Filed on behalf of Medtronic Vascular, Inc.

By: David L. Cavanaugh, Reg. No. 36,476 (Lead Counsel)
Alexis Cohen, Reg. No. 76,998 (First Back-up Counsel)
Gregory Lantier (*pro hac vice* to be filed) (Back-up Counsel)
Jennifer Graber, Reg. No. 80,059 (Back-up Counsel)
Gilbert Smolenski, Reg. No. 78,549 (Back-up Counsel)

Wilmer Cutler Pickering Hale and Dorr LLP 1875 Pennsylvania Avenue, NW Washington, DC 20006

### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC VASCULAR, INC.,

Petitioner,

v.

TMT SYSTEMS, INC,

Patent Owner.

IPR Trial No. IPR2021-01533

U.S. Patent No. 7,101,393

PETITION FOR INTER PARTES REVIEW OF CLAIMS 1, 2, 4, 10, 11, 26 OF U.S. PATENT NO. 7,101,393 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

# **Table of Contents**

I.	Introd	Introduction1	
II. Mandatory 1		atory Notices	
	A.	Real Parties in Interest	
	B.	Related Matter	
	C.	Counsel	
	D.	Service Information4	
III.	Certif	tification of Grounds for Standing under 37 C.F.R. §42.104(a)4	
IV.	Overv	view of Challenge and Relief Requested5	
	A.	Prior Art Patents and Printed Publications Relied Upon5	
	B.	Grounds of Challenge	
	C.	Relief Requested	
V.	Overview of the State of the Art and the '393 Patent7		
	A.	The State of the Art7	
	B.	The '393 Patent12	
	C.	Summary of the '393 Patent's Prosecution16	
VI.	Perso	n of Ordinary Skill in the Art17	
VII.	Claim	Construction18	
	A.	"shape of a M"/"shape of multiple Ms"/"M configuration" (claims 1, 2, 26)	
	B.	"telescoping arm"/"telescoping arms" (claims 1, 2, 26)21	
	C.	Remaining Claim Terms	
VIII.	Stelter, Quiachon, and Hartley Each Disclose the Attachment Device Claimed in the '393 Patent		
IX.	Ground I: Challenged Claims 1, 2, 4, 10, 11, and 26 Are Anticipated by Stelter		
	A.	Independent Claim 1	
	B.	Dependent Claim 2	
	C.	Dependent Claim 441	

	D.	Dependent Claim 10	.42
	E.	Dependent Claim 11	.43
	F.	Independent Claim 26	.44
X.	Grou	nd II: Challenged Claims 1, 2, 4, 11, and 26 Are Anticipated by	
	Quiac	chon	.48
	A.	Independent Claim 1	.48
	B.	Dependent Claim 2	.58
	C.	Dependent Claim 4	.60
	D.	Dependent Claim 11	.61
	E.	Independent Claim 26	.62
XI. Ground III: Challenged Claim 10 Would Have Been Obvious		nd III: Challenged Claim 10 Would Have Been Obvious over Quiach ew of Lau	
	A.	Dependent Claim 10	.65
	В.	Secondary Considerations of Nonobviousness Do Not Negate the Above Obviousness Grounds.	68
XII.		nd IV: Challenged Claims 1, 2, 4, 10, 11, and 26 Are Anticipated by ey	
	A.	Independent Claim 1	
	B.	Dependent Claim 2	
	C.	Dependent Claim 4	
	D.	Dependent Claim 10	
	Е.	Dependent Claim 11	
	<u>-</u> . F.	Independent Claim 26	
XIII	- •	etionary Denial Under §314(a) Is Not Warranted	
		lusion	
· · •			

# **TABLE OF AUTHORITIES**

# Page(s)

# Cases

Arthrex, Inc. v. Smith & Nephew, Inc., 935 F.3d 1319 (Fed. Cir. 2019), cert. denied, 141 S. Ct. 236 (2020)27
Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801 (Fed. Cir. 2002)
<i>Dish Network L.L.C. v. Broadband iTV, Inc.</i> , No. IPR2020-01267, Paper 15 (Jan. 21, 2021)
<i>Google LLC v. Uniloc 2017 LLC</i> , No. IPR2020-00441, Paper 13 (July 17, 2020)
Motorola Mobility LLC v. Ironworks Patents, LLC, No. IPR2021-00420, Paper 11 (July 22, 2021)
<i>Nokia of America Corp. v. IPCom, Gmbh &amp; Co. KG,</i> No. IPR2021-00533, Paper 10 (Aug. 12, 2021)
<i>Ohio Willow Wood Co. v. Alps South, LLC,</i> 735 F.3d 1333 (Fed. Cir. 2013)
<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , No. IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020)
Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d 1358 (Fed. Cir. 2011)
Woods v. DeAngelo Marine Exhaust, Inc., 692 F.3d 1272 (Fed. Cir. 2012)
Docketed Cases

TMT Systems,	, Inc. v. Medtronic, Inc. & Medtronic USA, Inc.,	
No. 6:20-cv	cv-00973-ADA (W.D. Tex.)	3

## Statutes

35 U.S.C.	
§102	6
§102(a)	5, 6
§102(b)	5, 6
§102(e)	5, 6
§102(g)	
§103	6
§312(a)(2)	3

#### I. Introduction

This is one (Petition B) of two concurrently filed petitions for *inter partes* review challenging claims 1, 2, 4, 10, 11, and 26 ("Challenged Claims") of United States Patent No. 7,101,393 ("the '393 patent," Ex.1101). This petition challenges those claims applying Patent Owner ("PO")'s litigation-inspired proposed construction of "telescoping arm" and "telescoping arms."<sup>1</sup> (*E.g.*, Ex.1141; Ex.1153; Ex.1154).

The '393 patent, titled "Percutaneous Endovascular Apparatus for Repair of Aneurysms and Arterial Blockages," issued from a patent application filed on July 22, 2003, over a decade after percutaneously-delivered endovascular stent grafts for the repair of aneurysms were first used in the United States and after the field of art was already crowded. The '393 patent claims an attachment device for securing an endovascular apparatus to an interior wall of a blood vessel that comprises "a plurality of telescoping arms" configured in the shape of an "M." The apparatus is

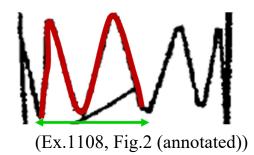
<sup>&</sup>lt;sup>1</sup> The concurrently filed petition challenges the same claims applying the proper claim construction of "telescoping arm" and "telescoping arms," which is the construction that the Defendants have proposed in parallel district court litigation and the construction that the PTO has applied in evaluating the patentability of claims in continuations of the '393 patent concerning "telescoping arms."

meant to treat different conditions, particularly abdominal aortic aneurysms ("AAA").

As explained in this petition, under PO's proposed claim construction advanced in parallel district court litigation (which reads out the claim requirement of "a plurality of telescoping arm" entirely), the '393 patent claims are anticipated by many prior art sinusoidal stent references. By 2002, stents featuring "a plurality of telescoping arms" under the PO's erroneous proposed claim construction and in which the arms are configured in an M-shape were the industry standard in AAA endovascular stent grafts, and were also well-known and in standard use in general cardiovascular technologies. This is illustrated, for example, in the two figures below—one from the '393 patent (left) and one example from the prior art (right):



(Ex.1101, Fig.13M (annotated))



This petition provides three examples of such anticipatory prior art (none of which were before the examiner during prosecution). Each of those prior art references discloses a radially expanding stent and meets all of the remaining limitations of the Challenged Claims. Had the Patent Office ("PTO") interpreted "telescoping arm" and "telescoping arms" as PO now proposes and considered any of these prior art references, the Challenged Claims of the '393 patent would have never been granted.

The Board should institute this petition and undertake an *inter partes* review of the Challenged Claims applying the claim constructions of "telescoping arm" and "telescoping arms" that PO is advancing in parallel district court litigation.

#### **II.** Mandatory Notices

#### A. Real Parties in Interest

Pursuant to 35 U.S.C. §312(a)(2), Petitioner identifies the following parties: Medtronic Vascular, Inc. (Petitioner), Medtronic Vascular Galway Unlimited Company, Medtronic Logistics LLC, Medtronic, Inc., and Medtronic USA, Inc.

Medtronic, Inc. and Medtronic USA, Inc. are the named defendants in the parallel district court litigation identified below. While Medtronic, Inc. has no involvement in any alleged acts of infringement, PO named it as a defendant and it is being identified as a real party in interest for that reason.

#### B. Related Matter

The '393 patent has been asserted in TMT Sys., Inc. v. Medtronic, Inc. and Medtronic USA, Inc., No. 6:20-cv-00973-ADA (W.D. Tex.).

#### C. Counsel

Lead Counsel:	David L. Cavanaugh (Reg. No. 36,476)
First Back-up Counsel:	Alexis Cohen (Reg. No. 76,998)

– 3 –

Back-up Counsel:Gregory Lantier (*pro hac vice* to be filed)Jennifer Graber (Reg. No. 80,059)Gilbert Smolenski (Reg. No. 78,549)

### D. Service Information

Email: David.Cavanaugh@wilmerhale.com;

Alexis.Cohen@wilmerhale.com;

Gregory.Lantier@wilmerhale.com;

Jennifer.Graber@wilmerhale.com;

Gilbert.Smolenski@wilmerhale.com.

Post & Hand Delivery: Wilmer Cutler Pickering Hale and Dorr LLP

1875 Pennsylvania Avenue NW,

Washington, DC 20006

Tel: (202) 663-6000, Facsimile: (202) 663-6363

Petitioner agrees to accept service by email.

## III. Certification of Grounds for Standing under 37 C.F.R. §42.104(a)

Petitioner certifies that the '393 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review on the grounds identified herein.

## IV. Overview of Challenge and Relief Requested

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1, 2, 4, 10, 11, and 26 ("Challenged Claims") of the '393 patent and requests each Challenged Claim be cancelled.

## A. Prior Art Patents and Printed Publications Relied Upon

Petitioner relies upon the following patents and printed publications:

- U.S. Patent No. 6,695,875 to Stelter ("Stelter," Ex.1108), issued on February 24, 2004 and filed on March 14, 2001, is prior art to the '393 patent under pre-AIA 35 U.S.C. §102(e).<sup>2</sup> Stelter was not before the PTO during prosecution of the '393 patent.
- U.S. Patent No. 5,824,044 to Quiachon ("Quiachon," Ex.1104), issued on October 20, 1998, and filed on September 3, 1996, is prior art to the '393 patent under pre-AIA 35 U.S.C. §§102(a), 102(b), and 102(e). Quiachon was not before the PTO during prosecution of the '393 patent.
- 3. WO 99/29262 to Hartley ("Hartley," Ex.1105), published on June 17, 1999, and filed on December 9, 1998, is prior art to the '393 patent under pre-AIA

<sup>&</sup>lt;sup>2</sup> The '393 patent was examined under pre-AIA rules. (*E.g.*, Ex.1102). Although this petition applies pre-AIA rules, the relied-upon references also qualify as prior art post-AIA.

35 U.S.C. §§102(a), 102(b), and 102(e). Hartley was not before the PTO during prosecution of the '393 patent.

U.S. Patent No. 5,919,225 to Lau ("Lau," Ex.1107), issued on July 6, 1999, and filed on July 14, 1997, is prior art to the '393 patent under pre-AIA 35 U.S.C. §§102(a), 102(b), and 102(e). Lau was not before the PTO during prosecution of the '393 patent.

#### B. Grounds of Challenge

Under Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner requests cancellation of claims 1, 2, 4, 10, 11, and 26 of the '393 patent as unpatentable under 35 U.S.C. §§102 and 103 based on the following grounds.

Ground	35 U.S.C. §	Claims	References
Ι	102	1, 2, 4, 10, 11, 26	Stelter
II	102	1, 2, 4, 11, 26	Quiachon
III	103	10	Quiachon in view of Lau
IV	102	1, 2, 4, 10, 11, 26	Hartley

### C. Relief Requested

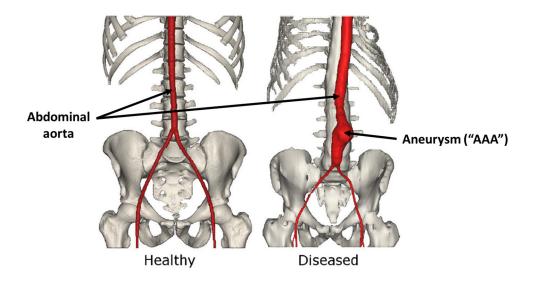
Petitioner requests that the Board cancel the Challenged Claims because they are unpatentable under 35 U.S.C. §§102 and 103.

## V. Overview of the State of the Art and the '393 Patent

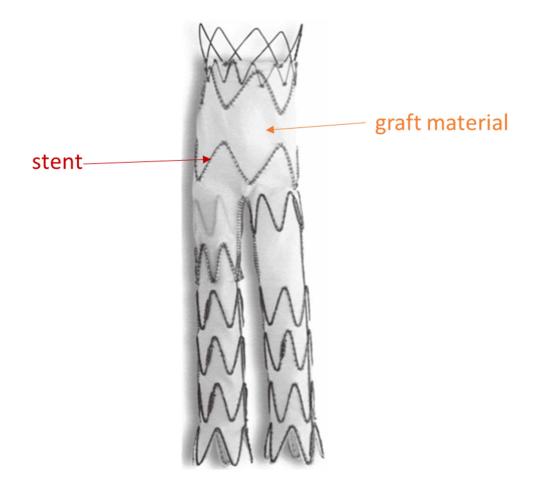
## A. The State of the Art

### 1. Traditional Treatment of Aneurysms

An "aneurysm" occurs when there is a weakening in the walls of the blood vessels that carry blood from a person's heart to their organs. (Declaration of Dr. Elliot Chaikof, Ex.1103, ¶¶29-30). This causes an abnormally large bulge in the blood vessel wall, shown below. (*Id.*, ¶30). This bulge can rupture and cause internal bleeding, and sometimes lead to death. (*Id.*). Aneurysms are especially common in a patient's abdominal aorta—the main blood vessel carrying blood to a patient's legs. (*Id.*, ¶¶29-30). An aneurysm in the abdominal aorta is called an abdominal aortic aneurysm ("AAA"). (*Id.*, ¶30).

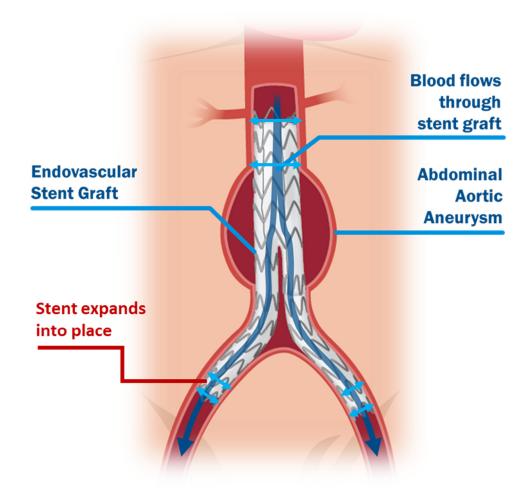


Beginning in the 1970s, minimally invasive (also called "percutaneous") techniques to repair aneurysms emerged as an alternative to open surgery, and the first percutaneous repair of AAA was reported in 1991. (*Id.*, ¶¶31-34). To repair an aneurysm percutaneously, "endovascular stent grafts" were used. (*Id.*, ¶32). Such devices include a metal ring or scaffold (i.e., the "stent") that holds the graft open by pressing against the wall of the blood vessel. (*Id.*). An example of a prior art endovascular stent graft is shown below:



(Ex.1137, S148; Ex.1103, ¶38).

An endovascular stent graft can be compressed to a small profile such that it may be inserted through a patient's blood vessels (e.g., the femoral artery) and directed to the aneurysm site. (Ex.1103, ¶32). During endovascular surgery, the compressed stent graft is held inside a hollow tube. (*Id.*). Once at the site of the aneurysm, the tube is removed, and the stent expands into place, either on its own or with the use of a balloon. (*Id.*). The stent secures the graft against the blood vessel walls, which allows blood to flow through the stent graft device and bypass the aneurysm. (*Id.*). This process is shown below:

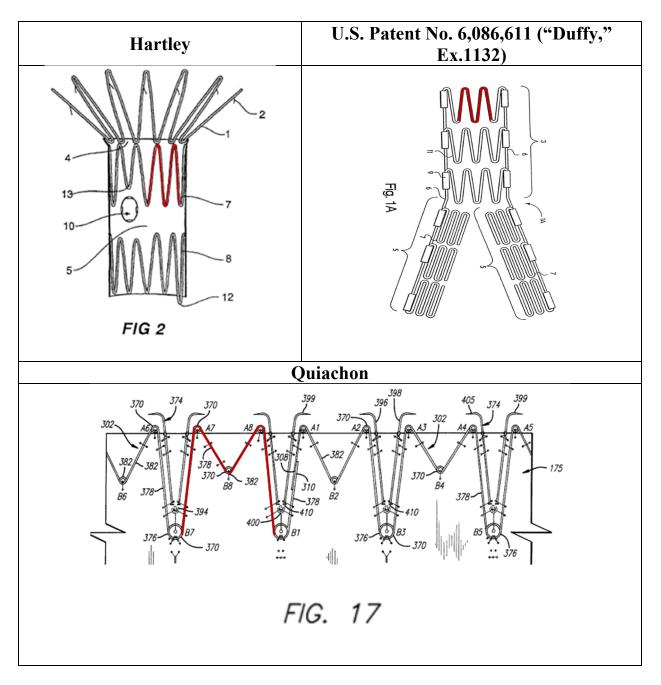


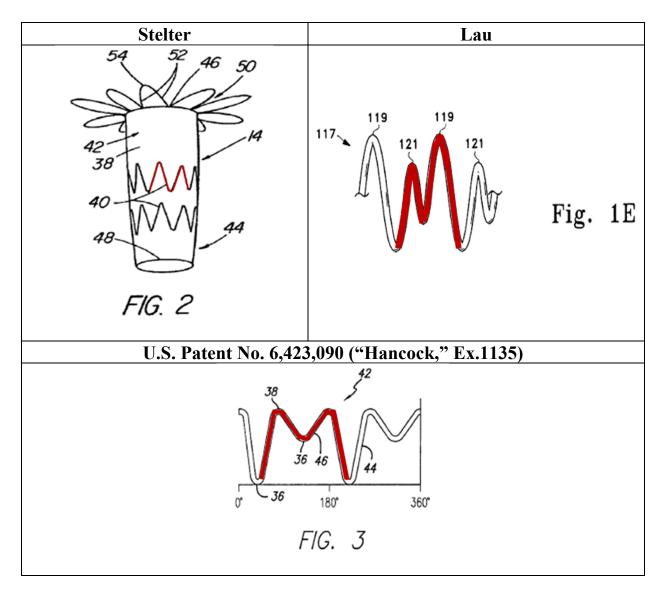
(*Id*.).

# 2. Endovascular Stent Grafts Were Well Described in the Prior Art and Used in Practice in the 1990s

Throughout the 1990s, endovascular surgery for AAA spread globally, and devices were developed to treat more complex aneurysms. (Ex.1103, ¶¶35-43, 46). Medtronic entities were at the forefront of this innovation, developing and testing two endovascular stent grafts before the year 2000: AneuRx and Talent. (*Id.*, ¶¶37-38).

Attachment devices with arms in the shape of an M that radially expand (which PO contends are "telescoping arms" under its proposed claim construction), were well-known before the '393 patent was filed. An operational endovascular stent graft must both successfully compress into a small enough profile for insertion through a patient's blood vessel and be able to expand securely into place at the aneurysm site. (*Id.*, ¶39). Designers developed a number of different zig-zagging sinusoidal stents in which the arms form an "M" shape. (*Id.*, ¶¶39-43). These different shapes, shown below, were known to meet both compressibility and expandability requirements. (*Id.*).



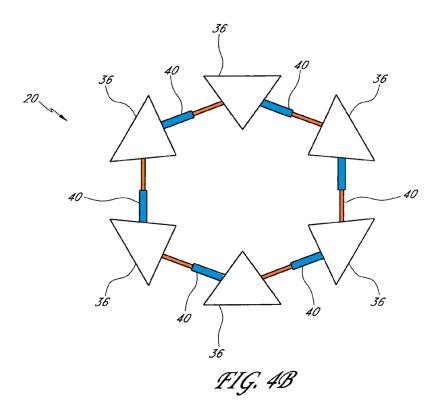


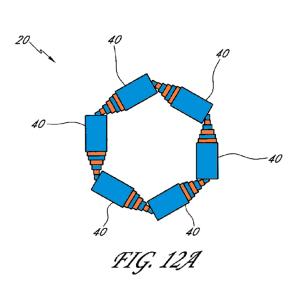
### B. The '393 Patent

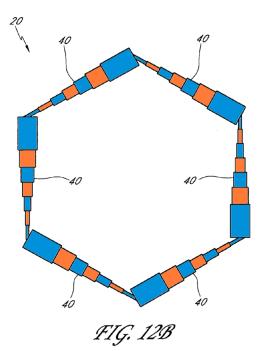
The '393 patent describes an "attachment device," e.g., a stent, "having an expandable attachment device for securing the endovascular apparatus to an interior wall of a lumen [i.e., blood vessel]." (Ex.1101, 1:9-11). The patent describes that "[t]he expandable attachment device may include a plurality of telescoping arms that are joined together to form an expandable ring." (*Id.*, 1:66-2:1). "Once positioned at the site of an aneurysm or arterial blockage, the telescoping attachment device can

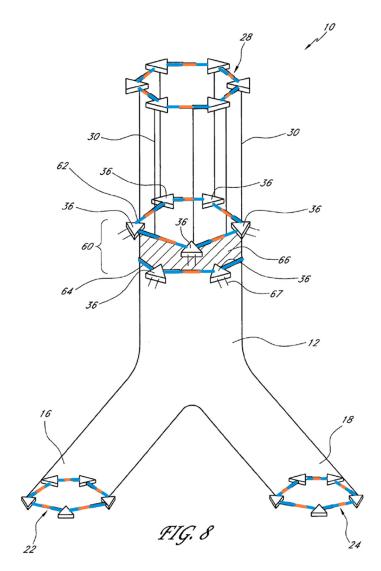
be expanded to hold the endovascular apparatus in place adjacent to the inner lumen wall." (*Id.*, 2:11-14). The '393 patent states that "*[e]ach* telescoping arm is similar to an expandable presentation pointer. Alternatively, *each* telescoping arm may function like an accordion." (*Id.*, 2:38-40).

All of the figures in the '393 patent depict "presentation pointer" embodiments of the telescoping arm. The majority of depictions of this expandable ring feature a plurality of telescoping arms that are joined together in a single plane. In these embodiments, the "telescoping arms" form a flat ring.



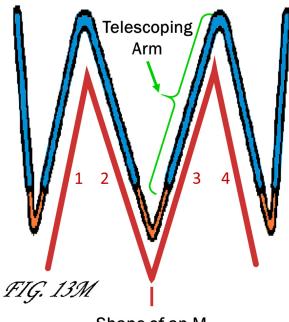






(Id., Figs.4, 8, 12).

Unlike Figures 4, 8, and 12 above, Figure 13 depicts a plurality of presentation-pointer telescoping arms that are "positioned in multiple planes." In Figure 13, each set of four adjacent telescoping arms form the shape of an "M," as depicted below.



Shape of an M

(*Id.*, Fig.13). The arms are operatively connected such that when one arm moves (e.g., arm 1), another arm (e.g., arm 2) moves. In other words, each arm is functionally connected to the adjacent arms. Notably, Figure 13 is never described as depicting a telescoping arm that functions like an accordion. (Ex.1103,  $\P$ 52-67).

#### C. Summary of the '393 Patent's Prosecution

The '393 patent was filed as a patent application on July 22, 2003 as Application No. 10/624,864. (*See* Ex.1101). The '393 patent claims priority to provisional application No. 60/397,745 filed on July 22, 2002. (Ex.1101, Feb. 28, 2017 Certificate of Correction; Ex.1102, 39; Ex.1147; Ex.1103, ¶¶68-69).

The examiner required the applicant to elect a single distinct species for prosecution on the merits, and the applicant elected the species represented by Figure

13. (Ex.1102, 112-116, 126). The applicant noted that "the configuration of the telescoping arms, e.g., the 'M configuration' shown in Figure 13, serves to provide additional support and force against a lumen; thus, this configuration provides a fixation capability to the attachment device. The fixation component is in this combination of telescoping arms." (Ex.1102, 126).

The '393 patent issued on September 5, 2006. (Ex.1101; Ex.1103, ¶¶70-78).

#### VI. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA") at the time of the alleged invention would be a medical practitioner, with experience using endovascular stent grafts and with training, experience, or familiarity applying principles of engineering to the design, development, or testing of endovascular devices; and/or an engineer, having at least a bachelor of science degree and with several years of experience in the design, development, or testing of endovascular devices and their clinical use; a higher level of education could reduce the number of years of experience required. (Ex.1103, ¶¶26-28). A POSA would be familiar with the design and operation of endovascular stent grafts and the equipment and tools required to treat a patient using an endovascular stent graft. (*Id.*).

#### VII. Claim Construction

The parties involved in parallel district court litigation have briefed their differing claim construction positions. The court has not yet construed the claims.<sup>3</sup> Petitioner reserves all rights with respect to claim construction. Petitioner proposes the following constructions, but notes that with the exception of "telescoping arm" and "telescoping arms," this petition demonstrates that the prior art teaches each and every limitation under either Petitioner's proposed claim construction of PO's proposed claim construction advanced in the parallel district court litigation.<sup>4</sup>

<sup>&</sup>lt;sup>3</sup> As of the date of this petition, no *Markman* hearing is scheduled, pending resolution of venue-related issues. If the court construes the claim language, Petitioner will inform the Board promptly.

<sup>&</sup>lt;sup>4</sup> The prior art reference in Ground I teaches each and every limitation under Petitioner's correct claim construction for the "M" shape terms, and the prior art references in Grounds II-IV teach each and every limitation under both PO's proposed claim construction advanced in the parallel district court litigation and Petitioner's proposed construction for the "M" shape terms.

# A. "shape of a M"/"shape of multiple Ms"/"M configuration" (claims 1, 2, 26)

These terms should be given their plain and ordinary meaning, which is readily understandable. There was no specialized meaning of "M" in the field at the time of the alleged invention. (Ex.1149, 265 (testimony of named inventor); Ex.1103, ¶102). Nothing in the intrinsic evidence defines "M" more narrowly than its ordinary meaning. (Ex.1101, 5:36-46, 6:22-40). This can include "M" shapes in which the arms forming an M are equal in length as well as M shapes in which the arms differ in length. (*Id.*, Figs.13H-13U, 5:31-46, 6:36-40; Ex.1103, ¶102; Ex.1102, 147 ("the telescoping arms 'zigzag' back and forth in forming the perimeter or appear as a series of Ms or Vs."); Ex.1148, 115 ("In the specific illustrated embodiment, it appears that the right side of each leg is in the form of a tubular 'V' shaped structure, each leg of which telescopically receives a leg of a 'V' wire shaped structure on the left side of the illustration.")).

PO seeks in parallel district court litigation to improperly narrow claim scope by limiting the claims to an "M" in which "the pair of inner arms of the M are a different length than the pair of outer arms." (Ex.1141, 3). But there is nothing in the plain language of the term "M" that would limit it to only Ms with differentlength arms. Moreover, the written description references telescoping arms in an "M configuration" in only two locations; neither shows, provides, explains, or discusses any specific shape of the "M configuration." (Ex.1101, 5:36-46, 6:37-40). To the contrary, the written description refers to Figures 13 and 15 as depicting the "M configuration," both of which show an "M" with arms of equal length. (*See id.*, Figs. 13A-13U, 15).<sup>5</sup>

Indeed, the Board has repeatedly rejected PO's position on the "M" limitations. All *seven times* that PO has sought claims in continuation applications that require an "M" with different-length arms, the claims were rejected for lack of written description. (*See, e.g.*, Ex.1148, 176, 213, 330-331, 602-603, 863-864; Ex.1152, 93, 166; Ex.1103, ¶¶79-89). As the Board has explained in affirming those rejections, there is no evidence "that mere reference to an 'M' would be recognized by one of ordinary skill in the art as necessarily providing shorter middle struts or different angles between legs." (Ex.1148, 330-331). PO's repeated attempt to narrow the scope of the "M" limitations here should also be rejected and those terms instead given their plain and ordinary meaning. (Ex.1103, ¶¶102-103).

<sup>&</sup>lt;sup>5</sup> In the parallel district court action, PO pointed to Medtronic marketing materials for the accused Endurant product to support its arguments regarding the meaning of an "M" shape. Those materials post-date the '393 patent by many years and are not probative extrinsic evidence of the '393 patent claims' meaning.

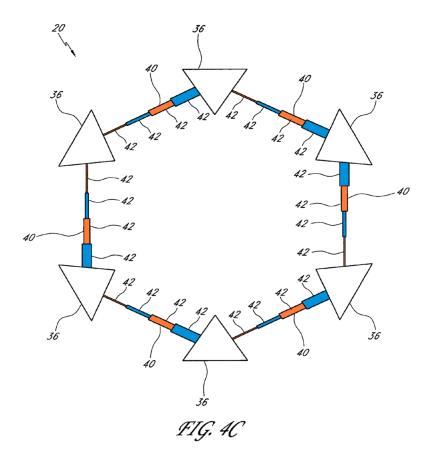
## B. "telescoping arm"/"telescoping arms" (claims 1, 2, 26)

The terms "telescoping arm" and "telescoping arms" should be construed in accordance with their plain and ordinary meaning in light of the intrinsic evidence. A "telescoping arm" means "an arm that telescopes." "Telescoping arms" means "more than one telescoping arm."

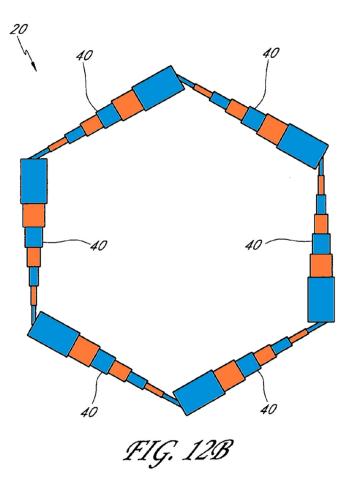
"Telescoping" has a plain meaning and there was no specialized meaning of "telescoping" in the art when the patent was filed. (Ex.1103, ¶96). The primary dispute between the parties in parallel district court litigation is whether (as Petitioner contends) each arm must telescope or (as PO contends) individual arms need not telescope.

The intrinsic record is clear that each arm must telescope. For example, the specification explains that "*[e]ach* telescoping arm is similar to an expandable presentation pointer. Alternatively, *each* telescoping arm may function like an accordion." (Ex.1101, 2:38-40; *see also id.* 5:16-21 (telescoping arms are constructed from "nested tubes," that are "sized so as to fit within one another")).

Moreover, every one of the '393 patent's figures depict that each arm telescopes. For example, Figure 4C shows six telescoping arms (40) each connected using a "fixation component" (36):

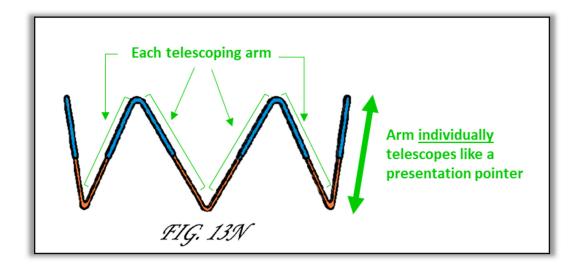


(*Id.*, Fig.4C, 5:12-25; *see also id.*, Fig.8). Similarly, Figure 12 shows arms "telescoping" like a presentation pointer and "positioned in a single plane":



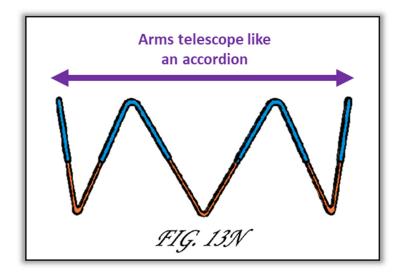
(Id., Fig.12B, 5:34-35).

Figure 13, which is the species that PO elected following a restriction requirement, likewise depicts "presentation pointer"-type telescoping arms. However, unlike Figures 4 and 12, the telescoping arms are "positioned in multiple planes" in an "M configuration":



(*Id.*, Fig.13N, 5:36-46). Thus, the intrinsic record demonstrates that a "telescoping arm" is an "arm that telescopes" and that "telescoping arms" refers to "more than one telescoping arm." (*See also* Ex.1103, ¶¶93-97).

In parallel district court litigation, PO seeks to expand the scope of the claims by arguing that the term "telescoping arm" does not require an arm that telescopes; instead, PO posits that "telescoping arms" refers to a set of arms (none of which *individually* telescopes) arranged in a circle that expands radially. (Ex.1141, 1).



(Ex.1101, Fig.13N, 2:39-40; Ex.1103, ¶¶98-99). In making this argument, PO solely relies on two unrelated disclosures in the '393 specification: (1) the statement that, "[a]lternatively, each telescoping may function like an accordion," (Ex.1101, 2:39-40), and (2) Figure 13. Its argument does not withstand scrutiny.

*First*, the sentence at column 2, lines 39-40 states the opposite of what PO contends. Rather than stating that a group of arms can telescope, it says "*each*" telescoping arm may function like an accordion. *Second*, Figure 13 provides no support for PO's proposed construction, both because it is nowhere described as depicting an "accordion"-type telescoping arm and because, to the contrary, it depicts individually telescoping arms of the presentation pointer type, as shown above.

Moreover, PO's proposed construction is contrary to how examiners and the Board have previously understood the "telescoping arms" limitation. Prior to the '393 patent's issuance, the applicant filed a continuation-in-part application, which included claims requiring a "plurality of M configuration springs compris[ing] a *plurality of telescoping arms*." (Ex.1148, 190-191). The examiner rejected this claim as unpatentable over Quiachon in view of U.S. Patent No. 6,165,214 to Lazarus ("Lazarus," Ex.1106), concluding that "it would have been obvious to make the struts [i.e., "arms"] of Quiachon et al telescoping as taught by Lazarus" (*id.*, 369-370)—a determination later affirmed by the Board. (*Id.*, 405). The examiner thus

understood "telescoping arms" to require that each arm individually telescopes as taught by Lazarus; otherwise, there would have been no need to combine Lazarus with Quiachon. Quiachon would already include "telescoping arms" under PO's proposed construction.

#### C. Remaining Claim Terms

The remaining claim terms in the Challenged Claims should be given their plain and ordinary meaning, as explained below. (Ex.1103, ¶101). PO's attempts to import extraneous limitations into the claims should be rejected.

1. "endovascular apparatus" (claims 1, 26). In parallel district court litigation, PO contends that the preambles to the Challenged Claims are limiting and seeks to narrowly construe the term "endovascular apparatus" appearing therein to mean "endovascular graft for the treatment of aneurysms or arterial blockages." (Ex.1141, 1). But PO cannot overcome the presumption that the preamble is not limiting, because the preamble fails to recite "essential structure or steps, or...is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com*, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). And even if the preamble was limiting, PO's attempt to import functional limitations into the term "endovascular apparatus" should be rejected and the term given its plain and ordinary meaning. (Ex.1103, ¶104).

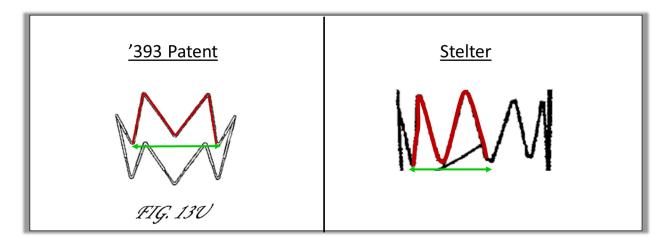
2. "operatively connected"/"operatively coupled" (claims 1, 26). These terms should be given their plain and ordinary meaning: "distinct structures functionally [connected/coupled]." (Ex.1103, ¶105). However, in parallel district court litigation, PO seeks to import functional limitations into these terms by requiring the telescoping arms to be "connected to one another to form a perimeter of variable length capable of reducing leakage around the perimeter of the tubular sleeve" (operatively connected) or "positioned in multiple planes at an angle so that multiple telescoping arms form the shape of a M *capable of exerting enough radial* force when expanded to fix into the aorta and thereby reduce blood leaks around the endovascular graft" (operatively coupled). (Ex.1141, 2-3). Nothing in the intrinsic record justifies importing these functional limitations as a requirement of the purported invention;<sup>6</sup> PO's attempt to import them into the claims should be rejected. See, e.g., Arthrex, Inc. v. Smith & Nephew, Inc., 935 F.3d 1319, 1330 (Fed. Cir. 2019); Woods v. DeAngelo Marine Exhaust, Inc., 692 F.3d 1272, 1284 (Fed. Cir. 2012).

<sup>&</sup>lt;sup>6</sup> Notably, PO's proposed construction further unduly limits the scope of the claimed attachment device for use only in the aorta, in direct contradiction to the breadth of the specification. (*E.g.*, Ex.1101, 1:7-9 ("The present invention relates generally to an endovascular apparatus for the treatment of aneurysms or arterial blockages.")).

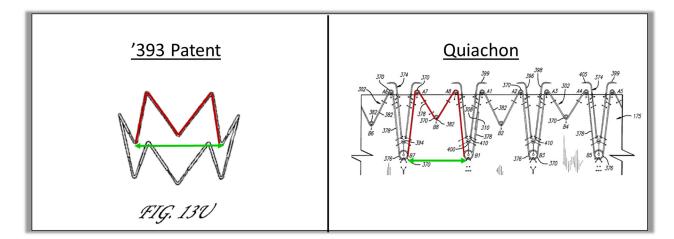
## VIII. Stelter, Quiachon, and Hartley Each Disclose the Attachment Device Claimed in the '393 Patent Under PO's Broad Construction

Years before the earliest claimed priority date of the '393 patent, other inventors had already published patents and patent publications describing attachment devices in the shape of an M and with telescoping arms under PO's erroneously broad proposed claim construction. (Ex.1103, ¶¶47-51, 100, 106-110).

Under Petitioner's proposed construction of "shape of a M" and PO's construction of "telescoping arms," Stelter discloses an attachment device having a plurality of **telescoping arms** operatively connected to form **the shape of an M**. (Ex.1103, ¶107). Stelter teaches "a plurality of self-expanding stents 40 that are secured to and along the graft material," and "attachment stent 50 [which]...expand laterally to press against the vessel wall upon release at deployment." (Ex.1108, 4:51-5:1, Fig.2).

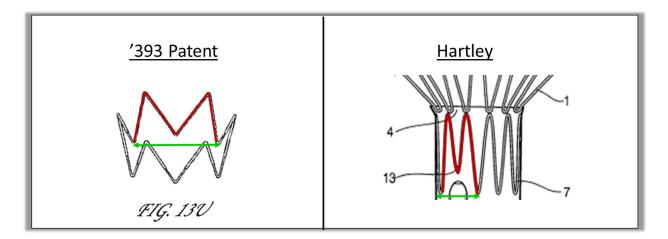


Under PO's proposed constructions of "telescoping arm"/"telescoping arms," and either PO's or Petitioner's proposed construction of "shape of an M," Quiachon teaches "**telescoping arms**," which it calls struts, of differing lengths that expand "graft 55 from a first compressed or collapsed position to a second expanded position and provides a fluid tight seal between the graft and corporeal lumen wall" and that form **the shape of an M**. (Ex.1104, 15:10-14; Ex.1103, ¶108). This configuration allows the struts to "telescope" (under PO's construction) to an "expanded position" as soon as the attachment system is removed from the sheath (which Quiachon calls a "capsule") at the site of an aneurysm. (Ex.1104, 20:13-28).



Finally, under PO's proposed constructions of "telescoping arm"/"telescoping arms," and either PO's or Petitioner's proposed construction of "shape of an M," Hartley likewise discloses an attachment device having a plurality of **telescoping arms** operatively connected to form **the shape of an M**. (Ex.1103, ¶109). Hartley

explains that, once released, its stent is allowed "to expand to its full extent, holding it against the aortic wall with a radial force." (Ex.1105, 6:1-4).



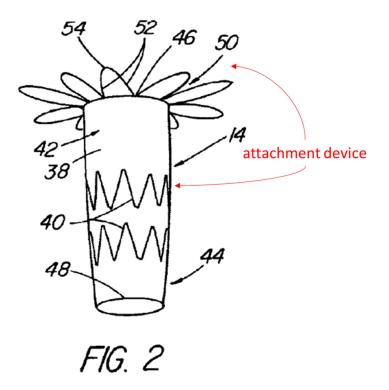
# IX. Ground I: Challenged Claims 1, 2, 4, 10, 11, and 26 Are Anticipated by Stelter

- A. Independent Claim 1
  - 1. Element 1p: "An attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen, the device comprising"

If limiting, Stelter discloses an "attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen." The '393 patent explains that an "attachment device" is made from arms "joined together to form an expandable ring" which "may function similar to *stents*." (Ex.1101, 1:66-2:2).

Stelter discloses an attachment device (e.g., self-expanding stents 40 and/or attachment stent 50) that is expandable from a first state to a second state for securing

an endovascular apparatus to an interior wall of a lumen. (Ex.1108, Figs. 1-7, 15-18, 2:9-30, 2:36-56, 3:47-50, 4:31-5:54, 6:27-34, 8:31-45, 10:21-62; Ex.1103, ¶¶111-117).



(*Id.*, Fig.2). Stelter explains that its attachment tube comprises a plurality of selfexpanding stents (40) secured to and along the graft material of the tube, and an attachment stent (50) which expands laterally to press against the vessel wall upon release at deployment. (*Id.*, 4:51-5:1; *see also* 4:51-56 ("a plurality of selfexpanding stents 40 [] are secured to and along the graft material either along the outer surface or inner surface of the graft material."); 4:62-5:1 ("An attachment stent 50 is secured to the proximal end 46 of attachment tube 14 containing pairs of struts

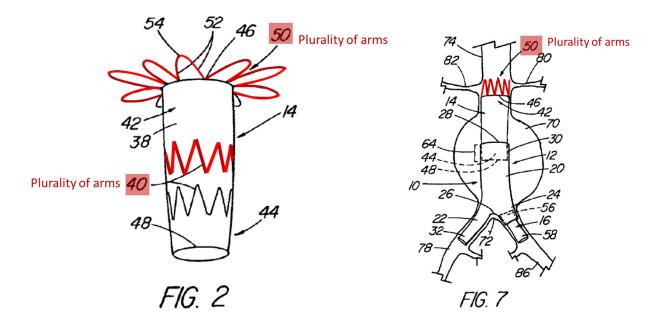
52 shown joined at ends 54...expand laterally to press against the vessel wall upon release at deployment."); 3:5-12 (disclosing "an attachment region having an attachment stent for attachment to a vessel wall")).

Stelter also discloses an "endovascular apparatus" under PO's improper construction because its attachment tube can treat aneurysms. (*Id.*, Abstract, 3:13-22, Ex.1103, ¶114).

#### 2. Element 1a: "a plurality of telescoping arms"

Stelter discloses a plurality of telescoping arms under PO's proposed construction of "telescoping arms." (Ex.1103, ¶¶118-122).

Stelter discloses a plurality of arms (e.g., the arms or struts of element 40 and/or the struts 52 of element 50). (Ex.1108, Figs.1-4, 15-18, 4:51-5:10; Ex.1103, ¶¶118-119). Stelter discloses "*a plurality of self-expanding stents 40* that are secured to and along the graft material either along the outer surface or inner surface of the graft material" and "[a]n *attachment stent 50* is secured to the proximal end 46 of attachment tube 14 containing pairs of struts 52 shown joined at ends 54...*expand laterally to press against the vessel wall* upon release at deployment." (Ex.1108, 4:51-5:10).



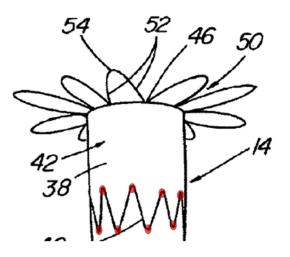
(Id., Figs.2, 7).

Stelter discloses telescoping arms under PO's proposed construction. (*Id.*, 1-7, 15-18, 2:9-30, 2:36-56, 3:47-50, 4:31-5:54, 6:27-34, 8:31-45, 10:21-62; Ex.1103, ¶¶120-122). Stelter also states that stents 40 are "self-expanding" and attachment stent 50 is fabricated to "diverge and expand laterally to press against the vessel wall upon release at deployment." (*Id.*, 4:51-5:1; 9:26-44 ("the ends 54 of struts 52 selfexpand radially outwardly to engage the vessel wall")).

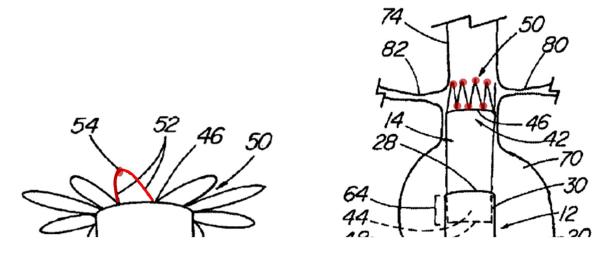
### 3. Element 1b: "the arms being operatively connected to one another so as to form a perimeter of variable length"

Stelter discloses "the arms being operatively connected to one another so as to form a perimeter of variable length." (Ex.1103, ¶¶123-130).

Stelter discloses arms that are operatively connected to one another (e.g., the arms or struts of element 40 and/or the struts 52 of element 50). (Ex.1108, Figs. 1-7, 15-18, 4:31-5:54, 6:27-34, 8:31-45). Stelter describes "a plurality of self-expanding stents 40," (*id.*, 4:51-56) and "pairs of *joined struts* 52 of the attachment stent 50," (*id.*, 4:53-59), and depicts in Figure 2 arms connected together:



Stelter also discloses "attachment stent 50 is secured to the proximal end 46 of attachment tube 14 containing pairs of *struts 52 shown joined at ends 54*" as depicted below in Figures 2 and 7. (*Id.*, 4:51-5:10, Figs.2, 7).



Stelter further discloses the arms are operatively connected to one another to form a perimeter of variable length, i.e., that the perimeter of the device, when viewed from above the device, changes in length, also known as radial expansion. Stelter teaches stents 40 are "self-expanding" and attachment stent 50 is fabricated to "diverge and expand laterally to press against the vessel wall upon release at deployment." (*Id.*, 4:31-5:1; Ex.1103, ¶¶123-127). Stelter further states that "the ends 54 of struts 52 self-expand radially outwardly to engage the vessel wall." (*Id.*, 9:26-44).

As detailed above, in parallel district court litigation, the parties dispute the construction of the term "[the arms being] operatively connected [to one another so as to form a perimeter of variable length." Stelter's stent arms are operatively connected because the arms are physically connected to adjacent arms such that when one arm moves, another arm moves (i.e., each arm is functionally connected

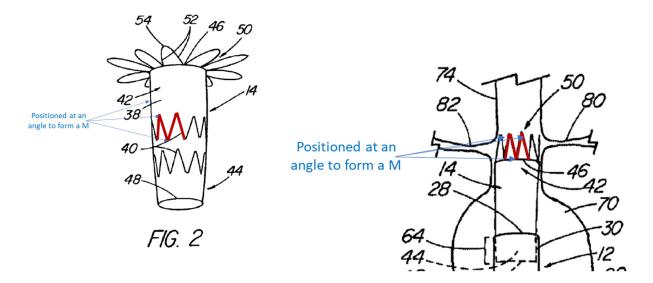
to the adjacent arms). (Ex.1103, ¶123-124). Even if the claims require the additional functional limitations (i.e., requiring reducing blood leakage around the graft), as PO improperly contends, Stelter discloses this claim element because it teaches that "the attachment tube proximal end includes an attachment stent for vessel wall attachment at the aneurysm proximal neck, *with the attachment tube fully sealing relative to the aorta* while permitting free flow to the renal arteries." (Ex.1108, 2:19-25; Ex.1103, ¶¶128-130).

# 4. Element 1c: "wherein the telescoping arms are operatively coupled to one another at an angle so that multiple telescoping arms form the shape of a M"

Stelter discloses "telescoping arms are operatively coupled to one another at an angle so that multiple telescoping arms form the shape of a M" under Petitioner's proposed construction of "the shape of an M." (Ex.1103, ¶¶131-138).

As described above in Section IX.A.2, incorporated by reference, Stelter teaches "telescoping arms" under PO's proposed construction.

As detailed above in Section VII.A, in parallel district court litigation, the parties dispute the construction of "shape of a M." Petitioner contends that this term should be accorded its plain meaning—i.e., any M shape. Under this proper construction, Stelter discloses the telescoping arms are operatively coupled to one another at an angle so that multiple telescoping arms form the shape of an M:



(Ex.1108, Figs.2, 7, 4:51-56, 4:62-5:1, 6:27-34; Ex.1103, ¶¶132-134).

Additionally, in parallel district court litigation, the parties dispute the construction of the term "[the telescoping arms are] operatively coupled [to one another at an angle so that multiple telescoping arms form the shape of a M]." Once again, PO seeks to import narrowing functional limitations into this term and proposes that it be construed to mean "the telescoping arms are positioned in multiple planes at an angle so that multiple telescoping arms form the shape of a M capable of exerting enough radial force when expanded to fix into the aorta and thereby reduce blood leaks around the endovascular graft." (Ex.1141, 2-3). Petitioner contends that this claim language "operatively coupled" should receive its plain meaning. As previously noted, Stelter's stent arms are operatively coupled because the arms are physically coupled to adjacent arms such that when one arm

moves, another arm moves (i.e., each arm is functionally connected to the adjacent arms). (Ex.1103, ¶¶132-133).

But even if PO's incorrect construction were adopted, Stelter teaches this limitation. (Ex.1103, ¶¶135-137). Stelter teaches that the attachment stent contains "pairs of struts" that are "so fabricated as to be spring biased for the ends 54 to tend to diverge and expand laterally to press against the vessel wall upon release from deployment." (Ex.1108, 4:62-5:1). Stelter further states that "the ends 54 of struts 52 self-expand radially outwardly to engage the vessel wall." (*Id.*, 9:26-44). Stelter explains that "the attachment tube proximal end includes an attachment stent for vessel wall attachment at the aneurysm proximal neck, *with the attachment tube fully sealing relative to the aorta* while permitting free flow to the renal arteries." (*Id.*, 2:19-25). A POSA would thus understand that the device fixes into the aorta and reduce blood leaks. (Ex.1103, ¶137).

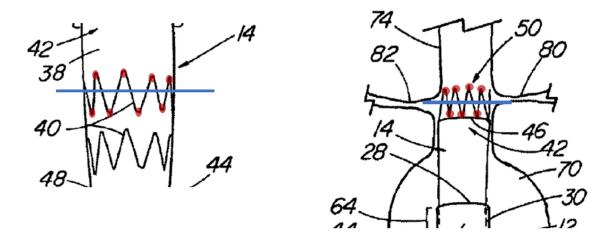
#### B. Dependent Claim 2

Claim 2 depends from claim 1, and the analysis for claim 1 in Section IX.A is incorporated by reference.

# 1. Element 2a: "wherein the perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms"

Stelter discloses the "perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms." (Ex.1103, ¶¶139-143).

For the reasons described above in Section IX.A.3, Stelter teaches the perimeter of variable length. (Ex.1108, Figs.1-7, 15-18, 4:31-5:54, 6:27-34, 8:31-45). Stelter also discloses the perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms. (Ex.1103, ¶¶141-143). As explained above in Section IX.A.2, Stelter teaches telescoping arms under PO's proposed claim construction. (Ex.1108, Figs.1-7, 15-18, 2:9-30, 2:36-56, 3:47-50, 4:31-5:54, 6:27-34, 8:31-45, 10:21-62). Additionally, as explained above in Section IX.A.4, Stelter teaches self-expanding stents 40 and attachment stent 50 are entirely made up of struts that "zig-zag" or are sinusoidal, where the connection between the different struts occurs along two different planes, as depicted in Figures 2 and 7 below.

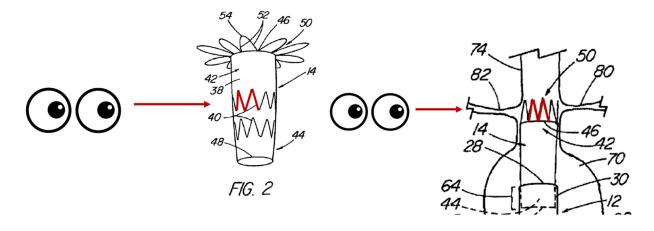


Thus, the arrangement of arms self-expanding stents 40 and attachment stent 50 consists essentially of the shape of multiple Ms around the perimeter of the attachment system. (Ex.1103, ¶143).

2. Element 2b: "wherein the shape of the M is visible when viewed from a plane containing the perimeter of variable length, but is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of variable length"

Stelter discloses "the shape of the M is visible when viewed from a plane containing the perimeter of variable length, but is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of variable length." (Ex.1103, ¶¶144-150).

For the reasons described above in Section IX.A.3, Stelter teaches the shape of an M under Petitioner's proposed construction. This is visible when viewed from a plane containing the perimeter of variable length:



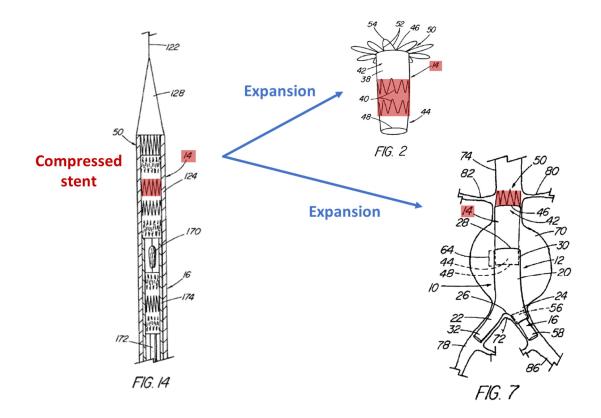
(Ex.1108, Figs.2, 7; Ex.1103, ¶148). From a direction perpendicular to the plane containing the perimeter of variable length, i.e., looking down from the top of the graft 55, the M shape would not be visible, but rather look like a nearly flat line. (Ex.1103, ¶149).

#### C. Dependent Claim 4

Claim 4 depends from claim 1, and the analysis for claim 1 in Section IX.A is incorporated by reference. Claim 4 further limits claim 1 by reciting "wherein the ends of adjacent arms are operatively connected for pivotable movement."

Stelter discloses ends of adjacent arms that are operatively connected for pivotable movement. (Ex.1108, Figs. 1-7, 14-18, 2:9-30, 2:36-56, 3:47-50, 4:31-5:54, 6:27-34, 8:31-45, 10:21-62; Ex.1103, ¶¶151-155). For the reasons described above in Section IX.A.3, Stelter teaches arms operatively connected to one another. Stelter further teaches that "the attachment tube proximal end includes an attachment stent for vessel wall attachment at the aneurysm proximal neck, with the attachment

tube fully sealing relative to the aorta while permitting free flow to the renal arteries." (*Id.*, 2:19-25). Stelter also teaches that the attachment tube contains "pairs of struts" that are "so fabricated as to be spring biased for the ends 54 to tend to diverge and expand laterally to press against the vessel wall upon release from deployment." (*Id.*, 4:62-5:1). Also, as explained by Dr. Chaikof, a POSA reading Stelter would understand that Stelter's stent pivots and adapts to a patient's blood vessel, because a patient's vasculature is not a perfect cylinder. (Ex.1103, ¶154).



#### D. Dependent Claim 10

Claim 10 depends from claim 1, and the analysis for claim 1 in Section IX.A is incorporated by reference. Claim 10 further limits claim 1 by reciting "wherein

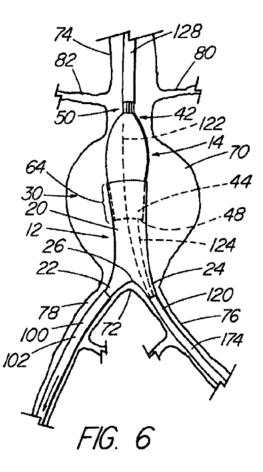
the arms are made of a nickel-titanium alloy." Stelter discloses that the arms may be made of "nitinol." (Ex.1108, 10:45-47; Ex.1103, ¶156). The patent explains that nitinol is a nickel titanium alloy within the scope of the claims, which is consistent with a POSA's understanding of a "nickel-titanium alloy." (Ex.1101, '393 patent, 2:52-58; Ex.1103, ¶¶44-45, 156).

#### E. Dependent Claim 11

Claim 11 depends from claim 1, and the analysis for claim 1 in Section IX.A is incorporated by reference. Claim 11 further limits claim 1 by reciting "wherein the attachment device when in the first state possesses a first profile that is sufficiently small to permit it to be percutaneously inserted via catheter into a patient's femoral artery."

Stelter discloses "the attachment device when in the first state possesses a first profile that is sufficiently small to permit it to be percutaneously inserted via catheter into a patient's femoral artery." (Ex.1103, ¶157-160). Stelter explains that the delivery of its stent graft assembly to the site of the abdominal aortic aneurysm comprises "endovascularly introduc[ing]" the delivery system "by way of the contralateral iliac artery," i.e., the femoral artery. (Ex.1108, Figs.6-7, 6:24-26; 2:50-54, 4:31-50, 5:44-54, 6:4-44; Ex.1103, ¶158-159).

#### U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



- F. Independent Claim 26
  - 1. Element 26p: "An attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen, the device comprising"

The analysis in Ground I, Element 1p at Section IX.A.1 is incorporated by

reference. (Ex.1103, ¶161).

## 2. Element 26a: "a plurality of telescoping arms forming a closed loop"

Stelter discloses a "plurality of telescoping arms forming a closed loop."

(Ex.1103, ¶162-164).

Stelter discloses telescoping arms under PO's proposed claim construction. *See* Section IX.A.2. Stelter also teaches a plurality of telescoping arms forming a closed loop. (Ex.1103, ¶163-164). Stelter teaches that a plurality of self-expanding stents 40 are "secured to and along the outer surface or inner surface" of the attachment tube, which is a loop, and that an "attachment stent 50 is secured to the proximal end 46 of attachment tube 14 containing pairs of struts 52 shown joined at ends 54 that...expand laterally to press against the vessel wall upon release at deployment." (Ex.1108, 4:51-5:1; *see also id.*, Fig.2, 5:28-32; Ex.1103, ¶163-164). The figures in Stelter show that the stents 40 and 50 form a closed loop:

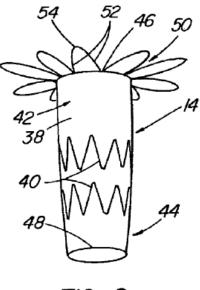
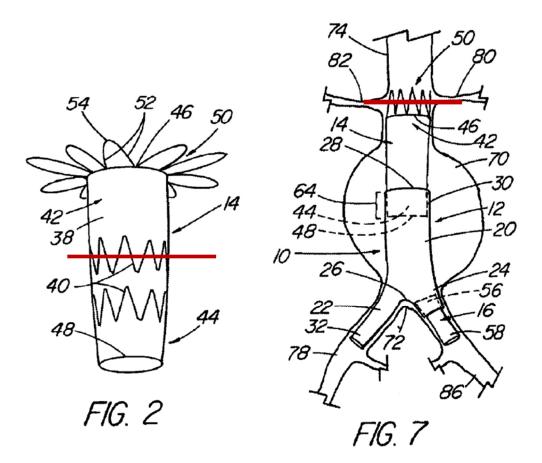


FIG. 2

(*Id.*, Fig.2, 4:31-5:54; Ex.1103, ¶163-164).

## 3. Element 26b: "wherein the closed loop defines a plane by its circumference"

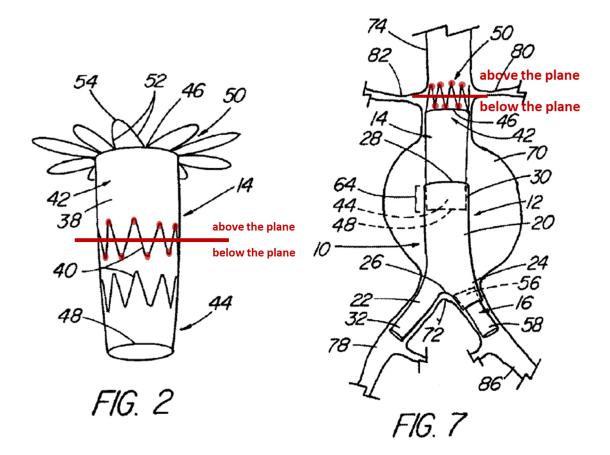
Stelter discloses the "closed loop defines a plane by its circumference." (Ex.1103, ¶¶165-167). Stelter's arms in a closed loop of defines a plane by its circumference as shown in red annotations below:



(Ex.1108, Figs.2, 7, 4:31-5:54; Ex.1103, ¶167). A POSA would have understood that the attachment system in Stelter forms a closed loop, which would define a plane by its circumference when viewed from the perspective noted above. (Ex.1103, ¶¶166-167).

## 4. Element 26c: "wherein each telescoping arm is connected to another telescoping arm above or below the plane"

Stelter discloses each telescoping arm is connected to another arm above or below the plane, as depicted in the annotated figure below:



(Ex.1108, Figs.2, 7, 4:31-5:54; Ex.1103, ¶¶168-169).

## 5. Element 26d: "wherein the plurality of telescoping arms are coupled together in an M configuration"

Stelter discloses "the plurality of telescoping arms are coupled together in an M configuration." (Ex.1103, ¶¶170-171). Claim 26, element 26d recites the same

limitation of claim 1, element 1c, and the analysis for claim 1, element 1c in Section

IX.A.4 is incorporated by reference.<sup>7</sup>

# X. Ground II: Challenged Claims 1, 2, 4, 11, and 26 Are Anticipated by Quiachon

A. Independent Claim 1

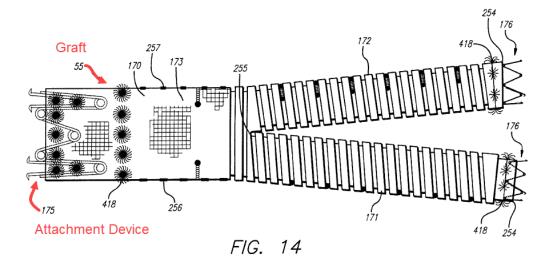
#### 1. Element 1p: "An attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen, the device comprising"

If limiting, Quiachon discloses an "attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen." (Ex.1103, ¶¶172-178). The '393 patent explains that an "attachment device" is made from arms "joined together to form an expandable ring" which "may function similar to *stents*." (Ex.1101, 1:66-2-2).

Quiachon discloses an attachment device (e.g., element 175 of Figs.14, 17) that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen. (Ex.1104, Abstract, Figures 14-19, 1:13-17, 1:66-2:13, 2:41-43, 2:52-60, 5:39-41, 6:3-6, 13:54-64, 15:3-16:16, 16:32-45;

<sup>&</sup>lt;sup>7</sup> In parallel district court litigation, PO has stated that "M configuration" (claim 26) and "shape of a M" (claim 1) and "shape of multiple Ms" (claim 2) all "share the same meaning." (Ex.1141, 3).

20:13-28, 24:5-32, 24:42-45, 25:10-43, 26:5-55, 27:52-55, 29:35-37, 30:14-16; Ex.1103, ¶¶173-177).



(Ex.1104, Fig.14). For example, Quiachon depicts "self-expanding superior attachment system 175" in Figures 14–19 and explains that the attachment system "serves to yieldably urge the graft 55 from a first compressed or collapsed position to a second expanded position and provides a fluid tight seal between the graft and corporeal lumen wall." (*Id.*, 15:3-14; *see also* 26:43-47 ("As soon as the distal capsule has cleared the superior attachment system 175, the superior extremity of the main tubular member expands outwardly under the force of the self-expanding attachment system which springs into engagement with the vessel wall 230."); 29:34-37 ("The graft 55 and attachment systems 175 and 176 remain secured to the vessel walls 230, 231 and 232, thereby sealing the aneurysm 226 from blood flow.").

The "attachment system" in Quiachon discloses the claimed "attachment device" as both components are expandable rings that function like stents and hold an endovascular graft open at the aneurysm site. (*Id.*, 15:3-14; Ex.1101, 1:66-2:2, 2:1-2; Ex.1103, ¶¶173-177).

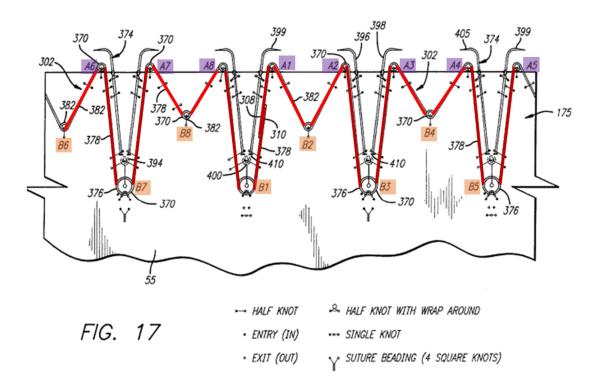
Further, Quiachon also discloses an "endovascular apparatus" under PO's improper construction because its graft 55, which includes attachment system 175, is for treating aneurysms. (Ex.1104, 13:54-58, 20:54-66, Ex.1103, ¶¶175-176).

#### 2. Element 1a: "a plurality of telescoping arms"

Quiachon discloses a plurality of telescoping arms under PO's proposed construction of "telescoping arms." (Ex.1103, ¶¶179-182).

Quiachon discloses a plurality of arms, which it calls "struts" (e.g., element 378). (Ex.1104, Figs.14-19, 15:15-16:16, 16:33-40; Ex.1103, ¶180). Quiachon discloses a "wire frame 302" that "is formed with eight **outward protruding apices numbered A1 through A8** respectively beginning at the protruding apex A1 closest to the first end." (Ex.1104, 15:29-32). "Each of the protruding apices **A1 through A8** are integrally connected to adjacent **base apices B1 through B8** by struts 378."

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



(Id., Fig.17).

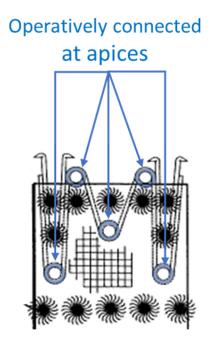
Quiachon discloses telescoping arms under PO's proposed construction. (*Id.*, Figs.14-19, 13:54-64, 15:3-16:16; Ex.1103, ¶¶181-182). Quiachon teaches that its attachment system has "a sinusoidal frame" that has "longitudinally inwardly directed base apices that are affixed to the graft longitudinally inward from the outer extremity." (Ex.1104, 15:15-29). Quiachon explains that "[e]ach attachment system serves to yieldably urge the graft 55 from a first compressed or collapsed position to a second expanded position and provides a fluid tight seal between the graft and corporeal lumen wall." (*Id.*, 15:3-14). Quiachon further explains that its apices are staggered which "serves the purpose of creating a narrow profile" in a collapsed position. (*Id.*, 15:36-59). This configuration allows the graft to expand to an

"expanded position" as soon as the attachment system is removed from the capsule. (*Id.*, 20:13-28). Thus, under PO's proposed construction of "telescoping arms," Quiachon teaches this element in its descriptions that the stent radially expands upon deployment. (Ex.1103, ¶181).

### 3. Element 1b: "the arms being operatively connected to one another so as to form a perimeter of variable length"

Quiachon discloses "the arms are operatively connected to one another so as to form a perimeter of variable length." (Ex.1103, ¶¶183-188).

Quiachon discloses arms (e.g., element 378) that are operatively connected to one another. For example, Quiachon explains that "wire frame is wound into helical coils or helices with one and a half rotations and include apices A1 through A8." (Ex.1104, 15:15-28; *see also* Figs.14-19, 15:15-16:16, 16:33-40, 1:13-17, 2:52-60, 6:3-6, 13:58-64, 20:13-28, 24:5-32, 26:43-47, 29:35-37, 30:14-16; Ex.1103, ¶¶183-185). Quiachon teaches that "[e]ach of the protruding apices A1 through A8 are *integrally connected* to adjacent base apices B1 through B8 *by struts 378*." (Ex.1104, 15:36-39). The arms operatively connected to one another can also be seen in Figure 14:



Quiachon further discloses arms that are operatively connected to one another to form a perimeter of variable length, i.e., that the perimeter of the device, when viewed from above the device, changes in length as the stent radially expands. (Ex.1103, ¶¶185-186). Quiachon teaches that its graft 55 is held in a "first compressed or collapsed position" and that the attachment system "serves to yieldably urge the graft 55 from a first compressed or collapsed position to a second expanded position and provides a fluid tight seal between the graft and corporeal lumen wall." (Ex.1104, 15:3-5, 15:10-14; Ex.1103, ¶186).

As detailed above, in parallel district court litigation, the parties dispute the construction of this claim limitation. Quiachon discloses this limitation under either of Petitioner's or PO's proposed constructions. Under Petitioner's proposed

construction that the terms "operatively connected" and "connected" should receive its plain meaning, which is "distinct structures functionally connected," Quiachon teaches this limitation because it describes that the struts 378 are distinct structures that are coupled using helical coils 370. (Ex.1104, 15:29-35; Ex.1103, ¶185). Under PO's proposed construction, this element is disclosed because Quiachon teaches that "[e]ach attachment system serves to yieldably urge the graft 55 from a first compressed or collapsed position to a second expanded position and *provides a fluid tight seal between the graft and corporeal lumen wall*." (Ex.1104, 15:10-14; Ex.1103, ¶¶187-188).

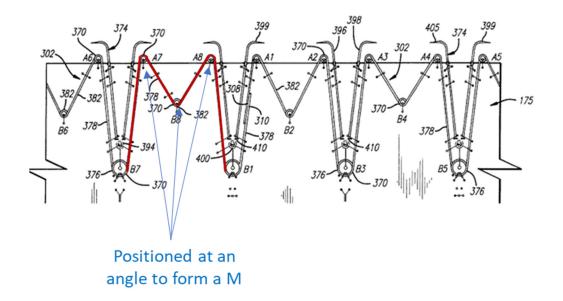
# 4. Element 1c: "wherein the telescoping arms are operatively coupled to one another at an angle so that multiple telescoping arms form the shape of a M"

Quiachon discloses "telescoping arms are operatively coupled to one another at an angle so that multiple telescoping arms form the shape of a M." (Ex.1103, ¶¶189-198). As described above in Section IX.A.2, incorporated by reference, Quiachon teaches "telescoping arms" under PO's proposed construction.

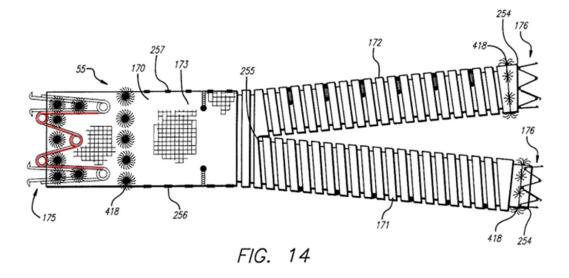
As detailed above in Section VII.A, in parallel district court litigation, the parties dispute the construction of "shape of a M." Petitioner contends that this term should be accorded its plain meaning—i.e., any M shape. PO contends in the parallel district court litigation that *only* an M in which the "inner arms are of differing length

than the outer arms" meets this requirement. (Ex.1141, 3). In other words, PO contends that only certain M shapes qualify.

But this dispute is of no moment for this ground because Quiachon discloses arms (e.g., element 378) that are operatively coupled to one another at an angle so that multiple arms form the shape of an M under either party's construction. (Ex.1103, ¶¶189-194). For example, Quiachon discloses that, "[a]s observed in FIG. 17, not all of the struts equal in length." (Ex.1104, 15:39-40; Figs. 14-19, 3:44-59, 15:3-16:32, 20:13-28; Ex.1103, ¶192). Rather, the struts are longer between apices A2-B3, B3-A3, B-5, A-6-B7, B7-A7, and A8-B1, and are shorter between apices A1-B2, B2-A2, A3-B4, B4-A4, A5-B6, B6-A6, A7-B8, and B8-A8. The different size arms are angled from one another and connected to form the shape of an M, as depicted in red annotations:



(Ex.1104, Fig.17; Ex.1103, ¶192)). The attachment system comprising the M-shaped struts is also depicted in Figure 14:



(Ex.1104, Fig.14; Ex.1103, ¶193).

Quiachon explains that "the length of the struts are configured to stagger the apices along different planes that are spaced longitudinally apart and are perpendicular to the axis of the graft 55 according to the pattern described below." (Ex.1104, 15:37-43). Quiachon teaches that this M-configuration "is an important objective of the present invention" because it "create[s] a narrow profile for the attachment system" and "accomplishes the purpose of minimizing the radial profile of the graft in the collapsed position." (*Id.*, 15:43-54; Ex.1103, ¶194).

Additionally, in parallel district court litigation, the parties dispute the construction of the term "[the telescoping arms are] operatively coupled [to one another at an angle so that multiple telescoping arms form the shape of a M]." Once

again, PO seeks to import narrowing functional limitations into this term and proposes that it be construed to mean "the telescoping arms are positioned in multiple planes at an angle so that multiple telescoping arms form the shape of a M capable of exerting enough radial force when expanded to fix into the aorta and thereby reduce blood leaks around the endovascular graft." (Ex.1141, 2-3). Petitioner contends that this claim language should receive its plain meaning. Quiachon teaches this limitation under the term's plain meaning because it describes that the struts 378 are distinct structures that are coupled using helical coils 370. (Ex.1104, 15:29-39; Ex.1103, ¶[189-190).

But even if PO's incorrect construction were adopted, Quiachon teaches this limitation. Quiachon discloses that "[e]ach attachment system serves to yieldably urge the graft 55 from a first compressed or collapsed position to a second expanded position and *provides a fluid tight seal between the graft and corporeal lumen wall*." (Ex.1104, 15:10-14; Ex.1103, ¶¶195-198). A POSA would thus understand that the device fixes into the aorta and reduce blood leaks. (Ex.1103, ¶198). Quiachon also explains that "[a]n inflatable membrane configured on the balloon catheter is used to firmly implant the attachment systems within the vessel. The bifurcated prosthesis and attachment systems are configured to remain in the vessel after the deployment catheters are withdrawn." (Ex.1104, Abstract; Ex.1103, ¶198). Finally, Quiachon teaches that the helical coils that connect struts 378 "contribute[] to the outward bias and spring of the entire attachment system." (Ex.1104, 17:10-11; Ex.1103, ¶197).

#### B. Dependent Claim 2

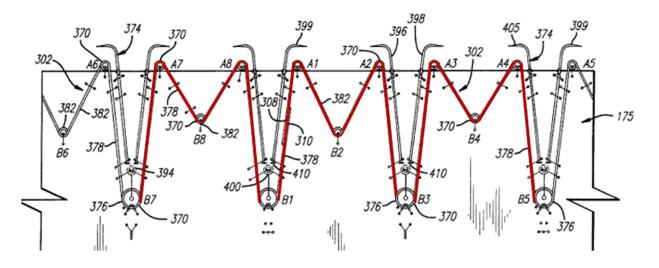
Claim 2 depends from claim 1, and the analysis for claim 1 in Section X.A is incorporated by reference.

# 1. Element 2a: "wherein the perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms"

Quiachon discloses the "perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms." (Ex.1103, ¶¶199-202).

For the reasons described above in Section X.A.3, Quiachon teaches the perimeter of variable length. Quiachon also discloses the perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms. As explained above in Section X.A.2, Quiachon teaches telescoping arms under PO's proposed claim construction. Additionally, as explained above in Section X.A.4, Quiachon teaches that the length of the struts are configured to stagger the apices along different planes, such that they form the shape multiple Ms:

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review

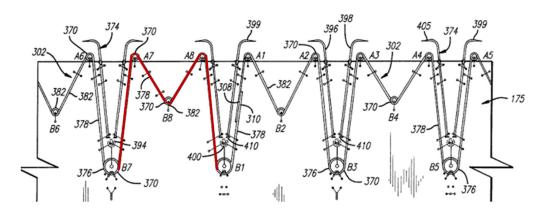


(Ex.1104, Fig.17); Ex.1103, ¶¶201-202). Quiachon further explains that the "two ends of the wire frame, 308 and 310, overlap and are welded to each other." (Ex.1104, 16:33-40; Figs.8-9, 14-20, 15:3-16:16, 16:32-45, 17:22-35). The attachment system which comprises this strut pattern is secured to a tubular member of the graft. (Ex.1104, 15:3-5). Thus, the arrangement of struts consists essentially of the shape of multiple Ms around the perimeter of the attachment system. (Ex.1103, ¶¶201-202).

2. Element 2b: "wherein the shape of the M is visible when viewed from a plane containing the perimeter of variable length, but is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of variable length"

Quiachon discloses "the shape of the M is visible when viewed from a plane containing the perimeter of variable length, but is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of variable length." (Ex.1103, ¶203-207)

For the reasons described above in Section X.A.3, Quiachon teaches the shape of an M containing the perimeter of variable length. This is visible when viewed from a plane containing the perimeter of variable length:



(Quiachon at Fig.17; Figs.8-9, 14-20, 15:3-16:16, 16:32-45, 17:22-35; Ex.1103, ¶205). From a direction perpendicular to the plane containing the perimeter of variable length, i.e., looking down from the top of the graft 55, the M shape would not be visible, but rather look like a nearly flat line. (Ex.1103, ¶206).

#### C. Dependent Claim 4

Claim 4 depends from claim 1, and the analysis for claim 1 in Section X.A is incorporated by reference. Claim 4 further limits claim 1 by reciting "wherein the ends of adjacent arms are operatively connected for pivotable movement."

Quiachon discloses the "ends of adjacent arms are operatively connected for pivotable movement." (Ex.1103, ¶¶208-210). For the reasons described above in Section X.A.3, Quiachon teaches arms operatively connected to one another. Quiachon further teaches that the graft expands from a compressed or collapsed position to an expanded position to provide "a fluid tight seal" between the graft and the blood vessel wall. (Ex.1104, 15:10-14). Further, Quiachon discloses that the struts 378 of wire frame 302 are connected via helical coils 370, which "contribute[] to the outward bias and spring of the entire attachment system," and lead to pivotable movement between the arms. (*Id.*, 17:10-11; Ex.1103, ¶210). Also as explained by Dr. Chaikof, a POSA reading Quiachon would understand that Quiachon's struts pivot and adapt to a patient's blood vessel, because a patient's vasculature is not a perfect cylinder. (Ex.1103, ¶210).

#### D. Dependent Claim 11

Claim 11 depends from claim 1, and the analysis for claim 1 in Section X.A is incorporated by reference. Claim 11 further limits claim 1 by reciting "wherein the attachment device when in the first state possesses a first profile that is sufficiently small to permit it to be percutaneously inserted via catheter into a patient's femoral artery."

Quiachon discloses "the attachment device when in the first state possesses a first profile that is sufficiently small to permit it to be percutaneously inserted via catheter into a patient's femoral artery." (Ex.1103, ¶¶211-213). Quiachon discloses "a femoral approach," where "the superior end of the graft resides within the most distal portion of the delivery catheter." (Ex.1104, 2:16-19; Ex.1103, ¶¶212-213). Specifically, Quiachon explains that a physician introduces a sheath ("capsule") into

the femoral artery and advances it through to the iliac artery to the desired location in the abdominal aorta. (Ex.1104, 25:5-15; 25:16-43). Quiachon explains "[i]t is an important objective of the present invention to create a narrow profile for the attachment system" because "the purpose of creating a narrow profile [is] for insertion into a capsule" to be percutaneously inserted into a patient's vasculature. (*Id.*, 25:43-49).

#### E. Independent Claim 26

1. Element 26p: "An attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen, the device comprising"

The analysis in Ground II, Element 1p at Section X.A.1 is incorporated by reference. (Ex.1103, ¶214).

### 2. Element 26a: "plurality of telescoping arms forming a closed loop"

Quiachon discloses a "plurality of telescoping arms forming a closed loop." (Ex.1103, ¶¶215-217).

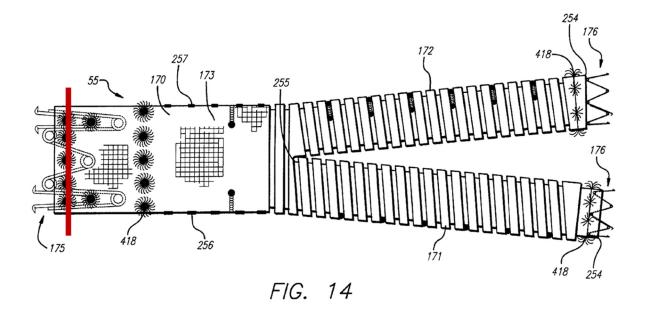
Quiachon discloses telescoping arms under PO's proposed claim construction.

*See* Section X.A.2. Quiachon also teaches a plurality of telescoping arms forming a closed loop. (Ex.1103, ¶216-217). Quiachon explains that "the first and second end struts of the single piece of wire frame are welded together to provide a continuous spring like attachment system." (Ex.1104, 15:21-26, 16:39-40 ("The two ends of

the wire frame, 308 and 310, overlap and are welded to each other."); Figs.14-16; Ex.1103,  $\P$ 216). A POSA reading Quiachon would have understood that welding the ends of the wire frame together forms a closed loop. (Ex.1103,  $\P$  $\P$ 216-217). Thus, Quiachon discloses a plurality of telescoping arms (under PO's proposed construction) forming a closed loop.

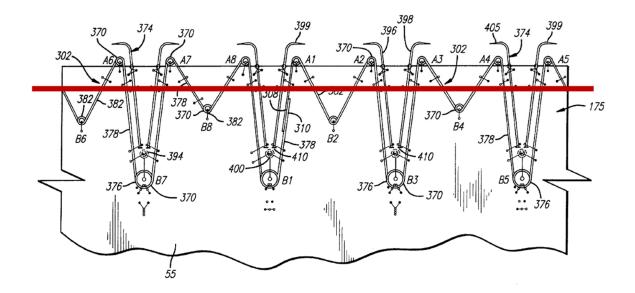
### **3.** Element 26b: "wherein the closed loop defines a plane by its circumference"

Quiachon discloses the "closed loop defines a plane by its circumference." (Ex.1103, ¶¶218-220). Quiachon's arms in a closed loop of defines a plane by its circumference as shown in red annotations below:

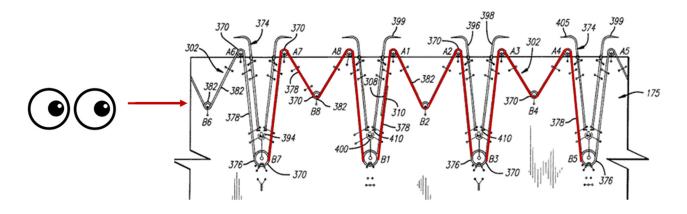


<sup>(</sup>Ex.1104, Fig.14; Ex.1103, ¶220).

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



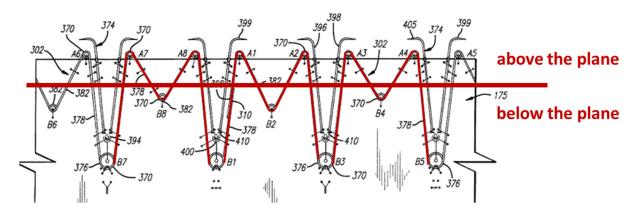
(Ex.1104, Fig.17; Ex.1103, ¶220). A POSA would have understood that the attachment system in Quiachon forms a closed loop, which would define a plane by its circumference when viewed from the perspective noted below. (Ex.1103, ¶220).



4. Element 26c: "wherein each telescoping arm is connected to another telescoping arm above or below the plane"

Quiachon discloses each telescoping arm is connected to another arm above or below the plane, as depicted in the annotated figure below:

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



(Ex.1104, Fig.17; Ex.1103, ¶¶221-222).

# 5. Element 26d: "wherein the plurality of telescoping arms are coupled together in an M configuration"

Quiachon discloses "the plurality of telescoping arms are coupled together in an M configuration." (Ex.1103, ¶223-224). Claim 26, element 26d recites the same limitation of claim 1, element 1c, and the analysis for claim 1, element 1c in Section X.A.4 is incorporated by reference.<sup>8</sup>

#### XI. Ground III: Challenged Claim 10 Would Have Been Obvious over Quiachon in View of Lau

#### A. Dependent Claim 10

Claim 10 depends from claim 1, and the analysis for claim 1 in Section X.A is incorporated by reference. Claim 10 further limits claim 1 by reciting "wherein the arms are made of a nickel-titanium alloy."

<sup>&</sup>lt;sup>8</sup> See supra n.6.

Quiachon in view of Lau discloses an attachment device "wherein the arms are made of a nickel-titanium alloy." (Ex.1103, ¶¶225-236). The '393 patent states that an "alloy of nickel and titanium" is "generally known as NITINOL<sup>TM</sup>." (Ex.1101, 2:52-58; Ex.1103, ¶¶44-45, 234).

Lau is directed to a "procedure[] for folding and also for delivering foldable stents or stent-grafts to a site within the human body." (Ex.1107, 7:33-35; see also 7:35-57, 9:54-10:14, 12:43-47, 13:33-14:7, claim 7; Ex.1103, ¶225-230). Lau explains: "It should be clear that a variety of materials variously metallic, super elastic alloys, and preferably nitinol, are suitable for use in these stents." (Ex.1107, 1:12-14). According to Lau, the "[p]rimary requirements of the materials are that they be suitably springy even when fashioned into very thin sheets or small diameter Various stainless steels which have been physically, chemically, and wires. otherwise treated to produce high springiness are suitable as are other metal alloys such as cobalt chrome alloys (e.g., ELGILOY), platinum/tungsten alloys...and especially the nickel-titanium alloys generically known as 'nitinol.'" (Id., 13:35-43; see also id. 7:53-55 ("a highly flexible, superelastic alloy such as nitinol" may be used to make Lau's M-shaped stent, "but may be of any suitable elastic material such as various of the medically accepted stainless steels."); id. 10:6-7 ("Wire used in these variations are typically of stronger alloys, e.g., nitinol and stronger spring stainless steels.")).

It would have been obvious to combine Quiachon with Lau because (1) Lau teaches that nitinol could be used instead of ELGILOY, and (2) the knowledge generally available in the art taught that nitinol was a good material to use for endovascular stent grafts and that nitinol was an alternative design choice to ELGILOY. (Ex.1103, ¶231-236).

First, Lau teaches that nitinol and ELGILOY are interchangeable. Like Quiachon, Lau is directed to an endovascular stent graft. Quiachon teaches that the attachment systems "are formed of a corrosion resistant material which has good spring and fatigue characteristics." (Ex.1104, 19:22-25). Quiachon identifies ELGILOY a "cobalt-chromium-nickel alloy" as being "particularly satisfactory" for this use. (Ex.1104, 19:25-28). Lau expressly teaches that nitinol is the preferred material for stents because of "its 'super-elastic' or 'pseudo-elastic' shape recovery properties, i.e., the ability to withstand a significant amount of bending and flexing and yet return to its original form without deformation." (Ex.1107, 13:33-35, 13:44-48). Although Lau explains that nitinol is the preferred material, it also explains that other materials could be used interchangeably to manufacture stents. (Ex.1107, 13:35-43). Indeed, Lau expressly teaches that using "metal alloys such as cobalt chrome alloys (e.g., ELGILOY) platinum/tungsten alloys, and especially the nickeltitanium alloys generically known as 'nitinol" are suitable. (Ex.1107, 13:35-43; Ex.1103, ¶233, 235). A POSA would have therefore been motivated to use the

nitinol material disclosed in Lau in the modified Quiachon attachment system because Lau discloses that nitinol is a preferred choice to the ELGILOY disclosed in Quiachon. (Ex.1103, ¶¶233, 235).

Second, the general knowledge available to a POSA prior to the '393 patent's filing would have motivated a POSA to use nitinol in the Quiachon attachment device. (Ex.1103, ¶¶44-45, 234). Nitinol was already well-known as being suited for use in endovascular stent grafts. (Ex.1103, ¶234; Ex.1101, 2:52-63). Selecting nitinol as an alternative choice would have been potentially desirable for a variety of reasons, e.g., if ELGILOY were not available or if a given medical device manufacturer already had an existing supply chain for nitinol in place but not for ELGILOY. (Ex.1103, ¶234-235). Therefore, a POSA would have been motivated to use the nitinol disclosed in Lau in the Quiachon attachment device.

A POSA would have had a reasonable expectation of success because nitinol was known to perform well in endovascular stent grafts and its properties were widely studied and known. (Ex.1103, ¶236).

# B. Secondary Considerations of Nonobviousness Do Not Negate the Above Obviousness Grounds.

Any attempt by PO to rely on alleged secondary considerations of nonobviousness cannot overcome the showing of obviousness detailed above. Where, as here, there is a strong showing of obviousness, relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g., Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011). In any event, PO cannot satisfy its burden of demonstrating a nexus between any alleged secondary consideration and the alleged invention of the '393 patent. *Cf. Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013).

### XII. Ground IV: Challenged Claims 1, 2, 4, 10, 11, and 26 Are Anticipated by Hartley

- A. Independent Claim 1
  - 1. Element 1p: "An attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen, the device comprising"

If limiting, Hartley discloses an "attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen." (Ex.1103, ¶¶237-242). The '393 patent explains that an "attachment device" is made from arms "joined together to form an expandable ring" which "may function similar to *stents*." (Ex.1101, 1:66-2-2).

Hartley discloses an attachment device (e.g., stents 7, 8) that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen. (Ex.1105, Abstract; *see also* Figs.2-10, 2:13-26, 4:18-34, 7:9-30, 8:12-19, 8:26-9:11; Ex.1103, ¶238-239). For example, Hartley discloses, "A prosthesis compris[ing] *Z* stents (7, 8) sutured to a graft (5) comprising a biocompatible material tube such as dacron." (Ex.1105, Abstract). Hartley discloses an attachment device, i.e., a stent, that is expandable from a first state to a second state, when a "trigger wire" is withdrawn and a "folded-biocompatible material" is unfurled, "allowing the stent to expand to its full extent, holding it against the aortic wall with a radial force." (Ex.1105, 6:1-4; Ex.1103, ¶239).

Hartley further discloses an attachment device that secures an endovascular apparatus to an interior wall of a lumen. (Ex.1103, ¶241). Hartley teaches "endoluminal aortic stents and a method of deployment of such stents which allows accurate placement of a covered stent in the aorta. In particular it is capable of being deployed and positioned accurately above the renal arteries in the treatment of infrarenal aortic aneurysmal disease." (Ex.1105, 1:4-9). Hartley describes Figure 11, "a view of the prosthesis 18 of the present invention in full deployment, with the delivery device 20 withdrawn, enabling free flow of blood through the aorta 30 and into the renal arteries 32 and 34 via the fenestrations 10 and 11." (Ex.1105, 10:8-11, Fig.11; Ex.1103, ¶241):

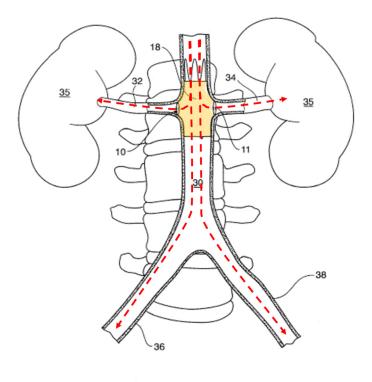


FIG 11

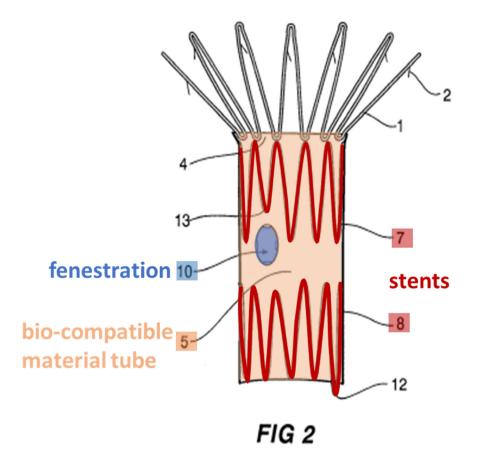
Hartley also discloses an "endovascular apparatus" under PO's improper construction because its endoluminal aortic stent that includes the stent is for treating aneurysms. (Ex.1105, 1, 4, 8-10, Ex.1103, ¶240).

### 2. Element 1a: "a plurality of telescoping arms"

Hartley discloses a plurality of telescoping arms under PO's proposed claim construction, which simply requires radial compression and expansion of the attachment device. (Ex.1103, ¶243-246).

Hartley discloses a plurality of arms (e.g., the arms of Z stent 7 or Z stent 8) that radially expand and compress. (Ex.1105, Figs.1-11, 6:1-4, 7:9-30, 9:28-34,

10:16-18, claim 13). For example, Hartley teaches a prosthesis comprising "Z stents (7, 8) sutured to a graft (5)":



(*Id.*, Fig.2).

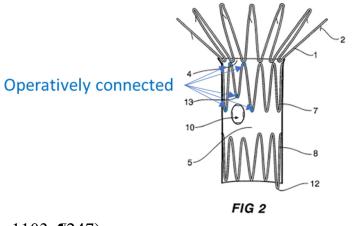
Hartley explains that "Two further stainless steel or nitinol Z stents 7 and 8 are fitted within the bio-compatible material tube 5." (*Id.*, Abstract, 2:13-20, 2:27-28, 3:18-19, 4:15-17, 7:9-30, 10:16-18; Ex.1103, ¶¶244-246). Hartley teaches that when its graft is unfurled, the stent is allowed "to expand to its full extent, holding it against the aortic wall with a radial force." (Ex.1105, 6:1-4). Thus, under PO's

proposed construction of "telescoping arms," Hartley discloses a plurality of telescoping arms. (Ex.1103, ¶¶244-246).

# **3.** Element 1b: "the arms being operatively connected to one another so as to form a perimeter of variable length"

Hartley discloses "the arms being operatively connected to one another so as to form a perimeter of variable length." (Ex.1103, ¶¶247-251).

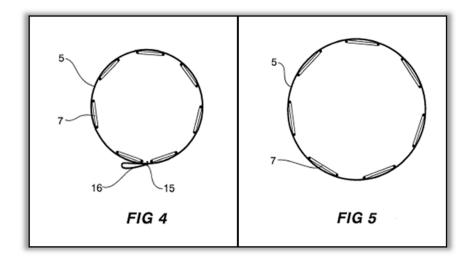
Hartley discloses the arms are operatively connected to one another. Hartley describes a stent graft "which is a single component device comprising two or more stainless steel or nitinol Z stents." (Ex.1105, 2:13-20). Z stents contain arms operatively connected to one another. (Ex.1103, ¶¶247-248). The arms operatively connected to one another can also be seen in Figure 2:



(Ex.1105, Fig.2; Ex.1103, ¶247).

Hartley discloses the arms are operatively connected to one another to form a perimeter of variable length. (Ex.1103, ¶249). When viewed from above, the perimeter of the stent changes in length, i.e., radially expands. (Ex.1105, Figs.4, 5,

6:2-4). As depicted in Figures 4 and 5, the stent arms form a perimeter of variable length, so that the stent can expand and be secured against the aortic wall with a radial force:



(Ex.1105, Figs.4, 5; *id.*, 6:2-4).

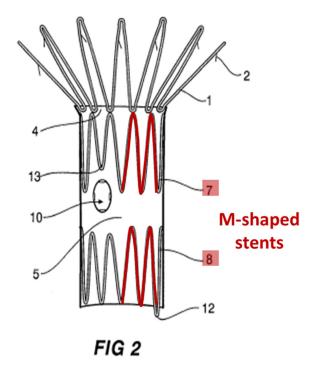
As detailed above, in parallel district court litigation, the parties dispute the construction of this claim limitation. Hartley's stent arms are operatively connected such that when one arm moves, the other arms also move (i.e., each arm is functionally connected to one another). (Ex.1103, ¶¶247-248). Even if the claims require the additional functional limitations (i.e., requiring reducing blood leakage around the graft), as PO improperly contends, Hartley discloses this claim element because it teaches that "the present invention in full deployment, with the delivery device 20 withdrawn, enable[es] free flow of blood through the aorta 30 and into the renal arteries 32 and 34 via the fenestrations 10 and 11." (Ex.1105, 10:8-11;

Ex.1103, 250-251). Hartley further explains that when its graft is unfurled, the stent is allowed "to expand to its full extent, holding it against the aortic wall with a radial force." (Ex.1105, 6:1-4).

# 4. Element 1c: "wherein the telescoping arms are operatively coupled to one another at an angle so that multiple telescoping arms form the shape of a M"

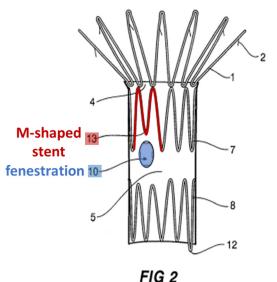
Hartley discloses "telescoping arms that are operatively coupled to one another at an angle so that multiple arms form the shape of an M." (Ex.1103, ¶¶252-258). As described above in Section XII.A.2, incorporated by reference, Hartley teaches "telescoping arms" under PO's proposed construction.

As detailed above in Section XII.A, in parallel district court litigation, the parties dispute the construction of "shape of a M." Hartley discloses arms (e.g., Z stent 7) that are operatively coupled to one another at an angle so that multiple arms form the shape of an M under either party's construction. (Ex.1103, ¶¶252-258). For example, Hartley teaches "Z stents (7, 8) sutured to a graft (5)" that are already in the "shape of an M", as illustrated below:



(Ex.1105, Fig.2). Hartley also describes "at least one fenestration (10) in the dacron tube corresponding to an intersecting artery opening." (*Id.*, Abstract; Ex.1103, ¶255). Hartley explains that, in order to accommodate the fenestration, "[a]t least one of the Z stents may include one or more shortened loops to enable location of the fenestrations." (Ex.1105, 3:18-19). Shortening a loop of the Z stent results in an M-shaped stent with longer outer arms than inner arms, under PO's proposed construction, as depicted in Figure 2:

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



110 2

(even under Patent Owner's proposed narrow construction)

(Ex.1105, Fig.2; Ex.1103, ¶254; *see also* Ex.1105, 7:27-30 ("As can be particularly seen in FIG. 2, which shows the inside view of the prosthesis, there is a shortened loop 13 of one of the crowns of the top inner Z stent 7 which permits placement of the fenestrations for the renal arteries at the desired position.")).

Additionally, in parallel district court litigation, the parties dispute the construction of the term "[the telescoping arms are] operatively coupled [to one another at an angle so that multiple telescoping arms form the shape of a M]." Once again, PO seeks to import narrowing functional limitations into this term and proposes that it be construed to mean "the telescoping arms are positioned in multiple planes at an angle so that multiple telescoping arms form the shape of a M capable of exerting enough radial force when expanded to fix into the aorta and thereby reduce blood leaks around the endovascular graft." (Ex.1141, 2-3).

Petitioner contends that this claim language should receive its plain meaning. As previously noted, Hartley's stent arms are operatively coupled such that when one arm moves, the other arms also move (i.e., each arm is functionally connected to one another). (Ex.1103, ¶252).

But even if PO's incorrect construction were adopted, Hartley teaches this limitation. (Ex.1103, ¶256-258). Hartley explains that "the present invention in full deployment, with the delivery device 20 withdrawn, enable[es] free flow of blood through the aorta 30 and into the renal arteries 32 and 34 via the fenestrations 10 and 11." (Ex.1105, 10:8-11; Ex.1103, ¶258). Hartley further explains that when its graft is unfurled, the stent is allowed "to expand to its full extent, holding it against the aortic wall with a radial force." (Ex.1105, 6:1-4). A POSA would thus understand that the device fixes into the aorta and reduce blood leaks. (Ex.1103, ¶258).

#### B. Dependent Claim 2

Claim 2 depends from claim 1, and the analysis for claim 1 in Section XII.A is incorporated by reference.

# 1. Element 2a: "wherein the perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms"

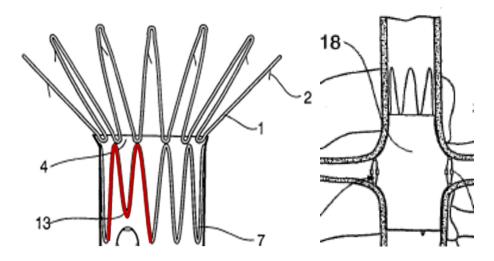
Hartley discloses that the perimeter of variable length consists essentially of the plurality of telescoping arms arranged so as to form the shape of multiple Ms. (Ex.1103, ¶¶259-263).

For the reasons described above in Section XII.A.3, Hartley teaches a perimeter of variable length. Hartley also discloses the perimeter of variable length consists essentially of the plurality of arms arranged so as to form the shape of multiple Ms. Hartley teaches that "[t]here may be more than two said Z stents attached to the bio-compatible material tube and *two or more than two fenestrations* according to the number of intersecting arteries." (Ex.1105, 4:15-17; *see also id.* 10:21-22, claim 14; Ex.1103, ¶¶261-262). Hartley also explains that "[a]t least one of the Z stents may include one or more shortened loops to enable location of the fenestrations," which results in M-shaped stents. (Ex.1105, 3:18-19; Section VII.A.4). Therefore, Hartley teaches that the perimeter of variable length consists essentially of stent arms in the shape of multiple Ms. (Ex.1103, ¶¶261-263).

Hartley also discloses that the multiple Ms are formed from an arrangement of a plurality of telescoping arms under PO's proposed claim construction. *See* Section XII.2. 2. Element 2b: "wherein the shape of the M is visible when viewed from a plane containing the perimeter of variable length, but is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of variable length"

Hartley discloses the shape of the M is visible when viewed from a plane containing the perimeter of variable length, but is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of variable length. (Ex.1103, ¶264-268).

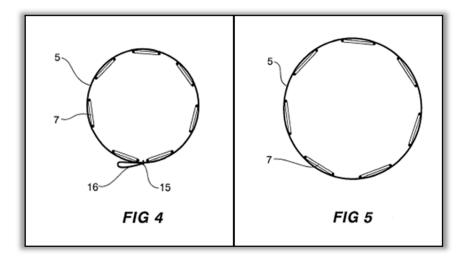
For the reasons described above in Section XII.A.3, Hartley teaches the shape of an M containing the perimeter of variable length. This is visible when viewed from a plane containing the perimeter of variable length:



(Ex.1105, Figs.2, 11; Ex.1103, ¶266).

Hartley further discloses the shape of the M is not visible when the device is viewed from a direction perpendicular to the plane containing the perimeter of

variable length. Hartley depicts its stents from a cross-section view, where the M-shape is not visible, as follows:



(Ex.1105, Figs. 4, 5; Ex.1103, ¶267).

### C. Dependent Claim 4

Claim 4 depends from claim 1, and the analysis for claim 1 in Section XII.A is incorporated by reference. Claim 4 further limits claim 1 by reciting "wherein the ends of adjacent arms are operatively connected for pivotable movement."

Hartley discloses ends of adjacent arms that are operatively connected for pivotable movement. (Ex.1103, ¶¶269-270). For the reasons described above in Section XII.A.3, Hartley teaches arms operatively connected to one another. Hartley further teaches that "the said fully deployed stent ensures the flow of blood at the intersection of the arteries to be treated." (Ex.1105, 4:18-34; *id.* 10:8-11 ("[The stents] in full deployment, with the delivery device 20 withdrawn, enable[e] free

flow of blood through the aorta 30 and into the renal arteries 32 and 34 via the fenestrations 10 and 11."). As explained by Dr. Chaikof, a person of skill in the art reading Hartley would understand that Hartley's stent arms are configured to pivot and adapt to a patient's blood vessel, because a patient's vasculature is not a perfect cylinder. (Ex.1103, ¶270).

#### D. Dependent Claim 10

Claim 10 depends from claim 1, and the analysis for claim 1 in Section XII.A is incorporated by reference. Claim 10 further limits claim 1 by reciting "wherein the arms are made of a nickel-titanium alloy."

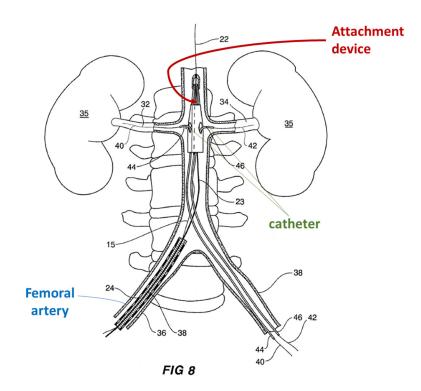
Hartley discloses the arms are made of nitinol. Hartley discloses arms made of nitinol, describing a "proximal stainless steel or nitinol Z stent." (Ex.1105, 7:10-11; *see also id.* 2:13-20; Ex.1103, ¶271).

#### E. Dependent Claim 11

Claim 11 depends from claim 1, and the analysis for claim 1 in Section XII.A is incorporated by reference. Claim 11 further limits claim 1 by reciting "wherein the attachment device when in the first state possesses a first profile that is sufficiently small to permit it to be percutaneously inserted via catheter into a patient's femoral artery."

Hartley discloses the attachment device when in the first state possesses a first profile that is sufficiently small to permit it to be percutaneously inserted via catheter

into a patient's femoral artery as further required by dependent claim 11. (Ex.1103,  $\P$ [272-274). Hartley discloses inserting its stent graft by "compressing the graft and placing it into a sheath which fits snugly around said top cap, said prosthesis, the Z stents" for insertion "through a femoral artery in a groin." (Ex.1105, 4:18-34). Hartley further explains that "prosthesis 18 of the present invention" is introduced into "the aorta 30 via a groin incision to one of the femoral arteries 36" by being "snugly under the sheath" which "holds the prosthesis in position [] on insertion," (Ex.1105, 8:22-9:5), using "catheters 44 and 46" to "safely and accurately position" the prosthesis, (*id.* 9:24-27), as depicted in Figure 8:



(Ex.1105, Fig.8; Ex.1103, ¶273).

### F. Independent Claim 26

1. Element 26p: "An attachment device that is expandable from a first state to a second state for securing an endovascular apparatus to an interior wall of a lumen, the device comprising"

The analysis in Ground IV, Element 1p at Section XII.A.1 is incorporated by reference. (Ex.1103, ¶275).

# 2. Element 26a: "a plurality of telescoping arms forming a closed loop"

Hartley discloses a plurality of telescoping arms forming a closed loop. (Ex.1103, ¶¶276-277).

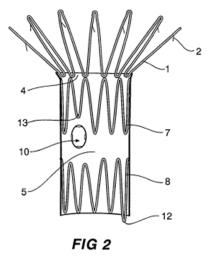
Hartley teaches a plurality of arms forming a closed loop. Hartley describes its Z stents as sewn to the "top ring" of its bio-compatible material *tube*, (Ex.1105, 5:12-14), as depicted for example in Figure 5:



FIG 5

(Ex.1105, Fig.5; Ex.1103, ¶277). The Z stent extends proximally from the biocompatible material tube, and two further stents are fitted within and around the biocompatible material tube, as depicted in Figure 2:

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



## (Ex.1105, Fig.2; Ex.1103, ¶277).

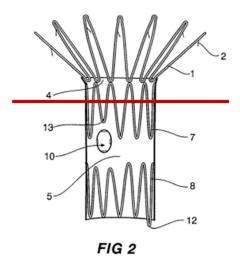
Hartley also discloses multiple telescoping arms under PO's proposed claim construction. *See* Section XII.A.2.

# **3.** Element 26b: "wherein the closed loop defines a plane by its circumference"

Hartley discloses the closed loop defines a plane by its circumference. (Ex.1103, ¶¶278-280).

The circumference of the arms in a closed loop of Hartley defines a plane, as depicted below:

U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review



(Ex.1105, Fig.2; Ex.1103, ¶280).

# 4. Element 26c: "wherein each telescoping arm is connected to another telescoping arm above or below the plane"

Hartley discloses that each arm is connected to another arm above or below the plane. (Ex.1103, ¶¶281-282).

Hartley discloses that each arm is connected to another arm above or below

the plane, as depicted in the annotated figure below:

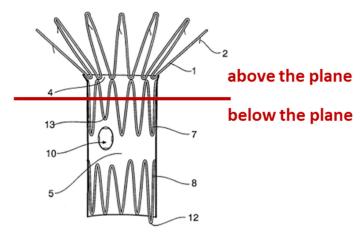


FIG 2

(Ex.1105, Fig.2; Ex.1103, ¶282).

Hartley also discloses multiple telescoping arms under PO's proposed claim construction. *See* Section XII.A.2.

# 5. Element 26d: "wherein the plurality of telescoping arms are coupled together in an M configuration"

Hartley discloses an attachment device wherein the plurality of telescoping arms are coupled together in an M configuration. (Ex.1103, ¶283-285). Claim 26, element 26d recites the same limitation of claim 1, element 1c, and the analysis for claim 1, element 1c in Section XII.A.4 is incorporated by reference.<sup>9</sup>

### XIII. Discretionary Denial Under §314(a) Is Not Warranted

Petitioner respectfully requests the Board not exercise its discretion to deny institution under *Fintiv*. In the parallel district court proceeding, there is no trial date set, no *Markman* hearing scheduled, and no scheduling order.<sup>10</sup> *See Google LLC v*. *Uniloc 2017 LLC*, IPR2020-00441, Paper 13 at 35 (July 17, 2020) ("The fact that no trial date has been set weighs significantly against exercising our discretion to deny

<sup>&</sup>lt;sup>9</sup> See supra n.6.

<sup>&</sup>lt;sup>10</sup> In January 2021, the district court provided an estimated trial date of April 25, 2022, that was tied to the timing of the *Markman* hearing. However, the *Markman* hearing was not held as scheduled, and will not be scheduled at least until a pending inter-district motion to transfer is resolved. (Ex.1150, 1).

institution of the proceeding."); *Motorola Mobility LLC v. Ironworks Patents, LLC*, IPR2021-00420, Paper 11 at 8-9 (July 22, 2021) (fact that "no specific trial date or claim construction ruling date" had been set weighed against discretionary denial). Moreover, Defendants have filed motions to dismiss and transfer that remain pending and inject further uncertainty into the timing of trial. *Dish Network L.L.C. v. Broadband iTV, Inc.*, IPR2020-01267, Paper 15 at 17-18 (Jan. 21, 2021) (a pending motion to transfer provides "at least some persuasive evidence that delays are possible").

Much work also remains to be done in the co-pending proceeding. Fact discovery on the merits only began in July 2021, final contentions have not been served, and neither expert discovery nor summary judgment briefing has begun. Nor has the district court issued any substantive orders. The parties and the district court, therefore, have not made a substantial investment in litigating the invalidity of the '393 patent. *Nokia of America Corporation* v. *IPCom, Gmbh & Co. KG*, IPR2021-00533, Paper 10 at 9-11 (Aug. 12, 2021) (investment factor weighed against discretionary denial where district court had not issued substantive orders, no *Markman* hearing had occurred, and discovery and dispositive-motion deadlines were in the future).

Further, Defendants have raised invalidity defenses in the co-pending proceeding that could not be raised before the Board. In particular, Defendants

identified eight prior art products in preliminary invalidity contentions and raised a defense under 35 U.S.C. §102(g) based on research and development by one of Medtronic's affiliates. Ex.1151, Preliminary Invalidity Contentions, at 25-26.

Finally, Petitioner stipulates that, if this IPR is instituted, Defendants will not advance the grounds that are raised or reasonably could have been raised in this IPR in the co-pending district court proceeding, eliminating any overlap between the IPR and the co-pending district court proceeding. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020) (precedential as to § II.A).

#### **XIV.** Conclusion

Based on the foregoing, there is a reasonable likelihood that claims 1, 2, 4, 10, 11, and 26 of the '393 patent are unpatentable. Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

By:/David L. Cavanaugh/ David L. Cavanaugh Registration No. 36,476

Counsel for Medtronic Vascular, Inc.

### **CERTIFICATE OF COMPLIANCE**

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,298 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R.§42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. §42.24(a)(1).

/Gilbert T. Smolenski/ Gilbert T. Smolenski Registration No. 78,549

## **CERTIFICATE OF SERVICE**

I hereby certify that, on September 23, 2021, I caused a true and correct copy

of the following materials:

- Petition for Inter Partes Review of U.S. Patent No. 7,101,393
- Petitioner's Appendix of Exhibits
- Exhibits 1101-1154
- Certificate of Compliance Regarding Word Count
- Fee Authorization
- Power of Attorney
- Petitioner's Ranking and Explanation of Material Differences Between Petitions

to be served via Federal Express on the Patent Owner at the following

correspondence address of record as listed on PAIR:

### TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVELAND OH 44114

A courtesy copy of this Petition and supporting materials was also served

electronically upon Patent Owner's counsel of record in the related district court

litigation, Case No. 6:20-cv-00973-ADA (W.D. Tex.), at the following addresses:

- <u>dgindler@milbank.com</u>
- <u>breed@milbank.com</u>
- <u>clynch@milbank.com</u>
- jtran@milbank.com
- <u>mgalchus@milbank.com</u>
- jramos@milbank.com

- jfernan1@milbank.com
- <u>ldrake@milbank.com</u>
- <u>mgrover@milbank.com</u>
- <u>ccapshaw@capshawlaw.com</u>
- <u>ederieux@capshawlaw.com</u>

/Gilbert T. Smolenski/ Gilbert T. Smolenski Registration No. 78,549

# **Petitioner's Appendix of Exhibits**

Exhibit Number	Description
1101.	U.S. Patent No. 7,101,393
1102.	File History of U.S. Patent No. 7,101,393
1103.	Declaration of Dr. Elliot Chaikof with Curriculum Vitae
1104.	U.S. Patent No. 5,824,044 to Quiachon
1105.	International Patent Publication No. WO 99/29262 to Hartley
1106.	U.S. Patent No. 6,165,214 to Lazarus
1107.	U.S. Patent No. 5,919,225 to Lau
1108.	U.S. Patent No. 6,695,875 to Stelter
1109.	U.S. Patent No. 5,797,951 to Mueller
1110.	Cooley et al., <i>Technique of "Open" Distal Anastomosis for</i> <i>Ascending and Transverse Arch Resection</i> , Cardiovascular Diseases, Bulletin of the Texas Heart Institute, 8(3):421 (September 1981)
1111.	Livesay et al., Open Aortic Anastomosis: Improved Results in the Treatment of Aneurysms of the Aortic Arch, Cardiovascular Surgery 1981, 66(2):I-122 (August 1982)
1112.	Duerig et al., <i>An overview of nitinol medical applications</i> , Materials Science & Engineering A273-275:149 (1999)
1113.	Parodi, Endovascular Repair of Abdominal Aortic Aneurysms, Advances in Vascular Surgery 1:85 (1993)

Exhibit Number	Description
1114.	<i>Open Repair of Abdominal Aortic Aneurysms (AAA)</i> , North Bristol NHS Trust (January 2018)
1115.	U.S. Patent No. 4,140,126 to Choudhury
1116.	International Patent Publication No. WO 01/08600 to Walak
1117.	Criado et al., <i>Abdominal Aortic Aneurysm: Overview of Stent-Graft Devices</i> , Journal of American College of Surgery, 194(S1):S88 (January 2002)
1118.	Parodi et al., <i>Transfemoral Intraluminal Graft Implantation for</i> <i>Abdominal Aortic Aneurysms</i> , Annals of Vascular Surgery, 5(6):491 (1991)
1119.	Parodi et al., Endoluminal Aortic Aneurysm Repair Using a Balloon-Expandable Stent-Graft Device: A Progress Report, Annals of Vascular Surgery, 8(6):523 (1994)
1120.	May et al., Treatment of Complex Abdominal Aortic Aneurysms by a Combination of Endoluminal and Extraluminal Aortofemoral Grafts, J. Vascular Surgery, 19(5):924 (May 1994)
1121.	Yusuf et al., <i>Transfemoral endoluminal repair of abdominal</i> <i>aortic aneurysm with bifurcated graft</i> , Lancet, 344:650 (Sept. 1994)
1122.	Gordon et al., A Self-Expanding Endoluminal Graft for Treatment of Aneurysms: Results Through the Development Phase, Aust. N.Z. J. Surgery, 66(9):621 (1996)
1123.	Ivancev et al., Abdominal Aortic Aneurysms: Experience with the Ivancev-Malmö Endovascular System for Aortomonoiliac Stent- Grafts, J. Endovascular Surgery, 4(3):242 (1997)

# U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review

Exhibit Number	Description
1124.	Roeder et al., <i>Historical Aspects and Evolution of Fenestrated</i> <i>and Branched Technology</i> , Endovascular Aortic Repair, 3 (2017)
1125.	Holtham et al, <i>The Vanguard Endovascular Stent-graft: Mid-</i> <i>term Results from a Single Centre</i> , Eur. J. Vascular & Endovascular Surgery, 27:311 (March 2004)
1126.	EP1113764 to Fearnot
1127.	International Patent Publication No. WO 98/53761 to Hartley
1128.	Wright et al., Percutaneous Endovascular Stents: An Experimental Evaluation, Radiology, 156:69 (July 1985)
1129.	U.S. Patent No. 4,580,568 to Gianturco
1130.	EP0423916 to Gianturco
1131.	Volodos, <i>The First Steps In Endovascular Aortic Repair: How It All Began</i> , J. Endovascular Therapy, 20(Supplement):I-3 (2013)
1132.	U.S. Patent No. 6,086,611 to Duffy
1133.	U.S. Patent No. 6,878,161 to Lenker
1134.	U.S. Patent No. 5,387,235 to Chuter
1135.	U.S. Patent No. 6,423,090 to Hancock
1136.	U.S. Patent No. 5,855,601 to Bessler
1137.	Criado et al., Update on the Talen aortic stent-graft: A preliminary report from United States phase I and II trials, J. Vascular Surgery, 33(2):S146 (2001)
1138.	U.S. Patent No. 6,083,258 to Yadav

# U.S. Patent No. 7,101,393 Petition for *Inter Partes* Review

Exhibit Number	Description
1139.	U.S. Patent No. 6,309,343 to Lentz
1140.	Criado, et al., <i>Early Experience with the Talent Stent-Graft</i> <i>System</i> , Texas Heart Institute Journal, 27(2):128 (2000)
1141.	ECF No. 84, Joint Claim Construction Statement, No. 6:20-cv- 00973-ADA (June 28, 2021 W.D. Tex.)
1142.	ECF No. 42, TMT Systems, Inc.'s Opening Claim Construction Brief, No. 6:20-cv-00973-ADA (May 4, 2021 W.D. Tex.)
1143.	ECF No. 87, Defendants Medtronic, Inc.'s and Medtronic USA, Inc.'s Opening Claim Construction Brief, No. 6:20-cv-00973- ADA (June 28, 2021 W.D. Tex.) (originally filed May 24, 2021)
1144.	ECF No. 87-22, Declaration of Elliot L. Chaikof, M.D., Ph.D. in Support of Medtronic, Inc.'s and Medtronic USA, Inc.'s Opening Claim Construction Brief, No. 6:20-cv-00973-ADA (June 28, 2021 W.D. Tex.) (originally filed May 24, 2021)
1145.	ECF No. 67, TMT Systems, Inc.'s Reply Claim Construction Brief, No. 6:20-cv-00973-ADA (June 4, 2021 W.D. Tex.)
1146.	ECF No. 81, Defendants Medtronic, Inc.'s and Medtronic USA, Inc.'s Sur-Reply Claim Construction Brief, No. 6:20-cv-973- ADA (June 15, 2021 W.D. Tex.)
1147.	Provisional Patent Application No. 60/397,745
1148.	Excerpts of the File History of Pending Continuation-In-Part Application Serial No. 11/484,331 (through Sept. 16, 2021)

Exhibit Number	Description
1149.	ECF Nos. 87-2 to 87-21, Exhibits Filed with Defendants Medtronic, Inc.'s and Medtronic USA, Inc.'s Opening Claim Construction Brief, No. 6:20-cv-00973-ADA (June 28, 2021 W.D. Tex.) (originally filed May 24, 2021)
1150.	Second Amended Standing Order Regarding Motions for Inter- District Transfer (Aug. 18, 2021 W.D. Tex.)
1151.	Medtronic, Inc.'s Redacted Preliminary Invalidity Contentions (Apr. 4, 2021)
1152.	Excerpts of the File History of Abandoned Continuation Application Serial No. 13/075,532
1153.	ECF No. 39, Second Amended Complaint for Patent Infringement (Public Version), No. 6:20-cv-00973-ADA (April 28, 2021 W.D. Tex.)
1154.	ECF No. 38-2, Exhibit 3 to Second Amended Complaint for Patent Infringement, No. 6:20-cv-00973-ADA (April 19, 2021 W.D. Tex.)