & Partner GbR<br>Patentanwälte<br>Sohnckestrasse 12<br>D-81479 München (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted 29 October 2007 revoking European patent No. 0803264 pursuant to Article 102(1) EPC.** |

**Composition of the Board:**

**Chairman:** M. Noël
**Members:** D. Valle
A. Pignatelli

## Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 14 December 2007 against the decision of the opposition division posted on 29 October 2007 to revoke the patent for lack of inventive step. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 28 February 2008.

II. The following documents are considered in the present decision:

D1 = EP - A - 0669 142
D2 = WO - A - 95/28982
D7 = US - A - 4 705 707
D19 = EP - A - 0380 270
D20 = US - A- 4 748 982
D21 = Handbook - Hellerich/Harsch/Haenle, Werkstoff-Führer Kunststoffe, 4. Aufl. 1986, Section "Polyolefine" (pages 9-13)
D22 = Excerpts from "Handbook of Polymer Data - Applied Volume"

III. Oral proceedings were held on 9 December 2009.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the auxiliary requests 1 to 3 all filed on 15 October 2008.

The respondent (opponent) requested that the appeal be dismissed and the patent be revoked.

IV. Claim 1 of the main request reads as follows:

"An interventional catheter comprising a catheter tube (1, 12, 23) having two superposed layers (2-3, 13-14, 24-25) of materials secured together and with mechanical properties differing from one another, a guidewire lumen (5, 16, 29) in said catheter tube for the sliding fit of a guidewire (6, 17, 30), and a balloon (7, 20) with a distal end (8, 21) sealingly surrounding said catheter tube, whereby the catheter tube has an inner layer (2, 13, 24) forming the guidewire lumen (5, 16, 29) and an outer layer forming an outer surface of the catheter tube (1, 12, 23), characterized in that it comprises mediator layer means (4, 15, 26) arranged between said inner layer (2, 13, 24) and said outer layer (3, 14, 25) for the adhesive anchorage of said layers thereto, wherein said mediator layer means (4, 15, 26) are formed on the basis of a low density polyethylene".

Claim 1 of the first auxiliary request reads as follows:

"An interventional catheter comprising a catheter tube (1, 12, 23) having two superposed layers (2-3, 13-14, 24-25) of materials secured together and with mechanical properties differing from one another, a guidewire lumen (5, 16, 29) in said catheter tube for the sliding fit of a guidewire (6, 17, 30), and a balloon (7, 20) with a distal end (8, 21) sealingly surrounding said catheter tube, whereby the catheter tube has an inner layer (2, 13, 24) forming the guidewire lumen (5, 16, 29) and an outer layer forming an outer surface of the catheter tube (1, 12, 23),

characterized in that it comprises mediator layer means (4, 15, 26) arranged between said inner layer (2, 13, 24) and said outer layer (3, 14, 25) for the adhesive anchorage of said layers thereto, wherein said inner and outer layers (2-3, 13-14, 24-25) and said mediator layer means (4, 15, 26) are coextruded and congruent in length, and wherein said mediator layer means (4, 15, 26) are formed on the basis of a low density polyethylene."

V. The appellant argued that the subject-matter of claim 1 of the main request involved an inventive step having regard to D2, which was considered the closest state of the art.

D2 did not disclose the first characterizing feature of claim 1, according to which mediator layer means (4, 15, 26) are arranged between said inner layer (2, 13, 24) and said outer layer (3, 14, 25) for the adhesive anchorage of said layers thereto.

The problem underlying the present invention had to be seen primarily in providing a superior adhesion performance in a wide variety of configurations of the inner and outer layer, in accordance with paragraph 15 of the patent specification. The patent in suit generally aimed at reaching a trade-off between the contrasting requirements of an interventional catheter such as pushability, kinking resistance, flexibility, easy manufacturing. The intermediate layer of the invention should allow for an independent selection of suitable materials for the inner and outer layers and for a satisfactory adhesion between these layers.

No sufficient hints were contained in D2 in order to lead the skilled person in the field in an obvious way to the invention. In any case the subject-matter of claim 1 of the first auxiliary request involved an inventive step having regard to D2 alone or in combination with other prior art documents. D19 should not be introduced into the proceedings because it was late-filed and not relevant. The other combinations were not substantiated.

VI. The respondent contested the arguments of the appellant and maintained that the subject-matter of claim 1 of the main request did not involve an inventive activity having regard to D2 and the common technical knowledge of a person skilled in the art represented e.g. by excerpts from handbooks D21 and D22.

Also the subject-matter of claim 1 of the first auxiliary request did not involve an inventive activity vis-à-vis the teaching of D2 and the general knowledge of the skilled person or considered in combination with D1, D7, D19 or D20.

For example, D2 disclosed intermediate layers of undefined length which could in any case be extended and made congruent in length with the inner and outer layers without any inventive skill being involved. Also D1 showed a catheter construction with layers congruent in length. D19 showed a medical tubing made of three coextruded layers, having an intermediate bonding layer made of low density polyethylene, whereby problems of flexibility and strengthening the tubing were addressed (see column 2, lines 28-30; column 3, lines 52-55; column 4, lines 47-52).

D19 and D20 should be introduced into the proceedings because of their relevance.

## Reasons for the Decision

1. The appeal is admissible.

2. *Main request - Inventive step*

2.1 D2 is indisputably the closest prior art document. D2 (see Figure 1E) discloses an interventional catheter comprising a catheter tube having two superposed layers (11, 15) of materials secured together and with mechanical properties differing from one another (see paragraph bridging pages 11 and 12), a guidewire lumen (14) in said catheter tube for the sliding fit of a guidewire, and a balloon with a distal end sealingly surrounding said catheter tube (see page 29, last paragraph; the balloon necessarily sealingly surrounds the catheter at both ends, in order to properly function), whereby the catheter tube has an inner layer (15) forming the guidewire lumen (14) and an outer layer forming an outer surface (11) of the catheter tube, whereby the catheter comprises mediator layer means (transition section (19)) arranged between said inner layer (15) and said outer layer (11) for the anchorage of said layers thereto (see paragraph bridging pages 10 and 11).

However, D2 does not disclose the last feature of claim 1 that:

"said mediator layer means (4, 15, 26) are formed on the basis of a low density polyethylene".

The appellant's argument that D2 does not disclose the first characterizing feature of claim 1 cannot be followed because the first appeal decision T 345/05, point 3.1 of the grounds, concerning the novelty of the claim, already found that this feature was disclosed by D2. These findings must be followed in the present case also because it is evident that Figure 1E of D2 shows mediator layer means (the two wedged materials incorporated into the transition section (19)) for the adhesive anchorage of the two surrounding layers (11, 15) (see page 33, last line).

2.2 The Board concurs with the appellant that the problem underlying the present invention has to be seen primarily in providing a superior adhesion performance in a wide variety of configurations of the inner and outer layer, in accordance with paragraph [15] of the patent specification and that the patent in suit generally aims at reaching a trade-off between the contrasting requirements of an interventional catheter such as pushability, kinking resistance, flexibility, easy manufacturing. The intermediate layer of the invention further allows for an independent selection of suitable materials for the inner and outer layers and for a satisfactory adhesion between these layers.

2.3 However, the solution given by the distinguishing feature of claim 1 is a trivial measure. It is obvious that the person skilled in the field would choose a suitable material for the mediator layer according to the specific circumstances. The choice of a low density

polyethylene is also considered as a simple workshop activity without any inventive skill being involved since this material is common in the field and well-known for its properties. It has also to be noted that the claimed mediator layer means are formed only "on the basis" of a low density polyethylene, which means that also a mixture of low density polyethylene and other materials is covered by the wording of the claim.

Furthermore, D2 discloses the use of stiff high density polyethylene (HDPE) for the inner layer (see page 33, line 15) whereas for the outer layer a thermoplastic elastomer can be used (page 33, lines 20, 21). Further, the intermediate layers forming the transition section 19 have to be softer than the stiff inner layer (see page 12, lines 12-19). Since it is well-known (e.g. from D21 and D22) that low density polyethylene is softer than high density polyethylene it will be obvious for the person skilled in the art to select also for the intermediate layer of the claimed catheter a low density polyethylene.

The decision under appeal further states that no mention of a suitable material for the mediator layer is made in D2. It appears that this is not completely correct. As already stated in the previous appeal concerning the novelty of the claims (see T 345/05, point 3.2 of the reasons) D2 specifically discloses on page 33, lines 13 to 24 that HDPE (high density polyethylene) can be used for the stiff (inner) layer or section of a tubing. According to page 12, first full paragraph of D2, in the embodiment of Figure 1E, the catheter is made of four materials of different stiffness, the stiffest material of the proximal

section 18 forming the interior layer 15 and being wedged into a less stiff material in portion 19C. This less stiff material is in turn wedged into a softer material in portion 19b, which in turn is wedged into the softest material in portion 19a of transition section 19, the softest material forming the outer layer 11. It follows that the catheter of Figure 1E is made of four materials (axially) disposed in decreasing value of stiffness, which is also recited in claim 3 of D2. The two intermediate materials which represent the mediator layer means in the invention, therefore, appear to be formed "on the basis" of a polyethylene with lower density (softer), in comparison with the HDPE material of the stiffest inner layer 15.

2.4 For these reasons, the subject-matter of claim 1 of the main request does not involve an inventive step with respect to the teaching of D2 alone having regard to the general knowledge of a person skilled in the art.

3. *First auxiliary request*

3.1 Claim 1 of the first auxiliary request contains the additional feature that the inner and outer layers (2-3, 13-14, 24-25) and the mediator layer means (4, 15, 26) are coextruded and congruent in length.

This feature is not disclosed in full by D2. While D2 discloses coextrusion of the layers forming the tube, as illustrated by Figure 7 and the corresponding passages of this document, it does not disclose that the layers are congruent in length.

3.2 The corresponding objective and more specific problem has therefore to be seen in the further improvement of the adherence of the layers to each other in particular to avoid separation of the layers under extreme conditions of stress on the catheter shaft (see patent, paragraph [7].

The solution is given by the distinguishing features of claim 1 over D2 and is not obvious. The congruence in length enhances considerably the adhesion of the adjacent layers and is not hinted at by the opposed prior art as demonstrated below.

3.3 The respondent's arguments failed to convince the Board for the following reasons.

In the Board's view, the intermediate layers of D2 (transition section 19) are clearly restricted to a limited length of the tubing (see the bottom of page 9 and top of page 10). The wedge structure forms in fact a "virtually unbreakable joinder" (see paragraph bridging pages 10 and 11) having necessarily a short length.

Regarding D1, it is noted that the tubing of D1 involves only two clearly identified layers bounded together, but not necessarily congruent in length within the meaning of the present patent, i.e. three layers extending all over the length of the catheter tube (see patent, paragraph [22]. By this construction, the adhesion characteristics between the layers of the catheter of the invention are notably enhanced, as convincingly explained by the appellant at the oral proceedings.

D19 and D20 have not been admitted into the procedure by the opposition division and the appellant further objected against their admission. The Board does not see any reason to challenge the discretion of the first instance, the more so since these documents are not more relevant than the documents already on file. Moreover, even if they had been considered, they would not seriously challenge the inventive step of the claimed subject-matter.

As a matter of fact D19 relates to flexible medical solution tubings, and therefore belongs to a field remote from that of the interventional catheters of the invention. Moreover, the main purpose of the intermediate layer and the whole construction of D19 is to impart enhanced flexibility to the film tubing and not to improve the adhesion between the inner and outer layers (see column 2, lines 2-4 and column 3, lines 52-54). Therefore, there would be no hint to combine D2 with D19.

D20 does not disclose the use of polyethylene and is concerned with a catheter with no concentric layers. The catheter comprises two tubular portions 12a, 12b extruded from a polyolefin and the abutting extremities are then bonded together by application of heat. Therefore, coextrusion of a multi-layer structure congruent in length is not suggested.

D7 is not concerned with interventional catheters but with the remote field of moisture barrier packaging films. Although coextrusion is used to make a multi-layer polymer film, congruence in length is not an

issue in this document, given the differences in the shape of the product and the application as a bag.

Therefore the skilled person would not consider this document in combination when faced with the problem of improving the adhesion between the layers of a catheter shaft undergoing extreme conditions of stress.

3.4 For these reasons the Board is satisfied that the subject-matter of claim 1 of the first auxiliary request involves an inventive step over the state of the art.

## 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 with the following claims and figures:

   - Claims 1 to 8 according to the first auxiliary request filed with letter of 15 October 2008;
   - Figures 1 to 3 as granted;

   and a description to be adapted.

The Registrar: The Chairman:

D. Sauter M. Noël