

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 12 October 2016**

Case Number: T 0891/12 - 3.2.02

Application Number: 04811126.4

Publication Number: 1708775

IPC: A61M25/00, A61M25/10, A61F2/06

Language of the proceedings: EN

Title of invention:
Catheter tip

Patent Proprietor:
Boston Scientific Limited

Opponent:
Abbott Laboratories Vascular Enterprises, Ltd.

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty (yes)
Inventive step (yes)

Decisions cited:

T 0003/90

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0891/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 October 2016

Appellant: Abbott Laboratories Vascular Enterprises, Ltd.
(Opponent) Earlsfort Centre, Terrace
Dublin 2 (IE)

Representative: Hoefler & Partner Patentanwälte mbB
Pilgersheimer Straße 20
81543 München (DE)

Respondent: Boston Scientific Limited
(Patent Proprietor) Clarendon House
2 Church Street
Hamilton HM11 (BM)

Representative: Vossius & Partner
Patentanwälte Rechtsanwälte mbB
Siebertstrasse 3
81675 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
30 January 2012 concerning maintenance of the
European Patent No. 1708775 in amended form.

Composition of the Board:

Chairman E. Dufresne
Members: M. Stern
C. Körber

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision posted on 30 January 2012 concerning maintenance of the European Patent No. 1 708 775 in amended form. In the decision under appeal, the Opposition Division held that the patent as amended during the opposition proceedings satisfied the requirements of the EPC, in particular those of novelty and inventive step in view of the following documents:

E1: WO-A-01/89620

E4: US-A-5 728 063.

II. Notice of appeal was filed on 10 April 2012 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 8 June 2012.

III. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the the appeal be dismissed.

Both parties requested oral proceedings on an auxiliary basis.

IV. The Board presented its provisional opinion in a communication annexed to the summons to oral proceedings dated 28 July 2016.

V. By letter dated 4 October 2016 the appellant informed the Board that nobody would be attending the oral proceedings on its behalf. These were consequently cancelled by order dated and notified 5 October 2016.

VI. Claim 1 held allowable by the Opposition Division reads as follows:

"A catheter comprising:

- a catheter shaft (12) having a proximal end and a distal end;
- an inflation balloon (44) having a proximal waist portion (54) and a distal waist portion (56);
- and a catheter tip (20) having a proximal end, a distal end, a main shaft portion and a distal shaft portion said catheter tip (20) proximal end being coupled to said catheter shaft (12) distal end, said balloon distal waist portion (56) being attached to said catheter tip (20) distal shaft portion;
- said catheter tip main shaft portion being substantially coextensive with said balloon (44) and
- said balloon proximal waist portion (54) is coupled to an outer catheter shaft (40) characterized in that
- the catheter tip (20) further comprises a plurality of recessed portions (34)."

Claims 2 to 8 are dependent claims.

VII. The arguments of the appellant relevant for the present decision are summarised as follows:

Novelty - Article 54 EPC

Document E4 anticipated the catheter defined in claim 1. The claimed definition of "said catheter tip (20) proximal end being coupled to said catheter shaft (12) distal end" did not require the catheter tip and the catheter shaft to be two different components. According to paragraph [0039] of the patent in suit,

the term "coupled" should be interpreted as involving an attachment of the shaft to the tip of the catheter, for example by gluing, heat bonding, RF welding or laser welding. However, in view of the expression "In another embodiment ..." at the beginning of paragraph [0070] of the patent, the term "coupled" had to be understood as also including an embodiment in which shaft and tip formed a single component. This passage in combination with column 5, lines 50 to 54 of the patent conveyed the information that it was entirely arbitrary which portion of the catheter was considered to be the shaft and which the tip. As shown in Figure 4 of E4, the catheter tip comprised a plurality of recessed portions into which markers or reinforcement layers were inserted. Moreover, column 10, lines 4 to 12 of E4 disclosed liquid perfusion ports or holes near the distal end 5, which, in view of the extremely broad claimed definition, should be understood as recessed portions in the sense of the claim.

Inventive step - Article 56 EPC

The catheter of claim 1 lacked inventive step over the combination of E1 with E4. The closest prior art was the catheter of Figure 3 of E1. The catheter of claim 1 differed from E1 in that the tip comprised a plurality of recessed portions. The technical problem to be solved consisted in providing the catheter tip with recesses for different purposes. Document E4 suggested to the skilled person to provide the catheter with recesses for markers, stiffening elements or improvements for perfusion. Hence, in view of E1 and E4, the subject-matter of claim 1 lacked inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. In its communication annexed to the summons to oral proceedings, the Board presented a preliminary reasoned assessment of the objections raised by the appellant and indicated that the subject-matter of claim 1 appeared to satisfy the requirements of novelty and inventive step. In its reply, the appellant stated only that it would not be attending the oral proceedings.

In accordance with established case law, the Board considers this statement to be equivalent to a withdrawal of the appellant's earlier request for oral proceedings on an auxiliary basis (T 3/90, OJ 1992, 737, point 1 of the Reasons). The Board therefore duly cancelled the oral proceedings and decides the case on the basis of the present state of the file.

3. The invention

The claimed invention is directed to a balloon catheter (as depicted for example in Figure 2) comprising, in essence, a shaft (12), a tip (20) coupled to the shaft, an outer shaft (40) and a balloon (44), wherein the distal waist portion (56) of the balloon is attached to the tip and the proximal waist portion (54) of the balloon is coupled to the outer shaft, the tip main shaft portion being substantially coextensive with the balloon, and the tip comprises a plurality of recessed portions (34).

As described in the patent in suit (column 7, lines 33 to 40), one of the purposes of the recessed portions is

to act as storage recesses for portions of the balloon (for example, the conical portions 46 shown in Figure 5) when the balloon is in an uninflated state, thereby allowing the catheter to have a lower profile. Another purpose of the recessed portions is to allow the catheter tip to have greater flexibility for bending about the longitudinal axis (column 7, lines 41 to 45).

4. *Novelty - Article 54 EPC*

4.1 Document E4 discloses a balloon catheter (Figure 4) which comprises, in essence, a shaft (inner catheter 102), a tip (soft distal tip 122) whose proximal end is coupled to the distal end of the shaft (column 11, lines 4 to 5), an outer shaft (104) and a balloon (106), wherein the proximal waist portion of the balloon is coupled to the outer shaft (sentence bridging columns 10 and 11).

Since the claim defines the tip's proximal end as *coupled* to the shaft's distal end, the Board considers that the tip and the shaft need to be two distinct components, rather than a single one as argued by the appellant. Paragraph [0070] of the patent in suit does not give any indication either that the definition is supposed to encompass a single-component catheter. In E4, only tip 122 may be equated to a catheter component which is *coupled* to the catheter shaft distal end, as defined in claim 1.

4.2 In the balloon catheter of E4, the distal waist portion of the balloon is attached to the distal end of the shaft (102) (sentence bridging columns 10 and 11), rather than *to the tip* as required by claim 1 (feature 0.3.6 mentioned by the parties). From this it

follows, moreover, that in E4 the tip main shaft portion is not *substantially coextensive* with the balloon, as also required by claim 1 (feature O.3.7 mentioned by the parties).

Furthermore, in E4 the catheter tip (122) does not comprise the claimed *plurality of recessed portions* (feature K mentioned by the parties). In fact, Figure 4 of E4 shows that the catheter tip 122 has just one recessed portion into which a radiopaque marker ring 124 is embedded (column 11, lines 6 to 7). Contrary to the appellant's view, Figure 4 shows that the additional recessed portions provided for embedding reinforcement layers (112, 114) are arranged not on the catheter tip (122) but on the catheter shaft (102) to which the tip is coupled or attached.

The appellant equated also the liquid perfusion ports or holes near the distal end 5 of the outer catheter sheath in the (alternative) embodiment of Figure 1 (column 10, lines 4 to 12) to the claimed feature of recessed portions of the catheter tip. The Board finds this argument likewise unconvincing. Recessed portions of a catheter should be seen to be, within the normal technical meaning of the expression, set-back, depressed or indented small spaces of a catheter. Hence, the longitudinal liquid perfusion ports or holes of E1 do not fall under the term "recessed portions" in claim 1.

- 4.3 In view of these differences with respect to E4, the Board concludes that the subject-matter of claim 1 is novel, so that the requirements of Article 54 EPC are fulfilled.

5. *Inventive step - Article 56 EPC*

5.1 The appellant considered the embodiment of the catheter of Figure 3 of E1 to be the closest prior art. In this embodiment, the tubular member 3 is composed of two different materials for the proximal part 4 and the distal part 5, respectively. These parts are coupled at zone 10 which, according to page 5, last paragraph, may lie at the proximal side of balloon 7. Thus, the proximal part 4 equates to the claimed "catheter shaft", whilst the distal part 5 equates to the claimed "catheter tip". Hence, in the terminology of the claim, the balloon distal waist portion is attached to the catheter tip distal shaft portion and the balloon proximal waist portion is coupled to an outer shaft 6. The distal part 5 is disclosed on page 5, last sentence as being highly flexible, providing the catheter with the necessary flexibility.

5.2 The catheter of claim 1 differs from that of Figure 3 of E1 in that the catheter tip comprises a plurality of recessed portions.

5.3 The appellant apparently considered that the technical problem to be solved consists in providing the catheter tip with recesses for different purposes. It also indicated that E4 suggested to the skilled person to provide the catheter with recesses for markers, stiffening elements or improvements for perfusion. Thus, the appellant concluded that the subject-matter of claim 1 lacked inventive step over the combination of E1 with E4.

5.4 In the Board's view, this line of argument falls short of a proper problem-solution approach showing that the

skilled person would have readily arrived at the claimed catheter by combining E1 with E4.

- 5.4.1 Firstly, the technical problem as formulated by the appellant already includes its solution. Therefore, it is not the correct objective technical problem formulated according to the problem-solution approach for analysing inventive step.
- 5.4.2 In this respect the Board notes that the patent in suit mentions specific effects which the distinguishing features have (point 3 above), such as providing a space for storing portions of the balloon when the balloon is in an uninflated state, which allows the catheter to have a lower profile, and providing the catheter tip with greater flexibility for bending about the longitudinal axis.
- 5.4.3 Document E4 discloses just a single recessed portion on the tip of E4 for housing a radiopaque marker (point 4.2 above), whereby E4 fails to disclose a catheter tip with a plurality of recessed portions, in particular with the purpose of increasing the tip's flexibility or storing portions of the uninflated balloon.
- 5.5 Therefore, it has not been shown that the skilled person would have combined E1 with E4 to solve a particular objective technical problem, and even if he did, he would have not arrived at the claimed subject-matter.

The Board therefore concludes that the subject-matter of claim 1 is not rendered obvious by the combination of E1 with E4.

5.6 As a consequence, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC. This applies a fortiori to the preferred embodiments of dependent claims 2 to 8.

6. It follows that none of the objections put forward by the appellant prejudices the maintenance of the patent in the form proposed in the decision under appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated