UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Norfolk Division

W.L. GORE & ASSOCIATES, INC.,

Plaintiff,

v. **Civil Action No. 2:10cv441**

MEDTRONIC, INC., MEDTRONIC USA, INC., and MEDTRONIC VASCULAR, INC.,

Defendants.

OPINION AND ORDER

I. INTRODUCTION

The patent infringement action before the Court was brought by Plaintiffs W.L. Gore & Associates, Inc., and Gore Enterprise Holdings, Inc.,[1] (collectively "Gore"), against defendants Medtronic, Inc., Medtronic USA Inc., and Medtronic Vascular

[1] On January 30, 2012, as the result of a decision to dissolve Gore Enterprise Holdings, Gore Enterprise Holdings transferred all of its rights to the '870 patent to W.L. Gore & Associates, Inc., including the right to sue for past infringement. As a result of this transfer of rights, on February 15, 2012, the parties agreed to stipulate to the entry of a Third Supplemental Complaint in which "W.L. Gore & Associates, Inc. will be substituted as the plaintiff for Gore Enterprise Holdings, Inc. and stand in the shoes of Gore Enterprise Holdings, Inc." Consent Motion for Entry of Third Supplemental and Amended Compl., ECF. 169. Thus, Gore Enterprise Holdings, Inc., is no longer a party in this case and a Third Supplemental Amended Complaint was filed on February 15, 2012 reflecting this substitution. ECF Nos. 124-1, 170. Medtronic filed an Answer to Plaintiff's Third Supplemental Amended Complaint on February 28, 2012. ECF No. 182.

Inc., (collectively "Medtronic"). The patent-in-suit claims a method of making a tubular intraluminal stent graft.

A five-day bench trial was held in February 2012. This Opinion and Order addresses and resolves all remaining motions and merits determinations and constitutes the Court's Findings of Fact and Conclusions of Law pursuant to Federal Rule of Civil Procedure 52(a).

II. BACKGROUND

A. Procedural Background

On September 3, 2010, Gore filed this suit against Medtronic, alleging infringement of Gore's United States Patent No. 5,810,870 ("the '870 patent"), entitled "Intraluminal Stent Graft." United States Patent No. 5,810,870 (filed on June 7, 1995) (issued on September 22, 1998), Joint Exhibit ("JX") 1. The '870 patent claims a "tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porus expanded polytetrafluoroethylene which is less than 0.10mm thick." '870 patent at Abstract. Gore alleges that Medtronic's Talent Abdominal Stent Graft, the AUI components to the Talent Abdominal Stent Graft, and the Talent Thoracic Stent Graft infringe claims 12, 16, and 19 of the '870 patent, which are directed to methods of making a tubular intraluminal stent graft.

Medtronic moved to dismiss the Complaint on November 19, 2010, and on April 20, 2011 the Court issued an opinion denying Medtronic's motion to dismiss and granting Gore leave to amend the Complaint. ECF No. 40. On October 25, 2011, this Court conducted a hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996), and issued an Opinion and Order on December 16, 2011, construing the eight disputed claim terms. See W.L. Gore & Assocs., v. Medtronic Inc., 778 F. Supp. 2d 667, 2011 U.S. Dist. LEXIS 143585 (E.D. Va. 2011). Subsequently, on February 3, 2012, this Court issued an Opinion and Order denying Gore's Motion to Dismiss Medtronic's inequitable conduct counterclaim pursuant to Rule 12(b)(6). See W.L. Gore & Assocs., v. Medtronic Inc., 2012 U.S. Dist. LEXIS 13611 (E.D. Va. 2012).

The bench trial in this case commenced on February 13, 2012. On February 17, 2012, after final arguments had concluded, the Court took all outstanding issues under advisement and ordered preparation of a transcript of trial proceedings so that it could carefully consider the merits of the case.

B. Witnesses at Trial

During the five-day bench trial, all parties were provided the opportunity to present evidence.[2] On the claim of infringement against Medtronic, Gore first called Dr. James Lewis, Bench Trial Transcript at 98, ECF No. 175, Dr. David J. Myers, Tr. at 146, and Mr. Wayne House, Tr. at 226, all of whom are listed inventors on the '870 patent. Gore also called Dr. Joel Berry, Tr. at 288, who was offered as an expert in stent grafts and the methods of manufacturing stent grafts. The Plaintiff also submitted a number of witnesses through deposition testimony:

- Mr. Treavor Greenan - a former engineer with World Medical who helped design the Talent stent graft. Tr. at 283.
- Mr. Richard Thomas - a former Medtronic employee who testified about the design and development of the Talent product. Tr. at 284.
- Mr. Gene Park - a former Medtronic employee who testified as to the Talent product's design and development. Tr. at 285.
- Mr. Mark Spreeman - a Medtronic employee who testified about the FDA process for the Talent device. Tr. at 286.
- Mr. Pedro Vargas - a Medtronic employee who testified about the manufacturing of the Talent device as well as the import/export process for the device. Tr. at 286.

Gore also offered Dr. Ace Baty, Tr. at 432, a Gore employee who testified as to the competitive market of stent grafts and the relationship between W.L. Gore and Gore Enterprise Holdings. Last, Dr. Jeffery Stec, Tr. at 505, was offered by Gore as an

[2] The trial transcript is docketed at ECF Nos. 175, 176, 177, 178, 179, 180 and 181. All references to the trial transcript are in the format "Tr." followed by the page number.

expert on the issue of damages. As a rebuttal witness, Gore later called Dr. Frank Veith, Tr. at 1040, and offered him as an expert in vascular surgery, endovascular procedures and stent grafts.

In response to Gore's infringement case, Medtronic offered Dr. Gary Loomis, Tr. 630, as an expert in the area of medical devices and materials for such devices, intraluminal devices, stents, grafts, and methods of making stents and grafts. Dr. Loomis offered his opinion of non-infringement as well as his opinion on the issue of obviousness. Medtronic also offered two fact witnesses through Mr. Roberto Flores, a Medtronic Mexico employee who testified as to the import/export process for the Talent device, Tr. 906, and Dr. Kweli Thompson, Tr. 930, the Vice President of Marketing for Medtronic's endovascular therapies business who testified to the competitive market for the Talent device. Additionally, Medtronic called Dr. Christopher Zarins, Tr. 1077, as an expert in the clinical use of stent grafts and vascular grafts for the treatment of aortic aneurysms. Last, Dr. Vince Thomas was offered as Medtronic's damages expert, Tr. 1004.

Having had the opportunity to observe the demeanor and hear the testimony of witnesses testifying live at trial, the Court has made certain credibility determinations, as well as determinations relating to the appropriate weight to accord the

testimony. Such determinations are set forth below where relevant.

III. FINDINGS OF FACT

The Court's findings of fact are not limited to those in this section, but also include any credibility determinations or other determinations that appear below. Many of the Findings of Fact are substantiated with citations to testimony or documentary evidence or a combination thereof; however, such citations are not meant to be exhaustive authority for the finding. Some of the findings are based on the record or inferences from the record which are not cited. All proposed findings of fact and conclusions of law inconsistent with those set forth herein are rejected.

A. The '870 patent and claims

As noted above, the '870 patent was issued on September 22, 1998 and names David J. Myers, James D. Lewis, Wayne D. House, and Karl E. Schwarz as inventors.[3] Stipulation of Undisputed Facts, ECF No. 150 at 10, ¶ 8. The '870 patent issued from U.S. Patent Application No. 479,931 ("the '931 application") which was filed on June 7, 1995. Id. at ¶ 9. The '931 application was a divisional application from U.S. Patent Application No.

[3] The '931 application was assigned from the inventors to W.L. Gore on December 1, 1993. Plaintiff's Exhibit ("PX") 607. W.L Gore assigned the '870 patent to Gore Enterprise Holdings on August 25, 1999. PX 608. Gore Enterprise Holdings reassigned the '870 patent to W.L. Gore on January 30, 2012.

109,214 ("the '214 application") which was filed on August 18, 1993 and resulted in U.S. patent No. 5,735,892 ("the '892 patent" or "the parent patent"). Id. at ¶ 10. Both the '870 patent and the '892 parent patent contain the same specification. Loomis Direct, Tr. 635, ECF No. 177.

The asserted claims in this action are claims 12, 16 and 19 of the '870 patent. ECF. No 150 at ¶ 1. Claims 16 and 19 depend from independent claim 15. Loomis Direct, Tr. 645:13-17, ECF No. 177. The asserted claims are methods of making a tubular intraluminal graft and are set out below:

> 12. A method of making a tubular intraluminal graft comprising:
> a)selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
> b)affixing a tubular covering to the exterior surface of the tubular, diametrically adjustable stent, said covering being less than 0.10 mm thick and said tubular covering having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.
>
> 15. A method of making a tubular intraluminal graft comprising:
> a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall, said tubular, diametrically adjustable stent having a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter, wherein said tubular, diametrically adjustable stent has been diametrically adjusted to the enlarged diameter;
> b)affixing a tubular covering to the tubular, diametrically adjustable stent; and

c) collapsing the tubular, diametrically adjustable stent to about the collapsed diameter

wherein the tubular covering is affixed to the exterior surface of the tubular, diametrically adjustable stent.

16. A method according to claim 15 wherein said tubular covering is less than about 0.10 mm thick.

17. A method according to claim 16 wherein said tubular covering is of porous expanded PTFE.

'870 Patent, col. 10, JX 1.

After the Markman hearing, the Court concluded the following definitions applied to the eight disputed terms:

"stent" means "elongated members forming a substantially cylindrical and rigid structure;"

"wall" means "a substantially cylindrical plane defined by the structure of the stent;"

"multiplicity of openings": "multiplicity" means "two or more" and "opening" requires no construction and was given its plain and ordinary meaning;

"covering" needed no construction and was given its plain and ordinary meaning to one of skill in the art. However, the Court expressly refused to limit the covering material only to ePTFE;

"affixing" needed no construction and was given its plain and ordinary meaning. However, the Court refused to limit the term "affixing" to any particular method;

"seam extending from the exterior surface through to the luminal surface of the tubular covering" needed no construction and was given its plain and ordinary meaning. However, the Court expressly refused to limit this phrase to a seam created by an overlap;

"has been diametrically adjusted to the enlarged diameter" needed no construction and was given its plain and ordinary meaning;

"luminal surface" means "interior surface."

Markman Opinion, ECF No. 92, W.L. Gore & Assocs., v. Medtronic Inc., 778 F. Supp. 2d 667, 2011 U.S. Dist. LEXIS 143585 (E.D. Va. 2011).

B. The Specification

The specification of the '870 patent explains that the intraluminal stent graft described has a number of potential uses, including but not limited to "maintain[ing] patency after an occluded vessel has been re-opened" and "repair[ing] aneurysmal vessels, particularly aortic arteries." '870 patent at col 1:33-41, JX 1. The specification of the '870 patent describes four embodiments of the invention, each of which has both a stent and at least one covering with the stent. Id. at col 4-8.

In Example 1, a nitinol wire stent, meeting the limitations of "tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent" is selected and then a covering of ePTFE is subsequently affixed to both luminal and exterior surfaces of the stent. Id. at col 4:51-54. Figure 1 of the patent shows a side-view of the nitinol wire stent described in Example 1 and Figure 4 shows a cross-sectional view of

Example 1 where a covering has been affixed to both the exterior and luminal surfaces of the stent.

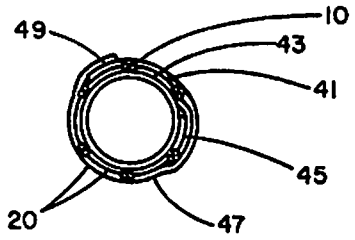


FIG. 4

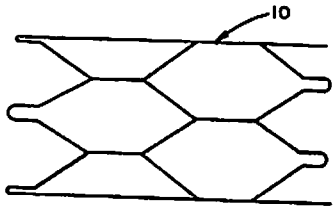


FIG. 1

'870 patent, Figure 1 & 4.

In Example 2, a nitinol wire stent (see Figure 1 above), meeting the limitations of "tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent" is selected and then a covering of ePTFE is subsequently affixed to the luminal surface only. '870 patent at col. 6:15-19. Figure 5 of the '870 patent shows a cross-sectional view of an example of the invention with a covering only on the luminal surface of the stent:

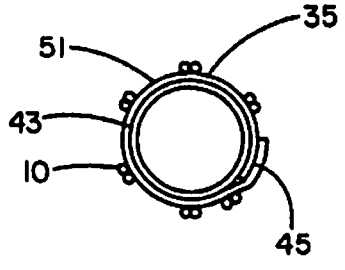


FIG. 5

'870 patent, Figure 5.

Example 3 of the specification describes selecting a commercially available balloon-expandable Palmaz stent meeting the limitations of "tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent" that has an ePTFE covering affixed to the exterior surface. This exterior covering and seam is depicted in Figure 6 of the patent. A picture of the commercially available Palmaz stent (showing the number 1 in the bottom left corner of the image) described in Example 3 is also depicted below:

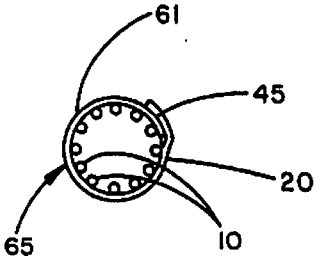
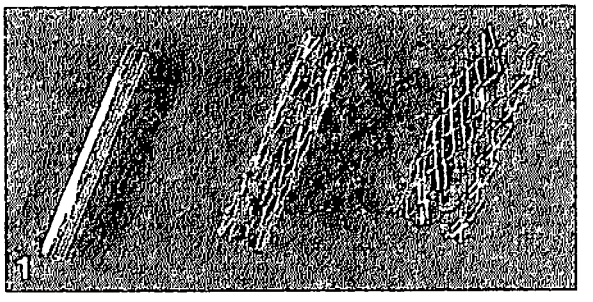


FIG. 6



'870 patent, Figure 6; Def. Demonstrative Exhibit 1, ECF No. 186 at 14.

Last, Example 4 describes a braided stainless steel wire stent (a wire is first given a coating and then is braided into a stent) meeting the limitations of a "tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent" which is then given a ePTFE covering on the exterior surface of the stent only.

Thus, the specification describes various types of stents that can be used with the invention and that would meet the requirements of being "tubular," "diametrically adjustable," "having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent."[4]

C. The Accused Products

Gore accuses the methods of making two Medtronic products: the Talent Abdominal Stent Graft and the Talent Thoracic Stent Graft.

The Talent Abdominal Stent Graft is approved for the endovascular treatment of abdominal aortic aneurysms. The Talent Abdominal Stent has various sizes; Gore specifically alleges that the method of making two Talent Abdominal components infringes claims 12, 16 and 19 of the '870 patent: (1) Talent Abdominal Bifurcated stent graft and (2) Talent Abdominal Aorto-Uni Iliac ("AUI") stent graft. Either the Bifurcated or the AUI can serve as the primary stent graft used for treating abdominal aortic aneurysms.

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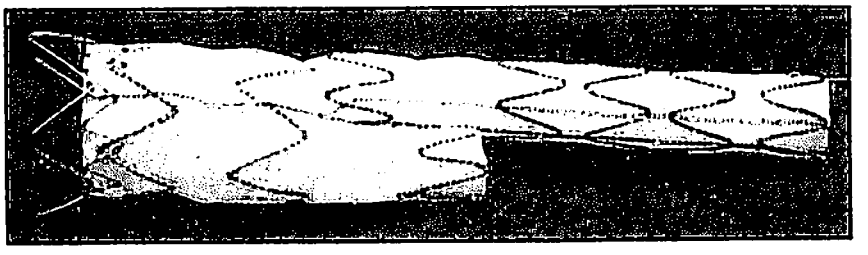
[4] For example, the specification discloses: "stents of the Palmaz type as taught by U.S. Pat. No. 4,776,337," "stents of braided wire made as taught by Wallsten U.S. Pat. No. 4,544,771," "stents formed of wire as taught by Gianturco, U.S. Patent No. 4,580,568," and "stents formed of Nitinol wire made as taught by PCT US 92/03481." See '870 Patent at 2:43-55; 3:49-55.

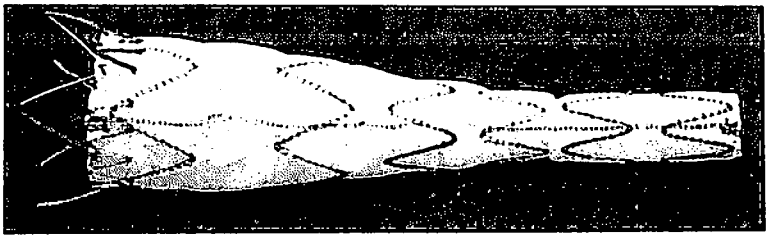
The Talent Thoracic stent grafts are approved to treat thoracic aortic aneurysms. The Talent Thoracic stent graft consists of a: 1) Proximal Main, 2) Distal Main, 3) Proximal Extension, and 4) Distal Extension; each having various sizes. The accused manufacturing process for making all of the Talent Thoracic stent grafts is the same. Either the Proximal Main or the Distal Main components can serve as the primary component of the Talent Thoracic stent graft. Gore offered an infringement analysis for the Proximal Main and the Distal Main collectively as the "Thoracic Main Component."

Thus, in summary, Gore accuses three Talent manufacturing processes[5]:

1) Process for making the Talent Bifurcated Component

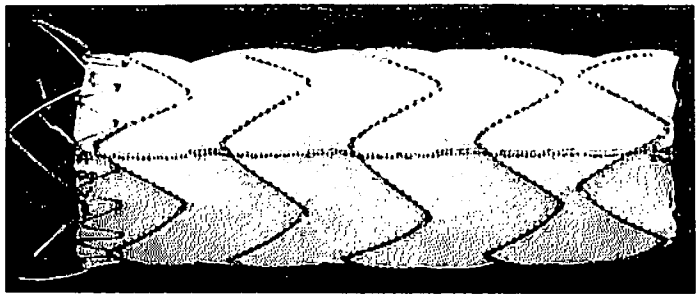


2) Process for making the Talent AUI Component



[5] The images depicted below were taken from Plaintiff's demonstrative slides displayed at trial and are representative of the actual devices admitted as evidence and upon which the Court relies.

3) Process for making the Thoracic Main Component



D. Accused Product Manufacturing Process

The manufacturing processes for the accused Talent products is undisputed, see stipulation ECF No. 173, and is set out in Medtronic's Premarket Approval ("PMA") submissions to the U.S. Food and Drug Administration ("FDA"). JX4-JX11. The manufacturing process involves eight steps as set out in the protocols.

1) Talent Stent Graft Kitting

The first protocol followed in the manufacturing process is MI 143, entitled Talent Stent Graft Kitting. JX 10. This process takes place in Mexico. The kitting process starts by having the operator "select," on a computer program, which Talent device is to be built. Id. at MED0063877. This software then provides the operator with a bill of materials. Id. at MED0063877. The operator then gathers the necessary components listed on the bill of materials required to build the device. Id. at MED0063878-79. The components include the graft material, which is cut from a roll and inspected, the nitinol Z-

shaped rings, referred to as "springs," that comprise the stent components, the support spring material, the suture material, and the marker bands. Id. These components are all placed into an appropriately labeled zip-lock bag or other container which will then be assigned to a production line. Id. at MED0063878-80. The process described in MI 145 is the same for all Talent stent graft components. Id. at MED0063874.

2) Graft Sizing, Cutting and Seaming

The second protocol followed in the manufacturing process is MI 135, entitled Graft Sizing, Cutting and Seaming. JX 4. In this step, the operator takes inventory of the components and inspects the graft material from the zip-lock bag. Id. at MED00638885. The operator then determines the location (internal or external) of the spring areas for sizing and seaming, which is provided in the chart on MED0063887. The operator cuts the graft material, either manually or using a machine, into the appropriate shape for the device to be built. Id. at MED006388-97. The operator then folds the graft material into a tubular shape and sews the appropriate edges of material together with sutures, forming a hollow tube with a seam where the edges of material have been sewn together. Id. The integrity of the graft material following this process is inspected, as well as the diameter and length of the constructed tube. Id.

3) External Spring Suture - Talent Abdominal Stent Graft

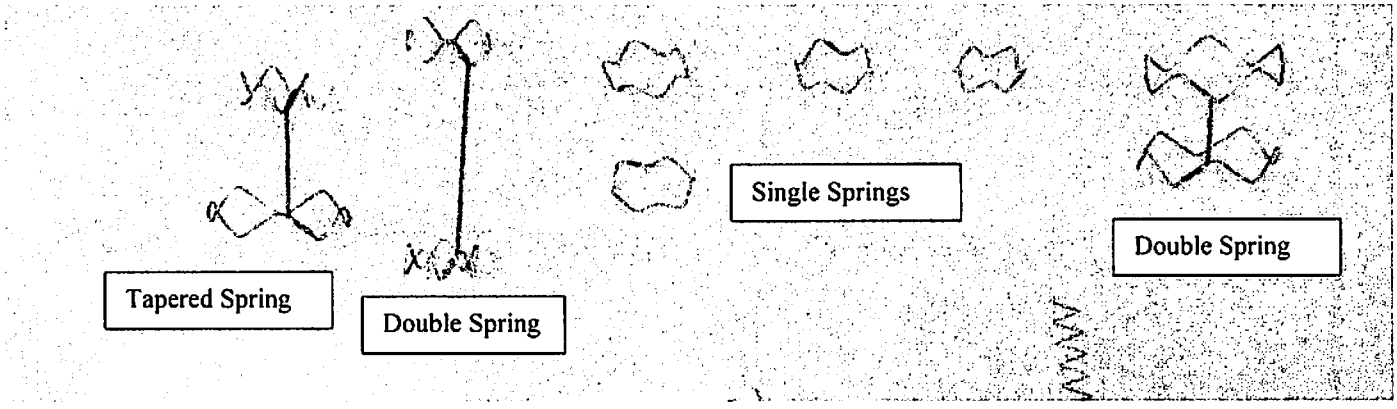
The next protocol followed in the manufacturing process, MI 137, only applies to the Talent Abdominal Stent Graft and is entitled External Spring Suture. JX 5. The process for manufacturing the Talent Thoracic Stent Graft does not follow the MI 137 protocol, because all the springs in the Talent Thoracic Stent Graft components are located internal to the graft covering. The operator first places a spring sewing mandrel into the graft material and then positions a component referred to as a "double spring," which is comprised of two Z-shaped nitinol rings connected by a straight nitinol wire ("connecting bar"), onto the exterior surface of the graft tube. Id. at MED00637907-08. The connecting bar is then sewn to the graft material using locking stiches. Id. at MED00637909. Next, the double springs are sewn. Id. The operator then sews any single springs to the exterior of the graft tube, proceeding from the proximal end of the stent graft to the distal end. Id. at MED0063911. Last, the external bare spring is attached. Id. at MED0063912. The operator then inspects the external springs to ensure proper connecting bar orientation, stitch density, graft material integrity, graft diameter, graft length, and spring placement. Id. at MED0063914-15.

4) Internal Spring Suture

The next protocol followed in the manufacturing process of the Talent Abdominal and Thoracic Stent Grafts is MI 138, entitled Internal Spring Suture. JX 6. This step involves sewing the internal springs to the interior of the graft tube. Id. at MED0063923-29. The type and number of springs sewn inside the graft material varies depending upon which component the operator is assembling. Id. For straight and tapered grafts, the double spring is compressed and inserted into the graft material. Id. at MED0063923. Once the spring is placed in the appropriate position within the graft material, the compression is released and the proximal spring of the double spring is sewn to the graft material. Id. at MED0063923-24. The remaining single springs are then sewn in descending order. Id. The distal spring of the double spring will be the last spring of the graft to be sewn. Id.

For the Bifurcated grafts, a tapered spring is placed inside the graft material first, then sewn. Id. at MED0063925. The stub leg (the smaller spring of the tapered spring) is sewn first. Id. The larger spring of the tapered spring is sewn next. Id. After the tapered spring is placed within the graft material of the Bifurcated component and sewn, the double spring is then placed inside the graft material. Id. The bare spring of the double spring is then sewn. Id.

Below are images of the different springs discussed and utilized in the manufacturing process for the three accused devices; these images are taken from the Defendants proposed findings of fact, ECF No. 186 at 14, and are representative of what was discussed and displayed during the trial.



5) Stent Graft Edge Finish

The next step in the accused method of manufacturing the Talent stent grafts is MI 140, which is the stent graft edge finishing. JX 7. The operator cuts and heats the edges of the graft material so that they can form the appropriate shape, called "end configuration." Id. at MED0063934-37. When finished, the operator inspects the constructed stent graft to ensure proper end configuration, graft material integrity, graft length, and label. Id. at MED0063938-39.

6) Marker Band Forming and Attachment

The next protocol followed in the manufacturing process of the Talent stent grafts is MI 140, entitled Marker Band Forming and Attachment. JX 8. The operator cuts and shapes radiopaque

wires into figure-eight shapes and sews them to the graft material. Id. at MED0063945-54. When finished, the operator inspects the stent graft for proper band position, marker band stitching, graft material integrity, and knot suture integrity. Id. at MED0063955-56.

7) Cutting and Attaching Support Springs

The next step in the accused method of manufacturing the Talent stent grafts is MI 143, entitled Cutting and Attaching Support Spring. JX 9. The operator cuts and shapes Z-shaped nitinol wire into springs referred to as "support springs," and sews the support springs to the edge of the graft material at the proximal end of the device. Id. at MED0063961. When finished, the operator inspects the stent graft for proper support spring integrity, graft material integrity, and label. Id. at MED0063965-66.

8) Talent Test Plan for Stent Grafts

The final step in the manufacturing process of the Talent stent grafts is QI 226, entitled Talent Test Plan for Stent Grafts. JX 11. This protocol outlines the inspection procedures performed on the completed stent grafts. Id. at MED0170367-81. After completing the QI 226 protocol, the completed Talent stent grafts are shipped from Medtronic's manufacturing facilities in Mexico to a separate location for loading into a delivery system and packaging.

E. Import / Export Process

In submissions to the FDA, Medtronic lists "Medtronic Inc." as the manufacturer, having a principal place of business in Minneapolis, MN. Premarket Approval ("PMA") 2006 Submission, PX69 at MED0058611; PMA 2007, PX70 at MED0019723. In listing its "Manufacturing Facilities and Specification Developer," Medtronic listed both "Medtronic Vascular," with manufacturing locations in Santa Rosa and Windsor CA, and "Medtronic Mexico," with its manufacturing location in Tijuana, Mexico. PMA 2006 at MED0058611-12; PMA 2007 at MED0019723.

From 2004 until present, the Talent stent grafts were manufactured in Mexico by Medtronic Mexico. PX 765, Depo. Vargas Tr. at 1. The manufacturing location of the Talent stent-grafts has not changed during the relevant time periods in this suit. However, what has changed is the location where the completed Talent stent grafts are assembled into a delivery system.

From 2004 until April 2008, the completed Talent stent grafts were shipped to the United States for insertion into a device delivery system. PX 134; PX 765, Depo. Vargas Tr. at 1; R. Flores Direct, Tr. 916-917. Specifically, the products were shipped via a local freight company from Tijuana to San Diego, California. R. Flores Direct, Tr. 916-917. Once the product

arrived in San Diego and had FDA approval[6], UPS would send the product next day to the Santa Rosa, CA facility. Id. During that same time period, after insertion into the delivery system, the Talent stent-grafts with the delivery systems were shipped outside of the United States for eventual sale and use in foreign countries as the Talent stent grafts were not approved for sale or use in the United States.

From June 2008 until December 2008, the Talent stent grafts were still being shipped into the United States, to Santa Rosa, CA, for insertion into a delivery system. However, during that same time period, the Talent stent graft had received FDA approval, and so some Talent stent grafts with delivery systems remained in the United States for sale and others were still shipped out to foreign countries for sale.

In January 2009, the location where the Talent stent grafts were inserted into the delivery system began to transition from the United States to Galway, Ireland. PX 765, Depo. Vargas Tr.

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[6] The entry codes that were used to ship these products for FDA purposes from Mexico to California were Import for Export (IFE) or Temporary Importation Bond (TIB). R. Flores Direct, Tr. 914-915. IFE is an entry that was created for a product that is sent to the United States only for extra processing but then will be shipped out again; IFE products cannot be sold in the United States. Id. at 915. TIB is an entry used for products that are shipped into the U.S. without first clearing customs. These products must be shipped with a bond that acts as a warranty that the products will soon be shipped out of the United States. Id. at 916.

at 1. Starting in August of 2009 and until present, Medtronic Ireland inserts all completed Talent stent-grafts into delivery systems in Galway, Ireland prior to the products' eventual sale and use. PX 765, Depo. Vargas Tr. at 1. From January 2009 through the date of trial, all completed Talent stent grafts were shipped from Mexico, to Galway, Ireland via UPS.

However, since 2009, once the products are given to UPS in Mexico, they are first routed into the United States before eventually being flown to Galway, Ireland. PX 765, Depo. Vargas Tr. at 2; R. Flores Direct, Tr. 908, ECF No. 179. Specifically, a UPS truck picks up the products from the Medtronic Mexico facility in Tijuana and drives them to the Tijuana Airport. DX091 at MED0481742; R. Flores Direct, Tr. 908. The products are then flown to Ontario, California. Next, from California, the products are flown to Louisville, Kentucky. From Kentucky the products are flown to Cologne, Germany, where the product is then moved to Dublin, Ireland and Shannon, Ireland before eventually arriving in Galway, Ireland. Id.

F. Contentions related to Direct Infringement

Medtronic's (non-invalidity-related) theory of the case focuses on undermining Gore's proof with respect to three requirements of the '870 patent:

(1) Medtronic contends that its process of bagging the components for the Talent stent into a "kitting bag,"

does not constitute "selecting" a stent as required by Step A of claims 12 and 15;

(2) Medtronic contends that Gore has not shown that the steps of claims 12 and 15 are performed sequentially as required by the patent because a "stent" with all the characteristics required by Step A is not formed and selected before the "affixing" step takes place;

(3) Medtronic contends that even if the Court finds the steps are performed sequentially in Talent's manufacturing process, Talent's products do not meet the claim language because:

a. The Talent product does not meet the Court's construction of "stent", and

b. The Talent product does not contain a "seam extending from the exterior surface through to the luminal surface."

Additionally, Medtronic argues that a portion of Plaintiff's claims must fail under 35 U.S.C. § 271(g) based on the fact that the *named defendants* did not actually "import" the product into the United States.

G. Person of Ordinary Skill in the Art

Gore's expert, Dr. Berry, proposed that a hypothetical person of ordinary skill in the art at the time of the invention with respect to the technical field of the intraluminal stent

graft '870 patent would: 1) have a degree in mechanical or biomedical engineering AND at least 5 years of experience in both developing and making stents or stent grafts; OR 2) be a physician with at least three years of experience in both developing and making stents or stent grafts and in the endovascular placement of stent grafts. Dr. Berry Direct, Tr. 298-97, ECF No. 176. Dr. Berry also noted that this person may also work in collaboration with other scientists and or physicians who have experience making and using stents and stent grafts. Id.

Medtronic's expert, Dr. Loomis, proposed that a hypothetical person of ordinary skill in the art at the time of the invention with respect to the technical field of the intraluminal stent graft '870 patent would have: 1) a degree in biomedical, mechanical, or chemical engineering, polymer chemistry or material science; 2) knowledge of the vascular system of mammals; and 3) 3-5 years' experience in intravascular device design and methods of making intravascular devices, including knowledge of stents and materials suitable for covering stents. Dr. Loomis Direct, Tr. at 639:2-9, ECF No. 177.

The Court chooses to adopt Dr. Berry's proposed standard for a person of ordinary skill in the art. The Court chooses Dr. Berry's standard both because it is a bit more rigorous than Dr. Loomis' and because the Court finds the required experience

to be more directly on point with the stent graft issues of this particular patent. However, all of the Court's factual findings and legal conclusions would remain the same even if the definition of Medtronic and Dr. Loomis were adopted. Thus, the relatively minor differences in the definitions propounded by Gore and Medtronic have no material effect on the analysis or ultimate conclusions in this matter.

IV. Evidentiary Issues

During the bench trial, both parties made oral motions for judgment on partial findings pursuant to Rule 52(c). Tr. 1035. Rule 52(c) reads:

> If a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue. The court may, however, decline to render any judgment until the close of the evidence. A judgment on partial findings must be supported by findings of fact and conclusions of law as required by Rule 52(a).

Fed. R. Civ. Pro. 52(c). Thus, Rule 52(c) permits a judge to enter judgment as a matter of law on partial findings once "a party has been fully heard on an issue." Id. "To grant JMOL under Rule 52(c), a district judge must weigh the evidence and resolve credibility." Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1343 (Fed. Cir. 2000). "A judgment on partial findings is made after the court has heard

all the evidence bearing on the crucial issue of fact." Fed. R. Civ. Pro 52(c), Advisory Committee Notes 1991.

Consistent with the terms of Rule 52(c), the Court exercised its discretion to reserve judgment on the motions during trial. Fed. R. Civ. Pro. 52(c) ("The court may, however, decline to render any judgment until the close of the evidence."). The Court now concludes that the best course of action is to render a judgment based on all the evidence, testimony, and applicable law. Accordingly, the Rule 52(c) motions are DENIED.

V. INFRINGEMENT DISCUSSION AND CONCLUSIONS OF LAW

A. Burden of Proof and Legal Standards

The infringement analysis is a two-step process – the first step is proper construction of the relevant claims, and the second step is a comparison of those claims to the accused product or method. Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009); see also, Cordis Corp. v. Boston Scientific Corp., 658 F.3d 1347, 1354 (Fed. Cir. 2011) ("First the Court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device.").

To prove infringement, a plaintiff must prove the presence of each and every claim element or its equivalent in the accused method or device. Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d

1292, 1301 (Fed. Cir. 2011). Specifically, "[t]o infringe a method claim, a person must have practiced all steps of the claimed method." Lucent Techs. v. Gateway, Inc., 580 F.3d 1301, 1317 (Fed. Cir. 2009). Furthermore, infringement is a question of fact reviewed for substantial evidence, Id. (citing Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1332 (Fed. Cir. 2008), and the patent owner bears the burden of proving any such infringement by a ***preponderance of the evidence***. See e.g., Cross Med. Prods, Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed. Cir. 2005); Carroll Touch Inc. v. Electro Mechanical Systems, Inc., 15 F.3d 1573, 1578 (Fed. Cir. 1993). To satisfy this standard, a patent owner need not offer "definite" proof of infringement, but instead must demonstrate that "infringement was more likely than not to have occurred." Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1341 (Fed. Cir. 2005) (citing Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001)).

1. Literal Infringement

Literal infringement exists if any one of a patent's asserted claims covers the alleged infringer's product or process. See Markman v. Westview Instr., 517 U.S. 370, 374, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). However, literal infringement requires that the accused method contain each

limitation of the asserted claim exactly; any deviation from the claim will preclude a finding of literal infringement. Litton Sys. Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed. Cir. 1998); Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998). Proof of any such literal infringement may be based on direct or circumstantial evidence. See Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1372 (Fed. Cir. 2009) ("A patentee may prove infringement by any method of analysis that is probative of the fact of infringement . . . and circumstantial evidence may be sufficient . . . .") (citations and internal quotes omitted).

2. Doctrine of Equivalents

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)). Such a finding requires a showing that "the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs substantially the same function in substantially the same way with substantially the same result as

each claim limitation of the patented product or method." AquaTex Indus., Inc. v. Techniche Solutions, 479 F.3d 1320, 1326 (Fed. Cir. 2007).

Thus, the doctrine of equivalents prevents an accused infringer from avoiding liability for infringement where its product has only minor or insubstantial differences from the claimed invention but retains the invention's essential identity. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 564 (Fed. Cir. 2000), overruled on other grounds, 535 U.S. 722, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002). Otherwise, "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing." Toro Co. v. White Consolidated Indus., Inc., 266 F.3d 1367, 1370 (Fed. Cir. 2001).

There are two tests commonly used to analyze infringement under the doctrine of equivalents. The first test is often referred to as the "function-way-result" test and "asks whether an element of an accused product 'performs substantially the same function in substantially the same way to obtain the same result' as an element of the patented invention." American Calcar, Inc. v. American Honda Motor Co., Inc., 651 F.3d 1318, 1338 (Fed. Cir. 2011). The second way to prove infringement under the doctrine of equivalents is to show that the

differences between the claimed element and the corresponding infringing element are "insubstantial." See e.g., Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370, 1382 (Fed. Cir. 2006); Honeywell Intern. Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1139 (Fed. Cir. 2004).

Proof of such equivalency may be made "through testimony of experts or others versed in the technology; by documents, including texts and treatises; and of course, by the disclosures of the prior art." Hilton Davis, 62 F.3d at 1520 (quoting Graver Tank, 339 U.S. at 609). The Federal Circuit has explained that to support a finding under the doctrine of equivalents:

> [A] patentee must . . . provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the function, way, result test when such evidence is presented to support a finding of infringement under the doctrine of equivalents. Such evidence must be presented on a limitation-by-limitation basis.

Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996); see also American Calcar, 651 F.3d 1318, 1338-39. However, the doctrine of equivalents is a limited doctrine. It was "designed to protect inventors from unscrupulous copyists and unanticipated equivalents" and should not be applied so broadly that it becomes "the second prong of

every infringement charge, regularly available to extend protection beyond the scope of the claims[.]" Kinzenbaw v. Deere & Co., 741 F.2d 383, 389 (Fed. Cir. 1984). Further, the doctrine should never be used to vitiate a claim term because potential competitors should be able to rely upon the language of the patent claims. Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc., 206 F.3d 1408, 1416 (Fed. Cir. 2000). The burden is on the patent owner to provide, on a limitation-by-limitation basis, particularized testimony or evidence of the insubstantiality of the differences or the satisfaction of the function-way-result test. Texas Instrs. Inc., 90 F.3d at 1567.

3. Direct Infringement under Section 271(a)

Gore has brought this action for infringement under both 35 §§ U.S.C. 271(a) and 271(g), the two U.S. statutes governing direct infringement.[7] 271(a), the general direct infringement statute, covers "any patented invention." 35 U.S.C. § 271(a). In contrast, Section 271(g) is specific to the importation or

[7] However, the Court notes that Gore did not address Section 271(a) in their proposed findings of fact and conclusions of law submitted to the Court and instead only argued infringement under 271(g). Specifically, Gore stated: "Gore accuses Medtronic of infringement under 35 U.S.C. § 271(g)." Gore Proposed Findings of Fact at 155, ECF No. 128, 185. Thus, it is unclear to the Court whether Gore intends to waive its infringement argument under Section 271(a) since this Section is still asserted in its Third Amended Complaint. See Third Amend. Complaint at ¶ 1, ECF No. 124, Exhibit A.

sale of a "product which is made by a process patented in the United States." 35 U.S.C. § 271(g).

A U.S. patent grants to the patentee "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U.S.C. § 154(a)(1). Thus, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

A claim for direct patent infringement under Section 271(a) requires, as an element of the claim, proof that the infringing activity took place *in the United States*. NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1313 (Fed. Cir. 2005) (emphasis added). The Patent Act of 1952 defines United States as "the United States of America, its territories and possessions." 35 U.S.C. § 100(c). Medtronic argues that they did not directly infringe Gore's method claims, as they did not make, use, offer for sale, or sell the claimed methods "within" the United States. Specifically, Defendants argue that they did not directly infringe under the "make" or "use" prongs, because they did not make or use the patented methods "within the United States."

In analyzing the Defendant's contention, the first prong to consider is the "make" or "use" prong of 271(a). The concept of "use" of a patented method or process is fundamentally different from the use of a patented system or device. In re Kollar, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (recognizing "the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps . . . . [A process] consists of doing something, and therefore has to be carried out or performed."). The Federal Circuit has noted:

> Because a process is nothing more than the sequence of actions of which it is comprised, the use of a process necessarily involves doing or performing each of the steps recited. This is unlike use of a system as a whole, in which the components are used collectively, not individually. **We therefore hold that a process cannot be used "within" the United States as required by section 271(a) unless each of the steps is performed within this country.**

NTP, Inc. v. Research in Motion, Ltd., 418 F.3d at 1318 (emphasis added). Thus, a finding of direct infringement under the "make" or "use" prong of Section 271(a) is precluded by the fact that the accused products are largely manufactured in Mexico and thus each step of the patented process is not performed "within" the United States.

However, the Court must also consider direct infringement under Section 271(a) pursuant to the "sells" or "offers to sell"

prong. The Federal Circuit's 2005 NTP opinion left open the question of whether method claims can be infringed under the "sells" and "offers to sell" prongs of Section 271(a), though commenting in dicta that "the legislative history of § 271(a) indicated Congress's understanding that method claims could be directly infringed only under the 'use' prong of § 271(a)." NTP, 418 F.3d at 1320. In Ricoh, the Federal Circuit again left open the question, but did make clear that if a method claim could be infringed under the "sell" prong, then the seller must sell the performance of the method or process itself in order for the sale to be actionable as direct infringement under 271(a). Ricoh Co., Ltd. v. Quanta Computer Inc., 550 F.3d 1325, 1335 (Fed. Cir. 2008) (holding that a party that sells or offers to sell software containing instructions to perform the patented method does not infringe the patent under § 271(a)). However, the Ricoch court agreed that since a "process" or method refers to a sequence of events, "the concept of a sale or offer of sale to the actual carrying out of a sequence of actions is ambiguous." Id. In summary, the Federal Circuit has never found a method claim to infringe the "sells" or "offers to sell" prong of Section 271(a), though it has never directly addressed the issue despite the dicta noted above. Therefore, it remains unclear whether a difference exists between selling the "performance of a method" and selling a final product that

encompasses a method of making that product. See, e.g., Quanta Computer, Inc. v. LG Elecs., Inc., 128 S. Ct. 2109, 2117 (2008) ("[A] patented method may not be sold in the same way as an article or device, but methods nonetheless may be 'embodied' in a [final] product . . . ."); WesternGeco L.L.C. v. ION Geophysical Corp., 2012 U.S. Dist. LEXIS 57927, *17 (S.D. Tex. Apr. 25, 2012) (noting that, under 271(a), had the defendant put forth evidence that plaintiff was not actually "offering to perform" the method claim, but was only "selling the products themselves" summary judgment for non-infringement would have been appropriate). Gore put forth no evidence during trial to assist the Court in analyzing this prong other than the conclusory fact, upon which both parties appear to agree, that the Medtronic Talent products were sold in the United States beginning in December of 2008.

Last, Section 271(a) also states infringement can occur if the accused infringer "**imports** into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a) (emphasis added). The "imports" prong of Section 271(a) is in many ways similar to the "sells" prong in that it is unclear whether Congress intended this prong to apply to method claims. The Federal Circuit in NTS again left open the possibility that a method claim could be infringed under the "imports" prong of 271(a):

> Like the sell and offer to sell provisions discussed supra, **the question of whether a method claim can be infringed by importation is a difficult one conceptually**. The legislative history cited with respect to the sell and offer to sell provisions indicates that Congress did not consider the "import" prong of section 271(a) to apply to method claims. However, we need not decide that broad issue.

NTP, Inc., 418 F.3d at 1321 (emphasis added). Earlier this year, the Federal Circuit came much closer to deciding the issue left open in NTP. In Zoltek, the court in dicta stated that "[t]itle 35 U.S.C. Section 271(a) **does not** protect against the importation of products made by a patented ***process***, but § 271(g) states that '[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer.'" Zoltek Corp. v. United States, 672 F.3d 1309, 1322 (Fed. Cir. 2012) (emphasis added). The Zoltek court's statement seems to make clear that while 271(a) may protect against infringement through importation of a product or apparatus patented in the United States, it does NOT protect against the importation of a product into the United States that is patented only by a process or method claim.[8] However, while 271(a) does not appear to offer

[8] The Zoltek court's statement as to 271(a) and method claims appears to be in line with other Federal Circuit opinions. For example, in Gemtron Corp. v. Saint-Gobain Corp., the Federal Circuit stated that under 271(a) "if an infringing ***product*** is manufactured outside of the United States, a person infringes if

importation protection to method or process claims, 271(g) clearly does. Moreover, because Gore has only argued infringement under 271(g), which provides the same relief as 271(a), it is unnecessary for the Court to also consider importation infringement under 271(a).

Thus, the only remaining avenue left open under 271(a) for infringement is the "sale" or "offer for sale" of the products within the United States. Since the Federal Circuit appears to have concluded that this prong does not apply to method claims, and since the law is currently unclear as to whether selling a final product within the United States would even qualify as the "sale" or "performance" of a method claim, it appears the proper course is for this Court to consider infringement only under 271(g).[9]

4. Direct Infringement under Section 271(g)

The Court is now left to consider the issue of infringement under Section 271(g). Section 271(g) reads:

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he ***imports the product***, or uses, offers to sell, or sells it in the United States." 572 F.3d 1371, 1380 (Fed. Cir. 2009) (emphasis added). The Gemtron court went on to conclude that frames manufactured in Mexico did infringe under Section 271(a) since the parties did not dispute that they were imported, used, and sold within the United States. Id. at 1381. However, the Gemtron court made clear that the patented claim was an apparatus claim and not a process claim. Id. at 1380.

[9] It also appears Gore may have abandoned a claim under 271(a) since they made no mention of the statute in their proposed conclusions of law and put forth no clear evidence or argument directed towards satisfying the elements of 271(a) at trial.

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a **product which is made by a *process* patented in the United States** shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--
>
> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g) (emphasis added). Thus, the relevant question is whether Medtronic can be said to have imported into the United States or to have offered to sell, sold, or used "within the United States a product which is made by a process patented in the United States" and thus can be found to have infringed 35 U.S.C. § 271(g).

Section 271(g) requires two separate inquiries. First, a patentee must establish that an accused infringer imported, sold or used a product made by a method or process falling within the scope of a claim in the patent. See Novo Nordisk of North America, Inc. v. Genentech, Inc., 77 F.3d 1364, 1367-68 (Fed. Cir. 1996). Thus, "271(g) requires importation or sale of the product of a patented process practiced abroad, before infringement can be established . . . ." Cardiac Pacemakers,

Inc. v. St. Jude Med., Inc., 576 F.3d 1348, 1369 (Fed. Cir. 2009).

Second, if the patentee proves that the process literally infringes the patent, the Court must then determine whether the "materially changed" exception of Section 271(g) applies. 35 U.S.C. § 271(g) ("A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product"). "This exception is in place because product is not "made by" a patented process as required by 271(g) if the product was (a) materially changed by later processes, or (b) the product is only a trivial or non-essential part of another product. Eli Lilly & Co. v. Am. Cyanamid Co., 82 F.3d 1568, 1571-73 (Fed. Cir. 1996). This exception requires the Court to consider whether there is a "real difference between the product imported, offered for sale, sold or used in the United States and the products produced by the patented process." Bio-Technology General Corp. v. Genetech, Inc., 80 F.3d 1553, 1560 (Fed. Cir. 1996); Eli Lilly, 82 F.3d at 1573 ("To determine whether the 'materially changed' provision applies, the court must look to the substantiality of the change between the product of the patent process and the product that is being imported."). However, no facts are currently before

the Court that could support applying this "exception" to 271(g) and no argument was made by Medtronic that they believed this exception should be applied. Therefore, the Court must focus on the first inquiry - whether Gore has established that Medtronic imported, sold or used a product made by a method or process falling within the scope of a claim in the patent.

B. Step One - Term Construction

Before the Court looks at the issue of importation and sale under 271(g), the Court will first decide if Medtronic's Talent devices are made by a method or process that falls within the scope of one of the claims at issue. However, in the process of conducting the bench trial, it became clear to the Court that the parties disagreed as to the legal meaning of several key claim terms and that resolution of these terms could have a significant impact on infringement. Although it appears such claim construction could have occurred during the Markman hearing, in order for the Court to make its factual findings, it must take a side trip and construe the legal meaning of these disputed terms before specifically analyzing Medtronic's method of manufacturing the three accused Talent products.[10]

[10] With the exception of the term "rigid," it appears the remaining disputed terms could have been addressed at the Markman stage. It is unclear to the Court why the parties did not seek to have these term disputes resolved during the Court's earlier claim construction.

Under this first step of claim construction, reference is made to the intrinsic evidence of record, which includes the language of the claim itself and other issued claims, the patent specification, and the prosecution history. Markman, 52 F.3d 979. Words in a claim will be given their ordinary or accustomed meaning in view of the specification to one of ordinary skill in the art at the time of the invention. Phillips v. AWH Corp., 415 F.3d 1303, 1316-1317 (Fed. Cir. 2005). "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. "In examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims." CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2002)).

1. Comprising

The first issue the Court addresses pertains to the meaning of the term "comprising" and whether the recited steps in claims 12 and 15 must be performed in sequential order. Claims 12 and

15 both begin with the phrase, "a method of making a tubular intraluminal graft comprising:", before the claim goes on to list the required steps. '870 patent at claim 12 & 15, JX 1.

It is well established that the transitional term "comprising" is a "term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997); see also Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."). The use of the term "comprising" suggests that additional unrecited elements or method steps are not excluded. CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1235 (Fed. Cir. 2005); see also Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1319 (Fed. Cir. 2009) ("In the patent context, the term 'comprising' is well understood to mean 'including but not limited to.'"). However, while "comprising" permits additional elements not required by a claim, it "does not remove the limitations that are present." Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1409 (Fed. Cir. 2004). During trial, it appeared both parties agreed that, consistent with this case law, the

comprising claims allow additional steps to be added in between the recited steps. Dr. Loomis Cross, Tr. at 818:25-819:7.[11]

"[A]lthough a method claim necessarily recites the steps of the method in a particular order, as a general rule the claim is ***not limited to performance of the steps in the order recited***, unless the claim explicitly or implicitly requires a specific order." Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1345 (Fed. Cir. 2008) (citing Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1342-43 (Fed. Cir. 2001)) (emphasis added). "The specification or prosecution history may also require a narrower, order-specific construction of a method claim in some cases." Id. Thus this Court must look to the claim language, the specification and the prosecution history to decide whether there is support for limiting the patented method steps to a specific order. See Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1369 (Fed. Cir. 2003) (noting that first the court must look to "the claim language to determine if, as a matter of logic or grammar, [the steps] must be performed in the order written" and if not, then second the court looks to "the rest of the specification to

[11] Though Dr. Berry never actually offered an opinion on the meaning of the term "comprising," or on the preamble phrasing of the claim language, Gore's closing argument made clear that they did not dispute Dr. Loomis' opinion that "comprising" allowed additional steps to be performed in a method claim.

determine whether it directly or implicitly requires such a narrow construction").

In this case the Court finds that the plain language of claim 12 and claim 15 clearly implies that Step A has to be performed before Step B. Step B instructs the maker to "affix" the covering "to ***the*** tubular, diametrically adjustable stent", clearly referring to the stent just "selected" in Step A. '870 patent, claim 12 & 15 (emphasis added); Dr. Loomis Direct, Tr. 642-643; see also, Mantech Envtl. Corp. v. Hudson Envtl. Servs., 152 F.3d 1368, 1376 (Fed. Cir. 1998) (holding that "the sequential nature of the claim steps is apparent from the plain meaning of the claim language and nothing in the written description suggests otherwise"). Additionally, the plain language of Step C in claim 15 similarly implies that Step B must be performed before Step C. Step C states "collapsing ***the*** tubular, diametrically adjustable stent to about the collapsed diameter," also clearly referring to the stent on which the covering was just affixed in Step B. '870 patent, claim 15 (emphasis added); Dr. Loomis Direct, Tr. 644 (noting Step C has the same "antecedent basis" that requires Step C occur after Step A and Step B).

Thus, the Court finds that although both claim 12 and 15 use the term "comprising," which allows additional steps to be performed, the steps that are recited must still be performed

sequentially, in the order in which they are claimed. Because claim 16 and 19 depend from claim 15, the same sequencing of steps applies to those claims as well. Dr. Loomis Direct, Tr. 645:6-17.

2. Selecting

Step A of claims 12 and 15 both read: "**selecting** at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall . . . ." '870 at 12, 15 (emphasis added). Although the term "selecting" was not construed at the Markman stage of litigation, a key dispute at trial was whether Medtronic's process of bagging the components necessary to make the various Talent devices was enough to satisfy the "selecting" requirement found in Step A of claims 12 and 15.

Gore's expert, Dr. Berry, explained that since, after the term "selecting," the claim language goes on to list specific physical characteristics of a stent, it was important for him to look at the physical characteristics of the final Talent products in addition to the method of making the devices in order to analyze whether a stent with the appropriate characteristics was "selected." Dr. Berry Direct, Tr. at 310:2-25. Dr. Berry went on to opine that the actual "selecting" process took place when the Medtronic operator "selects" the intended Talent device through a computer program and then bags

all the components necessary to actually build the device. Id. at 324:20. Dr. Berry supported his opinion with Medtronic's Kitting Protocol which instructs the operator to "select the required device" and then to follow the progression of the related work order and collect all the items that go into the final product, placing them in a bag or kit. MI145 Kitting Protocol, JX 10. Thus, once all the various components have been placed in the kitting bag, it is at this time that Dr. Berry says Medtronic's manufacturing process has "selected" a stent with the various characteristics listed in claim 12 and 15 of the '870 patent. Id. at 329:3-5; Kitting bags, DX88-DX90. Alternatively, if this Court finds that the kitting process does not literally constitute "selecting" according to the claim language, Dr. Berry argues that the limitation is still met under the doctrine of equivalents. In Dr. Berry's opinion, the selecting and collecting of the Talent components for a particular device kit has the same function as if you select a fully formed stent device. Id. at 333-34. Dr. Berry stated that the kit is functionally the same thing as a finished stent product because according to the Medtronic work order placed inside the kit, those components will eventually be built, following specific instructions, into a particular, specifically selected, stent device. Id. at 335: 1-19.

In contrast, Medtronic's expert, Dr. Loomis, opined that Medtronic's kitting process for its Talent products does not satisfy the "selecting" requirement of claims 12 and 15 of the '870 patent. Dr. Loomis Direct, Tr. at 650:10. Dr. Loomis supports this opinion by stating that the claim language requires "physical selection of [the] stent" to which the covering from Step B is going to be affixed. Id. However, according to Dr. Loomis, the kitting bag merely contains a series of parts and does not contain a fully formed stent as described in Step A. Id. As mentioned earlier, both parties agree that the language of claims 12 and 15 requires Step A be performed before Step B. In Dr. Loomis's opinion the "selecting" step as described in the claim is never met in Medtronic's manufacturing process because the covering is affixed to the double spring before a "stent" is ever formed. Id. at 660:13-16. Thus Step B is occurring before Step A.

Furthermore, in Dr. Loomis' opinion, a stent as described in Step A is never formed during Medtronic's process of manufacturing the Talent products. Because the individual springs and the double springs are never attached to each other in any way, and they are only connected by the graft material, Dr. Loomis argues such a method of manufacturing could never meet the requirements of "stent" as used in the '870 patent. Id. at 662:3-12. However, on cross, Dr. Loomis conceded that

Medtronic's manufacturing process begins when a user goes to the computer and selects "the process [to make a specific product] and the listing of all the components necessary to practice that process." Dr. Loomis Cross, Tr. at 832: 13-18. Dr. Loomis also agreed that before the user makes the selection on the computer, they know how the device is going to look and what size it is going to be and the user has actual instructions for exactly how to assemble the parts. Id. at 832-833. Last, Dr. Loomis agreed that one could "select" the stent and then, since the word "comprising" allows additional steps, an added step of "making the stent" could be inserted before the affixing step. Id. at 819-822. However, Dr. Loomis explained that at the selecting step the user must "select a stent that meets all the limitations of Step A," and in his opinion that step is never met because the affixing step happens before a stent is formed, which is simply not allowed by the claim language. Id. at 822; Dr. Loomis Redirect, Tr. at 854:5-9.

In considering these arguments, the Court first notes that at the Markman stage of litigation, in construing the term "stent," the Court specifically rejected an argument from Medtronic that the chosen stent must be "commercially available." Markman Op. at 12, ECF No. 92 (declining to import a functional limitation into the definition of "stent" or to limit it to a commercially available device). This in many ways

relates to the arguments now before the Court regarding the meaning of "selecting" and whether one must "select" a premade or fully formed stent.

In determining the meaning of this disputed term, the Court first examines the claim language and the specification. See Phillips, 415 F.3d at 1314 (noting "the claims themselves provide substantial guidance as to the meaning of particular claim terms"); Vitronics, 90 F.3d at 1582 (stating that "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."). The word "selecting" only appears twice in the '870 patent, in Step A of claim 12 and claim 15. Looking to the specification of the '870 patent for guidance, the Court found it helpful to consider the four embodiments described in the patent. In example 1, the patent states that, "A Nitinol wire stent 10 (Nitinol Medical Technologies, Boston, Mass.) of the type described by FIG. 1 was provided with both a luminal covering and an exterior covering of expanded PTFE film." '870 Patent col 4:51-54, JX1. Example 1 then explains that "This 3cm long stent was formed from 0.25mm diameter Nitinol wire into a tubular shape of interlocking hexagons." '870 at 4:54-56. The Court finds that the use of the word "formed" in conjunction with a description of how the Nitinol wire is shaped is essentially informing the reader that

either: 1) this particular Nitinol stent was made/formed by the inventor himself in Example 1, or 2) even if the inventor used a "pre-made" Nitinol stent, the reader of the patent could choose to "form" the stent himself by shaping the "Nitinol wire into a tubular shape of interlocking hexagons." Id. Similarly, Example 2 of the '870 patent merely references the use of a "Nitinol wire stent of the same type used for Example 1." '870 at 6:15-16. Thus, Example 2 incorporates the description of how to "form" a Nitinol wire stent found in Example 1 into Example 2. However, unlike Examples 1 and 2 of the patent, Example 3 simply references a commercially available stent: "A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, N.J.) was adjusted from its collapsed outside diameter of 8.0mm . . . ." '870 at 7:6-9. Last, Example 4 again describes the inventor actually making or forming the stent himself. Example 4 first states that a "0.07mm diameter single strand stainless steel wire" is provided with an ePTFE covering that is heat adhered to the wire. '870 at 7-8. This wire is then cut into shorter lengths and fed into a machine that braids the wire into a stent. '870 at 8:10-13. Thus, the plain language of the specification and the embodiments of the patent make clear that one need not use a pre-made or commercially available stent and could instead "make" the stent from scratch.

The question now is what effect, if any, this has on the meaning of "selecting" as used in claims 12 and 15. According to Medtronic and Dr. Loomis' definition, this simply means that in Examples 1, 2 and 4, if a stent is made from scratch, it is not truly "selected" until the user has finished making it and it is fully formed. However, according to Gore and Dr. Berry's definition, in addition to the option of "selecting" a premade or fully formed stent, the "selecting" step can also occur once a user chooses to make from scratch a stent with all of the qualities required of the claim (tubular, diametrically adjustable, multiplicity of openings, etc.).

Having reviewed the claim language, the specification and the prosecution history, as well as the expert opinions offered at trial, the Court finds that nothing in the intrinsic evidence indicates that the "selected" stent must be pre-made or already formed. The specification and the claim language seem to leave open two possibilities: 1) One of ordinary skill in the art "selects" a premade, commercially available stent with the attributes listed in Step A of the claims, **or** 2) One of ordinary skill in the art chooses to make from scratch a particular stent that has the qualities listed in Step A.

In addition to the claim language and the specification, dictionaries and treatises are "among the many tools that can assist the court in determining the meaning of particular

terminology to those of skill in the art of the invention." Phillips, 415 F.3d at 1318. The ordinary meaning of "select" is to "carefully choose as being the best or most suitable" or "to choose or pick out in preference to another or others." See Oxford Dictionaries Pro (April 2010), www.english.oxforddictionaries.com, and Oxford English Dictionary, Online Version (March 2012), www.oed.com. These definitions appear to support the conclusion that the term "selecting" in Step A of claim 12 and 15 simply represents a "choice," and satisfaction of this requirement is not dependent on whether it is the "choice to make" a stent with the necessary characteristics **or** "the choice to use an already formed" stent with particular characteristics.

Thus, choosing or "selecting" a "kitting bag" that contains all of the parts necessary to create a particular stent with the qualities listed in Step A as well as directions detailing the process or method of making that stent could be enough to satisfy the "selecting" step of claims 12 and 15. However, it remains to be seen whether the items selected constitute a "stent," with the required characteristics listed in Step A.

3. Rigid

In determining whether infringement has occurred, the Court must consider whether the accused devices meet the Court's construction of the term "stent." As mentioned above, the Court

defined stent as "elongated members forming a substantially cylindrical and rigid structure." Markman Op. at 16, ECF No. 92. At trial it became clear that the parties had differing views as to the meaning of "rigid." The Federal Circuit has noted that ordinarily courts do not construe words that do not actually appear in the claims. Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322, 1334 (Fed. Cir. 2009). However, the Federal Circuit has also noted that "in those cases in which the correct construction of a claim term necessitates a derivative construction of a non-claim term, a court may perform the derivative construction in order to elucidate the claim's meaning." Advanced Fiber Techs. Trust v. J&L Fiber Servs., 674 F.3d 1365, 1373-74 (Fed. Cir. 2012)(noting the construction of non-claim term still follows established claim construction principles).

Gore's expert, Dr. Berry, as one of ordinary skill in the art, opined that "rigid" as used in the Court's claim construction, means having "enough rigidity that [the stent] can hold the device open in a cylindrical shape and also perform its function by being even more rigid than the blood vessel into which it is implanted." Dr. Berry Direct, Tr. at 314:17-20. Medtronic's expert, Dr. Loomis, though not giving a specific definition of rigid, opined that the single and double springs used by the Medtronic Talent devices are "the opposite of rigid,

which is flexible." Dr. Loomis Direct, Tr. at 669: 18-19. However, on cross-examination, Dr. Loomis agreed that any meaning of rigid must still be "flexible enough for the device to be collapsed from its fully extended state to a collapsed state small enough to fit into the delivery device." Dr. Loomis Cross, Tr. at 841:19-25.

However, on cross-examination, Dr. Berry admitted that in analyzing "rigidity" he considered the fully formed Talent device, including the covering, and not just the "stent" alone. Dr. Berry Cross, Tr. at 396:19-24. Additionally, Dr. Berry (Gore's expert) seemed to admit that the double spring and the single springs on their own were not rigid and that they must be connected to, or through, the covering before the stent would become rigid. Id. at 401:9-15. Dr. Loomis did not give an opinion on the rigidity of the final Talent devices and did not consider the rigidity of any combination of springs to determine whether they met his definition of rigid. Dr. Loomis Cross, Tr. at 844:2-7.

The Court finds that Dr. Berry's definition of "rigid" more properly comports with the plain and ordinary meaning to one of skill in the art as well as with the Court's intention and use of the word when it defined a stent as "substantially cylindrical and rigid." As Dr. Berry stated, it is clear to one of ordinary skill in the art that the stent graft must have

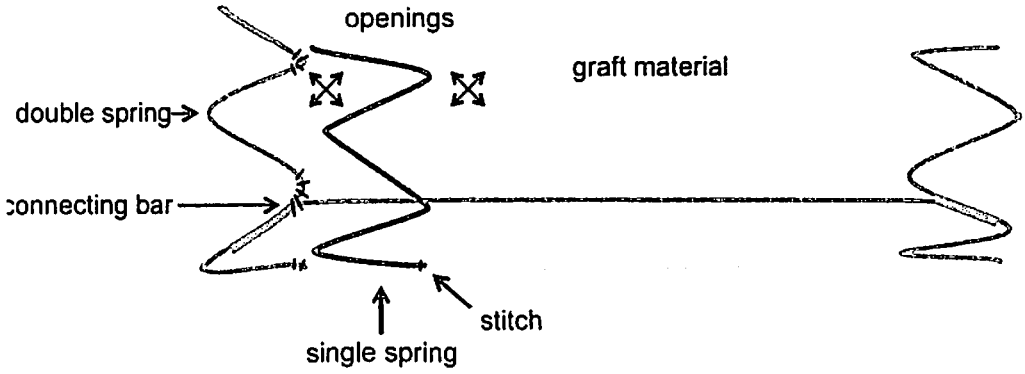
enough flexibility to be compressed down into the delivery device while at the same time having "enough rigidity that [the stent] can hold the device open in a cylindrical shape and . . . [remain] more rigid than the blood vessel into which it is implanted." Dr. Berry Direct, Tr. at 314:17-20. Thus, although under the Court's construction a "stent" must be "substantially . . . rigid," the Court does not agree with Dr. Loomis that this means the device must have little to no flexibility.

4. Affixing

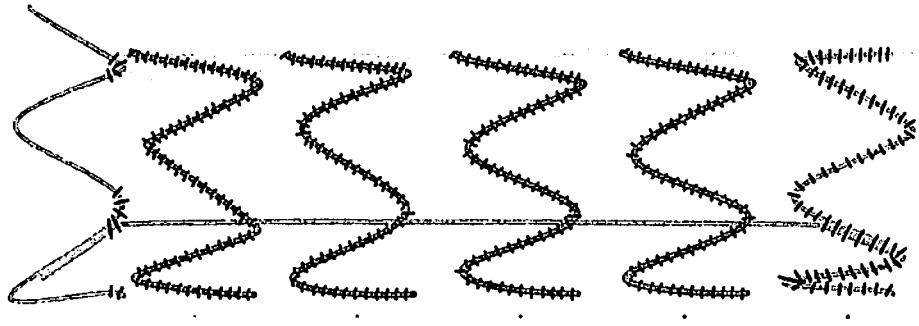
Another disputed term at trial was "affixing." Step B of both claim 12 and 15 begins: "affixing a tubular covering to . . .", although the following language differs slightly from claim 12 to claim 15. As background, it appeared undisputed at trial that once the double spring is placed into the covering it is first attached with a "locking stitch" on the "apex area"[12] of the spring and this stitch essentially holds the spring in place. JX6 at MED0063923; Dr. Berry Direct, Tr. at 343-344. Then, according to animation shown at trial and testimony from experts, a single spring comes in and is also attached with a "locking stitch" on the apex. Id. The graphic images that appear below are taken from the demonstrative exhibits displayed by Plaintiff at trial and are representative of the

[12] An image of the "apex area" appears in the Internal Spring Suture protocol; "Apex" essentially refers to the vertex or corners of the zigzag springs. MI 138, JX6 at MED0063924.

manufacturing process described in the protocols admitted as evidence.



It is only after these initial, "locking stitches" are complete that the body of the single spring is then thoroughly or securely stitched to the covering. Subsequently, the second single spring is brought in and the body of that spring is thoroughly sutured before the third single spring is inserted; this process is repeated until all the springs are in place.



At trial, Gore's expert, Dr. Berry, opined that for purposes of determining *when* the affixing stage begins, the Court should distinguish these initial "locking stitches" from the later, more thorough stitches that attach the entire body of the spring to the covering. Specifically, Dr. Berry argued that

these initial stiches are not really the "affixing" of the covering, but rather they are just stitches that are "thrown on" to hold the springs in place until the true affixing stage begins. Dr. Berry Direct, Tr. at 343-344. According to Dr. Berry, with respect to the Talent device, it is only later, after the first single spring comes in, and after a stent with all the characteristics listed in Step A has been formed, that the true affixing stage begins as the body of each single spring is then thoroughly "affixed" to the covering. Id. at 345:15-17.

In contrast, Medtronic's expert, Dr. Loomis, disagrees that these "initial stitches" should be distinguished from the later full body spring stitches. Dr. Loomis, opined that as soon as the covering is sutured to the double spring with the initial stiches, the "affixing" step has happened and because both parties agree the double spring is not a "stent" and does not have a multiplicity of openings, there can be no infringement. Dr. Loomis Direct, Tr. at 660:13-21.

Though Dr. Loomis disagrees that these "initial stitches" should be distinguished from the later full body spring stitches for purposes of determining the "affixing" element, no testimony was ever offered by Medtronic disputing that these initial stitches do in fact occur. Thus, the Court factually accepts that the springs are first secured with an initial stitch or

"locking" stitch before the full body of the single spring is thoroughly stitched to the covering.

In construing this term the Court first notes that at the Markman stage, the Court choose not to limit "affixing" to any particular method (suturing, heat, etc.), and instead gave the term its plain and ordinary meaning.[13] Markman Op. at 34, ECF No. 92. The Court agrees with Medtronic and Dr. Loomis' opinion and finds that the initial stitches do constitute "affixing" as that term would be construed by one of ordinary skill in the art at the time of the invention. Thus, the "affixing" stage *begins* with the initial "locking stitches." The Court also agrees with Gore and Dr. Berry that the plain and ordinary meaning of "affixing," as used in the claim language, contemplates that by the end of the affixing stage, the covering will be adhered to the stent structure in such a way that the covering will be secure and suitable for use in a lumen. But it is clear that the initial "locking stitches" alone do not thoroughly secure the covering. The actual "affixing" of the covering to the stent is a process; such a process, in this case through suturing, itself has a beginning and end. Because the manufacturing protocols never mention *removing* these initial

[13] The Court notes that at the Markman stage of litigation no arguments were made as to *when* the affixing stage began; instead, the parties disputed only *by what method* the affixing process must occur (suturing, heat adhesion, glue, etc.).

stitches after the true affixing sutures are in place, these "locking stitches," regardless of whether they were initially used to hold the springs in place, ultimately act as stitches that secure the covering to the stent. Thus, the Court rejects Gore's argument that the affixing stage does not begin until the body of the first single spring is thoroughly sutured, and the Court instead finds that the initial "locking stitches" constitute the beginning of the affixing stage.

Although the Court has now held that the affixing stage begins with the initial "locking stitches," the ultimate question of whether a "stent" must be fully-formed before the affixing stage *begins* or before the affixing stage is *complete* will be addressed later in this opinion.

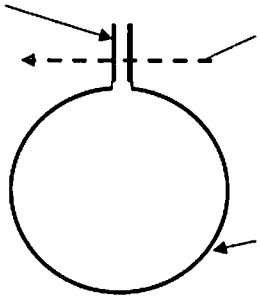
5. Seam

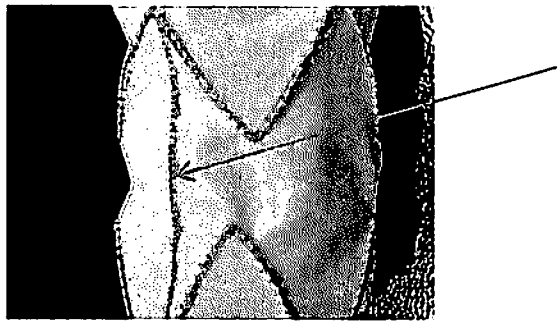
Claim 12 (Step B) reads:

> b) affixing a tubular covering to the exterior surface of the tubular, diametrically adjustable stent, said covering being less than 0.10mm thick and said tubular covering having an exterior surface, a luminal surface and **a seam extending from the exterior surface through to the luminal surface of the tubular covering.**

'870 patent claim 12 (emphasis added). Claim 15 does not contain the above "seam" language. In its Markman opinion, the Court ruled the phrase "seam extending from the exterior surface through to the luminal surface" was not limited to an overlapping seam and gave the term its plain and ordinary

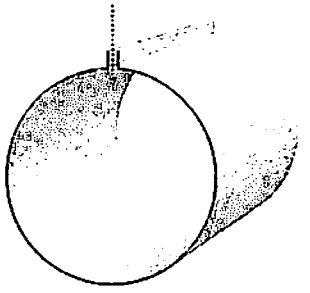
meaning. At issue now is whether the seam used by the accused devices (depicted below) is a seam contemplated by the claim language. A photo of the seam created by the accused process is shown below along with a drawing depicting the seam. These images were taken from the defendants proposed findings of fact and accurately represent what was displayed and discussed at trial. ECF No. at 80-81.



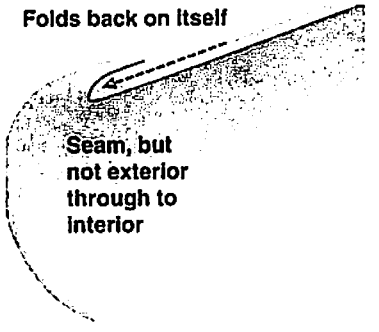


Gore's expert, Dr. Berry described the meaning of a "seam extending from the exterior surface through to the luminal surface of the tubular covering" as the ability to see the interface of the material - the seam - on the exterior surface of the stent covering and on the luminal (interior) surface of the stent covering. Dr. Berry Direct, Tr. at 351:17-19. Dr. Berry went on to describe this seam as an interface of material that forms a "passageway," on a micro particle level, that would extend from the exterior surface of the device through to the luminal surface. Id. at 353:18-24. The graphic image below was

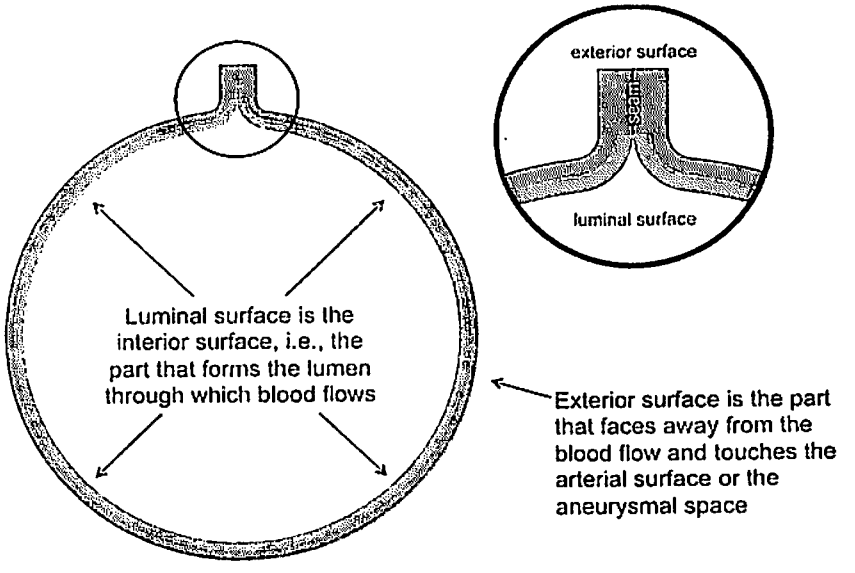
taken from the demonstrative exhibits displayed by Plaintiff at trial and depicts Dr. Berry's "passageway" definition.



In Dr. Berry's opinion, both the Talent device seam, and an overlapping seam (as used in the patent embodiments), would meet the claim language because they both create a passageway that extends from the exterior surface through to the luminal surface of the covering. Id. at 356:1-7. Dr. Berry gave an example of a seam which would not meet the claim language and described that seam as one where the ends of the tube are folded back on itself. Id. at 354: 18-21. The reason this type of "cuffed" seam does not meet the claim language, according to Dr. Berry, is because the seam creates a dead end; there is no interface that creates a passageway from the exterior surface through to the luminal surface. Id. at 355. The graphic images below were taken from the demonstrative exhibits displayed by Plaintiff at trial and depict a dead-end or "cuffed" seam.



According to Dr. Berry and Gore, the exterior surface, as used in the claim language, is the side of the covering that faces away from the blood flow and touches the arterial surface or the aneurysmal space. The luminal surface is the interior surface; the surface that forms the lumen through which the blood flows. Thus, according to Dr. Berry, the tip of the Talent seam is on the "exterior surface" of the covering, while the interior fold of the seam is part of the luminal surface. Therefore, this interface of material, or seam, forms a passage way from the exterior surface through to the luminal surface of the tubular covering. The graphic image below was taken from the demonstrative exhibits displayed by Plaintiff at trial and depicts this description.



Dr. Berry also explained his definition of seam makes sense as it would have been important for the inventors to differentiate the commonly used "dead end" or "cuffed" seam from

a seam that extends from the exterior to the interior surface. In order to get the desired thinness, the inventors needed to make clear that a user could not use commercial vascular grafts or other extracted tubes. One of the common techniques at the time for creating a graft-covering was to extract the ePTFE material through a machine that creates a seamless tube. However, this seamless tube technique did not produce the sufficiently thin covering the inventors required for the '870 patent because the material would not remain intact when extruded from the machine. Dr. Lewis Direct, Tr. 122-123, 125 (explaining that a problem with "trying to extrude real thin tubes is they tend to split as they exit the extruder" and so to get the necessary thinness and "to make a tube out of a sheet or a film, it was inevitable to have a seam"). Thus, as described in the '870 patent, the inventors instead started with a thin flat sheet that they could then wrap to create a tube with the necessary thinness. According to Gore, the "seam" language is not really a design feature as much as a necessitated result from using a sufficiently thin flat sheet of graft material as opposed to a premade or extracted tube of material.

In contrast, Medtronic's expert, Dr. Loomis, as one of ordinary skill in the art, stated that "a seam is just an interface between two surfaces, either of the same material or dissimilar material." Dr. Loomis Direct, Tr. at 665: 1-2; Dr.

Berry Cross, Tr. at 409:13-15 (agreeing that a seam is an interfacing of surfaces). In Dr. Loomis's view, the claim language is not describing a "passageway" from the exterior side to the interior side; rather, the language is describing an interface of surfaces and requiring that in creating the seam, the interior surface be interfaced or touching, the exterior surface. Id. at 667. The seam used by the Talent products does not meet this definition in Dr. Loomis' opinion because it is an interface of two interior surfaces. Id. An example of a seam that would meet that definition, according to Dr. Loomis, is an overlapping seam. Id. Dr. Loomis did not offer any other examples of seams that would meet his definition other than an overlapping seam. Dr. Loomis Cross, Tr. at 849: 19-25.

In evaluating the testimony of both experts, the Court must keep in mind its original construction of "seam extending from the exterior surface through to the luminal surface." Although the Court gave the phrase its plain and ordinary meaning, the Court did specifically hold that this phrase was not limited solely to an "overlapping seam." Markman Op. at 39 ("There is nothing in the language of the claims, the specification, or the prosecution history that mandates a 'seam extending from the exterior surface through to the luminal surface' be created by an overlap.").

The Court first finds that the plain and ordinary meaning of a "seam," as agreed to by both experts in this case, is an "an interface between two surfaces, either of the same material or dissimilar material." Dr. Loomis Direct, Tr. at 665: 1-2; Dr. Berry Direct, Tr. at 353:18-24 (also describing the seam as an "interface" of material). However, even after defining "seam," the real dispute is what the phrase "extending from the exterior surface through to the luminal surface of the tubular covering" means and whether the Talent seam would meet that definition. The Court finds that Dr. Berry's opinion explaining that this phrase describes an interface of material forming a "passageway," on a micro particle level, that extends from the exterior surface of the device covering through to the luminal surface, most properly comports with the meaning to one of skill in the art at the time of the invention. Id. at 353:18-24, 354:2-5. The Court rejects Dr. Loomis' definition because it in effect limits the seam to an "overlap," and that argument was already rejected by this Court at the Markman stage.

Dr. Berry's definition is also supported by the prosecution history of the '870 patent. During patent litigation for the '931 application (the application for the '870 patent), the patent examiner initially rejected claim 39 (now claim 12) as being anticipated by Khosravi, a piece of prior art. In responding to the rejection the inventors argued that Khosravi

was different because it used "tubes [that] do not have a seam extending through between their outer and inner surfaces." '931 application prosecution history, JA-65, ECF No. 66 (emphasis added). Additionally, in the same response, the inventors characterized their invention's seam again by saying the stent covering "has a seam extending through between the exterior and luminal surfaces of the covering." Id. (emphasis added); see also JA-83 (again stating that the covering has "a seam extending through between its exterior and luminal surfaces"). In a second response to claim 39's rejection, the applicants differentiated the prior art by explaining: "This claim [claim 39] describes a method of providing the exterior surface of a stent with a tubular covering of material which has a seam extending through the covering material." JA-83 (emphasis added). Further support can be found in the prosecution history for the '214 application (the parent patent). In responding to the patent examiner's rejections, the applicants submitted new claims stating: "New claims 72-88 are based (sequentially) on the allowed claims but delete the seamline limitation . . . ." '214 Application Prosecution History, JA-181 (emphasis added). A review of submitted claims 72-88 clearly show the applicants deleted all reference to a "seam extending from the exterior surface through to the luminal surface of the tubular covering." JX 174-176.

Thus, the prosecution history supports the conclusion that the seam language in the claim was simply a way for the inventors to require a "seamline," one that extended "through the covering material", in between the "outer and inner" or the "exterior and luminal" surfaces of the covering. The patent applicants themselves used this language to differentiate from prior art that only disclosed a tube of material without any kind of seam. This is in line with Dr. Berry's argument that the seam language in claim 12 implies a "passageway" and was a way for the inventors to explain that a seamless tube of material or a cuffed, dead-end type seam was not what the invention was claiming. The applicants themselves described the seam as going "through" or "in between" the exterior and luminal surfaces and the Court finds that the Talent seam does just that.

C. Step Two - Infringement Analysis

Using the terms and phrases just construed, the Court will now analyze whether the three separate accused Talent devices infringe claims 12, 16 and 19 of the 870' patent. In considering all the elements and limitations of the claims the Court finds it is helpful to chart the requirements:

CLAIM 12	
A method of making a tubular intraluminal graft comprising:	
a) selecting at least one tubular, diametrically adjustable stent	

1 - selecting	
2 - stent ("elongated members forming a substantially cylindrical and rigid structure")	
3 - tubular	
4 - diametrically adjustable	
having an exterior surface, a luminal surface and a wall, and	
having a multiplicity of openings through the wall of the stent;	
b) affixing a tubular covering to the exterior surface of the tubular diametrically adjustable stent,	
said covering being less than 0.10mm thick and,	
said covering having an exterior surface, a luminal surface, and	
a seam extending from the exterior surface through to the luminal surface of the tubular covering.	

CLAIM 16 and 19	
15. A method of making a tubular intraluminal graft comprising:	
a) selecting at least one tubular, diametrically adjustable stent	
1 - selecting	
2 - stent	
3 - tubular	
4 - diametrically adjustable	
having an exterior surface, a luminal surface and a wall, and	
having a multiplicity of openings through the wall,	
said tubular, diametrically adjustable stent having a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter,	
wherein said tubular, diametrically adjustable stent has been diametrically adjusted to the enlarged diameter;	
b) affixing a tubular covering to the tubular, diametrically adjustable stent; and	

c) collapsing the tubular, diametrically adjustable stent to about the collapsed diameter	
Wherein the tubular covering is affixed to the exterior surface of the tubular, diametrically adjustable stent.	
16. A method according to claim 15 wherein said tubular covering is less than about 0.10mm thick.	
19. A method according to claim 16 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.	

1. Talent Thoracic Main Stent Graft

Literal Infringement

The Court begins by considering one of the most important elements: whether the accused Talent devices have a "stent" component as used in the claim language and as defined by this Court at the Markman stage. A "stent" has been defined as "elongated members forming a substantially cylindrical and rigid structure." Markman Op. at 16, ECF No. 92. Additionally, the language of claim 12 and 15 requires the "stent" be diametrically adjustable, have an exterior surface, a luminal surface, a wall, and a multiplicity of openings through the wall of the stent. As discussed in the manufacturing process section above, the structure of the Medtronic thoracic stent begins with a "double spring" being inserted into the covering and attached, and then multiple single springs are also inserted individually and attached.

Gore's expert, Dr. Berry opined that the Talent thoracic stent device has a "stent" as defined by the Court's claim

construction and satisfies the characteristics listed in the claim language. Dr. Berry looked at the final stent device in determining whether a "stent" existed and admitted he was "using the advantage of the covering to create the stent." Dr. Berry Cross, Tr. at 397:8-10. Dr. Berry opined that the final Talent products had "elongated members" in the form of "metallic structures that are elongated, tracing out a circumference along the length of the stent." Dr. Berry Direct, Tr. at 312:21-23. Dr. Berry also stated that in addition to the zigzag single springs, the double spring connecting bar (or "cross bar"), was also an elongated member "traversing the length of the device." Id. at 313:5-7. Dr. Berry opined that the elongated members formed a "substantially cylindrical structure" since they trace a circumference and the single springs are "stacked lengthwise to form a substantially cylindrical structure." Id. at 313:19-21. Additionally, Dr. Berry stated these elongated members form a "substantially rigid structure" because the metallic portion of the device holds the device open in a cylindrical shape and is more rigid than the blood vessel into which its implanted. Id. at 314:9-20. Dr. Berry also found that the device was tubular, Tr. at 315:20-22, had an exterior surface and a luminal surface, Tr. at 318, and a wall, Tr. at 318:21-24. Last, looking at the final device, Dr. Berry found that all the Talent stent devices had "two or more" openings and thus the stent has

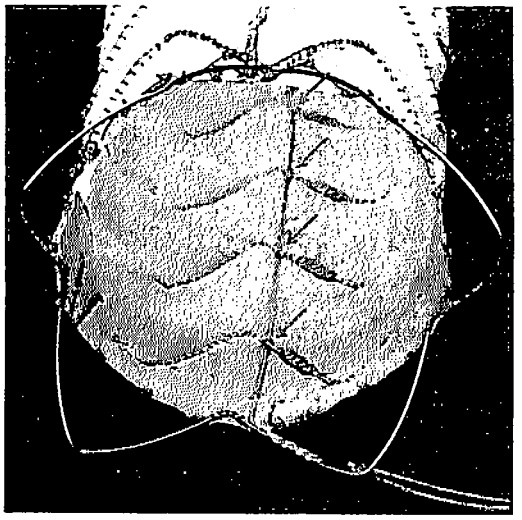
a "multiplicity of openings" as required by the claim language. Id. at 320-321 (noting the Court's construction of multiplicity of openings was "two or more" openings). Last, though not specifically analyzed, Dr. Berry agreed this stent was also "diametrically adjustable." Id. at 321.

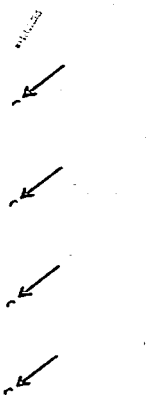
Medtronic's expert, Dr. Loomis, in contrast, never analyzed the final fully formed Talent stent graft devices to determine whether they met the definition of "stent." Dr. Loomis Cross, Tr. at 850:1-4. In Dr. Loomis' opinion, the correct analysis was to look only to the manufacturing process in order to consider when, if ever, a stent meeting the Court's definition and containing the characteristics listed in the claim language, was selected prior to the affixing step. To begin, Dr. Loomis opined that none of the individual metal parts (the double spring, the tapered spring, or the single springs) met the Court's definition of "stent" and none had the characteristics required by the claims. Dr. Loomis Direct, Tr. at 651:18-20. Specifically, Dr. Loomis explained that in his opinion these parts were lacking two limitations: 1) elongated members (at best the double spring had one elongated member but not two and the single springs had none), and 2) a multiplicity of openings. Id. at 652:1-11. Significantly, on cross-examination, Dr. Berry agreed with Dr. Loomis when asked whether the double spring, the tapered spring, or the single springs, each individually, could

meet the definition of "stent" and he stated they could not. Dr. Berry Cross, Tr. at 387:13-15. Dr. Loomis went on to explain that in his opinion, since both parties agree the double spring by itself is not a stent, a "stent" is not formed *before* the "affixing" process begins, which is sequentially required under the claim language. Dr. Loomis argued that if the double spring had been a "stent" under the Court's definition and had satisfied the characteristics listed in the claim, then once the covering was affixed to the double spring there would have been infringement. Dr. Loomis Direct, Tr. at 660: 10-16.

Furthermore, Dr. Loomis opined that even if the initial suturing of the double spring did not constitute "affixing" under the claim, a stent is still not formed once the single spring comes in and is sutured. Id. at 662:8. Dr. Loomis explained no stent is formed with the addition of the single spring because "they're just individual components that are individually sutured in" and are not physically connected to each other in any way. Id. at 662:10-16. According to Dr. Loomis, the fact that the springs are connected by the graft material is not enough to satisfy the claim language; in other words, a true physical connection of the springs would be required. Id. Thus, Dr. Loomis agrees that if the single springs were wired together or attached to the double spring so as to form a single device before the covering was affixed to

that device, it would be a "stent" and the process would infringe the claim language of the '870 patent. Id. at 663:7-18. However, according to Dr. Loomis, this would be a "totally different process" than the one used by Medtronic. Id. On cross-examination, Gore questioned Dr. Loomis' opinion that the springs were not connected to the double spring by showing him a statement from a Medtronic submission to the FDA which said: "The Talent Thoracic Stent Graft is composed of a series of serpentine springs stacked in a tubular configuration and connected by a full length connecting bar. These structures form the frame of the stent." PX344A at MED0089269 (emphasis added); Tr. at 827-828. Gore also, by showing Dr. Loomis enlarged photos of the Thoracic Device (see images with arrows below) as well as the actual device itself, pressed Dr. Loomis to acknowledge that the individual springs were in fact "sutured to the connecting bar." Dr. Loomis Cross, Tr. 828:14-15.





However, Dr. Loomis disagreed and stated that the manufacturing instructions never discuss "wrapping the suture around the connecting bar to in some way connect the spring with the connecting bar" and that only the "spring is sutured, and the connecting bar just happens to be passing underneath the spring." Id. at 829:18-25.

In the Court's analysis of whether a "stent" under the Court's definition and the claim language exists, one of the first questions is whether the Court should analyze the final, fully formed Talent device, or whether it should look only to the manufacturing process to see if a stent is ever truly formed. If the Court chooses to look only to the manufacturing process to see when, if ever, a stent is formed, the Court must keep in mind that it was earlier determined that the steps of the claims must be performed sequentially. Additionally, the Court also earlier held that though the "affixing" step is not truly complete until the components are thoroughly sutured such that the covering would be secure when implanted in the lumen, the "affixing" step at least begins with the initial "locking stitches." Thus, the Court must now determine whether a "stent" must be fully formed before the "affixing" process is *complete* or whether it must be fully formed before the "affixing" process *begins*.

First, the Court must agree with Dr. Loomis that in assessing a ***method of making an intraluminal graft***, the Court must consider the accused manufacturing process itself and not the final fully formed product alone. See BMC Res., Inc. v. Paymentech, L.P., 498 F.3d 1373, 1378-79 (Fed. Cir. 2007) ("Direct infringement requires a party to perform or use each and every step or element of a claimed method or product."); Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is directly infringed only by one practicing [all steps of] the patented method."). On cross-examination, Dr. Berry appeared to testify that although he was opining as to the infringement of the accused manufacturing process, he had never held the individual stent components in his hand; he had only ever held the fully formed stent graft products.[14] Dr. Berry Cross, Tr. at 387:16-17. Because the Court must determine whether "each and every step or element of the claimed method" is infringed, the Court cannot agree that it is proper to only look to the final fully formed stent when analyzing a *method of making* a stent graft. BMC Res., Inc, 498 F.3d at 1378-79.

Next, the Court considers whether "stent" must be formed before the "affixing" process *begins* or before the "affixing"

[14] The Court notes that although Dr. Berry never held the individual components in his hand, he did analyze the manufacturing process protocols and understood how each component came together to form the final device.

process is *complete*. As discussed earlier, the plain language of the claim requires each step be performed sequentially. Specifically, Step B reads: "**Affixing** a tubular covering **to the** exterior surface **of the** tubular, diametrically adjustable **stent** . . . ." '870 patent at 12 & 15. Because the claim language clearly implies that the covering is to be affixed to "the stent," the Court finds that such "stent" must be fully formed before the "affixing" stage even *begins*. Furthermore, the Court accepts the uncontested assertion that none of the individual metal springs (the double spring, tapered spring, or single springs) are alone "stents" with the characteristics required by claims 12 and 15. Thus, since both parties agree the double spring is not a "stent" with the characteristics required by Step A, the affixing stage begins before a "stent" is formed and therefore no infringement can occur.

However, even if the Court had agreed with Gore and found that the "affixing" process does not begin until after the first single spring comes in, the Court still finds that a "stent" is not formed with the addition of the single spring. The construed definition of "stent" is "elongated members forming a substantially cylindrical and rigid structure."[15] First, the

[15] As background, in construing "stent" at the Markman stage, this Court made clear that because the claim language, the specification and the prosecution history made no mention of one particular function of a stent, the Court would not import a

Court agrees with Gore and Dr. Berry that at the point the single spring is inserted and secured to the covering by a "locking stitch," the "elongated members" element is satisfied. Dr. Berry Direct, Tr. at 312:21-23 (noting the zigzag springs were "metallic structures" and "elongated, tracing out a circumference across the length of the stent"). The double springs, the single spring and the connecting bar are all metallic structures that either trace the circumference of the structure or, in the case of the double spring's connecting bar, traverse the length of the stent. Id. at 312-313 (opining that the double spring's cross bar was also an elongated member). Next, the Court must assess whether the elongated members form "a substantially cylindrical and rigid structure." It is here that the Court must find that the infringement allegation again fails for two reasons. First, the Court finds that the use of the term "structure" implies that the elongated members must be connected in some way to form a single device.[16] The Court

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functional limitation into the construction of the term. Markman Op. at 14. The Court also rejected a proposed definition of "interconnected wires" and found that "elongated members" better encompassed all the possible "stent" examples referenced in the specification and in the preferred embodiments. Id. at 15. (quoting the '870 patent: "while the stent shown is made from metal wire, a perforated sleeve having perforations of suitable shape, size and quantity may also be used").

[16] This conclusion is further supported by the claim language's use of "stent" in the singular form, implying any metallic pieces must connect to form a single structure. Additionally,

disagrees with Dr. Loomis that no connection is ever formed between the double spring and the single springs; it is clear from looking at the Thoracic device that each single spring is connected to the double spring's connecting bar through a single suture that loops around both members and connects them to the covering. However, this connection is not formed until the "affixing" stage, when the bodies of the single springs are thoroughly sutured to the covering. Both parties agree the initial locking stiches do not connect the single springs to the double spring. Thus, the formation of the stent "structure" and the affixing of the covering happen simultaneously. As mentioned earlier, the language of the claims requires the steps be performed sequentially, and the Court finds simultaneous performance cannot satisfy that requirement. See Mantech Environmental Corp. v. Hudson Environmental Services, 152 F.3d 1368, 1375-76 (Fed. Cir. 1998) (finding that because the "sequential nature of the claim steps [was] apparent from the plain meaning of the claim language," the steps could ***not*** "be performed in any order, or simultaneously," they had to be performed sequentially) (emphasis added).

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the claim requires that the stent have a single "wall" with a "multiplicity of openings" through that wall. '870 patent, claim 12 & 15. Logically, that stent can only have a multiplicity of openings through the wall if the elongated members are *connected* in such a way as to create these openings.

A second reason the Court finds "a substantially cylindrical and rigid structure" cannot be found is that the Court cannot agree that, at the point when the single spring is inserted and secured by a "locking stitch," the device is "rigid." As earlier construed in this opinion, "rigid" simply means the device has "enough rigidity that [the stent] can hold the device open in a cylindrical shape and . . . [remain] more rigid than the blood vessel into which it is implanted." Dr. Berry Direct, Tr. at 314:17-20. However, the Talent Thoracic device cannot meet this definition until all the single springs have been thoroughly affixed to the covering. At the point Gore asks the Court to analyze whether the device satisfies the requirements for a "stent," both the double spring and the single spring are connected to the covering only by the initial locking stiches. Merely touching the device could cause the middle portion of the covering to collapse (since the middle single springs have not yet come into the device) and the single spring to fall over (since it is only connected to the covering with a single stitch in one place). Thus, clearly the elongated members cannot yet "hold the device open in a cylindrical shape and . . . [remain] more rigid than the blood vessel into which it is implanted." The Thoracic device is eventually "rigid;" however, it is not until the affixing stage is complete.[17] Thus,

[17] Even if the accused device becomes "rigid" at some point

because a "stent," as construed by the Court, is not formed *before* the covering is "affixed," even under Gore's alternative definition of *when* the affixing process begins, no literal infringement of claim 12 can occur.[18] Additionally, although the Court earlier held Talent's kitting bag process could constitute "selecting," satisfaction of this element was contingent on the Court finding that the manufacturing process chosen formed a "stent" before the affixing process begins. Since no stent satisfying the Court's definition is formed before the affixing process begins, the "selecting" element can also not be met.

Because claim 15, on which claim 16 and 19 depend, also requires the selection of a "stent," infringement of claims 16 and 19 can also not be found.[19]

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before the affixing process is complete, it clearly does not become rigid before the affixing process begins (for the same reasons explained above). Since the Court has concluded that the sequential nature of the claim requires the stent be fully formed before the affixing stage even begins, this too would be enough to preclude infringement.

[18] In looking at the other elements of the claim, the Court acknowledges that the covering is on the "exterior surface" of the Talent devices and that the covering is less than 0.10mm and has an exterior surface and a luminal surface. Dr. Berry Direct, Tr. at 347:18-22; PX314A at MED0062966; Tr. at 349:2-20. The Court also finds the Talent devices are diametrically adjustable. Additionally, as construed earlier in the opinion, the Court finds the seam used on the Talent devices is a "seam extending from the exterior surface through to the luminal surface of the tubular covering."

[19] The Court acknowledges that Medtronic did not contest that the Talent device had "a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter" and that the device "ha[d] been

Doctrine of Equivalents

The Court must now assess whether infringement of the Talent Thoracic stent may still be found under the doctrine of equivalents. The essential inquiry underlying the doctrine of equivalents is whether the accused product or process contains elements identical or equivalent to each element of the claimed invention. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997).

The element the Court ultimately found lacking above was that the steps were not performed sequentially, as required by the plain meaning of the claim language; meaning no "stent" was ever selected or in existence *before* a covering was affixed. However, there are multiple layers to this conclusion. First, the initial "locking stitch" was found to begin the affixing process and both parties agreed the double spring was not a "stent." Second, even assuming the "affixing" process did not begin until after the addition of the first single spring, application of the Court's claim construction to the accused device revealed that the double and single spring did not form a single "structure," since there was no connection between the

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diametrically adjusted to the enlarged diameter." Dr. Berry Direct, Transcript 361:10-16; 364: 15-20. Additionally, the Court acknowledges the manufacturing protocol also provides for "collapsing the" Talent device "to about its collapsed diameter" when loading the Talent products into the loading device. PX 316B.

elongated members until the affixing stage. Third, application of the Court's claim construction revealed that the device was not "rigid" until all the springs had been inserted and thoroughly stitched. Thus, since the "stent" formation and the covering affixing happen simultaneously, the sequential requirement in the claim language that necessitates that a "stent," with all the characteristics listed in Step A, exist before the covering is affixed to it in Step B is simply never satisfied. See Mantech Environmental Corp., 152 F.3d at 1375-76 (steps in method claim for remediating region of contaminated groundwater must be performed in written order because each step referred to activity performed in prior step); Depuy Orthopaedics, Inc. v. Androphy, 2000 U.S. Dist. LEXIS 661, at *55 (N.D. Ill. Jan. 19, 2000) ("If a step in a method claim as written relies on a device already physically in existence or the result of another step, then the existence of those physical constraints act as a condition precedent on that method step.").

The Court must now ask whether there is "equivalence" between the elements of Medtronic's manufacturing process and the claimed elements of the patented process. Since Step B relies on the existence of the result in Step A, the essential missing element in the accused manufacturing process is that Step A is not performed before Step B. Under the "function-way-result test," the Court must consider whether the accused

process of creating the stent and affixing the covering *simultaneously*, "performs substantially the same function in substantially the same way to obtain the same result" as first selecting and making a fully formed stent *before* affixing the covering. American Calcar, Inc. v. American Honda Motor Co., Inc., 651 F.3d 1318, 1338 (Fed. Cir. 2011). Alternatively, the Court can consider whether the differences between the claimed element and the corresponding infringing element are "insubstantial." See e.g., Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370, 1382 (Fed. Cir. 2006). However, the Court must keep in mind that the doctrine of equivalents is limited by the "all elements rule," which provides that "the doctrine of equivalents does not apply if applying the doctrine would vitiate an entire claim limitation." Asyst Techs., Inc. v. Emtrack, Inc., 402 F.3d 1188, 1195 (Fed. Cir. 2005).

As discussed earlier, Step B in claim 12 and 15 states the covering is affixed to the exterior surface "of **the** tubular, diametrically adjustable stent," clearly referring to the stent just "selected" in Step A. '870 patent, claim 12, 15 (emphasis added). Thus, the "stent" referred to in Step A has to be in existence before Step B can occur; at trial, neither party disputed this conclusion. Even if Medtronic satisfied Step A's "selecting" through its "kitting bag process," Gore acknowledged

that an additional step of "making that stent" would have to occur before Step B could be completed. Thus, when the language of the claim is broken down, it must be limited to sequential steps where a stent is in existence before the covering is affixed.

The '870 patent's process, as construed by this Court, contains at least two separate elements which produce a final product, and under the language of the patent claim this process must occur in sequence. By contrast, in the accused manufacturing process, the formation of the stent and the affixing of the covering to the stent occur simultaneously. This difference in the manufacturing process is not merely a combination of the '870 patent elements. Rather, it is essentially a new method by which one of the requirements of Step B - that "the stent" of Step A be fully formed before the covering is affixed - is entirely eliminated. Because such a theory of equivalents would entirely vitiate a particular claim element, no infringement can be found.[20] Warner-Jenkinson Co.,

[20] Dr. Loomis agreed with this conclusion and opined that the doctrine of equivalents does not work in this case for two reasons. First, according to Dr. Loomis, the Talent devices lack a "stent" as defined by the Court and as used in the claim language, and "if an element is missing, then you can't have an equivalent." Dr. Loomis Direct, Tr. at 672:7-9. Second, Dr. Loomis opined that Medtronic's method of making the stent was not done "substantially the same way" as would be required for the doctrine of equivalents. Id. at 671:24. Additionally, on cross-examination, Dr. Berry agreed that choosing a premade

520 U.S. at 29 ("It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.").

In Wooster Brush Co. v. Newell Operating Co., the Federal Circuit affirmed a district court's finding of non-infringement and held that where the patent called for two distinct, sequential applications of bonding material, an accused device using only a single application of bonding material could not meet the equivalents test. 2000 U.S. App. LEXIS 14132, *12 (Fed. Cir. June 9, 2000) (unpublished). The court noted that "[c]learly, one application of adhesive cannot occur sequentially, and thus, the absence of two sequential applications in the accused process renders them non-infringing." Id.; see also Am. Calcar, Inc, 651 F.3d at 1339 (agreeing that "finding a signal from one source to be equivalent to 'signals from a plurality of sources' would vitiate that claim limitation by rendering it meaningless.").

Similarly, Medtronic's Talent manufacturing process eliminates the sequential requirement entirely and cannot be

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stent and wrapping it with a covering was a "different way" of creating a stent graft than taking a series of springs and suturing them frame by frame under an already seamed cover. Dr. Berry Cross, Tr. at 407:13-15.

found to infringe under the equivalents test.[21] See also Mantech Environmental Corp., 152 F.3d at 1375-76 (finding that steps which were "performed in any order, or simultaneously," could **not** satisfy the sequential nature of the claim language).

2. Talent Abdominal Aorto-Uni ("AUI") Stent Graft

The AUI component differs slightly from the Thoracic Main component in that it has two "tapered" double springs. Additionally, some of the AUI components have both internal and external springs. However, for purposes of infringement here, both parties agreed the "external spring" protocol has no effect on the infringement analysis and need not be considered.[22] Dr.

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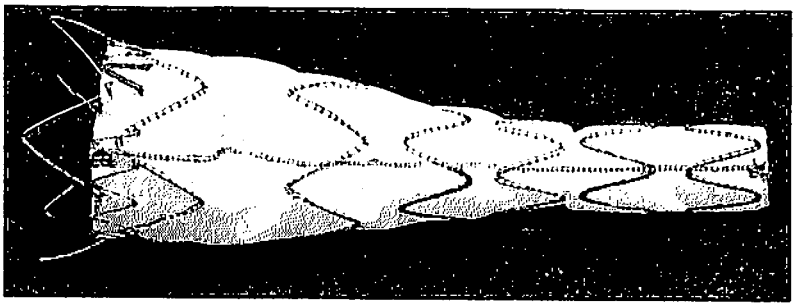
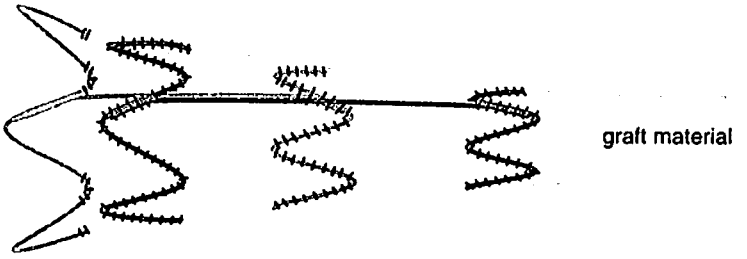
[21] Additionally, the Court finds that Gore has failed to meet its evidentiary burden of demonstrating by particularized testimony that "equivalence" existed between the accused manufacturing process and the patented process. "[A] patentee must . . . provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the 'function, way, result' test when such evidence is presented to support a finding of infringement under the doctrine of equivalents. **Such evidence must be presented on a limitation-by-limitation basis.**" Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996) (emphasis added). Though arguments were made through Dr. Berry and in Gore's proposed findings of fact and conclusions of law that the "kitting bag process" was the equivalent to selecting a premade stent, no equivalence arguments were ever made as to whether Medtronic's process of forming the stent and affixing the covering *simultaneously* was the equivalent to performing the steps sequentially, i.e., affixing the covering *after* a stent has been fully formed.

[22] Additionally, the Court notes that the smallest size of the AUI component was not part of Dr. Berry's infringement analysis and thus the Court also does not consider that size in its analysis. Dr. Berry Direct, Tr. at 301:21-23.

Loomis Direct, Tr. at 670:14-16; Dr. Berry Direct, Tr. at 330:1-2. Like the Thoracic stent, the AUI construction begins with a double spring being inserted into a seamed covering and then secured with initial "locking stiches." Dr. Berry Direct, Tr. at 368. However, unlike the Thoracic stent, a second double spring is inserted next and is secured to the covering with initial locking stitches.[23] Id. at 369:4-5. The photo and graphic image below were taken from the demonstrative exhibits displayed by Plaintiff during trial and are representative of the AUI device and manufacturing process.





[23] At trial it was clarified that some Medtronic AUIs have only one interior double spring and not two interior double springs. Dr. Berry Redirect, Tr. at 418 (noting that whether the AUIs had one double spring or whether they had two double springs had no effect on his infringement opinion). However, whether the AUI component has one interior double spring or two interior double springs does not affect the Court's analysis.

Again, Gore's expert, Dr. Berry opines, for the same reasons stated for the Thoracic stent, that at the point the second double spring is inserted and secured with a "locking stitch," "a stent is formed meeting the court's claim construction of a stent with a multiplicity of openings[.]" Id. at 369:9-12. It is only *after* the second double spring comes in and is secured with a locking stitch that the bodies of the double springs are thoroughly stitched to the covering. Id. at 369:15-20.

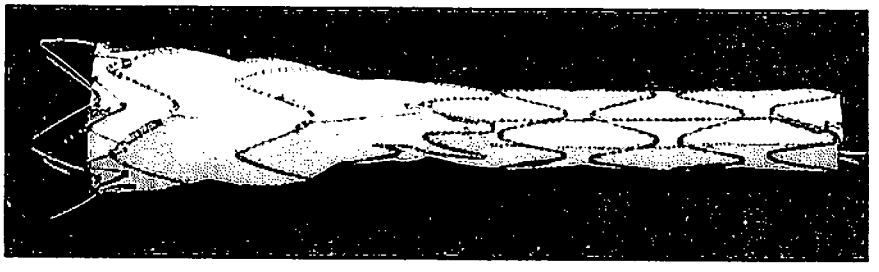
Medtronic's expert, Dr. Loomis, again opined that the AUI device does not infringe for the same reasons as the Thoracic device. Dr. Loomis Direct, Tr. at 671:1-2. However, Dr. Loomis technically gave no opinion as to whether the combination of the two double springs could meet the limitations of the claim. Dr. Loomis Cross, Tr. at 850:1-4.

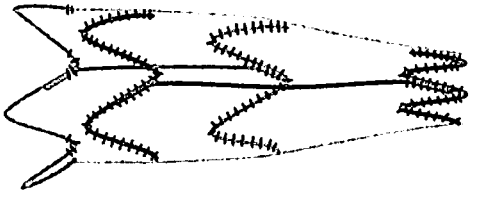
The Court finds the accused manufacturing process for the AUI component does not infringe literally or under the doctrine of equivalents for the same reasons given for the Thoracic component. No substantial difference between the manufacturing process of the AUI component and the manufacturing process of the Thoracic component exists that would change the Court's prior analysis.

3. Talent Abdominal Bifurcated Stent Graft

The Bifurcated component differs slightly from the Thoracic Main and AUI components in that the graft splits and has two

legs, a longer leg and a shorter leg. Additionally, some of the Bifurcated components have both internal and external springs. However, again, for purposes of infringement here, both parties agreed the "external spring" protocol has no effect on the infringement analysis and need not be considered. Dr. Loomis Direct, Tr. at 670:14-16; Dr. Berry Direct, Tr. at 330:1-2. The photo and graphic image below were taken from the demonstrative exhibits displayed by Plaintiff during trial and are representative of the Bifurcated device and manufacturing process.





Like the Thoracic and the AUI stents, the Bifurcated component construction also begins with a double spring being inserted into a seamed covering and then secured with initial "locking stiches." Dr. Berry Direct, Tr. at 372:14-22. Next, like the AUI component, a second double spring is inserted and

is secured to the covering with initial locking stitches. Id. at 373:21-22. This second double spring forms the short leg of the Bifurcated component. Id. at 13-17. Again, Gore and Dr. Berry opine, for the same reasons stated for the Thoracic, that at this point a stent is formed meeting the Court's claim construction of a stent with a multiplicity of openings. Id. at 372-373; 374:2. The two double springs' connecting bars are diametrically opposed, 180 degrees from each other. Id. at 373:2-6. It is only after the second double spring comes in and is secured with an initial "locking stitch" that the bodies of the double springs are then thoroughly stitched to the covering. Id. at 373:20-22. Thus, Dr. Berry opined that Medtronic's bifurcated process infringed claims 12, 16 and 19 of the '870 patent. Id. at 372:23-25; 374:22-23.

Dr. Loomis again opined that the Bifurcated device does not infringe for the same reasons explained above with respect to the Thoracic device. Dr. Loomis Direct, Tr. at 671:14-16. However, Dr. Loomis technically gave no opinion as to whether the combination of the two double springs could meet the limitations of the claim. Dr. Loomis Cross, Tr. at 852:1-4.

The Court finds the accused manufacturing process for the Bifurcated component does not infringe literally or under the doctrine of equivalents for the same reasons given for the Thoracic component. No substantial difference between the

manufacturing process of the Bifurcated component and the manufacturing process of the Thoracic component exists that would change the Court's prior analysis.

4. "Importation" under 35 U.S.C. § 271(g)

In addition to the reasons given above for non-infringement, as argued by Medtronic at trial, the Court also finds that at least a portion of Plaintiff's claims would fail based on the fact that the *named defendants* did not actually "import" the product into the United States.

As explained earlier, the accused Talent devices were actually manufactured by Medtronic Mexico, located in Tijuana, Mexico. Medtronic Mexico appears to be a subsidiary of Medtronic, Inc. However, the exact structure of the company and control of divisions is something that was not argued by either party. Thus, the question before the Court is whether one of the named defendants can qualify as the "importer" under 271(g) since they controlled Medtronic Mexico or whether Gore should have named Medtronic Mexico specifically.

Courts have found the terms "importation" and "import" in Section 271(g) "to have their plain and ordinary meaning of bringing goods into the United States from another country." Bristol-Myers Co. v. Erbamont Inc., 723 F. Supp. 1038, 1043 (D. Del. 1989); Pfizer Inc. v. Aceto Corp., 853 F. Supp 104, 106 (S.D.N.Y. 1994). In Pfizer, the district court found that a

foreign manufacturer was not liable under Section 271(g) merely because it knowingly sold the product to an "importer." Pfizer Inc., 853 F. Supp at 106. Similarly, a California district court granted a motion to dismiss holding that an entity which played some role in "coordinating" the shipments of goods from Hong Kong to the United States at the behest of a second entity could not be held liable under 271(g). Cybiotronics, Ltd. v. Golden Source Elecs., Ltd., 130 F. Supp. 2d 1152, 1174 (C.D. Cal. 2001).[24] Thus, courts have agreed that the primary target of 271(g) is not necessarily the manufacturer of the patented process, but rather the "importer" of the patented process. See, e.g., Tec Air v. Nippondenso Mfg. U.S.A., 1997 U.S. Dist. LEXIS 1081, *9 (N.D. Ill. Jan. 28, 1997) (interpreting Section 271(g) to apply only to the entity that actually imports the patented product into the United States).

The Federal Circuit has looked to the legislative history of Section 271(g) in construing its meaning. The legislative

[24] The Cybiotronics court explained that "whatever role Smoothline may have played in the handling of shipments of products to the United States, it did so at all times under the aegis of NAFT's supervision, and the products were at that time the 'property' of NAFT" and thus Smoothline could not be said to be the legal "importer" under 271(g). Id. at 1175. The Cybiotronic's court went on to state that even if what "Smoothline did in this case could be said to violate the 'spirit' of the patent statute" and that it was avoiding "liability only by maintaining the 'fiction' of another entity (NAFT) acting as the 'importer' of record," the fact remained that under 271(g) liability may only attach to the entity that actually imports into the United States. Id. at 1176.

history of the statute makes clear that Congress intended liability to specifically reach the actual importer or seller of a foreign manufacturer's product. In analyzing the legislative history of 271(g) the Federal Circuit stated:

> The enactment of 35 U.S.C. § 271(g) was part of the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107. It was explained that § 271(g) was intended to provide "patent owners the new right to sue for damages and seek an injunction in Federal district court when someone, without authorization, uses or sells in the United States, or imports into the United States a product made by their patented process." S. Rep. No. 100-83 at 27 (1987). The purpose of § 271(g) was to authorize the district courts to adjudicate and impose liability for infringement based on the overseas practice of processes patented in the United States, upon importation of the products of those processes. Previously, remedy was available only by exclusion action under the Tariff Act.

Kinik Co. v. ITC, 362 F.3d 1359, 1362 (Fed. Cir. 2004).[25]

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[25] The Pfizer district court also looked to the legislative history and stated:

> The House and Senate reports accompanying the Process Patents Amendments Act of 1987 are replete with commentary specifying that "the offending act is the importation of a product made through the use of a protected process patent or its subsequent sale within the United States." H.R. Rep. No. 60, 100th Cong., 1st Sess. 6. "Liability exists . . . only if the importation, sale or use of the product occurs in the United States during the term of such process patent." *Id.* at 13. Moreover, in remarks made on the floor of the Senate, Senator Frank Lautenberg of New Jersey summed up the purpose of the legislation thus: "While U.S. courts may not reach a foreign manufacturer that has no presence in the United States, the bill would allow a patent owner to enforce its patent in the U.S. courts against the importer or seller of the foreign manufacturer's product." *Process Patent Amendments Act of 1987: Hearing on S. 568 Before the Subcomm. on*

Since the evidence before the Court makes clear that Medtronic Mexico is the actual importer in this case, the question is whether one of the named defendants can be found to be vicariously or jointly liable because they "controlled" or owned Medtronic Mexico. "For process patent or method patent claims, infringement occurs when a party performs all the steps of the process." BMC Res., Inc. v. Paymentech, L.P., 498 F.3d 1373, 1378-79 (Fed. Cir. 2007). "A party cannot avoid infringement, however, simply by contracting out steps of a patented process to another entity. In those cases, the party in control would be liable for direct infringement. It would be unfair indeed for the mastermind in such situations to escape liability."[26] Id. at 1381. Thus, vicarious liability can arise when one party controls or directs the actions of another to perform one or more steps of the method. Id. at 1379; Muiauction, Inc. v. Thomas Corp., 532 F.3d 1318 (Fed. Cir. 2008). To show such "control," an agency relationship or other contractual obligation to perform the steps must exist. Centillion Data Sys., LLC v. Qwest Communs. Int'l, 631 F.3d

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Patents, Copyrights and Trademarks of the Senate Comm. on the Judiciary, 100th Cong., 1st Sess. 21 (1987). Pfizer Inc., 853 F. Supp at 106.

[26] Under 271(b) and (c), a party can be held liable for indirect infringement by contributing to a third party's infringement or by actively inducing a third party to infringe. However, Gore's complaint does not assert claims of indirect infringement against Medtronic.

1279, 1287 (Fed. Cir. 2011). Furthermore, one must exercise "'control or direction' over the entire process such that each step is attributable to the controlling party, i.e., 'the mastermind.'" Muniauction, Inc., 532 F.3d at 1329 (noting also that "mere arms-length cooperation" will not give rise to direct infringement by any party).[27]

Thus, the Court must now consider, based on the evidence admitted at trial, whether one of the named defendants (Medtronic Inc., Medtronic Vascular, or Medtronic USA Inc.) can be said to have sufficiently controlled or directed Medtronic Mexico such that the named defendants themselves can be said to have performed every step of the asserted claims. The Court notes that no vicarious liability or "control" arguments were specifically made by Gore in opening or closing, through witnesses, or in their proposed findings of fact and conclusions of law to assist the Court in attributing liability to the named defendants.

[27] The Court notes that the Federal Circuit has not yet analyzed joint infringement or vicarious liability in connection with infringement under 271(g). However, some courts have implied that the "direct or control" standard is inappropriate in a Section 271(g) case as the statue focuses on the importer of the products and not on the manufacturer of the products. See e.g., Flexsys Am. LP v. Kumho Tire U.S.A., Inc., 726 F. Supp. 2d 778, 799 (N.D. Ohio 2010) (noting that it is irrelevant under 271(g) who manufactured the goods so long as they were manufactured using a patented process).

The Court is left to decide whether any of the evidence admitted at trial can support a vicarious liability theory. First, the Court notes that each of the manufacturing protocol documents have "Medtronic Vascular" stamped in the bottom left corner of each page. JX4-JX11. However, most of the protocols also begin by stating "This document applies to all Talent graft devices manufactured by Medtronic Mexico at Tijuana, Mexico Facilities." JX4 at MED0063883; JX 5 at MED0063903; JX 6 at MED0063919; JX7 at MED0063931; JX9 at MED0063959; JX10 at MED0063875.

Second, in the Modular Premarket Approval ("PMA") documents submitted to the FDA by Medtronic Vascular, it is made clear that the manufacturing of the Talent products takes place at two main facilities: 1) the Medtronic Vascular facility in Santa Rosa, California and 2) the Medtronic Mexico facility in Tijuana, B.C.. PMA 2006, PX69 at MED0058703; PMA 2007, PX70 at MED0019723. Specifically, in the PMA submission, Medtronic Inc. is listed as the actual "Manufacturer" while Medtronic Vascular and Medtronic Mexico are listed as "Manufacturing Facility and Specific Developers."[28] PMA 2006 at MED0058611-12; PMA 2007 at MED0019723. Medtronic Vascular and Medtronic Mexico have

[28] "Medtronic Vascular moved the Talent Thoracic Stent Graft manufacturing facility from Sunrise, FL, to Medtronic Mexico and the ColiTrac Delivery System from Sunrise, FL, to Santa Rosa, CA in 2002." PMA 2007 at MED0019780.

separate "Establishment Registration Numbers." Id. However, in the "Production Flow" section of the PMA submission, Medtronic makes clear that "Medtronic Vascular is a division of Medtronic Inc." and makes no mention of Medtronic Mexico also being a division of Medtronic Inc. PMA 2006 at MED0058703. Instead, Medtronic Mexico is described as "a facility that is approved to manufacture the Talent Abdominal Stent graft" and the facility where "all stent graft manufacturing and product processes are performed." Id. at MED0058704.

The PMA goes on to state that "a quality contract is maintained between Medtronic Mexico and Medtronic Vascular that defines the responsibilities for the manufacturing of endovascular stent grafts." Id. (emphasis added); see also Id. at MED0058706. The relationship between Medtronic Vascular and Medtronic Mexico is described in this FDA submission through various statements: 1) "Medtronic Vascular controls the design of the stent grafts and provides detailed instructions and specifications to Medtronic Mexico for manufacturing. Any changes to the stent graft manufacturing processes or specifications are first reviewed and approved by Medtronic Vascular;" 2) "All raw material suppliers for the stent grafts have been qualified by Medtronic Vascular . . . . No changes to raw material specifications will be made without prior approval from Medtronic Vascular;" and 3) Changes initiated by Medtronic

Mexico that affect Medtronic Vascular must be approved by Medtronic Vascular and vice-versa, changes by Medtronic Vascular that affect Medtronic Mexico may also require approval by Medtronic Mexico.[29] Id. at MED0058705; see also id. at MED0058712 (making similar statements about Medtronic Vascular's control and oversight over Medtronic Mexico's manufacturing process for the Occluder Stent Graft). Significantly, under the "Quality System" section, the PMA states that "Medtronic Mexico operates under the management of Medtronic Cardiac Surgery (Brooklyn Park, Minnesota), a division of Medtronic Inc." Id. Last, under the "Supplier Management Program" section, the PMA states that "Medtronic Mexico, the stent graft subassembly manufacturing facility for Talent Stent Grafts, is qualified per DOP 114911 and is considered an Inter-Company Facility." Id. at MED0058725 (emphasis added).

Third, Medtronic Mexico was the actual entity that contracted with UPS to ship the products to Medtronic Ireland; Medtronic Vascular was not listed on these contracts. DX103, DX 124, DX626. Additionally, testimony from witnesses at trial made clear from 2004 until April 2008, Medtronic Mexico shipped

[29] The types of changes where this "approval" is required are described in document DOP 113316 (DCR Procedure - Santa Rosa Requirements). This document was attached as Appendix 30 to the 2006 Modular PMA, however, it does not appear to have been admitted as evidence before this Court. PMA 2006, PX 69 at MED0058705.

the completed Talent stent grafts to the United States for insertion into a delivery system. PX 134; PX 765, Depo. Vargas Tr. at 1; R. Flores Direct, Tr. 916-917. Specifically, during that time period, the products were shipped via a local freight company from Tijuana to San Diego, California. R. Flores Direct, Tr. 916-917. The Court has found nothing that specifically evidences that Medtronic Vascular "controlled or directed" Medtronic Mexico in this shipping/importing process.

In summary, the Court finds by a preponderance of the evidence that Medtronic's PMA submissions support the conclusion that Medtronic Vascular "controlled and directed" Medtronic Mexico's subassembly manufacturing of the Talent stent graft products. However, controlling Federal Circuit precedent discussed earlier makes clear that it is not the manufacturer but the importer who is liable under the statue. Thus, if the Court is to apply joint infringement or vicarious liability to Section 271(g) infringement, it appears it must also find evidence that Medtronic Vascular or one of the other named defendants, directed or controlled the actual importing activity of Medtronic Mexico. The Court finds that the evidence submitted at trial is simply insufficient to support such a conclusion.

Medtronic Mexico is the entity listed on all shipping contracts admitted during trial. If the Court were to draw a

contrary conclusion and find that one of the named defendants "directed or controlled" this importing/shipping activity, it would be a mere assumption. If the Court had before it the actual contract (or even testimony about the contract) between Medtronic Vascular and Medtronic Mexico which detailed instructions for Medtronic Mexico to ship the products to the insertion delivery facility in the United States upon the products' completion, this Court's conclusion might be different. However, no such evidence is before the Court.

Thus, a portion of Gore's Section 271(g) infringement claim against the named Medtronic defendants must also fail because they have failed to produce evidence that demonstrates any of the named defendants are the actual "importers" or that any of the defendants are vicariously liable for the actions of Medtronic Mexico because they directed or controlled the importation activity.[30]

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[30] The Court notes that infringement under 271(g) can also be found if the named defendants "offered to sell, sold, or used" the infringing product "within the United States." 35 U.S.C. § 271(g). The Talent products were approved for sale and sold in the United States beginning in 2008. Thus, the Section 271(g) importation issue would only foreclose claims on everything before 2008. However, it is unnecessary for the Court to further address these potential remaining avenues for infringement under 271(g) since the Court earlier found that the accused products do not infringe claims 12, 16 and 19 of the '870 patent.

VI. COUNTERCLAIMS

The Federal Circuit has held that a district court has discretion to dismiss counterclaims of invalidity where it finds no infringement. Nystrom v. TREX Company Inc., 339 F.3d 1347, 1351 (Fed. Cir. 2003); Liquid Dynamics Corp. v. Vaughan Company, Inc., 355 F.3d 1361, 1371 (Fed. Cir. 2004). Thus, since no infringement was found, the Court exercises its discretion and hereby **DISMISSES** as moot Medtronic's invalidity and unenforceability counterclaims.

VII. CONCLUSION

For the reasons set forth above, the Court finds in favor of defendants and **HOLDS** that the accused manufacturing processes do not infringe claims 12, 16 or 19 of the '870 patent. Additionally, Medtronic's invalidity and unenforceability counterclaims are **DISMISSED** as moot.

The Clerk is **REQUESTED** to send a copy of this Opinion and Order to counsel of record for the parties.

It is so **ORDERED**.

/s/

Mark S. Davis
UNITED STATES DISTRICT JUDGE

Norfolk, Virginia
June 18 2012