# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

COOK INCORPORATED Corporate Parent COOK GROUP INCORPORATED,	) )
Plaintiff,	) )
VS.	)
ENDOLOGIX, INC.,	) )
Defendant.	) ) No. 1:09-cv-01248-TWP-DKL _ )
ENDOLOGIX, INC.,	) )
Counter Claimant,	)
VS.	) )
COOK INCORPORATED,	)
Counter Defendants.	) ) )

# ENTRY ON ENDOLOGIX'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT OF THE PATENTS-IN-SUIT

This matter is now before the Court on Defendant Endologix, Inc.'s ("Endologix") motion for summary judgment of noninfringement of Plaintiff Cook Incorporated's ("Cook") U.S. Patent Nos. 5,035,706 ("'706") and 5,755,777 ("'777"). (Dkt. 179). As noted in prior entries, Cook has brought suit against Endologix alleging Endologix's Powerlink stent and Intuitrak delivery system infringe upon the '706 and '777 patents. The Court previously issued an Entry on Claim Construction (Dkt. 145) pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Endologix argues that under the Court's claim construction, its products "lack features specifically required by the Cook patents-in suit, and do not infringe as a matter of

law." Dkt. 180 at 5. For the following reasons, the Court **GRANTS in part** and **DENIES in part** Endologix's motion (Dkt. 179).

# I. BACKGROUND

# A. Type of devices<sup>1</sup>

This patent dispute involves medical devices that treat abdominal aortic aneurysms ("AAA"). An AAA is caused by a weakening of the wall of the aorta, the largest human artery. This weakening can cause a balloon-like enlargement to develop in the aorta, increasing the chances of aorta ruptures, which are often fatal.

Until the 1990's, AAAs were typically treated through surgery that was incredibly risky and painful. The surgeon had to open the patient's chest and/or abdomen; move the patient's intestines to expose the aorta; cut out the diseased portion of the patient's aorta; and sew a new graft conduit into the aorta while interrupting blood flow to the patient's lower body. Given the invasive and traumatic nature of this procedure, the patient faced a long and uncertain recovery.

Thankfully, brilliant innovators pushed technology forward. Eventually, surgeons began using self-expanding stent grafts, or small tubular wire cages ("stents") covered with fabric grafts ("grafts"), to treat AAAs. These stent-based procedures obviate the need to cut open the patient's chest and/or abdomen, move intestines, and interrupt blood flow to the lower body. In turn, these stent-based procedures are far less risky and invasive, requiring shorter hospital stays and less recovery time.

Generally, to effectuate these procedures, the surgeon inserts a tube containing an expandable stent graft into the patient through a small incision, usually in the groin to give access to the femoral artery. The tube carries the stent, in a compressed state, to the treatment site. Once there, the stent is released and it self-expands into position. Upon expanding, the

<sup>&</sup>lt;sup>1</sup> Portions of the following sections are reproduced from the Court's Entry on Claim Construction. (Dkt. 145).

stent serves as a new pathway for blood flow down the aorta, relieving pressure on the AAA and thus preventing a rupture.

# **B.** Parties and products

Numerous companies make stents, including Cook and Endologix. Cook's flagship stent is called the Zenith (which is not at issue). Endologix's device is called the Powerlink. Cook alleges that Endologix, through the sale of its Powerlink stent and accompanying delivery system (the "Intuitrak"), is infringing two Cook patents: (1) the '706 patent, which relates to the actual stent; and (2) the '777 patent, which relates to the delivery system that carries the stent to the treatment site.

# C. The '706 Patent

Cook has stood at the forefront of endovascular technology for several decades. Significantly, Cook's '706 patent claims an improvement on an earlier Cook patent, U.S. Patent No. 4,580,568 ("'568 patent"). The '568 patent (which expired in 2004 and was not asserted in this case) covers a specific type of self-expanding stent known as a Z-stent, which is made from a single wire bent into a "zig-zag" shape. A depiction of a Z-stent is set forth below.



Fig.1

Z-stents can be compressed, inserted into a vessel, and then re-expanded by virtue of the spring-expanding nature of their wire. This self-expanding stent technology was, in Cook's words, "wildly successful." Z-stents were not a cure-all, however. They were often too short,

meaning stenting over long lengths required multiple stents, each delivered through a separate catheterization. Physicians wanted a stent that could treat longer passageways with only a single catheterization.

The '706 patent—which embodies an improvement of the '568 patent—helped fill this void, covering a method of connecting several Z-stents together. The application for the '706 patent was filed in 1989 and the '706 patent was issued in 1991. Importantly, the '706 patent uses a series of "eyes" on one end of the stent that interlock with a matching set of eyes on another stent. As Cook states, "the interlocking stent assembly permits and assures a combination of stents that can be deployed at the same time and over longer vessel lengths, to provide a simpler, and less invasive medical procedure." Dkt. 107 at 13. Figure 5 of the '706 patent (reproduced below) depicts an example of such a stent assembly.



Like the original '568 patent, the '706 preferred embodiment is formed from a single wire formed in a "closed zig-zag configuration." Dkt. 181-2 at 7 col. 3:62. "The ends of the wire are closed by a sleeve [represented by '12' in Fig.5,] which is welded or tightly squeezed against the ends of the wire to produce a continuous or endless configuration." Dkt. 181-2 at 7 col. 3:62–65.

Cook alleges infringement of claims 6 and 12 of the '706 patent. Claim 6 read:

# Claim 6:

A method for combining a first and second self-expanding stent to form a stent assembly for insertion into a body passageway comprising the steps of:

forming a first stent from a continuous first length of wire formed into a closed zig-zag configuration having an endless series of straight sections joined at their ends by a plurality of bends;

forming a second stent from a continuous second length of wire formed into a closed zig-zag configuration having an endless series of straight sections joined at their ends by a plurality of bends, the bends at one end defining eyes open at the straight sections of the second stent;

engaging the eyes at the one end of the second stent about bends at one end of the first stent; and closing the eyes at the one end of the second stent.

Dkt. 181-2 at 9 col. 7:13-28.

Claim 12 of the '706 patent reads as follows:

# Claim 12:

A stent assembly comprising:

a first wire formed into a closed zig-zag configuration including;

an endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a first stent;

and

a second wire formed into a closed zig-zag configuration including;

a second endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a second stent;

a set of eyes formed at several of said bends at one of said opposite ends;

wherein said first and second stents are resiliently contractable into smaller first shape for conveyance through a body passageway;

wherein said first and second stents are resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway; and

wherein said set of eyes of said second stent are engaged about said first wire at one of said opposite ends of said first wire.

Dkt. 181-2 at 9 col. 8:35–59. The parties disputed many of the claims' terms for purposes of *Markman* construction. Of particular relevance to this motion, the Court defined the phrase "closed zig-zag configuration" as meaning a "zig-zag structure with the two ends of the wire joined together." Dkt. 145 at 23.

# **D.** The Powerlink Stent

Endologix's Powerlink is comprised of a stent cage covered with an ePTFE graft cover. The stent cage is comprised of a main body and two iliac legs, as illustrated by the figure below.



The main body and iliac legs are each formed from a single wire, for a total of three wires in the completed stent. Each piece of wire is wrapped into a helical pattern to form a "distinctive diamond-shape cellular mesh design." Dkt. 183-13 at 3 § 3.2.2. The legs are then attached to the main body to create a "unibody" design as seen above. Dkt. 183-13 at 3 § 3.2.2. As Endologix states, "[t]he ends of the wires forming each stent cage component remain spaced

apart by the length of [the stent cage]," Dkt. 180 at 14, and each end is wrapped around an adjoining portion of the stent body. Dkt. 180 at 19. This concept is illustrated below.



# E. The '777 Patent

The '777 patent discloses a delivery device involving a self-expanding prosthesis. Prior to the '777 patent, delivery systems were ill-suited for AAA repairs. For instance, they were too large to be inserted through remote vessels in a patient's leg, used sharp and traumatic structures that could damage vessels during a procedure, and were subject to inaccurate positioning. The '777 patent helped ameliorate these problems, reducing the risk of vessel damage and allowing for less complicated and more accurate prosthesis placement. The original patent application for what later became the '777 patent was filed in 1991 and the '777 patent was issued in 1998.

Generally, the delivery device contemplated by the '777 patent involves a self-expanding prosthesis that is positioned on a carrier, which holds the prosthesis in position during delivery. The carrier is inserted into a tubular introducer sheath. The prosthesis is carried on a region of the carrier called the stem. The sheath is inserted through a small incision in the patient's

femoral artery and snaked through the patient's arteries to the aorta where the self-expanding prosthesis is released. A three dimensional example of the '777 patent is depicted below.



Cook asserts Claims 1 and 21–30 of the '777 patent.<sup>2</sup> Given the large number of Claims at issue, the Court will not recite them.

The parties disputed many of the terms in the asserted claims. Of particular relevance, the court construed the term "vascular dilator head region having a fixed shape" as "an end of the central carrier that expands the vessel during the introduction of the sheath into the vessel having a shape that cannot change." Dkt. 145 at 43.

# F. The Intuitrak Delivery System

Endologix's Intuitrak system is a delivery system used to deploy the Powerlink stent graft. The stent graft is preloaded into the delivery system and released at the treatment site. The Intuitrak includes a radiopaque tip at the distal end of the device, which is made of a flexible material called Pebax. The tip has a generally tapered or conical shape that expands the vessel during introduction of the introducer sheath to the vessel. Additionally, the Intuitrak has an integrated introducer sheath, and inner core. The device is illustrated below.

<sup>&</sup>lt;sup>2</sup> On July 20, 2010, the PTO issued a reexamination certificate, confirming the patentability of the delivery system. In doing so, the PTO confirmed the patentability of amended Claim 1 and over 10 other Claims. Additionally, the PTO confirmed the patentability of the device recited in Claim 11, but, in doing so, required Cook to add that the "delivery system is characterized by absence of a guiding catheter" in light of the prior art.

#### Figure 4. IntuiTrak Delivery System for Powerlink Bifurcated Stent Grafts



## G. Claim Construction

After a *Markman* hearing, the Court issued its Entry on Claim Construction, in which it construed two terms that are particularly relevant to this motion. Regarding the '706 patent, the Court defined the phrase "closed zig-zag configuration" as meaning a "zig-zag structure with the two ends of the wire joined together." Dkt. 145 at 23. Regarding the '777 patent, the Court defined the phrase "vascular dilator head region having a fixed shape" as "an end of the central carrier that expands the vessel during the introduction of the sheath into the vessel having a shape that cannot change." Dkt. 145 at 43.

## **II. LEGAL STANDARD**

Like any other case, summary judgment is appropriate in a patent case "when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994) (citations omitted). A genuine issue of material fact precluding summary judgment exists where the non-movant presents evidence such that, if the trial record were the same as the summary judgment

record, the fact finder could reasonably find in non-movant's favor. *Hall v. Aqua Queen Mfg.*, *Inc.*, 93 F.3d 1548, 1553 n.3 (Fed. Cir. 1996).

The party moving for summary judgment bears the burden of demonstrating that no genuine issues of material fact exist. *Meyers v. ASICS Corp.*, 974 F.2d 1304, 1306–07 (Fed. Cir. 1992). The movant also bears the responsibility of informing the court of the basis for the motion and identifying those portions of the record that establish the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). When a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials, but instead must "set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e). "If the opposing party does not so respond, summary judgment should, if appropriate, be entered against that party." Fed. R. Civ. P. 56(e). Finally, "on summary judgment the inferences to be drawn from the underlying facts contained in [affidavits, attached exhibits, and depositions submitted] must be viewed in the light most favorable to the party opposing the motion." *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

#### **III. DISCUSSION**

Cook contends that its competitor Endologix—a relative newcomer to the market for endovascular technology, at least compared to Cook—is infringing the '706 patent through the sale of its Powerlink stent graft and the '777 patent through the sale of its Intuitrak delivery system. The determination of patent infringement is a two-step inquiry. First, the court must construe the asserted patent claims as a matter of law. *Markman*, 517 U.S. at 372–74 which the Court has completed (See Dkt. 145). "Second, the court must determine whether the accused product or process contains each limitation of the properly construed claims, either literally or by substantial equivalent." *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1357 (Fed.

Cir. 2005). The second step is a question of fact. *Id.* A genuine dispute over any material fact in this inquiry makes summary judgment improper. *See, e.g., id.* at 1260; *Crown Packaging Tech., Inc.v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1315 (Fed. Cir. 2009); *Dorel Juvenile Group, Inc.v. Graco Children's Prods., Inc.*, 429 F.3d 1043, 1047 (Fed. Cir. 2005). The Court will examine Endologix assertions of noninfringement in turn.

#### A. Literal Infringement of the '706 Patent

Literal infringement occurs when "every limitation set forth in a claim . . . [is] found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "[A] literal infringement issue is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). The analysis begins by comparing each limitation in every disputed claim to discover if the limitations are present in the accused device. If even one limitation is not met, a literal infringement claim fails.

Endologix contends that the "closed zig-zag configuration" limitation found in both Claims 6 and 12 of the '706 patent is dispositive of the infringement issue "because the ends of the wire forming the Powerlink's main body and limbs are *not* 'joined together," as required in the asserted claims in the '706 patent. Dkt. 180 at 5. Cook asserts on summary judgment that "[t]he phrase 'joined together' does not require direct contact or even close proximity" between the ends of a wire. Dkt. 200 at 25. Specifically, it argues that the ends of a wire could be spaced apart or located at opposite ends of the stent and still be "joined." Rather than establish a genuine issue of material fact, with this argument Cook attempts to circumvent the Court's claim construction with creative argument. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d

1312, 1321 (Fed. Cir. 2009) ("Once a district court has construed the relevant claim terms, and unless altered by the district court, then that legal determination governs for purposes of trial.").

Cook posits its expert's opinion that a person of ordinary skill in the art would understand "that joining does not require a particular spatial relationship between the ends of the length of wire forming the stent." Dkt. 200-2 at 43-44. By way of illustration, Cook and its expert point to the '706 preferred embodiment, which states, "The ends of the wire are closed by a sleeve 12 which is welded or tightly squeezed against the ends of the wire to produce a continuous or endless configuration." Dkt. 181-2 at 7 col. 3:62-65. According to the expert, the '706 preferred embodiment "contemplates using an intermediate mechanical structure to link the ends of the wire together, rather than joining the ends of the wire directly together." Dkt. 200-2 at 44. Moreover, Cook argues the Court's construction of the relevant term "does not in any way limit the manner in which the two ends are joined together." Dkt. 200 at 26. Thus, Cook argues, the Powerlink's ends are joined by "mechanical links formed throughout the Powerlink stent cage structure." Dkt. 200 at 26. The Court agrees that neither the patent nor the claim construction limits the method of connection to a sleeve, thus leaving the door open for other methods of joining the ends of the wire, such as attaching, coupling, assembling, linking, crimping, or twisting. But the limitation at issue does not refer to the method of joining the ends; it only requires that the ends be joined. Dkt. 181-2 at 9 col. 7:17. Thus, the focus is on whether the ends are joined, not how. It is undisputed that the Powerlink is constructed from a single wire in a manner leaving the two ends separated by the length of the stent and located in opposite locations. Because the claim requires these two ends to be joined, the Powerlink structure does not literally meet a limitation of the '706 patent.

Cook's expert further opines that "person of ordinary skill would have understood that 'the two ends of the wire' refers to any two ends of a wire that can be closed or joined to form a stent having a continuous or endless configuration." Dkt. 200-2 at 42-43. He asserts that the Powerlink is created from a single wire consisting of multiple segments, or internal lengths, each of which have "ends" that are joined to create multiple stents within the main body structure. It stretches credulity to suggest that the Powerlink structure is in actuality three separate stent structures. Cook is correct that the construction documents for the Powerlink identify three or more segments of the single wire that are twisted and attached to create the main body or leg stents, but nowhere are the segments referred to as individual stents.<sup>3</sup> See Dkt. 181-4 at 5 (describing the Powerlink as a "stent graft made in one piece"). And "it is well settled that an expert's unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact. A party may not avoid that rule by simply framing the expert's conclusion as an assertion that a particular critical claim limitation is found in the accused device." Arthur A. Collins, Inc. v. N. Telecom Ltd., 216 F.3d 1042, 1046 (Fed. Cir. 2000). Here, the expert's opinion that the Powerlink's main body structure is made of multiple stents, each with ends that are joined, is no more than an unsupported conclusion that the accused device contains a critical claim limitation, and does not create a genuine issue of material fact.

Because Endologix's Powerlink structure does not have a "closed zig-zag configuration" as disclosed by Claims 6 and 12, it does not literally infringe Cook's '706 patent. Therefore, summary judgment on the issue of literal infringement for Endologix is granted.

<sup>&</sup>lt;sup>3</sup> In the Court's view, this feature is more akin to a different Claim 6 limitation describing "straight sections joined at their ends by a plurality of bends." Dkt. 181-2 at 9 col. 7:18–19. Therefore, this feature does not satisfy the limitation requiring a "closed zig-zag configuration," and "courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth." *Oak Tech., Inc. v. Int'l Trade Comm'n*, 248 F.3d 1316, 1329 (Fed. Cir. 2001).

# **B.** Infringement of the '706 Patent by the Doctrine of Equivalents

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). The doctrine is often applied using the function-way-result test, which states"[a]n accused product that does not literally infringe a claim may infringe under the doctrine of equivalents if 'it performs substantially the same function in substantially the same way to obtain the same result." *Southwall Techs.*, 54 F.3d. at 1579 (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)). Or, courts may apply the all limitations test which "holds that an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent." *Freedman Seating Co.*, 420 F.3d at 1358.

In *Warner-Jenkinson*, the Supreme Court stated that regardless of the linguistics used, the pertinent inquiry requires "[a] focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements." *Warner-Jenkinson Co.*, 520 U.S. at 40. Courts must consider the totality of circumstances in each case to determine whether an alleged infringing device "can fairly be characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless." *Freedman Seating Co.*, 420 F.3d at 1359. The Court is obliged to grant summary judgment "where the evidence is such that no reasonable jury could determine two elements to be equivalent." *Bai*, 160 F.3d at 1353–54 (quoting *Warner-Jenkinson Co.*, 520 U.S. at 38 n.8).

Cook has alleged Endologix infringes the '706 patent under the doctrine of equivalents because among other things, the Powerlink stent cages and their individual segments perform

substantially the same function (forming a stent), in substantially the same way (with a continuous closed configuration), to achieve substantially the same result (a resiliently contractable and expandable hoop structure) as a wire formed into the "closed zig-zag configuration" of the asserted '706 claims. Dkt. 200 at 2.

Endologix, however, contends that on the '706 patent, the theory of claim vitiation precludes a finding of infringement under the doctrine of equivalents. *See Freedman Seating Co.*, 420 F.3d at 1358 ("[A]n element of an accused product is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation."). Relying on numerous Federal Circuit cases,<sup>4</sup> it specifically argues the Powerlink contains "the very antithesis or opposite of the claim limitation—the asserted claims require ends 'joined together' and the Powerlink ends are *not* joined together." Dkt. 180 at 22. Therefore, it argues the Powerlink cannot contain an equivalent of a "closed zig-zag configuration" without rendering the requirement meaningless.

Cook responds that the Powerlink does not embrace the antithesis of a "closed zig-zag configuration," because "the ends of the wire plainly are joined in some manner; they are not 'separate' or 'disconnected.'" Dkt. 200 at 29. Cook argues that its position "does not seek to

<sup>&</sup>lt;sup>4</sup> For example, Endologix relies upon *Moore U.S.A. v. Standard Register Co.*, 229 F.3d 1091 (Fed. Cir. 2000). There, the plaintiff argued summary judgment on noninfringement was precluded under the doctrine of equivalents. At issue was a claim limitation requiring "50.001%" or a majority of length. *Id.* at 1106. Plaintiff argued the defendant's use of 47.8% length was an insubstantial difference that was the equivalence of 50.001%. The court rejected this argument. It held:

the applicant's use of the term "majority" is not entitled to a scope of equivalents covering a minority for at least two reasons. First, to allow what is undisputedly a minority (i.e. 47.8%) to be equivalent to a majority would vitiate the requirement that the "first and second longitudinal strips of adhesive... extend the majority of the lengths of said longitudinal marginal portions." If a minority could be equivalent to a majority, this limitation would hardly be necessary, since the immediately preceding requirement of a "first and second longitudinal strips of adhesive disposed in said first and second longitudinal marginal portions, respectively of said first face" would suffice. Second, it would defy logic to conclude that a minority – the very antithesis of a majority – could be insubstantially different from a claim limitation requiring a majority, and no reasonable jury could find otherwise.

Id. (internal citation omitted).

include 'open' configurations within the meaning of the claimed 'closed' configurations." Dkt. 200 at 29 n.16. Instead, Cook's position is "that the [Powerlink's] mechanical linking structures join the ends of the wires together, whether literally or equivalently, to create 'closed' zig-zag configurations." Dkt. 200 at 29 n.16.

Endologix has failed to establish claim vitiation as a matter of law. Although the Powerlink's ends are not joined together in a manner to establish literal infringement, it is undisputed that the ends of the Powerlink wire are joined to the stent structure. The wires are not disconnected, which in the Court's view, more aptly captures the "antithesis" of "the ends of the wire joined together." Considering the facts in the light most favorable to Cook, the Court cannot conclude as a matter of law that if this feature of the Powerlink's structure is determined to be the equivalent of a "closed zig-zag configuration," then that limitation would be rendered meaningless.

Because Endologix has not put forth any additional evidence or argument that establishes the Powerlink is substantially different than the '706 patent, there are genuine issues of material fact for trial. Therefore, the Court agrees with Cook that it is for the jury to decide whether the Powerlink's ends are "joined together" in a manner creating the equivalent of a "closed zig-zag configuration." Summary judgment on this issue is accordingly denied.

# C. Literal Infringement of the '777 Patent

As set forth above, literal infringement occurs when "every limitation set forth in a claim . . . [is] found in an accused product, exactly." *Southwall Techs., Inc.*, 54 F.3d at 1575. The Court will grant "summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." *Bai*, 160 F.3d at 1353. The

analysis begins by comparing each limitation in every disputed claim to discover if the limitations are present in the accused device. If even one limitation is not met, a literal infringement claim fails.

Endologix contends the "having a fixed shape" limitation found in the '777 patent's asserted claims is dispositive of the infringement issue because the Intuitrak's vascular head dilator region ("tip") changes shape. Specifically, Endologix argues the Intuitrak tip "was intentionally designed to be flexible so that it can easily bend and conform to the patient's vasculature as it travels from the insertion site to the treatment site." Dkt. 180 at 26; Dkt. 183-13 at 5 § 7.1.1 ("Flexible material with tapered tip that will allow the introducer sheath to track to the desired site in the anatomy without kinking."). It argues that the tip's ability to flex and bend to fit a particular patient's vasculature demonstrates that the tip can change shape. For example, Endologix explains that the tip "can easily change between an 'I' and 'J' shape ..., or assume even more complex shapes like an 'S' shape." Dkt. 205 at 21. Endologix's expert further explains that the

tip is very flexible and is capable of being manipulated to match the most tortuous of vasculatures. This includes being bent in more than just one place at a time along its length. I have also observed on withdrawal of the IntuiTrak carrier that the tip can have a memory, frequently remaining bent or curved as a result of its passage through the patient's vasculature. These facts are inconsistent with the tip having a shape "that cannot change" and meeting the claim limitation "having a fixed shape."

Dkt. 183-3 at 9.

Cook responds that despite flexing and bending, the Intuitrak's tip always maintains its generally tapered or conical shape. Specifically it argues that the flexibility of Intuitrak's tip is a necessary design feature of vascular dilators and does not establish that the tip changes shape. Cook's expert opines that a person of ordinary skill in the art would not equate a "change in

shape" with flexing or a deformation of shape that is "typically reversed once the dilator is no longer in contact with the vessel wall." Dkt. 200-2 at 79–80. Additionally, Cook asserts that an inflexible or rigid vascular dilator would be inoperable or dangerous. *See AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1278 (Fed. Cir. 2011) ("While inoperability in itself does not doom AIA's construction, a construction that renders the claimed invention inoperable should be viewed with extreme skepticism." (internal quotation marks omitted)). To support this point, Cook offers the deposition testimony of Endologix's expert who stated that use of a rigid dilator "would not be advisable.... [it] could be traumatic to the vessel wall." Dkt. 200-15 at 67:18–21. Cook's own expert similarly opined that "[i]n order to safely introduce the dilator head into the vascular system, and then navigate through curving and diseased blood vessels to the abdominal aneurysm, the vascular dilator head structure *must* be flexible." Dkt. 200-2 at 80.

The Court finds Cook has established a genuine issue of material fact regarding whether the Intuitrak tip "has a shape that cannot change." Endologix has not provided the Court with evidence that, as a matter of law, the Court's construction of the limitation "having a fixed shape" in the '777 patent does not encompass tips that bend or flex but do not retain the bent or flexed shape. The Court cannot say that a reasonable jury would conclude that the Intuitrak tip does not literally infringe the '777 patent. Therefore, summary judgment on this issue is denied.

#### **IV. CONCLUSION**

For the reasons set forth above, the Court **GRANTS** in part and **DENIES** in part Endologix's motion for summary judgment of noninfringement (Dkt. 179). Specifically, the Court grants Endologix's motion with respect to noninfringement of the '706 patent by literal infringement, but denies Endologix's motion with respect to noninfringement of the '706 patent under the doctrine of equivalents and the '777 patent by literal infringement.

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Hon. Tanya Walton Pratt, Judge United States District Court Southern District of Indiana

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