

Internal distribution code:

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

**Datasheet for the decision
of 6 March 2008**

Case Number: T 0239/06 - 3.2.02

Application Number: 99918770.1

Publication Number: 0981385

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:

Stent deploying catheter system and balloon catheter

Applicant:

Advanced Cardiovascular Systems, Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 54

Keyword:

"Novelty (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0239/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 6 March 2008

Appellant: Advanced Cardiovascular Systems, Inc.
P.O. Box 58167
Santa Clara CA 95052 (US)

Representative: Molnia, David
df-mp
Fünf Höfe
Theatinerstrasse 16
D-80333 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 21 September 2005
refusing European application No. 99918770.1
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
M. Vogel

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 17 November 2005 against the decision of the examining division posted on 21 September 2005 to refuse the application. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 30 January 2006.
- II. The examining division held that the patent application did not meet the requirement of Art. 54 EPC (lack of novelty) having regard to
- D18 = US - A - 5 409 495.

- III. Oral proceedings took place on 6 March 2008.

The appellant requested that the decision under appeal be set aside and that a European Patent be granted on the basis of claim 1 as filed with letter of 22 July 2004 and claims 2 - 7 as filed with letter of 15 December 2003. Moreover he requested that the matter be remitted to the first instance for further examination in case that the board should find the subject-matter of claim 1 to be novel.

- IV. Claim 1 reads as follows:

"An intravascular catheter system for implanting a stent in a patient's body, comprising:
a) a catheter (10) having an elongated shaft (11) with proximal and distal ends and an inflation lumen (21) extending within at least a portion of a distal shaft section (13) to a location spaced proximally from the

distal end, the catheter (10) being characterized in that

b) an essential wingless radially expansive uninflated compliant balloon (14) formed of polymeric material is mounted on the distal section (13) of the catheter shaft (11) which has a proximal and distal portion sealingly secured to an outer surface of the catheter shaft (11) which has an interior chamber (15) in fluid communication with the inflation lumen (21) and which is inflatable to an expanded state; and with

c) an expandable stent (16) disposed about and mounted onto the essentially wingless uninflated balloon (14), so that radial expansion of the balloon (14) expands the stent (16) mounted thereon and implants the stent (16) in the body."

V. The appellant argued as follows:

The subject-matter of claim 1 differed from the catheter system according to D18 in that the balloon was essentially wingless.

D18 did neither explicitly no implicitly disclose a wingless balloon. Certainly, D18 did not explicitly disclose a balloon having wings either. However, since at the filing date of D18 usually winged balloons had been used, it had to be concluded that the balloon shown in D18 had also wings. This conclusion was supported by the fact that lubrication was placed between all the interfacing surfaces of the restraining bands, balloon and sleeves (see D18, column 5, lines 20-25), which obviously was provided in order to reduce the friction between the balloon and the bands or sleeves during unfolding of the wings.

The statement in D18, column 4, lines 20 to 23, according to which the sleeve and/or bands ensure that the balloon will deflate into a uniform, round balloon, and not into an undesirable flat or pancake shape, known as balloon winging did not mean that the balloon of D18 was essentially wingless. A winged balloon in the sense of the invention was a balloon having prearranged longitudinal local foldings circumferentially distributed over the balloon surface and not just a balloon which could be flattened during deflation. Therefore the balloon according to D18 could have wings although balloon winging during deflation had to be avoided.

Consequently, D18 did not clearly and directly disclose an essentially wingless balloon and the subject-matter of claim 1 was novel.

Reasons for the Decision

1. The appeal is admissible.
2. *Novelty*
 - 2.1 D18 explicitly discloses (see in particular Figures 1 and 2) an intravascular catheter system for implanting a stent in a patient's body, comprising:
 - a) a catheter (20) having an elongated shaft (21) with proximal and distal ends and an inflation lumen (28) extending within at least a portion of a distal shaft section to a location spaced proximally from the distal end,

- b) a radially expansive uninflated compliant balloon (22) formed of polymeric material (see column 5, lines 32 - 34) mounted on the distal section of the catheter shaft which has a proximal and distal portion sealingly secured to an outer surface of the catheter shaft (see column 5, lines 32 - 36) which has an interior chamber in fluid communication with the inflation lumen and which is inflatable to an expanded state (see Figure 2); and
- c) an expandable stent (25) disposed about and mounted onto the uninflated balloon, so that radial expansion of the balloon expands the stent mounted thereon and implants the stent in the body.

The question to be answered is therefore whether or not D18 additionally discloses that the balloon is essentially wingless.

On the basis of the description of the present patent application (see in particular page 6, lines 10 to 20) the term "wings" has to be interpreted as any kind of longitudinal creases or foldings present in the deflated balloon.

According to D18, column 4, lines 20 to 26, the sleeve and/or bands ensure that the balloon will deflate into a uniform, round balloon, and not into a undesirable flat or pancake shape known as "balloon winging".

The fact, that the balloon according to D18 deflates into a uniform, round balloon excludes that the balloon has any kind of longitudinal creases or foldings after deflation. Since this is only possible when the balloon is also uniform and round before it is inflated, D18

discloses at least implicitly that the balloon is an essentially wingless balloon.

2.2 The appellant's argumentation that this feature is not disclosed in D18 is not convincing. Even if it was true that at the filing date of D18 usually winged balloons have been used (which has not been sufficiently proven), this does not mean that also the balloon of D18 inevitably must be a winged balloon. Also the fact, that lubrication is provided between the balloon and the sleeves and restraining bands does not allow concluding that the balloon has wings. There is no statement in D18 which shows that lubrication is provided for reducing the friction between the balloon and the bands or sleeves when wings are unfolded, and the provision of lubrication is also suitable for example to allow relative movement between the balloon and the sleeves or bands when these elements made of different materials are stretched during inflation. Finally the appellant's view that the expression "uniform, round balloon" would also encompass a winged balloon where the folds are uniformly distributed around the balloon surface cannot be shared by the board, since the terms "uniform" and "round" clearly exclude a shape which is not uniformly round as would be the case for a winged balloon. Moreover it is not likely that the deflation of the balloon results in uniformly distributed folds around its surface.

Therefore the board is convinced that all features of claim 1 are disclosed by D18.

Accordingly claim 1 is not novel.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner