IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	)	Civ. No. 97-550-SLR (consolidated)
MEDTRONIC AVE, INC., Plaintiff, v. CORDIS CORPORATION, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP, Defendants.	)	Civ. No. 97-700-SLR
BOSTON SCIENTIFIC CORPORATION, Plaintiff, v. ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., Defendants.	)	Civ. No. 98-19-SLR
CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION	)	Civ. No. 98-197-SLR

and SCIMED LIFE SYSTEMS, INC.,)
)
Defendants.)

Steven J. Balick, Esquire and John G. Day, Esquire of Ashby & Geddes, Wilmington, Delaware. Counsel for Cordis Corporation, Johnson & Johnson, Johnson & Johnson Interventional Systems Co., Ethicon, Inc. and Expandable Grafts Partnership. Of Counsel: Gregory L. Diskant, Esquire, Eugene M. Gelernter, Esquire, William F. Cavanaugh, Jr., Esquire and Michael J. Timmons, Esquire of Patterson, Belknap, Webb & Tyler, LLP, New York, New York. Theodore B. Van Italie, Jr., Esquire and Eric I. Harris, Esquire of Johnson & Johnson, New Brunswick, New Jersey.

Karen Jacobs Louden, Esquire and Philip H. Bangle, Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Medtronic Vascular, Inc. Of Counsel: Raphael V. Lupo, Esquire, Donna M. Tanguay, Esquire, Mark G. Davis, Esquire, D. Michael Underhill, Esquire and Natalia V. Blinkova, Esquire of McDermott, Will & Emery, Washington, D.C.

Josy W. Ingersoll, Esquire and Christian Douglas Wright, Esquire of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Counsel for Boston Scientific Corporation and Scimed Life Systems, Inc. Of Counsel: George E. Badenoch, Esquire, Charles R. Brainard, Esquire, Albert J. Breneisen, Esquire and Mark A. Chapman, Esquire of Kenyon & Kenyon, New York, New York.

MEMORANDUM OPINION

Dated: September 21, 2004
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

The above captioned litigation has a long and convoluted history, which will not be repeated at any length in this opinion. Upon remand from the Federal Circuit, see Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003), I was directed, inter alia, to amend my claim construction of the "substantially uniform thickness" limitation consistent with the guidance given by the appellate court. I did so by order dated February 17, 2004.[1] (D.I. 1201)[2] Before me presently are the

---

[1]In my February 17, 2004 order, I construed the "substantially uniform thickness" limitation as meaning that "the thickness of the wall of the stent be largely or approximately uniform along its length and between members to allow uniform expansion of the stent." (D.I. 1201 at 6) Plaintiff has filed a motion for reconsideration based, inter alia, on the Federal Circuit's discussion of the "substantially uniform thickness" limitation in subsequent litigation involving some of the same parties and some of the same technology, Cordis Corp. v. Boston Scientific Corp., No. 04-1098, 2004 WL 1194246 (Fed. Cir. May 28, 2004). (D.I. 1231, ex. A) More specifically, the panel in the above cited case characterized its revised claim construction in this case as follows: "[T]his court revised the construction of 'substantially uniform thickness' to mean that 'the walls must be of largely or approximately uniform thickness' and that 'a wall that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents.'" Id. at 5 (citing Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d at 1360, 1362). The panel did not refer in its discussion to the added requirement that "the thickness of the wall surface be sufficiently uniform along its length and between members to allow uniform expansion of the stent," as had the court in this case. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d at 1360.

Having reflected further on this matter, in light of the Federal Circuit's discussion (not binding, of course) and in light of the other limitations which have not been construed to add a functional element, the motion for reconsideration is granted. The "substantially uniform thickness" limitation shall

motions for partial summary judgment on amendment-based prosecution history estoppel filed by Medtronic AVE, Inc., Boston Scientific Corporation and Scimed Life Systems, Inc. ("defendants"). For the reasons that follow, I conclude that plaintiff Cordis Corporation is not estopped from seeking infringement by equivalents. Therefore, defendants' motions shall be denied.

II. LEGAL STANDARD

The United States Supreme Court, in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002), reaffirmed the vitality of the doctrine of equivalents: "The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." Id. at 732. As explained by the Court,

> [i]t is true that the doctrine of equivalents renders the scope of patents less certain. It may be difficult to determine what is, or is not, an equivalent to a particular element of an

---

be construed to mean that the walls "must be of largely or approximately uniform thickness."

The other limitation at issue is the "smooth surface" limitation, construed as meaning that the "outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch." (D.I. 1127 at 9) As noted above, there is no functional limitation in the construction, e.g., the wall surface must be smooth enough to accommodate intraluminal delivery.

[2]All docket item numbers in this opinion refer to the docket in the lead case, Cordis Corp. v. Medtronic AVE, Inc., et al., Civ. No. 97-550-SLR (consolidated).

> invention. If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. In addition the uncertainty may lead to wasteful litigation between competitors, suits that a rule of literalism might avoid. These concerns with the doctrine of equivalents, however, are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.

Id.

Having declared "that equivalents remain a firmly entrenched part of the settled rights protected by the patent," id. at 733, the Supreme Court went on to discuss the limits placed on the doctrine of equivalents by prosecution history estoppel.

> Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.

Id. at 734-735. In other words, the prosecution history of a patent, as the public record of the patent proceedings, serves

the important function of identifying the boundaries of the patentee's property rights. Once a patentee has narrowed the scope of a patent claim as a condition of receiving a patent, the patentee may not recapture the subject matter surrendered.

In order to determine what equivalents are included within the scope of the subject matter surrendered by a narrowing amendment, the Supreme Court has been mindful of

> the purpose of applying the estoppel in the first place -- to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment. By amending the application, the inventor is deemed to concede that the patent does not extend as far as the original claim. It does not follow, however, that the amended claim becomes so perfect in its description that no one could devise an equivalent. After amendment, as before, language remains an imperfect fit for invention. The narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is. There is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of amendment and beyond a fair interpretation of what was surrendered. Nor is there any call to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted. . . .

Id. at 737-738. The Court concluded that "the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question." Id. at 740. Although "[a] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory

between the original claim and the amended claim," a patentee may overcome the presumption that prosecution history estoppel bars a finding of equivalence by demonstrating, inter alia, that "the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question." Id.

The reason for applying the principles of prosecution history estoppel to claims that have been narrowed by amendment has been expanded to include all of the patent claims containing the narrowing limitation, regardless of whether they themselves were ever amended. This theory of "infectious estoppel" generally is credited to the analysis of the Federal Circuit in Builders Concrete, Inc. v. Bremerton Concrete Products Co., 757 F.2d 255 (Fed. Cir. 1985). In that case, claim 1 of the patentee's application was amended to include certain "passage limitations" originally included in application claims 2 and 11. The amendment was made in view of the prior art. Although application claim 11 was the only claim at issue and had always included the "passage limitations," the Federal Circuit concluded that the patentee was estopped

> from interpreting application claim 11 (patent claim 10) to encompass that which was relinquished in the successful argument for patentability of amended claim 1. Although claim 10 is the only claim in suit, the prosecution history of all claims is not insulated from review in connection with determining the fair scope of claim 10. To hold otherwise would be to exalt form over substance and distort the logic of this

> jurisprudence, which serves as an effective and useful guide to the understanding of patent claims. The fact that the "passage" clause of patent claim 10 was not itself amended during prosecution does not mean that it can be extended by the doctrine of equivalents to cover the precise subject matter that was relinquished in order to obtain allowance of claim 1. It is clear from the prosecution history that the allowance of claim 1, the broadest claim with respect to the other elements of the float, depended on the amendment narrowing its "passage" definition to that of claim 10.

Id. at 260.

III. DISCUSSION

In accordance with the above standards, it is plaintiff's burden to demonstrate, by a preponderance of the evidence, that the rationale underlying the amendments bears no more than a tangential relation to the equivalents in question.

A. Prosecution History

All the asserted claims of the '762 patent - claims 23, 51 and 54 - contain or incorporate limitations requiring that the wall surface have a "substantially uniform thickness" and be "smooth." Claim 23 included these limitations from the outset;[3]

[3]Claim 23 originally depended from claim 13. Claim 13 included the "substantially uniform thickness" limitation; dependent claim 23 added the "smooth surface" limitation. During the reexamination process, claim 13 was amended to include the "smooth surface" limitation and claim 23 was cancelled. Ultimately, claim 13 was cancelled, the cancellation of claim 23 was cancelled, and claim 23 became an independent claim with all the limitations of cancelled independent claim 13. (AVE trial exhibit 2074, "DX 2074", at PWRAP 1458-1459, PWRAP 3039, PWRAP 3243)

other claims (e.g., independent claims 35 and 37) omitted those limitations.

In October 1997, plaintiff filed a reexamination request for the '762 patent in which it identified several patents that had not been of record in the original prosecution, including the Ersek '744 patent. In its request for reexamination, plaintiff distinguished independent claim 13 from the Ersek fixation sleeve by describing the latter device as being "neither designed nor intended to be delivered intraluminally into a body passageway because of its having sharp projecting edges in its first diameter prior to its expansion." (DX 2074 at PWRAP 1434) With respect to dependent claim 23, plaintiff described "the outside surface of the Ersek fixation sleeve [as having] narrow, outwardly projecting edges when in its first diameter and does not have a smooth outside wall surface." (Id. at PWRAP 1436)

On June 1, 1998, the examiner issued an office action in which he rejected several claims over the prior art that included Ersek. As to claim 13, the examiner opined that the Ersek fixation sleeve could be considered an "intraluminal" member because it was implanted within a blood vessel or, alternatively, was capable of being so delivered "by percutaneous insertion into the artery by appropriate instrumentation." (Id. at PWRAP 3015-3016) With respect to claim 23, the examiner opined that "the outside of the wall surface of the Ersek tubular member 16 is

'smooth,'" even while acknowledging that "the Ersek members 22 which form the wall are twisted . . . such that the outside of the wall surface is, for the most part, narrow edges rather than the wider surfaces of the ribbon-like members 22." (Id. at PWRAP 3016)[4]

On July 21, 1998, plaintiff filed an amendment in response to the office action in which it added the "smooth surface" limitation to claim 13 and added both the "substantially uniform thickness" and "smooth surface" limitations to claims 35 and 37. It also added, inter alia, new claims 51 and 54, which included both limitations. (Id. at PWRAP 3039-3044) In its accompanying remarks, plaintiff distinguished the Ersek invention in various ways. First, plaintiff distinguished the Ersek by function: "There is no teaching within the Ersek patent that the sleeve 16 may be utilized to **treat** an obstructed body passageway. The sole and only teaching within the Ersek patent regarding utilization

---

[4]The examiner discussed the "uniform thickness" limitation in connection with dependent claim 6:

> As to claim 6, the thin walled tubular member (the Ersek fixation sleeve) and the elongate members (members 22 in the fixation sleeve) have a uniform wall thickness since the members 22, although twisted, have the same thickness as the remainder of the sleeve. In other words, the sleeve is formed from a sheet of material having uniform thickness and the twisting of the members 22 does not change their thickness.

(Id. at PWRAP 3009)

of sleeve 16 is as a **fixation device** in substitution for sutures." (Id. at PWRAP 3048) Plaintiff then distinguished Ersek by structure: "To aid in fixation and to resist forces tending to pull out the implanted prosthetic device, the Ersek sleeve has outwardly projecting sharp metal edges." (Id.) Plaintiff further described the Ersek sleeve, inter alia, as having a "non-uniform wall of varying thickness" and "inner and outer surfaces . . . [that] are not smooth." (Id. at PWRAP 3049; see also PWRAP 3054-3055, 3057) Finally, plaintiff distinguished Ersek by result: "In contrast to the minimally invasive procedure of Dr. Palmaz, the Ersek patent teaches a method of implanting a prosthesis in a living body during an open surgical procedure" as a substitute for sutures. (Id. at PWRAP 3048)

A Notice of Intent to Issue Reexamination Certificate was executed on August 25, 1998. (Id. at PWRAP 3252) In explaining his reasons for allowing claim 23 over Ersek, the examiner stated that, upon reconsideration,

> the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the ridge has a thickness which is twice as great as the strand. The outside of

> the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve.

(Id. at PWRAP 3257-3258)

B. Analysis

In applying the "tangential relation" criterion, courts are directed by Festo and its progeny to focus "on the patentee's objectively apparent reason for the narrowing amendment," as well as "the context in which the amendment was made." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369-1370 (Fed. Cir. 2003)(en banc)("Festo III"). If the "reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent," then the "tangential relation" criterion has been satisfied. Id. at 1369. Clearly, "an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." Id.

Having reviewed the prosecution history and the papers submitted by the parties, I conclude at the outset that the Ersek prior art does not contain the equivalents at issue. In this regard, I find that the accused devices (stents delivered intraluminally for the treatment of obstructed body passageways)

and the Ersek fixation sleeve (a prosthesis implanted during an open surgical procedure as a substitution for sutures) are "disparate devices with no logical connection to one another." (Id. at PWRAP 3061-3062) Having found that the prior art device bears no more than a tangential relation to the equivalents at issue, the question remains as to whether the amendments made to distinguish the prior art device should be found to bear more than a tangential relation to those same equivalents.

Defendants argue that "a narrowing amendment will not be considered to be tangentially related if the disputed limitation was "directly at issue' during prosecution.'" (D.I. 1234 at 20) If this were the proper standard, then defendants should prevail. Certainly the "substantially uniform thickness" and "smooth surface" limitations were "at issue" during the reexamination proceedings, in that they were added to various claims in order to distinguish Ersek and were discussed in that context. Further, these same limitations are "at issue" in this litigation, as defendants contend that their accused products may be distinguished from the inventive device as not having wall surfaces that are "smooth" or of a "substantially uniform thickness."

Plaintiff argues in response that defendants are not employing the correct inquiry. By focusing on "whether the amendment itself narrows the scope of the claim in a way that

affects the equivalent[s] in question," defendants are making superfluous the tangential relation exception to the presumptive bar imposed under Festo. As the court observed in Amgen, Inc. v. Hoechst Marion Roussel, Inc., 287 F. Supp.2d 126 (D. Mass. 2003): "If this were the test, it would be an impossible one - the only reason why the dispute arises is **because** the equivalent is related to the amendment and thereby affected." Id. at 150. According to plaintiff, "[t]he correct inquiry is whether the **rationale** underlying the amendment, the 'reason the amendment was submitted' - not the amendment itself - is more than peripherally related to the equivalent in question." (D.I. 1241 at 29, citing Amgen, 287 F. Supp.2d at 150)

In this case, the reason the amendments were submitted was to distinguish a prior art device that is only tangentially related to either the inventive or the accused devices. More specifically, with respect to the "substantially uniform thickness" limitation, the Federal Circuit in this case found that, "[i]n addressing Ersek, Cordis focused on the double thickness of the bridge portions of Ersek's walls;" "Cordis's basis for distinguishing Ersek appears to have been that Ersek's walls were at least twice as thick at the intersections of strands as along the strands themselves." Cordis, 339 F.3d at 1361. As concluded by the Federal Circuit, "a wall that varies in thickness by as much as 100 percent cannot be said to be of

'substantially uniform thickness' either literally or by equivalents." Id. at 1362. Similarly, in distinguishing the Ersek device as lacking a "smooth surface," plaintiff focused on the "outwardly projecting edges" of the Ersek device which were intended to "embed themselves into the vessel wall to hold the sleeve 16 and its associated graft in place," not for the intraluminal delivery of the sleeve 16 through the vascular system. (DX 2074 at PWRAP 3049, 3055)[5] Clearly the structure of the Ersek device is the antithesis of the equivalent structures at issue.

IV. CONCLUSION

The doctrine of equivalents remains fertile ground for litigation, as it is often difficult to harmonize this jurisprudence with the particular facts presented. In this case,

[5]The facts of record are very different from those reviewed in Talbert Fuel Sys. Patents Co. v. Unocal Corp., 347 F.3d 1355 (Fed. Cir. 2003). In that case, the patentee added a temperature range in order to distinguish prior art references with higher temperature ranges. The accused product had a temperature range between that claimed and that of the prior art references. The Federal Circuit held that the patentee could not assert the doctrine of equivalents because of amendment based prosecution history estoppel: "[T]he reason for Talbert's amendment cannot be deemed 'tangential' to the Unocal alleged equivalent. The boiling range and carbon content were at issue during prosecution, and were the direct, not tangential, reason for the narrowing amendments to these claim limitations." Id. at 1360. In other words, in Talbert, the narrowing amendment was made to avoid prior art that "embrace[d] the alleged equivalent." Id. at 1359. In contrast, the amendment at bar was made to distinguish a reference (Ersek) that does not contain the structure of the equivalents in dispute.

consistent with the compelling facts of record and the equitable principles discussed above, I conclude that plaintiff is not estopped from seeking infringement by equivalents. Therefore, defendants' motions for partial summary judgment on amendment-based estoppel are denied. An appropriate order shall issue.