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Datasheet for the decision of 21 February 2013

Case Number: T 2403/10 - 3.2.08

Application Number: 99902265.0

Publication Number: 1047356

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Extendible stent apparatus

Patent Proprietor:
Advanced Stent Technologies, Inc.

Opponent:
Trireme Medical, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 100(a)(b)(c), 54, 56, 84, 83, 123(2)(3), 114(1)(2)
RPBA Art. 12(4)

Keyword:
"Admission of late-filed document (no)"
"Sufficiency of disclosure - Main Request - (yes)"
"Novelty and inventive step - Main Request - (yes)"
"Clarity and admissibility of amendment - Main Request - (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 2403/10 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 21 February 2013

Appellant: (Opponent)
Trireme Medical, Inc.
7060 Koll Center Parkway, Suite 300
Pleasanton, CA 94566 (US)

Representative:
Kazi, Ilya
Mathys & Squire LLP
120 Holborn
London EC1N 2SQ (GB)

Respondent: (Patent Proprietor)
Advanced Stent Technologies, Inc.
Suite A
4070 Nelson Avenue
Concord, CA 94520 (US)

Representative:
Hermann, Gerhard
Vossius & Partner
Siebertstraße 4
D-81675 München (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 8 October 2010 rejecting the opposition filed against European patent No. 1047356 pursuant to Article 101(2) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 8 October 2010 the opposition division rejected the opposition against European patent No. 1 047 356.

II. On 2 December 2010, the appellant (opponent) lodged an appeal against this decision, paying the appeal fee on 7 December 2010.

The statement setting out the grounds of appeal was received on 18 February 2011. The appellant argued that the patent as granted contravened Articles 100(a), (b) and (c) EPC and that disregarding document D0, which was not admitted by the opposition division since it was late-filed and held to be irrelevant, represented a substantial procedural violation.

III. In an official communication of 19 October 2012 annexed to the summons to oral proceedings, the Board gave its provisional view on the case. Particular reference was made to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA), according to which it is within the Board's discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings.

Oral proceeding took place before the Board on 21 February 2013. The following requests were made:

The appellant requested that

- the decision under appeal be set aside and
- the patent be revoked.

The respondent (patent proprietor) requested that

- the decision under appeal be set aside and
- the patent be maintained on the basis of claims 1 to 12 of the main request or, alternatively, on the basis of claims 1 to 11 of the auxiliary request, both filed at the oral proceedings.

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

"A stent for placement in a bifurcated body lumen having a main branch (12) and a side branch (15), said stent comprising:

a main tubular stent body having a proximal end (26), a distal end (28), a lumen therethrough, and at least one side opening (16) located between the proximal end (26) and the distal end (28), said side opening has a plurality of laterally deployable elements (38) disposed around said side opening (16), wherein upon expansion of an expandable portion of the stent comprising the laterally deployable elements, the laterally deployable elements extend outwardly from the tubular stent body and inwardly into the side branch, **characterized by** that prior to expansion, the laterally deployable elements are aligned in a tubular envelope defined by the tubular stent body."

V. The following documents have played a role for the present decision:

D0 WO-A-97/45073;
E1: WO-A-97/41803;

E2: US-A-5 617 878;
E3: EP-A2-0 804 970 and
E8: WO-A-96/34580.

VI. The appellant's arguments relevant to the present decision can be summarized as follows:

Articles 84, 123(2), 123(3) EPC; admission of the main request on appeal

The objections under Articles 84 and 123(2) EPC to the terms "disposed about" and "upon expansion" featuring in claim 1 as granted were already raised during the opposition proceedings and thus had been known to the respondent a very long time. The amendments to the granted claims in the appeal proceedings to overcome these objections could have been presented much earlier by the respondent and, therefore, the revised set of claims submitted at the oral proceedings should be rejected by the Board as late-filed.

Replacing the term "disposed about" featuring in claim 1 as granted by "disposed *around*" in revised claim 1 infringed Article 123(3) EPC since "disposed *around*" had a different meaning.

Moreover, the wording "upon expansion of *an expandable portion of the stent comprising the lateral deployable elements*" was unclear in its meaning and misleading, since any portion of the stent or the whole stent was expandable. Thus, the requirements of Article 84 EPC were not met by revised claim 1.

The scope of claim 1 also covered an "automatic" deployment of the laterally deploying elements simply when any unspecified part of the stent was expanded, a fact that was not disclosed in the application as originally filed. Rather, as only set out on page 5, lines 13 to 15 of the application as filed, the expandable portion (38) comprising the laterally deploying elements was extended into the branch vessel by inflation of a balloon which pushed the expandable portion outward radially and laterally to the side opening into the branch vessel. Moreover, the original application specified on page 5, lines 23, 24 that the deployable elements were "disposed around the side opening, as described above" (i.e. on page 4, lines 11 to 13), which meant that they were attached or coupled to a peripheral edge of the side opening. These features were, however, not included in claim 1. Hence, the subject matter of claim 1 of the main request was broader than justified by the application as filed and, therefore, contravened Article 123(2) EPC.

Given this situation, the amended set of claims submitted during the oral proceedings should not be admitted into the appeal proceedings.

Article 83 EPC:

Nothing in the description disclosed or suggested how a person of ordinary skill might implement deployable elements which extended "automatically" upon extension of the main stent or an extendable portion of the stent. Rather, the description merely disclosed using a separate balloon and failed to provide a detailed description of carrying out the claimed stent according

to this interpretation of the claims. Hence, the skilled person would not be able to put this invention into practice. Therefore, claim 1 contravened Article 83 EPC.

Admission of document D0 into the opposition proceedings and the appeal proceedings:

Document D0 was cited as category "X" in the European Search Report against original claims 1 to 8 and 15, which the opposition division considered as being the basis for the claims underlying the decision. Given both the appellant's clear verbal and graphic explanations and the EPO's earlier "X" categorisation supporting the appellant's detailed reasoning that document D0 was *prima facia* novelty-destroying, the opposition division declined to admit or consider this document, stating that it was not *prima facie* relevant. The opposition division's decision did not give reasons why the technical features of D0 referred to by the appellant were not relevant and, therefore, ignored. Having regard to Article 114(1) EPC, it was entirely objectively reasonable for the opposition division to review on its own motion whether the claims were distinguished at least from the original "X" documents from the European Search Report, in particular in the light of anything in the opposition which might have a bearing on the scope of the claims. Failure to admit D0 therefore ran contrary to the requirements of Article 114(1) EPC.

Article 54 EPC:

The subject matter of claim 1 was not novel over the technical disclosure of document E1. Figures 2 and 3 of E1 disclosed a bifurcation stent comprising a first and second section, the second stent section (55) having a side opening (slit or cut 58) located between the stent's proximal and distal ends. The side opening exhibited two laterally deployable elements (flaps 52, 53; E1, Figure 3) which extended outwardly from the tubular stent body and inwardly into the side branch (first stent 45). Before folding away the laterally deployable flaps 52 and 53 from the longitudinal cut 58 to expose the opening, they were aligned in the tubular stent body 55 (E1, Figures 2 and 3, page 12 last paragraph to page 13, line 20).

Moreover, Figure 16 of E1 disclosed a tubular stent body 100 having a side opening (intersection point) between the distal and proximal ends, the side opening comprising a plurality of laterally deployable elements.

The wording of claim 1 of the patent could be read to encompass the embodiment illustrated in Figure 12 of E1 showing a deployable right hand branch. It was clear from E1, Figure 12 that before implanting, the stent and the laterally deployable elements were aligned in a compressed tubular configuration which was extended when the stent was positioned at the diseased stenotic area of a vessel.

Furthermore, claim 1 lacked novelty over document E3, which was also concerned with an expandable bifurcated stent. Figures 17 and 18 and the accompanying text in

column 4, lines 41 to 45 and column 7, lines 49 to 55 disclosed a branch securing lip which was pushed outwards when opening 135 was enlarged and which corresponded to the laterally deployable elements of the claim.

Moreover, claim 1 was anticipated by document E2. In particular Figures 9 and 10 of document E2 disclosed a graft having a side opening. The terms "graft" and "stent" were interchangeable. Once the graft was in position, opening 38 was extended across the surface of the stent, as shown in Figures 10 and 11. A portion of the graft was extended outwardly from the graft and inwardly into the side branch. Thus, the extended opening 38 formed elements which were deployed laterally from the graft. Prior to expansion, the graft body, which became the opening extending into the side branch, formed part of and was aligned with the tubular graft body.

The subject matter of claim 1 also lacked novelty over document E8, which disclosed an expandable bifurcation stent illustrated in Figures 4 and 7. Prior to insertion into the vessel, the main stent 110, 120 was connected to a branch stent portion 140, which comprised a plurality of laterally deployable elements disposed around the side opening. As was apparent from Figure 5, main stent 110 and branch stent portion 140 were aligned in a tubular envelope 260 defined by the stent body.

Article 56 EPC:

Starting from document E3 as the closest prior art, the (single) side branch securing lip 180 in Figure 18 was equivalent to one of the laterally deployable elements of the claim. Confronted with the problem of providing a better security or stability when joining the second stent branch lumen 195, it was obvious for the skilled person to provide more than one, i.e. a plurality of lips or deployable elements around the side opening, which simply required a trivial manufacturing step.

The subject matter was, however, also obvious from the technical teaching of document E3 in combination with that of E2 which showed an expanded graft portion (opening 38) extending into the side vessel. No functional or practical difference existed between the laterally deployable elements of claim 1 and the expanded graft portion of E2 and the securing lip of E3. E2 further showed that the graft or stent was navigated to the diseased part of the vessel before opening 38 was created through the graft and then extended. The expandable opening was therefore aligned in the tubular envelope of the stent body, as required in claim 1 of the patent.

Consequently, the subject matter of claim 1 lacked inventive step in view of E3 in combination with the general technical knowledge of the person skilled in the art or, alternatively, with the technical disclosure of document E2.

VII. The respondent's arguments can be summarized as follows:

Articles 84, 123(2),(3) EPC:

The amendments to claim 1 were based on page 5, lines 23 to 25 and page 4, lines 11 to 19 and were provided in particular in response to the appellant's objections under Articles 84 and 123(2)(3) EPC. The term "disposed *around*" was narrower in its meaning than "disposed about" and thus did not contravene Article 123(3) EPC. The claims of the main request therefore should be admitted into the appeal proceedings.

Article 83 EPC:

It was visible in Figure 7 of the patent specification that prior to expansion, the laterally deployable elements were aligned in a tubular envelope defined by the tubular stent body. Upon expansion of the stent's expandable portion comprising the laterally deployable elements they were extended outwardly from the tubular stent body and inwardly into the side branch, for instance by using a balloon catheter as shown in Figures 8, 9, 13E and 13F. Hence, the claimed invention was described in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Articles 54, 56 EPC:

None of the documents considered upon appeal disclosed a stent having a side opening with a plurality of laterally deployable elements disposed around said opening. Given this situation, even when considering

the disclosure of E3 in combination with the general technical knowledge of a person skilled in the art or, alternatively, in combination with the graft described in E2, the skilled person would not arrive at the claimed stent since no incentive was given in any of documents E3 and E2 to provide a side opening with laterally deployable elements disposed around said opening.

The subject matter of claim 1 was therefore novel and involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments, Articles 123(2),(3); 84 EPC; admission of the amended set of claims

2.1 Claim 1 as granted is based essentially on the technical features set out in claims 1 to 3 as originally filed. Although original claim 3 refers back to original claim 2 and thus specifies that the laterally deployable elements are formed as an integral part of the tubular stent body structure, page 4, lines 15 to 19 of the original description also make it also clear that, alternatively, the deployable elements could be formed separately and subsequently attached by crimping, welding, folding or interference fitting. Hence, there is no need to restrict claim 1 as granted to the embodiment defined in originally filed claims 2 and 3.

2.2 Claim 1 as granted has been amended on appeal by
(i) including the term "wherein upon expansion *of an expandable portion of the stent comprising the laterally deployable elements* the laterally deployable elements extend outwardly from the tubular stent body" and
(ii) replacing the term "disposed about" by "disposed *around*" the side opening.

Amendment (i) has a basis in the passage bridging page 10, last paragraph to page 11, line 5 of the application as originally filed which states that, after positioning and affixing in place by radial expansion of the main stent 40, in a further step the (optional) expandable portion 38 of the main stent 40 is expanded radially in an at least partially perpendicular manner to the sides of the main stent side opening 16, as shown in Figure 8. Amendment (i) thus defines that the deployable side elements are not laterally extended simply by expanding any part of the stent body.

The wording (ii) "disposed *around* the side opening" is literally found on page 5, lines 23 to 25. In the Board's understanding the term is narrower in its meaning than "disposed about the side opening" and, therefore, represents a limitation rather than an enlargement of the scope of claim 1, contrary to the appellant's interpretation.

2.3 The amendments to claim 1 therefore satisfy the requirements of Articles 84 and 123(2),(3) EPC. Given that the amendments are aimed at overcoming the objections raised by the appellant under Articles 123

and 84 EPC and that they are easy to understand, the Board decided to admit the respondent's revised set of claims submitted at the oral proceedings.

3. Sufficiency of disclosure, Article 83 EPC

3.1 Article 83 EPC stipulates that the application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Contrary to the appellant's view, sufficiency of disclosure within the meaning of this Article is not confined to the claims, but must be assessed on the basis of the application as a whole, including the description, claims and figures - supplemented by the common general knowledge of the person skilled in the art. According to the established jurisprudence of the boards of appeal (Case Law, 6th edition, 2010, II.A.3 b), c), 4.1 and 4.2), the requirements of Article 83 EPC are satisfied if it is possible to reproduce the claimed product, i.e. in the present case the claimed stent, using the original application documents without any inventive effort over and above the ordinary skills of a practitioner.

According to Rule 42(1)(e) EPC, the description must describe in detail at least one way of carrying out the claimed invention, using examples where appropriate and referring to the drawings, if any.

3.2 In the present case, it is undisputed that the description of the patent in suit discloses working examples of the claimed stent, which are illustrated in Figures 7 to 9 and 13E to 13H. The accompanying text on page 10, last paragraph to page 11, line 25 and on

page 14, last paragraph to page 15, line 25 of the application as filed (paragraphs [0035], [0036] and [0047] of the patent specification) describes in detail that during affixing the stent body by expansion in the blood vessel, the laterally deployable elements remain aligned in the tubular sheath defined by the tubular stent body. Then, in a further step, the deployable elements disposed around the side opening are extended laterally, for example by a balloon catheter which is advanced into the side opening 102 so that the balloon 502 can expand within the side opening 102 to open and extend laterally the deployable elements (loops 106), as is illustrated for example in Figures 13E and 13F.

On the basis of the detailed technical information which the patent specification provides, the person skilled in the art is able to put into practice the extendible stent apparatus defined in claim 1. Therefore, the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and therefore meets the requirements of Article 83 EPC.

4. Admission of document D0 into the appeal proceedings

4.1 Document D0 was filed during the opposition proceedings but after the nine-month opposition period. The claims as granted being unchanged, the opposition division considered D0 as being late-filed and not prima facie relevant to the subject matter of claim 1 then on file. Hence, D0 was not admitted by the opposition division.

4.2 If an opposition division did not take into consideration late-filed documents under Article 114(2)

EPC, during appeal it has to be assessed whether the opposition division exercised its discretion correctly.

It is evident from point 2 of the minutes of the oral proceedings before the opposition division that the technical disclosure of D0 was discussed by the parties and assessed by the opposition division. The appellant referred in particular to Figure 12 of D0 and argued that this embodiment disclosed the features of claim 1 and therefore was *prima facie* relevant. After deliberation, the chairman of the opposition division announced that the technical disclosure of D0 was considered as being not prima facie relevant and, consequently, D0 was disregarded in the opposition proceedings.

Contrary to the appellant's position, the opposition division gave in paragraph 2.2 of the impugned decision detailed reasoning as to why document D0 was considered not *prima facie* relevant. In particular it was held that Figure 12 or page 3, lines 14 to 19 of D0 only disclosed component stents to be placed in a bifurcated configuration in a branched vessel in order to provide substantially continuous support for the vessel and the region of the vessel junction. The opposition division further reasoned that the bifurcation stent described in document D10 did not disclose laterally deployable elements disposed around the side opening of the stent and which were aligned in a tubular envelope defined by the tubular stent body prior to expansion.

It is, therefore, evident from the minutes and the decision of the opposition division that the appellant was given adequate time and opportunity to make

representations on the technical disclosure of document D0 and its relevance with respect to the subject matter of claim 1 as granted and that the impugned decision gives reasons as to why D0 was rejected.

Having considered the appellant's arguments and comments on D0 at the oral proceedings on appeal, the Board cannot see any reason to go against the opposition division's assessment of the technical disclosure of D0 and sees no justification either for the contention why the opposition division exercised its discretion incorrectly in deciding not to admit D0 into the opposition proceedings. The Board therefore considers it appropriate to make use of its discretion under Article 12(4) RPBA not to admit document D0 into the appeal proceedings.

It is also noted that, when assessing the grounds of opposition and the evidence and arguments submitted by the parties in support of these grounds, the opposition division is not obliged to reconsider prior art documents rated "X" in the European Search Report unless the parties have referred to such prior art.

5. Novelty; Article 54 EPC

Document E1:

As to document E1, the appellant referred to Figures 2, 3, 12 and 16 and the accompanying text.

Although opening 54 in Figure 3 represents a side opening, which is created by folding outwardly flaps 52, 53 away from the longitudinal cut 57 shown in Figure 2,

there is no disclosure of a stent which comprises laterally deployable elements (flaps) around a side opening and that prior to expansion the elements are aligned in a tubular envelope defined by the stent body. Contrary to the claimed stent, opening 54 in Figure 3 of E1 is only created by folding the pair of flaps 52, 53 away from the longitudinal cut 57.

Figure 12 of E1 illustrates a bifurcated passageway 150 comprised of a proximal passageway 155 and two distal passageways 160, 165. Contrary to the appellant's view, there is no side opening between the proximal and distal ends of a stent body, having laterally deployable elements disposed around the side opening.

The stent depicted in E1, Figure 16 has a proximal end 102 (primary passageway 103) and a distal end 104 comprising a pair of secondary passageways 105, 106. Primary and secondary passageways are connected at intersection point 107 by first and second connection tabs 111 and 113, shown in Figure 18. There is no disclosure whether the loops extending from the intersection point 107 into the secondary passageway 105 (E1, Figure 16) are aligned in a tubular envelope defined by the stent body prior to expansion, as claim 1 of the patent requires.

Document E2:

The main stent body according to E2 is formed by a graft, typically made of Dacron (E2, column 4, lines 43 to 55). A laser cautery device 10 is positioned by the surgeon at the visualized point of intersection between graft 33 and renal artery 29 and an opening 38 is cut

through the graft at the point of intersection (E2, Figures 9, 10). Thereafter, the opening is extended across the surface of stent 17. However, the known graft does not comprise deployable elements disposed around a side opening and which, prior to expansion, are aligned in the tubular envelope defined by the tubular stent body. Thus the technical concept of the graft disclosed in E2 is entirely different from the stent claimed in the patent in issue.

Document E3:

The embodiment shown in Figures 17 and 18 and described in column 7, lines 53 to 55 of E3 discloses a stent having a side opening (branch aperture 135) which is pushed outward to form a branch securing lip 180 to engage with the second branch lumen 195 (E3, Figure 18). However, the known stent does not disclose a plurality of laterally deployable elements disposed around the side opening and aligned in a tubular envelope defined by the tubular stent body prior to expansion. Contrary to the appellant's position, side branch securing lip 180 is a portion of the main stent and cannot be considered to represent a (single) separate deployable element before the enlargement of branch aperture 135. Hence, no laterally deployable element is present in the known stent prior to expansion, as required by claim 1.

Document E8:

E8 discloses a bifurcated endoprosthesis comprising a proximal section 110 and two distal tubular sections 120, 140 as well as two connectors 130, 150 (E8,

claim 1). However, a tubular main stent body having a proximal and distal end and at least one side opening located between both ends cannot be identified in E8. Even if the proximal section 110 of the stent is provided with chamfer 115, which could be regarded as representing a side opening according to claim 1 of the patent, this opening does not comprise a plurality of the laterally deployable elements disposed around said opening.

Given that none of the documents E1 to E3 and E8 anticipates the claimed stent, the subject matter of claim 1 is novel.

6. Inventive step:

6.1 E3 and common general knowledge

As previously mentioned, E3 discloses in column 7, lines 53 to 55 that "as the branch aperture 135 is enlarged, a portion of the stent defining the aperture 135 is pushed outward to form a branch securing lip 80". The appellant argued that faced with the problem of obtaining a better stability and security between the first and second leg portion, the skilled person would, by a trivial manufacturing step, provide more (i.e. a plurality of) securing elements in the form of laterally deployable elements.

However, no incentive is discernible for the skilled person to provide aperture 135 with surrounding separate laterally deployable elements, which upon expansion of the expandable portion of the stent comprising these deployable elements, extend outwardly

from the tubular stent body. Arguing in that way could be done only on the basis of hindsight. It is also noted that compared with the single securing lip shown in the stent of E3, which is a relatively simple construction, elaborate re-designing of the side opening would have been required to provide the stent's side opening according to E3 with (separate) laterally deployable elements of the claimed stent, which are folded outwardly e.g. by inflation of a balloon inserted in the side opening.

6.2 E3 and E2

As opposed to the stent of E3 having a (single) branch securing lip, the (Dacron) graft described in E2 exhibits an opening 38 which has been extended across the surface of the stent. However, neither E3 nor E2 provides a plurality of laterally deployable elements which are disposed around the side opening, which, prior to expansion, are aligned in a tubular envelope of the stent body and which, upon expansion of the stent's expandable portion comprising these elements, extend outwardly from the tubular stent body.

Hence, the combined teaching given in documents E3 and E2 would not lead to the claimed stent in an obvious way.

6.3 Consequently, the subject matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the following documents:

   Claims 1 to 13 according to the main request filed at the oral proceedings;

   Description, columns 1 to 13 as granted;

   Figures 1 to 13H as granted.

The Registrar: The Chairman:

V. Commare T. Kriner