PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN BALLOON DILATION DEVICES, SYSTEMS, AND COMPONENTS THEREOF**	**Inv. No. 337-TA-1449**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Doris Johnson Hines

(June 26, 2026)

Appearances:

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This is the final initial determination in *Certain Balloon Dilation Devices, Systems, and Components Thereof*, Investigation No. 337-TA-1449. Notice of Investigation, 90 Fed. Reg. 22116 (May 23, 2025) (EDIS Doc. ID 852546), and 19 C.F.R. §§ 210.10(b)(1) and 210.42(a)(1).

I. INTRODUCTION

A. Procedural History

Complainants Entellus Medical, Inc., Stryker Corporation, and Stryker Sales, LLC filed a complaint alleging a violation of 19 U.S.C. § 1337 based on the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain balloon dilation devices, systems, and components thereof by Fiagon GmbH, Fiagon AG Medical Technologies, Fiagon NA Corporation, Fiagon NA, LLC, and Hemostasis, LLC. Notice of Investigation and Complaint at ¶¶ 2 and 56–74 (EDIS Doc. ID 849027). Stryker accuses Fiagon of infringing claims in three related patents: U.S. Patent Nos. 11,083,878 (JX-1); 11,090,472 (JX-2); and 12,274,847 (JX-3). Complaint at ¶¶ 6 and 57–63.

The Commission instituted an investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products . . . by reason of infringement of one or more of claims 1–11, 14–15, and 19–30 of the '878 patent; claims 1–16, 18–22, 24–25, 27, and 29–30 of the '427 patent; and claims 1–4, 6–12, 15–20, and 22 of the '847 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

Notice of Investigation.

The "plain language description of the accused products or category of accused products, which defines the scope of the investigation, is '(a) balloon dilation devices; (b) systems containing the same for tracking, guiding, illumination, and/or navigating cavities, and (c) components thereof

consisting of: (i) components of the balloon dilation devices; and (ii) components for tracking, guiding, illuminating, and/or navigating used in balloon dilation devices and with systems containing the same.'" *Id.*, citing 19 C.F.R. § 210.10(b)(1). The notice did not direct me to consider the public interest. *Id.*; *see* 19 U.S.C. § 1337(d)(1) and 19 C.F.R. §§ 210.10(b)(2) and 210.42(a)(1)(ii)(C).

Stryker initially asserted infringement of sixty-nine claims across the asserted patents, *see* Complaint at ¶ 6, and filed a motion to terminate various of the claims, which was granted. Order No. 17 (EDIS Doc. ID 868005), *unreviewed by* Comm'n Notice (EDIS Doc. ID 870625). Stryker currently asserts infringement of claims 1, 14, 20, 22, and 23 of the '878 patent, claim 1 of the '472 patent, and claims 1 and 11 of the '847 patent. *Id.*

Before the evidentiary hearing, certain claim terms were construed, Order No. 15 (EDIS Doc. ID 865929). A motion to strike filed by Fiagon was denied. Order No. 16 (EDIS Doc. ID 866285).

The parties filed pre-hearing briefs. Stryker Pre-Hearing Br. (EDIS Doc. ID 868416)[1] and Fiagon Pre-Hearing Br. (EDIS Doc. ID 868399). A pre-hearing conference was held (EDIS Doc. ID 869017), and the evidentiary hearing was on January 14–16 and 20–21, 2026.[2] The parties moved to correct the hearing transcript, which was granted. Order No. 20 (Jan. 28, 2026) (EDIS Doc. ID 870509). The parties filed post-hearing briefs. Stryker Br. (EDIS Doc. ID 872113), Fiagon Br. (EDIS Doc. ID 872106), Stryker Reply (EDIS Doc. ID 873295), and Fiagon Reply (EDIS Doc. ID 873272). As required by the Ground Rules, the parties each filed a statement of uncontested

[1] Stryker filed an errata to its pre-hearing brief. (EDIS Doc. ID 868974).

[2] The public transcripts are at EDIS Doc. IDs 869019 (day 1), 869178 (day 2), 869539 (day 3), 869542 (day 4), and 869717 (day 5). The confidential transcripts are at EDIS Doc. IDs 869018 (day 1), 869177 (day 2), 869538 (day 3), 869541 (day 4), and 869716 (day 5).

claim elements. Stryker Statement (EDIS Doc. ID 873286), Fiagon Statement (EDIS Doc. ID 873274). Stryker also filed a motion to strike, Motion Docket No. 1449-09, which Fiagon opposed. Stryker Mot. (EDIS Doc. ID 870173), Fiagon Opp. (EDIS Doc. ID 871778). For the reasons detailed below, Motion No. 1449-09 is DENIED.

The target date was initially set for September 28, 2026, Order No. 4 (EDIS Doc. ID 852764), and was extended through October 26, 2026, making this final initial determination is due no later than June 26, 2026. Order Nos. 21 and 22. (EDIS Doc. IDs and 883395 and 885333).

B. The Parties

1. Complainants

The Notice of Investigation names three complainants: (1) Entellus Medical, Inc., (2), Stryker Corporation, and (3) Stryker Sales, LLC. 90 Fed. Reg. at 22116. Entellus Medical. Inc. is a Minnesota corporation, which was acquired by Stryker in 2018. Complaint Exs. 4 and 14. Stryker Corporation is U.S. company headquartered in Kalamazoo Michigan. Tr. (Foley) at 51:2–8. Stryker Sales, LLC is U.S. company located in Kalamazoo, Michigan. Complaint at cover.

2. Respondents

The Notice of Investigation names five respondents: (1) Fiagon GmbH, (2) Fiagon AG Medical Technologies, (3) Fiagon NA Corporation, (4) Fiagon NA, LLC, and (5) Hemostasis, LLC. 90 Fed. Reg. at 22117.

Fiagon GmbH is a German company headquartered in Hennigsdorf, Germany. Response to Complaint at ¶ 15–16 (EDIS Doc. ID 855931).

In its response to the Complaint, Fiagon states that "[p]roposed respondent Fiagon AG Medical Technologies has not existed since 2020 when it was renamed Intersect ENT International GmbH, which was subsequently merged into Fiagon GmbH. *Id.* at ¶ 17. In its post-hearing brief, Stryker states that Fiagon AG Medical Technologies is a German company with a principal place

of business in Hennigsdorf, Germany. Stryker Br. at 7. The evidence Stryker cites does not support that proposition. JX-296C (Solberg Tr.) at 20:13–14 (irrelevant); JX-292C (Stoupignan Tr.) at 21:19–25:5 (stating that Fiagon AG owned Fiagon GmbH and Fiagon NA before the Intersect acquisition); and CX-29C (not mentioning Fiagon AG Medical). The evidence does not support that Fiagon AG Medical Technologies is an existing entity.

In their response to the complaint, respondents state that it "is not aware of a Fiagon NA Corporation." In its initial post-hearing brief, Stryker does not specifically address Fiagon NA Corporation. Stryker Br. at 6–8. The evidence does not support that Fiagon NA Corporation is an existing entity.

Fiagon NA LLC is a Delaware limited liability company. Response to Complaint at ¶ 18.

Hemostasis, LLC is a Delaware limited liability company. Complaint Ex. 46 at 3. Complaint at ¶ 22 and Complaint Ex. 37.

The evidence does not support that either Fiagon AG Medical Technologies or Fiagon NA Corporation is an existing entity. Through the remainder of this initial determination, Fiagon GmbH, Fiagon NA, LLC, and Hemostasis, LLC are collectively referred to as Fiagon or respondents.

C. The Asserted Patents and Claims

The '878, '472, and '847 patents are each titled "Method and Articles for Treating the Sinus System" and relate to methods of treating sinusitis by advancing a balloon dilation catheter into a drainage pathway for treatment. The '878 patent issued on August 10, 2021, the '472 patent issued on August 17, 2021, and the '847 patent issued on April 15, 2025. Each claims priority to application No. 12/479,521 and has an identical specification.

The specification discloses that sinus cavities have drainage passageways opening into the nasal passages including an ostium, which when inflamed, causes interrupted mucous drainage

that can result in infection or inflammation called sinusitis. '878 patent at 1:34–49. Balloon dilation is a method of treating constricted sinus pathways. *Id.* at 1:55–59. In a balloon dilation device, "the inflatable balloon is inserted into the constricted sinus passageway in a deflated state. The balloon is then expanded to open or reduce the degree of constriction in the sinus passageway being treated to facilitate better sinus drainage and ventilation." *Id.* at 1:59–63. The asserted claims are directed to balloon dilation catheters and methods of treating drainage pathways of sinus cavities using balloon dilation catheters. Stryker asserts claims 1, 14, 20, and 22–23 of the '878 patent, which recite:

1. [a] A balloon dilation catheter comprising:

> [b] a handle having a proximal end and a distal end, wherein the handle comprises a first port at the proximal end of the handle and a second port at the proximal end of the handle;
>
> [c] an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member, wherein the first port is in fluid communication with the lumen at the proximal end of the inner guide member;
>
> [d] a shaft mounted about a periphery of the inner guide member, wherein a portion of the inner guide member extends distally of a distal end of the shaft;
>
> [e] a support member defining a tube that is disposed about a periphery of a first section of the shaft, wherein the first section of the shaft is adjacent to the handle, wherein a second section of the shaft extends distally from a distal end of the support member;
>
> [f] an inflatable balloon disposed about the inner guide member; and
>
> [g] an inflation lumen extending from the second port of the handle to the inflatable balloon,
>
> [h] wherein a center axis of the first port is coaxial with a longitudinal axis of the proximal portion of the inner guide member in the handle,

[i] wherein a center axis of the second port is transverse to the longitudinal axis of the proximal portion of the inner guide member in the handle,

[j] wherein the distal portion of the inner guide member is malleable, and

[k] wherein the inner guide member comprises a hypotube formed from stainless steel.

14. The balloon dilation catheter of claim 1,

[a] further comprising a means for determining a location of the distal end of the inner guide member within at least one anatomic structure,

[b] wherein the inflatable balloon is adapted to dilate the at least one anatomic structure,

[c] wherein the at least one anatomic structure is selected from a group consisting of: a sinus cavity, a drainage pathway of the sinus cavity, and an ostium of the sinus cavity, and

[d] wherein the sinus cavity is selected from a group consisting of a maxillary sinus cavity, a frontal sinus cavity, an ethmoid sinus, and a sphenoid sinus cavity.

20. The balloon dilation catheter of claim 1, wherein the support member comprises a hypotube formed of stainless steel.

22. [a] A method of treating a drainage pathway of a sinus cavity, the method comprising:

[b] providing a balloon dilation catheter comprising:

[c] a handle having a proximal end and a distal end,

[d] an inner guide member comprising a proximal portion and a distal portion,

[e] wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member,

[f] a shaft mounted about a periphery of the inner guide member, wherein a portion of the inner guide member extends distally of a distal end of the shaft,

> [g] a support member comprising a tube that is disposed about a periphery of a first section of the shaft, wherein the first section of the shaft is adjacent to the handle, wherein a second section of the shaft extends distally from a distal end of the support member, and
>
> [h] an inflatable balloon disposed about the inner guide member;
>
> [i] forming a bend in the inner guide member at a location that is distal to a distal end of the support member to change a shape of the inner guide member;
>
> [j] after forming the bend in the inner guide member, advancing, via a nasal passageway, the inner guide member to a target location in a drainage pathway of a sinus cavity; and
>
> [k] after advancing the inner guide member to the target location, inflating the inflatable balloon to dilate the drainage pathway of the sinus cavity,
>
> [l] wherein inflating the inflatable balloon is performed while the inflatable balloon extends along the bend in the inner guide member.
>
> 23. The method of claim 22, further comprising, while advancing the inner guide member to the target location, tracking a location of the inner guide member using an image guided surgery system.

'878 patent at claims 1, 14, 20, and 22–23 (bracketed element labels added).[3]

Stryker asserts claim 1 of the '472 patent, which recites:

> 1. [a] A balloon dilation catheter comprising:
>
> [b] a handle having a proximal end and a distal end;
>
> [c] an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member;
>
> [d] a shaft mounted about a periphery of the inner guide member, wherein a portion of the inner guide member extends distally of a distal end of the shaft;

[3] Stryker and Fiagon use different claim element labels. This Initial Determination uses Stryker's convention from its initial post-hearing brief.

[e] a support member defining a tube that is disposed about a periphery of the shaft, wherein the support member has a length that extends along at least a portion of the shaft; and

[f] an inflatable balloon disposed about the inner guide member,

[g] wherein a distal end of the support member is located proximal to a bend in the inner guide member, and

[h] wherein the inflatable balloon is inflatable with the inflatable balloon extending along the bend in the inner guide member.

'472 patent at claim 1 (bracketed element labels added).

Stryker asserts claims 1 and 11[4] of the '847 patent, which recite:

1. [a] A balloon dilation device comprising:

[b] a handle having a proximal end and a distal end;

[c] an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member,

[d] wherein the distal portion of the inner guide member is malleable such that the distal portion of the inner guide member is configured to be shaped with an angle of 0 degrees to 120 degrees relative to the proximal portion of the inner guide member,

[e] wherein the inner guide member is a stainless steel hypotube;

[f] a polymeric shaft mounted about a periphery of the inner guide member; and

[g] an inflatable balloon coupled to the polymeric shaft and disposed about the inner guide member,

[h] wherein the inner guide member has a rigidity that is greater than a rigidity of the polymeric shaft,

[4] Stryker does not assert claim 10 of the '847 patent, but because asserted claim 11 depends from claim 10, it is also considered.

> [i] wherein a portion of the inner guide member extends distally of a distal end of the polymeric shaft and a distal end of the inflatable balloon, and
>
> [j] wherein the inner guide member has an inner diameter in a range of about 0.508 mm (0.02 inch) to about 1.27 mm (0.05 inch) and a wall thickness between about 0.2032 mm (0.008 inch) to about 0.3048 mm (0.012 inch).
>
> 10. The balloon dilation device of claim 1, wherein the distal end of the inner guide member comprises a bulbous tip.
>
> 11. The balloon dilation device of claim 10, wherein the bulbous tip has an outer diameter between 1 mm and 3 mm.

'847 patent at claims 1, 10, and 11 (bracketed element labels added).

D. The Accused Products

The accused products are the VenSure balloon dilation devices and Cube Navigation System. The VenSure devices are balloon dilation catheters. JX-136.1C.2; JX-136.2C.2; and JX-136.5C.2 (instructions for use). There are four VenSure versions: (1) VenSure (basic version), (2) VenSure Light (with light confirmation), (3) VenSure Nav (with navigation), and (4) VenSure ET (with a 45 degree pre-bend at the tip). *Id.* Each VenSure device uses the same balloon, bending tool, inflation device, and extension line. JX-136.5C.2 and *see* JX-136.1–4C and 6C. The accused VenSure devices are shown below:

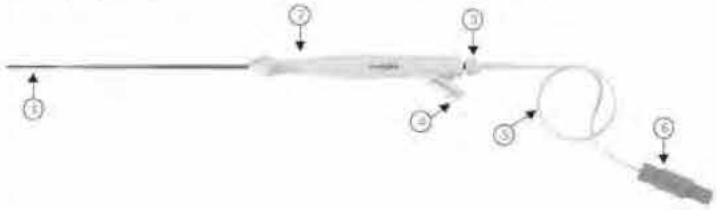


CDX-1.2C.3.

The Cube Navigation System is used with the VenSure Nav, shown below:



Figure 3 VenSure® Nav (Navigation-Ready) Balloon Device



1. Balloon
2. Device Handle
3. Sensor Carrier
4. Balloon Inflation/Dilation Port (luer fitting)
5. Navigation Cable
6. Navigation Connector Plug

CX-1216.7; Tr. (Griffis) at 367:23–368:16; JX-136.1C.3 ("The VenSure Nav Balloon device (Figure 3) is a navigation-ready version that is compatible with the Cube Navigation System allowing for image-guided visualization when connected to the Cube Navigation System.")

Stryker asserts infringement as follows:

Patent	All VenSure Products	VenSure, VenSure Light, and VenSure Nav	VenSure Light and VenSure Nav	VenSure Nav and Cube Navigation System
'878	1, 20	22[5]	14	23
'472	1			
'847	1 and 11			

Stryker Br. at 13–14.

[5] While Stryker's chart indicates that claim 22 is infringed by use of all VenSure products, Stryker does not assert infringement of claim 22 by the VenSure ET. *Compare* Stryker Br. at 13 (including VenSure ET) *with* Stryker Br. at 106 (omitting VenSure ET).

E. The Domestic Industry Products

The XprESS Ultra and XprESS LoProfile balloon dilation devices are domestic industry products and are shown below:



CX-618C.26 (XprESS Ultra device with green distal portion); CX-617C.16 (XprESS LoProfile device with orange distal portion); CDX-1.4C.3; Tr. (Curtin) at 143:7–144:14; JPX-2 (XprESS Ultra); and JPX-3 (XprESS LoProfile). The XprESS Ultra and XprESS LoProfile devices are used with a PathAssist LED light fiber, as shown below:

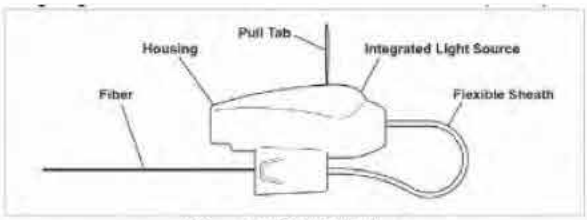


Figure 1 LED Light Fiber

JX-122.1.6. The light fiber provides illumination for the balloon catheter devices. *Id.*

The XprESS Ultra and XprESS LoProfile are essentially identical, the only difference being that the Ultra has a smaller hypotube and is not compatible with the TGS Guidewire. Tr. (Curtin) at 152:12–25. The TGS Guidewire is an electromagnetic device that can be inserted into the hypotube of the XprESS LoProfile device for tracking. JX-133.2.2 (TGS Guidewire

instructions for use); Tr. (Curtin) at 152:4–8 and 153:3–24. The TGS Guidewire is used with the Stryker ENT Navigation System and the XprESS LoProfile. CX-1220C.3

The NextGen XprESS is a balloon dilation catheter, [redacted] It is shown below:

[redacted]

CX-1382C; JX-133.3C; JX-137C; and Tr. (Curtin) at 172:23–173:16. Stryker says it plans to [redacted] Tr. (Curtin) at 170:5–20. To date, Stryker has made the NextGen XprESS in the United States [redacted] *Id.* at 170:21–171:20. Stryker asserts a domestic industry as follows:

Patent	XprESS Ultra and XprESS LoProfile	NextGen XprESS	XprESS LoProfile with Stryker ENT Nav System and NextGen XprESS
'878	1, 14, 20, 22	22	23
'472	1	1	
'847	1, 11	1, 11	

Stryker Br. at 14.

II. STATUTORY AUTHORITY

Congress has directed that "[t]he Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative." 19 U.S.C. § 1337(b)(1). Section

337(a)(1)(B) declares unlawful "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent . . . ." 19 U.S.C. § 1337(a)(1)(B).

The Commission has "statutory authority to investigate an alleged violation by the named respondents pursuant to section 337 [when] such respondents have allegedly imported, sold for importation, or sold after importation articles that are alleged to infringe a U.S. patent." *Certain Liquid Transfer Devices with an Integral Vial Adapter*, Inv. No. 337-TA-1362, Comm'n Op. at 7 (Jul. 26, 2024) (EDIS Doc. ID 827305).[6] The Commission has authority over "accused products based on their alleged importation, sale for importation, or sale after importation into the United States." *Id.* at 8. "Thus, for purposes of establishing the Commission's authority to investigate an alleged violation under section 337(a)(1)(B), a complainant must allege that a violation of section 337 has occurred, *i.e.*, that a respondent imported, sold for importation, or sold after importation an article that infringes a claim of a U.S. patent and that a domestic industry exists or is in the process of being established, among other statutory requirements." *Id.* at 9.

The Commission has statutory authority over this investigation because Stryker alleges: (1) importation, sale for importation, or sale after importation by Fiagon of the VenSure devices and components that infringe certain claims of the asserted patents; and (2) the existence of a

[6] Stryker addresses standing and jurisdiction. Stryker Br. at 28–30. The Commission has made clear that "constitutional standing does not apply to section 337 investigations" and that statutory authority to investigate an alleged violation is the touchstone and not subject matter jurisdiction, personal jurisdiction, and/or in rem jurisdiction. *Id.* at 6–10. *See also Certain Compact Wallets and Components Thereof*, Inv. No. 337-TA-1355, Comm'n Op. at 9–12 (Jul. 29, 2024) (EDIS Doc. ID 829449) and *Certain Dermatological Treatment Devices and Components Thereof*, Inv. No. 337-TA-1356, Comm'n Op. at 16–17 (Jun. 3, 2025) (EDIS Doc. ID 852602).

domestic industry for each asserted. I conclude that the Commission has statutory authority with respect to this investigation.

III. OWNERSHIP OF THE ASSERTED PATENTS

"To bring a complaint before the International Trade Commission, 'at least one complainant [must be] the owner or exclusive licensee of the subject intellectual property.'" *Roku, Inc. v. Int'l Trade Comm'n*, 90 F.4th 1367, 1372 (Fed. Cir. 2024), quoting 37 C.F.R. § 210.12(a)(7). The evidence supports that Stryker Corp. owns the asserted patents. *See* JX-7 ('878 patent); JX-8 ('472 patent); JX-10 (from Entellus to Stryker); JX-11 ('847 patent), JX-12 (provisional application), and *see SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1327-28 (Fed. Cir. 2010) ("The recording of an assignment with the PTO . . . creates a presumption of validity as to the assignment and places the burden to rebut such a showing on one challenging the assignment."). Fiagon does not dispute that Stryker Corp. owns the asserted patents. *See generally* Fiagon Reply. Because the evidence demonstrates that Stryker Corp. is the owner by assignment of the asserted patents, I conclude Stryker was entitled to file its complaint in this investigation.

IV. IMPORTATION

To prove a violation of section 337, Stryker must show that Fiagon engaged in the "importation into the United States, the sale for importation, or the sale within the United States after importation" of "articles that infringe a valid and enforceable United States patent " and that Fiagon is "the owner, importer, or consignee" of those articles. 19 U.S.C. § 1337(a)(1)(B)(i). Fiagon challenges importation generally and that it has imported "articles that infringe." Fiagon Reply at 113–136.

A. Importation

The evidence supports that that all complete VenSure devices were imported into the United States before the '878 patent issued. Tr. (Norman) at 710:21–711:8. The '878 patent is the

first to issue of the asserted patents. JX-1–JX-3. The evidence thus supports that no complete VenSure device was imported into the United States after any of the asserted patents issued. The evidence also supports that no complete device imported before the '878 patent issued was used or sold within the United States after the '878 patent issued. Tr. (Norman) at 711:17–715:25. Stryker does not assert that any pre-patent-issuance importation of a complete VenSure device violates section 337. Stryker Br. at 29–32. Nor could it because an article cannot infringe a patent before the patent issues. "[A] patent does not exist until it is granted. . . Patent rights are created only upon formal issuance of the patent." *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 429, 483 (Fed. Cir. 1996) (affirming dismissal of declaratory judgment filed before patent issuance); *see also Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996) (affirming grant of summary judgment of no induced infringement, explaining that inducement cannot be predicated on pre-issuance activity).

There is no dispute that components of the accused products were imported after each of the asserted patents issued, including the Y-connector, the handle shells, components of the indeflator, the bending tool, and the Light Guide and Sensor Carrier. Tr. (Neville) at 271:6–273:16; and *see* Fiagon Response to Complaint, Ex. A at 1–3 (identifying imported components of the accused products) (EDIS Doc. ID 855931). Fiagon has also imported the Cube Navigation System after the asserted patents issued. Tr. (Neville) at 273:10–16.

Fiagon suggests that the importation requirement is not met because the components are not material. Fiagon Reply at 118. "Whether imported components meet any claim limitations or have a nexus to the asserted claims is irrelevant to the issue of whether there is an 'importation into the United States' of those components." *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 22 (Aug. 3, 2021) (EDIS Doc.

ID 750094) and *Certain Chemical Mechanical Planarization Slurries and Components Thereof*, Inv. No. 337-TA-1204, Comm'n Op. at 12 (Jan. 6, 2022) (EDIS Doc. ID 759875) ("In determining whether the importation requirement is met, the Commission does not examine whether the imported [component] is an 'integral' component in the accused product or whether the imported component is part of an 'important step' that is 'essential' and/or 'indispensable' to the production of the final accused product.") "Here, the evidence shows that [Fiagon's] importation of its [Y-connector, handle shells, components of the indeflator, bend tool, Light Guide, Sensor Carrier, and Cube] from [outside the United States] for assembly in [or use with] its accused [VenSure products] satisfies the importation requirement under section 337(a)(1)(B)." *High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 22. The evidence supports that the importation requirement has been met.

B. Articles that Infringe

In addition to showing importation, Stryker must demonstrate that the imported components are "articles that infringe." *High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 22 and *Chemical Mechanical Planarization Slurries*, Inv. No. 337-TA-1204, Comm'n Op. at 13. Stryker identifies imported items as the Y-connector, handle shells, bend tool, certain components of the indeflator (inflation/deflation) device, Cube Navigation System, Light Guide, and Sensor Carrier. Stryker Br. at 33; Tr. (Neville) at 271:6–273:16; and *see* Fiagon Response to Complaint, Ex. A at 1–3 (identifying imported components of the accused products) (EDIS Doc. ID 855931). Fiagon does not dispute that these items are imported. Fiagon Reply at 117–32.

The handles and Y-connectors are parts of complete VenSure devices. Stryker Br. at 53 (showing handles) and 56, 62, and 67 (showing clear Y-connector) and Tr. (Neville) at 271:22–272:8. The bending tool is used to bend a distal end of the balloon catheter device, which is a step

of claim 22 of the '878 patent and which is used to make the bend recited in claim 1 of the '472 patent. Stryker Br. at 85–86 (showing bending tool), 116–122 (showing use of the bending tool for "forming a bend" in element 22[i] of the '878 patent), and 242–47 (showing use of the bending tool for "a bend in the inner guide member" in element 1[g] of the '472 patent) and JX-0136C.04. The indeflator is used to inflate the balloon as recited in element 22[k] of the '878 patent. Stryker Br. at 125–26 (identifying use of inflation device with respect to claimed "inflating the inflatable balloon") and JX-0136C.04. The Light Guide is included in the VenSure Light and used to emit light from the tip and the Sensor Carrier is used to detect a signal in conjunction with the Cube Navigation System. Both are alleged to be structure corresponding to the "means for determining" in claim 14 of the '878 patent. Stryker Br. at 88–94 (Sensor Carrier) and 95–100 (Light Guide) and JX-0136C.04. The Cube Navigation System and Sensor Carrier are part of the image guided surgery system alleged to meet claim 23 of the '878 patent. Stryker Br. at 127–35.

Fiagon contends that certain of these items are accessories and not components and thus not within the scope of the investigation. Fiagon Reply at 118. As detailed in the immediately preceding paragraph, however, the items Stryker identifies as imported are parts of the balloon dilation device accused to infringe the asserted claims (handles, Y-connector, Light Guide, and Sensor Carrier) or are used with an accused balloon device to perform a claimed method or form a bend in the accused balloon dilation device (bending tool, indeflator, Sensor Carrier, and Cube Navigation System). As a result, these items are components of an accused balloon dilation device or system and thus within the scope of the investigation.

When the complaint in this investigation was filed, [redacted]. Tr. (Spearman) at 734:16–735:1. The VenSure devices/systems are

sold to consumers who use them. Fiagon is accused of directly and indirectly infringing the asserted claims.

The direct infringement allegations here are like those in *Blood Cholesterol Testing Strips*. There, ACON Labs imported test strips and a meter which were used by ACON to practice the claimed method. *Certain Blood Cholesterol Testing Strips and Associated Sys. Containing the Same*, Inv. No. 337-TA-1116, Comm'n Op. at 24 (May 1, 2020) (EDIS Doc. ID 709361). The Commission explained that *Suprema* and *Comcast* were equally relevant to direct infringement. *Id.* at 28. It explained that "use" is infringement, and the evidence showed that when the products were used according to the directions for use and a blood sample was applied, ACON itself directly infringed. *Id.* at 28–29. The Commission explained that the claim language read on the structure and operation of the products when used with a blood sample. *Id.* at 29–30. Thus, the Commission held that based on the finding that the products were designed to infringe and were used to infringe they were "articles that infringe." This is consistent with the logic in *Chemical Mechanical Planarization Slurries*, in which a respondent used an imported component "to make the infringing slurries in the United States and thereby directly infringes the asserted composition claims." Inv. No. 337-TA-1204, Comm'n Op. at 19. Here, too, the imported components are designed to be combined by Fiagon into infringing articles, which it then sells to customers. Under Commission precedent, the imported components are "articles that infringe."

The indirect infringement allegations here are like those in *High-Density Fiber Optic Equipment*. There, the complainant sought to establish a violation by way of induced infringement based on "importation of [redacted component]s, assembling them with other materials to complete the accused chassis, selling the chassis to customers in the United States, and encouraging, teaching, or otherwise aiding its customers to use the accused chassis, at least some

of the time, in combination with one or more domestically-produced accused modules." Comm'n Op. at 28, *see also id.* at 28–29 (similar theory). The Commission held that the modules were articles that infringe because they were similar to products at issue in other cases finding that components of the patented invention were within section 337, most notably *Comcast Corp. v. Int'l Trade Comm'n*, 951 F.3d 101 (Fed. Cir. 2020). *Id.* The Commission rejected arguments that non-infringing uses were relevant because the complainant accused the respondent of induced infringement. *Id.* at 30. The Commission also explained that the imported modules were a claim element, and that all that was required to form the infringing combination was to insert the modules into a chassis. *Id.* at 31. As in *High Density Fiber Optic Equipment*, the imported components here are combined with other components to create infringing devices, and the importer is accused of inducing or contributing to infringement by its customers. These are "articles that infringe" under Commission precedent.

V. LEVEL OF ORDINARY SKILL

One of ordinary skill in the art is a hypothetical person who is presumed to be aware of all pertinent prior art. *See In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The Federal Circuit has "identified a non-exhaustive list of factors that may guide the fact finder in finding the appropriate level of skill in the art, which include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Best Med. Int'l, Inc. v. Elekta Inc.*, 46 F.4th 1346, 1353 (Fed. Cir. 2022) (internal quotation and citation omitted).

The claim construction order found that one of ordinary skill would have had an educational background in biomedical engineering, electrical engineering, mechanical engineering, chemical engineering, or an equivalent or a Doctor of Medicine (MD) or equivalent,

or would have 1–2 years of experience designing or using medical instruments. Order No. 15 at 4. At the evidentiary hearing, the parties' experts applied that or immaterially different definitions. *See, e.g.*, Tr. 318:11–15 (Griffis), 820:25–821:2 (Burban), 1106:18–21 (Griffis). The parties do not argue that any issue hinges on the level of ordinary skill. I adhere to the level of skill articulated in the claim construction order. *See Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1372 (Fed. Cir. 2016).

VI. CLAIM CONSTRUCTION

It is a bedrock principle of patent law that the claims of a patent define the invention for which the patentee is entitled to exclusionary rights. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, different sources may carry different weights "in light of the statutes and policies that inform patent law." *Id.*

Claim terms generally receive their ordinary and customary meaning, which is the meaning they would have, at the time of the invention, to one of ordinary skill in the art after reading the entire patent. *Id.* at 1312-13 and 1321. A patent's specification "'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1315, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The prosecution history, if in evidence, should also be considered. *Id.* at 1317 and *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). It is "the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making

the claim scope narrower than it would otherwise be." *Id.* "[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

For some claim terms, a "court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). Extrinsic evidence is "'all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317, quoting *Markman*, 52 F.3d at 980. While expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art," such testimony is "generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* at 1318-19. Extrinsic evidence can also be less reliable than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319. Courts discount extrinsic evidence "'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" *Id.* at 1318, quoting *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)

A. Construed Terms

In Order No. 15 several terms were construed as follows:

Term and Claims	Construction
inner guide member '878 patent claims 1, 14, 22–23, '472 patent claim 1, and '847 patent claim 1	Requires no construction other than that there is no requirement that they are movable relative to the shaft/polymeric shaft
shaft/polymeric shaft '878 patent claims 1, 22, '472 patent claim 1, '847 patent claim 1	Requires no construction other than that there is no requirement that they are movable relative to the inner guide member
means for determining a location of the distal end of the inner guide member within the at least one anatomic structure '878 patent claim 14	Subject to 35 U.S.C. § 112, ¶ 6[7] Function: determining a location of the distal end of the inner guide member within at least one anatomic structure Corresponding structure: an antenna, transmitter, optical reflectors, emitted light, light fiber, or the like to determine the orientation and/or positioning of the balloon dilation catheter or distal end thereof, and equivalents thereof

Order No. 15 at 5–27.

B. Disputed Terms

During claim construction, certain terms in claim 1 of the '847 patent were asserted by Fiagon to be indefinite, were briefed by the parties, but were not addressed in the claim construction order. Those terms either address the "rigidity" of the inner guide member and polymeric shaft or use of the word "about" when numeric ranges are recited. Fiagon and Stryker both incorporate by reference their claim construction arguments into their post-hearing briefs and

[7] The Leahy-Smith America Invents Act (AIA) redesignated § 112, ¶ 6 as § 112(f). *See* AIA, Pub. L. No. 112-29, sec. 4(c), 125 Stat. 284, 296 (2011). The asserted patents are subject to the pre-AIA version of the Patent Act because the original application from which they claim priority was filed before September 16, 2012. *See id.* § 4(e), 125 Stat. at 297; *see also Media Rights Techs., Inc. v. Cap. One Fin. Corp.*, 800 F.3d 1366, 1371, n.1 (Fed. Cir. 2015).

make no further arguments in their post-hearing briefs. Fiagon Br. at 8, 140, 147, 174 and Stryker Reply at 85.[8]

The parties filed initial and responsive claim construction briefs. Stryker CC Br. (EDIS Doc. ID 859741); Fiagon CC Br. (EDIS Doc. ID 859685); Stryker CC Reply (EDIS Doc. ID 860769); and Fiagon CC Reply (EDIS Doc. ID 860761). The parties filed expert declarations with their claim construction briefs. Stryker CC Br., Ex. A (Griffis Decl.); Fiagon CC Br., Ex. 17 (Burban Decl.); and Stryker CC Reply, Ex. C (Griffis Suppl. Decl.).[9] Neither expert testified at the claim construction hearing. 9/8/2025 Tr. (EDIS Doc. ID 861451).The parties do not point to any additional evidence on the indefiniteness issues from the evidentiary hearing. Fiagon Br. at 8, 140, 147, 174 and Stryker Reply at 85.

A patent's claims must "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). This definiteness requirement demands that "a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S.898, 910 (2014). The standard aims to strike a "delicate balance" between the "inherent limitations of language" and the need for patents "precise enough to afford clear notice of what is claimed, thereby apprising the public of

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[8] Fiagon incorporates by reference indefiniteness arguments regarding claims in the '472 and '878 patents. Fiagon Br. at 140 and 147. Those arguments relate to terms in claims that are no longer asserted. Joint Chart at term 4 ('472 patent claim 13), term 5 ('472 patent claim 27), and term 7 ('878 patent claim 7). Likewise, Fiagon made indefiniteness arguments regarding claims in the '847 patent that are no longer asserted. Joint chart at terms 7–10 ('847 patent claims 6, 7, 17, and 18). Because the claims in which those terms appear have been terminated, those indefiniteness challenges are not addressed here.

[9] Fiagon filed other declarations with its claim constructions briefs but they do not address the indefiniteness issues in the remaining asserted claims. Fiagon CC Br., Ex. 22 (Brodner Decl.) and Fiagon CC Reply, Ex. 55 (Brodner Reply Decl.).

what is still open to them." *Id.* at 909 (internal quotations and citations omitted). "The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Id.* at 910. "As long as claim terms satisfy this test, relative terms and words of degree do not render patent claims invalid." *One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1066–67 (Fed. Cir. 2017).

1. Rigidity

Element 1[h] of the'847 patent recites "wherein the inner guide member has a rigidity that is greater than a rigidity of the polymeric shaft." Fiagon argues this term is indefinite. Fiagon CC Br. at 32–35 and Fiagon Reply CC Br. at 20–23. Stryker disagrees. Stryker CC Br. at 31–33 and Stryker Reply CC Br. at 23–26.

Fiagon argues that this term is indefinite because (1) there are different ways of measuring rigidity and it is not clear which would be used and (2) depending on the material chosen for the inner guide member and polymeric shaft, the measure of rigidity could change depending on the direction in which a force is applied. Fiagon CC Br. at 32–35.

The parties present competing expert declarations. Fiagon relies on a declaration from its expert, Dr. Burban, and Stryker relies on declarations from its expert, Mr. Griffis. Burban Decl. ¶¶ 44–101; Griffis Decl. ¶¶ 76–82; and Griffis Suppl. Decl. ¶¶ 64–72. Neither expert testified at the claim construction hearing and neither expert testified on indefiniteness at the evidentiary hearing.

Claim 1 of the '847 patent recites that the inner guide member is a stainless steel hypotube and the shaft is polymeric. Fiagon argues that there are various ways to measure rigidity, namely Young's Modulus, Shear Modulus, Torsional Rigidity, and Flexural rigidity. Burban Decl. at ¶¶ 49–73 and Fiagon Br. at 33–34. Fiagon contends that the Young's Modulus of gold is higher than that of silver but that the Shear Modulus of silver is higher than that of gold. *Id.* at ¶¶ 85–88.

Thus, according to Fiagon, "to compare the rigidity of two materials, one needs to know which property to compare and the '847 Patent does not specify which property to compare." *Id*. at 88. Fiagon also argues that when materials are anisotropic, they can have different rigidities in different directions and that the claimed polymeric shaft can be anisotropic. Fiagon Br. at 34–35 and Burban Decl. at ¶¶ 89–100. According to Fiagon, "even if one knew which rigidity parameter to use, it would still be unclear how to deal with anisotropic materials." Burban Decl. at ¶ 101.

But Fiagon does not address how rigidity measurements of silver and gold are relevant in the context of the claimed materials of the inner guide member (stainless steel) and the shaft (polymeric). That is, Fiagon presents no evidence that any of the different ways of measuring rigidity would lead to different results for a stainless steel hypotube and a polymeric shaft, including whether the polymer shaft was anisotropic or not. The claimed "rigidity," therefore is not like the measures in the cases Fiagon relies on. Fiagon Br. at 32. Instead, in both *Teva* and *Dow*, different ways to measure could have different results in the context of the claims, and there was no evidence of which way to measure. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344–45 (Fed. Cir. 2015) (three measures of molecular weight); *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 633–35 (Fed. Cir. 2015) (four methods to measure slope of strain hardening with different results). Fiagon has not shown that is the case here.

Further. as Stryker argues, the specification supports that "the inner guide member 14 is advantageously rigid to enable the balloon dilation catheter 10 to be positioned without the need on a separate guiding catheter or wire guide in most, if not all circumstances." Griffis Decl. at ¶ 78, citing '847 patent at 3:64–66. Further, the specification states that "[b]oth the shaft 30 and the balloon 36 are preferably formed of high strength but flexible polymeric materials such as polyamides (e.g., Nylon), PEBAX or the like." *Id*., citing '847 patent at 6:30–33. Based on the

disclosure in the specification, Stryker persuasively argues that one of skill would understand that "rigidity" in the claim refers to a structure's resistance to deformation when a load is applied to the structure. Stryker Br. at 32 and Griffis Decl. at ¶¶ 78–79.

Fiagon has not shown by clear and convincing evidence that the term "rigidity" renders claim 1 of the '847 patent invalid as indefinite.

2. "About" Terms

Fiagon argues that two terms in claim 1 of the '847 patent are indefinite based on their use of the word "about":

- the inner guide member has an inner diameter in a range of about 0.508 mm (0.02 inch) to about 1.27 mm (0.05 inch)
- the inner guide member has . . . a wall thickness between about 0.2032 mm (0.008 inch) to about 0.3048 mm (0.012 inch)

Joint Chart at 5–6; Fiagon CC Br. at 36–37; and Fiagon CC Reply at 23–27. Stryker argues that these terms are not indefinite. Stryker CC Br. at 35–37 and Stryker CC Reply at 26–29.

Fiagon has not proven by clear and convincing evidence that "about" renders these terms indefinite. As Stryker argues, the Federal Circuit has repeatedly construed "about" to have a plain and ordinary meaning of "approximately." Stryker CC Br. at 35–36, citing *Ferring B.V. v. Watson Lab'ys, Inc.*, 764 F.3d 1382, 1386 (Fed. Cir. 2014) and *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369–70 (Fed. Cir. 2005). Fiagon, supported by Dr. Burban, argues that there is no objective measure by which to determine the scope of what falls within the claimed ranges. Fiagon CC Br. at 36–37, citing Burban Decl. ¶¶ 126, 129–32.

Stryker persuasively argues that one of skill would understand that the term "about" is intended to accommodate reasonable variation inherent in real-world conditions and that precise measurements in this field are often subject to small fluctuations due to manufacturing tolerances, measurement limitations, and variability across materials. Stryker CC Br. at 35–36 and Griffis

Decl. at ¶¶ 91–93. Fiagon has not shown this is not the case and has not shown any instance in which it would be unclear whether a product does or does fall within the scope of either of the "about" claim terms.

Fiagon cites *Amgen Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1217–18 (Fed. Cir. 1991), which found the term "about" indefinite. Fiagon Br. at 36. That case, however, is not analogous. There, the term was "at least about 160,000" IU/AU. *Id.* at 1217. The court explained that the prior art disclosed 128,620 IU/AU and the Examiner rejected claims to "at least 120,000" which resulted in the amended claimed language of "at least 160,000." *Id.* at 1217–18. The district court had held the claims invalid as indefinite because the word "about" was an effort to recapture some amount of claim scope down to 120,000 IU/AU, there was no evidence showing how much scope was recaptured, and the expert could not identify what would fall within the newly-claimed range. *Id.* at 1218. The Federal Circuit upheld the indefiniteness finding, stating that "[w]hen the meaning of claims is in doubt, especially when, as is the case here, there is close prior art, they are properly declared invalid." The court specifically cautioned that its "holding that the term 'about' renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims." Fiagon has not shown that these terms were meant to recapture or do recapture some range or that there is any lack of clarity as to the range.

As for the other case cited by Fiagon, *Enviro Tech Chemical Services*, the district court found that the intrinsic record was inconsistent on the meaning of "about" as applied to pH level. *Enviro Tech Chem. Servs., Inc. v. Safe Foods Corp.*, No. 4:21-CV-00601-LPR, 2022 WL 17721179, at *12–16 (E.D. Ark. Dec. 15, 2022). The Federal Circuit affirmed, noting the inconsistencies relied on by the district court. *Enviro Tech Chem. Servs., Inc. v. Safe Foods Corp.*, 174 F.4th 919, 922–923 (Fed. Cir. 2026). The Federal Circuit also noted that during prosecution,

the patentee amended the lower end of the claimed pH range from "about 7.3" to "about 7.6" to overcome prior art. *Id.* at 923. The court stated that "[a]n important determinant in our decision here is the very fact that what is now claim 1 was amended in respect to pH to avoid prior art, which was as close as a pH of 7.0" and "required the clams to be amended." *Id.* In that circumstance, "the definiteness requirement of § 112 necessitates much more clarity than using the vague term 'about.' The prior art is almost 'about' a pH of 7.6." Thus, as in *Amgen*, uncertainty about the scope of the claim following amendment to avoid prior art resulted in indefiniteness. That is not the situation here. Nor is there any indication that the intrinsic record provides inconsistencies regarding the meaning of "about" in the claims.

Fiagon has not shown by clear and convincing evidence that the "about" claim terms are indefinite.

VII. ALLEGED BIAS OF FIAGON'S EXPERT

Stryker contends that the impartiality of one of Fiagon's experts, Dr. Burban, "should be seriously questioned given the positions he has taken and his deep-seated involvement with Respondents and their founders, the Spearmans, for many years prior to this dispute." Stryker Br. at 49. Fiagon counters that Dr. Burban has substantial experience in the ENT space, far exceeding that of Stryker's expert, Mr. Griffis, and notes that the amount of Dr. Burban's investments in Hemostasis and Stryker "are about the same as Mr. Griffis's income from this matter." Fiagon Reply at 2–3.

As an initial matter, the cases Stryker relies on were in different procedural postures. In *AgriChem, Inc. v. Loveland Indus., Inc.*, 843 F. Supp. 520, 530 (D. Minn. 1994), the district court denied summary judgment of invalidity based on the on-sale bar because a supporting declaration was by a long-term employee of the parent company of the moving party, making his credibility "subject to attack," and because a diagram the declarant relied on was not clearly dated and did

not indicate that it related to the prior art system. As contrasted with *AgriChem*, this investigation is not in a summary determination posture.

In *Bhaghat v. USPTO*, No. 23-1545, 2024 WL 1433465 at *9 (Fed. Cir. Apr. 23, 2024), the Federal Circuit held that the district court did not abuse its discretion when it did not exclude an expert's testimony based on a *Daubert* challenge premised on allegations of "significant financial interest" of the expert. As contrasted with *Bhaghat*, there was no *Daubert* challenge to Dr. Burban.

Stryker has not established that Dr. Burban's impartiality is so in question that his opinions should be considered not credible. Dr. Burban was previously employed by Hemostasis. Tr. (Burban) at 795:23–796:23 and 1076:8–17. That alone does not render him wholly unreliable. [redacted] *Id.* at 801:25–802:1. Stryker has not established that [redacted] render his opinions wholly unreliable. *Id.* at 1076:18–1077:17. Moreover, Dr. Burban testified that he believes [redacted] and does not believe [redacted] *Id.* at 802:2–9. I agree with Fiagon that Dr. Burban has not been shown to have personal or financial issues that render his testimony so impartial as to not be considered. Fiagon Reply at 2–3.

Dr. Burban's professional affiliations and financial holdings will be considered when assessing the weight given to his testimony.

VIII. INFRINGEMENT

Section 337 prohibits certain importation-related actions concerning articles that "(i) infringe a valid and enforceable United States patent" or that "(ii) are made produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B).

The Patent Act provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). "Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

The Patent Act also proscribes indirect infringement, namely induced and contributory infringement. "[A] violation of Section 337 may arise from an act of induced infringement." *Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1351 (Fed. Cir. 2015) (en banc). "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). There are three requirements of induced infringement: (1) "there must be direct infringement by a third party"; (2) "the inducer must know that the induced acts constitute patent infringement"; and (3) "the inducer must take active steps to encourage direct infringement." *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, 146 S. Ct. 1391, 1396 (2026) (internal quotation marks and citations omitted). Intent may be shown through circumstantial evidence. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1322 (Fed. Cir. 2009).

As to contributory infringement, "[w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition . . . constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(c). "Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement." *Commil USA, LLC v. Cisco*

Sys., Inc., 575 U.S. 632, 639, citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964). "[T]o prevail on contributory infringement in a Section 337 case, the complainant must show *inter alia*: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

In a section 337 investigation, the complainant bears the burden of proving infringement by a preponderance of the evidence. *See Spansion*, 629 F.3d at 1349. This standard "requires proving that infringement was more likely than not." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341, n.15 (Fed. Cir. 2005).

Stryker argues that: (1) all VenSure products infringe claims 1 and 20 of the '878 patent, claim 1 of the '472 patent, and claims 1 and 11 of the '847 patent, Stryker Br. at 13–14; (2) the VenSure, VenSure Light, and VenSure Nav infringe claim 22 of the '878 patent, *id.* at 106–126;[10] (3) the VenSure Light and VenSure Nav infringe claim 14 of the '878 patent, *id.* at 87–105; and (4) the VenSure Nav and Cube Navigation System together infringe claim 23 of the '878 patent, *id.* at 127–35. Stryker also argues that Fiagon indirectly infringes every asserted claim. *Id.* at 135–167 ('878 patent), 250–252 ('472 patent), and 293 ('847 patent). Fiagon disputes certain claim elements as to direct infringement and disputes indirect infringement. *See* Fiagon Reply at 7–112 and Fiagon Statement.

[10] Stryker's chart of asserted claims indicates that all VenSure products infringe claim 22. Stryker Br. at 13–14. Stryker, however, does not argue that the VenSure ET infringes claim 22. Stryker Br. at 106 ("use of the VenSure, VenSure Nav, and VenSure Light for sinus procedures meets all the limitations of method Claim 22"); *see also* Fiagon Reply at 32 ("Complainants' brief only discusses the VenSure, VenSure Nav, and VenSure Light with respect to" method claim 22.)

A. The Asserted Independent Claims

The subject matter of the asserted independent claims (claims 1 and 22 of the '878 patent, claim 1 of the '472 patent, and claim 1 of the '847 patent) overlaps to a substantial degree. This is demonstrated not only by the similarity of the claim language but by the fact that both parties repeatedly refer to and incorporate by reference arguments on related claim elements. *See, e.g.*, Stryker Br. at 109, referring to arguments made with respect to '878 patent element 1[a] when addressing '878 patent element 22[b] and Fiagon Reply at 32, incorporating by reference arguments made with respect to '878 patent element 1[c] when addressing '878 patent element 22[e]. As a result, related claim elements of the asserted independent claims are considered together.

1. Balloon Dilation Catheter

Element 1[a] of the '878 patent, 1[a] of the '472 patent, and 1[a] of the '847 patent recite "[a] balloon dilation catheter comprising." Stryker contends these elements are met. Stryker Br. at 52–53 ('878 patent element 1[a]), 239 ('472 patent element 1[a]), and 262–63 ('847 patent element 1[a]. Fiagon does not dispute that these elements are met. Fiagon Statement at 2, 5, and 6.

The evidence supports that the VenSure products meet these elements because they are balloon dilation catheters. Tr. (Griffis) at 330:18–333:8; CX-613C.62 (photograph of VenSure device); CX-614C.56 (photograph of VenSure Nav device); CX-615C.71 (photograph of VenSure Light device); and CX-616C.54 (photograph of VenSure ET device). The indications for use for the VenSure, VenSure Nav, and VenSure Light state that the VenSure Balloon Dilation System, is used to "access and treat the frontal ostia/recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures." JX-136.1C.1. The indications for use for the VenSure, VenSure Nav, and VenSure Light as well as those for the

VenSure ET state that they are "used to dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in adult patients using a transnasal approach." *Id.* and JX-136.2C (VenSure ET). Additional evidence cited by Stryker supports that the VenSure products are balloon dilation catheters. Stryker Br. at 52–53 (citing evidence). The evidence supports that the VenSure, VenSure Nav, VenSure Light, and VenSure ET meet element 1[a] of the '878 patent, element 1[a] of the '472 patent, and element 1[a] of the '847 patent.

Elements 22[a] and [b] of the '878 patent recite "A method of treating a drainage pathway of a sinus cavity, the method comprising: providing a balloon dilation catheter comprising." Stryker contends that these elements are met. Stryker Br. at 108–11. Fiagon does not dispute that these elements are met. Fiagon Statement at 4. The indications for use explain that the VenSure, VenSure Nav, and VenSure Light are used to treat a drainage pathway of a sinus cavity using a balloon dilation catheter. Tr. (Griffis) at 379:21–381:17 and JX-136.1C.1. The evidence supports that users of the VenSure, VenSure Nav, and VenSure Light practice elements 22[a] and 22[b] of the '878 patent.

2. Handle

Element 1[b] of the '878 patent, element 22[c] of the '878 patent, element 1[b] of the '472 patent, and element 1[b] of the '847 patent recite "a handle having a proximal end and a distal end." Stryker contends that these elements are met. Stryker Br. at 53–61 ('878 patent claim 1), 111–114 ('878 patent claim 22), 239 ('472 patent claim 1), and 263 ('847 patent claim 1). Fiagon does not dispute these elements. Fiagon Statement at 3–6.[11] The evidence supports that each of the VenSure devices have a handle, as shown below:

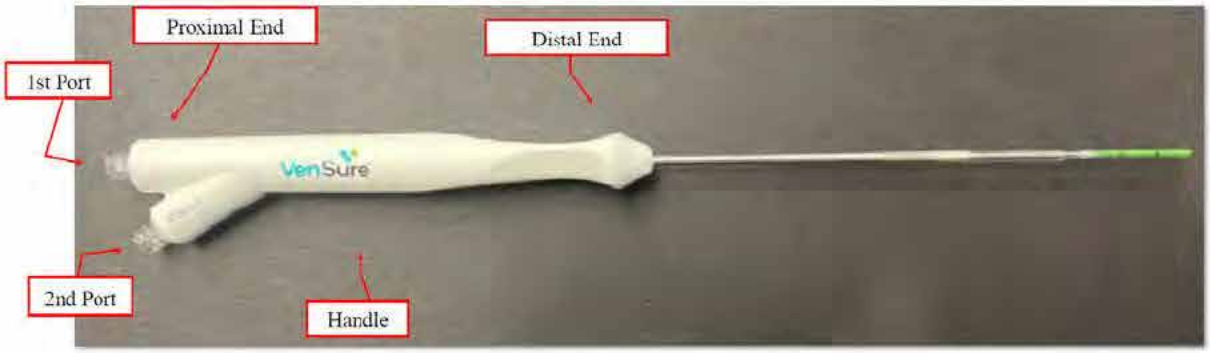
[11] Fiagon disputes that the handle of the VenSure devices comprises first and second ports, as addressed below, but does not dispute that those devices have a handle.



Stryker Br. at 53 and Tr. (Griffis) at 333:7–334:2 ('878 patent element 1[b]), 383:3–384:4 ('878 patent element 22[c]), 407:5–18 ('472 patent element 1[b]), and 421:23–422:11 ('847 patent element 1[b]). The evidence supports that these elements are met.

Element 1[b] of the '878 patent additionally recites "wherein the handle comprises a first port at the proximal end of the handle and a second port at the proximal end of the handle." Stryker contends that this elements is met. Stryker Br. at 53–61. Fiagon disputes that the handle of the VenSure devices comprise first and second ports. Fiagon Reply at 7–18 and Fiagon Statement at 3–6.

Mr. Griffis testified regarding an annotated photograph of a VenSure showing where, in his opinion, the handle, distal and proximal ends, and first and second ports are located:



CDX-1.2C.7; CX-613C.11 and Tr. (Griffis) at 333:17–334:22. The CAD drawings relied on by Mr. Griffis show handle-related parts of a VenSure device:

[redacted]

CDX-1.2C.8,[12] citing JX-134.1C.4 (top); JX-134C.18C.1 (bottom left); and JX-134C.19C.1 (bottom right). Fiagon's expert provided the following illustrated photo of the VenSure handle:



Fiagon Reply at 12, showing RDX-25C.220 (Burban); Tr. (Burban) at 1017:16–1018:5; RDX-12C.32 (Norman); Tr. (Norman) at 708:6–15; RDX-26.6 (Griffis cross); Tr. (Griffis) at 644:25–

[12] Mr. Griffis's demonstratives cite CX-604C, which was not admitted. *See* Final Exhibit List (EDIS Doc. ID 871595). CX-604C appears to have been an infringement claim chart, which is obviously not evidence. *See* Complainants' Pre-Hearing Statement, Ex. E at 18 (EDIS Doc. ID 869126).

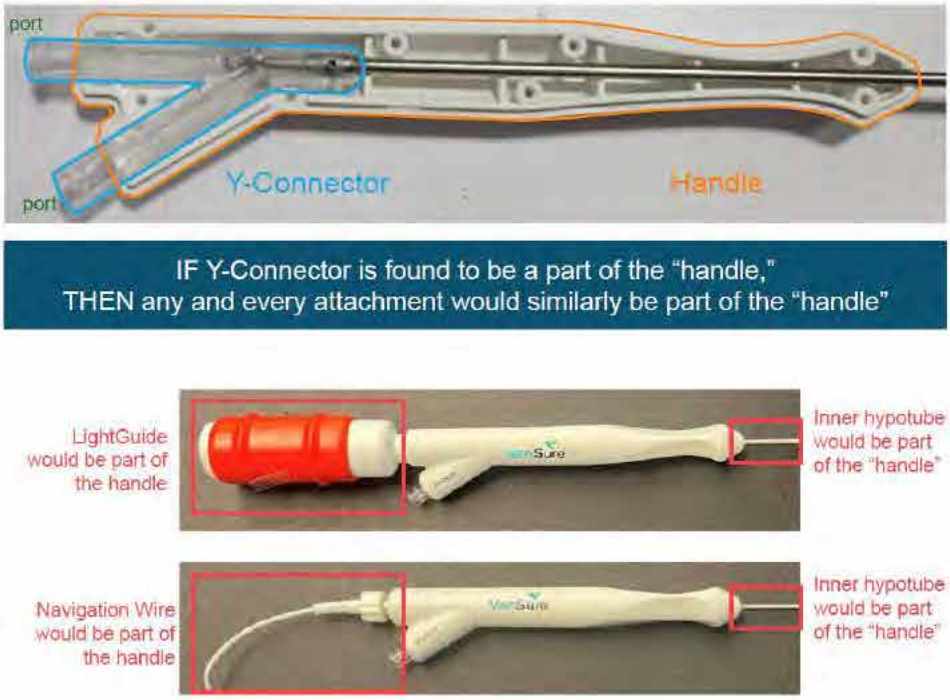
645:19. There is no dispute about this portion of the structure of the VenSure products: the Y-connector is a separate structure held in place by the two plastic pieces of the handle. *See generally* Fiagon Reply at 7–18; Tr. (Griffis) at 645:15–19; and Tr. (Burban) at 1017:15–1018:5.

Fiagon's expert, Dr. Burban, testified that '878 patent element 1[b] is not met because in his opinion, it requires that the first and second ports are integrally formed with the handle. Tr. (Burban) at 1016:3–1017:15. Fiagon relies on a portion of the specification which it argues discloses two embodiments: "The port 22 may be integrally formed with the handle 12 or, alternatively, the port 22 may be a separate structure that is secured to the handle 12 during assembly." '878 patent at 6:44–47 and Fiagon Reply at 7–8. Fiagon argues that '878 patent element 1[b] claims the former while claim 2 of the '847 patent recites the latter because it recites "a first port at the proximal end of the handle." *Id.* at 8–9. Fiagon's reliance on '847 patent claim 2 is puzzling because the language of claim 2 is also in '878 patent claim 1 (reciting "a first port at a proximal end of the handle"). The only difference is that '878 patent element 1[b] recites that the handle "comprises" a first port. The word "comprises," however, does not mandate that the port is integral with (i.e., made of the same material as) the handle.

Fiagon's reliance on *Bayer Pharma Aktiengesellschaft v. Mylan Pharms. Inc.* is misplaced. *See* Fiagon Reply at 10. There, the claim recited "administration of a first product comprising rivaroxaban and aspirin." 152 F.4th 1400, 1406 (Fed. Cir. 2025) (highlighting omitted). The PTAB held that this term could encompass separate dosage forms (one of rivaroxaban and another of aspirin), but the Federal Circuit disagreed, explaining that the claim language and specification did not support this. Instead, the claim language "first product comprising rivaroxaban and aspirin" directly tracked language in the specification disclosing a combination dosage of both rivaroxaban and aspirin. *Id.*

Here, by contrast, there is no such direct tracking between the specification and the claim language. That is, unlike in *Bayer*, the claim language reciting that the "handle comprises a first port . . . and a second port" does not "more closely mirror[]" the disclosure in the specification that the port may be integral with the handle. Instead, the specification repeatedly discloses handle 12 with a distal end 26 and a proximal end 24 and with ports 22 and 38 at the proximal end of the handle. '878 patent at Figs. 1, 2A, 2B, 3A, 3B, and 4. The specification further discloses that port 22 can be integrally formed with the handle 12 or a separate structure that is secured to handle 12. '878 patent at 6: 44–47. Nothing in the claim language requires that the ports 22 and 38 be made of the same material as the handle, i.e., be integral with them, especially given the disclosure that the ports can be the same or separate structure that is still considered to be part of the handle. *Id.* at 6:39–51. Element 1[b] of the '878 patent does not use the term "integrally formed" and includes no language mandating or even suggesting that the embodiments of Figs 3B and 4 are excluded. *See Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1355 (Fed. Cir. 1998) ("A claim construction that does not encompass a disclosed embodiment is thus rarely, if ever, correct and would require highly persuasive evidentiary support.") (internal quotation marks omitted). Fiagon's arguments are unsupported by the claims and specification.

Fiagon also argues that if the ports are part of the handle, the VenSure Light and VenSure Nav do not infringe because the Light and Nav attachments, shown in the lowermost two photos below would become part of the handle meaning that the ports would no longer be located at the proximal end of the handle, as shown below:



Fiagon Reply at 17– 18, citing Tr. (Burban) at 1020:20–1021:7 and RDX-25C.227.

There is no support for the proposition that the separate LightGuide accessory (shown in orange above) or the separate Navigation Wire (shown in the lowermost photo) are part of the handle. By contrast, as shown in the patent figures, and as supported by the specification, ports 22 and 38 are part of the handle, whether made of the same material or made of different material and connected to it, as shown for example, in Figs. 3A and 4:

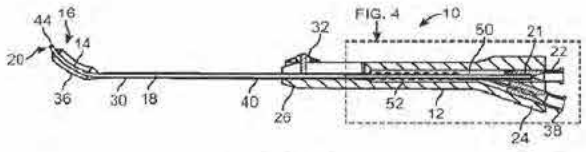


FIG. 3B

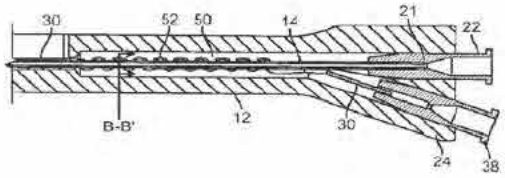


FIG. 4

Fiagon's interpretation would exclude the embodiments of Figs. 3B and 4, which have a ports that are not integral but are held in place. Similarly, Fiagon's argument that the LightGuide and Navigation Wire are part of the handle when they are only attached to one of the ports is unsupported at last because they are not even within the handle, but are attached to a port.

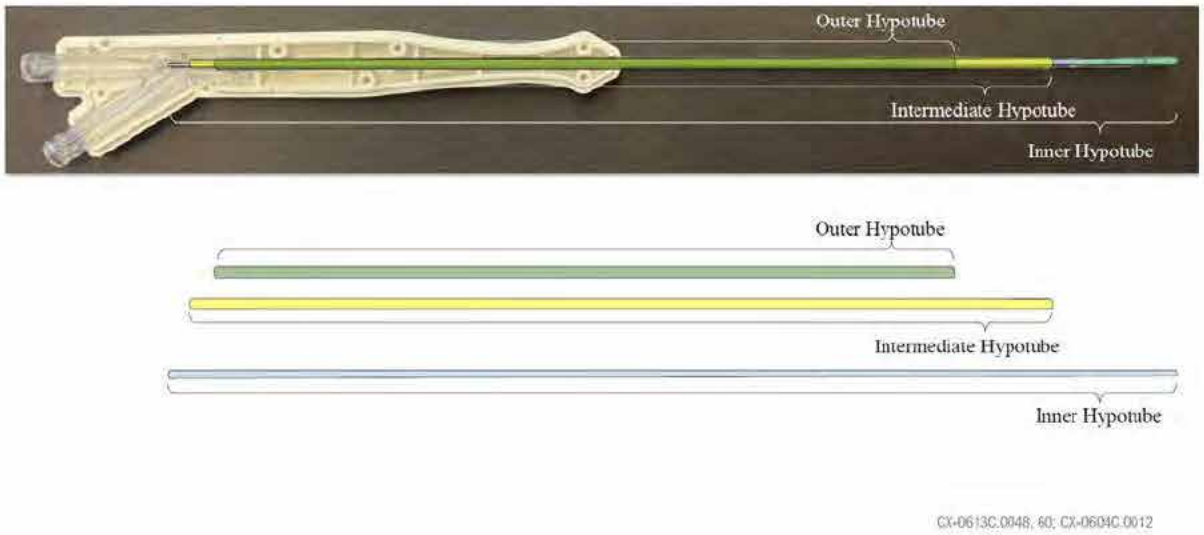
The evidence supports that '878 patent element 1[b] is met by the accused VenSure products.

3. Inner Guide Member

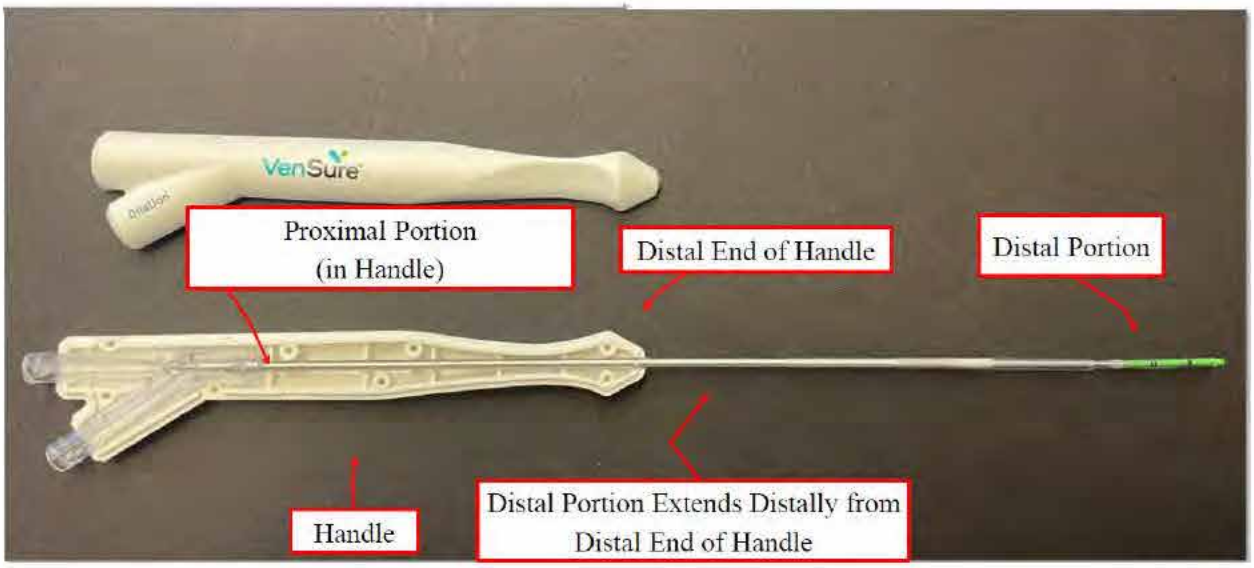
a) Structure

Elements 1[c], 22[d] and [e] '878 patent, element 1[c] of the '472 patent, and element 1[c] of the '847 patent recite: "an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member." Stryker contends that these elements are met. Stryker Br. at 61–70 ('878 patent element 1[c]), 115 ('878 patent elements 22[d] and 22[e]), 240 ('472 patent element 1[c]), and 263 ('847 patent element 1[c]). Fiagon disputes that "the distal portion of the inner guide member extends distally from the distal end of the handle." Fiagon Statement at 3–6 and Fiagon Reply at 19–22 ('878 patent element 1[c]), 32 ('878 patent element 22[d]), 76 ('472 patent element 1[c]), and 107 ('847 patent element 1[c]).

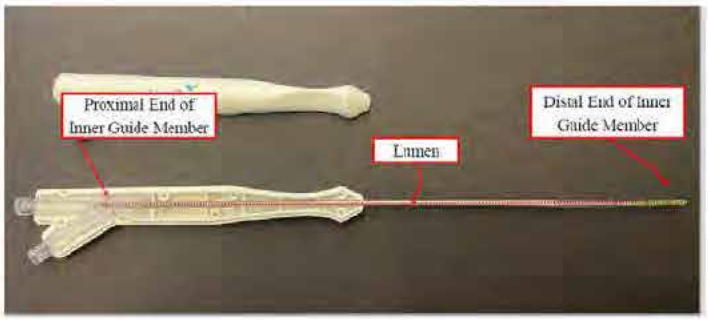
There is no dispute about the structure of the VenSure products. The evidence supports that each has three hypotubes connected to the Y-connector within the handle, as shown in the annotated photo below:



CDX-1.2C.13, citing CX-613C.60; JX-157C.67 (510(k) submission indicating that the "shaft is made up of three hypotubes connected to the Y-connector and extending . . . past the distal end of the handle"); Tr. (Griffis) at 338:21–340:16; and JX-134.3C.2 (engineering drawing). Mr. Griffis opined that the inner hypotube is the claimed inner guide member. Tr. (Griffis) at 341:2–19. The evidence supports that the proximal portion of the inner guide member is in the handle while the distal portion of the inner guide member extends distally from the distal end of the handle, as shown below:



CDX-1.2C.18, citing CX-613C.60 and Tr. (Griffis) at 342:8–24. The evidence also supports that the inner hypotube comprises a lumen extending from a proximal end to a distal end, as shown below:



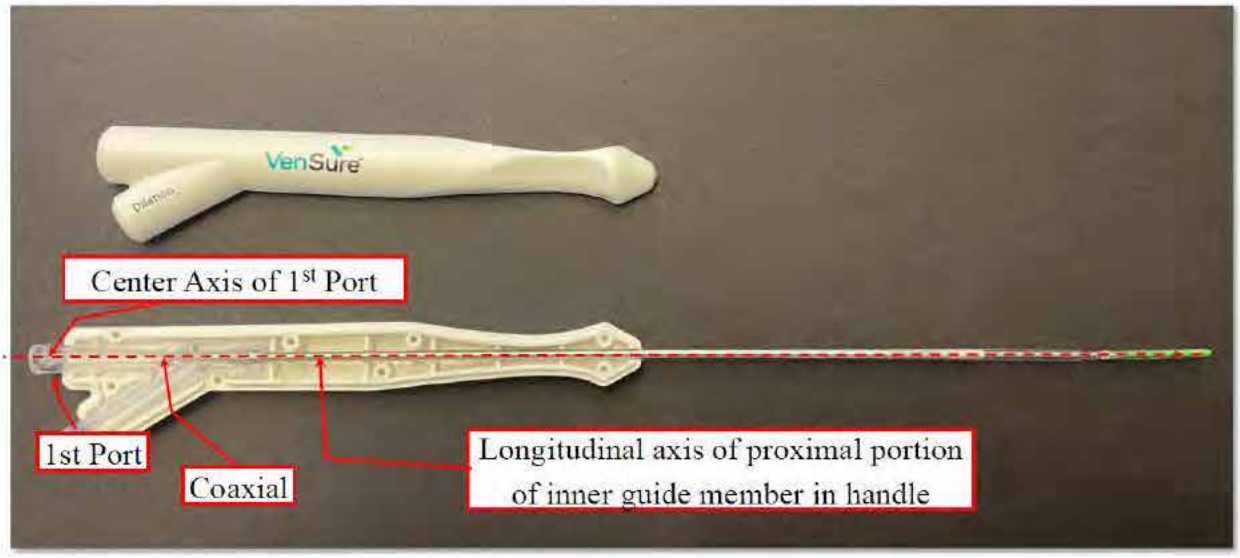
[redacted]

CDX-1.2C.18, citing CX-613C.60; Tr. (Griffis) at 342:10–345:1; and JX-134.10C.2.

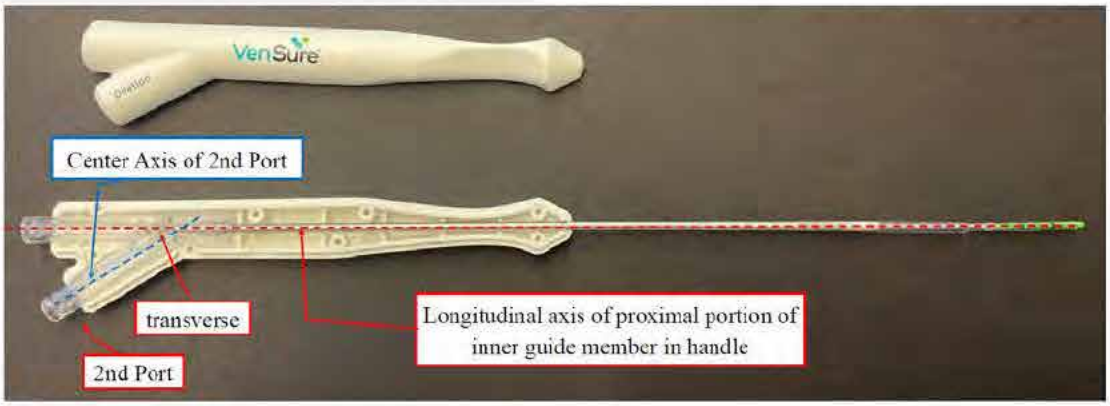
Fiagon's dispute regarding these claim elements is an extension of the argument it made regarding the handle and ports with respect to element 1[b] of the '878 patent. In particular, Fiagon argues that if "something becomes part of the handle merely because it is attached to the or held in place by the handle, then the inner hypotube [of the accused products] is part of the handle and cannot 'extend distally' from itself." Fiagon Reply at 20. I agree with Stryker that this argument is nonsensical and inconsistent with the specification, which shows the inner guide member within the handle and extending from it. *See*, for example, Figs. 3B and 4 of the '878 patent. Moreover, there is no support in the claim language or in the specification that the portion of the inner guide member that extends distally from the handle is part of the handle. The evidence supports that the VenSure devices meet these claim elements.

Element 1[c] of the '878 patent further recites "wherein the first port is in fluid communication with the lumen at the proximal end of the inner guide member." Stryker contends this element is met. Stryker Br. at 66–70. Fiagon does not dispute that this element is met. Fiagon Statement at 3. The evidence supports that the first port of the VenSure devices is in fluid communication with the lumen at the proximal end of the inner hypotube. Tr. (Griffis) at 343:10–348:1; JX-134.10C.2, 6, and 8; CX-613C.50; and CX-614C.14–15. The evidence supports that a sterile saline or water-filled syringe can be connected to the first port to irrigate through the balloon. JX-136C.6 and 8. The evidence supports that the VenSure devices meet this portion of element 1[c] of the '878 patent.

Elements 1[h] and 1[i] of the '878 patent respectively recite "wherein a center axis of the first port is coaxial with a longitudinal axis of the proximal portion of the inner guide member in the handle[]" and "wherein a center axis of the second port is transverse to the longitudinal axis of the proximal portion of the inner guide member in the handle." Stryker contends that these elements are met. Stryker Br. at 80–82. Fiagon does not dispute that these elements are met. Fiagon Statement at 3. As to element 1[h], the evidence supports that the center axis of the first port is coaxial with the longitudinal axis of the proximal portion of the inner guide member, as shown in the annotated image below:



CDX-1.2C.43, citing CX-613C.60; Tr. (Griffis) at 356:22–358:5. As for element 1[i], the evidence supports that the center axis of the second port is transverse to the longitudinal axis of the proximal portion of the inner guide member in the handle, as shown in the annotated image below:



CDX-1.2C.46, citing CX-613C.60; Tr. (Griffis) at 358:6–360:23; and JX-134.20C.3. The evidence supports that elements 1[h] and 1[i] of the '878 patent are met by the VenSure accused products.

Element 1[k] of the '878 patent recites "wherein the inner guide member comprises a hypotube formed from stainless steel." Element 1[e] of the '847 patent recites "wherein the inner guide member is a stainless steel hypotube." Stryker contends these elements are met. Stryker Br. at 86–87 ('878 patent element 1[k]) and 267 ('847 patent element 1[e]). Fiagon does not dispute

'878 patent element 1[k] but does dispute '847 patent element 1[e]. Fiagon Statement at 3, 6 and Fiagon Reply at 106–07.

The evidence supports that the inner hypotube, which Stryker points to as the claimed inner guide member, is a hypotube formed from stainless steel. Tr. (Griffis) at 363:16–365:17; JX-157C.67 (510(k)); and JX-134.5C. The evidence thus supports that element 1[k] of the '878 patent is met by the accused VenSure products.

For element 1[e] of the '847 patent, Fiagon disputes that this element is met based on Stryker's argument that the hypotube includes a PEBAX jacket for purposes asserting infringement of claims 10 and 11, which recite that the inner guide member comprises a bulbous tip (claim 10) and its dimensions (claim 11). Fiagon Reply at 106. Element 1[e] of the '847 patent recites "wherein the inner guide member is a stainless steel hypotube." Fiagon argues that this requires the entire inner guide member, including the bulbous tip of claims 10 and 11, to be stainless steel and only stainless steel. *Id.* at 106–07. The claim language does not support Fiagon's argument. While claim 1 recites that the inner guide member "is" stainless steel, claim 10 recites that the inner guide member "comprises" an additional element, namely a bulbous tip. The "is" language of claim 1 does not necessarily limit the material of the bulbous tip additionally recited in claim 10. The evidence supports that element 1[e] of the '847 patent is met by the accused VenSure products.

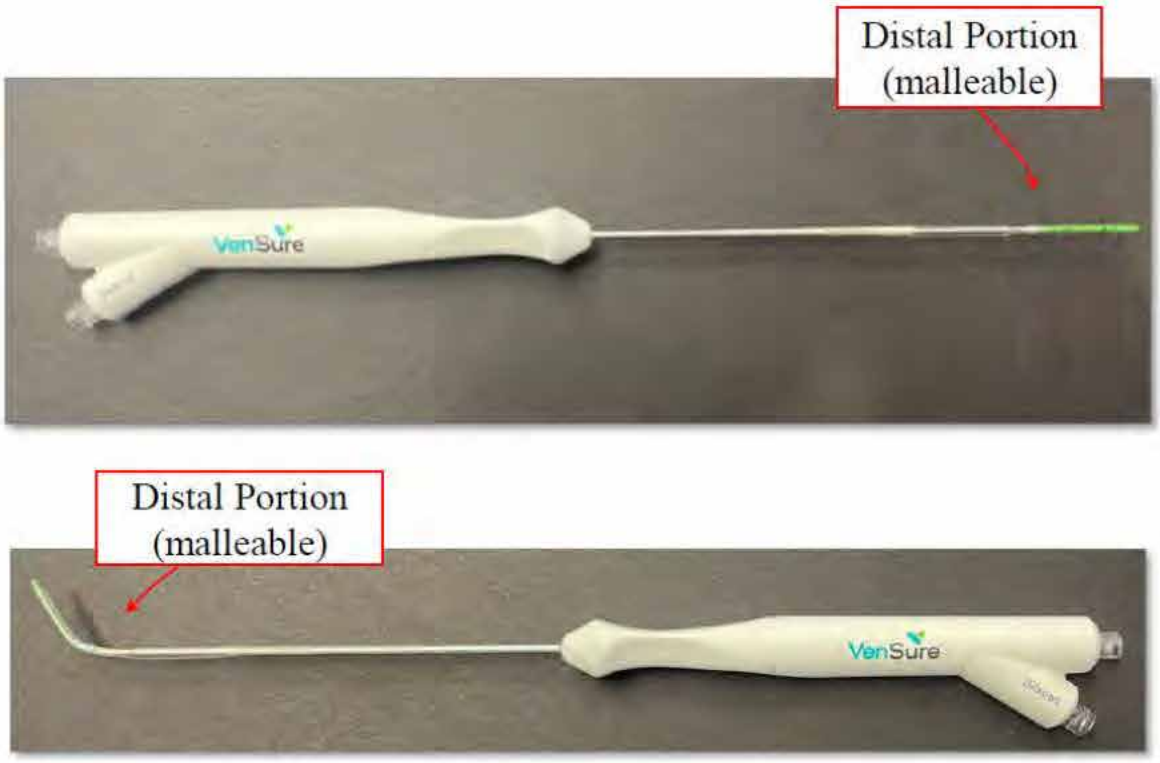
Element 1[j] of the '847 patent recites "wherein the inner guide member has an inner diameter in a range of about 0.508 mm (0.02 inch) to about 1.27 mm (0.05 inch) and a wall thickness between about 0.2032 mm (0.008 inch) to about 0.3048 mm (0.012 inch)." Stryker contends this element is met. Stryker Br. at 283–285. Fiagon does not dispute that this element is met. Fiagon Statement at 6. The evidence (engineering drawings and Mr. Griffis's measurements)

supports that the inner diameter of the inner guide member is approximately 0.033 inches and the wall thickness is approximately 0.009 inches, which fall within the recited dimensions. Tr. (Griffis) at 439:22–440:23; JX-134.3C.2 (engineering drawing); and CDX-1.2C.193. The evidence supports that element 1[j] of the '847 patent is met by the accused VenSure products.

b) Malleable/Bendable

Element 1[j] of the '878 patent recites "wherein the distal portion of the inner guide member is malleable." Element 22[i] of the '878 patent recites "forming a bend in the inner guide member at a location that is distal to a distal end of the support member to change a shape of the inner guide member." Elements 1[g] and 1[h] of the '472 patent recite "wherein a distal end of the support member is located proximal to a bend in the inner guide member" and "wherein the inflatable balloon is inflatable with the inflatable balloon extending along the bend in the inner guide member." Element 1[d] of the '847 patent recites "wherein the distal portion of the inner guide member is malleable such that the distal portion of the inner guide member is configured to be shaped with an angle of 0 degrees to 120 degrees relative to the proximal portion of the inner guide member." Stryker contends these elements are met. Stryker Br. at 82–86 ('878 patent element 1[j]), 116–22 ('878 patent element 22[i]), 242–49 ('472 patent elements 1[g] and [h]), and 263–67 ('847 patent element 1[d]). Fiagon does not dispute any of these elements. Fiagon Statement at 3–6.

The evidence supports that a distal portion of the inner hypotube (the inner guide member) is malleable, as shown below:



Tr. (Griffis) at 360:25–361:13; CDX-1.2C.50 (above top: VenSure, VenSure Light, and VenSure Nav and above bottom: VenSure ET); CX-613C.11, 74, 80, and 81 (VenSure); and CX-616C.13 (VenSure ET). The component specifications for the hypotube show it is annealed to make it readily bendable. Tr. (Griffis) at 361:14–362:7 and JX-134.5C. The evidence supports that the VenSure ET is sold with a bend in the inner guide member that is located proximal to the distal end of the support member. Tr. (Griffis) at 414:7–415:1; CX-616C.13. For the VenSure, VenSure Light and VenSure Nav devices, the evidence supports that they are designed to be bent and are bent by users such that the bend is proximal to the distal end of the support member and that Fiagon provides instructions to do so using the bending tool. Tr. (Griffis) at 415:2–417:9 CX-613C.80; JX-136.1C.7; and JX-157C.133. Mr. Griffis also testified that Fiagon quality engineers bend the inner guide member during testing. Tr. (Griffis) at 417:10–418:16; CX-1020C.2; and CX-1084C.2. The instructions for use also refer to the malleability of the hypotube. Tr. (Griffis) at 362:8–22;

JX-136.1C.2; and JX-136.2C.2. Mr. Griffis also testified that he bent the distal portion of the hypotube. Tr. (Griffis) at 362:23–363:10. The evidence thus supports that '878 patent element 1[j], '472 patent element 1[g], and the portion of '847 patent element 1[d] reciting, "wherein the distal portion of the inner guide member is malleable," are met.

As to the remainder of element 1[d] of the '847 patent, the evidence supports that the bending tool allows the distal portion of the hypotube to be shaped at an angle from 0 to 135 degrees. *Id.* at 425:20–426:13 and JX-157C.84. Fiagon instructions also show the bending angles on the bending tool for targeted sinuses, as shown below:

28. Insert the distal tip of the device into the desired bending slot of the bending tool

NOTE: The Balloon is delivered in a straight bend configuration, and it is recommended to complete the balloon dilation of the sphenoid and/or frontal sinus(es) before the treatment of the maxillary sinus(es).

NOTE: The VenSure® tip can be shaped a maximum of eight (8) times.

NOTE: The bending angles of the bending tool are as follows:

Straight	0°	**Sphenoid**	12.5°	**Frontal**	80°	**Maxillary**	110° **or** 130°	**Eustachian Tube**	45°

29. While holding the bending tool in one hand, grab the metal shaft of the VenSure®, closest to the bending tool edge, and begin to bend downwards until the desired angle is achieved. The balloon tip is shaped/bent according to the target sinus and the Eustachian tube using the supplied Bending Tool. If the angle is too acute, the user may stop the bend before reaching the full bend on the Bending Tool.



Tr. (Griffis) at 426:18–427:25 and JX-136.1C.7. This supports that the requirement in element 1[d] of the '847 patent that "the distal portion of the inner guide member is configured to be shaped with an angle of 0 degrees to 120 degrees relative to the proximal portion of the inner guide member" is met.

As to element 22[i] of the '878 patent and the VenSure, VenSure Light, and VenSure Nav, the evidence supports that users use the packaged bending tool to bend the inner guide member to the desired angle because all sinuses require bending to access the sinuses without injury to the patient. Tr. (Griffis) at 391:9–396:12 (users bend the distal end of the inner guide member during procedures to access sinuses in a minimally invasive way); *see also* JX-136.1C.4 and 7 (instructing

users to bend the tip at specific angles for each sinus cavity); JX-136.2C.3–5; JX-157C.133 (501(k)), CX-613C.80. The evidence supports that Fiagon instructs users to advance the inner guide member to a target location, and users do so to treat patients. Tr. (Griffis) at 396:13–397:17; *see also* JX-136.1C.8 and JX-136.2C.5 (instructing users to advance the device to position the balloon within a target).

Element 1[g] of the '472 patent recites "wherein a distal end of the support member is located proximal to a bend in the inner guide member[.]" Stryker argues that this element is met in the VenSure ET because it is sold with a bend in the inner guide member. Stryker Br. at 242, Tr. (Griffis) at 414:7–415:1, and CX-616C.13. There is no dispute, and the evidence supports this is the case. As for the VenSure, VenSure Nav, and VenSure Light, Stryker the evidence supports that each device is sold without a bend and is modified by a user with the accompanying bending tool when performing a dilation procedure. Stryker Br. at 243–47. Stryker cites the same evidence discussed above to argue that Fiagon directly infringes during quality assurance, and physicians and healthcare providers directly infringe when they form a bend by following the instructions for use. *Id.* As Mr. Griffis explained, if a bend is not formed, the patient may be injured. Tr. (Griffis) at 395:21–396:12. This is not disputed by Fiagon. The evidence supports that this element is met.

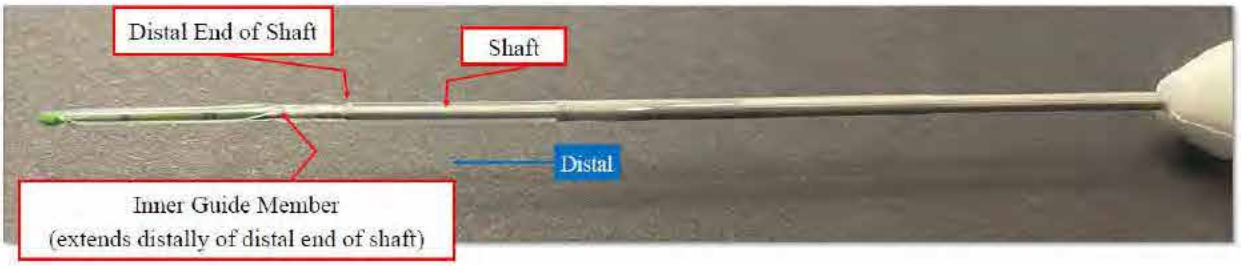
The evidence supports that '878 patent elements 1[j] and 22[i], '472 patent elements 1[g] and 1[h], and '847 patent element 1[d] are met.

4. Shaft/Polymeric Shaft

Element 1[d] of the '878 patent, element 22[f] of the '878 patent, and element 1[d] of the '472 patent recite: "a shaft mounted about a periphery of the inner guide member, wherein a portion of the inner guide member extends distally of a distal end of the shaft." Stryker contends that these elements are met. Stryker Br. at 70–73 ('878 patent element 1[d]), 116 ('878 patent

element 22[f]), 240 ('472 patent element 1[d]). Fiagon does not dispute that these elements are met. Fiagon Statement at 3–5.

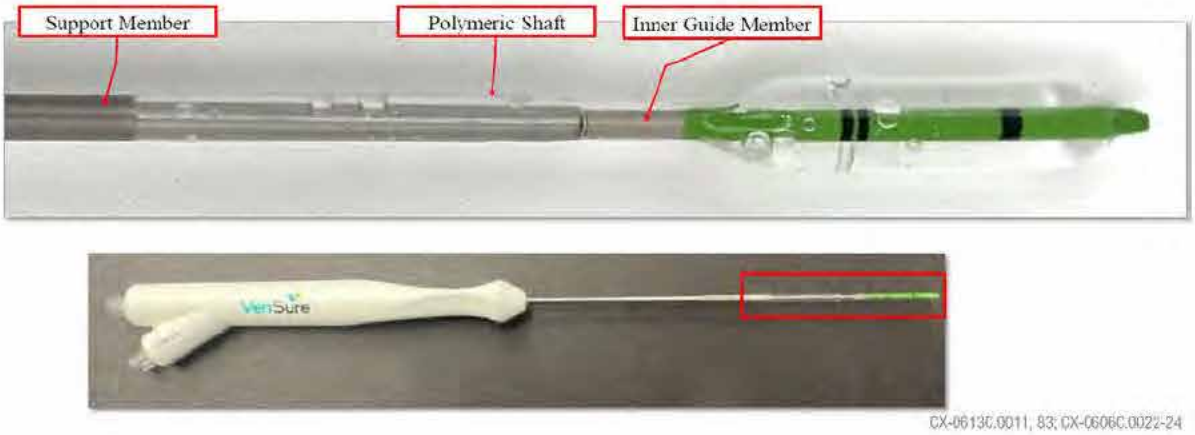
The evidence supports that the intermediate hypotube component of the VenSure devices is a shaft. It is mounted about the periphery of the inner hypotube (the inner guide member) and a portion of the inner hypotube extends distally of the distal end of the shaft, as shown below:



Tr. (Griffis) at 348:4–349:17, 386:21–388:8, and 410:6–412:1; CX-613C.13; and JX-134.10C.1–2. The evidence supports that these elements are met.

Element 1[f] of the '847 patent recites "a polymeric shaft mounted about a periphery of the inner guide member." Stryker contends that this element is met. Stryker Br. at 268–275. Fiagon disputes that this element is met. Fiagon Reply at 78–96 and Fiagon Statement at 6.

Stryker points to a polymeric structure between a support member (on the left) and a balloon (on the far right) and situated around the periphery of the inner guide member, as shown below:



CX-0613C.0011; 83; CX-0606C.0022-24

CDX-1.2C.177, citing CX-613C.11 and 83 and Tr. (Griffis) at 429:9–25. The evidence supports that the polymeric structure provides a lumen for inflation liquid to travel into the balloon. Tr. (Griffis) at 429:12–19.

The evidence supports that Fiagon has used two different structures, [redacted] Tr. (Griffis) at 355:3–19, 430:1–22; JX-134.13C.1 ("Outer Tubing Bump Extrusion"); and JX-134.17C ("Extended Leg Balloon"). The evidence supports that each of these structures are part of the balloon of the VenSure devices. [redacted] Fiagon Reply at 85, citing Tr. (Norman) at 704:21–706:4 and Tr. (Burton) at 1023:8–1024:4 and 1024:15–1025:4. Dr. Burban showed the extended leg and bump extrusion below:



RDX-25C.233, citing JX-135.6C.5 (manufacturing description, upper photo) and JX-135.4C.11 (manufacturing process instructions, lower photo). Fiagon contends that neither the extended leg

nor the bump extrusion can be the claimed "polymeric shaft" because both are part of the balloon, which is a separately claimed structure. *See* Fiagon Reply at 85–89.

Claim 1 of the '847 patent recites "a polymeric shaft mounted about a periphery of the inner guide member" and "an inflatable balloon coupled to the polymeric shaft and disposed about the inner guide member." Fiagon argues that because the components Stryker points to are part of the balloon, they cannot be the separately recited polymeric shaft.

Mr. Griffis testified that the component he identified (the extended leg or bump extrusion) is proximal to the balloon and not part of the balloon. *Id.* at 430:23–431:11 ("the balloon in the claim language is the inflatable element within the device. And, therefore, the proximal section which is the polymeric shaft mounts at about a periphery of the inner guide member is not a balloon"). Mr. Griffis further testified that the portion he identified as the shaft does not inflate like a balloon and is not the dilation component of the device; that is the balloon. Mr. Griffis testified:

> Well, the balloon is the component that's meant to be inflated. So when the balloons are formed, they are formed using what's called blow-molding process. And so you start with an elongate tubular plastic structure, and then what you do is you place it in a mold, and then you pressurize it, you stretch it out. Then there's a component of it that forms into a much larger diameter, in this case that is the balloon component, and it becomes a much thinner wall in construction, and that allows it to be wrapped into a low profile in the device, while it's inserted into the patient. And when it's pressurized with fluid, it then inflates and becomes the dilation component of the device. In this case the polymeric shaft that's mounted about a periphery of the inner guide member does not do those things.

Id. at 431:19–432:10.

Dr. Burban testified that the extended leg and bump extrusion are each part of the same structure as the balloon and therefore cannot be the claimed polymeric shaft. Tr. (Burban) at 1022:19–22 ("the claim is disclosing two separate structures, and in the case of the alleged polymeric shaft and inflatable balloon, they are one single structure, and, therefore, they cannot

infringe"). Dr. Burban also testified that he performed an experiment in which the balloon was inflated with colored water and then measured. He determined that the fluid went into what was identified as the claimed polymeric shaft and was somewhat inflated. Tr. (Burban) at 1025:7–1027:5; RX-381 (inflated measurement of 2.61 mm); and RX-383 (initial measurement of 1.96 mm). Stryker responds that Dr. Burban's test was not reliable because Dr. Burban squeezed the shaft with calipers so that the measurement post-inflation was artificially increased. Stryker Br. at 273–275. Stryker also notes that the instructions for use of the VenSure products and Fiagon's 510(k) submission to FDA both separately identify the balloon and balloon shaft:

Balloon dimensions	Diameter - 6mm Length - 18mm
Balloon Shaft Dimensions	Working Length – 145mm Distal Tip Diameter – 1.81mm Proximal Shaft Diameter – 2.4mm Malleability Region – 40mm

Balloon dimensions	**Diameter:** 6mm **Length:** 18mm
Balloon Shaft Dimensions	**Working Length:** 145mm **Distal Tip Diameter:** 1.81mm **Proximal Shaft Diameter:** 2.4mm **Malleability Region:** 40mm

JX-136.1C.2 (instructions for use, left) and JX-158C.78 (510(k), right). In addition, data on inflation testing of the VenSure balloon provided to FDA did not include data on the balloon shaft. JX-158C.183.

Claim 1 of the '847 patent separately recites "a polymeric shaft mounted about a periphery of the inner guide member" and "an inflatable balloon coupled to the polymeric shaft." Where a claim lists elements separately, "the clear implication of the claim language is that those elements are distinct components of the patented invention." *Becton, Dickinson and Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (internal quotations and citations omitted). Based on *Becton*, the Federal Circuit has articulated a presumption that separately recited claim elements are separate components. *Kyocera Senco Industrial Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1382 (Fed. Cir. 2022) (presumption that separately listed components are distinct); *Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049, 1058 (2024) ("[W]e have explained that there is a 'presumption' that separately listed claim limitations may indicate separate and distinct physical

structure, but that presumption may always be rebutted in the context of a particular patent."). The Commission has considered this presumption as well. *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof*, Inv. No. 337-TA-1368, Comm'n Op. at 81–87 (Feb. 19, 2025) (EDIS Doc. ID 843889). Because claim 1 of the '847 patent separately recites the polymeric shaft and the balloon and recites that they are "coupled," the *Becton* presumption applies. The question, therefore, is whether it has been overcome.

Stryker contends that "the polymeric shaft is not a balloon, but a separate structure with a different size, shape, location, and purpose." Stryker Br. at 270. The evidence supports that the extended leg and bump extrusion have a different size, shape, location, and purpose from the portion of the balloon that is used for dilation. The evidence does not support that the extended leg and bump extrusion are separate structure from the balloon. Instead, the evidence supports that they are part of the overall balloon structure. Indeed the instructions for use and the FDA 510(k) relied on by Stryker confirm this, calling the extended leg and bump extrusion the "balloon shaft." JX-136.1C.2 and JX-158C.78. The evidence does not support that the extended leg and bump extrusion are separate structure from the overall balloon.

In *Certain Vaporizer Devices*, the Federal Circuit considered whether disclosure in the specification supported that the *Becton* presumption was overcome. There, the claim separately recited a mouthpiece and a storage component. Because the specification disclosed that the mouthpiece and storage component could be part of the same component, the Commission rejected the argument that the patent "repeatedly and exclusively discloses a mouthpiece that is a separate component from the storage chamber" and found that the *Becton* presumption was overcome.

The '847 patent discloses that "balloon 36 is mounted on the shaft 30 so as to form a fluidic seal between the two components. The balloon 36 may be bonded to the shaft using a weld,

adhesive, or the like. Alternately, the balloon 36 may be secured to the shaft using a mechanical connection. Generally, any technique known to those skilled in the art may be used to secure to the balloon 36 to the shaft 30." '847 patent at 6: 6:15–21. The specification further discloses that "[b]oth the shaft 30 and the balloon 36 are preferably formed of high strength but flexible polymeric materials such as polyamides (e.g., Nylon), PEBAX or the like. The balloon 36 may be 'blow molded' to a relatively thin wall thickness, and capable of holding relatively high pressures from about 6 atmospheres to about 20 atmospheres of inflation pressure. The balloon 36 is inflated using a fluid which is typically a liquid such as water or saline. *Id.* at 6:30–38. The specification also discloses that inflation lumen 48 is part of the shaft 30 such that the inflation fluid passes through port 38 into lumen 48 of shaft 30 and into the interior of the balloon 36. *Id.* at 6:52–62 and Figs. 5A and 5B.

The specification supports that the balloon and shaft may be made of the same material joined together by known techniques, including by bonding or welding. This disclosure supports that the polymeric shaft and balloon can be separate parts of the same overall structure, thus overcoming the *Becton* presumption. Accepting Fiagon's arguments that the extended leg and bump extrusion in the VenSure devices are part of the overall balloon, the specification supports that such structures may correspond to the claimed polymeric shaft. This is further supported by the function the extended leg and bump extrusion perform as a fluid lumen for the balloon, the same as the shaft 30 (including lumen 48) in the patent. The evidence supports that element 1[f] of the '847 patent is met.

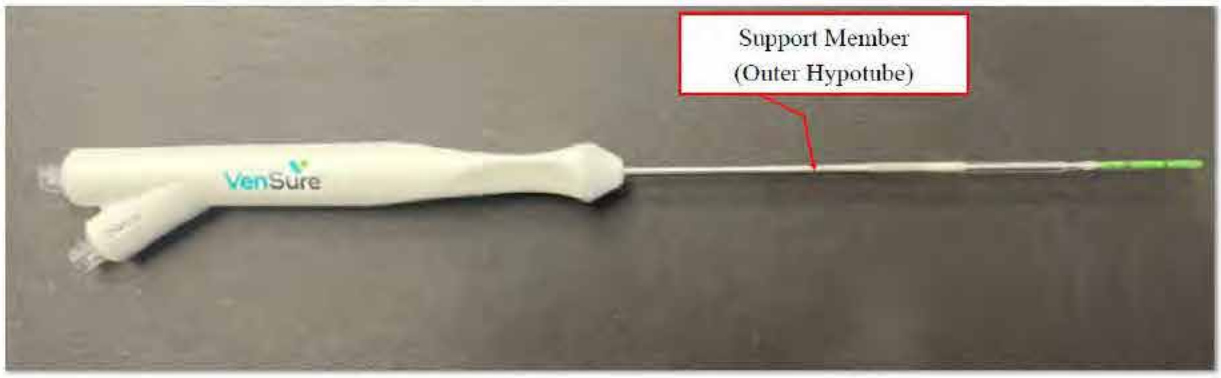
Element 1[h] of the '847 patent recites "wherein the inner guide member has a rigidity that is greater than a rigidity of the polymeric shaft." Stryker contends that this element is met. Stryker Br. at 280–281. Fiagon does not dispute that this element is met. Fiagon Statement at 6. The

evidence supports that the inner guide member of the VenSure devices is made of steel, the polymeric shaft is made of a polymer, and the inner guide member has a greater rigidity than the polymeric shaft. Tr. (Griffis) at 435:10–438:3; *see also* JX-134.5C (hypotube); JX-134.17C (extended leg); JX-134.14C (bump extrusion); and CX-619C.5 (simulation report). The evidence supports that this element is met.

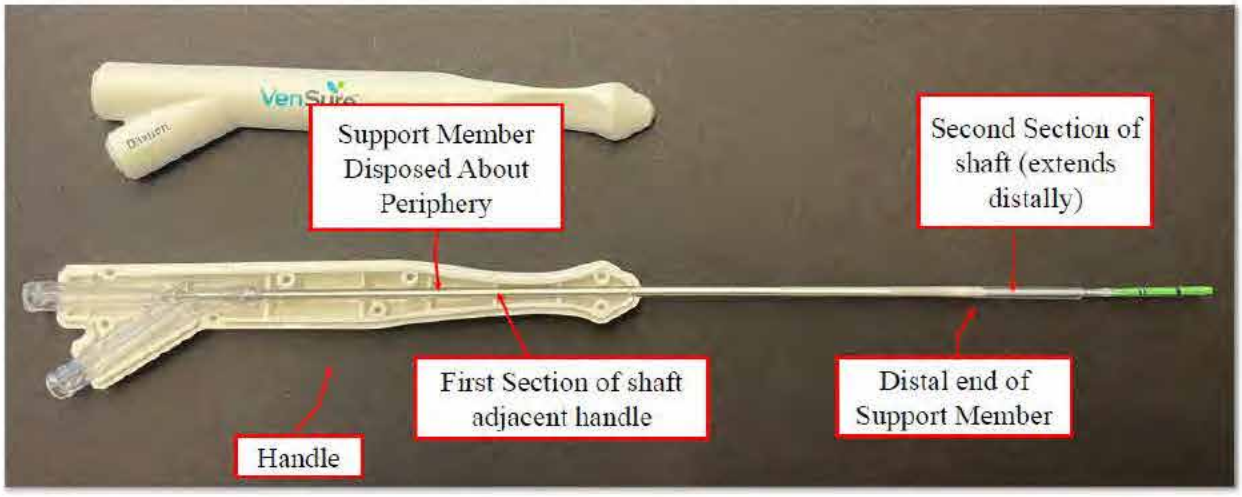
5. Support Member

Element 1[e] of the '878 patent recites "a support member defining a tube that is disposed about a periphery of a first section of the shaft, wherein the first section of the shaft is adjacent to the handle, wherein a second section of the shaft extends distally from a distal end of the support member." Element 22[g] of the '878 patent recites "a support member comprising a tube that is disposed about a periphery of a first section of the shaft, wherein the first section of the shaft is adjacent to the handle, wherein a second section of the shaft extends distally from a distal end of the support member." Element 1[e] of the '472 patent recites "a support member defining a tube that is disposed about a periphery of the shaft, wherein the support member has a length that extends along at least a portion of the shaft." Stryker contends these elements are met. Stryker Br. at 73–75 ('878 patent element 1[e]), 116 ('878 patent element 22[g]), and 240–42 ('472 patent element 1[e]). Fiagon does not dispute that these elements are met. Fiagon Statement at 3–5 and *see generally* Fiagon Reply.

The evidence supports that the VenSure products have an outer hypotube that is a support member, as shown below:



Tr. (Griffis) at 350:13–352:17, 388:9–390:14, and 412:2–413:5; CDX-1.2C.3, annotating CX-613C.11. The outer hypotube is disposed about the intermediate hypotube (shaft) where the shaft is adjacent to the handle and extends distally from the outer hypotube, as shown below:



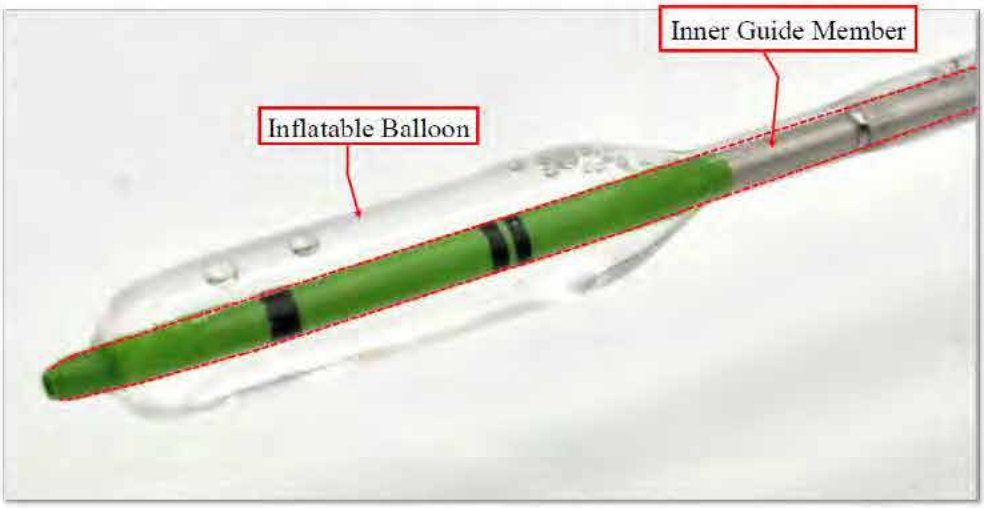
CDX-1.2C.34, annotating CX-613C.60; JX-157C.68; and *see* CDX-1.2C.95, 97, 139, and 140. The evidence supports that these elements are met.

6. Balloon and Inflation Lumen

Elements 1[f] and 22[h] of the '878 patent and element 1[f] of the '472 patent recite "an inflatable balloon disposed about the inner guide member." Stryker contends these elements are met. Stryker Br. at 75–78 ('878 patent element 1[f]), 116 ('878 patent element 22[h]), and 242

('472 patent element 1[f]). Fiagon does not dispute that these elements are met. Fiagon Statement at 3–5.

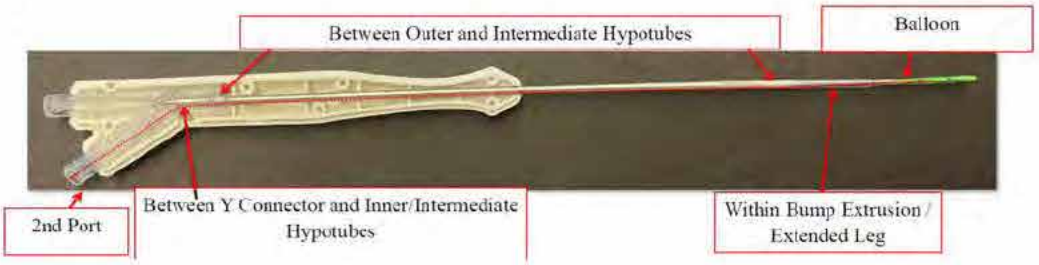
The evidence supports that the inflatable balloon in the VenSure devices is disposed about the inner hypotube (inner guide member). Tr. (Griffis) at 352:18–354:20, 390:15–391:8, and 413:6–24. The annotated image below of a VenSure device shows an inflatable balloon:



CDX-1.2C.36, annotating CX-613C.78; JX-134.17C and *see* CDX-1.2C.99 and 142. The evidence supports that these elements are met.

Element 1[g] of the '878 patent recites "an inflation lumen extending from the second port of the handle to the inflatable balloon." Stryker contends this element is met. Stryker Br. at 78–80. Fiagon does not dispute this element is met. Fiagon Statement at 3.

The evidence supports that an inflation lumen is formed by the space on the interior of the Y-connector between the outer and intermediate hypotubes, extending to the balloon, as shown below:



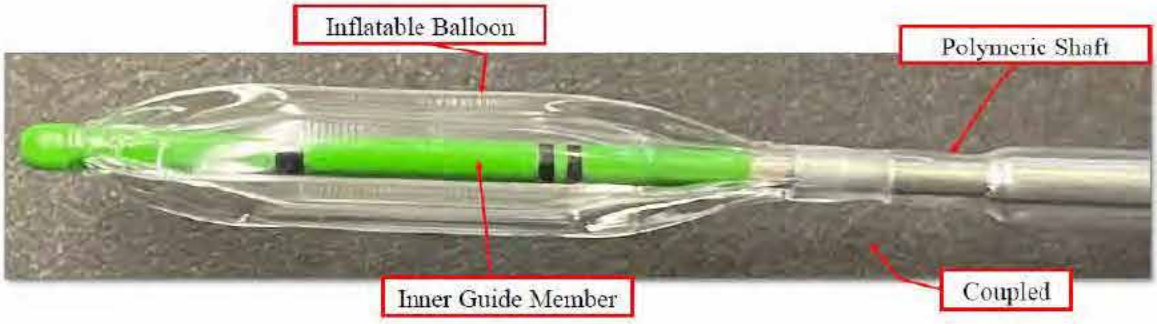
Tr. (Griffis) at 354:21–356:21; CDX-1.2C.40, annotating CX-613C.48. The evidence supports that this element is met.

Element 1[g] of the '847 patent recites "an inflatable balloon coupled to the polymeric shaft and disposed about the inner guide member." Stryker contends this element is met. Stryker Br. at 276–80 ('847 patent element 1[g]). Fiagon disputes that this element is met. Fiagon Statement at 3–6 and Fiagon Reply at 96–99. Fiagon incorporates by reference the arguments it made for element 1[f] of the '847 patent, namely that the extended leg and bump protrusion in the VenSure devices are part of the balloon and thus the VenSure devices do not have a separate polymeric shaft and balloon as claimed. Fiagon Reply at 96 and 97 (incorporating arguments by reference). if the inner guide member includes the PEBAX jacket at the distal end, the balloon is not disposed about the inner guide member because the PEBAX jacket is part of the balloon. Fiagon Reply at 22. For the same reasons discussed with respect to '847 patent element 1[f], the *Becton* presumption has been overcome and the evidence supports that the different portions of the overall balloon structure meet the claimed polymeric shaft and inflatable balloon.

Fiagon argues that the polymeric shaft cannot be part of the overall balloon because the claim recites that the balloon is coupled to the polymeric shaft and the "balloon cannot be 'coupled' to itself." Fiagon Reply at 98–99. Fiagon relies on *Cutsforth, Inc. v. Moviepower, Inc.*, 643 Fed. App'x 1008 (Fed. Cir. 2016). Fiagon Reply at 99. There, the "claims-at-issue recite[d] 'a brush catch coupled to the beam.'" *Id.* at 1012. The PTAB found that the brush catch could be a sub-

component of the of the beam and be coupled to beam. The Federal Circuit disagreed, stating that the brush catch had "to be a physical structure that is separate from, and not a sub-component of, the claimed 'beam.' *Id.* The court reasoned that it "goes beyond the plain meaning of 'coupled' to say that a sub-component (e.g., an engine in a car) is 'coupled to' the component as a whole (e.g., the car)" and that "[n]o evidence shows that the inventors intended to deviate from the plain meaning of 'coupled to.'" *Id.* at 1012–1013. Here, the specification supports that the shaft and ballon can be part of the same overall structure because they may be bonded together by, for example, an adhesive or weld. The meaning of "coupled" in the claim must be considered in that context. "Because the components of the preferred embodiment . . . are permanently attached, [Fiagon's] proposed 'structurally separate' limitation to mean that an infringing [device] must be assembled from what was once [two] (structurally separate) parts" is rejected. *Colassi v. Cybex, Int'l, Inc.*, 221 Fed. App'x 973, 975 (Fed. Cir. 2007).

The evidence supports that the VenSure products with the bump extrusion include an inflatable balloon that is coupled, i.e., joined, to the polymeric shaft and disposed about the inner guide member, as shown below:



Tr. (Griffis) at 432:19–434:18; JX-135.3C.5; and JX-134.13C. Dr. Burban agreed that for the VenSure products with the bump extrusion, the components of the balloon, the shaft and the inflatable balloon, are joined together by laser welding, which essentially fuses them together. Tr.

(Burban) at 1023:21–1024:4. As for the VenSure products with the extended leg, the evidence supports that the extended leg and balloon are formed simultaneously by blow molding. Tr. (Griffis) at 434:19–435:6. Because the specification discloses that the shaft and balloon can be made of the same material, "coupled" in the claim does not require that the shaft and balloon be separately manufactured and then later joined together. The evidence supports that both versions of the Fiagon product, with the bump extrusion and the extended leg, meet element 1[g] of the '847 patent.

Element 1[i] of the '847 patent recites "wherein a portion of the inner guide member extends distally of a distal end of the polymeric shaft and a distal end of the inflatable balloon." Stryker contends that this element is met. Stryker Br. at 281–283. Fiagon disputes that this element is met. Fiagon Statement at 6 and Fiagon Reply at –105.

Stryker contends that a portion of the inner guide member of the VenSure devices extends distally of the distal end of the polymeric shaft and a distal end of the inflatable balloon, as shown below:



CDX-1.2C.190, annotating CX-613CC.78 and Tr. (Griffis) at 438:4–24. Mr. Griffis testified that in his opinion, the balloon of the VenSure devices does not extend all the way to the distal tip of

the hypotube and that, instead, a PEBAX jacket, which does not inflate and which forms part of the bulbous tip of the device, surrounds the inner guide member and extends beyond the distal end of the balloon. *Id.* at 438:25–439:15.

Fiagon argues that the inner guide member does not extend beyond the distal end of the balloon because the green PEBAX jacket is part of the balloon. Fiagon Reply at 99–105. Dr. Burban testified that the balloon is laser welded to the PEBAX, making the balloon part of the distal tip. Tr. (Burban) at 1034:6–1035:2. Mr. Griffis persuasively explained, however, that the portion of the PEBAX jacket that extends distally is not inflatable and thus is not part of the claimed "inflatable balloon." Tr. (Griffis) at 439:1–12. Similar to Fiagon's argument on the polymeric shaft, while the PEBAX jacket extends to the distal tip, that portion is not the inflatable balloon, just as the portion proximal of the balloon is the polymeric shaft, not the inflatable balloon. The evidence supports that element 1[i] of the '847 patent is met.

7. Claim 22

a) Additional Elements of Claim 22

Elements 22[j], [k], and [l] of the '878 patent recite:

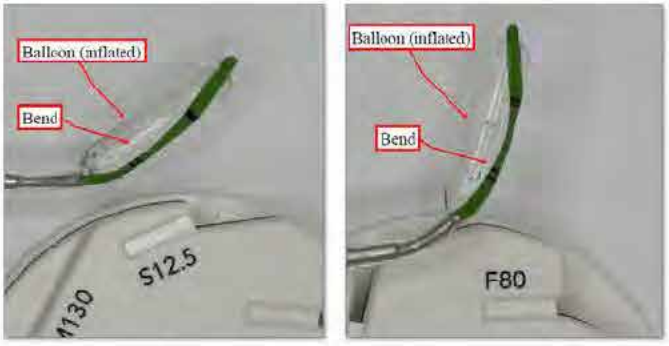
> [j] after forming the bend in the inner guide member, advancing, via a nasal passageway, the inner guide member to a target location in a drainage pathway of a sinus cavity; and
>
> [k] after advancing the inner guide member to the target location, inflating the inflatable balloon to dilate the drainage pathway of the sinus cavity,
>
> [l] wherein inflating the inflatable balloon is performed while the inflatable balloon extends along the bend in the inner guide member.

Stryker contends these elements are met by the VenSure, VenSure Light, and VenSure Nav devices. Stryker Br. at 122–126. Fiagon does not dispute that these elements are met. Fiagon Statement at 4 and Fiagon Reply at 32–36.

The evidence supports that Fiagon instructs users to advance the device forward to position that balloon within the target structure, which are drainage pathways for a sinus cavity. Tr. (Griffis) at 396:24–397:12; JX-136.1C.8; and JX-136.2C.5. The evidence supports that users perform the step of advancing in all procedures with the VenSure devices because unless the balloon is advanced to the target site, no dilation can occur. *Id.* at 397:13–17.

The evidence supports that Fiagon instructs users to inflate the balloon to dilate the drainage pathway. Tr. (Griffis) at 397:18–398:15; JX-136.1C.8; and JX-136.2C.5 (instructing users to inflate the balloon once advanced to the target). The evidence supports that users perform the step of inflating the balloon in all procedures with the VenSure device because "inflating the balloon is how you achieve dilation." Tr. (Griffis) at 398:16–19

The evidence supports that inflating the inflatable balloon is performed while the inflatable balloon extends along the bend in the inner guide member. Tr. (Griffis) at 398:20–399:11; CX-613C.92–93; JX-299C (Norman Dep.) at 203:10–25. Mr. Griffis testified that he inflated the balloon in various samples verified that the balloon "actually inflates along the bend in the inner guide member," as shown below:



Tr. (Griffis) at 399:5–11 and CX-613C.92–93.

The evidence supports that elements 22[j], [k], and [l] are met.

b) Evidence of Direct Infringement

Fiagon contends that Stryker fails to cite evidence that Fiagon itself has practiced method claim 22 using any accused product and that Stryker's expert instead focused on clinicians and third party users. Fiagon Reply at 33–34. To assess infringement of a method claim, however, it is sufficient to establish direct infringement by someone, not necessarily the accused party. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2015) (explaining that "inducement liability may arise 'if, but only if, [there is] . . . direct infringement.'"), citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961) (alteration in original). Substantial evidence supports that users of Fiagon's products, consistent with the instructions provided to them by Fiagon, have performed the method steps recited in claim 22 and Fiagon does not seriously contend otherwise. Videos provided by Fiagon demonstrate use of the VenSure devices to perform sinus dilation with a bend already formed at the distal end of the device, being advanced to a target location, and with a ballon used for dilation which is inflated along the bend of the inner guide member. Tr. (Griffis) at 404:14–405:14; CX-1036; CX-1075; and CX-73C.16. The evidence supports direct infringement of method claim 22.

c) Vicarious Liability

Stryker argues that Fiagon has "directly infringed method claim 22 vicariously by providing the VenSure, VenSure Light, and VenSure Nav to a number of users who are controlled by Respondents by express agreement to use the products in accordance with the IFUs to practice the claimed method." Stryker Br. at 106–08. This is disputed by Fiagon. Fiagon Reply at 33–36.

As an initial matter, I disagree with Fiagon that Stryker waived a vicarious liability argument by not raising it in its prehearing brief. Fiagon Reply at 34. While Stryker did not use the words "vicarious" or "vicariously liable," Stryker argued that:

> Respondents have also directly infringed method claim 22 by selling or providing the VenSure, VenSure Light, and VenSure Nav to users, such as physicians and health care providers, who are controlled by Respondents by express agreement to use the VenSure, VenSure Light, and VenSure Nav in accordance with the IFUs to practice the claimed method.

Stryker Prehearing Br. at 118. By arguing that physicians and health care providers controlled by Respondents perform the claimed method, Stryker made the vicarious liability argument. Stryker also cited in its prehearing brief the same exhibits it cites in post-hearing brief. *Compare id. with* Stryker Br. at 107–08 (both citing CX-1115C, CX-1073C, CX-1074C, CX-1097C, CX-1098C, CX-1124C, CX-1108C, and CX-1112C). This is more than "a single, vague reference to 'control' without further elaboration." Fiagon Reply at 34. Stryker did not waive this argument.

For an alleged infringer to be vicariously liable, the acts of a second party must be attributable to the alleged infringer. *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l Inc.*, 631 F.3d 1279, 1286 (Fed. Cir. 2011). This typically occurs if the alleged infringer "acts through an agent (applying traditional agency principles) or contracts with another to perform one or more steps of a claimed method." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022–23 (Fed. Cir. 2015) (en banc). Vicarious liability "can also be found when an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance." *Id.* at 1023. *Centillion* and *Akamai* provide two data points for the kind of customer behavior that will or will not be sufficient for a seller to be vicariously liable. In *Centillion*, the evidence showed it was entirely the decision of the customer whether to install and operate software. This was insufficient for vicarious liability. 631 F.3d at 1287. In *Akamai*, the accused infringer performed numerous steps to ensure its customers used their service in an infringing way. That was sufficient for vicarious liability. 797 F.3d at 1024–25.

Here, the evidence shows that [redacted] as shown below:



CX-1115C.2 (evaluation use agreement); *see also* CX-1073C; CX-1074C; CX-1097C; CX-1098C; CX-1108C; CX-1112C; and CX-1124C.

Stryker's vicarious liability arguments fail for two reasons. First, as Fiagon argues, the instructions for use identify a use that is outside the scope of claim 22, namely dilating the Eustachian tube. Fiagon Br. at 35 and JX-136.1C.1 Thus, even if evaluators were contracted to use the device, they may use it for a purpose that does not infringe claim 22. There is no evidence that any of the contracted evaluators actually used any device in an infringing way, and it cannot be presumed that they did so based on the evidence presented. For this additional reason, the evidence does not support vicarious liability with respect to the VenSure, VenSure Nav or VenSure Light.

Second, the evidence does not establish any agreement for the use of the VenSure, only the VenSure Nav and VenSure Light. Fiagon Br. at 35. As Fiagon shows, the evaluation agreements are focused on the VenSure Nav and VenSure Light. *Id.*, citing CX-1073C; CX-1074C; CX-

1097C; CX-1098C; CX-1108C; CX-1112C; CX-1115C; and CX-1124C. For this additional reason, the evidence does not support vicarious liability with respect to the VenSure.

B. '878 Patent Dependent Claims

1. Claim 14

Claim 14 depends from claim 1. Stryker alleges that the VenSure Nav and VenSure Light infringe claim 14. Stryker Br. at 13–14.

a) Element 14[a]

Element 14[a] recites "The balloon dilation catheter of claim 1, further comprising a means for determining a location of the distal end of the inner guide member within at least one anatomic structure." Stryker contends that this element is met. Stryker Br. at 87–100. Fiagon does not dispute this element. Fiagon Statement at 3 and Fiagon Reply at 27–31.

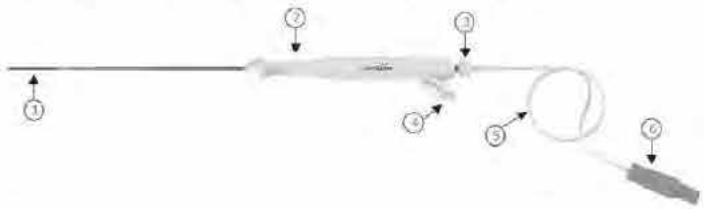
This term was construed as being subject to § 112, ¶ 6 with a function of: determining a location of the distal end of the inner guide member within the at least one anatomic structure; and corresponding structure of: an antenna, transmitter, optical reflectors, emitted light, light fiber, or the like to determine the orientation and/or positioning of the balloon dilation catheter or distal end thereof, and equivalents thereof. Order No. 15 at 27.

The evidence supports that the VenSure Nav has a Sensor Carrier, which determines the location of the distal end of the inner guide member within an anatomic structure and has the structure of an antenna. Tr. (Griffis) at 367:23–369:21 ("the passive electromagnetic sensor has the structure of an antenna"). The instructions for use of the VenSure Nav explain that the Sensor Carrier enables the use of image guidance, as detailed below:

VenSure® Nav Balloon

The VenSure® Nav Balloon device (Figure 3) is a navigation-ready version that is compatible with the Cube Navigation System allowing for image-guided visualization when connected to the Cube Navigation System. The VenSure® Nav contains an integrated sensor carrier that enables the use of image guidance through "plug and play" tracking capability when used with the Cube Navigation System. The sensor carrier detects a signal within a low-energy magnetic field delivered from the navigation unit. The navigation software then displays the location of the balloon device's tip within multiple patient image planes and other anatomic renderings. The sensor carrier is directly integrated into the VenSure® Balloon in the VenSure® Nav version.

Figure 3 VenSure® Nav (Navigation-Ready) Balloon Device



1. Balloon
2. Device Handle
3. Sensor Carrier
4. Balloon Inflation/Dilation Port (luer fitting)
5. Navigation Cable
6. Navigation Connector Plug

Id. at 367:23–368:21; JX-136.1C.3. Mr. Griffis examined a VenSure Nav and confirmed that it contains a sensor coil, which is an antenna. Tr. (Griffis) at 368:22–369:17. Fiagon's 510(k) submission confirms there is a sensor coil that acts as an antenna. *Id.* at 369:18–370:13 and JX-158C.131 (passive sensor coil). The evidence supports that the sensor coil (antenna) determines the location of the distal end of the inner guide member within at least one anatomical structure. Tr. (Griffis) at 370:12–372:21.

The evidence supports that the handpiece of the VenSure Light contains a light fiber attached to a first port, which is used to determine the location of the distal end of the inner guide within an anatomic structure member using transillumination by which the tip of the device can be located by shining a light through the patient's skin. Tr. (Griffis) at 372:23–376:10; JX-158C.77 (510(k), describing lightguide accessory); and JX-136.1C.3. The evidence supports that the VenSure Light performs the claimed function and has the claimed structure. *Id.*

The evidence supports that this element is met by the VenSure Nav and VenSure Light.

b) Elements 14[b], [c], and [d]

Elements 14[b], 14[c], and 14[d] recite:

> [b] wherein the inflatable balloon is adapted to dilate the at least one anatomic structure,
>
> [c] wherein the at least one anatomic structure is selected from a group consisting of: a sinus cavity, a drainage pathway of the sinus cavity, and an ostium of the sinus cavity, and
>
> [d] wherein the sinus cavity is selected from a group consisting of a maxillary sinus cavity, a frontal sinus cavity, an ethmoid sinus, and a sphenoid sinus cavity.

'878 patent at claim 14. Element 14[b] recites that the inflatable balloon is adapted to dilate at least one anatomic structure. The at least one anatomic structure in element 14[b] is identified in Markush[13] format in element 14[c] as a sinus cavity, a drainage passageway of the sinus cavity and an ostium of the sinus cavity (i.e., entrance or opening). The cavities in element 14[c] are further detailed in Markush format in element 14[d] as the maxillary sinus cavity, the frontal sinus cavity, the ethmoid sinus, and the sphenoid sinus cavity. Putting these together, the claim recites that the inflatable balloon is adapted to dilate at least one of (1) the maxillary sinus cavity, the drainage passageway of the maxillary sinus cavity, and the ostium of the maxillary sinus cavity; (2) the frontal sinus cavity, the drainage passageway of the frontal sinus cavity, and the ostium of the frontal sinus cavity; (3) the ethmoid sinus, the drainage passageway of the ethmoid sinus, and the ostium passageway of the ethmoid sinus; and (4) the sphenoid sinus cavity, the drainage passageway of the sphenoid sinus cavity, and the ostium passageway of the sphenoid sinus cavity. Stryker contends that these elements are met. Stryker Br. at 100–05. Fiagon disputes that these elements are met. Fiagon Reply at 27–31. The dispute is whether the claim is limited to a balloon

[13] A Markush claim is a particular kind of claim that lists alternative species or elements that can be selected as part of the claimed invention. *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 (Fed. Cir. 2016). This typically appears in the form: "a member selected from the group consisting of A, B, and C." *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1372 (Fed. Cir. 2005).

dilation catheter with an inflatable balloon adapted to dilate just the specifically identified sinus cavities or whether the device can also be used to dilate other anatomical structures.

There is no dispute that the VenSure Nav and VenSure Light are adapted to dilate at least one of the listed anatomic structures. Tr. (Griffis) at 376:11–377:20; JX-136.1C.1–2 (discussing use of the VenSure to "access and treat the frontal ostia/recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach."). Although Stryker appears to argue otherwise, Stryker Br. at 101–03, its expert, Mr. Griffis, testified that the VenSure Nav and VenSure Light are also adapted to dilate an unlisted anatomical structure, the Eustachian tube. Tr. (Griffis) at 638:6–20 (agreeing that the VenSure Nav and VenSure Light "are also indicated for use in the Eustachian tube in addition to use within the sinuses"); *see also* JX-136.1C.1 (Instructions for Use for VenSure Nav and VenSure Light with an indication for use "[t]o dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in adult patients using a transnasal approach."). The question thus is whether the ability to use the VenSure Nav and VenSure Light to determine a location of the distal end of the inner guide member within and dilate the Eustachian tube in addition to the ability to use them to determine a location of the distal end of the inner guide member within and dilate one of the claimed anatomic structures means that the claim is not infringed.

I agree with Stryker that the "consisting of" language in elements 14[c] and [d] does not make a device that can determine a location of the distal end of the inner guide member within and dilate at least one of the claimed anatomic structures non-infringing because it can additionally determine a location of the distal end of the inner guide member within and dilate other unclaimed anatomic structures. *See* Stryker Br. at 104–05.

In *Amgen*, the Federal Circuit considered a claim reciting "[a] pharmaceutical comprising" with one element requiring a particular weight percentage of diluent selected from a Markush group while other elements, a binder and a disintegrant, were not in Markush format. *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368, 1372 (Fed. Cir. 2020). The Federal Circuit explained that the claim used the "comprising" transitional phrase for the whole claim, which "is the standard transition term used to make clear that the claim does not preclude the presence of components or steps that are in addition to, though not inconsistent with, those recited in the limitations that follow." *Id.* at 1378–79 (citing cases). The Federal Circuit thus held that other optional binders and disintegrants not recited in the Markush group could be included in the claimed formulation. *Id.* at 1379. The Federal Circuit distinguished other cases in which it considered claims with Markush language, stating that the "decisive issue" was "critically different." *Id.* at 1378. The court stated:

> The issue is whether all binders or disintegrants in the claimed formulation are subject to the specific binder or disintegrant limitations. The answer, we conclude, is no. There is no language in Amgen's claim indicating that every binder or disintegrant in the claimed formulation must be within the Markush groups. Instead, the claim recites "at least one" binder or disintegrant "selected from the group consisting of" various excipients. And the limitations merely require that those particular binders or disintegrants meet the specified weight-percentage requirements, which is not inconsistent with the overall composition containing other binders or disintegrants. The plain language of this claim requires "at least one" of the Markush members and certainly does not indicate that the *only* binders and disintegrants in the claimed formulation are those listed in the groups. And we do not see a sufficient basis for a different conclusion in the specification or in the prosecution history we have recited.

Id. The claim structure here is similar to that in *Amgen*. Element 14[a] recites: "The balloon dilation catheter of claim 1, further comprising a means for determining a location of the distal end of the inner guide member within *at least one* anatomic structure." (emphasis added). As in *Amgen*, the plain language of the claim "requires 'at least one' of the Markush members and certainly does

not indicate that the *only* [locations that can be determined and dilated by the claimed balloon dilation catheter] are those listed in the groups." *Id.*

The court in *Amgen* also found it important that the claim used "comprising" language, which "is the standard transition term used to make clear that the claim does not preclude the presence of components or steps that are in addition to, though not inconsistent with, those recited in the limitations that follow" and "reinforce[d] the conclusion that the language of those limitations is best construed not to foreclose such additional binders and disintegrants." *Id.* at 1378–79. The *Amgen* court concluded that "optional additional binders and disintegrants not recited in the Markush group may be included in the claimed formulation." As in *Amgen*, claim 14 uses the open-ended word "comprising" and recites "further comprising a means for determining a location of the distal end of the inner guide member within at least one anatomic structure[.]" Elements 14[c] and [d], while using "a group consisting of" language and requiring that the claimed device include a balloon adapted to dilate the at least one of the specifically named structures, does not prevent the device from additionally being used in other unclaimed anatomical structures. Construing the claim the way Fiagon urges would eliminate the "at least one" language and improperly limit the "comprising" transitional phrases.

Fiagon contends that the "use of 'consisting of' creates a strong presumption that the Markush group is a closed group—meaning that the balloon must only dilate those anatomic structures and no other anatomic structure." Fiagon Reply at 27 (emphases removed). That argument was rejected in the claim construction order and is rejected again here. Order No. 15 at 18–23. Element 14[a] recites "The balloon dilation catheter of claim 1, further comprising a means for determining a location of the distal end of the inner guide member within at least one anatomic structure." The use of "at least one" and the open-ended "comprising" supports that other anatomic

structures than those in the Markush groups are encompassed within the scope of claim 14. Fiagon quotes out of context a sentence from the claim construction order stating that "[t]he Markush groups limit what anatomic structures are dilated in a balloon catheter device within the scope of the claims." Fiagon Reply at 27, quoting Order No. 15 at 23. In claim 14, "the at least one" anatomical structure must be selected from the Markush groups. The claim does not exclude and from its use of "at least one" and "comprising" supports the inclusion of other anatomical structures not within the Markush groups.

I disagree with Fiagon that this would contradict the claims. Claim 14 requires that the inflatable balloon is adapted to dilate "the at least one" specifically identified anatomical structure. It is unclear how determining a location of the distal end of the inner guide member within an additional and different anatomic structure not listed in the Markush groups and dilating it is inconsistent with this language. *See* Fiagon Reply at 30–31.

The evidence supports that these elements are met and thus that the VenSure Nav and VenSure Light devices infringe claim 14.

2. Claim 20

Claim 20 of the '878 patent recites "The balloon dilation catheter of claim 1, wherein the support member comprises a hypotube formed of stainless steel." Stryker argues that the VenSure products meet the additional elements of this claim. Stryker Br. at 105–106. Fiagon Reply at 31 and Fiagon Statement at 4. The evidence supports that the support member (outer hypotube) is a hypotube made of stainless steel. Tr. (Griffis) at 377:21–379:20; JX-134.11C.2 (specification for tubing); and JX-157C.68 (510(k)). The evidence supports that the additional elements of this claim are met, and that the VenSure products infringe claim 20.

3. Claim 23

Claim 23 of the '878 patent recites "The method of claim 22, further comprising, while advancing the inner guide member to the target location, tracking a location of the inner guide member using an image guided surgery system." Stryker argues that the combination of the VenSure Nav and Cube Navigation System meet this claim. Stryker Br. at 127–35. This is not disputed by Fiagon. Fiagon Reply at 36 and Fiagon Statement at 4.

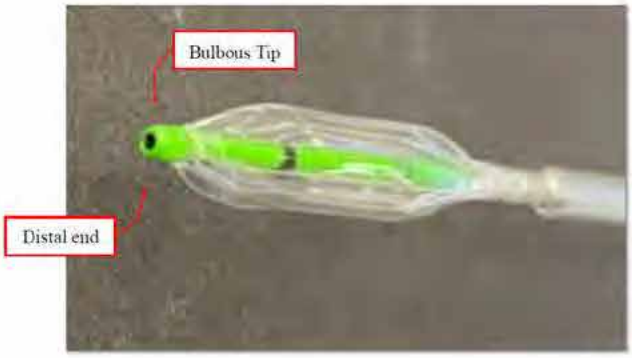
The evidence supports that use of the VenSure Nav with the Cube Navigation System satisfies the additional elements of this claim because, together they track the location using an image-guided surgery system. Tr. (Griffis) at 399:19–405:22; CX-73C.10, CX-1216.1 (product catalog); JX-136.1C.1, 3, and 5–6 (VenSure Nav instructions for use); JX-136.3C.36 (Cube instructions for use); JX-157C.73 and 79 (510(k) navigation capability); and JX-299C (Norman Dep.) at 205:24–206:9 (describing how a physician tracks the distal end of the device using the Cube). The evidence supports that the additional requirements of claim 23 are met and that use of the VenSure Nav and Cube Navigation System infringes claim 23.

C. '847 Patent Dependent Claims

1. Claim 10

Claim 10 is not asserted but is addressed because asserted claim 11 depends from it. Claim 10 recites "The balloon dilation device of claim 1, wherein the distal end of the inner guide member comprises a bulbous tip." Stryker argues that this element is met. Stryker Br. at 285–91. Fiagon disputes this. Fiagon Reply at 108–112.

The evidence supports that the VenSure products have an atraumatic, bulbous tip made of Pebax, as shown below:



Tr. (Griffis) at 441:19–442:7; CX-854C.20 (photo); and CX-613C.22 and 78 (photos). Fiagon's 510(k) submission describes a "ball tip," "atraumatic tip" or "atraumatic ball-tip" on its device. Tr. (Griffis) at 442:8–16; JX-157C.83 (ball tip dimensions); and JX-158C.107–08. Other documents relating to the VenSure products describe this feature. Tr. (Griffis) at 442:17–444:13; JX-136.1C.2 (VenSure, VenSure Light, VenSure Nav instructions for use: the distal end of the device includes an atraumatic tip); JX-136.2C.2 (VenSure ET instructions for use: the distal end of the device includes an atraumatic tip); CX-78C.16 (VenSure ET atraumatic polymer ball tip); and JX-42.4 (describing sinus dilation with a malleable atraumatic tip). Fiagon's expert, Dr. Burban, also described the tip as atraumatic. Tr. (Burban) at 1031:23–1032:12 (the Pebax provides an atraumatic tip).

The dispute raised here is the same as raised for claim 1 of the '847 patent: whether the "inner guide member" can be stainless steel and "comprise" a bulbous tip that is not stainless steel. Fiagon Reply at 108–112. For the same reasons discussed for element 1[e] of the '847 patent, bulbous tip is not required to be made of stainless steel. The evidence support that the additional requirements of claim 10 are met and that the VenSure, VenSure ET, VenSure Nav, and VenSure Light infringe claim 10.

2. Claim 11

Claim 11 recites "The balloon dilation device of claim 10, wherein the bulbous tip has an outer diameter between 1 mm and 3 mm." Stryker argues that this element is met. Stryker Br. at 291–93. Fiagon does not dispute that the additional requirements of this claim are met. Fiagon Reply at 108–111 and Fiagon Statement at 6.

The evidence supports that the bulbous tip in the accused VenSure products has an outer diameter between 1mm to 3mm. Tr. (Griffis) at 444:17–446:15; JX-134.1C.2 (drawings); JX-136.1C.2 (VenSure, VenSure Light, VenSure Nav instructions for use, distal tip diameter 1.81mm); JX-136.2C.2 (VenSure ET instructions for use, distal tip diameter 1.81mm); and JX-157C.83 (VenSure, VenSure NAV, ball tip diameter 1.63mm). The evidence supports that the additional element of this claim is met and that the accused VenSure products infringe claim 11 of the '847 patent.

D. Indirect Infringement

Stryker argues that Fiagon indirectly infringes every asserted claim. Stryker Br. at 135–167 ('878 patent), 250–52 ('472 patent), and 293 ('847 patent). Fiagon disputes that it indirectly infringes any claim. Fiagon Reply at 36–44 ('878 patent), 77 ('472 patent), and 112 ('847 patent).

As an initial matter, Fiagon states that "Respondents renew their objection to consideration of indirect infringement because—until Mr. Griffis's opening report—inducement was only mentioned in a one-paragraph interrogatory response that did not allege contributory infringement." Fiagon Reply at 36. The parties in this investigation agreed among themselves that final contentions would not be exchanged until after issuance of the claim construction order. *See* Order No. 16 at 2 (EDIS Doc. ID 867143). Issuance of that order was delayed because of the lapse of government appropriations. Thereafter, the parties agreed "to forego a final round of contentions and treat the expert reports as the final disclosure." Fiagon Opp. to Motion to Strike at 13 (EDIS

Doc. ID 869338). Fiagon's objection here, to a procedure it agreed to, is overruled. For the same reason, Fiagon's argument that Stryker waived an argument of contributory infringement is rejected. Fiagon Reply at 41.

1. Knowledge and Intent

A respondent is liable for induced infringement if they actively induce infringement of a patent. 35 U.S.C. § 271(b). Active inducement requires that the respondent have both knowledge of the patent and knowledge that the induced acts constitute infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639 (2015) ("liability for inducing infringement attaches only if the defendant knew of the patent and that 'the induced acts constitute patent infringement'"), quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 536 U.S. 754, 766 (2011). Like induced infringement, "contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement." *Commil*, 575 U.S. at 639.

Stryker argues that Fiagon has the required knowledge and intent to indirectly infringe. Stryker Br. at 143–63. Fiagon argues that it does not have the required intent because it had a good faith belief in non-infringement. Fiagon Reply at 36–41.

There is no dispute that Fiagon knew of the '878 and '472 patents by May 2022. JX-291C (Spearman Dep.) at 181:23–182:19; CX-56C; and Tr. (Spearman) at 763:20–764:12 (Fiagon aware of the '878 and '472 patents by May 2022). There is also no dispute that Fiagon knew of the '847 patent at least as of the service of the complaint in this investigation. *Certain Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 19 (Apr. 5, 2016) (EDIS Doc. ID 577827) (service of a 337 complaint provides knowledge of the asserted patents for both induced and contributory infringement) and *see* Tr. (Spearman) at 765:12–25 (agreeing that Fiagon knew of the '847 patent after the complaint was filed).

The parties dispute whether Fiagon had the necessary intent. Stryker argues that Fiagon knew it infringed or was recklessly blind to its infringement, thus demonstrating intent. Stryker Br. at 142–160. Fiagon argues that it had a good faith belief of non-infringement, thus negating intent. Fiagon Reply at 36–43.

Good faith belief of noninfringement can negate the required intent to indirectly infringe. *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1307 (Fed. Cir. 2006) (en banc in relevant part). Demonstrating a good faith belief requires evidence of the legal and factual basis of that belief. *Beverage Brewing Capsules*, Comm'n Op. at 21 (rejecting good faith belief argument where corporate witness provided "nothing more than a conclusory assertion by an executive that their products do not practice two limitations of the asserted claims."). An opinion of counsel, however, is not required to negate intent. *See Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir. 2009) (affirming denial of JMOL of induced infringement, finding that the jury could have concluded the defendant reasonably believed product contained same combination of antimicrobial components as prior art); *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 110, 1024 (Fed. Cir. 2009) (affirming denial of JMOL of induced infringement, finding that the jury could have believed defendants' testimony that they were practicing the prior art).

Fiagon relies on the testimony of Mr. Brian Spearman, the general manager of Fiagon NA LLC and managing director of Fiagon GmbH, to support its good faith belief of non-infringement. Fiagon Reply at 36–38 and Tr. (Spearman) at 728:18–23. Mr. Spearman testified that at the time of the Fiagon acquisition, in May of 2022, Fiagon believed it did not infringe the'878 and '472 patents because, "I think specifically we would say these are sliding shaft/balloon patents." Tr. (Spearman) at 765:1–11. Based on Mr. Spearman's immediately following testimony, however, the evidence supports that this conclusion was not based on reading the claims of the '878 and

'472 patents at that time. Mr. Spearman testified that after the complaint in this investigation was filed in 2025, individuals at Fiagon "went a little further" and "read the descriptions; we read the claims; we read the abstracts." And doing so, Fiagon understood the claims of the asserted patents do not recite a movable shaft, as recited in earlier-issued patents in the same family. *Id.* at 765:16–24. This testimony supports that as of May 2022, Fiagon had not read the claims of the '878 and '472 patents because if they had, they would have realized those claims did not recite a movable shaft, which the testimony of Mr. Spearman shows, Fiagon did not appreciate until after the complaint in this investigation was filed. As the Commission has noted, "[a]lthough *Commil* suggests that a good-faith belief of noninfringement protects against a claim of indirect infringement, such a belief must be reasonable." *Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 20. The evidence does not support that Fiagon's belief in May 2022 as to the '878 and '472 patents was reasonable because it was not based on a review of the claims of those patents.

After the complaint in this investigation was filed, Mr. Spearman testified that Fiagon reviewed the claims of the asserted patents. Mr. Spearman also testified that Fiagon reviewed an unidentified portion of a prosecution history: "We opened up the Patent Examiner's response and could see the section right there where they are saying you can't have a fixed device, and they said don't worry, we have a sliding device." Tr. (Spearman) at 766:14–20. It is unclear from this testimony what Mr. Spearman is referring to in the prosecution history and Fiagon does not say. Fiagon Reply at 37. And Fiagon does not argue, and has never argued, that during prosecution of any of the asserted patents Stryker argued or suggested that the claims are limited to a device with a movable shaft. Order No. 15 at 16–18. To the extent Mr. Spearman's testimony is understood, Fiagon's reliance on a prosecution history relating to materially different claims (those reciting a

movable shaft) does not support a good faith belief of non-infringement. Other than an unclear reference to a prosecution history, Mr. Spearman testified that, "Anyway, we looked at it all. Oh, my gosh. This is crazy. We still don't violate these patents in any way. I don't know how they could believe this. And we were looking for counsel." Tr. (Spearman) at 766:21–24. Because it provides no further explanation, this testimony does not support a good faith belief of non-infringement.

Fiagon also relies on an e-mail string in April 2025, which Mr. Spearman testified supported that the asserted patents recite a movable shaft. Fiagon Reply at 37–38; Tr. (Spearman) at 767:16–768:11; and RX-442C.1. There, Mr. Spearman states that "I believe every independent claim of Entellus discloses an inner guide member, a shaft and a support tube. As we all agree, it is ludicrous for them to assert that our intermediate hypotube performs the same function as their shaft. Their shaft is movable, ours is fixed." Assuming for the sake of argument that Mr. Spearman's statement that "[t]heir shaft is movable" refers to the claims of the asserted patents, and not Stryker's commercial product, such an understanding was not reasonable because the claims do not. Indeed, this was recognized by Mr. Spearman, who testified that after the complaint in this investigation was filed, which was on April 18, about a week before the April 25 e-mail string, Fiagon understood that the claims of the asserted patents did not recite a movable shaft. Based on the evidence, including Mr. Spearman's testimony, Fiagon has not shown a reasonable and good faith belief of non-infringement sufficient to defeat a finding of intent. *Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 20–21. Because Fiagon's good faith belief of non-infringement argument is rejected on the merits, Stryker's motion to strike, Mot. No. 1449-09, is DENIED as moot.

Stryker contends that Fiagon knew its acts constituted infringement based on the complaint it filed in this investigation. Stryker Br. at 143–144. The evidence supports that Stryker's complaint, with allegations of direct, induced, and contributory infringement, put Fiagon on notice of Stryker's allegations infringement. *See* Complaint at ¶¶ 56 and 61 and Exs. 8–10 (claim charts). "[D]espite being made aware of their infringement through the claim charts, [Fiagon] continued to sell products with specific instructions" for their use. *Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 20 and JX-136.1C and 136.2C (instructions for use). Absent a reasonable and good faith belief in non-infringement, the evidence supports the knowledge and intent requirements of indirect infringement. *Id.* at 21.

2. Induced Infringement

Stryker argues that Fiagon induces infringement by selling the accused VenSure products to customers and instructing them, via its instructions for use, to use those products in an infringing manner. Stryker Br. at 135–142 ('878 patent), 250 ('472 patent), and 293 ('847 patent). Except for arguing that it had a good faith belief of non-infringement (and contesting direct infringement), Fiagon does not contest induced infringement. Fiagon Reply at 43 ('878 patent), 77 ('472 patent), and 112 ('847 patent).

Fiagon acknowledges that its instructions for use are followed by users. JX-291C (Spearman Dep.) at 138:6–139:5 (surgeons use the instructions for use) and Tr. (Burban) at 708:17–22 (instructions for use describe how the device is used), 1025:15–16 (Dr. Burban followed the instructions for use), and 1071:24–1072:16 (Dr. Burban bent the device per the instructions for use). The evidence supports that Fiagon's instructions for use instruct a user how to perform balloon dilation. *See* Tr. (Griffis) at 331:20–333:8; JX-136.1C (VenSure, VenSure Nav, and VenSure Light instructions for use); and JX-136.2C (VenSure ET instructions for use), 379:21–383:2 (instructions for use support that users practice method claim 22 of the '878 patent),

393:20–399:11 (instructions for use support that users form a bend in the inner guide member as recited in method claim 22 of the '878 patent); JX-291C (Spearman Dep.) at 41:24–42:21 (surgeons will bend the device), JX-157C.54–55 (501(k) submission identifying indications for use). The evidence thus supports that Fiagon induces infringement of every asserted claim that is directly infringed.

3. Contributory Infringement

Stryker contends that Fiagon contributorily infringes claims 22 and 23 of the '878 patent by selling the VenSure, VenSure Light, and VenSure Nav products. Stryker Br. at 163–165. Fiagon contends that each of the VenSure, VenSure Light, and VenSure Nav products has a substantial non-infringing use because it is indicated for use in the Eustachian tube. Fiagon Reply at 41.

"[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). "In assessing whether an asserted noninfringing use [is] 'substantial,' the [factfinder is] allowed to consider not only the use's frequency, but also the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). The burden is on the patentee to show "the lack of substantial non-infringing uses." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012).

Claim 22 of the '878 patent recites a "method of treating a drainage pathway of a sinus cavity" and "advancing, via a nasal passageway, the inner guide member to a target location in a drainage pathway of a sinus cavity." The evidence supports that there is a substantial non-infringing use, namely dilation of the Eustachian tube. JX-136.1C.1 (instructions for use for the VenSure, VenSure Light, and VenSure Nav, stating an indication for use as "[t]o dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in

adult patients using a transnasal approach.") and Tr. (Griffis) at 638:6–20 ("Q: And you agree that the VenSure, VenSure Nav, and VenSure Light are also indicated for use in the Eustachian tube in addition to use within the sinuses, correct? A: Yes.").

Stryker contends that as to claims 14 and 22 of the '878 patent, "the VenSure Light and VenSure Nav, with their respective LightGuide light fiber and Sensor Carrier navigation wire accessories, are only listed in the [instructions for use] as indicated for sinus procedures." Stryker Br. at 165. Stryker contends that the VenSure Light and Light Guide infringe claim 14, Stryker Br. at 95–100, and contends that VenSure Nav and Sensor Carrier infringe claims 14 and 23, *id.* at 88–95 (claim 14) and 127–135 (claim 23). Stryker does not contend that the Light Guide or Sensor Carrier are required to practice claim 22. *See* Stryker Br. at 106–127. As a result, their use is irrelevant to whether there is a substantial non-infringing use as to claim 22. The evidence supports that there is a substantial non-infringing use in dilation of the Eustachian tube. As a result, there is no contributory infringement of claim 22 of the '878 patent.

As to claim 23 of the '878 patent, in asserting direct infringement, Stryker contends that the VenSure Nav when used with the Cube Navigation System meets the additional requirements of this claim. Stryker Br. at 127–135. The evidence supports that the Cube has substantial non-infringing uses because it can be used for procedures other than sinus surgeries. Tr. (Spearman) at 758:16–760:1 (Cube can be used for spine and brain procedures); RX-361C (brain procedures); RX-363.5 (spine procedures) and 11 (brain procedures). As a result, there is no contributory infringement of claim 23 of the '878 patent.

Stryker mentions claims 1, 14, and 20 of the '878 patent, claim 1 of the '472 patent, and claims 1 and 11 of the '847 patent in alleging contributory infringement. Stryker Br. at 163–65 ('878 patent), 251 (first full paragraph as to '472 patent), and 293 (second full paragraph as to '847

patent). Stryker's arguments for these claims lack any citation to supporting evidence. For example, Stryker cites no evidence to support that the VenSure Products are "a component" that constitutes "a material part of the invention" for these claims or that they are not staple articles and lack substantial non-infringing uses. The evidence does not support contributory infringement as to claims 1, 14, and 20 of the '878 patent, claim 1 of the '472 patent, or claims 1 and 11 of the '847 patent.

Stryker also accuses Fiagon of contributorily infringing by importing components used in the accused devices, such as the Handle Shell Side 1 and 2, Y-Connector, LightGuide, and Sensor Carrier. Stryker Br. at 165–67 ('878 patent), 251–252 (as to components for the '472 patent), and 293 (as to components for the '847 patent). The Federal Circuit has said that "to prevail on contributory infringement in a Section 337 case, the complainant must show" "the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion*, 629 F.3d at 1353. Stryker's arguments as to components do not explain or cite evidence for the proposition that "the accused components that contributed to another's direct infringement." As a result, Stryker has failed to demonstrate contributory infringement as to components.

IX. DOMESTIC INDUSTRY—TECHNICAL PRONG

For a patent-based complaint, a violation of section 337 occurs "only if an industry in the United States, relating to the articles protected by the patent . . . exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). The complainant bears the burden of proving a domestic industry. *Zircon Corp. v. Int'l Trade Comm'n*, 101 F.4th 817, 821 (Fed. Cir. 2024). The domestic industry requirement has two prongs, technical and economic. *See id.* at 821 & n.3.

A complainant satisfies the technical prong of the domestic industry requirement in a patent-based section 337 investigation when it establishes that its identified "domestic industry

products are 'protected by the patent' at issue." *Id.* at 821, n.3; *see* 19 U.S.C. §§ 1337(a)(2) and (3). "The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the complainant must establish by a preponderance of the evidence that an asserted domestic industry product practices at least one valid claim of the asserted patent. *Certain Vision-Based Driver Assistance System Cameras, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-907, Comm'n Op. at 36 (Feb. 2019) (EDIS Doc. ID 673954).

Stryker asserts that its XprESS Ultra and XprESS LoProfile practice claims 1, 14, 20, and 22 of the '878 patent, claim 1 of the '472 patent, and claims 1 and 11 of the '847 patent. Stryker Br. at 14. Stryker asserts that the NextGen XprESS practices claim 22 of the '878 patent, claim 1 of the '472 patent, and claims 1 and 11 of the '847 patent. *Id.* Stryker asserts that the XprESS LoProfile and NextGen XprESS when used with the ENT Nav System practices claim 23 of the '878 patent. *Id.*

A. Independent Claims

As with infringement, related claim elements are addressed together in consider'878 patent claims 1 and 22, '472 patent claim 1, and '847 patent claim 1.

1. Balloon Dilation Catheter

Element 1[a] of the '878 patent, 1[a] of the '472 patent, and 1[a] of the '847 patent recite "[a] balloon dilation catheter comprising." Stryker contends these elements are met. Stryker Br. at 167–68 ('878 patent element 1[a]), 252 ('472 patent element 1[a]), 294 ('847 patent element 1[a]). Fiagon does not dispute that these elements are met. Fiagon Statement at 8–11. Mr. Griffis testified that the XprESS devices are balloon dilation catheters. Tr. (Griffis) at 473:17–474:18; JX-

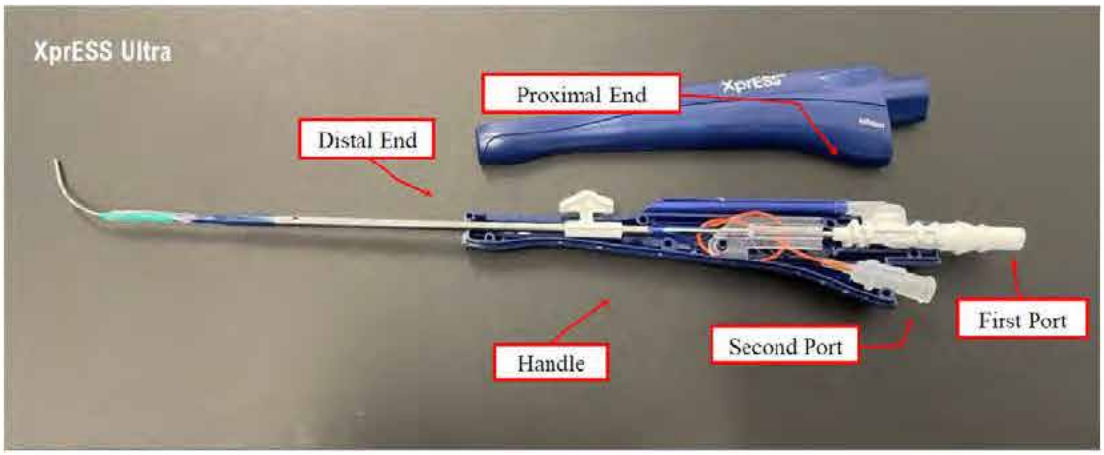
133.1.1; CX-855C.1; JX-131.1C; and JX-133.3C.3. The evidence supports that these elements are satisfied.

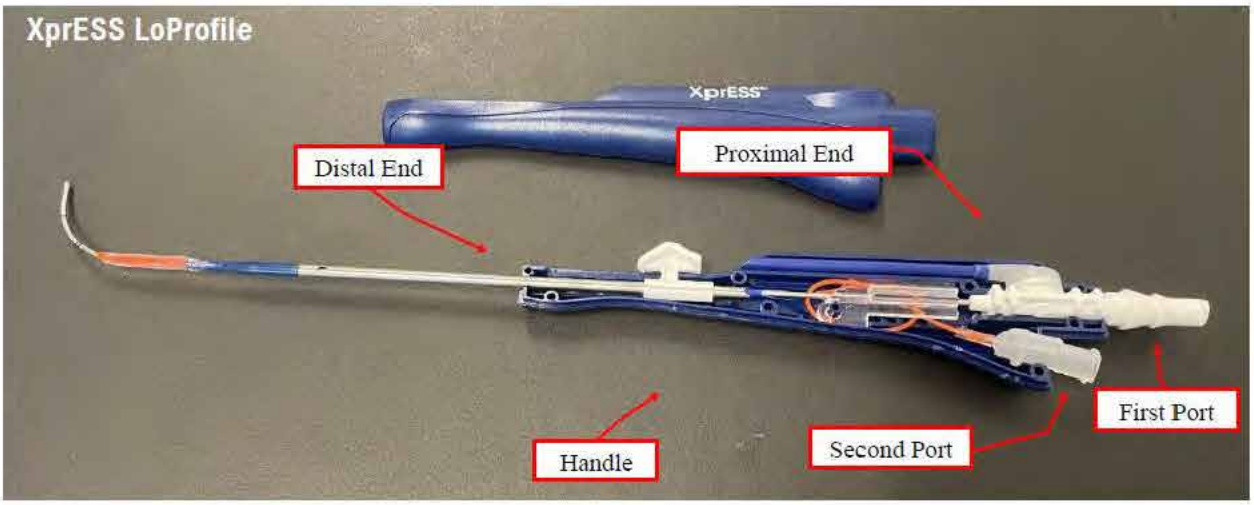
Elements 22[a] and [b] of the '878 patent recite "A method of treating a drainage pathway of a sinus cavity, the method comprising: providing a balloon dilation catheter comprising." Stryker contends that these elements are met. Stryker Br. at 211–13. Fiagon does not dispute that these elements are met. Fiagon Statement at 9. The instructions for use for the XprESS LoProfile and Ultra show that they are used to treat a drainage pathway of a sinus cavity. The draft instructions for use for the NextGen indicates [redacted]. Tr. (Griffis) at 522:14–523:18; JX-133.1 (LoProfile and Ultra instructions for use); and JX-133.3C.3 (NextGen draft instructions for use). The evidence supports that these elements are satisfied.

2. Handle

Element 1[b] of the '878 patent, element 22[c] of the '878 patent, element 1[b] of the '472 patent, and element 1[b] of the '847 patent recite "a handle having a proximal end and a distal end." Stryker contends these elements are met. Stryker Br. at 168–70 ('878 patent claim 1), 214–15 ('878 patent claim 1), 252 ('472 patent claim 1), 294 ('847 patent claim 1). Fiagon does not dispute these elements. Fiagon Statement at 8–11.[14] The evidence supports that the XprESS Ultra and LoProfile devices have a handle, as shown below:

[14] Fiagon disputes that the handle of the XprESS devices comprises first and second ports, as addressed below, but does not dispute that they have a handle.





Stryker Br. at 169 and Tr. (Griffis) at 475:19–477:8; CX-617C.51 (LoProfile, annotated); CX-618C.73 (Ultra, annotated); and CDX-1.4C.7–8. The evidence also supports that the NextGen has a handle, as shown below:

[redacted]

CX-855C.1 and CDX-1.4C.81. The evidence supports that these elements are met.

Element 1[b] of the '878 patent additionally recites "wherein the handle comprises a first port at the proximal end of the handle and a second port at the proximal end of the handle." Stryker contends that this element is met. Stryker Br. at 214–15. Fiagon disputes that the handle of the XprESS devices comprises first and second ports. Fiagon Reply at 44–50 and Fiagon Statement at 8. As shown in the annotated photographs above, the evidence supports that the XprESS devices have first and second ports in the handle. Tr. (Griffis) at 477:25–478:11 and 527:12–22; JX-130.1C.1 (LoProfile); JX-129.1C.1 (Ultra); and CX-855C.3 (NextGen).

Fiagon's argument for this limitation is the same as to the argument it made on infringement, namely that claim 1 requires ports that are integral to the handle rather than separate from the handle. Fiagon Reply at 44–50. As discussed regarding infringement, the claim language does not require the ports to be integral.

The evidence supports that these elements are satisfied.

3. Inner Guide Member

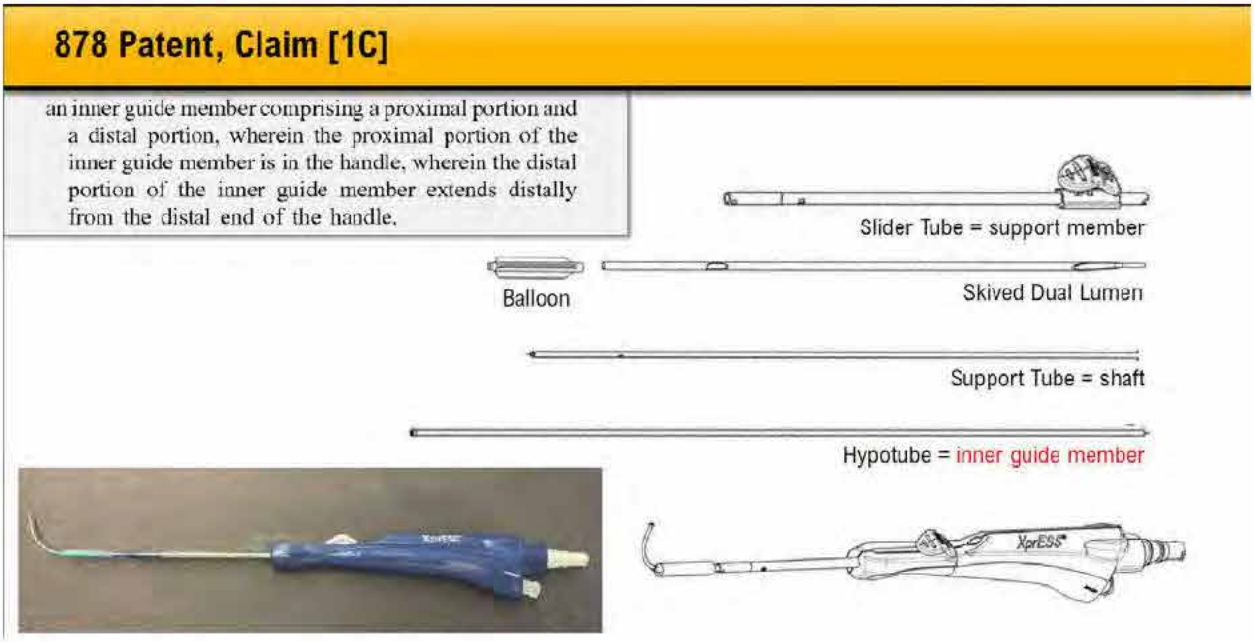
a) Structure

Elements 1[c], 22[d] and [e] of the '878 patent, element 1[c] of the '472 patent, and element 1[c] of the '847 patent recite: "an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member." Stryker contends that these elements are met. 170–73 ('878 patent element 1[c]), 215–19 ('878 patent elements 22[d] and [e]), 253 ('472 patent element 1[c]), 294–95 ('847 patent element 1[c]). Fiagon disputes that "the distal portion of the inner guide member extends distally from the distal end of the handle." Fiagon Statement at 8–11

and Fiagon Reply at 50–53 ('878 patent element 1[c]), 71–72 ('878 patent element 22[e]), 77–78 ('472 patent element 1[c]), 112 ('847 patent element 1[c]).

There is no dispute about the structure of the XprESS products. *See* Fiagon Reply at 62 ("the structure of the DI Products is undisputed"). The evidence supports that there is an inner hypotube, extending from the handle, which Mr. Griffis identified as the claimed inner guide member. Tr. (Griffis) at 478:12–479:8 and 527:23–531:21; JX-130.2C.1 (LoProfile); JX-129.2C.1 (Ultra); and CX-855C.2 (NextGen).

The evidence supports that the XprESS devices include a slider tube (identified as the claimed support member), a dual lumen holding the balloon, a support tube (identified as the claimed shaft), and a hypotube (identified as the claimed inner guide member), as shown below:



Tr. (Griffis) at 479:9–482:11 (Ultra and LoProfile) and 530:14–531:21; CDX-1.4C.12–13 (Ultra); JX-129.1C.1 (Ultra); JX-129.2C.1 (Ultra); JX-129.3C.1 (Ultra); JX-129.4C.1 (Ultra); CX-618C.41 (Ultra photograph); CDX-1.4C.14 (LoProfile); JX-130.1C.1 (LoProfile); JX-130.2C.1

(LoProfile); JX-130.3C.1 (LoProfile); JX-130.4C.1 (LoProfile); CX-617C.16 (LoProfile photograph); CDX-1.4C.86–87 (NextGen); and CX-855C.2 (NextGen).

The evidence supports that a proximal portion of the inner guide member is within the handle while a distal portion extends distally from the distal end of the handle. Tr. (Griffis) at 480:15–482:12 and 530:17–531:8. The evidence also supports that in each of the XprESS devices, the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member. Tr. (Griffis) at 482:13–484:17 (LoProfile and Ultra) and 531:9–21 (NextGen); CDX-1.4C.16 (LoProfile and Ultra); CDX-1.4C.88 (NextGen); JX-129.5C.1 (Ultra); JX-130.5C.1 (LoProfile); CX-855C.13 (NextGen).

Fiagon's dispute here is the same as it raised for infringement, namely that if "something becomes part of the handle merely because it is held in place by or connects with the handle, then the inner hypotube [of the domestic industry products] is also part of the handle and cannot extend distally from itself." Fiagon Reply at 50–51. This argument is rejected for the same reasons it was rejected for infringement.

Element 1[c] of the '878 patent further recites "wherein the first port is in fluid communication with the lumen at the proximal end of the inner guide member." Stryker contends this element is met. Stryker Br. at 173–75. Fiagon does not dispute that this element is met. Fiagon Statement at 8. The evidence supports that in the XprESS devices, the first port is in fluid communication with the lumen at the proximal end of the inner guide member at the proximal end of the inner guide member. Tr. (Griffis) at 484:18–488:5; JX-130.5C.1 (LoProfile); JX-129C.5C.1 (Ultra); JX-133.1.1 (LoProfile and Ultra instructions for use); CX-617C.51(LoProfile); CX-618C.73(Ultra); and CX-855C.5–8 (NextGen).

The evidence supports that elements 1[c], 22[d] and [e] of the '878 patent, element 1[c] of the '472 patent, and element 1[c] of the '847 patent are met by the XprESS devices.

Elements 1[h] and 1[i] of the '878 patent respectively recite "wherein a center axis of the first port is coaxial with a longitudinal axis of the proximal portion of the inner guide member in the handle[]" and "wherein a center axis of the second port is transverse to the longitudinal axis of the proximal portion of the inner guide member in the handle." Stryker contends that these elements are met. Stryker Br. at 192–93. Fiagon does not dispute that these elements are met. Fiagon Statement at 8. As to element 1[h], the evidence supports that the center axis of the first port in the XprESS devices is coaxial with the longitudinal axis of the proximal portion of the inner guide member in the handle. Tr. (Griffis) at 499:20–501:20; CX-618C.73; CX-617C.54; and CDX-1.4C-41–42 (annotated images). As to element 1[i], the evidence supports that center axis of the second port is transverse to the longitudinal axis of the proximal portion of the inner guide member in the handle. Tr. (Griffis) at 501:21–503:10; CX-618C.73; CX-617C.54; CX-855C; and CDX-1.4C-41–42 (annotated images). The evidence supports that elements 1[h] and 1[i] of the '878 patent are met by the XprESS products.

Element 1[k] of the '878 patent recites "wherein the inner guide member comprises a hypotube formed from stainless steel." Element 1[e] of the '847 patent is similar and recites "wherein the inner guide member is a stainless steel hypotube." Stryker contends these elements are met. Stryker Br. at 201–02, 295. Fiagon does not dispute that these elements are met. Fiagon Statement at 8, 11. The evidence supports that the inner guide member is a stainless steel hypotube in all the XprESS devices. Tr. (Griffis) at 507:3–508:3 and 611:6–12; Tr. (Curtin) at 151:3–152:11 and 153:25–154:7; JX-129.8C.1; JX-130.6C.1; and JX-133.3C.12. The evidence supports that these elements are satisfied.

Element 1[j] of the '847 patent recites "wherein the inner guide member has an inner diameter in a range of about 0.508 mm (0.02 inch) to about 1.27 mm (0.05 inch) and a wall thickness between about 0.2032 mm (0.008 inch) to about 0.3048 mm (0.012 inch)." Stryker contends this element is met. Stryker Br. at 312–14. Fiagon does not dispute this element. Fiagon Statement at 11. The evidence supports that the inner guide member's inner diameter and wall thickness fall within the claimed ranges. Tr. (Griffis) at 623:17–625:1; JX-130.6C.1; JX-129.6C.1; CX-855C.14; and JX-131.1C. The evidence supports that this element is satisfied.

b) Malleable/Bendable

Element 1[j] of the '878 patent recites "wherein the distal portion of the inner guide member is malleable." Element 22[i] of the '878 patent recites "forming a bend in the inner guide member at a location that is distal to a distal end of the support member to change a shape of the inner guide member." Elements 1[g] and [h] of the '472 patent recite "wherein a distal end of the support member is located proximal to a bend in the inner guide member, and wherein the inflatable balloon is inflatable with the inflatable balloon extending along the bend in the inner guide member." Element 1[d] of the '847 patent recites "wherein the distal portion of the inner guide member is malleable such that the distal portion of the inner guide member is configured to be shaped with an angle of 0 degrees to 120 degrees relative to the proximal portion of the inner guide member." Stryker contends these elements are met. Stryker Br. at 194–201 ('878 patent element 1[j]), 233–35 ('878 patent element 22[1]), 258–62 ('472 patent elements 1[g] and [h]), and 295–300 ('847 patent element 1[d]). Fiagon contends that the domestic industry products do not have a distal portion of the inner guide member that is malleable. Fiagon Reply at 62–69 ('878 patent claim 1) and 112–13 ('847 patent claim 1). Fiagon thus disputes elements 1[j] of the '878 patent and element 1[d] of the '847 patent, but not the remainder of these elements. Fiagon Statement at 8–11.

There is no dispute about the structure of the XprESS devices. Fiagon Reply at 62. The evidence supports that the XprESS devices undergo an annealing process to make a portion of the stainless steel hypotube (the inner guide member) malleable. Tr. (Curtin) at 162:1–22. This process results in a gradient of malleability. *Id.* This allows the malleable portion of the hypotube to be bent to an angle of 0 to 120 degrees. *Id.* at 164:5–16 and Tr. (Griffis) at 605:21–611:12; JX-133.1.1; CX-1192C; CX-617C.110; and CX-618C.95. The malleable portion of the hypotube does not cover the entire distal end of the hypotube, as shown below:



Tr. (Griffis) at 503:17–505:1; CDX-1.4C.48 (annotated versions of JX-130.7C.1 and JX-129.7C.1); *see also* Tr. (Burban) at 1071:8–1074:18. The evidence supports that the XprESS devices are packaged with a bending tool, which is used by users to form a bend in the malleable portion of the inner guide member to change its shape in accordance with the instructions for use of the device. Tr. (Griffis) at 542:15–548:5; JX-133.1.4; JX-133.3C.10–11; CX-618C.60 and 95; CX-617C.28 and 110; JX-137C.6; CX-1192C (video showing use of bending tool); CX-855C.1; *see also* Tr. (Curtin) at 159:8–160:9, 164:5–8, 171:17–20, and 173:25–174:9. [redacted] Tr. (Griffis) at 609:25–610:17 and 611:2–12; JX-137C.6; and JX-133.3C.10 and 12.

Fiagon argues that '878 patent element 1[j] and '847 patent element 1[d] are not met because the claim requires the entirety of the hypotube outside the handle to be malleable, not just the portion in the XprESS devices. Fiagon Reply at 62–69. Fiagon argues that because the claims recite that "the distal portion of the inner guide member extends distally from a from the distal end of the handle," the entirety of the inner guide member outside of the handle must be malleable. That, however, is not required by the claim language. Instead, claim 1 of the '878 patent and claim 1 of the '847 patent recite that the inner guide member has a proximal portion and a distal portion, the distal portion extends distally from the distal end of the handle, and the distal portion of the inner guide member is malleable. Nowhere does the claim require that the "distal portion" of the inner guide member is the entirety of the inner guide member outside of the handle. Instead, the "distal portion" is a portion of the inner guide member extending distally of the distal end of the handle, meaning that it is outside the handle. Further, when it was important to ascribe a feature to the entirety of the inner guide member, the claims do so. Claim 1 of the '878 patent and claim 1 of the '847 patent recite a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member.

This is supported by the specification, which explains that the inner guide member 14 may be pre-shaped to have a "curved distal portion 16." JX-1 at 4:3–5 and 5:65–6:2. Fig. 6A "illustrates an inner guide member 14 that includes a curved distal portion 16 that terminates in a straight segment 46." *Id.* at 7:60–61. The specification thus supports that the distal portion of the inner guide member is not necessarily the entirety of the inner guide member outside of the handle.

The evidence supports that these elements are met.

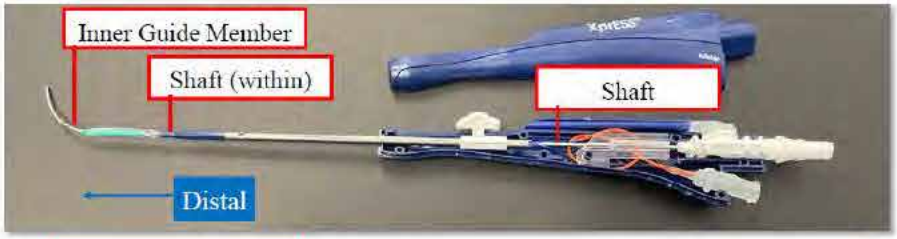
4. Shaft / Polymeric Shaft

Element 1[d] of the '878 patent, element 22[f] of the '878 patent, and element 1[d] of the '472 patent recite: "a shaft mounted about a periphery of the inner guide member, wherein a

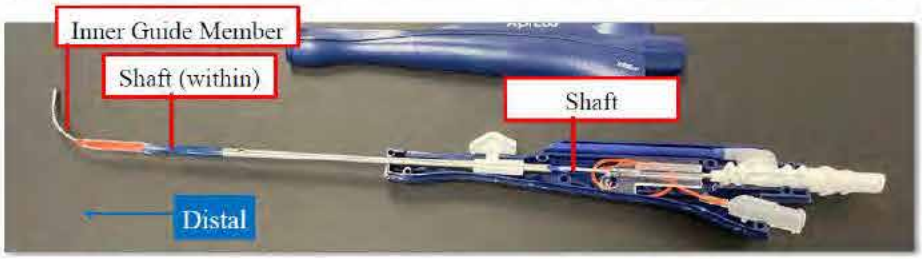
portion of the inner guide member extends distally of a distal end of the shaft." Stryker contends that these elements are met. Stryker Br. at 175–78 ('878 patent element 1[d]), 219–21 ('878 patent element 22[f]), 253 ('472 patent element 1[d]). Fiagon does not dispute that these elements are met. Fiagon Statement at 8–11.

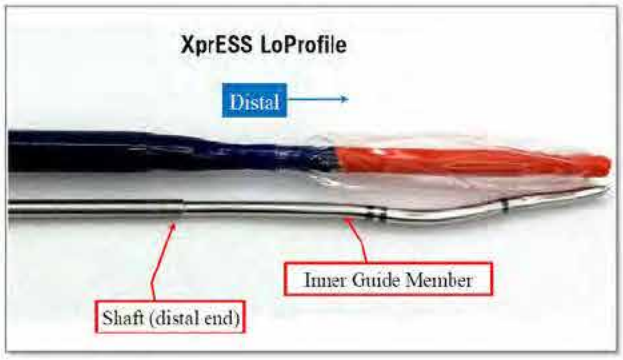
The evidence supports that the XprESS devices have a support tube, which is identified as the claimed shaft, mounted about the periphery of the inner guide member, and that a portion of the inner guide member extends distally of the distal end of the shaft, as shown below:

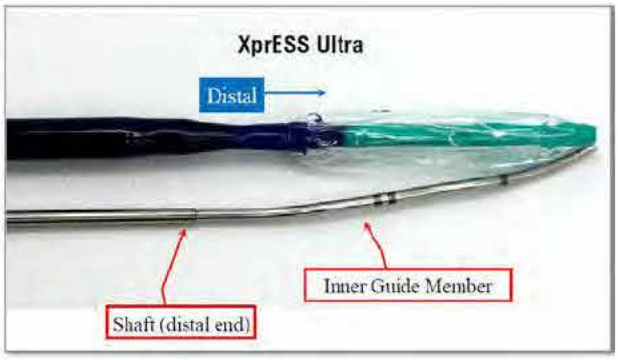
XprESS Ultra



XprESS LoProfile





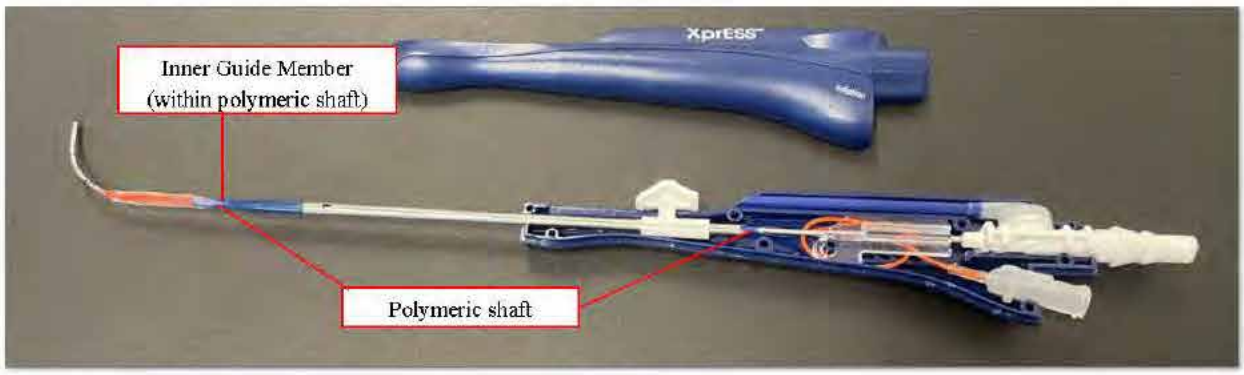


CDX-1.4C.24–25; Tr. (Griffis) at 488:7–493:1; JX-130.2C.1; JX-129.2C.1; JX-130.1C.1; JX-130.3C.1; JX-130.4C.1; CX-617C.16, 51, and 114; CX-618C.73 and 98; and CX-1272C.21. [redacted]

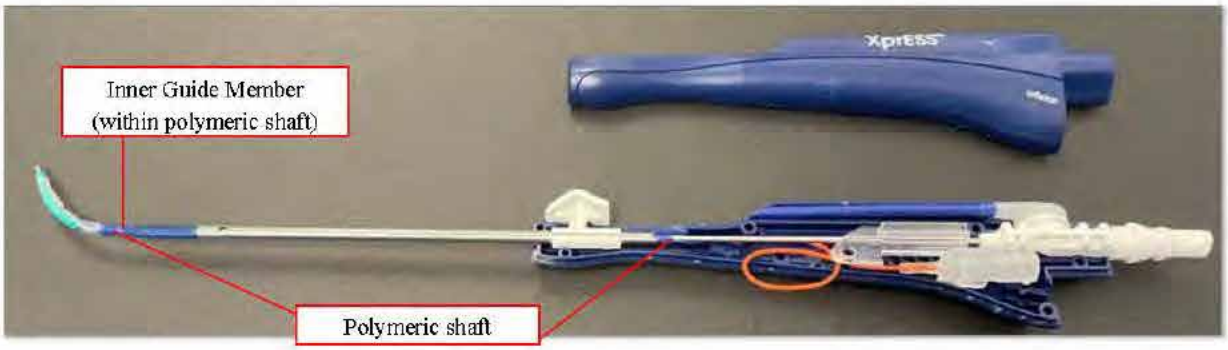
[redacted]. Tr. (Griffis) at 533:13–535:23; CX-855C.2, 8, and 9; and CDX-1.4C.92. The evidence supports that these elements are met.

Element 1[f] of the '847 patent recites "a polymeric shaft mounted about a periphery of the inner guide member." Stryker contends that this element is met. Stryker Br. at 300–05. Fiagon does not dispute that this element is met. Fiagon Statement at 11. The evidence supports that the XprESS LoProfile and Ultra have a skived dual lumen component that is manufactured from Pebax, and the inner guide member is inserted through it, as shown below:

XprESS LoProfile



XprESS Ultra



Tr. (Griffis) at 611:13–614:25; JX-129.13C.1; JX-129.14C.1; JX-130.1C.1; JX-130.2C.1; JX-130.3C.1; JX-130.12C.1; JX-130.13C.1; CX-617C.16 and 51; CX-618C.41 and 69; and CDX-1.4C.201–206. [redacted]. Tr. (Griffis) at 615:1–20; CX-855C.2 and 8; JX-131.1C; and CDX-1.4C.207. The evidence supports that this element is met.

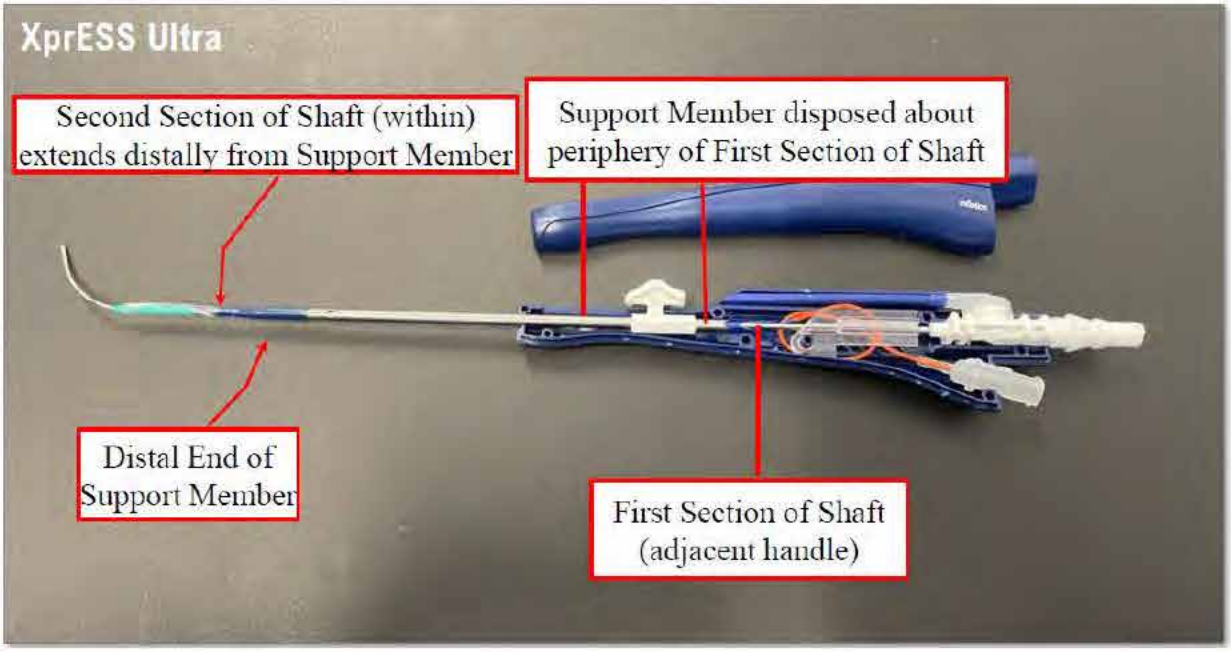
Element 1[h] of the '847 patent recites "wherein the inner guide member has a rigidity that is greater than a rigidity of the polymeric shaft." Stryker contends that this element is met. Stryker Br. at 308–10. Fiagon does not dispute that this element is met. Fiagon Statement at 11. The evidence supports that the inner guide member, which is made of stainless steel, has a rigidity that is greater than the rigidity of the Pebax polymeric shaft, using the elastic (Young's) modulus as a measure. Tr. (Griffis) at 618:19–620:17; JX-130C.6C.1; JX-133.3C.12; JX-129.8C.1; JX-129.14C.1; and JX-130.13C.1. The evidence supports that this element is satisfied.

5. Support Member

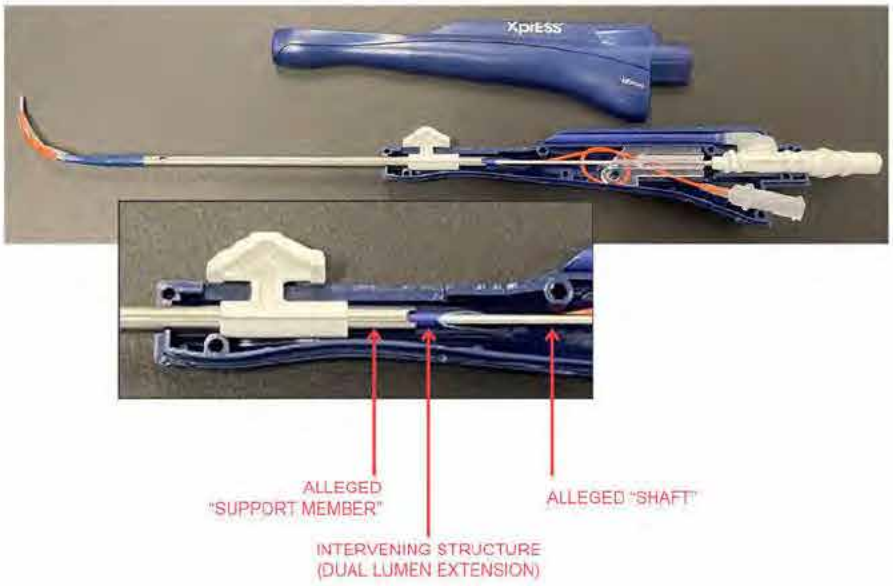
Element 1[e] of the '878 patent recites "a support member defining a tube that is disposed about a periphery of a first section of the shaft, wherein the first section of the shaft is adjacent to the handle, wherein a second section of the shaft extends distally from a distal end of the support member." Element 22[g] of the '878 patent recites "a support member comprising a tube that is disposed about a periphery of a first section of the shaft, wherein the first section of the shaft is adjacent to the handle, wherein a second section of the shaft extends distally from a distal end of the support member." Element 1[e] of the '472 patent recites "a support member defining a tube that is disposed about a periphery of the shaft, wherein the support member has a length that extends along at least a portion of the shaft." Stryker contends these elements are met. Stryker Br. at 178–88 ('878 patent element 1[e]), 221–24 ('878 patent element 22[g]), 253–57 ('472 patent element 1[e]). Fiagon disputes these elements. Fiagon Reply at 54–62 ('878 patent claim 1), 72 ('878 patent claim 22), and 78 ('472 patent claim 1).

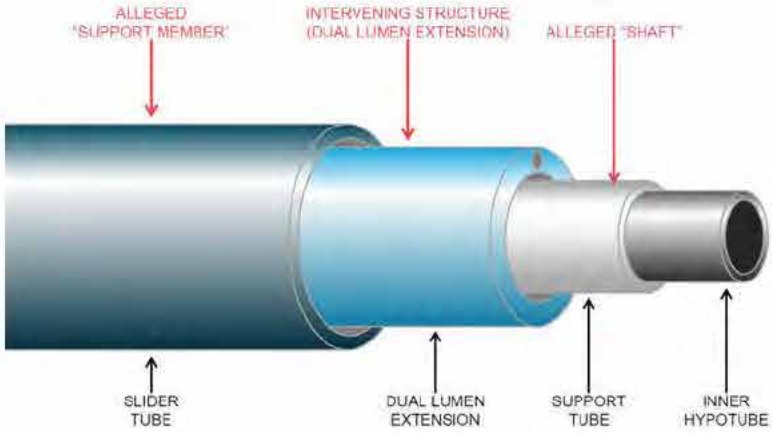
There is no dispute about the structure of the XprESS products. Stryker argues that the support member is the slider tube of the XprESS products. Stryker Br. at 178; Tr. (Griffis) at 493:12–22; JX-130.2C.1; and JX-129.2C.1. The evidence supports that a first section of the shaft

is surrounded by the slider tube and a second section extends distally from a distal end of the support member, as shown below:



CDX-1.4C.29 and *see* Tr. (Griffis) at 494:4–495:25; CX-618C.73 and 98; and CX-617C.51 and 114. Between the slider tube and the support member in the Ultra and LoProfile is the skived dual lumen extrusion, as shown below:





RDX-25C.308–310, showing JX-129.4; Tr. (Burban) and 1061:9–21 and Tr. (Griffis) at 664:12–666:10. [redacted]. Tr. (Griffis) at 538:9–540:5; CX-855C.1, 2, and 8; and JX-131.1C.

Fiagon argues that the support member is not disposed about a periphery of a first section of the shaft because of the skived dual lumen extrusion is between the slider tube and the support tube. Fiagon Reply at 54. Fiagon contends that "disposed about a periphery" precludes any intervening structure. Tr. (Burban) at 1060:20–1061:5. Fiagon's argument is unpersuasive. The

plain meaning of "disposed about a periphery" does not preclude intervening structure. In addition, as Stryker argues, Fiagon's interpretation essentially reads a negative limitation into the language. Stryker Br. at 182–83. There is no support for such a negative limitation. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1322–23 (Fed. Cir. 2003) (rejecting construction that would include a negative limitation that had no support in the explicit language, no inherent support, and no disclaimer or lexicography). Fiagon argues that under Stryker's position, "about the periphery" would have no meaning when compared with other terms, like the requirement that the inflatable balloon be "disposed about the inner guide member." Fiagon Reply at 54. I disagree. "About the periphery" means around; it does not require, explicitly or otherwise, that there be no intervening structure. Fiagon argues that the specification only shows this structure. *Id.,* citing '878 patent at 4:21–22 and 6:65–7:1. But it is improper to limit claims to preferred embodiments, particularly where, as here, there is no express requirement in the claims. Fiagon faults Stryker for failing to identify structural arrangements that would not infringe, *id.* at 56–57, but that is not the relevant question. Instead, the question is whether the XprESS devices include a support member defining a tube that is disposed about a periphery of a first section of the shaft, as claimed. The evidence supports that they do. The evidence supports that this element is satisfied.

6. Balloon and Inflation Lumen

Elements 1[f] and 22[h] of the '878 patent and element 1[f] of the '472 patent recite "an inflatable balloon disposed about the inner guide member." Element 1[g] of the '847 patent recites "an inflatable balloon coupled to the polymeric shaft and disposed about the inner guide member." Stryker contends these elements are met. Stryker Br. at 188–89 ('878 patent element 1[f]), 224–26 ('878 patent element 22[h]), 257–58 ('472 patent element 1[f]), 305–08 ('847 patent element 1[g]). Fiagon does not dispute that these elements are met. Fiagon Statement at 8–11.

The evidence supports that the XprESS Ultra and LoProfile devices include a balloon that is coupled to the polymeric shaft and disposed about the inner guide member, as shown below:

XprESS Ultra



XprESS LoProfile



Tr. (Griffis) at 496:1–497:1 and 616:20–617:24; CX-618C.73; CX-617C.51; JX-133.1.3–4; JX-130.4C.2; JX-129.3C.2; CDX-1.4C.209–210. [redacted] Tr. (Griffis) at 541:11–542:14; CX-855C.1; JX-131.1C; and JX-137C.6. The evidence supports that these elements are met.

Element 1[g] of the '878 patent recites "an inflation lumen extending from the second port of the handle to the inflatable balloon." Stryker contends this element is met, Stryker Br. at 189–91, which is not disputed, Fiagon Statement at 8. The evidence supports that the XprESS devices contain an inflation lumen that runs from the second port of the handle to the inflatable balloon. Tr. (Griffis) at 497:2–499:19; CX-618C.26 and 85; CX-617C.16, 51, and 64; JX-129.13C.1; JX-130.12C.1; and CDX-1.4C.36–39. The evidence supports that this element is met.

7. Claim 22

a) Additional Elements of Claim 22

Elements 22[j], [k], and [l] of the '878 patent recite:

> [i] forming a bend in the inner guide member at a location that is distal to a distal end of the support member to change a shape of the inner guide member;
>
> [j] after forming the bend in the inner guide member, advancing, via a nasal passageway, the inner guide member to a target location in a drainage pathway of a sinus cavity; and
>
> [k] after advancing the inner guide member to the target location, inflating the inflatable balloon to dilate the drainage pathway of the sinus cavity,
>
> [l] wherein inflating the inflatable balloon is performed while the inflatable balloon extends along the bend in the inner guide member.

Stryker contends these elements are met. Stryker Br. at 230–34, which is not disputed, Fiagon Statement at 9.

The instructions for use for the XprESS products direct users to advance the inner guide member after forming a bend in the inner guide member. Tr. (Griffis) at 548:6–550:5; JX-133.1.4; JX-133.3C.12. The instructions also direct users to inflate the balloon to dilate the drainage pathway after the inner guide member is advanced to the target location. Tr. (Griffis) at 550:16–552:4; JX-133.1.4–5; and JX-133.3C.12. This is done after forming a bend and after advancing the inner guide member. Tr. (Griffis) at 552:21–553:5. Videos show use of the device to dilate the sinus. Tr. (Griffis) at 552:5–20; CX-1189C; and CX-1210C. The balloon is positioned along the bend when the balloon is inflated. Tr. (Griffis) at 553:6–554:6; CX-617C.50; CX-618C.69; CX-1189C (video showing use of device); and CX-1201C (same). [redacted]. JX-133.3C.10 and 12.

The evidence supports that these elements are satisfied.

b) Evidence of Use Within the United States

Stryker contends that there is evidence of use of the XprESS Products, including the NextGen XprESS, in the United States. Stryker Br. at 14–22, 211–12. Fiagon only disputes this for the NextGen XprESS. Fiagon Reply at 72–75.

Stryker has sold significant quantities of XprESS Ultra and LoProfile devices in the United States. Tr. (Curtin) at 188:3–17. The evidence supports that claim 22 is practiced when physicians in the United States use the products in accordance with their instructions for use for sinus procedures. Tr. (Griffis) at 521:15–523:18; JX-133.1.1; and JX-133.3C.3; *see also* Tr. (Curtin) at 162:23–164:8. As for the NextGen XprESS, the evidence supports that [redacted] [redacted]. *Id.* at 170:21–171:14 and 172:5–173:12.

Fiagon only disputes that there is evidence of use of the NextGen XprESS in the United States. Fiagon Reply at 72–75. Fiagon argues that the evidence is "questionable" because there is no documentary evidence of use of the NextGen product [redacted]. *Id.* While Fiagon is correct that there is no requirement to accept Dr. Curtin's testimony, there is also no requirement that it be rejected. Sworn witness testimony may be credited. *Certain Solid State Drives, Stacked Elecs. Components, and Prods. Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 21 (June 29, 2018) (EDIS Doc. ID 649139). Dr. Curtin is the director of research and development for Stryker ENT. Tr. (Curtin) at 141:1–2. His role involves development of new products, which covers the NextGen XprESS. *Id.* at 131:3–10 and 142:16–21. Dr. Curtin persuasively and credibly testified regarding the development stage of the NextGen XprESS including that research began [redacted] *Id.* at 170:5–20. Dr. Curtin's testimony regarding testing of the NextGen XprESS in the United States [redacted] was credible and supports use of the device in the United States.

The evidence supports that the XprESS products, including the NextGen XprESS, have been used in the United States.

B. '878 Patent Dependent Claims

1. Claim 14

Stryker contends that the XprESS Ultra and LoProfile practice claim 14 of the '878 patent. Stryker Br. at 14.

a) Element 14[a]

Element 14[a] recites "The balloon dilation catheter of claim 1, further comprising a means for determining a location of the distal end of the inner guide member within at least one anatomic structure." Stryker contends that this element is met. Stryker Br. at 202–09. Fiagon does not dispute this element. Fiagon Statement at 8.

This term was construed as subject to § 112, ¶ 6 with a function of: determining a location of the distal end of the inner guide member within the at least one anatomic structure; and corresponding structure of: an antenna, transmitter, optical reflectors, emitted light, light fiber, or the like to determine the orientation and/or positioning of the balloon dilation catheter or distal end thereof, and equivalents thereof. Order No. 15 at 27. For both the Ultra and LoProfile, Stryker relies on the PathAssist LED light fiber, and for the XprESS LoProfile, Stryker also relies on the TGS Guidewire.

The Ultra and LoProfile devices include the PathAssist LED light fiber, which illuminates sinus structures to determine the location of the distal end. Tr. (Griffis) at 514:15–515:15. The evidence supports that the light fiber illuminates sinus structures via transillumination. *Id.* at 515:16–518:3; CX-617C.16; CX-618.33; JX-133.1.6 (instructions for use); CX-1295.2; JX-102C.12; CX-1212C (video showing use of light fiber for transillumination); and CX-1191 (same).

The PathAssist LED light fiber satisfies this element because it performs the claimed function and has the claimed structure of a light fiber.

The TGS Guidewire includes an antenna that allows the user to locate the distal end. Tr. (Griffis) at 510:11–511:8 and JX-133.2.2. As Mr. Griffis explained, the distal portion of the Guidewire contains an induction coil (antenna) that transmits a signal, allowing a user to track the location of the tip. Tr. (Griffis) at 511:9–514:14; CX-1220C.3; CX-617C.91; CX-1212C (video showing use of Guidewire to track tip location); and CX-1189C (same). The TGS Guidewire satisfies this element because it performs the claimed function and has the claimed structure of an antenna. The evidence supports that the additional requirements of element 14[a] are met by the Ultra and LoProfile devices.

b) Elements 14[b], 14[c], and 14[d]

These elements recite:

> [b] wherein the inflatable balloon is adapted to dilate the at least one anatomic structure,
>
> [c] wherein the at least one anatomic structure is selected from a group consisting of: a sinus cavity, a drainage pathway of the sinus cavity, and an ostium of the sinus cavity, and
>
> [d] wherein the sinus cavity is selected from a group consisting of a maxillary sinus cavity, a frontal sinus cavity, an ethmoid sinus, and a sphenoid sinus cavity.

'878 patent at claim 14. Stryker contends that these elements are met. Stryker Br. at 209. There is no dispute that the Ultra and LoProfile devices are adapted to dilate one of the claimed anatomic structures. Tr. (Griffis) at 518:4–519:21 and JX-133.1.1. The dispute here is the same as raised for infringement, namely that the Ultra and LoProfile devices can also be used in the Eustachian tube. Fiagon Reply at 70–71. This argument is rejected for the same reason it was rejected in addressing infringement.

The evidence supports that the additional requirements of elements 14[b], 14[c], and 14[d] are met by the Ultra and LoProfile devices.

2. Claim 20

Claim 20 recites "The balloon dilation catheter of claim 1, wherein the support member comprises a hypotube formed of stainless steel." Stryker contends the additional requirements of this claim are met, Stryker Br. at 105–06, which is not disputed, Fiagon Statement at 9. The evidence supports that the slider tube is a stainless steel hypotube. Tr. (Griffis) at 520:23–521:14 and JX-129.12C.1 (hypotube engineering drawing). The evidence supports that the additional requirements of claim 20 are satisfied.

3. Claim 23

Claim 23 recites "The method of claim 22, further comprising, while advancing the inner guide member to the target location, tracking a location of the inner guide member using an image guided surgery system." Stryker contends this element is met by the LoProfile and NextGen devices when used with its ENT Nav System, Stryker Br. at 127–35, which is not disputed, Fiagon Statement at 10.

Stryker's ENT Nav System is an image-guided surgery system. Tr. (Griffis) at 574:25–575:6. Stryker's instructions for use explain that its TGS Guidewire is used with the ENT Nav System to display the position of the instrument. Tr. (Griffis) at 572:13–574:6 and 577:17–578:12; JX-133.2.2; JX-133.1.4; and JX-133.3C.12. The sensor in the TGS Guidewire allows it to be tracked. Tr. (Griffis) at 574:7–574:24. The evidence supports that the TGS Guidewire is used to track the tip of the device in an image-guided surgery. *Id.* at 575:7–577:16; CX-1220C.3; CX-1189C; and JX-133.3C.12.

The evidence supports that the additional requirements of claim 23 are satisfied by the XprESS LoProfile and NextGen, when used with the ENT Navigation system.

C. The '847 Patent Dependent Claims

1. Claim 10

Claim 10 of the '847 patent recites "The balloon dilation device of claim 1, wherein the distal end of the inner guide member comprises a bulbous tip." Stryker contends the additional requirements of claim 10 are met by the XprESS devices. Stryker Br. at 314–15. This is not disputed by Fiagon. Fiagon Reply at 112–13. The evidence supports that the tips of the inner guide member of the XprESS devices are bulbous. Tr. (Griffis) at 625:22–628:9; CX-617C.17; CX-618C.30; CX-1295.1; JX-137C.6; CX-855C.15; and JX-131.1C. The evidence supports that the additional requirements of claim 10 are met.

2. Claim 11

Claim 11 of the '847 patent recites "The balloon dilation device of claim 10, wherein the bulbous tip has an outer diameter between 1 mm and 3 mm." Stryker contends that the additional requirements of claim 11 are met by the XprESS devices. Stryker Br. at 316–19. This is not disputed by Fiagon. Fiagon Statement at 11. The evidence supports that the outer diameter of the bulbous tip falls within the claimed range. Tr. (Griffis) at 628:24–630:14; JX-130.6C.2; JX-129.6C.2; JX-133.3C.2; CX-855C.15; and JX-131.1C. The evidence supports that the additional requirements of claim 11 are met.

X. VALIDITY

Patents are presumed valid. 35 U.S.C. § 282(a); *see Microsoft Corp. v. i4i Ltd. P'ship*, 131 564 U.S. 91, 95 (2011). A party asserting invalidity must overcome this presumption by clear and convincing evidence. *Mayborn Grp. v. Int'l Trade Comm'n*, 965 F.3d 1350, 1355 (Fed. Cir. 2020); *see also Microsoft*, 564 U.S. at 103.

A. Prior Art Invalidity

Fiagon argues that most of the asserted claims are obvious over a combination of Chang, Goldfarb, Becker, Dubuclet, and the knowledge of one of skill. For claim 23 of the '878 patent, Fiagon relies on the combination of Chang, Goldfarb, Becker, Dubuclet and the knowledge of one of skill, as well as Vilsmeier. For claim 11 of the '847 patent, Fiagon relies on the combination of Chang, Goldfarb, Becker, Dubuclet and the knowledge of one of skill, as well as Morriss. Fiagon Br. at 8–109 ('878 patent claims), 141–47 ('472 patent), and 148–73 ('847 patent). Stryker disputes Fiagon's prior art invalidity challenges. Stryker Reply at 11–52 ('878 patent), 52–53 ('472 patent), and 54–71 ('847 patent).

1. Legal Standard

A claim is invalid as obvious if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Obviousness is a determination of law based on underlying questions of fact. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1374 (Fed. Cir. 2011). The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level of skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 399 (2007), citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, copying, and the failure of others. *Id.* When present, secondary considerations "give light to the circumstances surrounding the origin of the subject matter sought to be patented," but they are not necessarily dispositive on the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l*, 618 F.3d 1294, 1304–06 (Fed. Cir. 2010). For secondary considerations to be

given substantial weight in an obviousness determination, there must be a nexus between the evidence and the merits of the claimed invention. *See W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372–73 (Fed. Cir. 2010), citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

When a claim is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine known elements in the way claimed by the patent. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. at 417–418. Thus, when a respondent relies on a combination of multiple prior art references to show obviousness, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted). Because obviousness is not determined at the time of litigation, "[t]he great challenge of the obviousness judgment is proceeding without any hint of hindsight." *Star Scientific*, 655 F.3d at 1375 (Fed. Cir. 2011).

2. References Relied On and Status as Prior Art

Fiagon identifies a number of documents in its summary of the scope and content of the prior art. Fiagon Br. at 5–7 and 9 (chart). The first six are those that Fiagon contends are its combinations of prior art, which are primarily the first four (Chang, Goldfarb, Becker, and Dubuclet (along with the knowledge of one of skill)) in combination with Vilsmeier for claim 23 of the '878 patent and Morriss for claim 11 of the '847 patent. *See id.* at 9. Of the remaining, in addition to the combination of Chang, Goldfarb, Becker, Dubuclet the knowledge of one of skill, Vilsmeier, and Morriss, Fiagon relies on: (1) Makower as to claims 10 and 11 of the '847 patent,

Fiagon Br. at 167 and 173; (2) Dollar as element 1[b] of the '878 patent, *id.* at 16[15]; (3) Miller as to elements 1[c], 1[h], and 1[i] of the '878 patent, *id.* at 19, 40, and 42; (4) Goldfarb II as to motivation to combine Goldfarb and Chang, *id.* at 15; and (5) BrainLAB as to claims 14 and 23 of the '878 patent, *id.* at 71 and 91. Fiagon relies on Makower, Chang II, Dollar, Goldfarb II, and Chang III to rebut secondary considerations of non-obviousness. *Id.* at 94 and 96.

Fiagon asserts the following obviousness combinations for the '878 patent:

'878 Patent Claim	Obviousness Grounds
1	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 1.
14	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 14. Chang, Goldfarb, Becker, and Dubuclet in view of Vilsmeier and the Knowledge of a POSITA render obvious Claim 14.
20	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 20.
22	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 22.
23	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 23. Chang, Goldfarb, Becker, and Dubuclet in view of Vilsmeier and the Knowledge of a POSITA render obvious Claim 23.

Fiagon Br. at 9. For claim 1 of the '472 patent, Fiagon relies on the following combination:

'472 Patent Claim	Obviousness Grounds
1	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 1.

Id. at 141. For claims 1 and 11 of the '847 patent, Fiagon relies on the following combinations:

[15] As noted, the parties used different labeling conventions when addressing individual claim elements. This decision uses Stryker's conventions.

'847 Patent Claim	Obviousness Grounds
1	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 1.
10	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 10. Chang, Goldfarb, Becker, and Dubuclet in view of Morriss and the knowledge of a POSITA render obvious Claim 10.
11	Chang in view of Goldfarb, Becker, Dubuclet, and the knowledge of a POSITA render obvious Claim 11. Chang, Goldfarb, Becker, and Dubuclet in view of Morriss and the knowledge of a POSITA render obvious Claim.

Id. at 148.

As to prior art status of the six references Fiagon primarily relies on, the evidence supports that: (1) U.S. Patent Publication No. 2006/0210605 to Chang (JX-197) published on September 21, 2006; U.S. Patent Publication No. 2007/0249896 to Goldfarb (JX-173) published on October 25, 2007; (3) U.S. Patent Publication No. 2007/0073269 to Becker (JX-31) published on March 29, 2007; (4) U.S. Patent Publication No. 2009/0076446 to Dubuclet (JX-198) was filed on September 14, 2007 and published on March 19, 2009; (5) U.S. Patent No. 6,351,659 to Vilsmeier (RX-179) issued on February 26, 2002; and (6) U.S. Patent No. 8,118,757 to Morriss (JX-199) issued on February 21, 2012 and published on October 30, 2008 as U.S. Patent Publication No. US 2008/0269643. The asserted patents each have an earliest filing date of June 5, 2009. *See* JX-1; JX-2; and JX-3.

The evidence supports that: (1) each of Chang, Goldfarb, Becker, and Vilsmeier is prior art under 35 U.S.C. § 102(b); (2) Dubuclet is prior art under 35 U.S.C. § 102(e); and (3) Morriss

(the patent publication) is prior art under 35 U.S.C. § 102(a). *See* Fiagon Br. at 5–6.[16] The prior art status of the six primary references is not disputed by Stryker. *See* Stryker Reply.

3. Analysis

a) Chang

The primary reference Fiagon relies on is Chang, which is directed to devices for treating sinusitis. JX-197. Chang recognizes that balloon dilation devices were used in the prior art, but did not "disclose designs for flexibly navigating through the complex nasal anatomy." *Id.* at ¶ 17. Chang disparages prior art with a stiff hypotube, stating:

> United States patent publication No. 2004/0064150 A1 (Becker) discloses balloon catheters formed of a stiff hypotube to be pushed into a sinus. The balloon catheters have a stiff hypotube with a fixed pre-set angle that enables them to be pushed into the sinus. In at least some procedures wherein it is desired to position the balloon catheter in the ostium of a paranasal sinus, it is necessary to advance the balloon catheter through complicated or tortuous anatomy in order to properly position the balloon catheter within the desired sinus ostium. Also, there is a degree of individual variation in the intranasal and paranasal anatomy of human beings, thus making it difficult to design a stiff-shaft balloon catheter that is optimally shaped for use in all individuals. Indeed, rigid catheters formed of hypotubes that have pre-set angles cannot be easily adjusted by the physician to different shapes to account for individual variations in the anatomy. In view of this, the Becker patent application describes the necessity of having available a set of balloon catheters, each having a particular fixed angle so that the physician can select the appropriate catheter for the patient's anatomy. The requirement to test multiple disposable catheters for fit is likely to be very expensive and impractical. Moreover, if such catheter are disposable items (e.g., not sterilizable and reusable) the need to test and discard a number of catheters before finding one that has the ideal bend angle could be rather expensive.

Id. at ¶ 18. According to Chang, "there is a need for new devices and methods for easily navigating the complex anatomy of the nasal cavities and paranasal sinuses and for treating disorders of the

[16] Fiagon's arguments on the prior art status of the many references it relies on is confusing and, in some instances, wrong. For example, Fiagon contends that the references are prior art under both the AIA and the pre-AIA versions of the statute but does not explain why both versions of the statute apply.

paranasal sinuses with minimal complications due to individual variations in anatomy and causing minimal trauma to or disruption of anatomical structures that are not pathogenic." *Id.* at ¶ 20.

Chang discloses using "introducing devices" and "working devices." An introducing device is used to facilitate insertion of working devices. *Id.* at ¶ 23. A working device may be a balloon catheter. *Id.* Chang describes steps performed using introducing and working devices to perform sinus procedures. For example, in explaining Figs. 2A–2D, Chang discloses that a first introducing device, guide catheter 200, is inserted in the nose, followed by a second introducing device, guidewire 202, which is inserted through the guide catheter 200, followed by a working device, balloon catheter 204, which is inserted over the guidewire 202. *Id.* at ¶ 139.

Figs. 9A–9D "show components that may be used alone or in various combinations to perform transnasal procedures," as depicted below:

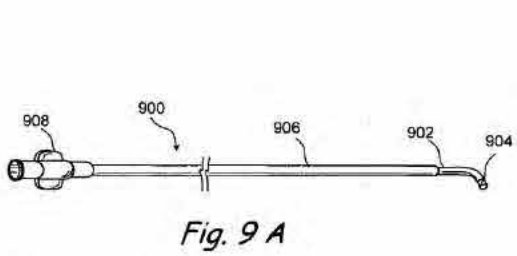


Fig. 9 A



Fig. 9 B

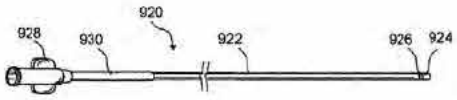


Fig. 9 C

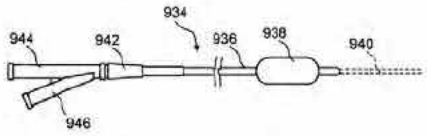


Fig. 9 D

Id. at Fig. 9 and ¶ 184. In describing "a method of treating sinusitis by dilating an opening in a paranasal sinus," Chang explains that a guide device 900 (Fig. 9A) is inserted through the nose, followed by a guidewire 910 (Fig. 9B), such that the distal end of the guidewire emerges out of the distal end of the guide device 900. *Id.* at ¶¶ 189–90. "Thereafter, a suitable balloon catheter

934[17] [Fig. 9D] is passed over guidewire 910 through guide device 900, into the opening of the paranasal sinus." *Id.* at ¶ 191. Balloon catheter 934 is then positioned across a target region to be dilated. *Id.*

Balloon catheter 934 comprises an elongate shaft 936 that may be made from "suitable biocompatible polymers including, but not limited to Nylon, Pebax, polyethylene, etc." *Id.* at ¶ 188. It also includes a marker on the proximal shaft which indicates approximately the exit of the balloon from the distal end of the guiding catheter 900. *Id.* Chang explains that the visual marker is "used to verify relative location of balloon 938 relative to distal end of guide device when balloon catheter 934 is used introduced [sic] through guide device 900." *Id.* When the balloon completely exits the distal end of guide device 900, "erroneous inflation of balloon 938 within guide device 900 can be prevented." *Id.*

Chang also discloses that the guidewire 910 can be preloaded in guide device 900 and that the balloon catheter 934 may be preloaded over guidewire 910, which is in turn preloaded inside guide device 900. *Id.* at ¶ 194. In that configuration, the balloon catheter 934, guidewire 910, and guide device 900 can be introduced in the nasal cavity "such that the distal end of the combination is positioned near a desired target region." *Id.* "Thereafter, guidewire 910 is advanced into the desired target region such as a sinus cavity. Thereafter, balloon catheter 934 is advanced over guidewire 910. Balloon 938 is then inflated to dilate an anatomical region." *Id.* Chang discloses "[s]everal variations" of procedures to treat sinusitis by dilation using balloon catheter 934. In

[17] Chang alternatively discloses that a balloon catheter can be used with a puncturing device, as shown in Fig. 3. Chang at ¶¶ 37 and 147. The puncturing device creates an artificial opening in the maxillary sinus. Tr. (Griffis) at 1260:22–1261:20. Fiagon's expert did not rely on Chang's Fig. 3 or related disclosure in asserting invalidity. *See* Fiagon Br. at 56 (addressing Fig. 3 without citation to any testimony from its expert) and *see* RDX-25C.

each, the balloon catheter is used with both the guide device 900 and guidewire 910 in different arrangements. *Id.* at ¶¶ 189–199.

Chang discloses another embodiment of its balloon catheter in Fig. 14:

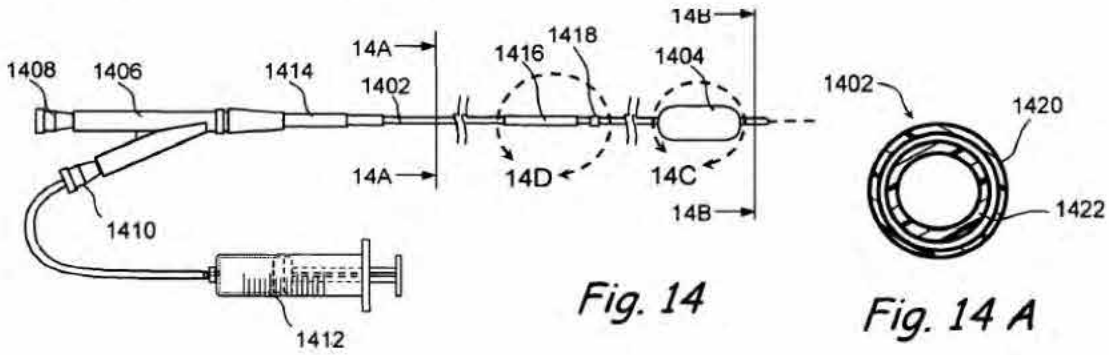


Fig. 14 Fig. 14 A

Id. Chang states that balloon catheter 1400 in Fig. 14 can be used as the balloon catheter 934 in Fig. 9D. *Id.* at ¶ 212. Balloon catheter 1400 includes elongate shaft 1402, which "comprises a guidewire lumen to allow balloon catheter 1400 to be introduced over a guidewire." *Id.* A balloon 1404 is located on elongated shaft 1402. *Id.* Elongate shaft 1402 comprises an outer tube 1420 and an inner tube 1422, which "can be made of suitable biocompatible materials, including but not limited to Pebax, Nylon, etc." *Id.* at ¶ 213 and Fig. 14A. The inner tube 1422 comprises a guidewire lumen and the lumen between the outer tube 1420 and the inner tube 1422 "encloses a balloon inflation lumen that is in fluid communication with balloon 1404." *Id.*

Balloon catheter 1400 includes a Y-connector 1406 with a first port 1408 "that leads to [the] guidewire lumen in balloon catheter 1400" and a second port 1410 that is in fluid communication with the balloon inflation lumen. *Id.* at ¶ 212. "A stress relief tubing 1414 may be located between the 'Y' connector and the elongate shaft 1402." *Id.* Fig. 14 also shows shaft markers 1416 and 1418, which are used to "verify the location of the balloon relative to the end of a guide device when the balloon catheter 1404 [sic, 1400] is introduced through the guide device." *Id.* at ¶ 213.

Chang also discloses various embodiments of guide devices that can be used with the system shown in Figs. 9A–9D and by extension the balloon catheter shown in Fig. 14. *Id.* at ¶ 200 and Figs. 10 and 11 and ¶ 212 (the balloon catheter in Fig. 14 may be used as balloon catheter 934 in Fig. 9D). The guide devices shown Chang's Figs. 10 and 11 comprise an elongate tube made of suitable biocompatible materials, such as Nylon and Pebax, and a hypotube made of stainless steel, titanium, Nitinol, or a Nylon polymer. *Id.* at ¶ 200 and Fig. 10A, elements 1002 and 1006) ¶ 201 and Fig. 10B, elements 1012 and 1016, ¶ 202 and Fig. 10C, elements 1022 and 1026, ¶ 203 and Fig. 10D, elements 1032 and 1036, ¶ 204 and Fig. 10E, elements 1042 and 1046, and *see* ¶ 207 and Fig. 11, elements 1102 and 1106.

b) Comparison to the Claims

Each asserted claim recites a balloon dilation catheter with a handle, an inner guide member that is malleable or has a bend and that has an inflatable balloon disposed on it, and a shaft. Each asserted claim also recites that a proximal portion of the inner guide member is in the handle. Claim 1 of the '878 patent and claim 1 of the '847 patent recite that the inner guide member is stainless steel. Claims 1 and 22 of the '878 patent and claim 1 of the '472 patent additionally recite that the balloon dilation catheter includes a support member.

Fiagon relies on Fig. 14 of Chang (with colored labeling it added):

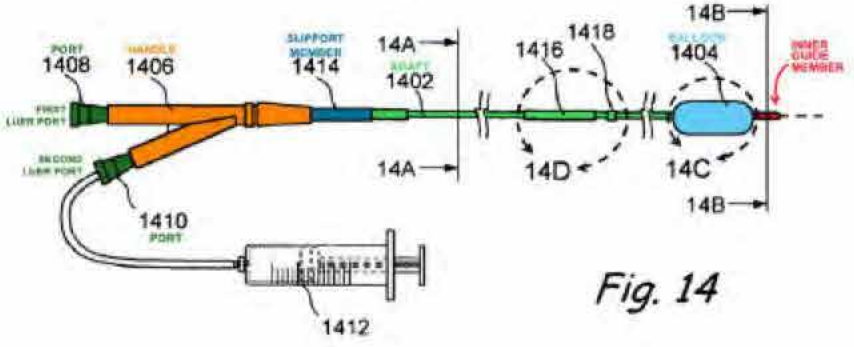


Fig. 14

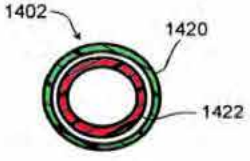


Fig. 14 A

RDX-25C.34. According to Fiagon, Chang's Y-connector 1406 is the claimed handle, outer tube 1420 is the claimed shaft, inner tube 1422 is the claimed inner guide member, and stress relief tubing 1414 is the claimed support member. Fiagon Br. at 11–13 (handle), 17 (inner guide member), 29 (shaft), and 31–32 (support member). Stryker disputes that:

> (1) Chang discloses that inner tube 1422 is malleable or has a bend, Stryker Reply at 28–36 ('878 patent element 1[j]), 46 ('878 patent element 22[i]), 53 ('472 patent element 1[g]), and 55–59 ('847 patent element 1[d]);
>
> (2) Chang discloses that inner tube 1422 is stainless steel *id.* at 36–41 ('878 patent claim 1[k]) and 55–59 ('847 patent claim 1[e]);
>
> (3) Chang's Y-connector 1406 is a handle, *id.* at 12–19 ('878 patent element 1[b]), 46 ('878 patent element 22[c]), 52 ('472 patent element 1[b]), and 55 ('847 patent element 1[b]); and
>
> (4) Chang discloses that a proximal portion of inner tube 1422 extends into Y-connector 1406, *id.* at 19–24 ('878 patent element 1[c]), 46 ('878 patent element 22[e]), 53 ('472 patent element 1[c]), and 55 ('847 patent element 1[c]);

Arguments (1) and (2) focus on the claimed inner guide member while arguments (3) and (4) focus on the claimed handle. They are addressed in turn.

(1) Inner Guide Member

Each of the asserted claims recite that the inner guide member is malleable or bendable. Specifically, element 1[j] of the '878 patent recites that "the distal portion of the inner guide member is malleable"; element 22[i] of the '878 patent recites "forming a bend . . . to change the shape of the inner guide member"; element 1[g] of the '472 patent recites that "a distal end of the support member is located proximal to a bend in the inner guide member"; and element 1[d] of the '847 patent recites that "the distal portion of the inner guide member is malleable such that the distal portion of the inner guide member is configured to be shaped with an angle of 0 to 120 degrees relative to the proximal portion of the inner guide member."

Certain claims recite that the inner guide member is stainless steel. Specifically, element 1[k] of the '878 patent recites that "the inner guide member comprises a hypotube formed from stainless steel" and element 1[e] of the '847 patent recites that "the inner guide member is a stainless steel hypotube."

The evidence does not support that Chang discloses or suggests that its inner tube 1422 is malleable or has a bend or that it is made of stainless steel. Instead, the evidence supports that the inner tube 1422 of Chang's balloon catheter, shown in Fig. 14, is flexible and intended to be used with a rigid guide catheter and a guide wire. Tr. (Griffis) at 1123:14–1125:7, 1130:3–13 ("Chang's balloon catheter, it's a flexible construct . . . meant to be advanced over the guidewire and through a preplaced guide device"), 1290:17–1291:11 (Fig. 14 of Chang relates to the use of a guide catheter, guidewire, and flexible balloon catheter in combination) and 1309:18–24 (one of skill in the art when the asserted patents were filed would have understood that a flexible balloon catheter would be used with a guide catheter and that flexibility at the distal segment was necessary).

Dr. Griffis credibly explained that Chang discloses a rigid guide catheter and a guidewire used to direct a flexible balloon catheter toward a treatment area and that the ballon catheter devices in Figs. 9 and 14 of Chang are "necessarily flexible." Tr. (Griffis) at 1122:8–21, 1125:27, 1148:18–1150:6, and 1309:18–24 and RDX.33C.73–74. Mr. Griffis also credibly testified that Chang's system will not work if its tube 1422 is not flexible, i.e., if it is malleable or bent, because it would become stuck in the guide catheter or deflect and become difficult to remove. Tr. (Griffis) at 1150:7–1151:2 and 1302:3–1303:4 and CDX-33C.75–78.

That Figs. 9 and 14 of Chang are directed to a flexible balloon catheter is further supported by Chang's disclosure that suitable biocompatible polymers are used to form outer tube 1420 and inner tube 1422. Chang at ¶ 213. Mr. Griffis credibly testified that one of skill would understand

that a "suitable" material would have to be flexible "if it was going to traverse through the guide catheter and over a guidewire." Tr. (Griffis) at 1242:12–14. Mr. Griffis did not, as Fiagon argues, exaggerate Chang's disclosure. Fiagon Br. at 57. Instead, he persuasively testified that the shaft component in Chang's Fig. 14 is flexible. Tr. (Griffis) at 1242:24–1243:2 ("I've been using these polymers for 34 years, and I can tell you that in every instance where I have referred to that use in combination with a balloon catheter, it's because the balloon catheter was meant to be flexible"), and 1243:7–10 ("In this particular case, Pebax and nylon used in the fashion that Chang disclosed would be flexible if they were going to be used like a balloon catheter shown in [Fig. 9]."") This is contrasted with the guide catheters in Chang's Figs. 10 and 11, which include a hypotube made of stainless steel or similar materials. Chang at ¶¶ 188 (Fig. 9), 200–204 (Fig. 10), 207 (Fig. 11), and 213 (Fig. 14).

Chang also disparages ballon catheter devices that "have a stiff hypotube with a fixed pre-set angle," stating that it "is difficult to design a stiff-shaft balloon catheter that is optimally shaped for use in all individuals" and that "rigid catheters formed of hypotubes that have preset angle cannot be easily adjusted by the physician to different shapes to account for individual variations in the anatomy." JX-197 at ¶ 18. Mr. Griffis credibly testified that Chang teaches away from the balloon catheter devices in Figs. 9 and 14 having stiff hypotubes. Tr. (Griffis) at 1297:8–12.

Fiagon relies on Chang's disclosure as to Figs. 6A–6G illustrating "partial perspective views of several embodiments of shaft designs for the various devices disclosed herein," JX-197 at ¶ 172, and in particular Chang's disclosure in Fig. 6G of "an embodiment of a device comprising a shaft 628 comprising a proximal portion 630, a distal portion 632, a working element 634, and a plastically deformable region 636 located between the proximal portion 630 and distal portion 632," as shown below:

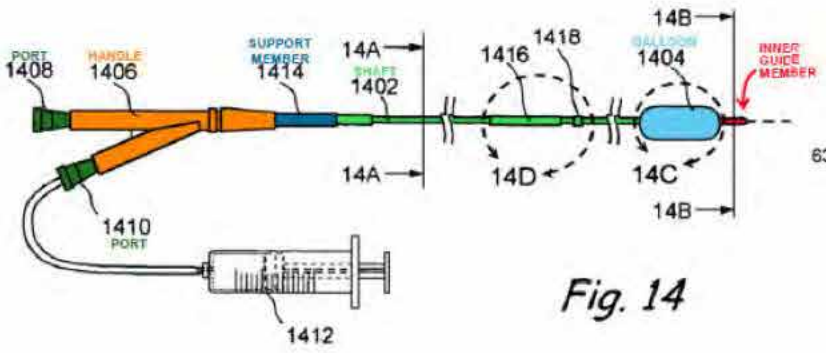


Fig. 14

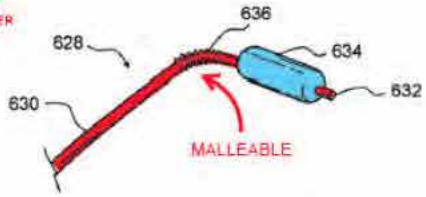


Fig. 6 G

Id. at ¶ 173 and Stryker Br. at 44–47. Fiagon argues that Chang teaches that the embodiment in Fig. 14 can be modified to include the plastically deformable region of Fig. 6G. Tr. (Burban) at 908:17–24. Dr. Burban relies on a discussion of Figure 6G, disclosing a "plastically deformable[18] region 636" on the shaft. *Id.* at 858:19–860:20, 861:15–2. Dr. Burban testified that Chang's teachings about Fig. 6G apply to all devices, including the balloon catheter shown in Fig. 14 because Chang states that Figs. 6A–6G "illustrate partial perspective views of several embodiments of shaft designs for the various devices disclosed herein" and that plastically deformable region 636 may be located within working element 634, which is a balloon device. Tr. (Burban) at 862:3–25 and 909:11–20 and Chang at ¶¶ 172–73. Chang discloses that the shaft designs of Figs. 6A–6G "are especially useful for devices that encounter high torque or burst pressures or require enhanced pushability, steerability and kink resistance[,]" which Dr. Burban testified includes balloon catheters. *Id.*

In contrast to devices in Chang's Fig. 6, which "encounter high torque or burst pressures or require enhanced pushability," suggesting stiffness, the evidence supports that shaft 1402 in the

[18] Dr. Burban testified that plastically deformable means malleable, and that a malleable or plastically deformable device is bendable and "holds its bend." Tr. (Burban) at 860:18–861:14. This does not appear to be disputed by the parties.

embodiment shown in Fig. 14, made up of inner tube 1422 and outer tube 1420, are composed of flexible materials such as Pebax or nylon. Tr. (Griffis) at 1124:16–1125:7 and Chang at ¶ 213. This is because Chang's balloon catheter is intended to be used with a rigid guide catheter and guidewire. *Id.* Mr. Griffis persuasively testified that for the balloon catheter in Chang to travel over the guidewire and through the guide catheter, it needs to be flexible. *Id.* at 1148:18–1150:6 and CDX-33C.73–75. The evidence supports that replacing Chang's inner tune 1422 with a malleable or bendable component would not work because the balloon catheter would become stuck in the guide device or would be very difficult to remove independent of the guide device. *Id.* at 1150:7–1151:3.

Mr. Griffis likewise credibly testified that a prebent malleable stainless steel hypotube would not work in Chang because the same issues would arise, namely it would only be able to be advanced "up and to the point at which you had preformed or prebent the balloon catheter disclosed by Chang. And at that point either it would become stuck and you'd have to withdraw or you would have to deform it and remove the bend in the malleable inner guide member identified by Dr. Burban for it to continue to advance through the guide catheter." *Id.* at 1151:5–22. The evidence supports that notwithstanding Chang's disclosure regarding Fig. 6, one of skill in the art would not modify Chang's inner tube 1422 to be malleable, have a bend, or be stainless steel because it would get stuck in the guide device and would not work. Tr. (Griffis) at 1302:1303:4 and 1306:12–22.

Chang states that the components in its Figs. 9A–9D "may be used alone or in various combinations to perform transnasal procedures." Chang at ¶ 184. Fiagon references the even broader statement in Chang that:

> Still further in accordance with the invention, there are provided tubular guides, guidewires, balloon catheters, tubular sheaths and related methods for using such

> devices individually or in various combinations to dilate openings of paranasal sinuses (e.g., any transnasally accessible opening in a paranasal sinus or cranio-facial air cell, including but not limited to; natural ostia, surgically or medically altered ostia, surgically created or man made openings, antrostomy openings, ostiotomy openings, trephination openings, burr holes, drilled holes, ethmoidectomy openings, anatomical passageways, natural or man made passages, etc.) or other anatomical structures such as structures within the head or a human or animal subject that comprise bone covered at least in part by mucosal tissue.

Fiagon Br. at 56, citing Chang at ¶ 25. From this, and without citing any testimony from its expert, Fiagon contends that one of skill would understand that the balloon catheters in Chang's Figs. 9 and 14 could be used without a guide catheter. Fiagon Br. at 55–56. Chang, however, consistently discloses that balloon catheter 934 in Fig. 9 and balloon catheter 1400 in Fig. 14 are used with a guide catheter. Chang at ¶¶ 189–194 (describing use of guide catheter with balloon catheter), 212 (balloon catheter in Fig. 14 can be used as balloon catheter 934), and 213 (use of visual markers to ensure balloon is not inflated in guide catheter). And Mr. Griffis credibly testified, that is how one of skill would understand Chang. Tr. (Griffis) at 1148:18–1149:3, 1150:15–25, and 1151:1–12, 1152:17–1153:4.

Fiagon contends that "when Chang teaches that the malleable tube could be used with any 'of the devices mentioned herein,' that teaching applies to Figure 14 and it would be obvious to modify Figure 14 accordingly." Fiagon Br. at 63. Fiagon relies on testimony from Dr. Burban, but Dr. Burban never explains why one of skill would jettison the flexible catheter design of Figs. 9 and 14 based on a general suggestion that different tubes can be used in different devices especially in view of Chang's caution about stiff hypotubes. I credit the testimony of Dr. Griffis that one of skill would not. Tr. (Griffis) at 1152:17–1153:4.

The fact that Chang states that balloon catheter 1400 *may* be used as the balloon catheter 934 does not support that Chang suggests using it without a guide catheter, as Fiagon argues, without any supporting testimony from its expert. Fiagon Br. at 55. In fact, Chang's disclosure

specifically relating to Fig. 14 supports that it is used with a guide catheter. Chang at ¶ 213 (addressing avoiding inflating the ballon within the guide catheter).

Pointing to ¶ 188 of Chang, Fiagon contends, again without citation to any testimony from its expert, that "Chang includes a second teaching for Figure 9 for use without a guide catheter—the balloon catheter could have a 'fixed guidewire' that can be used to navigate the catheter through the anatomy." Fiagon Br. at 57. Chang states that, "[i]n an alternate embodiment, balloon catheter 934 comprises a fixed guidewire 940 such that the distal end of fixed guidewire 940 forms the distal end of balloon catheter 934. Fixed guidewire 934 may be used for navigation balloon catheter 934 through the anatomy." Chang at ¶ 188. It is hard to know what to make of this ungrammatical sentence. It appears, however, to be consistent with later disclosure in Chang that balloon catheter 934 may be preloaded over guidewire 910, with that combination in turn being preloaded into guide device 900. Chang at ¶ 194. As support for its argument that this is disclosure of using balloon catheter 934 without a guide device, Fiagon points to testimony from Mr. Drontle, one of the named inventors. Fiagon Br. at 57. This testimony, however, does not relate to what Chang discloses but instead, as Fiagon says, relates to the structure of a Stryker product. *Id.* (referring to Stryker XprESS products). That testimony is irrelevant to how one of skill in the art would understand Chang. The unclear statement in Chang unsupported by testimony from Fiagon's expert does not support that Chang discloses using balloon catheter 934 without a guide device.

Fiagon next argues that Mr. Griffis testified that the stress relief tubing 1414 of Chang is not needed because Chang uses a guide catheter. From that, again without citation to any testimony from its own expert, Fiagon extrapolates that because Fig. 14 shows stress relief tubing, one of skill "would conclude the Figure 14 catheter can be used without a guide catheter." Fiagon Br. at 57. The evidence contradicts Fiagon's argument. In testimony immediately after that cited by

Fiagon, Mr. Griffis explained that Chang's stress relief tubing "is meant to be a transition between a more rigid feature [the Y-connector] and then a more flexible feature [shaft 1402 including inner tube 1422] to prevent kinking or buckling." Tr. (Griffis) at 1247:25–1248:7. Mr. Griffis did not testify, and his testimony cannot be reasonably read as implying, that the use of stress relief tubing supplants the use of a guide catheter. This, in fact, is inconsistent with Chang which identifies stress relief tubing in a single sentence and explains that a balloon catheter with stress relief tubing is used with a guide catheter. Chang at ¶ 212 ("A stress relief tubing 1414 may be located between 'Y' connector 1406 and elongate shaft 1402") and ¶ 213 (describing use with a guide device).

Fiagon next criticizes Mr. Griffis for not presenting "any testimony that anything in the Figure 14 embodiment would need to be modified to use it without a guide catheter." Fiagon Br. at 61. This makes no sense.[19] The evidence supports that balloon catheter 1400 in Chang is used with a guide catheter. Mr. Griffis was under no obligation to explain how to modify an embodiment that Chang does not disclose.

Fiagon also argues that the same architecture for a balloon catheter can be used with or without a guide catheter, relying on testimony from Dr. Burban:

> Q. Okay. Now, is there any reason why the Fig. 14 device modified as you suggest could not be used without a guide catheter?
>
> A. There's no reason. Chang even teaches that devices can be used without guide catheters as well.
>
> Q. Okay. Is there anything special about the architecture of balloon catheters that are used without guide catheters as compared to those that are?
>
> A. Other than the material of the inner guide member, no.

[19] This argument is also inconsistent with Dr. Burban's repeated testimony that it was necessary to modify Chang's Fig. 14. Tr. (Burban) at 908:17–24, 973:24–975: 4, and 988:15–18.

Fiagon Br. at 61, citing Tr. (Burban) at 982:11–20. While Chang may teach that some devices can be used without guide catheters, the evidence supports that the balloon catheters in Figs. 9 and 14 are used with guide catheters. And Mr. Burban's testimony that there is "nothing special about the architecture of balloon catheters that are used without guide catheters as compared to those that are" improperly tosses aside the teachings of the many prior art references Fiagon relies on in asserting obviousness in favor of a hindsight-informed view in light of the claims.

Clear and convincing evidence does not support that Chang discloses or suggests a ballon catheter with a malleable or bendable inner guide member as recited in each of the asserted claims.

Fiagon contends that "Dubuclet and Becker confirm that malleable distal regions were conventional and used to customize the catheter shape to patient anatomy." Fiagon Br. at 47 (claim 1 of the '878 patent), 81–82 (addressing Chang and Becker as to the "forming a bend in the inner guide member" in element 22[i] of the '878 patent), 145–146 (incorporating discussion of '878 patent claims 1 and 22 for the "bend in the inner guide member" in '472 patent claim element 1[g]), and 151–154 (incorporating discussion of claim 1 of the '878 patent with respect to the "wherein the distal portion of the inner guide member is malleable" limitation of element 1[d] of the '847 patent). Stryker disputes that one of skill would make the inner tube 1422 of Chang malleable or bendable based on Dubuclet or Becker. Stryker Reply at 33–36 ('878 patent claim 1), 46–47 (claim 22 of the '878 patent), 53–54 ('472 patent), and 55–59 ('847 patent).

Fiagon does not establish why one of skill would modify Chang's Fig. 14 to be used without a guide catheter. While Dubuclet does not require a guide catheter, that does not mean one of skill would modify Chang to not use a guide catheter; there is not, for example, a reason why using a guide catheter is a deficiency in Chang. *See* Fiagon Br. at 62–63. Dr. Burban's testimony does not show otherwise; it focuses on prior art that had stiff hypotubes. But as Mr. Griffis

explains, Becker discloses a different configuration of tubes. Tr. (Griffis) at 1162:4–19. As for Dubuclet, while Dr. Burban explains that its balloon catheter can be used without a guide catheter, he does not provide a reason why one of skill would modify Chang to do so. Tr. (Burban) at 984:9–985:6. Dr. Burban testified that one of skill would understand when a flexible catheter would be necessary as opposed to a rigid one but did not establish that one is preferable. *Id.* at 985:19–986:2. Dr. Burban's opinion is premised on his incorrect conclusion that Chang does not use a guide catheter with the balloon catheters in Figs. 9 and 14. *Id.* at 987:7–988:6. The evidence supports that the balloon catheters in Chang Figs. 9 and 14 are used with a guide catheter, and the evidence does not support that it would be obvious to modify Chang to not use a guide catheter.

The evidence does not support that Chang alone, or Chang in combination with Becker and Dubuclet, disclose or suggest an inner guide member that is malleable or has a bend or that is made of stainless steel, as claimed.

(2) Handle

Each of the asserted claims recites a balloon catheter device with a handle and that a proximal portion of the inner guide member is in the handle. Specifically, elements 1[b] and [c] of the '878 patent recite "a handle having a proximal end and a distal end, wherein the handle comprises a first port at the proximal end of the handle and a second port at the proximal end of the handle" and "an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle"; elements 22[c], [d], and [e] of the '878 patent recite "a handle having a proximal end and a distal end, an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle"; elements 1[b] and [c] of both the '472 and '847 patents recite "a handle having a proximal end and a distal end" and "an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member

is in the handle." The evidence does not support that Chang discloses a balloon catheter device with a handle or that a proximal portion of its inner tube 1422 is in the handle.

Fiagon contends that Chang's Y-connector, as shown below, is the claimed handle:

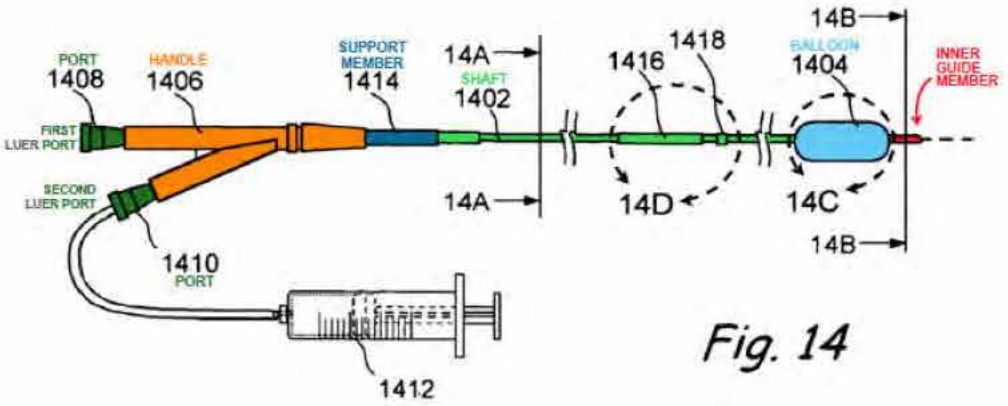


Fig. 14

Fiagon Br. at 11–13; Tr. (Burban) at 826:5–827:5; Chang at ¶ 212 and Fig. 14; and RDX-25C.36. Dr. Burban testified that "the Y-connector is where anybody would hold on to the device. I've used Y-connectors in my career. . . . So it seemed reasonable and obvious that's the handle. Even though it's called a Y-connector, you've got to hold onto this thing somewhere. So Chang didn't call it a handle, but I believe it's a -- the Y-connector is the handle." Tr. (Burban) at 826:12–827:5.

Mr. Griffis testified that Chang's Y-connector is not a handle. In particular, Mr. Griffis testified that Chang does not call its Y-connector a handle and one of skill would not have understood Chang's Y-connector to be a handle but instead to be where its two ports are accessed. Tr. (Griffis) at 1129:12–24. Mr. Griffis explained that because Chang's flexible balloon catheter is loaded onto the guidewire, which has a small diameter, the distal end of the device would be grasped and loaded "so that you could feed the wire through it." Then, Chang's balloon catheter would be advanced over the guidewire and into the guide device by "grasping it at different locations along the shaft until, ultimately, the device was positioned through the guide device." Mr. Griffis recognized that "at that point you would be interacting with the Y-connector so that

you could either add additional components, like a Tuohy-Borst valve, which then locks the guidewire in relative position with the balloon dilation device, or you connect up the inflation/deflation port to an extension line or a syringe." Tr. (Griffis) at 1129:25–1131:8. In Mr. Griffis's opinion, although there are a variety of locations along the body of Chang's balloon catheter at which it is meant to be contacted (i.e., grasped), none of them are a handle. *Id.* at 1131:9–17.

The fact that Chang does not call its Y-connector a handle is not dispositive. *See* Stryker Reply at 12. Mr. Griffis's testimony on whether Chang nonetheless discloses a handle is credible and comports with the specification. The specification states that the handle is "configured to be gripped or otherwise manipulated by the operator." '878 patent at 3:60–62 and 11:27–29 (same). The fact that portions of Chang may be gripped or manipulated does not mean they are configured that way and does not make them a handle. *See* Tr. (Griffis) at 1262:14–1263:4. This is common sense. Take a coffee mug and a drinking glass. A typical coffee mug has a handle, that is, a part configured to be grasped or held. A typical drinking glass, while intended to be grasped or held, does not. Not everything intended to be grasped or held is a handle, which was Dr. Burban's position. Tr. (Burban) at 826:13–22 ("you've got to hold onto this thing somewhere"). Dr. Burban's testimony on this point was not credible. I agree with Mr. Griffis that the fact that parts of Chang's balloon catheter will be held or grasped by a user does not mean that those parts are a handle. In addition, the flexible nature of Chang's balloon catheter and how it is threaded onto a guide wire and inserted into the guide catheter support that Chang's Y-connector is not a handle.

Fiagon argues that during prosecution, the Examiner referred to "a Y-connector like Chang's as a 'handle.'" Fiagon Br. at 13, citing JX-6.149. There, the Examiner was addressing Miller (the same reference Fiagon relies on) and indicated that its "Y-shaped fluid control and

access device, e.g. a Luer-Lok" was a handle. JX-6.147–49 and RX-346 at ¶ 52. The evidence shows that while the applicant did not address that characterization, they stated that "Miller is specifically directed to neurovascular, coronary, or peripheral microcatheters, which are specifically required to have a flexible structure for the alleged inner guide member." JX-6.232. Following claim amendments and that and other arguments, the claims were allowed. *Id.* at 253. Mr. Griffis credibly testified that one of skill would not consider Miller's Y-connector as a handle. Tr. (Griffis) at 1132:16–1133:11.

Fiagon next argues that if Chang's Y-connector is not a handle, "Goldfarb teaches handles can be used for guide catheters to be inserted in the sinuses." Fiagon Br. at 14–15. Goldfarb is directed to using an endoscope during a transnasal procedure. JX-173 at ¶ 12. There, sinus guide assembly 10 includes a sinus guide 12 and an endoscope 14, as shown below:

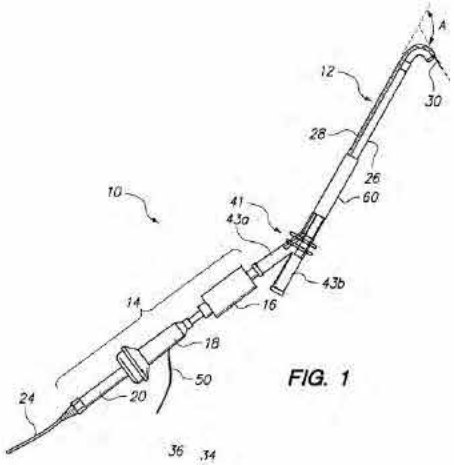


FIG. 1

Id. at Fig. 1 and ¶ 13. In Goldfarb, the endoscope 14 is attached to one of the ports of the sinus guide catheter 12 and an endoscope channel 28 runs along sinus guide body 26, which comprises a tube and a lumen. *Id.* at Figs. 1 and 3 and ¶ 93. Goldfarb discloses a handle 60 in the sinus guide catheter 12, as shown below:

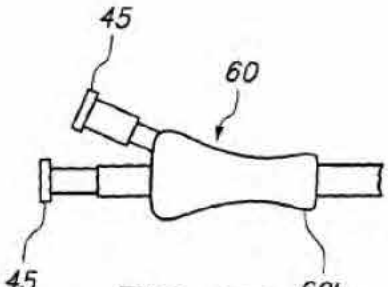


FIG. 5A

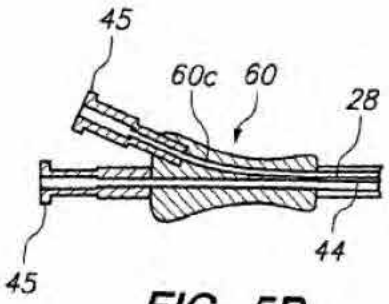


FIG. 5B

Id. at Figs. 5A and 5B and ¶¶ 107–08. Goldfarb also discloses that in lieu of endoscope 14, a balloon catheter as disclosed in Chang can be inserted into channel 28. *Id.* at ¶ 109 (stating that the devices disclosed in application serial no. 11/150,847, the application that issued as Chang, can be inserted into channel 28) and *see* Tr. (Burban) at 829:3–6 (Goldfarb incorporates Chang by reference). Inserting Chang's ballon catheter results in handle 60 being on the guide catheter 12 and not on the balloon catheter. *See* Tr. (Griffis) at 1134:5–18. Mr. Griffis credibly and persuasively explained that Goldfarb's guide catheter has a different structure and purpose from Chang's balloon catheter and one of skill would not have been motivated to add Goldfarb's handle to Chang's Y-connector. *Id.* at 1133:25–1135:11. Indeed, the fact that Goldfarb discloses attaching Chang's balloon catheter with just its Y-connecter to channel 28 with the separate handle 60 on Goldfarb's sinus guide 12 supports that one of skill would not have been motivated to add a handle to Chang.

Fiagon argues that another reference, Goldfarb II, provides a motivation to combine Goldfarb and Chang. Fiagon Br. at 15–16. Goldfarb II, like Chang, discloses a system with a guide catheter 40, guide wire GW, and a balloon catheter 10. RX-294 at Figs. 1 and 2 and ¶¶ 33 and 45. Goldfarb II discloses that an "optional handle may be attached to the dilation catheter or to a guide catheter through which the dilation catheter is inserted." *Id.* at ¶ 9. In disclosing details of its optional handle, Goldfarb II describes a dilation catheter/guide catheter system with optional

handle. *Id.* at ¶ 53 (title). As shown and described, Goldfarb II discloses the optional handle attached to the guide catheter and does not show or provide any details on where or how a handle would be connected to the balloon dilation catheter. I credit Mr. Griffis's testimony that in Goldfarb II, the handle is not attached to the balloon catheter but is attached to the guide catheter. Tr. (Griffis) at 1135:13–25. Fiagon has not demonstrated that a statement in Goldfarb II provides a motivation to add the handle on Goldfarb's guide catheter to Chang's flexible balloon catheter.

Fiagon also argues that Dollar would motivate one of skill "to include a handle for a balloon catheter with multiple proximal ports and further illustrating that having a handle with two ports is simply a known design choice for a balloon catheter." Fiagon Br. at 16. The evidence supports that Dollar discloses a pistol grip handle used with a stiff shaft device that is much larger than the Y-connector in Chang's flexible balloon catheter device. Tr. (Griffis) at 1136:1–19, JX-98, and Stryker Reply at 17. Recognizing Mr. Griffis's criticisms, Fiagon contends that "Dollar [is] not cited to combine with Figure 14 [of Chang] but rather for the proposition that handles with proximal ports were known in balloon catheter devices." Fiagon Br. at 16. The evidence does not support, however, that Dollar would motivate one of skill to add a handle to Chang.

The evidence does not support that based on Chang alone or in combination with any of Goldfarb, Goldfarb II, or Dollar, one of skill in the art would have been motivated to add a handle to Chang's balloon catheter.

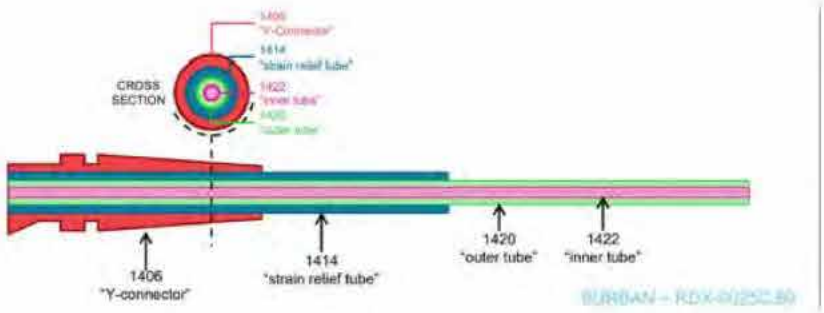
(3) Inner Guide Member in Handle

The asserted claims each recite that a proximal portion of the inner guide member is in the handle. '878 patent elements 1[c] and 22[e], '472 patent element 1[c], and '847 patent element 1[c]. Fiagon contends that this requirement is disclosed in Chang. Fiagon Br. at 17–24 ('878 patent claim 1), 78–79 ('878 patent claim 22), 143 ('472 patent claim 1), and 150–151 ('847 patent claim 1). In particular, Fiagon contends that one of skill would understand that Chang's "inner tube 1422

extends into the y-connector." Fiagon Br. at 18. This is disputed by Stryker. Stryker Reply at 19–24, 46, 53, and 55.

As detailed above, the evidence does not support that Chang itself or in combination with Goldfarb, Goldfarb II, or Dollar discloses or suggests a balloon catheter with a malleable or bendable inner guide member and with a handle. As a result, that prior art does not disclose that a proximal portion of the inner guide member is in the handle. The evidence additionally supports that Chang does not disclose or suggest that a proximal portion of its inner tube 1422 extends into its Y-connector.

Chang does not show the internal structure of its Y-connector but states that "[t]he proximal end of 'Y' connector 1406 comprises a first luer port 1408 that *leads to* a guidewire lumen in balloon catheter 1400." Chang at ¶ 212 (emphasis added) and Tr. (Burban) at 832:8–23. Dr. Burban explained that "In order to lead to it, it has to have a lumen that leads to the inner guide member. And for adding -- if you're advancing a guide member, you want a smooth passage so that the guidewire does not get obstructed on its way down the lumen." Tr. (Burban) at 832:16–23. Dr. Burban also testified that for inflation lumen 1410 not to leak, the inner tube 1422 must extend into the Y-connector. *Id.* at 833:422 and *see* 836:22–838:6. Dr. Burban provided the drawing below that he created showing how, in his view, Chang supports that the inner tube 1422 extends into the Y-connector:



Fiagon Br. at 20 and RDX-25C.60.[20]

I agree with Stryker that Chang does not disclose or suggest that a proximal portion of the inner guide member is in the handle. As Mr. Griffis explained, Chang does not explicitly show or disclose that Chang's inner tube 1422 extends into the Y-connector. Tr. (Griffis) at 1140:4–1141:2. Instead, Chang discloses stress relief tubing 1414 between (i.e., intermediate) the Y-connector 1406 and the shaft 1402 (of which inner tune 1422 is a part), and is silent as to the structure within the stress relief tubing or leading to the Y-connector. *Id.* at 1141:3–18.[21] Further, I agree with Mr. Griffis that "leads to" does not necessarily mean that the port and guidewire lumen are connected the way Dr. Burban opines they are. And while Mr. Griffis agreed that there would be a pathway from Chang's port 1408 to the guidewire lumen, that does not mean that inner tube 1422 is positioned in the Y-connector. *Id.* at 1141:19–1142:2 and 1143:15–1144:3. I also agree with Mr. Griffis that putting a proximal portion of the inner tube 1422 into Chang's Y-connector would require modifications to accommodate that structure. *Id.* at 1144:11–18.

Fiagon argues that to the extent Chang does not disclose or suggest that its inner tube 1422 extends into the Y-connector, Becker renders it obvious. Fiagon Br. at 26–29. Dr. Burban identified the inner guide member of Becker in red:

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[20] While Dr. Burban's figure purports to show the internal structure of Chang's Y-connector, it does not depict the arms of the Y and how they would connect with the structure that he shows. This incomplete rendering and explanation do not support that Chang discloses or suggests that inner tune 1422 extends into Chang's Y-connector.

[21] I disagree that in stating that the stress relief tubing is located *between* Y-connector 1406 and shaft 1402, Chang is necessarily describing a coaxial relationship, as Fiagon argues. Fiagon Br. at 20–21. Chang shows only a longitudinal relationship of elements 1406, 1414, and 1402 in Fig. 14 and only shows a longitudinal relationship of elements 944, 942, and 936 in Fig. 9. If Chang intended to address a coaxial relationship, there would have been a disclosure of some kind, as there was for the structures shown in Figs. 14A and 14E.

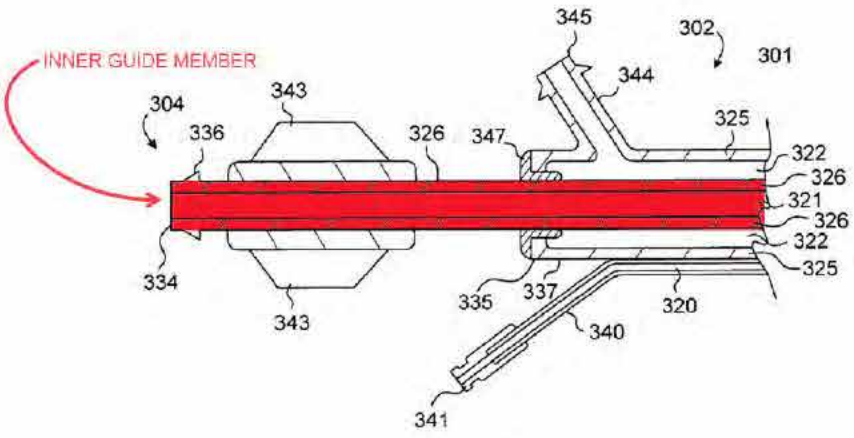


FIG. 1C

RDX-25C.52 and Tr. (Burban) at 842:12–19. Dr. Burban testified that in Becker, a suction tube 326 (inner guide member) runs through the wings 343 (a handle) to a connector 336 (a port) on the proximal end of the wings. Tr. (Burban) at 842:20–844:20; and Becker at ¶¶ 82 and 87 and Figs. 1A–1C. Dr. Burban testified that one of skill would combine Chang with Becker because Becker is in the same field of balloon catheters, and one of skill would understand Becker discloses a simple means of connecting the lumen to the port, which he stated was "using a known structure to achieve predictable results." Tr. (Burban) at 846:13–847:3.

Chang references an earlier patent publication of Becker, U.S. Patent Publication No. 2004/0064150, states that it "discloses balloon catheters formed of a stiff hypotube to be pushed into a sinus," and states that such a devices are undesirable. Chang at ¶ 18. The Becker prior art Fiagon relies on likewise discloses catheters that "have sufficient stiffness and column strength that the balloon carrying distal segment of the catheter can be pushed into the prepared opening, natural ostium or duct, choana or sinus to be excised." Becker at Abstract and ¶ 16 ("the catheter should remain sufficiently stiff to withstand lateral or torsional forces required to push the deflated balloon section through the small opening in the tissue"). Mr. Griffis testified that Chang recognized the risks associated with "the particular approach that's disclosed in Becker" and thus

discloses a flexible balloon catheter used in combination with a guide device and a guidewire. Tr. (Griffis) at 1260:3–9.

Dr. Burban testified that Chang's reference to Becker supports that a "stiff hypotube balloon catheter can be pushed into a sinus." Tr. (Burban) at 983:4–15. Fiagon argues that Chang's disclosure as to Becker is not a teaching away but part of "general teachings [that] flexible or rigid devices could be used." Fiagon Br. at 60–61. Mr. Griffis's testimony on this point is more credible. The portion of Chang discussing Becker recognizes the need to advance a balloon catheter through "complicated or tortuous anatomy" and the degree of individual anatomical variation "thus making it difficult to design a stiff-shaped balloon catheter that is optimally shaped for use in all individuals." This is not a teaching that "flexible or rigid devices could be used," as Fiagon argues. The evidence supports that Chang teaches away from using the stiff shafted devices of Becker.

The evidence does not support that one of skill would be motivated to combine Chang and Becker as urged by Fiagon. The evidence does not support that the prior art relied on by Fiagon discloses or suggests that a proximal portion of the inner guide member is in the handle as recited in '878 patent elements 1[c] and 22[e], '472 patent element 1[c], and '847 patent element 1[c].

4. Secondary Considerations of Non-Obviousness

Stryker argues that the secondary considerations of commercial success, long-felt need, and copying support that the asserted claims are not obvious. Stryker Reply at 71–85. Fiagon disagrees. Fiagon Reply at 92–109.

"Objective indicia of nonobviousness must be considered in every case where present." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016). Evidence of such indicia "may often be the most probative and cogent evidence in the record," *id.* at 1052, *quoting Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), and "guard against slipping into use of hindsight." *Id.*, *quoting Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966).

Such evidence can include "commercial success enjoyed by devices practicing the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unsatisfied need for the invention." *Id.*

a) Nexus

To accord substantial weight to secondary considerations, the evidence must have a nexus to the claims. That is, there must be a legally and factually sufficient connection between the evidence and the patented invention. The patentee bears the burden of showing that a nexus exists. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). "A showing of nexus can be made in two ways: (1) via a presumption of nexus, or (2) via a showing that the evidence [of secondary considerations] is a direct result of the unique characteristics of the claimed invention." *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed. Cir. 2023).

Stryker argues that a presumption of nexus applies because the XprESS Products are coextensive with the asserted claims. Stryker Br. at 71, citing *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir 2018). To establish coextensiveness, a party must demonstrate that the commercial products "are the inventions disclosed in the challenged claims." *Polaris*, 882 F.3d at 1072. Coextensiveness is a question of fact. *Fox Factor, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019).

Stryker is entitled to a presumption of nexus to the extent that its objective evidence is tied to a specific product that embodies the claimed features, and is coextensive with them. *Volvo Penta*, 81 F.4th at 1210. As in *Polaris*, where the patents covered an entire vehicle, here, the patents cover an entire balloon dilation device. 882 F.3d at 1073. In addition, as detailed above, Stryker has demonstrated that its domestic industry products embody the claimed features of the asserted patents. I conclude that Stryker is entitled to a presumption of nexus.

Fiagon has not rebutted the presumption. Fiagon argues that Stryker's commercial success depends on Acclarent's technology, which Stryker licensed following a lawsuit. Fiagon Br. at 92–93. But Fiagon does not show that Stryker practices any Acclarent patent and thus that commercial success is attributable to these patents. Citing no legal support for its position, Fiagon also argues that commercial success cannot be attributed to the asserted patents because they were not pursued for more than ten years after the initial application was filed. Fiagon Br. at 93. Finally, Fiagon argues that Stryker relies on unclaimed features. Fiagon Br. at 94–98. But for each unclaimed feature, Fiagon argues that the feature was in the prior art: the combination of the seeker-like tip with a balloon catheter, *id.* at 94–95, the ball tip, *id.* at 95, handle, light fiber, navigation system, and other elements, *id.* at 96–97, and guidewire, *id.* at 97–98. At most, Fiagon shows that some of the reason for commercial success is attributable to unclaimed features: [redacted]; other features it lists, however, are related to claimed features: [redacted] *Id.* at 95. The Federal Circuit has "never held that the existence of one or more unclaimed features, standing alone, means nexus may not be presumed" because "there is rarely a perfect correspondence between the claimed invention and the product." *Fox Factory*, 944 F.3d at 1374; *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 1360–61 (Fed. Cir. 2021) (same).

Finally, Fiagon argues that Stryker's market research undermines nexus because it shows consumers prefer [redacted] *Id.* at 98, citing JX-183C.35–36 and Tr. (Griffis) at 1004:15–24. But several of these are patented features: [redacted]. Fiagon again argues that because these are in the prior art, there is no nexus. Fiagon

Br. at 98. But there is no evidence that any prior art has the complete set of claimed features, which contributes to the commercial success of Stryker's products. Fiagon has failed to rebut the presumption of nexus.

b) Commercial Success

Stryker argues that commercial success supports non-obviousness. Stryker Reply at 72–80. The evidence supports that between January 2020 and April 2025, more than [redacted] units of XprESS devices were sold to [redacted], generating over [redacted] in worldwide revenue from 2018 through June 2025. CX-1288C; Tr. (Curtin) at 149:19–21; Tr. (Rowe) at 227:18–21; and Tr. (Griffis) at 1199:3–15. Mr. Spearman agreed that the XprESS products have been commercially successful and testified that Fiagon's VenSure products have been commercially successful as well. JX-291C (Spearman Dep.) at 148:15–21. Fiagon disputes whether Stryker has proven a nexus between commercial success and the asserted patents, Fiagon Br. at 92–99, but does not substantively dispute the volume of Stryker's sales or Stryker's revenues from those sales. The evidence supports that the XprESS and VenSure products have been commercially successful. That evidence, however, is tempered by the fact that Acclarent is a market leader and there has been no evidence that the Acclarent products practice the asserted claims. JX-183C.52; JX-184C.51; and Tr. (Burban) at 1006:23–1007:5. The evidence of commercial success thus weighs only modestly in favor of non-obviousness. Moreover, my conclusions on obviousness would be unchanged if there was no evidence of commercial success.

c) Long-felt Need

Stryker argues that long-felt need supports non-obviousness. Stryker Reply at 80. Fiagon disputes this. Fiagon Br. at 107–08. Stryker's evidence largely is from Mr. Drontle, one of the named inventors, who testified about Acclarent's Relieva device and what he said were its deficiencies, including being cumbersome and requiring multiple users. Tr. (Drontle) at 91:16-

99:7. As to long-felt need, Mr. Drontle's testimony is undercut by the fact that Acclarent remains a market leader in the balloon dilation catheter space. JX-183C.52; JX-184C.51; and Tr. (Burban) at 1006:23–1007:5. The evidence does not support long-felt need.

d) Copying

Stryker argues that copying supports non-obviousness, Stryker Reply at 81–85, which Fiagon disputes, Fiagon Br. at 99–106.

The Federal Circuit has explained that "[n]ot every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent. Rather, copying requires the replication of a specific product. This may be demonstrated either through internal documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a virtually identical replica, or access to, and substantial similarity to, the patented product (as opposed to the patent)." *Iron Grip Barbell Co., Inc. v. USA Sorts, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (internal citations omitted). In addition, as relevant here, "FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries." *The Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1349 n.3 (Fed. Cir. 2008).

The fact that Fiagon knew of Stryker's earlier patents in the family of the asserted patents and had access to an XprESS device does not necessarily lead to a conclusion of copying. Stryker Reply at 81–85. The fact that Fiagon made statements to the FDA regarding equivalence likewise does not support copying. Instead, the evidence supports that there are substantial differences between Fiagon's VenSure products and Stryker's XprESS products, namely the VenSure has a pre-loaded guidewire and a fixed balloon. CX-1197C.6. The evidence does not support that Fiagon copied Stryker's products, and thus does not support this secondary consideration of non-obviousness.

5. Conclusion

In weighing all the *Graham* factors, the evidence does not support that the asserted claims are invalid as obvious. The differences between the prior art and claims are significant, and Fiagon has not established that one of skill would be motivated to combine and modify the prior art to meet the claims. While the evidence of commercial success modestly supports non-obviousness, my conclusions on obviousness would be unchanged without that evidence.

B. Written Description

Fiagon contends that all the asserted claims are invalid based on lack of written description. Fiagon Br. at 109–132. Stryker disagrees. Stryker Reply at 85–102.

1. Legal Standard

The specification must provide a written description of the claimed invention that "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) and 35 U.S.C. § 112, ¶ 1. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

"Whether the written description requirement of 35 U.S.C. § 112 is met in a given case is a question of fact." *Enanta Pharms., Inc. v. Pfizer Inc.*, No. 2025-1427, 2026 WL 1791832 at *3 (Jun. 23, 2026) *and see Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). Assessing whether the inventor had possession of the claimed invention "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Brita LP v. Int'l Trade Comm'n*, 156 F.4th 1326, 1331 (Fed. Cir. 2025) (internal quotation marks omitted). "[T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*,

398 F.3d at 1351. The level of detail required to satisfy the written description requirement "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 398 F.3d at 1351 and *see Amgen*, 314 F.3d at 1330 (identifying the "fact intensive nature" of the inquiry).

As with a prior art invalidity challenge, a challenger must demonstrate that claims are invalid for lack of written description by clear and convincing evidence. *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009) and *see Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276, Comm'n Op. at 55 (Nov. 14, 2023) (EDIS Doc. ID 808521).

2. Analysis

The issue is whether the asserted claims, which do not recite a movable shaft, instead reciting a shaft ('878 patent claims 1 and 22 and '472 patent claim 1) or a polymeric shaft ('847 patent claim 1), are supported by the written description.

It is not disputed that the claims in the many earlier patents in the same family as the asserted patents recite a movable shaft, which is used to advance the ballon to the tip of the device for dilation. JX-30 (earlier patent claims) and Tr. (Burban) at 817:7–15. It is not disputed that the specification includes multiple disclosures of a movable shaft and that the originally filed claims recited a movable shaft. Fiagon Br. at 116–22, Order No. 15 at 13–14, and JX-33.24. It is not disputed that during prosecution of claims in earlier related patents, prior art was distinguished based on the movable shaft recited in those claims. Fiagon Br. at 123–124, Order No. 15 at 15–18, JX-33.236–37, and JX-36.102–04. It is also not disputed that after Fiagon obtained FDA approval for its VenSure device, which does not have a movable shaft, Stryker filed the applications that issued as the asserted patents, which do not recite a movable shaft. RX-322C.1 (indicating

awareness by Stryker of FDA approval of VenSure in around December 2020) and JX-1 (earliest filing date of applications that issued as the asserted patents on December 27, 2020).

The Federal Circuit has considered situations in which a patentee broadened their claims in continuing applications to remove or broaden a limitation in earlier claims. In *Gentry Gallery, Inc. v. Berkline Corp.*, the court concluded that a claim directed to a sectional sofa with control means "mounted on the double reclining seat sofa section" was invalid as not supported by the specification because "the original disclosure clearly identifies the console as the only possible location for the controls," which was supported by testimony of the inventor that he "considered the location of the recliner controls on the console to be an essential element of his invention." 134 F.3d 1473, 1475 and 1478–79 (Fed. Cir. 1998). As a result, the "original disclosure serve[d] to limit the permissible breadth of [the] later-drafted claims." *Id.* at 1479.

Likewise, in *Tronzo v. Biomet, Inc.*, the claims recited an acetabular cup prosthesis (artificial hip socket) and were filed in a continuation-in-part application. The question was whether the claims were entitled to the filing date of the original application because, if not, the patentee had "conceded that intervening prior art would anticipate." 156 F.3d 1154, 1158 (Fed. Cir. 1998). The court concluded that the claims were not entitled to the original filing date because the original specification did not support their breadth. The asserted claims recited an acetabular cup without reciting its shape, while the original disclosure "describe[d] the invention as a 'trapezoid,' a 'truncated cone,' or a cup of 'conical shape.'" *Id.* at 1159. In addition, the specification "specifically distinguishe[d] the prior art as inferior and tout[ed] the advantages of the conical shape." *Id.*, quoting the specification as stating that "[a]nother extremely important aspect of the present invention resides in the configuration of the acetabular cup as a trapezoid or a portion of a truncated cone." The court found that such "statements make clear that the [asserted]

patent discloses *only* conical shaped cups and nothing broader" and that the original specification did not support "the later-claimed, generic subject matter" in the asserted claims. *Id.* (emphasis in original) and *see Synthes USA, LLC v. Spinal Kinetics, Inc,*, 734 F.3d 1332, 1341–42 (Fed. Cir. 2013) (affirming jury verdict of no written description for claims directed to intervertebral implants with a "plate including a plurality of openings" where the "original disclosure claimed and disclosed a plurality of grooves and a plurality of channels, but did not describe 'openings' generally" and where the evidence supported that "there are significant biomechanical property differences between using peripheral grooves and interior slots.") and *LizardTech, Inc. v. Regents of the Univ. of Cal.*, 424 F.3d 1336, 1344–46 (Fed. Cir. 2005) (affirming grant of summary judgment of invalidity based on lack of written description where claims to a seamless discrete wavelet transform (DWT) did not recite the only disclosed way of generating a seamless DWT).

In *ICU Medical*, the Federal Circuit similarly held that claims to medical valves "used in the transmission of fluid to or from a medical patient, such as when using an IV," were invalid for lack of written description because "the specification describes only medical valves with spikes." 558 F.3d at 1372 and 1378. The specification there described the invention as including a "two-way valve [that] is employed utilizing a reusable seal that may be repeatedly pierced by an enclosed, protected, non-metallic spike rather than an exposed metal needle." *Id.* at 1375, quoting U.S. Patent No. 6,572,592 at 2:45–48. The court concluded that based on the disclosure in the specification, "a person of skill in the art would not understand the inventor . . . to have invented a spikeless medical valve." *Id.* at 1378.

Thus, through cases like *Gentry Gallery*, *Tronzo*, *Synthes*, *LizardTech*, and *ICU*, the Federal Circuit has found that omission or broadening of a claim element can be inconsistent with the specification and render claims invalid for lack of written description. The Federal Circuit has

also found that such claims may be supported by the specification and thus not invalid for lack of written description. The fundamental question is one of fact: whether "a skilled artisan would reasonably conclude, based on the patent's disclosure and the knowledge of a person skilled in the art, that the applicant possessed" the invention as broadly claimed. *Medtronic, Inc. v. Teleflex Innovations S.A.R.L*, 69 F.4th 1341, 1354 (Fed. Cir. 2023).

In *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, the Federal Circuit reversed the district court's finding, after a bench trial, that claims that omitted reciting a glidant were invalid for lack of written description. 111 F.4th 1358, 1372 (Fed. Cir. 2024). Considering the specification, the Federal Circuit identified support for embodiments that "contemplate a formulation that both includes and does not include a glidant," while recognizing that "the specification does largely focus on more detailed formulations that include a glidant." *Id.* at 1173–74. As the challenger did in Allergan, Fiagon argues that the "specification consistently, repeatedly, and exclusively describes the shaft and balloon as sliding or advancing over the 'inner guide member'" and points to figures and disclosure in the specification. Fiagon Br. at 111–12. It is true, and Mr. Griffis agreed, that the disclosed embodiments have a movable shaft. *Id.* at 111 and Tr. (Griffis) at 1208:12–17.

The specification, however, recognizes that "the inner guide member 14 is advantageously rigid to enable the balloon dilation catheter 10 to be positioned without the need of a separate guiding catheter or guide wire in most, if not all instances." '878 patent at 5:51–55 and *see* Stryker Reply at 89. In doing so, the specification specifically points to Fig. 3B, which shows the balloon extended. This disclosure supports uses or advantages of the balloon catheter device beyond a movable shaft and supports that the specification is not limited to a balloon catheter with a movable

shaft though, to be sure, as in *Allergan*, the specification here largely focuses on embodiments with a movable shaft. 111 F.4th at 1374.

More specifically, the evidence supports that the specification discloses multiple problems with the prior art, one of them being allowing a balloon catheter device to be positioned without the need of a separate guiding catheter or guide wire. '878 patent at 5:51–55 and *see* 8:65–9:7 (discussing use of CT (computerized tomography) guidance to allow positioning of the device "with just a single hand[.]"). This problem (and its solution) do not require that the balloon dilation catheter have a movable shaft. Tr. (Griffis) at 1107:25–1108:18 (addressing CDX-33C.8 and col. 5, lines 51–55 and stating that this disclosure does not require "relative movement between the inner guide member and a shaft"). This express purpose supports that the described invention is not limited "to the embodiment or purpose that is the focus of the specification." *ScriptPro LLC v. Innovation Assocs., Inc.*, 833 F.3d 1336, 1341 (Fed. Cir. 2016).

In *ScriptPro*, the court concluded that the patent's "express disclosure that storing and sorting can be done in numerous ways disguishe[d it] from *Gentry Gallery* and *ICU Medical*" in which "the specifications clearly limited the scope of the inventions in ways the claims clearly did not." *Id.* The same is true here, where the specification discloses a purpose of the invention as eliminating "the need for a separate guiding catheter or guide wire in most, if not all instances," states other advantages of the inner guide member, and does not state that a movable shaft is essential, necessary, or required, which distinguishes cases like *Gentry Gallery*, *ICU Medical*, and *Tronzo*, in which the specification supported that the disclosed inventions were limited to certain features. Tr. (Griffis) at 1107:25–1108:18, 1114:5–21 (the specification does not state that a movable shaft is required, essential, or necessary), and 1115: 7–20 (discussing CDX-3.21 and '878 patent at 5:51–55, 4:50–52, 7:56–59, and 6:30–33 and stating that features disclosed in the

specification of "the inner guide member being advantageously rigid to enable the balloon dilation catheter to be positioned for treatment without the use of a separate guiding catheter or guidewire, as well as being able to be bent into a variety of shapes, desirable shapes, in a malleable inner guide member that would be formed to accommodate whatever sinus was intended for treatment by the device" are "independent of any kind of movement of the individual components."). *See Medtronic*, 69 F.4th at 1354 (the specification did not indicate that the unclaimed feature was "critical to the invention").

In *Allergan*, the Federal Circuit emphasized the importance of an objective inquiry "into the four corners of the specification *from the perspective of a person of ordinary skill in the art*," noting the propriety of reliance on expert testimony when evaluating written description. 111 F.4th at 1376 (internal quotation marks omitted and emphasis in original). Here, Mr. Griffis's expert testimony supports that one of skill in the art would conclude, based on the four corners of the specification, that the inventors possessed both a moveable and non-movable shaft balloon dilation catheter.

Fiagon argues that because "the specification 'provides nothing to indicate that the inventors possessed the full scope of the genus that they chose to claim'—specifically the fixed-shaft species required to prove infringement—the Asserted Claims are invalid for lack of written description." Fiagon Br. at 110, quoting *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337 (Fed. Cir. 2021). In *Juno*, the court considered written description support in the context of claims directed to a nucleic acid polymer encoding a three-part chimeric antigen receptor (CAR) for a T cell. *Id.* at 1333. Part of the CAR was the binding element, "which is the portion of the CAR that determines what target molecule or antigen the CAR can recognize and bind to." *Id.* One type of binding element is a single-chain antibody variable fragment (scFv). *Id.*

The accused infringer argued that the claims, directed to an scFV genus covered an "enormous number (millions of billions) of scFv candidates, only a fraction of which satisfy the functional binding [claim] limitation for any given target." *Id.* at 1336. The Federal Circuit found that substantial evidence did not support the jury verdict on written description because the specification disclosed only "two example scFVs for binding two different targets" and did not provide "amino acid sequences or other distinguishing characteristics of the scFvs that bind." *Id.* at 1336 and 1339. "Without more guidance, in a vast field of possible CD19-specific scFvs with so few of them known, no reasonable jury could find the inventors satisfied the written description requirement." *Id.* at 1340.

The situation here is quite different and does not involve "millions of billions" or a "vast field" of species within a broad genus. Nor do the claims here functionally recite a desired result. *Crown Packaging Technology, Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011) (distinguishing "broad genus claims or function claims simply describing [a] desired result"). Instead, here, there is a binary choice, a movable shaft or a non-movable shaft. *Hynix*, 645 F.3d at 1352 ("the supposed genus consists of only two species, a multiplexed and a non-multiplexed bus"). Fiagon's expert agreed. Tr. (Burban) at 807:16–21 (a fixed balloon or a moving shaft "were the two structures or types of balloons to consider"). That is important because satisfaction of the written description requirement "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 398 F.3d at 1351 and *see Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004) (considering predictability in written description analysis). The nature and scope of the claims and the complexity and predictability of the technology here are nothing like that in *Juno*.

The situation here is much more similar to that in *Hynix*, where the patentee amended claims in continuation applications directed to memory technology to delete a requirement of a "multiplexed bus." 645 F.3d at 1336. In considering a written description challenge, the Federal Circuit noted that "there is no categorical rule that a species cannot suffice to claim the genus" and, in that instance, "the supposed genus consists of only two species, a multiplexed and a non-multiplexed bus." *Id.* at 1352. The same is true here—there are two choices, a movable shaft or a non-movable shaft. The court pointed out that "Hynix has not argued that the disclosure of the multiplexed bus was not representative of the genus of buses that encompasses both the narrow multiplexed bus and the non-multiplexed bus." *Id.* Likewise here, while Fiagon spends much effort arguing that the specification discloses a moveable shaft and that in prosecuting claims reciting a moveable shaft, Stryker focused on that claim element, Fiagon Br. at 110–124, it does not argue that disclosure of a movable shaft is not representative of a genus of shafts that encompass movable and non-movable shafts.

Instead, Fiagon argues that "there are technical challenges to implementing [a fixed shaft] device not addressed by the Asserted Patents." Fiagon Br. at 127, citing Tr. (Norman) at 691:13–692:21. Mr. Norman testified that with its fixed-balloon design, Fiagon had to make sure the balloon could withstand bending and insertion forces, which required grit blasting steps to improve bond adhesion and bond strength and "a very thick double wall to prevent the balloon from leaking." Tr. (Norman) at 691:17–692:4 and 692:18–21. To ensure good visibility, Mr. Norman testified that Fiagon implemented a "four pleat-and-fold configuration" and an annealing step. *Id.* at 692:5–17. It is not disputed that the issues identified by Mr. Norman are not specifically identified in the specification.

Fiagon analogizes the situation here with that in *Synthes*, contending that Mr. Norman's testimony is circumstantial evidence that the written description requirement is not met. Fiagon Br. at 127. The situation recounted by the Federal Circuit in *Synthes*, however, is far different from that here. In *Synthes*, the evidence supported that it was a "careful and time-consuming task," requiring "months of work" to move from using peripheral grooves (which were disclosed) to interior slots (which were not disclosed) and required the alleged infringer to "determine the precise size and location of the slots to ensure that the cover plates used as little metal as possible, reduced fiber wear, and still performed all the necessary functions of the device." 734 F.3d at 1343. The whole of this work was "at least circumstantial evidence that it would not be evident that peripheral grooves on the cover plate would disclose to skilled artisans that internal slots would serve the same function." *Id.* Here, Mr. Norman's rather conclusory testimony does not demonstrate "months of work" or the types of time-consuming technical hurdles that would support lack of written description support for a non-movable shaft device.

Fiagon also argues that a meeting summary after Stryker learned that Fiagon received FDA approval for its VenSure device supports that there is no written description support for a balloon catheter device without a movable shaft. Fiagon Br. at 124–126 and RX-316C. Whether there is written description support is assessed based on an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary kill in the art." *Ariad*, 598 F.3d at 1351. The meeting summary Fiagon points to does not reflect such an inquiry. As recounted by Fiagon, the "very first actionable item" was to "look into patent infringement of the balloon device." Fiagon Br. at 126 and RX-316C.2. The evidence supports that the identified "looking" resulted in the filing of the applications that issued as the asserted patents because none of Stryker's existing patents could be asserted because they all claimed a movable shaft. That by itself, however, does

not support that the claims lack written description; instead it supports that at that time, Stryker did not have any claims that it could assert against the VenSure device. Likewise, the fact that the applications were filed as Track One, that Mr. Kray had a Fiagon balloon catheter when he drafted the claims of the asserted patents, or that prototypes made before the original application was filed, do not support that the specification does not provide written description support for the claims. *See* Fiagon Br. at 126.

As in *Hynix*, "substantial evidence supports that the invention would not be undermined by the use of a [non-movable shaft]," including testimony from Stryker's expert. *Hynix*, 645 F.3d at 1352. As noted, Mr. Griffis testified that one benefit of the invention was being to enable positioning of the catheter without use of a guide catheter or guidewire, and a movable shaft is not required or necessary to achieve that benefit. Tr. (Griffis) at 1115:7–20, 1116:3–5. In addition, as in *Hynix*, one of the inventors, Mr. Drontle, testified that the "three-handed, clumsy procedure" of the prior art, requiring multiple different devices, inspired the invention, consistent with the specification's disclosure that the invention enables the balloon dilation catheter to be positioned "without the need of a separate guiding catheter or guide wire in most, if not all, instances." *Hynix*, 645 F.3d at 1352; Tr. (Drontle) at 96:1–16 and 111:8–20; and JX-1 at 5:51–55. This evidence, in addition to the disclosure in the specification supporting a different purpose for the invention other than a movable shaft, addressed above, distinguishes this situation from cases such *ICU Medical* and *LizardTech*. *Hynix*. 645 F.3d at 1352–53.

The context here also supports that the claims are not invalid for lack of written description. *See Ariad*, 598 F.3d at 1351 (recognizing that "whether a patent complies with the written description requirement will necessarily vary depending on context" and that "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of

the claims and on the complexity and predictability of the relevant technology"). Here, the evidence supports the relative lack of complexity of the involved technology and that the relevant technology is not unpredictable.[22] In addition, the binary choice between a movable shaft and a non-movable shaft supports that the asserted claims are not invalid for lack of written description.

As to that binary choice, Stryker points out that the specification of the asserted patents incorporates by reference U.S. Patent Publication No. 2010/0211007 to Lesch. Stryker Br. at 97–98 and JX-85. The specification states that "[o]ne exemplary inflation device that may be used in connection with the balloon dilation catheter 10 is described" in Lesch "and is incorporated by reference as if set forth fully therein." '878 patent at 4:44–49. Lesch illustrates an "inflation device 10 coupled to a balloon catheter 104" in which the "dilation balloon 100 is disposed on or near the distal end 108 of the elongate member 102" of the balloon catheter 104. JX-85 at ¶ 49. It is not disputed that Lesch discloses a non-movable shaft used with its inflation device. Fiagon Br. at 129–132. Like the specification of the asserted patents, Lesch identifies the benefit of a single operator performing a dilation procedure as opposed to multiple separate devices being required. JX-85 at ¶¶ 5–6 and 49. The incorporation by reference of Lesch (and its disclosures regarding the use of its inflation device with a balloon catheter) further supports that one of skill in the art would conclude that the inventors had possession of "the idea of a fixed balloon," that is, a non-movable shaft. Tr. (Griffis) at 1113:12–1114:4.

Fiagon's expert, Dr. Burban, did not address the incorporation by reference of Lesch. Tr. (Burban) at 806:22–820:16. Fiagon contends that the specification incorporates by reference only the inflation device of Lesch, not its balloon catheter. Fiagon Br. at 129–130. In support, Fiagon

[22] *Cf. Synthes*, 734 F.3d at 1344 ("the jury was free to conclude, based on evidence that the use of internal slots for these devices was not predictable").

relies on *Zenon Environmental, Inc. v. U.S. Filter Corp*. *Id*. There, however, the incorporation language stated that "relevant disclosures" of the identified documents were incorporated by reference. 506 F.3d at 1379. As a result, the Federal Circuit disagreed with the trial court's conclusion that the entire disclosures of the identified documents were incorporated, concluding instead that the "plain language expressly limits the incorporation to only relevant disclosures of the [identified documents], indicating the disclosures are not being incorporated by reference." *Id*. The incorporation language here is different, stating that Lesch "is incorporated by reference as if fully set forth herein." That language supports that the entirety of Lesch was incorporated by reference into the specification. *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 907–09 (Fed. Cir. 2018) (explaining that the phrase "incorporated herein by this reference[]" resulted in a "broad incorporation" of the entire reference).

Fiagon next argues that even if Lesch's balloon catheter were incorporated by reference, Lesch does not provide a written description of the invention" because "[t]he issue is whether the inventors had possession of the full scope of the claimed invention, which requires teaching a 'configuration of elements,' rather than one of the limitations in a different context." Fiagon Br. at 130 (emphasis removed). In particular, Fiagon argues that to show possession of a non-movable shaft, the specification must "show possession of embodiments of the claimed invention having a fixed shaft having all of the other elements of the claim." Fiagon Br. at 131 (emphasis removed). This, however, misstates the law. *Rex Medical, L.P. v. Intuitive Surgical, Inc.*, 156 F.4th 1289, 1305–06 (Fed. Cir. 2025). There, the Federal Circuit stated that an argument that the specification must provide written description support for the infringing configuration "misses the mark" because the question was not whether the patent described the accused configuration "it was whether the disclosure of the application reasonably conveys to those skilled in the art that the

inventor had possession of the subject matter claimed." *Id.* at 1306 and *Ariad*, 598 F.3d at 1351. (The test for sufficiency of the written description "is whether the disclosure of the application relied on reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.")

There is, therefore, no requirement that a specific embodiment with all claimed features be disclosed, as Fiagon argues. Nor does *Juno*, cited by Fiagon, support such a requirement. *See* Fiagon Br. at 131. The claim in *Juno* was to a genus of nucleic acid polymers and the Federal Circuit stated that "the written description must lead a person of ordinary skill in the art to understand that the inventors possessed the entire scope of the claimed invention." 10 F.4th at 1337. *Juno* thus does not require the specification to show "possession of embodiments of the claimed invention having a fixed shaft having all of the other elements of the claim," as Fiagon argues.

In *Hynix*, the Federal Circuit recognized that *ICU Medical* supported an argument that the claims there were invalid based on a lack of written description. *Hynix*, 645 F.3d 1352–53. But substantial evidence, in the form of expert and inventor testimony, supported that the written description requirement was met. *Id.* The same could be said here. A careful review of the evidence, however, demonstrates that the specification addresses a problem not requiring a movable shaft. Expert and inventor testimony also support that one of skill would not understand the specification as limited to balloon catheter devices with a movable shaft. In addition, the specification incorporates by reference an exemplary inflation device used with balloon catheter with a non-movable shaft and in which the dilation balloon is disposed at the distal end of the device and is identifying as addressing the same problem as the specification. Together, the evidence supports that there is written description support for the asserted claims and their

recitation of a shaft or a polymeric shaft. Fiagon has not demonstrated by clear and convincing evidence that the claims are invalid for lack of written description.

XI. PROSECUTION LACHES

Fiagon argues that the asserted patents are unenforceable for prosecution laches, Fiagon Br. at 133–40, which Stryker disputes, Stryker Reply at 102–06.

A. Legal Standard

Prosecution laches is an equitable defense to patent infringement. *Cancer Research Tech. Ltd. v. Barr Labs, Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010) and *see Certain Hydrodermabrasion Systems and Components Thereof*, Inv. No. 337-TA-1408, Comm'n Op. at 12–14 (Apr. 7, 2026). (EDIS Doc. ID 878087). The doctrine of prosecution laches "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances." *Cancer Research*, 625 F.3d at 728. There are no firm guidelines in determining whether prosecution laches applies. The doctrine, however, "should be used sparingly lest statutory provisions be unjustifiably vitiated" and "should be applied only in egregious cases of misuse of the statutory patent system." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385–86 (Fed. Cir. 2005).

To demonstrate prosecution laches, an accused infringer must show: (1) the patent holder's delay in prosecution was unreasonable and inexcusable under the totality of circumstances; and (2) the accused infringer suffered prejudice attributable to the delay. *Cancer Research*, 625 F.3d at 729. A determination of unreasonable delay requires "an examination of the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims." *Symbol Techs.*, 422 F.3d at 1385 (internal quotation marks omitted). To establish prejudice, "an accused infringer must show evidence of intervening rights, that is, that

the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay." *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1362 (Fed. Cir. 2021) (internal quotation marks omitted) and *see Google LLC v. Sonos, Inc.*, No. 24-1097, 2025 WL 2473258 at *6 (Fed. Cir. Aug. 28, 2025).

"When prosecution laches is raised as a complete defense to patent infringement, courts have applied the clear and convincing standard." *Natera, Inc. v. ArcherDX, Inc.*, 690 F. Supp .3d 437, 445 (D. Del. 2023) and *see Wirtgen America, Inc. v. Caterpillar, Inc.*, 746 F. Supp. 3d 218, 226 (D. Del. 2024).

B. Analysis

The parties raise two procedural issues, which will be addressed first. Fiagon contends there should be a presumption of prejudice. Fiagon Br. at 135–36, citing *Hyatt*, 998 F.3d at 1369 and 138. In *Hyatt*, the Federal Circuit held that for purposes of a § 145 action, there was a presumption of prejudice where there was a delay of six years or more. 998 F.3d at 1370. That presumption, however, was in the context of a § 145 action, not in the context of a defense of prosecution laches. *Id.* at 1366–69. The district court in Delaware recently reached the same conclusion, stating that it was "not convinced that the presumption applies when prosecution laches is asserted as a defense against infringement." The court explained that the "Federal Circuit's holding in Hyatt expressly limits the presumption to 'the context of a § 145 action,'" and stated that it was "not persuaded that the presumption should extend beyond that setting." *GlaxoSmithKline Biologicals SA v. Pfizer Inc.*, No. 24-512-GBW, 2026 WL 1732953, at *4 (D. Del. Jun. 16, 2026) and *see Wirtgen*, 746 F. Supp. 3d at 227 (expressing skepticism regarding applying the *Hyatt* presumption in the context of prosecution laches and citing cases). I likewise reject a presumption of prejudice.

Next, Stryker contends that there "has never been a finding of prosecution laches upheld based on prosecution of a post-GATT patent (i.e., since the patent term limit change)," suggesting that the defense is not available or diminished in the post-GATT context. Stryker Reply at 102. Fiagon characterizes Stryker's argument as "strange," because "the Federal Circuit in *Google* addressed the merits of the defense" in the post-GATT context. Fiagon Reply at 135. This is true. The Federal Circuit in *Google* addressed prosecution laches on the merits, supporting that the defense is viable post-GATT. *Google*, 2025 WL 2473258, at *7 and *see Hydrodermabrasion*, Inv. No. 337-TA-1408, Comm'n Op. at 14. The district court in *GSK* addressed this issue as well and, adopting the analysis of a district court in Texas, stated it was "not persuaded that a lack of explicit applicability of prosecution laches to 'post-GATT' patents at the Federal Circuit has abrogated prosecution laches for 'post-GATT' patents" and found that prosecution laches was not unavailable as a matter of law. *GSK Biologicals*, 2026 WL 1732953, at *4, quoting *Mojo Mobility, Inc. v. Samsung Elecs. Co.*, No. 22-398, 2024 WL 3354705, at *1 (E.D. Tex. Jun. 11, 2024), *report and recommendation adopted*, 2024 WL 3350884 (E.D. Tex. Jul. 9, 2024). The same is true here.

Fiagon argues unreasonable delay based on the many patents with claims including a movable shaft that issued in the years before Stryker filed the applications that issued as the asserted patents and Stryker's intent to capture Fiagon's products by drafting the claims in those applications. Fiagon Br. at 133–36.[23] Ultimately, what Fiagon has shown is a long passage of time combined with an intent to draft claims to cover Fiagon's products. That, however, does not show unreasonable delay. "[I]t is not improper for an applicant to broaden his claims during prosecution in order to encompass a competitor's products, as long as the disclosure supports the broadened

[23] Fiagon also states that the timeline of prosecution "demonstrates that the Asserted Patents were filed in response to . . . Intersect's decision to purchase Fiagon." Fiagon Br. at 4.

claims. If the disclosure does not support the broadened claims, the applicant will not be accorded priority based on the original disclosure, and the claims may be invalidated." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988); *Wirtgen*, 746 F. Supp. 3d at 746 ("even a finding that a party drafted patent claims to cover its competitor's products does not by itself require a finding of prosecution laches"), (cleaned up and quoting *SynQor, Inc. v. Artesyn Techs., Inc.*, No. 2:07-cv-497-TJW-CE, 2011 WL 2729214, at *7 (E.D. Tex. Jul. 13, 2011). As explained elsewhere in this initial determination, the asserted claims do not lack written description support. In addition, there is no evidence Stryker engaged in anything other than the routine continuation process. Fiagon relies on Stryker's failure to establish the reasonableness of its conduct, but it is Fiagon's burden to demonstrate prove unreasonable delay. *See* Fiagon Br. at 136. Fiagon has not done so.

Fiagon's conduct falls well short of the egregious conduct in cases in which prosecution laches findings have been upheld by the Federal Circuit. In *In re Bogese*, the Federal Circuit upheld a finding of prosecution laches where the patentee repeatedly received a final rejection, abandoned the application, and filed continuations with the same rejected claims. 303 F.3d 1362, 1364–65 (Fed. Cir. 2002). In *Hyatt*, there was a delay of at least seven and as many as 19 years before presenting the claims, the patents claimed priority to several applications, the patents had hundreds of pages of text and included over 300 claims per application, and the applicant rewrote claims entirely or significantly midway through prosecution. 998 F.3d at 1353–54, 1367–69. The circumstances in *Personalized Media Communications* were like those in *Hyatt*: atypically long and complex patents with massive increases in claims and conduct that made it difficult for PTO examination. *Personalized Media Commc'ns, LLC v. Apple Inc.*, 547 F.4th 1346, 1350–53 (Fed. Cir. 2023). In *Symbol*, there were 18 to 39-year periods between filing and issuance and the

evidence showed the patentee engaged in "culpable neglect during the prosecution." 422 F.3d at 1385. Here, the circumstances are different. All Fiagon has shown is that Stryker continued to file continuations, getting patents issued, and ultimately filed continuation applications with claims of different scope.

Courts have concluded conduct like that here does not demonstrate unreasonable delay. *See Natera*, 690 F. Supp. 3d at 446–48 (finding no prosecution laches where the patentee filed continuations but diligently prosecuted them and there was no evidence of attempts to unduly delay prosecution) and *Wirtgen*, 746 F. Supp. 3d at 225–27 (no unreasonable delay where there were no unexplained gaps, even where the period of time was long and patents were broadened to cover the accused infringer's products). Further, Stryker filed the applications that issued as the asserted patents under Track One, so they received accelerated examination, and they each issued less than a year after they were filed. JX-1–3; JX-38.97; JX-39.87; and JX-40.04. This supports that Stryker was diligently prosecuting the applications that issued as the asserted patents. *Natera*, 690 F. Supp. 3d at 447 and *see Seagen Inc. v. Daiichi Sankyo Co., Ltd,*, 2022 WL 2789901, at *6 (E.D. Tex. Jul. 15, 2022).

Fiagon identifies no unexplained gaps, no evidence of intentional or neglectful delay, and no evidence of any misuse of continuation practice. At most, Fiagon has alleged Stryker engaged in routine use of continuation practice while amending its claims. Under the totality of the circumstances, Stryker's prosecution of the asserted patents does not amount to unreasonable and unexplained delay that constitutes an egregious misuse of the patent system that would warrant a finding of prosecution laches.

To establish prejudice, Fiagon "must show that the alleged delay in prosecution adversely affected the party with intervening rights." To show that a party was adversely affected, it must

show that the holder of intervening rights would have either done something differently or experienced a change in economic position as a result of the alleged delay in issuance of the patent-in-suit." *Shire Orphan Therapies LLC v. Fresenius Kabi USA, LLC*, No. 2015-cv-1102-GMS, 2018 WL 2684097 at *23 (D. Del. Jun. 5, 2023), citing *Cancer Research*, 625 F.3d at 731 and *see Natera*, 690 F.Supp.3d at 449.

As to a change in economic position, Fiagon argues that it invested [redacted] in bringing the VenSure products to market and that before the '847 patent issued (the last to issue of the asserted patents), "Respondents had increased their investment in the VenSure product line to [redacted]" Fiagon Br. at 137–138. As support, Fiagon relies on [redacted] which contains no indication as to what Fiagon actually spent. JX-142C. Fiagon also relies on the testimony of Mr. Spearman. Fiagon Br. at 137–138, citing Tr. (Spearman) at 700:11–702:8 and 702:6–8. While it cannot be disputed that Fiagon expended resources in developing its VenSure products, the record is not clear as to what Fiagon actually expended. Fiagon has not demonstrated a change in economic position.

Fiagon has also not shown that it would have done something differently. The evidence supports that Fiagon believed it would be easy to change the VenSure devices so they would not infringe the asserted patents. RX-442C.1 ("get rid of the intermediate hypotube" or use "a single, thick walled hypotube") and Tr. (Spearman) at 767:16–24. But there is no evidence that Fiagon ever attempted to do so, supporting that Fiagon would not have changed course if the asserted patents had issued earlier. *See Natera*, 690 F. Supp. 3d at 449. Fiagon has not demonstrated that it was prejudiced by the alleged delay.

Fiagon has not demonstrated by clear and convincing evidence that the asserted patents are unenforceable for prosecution laches.

XII. DOMESTIC INDUSTRY—ECONOMIC PRONG

A. Legal Standard

"[A]n industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent . . . (A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3). "[S]atisfying any one of the clauses suffices for satisfying the economic prong of the domestic-industry requirement." *Lashify, Inc. v. Int'l Trade Comm'n*, 130 F.4th 948, 957 (Fed. Cir. 2025). The Federal Circuit has affirmed "use of the date of the filing of [the] complaint . . . as the relevant date at which to determine if the domestic industry requirement of Section 337 was satisfied." *Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601, n.6 (Fed. Cir. 2013).

As distinguished from subsections (A) and (B), under subsection (C), a nexus needs to be shown between investment and the asserted patents, as opposed to between investment and the domestic industry products. *See* 19 U.S.S. § 1337(a)(3) and *Certain Electronic Candle Prods, and Components Thereof*, Inv. No. 337-TA-1195, Comm'n Op., at 20–21 (Oct. 4, 2022) (EDIS Doc. ID 781605) ("the Federal Circuit has interpreted 'its' to mean the patent (or other enumerated IP right in subsections 337(a)(1)(B)-(E))"), citing *Interdigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295 (Fed. Cir. 2013)). To establish nexus, "the complainant must show the connection between its investments and the patented invention that it is exploiting." *Electronic Candle Prods.*, Comm'n Op. at 21. Such a nexus may be presumed when the domestic industry products are "physical embodiment[s] of the asserted patent[s]." *Id.* at 22.

The "terms 'significant' and 'substantial' in the statute refer to an increase in quantity, or to a benchmark in numbers," and require "a quantitative analysis"—"[q]ualitative factors cannot compensate for quantitative data that indicate insignificant investment and employment." *Lelo Inc.*

v. Int'l Trade Comm'n, 786 F.3d 879, 883, 885 (Fed. Cir. 2015). That said, a "finding of domestic industry cannot hinge on a threshold dollar value or require a rigid formula; rather, the analysis requires a holistic review of all relevant considerations that is very context dependent." *Wuhan Healthgen Biotech. Corp. v. Int'l Trade Comm'n*, 127 F.4th 1334, 1339 (Fed. Cir. 2025). Whether a complainant's investments demonstrate an economic domestic industry under the statute is based on a holistic review of the record, considering qualitative and quantitative significance "together as an integrated analysis." *Certain Semiconductor Devices and Products Containing the Same*, Inv. No. 337-TA-1414, Comm'n Op. at 38 (May 7, 2026) (EDIS Doc. ID 883116) and *see Wuhan*, 127 F.4th at 1338.

B. Analysis

Stryker contends that it satisfies the economic prong under each of clauses (A) (plant and equipment), (B) (labor or capital), and (C) (exploitation) of the statute. Stryker Br. at 319–34. Fiagon does not dispute that the economic prong is satisfied. *See generally* Fiagon Reply.

The evidence supports that the XprESS LoProfile and Ultra devices and the components provided with them have always been manufactured exclusively in the United States. The XprESS LoProfile and Ultra devices are currently manufactured in Portage, Michigan and were previously manufactured in Plymouth, Minnesota. Tr. (Curtin) at 148:21–149:18. Stryker's NextGen device is and will be manufactured in the United States. *Id.* at 177:7–10. The evidence supports that all of Stryker's domestic industry products are manufactured in the United States, whether they are sold within the United States or outside the United States. Tr. (Rowe) at 220:3–15. Stryker's Portage, Michigan headquarters, where its current manufacturing and other activities take place, is shown below:



Tr. (Rowe) at 217:20–24 and CDX.4C.3.

The evidence supports that Stryker's research and development activities for its domestic industry products take place exclusively in the United States. *Id.* at 177:11–15 (NextGen) and 182:12–19 (LoProfile and Ultra). None of Stryker's research and development activities for its domestic industry products is performed outside of the United States. *Id.* at 182:17–19 and *see* Tr. (Rowe) at 231:20–232:12.

Stryker maintains records for its costs of manufacturing the domestic industry products. Tr. (Rowe) at 220:16–21. Those include records for each SKU of those products. *Id.* at 222:3–224:22 and *see* CDX-4C.6–7, citing CX-1315C–1334C; CX-1338C–1363C; CX-1374C–1376C; and CX-1385C. Stryker's records include those showing the cost of goods sold (COGS) which break down the cost per unit of each domestic industry product as: (1) materials (raw materials and components); (2) labor (direct labor costs—the people who handle the product as it is being manufactured), burden (variable costs—those that change with the number of manufactured units and include inspections, sterilization, moving product, manufacturing scrap, and safety equipment); overhead (fixed manufacturing costs such as salaried employees, depreciation, utilities, and other costs associated with the manufacturing process); and subcontract (outside vendors and subcontractors). *Id.* at 224:25–226:6.

The evidence supports that Stryker's research and development activities are tracked by project and cost center. Dr. Curtin, Stryker ENT's director of research and development, explained how Stryker tracks expenses for its XprESS products. Tr. (Curtin) at 141:1–2 and 182:23–185:9. To identify the relevant research and development expenses, Stryker's expert, Ms. Rowe, worked with Dr. Curtin to identify the relevant cost centers. As to those expenses, the evidence supports that some cost centers are fully allocable to the domestic industry products, while others are not. *Id.* at 232:14–233:16, 236:6–11 and CDX-4C.17 [redacted] For costs not fully allocatable to the domestic industry products, Dr. Curtin explained that a revenue-based allocation was reasonable because [redacted]. Tr. (Curtin) at 185:10–186:9 and Tr. (Rowe) at 233:17–236:5 and 236:12–16. A revenue-based allocation was performed using U.S. sales of the domestic industry products between January 2020 and April 2025, a period through which the domestic industry products were over [redacted] of Stryker's ENT revenue. Tr. (Rowe) at 236:17–237:5 [redacted] CX-1401C (revenue data); and CDX-4C.18. Stryker also identifies labor costs for ENT sales and marketing employees, using a revenue-based allocation for those employees. Tr. (Rowe) at 239:14–241:10 and CDX-4C.24.

1. Plant and Equipment

For plant and equipment expenses, Stryker allocated its burden and overhead expenses. Stryker Br. at 329. Burden expenses are variable costs including inspections, sterilization, manufacturing scrap, and safety equipment and overhead expenses are fixed costs including salaried employees, depreciation, and utilities. Tr. (Rowe) at 224:25–226:6. Ms. Rowe performed an allocation to identify costs allocable to plant and equipment for the domestic industry products.

Id. at 226:7–19. Ms. Rowe used Stryker's [redacted] approach and determined that [redacted] percent of Stryker's burden costs should be allocated to indirect labor and [redacted] percent allocated to plant and equipment, and that [redacted] percent of Stryker's overhead costs should be allocated to indirect labor and [redacted] percent to plant and equipment. *Id.* at 228:5–229:7; CX-643C; CX-1387C (allocation data for burden and overhead expenses); and CDX-4C.13.

Based on those calculations, the evidence supports the following investments in plant and equipment related to the domestic industry products from January 2020 to April 2025:

[redacted]

CDX-4C.27; *see also* CDX-4C.12–14 (calculating allocations for plant and equipment).

2. Labor or Capital

Styker identifies manufacturing investments in labor (split between the direct, burden, and overhead categories), material, and subcontractors, research and development expenses in labor, research and development direct capital expenses, and sales and marketing. Stryker Br. at 320–329.

As discussed above, manufacturing expenses included both direct labor costs (fully allocated to labor or capital) and indirect labor costs under burden and overhead, which were allocated between plant and equipment and labor or capital. Tr. (Rowe) at 224:25–226:19. Burden expenses were divided with [redacted] percent allocated to indirect labor and [redacted] percent to plant and equipment, and overhead was divided with [redacted] percent of costs related to indirect labor and [redacted]

percent to depreciation and utilities, which were allocated to plant and equipment. *Id.* at 228:5–229:7; CX-1387C; CX-643C; and CDX-4C.13. Investments in labor or capital also included materials and subcontractor costs. Tr. (Rowe) at 224:25–226:19. For research and development costs, Ms. Rowe included employees as labor and direct expenses as capital, and she applied a revenue-based allocation for cost centers that were not fully allocable to the domestic industry products. *Id.* at 232:14–233:13, 233:17–237:5, CX-1401C. For sales and marketing, Ms. Rowe used the salaries of ENT employees, identified based on labor codes, and applied a revenue-based allocation. Tr. (Rowe) at 239:16–241:21.

The evidence supports the following investments in labor or capital for the domestic industry products from January 2020 to April 2025:



Tr. (Rowe) at 242:25–243:10; CX-633C (data summary); CX-634C (burden, overhead, and manufacturing); CX-644C (research and development); CX-654C (sales and marketing); and CDX-4C.28.

3. Exploitation

Because Stryker's identification of expenses for exploitation under subsection (C) is entirely a subset of expenses identified for subsection (B), I do not consider Stryker's arguments under subsection (C).

4. Significance

The evidence supports that Stryker's investments in plant and equipment, under subsection (A), and labor or capital, under subsection (B), are quantitatively and qualitatively significant. *See* Stryker Br. at 330–34.

The evidence supports that the domestic industry products are currently and have always been manufactured in the United States, whether they are sold within the United States or outside the United States. Tr. (Curtin) at 148:21–149:21 and Tr. (Rowe) at 220:5–15. The evidence supports that all research and development activities for the domestic industry products have been conducted in the United States. Tr. (Curtin) at 182:12–19 and 177:11–15. Manufacturing and research and development activities are essential to the domestic industry products and thus significant. *Wuhan*, 127 F.4th at 1339 (affirming significance where "all of Ventria's investments and activities related to researching, developing, and commercially producing Optibumin occurred within the United States."); *Certain Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83 (Apr. 28, 2020) (EDIS Doc. ID 709073) (finding significance where "all, *i.e.*, 100 percent, of [the relevant] expenditures relating to [the domestic industry products] occur[] in the United States."), *vacated and remanded on other grounds*, *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369 (Fed. Cir. 2022).

The evidence supports that from January 2020 to April 2025, Stryker's plant and equipment expenses represent [redacted] of its total manufacturing expenses for the domestic industry products, while its labor and capital expenses represent the remainder, that is, [redacted] of Stryker's total manufacturing expenses for the domestic industry products. Tr. (Rowe) at 230:16–231:2 and CDX-4C.15.

The evidence supports that Stryker's investments in the United States in manufacturing plant and equipment for the domestic industry products from January 2020 to April 2025 represent

about [redacted] of Stryker's overall ENT manufacturing costs and its investments in the United States in manufacturing labor and capital for the domestic industry products represent about [redacted] of Stryker's overall ENT manufacturing costs. *Id.* at 231:3–19; CX-666C; CX-1410C; and CDX-4C.16. The evidence supports that from 2023 through April 2025, Stryker's research and development labor expenses in the United States for the domestic industry products averaged [redacted] of Stryker's entire research and development labor expenses for its ENT division overall, which includes activities in [redacted]. In 2023, it was [redacted]; in 2024, it was [redacted]; in 2025, it was [redacted] Tr. (Rowe) at 239:1–13; CX-670C; CX-671C; CX-1364C; CX-1372C; and CDX-4C.22. The evidence supports that from January 2020 through April 2025, Stryker's sales labor expenses in the United States for the domestic industry products were [redacted] of its worldwide ENT sales labor expenses and its marketing labor expenses for the domestic industry products were [redacted] of its worldwide ENT marketing labor expenses. *Id.* at 241:22–242:11; CX-672C; CX-673C; JX-186C; CX-1395C; CX-1390C; CX-1391C; CX-1397C; CX-1392C; CX-1398C; CX-1393C; CX-1399C; CX-1349C; CX-1400C; and CDX-4C.25–26. These various metrics demonstrate that in a variety of ways Stryker's investments in its domestic industry products under both subsections (A) and (B) are significant.

The evidence also supports that the domestic industry products are significant to Stryker. U.S. sales of the domestic industry products make up [redacted] of its revenues for those products worldwide, and Stryker's gross margin on its domestic industry products is greater than its company-wide margin [redacted] Tr. (Rowe) at 243:18–244:24; CX-1288C; CX-660C; CX-826.28; CX-827.25; and CDX-4C.30–31. The evidence also supports that Stryker's investments in its domestic industry products from January 2020 through April 2025 are significant in the context of its worldwide revenue for those products. Its plant and equipment investments in

its domestic industry products are [redacted] of its worldwide revenue for the domestic industry products; its labor and capital investments in the domestic industry products are [redacted] of its worldwide revenue for the domestic industry products; and its research and development expenses in its domestic industry products are [redacted] of its worldwide revenue for the domestic industry products. Tr. (Rowe) at 244:25–245:16; CX-664C; CX-665C; CX-1288C; CX-667C; CX-668C; and CDX-4C.32. The evidence supports that Stryker's labor and capital investments in the domestic industry products are significant in the context of Stryker's revenues for its ENT division overall, representing [redacted] of all domestic ENT revenue. Tr. (Rowe) at 245:17–24; CX-665C; CX-1313C; CX-663C; and CDX-4C.33.

A holistic review of the record supports that Stryker's domestic investments in its domestic industry products in both plant and equipment, subsection (A), and labor or capital, subsection (B), are significant and that Stryker has demonstrated an economic domestic industry.

XIII. CONCLUSIONS OF LAW

1. The Commission has statutory authority over this investigation.
2. Stryker owns the asserted patents.
3. The importation requirement is satisfied.
4. Claims 1, 14, 20, 22, and 23 of the '878 patent have been shown to be infringed.
5. Claim 1 of the '472 patent has been shown to be infringed.
6. Claims 1 and 11 of the '847 patent have been shown to be infringed.
7. Claims 1, 14, 20, 22, and 23 of the '878 patent have not been shown to be invalid.
8. Claim 1 of the '472 patent has not been shown to be invalid.
9. Claims 1 and 11 of the '847 patent have not been shown to be invalid.
10. The '878, '472, and '847 patents have not been shown to be unenforceable.
11. The technical prong of the domestic industry requirement has been satisfied for the '878 patent.

12. The technical prong of the domestic industry requirement has been satisfied for the '472 patent.

13. The technical prong of the domestic industry requirement has been satisfied for the '847 patent.

14. The economic prong of the domestic industry requirement has been satisfied for the '878, '472, and '847 patents.

XIV. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The "Commission has broad discretion in selecting the form, scope and extent of the remedy" for violating section 337. *Philip Morris Prods. S.A. v. Int'l Trade Comm'n*, 63 F.4th 1328, 1339 (Fed. Cir. 2023) (internal quotation omitted). "[W]hen the circumstances of a particular investigation require," "the Commission has tailored its relief in light of the statutory public interest factors," including "exempt[ing] service parts, grandfather[ing] certain infringing products, and delay[ing] the imposition of remedies to allow affected third party consumers to transition to non-infringing products." *Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 28 (EDIS Doc. ID 698855) (Jan. 10, 2020). An administrative law judge must recommend an "appropriate remedy in the event that the Commission finds a violation," and recommend the "amount of the bond posted by the respondents during Presidential review of Commission action." 19 C.F.R. § 210.42(a)(1)(ii)(A), (B).

A. Limited Exclusion Order

"If the Commission determines, as a result of an investigation under [section 337], that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public-interest considerations], it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1). "By statute, the Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of the statutorily-

enumerated public interest factors counsel otherwise." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010).

Fiagon does not argue against issuance of a limited exclusion order, but contends that any such order should carve out: (1) "any products made solely with parts sourced from US Suppliers"; (2) "certified use of the VenSure ET product or other VenSure products for eustachian tube procedures"; and (3) the Cube Navigation System for uses other than with the VenSure devices. *Id.* at 137–38.

There is no need for a carveout from a limited exclusion order for products made solely with parts sourced from U.S. suppliers because such products, and their components, will never be imported. *See* Fiagon Reply at 138. There is no justification for a carveout for any of the accused VenSure devices because they all infringe at least claim 1 of the '878 patent, claim 1 of the '472 patent, and claim 1 of the '847 patent, which are not limited to sinus procedures.

As to the Cube Navigation System, the VenSure Nav device in combination with the Cube are found to infringe claim 23 of the '878 patent. Claim 23 depends from claim 22, which recites a method of treating a drainage pathway of a sinus cavity and includes steps of advancing the inner guide member to a target location in a drainage pathway of a sinus cavity and inflating the inflatable balloon to dilate the drainage pathway of the sinus cavity. The tracking of claim 23, performed by the Cube Navigation System, is thus in the context of a sinus cavity. As noted previously, there are substantial non-infringing uses of the Cube Navigation System outside of balloon dilation of sinuses. Tr. (Spearman) at 758:16–760:1 (Cube can be used for spine and brain procedures); RX-361C (brain procedures); RX-363.5 (spine procedures) and 11 (brain procedures). Given those substantial non-infringing uses and that fact that the Cube Navigation System is used for medical procedures, it is my recommendation that any limited exclusion order

include a certification provision as to the Cube Navigation System for uses outside of sinus dilation procedures.

Based on the parties' arguments and review of the record evidence, I recommend that if the Commission finds a violation of section 337, a limited exclusion order be issued with respect to products that infringe claims 1, 14, 20, 22, and 23 of the '878 patent, claim 1 of the '472 patent, and claims 1 and 11 of the '847 patent. Such an exclusion order should prohibit the unlicensed entry of infringing balloon dilation devices, systems, and components thereof manufactured abroad by or on behalf of Fiagon or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns. *See, e.g., Certain Photovoltaic Trunk Bus Cable Assemblies and Components Thereof*, Inv. No. 337-TA-1438, Limited Exclusion Order at ¶ 1 (Jun. 25, 2026) (EDIS Doc. ID 886198). I also recommend that any limited exclusion order include a standard certification provision as well as a certification provision as to the Cube Navigation System for uses outside of sinus dilation procedures.

B. Cease and Desist Order

"In addition to, or in lieu of" an exclusion order, "the Commission may issue and cause to be served on any person violating this section . . . an order directing such person to cease and desist from engaging in the unfair methods or acts involved." 19 U.S.C. § 1337(f)(1).

Cease and desist orders "are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order." *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm'n Op. at 49 (Sept. 29, 2021) (EDIS Doc. ID 754503). "A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found

in the investigation so as to not undercut the relief provided by the exclusion order." *Id.* at 49–50 (citations omitted).

Stryker contends that Fiagon has a commercially significant inventory of VenSure systems at a warehouse in White Bear Lake, Minnesota. Fiagon Br. at 337–38. The evidence does not support, however, that these products were imported. As noted previously, the evidence supports that Fiagon last imported a complete VenSure device before the first-to-issue of the asserted patents issued and has not sold in the United States an imported VenSure device since the '878 patent issued. Tr. (Norman) at 710:21–715:25.

Fiagon contends that any inventory of VenSure products "should exclude any products made solely with parts sourced from US Suppliers." Fiagon Reply at 138. Stryker identifies inventory of complete VenSure products for June, October, November, and December 2025. Stryker Br. at 338. These inventory numbers are not disputed by Fiagon. Fiagon Reply 138–139. Fiagon states that [redacted] Fiagon Reply at 113, n.17. Fiagon does not indicate that any of its inventory is made without imported components. Given that Fiagon has represented that it ceased importing components of the accused products, I recommend that any cease and desist order exclude from the definition of "covered articles" any balloon dilation device or system that does not include imported components.

Stryker also contends that Fiagon maintains a commercially significant inventory of foreign-sourced components "that can be used to create additional finished units of the infringing VenSure Products." Stryker Br. at 338; CX-1418C; Tr. (Griffis) at 471:3–472:24; CDX-1.3C-19; JX-201C.1; and JX-204C.1. Fiagon does not dispute that it has an inventory of imported components. Fiagon Reply at 138 ("The only inventory concerns a few imported components.").

Fiagon does not argue that its component inventory is not significant; Fiagon's only significance argument relates to whether its inventory of products includes [redacted] Fiagon Reply at 138. Based on the evidence and arguments, I find that Fiagon has a significant inventory of components.

Fiagon argues that if any cease and desist order issued, "carveouts should be made for accused products used for eustachian tube procedures (VenSure ET) and non-infringing uses of the Cube navigation product." *Id*. As with any limited exclusion order, the VenSure ET should not be categorically excluded from a cease and desist order if it is found to be an infringing product. And as to the Cube Navigation System, because it is a medical device used in a non-infringing way, I recommend that any cease and desist order exclude the Cube Navigation System for uses outside of sinus dilation procedures.

Based on the evidence and arguments, I recommend issuance of a cease and desist order against Fiagon for all claims for which there has been a violation, subject to the exclusions addressed above.

C. Bond

When the Commission enters an exclusion order or a cease and desist order, a respondent may continue to import and sell its products during the 60-day presidential review period under an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3); and *Certain Automated Put Walls*, Inv. No. 337-TA-1293, Comm'n Op. at 46 (Aug. 17, 2023) (EDIS Doc. ID 802614). Stryker bears the burden of establishing the need for a bond. *Automated Put Walls*, Inv. No. 337-TA-1293, Comm'n Op. at 47.

When reliable price information is available in the record, the Commission often sets the bond to eliminate the price differential between the domestic product and the infringing product.

Id. at 46. The Commission may also use a reasonable royalty rate to set the bond amount where it can be ascertained from the record. *Id.* "Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a 100 percent bond." *Id.* at 46–47.

There is no dispute that the parties are competitors. Tr. (Foley) at 71:3–73:1; Tr. (Ockree) at 207:4–208:7; JX-183C.52; and JX-184C.51. The evidence also supports that the parties compete based on price. Tr. (Foley) at 71:3–73:1.

The evidence supports the following price differentials between the XprESS LoProfile and XprESS Ultra and the four accused VenSure products based on sales data showing the average sales price:



Tr. (Rowe) at 247:17–248:18; CX-118C (VenSure sales data); CX-1288C (XprESS sales data); CX-1386C (XprESS sales data); CX-678C; CX-674C (Rowe: VenSure average sales price calculations); CX-659C (Rowe: XprESS average sales price calculations). The evidence supports that the average price differential for the XprESS LoProfile is [redacted] and for the XprESS Ultra is [redacted]. CX-678C.

Fiagon does not dispute the calculations of the average sales price. Instead, Fiagon argues that the price differentials are not reliable because it sells four models while Stryker sells two, and

each model has different features and prices. Fiagon Reply at 139. This is unpersuasive because Fiagon did not identify which products were most comparable and did not perform any price comparison, which it could have. Fiagon also argues that Mr. Spearman identified a higher list price for the VenSure products than the ones relied on by Ms. Rowe. Fiagon Br. at 139 (citing JX-301C (Spearman Dep.). This is unpersuasive because Ms. Rowe used the actual sales data Fiagon produced to calculate price differentials. CX-788C; CX-659C; and CX-674C. Fiagon also argues that there is no evidence of a price differential between the VenSure ET and Stryker's Eustachian tube product, which is not a domestic industry product. *Id.* at 140. This is unpersuasive because the evidence shows the only difference between the VenSure and VenSure ET is a pre-bent shaft. Thus, the VenSure ET is comparable to the XprESS products. Finally, Fiagon argues that no price differential was identified for the Cube Navigation System. *Id.* I agree. No evidence was presented to establish a bond for the Cube Navigation System.

Considering the evidence and the most comparable products, I recommend a bond of 61% for the VenSure products and components thereof, but no bond for the Cube Navigation System.

XV. INITIAL DETERMINATION ON VIOLATION

It is my initial determination that a violation of section 337 of the Tariff Act, as amended, has occurred by the importation into the United States, the sale for importation, or the sale within the United States after importation of certain balloon dilation devices, systems, and components thereof based on infringement of U.S. Patent Nos. 11,083,878, 11,090,472, and 12,274,847. I certify this Initial Determination and Recommended Determination to the Commission.

The Secretary shall serve the confidential version of this Initial Determination and Recommended Determination on counsel who have signed the Protective Order (Order No. 1). A public version will be served on all parties of record later.

This Initial Determination shall become the determination of the Commission under Rule 210.42(h) unless a party files a petition for review under Rule 210.43(a) or the Commission orders review under Rule 210.44. 19 C.F.R. § 210.42(d).

XVI. ORDER

Within seven days of the date of this document, the parties shall jointly submit a single proposed public version of the document with any proposed redactions in red. If the parties submit excessive redactions, I may require declarations from individuals with personal knowledge to justify each proposed redaction and explain specifically why the information sought to be redacted meets the definition of confidential business information in 19 C.F.R. § 201.6(a). The proposed redactions should be made electronically in one PDF file, with the proposed redactions submitted as "marked" but not yet "applied." The proposed redactions should be submitted by email to JohnsonHines1449@usitc.gov. They should not be filed on EDIS.

SO ORDERED.

Doris Johnson Hines
Administrative Law Judge