IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 07-333-SLR Civ. No. 07-348-SLR Civ. No. 07-409-SLR
JOHNSON & JOHNSON, INC. and CORDIS CORPORATION,	)	
Defendants.	)	

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 07-765-SLR
JOHNSON & JOHNSON, INC., CORDIS CORPORATION and WYETH,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 20th day of January, 2010, having heard oral argument on, 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. 7,217,286

("the '7286 patent"), 7,223,286 ("the '3286 patent"), 7,229,473 ("the '473 patent"), and 7,300,662 ("the '662 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. "**Stent**:" **A device for providing support for a lumen in the body**. This construction accurately describes the plain meaning of a stent, without adding limitations that are not required by the claim language itself.[1] This limitation appears in all of the asserted patents.

2. "**Biocompatible**:" **Able to perform its function in the body with an acceptable biological response.** This construction is consistent with the ordinary meaning of the term. *See, e.g.,* J.S. Temenoff & A.G. Mikos, *Biomaterials: The Intersection of Biology and Materials Science* 2 (2008) at A110-A111. This limitation appears in all of the asserted patents.[2]

3. "**Therapeutic agent**:" **A substance administered to treat or prevent a disease or condition.** Agreed upon by the parties. This limitation appears in the '7286 and '473 patents.

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[1]This construction is also consistent with prior constructions given in other of my stent cases. *See, e.g., Medtronic Vascular, Inc. v. Advanced Cardiovascular Sys., Inc.*, Civ. No. 98-80-SLR, 2005 U.S. Dist. LEXIS 822, at *1 (D. Del. Jan. 5, 2005) (defining stent as "a device implanted to maintain the patency of a vessel").

[2]Although the 1997 patents provide an explanation for the term "biocompatible" vis a vis "polymers" ("i.e., not elicit any negative tissue reaction or promote mural thrombus formation") (*see* '7286 patent, col. 6:37-39), the '662 patent does not contain similar language. Indeed, the absence of **any** negative tissue reaction upon implantation of a metal device coated with a polymer/drug mixture is not consistent with other language in the patent. *See, e.g.,* '7286 patent, col. 5:48-56 (using words like "diminish" and "inhibit").

4. "**Drug**:" **A substance administered to treat or prevent a disease or condition.** Agreed upon by the parties. This limitation appears in the '3286 and '662 patents.

5. "**Polymer**:" **A material formed by polymerization and comprising repeating units of the same (homopolymer) or different (copolymer) types of monomers.** This construction is consistent with the ordinary meaning of the word. *See, e.g., Webster's Third New International Dictionary* at 1759 (2002). This limitation appears in the '7286, '3286 and '473 patents.

6. "**Copolymer**:" **A polymer having two or more different types of monomers**. This construction is consistent with the ordinary meaning of the word. *See, e.g., American Heritage Dictionary of the English Language* at 415 (3d Ed. 1992). This limitation appears in the '7286, '3286, and '473 patents.

7. "**Polymeric carrier**:" **A material comprised of at least one polymer that is formulated with the therapeutic agent**. This construction is consistent with the specification. *See, e.g.,* '7286 patent, col. 6:34-54; '473 patent, col. 6:35-38. This limitation appears in the '7286 and '473 patents.

8. "**Polymeric coating**;" "**coating**:" **Covering layer(s) comprising a mixture of both a polymer and the therapeutic agent or drug.** The specification does not limit the coating to a single layer. *See, e.g.,* '3286 patent, col. 7:17-20; '473 patent, col. 7:21-24; '662 patent, col. 16:32-51. These limitations appear in the '3286, '473 and '662 patents.

9. "**Acrylate-based polymer or copolymer:**" **A polymer in which at least one of the types of monomers is based on the structure of a salt or ester of acrylic acid.** This construction is consistent with the ordinary meanings of the words used in this phrase, as explained above.[3] This limitation appears in the '7286, '3286, and '473 patents.

10. "**Fluorinated polymer**:" **A polymer containing one or more fluorine atoms**. This construction is consistent with the ordinary meaning of the words, as described above. This limitation appears in the '7286, '3286 and '473 patents.

11. "**Poly(ether-ester) copolymer**:" **A polymer containing one monomer that includes an ether and another monomer that includes an ester.** This construction is consistent with the ordinary meaning of the words, as described above. This limitation only appears in the '3286 patent.

12. "**Rapamycin or a macrocyclic lactone analog thereof**:" **Sirolimus or a macrocyclic lactone molecule with a structure similar to sirolimus.** This construction is consistent with the ordinary meaning of the phrase, without adding limitations that are not required by the claim language (or described in the specification). *See, e.g.,* '7286 patent, col. 6:4-5.[4] This limitation appears in the '7286, '3286, and '473

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[3]Given the ability of those skilled in the art to distinguish, based on chemical nomenclature, whether a substance is a homopolymer or a copolymer, and given that the patent describes both under the general rubric "polymer/drug mixture," I conclude that the patentees were simply inconsistent in their use of the term "polymer," rather than being their own lexicographers, as BSC argues. *See, e.g.,* '3286 patent, claims 1 ("polymer/drug mixture") and 10 (listing both homopolymers and copolymers).

[4]As of the time the '7286, '3286 and '473 patents were filed, "the precise mechanism of rapamycin [was] still under active investigation." '7286 patent, col.5:36-

patents.

13. "**Rapamycin**:" **Sirolimus and all analogs, derivatives and congeners that bind FKBP12 and possess the same pharmacologic properties as sirolimus.** This construction, limited to the '662 patent, is consistent with the specification of said patent. *See* '662 patent, col. 5:48-51.

14. "**Macrocyclic triene analog**:" **A macrocyclic triene molecule with a structure similar to rapamycin and that binds FKBP12.** This construction is consistent with the specification and claim language. *See* '662 patent, col. 5:48-51; col. 17:26-27.[5] This limitation appears only in the '662 patent.

15. "**An amount effective to inhibit neointimal proliferation**:" **An amount sufficient to diminish neointimal proliferation.** This construction is consistent with the ordinary meaning of the words. *See, e.g., Webster's Third New International Dictionary* at 1163 (2002) (to "check, restrain or diminish"). This limitation appears in the '7286, '3286, and '473 patents.

16. "**Provides a controlled release of said therapeutic agent over a period of several weeks**:" **Therapeutic agent is discharged gradually over the course of several weeks.** This construction is consistent with the ordinary meaning of the words and the specification. *See, e.g.,* '7286 patent, col. 3:50-55. This limitation appears in

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38. Consequently, there is no more specific teaching of how to identify those analogs that fall within the scope of the claim.

[5]In contrast to the 1997 patents, by the time the '662 patent was filed in 2004, the patentees were better able to describe "[t]he operation and various functions of rapamycin." '662 patent, col. 5:46-47.

the '7286, '3286, and '473 patents.

17. "**Releases**:" **Discharges.** See above. This limitation appears in the '3286 and '662 patents

18. "**Mixture**;" "**mixture thereof**;" "**blend thereof**;" "**incorporated into:**" **Combination of two or more substances, or the act of combining said materials.** This construction is consistent with the ordinary meaning of the words and with the specifications. *See, e.g.,* '7286 patent, col. 6:34-37; col. 7:20-21. These limitations appear in the '7286, '3286, and '662 patents.

19. "**Applied**;" "**applied thereto;**" "**onto the stent**;" "**affixed to the intraluminal stent**;" **Attached to the stent**. This construction is consistent with the ordinary meaning of the words without adding limitations that are not required by the claim language itself.[6] *See, e.g.,* '3286 patent, col. 7:19-22; '662 patent, col. 16:33-63. These limitations appear in the '3286, '473 and '662 patents.

20. "**In-stent late loss**:" **The minimal lumen diameter within the stent immediately following implantation minus minimal lumen diameter within the stent at a specified time following implantation.** The parties essentially are in agreement, except that BSC has argued that the above determination must in made consistent with specified protocols, given the variability of quantitative coronary angiography. Neither the claim language nor the specification of the '662 patent is so limited. *See* table 5, col

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[6]More specifically, BSC would add the word "directly" to the construction to distinguish the accused product, which has a primer between the bare metal surface of the stent and the polymer/drug mixture. As noted at oral argument, however, it is commonly understood that one can "apply" a coat of paint to a wall, even if there are multiples coats of primer and old paint on the wall already.

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21. "**In-stent diameter stenosis**:" **100 X [1 - minimal lumen diameter /reference vessel diameter)].** The parties are in agreement, except that BSC has argued that this calculation must be determined in accordance with a specific protocol, given the variability of quantitative coronary angiography. Neither the claim language nor the specification of the '662 patent is so limited.

22. "**Quantitative coronary angiography**:" **A test to measure the lumen diameter of coronary vessels.** This construction is consistent with the specification of the '662 patent, which does not describe "particular specified hardware and software, and technician assumptions," as proposed by BSC.

23. "**Mean in-stent late loss**:" **The average of in-stent late loss values**. This construction is consistent with the ordinary meaning of the words used in the claims and specification of the '662 patent.

24. "**Human population**:" **A class of people distinguished by particular traits or characteristics.** This construction is consistent with the ordinary meaning of the words without adding unnecessary limitations to the claims of the '662 patent.[7]

25. "**Mean in-stent diameter stenosis**:" **The average of in-stent diameter stenosis values.** This construction is consistent with the ordinary meaning of the words used.

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[7]J&J argues that this language should be limited to a group of "human patients" who are "candidates for coronary stent therapy" and who would be suitable for clinical testing. Given the lack of any protocols in the '662 patent in this regard, I decline to add this limitation to the claim.

26. "**About**:" **Approximately.** This language is consistent with the ordinary meaning of the word.

United States District Judge