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D E C I S I O N
of 2 February 2000

Case Number: T 1185/97 - 3.2.2

Application Number: 91918408.5

Publication Number: 0506918

IPC: A61M 29/00

Language of the proceedings: EN

Title of invention:

Self-expanding endovascular stent

Patentee:

SONG, Ho Young

Opponent:

WILLIAM COOK EUROPE A/S

Headword:

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Relevant legal provisions:

EPC Art. 56, 84, 123(2), 111(1)

Keyword:

"Late-filed request not clearly allowable (refused)"
"Inventive step (no)"

Decisions cited:

T 0153/85, T 0840/93

Catchword:

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D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 2 February 2000

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

Representative: Von Hellfeld, Axel, Dr.Dipl.-Phys.
Wuesthoff & Wuesthoff
Patent- und Rechtsanwälte
Schweigerstrasse 2
D-81541 München (DE)

Respondent: SONG, Ho Young
(Proprietor of the patent) 803, Keosung Kosok-mansion
1168-2, Jinbuk-dong
Cheonju-si
Cheonrabuk-do 560-160 (KR)

Representative: Meissner, Peter E., Dipl.-Ing.
Meissner & Meissner
Patentanwaltsbüro
Postfach 33 01 30
D-14171 Berlin (DE)

Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 10 November
1997 concerning maintenance of European patent
No. 0 506 918 in amended form.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
R. T. Menapace

Summary of Facts and Submissions

- I. Upon opposition by the appellant against the grant of European patent No. 0 506 918, the Opposition Division decided by interlocutory decision dated 10 November 1997 to maintain the patent in amended form.
- II. The appellant lodged an appeal on 10 December 1997 against this decision and paid the appeal fee on the same day. In its statement of grounds filed on 3 March 1998 the appellant objected, in addition to inadmissible extension of the subject-matter of claims 1, to lack of inventive step vis-à-vis the state of the art considered during the opposition proceedings and supplemented by three newly cited documents.
- III. The respondent (patent proprietor) replied to the appellant's contention by a letter dated 20 July 1998 and filed an amended claim 1, in which the last words "or urethane resin" were deleted to overcome the appellant's previous objection to extension.
- IV. In a communication dated 1 October 1999 sent following a summons to oral proceedings, the Board of Appeal informed the parties of its intention to focus the discussion on the inventive step of claim 1 having regard, in particular, to the disclosure in prior art documents:

D3: "Modified Gianturco expandable wire stents in experimental and clinical use" by J. ROSCH et al, Ann. Radiol. 1988, 31, No. 2, pages 100 to 103, and

D1: "Expandable Esophageal Metallic Stents Coating with Silicon Rubber", Journal of Korean Radiological Society, 26(5), pages 829 to 834, 1990.

D1A: English translation of D1.

- V. By letters dated 22 November 1999 and 12 January 2000, the parties brought additional arguments and filed further new documents in support thereof.
- VI. Oral proceedings were held on 2 February 2000 in the course of which the respondent filed amended claims according to a main and an auxiliary request, in replacement of claim 1 previously on file (see point III) and discussed at the very beginning of the oral proceedings. Should either of these new requests not be admitted by the Board, the respondent requested that it should be given a new opportunity to stand again by said previous claim 1 (called in the following "fall-back version").
- VII. Claim 1 according to the said fall-back version reads as follows:

"A stent comprising: a cylindrical frame (20) formed by a plurality of unit structures (21,22,23,24); each of said structure (21-24) being formed into a closed zig-zag configuration including an endless series of straight sections (111), joined by bends (112,212), and adjacent one another along the axis of the stent; connecting members, which connect said unit structures (22-24); anti-migration members (42,44), which have the same structure as said unit structures, and placed in

the ends of the upper and lower portions of said frame, wherein said anti-migration members (42,44) have larger diameters than the diameter of said frame (20), and are connected to said frame (20) by second connecting members (36,38), a mesh (91) which is wrapped whole around the outside of said frame (20) and the anti-migration members (42,44), wherein said mesh is coated with silicon rubber."

Claim 1 according to the main request differs from the above fall-back version by the incorporation of the words "in tandem" after the words "said unit structures (22-24)" at line 8 and by the incorporation of the features "whereby expansible parts (342) of the anti-migration members (42, 44) expanded from horizontal parts (341) and bended vertically" after the words "connecting members (36, 38)" at line 14.

Claim 1 according to the auxiliary request differs from the main request in replacing the above features (second incorporation) by the features "wherein the second connecting members (36, 38) consist of vertical parts (34, 341) and expansile parts (34, 342)."

VIII. During oral proceedings the parties argued as follows:

(i) The appellant:

- Document D3 discloses an expandable stent having all structural features recited in claim 1 of the fall-back version, with the exception of the last features according to which a mesh coated with silicon rubber is wrapped whole around the outside of the cylindrical frame and the anti-

migration members. Since, however, document D1 (English translation D1A) recommends the use of nylon meshed and silicon coated stents to treat malignant obstruction due to tumour ingrowth, the subject-matter of claim 1 is suggested by the combination of documents D3 and D1.

- The new main and auxiliary requests submitted by the respondent during the oral proceedings were filed late without any proper justification for such very late filing. Consequently, they should be disregarded already for this reason.

- Moreover, although the amendments brought to claim 1 according to the main or the auxiliary request have a counterpart in the patent specification, such amendments are not clear, grammatically and semantically incorrect and finally lead to improper extension of the claimed subject-matter beyond the content of the application as filed. In particular, parts 341 of the anti-migration members are contradictorily said to extend sometimes in the horizontal, sometimes in the vertical direction. All in all, the late filed amendments are not immediately allowable.

(ii) The respondent:

- In document D3 the conical skirts at the ends of the stent protrude conically, whereas the anti-migration members according to the invention are connected stepwise to the cylindrical body, so as to prevent with more efficiency any stent

displacement. (To this end, a sample of the patented stent was demonstrated during the oral proceedings.) Document D1 simply describes a uniform cylindrical stent coated with silicon rubber. It does not disclose, however, the further coating of the anti-migration members of larger diameter at both ends of the cylindrical body. As a consequence, this feature is not suggested.

- The new requests were filed in order to distinguish more specifically the claimed features from the state of the art, in particular having regard to the second connecting members for connecting the anti-migration members to the ends of the cylindrical main frame. These amendments were filed late, but due to communication and translation difficulties with the Korean client they should be admitted in the proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments and admissibility of the different requests*
 - 2.1 With respect to the version as maintained by the Opposition Division, claim 1 according to the fall-back version only differs in that the last words "or urethane resin" have been removed. Such deletion is admitted because the removed expression was neither present in the application as filed nor in claim 1 as

granted.

Moreover, this version is not regarded as late-filed since claim 1 as amended above was filed by the respondent at the very beginning of the appeal proceedings and in response to appellant's objection made in the statement of grounds. Therefore, this request is considered by the Board.

- 2.2 The main and auxiliary requests were submitted by the respondent in the course of the oral proceedings, after the previous version (fall-back) had been discussed. According to the constant Case Law of the Boards of Appeal (see in particular T 153/85, OJ EPO 1988, 1, point 2.1 and T 840/93, OJ EPO 1996, 335), late-filed requests can only be considered at a very late stage if they are clearly allowable.

In the present case, the amendments made to claim 1 of these requests give cause for additional objections as to clarity and adequate support under Articles 84 and 123(2) EPC, although, corresponding passages can be found in the description:

In claim 1 of the main request, the added expression "whereby expansible parts (342) of the anti-migration members (42, 44) expanded from horizontal parts (341) and bended vertically" is to be found in column 6, lines 23 to 25 of the patent specification.

In claim 1 of the auxiliary request, the added expression "wherein the second connecting members (36, 38) consists of vertical parts (34, 341) and expansile parts (34, 342)" is based on claim 7 as granted, which

in turn is identical to claim 7 as originally filed.

However, the above incorporated features refer to parts 341 of the anti-migration members which are said to be directed horizontally in one place of the description (claim 1 to the main request; description column 6, line 24; Figure 4) and vertically according to another (claim 1 of the auxiliary request; claim 7 as granted; claim 2 under appeal). When this contradiction was recognised by the respondent at the oral proceedings, it requested to be allowed to present even further amendments to the claims.

Moreover, the Board cannot recognise in how far the "expansible parts 342" according to the main request ("expansile" in the auxiliary request), are suitable to contribute to the expansion capabilities of the different cylindrical parts of the stent, since expansion is produced by the zig-zag configuration of the unit structures, of which parts 342 of the connection members are excluded. As was rightly explained in the application as originally filed (cf. page 11, lines 27 to 29), the diameter of the anti-migration members 44 depends on the length of horizontal parts 341 of the second connecting members 34. It results therefrom that parts 342 play no role in the diameter after expansion of the anti-migration members.

Despite numerous more or less appropriate corrections made in the patent description during the previous proceedings, the different structural parts of the stent and their respective functions are still neither clearly identified nor defined, so that the subject-

matter of claim 1 as a whole is neither clear nor unambiguously based on the description. Since the amendments brought to claim 1 according to either the main or the auxiliary request are not *prima facie* allowable, the late-filed requests are not admitted at this late stage of the proceedings (see Case Law, 3rd edition 1998, page 506).

Consequently, the fall-back version of the claims has to be examined as to its merits.

3. *Closest prior art and novelty*

3.1 Document D3 represents the closest prior art document. Using the terminology of claim 1 as it stands (fall-back version), document D3 discloses (cf. Figure 1) an expandable stent comprising a cylindrical frame formed by a plurality of unit structures, each formed into a closed zig-zag configuration, including an endless series of straight and bends sections (Figure 1A). Connecting members (monofilament lines) are provided for connecting adjacent unit structures (page 100, right column and page 101, right column, 2nd paragraph). Further, anti-migration members in the form of frusto-conical skirts having the same zig-zag configuration as that of the unit structures (Figure 1C) and diameters larger than the diameter of the central frame, are connected to both ends thereof by additional connecting members (monofilament lines). As explained in the left column of page 101, the function of the skirts is, among others, to prevent stent dislodgement, which is facilitated by the overall expanded diameter of the stent (page 101, right column, 2nd paragraph).

3.2 With respect to the disclosure of document D3 the subject-matter of claim 1 differs by the two last features namely:

- a mesh is wrapped whole around the outside of said frame and the anti-migration members,
- said mesh is coated with silicon rubber.

3.3 Since no other document than D3 comes closer to the subject-matter of claim 1 in suit, it must be regarded as novel within the meaning of Article 54(1) EPC.

4. *Inventive step*

4.1 The above distinguishing features, which relate to a mesh wrapped around the stent and coated with silicon rubber represent the solution to a technical problem which is more restricted than that originally defined, namely to prevent cancer cells from penetrating into the stent (patent, column 2, lines 8 to 10 and column 4, lines 14 to 17, the latter passage having been deleted from the patent specification in the version of the decision under appeal).

4.2 The Korean document D1 (see English translation D1A originating from the patentee itself and annexed by the appellant to the statement of grounds of opposition) discloses an expandable esophageal stent made of stainless-steel wire formed in a zig-zag pattern (top of pages 1 and 2). The stent is said to be made by the same method as that of Gianturco (page 1, last paragraph) which is also referred to in document D3 (page 100, left column), then covered by a nylon mesh

coated with silicon rubber, in order to prevent malignant obstruction due to tumour ingrowth (bottom of pages 6 and 7).

Faced with the above mentioned problem of avoiding tumour proliferation into the stent, the skilled person would immediately consider to use the solution proposed in document D1 which appears to be perfectly appropriate. In document D1 as in the contested patent (column 4, lines 2 to 3) the mesh is made of nylon (although not claimed) and coated with silicon. The same structure and the same materials will necessarily result in the same technical effects, the more since both stents are designed for the same application to the esophagus. Besides, the Board observes that the features now under consideration were originally considered as optional by the use of the introductory terms "It is preferable that" placed just before the features characterising the mesh (cf. column 4, lines 1 to 2). Although these terms were subsequently deleted from the description, they are still indicative of the cursory nature of said features.

The respondent's argument that document D1 does not suggest the provision of enlarged silicon coated anti-migration members at both ends of the central body is not convincing, since a proper assessment of document D1 does not require the consideration of the anti-migration members which were already known from the closest prior art document. On the other hand, a meaningful interpretation of document D1 requires that the mesh proposed therein must necessarily wrap the stent in its entirety, whatever its shape, in order to achieve full protection against obstruction by tumour

ingrowth.

Considering now that the general problem of avoiding ingrowth and proliferation of undesirable tissue inside the stent lumen so as to maintain its efficiency, was already referred to in document D3 (page 102, left column), such indication is regarded by the Board as a link between documents D3 and D1, which suggests the combined consideration of their disclosure

- 4.3 For the foregoing reasons, the Board is satisfied that the subject-matter of claim 1 according to the fall-back version lacks an inventive step, contrary to the requirements of Article 56 EPC.

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:

S. Fabiani

W. D. Weiß