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D E C I S I O N
of 30 July 2002

Case Number: T 0456/99 - 3.2.2

Application Number: 87903961.8

Publication Number: 0309471

IPC: A61B 6/00

Language of the proceedings: EN

Title of invention:
Catheter

Patentee:
TARGET THERAPEUTICS, INC.

Opponent:
1. WILLIAM COOK EUROPE A/S
2. TERUMO CORPORATION

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - no"

Decisions cited:
-

Catchword:
-



Case Number: T 0456/99 - 3.2.2.

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 30 July 2002

Appellant: TARGET THERAPEUTICS, INC.
(Proprietor of the patent) 47900 Bayside Parkway
Fremont, CA 94538 (US)

Representative: Senior, Alan Murray
J. A. KEMP & CO.
14 South Square
Gray's Inn
London WC1R 5JJ (GB)

Respondents:
(Opponent 1) WILLIAM COOK EUROPE A/S
Sandet 6
DK-4632 Bjaeverskov (DK)

Representative: Indahl, Peter Jensen (DK)
Internationalt Patent-Bureau
Hoeje Taastrup Boulevard 23
DK-2630 Taastrup (DK)

(Opponent 2) TERUMO CORPORATION
Shonan Center, 1500 Inokuchi, Nakai-machi
Ashigarakami-gun, Kanagawa Pref. 259-01 (JP)

Representative: Vollnhals, Aurel, Dipl.-Ing.
Patentanwälte
Tiedtke, Bühling, Kinne & Partner
Bavariaring 4
D-80336 München (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 12 March 1999
revoking European patent No. 0 309 471 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß

Members: M. G. Noel
R. T. Menapace

Summary of Facts and Submissions

- I. By decision of 12 March 1999 the Opposition Division revoked European patent No. 0 309 471 (International publication No. WO 87/07493) on the grounds of lack of inventive step.
- II. During the proceedings, documents D1 and D7 were, among others, considered:
- D1: "A new Catheter for Selective and Superselective Angiography" by R.J. Rosen, published April 18, 1986 in Cardiovascular and Interventional Radiology, Vol. 9, No. 1, 1986, pages 49 to 51.
- D7: "Braciocephalic Vessel: Selective and Superselective Catheterization" by A. Berenstein, Radiology, Vol. 148, No. 2, August 1983, pages 437 to 441.
- III. The appellant (patentee) lodged an appeal against the first instance's decision on 27 April 1999. Its statement of grounds was filed on 22 July 1999, along with two sets of claims according to a main and an auxiliary request, identical to those rejected in the opposition stage.
- The respondents (opponents 1 and 2) replied in writing on 17 April and 23 February 2000 respectively.
- IV. In a communication sent on 21 February 2002 following a summons to attend oral proceedings, the Board suggested to focus the discussion on documents D1 and D7 in particular.

V. In reply the appellant submitted on 26 June 2002 two additional sets of claims according to second and third auxiliary requests.

VI. Oral proceedings were held on 30 July 2002, during which the claims according to the different requests were discussed successively. At the end of the proceedings, the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of the auxiliary request made already during the opposition proceedings, or the second and third auxiliary requests both filed on 26 June 2002.

The respondents requested that the appeal be dismissed.

VI. The parties argued as follows:

(i) The appellant:

- The invention relates to a microcatheter to be inserted into a soft internal brain or liver tissue. The catheters disclosed in documents D1 and D7 are larger in diameter and stiffer than the catheter of the present invention. Therefore, they were not suitable to the tortuous paths of those vessels contemplated in the present patent.
- When assessing the merits of the claim not only the structural features but also the functional features of the claims have to be considered

since they are relevant for performing the specific applications.

- In order to avoid a torque loss and to resolve the problem of catheter buckling, the invention provides a plurality of segments having increasing flexibilities towards the distal end of the catheter. Documents D1 and D7 neither disclose a plurality of intermediate segments nor a clearance specifically dimensioned and adapted to small sized catheters.

(ii) The respondents:

- The invention resides principally in the ability of introducing a guidewire catheter along a tortuous path through small vessels, typically less than 3 mm lumen diameter. The various intended applications such as accessing soft internal brain or liver tissues are not limiting the scope of the claim. Therefore, only the structural features are of interest and actually to be considered.
- Documents D1 and D7 both disclose catheters to be used with guidewires which are suitable for accessing tortuous path within soft tissue vessels of less than 3 mm diameter.
- The problem of catheter buckling is primarily solved by the co-operation between the catheter tubing and the guidewire, in particular by giving the wire a continuously diminishing diameter or taper configuration in its distal end portion. This feature, however, is not

present in claim 1. An appropriate clearance between the guidewire and the catheter lumen is in every case necessary for performing proper sliding engagement and is regarded as a matter of a normal design procedure.

- Document D7 also discloses a tapered intermediate segment in the distal region of the catheter, the flexibility of which varies, therefore, progressively, as would do a plurality of intermediate segments of progressive flexibilities.

VII. The independent claims 1 according to the various requests read as follows:

Main request:

"A catheter (12) for use with a guidewire (14), the catheter being guidable from an external body access site to and into a soft internal brain or liver tissue, the catheter comprising:

an elongate tubular member having proximal and distal ends and an inner lumen (13) extending between the proximal and distal ends, said member being composed of:

a relatively stiff proximal segment (16) dimensioned to track the guidewire from the access site to a region adjacent the internal tissue;

a relatively flexible distal segment (18) constructed and dimensioned to track the guidewire from said region to a target site within the internal tissue along the

entire length of a tortuous path within the internal tissue of at least about 5 cm, through vessels of less than about 3 mm lumen inner diameter and around a plurality of sharp bends some of which may be of 90° or more, by means of an axially directed force applied to the distal segment through the proximal segment, the distal segment (18) having both a proximal portion and a distal portion and said proximal portion including one or more intermediate segments having lesser flexibility than the distal portion of the distal segment (18) and greater flexibility than the proximal segment (16)."

First auxiliary request:

As the preceding claim, supplemented by the following feature:

"wherein said distal portion and said intermediate segment(s) are each between 5 to 15 cm long."

Second auxiliary request:

"A catheter device comprising a guidewire (14) and a catheter (12) for use with the guidewire (14), the catheter being guidable over the guidewire from an external body access site to and into a soft internal brain or liver tissue, the catheter comprising:

an elongate tubular member having proximal and distal ends and an inner lumen (13) extending between the proximal and distal ends, said member being composed of:

a relatively stiff proximal segment (16) dimensioned to

track the guidewire from the access site to a region adjacent the internal tissue:

a relatively flexible distal segment (18) constructed and dimensioned to track the guidewire from said region to a target site within the internal tissue along the entire length of a tortuous path within the internal tissue of at least about 5 cm, through vessels of less than about 3 mm lumen inner diameter and around a plurality of sharp bends some of which may be of 90° or more by means of an axially directed force applied to the distal segment through the proximal segment, the distal segment (18) having both a proximal portion and a distal portion and said proximal portion including one or more intermediate segments having lesser flexibility than the distal portion of the distal segment (18) and greater flexibility than the proximal segment (16), wherein the guidewire (14) includes a distal end region (26) and is slidably receivable within said inner lumen (13) with a clearance between the distal end region of the guidewire (14) and said distal segment (18) of the catheter of between 0.05 to 0.12 mm (2 to 5 mils)."

Third auxiliary request:

"A catheter (12) for use with the guidewire (14), the catheter being guidable from an external body access site to and into a soft internal brain or liver tissue, the catheter comprising:

an elongate tubular member having proximal and distal ends and an inner lumen (13) extending between the proximal and distal ends, said member being composed of:

a relatively stiff proximal segment (16) dimensioned to track the guidewire from the access site to a region adjacent the internal tissue:

a relatively flexible distal segment (18) constructed and dimensioned to track the guidewire from said region to a target site within the internal tissue along the entire length of a tortuous path within the internal tissue of at least about 5 cm, through vessels of less than about 3 mm lumen inner diameter and around a plurality of sharp bends some of which may be of 90° or more by means of an axially directed force applied to the distal segment through the proximal segment, the distal segment (18) having both a proximal portion and a distal portion and said proximal portion including a plurality of intermediate segments, each said intermediate segment having lesser flexibility than the distal portion of the distal segment (18) and greater flexibility than the proximal segment (16) and each said intermediate segment being more flexible than the segment(s) proximal thereto."

Reasons for the decision

1. The appeal is admissible.
2. *Formal aspects*

The question of whether there are any formal objections to the current version of the claims need not be answered since all main claims (main and auxiliary requests) are anyway unallowable on other grounds, as set out hereinafter.

3. *Inventive step - Main request*

3.1 While being directed to a catheter for use with a guidewire, claim 1 according to the main request only comprises features of the catheter, i.e. the features of the segments forming the tubular member of the catheter.

According to the modified embodiment described in the patent specification from column 8, line 39 to column 9, line 6, the catheter comprises three parts. Following the same terminology the catheter is made of a stiff proximal segment 16 and a flexible distal segment 18 comprising itself a distal portion and a proximal portion, this latter including in turn one or more intermediate segments. The main characteristic of the invention is to confer to the catheter a progressively increasing flexibility from the proximal to the distal segments.

The problem to be solved (cf. column 2, line 58 to column 3, line 6) is to improve the advancement of the catheter along the guidewire in order to give access to a small lumen tortuous tissue pathway, that is a pathway involving a number of sharp bends of 90° or more through a vessel of less than about 3 millimeters inner diameter. In particular, the specific problem of catheter buckling should be avoided, as illustrated on Figure 10 (prior art) of the patent by the catheter deformation coming into contact with the wire bend, making further catheter advance along the wire difficult or impossible (cf. column 2, lines 35 to 45 and column 13, lines 46 to 53).

The claimed catheter is intended to be guidable into a

soft internal brain or liver tissue. The field of contemplated applications is, therefore, a wide one. But what is determinative for the present invention is that the catheter may be inserted within tortuous paths in vessel lumens of small diameters (cf. column 5, lines 40 to 43) in accordance with the definition given in the patent itself (column 12, lines 38 to 45).

- 3.2 Document D1 discloses a catheter for selective and superselective abdominal angiography, therefore a catheter suitable in particular for accessing liver tissues as claimed in claim 1. Further, this catheter is said to incorporate features of the Berenstein catheter previously reported under the reference [1], which is nothing else but document D7.

The catheter disclosed in document D1 allows for superselective catheterization of fourth-order visceral branches. According to the description under the heading "Materials and Methods", the known catheter is made of three parts, of which one proximal 70 cm portion consists of a 7F polyurethane braided wire shaft for torque control, one intermediate 5 cm more flexible portion consists of a 7F polyurethane without wire braiding and one distal 5 cm still more flexible portion is composed of a 5,5F soft thin-walled polyurethane. The purpose of the soft flexible tip portion is to follow tortuous curves more easily than did prior available catheters and to reduce the tendency of the catheter to buckle (cf. page 50).

The catheter diameters are expressed in terms of French sizes (F), the corresponding values in millimeters (mm) are given, for example, in the Annexe 2 filed with the appellant's response of 26 March 1998 during the

opposition proceedings (Neuroradiology, Third Edition, Chapter 18.2; Materials and Methods for Interventional Neuroradiology, by J.P. Spellman and W.L. Young). Thus, 7F corresponds to 2,30 mm outer diameter and 5F to 1,67 mm.

- 3.3 The wording of claim 1 differs from the disclosure of document D1 only by defining the dimensional and constructional features of the catheter by the characteristics of the tortuous path through which the distal segment of the catheter is intended to be fed, namely a plurality of sharp bends of 90° or more within vessels less than 3 mm lumen inner diameter over a distance of at least 5 cm. *Stricto sensu*, the subject-matter of claim 1 is, therefore, novel.

In addition to the fact that the above features of the claimed catheter do not characterise the catheter itself but rather its surroundings, i.e. its use *in situ*, the guidewire catheter known from document D1 presents dimensions which are suitable for its introduction through tortuous vessels lesser than 3 mm inner diameter.

Moreover, there is specified in document D7 (cf. page 437), the content of which is incorporated in document D1 by reference, that tortuosities of 90° or more may be reached with the assistance of appropriate guidewires. Still there, the tapered and more flexible intermediate portion of 10 cm presents dimensions (4F = 1,35 mm or 5F = 1,67 mm) which are suitable for its introduction through braciocephalic vessels of less than 3 mm diameter. As also generally reminded in document D7 (cf. page 437, 1st paragraph) whatever the type of the catheter used (torque catheter or flow-

guided balloon catheter), "they are usually small and require a flexible shaft to negotiate tortuous curves. In both instances, there is a compromise between the size, usable diameter, torque and flexibility of the catheter". Such considerations come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance.

3.4 Therefore, the subject-matter of claim 1 according to the main request does not involve an inventive step vis à vis the teaching of documents D1 and D7, having regard to the general knowledge of a person skilled in the art (Article 56 EPC).

4. *First auxiliary request*

Claim 1 according to the first auxiliary request differs from the main request by the incorporation of the content of the previous claim 2, according to which said distal portion and said intermediate segment(s) are each between 5 to 15 cm long.

As demonstrated above (cf. point 3.2), document D1 discloses an intermediate portion and a distal portion each 5 cm long, which fall within the range as claimed when considering the basic option with only one intermediate segment. The incorporated feature thus fails to add inventive step to the subject-matter of the previous claim 1.

Consequently, the subject-matter of claim 1 according to the first auxiliary request does not involve an inventive step, either.

5. *Second auxiliary request*

Claim 1 according to the second auxiliary request differs from the main request in that the catheter device comprises in combination a catheter and a guidewire, the guidewire being slidable within the catheter lumen and the catheter being guidable over the guidewire with a clearance between the corresponding distal ends of the guidewire and of the catheter in the range of 0,05 to 0,12 mm. These features result from the incorporation of claims 18 and 23 of the main request.

Both documents D1 and D7 recommend the use of a guidewire for facilitating the advancement of the catheter within tortuous paths of small diameters. The provision of a suitable clearance between the distal ends of the guidewire and the catheter is a prerequisite for all wire directed catheters so as to enable proper sliding of the catheter without buckling or crimping and to avoid the catheter tubing from pinching against the wire in the region of the bend. The determination of this clearance is thus the consequence of routine experimentations and optimisations, which are well within the competence of a person skilled in the art.

Therefore the subject-matter of claim 1 according to the second auxiliary request does not involve an inventive step within the meaning of Article 56 EPC, either.

6. *Third auxiliary request*

Claim 1 according to the third auxiliary request

differs from the main request by comprising a plurality of intermediate segments, each being more flexible than the segment proximal thereto.

While no document discloses a catheter having more than one intermediate segment, the provision of a plurality of intermediate segments of progressive flexibilities is based on the same idea as a catheter having a plurality of segments, each segment being progressively more flexible than the previous one towards the distal end of the catheter, as already disclosed by documents D1 and D7. Therefore, the provision of a plurality of intermediate segments instead of only one results from a mere multiplication of the same principle, which is directly suggested by the cited documents.

Further, document D7 discloses a tapered 10 cm distal (intermediate) segment (cf. Figure 1 and text referred to), which is equivalent to a plurality of intermediate segments having diameters successively reduced and, consequently, increased flexibilities.

Therefore, the subject-matter of claim 1 according to the third auxiliary request still lacks an inventive step as required by Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß