

United States District Court,
D. Delaware.

SCIMED LIFE SYSTEMS, INC., Boston Scientific Scimed, Inc., Boston Scientific Corporation and Medinol, LTD,
Plaintiffs.

v.

JOHNSON & JOHNSON, Cordis Corporation and Johnson & Johnson Interventional Systems, Inc,
Defendants.

Civil Action No. 99-904-SLR

Aug. 15, 2001.

Josy W. Ingersoll, Young, Conaway, Stargatt & Taylor, Wilmington, DE, for Plaintiffs.

Steven J. Balick, Ashby & Geddes, Wilmington, DE, for Defendants.

ORDER

SUE L. ROBINSON, **Judge.**

At Wilmington this 15th day of August, 2001, having heard oral argument on the papers submitted in connection with claim construction issues; and having reviewed the patents' drawings, specifications and claims with a view to ascertaining the invention; FN1

FN1. The '303, '120 and '018 patents share the same drawings and essentially the same specification.

IT IS ORDERED that the disputed claim language in the '303, '120 and '018 patents, as identified in the papers, shall be construed as follows, consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit:

1. The '303 Patent-Claim 6

a. "Stent." A device, made of a body-compatible material, used to widen a blood vessel or other body opening (also called a "lumen"), and to maintain the resultant size of the blood vessel or lumen. (Col.1, lns.13-17)

b. "Cell." An arrangement of structural elements that defines an enclosed space. (*Webster's Third New Int'l Dictionary* 359 (1993))

c. "**Member having a longitudinal component.**" A "member" is a structural element that has its ends at

different longitudinal positions with respect to the stent's longitudinal axis. A member's "longitudinal component" is the distance between the longitudinal positions of the first and second ends of the member. (Col. 4, ln. 66 to col. 5, ln. 6)

d. **"Loop."** A structural element that turns back on itself. (*Webster's* at 1335)

e. **"First loop" and "second loop."** Horizontally-facing (or C-shaped) loops at the cell's two longitudinal ends. (Col.5, lns .6-13)

f. **"Disposed between."** Positioned in the space that separates structural elements. (*Webster's* at 209)

g. **"Disposed generally opposite."** The first and second loops, defined as horizontally-facing structural elements, are positioned across from each other and. approximately aligned with each other along the longitudinal axis of the stent. (Col.5, lns.6-13)

h. **"Flexible compensating member or flexible link."** A structural element that is flexible with respect to the stent's longitudinal axis and must be aligned along the longitudinal axis of the stent.FN2 (Col.5, lns.13-31)

FN2. The patents describe the invention as a stent designed to maximize longitudinal flexibility in the unexpanded state (*see, e.g.*, '303 patent, col. 3, lns. 38-45), and to minimize longitudinal foreshortening in the expanded state (*see, e.g.*, '303 patent, col. 1, lns. 52-54; col. 3, ln. 3 to col. 4, ln. 18). In order to accomplish these objectives, the patents describe the structural elements of the stent as being disposed to accommodate movement in two different and compensating directions, a generally vertical direction (*see, e.g.*, '303 patent, col. 2, ln. 63 to col. 3, ln. 2; col. 5, lns. 6-13) and a generally horizontal or longitudinal direction (*see, e.g.*, '303 patent, col. 3, lns. 3-7; col. 5, lns. 13-37). (*See also* D.I. 138, Ex. 3 at 00174) Further, the patents teach that the structural elements that accommodate movement in the longitudinal direction must be aligned along the longitudinal axis of the stent, as opposed to being diagonal, helical or spiral. (D.I. 137, Ex. 9 at 00059-60; D.I. 138, Ex. 3 at 00175-76) More specifically, the patentee distinguished the Palmaz '417 patent on the following grounds:

Applicants have also amended Claim 1 to include the limitations of Claim 3 to indicate that the links connect apices of adjacent cells of adjacent rigid segments. This is in contrast to Palmaz '417 and Cardon whose links are spiral-shaped and therefore, do not connect apices of adjacent segments. Instead, they connect the apex of a first cell on one segment with the apex of a second cell (of the second segment) which is shifted from the one which is adjacent to the first cell. (D.I. 137, Ex. 9 at 00059-60) Based on this language, the court concludes that a flexible compensating member or flexible link must connect adjacent cells, but that neither the prosecution history nor the specification require that the physical connection be made at points directly opposite each other. Nor is there support in the prosecution history or specification for the added limitation suggested by defendants that the flexible compensating members or flexible links run parallel to each other (i.e., equidistant at all points) rather than merely lengthwise or in a longitudinal direction. *See, e.g.*, *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, No. 00-1454, 2001 WL 877575, at (Fed.Cir. Aug. 6, 2001).

i. **"Communicating with."** To have a common part, to be connected, join. (*Webster's* at 460)

j. **"Said first and said second ends disposed a variable longitudinal distance from each other."** The flexible compensating member or flexible link is positioned so that, upon expansion of the stent, the distance

between its two ends changes along the stent's longitudinal axis. (Col.5, Ins.38-62)

k. **"Disposed ... so as to substantially lessen the foreshortening of said stent upon its expansion."** This limitation encompasses an increase in the distance between the longitudinal positions of the ends of the flexible compensating members or flexible links that is caused by expansion of the stent by a balloon or other mechanical means.FN3

FN3. The court rejects defendants' suggestion that the structures of the stent must be capable of compensating for foreshortening without the aid of a balloon or other delivery device, as the use of a delivery device is clearly contemplated in the patent. (Col.1, Ins.17-21)

2. The '303 Patent-Claim 8

a. **"Area of inflection."** A portion of a stent element that is bent, i.e., a loop. (*Webster's* at 1160)

3. The '303 Patent-Claim 12

a. **"Uniform cellular structure."** The flexible connected cells of claim 6 have the same structure.

4. The '120 Patent-Claim 13

a. **"Meander."** A periodic or repeating pattern of structural elements oriented about a center line. (Col.2, Ins.61-63) **"First meanders"** and **"second meanders"** identify and differentiate two different patterns. (Col. 2, ln. 61; col. 7, ln. 19)

5. The '120 Patent-Claim 17

a. **"Changes in the shape of the loops provides rigidity."** One of the meander patterns must have horizontally-facing loops which change shape upon expansion in order to provide rigidity to the stent. (Col. 4, Ins. 28-30; col. 3, Ins. 1-7)

6. The '018 Patent-Claim 35

a. **"A plurality of first loops and a plurality of second loops ."** Two sets of loops.FN4

FN4. Although the phrases "a first loop" and "a second loop" are used in the specification to describe the horizontally-facing (C-shaped) loops at either end of a cell (col.5, Ins.7-14), the court finds that the phrases "first loops" and "second loops" should not be so limited, a conclusion supported by the fact that the function of minimizing foreshortening requires loops oriented in different directions.

b. **"Disposed and adapted to cooperate so that upon expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. (Col. 4, ln. 58 to col. 5, ln. 63) This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means. (Col .1, Ins.17-21) 7.

7. The '018 Patent-Claim 39

a. **"Said loops adapted so that said stent prior to expansion is substantially uniformly flexible along its longitudinal axis."** The first loops and second loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction, to provide substantially uniform flexibility to the unexpanded stent as one moves longitudinally along the stent.FN5 (Col. 3, lns. 39-50; col. 5, lns. 35-39)

FN5. Contrary to plaintiffs' interpretation, the phrase "substantially uniformly flexible" modifies the word "stent" in this claim, not the word "cells"; the cells must simply be flexible with respect to the longitudinal axis.

b. **"Said first loops and said second loops disposed and adapted to cooperate so that upon the expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

c. **"Said loops further adapted to impart rigidity."** At least some of the loops must be horizontally-facing loops which change shape to provide rigidity to the stent upon expansion. (Col.4, lns.23-26)

8. The '018 Patent-Claim 47

a. **"Stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis."** The structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent.

b. **"Apices."** Points at the two longitudinal ends of a cell of a stent. (*Webster's* at 99)

c. **"Plurality of flexible links."** Structural elements that serve to connect other structural elements but are themselves "disposed apart and generally opposite to one another." (*Webster's* at 1317; col. 12, ins. 33-35)

d. **"Each of said flexible links including a plurality of portions with neighboring portions having an area of inflection there between."** The flexible links are loops.

9. The '018 Patent-Claim 60

a. **"Wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The loops disposed on the first meander patterns and the loops disposed on the second meander patterns must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

10. The '018 Patent-Claim 63

a. **"Wherein said stent is adapted so that when it is expanded radially, its overall length reraains substantially the same because some elements of said stent grow in said tube's longitudinal direction while some elements of said stent shrink in said tube's longitudinal direction."** The stent must have structural elements oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one set of structural elements in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

D.Del.,2001.

Scimed Life Systems, Inc. v. Johnson & Johnson

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