UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ENDOTACH LLC,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 1:13-cv-01135-LJM-DKL
	)	
COOK MEDICAL INCORPORATED,	)	
	)	
Defendant.	)	

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

This order addresses outstanding motions for summary judgment in this case. Plaintiff Endotach LLC has moved for summary judgment on Defendant Cook Medical Incorporated's ("Cook's") defense that laches should bar Endotach's claims. Dkt. No. 143.[1] Cook has moved for summary judgment on Endotach's claims of infringement and willfulness; as well as its defenses of invalidity and laches. Dkt. No. 146. The Court has considered the parties arguments and concludes that no oral argument is necessary. The Court rules as follows.

I. SUMMARY JUDGMENT STANDARD

On cross-motions for summary judgment, the Court must apply the ordinary standards pursuant to Rule 56 of the Federal Rules of Civil Procedure ("Rule 56") as to each individual motion. *See McKinney v. Cadleway Props., Inc.*, 548 F.3d 496, 504 n.4 (7th Cir. 2008); *Chevron U.S.A. v. Mobil Prod. Tx. & N.M.*, 281 F.3d 1249, 1252-53 (Fed. Cir. 2002). In other words, each motion must be considered separately and the non-

[1] Unless specifically noted otherwise, all references to "Docket Numbers" or "Dkt. No." refer to the docket in this matter.

moving party given the benefit of favorable inferences. *Chevron*, 281 F.3d at 1253.

As stated by the Supreme Court, summary judgment is not a disfavored procedural shortcut, but rather is an integral part of the federal rules as a whole, which are designed to secure the just, speedy, and inexpensive determination of every action. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986); *see also United Ass'n of Black Landscapers v. City of Milwaukee*, 916 F.2d 1261, 1267–68 (7th Cir. 1990). Rule 56(a) provides in relevant part: "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

Once a party has made a properly-supported motion for summary judgment, the opposing party may not simply rest upon the pleadings but must instead submit evidentiary materials showing that a fact either is or cannot be genuinely disputed. Fed. R. Civ. P. 56(c)(1). A genuine issue of material fact exists whenever "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The nonmoving party bears the burden of demonstrating that such a genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Goodman v. Nat'l Sec. Agency, Inc.*, 621 F.3d 651, 654 (7th Cir. 2010). It is not the duty of the Court to scour the record in search of evidence to defeat a motion for summary judgment; rather, the nonmoving party bears the responsibility of identifying applicable evidence. *See Goodman*, 621 F.3d at 654; *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 (7th Cir. 1996).

In evaluating a motion for summary judgment, the Court draws all reasonable

inferences from undisputed facts in favor of the nonmoving party and views the disputed evidence in the light most favorable to the nonmoving party. *See Berry v. Peterman*, 60 F.3d 435, 438 (7th Cir. 2010); *Estate of Cole v. Fromm*, 94 F.3d 254, 257 (7th Cir. 1996). The mere existence of a factual dispute, by itself, is not sufficient to bar summary judgment. Only factual disputes that might affect the outcome of the suit in light of the substantive law will preclude summary judgment. *See Anderson*, 477 U.S. at 248; *JPM Inc. v. John Deere Indus. Equip. Co.*, 94 F.3d 270, 273 (7th Cir. 1996). Irrelevant or unnecessary facts do not deter summary judgment, even when in dispute. *See Clifton v. Schafer*, 969 F.2d 278, 281 (7th Cir. 1992). If the moving party does not have the ultimate burden of proof on a claim, it is sufficient for the moving party to direct the Court to the lack of evidence as to an element of that claim. *See Green v. Whiteco Indus., Inc.*, 17 F.3d 199, 201 & n.3 (7th Cir. 1994). "If the nonmoving party fails to establish the existence of an element essential to [its] case, one on which [it] would bear the burden of proof at trial, summary judgment must be granted to the moving party." *Ortiz v. John O. Butler Co.*, 94 F.3d 1121, 1124 (7th Cir. 1996).

II. BACKGROUND FACTS[2]

A. THE PATENTS IN SUIT

U.S. Patent No. 5,122,154 (the "'154 patent") and U.S. Patent No. 5,593,417 (the "'417 patent") (collectively, the "Rhodes patents"), are directed to intraluminal and endovascular grafts for placement within a blood vessel, duct, or lumen to hold it open. Dkt. No. 148-1, '154 Patent, Abstract; Dkt. No. 148-2, '417 Patent, Abstract. The grafts are composed of a flexible, tubular member or sleeve with multiple stents mounted on the periphery of the tube. *Id.* The '154 patent issued on June 16, 1992; the '417 patent issued on January 14, 1997. *See id.* Date of Patent.

1. The '154 Patent

The application that matured into the '154 patent was filed on August 15, 1990. Dkt. No. 153-1, at 12; Dkt. No. 144 at 5. The '154 patent issued on June 16, 1992. Dkt. No. 144 at 6.

The asserted claims of the '154 patent read:

> 1. An intraluminal graft for introduction within a portion of a blood vessel, duct or lumen of a living being, said graft comprising a sleeve and at least two stent means mounted thereon, said sleeve being an elongated member of a generally tubular shape having a longitudinal axis and formed of a first, relatively flexible, material, said material being impervious to the ingrowth of tissue therein, each of said stent means being generally ring-like in shape, [s]aid stent means being mounted about the periphery of a surface of said sleeve at selected points therealong to form (a) [sic] respective first

[2] The Court has attempted to set out the facts that are either undisputed or, if disputed, in the light most favorable to the non-moving party. Objections are ruled upon within this Order and any usable evidence is likewise set forth in the light most favorable to the non-moving party. If a party failed to support an objection with a citation to evidence in the record, the Court considered the evidence cited by the proffering party and set forth the facts supported by the evidence. In order to streamline this Order, unless otherwise noted the Court will cite to the ECF page number or numbers where the relevant facts are set forth in a party's brief and such citation should be presumed to include the exhibits cited therein.

sleeve sections, each of said first sleeve sections extending for respective portions of the length of said sleeve and being spaced from each other, said sleeve additionally comprising at least one second section, said second section being interposed between said at least two first sections, each of said stent means being arranged to be expanded from a compact state to an expanded state as said sleeve is so expanded so that the cross-section area of the interior of said sleeve is enlarged, said stent means when in said expanded state being resistant to contraction back to said compact state to thereby hold said sleeve in said compact state to thereby hold said sleeve in said expanded state, said graft being able to bend longitudinally with respect to said axis to enable said graft to be readily accommodated within a curved blood vessel, duct or lumen.

* * *

14. An intraluminal graft for introduction within a portion of a blood vessel, duct or lumen of a living being, said graft comprising a sleeve and stent means mounted thereon, said sleeve being an elongated member of a generally tubular shape having a longitudinal axis and formed of a first, relatively flexible, material, said material being impervious to the ingrowth of tissue therein, said sleeve comprising an outer peripheral surface, said stent means being generally ring-like in shape and mounted on said outer peripheral surface of said sleeve to form a first sleeve section, said stent means being arranged to be expanded from a compact state to an expanded state as said sleeve is so expanded so that the cross-sectional area of the interior of said sleeve is enlarged, said stent means when in said expanded state being resistant to contraction back to said compact state to thereby hold said sleeve in said expanded state, said graft being able to bend longitudinally with respect to said axis to enable said graft to be readily accommodated within a curved blood vessel, duct or lumen.

15. An intraluminal graft for introduction within a portion of a blood vessel, duct or lumen of a living being, said graft comprising a sleeve and stent means mounted thereon, said sleeve being an elongated member of a generally tubular shape having a longitudinal axis, an outer peripheral surface, and being formed of a first, relatively flexible, material, said material being impervious to the ingrowth of tissue therein, said stent means being generally ring-like in shape and mounted on said outer peripheral surface of said sleeve to form a first sleeve section, said first sleeve section extending for only a portion of the length of said sleeve to form a first sleeve section, said first sleeve section extending for only a portion of the length of said sleeve, said sleeve additionally comprising a second sleeve section contiguous with said first sleeve section, said stent means being arranged to be expanded from a compact state to an expanded state as said sleeve is so expanded so that the cross-sectional area of the interior of said sleeve is enlarged, said stent means when in said expanded state being resistant

> to contraction back to said compact state to thereby hold said sleeve in said expanded state, said first and second sleeve sections being able to bend longitudinally with respect to said axis to enable said graft to be readily accommodated within a curved blood vessel, duct or lumen.

Id. at 3-4 (citing '154 Patent, col.9, l.28 to col.10, l.67).

The parties had agreed on the meaning of two terms in the '154 patent, "first sleeve section[s]" and "second sleeve section[s]." Dkt. No. 102, Claim Construction Order, at 10 ("CCO"). The parties disputed two additional claim terms and, on April 10, 2013, the Court issued its Order on the construction of those terms. *See*, *generally*, *id.* The following chart summarizes the terms and the Court's construction:

CLAIM CONSTRUCTION CHART FOR THE '154 PATENT	
DISPUTED TERM	**COURT'S CONSTRUCTION**
"stent means"	"a generally ring-like, hollow support that is resistant to contraction back to a compact state once it has been expanded"
"resistant to contraction back"	"able to withstand the force or effect of"

Notwithstanding the Court's discussion regarding construction for these terms, the parties dispute the scope of the "resistant to contraction back" element. Dkt. No. 153-1 at 26-27; Dkt. No. 174 at 24-26; Dkt. No. 196 at 9-11. The Court explained this term at length stating, with respect to its limitation on the stent means:

> The plain meaning of the term stent, in combination with this material and/or mechanical requirement [(referring to the "resistant to contraction back" element)], limit the invention to that subset of stents that have the requisite structural properties. Whether those properties are obtained through the choice of material; or the design of the hollow, rink-like part; or a combination of the two, as disclosed in the description of the preferred embodiment; the invention does not preclude the use of a self-expanding stent.

CCO at 18. In further elaborating on the characteristics of "resistant to contraction back," the Court stated that "the stent must be able to withstand or hold off the force trying to close the sleeve once it has been expanded." *Id.* at 20. In other words, it must "hold the

sleeve in its expanded state." *Id.* However, the Court rejected the notion that contraction back is precluded and refused Cook's invitation to import a limitation from the preferred embodiment into the claims. *Id.* at 21-22.

In addition to their arguments about the scope of the "resistant to contraction back" element, the parties dispute the meaning of an additional term "impervious to the ingrowth of tissue therein." Dkt. Nos. 153-1 at 25-26; Dkt. No. 174 at 20-24; Dkt. No. 196 at 8-9.

2. <u>The '417 Patent</u>

The application that matured into the '417 patent was filed on November 27, 1995. Dkt. No. 153-1, at 14; Dkt. No. 144 at 6. The patent issued on January 14, 1997. Dkt. No. 144 at 6. According to the abstract, the stents of the graft in the '417 patented invention are mounted on the outer surface of the sleeve and have "anchoring projections" that "are preferentially oriented to include portions extending at an acute angle to the direction of the fluid flow to tightly engage the interior of the wall of the vessel, duct, or lumen under the force applied by the fluid flowing through the device." Dkt. No. 148-2, '417 Patent, Abstract.

The asserted claims of the '417 patent read:

> 1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface, said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular-member, said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior surface of the vessel, duct, or lumen, each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof, said trailing portion including at least one surface preferentially oriented to extend at an acute angle to the first

direction, whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said projections a force component to cause said at least one surface to tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place.

2. The device of claim 1 wherein said at least one surface is inclined upward in the first direction.

* * *

9. The device of claim 1 wherein said tubular member is a stent.

10. The device of claim 9 wherein said stent is expandable from a contracted state to an expanded state, said anchoring means engaging the interior surface of the vessel, duct, or lumen when said stent is in said expanded state to secure said device in place.

* * *

13. The device of claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.

Id. (citing Dkt. No 148-2, '417 Patent, col.9, l.23 to col.10, l.40).

During the claim construction phase of this case, the parties agreed to the meaning of the terms "first direction," and "preferentially oriented." CCO at 12. However, they disputed the meaning of the terms "tubular member;" "anchoring means;" "projections;" "engagement with" or "engaging;" "to tightly engage the interior surface of the vessel, duct or lumen to fixedly secure said device in place;" "a leading portion;" "a trailing portion;" "at least one surface;" and "stent." *Id.*

After a hearing, the Court construed the disputed terms as follows:

CLAIM CONSTRUCTION CHART FOR THE '417 PATENT	
DISPUTED TERM	**COURT'S CONSTRUCTION**
"tubular member"	"tubular member"
"anchoring means"	"multiple projections or protuberances with a leading portion and a trailing portion, such that one surface of the trailing portion is positioned at an acute angle relative to the direction of fluid flow"
"projections"	"protuberances or parts that extend outward from a surface"
"a leading portion"	"part of a projection oriented in the upstream direction of the fluid flow"
"a trailing portion"	"part of a projection oriented in the downstream direction of the fluid flow, with at least one portion positioned at an acute angle to the fluid flow"
"at least one surface"	"one portion, part or surface of the trailing portion of a projection oriented at an acute angle to the fluid flow"
"engagement with;" "engaging"	"to partly embed, interlock or enmesh"
"tightly"	"firmly"
"stent"	"a hollow support"

Notwithstanding the Court's discussion regarding construction of these terms, the parties continue to dispute the scope of the "tightly engage" limitation. Dkt. No. 153-1 at 36-37; Dkt. No. 174 at 26-29; Dkt. No. 196 at 23-24 & n.16. The claims require at least one surface of the anchoring means to "tightly engage" the interior surface of a vessel, duct, or lumen. Dkt. No. 148-2, '417 Patent, col.9, ll.43-45. In construing this term, the Court considered that "the patent teaches that 'to tightly engage,' the projections must 'burrow slightly into[] the interior wall of the vessel, duct, or lumen . . . ." COO at 39 (citing '417 Patent, col.4, ll.23-25). The Court opined that the definition must allow for both some level of penetration, but also allow for tight engagement that does not include penetration. *Id.* at 39-40. Therefore, with respect to penetration, the Court concluded that "if penetration is desirable, it is only into the initial surface layer of the vessel, duct, or lumen; it does not penetrate, or perforate, the entire wall of the passageway." *Id.* at 39. However,

if penetration is undesirable, the projections must be firmly contacting (or embedded or interlocked or enmeshed with) the interior wall of the vessel, duct, or lumen. *Id.* at 39-40.

The '417 patent cites several prior art references that disclose barbs for effecting "securement" of an intraluminal device. Dkt. No. 153-1 at 15-16. During prosecution, the inventor, Dr. Valentine Rhodes ("Dr. Rhodes"), distinguished the prior art references cited by the examiner by arguing that, unlike in those in his claim, the references did not disclose any anchoring means that "tightly engage." *Id.* at 16. He further argued that the prior art did not disclose "the shape being claimed [in the '417 patent], namely, that the projections include a trailing portion having at least one surface (e.g., a trailing surface) which is preferentially oriented to extend at an acute angle to the direction of the fluid flow." *Id.* at 24.

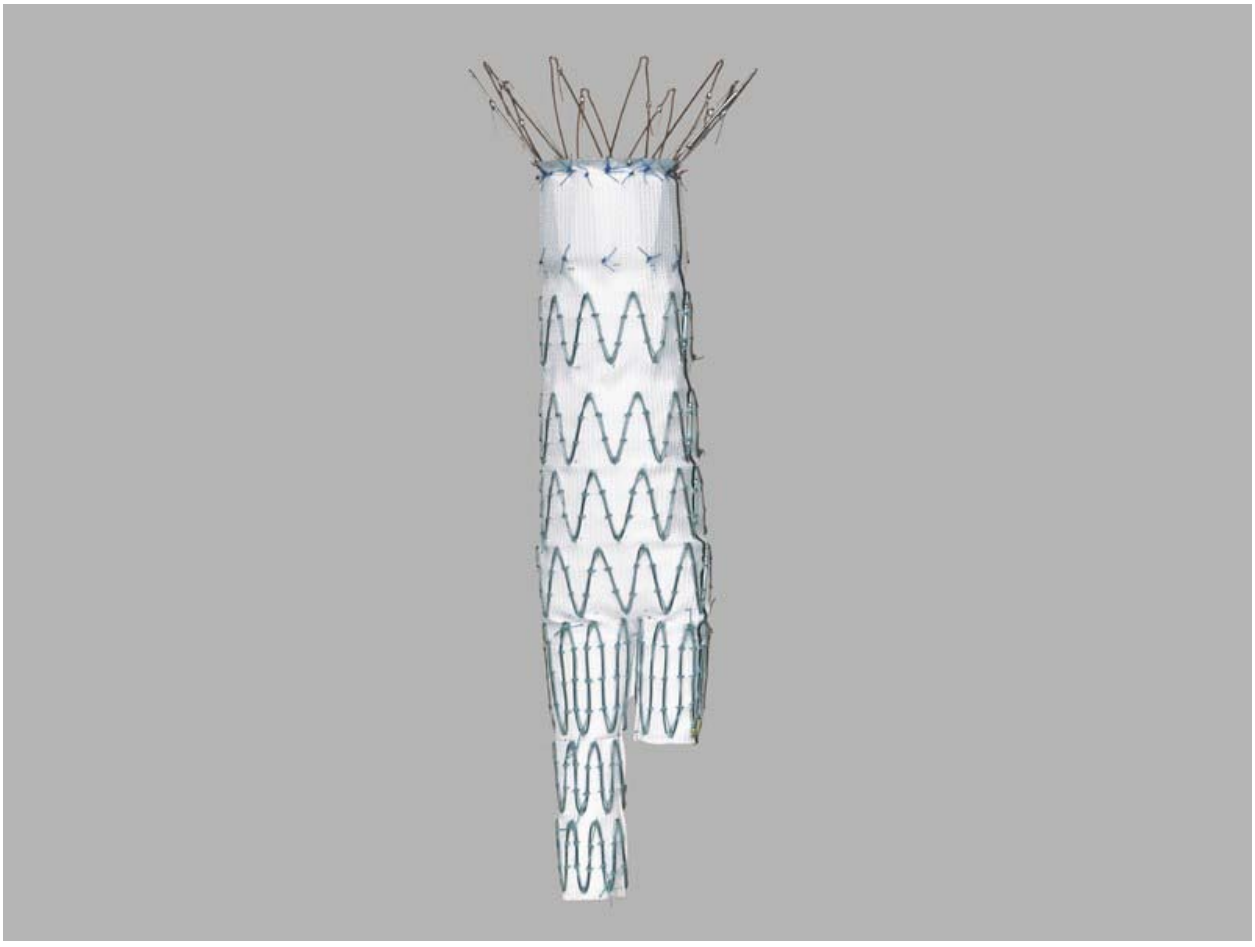
B. THE ACCUSED PRODUCTS

Endotach asserts that five of Cook's products infringe one or both of the Rhodes patents: (1) Zenith AAA Endovascular Graft ("Zenith AAA"); (2) Zenith Flex AAA Endovascular Graft ("Zenith Flex"); (3) Zenith Renu AAA Ancillary Graft ("Zenith Renu"); (4) Zenith Fenestrated AAA Endovascular Graft ("Zenith Fenestrated"); and (5) Zenith TX2 TAA Endovascular Graft ("Zenith TX2") (collectively, the "Accused Products"). Dkt. No. 153-1 at 11. The Accused Products are stent grafts made from a combination of materials and one or more self-expanding stents. *Id.*

In practice, a doctor places an accused product into a patient's aorta, the main blood vessel carrying blood away from the heart. *Id.* The aortic wall consists of three layers: the tunica intima (referred to as the intimal layer); the tunica media (referred to as the medial layer); and the tunica adventitia (referred to as the adventitial layer). *Id.* The

intimal layer, which is the initial or intimal layer inside the vessel, is comprised of an endothelial cell layer, a subendothelial layer, and an internal elastic lamina layer. *Id.*; Dkt. No. 174 at 12-13.

The Accused Products have sleeves that are made from a woven Dacron® polyester fabric. Dkt. No. 153-1 at 16. The fabric is porous, which allows for tissue growth into the graft sleeve. *Id.* The Zenith Flex, for example, looks like this:



See Cook Medical, Inc., online Product Catalog, available at https://www.cookmedical.com/product/-/catalog/zenith-flex-aaa-endovascular-graft-bifurcated-main-body-graft?ds=ndo_aaamain_webds#!, last visited Nov. 6, 2014.

The alleged "stent means" in the Accused Products are called "Z-stents," which

reflect their zig-zag configuration. Dkt. No. 153-1 at 16. Cook developed and patented them in the 1980s, years before the filing of dates of the Rhodes patents. *Id.* The stents may expand and contract slightly in response to forces in the body once the graft has been deployed. *Id.* at 16-17; Dkt. No. 174 at 14 & 25-26. Some of the Accused Products have fixation barbs. Dkt. No. 153-1 at 8; Dkt. No. 174 at 14. The fixation barbs provide "active fixation," meaning the barbs "will penetrate the aortic wall, to mimic the fixation that you might get with a suture, for example, in a surgical procedure." *Id.*

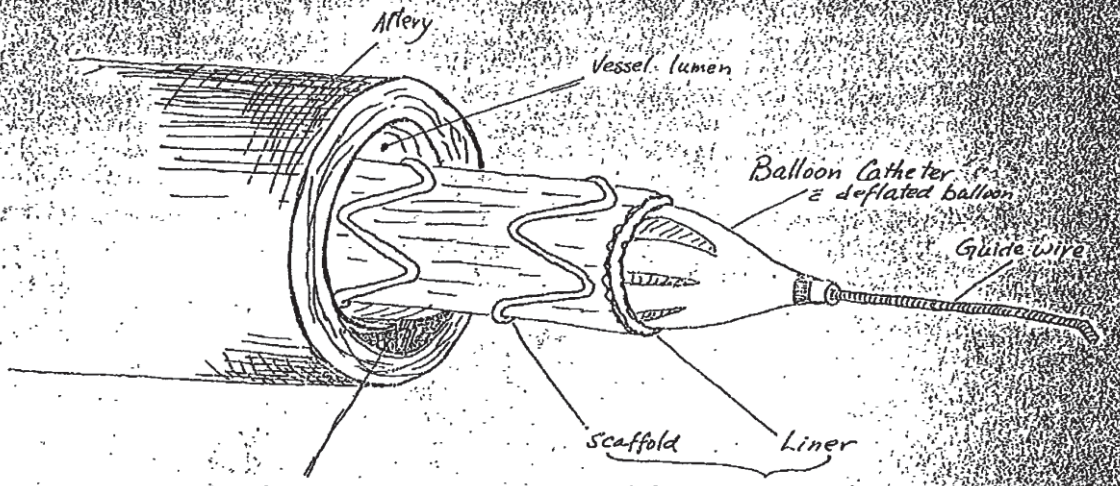
C. RELEVANT PRIOR ART

Dr. Peter Lee's Stent Grafts & U.S. Patent No. 5,123,917

In 1989, Dr. Peter Lee ("Dr. Lee") invented, and later patented, designs for stent grafts. Dkt. No. 153-1 at 17. Specifically, Dr. Lee prepared a detailed invention disclosure (the "Lee disclosure") and had it notarized on May 16, 1989. *Id.* The Lee disclosure focuses on creation of a suitable surface for controlled healing of an atheromatous cavity to help combat restenosis. Dkt. No. 148-9 at 2. The Lee disclosure discusses a design for an "endothelial resurface device [that] is to be inserted percutaneously and placed via the vascular luminal side. (See Figure 1)." Dkt. No. 148-9 at 3. Figure 1 is reproduced below.

Fig. I

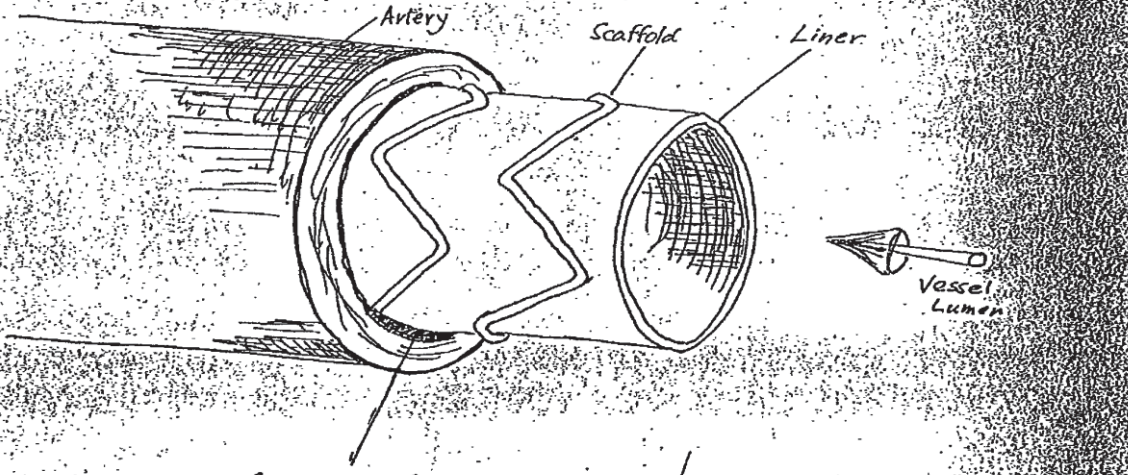
A. Device mounted on a Balloon Catheter at the Atheroma and positioned



Endothelial Resurface Device mounted on a Balloon Catheter

B. Device inflated and anchored in place (Balloon Catheter already withdrawn)

Endothelial Resurface Device in position on vessel wall



Peter Li 5/16/89

VALERIE L. SEKELY
Notary Public, State of Ohio
My Commission Expires JAN. 14, 1990

Id. at 8. The Lee disclosure teaches:

> The endothelial liner is a composite and thin membranous structure that would act as a surface for endothelialization and as a barrier between the hematological elements and the injured vascular media. This membranous structure is mounted on a scaffolding structure that will serve both to anchor the endothelial liner to the vascular wall and to withstand the pressure of cellular growth that would tend to distort the luminal integrity.

Id. at 3. Lee contemplated that the endothelial liner would "consist[] of a luminal surface and a vascular surface that could be made up of two different materials of different physical and biological properties." *Id. See also id.* at 3-4 (citing Figure 2). With respect to the scaffold, the Lee disclosure suggests "surgical stainless steel in a corrugated ring structure . . . anchored into the liner, either in-between the two membranes in the manufacturing process or it can be attached to the liner after the lining material has been fabricated." *Id.* at 5. Spacing of the rings would depend upon "its position of anchoring on the lining material," but "no inter ring metal connection is necessary." *Id.* Figures 2 and 3 are reproduced below.

Fig II

A. Longitudinal and detailed diagram of the Device lining the artery.

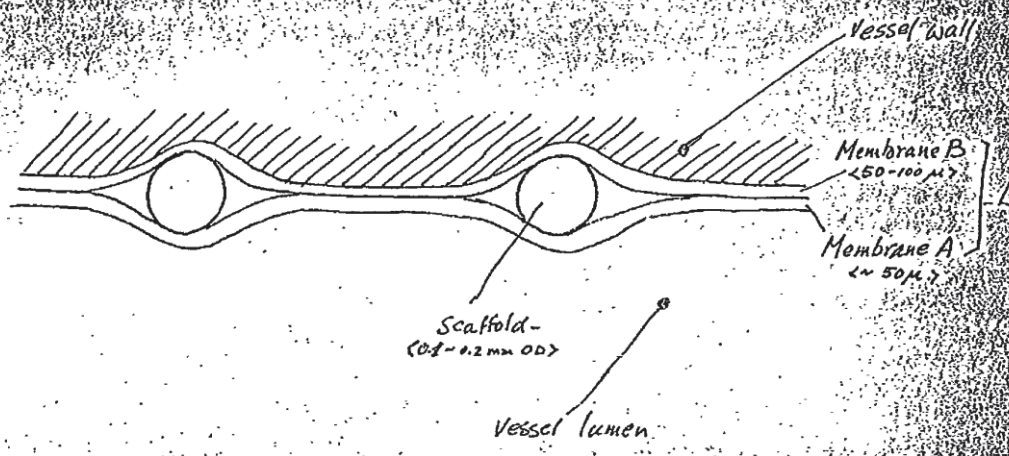


Diagram not to scale

B. Transverse section of the liner within the artery.

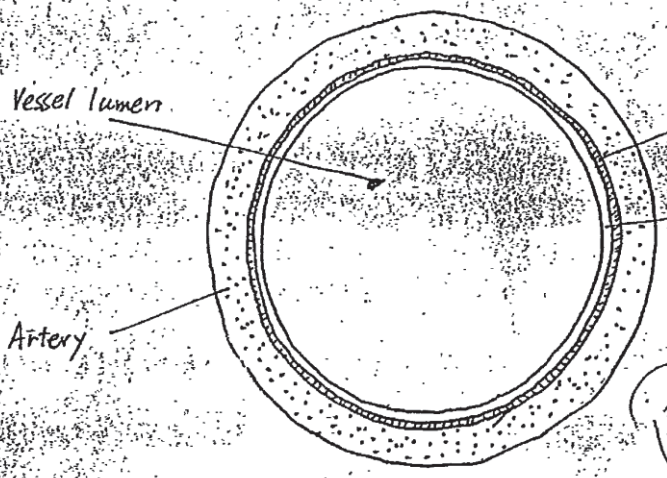


Diagram not to scale

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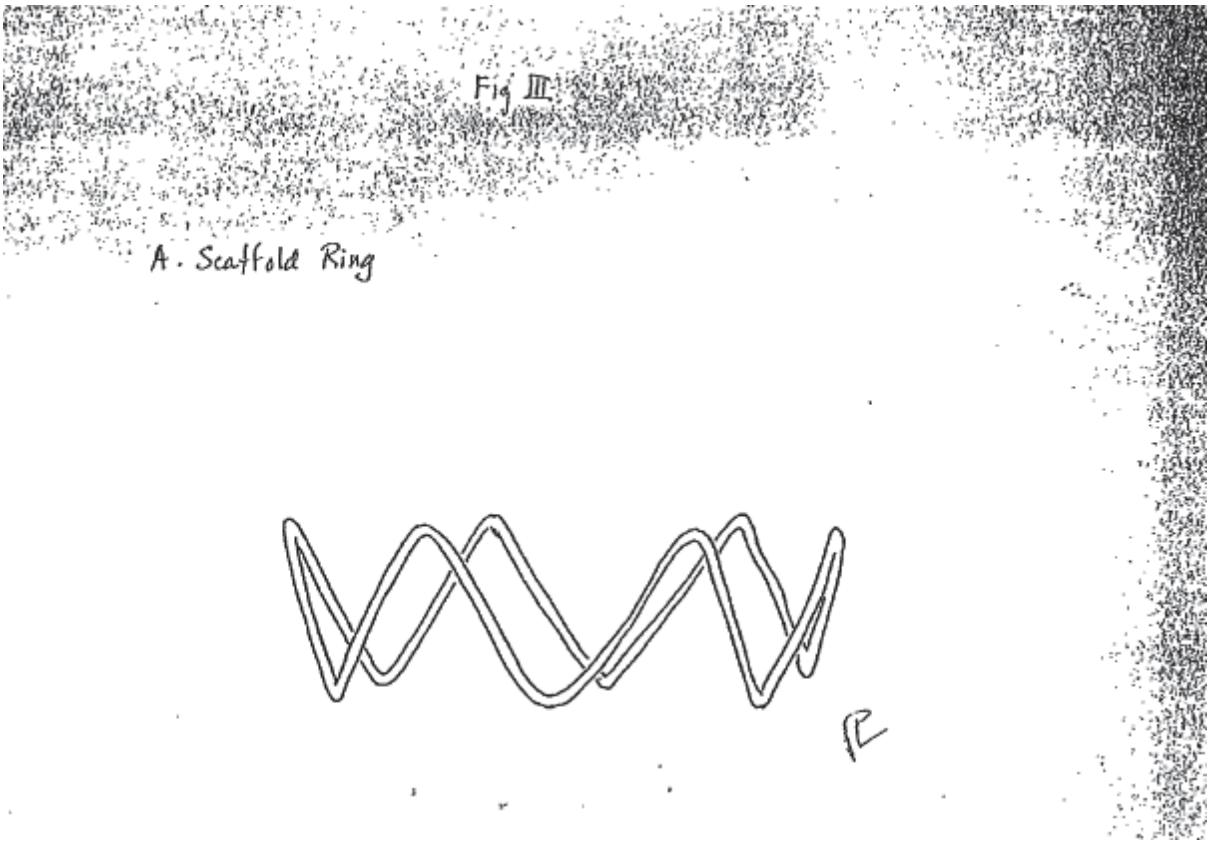

Id. at 9-10.

On April 24, 1990, Dr. Lee signed a declaration endorsing his patent application directed to his stent graft. Dkt. No. 153-1 at 18-19. Three days later, on April 27, 1990, Dr. Lee filed the application that matured into U.S. Patent No. 5,123,917 (the "Lee patent"). *Id.* at 19. The Lee patent is directed to "[a]n expandable intraluminal vascular graft [that] includes a flexible cylindrical inner tube having a[n] outer periphery and plurality of separate scaffold member[s] mounted on the outer periphery of the inner tube. The scaffold members are expandable, ring-like and provide circumferential rigidity to the graft." Dkt. No. 148-12, Lee Patent, Abstract. Although the Lee patent expresses a preference for the spaced scaffold members to be sandwiches between inner and outer membranes, *id.* col.5, ll.11-15, it discloses and claims an alternative embodiment where there is a single membrane with inner and outer surfaces and where "it would be

advantageous to provide the rings on the outside in order not to have any barrier to blood flow through the graft." *Id.* at col.7, ll.21-49; *id.* at col.8, ll.54-57.

D. FACTS RELATED TO LACHES DEFENSE

1. Pervasive, Open, and Notorious Activities Regarding the Accused Products Since 2003

On April 10, 2003, Cook announced the FDA's recommended approval of the accused Zenith AAA. Dkt No. 153-1 at 42. On May 27, 2003, an announcement stated that sales in the United States would begin immediately based on final Federal Drug Administration ("FDA") approval. *Id.* Sales began on June 11, 2003, with an announcement of the Zenith AAA's features, including "suprarenal fixation with anchoring barbs and modular graft design incorporating woven polyester supported by independent, stainless steel z-stent bodies. *Id.*

Over the next several years, press releases announced expansion of the Zenith product line upon FDA approval of the following Accused Products: Zenith Flex on April 15, 2004; Zenith Renu on June 9, 2005; Zenith TX2 on May 21, 2008; and Zenith Fenestrated on April 4, 2012. *Id.* Various press releases described the features of these products:

- Zenith Flex includes "more widely spaced stent bodies to allow the device to conform to tortuous anatomy." The design decreased "kink radius . . . allowing the device to bend around tighter turns in the aorta with less chance of kinking."

- "Like all the Zenith AAA Endovascular Graft main body components, the Renu . . . utilizes an uncovered suprarenal stent with anchoring barbs to provide strong proximal fixation and enhanced graft-to-vessel sealing."

- Zenith Renu has "Dacron or ePTFE" and "an uncovered suprarenal stent with anchoring barbs to provide strong proximal fixation and enhanced graft-to-vessel sealing."

- Zenith TX2 has "a self-expanding tube of surgical graft material reinforced with metal stent bodies [that] is sized to the diameter of the aorta" and has "a unique uncovered distal stent with fixation barbs to hold the device in place . . . ."

Id. at 42-43.

Further, since 2003, numerous trade publications also described the design, features, and sale of the Accused Products:

- "Cardiovascular Device Update" reported that the FDA approved the Zenith Fenestrated, stating that "[the graft is fabricated from woven polyester vascular graft material hand-sewn to self-expanding Z-stent bodies," and "is based on Cook's Zenith AAA endovascular graft design."

- "Vascular News" described the "advanced features" of the Zenith Flex, including "more widely spaced stent bodies to allow the device to conform to tortuous anatomy," and a decrease in "kink radius."

- "Endovascular Today" described the "Zenith Flex as having more widely spaced stent bodies to allow the device to better conform to tortuous anatomy."

- "Interventional News" published photos of the Zenith Fenestrated and Zenith Renu with barbs and the Z-stents sewn onto the graft material, and stated that "[l]ike all Zenith AAA Endovascular Graft main body components, the Renu . . . utilizes an uncovered suprarenal stent with anchoring barbs to provide strong proximal fixation and enhanced graft-to-vessel sealing."

- "Charlotte Weekly" published a drawing of the Zenith Flex showing spaced apart z-stents attached to graft material and suprarenal stent with anchoring barbs.

Id. at 43.

2. <u>Reduction to Practice, Conception & Licensing of the Rhodes Patents; & the Rhodes Trust</u>

Dr. Rhodes allegedly sketched early ideas of his invention on paper napkins and other scraps of paper, at least some of which he either threw away or otherwise destroyed shortly after drawing them. Dkt. No. 153-1, at 48; Dkt. No. 174 at 17. Brenda Rhodes ("Brenda"), Dr. Rhodes' wife, recalls that he had refined his idea regarding one device

that "fit everything" and sketched a design on napkins in or around May 1989. Dkt. No. 174 at 17. Sonja Dungan ("Dungan"), Dr. Rhodes' "longtime secretary," recalls discussing a "Chinese finger cuff" idea with Dr. Rhodes in September or October 1989, Dkt. No. 174 at 17, and further claims that on December 5, 1989, she witnessed and notarized Dr. Rhodes' "preliminary drawings," but she does not recall how long she reviewed the documents, and does not have a book in which she allegedly recorded the notarizations. Dkt. No. 153-1 at 50. In or around late March or late April 1990, Dr. Rhodes dictated a first draft of the '154 patent application via audiocassette tape and gave it to Dungan to transcribe. *Id.*

Some early sketches might have been in Dr. Rhodes' belongings and given to Brenda for safe-keeping; however, Brenda cannot find them and admits that some of Dr. Rhodes' and her papers may have been thrown away when she moved in 2009. Dkt. No. 153-1 at 48. Brenda did find in her files a document listing contact information for medical device companies, including Cook Incorporated. *Id.* at 48-49. However, she could not explain who created the document, where it came from, why certain text was blacked out, whether it was an attachment to another document, or how it came to be in her files. *Id.* at 49.

William Cuffari ("Cuffari") claims that he was a close friend of Dr. Rhodes' and that Dr. Rhodes showed him the early sketches of his design on paper napkins or other scraps and that he documented these meetings with Dr. Rhodes. *Id.* at 48. Cuffari claims that he kept papers and correspondence about Dr. Rhodes and/or his work, but they were destroyed in a 2005 flood. *Id.* Cuffari does not recall the season, day, month he allegedly

saw Dr. Rhodes' sketches, or when they might have been created; he only recalls seeing one alleged drawing in 1988. *Id.*

Barry Stein ("Stein") of Caesar Rivise, was Dr. Rhodes' patent counsel. *Id.* at 46. Stein has practiced at Caesar Rivise since 1972, and has been recognized as a "SuperLawyer" patent litigator since 2005. *Id.* Stein claims to be "one of the country's leading Intellectual Property lawyers" and "has spent his entire professional career enforcing and protecting his clients' patents . . . ." *Id.* at 46-47. Stein has prosecuted patent applications for medical devices for many decades, has long known of Cook, and understood Cook to be "a player" in the medical device industry. *Id.* at 49. Based on his experience, Stein has long been familiar with the cardiovascular industry and stent developments. *Id.*

USPTO records indicate that Stein prosecuted the Rhodes patents, but he "recall[s] little about these patent applications. It's over twenty years." *Id.* Stein has no independent recollection of the '417 patent at all. *Id.* Stein also does not remember anything relevant about drawings he turned over in discovery. *Id.* at 49-50. However, Endotach is relying upon Stein's documents to tell an invention story. *Id.* at 50 (citing Dkt. No. 136 at 5-9). From 1992 to 1995 Dr. Rhodes unsuccessfully attempted to license the Rhodes patents with at least six companies. *Id.* Stein represented Dr. Rhodes in these efforts but has no relevant recollection of them. *Id.*

In August 1995, Dr. Rhodes and Johnson & Johnson Interventional Systems Inc. ("JJIS") discussed licensing of the '154 patent. Dkt. No. 144 at 8. On November 1, 1995, those parties entered into a worldwide exclusive license agreement (the "JJIS License Agreement" or the "Agreement")) for the Rhodes patents. Dkt. No. 153-1 at 43. Stein

represented Dr. Rhodes during negotiations of the JJIS License Agreement, but does not recall those circumstances. *Id.* at 50. JJIS, now merged with Cordis Corporation, is a member of the Johnson & Johnson ("J&J") family of companies. *Id.* at 43; Dkt. No. 144 at 8. The JJIS License Agreement required the parties to "give prompt notice to one another of any infringement of a Licensed Patent by Third Parties as may come to their knowledge." Dkt. No. 153-1 at 43-44. Dr. Rhodes gave JJIS "the right to pursue legal action against infringement of a Licensed Patent by Third Parties." *Id.* at 44. If JJIS failed to sue within six months, Dr. Rhodes could sue. *Id.*

Paul Coletti ("Coletti") negotiated the JJIS License Agreement on behalf of JJIS, however, he does not recall the details. *Id.* at 49. He does not know any details regarding conception, reduction to practice, and/or diligence related to the Rhodes patents, although he testified that JJIS would have investigated those factors "as part of the due diligence prior to signing the license agreement;" JJIS likely performed a prior art search as part of that process as well. *Id.* JJIS produced no documents regarding either type of due diligence search. *Id.* JJIS never made or sold any product covered by the Rhodes patents. Dkt. No. 144 at 9.

JJIS knows Cook well. Dkt. No. 153-1 at 44. Since the early- to mid-1990s, they have "had a number of dealings," including "licenses[] and litigations and things like that." *Id.* However, JJIS and Dr. Rhodes never discussed whether or not the Accused Products infringed. *Id.* JJIS "keeps an analysis of competitive information about lots of products and companies," including Cook. *Id.* at 44. The JJIS competitive analysis program would have uncovered the Accused Products at least as early as 2003, upon the announcement of clinical trials and "immediate" sales of the Accused Products. *Id. See also* Dkt. No.

144 at 29 (discussing general information JJIS would receive regarding all medical devices entering the market). Coletti testified, "When Cook announces that it's going to run a clinical trial, or wants to introduce a product to the marketplace, [JJIS] generally learns about that the same way everybody does . . . via the wire services and things like that." Dkt. No. 153-1 at 44. JJIS would have learned about the Accused Products when they were introduced into the marketplace, or possibly sooner "through understandings with what's going on in the clinical trials." *Id.* *See also* Dkt. No. 144 at 10 (discussing awareness of Cook's products generally). Coletti testified that he could not recollect a determination of infringement with respect to the Rhodes patents and any Cook devices. Dkt. No. 171-1 at 15.

In 1996, Dr. Rhodes was forced to retire from his medical practice in New Jersey due to a terminal diagnosis of pulmonary fibrosis. Dkt. No. 144 at 9. Thereafter, the Rhodes family moved to Florida, where Rhodes passed away in December 2000. *id.*

The Valentine J. Rhodes Revocable Trust (the "Trust") was created on July 29, 1999, naming Dr. Rhodes and his wife, Brenda Rhodes ("Brenda"), co-trustees. *Id.* at 45. The Trust provided that property could be added to it via bequest, and gave the co-trustees power to hire attorneys, accountants, investment counsel, and others as deemed advisable. *Id.* at 45-46. When Dr. Rhodes died in the year 2000, the Trust received the Rhodes patents and the JJIS License Agreement. *Id.* at 46. Brenda, along with the Rhodes' daughters, Josette Carroll ("Carroll") and Amanda Rhodes-Finley ("Rhodes-Finley"), became co-trustees. *Id.*

The Trust received about $640,000.00 from Dr. Rhodes' life insurance policies. *Id.* Between 2001 and 2012, the Trust reported annual income of $2,500.00 to $46,000.00.

Id. In 2004, the Trust received a payment of $151,382.00. *Id.* During the period between November 2003 and August 2011, the Trust disbursed funds as follows:

- November 7, 2003: $138,249.00 to Bank of Bristol, Florida, on behalf of Carroll;
- Beginning in December 2008: monthly withdrawals of $3,000.00 to Carroll; and
- August 4, 2011: $170,000.00 to Brenda.

Brenda is a nurse. Dkt. No. 153-1 at 45. She was allegedly "intricately involved in" Dr. Rhodes' vascular medicine practice until his retirement, assisting him with "diagnosis and screening," "post-operative follow up and testing," and business activities and logistics. *Id.* During the time that they worked together, Brenda attended meetings with patent counsel; JJIS; and W.L. Gore & Associates, Inc. ("WL Gore"). *Id.* After Dr. Rhodes' death, Brenda worked as a school nurse. Dkt. No. 144 at 9.

Upon Dr. Rhodes' death, Brenda inherited about $3 million. Dkt. No. 153-1 at 45. In 2009, she received over $500,000.00; and over $150,000.00 in each of three other years since 2000. *Id.* At one time she lived in a "magnificent" waterfront property subject to a $2 million mortgage. *Id.*

Further, since 2003, Brenda bought a farm in Missouri for $1.3 million and a commercial franchise for $30,000.00. *Id.* Brenda also bought five luxury vehicles, gifted her children $240,564.000, and paid over $80,000.00 in house interest and taxes.[3] *Id.*

Robert Housen ("Housen"), of Housen Financial Group, offers investment and financial planning for "high net worth individuals." *Id.* at 46. Housen has advised Brenda on financial matters since Dr. Rhodes' death. *Id.* When Acacia Patent Acquisition LLC

[3] Brenda did not produce her tax returns for 2003-2005 or 2008. Dkt. No. 153-1 at 45.

("Acacia") contacted Brenda in 2009 about obtaining a license to the Rhodes patents, she turned to Housen to check whether Acacia was even a real company. *Id.*

Stein has represented Brenda since Dr. Rhodes' death, and from 2003 to 2009 communicated with her sporadically. *Id.* at 47; Dkt. No. 174 at 61. Mindful of Dr. Rhodes' patents, Brenda sent Stein an article about a J&J stent approved for sale in 2003 that she thought might be covered by the patents. Dkt. No. 153-1 at 47; Dkt. No. 171-1 at 15; Dkt. No. 171-1 at 18.

Further, in a testimonial for Acacia, Brenda states, in pertinent part:

> My late husband, Dr. Valentine Rhodes, was a vascular surgeon who dedicated his life to helping those in need. In order to provide the best care possible, he designed medical technologies that would improve surgical results. After he passed away, it became known that many companies he was in contact with had products similar to his inventions. When I spoke with our patent attorney, I was discouraged from exploring further, being told that I did not have the means to approach and negotiate with these large companies who were more sophisticated, had more money, and would simply look to delay everything through drawn out litigations.

Dkt. No. 148-37, at 2.

On November 20, 2009, Acacia, the parent company of Endotach, and Brenda entered into an Exclusive License Agreement for the '417 patent. Dkt. No. 144 at 10. On November 7, 2011, Acacia transferred its rights to the '417 patent from Acacia to Endotach. *Id.* at 10-11. Subsequently, Acacia and Brenda discussed adding an exclusive license to the '154 patent. *Id.* at 11. In responses to interrogatories, Endotach asserted that it was unaware of the Accused Products in this case until February 2010, Dkt. No. 144 at 11; however, in its response in opposition to Cook's Motion to Compel Regarding Endotach's Amended Privilege Log Provided After the Close of Business on the Last Day of Fact Discovery, Endotach stated that "in 2009 . . . Acacia first began developing a

strategy to enforce the patents-in-suit against possible infringers, including Cook Medical for the Accused Products here." Dkt. No. 171-1 at 16.

3. Cook's Investment in the Accused Products

Cook has spent many millions of dollars to develop the Accused Products, including biocompatibility, bench, graft permeability and animal testing; finite element analysis; clinical trials; preparing clinical data for the Food & Drug Administration ("FDA"); presenting to the FDA circulatory device panel and ultimately achieving FDA premarket approval. Dkt. No. 153-1 at 47. From 2003 to 2013, Cook invested hundreds of millions of dollars in marketing and sales of the Accused Products as well as hundreds of millions of dollars in royalties. *Id.* at 47-48. During that period of time, sales of the Accused Products has increased. *Id.* at 48.

4. Other Relevant Evidence

In 1993, in-house patent counsel for Cook Group, Inc., sent a letter/report "referring to the '154 patent, reflecting legal advice and request for legal advice re patent search" to Kem Hawkins ("Hawkins"), then Vice President of Cook Critical Care.[4] Dkt. No. 144

[4] Endotach used several references in privileges logs to assert that Cook knew about the Rhodes patents for years, but did nothing to change its allegedly infringing designs to avoid infringement. Dkt.No. 114 at 5-8. Cook objected to this evidence on the grounds that it is improper to draw negative inferences from a privilege log under relevant case law. Dkt. No. 171-1 at 29-30; 31-33 (citing, *inter alia*, *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343-44 (Fed. Cir. 2004)). The Court agrees that it is improper to draw adverse inferences from a privilege log. However, to the extent that Cook relied upon the privilege log in response to an interrogatory requesting information about when Cook became aware of the Rhodes patents, the fact of communications about the patents at a certain time is not an impermissible reference. Therefore, Cook's objection is **SUSTAINED in part and OVERRULED in part**; the Court will not use the privilege log information to make an adverse inference; however, it may consider the facts contained in the privilege log as it relates to the question of when Cook became aware of the Rhodes patents.

at 6 & n.1; Dkt. No. 171-1 at 11. Similarly, in 1995, in-house counsel sent a "[d]ocument identifying the '154 patent, and reflecting legal advice and request for legal advice re patent search." Dkt. No. 144 at 6-7; Dkt. No. 171-1 at 11.

In 2005, outside counsel for Cook sent a document to the file "referring to the '154 patent and the '417 patent, and reflecting legal advice and request for legal advice re clearance activities." Dkt. No. 144 at 7; Dkt. No. 171-1 at 12.

In 2007, a third party, Edwards Lifesciences ("Edwards") accused Cook Incorporated of infringing patents Edwards owned. Dkt. No. 144 at 7. As part of its defense in that suit, Cook Incorporated asserted that the Edwards' patents were invalid, in part, due to the '154 patent. *Id.* In 2007, several documents and/or emails between Cook Incorporated and counsel refer to the '154 patent and reflect legal advice and a request for legal advice "re N.D. Cal. Civil Action No. 03-3817;" or is an email "referring to the '154 patent, and reflecting legal advice and request for legal advice re opposition proceeding." Dkt. No. 144 at 7; Dkt. No. 171-1 at 12. Similar documents in 2008 identify or refer to the '154 patent and/or the '417 patent and "reflect[] legal advice and request for legal advice re clearance activities." Dkt. No. 144 at 8; Dkt. No. 171-1 at 12-13.

Cook's invalidity defenses for the '154 patent rely, in part, on an article by Dr. Alexander Balko (the person, "Dr. Balko;" the article, the "Balko article") and a patent on which Dr. Balko is named as an inventor. Dkt. No. 153-1 at 51. Endotach disagrees with Cook regarding what the Balko articles discloses. *Id.* Dr. Balko died on September 16, 2008.

On November 20, 2009, Brenda purported to grant Acacia an exclusive license (the "Acacia license") to the '417 patent. *Id.* On November 7, 2011, Acacia assigned the

Acacia license to Endotach. *Id.* Endotach asserts that it and Acacia did not file suit earlier in order "to conduct a proper investigation and clinical testing." *Id.* However, Endotach has not fully produced such clinical testing nor is it relying upon such data to prove infringement. *Id.* In fact, Endotach is not relying on any testing at all to show infringement by the Accused Products. *Id.*

Endotach's original complaint in which it asserted that Cook infringed the Rhodes patents was filed in the Northern District of Florida on June 21, 2012, and transferred to this Court on November 8, 2012. *Endotach LLC v. Cook Med. Inc.*, Cause No. 1:12-cv-01630-LJM-DKL ("*Endotach I*"), *Endotach I*, Dkt. Nos. 1 & 51. This case was filed on July 16, 2013. *Endotach LLC v. Cook Med. Inc.*, Cause No. 1:13-cv-01135-LJM-DKL, Dkt. No. 1. *Endotach I* was dismissed without prejudice on August 6, 2013. *Endotach I*, Dkt. No. 159.

In his report dated February 11, 2014, Endotach's expert, Dr. Silver, relies on a 2009 "Summary Basis of Decisions" review ("SBD review") of a bovine study conducted in 2002 regarding a device referred to as the TX2 TAA Endovascular Graft with Introduction System. Dkt. No. 153-1 at 51; Dkt. No. 174 at 17. Dr. Roy Greenberg ("Dr. Greenberg"), who led the 2002 study ("Greenberg study"), died on December 7, 2013. Dkt. No. 153-1 at 51.

III. CROSS MOTIONS FOR SUMMARY JUDGMENT ON LACHES

Both Endotach and Cook have moved for summary judgment on Cook's affirmative defense of laches. Laches is an equitable doctrine that is committed to the sound discretion of the Court. *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1032 (1992). Cook has the burden to prove two factors: (1) Endotach "delayed

filing suit for an unreasonable and inexcusable length of time from the time [Endotach] knew of reasonably should have known of its claim against [Cook]," and (2) "the delay operated to the prejudice or injury of [Cook]." *Id.* The unreasonableness of the delay is not fixed, but depends upon the circumstances of the case. *Id.* However, "[a] delay of more than six years raises a presumption that is it unreasonable, inexcusable, and prejudicial." *Wanlass v. Gen'l Elec. Co.*, 148 F.3d 1334, 1337 (Fed. Cir. 1998) (citing *Aukerman*, 960 F.2d at 1035-36). A plaintiff may rebut the presumption with evidence "sufficient to raise a genuine issue of material fact about either the excuse for or reasonableness of the delay, or the existence of the prejudice." *Id.* (citing *Aukerman*, 960 F.2d at 1037-38).

"The period of delay begins at the time the patentee has actual or constructive knowledge of the defendant's potentially infringing activities." *Id.* The rule on constructive knowledge is an old one: "'[W]here the question of laches is in issue the plaintiff is chargeable with such knowledge as he might have obtained upon inquiry, provided the facts already known to him were such as to put upon a man of ordinary intelligence the duty of inquiry.'" *Id.* at 1338 (quoting *Johnston v. Standard Mining Co.*, 148 U.S. 360, 370 (1893)). Circumstances that trigger a duty to investigate include "'pervasive, open and notorious activities'" such as "sales, marketing, publication, or public use of a product similar to or embodying technology similar to the patented invention, or published descriptions of the defendant's potentially infringing activities . . . ." *Id.* (quoting *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1553 (Fed. Cir. 1996)).

> Furthermore, constructive knowledge of the infringement may be imputed to the patentee even where he has no actual knowledge of the sales, marketing, publication, public use, or other conspicuous activities of

> potential infringement if these activities are sufficiently prevalent in the inventor's field of endeavor.

Id. In addition, Endotach "must accept the consequences of his transferor's conduct." *Lautzenhiser Techs., LLC v. Sunrise Med. HHG, Inc.*, 752 F. Supp. 2d 988, 1000 (S.D. Ind. 2010) (citing *Rome Grader & Mach. Corp. v. J.D. Adams Mfg. Co.*, 135 F.2d 617, 620 (7th Cir. 1943); *R2 Med. Sys., Inc. v. Katecho*, 931 F. Supp. 1397, 1412 (N.D. Ill. 1996)).

The Court must weigh and evaluate any excuse Endotach provides of the delay including, without limitation, other litigation, negotiations with the accused infringer, possible poverty and illness under limited circumstances, wartime conditions, the extent of infringement, and disputes over ownership of the patents-in-suit. *See Aukerman*, 960 F.2d at 1033 (citations omitted).

With respect to the prejudice or injury element, the prejudice must be material and can be either evidentiary or economic. *Id.* Evidentiary prejudice "may arise by reason of a defendant's inability to present a full and fair defense on the merits due to the loss of records, the death of a witness, or the unreliability of memories of long past events . . . ." *Id.* (citations omitted). "Economic prejudice may arise where a defendant . . . will suffer the loss of monetary investments or incur damages which likely would have been prevented by earlier suit." *Id.* (citations omitted). The key is whether there was "a *change* in the economic position of the alleged infringer during the period of delay." *Id.* (emphasis in original) (citing *Lake Caryonah Improvement Assoc. v. Pulte Home Corp.*, 903 F.2d 505, 510 (7th Cir. 1990)).

The Court should consider other equitable factors as well such as any egregious conduct or conscious copying on Cook's part, or Cook's ignorance of the patents or a good faith belief in the merits of defense. *Id.* at 1033-34.

Cook argues that JJIS had actual or constructive knowledge of Cook's allegedly infringing activities since at least 2003 because JJIS monitored press releases regarding the Accused Products as well as publications about clinical trials and FDA approvals of them. Dkt. No. 153-1 at 52-53; Dkt. No. 171-1 at 22-23. Cook argues that this actual knowledge triggered JJIS' duty to investigate. Dkt. No. 171-1 at 26. Further, Cook contends that its open and notorious activities should have put the Rhodes Trust on notice of its allegedly infringing activities because the Trust had JJIS, an exclusive licensee; and Stein, an experienced medical device patent lawyer, engaged to protect the Trust's interests. Dkt. No. 153-1 at 53-54; Dkt. No. 171-1 at 22-25. Most tellingly, Cook states, Endotach's reliance on publicly available information to prove infringement evidences how easily JJIS, the Rhodes Trust or Brenda could have performed an infringement analysis. Dkt. No. 171-1 at 27-28. In addition, Brenda showed her awareness of marketplace developments when she contacted Stein in 2003 to discuss whether stents sold by JJIS were covered under the JJIS Agreement. Dkt. No. 153-1 at 53-54. She further claims to have spoken with patent counsel about companies with products like those claimed in the Rhodes patents, but was discouraged from "exploring further." Dkt. No. 171-1 at 24-25. Cook concludes that Endotach was charged with knowledge of the allegedly infringing activities through JJIS, the Rhodes Trust and Brenda and there is no excuse for a ten-year delay in filing suit. Dkt. No. 153-1 at 54-55; Dkt. No. 171-1 at 23-

24. Cook also avers that JJIS, the Rhodes Trust and Brenda had assets available to assert claims against Cook prior to 2012. Dkt. No. 153-1 at 54-55; Dkt. No. 171-1 at 25.

Even if the presumption does not apply, Cook argues that "the undisputed facts show that the delay here was unreasonable and inexcusable and that Cook Medical was materially prejudiced as a result." Dkt. No. 153-1 at 55. First, the ten-year delay was unreasonable and inexcusable in light of the actual and/or constructive knowledge of JJIS, the Rhodes Trust and Brenda from Cook's open sales, marketing, publication, public use, and other conspicuous activities of infringement that were well-known by those in the industry. *Id.* at 55-56; Dkt. No. 171-1 at 29-30. Cook asserts that the delay caused both economic prejudice in the form of enormous capital and other investments in developing the Accused Products; and evidentiary prejudice in the form of lost records, the death of witnesses and the unreliability of memories. Dkt. No. 153-1 at 56-58; Dkt. No. 171-1 at 26-27 (discussing the lack of records from JJIS because of the passage of time) & 37-40 (discussing the lack of reduction to practice evidence; faded memories of Brenda, Stein, Dungan and Coletti; and the death of Dr. Balko and Dr. Greenberg, both of whom had knowledge with respect to Cook's merit defenses) & 30-37 (discussing the enormous capital investment Cook made to develop, market and sell the Accused Products and the lack of an opportunity to change strategy if a suit had been filed sooner).

Endotach asserts that Cook is not entitled to the laches presumption and, therefore, must prove each element of the defense because neither it nor its parent company, Acacia, were even aware of the Accused Products until February 2010, a mere 2.5 years before the original federal suit was filed. Dkt. No. 144 at 28. Even if the Court considers the alleged knowledge of Endotach's predecessors-in-interest, Endotach

argues, none of them "'knew or should have known of the allegedly infringing activity' until shortly before the filing of this suit." *Id.* at 29 (quoting *PSN Ill., Inc. v. Ivoclar Vivadent, Inc.*, 398 F. Supp. 2d 902, 906 (N.D. Ill. 2005)); Dkt. No. 174 at 55-58. Endotach claims that Brenda testified she was never aware of Cook's activities in the market, or even that it existed at all, and relied upon JJIS to notify her if there was anything that involved the Rhodes patents. Dkt. No. 144 at 29. Endotach further asserts that the testimony of JJIS' corporate representative makes clear that JJIS, shortly after signing the license, abandoned its efforts to enter the stent graft market and would have no reason to perform any infringement analysis related to the Rhodes patents even if it did have knowledge of Cook's open and notorious activity. *Id.* at 17; Dkt. No. 174 at 57-58 (discussing JJIS' lack of motivation to investigate infringement). Any general information JJIS received about Cook's activities and/or the Accused Products, Endotach states, "is not enough to start the laches clock." Dkt. No. 144 at 18 (citing *PSN*, 398 F. Supp. 2d at 907; *Wanlass v. Fedders Corp.*, 145 F.3d 1461, 1465 (Fed. Cir. 1998); *R2 Med. Sys.*, 931 F. Supp. at 1441). At a minimum, Endotach avers, this record rebuts any presumption of laches.

Without the presumption, Endotach argues that Cook cannot, as a matter of law, prove there was an unreasonable or unexcusable delay because JJIS had no actual or constructive knowledge of infringement; Brenda relied upon JJIS to notify her of any potential infringers and it never did; and Endotach/Acacia filed suit within 2.5 years of acquiring the rights to the Rhodes patents. *Id.* at 19-20; Dkt. No. 174 at 58. Further, Endotach claims that Cook cannot demonstrate the required prejudice for any alleged delay. Dkt. No. 144 at 20-27. Specifically, Endotach asserts that Cook cannot show economic prejudice because "'a business decision to capitalize on a market opportunity'"

does not equate to a "change . . . because of and as a result of the delay . . . ." *Id.* at 21 (quoting *Gassier Chair Co. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 774 (Fed. Cir. 1995)). *See also id.* at 23-25 (discussing, *inter alia*, *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290 (Fed. Cir. 1992)). Endotach also points to Cook's knowledge of the Rhodes patents as early as 1993 and failure to change its designs as evidence that there was no harm. *Id.* at 21-23, 25-26 (citing, *inter alia*, *Gassier Chair*, 60 F.3d at 776).

Similarly, Endotach contends that Cook cannot show evidentiary prejudice because Cook has successfully litigated this case and Brenda; Dungan; Stein; a former W.L. Gore & Associates, Inc., employee; and Cuffari have "amply identified all aspects of Dr. Rhodes' work on the patents-in-suit." *Id.* at 26-27. Endotach asserts that much of the evidence regarding infringement comes from Cook's own records or the public domain; therefore, there can be no basis for prejudice from any delay by Endotach or its predecessor entities. Dkt. No. 174 at 59-60. Further, Endotach argues that there are nearly 70 documents in evidence to support Cook's motion for summary judgment on invalidity; therefore, "Cook's strained attempt to cherry-pick minor pieces of information it cannot locate does not demonstrate evidentiary prejudice." *Id.* at 60.

The Court concludes that there is no material question of fact that the presumption of laches applies and even if it did not apply, Cook is entitled to summary judgment on its laches defense. Both JJIS and Brenda were under a duty in 2003 to investigate open and obvious alleged infringers. JJIS' representative testified that JJIS would have knowledge of Cook's entry into the endovascular graft market. Dkt. Nos. 153-1 at 44; Dkt. No. 144 at 29. Likewise, Brenda testified that she helped her husband in his practice and was knowledgeable about the patents. Dkt. No. 153-1 at 45. Further, Brenda knew

enough about the patented inventions and the device market to draw a specific J&J stent to Stein's attention in 2003. Dkt. No. 153-1 at 47; Dkt. No. 171-1 at 15; Dkt. No. 171-1 at 18. Whatever her role in the ownership of the Rhodes patents, as co-trustee of the Trust or as owner, Brenda had a duty to pay attention to other market developments. *See Wanlass v. Gen. Elec.*, 148 F.3d at 1338-39 (discussing the scope of the duty imposed on patentees to police their rights). In 2003, when the first Accused Product was approved for sale in the United States, there was enough information available in the marketplace for both JJIS and Brenda to determine if there was infringement or to prompt them to perform any testing necessary to assess infringement. Endotach's expert relies only on publically available information and pictures to assess infringement; therefore, Endotach has conceded that no elaborate testing is necessary. That being the case, the undisputed facts evidence that both JJIS and Brenda easily could have, and should have, investigated the Cook Accused Products when they were introduced into the marketplace beginning in 2003.

Endotach argues that both JJIS and Brenda had excuses for not investigating infringement: JJIS because it never entered the endovascular device market; Brenda because she was raising her children. Dkt. No. 144 at 17-18 & 29; Dkt. No. 174 at 57-58. Even if this is enough to overcome the presumption of prejudice, considering all of the remaining undisputed evidence, there is no question of fact that their decisions to ignore the market for the patents were unreasonable. As an exclusive licensee, JJIS had a contractual duty to protect the patent assets, which Brenda reasonably could have relied upon; JJIS' failure to live up to the duty, however, is a thin excuse when the delay in filing suit is nearly ten years. More importantly, Brenda, as the primary beneficiary of the

Rhodes patent estate (whether through the Trust or not), who knew how important her husband considered the new inventions, and reached out to counsel to protect the assets at least once, cannot be held to a standard lower than that of the original patentee. To conclude otherwise flies in the face of the requirement that a patentee be "charge[d] . . . with such knowledge as [she] might have obtained on reasonable, diligent inquiry." *PSN*, 398 F. Supp. 2d at 907 (citing *Wanlass v. Gen. Elec.*, 148 F.3d at 1338). This is not a case in which potential infringement was hidden or difficult to ascertain; it was open, notorious and obvious and a reasonable, diligent inquiry would have uncovered the potential infringement at least by late 2003 when the first Cook product was in full production. Therefore, constructive knowledge may be imputed to both JJIS and Brenda. *See Wanlass v. Gen. Elec.*, 148 F.3d at 1338-39 (stating that "constructive knowledge of the infringement may be imputed to the patentee even where he has no actual knowledge of the sales, marketing, publication, public use, or other conspicuous activities of potential infringement if these activities are sufficiently prevalent in the inventor's field of endeavor").

Endotach also asserts that its own 2.5 year delay was justified because it had to test the Accused Products before it filed suit. Dkt. No. 144 at 28. Even if JJIS' and Brenda's delays could not be imputed to Endotach, this argument is belied both by Endotach's arguments for broad claim constructions for the patents, which rely heavily upon the plain meaning of the relevant terms; and by Endotach's failure to rely upon any testing or evaluation of the Accused Products to prove infringement. Endotach's infringement expert relies upon publically available information to arrive at his conclusions

and there is nothing in the record to suggest that JJIS and Brenda could not have easily located the same information and performed a similar analysis.

There is also no question of material fact that Cook was prejudiced by the delay in being sued for infringement of the Rhodes patents. Here, over the nearly ten year delay, Cook invested large sums of money in development, promoting, and marketing its endovascular product line and, if it had been sued in a timely manner, could have altered its business strategy. There is no dispute that Cook has increased its market presence during the delay period. Further, although there is evidence that another Cook entity, Cook Group, Inc., had knowledge of at least the '154 patent, there is no indication that the entity sued in this case had been put on notice that it might be sued for infringement at any time. For these reasons, there is no material question of fact that Cook suffered economic prejudice because of the delay.

The undisputed facts further evidence that Cook has suffered evidentiary prejudice because of the delay as well. Endotach relies heavily upon the testimony of Brenda, Cuffari, Stein, and Dungan, to evidence that Dr. Lee's disclosure and patent are not prior art to the '154 patent. However, the testimony of those witnesses shows that their memories of the events in the question have faded and that valuable documentary evidence has been lost because of intervening events or because the witnesses simply cannot remember what happened to their own or Dr. Rhodes' files. Dkt. No. 174 at 17 (Dungan's testimony regarding a discussion of a "Chinese finger cuff"); Dkt. No. 153-1 at 48 (Cuffari testimony regarding drawings on napkins and any records being destroyed in a 2005 flood), 48-49 (Brenda's testimony regarding Dr. Rhodes' files and drawings), 49-50 (Stein's testimony that he did not recall anything about the drawings he turned over of

the alleged inventions or about Dr. Rhodes' efforts to license the patents), 50 (Dungan testimony regarding first draft of the '154 patent application). Many of the documents referenced were readily available when Cook first brought the Accused Products to market and for several years thereafter.

Even though the missing documents and faulty memories is enough standing alone to indicate evidentiary prejudice, there are other evidentiary issues. Cook's expert relies, in part, upon an article by Dr. Alexander Balko ("Dr. Balko" and the "Balko article"), and a corresponding patent, U.S. Patent No. 4,512,338 ("Balko '338 patent"), for its invalidity defense. Dkt. No. 153-1 at 51. Endotach, like Dr. Rhodes during prosecution of the '154 patent, disputes the breadth of these Balko disclosures. *Id.* However, Dr. Balko died on September 16, 2008. *Id.* Again, had Cook been sued closer in time to the introduction of the accused devices, Dr. Balko would have been available to testify. Although an inventor's testimony is not always the most reliable indicator of claim scope, his testimony would have been relevant. Further, Endotach's '417 patent infringement analysis relies, in part, on the Greenberg study. Dkt. No. 174 at 28-29. But, Dr. Greenburg died on December 7, 2013. Dkt. No. 153-1 at 51. If Endotach or its predecessors had sued on the Rhodes patents sooner, Dr. Greenberg would have been available to testify. Taking the impact of all of these pieces of evidence together, there is no material question of fact that Endotach has been prejudiced by the patent holders' delay in filing suit.

Endotach argues that if the Court concludes that the defense applies, then it should not bar any damages with respect to the TX2 and Fenestrated products, which were introduced within six-years of the June 2012 filing date of *Endotach I*. Dkt. No. 144 at 11,

n.6. Cook asserts that the delay associated with all the Accused Products should tack because "[t]he allegedly infringing structures in the Accused Products are, for purposes of Endotach's infringement contentions, functionally equivalent . . . ." Dkt. No. 171-1 at 16. The Court concludes that there is no real dispute that the allegedly infringing elements of the Accused Products are functionally equivalent and substantially constant; therefore, the doctrine of tacking applies to associate the delay with respect to the first Accused Product to all subsequent products. *See Intertech Licensing Corp. v. Brown & Sharpe Mfg. Co.*, 708 F. Supp. 1423, 1435 (D. Del. 1989).

For the foregoing reasons, the Court concludes that the presumption of laches applies and the undisputed facts evidence that Endotach's, and its predecessors-in-interests', delay in bringing suit was not excusable and that Cook suffered prejudice by the delay. Summary judgment in favor of Cook is appropriate on its defense of laches. "[L]aches bars relief on a patentee' claim only with respect to damages accrued prior to suit." *Aukerman*, 960 F.2d at 1041 (citing *Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 741 (Fed. Cir. 1984), *overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020 (Fed. Cir. 1992)). The '154 patent expired on August 15, 2010; therefore, operation of laches bars Endotach's recovery for any alleged infringement of that patent as a matter of law. With respect to the '417 patent, Cook assert that, if laches applies, Endotach's claim for damages prior to July 16, 2013, are barred because that is when the instant suit was filed. Dkt. No. 153-1 at 59. Endotach does not contest this issue; therefore, the Court concludes that Endotach's claim for damages on any alleged infringement of the '417 patent are barred prior to July 16, 2013, as a matter of law.

IV. INFRINGEMENT

The Court has concluded that Endotach cannot recover damages for any alleged infringement of the '154 patent; therefore, it need not address any infringement issues with respect to that patent.

With respect to infringement of the '417 patent, Cook asserts that the fixation barbs of the Accused Products are not "anchoring means" that "tightly engage" as those terms have been construed by the Court. Dkt. No. 153-1 at 17 & 36. Specifically, Cook argues that the barbs are designed to provide "active fixation" and "will penetrate the aortic wall, to mimic the fixation that you might get with a suture" and could "penetrate entirely through the vessel." *Id.* at 17 & 36. Further, Cook claims that Dr. Rhodes amended the "tightly engage" limitation during prosecution to overcome prior art; therefore, "he presumptively surrendered all equivalents . . . ." *Id.* at 36-37. Cook also asserts that the only evidence that Endotach relies upon to prove that the Cook barbs meet this limitation is a study that does not involve testing any of the Accused Products, which Endotach's expert acknowledged during his deposition. Dkt. No. 196 at 21-22. In any event, Cook avers that the study's results are actually consistent with other statements made by Dr. Greenburg, the study's author, about at least one of the Accused Products, "The Zenith graft . . . uses larger barbs that penetrate through the aortic wall." *Id.* at 23 (citing Dkt. Nos. 153-1 at 17 n.6 & 178-7 at S83). Finally, Cook contends that there is no evidence that the barbs discussed in the animal study or on the Accused Products "tightly engage" as a result of blood flow forces. *Id.* at 23-24.

Endotach claims that the barbs of the Accused Products infringe the "tightly engage" limitation because, according to Dr. Silver, "the force from the blood flowing

through the graft causes the barbs [to] penetrate into the intima layer and the internal elastic lamina layer, compressing the medial layer, but not penetrating into the medial or adventitial layers . . . ." Dkt. No. 174 at 28-29. Endotach relies upon the Greenberg study to confirm this opinion. *Id.* at 29. Endotach also asserts that it is unnecessary for any engagement with the inner surface to actually occur to meet the limitation because the claims only require "that the at least one surface of the trailing portion of the projections ***will*** tightly engage the interior surface of the vessel wall if the device is deployed within a vessel and when a fluid flows through the passageway of the graft and the device begins to migrate." *Id.* at 28 n.18 (emphasis by Endotach).

The Court concludes that Endotach has not evidenced a material question of fact that the barbs of the Accused Products meet the "tightly engage" element of the asserted claims of the '417 patent. The element requires that "at least one surface [of a projection on the outer periphery of the tubular member of the graft] . . . tightly engage the interior surface of the vessel, duct, or lumen to fixedly secure said device in place." The claims require that the force of the fluid flowing through the passageway of the tubular member causes the engagement. '417 Patent, col.9, 1.23 to col.10, l.40. The Court construed the element to require penetration of the interior surface layer of the passageway, duct, or lumen, but excludes complete perforation of the wall. Dkt. No. 102 at 38-40. Therefore, the barbs are "tightly engaged" when they are "firmly embedded, interlocked or enmeshed." *Id.* at 40. Endotach relies on Silver's report to evidence this element. Dkt. No. 174 at 28-29. Silver relies upon Cook's own product literature and testimony to support his conclusions, but the product literature does not describe whether the barbs are "tightly engaged" as required by the claims of the '417 patent. For example, the

literature reflects that suprarenal fixation barbs "[s]ecure[] [the] graft to [the] suprarenal wall, reducing the risk of migration and enhancing graft/vessel attachment." Dkt. No. 174-20 at 96, ¶ 246 (citing Bates No. END004388; see also CM0003699). It further suggests that the barbs are designed for "active fixation" to prevent migration of the device and that the fluid flow pulls both up and down and explains that the placement of the barbs is to prevent migration. *Id.* at 98, ¶ 246 (citing Bates No. CM0059433). Cook's witness' testimony is consistent with the literature:

> The purpose of the barbs on the suprarenal stent are intended to provide active fixation. By that, I mean that those barbs will actually engage the aortic wall, will penetrate the aortic wall, to mimic the fixation that you might get with a suture, for example, in a surgical procedure, rather than just relying on radial force.

Id. at 99, ¶ 246 (citing Biggs Dep. at 78). None of these references evidence that the barbs of the Accused Products meet the nuanced definition for "tightly engaged" that is required by the '417 patent because all of the references contemplate complete perforation of or penetration through the wall of the vessel, duct, or lumen, such as in suturing. As discussed by the Court in its Order on Claim Construction, "tightly engaged" does not include such perforation or penetration.

Silver also cites the Greenberg study for the proposition that the barbs of the Accused Products are "firmly embedded, interlocked or enmeshed," but do not penetrate the lumen. Dkt. No. 174 at 29. However, the Greenberg study is not directed to the Accused Products; rather it focuses on a prior design that has different barbs. Dkt. No. 196 at 21-22. Endotach's expert, Dr. Silver, admitted that testing related to other, non-accused products would yield different results. Dkt. No. 173-74, Silver Dep at 163-64. Further, there is no testimony or evidence that the two types of barbs are equivalent. As

such, the Greenberg study cannot be used to show infringement of the Accused Devices. Even if it were conclusive as to the Accused Devices, the data from the Greenberg study indicates that some barbs from the non-accused products completely penetrate the wall of the vessel in at least half of the samples. Dkt. No. 196 at 23 (citing Greenberg Study at CM014882-8889, 8891 & 8892). As previously discussed, the "tightly engaged" element prohibits such perforation or penetration.

For these reasons, the Court concludes that there is no evidence that the barbs of the Accused Products "tightly engage" the vessel, duct, or lumen as required by the '417 patent and summary judgment in favor of Cook is appropriate on Endotach's claim that the Accused Products infringe the '417 patent.

V. INVALIDITY

The Court has concluded that Cook is entitled to summary judgment on its laches defense, which precludes Endotach from proceeding with its claims that Cook infringed the '154 patent. The Court has also concluded that Cook is entitled to summary judgment on Endotach's remaining claim that the Accused Products infringe the '417 patent, from the date the suit was filed until the present. Although Cook raised an invalidity defense to infringement of the '417 patent based on anticipation, obviousness and written description, it has not made a counterclaim as to invalidity; therefore, the Court declines to address Cook's remaining arguments that it is entitled to summary judgment on its invalidity defense.

VI. CONCLUSION

The Court has concluded that summary judgment in favor of Defendant Cook Medical Incorporated is appropriate on its defense of laches, which precludes Plaintiff

Endotach LLC from recovering damages for any alleged infringement of U.S. Patent No. 5,122,154; the Court has also concluded that summary judgment in favor of Defendant Cook Medical Incorporated is appropriate on Plaintiff Endotach LLC's claim that Defendant Cook Medical Incorporated infringed U.S. Patent No. 5,593,417. Plaintiff Endotach LLC's Motion for Summary Judgment of No Laches is **DENIED**, Dkt. No. 143; Defendant Cook Medical Incorporated's Motion for Summary Judgment of Noninfringement, Invalidity, No Willfulness & Laches is **GRANTED in part and DENIED in part**, Dkt. No. 146. There being no further claims to adjudicate, the Court will enter judgment accordingly.

IT IS SO ORDERED.

DATE: 01/27/2015

LARRY J. McKINNEY, JUDGE
United States District Court
Southern District of Indiana

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