# IN THE UNITED STATES DISTRICT COURT

## FOR THE DISTRICT OF DELAWARE

MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC,	
Plaintiffs,	)
V.	) ) Civ. No. 98-80-SLR
ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORP.,	) ) )
Defendants.	) )
MEDTRONIC VASCULAR, INC.,	)
Plaintiff,	)
v.	) Civ. No. 98-478-SLR
BOSTON SCIENTIFIC CORP., BOSTON SCIENTIFIC SCIMED, INC. (formerly known as SCIMED LIFE SYSTEMS, INC. and MEDINOL, LTD.,	) ) ) )
Defendants.	) ) )
MEDTRONIC VASCULAR, INC.,	)
Plaintiff,	)
v.	) Civ. No. 04-034-SLR
BOSTON SCIENTIFIC CORP., BOSTON SCIENTIFIC SCIMED, INC. (formerly known as SCIMED LIFE SYSTEMS, INC.)	, ) ) )
Defendants.	)

## MEMORANDUM ORDER

At Wilmington this 5th day of January, 2005, having heard oral argument and having reviewed the papers submitted in connection with the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language in U.S. Patent Nos. 5,292,331 ("the '331 patent"), 5,674,278 ("the '278 patent"), 5,879,382 ("the '382 patent") and 6,344,053 ("the '053 patent"), as identified by the above referenced parties, shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit, as follows:

1. "Stent." Consistent with the ordinary meaning,<sup>1</sup> the independent asserted claims,<sup>2</sup> the written description<sup>3</sup> and the background of the art,<sup>4</sup> the court construes "stent" to mean "a device implanted to maintain the patency of a vessel."<sup>5</sup>

<sup>3</sup> '331 patent, col. 4, 11. 29-30; '278 patent, col. 4, 11. 24-25; '053 patent, col. 4, 11. 22-23.

<sup>4</sup>'331 patent, col. 2, 11. 16-22; '278 patent, col. 2, 11. 16-22; '053 patent, col. 2, 11. 18-24.

<sup>&</sup>lt;sup>1</sup><u>See</u> Stedman's Medical Dictionary 1336 (27th ed. 2002) (defining "stent" as a device "to assure patency of an intact but contracted lumen"); D.I. 241 at 887, 902.

<sup>&</sup>lt;sup>2</sup>Claim 1, '331 patent, col. 7, l. 1; claim 1, '278 patent, col. 6, ll. 55-56; claim 1, '053 patent, col. 6, l. 41; claim 8, '053 patent, col. 7, l. 9; claim 16, '053 patent, col. 7, l. 46; claim 24, '053 patent, col. 8, l. 14; claim 27, '053 patent, col. 8, l. 37.

<sup>&</sup>lt;sup>5</sup>Defendants argue that "stent" should be limited to a stand alone device, but the intrinsic evidence does not support such a construction. The written description clearly indicates that

#### 2. "Circular member."

Consistent with claim 1 of the '278 patent,<sup>6</sup> its prosecution history,<sup>7</sup> claims 8 and 16 of the '053 patent<sup>8</sup> and the written description,<sup>9</sup> the court construes "circular member" to mean "a stent."

<sup>6</sup> 278 patent, col. 6, ll. 54-56. <sup>7</sup>D.I. 240 at 393-397.

<sup>8</sup> 053 patent, col. 7, ll. 9-16, 46-61.

<sup>9</sup>In construing this term to mean "stent," the court reads the asserted claim in light of the complete written description and uses that description to "dictat[e] the manner in which the claims are to be construed" even though an exact definition is not given. <u>Scimed Life Sys., Inc. v. Advanced Cardiovascular</u> <u>Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001); see also</u> <u>Markman v. Westview Inst.</u>, 52 F.3d 967, 979-980 (Fed. Cir. 1995). The written description, shared by all the patents in suit, does not mention the terms "circular member," "stent member," "ring" or "endovascular support member." It does, however, describe at length the structure of a "stent." In fact, the structure of a stent, as described by the written description, is the structure given to "circular members," "stent members," "rings" and "endovascular support members."

<sup>&</sup>quot;multiple stents may be used in the treatment of a single lesion." ('331 patent, col. 6, ll. 26-31) Medtronic did not disclaim multiple stents during the prosecution of the '331 patent because its arguments were directed at connections between parts of the stent and not at the use of multiple stents to treat a single lesion. (D.I. 240 at 101, 151, 226) Nevertheless, even when used in multiples, each stent must be a functional stent.

3. **"Stent member**." Consistent with claim 1 of the '382 patent<sup>10</sup> and the written description,<sup>11</sup> the court construes "stent member" to mean "a stent."

4. "Ring." Consistent with the specification,<sup>12</sup> the court construes "ring" to mean "a stent."

5. **"Endovascular support member."** Consistent with the specification,<sup>13</sup> the court construes "endovascular support member" to mean "a stent."

6. "Comprising." The court finds that "comprising" is a term of art that means "the named elements are essential, but other elements may be added and still form a [device] within the scope of the claim,"<sup>14</sup> but elements that are otherwise excluded by the prosecution history or an explicit claim limitation are not claimed.<sup>15</sup>

<sup>10</sup> 382 patent, col. 6, 11. 44-57.

<sup>12</sup><u>See</u> <u>supra</u> note 9.

<sup>13</sup>See supra note 9.

<sup>14</sup>Stifung v. Renishaw PLC, 945 F.2d 1173 (Fed. Cir. 1991); see also Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1382 (Fed. Cir. 2000).

<sup>15</sup>See <u>Kustom Signals, Inc. v. Applied Concepts, Inc.</u>, 264 F.3d 1326, 1332 (Fed. Cir. 2001); <u>Spectrum Int'1, Inc. v.</u> <u>Sterilite Corp.</u>, 164 F.3d 1372, 1379-80 (Fed. Cir. 1998).

<sup>&</sup>lt;sup>11</sup><u>See</u> <u>supra</u> note 9.

7. "Wire-like." Consistent with claim 1 of the '331 patent and claim 1 of the '278 patent,<sup>16</sup> the written description<sup>17</sup> and the prosecution history,<sup>18</sup> the court construes "wire-like" to mean "a metal material capable of being bent to form peaks."<sup>19</sup>

<sup>16</sup> 331 patent, col. 7, ll. 3, 21-23; col. 8, ll. 6-7; 278 patent, col. 6, l. 55.

<sup>17</sup> '331 patent, col. 4, ll. 63-70; col. 5, ll. 1-13; '278 patent, col. 4, ll. 57-70; col. 5, ll. 1-7.

<sup>18</sup>D.I. 240 at 99, 111, 114, 124, 138, 172-73, 394.

<sup>19</sup>Defendants argue that the use of "wire-like" renders certain patent claims indefinite. The Federal Circuit has explained that a claim satisfies § 112  $\P$  2 if one skilled in the art would understand the bounds of the claim when read in light of the specification. See Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993). In determining whether this standard is met, the Federal Circuit has advised that a claim is not indefinite merely because it poses a difficult issue of claim construction. Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001). Rather, the Federal Circuit has held a claim sufficiently clear to avoid invalidity on indefiniteness grounds "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree." Id. "A determination of claim indefiniteness is a legal conclusion that is drawn from the Court's performance of its duty as the construer of patent claims." Personalized Media Communications, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998). The court finds that "wire-like" is not indefinite, as one of ordinary skill in the art could discern from the specification and prosecution history that the term was limited to a metal material that is capable of being bent.

8. "Substantially straight segments." Consistent with its ordinary meaning<sup>20</sup> and the written description,<sup>21</sup> the court construes "substantially straight segments" to mean "portions of the stent that are straight or nearly straight and extend the length of the stent."

9. "Each segment having a first and second ends, wherein the first end of the first segment is connected to the first end of a second segment, the second end of the second segment is connected to the second end of the third segment, the first end of the third segment is connected to the first end of the fourth segment, and so on until the second end of the [Nth/last] segment is connected to the second end of the first segment." Consistent with claim 1 of the '331 patent and claim 8 of the '053 patent,<sup>22</sup> the prosecution history<sup>23</sup> and written description,<sup>24</sup> the court construes this phrase to mean "the substantially straight segments are only connected at their ends by peaks. A peak joins

<sup>23</sup>D.I. 240 at 95, 101, 113, 124, 138, 151, 152, 174-78.

<sup>24</sup><u>See, e.q.</u>, '331 patent, col. 4, 11. 47-53.

<sup>&</sup>lt;sup>20</sup><u>See</u> American Heritage Dictionary 1213 (2d ed. 1984) (defining "substantial" to mean "considerable in importance, value, degree, amount or extent").

<sup>&</sup>lt;sup>21</sup> 331 patent, col. 5, 11. 14-15.

<sup>&</sup>lt;sup>22</sup> 331 patent, col. 7, 11. 1-12; '053 patent, col. 7, 11. 13-23.

two substantially straight segments and no additional elements."  $^{\prime\prime\,25}$ 

10. "The ends of respective pairs of the plurality of [N] substantially straight segments connected end to end." Consistent with the asserted claims of the '278 and '382 patents<sup>26</sup> and the prosecution history,<sup>27</sup> the court construes this phrase to mean "the substantially straight segments are connected only at their ends by peaks. A peak joins two substantially straight segments and no additional elements."

11. "Each segment having a first and second end, with a first end of a first segment connected to a first end of a second segment by a first turn; a second end of the second segment connected to a second end of a third segment by a second turn; a

<sup>26</sup>Claim 1, `278 patent, col. 6, ll. 57-59; claim 1, `382 patent, col. 6, ll. 51-52.

<sup>27</sup>D.I. 240 at 95, 101, 113, 124, 138, 151, 152, 174-78.

<sup>&</sup>lt;sup>25</sup>During the prosecution of the '331 patent, Mr. Boneau argued that his stent was different from the Palmaz stent because his stent only had upper and lower peaks. (D.I. 240 at 101, 113, 138, 151, 226) These arguments were in response to the examiner's assertion that, due to the use of "comprising," the additional "Palmaz elements" could be added to the Boneau stent as it was claimed. (See, e.g., id. at 146) Mr. Boneau asserted that these additional "Palmaz elements" could not be added to the "peaks" because then there would no longer be any "peaks." It is clear that Mr. Boneau disclaimed "Palmaz elements" and that these additional "Palmaz elements" were connections attached to the peaks because those are the only additional elements the Palmaz stent has. (Compare D.I. 240 at 214, fig. 2B, and '331 patent, fig. 1)

first end of the third segment connected to a first end of a fourth segment by a third turn, and so on until a second end of a Nth segment is connected to a second end of the first segment by an Nth turn." Based on claim 1 of the '053 patent,<sup>28</sup> written description<sup>29</sup> and prosecution history,<sup>30</sup> the court construes this phrase to mean "the substantially straight segments are connected only at their ends by peaks. A peak joins two substantially straight segments and no additional elements."

12. "The ends of the respective pairs of the plurality of segments connected to each other." Consistent with claim 16 of the '053 patent<sup>31</sup> and the prosecution history,<sup>32</sup> the court construes this phrase to mean "the substantially straight segments are connected only at their ends by peaks. A peak joins two substantially straight segments and no additional elements."

13. "Each segment being connected to adjacent segments at its ends by curved members." Consistent with claim 24 of the '053 patent and the prosecution history,<sup>33</sup> the court construes

<sup>28</sup> 053 patent, col. 6,	11. 41-65.
<sup>29</sup> 053 patent, col. 4,	11. 38-44.
$^{30}$ D.I. 240 at 95, 101,	113, 124, 138, 151, 152, 174-78.
<sup>31</sup> 053 patent, col. 7,	11. 50-53.
$^{32}$ D.I. 240 at 95, 101,	113, 124, 138, 151, 152, 174-78.
<sup>33</sup> D.I. 240 at 95, 101,	113, 124, 138, 151, 152, 174-78.

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this phrase to mean "the substantially straight segments are connected only at their ends by peaks. A peak joins two substantially straight segments and no additional elements."

14. "Each substantially straight segment, of each plastically deformable balloon-expandable endovascular support member, being connected to circumferentially adjacent segments at its ends." Consistent with claim 27 of the '053 patent, the prosecution history<sup>34</sup> and the written description, the court construes this phrase to mean "the substantially straight segments of a balloon-expandable stent, are only connected at their ends by peaks. A peak joins two substantially straight segments and no additional elements."

15. "With no segment overlapping any other segment." Consistent with claim 1 of the '331 patent<sup>35</sup> and its ordinary meaning,<sup>36</sup> the court construes this phrase to mean "the substantially straight segments are continuously connected only at their ends; therefore, none of the segments overlaps any other."

<sup>34</sup>D.I. 240 at 95, 101, 113, 124, 138, 151, 152, 174-78.
<sup>35</sup> 331 patent, col. 7, 11. 13-14.

<sup>&</sup>lt;sup>36</sup><u>See</u> American Heritage Dictionary 885-86 (2d ed. 1984) (defining "overlapping" as "to lie or extend over and cover part of").

16. **"Substantially straight, non-overlapping segments."** Consistent with its ordinary meaning,<sup>37</sup> the court construes this phrase to mean "portions of a stent that are straight or nearly straight and do not extend over or cover part of any other segment."

17. "Generally sinusoidally-shaped." Consistent with its ordinary meaning and the prosecution history,<sup>38</sup> the court construes this phrase to mean "a repeating pattern, formed by substantially straight segments connected by bends or curves, that generally resembles a sine wave because it does not double back on itself."

18. **"Capable of being compressed onto."** The court finds that no construction of this phrase is required, as no substitute terms could be clearer than the phrase itself.

19. "Catheter." Consistent with the its ordinary meaning to one of reasonable skill in the art<sup>39</sup> and the written description,<sup>40</sup> the court construes "catheter" to mean "a balloon catheter."

<sup>37</sup><u>Id.</u>; <u>id.</u> at 1213 (defining "substantial" to mean "considerable in importance, value, degree, amount or extent").

<sup>&</sup>lt;sup>38</sup>D.I. 241 at 993.

<sup>&</sup>lt;sup>39</sup><u>See</u> Stedman's Medical Dictionary 237 (27th ed. 2002) (defining "catheter" as "a tubular instrument for the passage of fluid from or into a body cavity").

<sup>&</sup>lt;sup>40</sup> 331 patent, col. 4, 11. 32-33; col. 5, 11. 36-67; col. 6, 11. 1-25.

#### 20. "Capable of being . . . forcibly expanded."

Consistent with its ordinary meaning,<sup>41</sup> the court construes this phrase to mean "capable of increasing from one diameter to another by application of force to overcome the resistance to expand."

21. **"Capable of retaining."** Consistent with asserted claims,<sup>42</sup> claim 1 of the '278 patent, claim 1 of the '382 patent, claim 1, 8, 16, 24 and 27 of the '053 patent,<sup>43</sup> written descriptions<sup>44</sup> and prosecution history of the '053 patent,<sup>45</sup> the court construes "capable of retaining" to mean "retaining its compressed configuration unaided."

<sup>44</sup><u>See, e.g.</u>, '278 patent, col. 5, ll. 48-51.

<sup>&</sup>lt;sup>41</sup><u>See</u> Stedman's Medical Dictionary 1696 (27th ed. 2002) (defining "expandable stent" as "increas[ing] its diameter"); American Heritage Dictionary 522-23 (2d ed. 1984) (defining "forcibly" as "[e]ffected through the use of force" and "force" as "power made operative against resistance"); <u>id.</u> at 476 (defining "expand" as "[t]o incrase the size . . . of").

<sup>&</sup>lt;sup>42</sup>Claim 1, 278 patent, col. 5, ll. 59-63; claim 1, '382 patent, col. 6, ll. 54-57; claim 1, '053 patent, col. 6, ll. 43-46; claim 8, '053 patent, col. 7, ll. 23-26; claim 16, '053 patent, col. 7, ll. 54-57; claim 24, '053 patent, col. 8, ll. 27-29; '053 patent, col. 8, ll. 42-46.

<sup>&</sup>lt;sup>43</sup> 278 patent, col. 5, ll. 59-63; '382 patent, col. 6, ll. 54-57; '053 patent, col. 6, ll. 43-46; col. 7, ll. 23-26, 54-57; col. 8, ll. 27-29, 42-46.

<sup>&</sup>lt;sup>45</sup>D.I. 241 at 996, 998-99.

22. **"Balloon-expandable**." Consistent with the independent claims of the '053 patent,<sup>46</sup> the prosecution history<sup>47</sup> and its ordinary meaning,<sup>48</sup> the court construes "balloonexpandable" to mean "capable of being increased from one diameter to another by inflating a balloon."

> Sue L. Robinson United States District Judge

<sup>47</sup>D.I. 241 at 997-99.

<sup>48</sup><u>See</u> American Heritage Dictionary 476 (2d ed. 1984).

<sup>&</sup>lt;sup>46</sup>Claim 1, '053 patent, col. 6, ll. 2-65; claim 8, '053 patent, col. 7, ll. 9-26; claim 16, '053 patent, col. 7, ll. 46-61.