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**Datasheet for the decision
of 11 March 2014**

Case Number: T 0653/10 - 3.3.10

Application Number: 95908358.5

Publication Number: 759788

IPC: A61L29/00

Language of the proceedings: EN

Title of invention:

THIN WALL CATHETER HAVING ENHANCED TORQUEABILITY
CHARACTERISTICS

Patent Proprietor:

SCHNEIDER (USA) INC.

Opponent:

Terumo Kabushiki Kaisha

Headword:

Relevant legal provisions:

EPC Art. 100(a), 56

Keyword:

Inventive step - (no) - all requests

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0653/10 - 3.3.10

**D E C I S I O N
of Technical Board of Appeal 3.3.10
of 11 March 2014**

Appellant: Terumo Kabushiki Kaisha
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 25 January 2010
rejecting the opposition filed against European
patent No. 759788 pursuant to Article 101(2)
EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division to reject the opposition against European patent No. 759 788.
- II. Its opposition had been filed on the ground that the subject-matter of the patent as granted did not involve an inventive step (Article 100(a) EPC).
- III. The documents filed during the opposition proceedings included the following:

D1: US 4 898 591

- IV. The opposition division considered that document D1 was the closest prior art, the problem underlying the claimed invention was the provision of alternative catheters to those of D1, the solution was catheters whose inner layer consisted essentially of an unmodified polyamide polymer and such a solution was not obvious having regard to the prior art in the light of the known disadvantages of such polymers, with the consequence that the subject-matter of claim 1 of the patent as granted was inventive.
- V. With the response to the grounds of appeal, the respondent (patent proprietor) filed a first and second auxiliary request. A third auxiliary request was filed under cover of a letter dated 4 July 2013.
- VI. Claim 1 of the patent as granted, which is the main request of the respondent, reads as follows:

"An intravascular catheter (10) comprising:

an elongated tubular body (12) having a proximal end (14), a distal end (16) and a lumen (18) extending therebetween, said tubular body (12) formed with

an inner layer (28) consisting essentially of an unmodified polyamide polymer,

a reinforcing sleeve (30) of braided filaments, the filaments having opposed free ends and the braided sleeve (30) surrounding said inner layer (28) and extending from said proximal end (14) of the tubular body (12) toward the distal end (16) of the tubular body (12) by a predetermined distance; and

an outer layer (32) including a polyether block amide (PEBA) of a predetermined durometer hardness in the range of from about 50 Shore D to 75 Shore D, said outer layer (32) at least partially covering said reinforcing sleeve (30) and having a wall thickness providing an outer diameter to said tubular body (12) in the range of from 0.99 mm to 2.64 mm (3 French to 8 French)."

Claim 1 of the first auxiliary request defines the inner layer (28) of the claimed catheter as follows:

"an inner layer (28) consisting essentially of an unmodified polyamide polymer, wherein nothing has been added to the polymer matrix that tends to substantially change its physical properties".

In claim 1 of the second auxiliary request, the inner layer is defined as follows:

"an inner layer (28) consisting essentially of an unmodified polyamide polymer, wherein said inner layer

(28) is of a 100 percent polyamide polymer having a wall thickness in the range of from about 25.4 to 203 μm (0.001 to 0.008 inches)".

Lastly, the definition of the inner layer of the catheter in claim 1 of the third auxiliary request reads as follows:

"an inner layer (28) consisting essentially of an unmodified polyamide polymer, wherein said inner layer (28) has a wall thickness in the range of from about 25.4 to 203 μm (0.001 to 0.008 inches)".

- VII. The board informed the parties that the patent in suit had been surrendered or had lapsed with effect for all the designated contracting states, and that the appeal proceedings would only be continued at the request of the appellant. In response, the appellant requested such continuation.
- VIII. The arguments of the appellant relevant for the present decision are the following:

Document D1 was the closest prior art. The difference between the claimed catheters and those of D1 was the absence of PEBA (polyether block amide) from the composition of its inner layer. The problem underlying the claimed invention was providing alternative catheters to those of document D1, and the solution, which was catheters whose inner layer consisted essentially of an unmodified polyamide polymer, was obvious in the light of D1, which disclosed nylon-11 as a suitable material. The subject-matter of claim 1 of the main request was, thus, not inventive.

The amendments in claim 1 of the auxiliary requests did

not add further distinguishing features vis-à-vis D1, so that their subject-matter was not inventive for the same reasons as that of the main request.

IX. The arguments of the respondent relevant for the present decision are the following:

D1 was the closest prior art, and the problem underlying the claimed invention was providing a catheter having a minimal outer diameter and a maximal inner diameter while still maintaining the necessary torqueability and pushability characteristics. The solution was catheters whose inner layer consisted essentially of an unmodified polyamide polymer. D1 taught away from the claimed solution, since the skilled person would not consider nylon-11 a suitable material in view of its disadvantages. In addition, the catheters made of nylon-11 did not have a reinforcing braid and, hence, belonged to a different catheter technology that could not be combined with the teaching of D1. For these reasons, the subject-matter of claim 1 of the main request was inventive. The same argument applied to the subject-matter of claim 1 of all the auxiliary requests.

The respondent informed the board that it would not be represented at the oral proceedings.

X. Oral proceedings before the board took place on 11 March 2014.

XI. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside and that European patent No. 759 788 be revoked.

- The respondent requested in writing that the appeal be dismissed (main request) or, subsidiarily, that the decision under appeal be set aside and that the patent be maintained on the basis of any one of the first, second or third auxiliary requests, the first or second auxiliary request as filed with letter dated 18 October 2010, or the third auxiliary request as filed with letter dated 4 July 2011.

XII. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request:

2. Inventive step:

Claim 1 of the main request relates to an intravascular catheter comprising:

- an inner layer which consists essentially of an unmodified polyamide polymer,
- a reinforcing sleeve and
- an outer layer including a polyether block amide (PEBA) of a defined hardness (50 to 75 Shore D) and a defined thickness (3 French to 8 French).

- 2.1 Closest prior art:

The parties and the opposition division considered document D1 as the closest prior art, and the board sees no reason to differ.

Document D1 discloses intravascular catheters whose composition of the inner and outer layers can be adjusted in order to produce a wide range of properties (column 3, lines 15-19) such as torsion modulus, flexibility and lubricity, without reducing lumen to external diameter ratio or employing incompatible or greatly different materials for the different catheters (column 3, lines 28-33).

It has not been contested that the catheters of D1 comprise a reinforcing sleeve and an outer layer as required by claim 1.

The parties were, however, divided as to whether an inner layer as disclosed in D1, containing nylon-11, which is an unmodified polyamide polymer, and PEBA, which is a polyether block amide, was an inner layer "consisting essentially of an unmodified polyamide polymer".

In favour of the respondent, the feature "consists essentially of an unmodified polyamide polymer" will be interpreted as excluding from the inner layer of the claimed catheter any other type of polymer such as PEBA. The following analysis of inventive step is carried out considering said feature as a distinction over the closest prior art document D1.

2.2 Technical problem underlying the invention:

The respondent defined the problem underlying the claimed invention as providing a catheter having a minimal outer diameter and a maximal inner diameter while still maintaining the necessary torqueability and pushability characteristics (see paragraph [7] of the patent in suit and point 6. of the submission of the

respondent dated 4 July 2011).

The respondent has not disputed that D1 already addresses this problem (see column 3, lines 15-19 and 28-32). The technical problem underlying the claimed invention amounts, therefore, to providing further catheters to those disclosed in document D1.

2.3 Solution:

The solution provided by claim 1 of the main request is a catheter characterised in that the inner layer consists essentially of an unmodified polyamide polymer.

2.4 Success:

The catheter obtained in the example of the patent in suit, with an inner layer consisting of an unmodified polyamide polymer which contained no further polymer, has a 8 Fr (2.64 mm) outer diameter, a lumen of 1.93 mm, and shows the desirable properties, see paragraph [22] of the patent in suit.

The problem as defined in point 2.2 above can thus be considered solved by the catheters according to claim 1.

2.5 Finally, it remains to be examined whether the claimed solution was obvious for the person skilled in the art.

Document D1 discloses that the relative amount of nylon-11 and PEBA of the inner and outer layers can be adjusted for optimising the properties of the catheter (column 4, lines 60-62). Preferably, the inner layer should contain less PEBA, which allowed enhancing

torsion modulus and column strength (column 4, line 66 to column 5, line 1) and provided structural strength to support the braid with minimum wall thickness (column 5, lines 3-6). D1, therefore, teaches using different relative amounts of nylon-11 and PEBA for the inner and outer layers, whereby the inner layer suitably contains less PEBA than the outer layer.

D1 further discloses that nylon-11 had been employed in the art to form catheters with suitable torsion modulus, flexibility and column strength (column 3, line 67 to column 4, line 2).

When trying to obtain further catheters, the skilled person would turn to the information provided in D1 that the inner layer of the catheter preferably contains less PEBA than the outer layer, and that nylon-11 alone forms catheters with the desired properties, and would choose nylon-11 as alternative suitable material for the inner layer without using inventive skills. The subject-matter of the main request is, therefore, not inventive in the sense of Article 56 EPC.

- 2.5.1 The respondent and the opposition division considered that the skilled person would not regard nylon-11 as a suitable material for the inner layer in view of the disadvantages disclosed in the passage on column 4, lines 2-6 of D1, which reads:

"nylon-11 offers no range of modulus and flexibility properties for enabling the torsion modulus and flexibility properties to be changed for different catheters without changing the tubular wall thickness".

However, this passage, in its whole context (column 3,

line 67 to column 4, line 6), does not disclose, as alleged by the respondent, that nylon-11 is not a suitable material for catheters but, instead, that it could fail to provide sufficient range of modulus and flexibility properties for every type of catheter.

Claim 1 does not restrict the type of catheter claimed, so that it also includes those with a modulus and flexibility suitably achievable by nylon-11. At least for these catheters, the use of nylon-11 for the inner layer is obvious in the light of D1 for the reasons explained above.

This argument of the respondent is, therefore, unsuccessful.

- 2.5.2 The respondent further argued that, since the catheters made only of nylon-11 did not contain a reinforcing braid, these catheters belonged to a different catheter technology. For this reason, the skilled person would not consider using nylon-11 for the manufacture of the catheters according to claim 1.

Column 3, lines 67 et seq. of D1 discloses that nylon-11 has been employed to form catheters, and that such catheters have suitable mechanical properties. Although blends of nylon-11 and polyether-polyamide copolymers (such as PEBA) require a reinforcing braid (column 4, lines 10-14), these blends allow optimisation of the physical properties of the catheters by merely changing the proportions of nylon-11 and copolymer (column 4, lines 19-22). The properties of nylon-11 and PEBA blends as a function of the PEBA content are disclosed on column 4, line 63 to column 5, line 6: increasing the amount of PEBA reduces the strength of the layer.

D1, thus, discloses that replacing nylon-11 by blends of nylon-11 and PEBA requires using a reinforcing braid due to its lower strength. It fails, however, to disclose that nylon-11 could not be used in combination with such a reinforcing braid. Furthermore, the skilled reader understands from the cited passages that if one of the layers is made of a blend of nylon-11/PEBA the catheter could still require a reinforcing braid to achieve the desired physical properties.

This argument of the respondent is also dismissed.

- 2.6 Since the subject-matter of claim 1 is not inventive in the sense of Article 56 EPC, the ground of opposition under Article 100(a) EPC precludes the maintenance of the patent as granted.

First auxiliary request:

3. Inventive step:

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the inner layer is defined as

"an inner layer (28) consisting essentially of an unmodified polyamide polymer, wherein nothing has been added to the polymer matrix that tends to substantially change its physical properties".

Since the assumption underlying the analysis of inventive step of the main request is that the wording of the claim excluded any PEBA from the inner layer of the claimed catheters, the distinguishing feature vis-à-vis D1 remains the same as for claim 1 of the main

request, with the consequence that the subject-matter of claim 1 of the first auxiliary request is not inventive for the reasons explained in point 2. above.

Since claim 1 of the first auxiliary request is not inventive in the sense of Article 56 EPC, this request is not allowable.

Second auxiliary request:

4. Inventive step:

The catheter according to claim 1 of the second auxiliary request requires an inner layer which is further limited with respect to the inner layer of claim 1 of the main request in that:

"the inner layer (28) is of a 100% polyamide polymer having a wall thickness in the range of from about 25.4 to 203 μm (0.001 to 0.008 inches)".

The feature "the inner layer is of a 100% polyamide polymer" does not add any further distinction vis-à-vis D1, and the wall thickness required by claim 1 is already disclosed in document D1 (column 5, lines 52-53). The inventive step analysis is, thus, identical to that for the subject-matter of claim 1 of the main request (see point 2. above), with the consequence that the subject-matter of claim 1 of the second auxiliary request is not inventive, and this request not allowable.

Third auxiliary request:

5. Inventive step:

Claim 1 of the third auxiliary request limits the subject-matter of claim 1 of the main request by specifying a wall thickness of the inner layer "*in the range of from about 25.4 to 203 μm (0.001 to 0.008 inches)*".

Since the wall thickness of the inner layer required by claim 1 of the third auxiliary request is already disclosed in document D1 (column 5, lines 52-53), the inventive step analysis remains the same as for the main request (see point 3. above).

The subject-matter of the third auxiliary request is, therefore, not inventive, with the consequence that this request is not allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



C. Vodz

P. Gryczka

Decision electronically authenticated