UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-00136
U.S. Patent No. RE 45,776

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 45,776

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I. PRELIMINARY STATEMENT

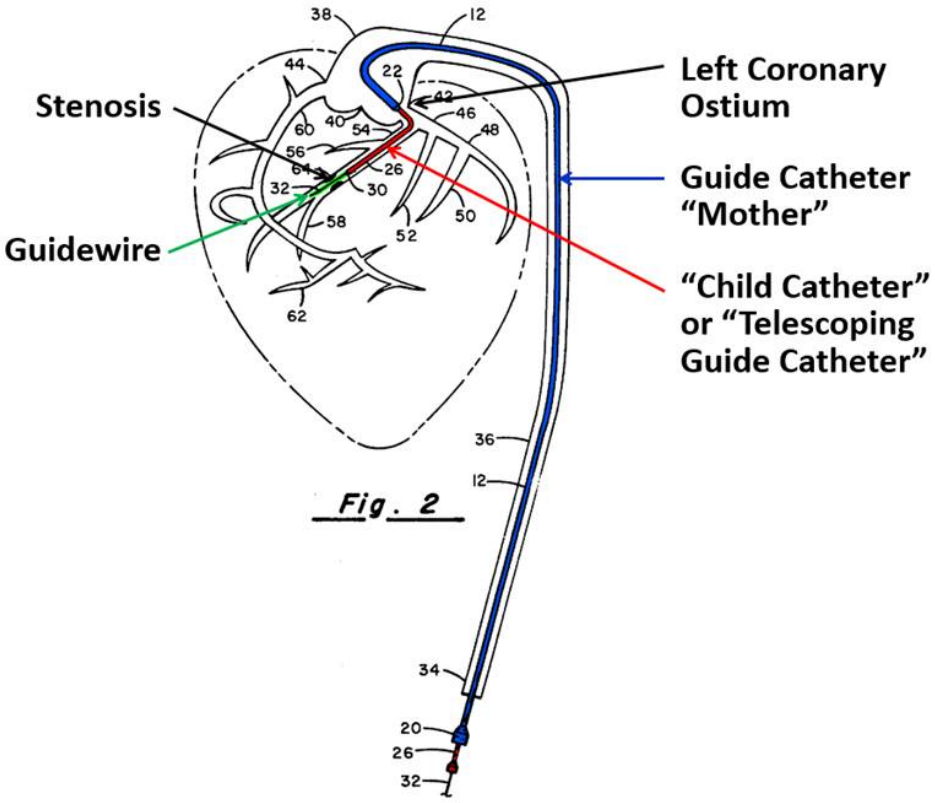
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 25-27, 29-33, 35-37, 39, 41-49, and 52-56 ("Challenged Claims") of U.S. Patent No. RE 45,776 ("the '776 patent," Ex-1401). The '776 patent is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id*., [54], [72]. The Challenged Claims were never the subject of a prior-art based Office Action, meaning there is no substantive file history for the '776 patent.

The '776 patent describes a catheter system that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a guide catheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*., Abstract; Figs. 8, 9. In so doing, the guide extension catheter delivers "backup support by providing the

[1] The '776 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1405, ¶¶ 71 n.6, 118. A POSITA knew that the "coaxial guide catheter" of the '776 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1409, 5:49-52 (referring to body 12 "as a guide catheter extension").

ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id*., 3:7-11; *see also id*., 8:24-35.

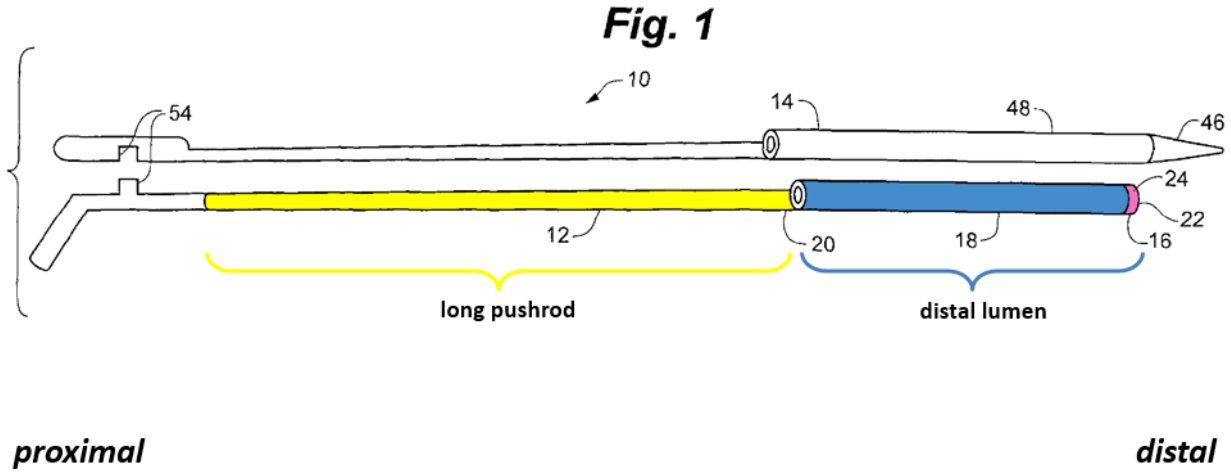
The '776 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. *Id.*, 2:46-62 (describing as the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-catheter assembly was well known in the art and described as a "mother-and-child assembly." Ex-1405, ¶¶ 70-80. The child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. Ex. 1405, ¶ 70.



Ex. 1454, Fig. 2 (annotations and color added).

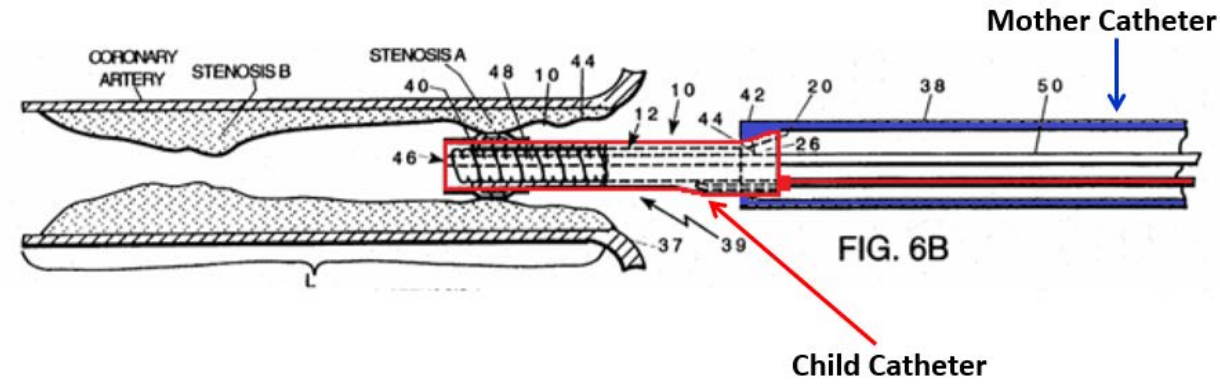
The child catheter in the original mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id.* The '776 patent alleges that such a design had certain drawbacks (Ex. 1401, 2:63-3:6; Ex-1405, ¶¶ 81-89) and modifies the child catheter of the mother-and-child assembly to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., tube) that is highly flexible so it can extend deep into the

coronary artery.



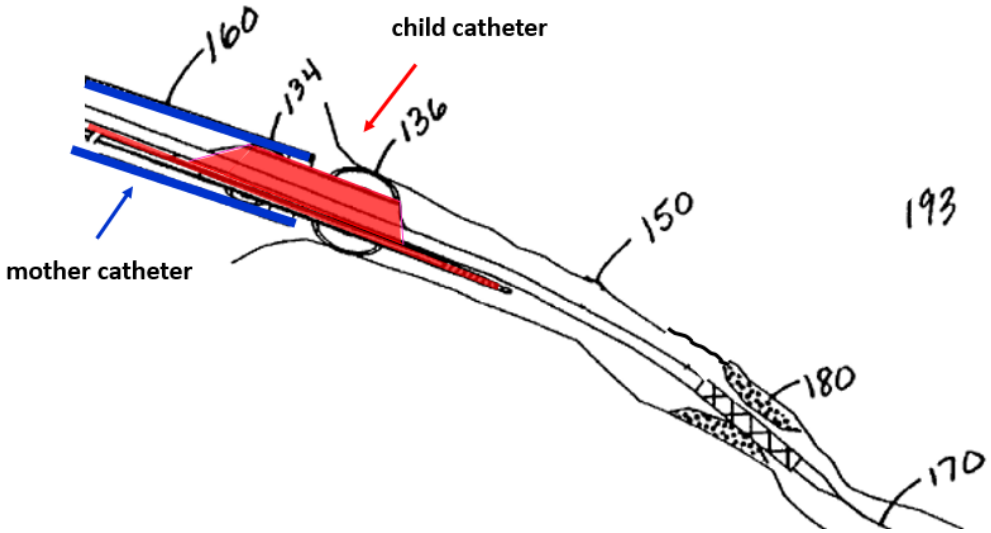
Ex. 1401, Fig. 1 (annotations and color added).

But such child catheters that served as guide extension catheters and had a short lumen connected to a long thin pushrod were already well-known in the art, as evidenced by U.S. Patent No. 5,439,445 ("Kontos"), which issued more than ten years before the earliest purported priority date of the '776 patent.



Ex. 1409, Fig. 6B (annotations and color added).

It was also evidenced by U.S. Patent No. 7,604,612 ("Ressemann").



Ex. 1408, Fig. 6B (annotations and color added).

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the ’776 patent are unpatentable. Accordingly, Petitioner respectfully requests institution of a trial and cancellation/invalidation of the Challenged Claims of the ’776 patent as unpatentable under 35 U.S.C. § 103.

II. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Party-in-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc. as real parties-in-interest. Medtronic plc is the ultimate parent of both entities.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the ’776 patent is currently the subject of litigation in two separate actions in the U.S. District

Court for the District of Minnesota: (i) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al*., No. 19-cv-01760 (D. Minn., filed July 2, 2019); and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) ("QXMedical Litigation").

Further, the '776 patent is a reissue of U.S. Pat. No. 8,292,850 ("the '850 patent"). The '850 patent was previously the subject of litigation (i) in the U.S. District Court for the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and (ii) at the PTAB in *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (P.T.A.B., terminated Aug. 11, 2014).

Petitioner is also concurrently filing another petition for IPR challenging the '776 patent based on prior art references having different priority dates and disclosures than the references discussed herein.

C. Lead and Backup Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner identifies the following counsel of record:

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D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), please direct all correspondence to lead and back-up counsel at the above addresses. Petitioner consents to electronic service at the above-identified email addresses.

III. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104, Petitioner certifies that the ’776 patent is available for IPR and that Petitioner is not barred or estopped from requesting such review.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 25-27, 29-33, 35-37, 39, 41-49, and 52-56 of the ’776 patent and cancellation of these claims as

unpatentable in view of the following grounds:[2]

No.	Grounds
1	Claims 25-27, 29, 33, 35-37, 39, 41-49, and 52 are rendered obvious by Kontos in view of Ressemann and/or the knowledge of a POSITA
2	Claims 30-32 and 53-56 are rendered obvious by Kontos in view of Ressemann, Takahashi, and/or the knowledge of a POSITA
3	Claim 52 is rendered obvious by Kontos in view of Ressemann, Kataishi, and/or the knowledge of a POSITA
4	Claims 53-56 are rendered obvious by Kontos in view of Ressemann, Takahashi, Kataishi, and/or the knowledge of a POSITA

IV. BACKGROUND

A. Overview of the Technology

Coronary artery disease ("CAD") occurs when plaque buildup narrows the arterial lumen. Ex-1405, ¶¶ 28, 30-32. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id.* In response, physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery,

[2] This Petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1405), and Dr. Richard A. Hillstead (Ex-1442), as experts in the field of the '776 patent. Petitioner also submits the declaration of Sylvia S. Hall-Ellis, PhD (Ex-1478) to support the authenticity and public availability of the documents cited herein.

and thus can treat CAD without the need for open-heart surgery. Ex. 1405, ¶¶ 29, 34-40.

PCI was developed more than forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. *Id.*, ¶¶ 33, 41. During PCI, after a physician uses a hollow needle to gain access to the patient's vasculature, a guide catheter is introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id.*, ¶¶ 34, 42-55. A hemostatic valve is placed at the proximal end of the guide catheter and remains outside the patient's body. *Id.*, ¶¶ 35, 54. The hemostatic valve prevents blood from exiting the patient's artery and keeps air from entering the bloodstream. *Id.*

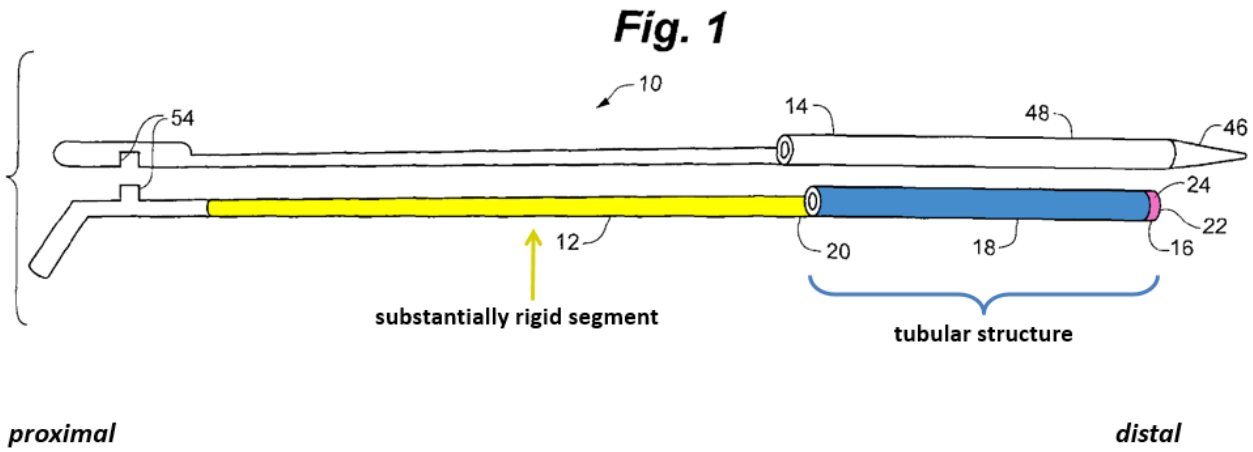
Another small diameter flexible guidewire can then be threaded through the lumen of the guide catheter to the target site. *Id.*, ¶¶ 56-58. This guidewire serves as a guiderail to advance a therapeutic catheter through the guide catheter and to the occlusion. *Id.* The therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. *Id.*, ¶¶ 59-67. This last step—crossing the therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium. *Id.*, ¶¶ 66-67. As discussed above, one way to ameliorate this backward force is to use a mother-and-child

catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. *Id.*, ¶¶ 68-80.

B. Overview of the ’776 Patent

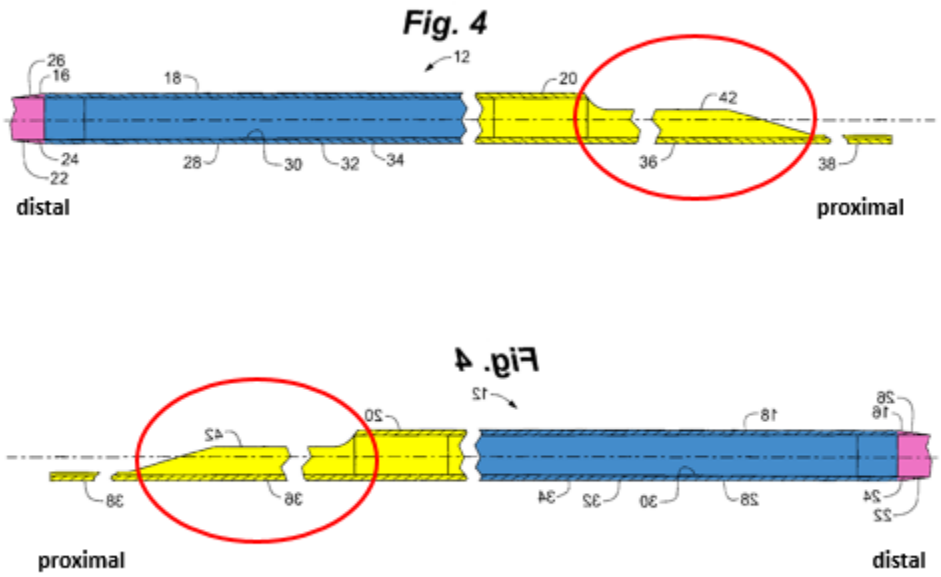
The ’776 patent relates “generally to catheters used in interventional cardiology procedures.” Ex. 1401, 1:37-38. In particular, the ’776 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends “beyond the distal end of the guide catheter and . . . into [a] branch artery.” *Id.*, Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id.*, 5:30-34; Ex-1405, ¶¶ 118-19.

The ’776 patent claims a guide extension catheter 12 that includes a substantially rigid segment (yellow) and a tubular portion (blue). Ex-1405, ¶ 120.



Id., 13:36-52, Fig. 1 (color added).

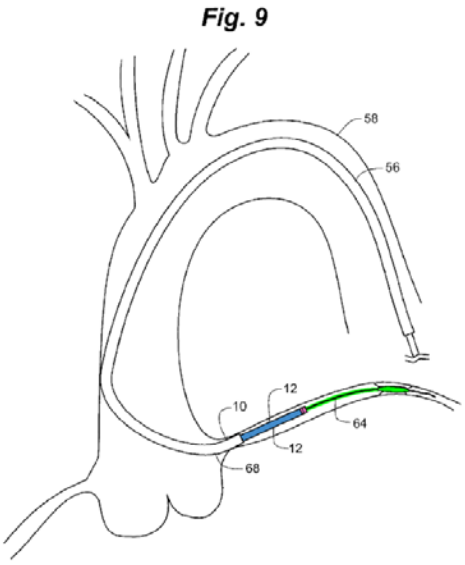
The ’776 patent also recites “a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure.” *Id*., 13:36-49. The specification, however, provides no written description support for the placement of this feature and, as shown below, only describes the partially cylindrical opening (red circle) positioned in the substantially rigid segment 20. Ex-1405, ¶ 121.



Ex. 1401, Fig. 4 (annotations and color added).

Regardless, as shown below, the ’776 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the distal tip (pink) of the extension catheter. Moving distally to proximally, the extension catheter’s tip (pink) and tubular portion (blue)

extend out of the distal tip of guide catheter 56. Ex-1405, ¶ 122.



Ex. 1401, Fig. 9 (color added).

C. Prosecution History of the ’776 Patent

The parent ’850 patent issued without an Office Action. *See generally* Ex. 1402. According to the Examiner, the claims of the ’850 patent were allowable because “adding a guide catheter to the claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.” *Id.* at 83 (Notice of Allowance at 3). In other words, he believed that a mother-and-child assembly—where the child catheter is characterized by a short distal lumen coupled to a proximally located pushrod—was not described in the art. The Examiner, however, was not aware of Kontos or Ressemann. Patent Owner sought reissuance in 2014. As with the original prosecution, the claims of the ’776 patent issued without any substantive Office Action rejecting the claims

as unpatentable. *See generally* Ex. 1403.

V. THE PERSON OF ORDINARY SKILL IN THE ART

If a person of ordinary skill in the art ("POSITA") was a medical doctor, s/he would have had (a) a medical degree, (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist. Alternatively, if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, a POSITA with a medical degree may have access to a POSITA with an engineering degree, and a POSITA with an engineering degree may have access to one with a medical degree. Ex-1405, ¶ 27; Ex-1442, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

Claim terms are typically given their ordinary and customary meanings, as would have been understood by a POSITA at the time of the invention, having taken into consideration the language of the claims, the specification, and the prosecution history of record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-16 (Fed. Cir. 2005) (*en banc*). When, as here, claim terms have been construed by a

district court, those constructions are properly considered during an IPR. 37 C.F.R. § 42.100(b). In the QXMedical Litigation, Patent Owner stipulated to the following constructions:

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1412 at 2)
- "interventional cardiology device(s)": "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters" (*Compare* Ex. 1412 at 21 (Dkt. 36-1) (Patent Owner construction), *with* Ex. 1464 at 1 n.1 (agreeing to Patent Owner's construction)).

Further, Patent Owner advanced,[3] and the district court adopted, the following constructions:

- "substantially rigid": "rigid enough to allow the device to be advanced within the guide catheter" (Ex. 1412 at 2 (Dkt. 36-1); Ex. 1413 at 15).

Additionally, the district court provided the following constructions:

- "partially cylindrical opening": "need[s] no construction and will be given [its] plain and ordinary meaning" (Ex. 1413 at 25-26)
- "lumen": "the cavity of a tube" (*Id.* at 25)

[3] The full list of constructions advanced by Patent Owner in the QXMedical Litigation are found at Ex. 1412 (Dkt. 36-1).

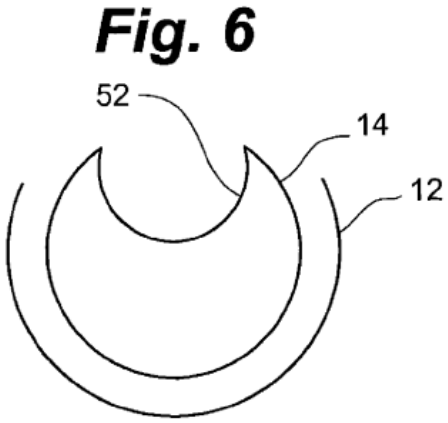
- "formed from a material more rigid than a material or material combination forming the tubular structure": "formed from matter that is more rigid than the matter forming the tubular structure" (*Id.* at 32)
- "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure": "formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure" (*Id.*).

Petitioner agrees with the above constructions for purposes of this IPR[4] (Ex-1405, ¶ 123-29) and proposes the following additional constructions:

A. "concave track" (cl. 37)

The '776 patent does not define the term "concave track." Ex. 1405, ¶ 130. It mentions that a cutout portion, which supports a track, "may" have certain amounts removed and "may" extend for certain lengths, and later refers to cutout portion 44, which is not labeled in a Figure. Ex. 1401, 4:24-33, 4:47-49, 7:39-40; Ex. 1405, ¶¶ 30-31. Figure 6, though, discloses a cross-sectional view of a concave track 52. Ex. 1401, 7:39-42, Fig. 6.

[4] Petitioner proposes these constructions for purposes of this IPR only and reserves the right to raise different constructions in other forums.



As a result, in the context of the ’776 patent, the claim term “concave track” means a “portion that is not fully circumferential.” Ex-1405, ¶ 131.

B. “flexural modulus” (cls. 52, 54)

The claim term “flexural modulus” had a known and established meaning by 2006 (Ex. 1442, ¶ 48), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means “[a] measure of resistance . . . to bending.” Ex. 1440 at 772. In other words, the “flexural modulus” is a measure of a device’s rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. Such an understanding is consistent with the ’776 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex. 1401, 7:31-38; Ex. 1405, ¶¶ 132-33. Stated differently, the extension catheter’s resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the

distal end is the most flexible (least rigid).[5]

VII. GROUND 1: KONTOS RENDERS CLAIMS 25-27, 29, 33, 35-37, 39, 41-49, AND 52 OBVIOUS IN VIEW OF RESSEMANN AND/OR THE KNOWLEDGE OF A POSITA.

A. Kontos

Kontos issued on August 8, 1995 and is prior art under pre-AIA § 102(b). During prosecution of the '776 patent (and its previous iteration, the '850 patent), Kontos was neither disclosed by Patent Owner, nor cited by the Examiner. *See generally* Exs-1001-03.

Kontos is entitled "Support Catheter Assembly." Ex. 1409, [54]. As the title suggests, Kontos discloses "[a] support catheter assembly for facilitating medical procedures, [and] includes a tubular body and a continuous lumen from its proximal end to its distal end." *Id.*, Abstract. In particular, Kontos describes "a support catheter assembly with particular utility in facilitating insertion of a PTCA balloon into a lesion." *Id.*, 1:9-13. Just like the coaxial guide catheter 12 of the

[5] In the QXMedical Litigation, Patent Owner stipulated to following construction of "flexural modulus": "a numeric, dimension-independent material property that captures the tendency of a material to bend." Ex. 1412 at 2. From this construction, it is unclear if Patent Owner agrees that a high flexural modulus means an increased resistance to bending.

'776 patent, support catheter 10 of Kontos includes a short lumen (body 12) coupled to a pushrod (insertion/manipulation wire 14) for "inserting, advancing, withdrawing and maneuvering the body [12] during a medical procedure." *Id.*, 3:45-46, Abstract. As explained below, support catheter 10 performs the same functions as the coaxial guide catheter 12 of the '776 patent; namely, it serves as a guide extension catheter for providing backup support, such that dislodging of the guide catheter from the coronary ostium is prevented. Ex. 1405, ¶¶ 136-37.

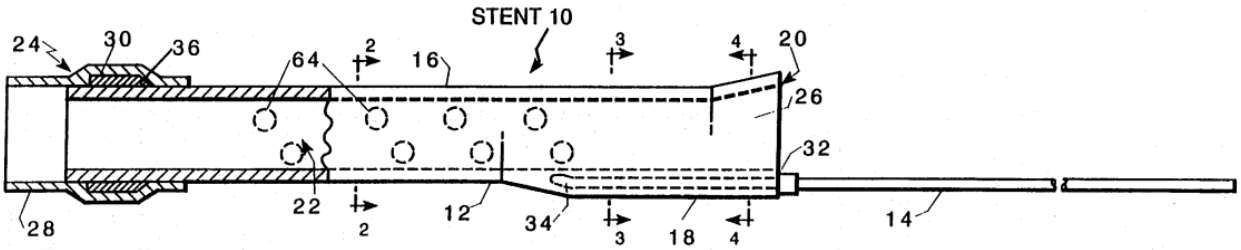


FIG. 1

Ex. 1409, Fig. 1.

Kontos explains that when removing a stenosis, "[t]he guide catheter . . . can generally reach only to the coronary ostia, whereas the lesion to be opened is most commonly located in one of the coronary arteries leading from the ostia." *Id.*, 1:39-42. Because of this, "the balloon catheter must negotiate the ostia, enter the coronary artery and pass through the coronary artery to the lesion without the help of the guide catheter." *Id.*, 1:42-46. Kontos explains, however, that "those skilled in the art know [that] the distal end of a PTCA catheter is made to be extremely soft and flexible," and thus is "readily susceptible to kinking and bending" during

navigation to the location of the stenosis to be removed. *Id.*, 1:30-38. Kontos describes an apparatus that solves this problem and "facilitate[s] the passage of the balloon catheter from the end of the guide catheter to the lesion." *Id.*, 1:46-49.

Specifically, as shown in Figure 6B (below), support catheter 10 is "inserted into and passed through . . . and out the distal end of the guide catheter [38] so as to function as an extension of the guide catheter [38] to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened." *Id.*, 2:16-23. This way, "the gap that PTCA catheter 40 must negotiate without assistance is made much shorter." *Id.*, 5:49-52; Fig. 6B.

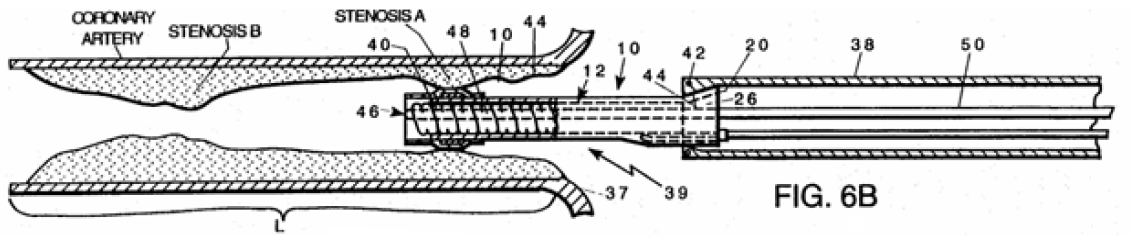


FIG. 6B

A POSITA would appreciate that Kontos's support catheter 10 operates no differently than coaxial guide catheter 12 of the '776 patent. Ex. 1405, ¶¶ 134-39. The support catheter 10 extends further into the coronary artery than the guide catheter, while permitting a therapeutic device (e.g., PTCA catheter) to be passed therethrough and provides backup support for the guide catheter, thereby preventing its dislodgment from the ostium. Ex. 1405, ¶¶ 136-37.

B. Ressemann

Ressemann was filed on August 9, 2002, and issued as U.S. Pat. No. 7,604,612 on October 20, 2009, meaning it is prior art under pre-AIA §102(e). During prosecution of the ’776 patent (and its previous iteration, the ’850 patent), Ressemann was neither disclosed by Patent Owner, nor cited by the Examiner. *See generally* Ex. 1401-03.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex. 1408, Abstract. The assembly includes a GC, which “may be positioned within the ostium of a target vessel,” (*id*., 12:26-30), and an evacuation sheath that is coaxially to and extends beyond the GC to treat a stenosis. *Id*., Abstract, 6:18-24, 12:9-14:39, Figs. 6A-6F; Ex-1405, ¶¶ 140-41.

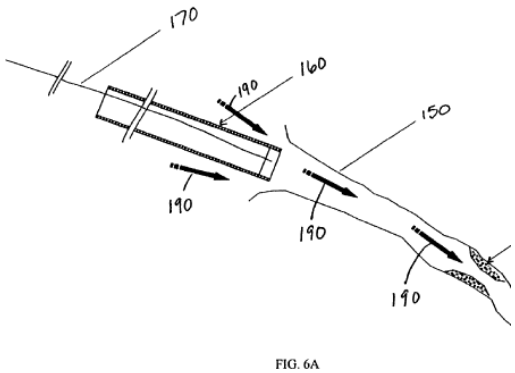


FIG. 6A

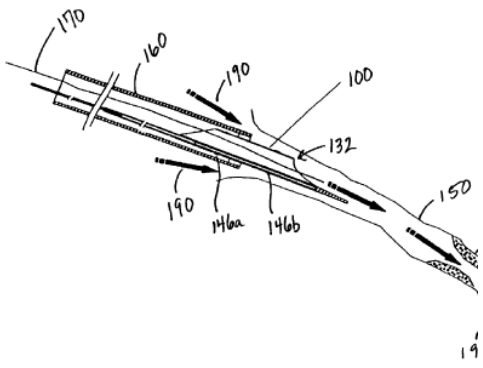


FIG. 6B

Sheath assembly is described for use in aspirating embolic material (*id*., Abstract; 12:9-13:34) and for stent or balloon delivery. *Id*., 6:25-34, 12:3-8; Ex-1405, ¶ 142.

The evacuation sheath includes a distal evacuation head. *Id*., 6:19-20; Figs. 1A, 1C, 11A. The head is "preferably made of a relatively flexible polymer such as low-density polyethylene, polyurethane, or low durometer Pebax® material." *Id*., 6:36-39 (illustrated below in pink). Ressemann also teaches, however, that the evacuation head may also include a kink-resistant structure, coil 139, which may be made of metal ribbon and covered in a polymer. *Id*., 6:66-7:12; 23:49-60.

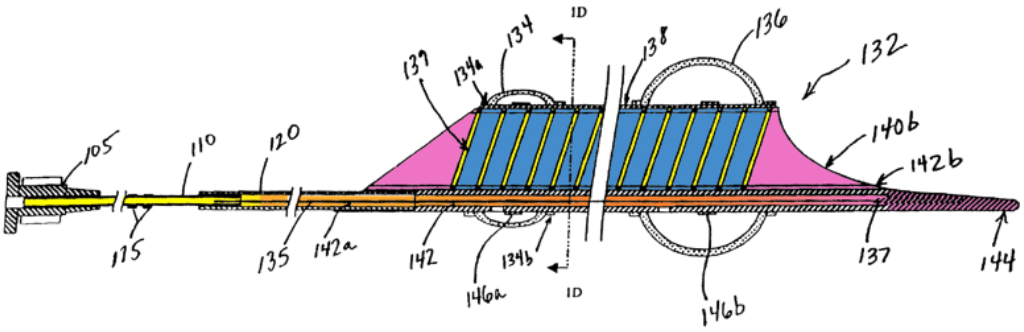


FIG. 1C

Id., Fig. 1C (color added); Ex. 1405, ¶¶ 143-44.

C. Claim 25

1. [25.pre] "A guide extension catheter for use with a guide catheter, comprising:"

To the extent the preamble is limiting, Kontos discloses a "guide extension catheter" (support catheter assembly 10) that is adapted for use with a guide

catheter. Ex. 1405, ¶ 154. Kontos provides that "[s]upport assembly 10 is composed of two major elements, a body 12 and an insertion/manipulation wire 14." Ex. 1409, 3:45-46, Fig. 1. Kontos further explains that "the support catheter [(10)] can be inserted into and passed . . . out the distal end of the guide catheter so as to function as an extension of the guide catheter to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened." *Id.*, 2:16-22, 3:45-46, 5:49-52 ("When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension, and the gap that PTCA catheter 40 must negotiate without assistance is made much shorter."); *see also id.*, Fig. 6B.

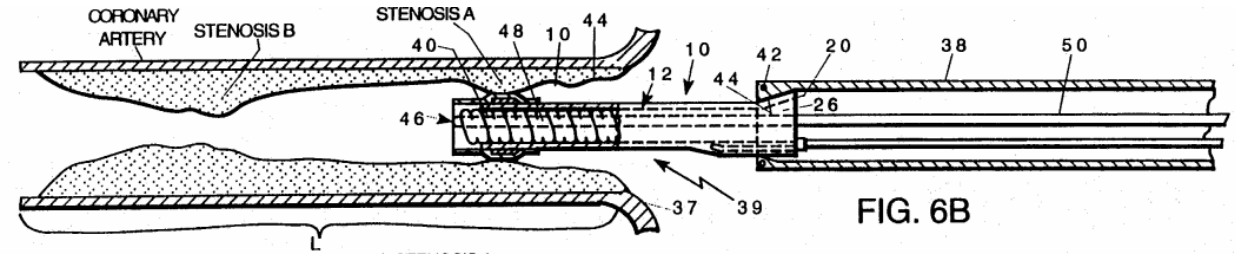


FIG. 6B

2. [25.a] "a substantially rigid segment;"

In Kontos's support catheter 10, the portion of the insertion/manipulation wire 14 that is proximal of tube 16 is the "substantially rigid segment." Ex. 1405, ¶ 155.

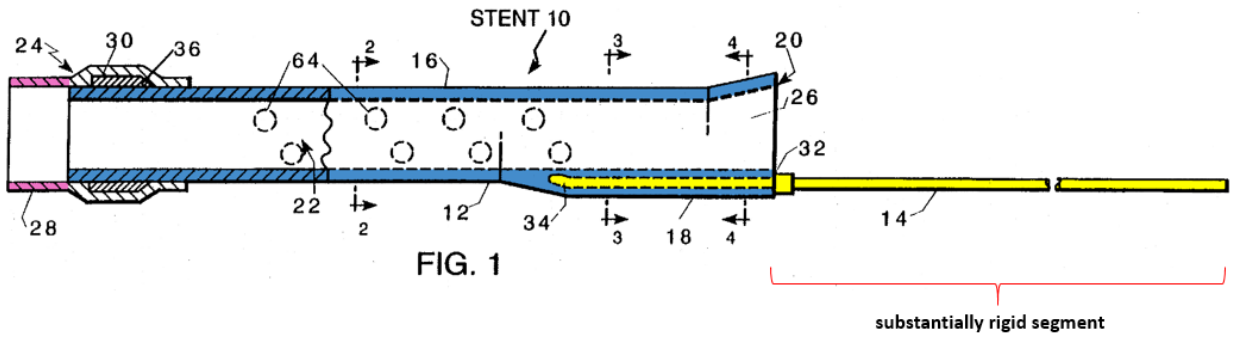


FIG. 1

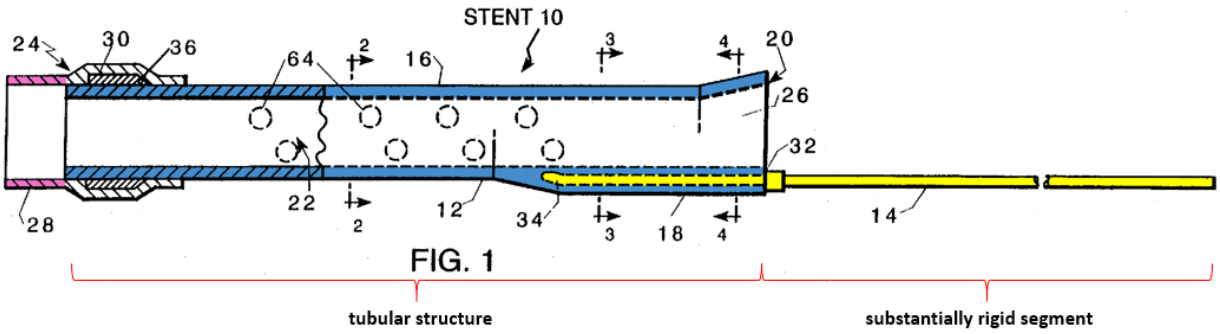
Ex. 1409, Fig. 1 (color added).[6] Wire 14 is a "substantially rigid segment" because the support catheter 10 is "advanced through guide catheter 38 to the distal end thereof" by "exerting axial force" on wire 14. *Id.*, 5:25-30; *see also id.*, Abstract.

[6] As explained below, the '776 patent precludes the substantially rigid segment from overlapping with the tubular structure. *See* Section VII.C.4, *infra*. Other patents in this family do not have a similar limitation and, for this reason, Petitioner interpreted those claims and the art as permitting Kontos's wire 14 (substantially rigid segment) to overlap with tube 16 (tubular structure). Such an interpretation acknowledges the realities of how these extension catheters can be manufactured (i.e., the pushrod connects with the tubular portion). For purposes of this IPR, however, Petitioner applies the claims as recited in the '776 patent and as interpreted by Patent Owner in the district court. Ex. 1477, 127:24-128:14, 144:9-22, 145:9-17.

Thus, wire 14 is "rigid enough to allow the device to be advanced within the guide catheter." Section VI, *supra*; Ex. 1405, ¶ 155.

3. [25.b] "a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and"

In Kontos's support catheter 10, tube 16 is the tubular structure defining a lumen and positioned distal to the substantially rigid segment. Ex. 1405, ¶ 156. As shown below, the tubular structure is distal to the substantially rigid segment. *Id.*; Ex. 1409, Fig. 1.



Ex. 1409, Fig. 1 (color and annotations added).

Tube 16 is a tubular structure with "a continuous lumen 22 therethrough from proximal end 20 to distal end 24." Ex. 1409, 3:49-50; *see also id.*, 3:56-57 ("[T]ube 16 is generally cylindrical."), Fig. 6C.

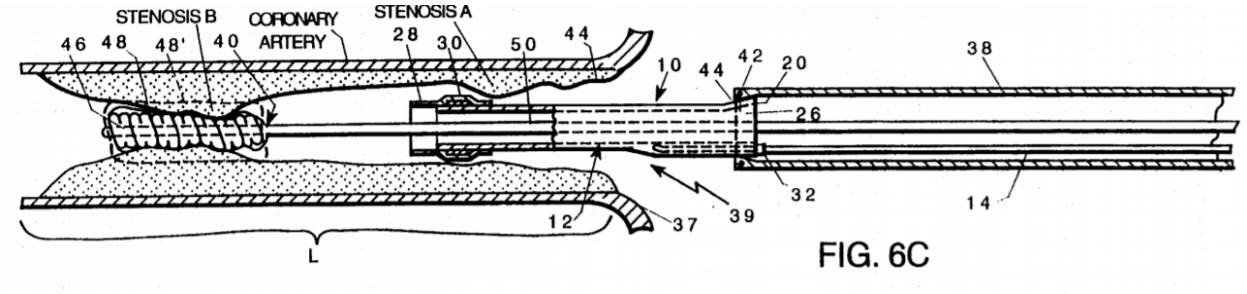


FIG. 6C

4. [25.c.i] "a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure,"[7]

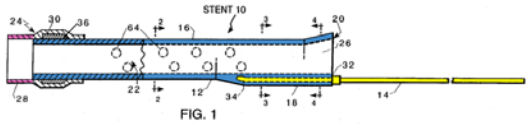
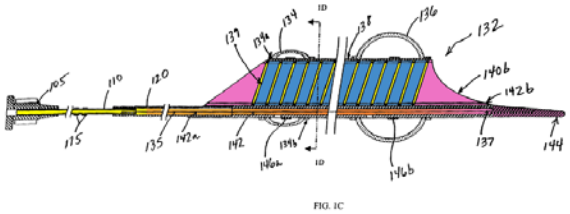
Kontos in view of Ressemann and/or the knowledge of a POSITA teaches a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure. Ex. 1405, ¶ 157; Ex. 1407, 3:47-50, 4:10-15, 4:27-32, Fig. 4. Ressemann and Kontos are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the '776 patent. Ex. 1405, ¶ 157.

[7] As set forth above, the '776 patent does not disclose a partially cylindrical opening positioned "between" the distal end of the substantially rigid segment and the proximal end of the tubular structure. *See* Section IV.B, *supra*. The only disclosure of the opening is in the substantially rigid portion. Despite Patent Owner's claim drafting game, it is clearly obvious to have a side opening in that location.

For example, Ressemann also discloses an assembly and method for using PTCA and stenting to treat vascular disease. *Id.*; Ex. 1405, ¶ 157; Ex. 1408, 6:25-34, 12:3-8, 23:8-11. The Ressemann assembly includes a GC, just like Kontos, that "may be positioned within the ostium of a target vessel." Ex. 1405, ¶ 157; Ex. 1408, 12:26-30. An evacuation assembly 100/2100[8] ("extension catheter") is then insertable through and extends beyond the distal end of the GC. Ex. 1405; ¶ 157, Ex. 1408, Abstract, 6:18-24, 12:9-12, 12:19-30, Figs. 6A-B. As shown below, the Ressemann extension catheter 100/2100, like the Kontos extension catheter (support catheter 10), can similarly be characterized by a short distal lumen (i.e., tube) that is coupled, at its proximal end, to a long thin pushrod. Finally, in Ressemann, as in Kontos, interventional cardiology devices, such as a balloon catheter, can be passed through the lumen of the extension catheter to treat the

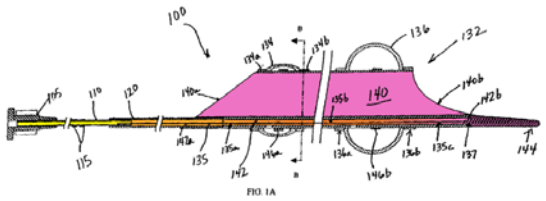
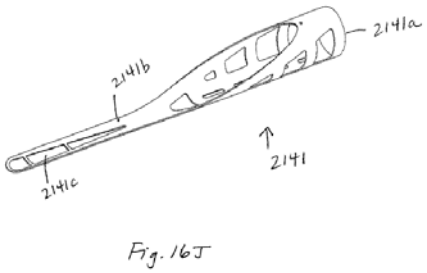
[8] Ressemann discloses different embodiments of its evacuation assembly. The first is the 100 series and the other is the 2100 series. As explained by Ressemann, "where these elements [for each embodiment] are substantially the same, similar reference numerals [were] used. Ex. 1408, 22:33-37. By way of example, in the evacuation assembly 100, the evacuation lumen in numbered 132, whereas in the evacuation assembly 2100, the evacuation lumen is numbered 2132. *Compare id.*, 6:17-35, *with id.*, 22:31-33.

stenosis. Ex. 1405, ¶ 157; Ex. 1408, 6:25-34; 12:3-8.

 Ex. 1409, Fig. 1A (color added)	 Ex. 1408, Fig. 1A (color added) (showing 100 evacuation assembly)

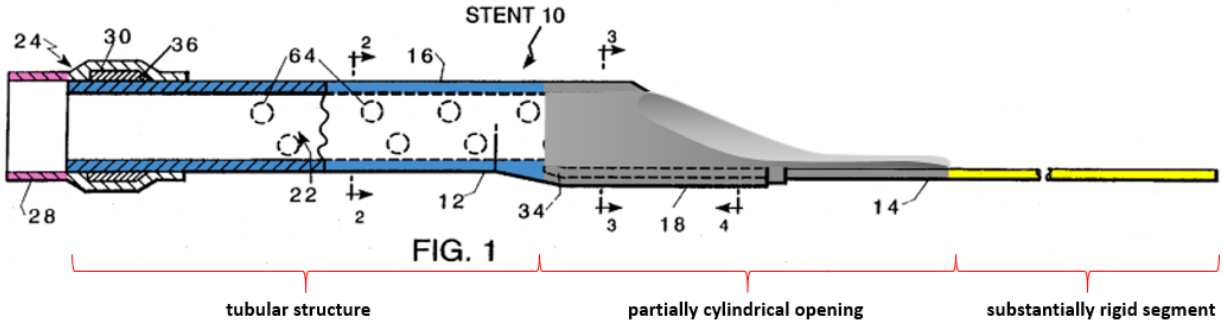
As shown above, Kontos does not teach a partially cylindrical opening. As seen in Kontos Figure 1, the proximal opening of tube 16 does not extend along the longitudinal axis of the tubular structure, meaning it is not a partially cylindrical opening. Partially cylindrical openings falling within the scope of the claim were, however, well-known in the art. Ex. 1405, ¶¶ 158-59; *see also id.*, ¶¶ 90-108; Ex. 1442, ¶¶ 73-78; Ex. 1407, 4:11; Ex. 1408, 12:9-13:60, Fig. 6A-6E; Ex. 1418, Fig. 7; Ex. 1432 at 119, Fig. 1; Ex. 1433, [0035], [0049], Fig. 2; Ex. 1435, [0066]; Ex. 1450, Fig.7; Ex. 1461, 6:9-11, Fig. 1B.

Ressemann is one such catheter assembly that uses a partially cylindrical opening. Ex. 1405, ¶¶ 160-61. In particular, Ressemann teaches an evacuation assembly 100/2100 ("extension catheter") where the entry to the evacuation lumen 140a/2140 is "preferably angled." Ex. 1408, 6:52-60 (100 embodiment); 24:33-38 (2100 embodiment).

 Ex. 1408, Fig. 1A (color added) (100 embodiment)	 Ex. 1408, Fig. 16J (2100 embodiment)

A POSITA would have been motivated, with a reasonable expectation of success, to add Ressemann's partially cylindrical opening—in particular, the support collar 2141 of evacuation assembly 2100[9]—to Kontos, as shown below. Ex. 1405, ¶¶ 161-74; Ex. 1442, ¶¶ 91-100.

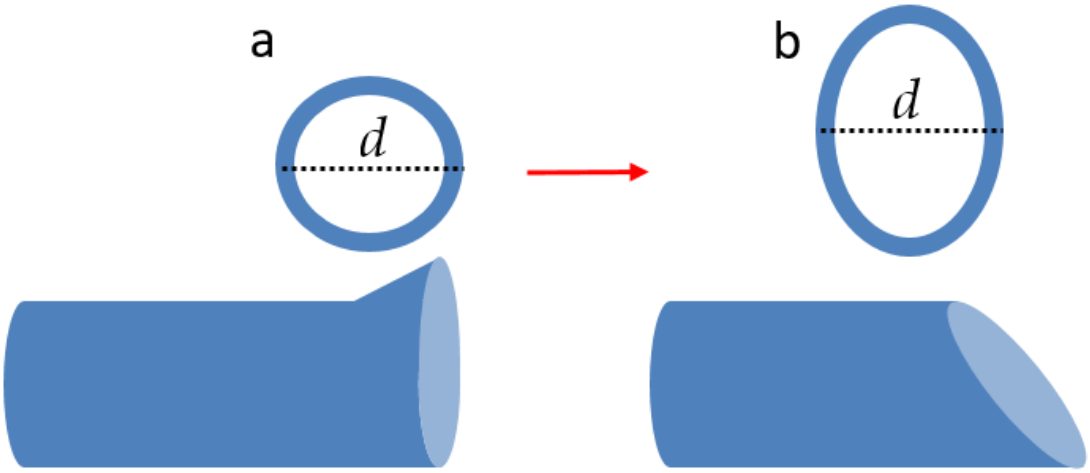
[9] A POSITA would have been motivated to use support collar 2141 for all the reasons set forth herein, including that it "serves to reinforce the proximal opening of the evacuation lumen 2140 in the presence of deforming forces." Ex. 1408, 24:49-55; *see also* Ex. 1442, ¶¶ 79-90. Petitioner need not demonstrate why a POSITA would choose the partially cylindrical opening of evacuation assembly 2100 as opposed to the partially cylindrical opening of evacuation assembly 100.



Ex. 1409, Fig. 1 (color added and modified by Petitioner).

A POSITA would have been motivated to modify Kontos to add a partially cylindrical opening proximal of the tubular structure, as taught by Ressemann, for multiple reasons. Ex. 1405, ¶¶ 162-72; Ex. 1442, ¶¶ 91-99. First, a POSITA would have known, as shown in the below figure, that use of a partially cylindrical opening could permit a reduction of the outer diameter of the catheter assembly without resulting in a commensurate reduction in the area of the point of entry to the extension catheter.

Novartis Pharm. Corp. v. W.-Ward Pharm. Int'l Ltd., 923 F.3d 1051, 1059 (Fed. Cir. 2019).



Ex. 1405, ¶ 163; Ex. 1442, ¶ 96.

In 1995, when Kontos issued, GCs were typically 7-8 French in diameter. Ex. 1405, ¶ 164. But by the purported priority date of the '776 patent, use of a 6 French GC had become more common. *Id.* These smaller GCs had several advantages (*id.*), but as the diameter of a GC decreases, so too does the diameter of the extension catheter. This, in turn, means that the proximal opening 20 of Kontos's tubular structure (tube 16) must decrease. *Id.*; Ex. 1409, Fig. 6B. And if the cross-sectional diameter of the proximal opening of the tubular structure becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex. 1405, ¶ 165. Therefore, as an alternative to the flared proximal opening 26 of the tubular structure (tube 16) in Kontos, a POSITA would have been motivated to use a partially cylindrical opening, as then the diameter of the GC could be reduced

without causing a commensurate reduction in the area of the proximal opening of the tubular structure of the extension catheter. *Id.*; Ex. 1442, ¶ 96.

Second, a POSITA would have been motivated to use a partially cylindrical opening because, as taught by Ressemann, doing so facilitates "smoother" reception of the interventional cardiology device as it enters the lumen of the child catheter. Ex. 1408, 6:52-57 (100 embodiment), 24:38-41 (2100 embodiment); *see also* Ex. 1405, ¶¶ 166-67; Ex. 1442, ¶ 97; Ex. 1426, 3:10-14. In particular, it was known that the interventional cardiology device could snag or become "hung-up" when entering the distal lumen of the child catheter. Ex. 1405, ¶ 168; Ex. 1442, ¶ 98. A partially cylindrical opening reduces this likelihood—by comparison to a vertical opening—meaning it promotes better advancement of the therapy catheter as it travels to the occlusion.[10] Ex. 1405, ¶¶ 166-67; Ex. 1442, ¶ 98.

[10] Kontos itself reflects the same concern, and provides funnel 26 to aid insertion of a therapy catheter. Ex. 1409, 3:66-68. A partially cylindrical opening is obvious because it provides the benefit Kontos seeks, as well as the additional benefits described herein. As an aside, it is irrelevant that Kontos's funnel can also be used in combination with annular ridge 44 to prevent unwanted advancement beyond the guide catheter 38. Marker ring 42 provides that function, and the interaction

Third, a POSITA additionally would have been motivated to use a partially cylindrical opening, as taught by Ressemann, because such a design promotes "smoother passage" of the catheter assembly as it navigates the tortuous vasculature. Ex. 1408, 6:52-57; *see also* Ex. 1405, ¶ 169; Ex. 1442, ¶ 99; Ex. 1425, Abstract, [0034]. In other words, adding a partially cylindrical opening to the lumen of the extension catheter reduces the amount of force that a physician must exert to advance the catheter through winding vasculature. Ex. 1405, ¶ 169; Ex. 1442, ¶ 99.

Fourth, a POSITA was motivated to add a partially cylindrical opening to the extension catheter because doing so permitted smooth re-entry if the proximal end of the extension catheter was extended beyond the distal end of the GC. Ex. 1405, ¶¶ 170-71; Ex. 1442, ¶¶ 92-95. For example, Kontos teaches an embodiment where "the bridge body 12/PTCA catheter assembly must be passed completely out of guide catheter 38 and advanced as a unit to the site of restriction B." Ex. 1409, 6:22-25.

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between funnel 26 and ridge 44 is an alternative, and therefore unnecessary, embodiment. *Id.* at 5:57-6:8.

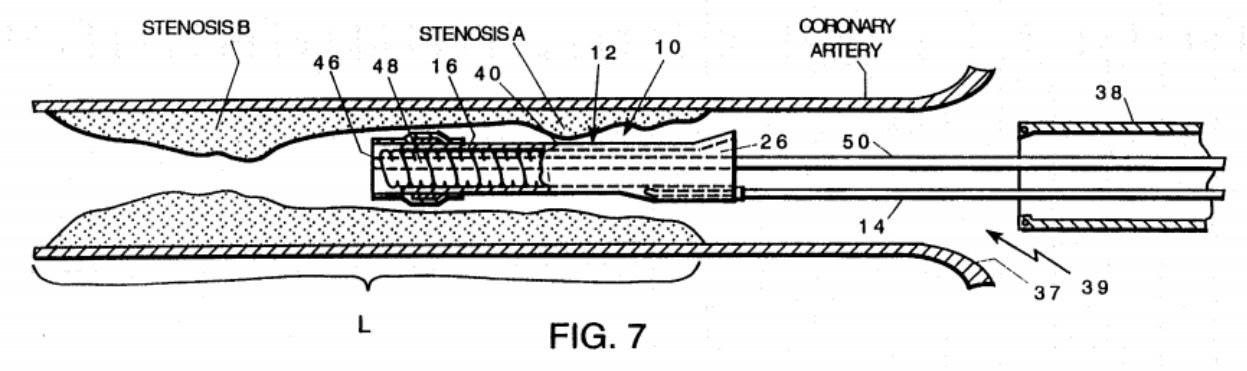


FIG. 7

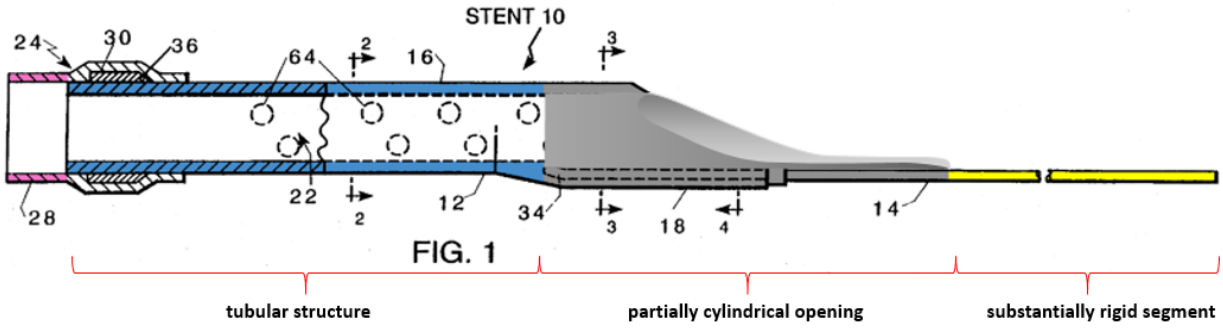
Ex. 1409, Fig. 7.

In such an embodiment, after the angioplasty is performed, the support catheter 10 must return to the guide catheter 38. Ex. 1405, ¶ 171; Ex. 1442, ¶ 92. A POSITA would recognize, however, that a flared proximal opening of the tubular structure (tube 12) was a poor design choice, as this protrusion could damage the internal coronary wall and hinder re-entry of the tubular structure into the GC as the tubular structure travels proximally toward the GC. Ex. 1405, ¶ 171; Ex. 1442, ¶ 94. The smaller cross-sectional diameter of a partially cylindrical opening would reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the GC. Ex. 1405, ¶¶ 171-72; Ex. 1442, ¶ 95; Ex. 1435, [0066] ("Proximal end 31 is preferably cut or formed at an angle to the seal axis to facilitate unimpeded entry of the seal's proximal end into the distal end of the guide catheter.")..

The prior art, including Ressemann, shows that the use of a partially cylindrical opening was well known. Ex. 1405, ¶¶ 95, 173. Employing

Ressemann's partially cylindrical opening (as opposed to an opening perpendicular to the longitudinal axis) with the Kontos device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. Ex. 1405, ¶ 173; Ex. 1442, ¶¶ 80, 89-91, 100 ; *see also KSR Int'l co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[I]f a technique has been used to improve one device, and a [POSITA] would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

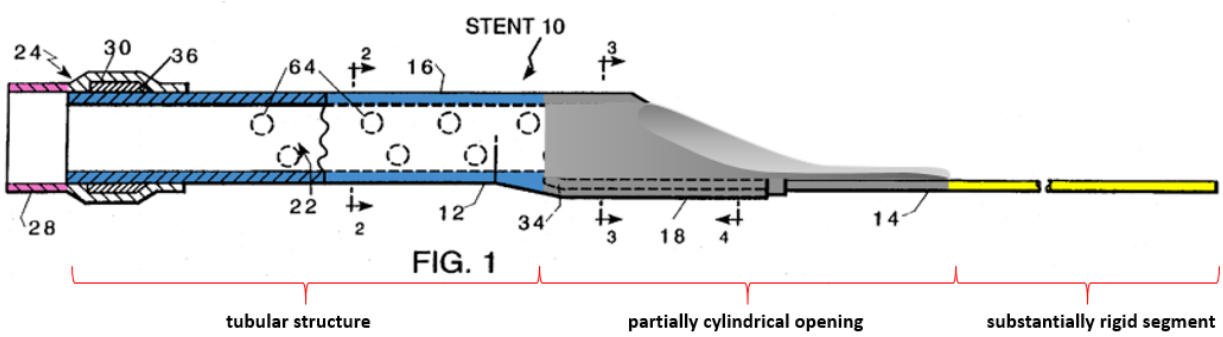
After adding Ressemann's partially cylindrical opening (support collar 2141) to Kontos, the resulting combination would result in, as shown below, a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure. Ex. 1405, ¶ 174.



Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

5. [25.c.ii] "the segment defining the partially cylindrical opening having an angled proximal end,"

As discussed for claim 25.c.i, a POSITA would have been motivated, with a reasonable expectation of success, to add a partially cylindrical opening proximal of Kontos's tubular structure. *See* Section VII.C.4, *supra*. In so doing, as shown below, the partially cylindrical opening necessarily would include a "segment defining the partially cylindrical opening having an angled proximal end." Ex. 1405, ¶ 175.



Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

6. [25.c.iii] "formed from a material more rigid than a material or material combination forming the tubular structure,"

Kontos in view of Ressemann and the knowledge of a POSITA teaches a partially cylindrical opening formed from a material more rigid than the tubular structure. Ex. 1405, ¶¶ 176-77. As discussed in 25.c.i, a POSITA would have been motivated, with a reasonable expectation of success, to add a partially cylindrical opening—in particular, Ressemann's support collar 2141—proximal of Kontos's tubular structure. *See* Section VII.C.4, *supra*. In so doing, the material forming the

partially cylindrical opening would have been more rigid than the material forming the tubular structure. Ex. 1442, ¶¶ 101-05; *see also* Section VI, *supra*.

As Ressemann explains, support collar 2141 "serves to reinforce the proximal end of the multi lumen tube 2138 and serves to reinforce the proximal opening of the evacuation lumen 2140 in the presence of deforming forces." Ex. 1408, 24:47-55. Ressemann further explains that support collar 2141 is preferably "a metallic material" with "suitable rigidity to prevent kinking." *Id.*, 25:13-16; *see also id.*, 24:62-67 (providing "flexibility transition between the proximal end of the evacuation head 2131 and the shaft [2100]"). Conversely, Kontos's tube 16 includes "any pliable material," but preferably is composed of a molded plastic material, such as polyethylene. Ex. 1409, 4:1-4. Based on known material properties, the support collar 2141 that comprises the partially cylindrical opening is more rigid than the tubular structure. Ex. 1405, ¶¶ 176-77; Ex. 1442, ¶ 105.

7. [25.c.iv] "and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,"[11]

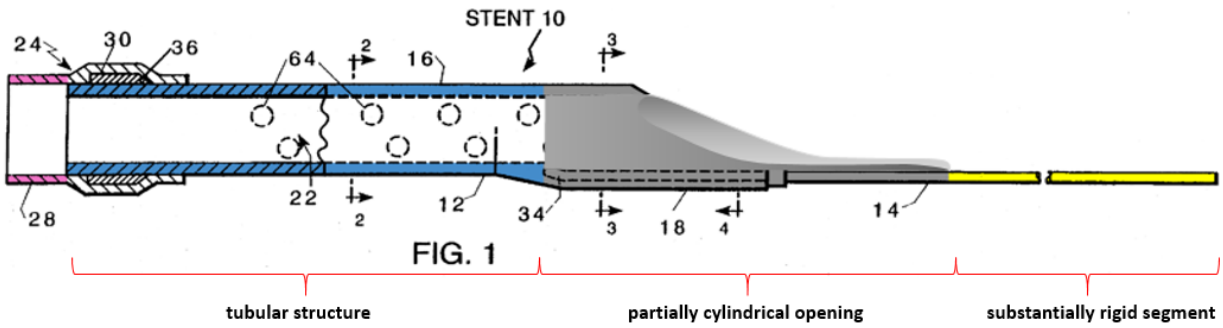
Kontos teaches that the extension catheter (support catheter 10) is positioned within the GC when it receives the interventional cardiology device. Ex. 1409, 7:45-52 (noting that "[b]ody 12 could be inserted first" into GC, and then "followed by the PTCA catheter 40"); *see also id.*, 4:66-5:2 ("[L]umen 22 should be at least large enough to permit passage therethrough of the deflated PTCA balloon."), 5:16-18, Figs. 6A-C. Therefore, the Kontos extension catheter (support catheter 10) is configured to receive one or more interventional cardiology devices when positioned within the guide catheter. Ex. 1405, ¶ 178.

8. [25.d] "wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen."

Kontos in view of Ressemann and the knowledge of a POSITA teaches a tubular structure with a single lumen at its proximal end. Ex. 1405, ¶ 179. As

[11] This claim element appears to recite an intended use ("configured ***to receive one or more interventional cardiology devices therethrough when the positioned within the guide catheter***") (emphasis added), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Out of an abundance of caution, Petitioner addresses this claim limitation.

shown below, Kontos discloses an extension catheter (support catheter 10) where a cross-section at the proximal end of the tubular structure defines a single lumen.[12] *Id.*



Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

D. Claim 26: "The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent the distal end of the substantially rigid segment and extends distally toward the tubular structure."

Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 26 obvious. Ex. 1405, ¶ 180. As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to add a partially cylindrical opening—in particular, Ressemann's support collar 2141—proximal of Kontos's tubular structure. *See* Section VII.C.4, *supra*. In so doing, the angled

[12] The addition of Ressemann's support collar 2141 to the Kontos support catheter 10, would not result in a tubular structure with more than one lumen. Ex. 1442, ¶ 107.

proximal end of the partially cylindrical opening necessarily originates adjacent the distal end of the substantially rigid segment and extends distally toward the tubular structure. Ex. 1405, ¶ 180.

E. Claim 27: "The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape."

Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 27 obvious. Ex. 1405, ¶ 181. As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's partially cylindrical opening into Kontos's support catheter 10. Section VII.C.4, *supra*. In so doing, a portion of the cylindrical opening necessarily includes an arcuate cross-sectional shape, which, according to the '776 patent, is a portion that "extends from 25% to 40% of the circumference of the tube." Ex. 1401, 7:12-14; Ex. 1405, ¶ 181.

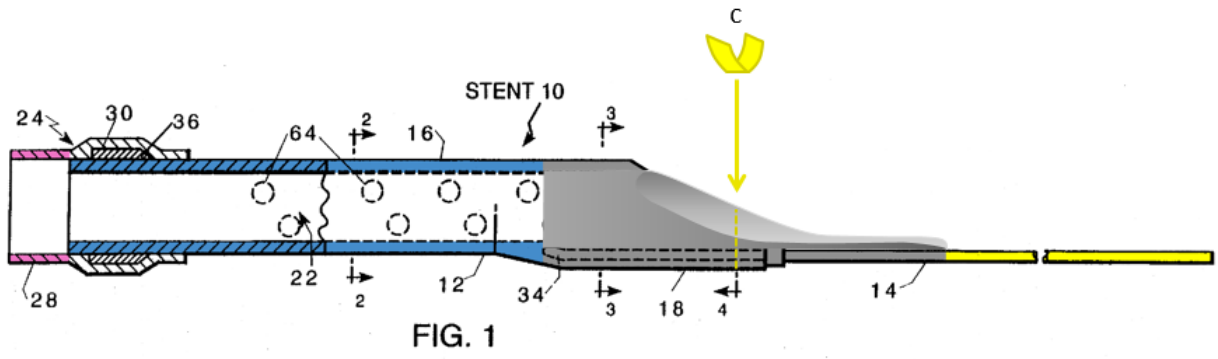


FIG. 1

Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

F. Claim 29: "The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of a cross-sectional circumference of a tube."

The Kontos-Ressemann combination renders claim 29 obvious for the same reason that claim 27 is obvious. Ex. 1405, ¶ 182. Indeed, claim 29 adds nothing of patentable weight and merely rephrases claim 27.

Claim 29 adds that the arcuate cross-section "radially extends 25% to 40% of a cross-sectional circumference of a tube." But as explained above for claim 27, the specification of the '776 patent already describes an arcuate cross-sectional shape in this fashion. Ex. 1401, 7:12-14. Stated another way, by reciting an arcuate portion in claim 27, Patent Owner necessarily recited a portion that extends 25% to 40% of the cross-sectional circumference of a tube. Ex. 1405, ¶ 182. Regardless, the Kontos-Ressemann combination necessarily discloses a partially cylindrical opening with an arcuate cross-section shape that radially extends 25% to 40% of a cross-sectional circumference of a tube, such that the arcuate shape sweeps an arc that is between 90° and 144° of a full circumference. *Id.*

G. Claim 33: "The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape."

Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 33 obvious. Ex. 1405, ¶ 183. As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to integrate

Ressemann's partially cylindrical opening into Kontos's support catheter 10. Section VII.C.4, *supra*. In so doing, a portion of the cylindrical opening necessarily includes a hemicylindrical cross-sectional shape, which, according to the '776 patent, is a portion that "desirably includes 40% to 70% of the circumference of the tube." Ex. 1401, 7:7-8; Ex. 1405, ¶ 183.

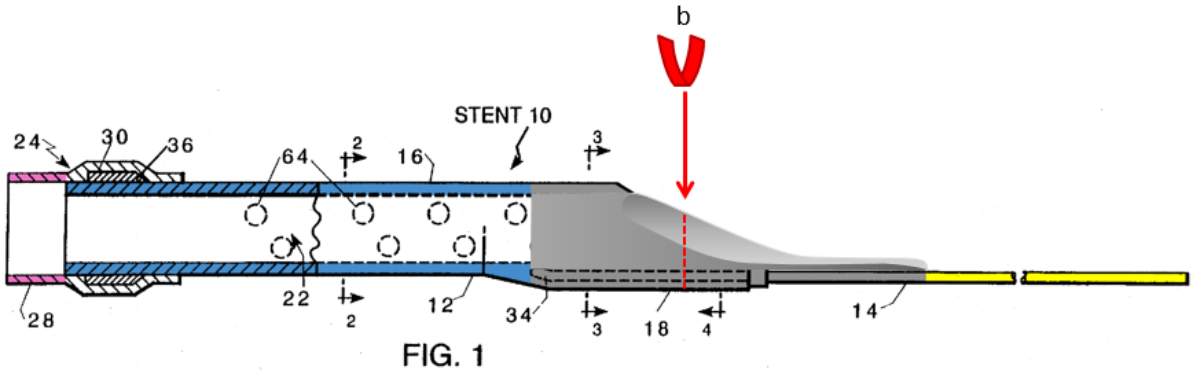


FIG. 1

Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

H. Claim 35: "The guide extension catheter of claim 33, wherein the hemicylindrical cross-sectional shape radially extends 40% to 70% of a cross-sectional circumference of a tube."

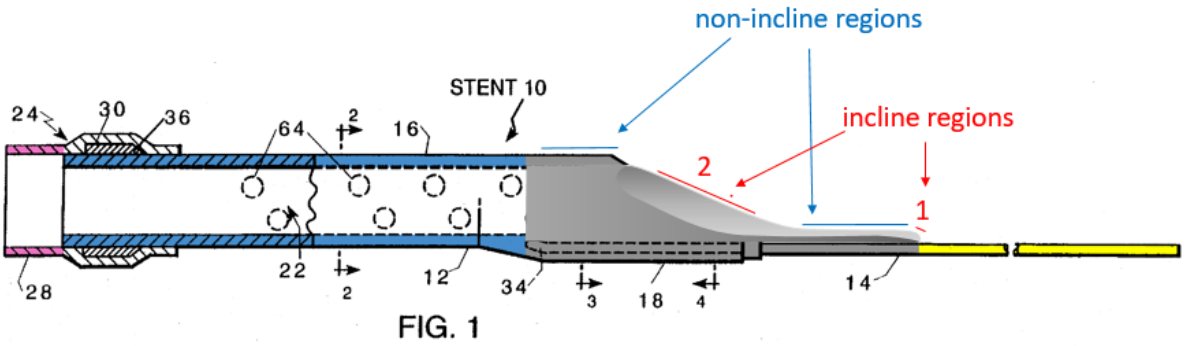
The Kontos-Ressemann combination renders claim 35 obvious for the same reason that claim 33 is obvious. Ex. 1405, ¶ 184. Indeed, claim 35 adds nothing of patentable weight and merely rephrases claim 33.

Claim 35 adds that the hemicylindrical cross-section "radially extends 40% to 70% of a cross-sectional circumference of a tube." But as explained above for claim 33, the specification of the '776 patent describes a hemicylindrical cross-sectional shape in this fashion. Ex. 1401, 7:7-8. Stated another way, by reciting a

hemicylindrical portion in claim 33, Patent Owner necessarily recited a portion that extends 40% to 70% of the cross-sectional circumference of a tube. Ex. 1405, ¶ 184. Regardless, the Kontos-Ressemann combination necessarily discloses a partially cylindrical opening with a hemicylindrical cross-section shape that radially extends 40% to 70% of a cross-sectional circumference of a tube, such that the hemicylindrical shape sweeps an arc that is between 144° and 252° of a full circumference. Ex. 1405, ¶ 184.

I. Claim 36: "The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region."

Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 36 obvious. Ex. 1405, ¶ 185. As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's partially cylindrical opening into Kontos's support catheter 10. Section VII.C.4, *supra*. In so doing, the segment defining the angled proximal end of the partially cylindrical opening necessarily includes inclined regions (red lines) that taper into non-inclined regions (blue lines). Ex. 1405, ¶ 185.



Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

J. Claim 37: "The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure."

Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 37 obvious. Ex. 1405, ¶ 186. As shown below, the proximal opening of Ressemann's support collar 2141 is "cut at an angle" (Ex. 1408, 24:33-38), meaning it has a portion with a partially cylindrical opening that is not fully circumferential, and thus, is concave. Ex. 1405, ¶ 186, Ex. 1408, Fig. 16J.

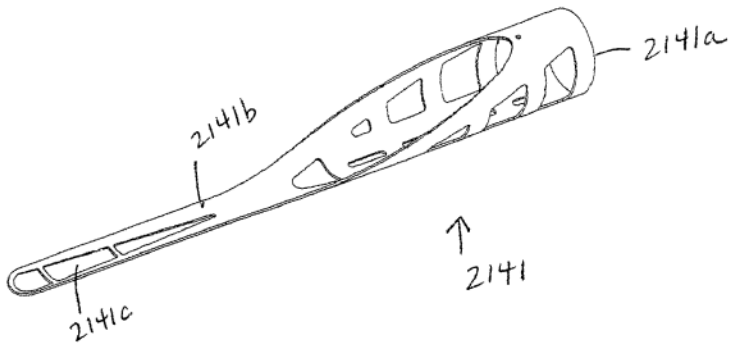


Fig. 16J

As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to combine Ressemann's support collar 2141 with Kontos's support structure 10. *See* Section VII.C.4, *supra*. In so doing, the concave track of Ressemann's support collar 2141 necessarily would have been continuous with Kontos's tube 16. Ex. 1405, ¶ 186; Ex. 1442, ¶¶ 106-07.

K. Claim 39: "The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a section of stainless steel."

The Kontos-Ressemann combination teaches claim 39. Ex. 1405, ¶ 187. In particular, Kontos teaches that the substantially rigid segment (wire 14) is stainless steel. Ex. 1409, 4:58-61. Thus, Kontos discloses that the substantially rigid segment can be formed from solid metal wire such as stainless steel. Ex. 1405, ¶ 187.

L. Claim 41: "The guide extension catheter of claim 25, wherein the substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure."

The Kontos-Ressemann combination teaches claim 41. Ex. 1405, ¶ 188. As shown by below arrows, the substantially rigid segment (wire 14) is eccentrically positioned (not concentric) relative to a cross section taken through the tubular structure (tube 16). *Id.*

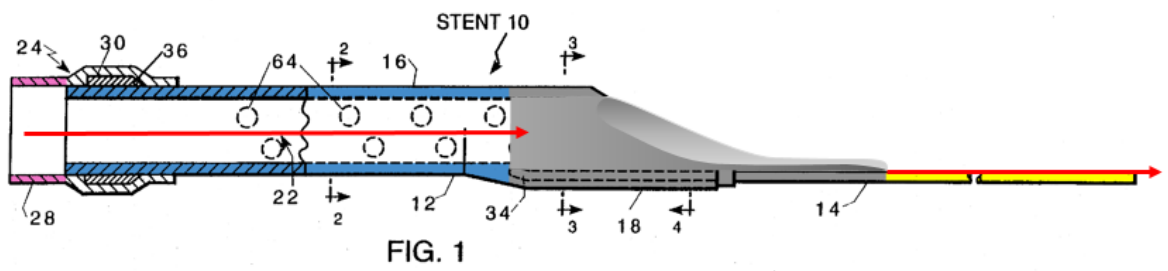


FIG. 1

Ex. 1409, Fig. 1 (color added) (modified by Petitioner).

M. Claim 42: "The guide extension catheter of claim 25, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure to be advanced within and partially through the guide catheter while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the substantially rigid segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure."

The Kontos-Ressemann combination teaches claim 42. Ex. 1405, ¶ 189. Kontos discloses that the substantially rigid segment (wire 14) has a 0.020 inch diameter and is made of stainless steel. Ex. 1409, 4:58-61. As discussed for claim 41, Kontos's wire 14 is positioned eccentrically relative to a cross section through tubular structure 16. Section VII.L, *supra*. Kontos's substantially rigid segment (wire 14) is used to advance the tubular structure (tube 16) until its distal portion "extend[s] beyond the distal end of guide catheter 38." Ex. 1409, 5:49-52; *see also* Section VII.C.2, *supra*. Kontos teaches that PTCA catheter 40 can then be advanced to the stenosis. Ex. 1409, 7:45-52. Thus, the substantially rigid segment is sufficiently sized to permit at least partial delivery of the one or more received interventional cardiology devices alongside the substantially rigid segment,

through the angled proximal end of the partially cylindrical opening (when coupled with Ressemann's support collar 2141), and through the lumen of the tubular structure. Ex. 1405, ¶ 189.

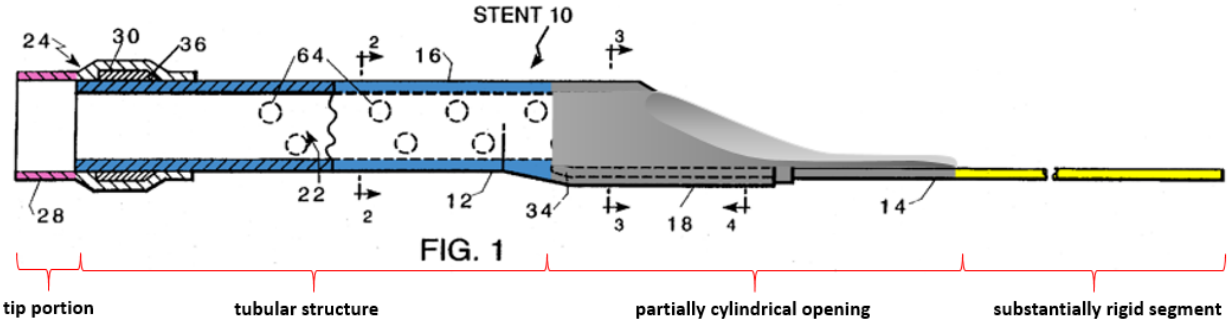
N. Claim 43: "The guide extension catheter of claim 25, wherein the substantially rigid segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the substantially rigid segment."

The Kontos-Ressemann combination teaches claim 43. Ex. 1405, ¶ 190. Kontos discloses that the substantially rigid segment (wire 14) has a 0.020 inch outer diameter. Ex. 1409, 4:58-61. Kontos also discloses that the lumen 22 of the tubular structure (tube 16) is 0.045 inches. *Id.*, 4:48-50. As a result, the diameter of the lumen of the tubular structure is greater than the diameter of the substantially rigid segment. Ex. 1405, ¶ 190.

O. Claim 44: "The guide extension catheter of claim 25, further comprising a tip portion positioned distal to the distal end of the tubular structure."

The Kontos-Ressemann combination teaches claim 44. Ex. 1405, ¶¶ 191-92. In Kontos, the tip portion is soft tip 28. *Id.* Soft tip 28 "is cylindrical in shape and extends coaxially from distal end 24 of tube 16" (tubular portion). Ex. 1409, 4:5-7. Soft tip 28 is composed of "any highly flexible material, "but preferably is composed of a soft plastic such as a copolymer of polyethylene and ethylvinylalcohol (EVA)." *Id.*, 4:7-11. As shown in Figure 1 (below), the tip

portion (soft tip 28) is distal to the distal-most portion of the tubular structure 16. Ex. 1405, ¶¶ 191-92; Ex. 1409, Fig. 1.



Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

P. Claim 45: "The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of a length of the tubular structure and surrounded by one or more polymer materials."

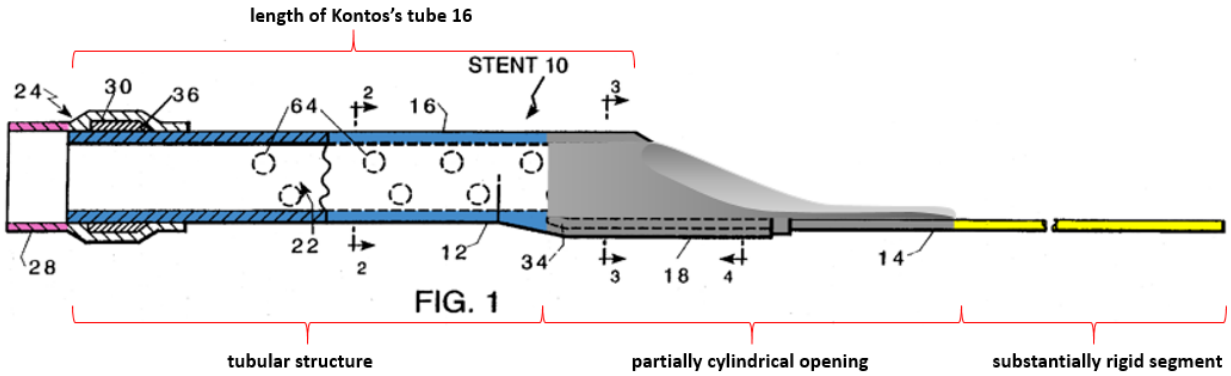
Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 45 obvious. Ex. 1405, ¶¶ 193-201. Metallic braiding or coiling was ubiquitous by the time of the claimed invention and was known to prevent or impart kink-resistance, thereby improving the pushability of the extension catheter. Ex. 1405, ¶ 193; Ex. 1442, ¶¶ 108-18; *see also* Ex. 1408, 6:66-7:12; Ex. 1446, Abstract; Ex. 1447, Abstract.

Ressemann teaches encassing a coil is a polymeric material. Ex. 1405, ¶¶ 194, 200; Ex. 1442, ¶¶ 109, 117. Ressemann and Kontos are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the '776 patent. Ex. 1405, ¶ 200. In

Ressemann, "tube 138 [of evacuation head 132] may be formed around a coil 139," and "[a] covering of polyurethane can then be applied to contain the coil 139." Ex. 1408, 7:8-12; Fig. 1C. A POSITA would have been motivated to add this design feature to tube 16 of Kontos because s/he knew that coiling, as taught by Ressemann, promoted pushability and prevented kinking during advancement of the catheter. Ex. 1408, 6:66-7:4; Ex. 1405 ¶ 200; Ex. 1442 ¶ 108-110, 116-17; *see also* Ex. 1446, Abstract; Ex. 1447, Abstract. Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given the numerous teachings in the art. Ex. 1405, ¶ 201; Ex. 1442, ¶ 118.

Q. Claim 46: "The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is 20 to 30 cm."

Kontos in light of Ressemann and/or the knowledge of a POSITA renders claim 46 obvious. Ex. 1405, ¶¶ 202-03. Kontos teaches that the tubular structure (tube 16) is approximately 1 foot (or 30.48 cm) in length. Ex. 1409, 4:52-54. As descibed for claim 25, however, a POSITA would have been motivated, with a reasonable expectation of success, to replace Kontos's funnel portion 26 with Ressemann's support collar 2141. Section VII.C.4, *supra*. In so doing, as shown below, the tubular structure (tube 16) would have been shortened, such that it was between 20-30 cm in length, to accommodate the addition of Ressemann's support collar 2141. Ex. 1405, ¶¶ 202-03; Ex. 1442, ¶¶ 117-21.



Ex. 1409, Fig. 1 (color and annotations added) (modified by Petitioner).

As discussed for claim 45, a POSITA would have been motivated, with a reasonable expectation of success to add coiling to tube 16 of Kontos in light of the teachings of Ressemann. Section VII.P, *supra*. The resulting coiling thus would have been between 20-30 cm in length. Ex. 1405, ¶¶ 202-03; Ex. 1442, ¶¶ 117-21.

R. Claim 47: "The guide extension catheter of claim 25, wherein the substantially rigid segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter."

The Kontos-Ressemann combination teaches claim 47. Ex. 1405, ¶ 204. Kontos discloses that the substantially rigid segment (wire 14) is made of stainless steel. Ex. 1409, 4:58-61. Similarily, the support collar 2141 from Ressemann is made of a "metallic material" with "suitable rigidity to prevent kinking." Ex. 1408, 25:13-16. Thus, based on the known properties of these materials, the substantially rigid segment and partially cylindrical opening comprise a rigid portion of the guide extension catheter. Ex. 1405, ¶ 204; Ex. 1442, ¶¶ 122-27.

S. Claim 48: "The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter."

The Kontos-Ressemann combination teaches claim 48. Ex. 1405, ¶ 205. As construed above, "reinforced portion" means a "portion made stronger by additional material or support." *See* Section VI, *supra*. Ressemann's support collar 2141 is made of a "metallic material" with "suitable rigidity to prevent kinking." Ex. 1408, 25:13-16. Further, the distal-most, "cylindrical portion 2141a . . . fits into the proximal opening of the evacuation lumen 2140" and can be covered in encapsulation material 2133. *Id.*, 24:55-58, 25:4-8. As a result, Ressemann's support collar 2141 provides additional material or support. Ex. 1405, ¶ 205.

Kontos's tubular structure (tube 16) preferably is composed of a molded plastic material, such as polyethylene. Ex. 1409, 4:1-4. As discussed for claim 45, metallic coiling would be an alternative, and obvious, alternative to reinforcing Kontos's tube 16. *See* Section VII.P, *supra*. Adding coiling to Kontos's tube 16, in light of Ressemann, would result in the tubular portion (tube 16) that is reinforced. Ex. 1405, ¶ 205; Ex. 1442, ¶¶ 128, 130.

T. Claim 49: "The guide extension catheter of claim 25, wherein a distal portion of the tubular structure is configured to anchor within an ostium[13] of a coronary vessel and resist axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion."[14]

The Kontos-Ressemann combination teaches claim 49. Ex. 1405, ¶¶ 206-14. The '776 patent provides that because the guide extension catheter is "extended through the lumen of the guide catheter and beyond the distal end of the guide

[13] Patent Owner drafted claim 49 such that the "distal portion" of the tubular structure of the extension catheter "anchor[s] within an ostium of a coronary vessel." That cannot be correct as the '776 patent specification teaches that the distal portion of the ***guide catheter*** anchors in the ostium, while the guide extension catheter is advanced further into the coronary artery. Ex-1401, Fig. 8. For purposes of this IPR, Petitioner assumes this was a drafting error and that the extension catheter need not anchor in the ostium.

[14] Claim 49 recites an intended use (e.g., "that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery") that should be afforded no patentable weight. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Out of an abundance of caution, Petitioner addresses this claim limitation.

catheter and inserted into the branch artery," it "assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion." Ex. 1401, Abstract; *see also id.* 5:14-34. The '776 patent explains that, essentially, it is the combination of a guide catheter and an extension catheter inserted into a coronary ostium that improves distal anchoring of the system, and that the presence of the extension catheter in the GC provides "stiffer back up support" than a guide catheter alone. *Id.*, 8:23-37. This combination is what allows the claimed system to resist dislodgement. Ex. 1405, ¶¶ 213-14.

Kontos discloses that "a physician inserts a guide catheter 38 through the aorta 37 and into a patient's coronary ostia 39 using known medical procedures." Ex. 1409, 5:11-15. Kontos further provides that "the support catheter can be inserted into and . . . out the distal end of the guide catheter so as to function as an extension of the guide catheter to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened." Ex. 1409, 2:16-22, 5:31-6:18, Figs. 6A-C. For this reason, because Kontos and the '776 patent contain the same teachings, to the extent the '776 patent has adequate written description support, a POSITA would understand that Kontos must inherently disclose or, at a minimum, render obvious when combined with the knowledge of a POSITA, the limitation of claim 49. Ex. 1405, ¶ 206; Ex. 1442, ¶¶ 161-65.

U. Claim 52:

1. [52.pre] "A guide extension catheter for use with a guide catheter, comprising:"

As discussed for claim 25, to the extent the preamble is limiting, Kontos discloses this claim limitation. *See* Section VII.C.1, *supra*; Ex. 1405, ¶ 215.

2. [52.a] "a substantially rigid segment;"

As discussed for claim 25, Kontos discloses this claim limitation. *See* Section VII.C.2, *supra*; Ex. 1405, ¶ 216.

3. [52.b] "a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and"

As discussed for claim 25, Kontos discloses this claim limitation. *See* Section VII.C.3, *supra*; Ex. 1405, ¶ 217.

4. [52.c.i] "a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure,"

As discussed for claim 25, the Kontos-Ressemann combination discloses this claim limitation. *See* Section VII.C.4, *supra*; Ex. 1405, ¶ 218.

5. [52.c.ii] "the segment defining the partially cylindrical opening having an angled proximal end"

As discussed for claim 25, the Kontos-Ressemann combination discloses this claim limitation. *See* Section VII.C.5, *supra*; Ex. 1405, ¶ 219.

6. [52.c.iii] "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure,"

Kontos in light of Ressemann and/or the knowledge of a POSITA teaches this limitation. Ex. 1405, ¶¶ 220-21. As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to integrate a partially cylindrical opening—in particular, Ressemann's support collar 2141—proximal of Kontos's tubular structure. *See* Section VII.C.4, *supra*. In so doing, the flexural modulus of the partially cylindrical opening necessarily would have been greater than the flexural modulus of Kontos's tube 16. *Id.*; Ex. 1442, ¶¶ 131-33.

Ressemann's support collar 2141 is preferably "a metallic material" with "suitable rigidity to prevent kinking." Ex. 1408, 25:13-16; *see also id.*, 24:62-67. Conversely, Kontos's tube 16 includes "any pliable material," but preferably is composed of a molded plastic material, such as polyethylene. Ex. 1409, 4:1-4. Based on known material properties, the support collar 2141 that comprises the partially cylindrical opening has a greater flexural modulus than tube 16 of the tubular structure. Ex. 1405, ¶¶ 220-21; Ex. 1442, ¶¶ 131-33.

7. [52.c.iv] "and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,"

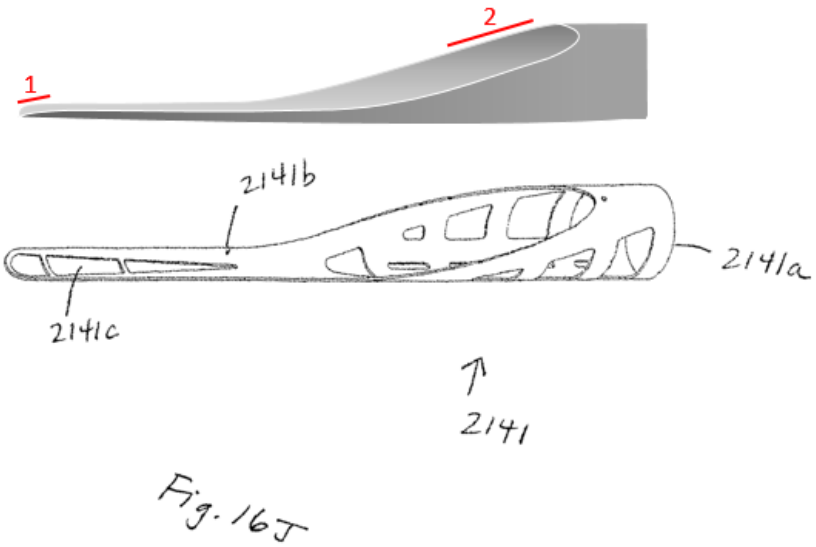
As discussed for claim 25, Kontos discloses this claim limitation. *See* Section VII.C.7, *supra*; Ex. 1405, ¶ 222.

8. [52.d] "wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen"

As discussed for claim 25, Kontos discloses this claim limitation. *See* Section VII.C.8, *supra*; Ex. 1405, ¶ 223.

9. [52.e] "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions."

Kontos in light of Ressemann and/or the knowledge of a POSITA teaches this limitation. Ex. 1405, ¶ 224; Ex. 1442, ¶¶ 134-36. Indeed, Ressemann's support collar 2141 teaches, as shown below, a proximally-located, partially cylindrical opening with at least two included regions.



Ex. 1408, Fig. 16J (annotations added).

The support collar 2141 has a first inclined slope at the proximal end of

support collar 2141 (shown as "1" above), a flat, non-inclined region, and a second inclined slope at the distal end of support collar 2141, (shown as "2" above). Ex. 1405, ¶ 224; Ex. 1442, ¶¶ 134-36. These inclined slopes are similar to what Patent Owner identifies in its infringement allegations in District Court. Ex. 1405, ¶ 224; Ex. 1442, ¶ 137. And as explained for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's partially cylindrical opening into Kontos's support catheter 10. *See* Section VII.C.4, *supra.* Thus, claim 52 is obvious. Ex. 1405, ¶¶ 215-24.

VIII. GROUND 2: KONTOS RENDERS CLAIMS 53-56 AND 30-32 OBVIOUS IN VIEW OF RESSEMANN, TAKAHASHI, AND/OR THE COMMON KNOWLEDGE OF A POSITA.

A. Takahashi

Takahashi et al. ("Takahashi") is entitled *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*" and published in 2004, making it prior art under pre-AIA § 102(b). Ex. 1478, ¶¶ 43-52. Takahashi is cited in the Background of the '776 patent, but was not the basis of an Examiner rejection during prosecution of either the '776 patent or the '850 patent. *See generally* Exs-1001-03. As a result, the Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *See Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (P.T.A.B. Jan. 17, 2019) (explaining that a reference that "was neither applied against the claims nor discussed by the Examiner" does not weigh in favor

of exercising discretion under § 325(d)); *Shenzhen Zhiyi Tech Co. v. iRobot Corp.*, IPR2017-02137, Paper 9 at 9-10 (P.T.A.B. Apr. 2, 2018) (declining to apply § 325(d) when the reference was merely cited in a Notice of Reference Cited on face of patent-in-question).

Takahashi explains that "[t]he five-in-six system is a method of inserting a 5 FR guiding catheter . . . into a 6 Fr guiding catheter to increase backup support." Ex. 1410 at 452. Takahashi states that the inner lumen of the 5 French and 6 French catheters is 0.059 inches and 0.071 inches (*id.*), which is less than a 1 French difference in inner diameters. Ex. 1405, ¶¶ 145-50; Ex. 1442, ¶¶ 138-39; Ex. 1410 at 452.

B. Claim 53

1. [53.pre] "A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:"

To the extent the preamble is limiting, Kontos teaches this claim element. Ex. 1405, ¶ 228. For example, Kontos discloses a guide extension catheter (support catheter 10) for use with guide catheter 38. Ex. 1409, 5:25-31, Figs. 6A-6C. Further, tube 16 is a tubular structure with "a continuous lumen 22 therethrough

from proximal end 20 to distal end 24." Ex. 1409, 3:49-50; *see also id.*, 3:56-57 ("[T]ube 16 is generally cylindrical.").[15, 16]

2. [53.a] "a substantially rigid segment;"

As discussed for claim 25, Kontos discloses this claim limitation. *See* Section VII.C.2, *supra*; Ex. 1405, ¶ 229.

3. [53.b.i] "a tubular structure defining a lumen and positioned distal to the substantially rigid segment,"

As discussed for claim 25, Kontos discloses this claim limitation. *See* Section VII.C.3, *supra*; Ex. 1405, ¶ 230.

[15] Kontos provides that "[s]upport assembly 10 is composed of two major elements, a body 12 and an insertion/manipulation wire 14." Ex. 1409, 3:45-46, Fig. 1. Tube 16 is a component of body 12. *Id.*, 3:47-52.

[16] An alternative (although incorrect) interpretation of the preamble of claim 53 could require the guide catheter to have a continuous lumen. If so, this is also satisfied by Kontos. *See, e.g.*, Ex. 1409, Figs. 6A-C (showing that support catheter 10 travels through lumen of guide catheter 38).

4. [53.b.ii] "the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and"

This claim element is rendered obvious by Kontos in view of Ressemann, Takahashi, and/or the knowledge of a POSITA. Ex-1405, ¶¶ 231-34. Kontos discloses a cross-sectional outer diameter and inner diameter of body 12 that is 0.055 inches and 0.045 inches, respectively. Ex-1409, 3:56-59, 4:48-50. Kontos does not disclose the cross-sectional inner diameter of the guide catheter. Ex-1405, ¶ 231. Takahashi, however, discloses a "five-in-six" system wherein the inner diameter of the 5 French catheter is not more than one French smaller than the cross–sectional inner diameter of the 6 French guide catheter. Ex-1405, ¶ 233; Ex-1442, ¶¶ 138-39; Ex-1410 at 452.

It would have been obvious to modify Kontos in light of Ressemann and Takahashi to achieve the not-more-than-one French differential. Indeed, Kontos, Ressemann, and Takahashi are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the '776 patent. Ex. 1405, ¶¶ 232-33.

A POSITA would have been motivated to combine Takahashi with the Kontos-Ressemann combination, given that the former teaches that the not-more-

than-one French differential improved backup support of its catheter assembly. *Id.*; Ex. 1442, ¶ 140-41. Specifically, Takahashi describes a "five-in-six system [as] a method of inserting a 5 Fr guiding catheter . . . into a 6 Fr guiding catheter to increase backup support." Ex. 1410 at 452.

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given the teachings of Kontos, Ressemann, Takahashi, and/or a POSITA's knowledge. Ex. 1405, ¶ 234; Ex. 1442, ¶¶ 142-45. In particular, as discussed for claim 25, a POSITA would have had a reasonable expectation of success when removing Kontos's funnel in favor of a proximal side opening. *See* Section VII.C.4, *supra*; *see also* Section VIII.B.5, *infra*. Doing so would result in a uniform inner diameter of the lumen of the extension catheter (tube 16) and permit a POSITA to achieve the not-more-than-one-French differential as taught by Takahashi. Ex. 1442, ¶¶ 142-45 (describing that use of side opening permits close seating of child and mother catheters and eliminates the need for a funnel at proximal end of the tubular structure, which results in a uniform inner-diameter of the tubular structure). Implementing the five-in-six system would increase the diameter of Kontos's body 12, but this modification was well within the skill of a POSITA, as appropriately sized catheters were ubiquitous in the art. Ex. 1442, ¶¶ 142-43; Ex. 1409, 5:59-62; Ex. 1410 at 452. Indeed, combining the teachings of Kontos with Adams and

Takahashi to achieve the not-more-than-one French differential would have been nothing more than combining prior art elements according to known methods to yield predictable results. Ex. 1405, ¶ 234; Ex. 1442, ¶¶ 142-45.

5. [53.c.i] "a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure,"

As discussed for claim 25, Kontos in combination with Ressemann discloses this claim limitation. *See* Section VII.C.4, *supra*; Ex. 1405, ¶ 235.

6. [53.c.ii] "the segment defining the partially cylindrical opening having an angled proximal end"

As discussed for claim 25, Kontos in combination with Ressemann discloses this claim limitation. *See* Section VII.C.5, *supra*; Ex. 1405, ¶ 236.

7. [53.c.iii] "and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter,"

As discussed for claim 25, Kontos in combination with Ressemann discloses this claim limitation. *See* Section VII.C.7, *supra*; Ex. 1405, ¶ 237.

8. [53.c.iv] "a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;"

As discussed for claim 25, Kontos in combination with Ressemann discloses this claim limitation. *See* Section VII.C.8, *supra*; Ex. 1405, ¶ 238.

9. [53.d] "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions."

As discussed for claim 52, Kontos in combination with Ressemann discloses this claim limitation. *See* Section VII.U.9, *supra*; Ex. 1405, ¶ 239.

C. Claim 54: "The guide extension catheter of claim 53, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure."

As discussed for claim 52, Kontos in combination with Ressemann discloses this claim limitation. *See* Section VII.U.6, *supra*; Ex. 1405, ¶ 240.

D. Claim 55: "The guide extension catheter of claim 53, wherein the segment defining the partially cylindrical opening includes portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape."

As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to integrate a partially cylindrical opening—in particular, Ressemann's support collar 2141—proximal of Kontos's tubular structure. *See* Sections VII.C.4, VIII.B.5, *supra*. In so doing, the partially cylindrical opening necessarily includes a portion having an arcuate cross-sectional shape (yellow), a portion having a hemicylindrical cross-sectional shape (red), and

a portion having a full circumference cross-sectional shape (blue).[17] Ex. 1405, ¶ 241.

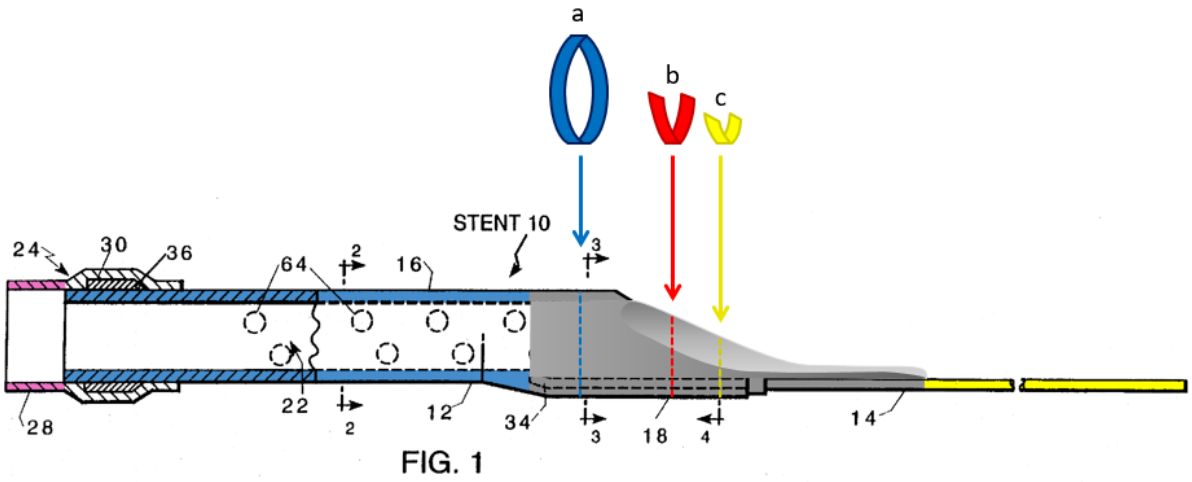


FIG. 1

Ex. 1409, Fig. 1 (annotations and color added).

E. Claim 56: "The guide extension catheter of claim 53, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be advanced partially through the guide catheter and into a coronary artery while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter."

Kontos in view of Ressemann, Takahashi, and/or the knowledge of a POSITA renders claim 56 obvious. Ex. 1405, ¶ 242. Kontos discloses that the substantially

[17] The specification of the '776 patent states that a hemicylindrical portion "desirably includes 40% to 70% of the circumference of the tube" and that an arcuate portion "extends from 25% to 40% of the circumference of the tube." Ex-1401, 7:7-8, 7:12-13.

rigid segment (wire 14) has a 0.020 inch diameter and is made of stainless steel. Ex. 1409, 4:58-61. The wire 14 is used to advance the support catheter 10 "through guide catheter 38" and into the coronary artery. *Id.*, 5:25-35; *see also id.*, Abstract. Kontos's wire 14 is positioned eccentrically relative to a cross section through tubular structure 21. Section VII.L, *supra*. Such an orientation preserves space, thereby maximizing the cross-sectional inner diameter of the lumen in the guide catheter. Ex. 1405, ¶ 242.

F. Claim 30: "The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter."[18]

As discussed above, Kontos in combination with Ressemann and/or the knowledge of a POSITA teaches the guide extension catheter of claim 25. *See*

[18] The '776 patent describes only three guide catheters. These guide catheters have an ***outer*** diameter—not an ***inner*** diameter—of 6 French, 7 French, and 8 French. Ex. 1401, 3:36-44. In others words, the '776 patent never describes a guide catheter with "a cross-sectional ***inner*** diameter of six French, seven French or eight French," as claimed. For this reason, Petitioner assumes this was a drafting error, and, for purposes of this Petition, interprets claim 30 as though it recites a French

Section VII.C, *supra*. If claim 30 requires that the inner diameter of the extension catheter not be more than 1 French smaller than the inner diameter of a 6 French, 7 French, or 8 French guide catheter (*see* Footnote 18), then for the same reasons discussed in claim 53, Kontos in combination with Ressemann, Takahashi, and/or the knowledge of a POSITA teaches the not-more-then-one French limitation, rendering claim 30 obvious. *See* Section VIII.B.4, *supra*; Ex. 1405, ¶ 225.

G. Claim 31: "The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from a proximal end to a distal end of the tubular structure."

Claim 31 is rendered obvious by Kontos in view of Ressemann, Takahashi, and/or the knowledge of a POSITA. Ex. 1405, ¶ 226. As explained for claim 53, the addition of Ressemann's support collar 2141 and Takahashi's increase in the diameter of tube 16 to implement the "five-in-six system" would require the removal of the funnel at the proximal end of the Kontos's tube 16. *See* Section VIII.B.4, *supra*. Doing so would result in Kontos's tubular structure (tube 16)

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size of the "outer diameter" of the guide catheter, meaning the claim would read as follows: "The guide extension catheter of claim 25, wherein the guide catheter includes a … cross-sectional [outer] diameter of six French, seven French or eight French …."

having a uniform inner diameter that also achieves the not-more-than-one-French differential. *See* Section VIII.B.4, *supra*; Ex. 1405, ¶ 226; Ex. 1442, ¶ 145.

H. Claim 32: "The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter."

Claim 32 is rendered obvious by Kontos in view of Ressemann, Takahashi, and/or the knowledge of a POSITA. Ex. 1405, ¶ 227. As explained for claim 53, a POSITA would have been motivated, with a reasonable expectation of success, in combining Kontos with Ressemann and Takahashi to implement a uniform inner diameter of the lumen of the extension catheter (tube 16) that achieved the not-more-than-one-French differential. Section VIII.B.4, *supra*. In so doing, tube 16 of Kontos would be appropriately sized to receive both balloon catheters and stents. Ex. 1405, ¶ 227; Ex. 1442, ¶ 139, 143; *see also* Ex. 1409, 4:66-5:2 (balloon catheter); Ex. 1410 at 456 (placing stent).

IX. GROUND 3: KONTOS RENDERS CLAIM 52 OBVIOUS IN VIEW OF RESSEMANN, KATAISHI, AND/OR THE COMMON KNOWLEDGE OF A POSITA.

A. Kataishi

Kataishi is a U.S. Patent Application published on January 20, 2005, and is prior art under §102(b). Ex. 1425, [43]. During prosecution of the '776 patent (and its previous iteration, the '850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. *See generally* Exs-1001-03.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex. 1425, [0001]. It teaches a distal opening with two inclines designed, in part, to improve the catheter's "crossing ability," which is its ability to smoothly reach a desired target site. *Id.*, Abstract, [0001]; s*ee also* Ex. 1442, ¶¶ 152-53. In addition to providing flexibility, the two-incline shape of the catheter's distal opening improves its ability to suction thrombi (Ex. 1425, Abstract, [0026]-[0027], Fig. 10), which corresponds to loading a thrombus into the catheter's distal end.

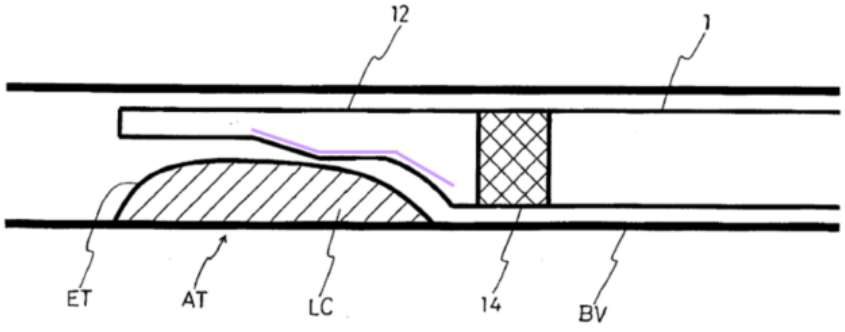
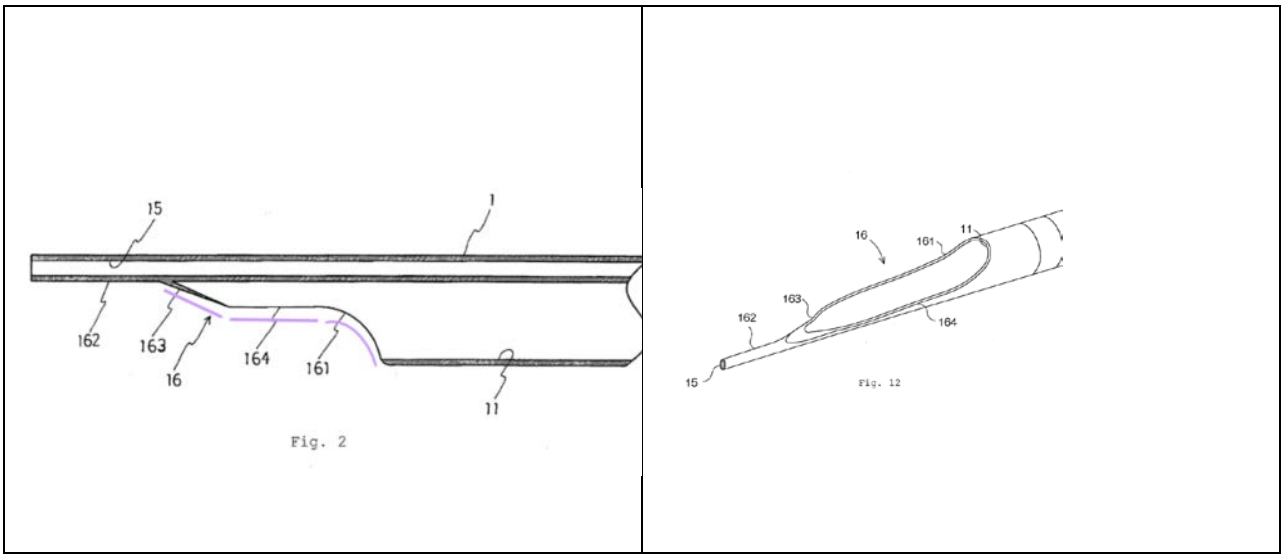


Fig. 10

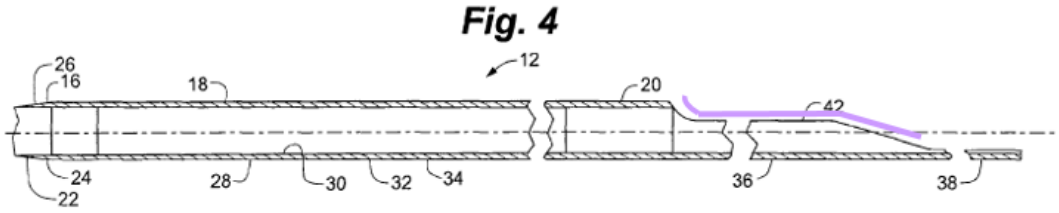
The distal end has an "angled cut surface, in which at least a part on the proximal end side of the angled surface is formed in a concave shape in the angled direction and the distal end side of the cut surface is formed to be flat and flexible." Ex. 1425, [0010]. The catheter tip is shown below. *Id.*, Figs. 2, 12; Ex. 1405, ¶¶ 152-53.



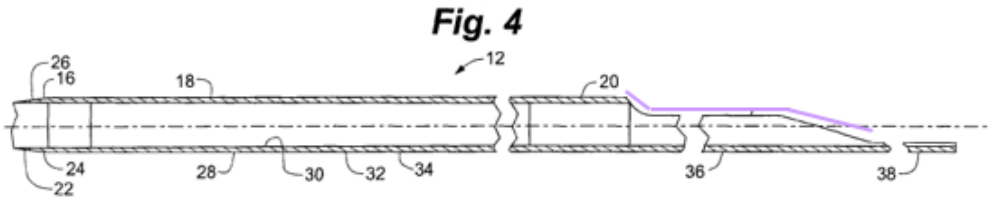
B. Claim 52

The Kontos-Ressemann combination teaches a partially cylindrical opening with at least two inclined regions. Section VII.U.9, *supra*. To the extent Patent Owner contends that this combination does not teach two inclined regions, Kataishi also teaches this limitation. Ex. 1405, ¶ 243; Ex. 1442, ¶¶ 150-51.

In an attempt to support claim 52, Patent Owner represented to the Examiner that Figure 4 of the '776 patent demonstrates two different inclined slopes in the partially cylindrical opening. Ex-1403b at 745 (Amendments at 27).



Ex. 1401, Fig. 4 (color added). Of course, as shown below, the disclosure in the '776 patent is no different than what was disclosed in Kataishi. *Compare id.*, Fig. 4 (color added), *with* Ex. 1425, Figs. 2, 10 (color added); Ex. 1405, ¶¶ 243-45.



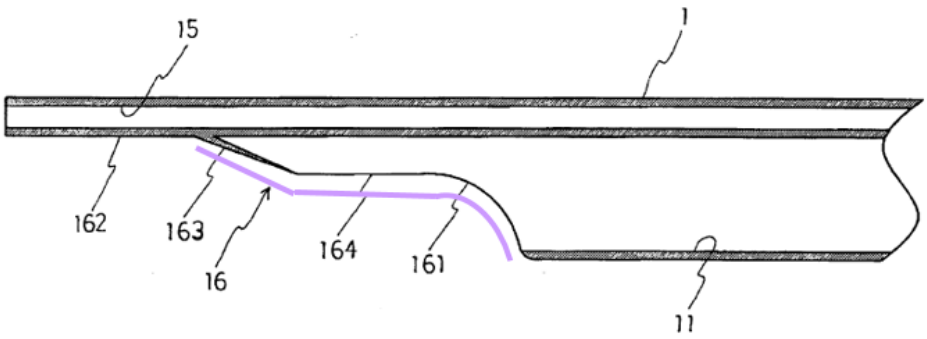


Fig. 2

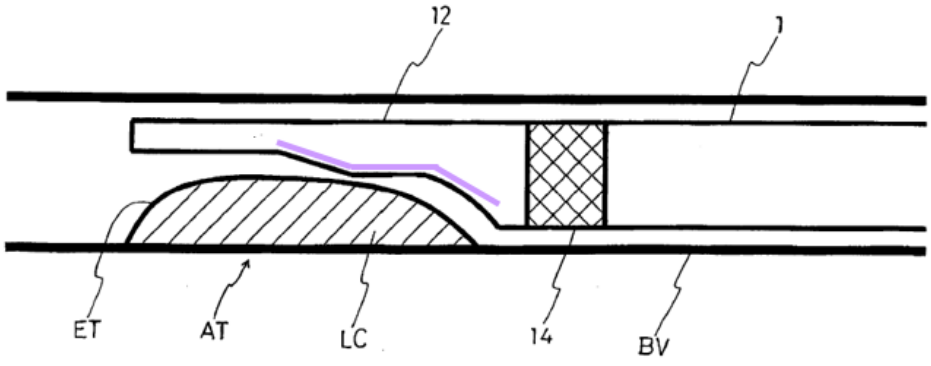


Fig. 10

It would have been obvious to modify the Kontos-Ressemann combination in

light of Kataishi to implement a two-inclined, partially cylindrical opening. Ex. 1405, ¶¶ 246-50. Indeed, Kontos, Ressemann, and Kataishi are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the '776 patent. Ex. 1405, ¶ 246; Ex. 1442, ¶¶ 147-50.

A POSITA had the motivation to modify Ressemann's support collar 2141 to include Kataishi's two-inclined, partially cylindrical opening. Ex. 1405, ¶¶ 247-49; Ex. 1442, ¶¶ 152-58. Kataishi teaches a suction catheter with a distal end designed to do two things: (i) improve crossability of the catheter; and (ii) provide superior loading of matter (thrombus) into the distal end of the suction catheter. Ex. 1425, [0010]. These advantages are accomplished by the shape of Kataishi's distal end. Ex. 1442, ¶¶ 152-53. These same considerations—crossability and the ability to load something into a catheter opening—apply equally to the proximal end of a catheter, especially catheters such as the Kontos-Ressemann combination in which loading is not just of thrombus, but of stents. Ex. 1405, ¶ 247; Ex. 1442, ¶ 154. As such, POSITA would be motivated to apply Kataishi's distal opening structure to the proximal opening of the Kontos-Ressemann combination.

First, adding a second, inclined slope to support collar 2141 would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. Ex. 1405, ¶ 248; Ex. 1442, ¶ 155. A POSITA would be

motivated to make this modification because it would allow the catheter to receive a therapy catheter, but still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex. 1425, Abstract [0026]-[0027], Fig. 10; Ex. 1455 at 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end); Ex. 1405, ¶ 248; Ex. 1442, ¶ 155.

Second, a POSITA was aware that angled openings in the sidewall of a catheter—located proximal of the catheter's distal end—can "minimize . . . kinking . . . during insertion." Ex. 1426, 3:6-14, 6:5-19, Fig. 2B; *see also* Ex. 1405, ¶ 249; Ex. 1442, ¶¶ 156-58. Ressemann acknowledges as much, noting that support collar 2141 "serves to reinforce the proximal opening of the evacuation lumen," meaning a POSITA knew that the reinforcement would also minimize kinking during insertion of the therapy catheter. Ex. 1408, 24:49-55. Locating the two-incline opening on the proximal side would minimize kinking, thereby improving the crossability of the device by avoiding drag on the inside of the guide catheter. Ex. 1405, ¶ 249; Ex. 1442, ¶¶ 156-58.

A POSITA would have a reasonable expectation of success, as creating two inclined slopes in a partially cylindrical opening would have been a routine task when manufacturing an extension catheter. Ex. 1442, ¶ 159; Ex. 1450, Fig. 7 (disclosing double incline, proximal side opening). As such, a POSITA would have

had a reasonable expectation of success in modifying the Kontos-Ressemann combination with the two-inclined, partially cylindrical opening disclosed in Kataishi. Ex. 1405, ¶¶ 250; Ex. 1442, ¶ 159.

The Kontos-Ressemann combination renders obvious each of the remaining limitations of claim 52 for the reasons stated in Ground 1. *See* Section VII.U.1-9, *supra*. Accordingly, Kontos in view of Ressemann, Kataishi and/or the knowledge of a POSITA also renders claim 52 obvious.

X. GROUND 4: KONTOS RENDERS CLAIMS 53-56 OBVIOUS IN VIEW OF RESSEMANN, TAKAHASHI, KATAISHI, AND/OR THE COMMON KNOWLEDGE OF A POSITA.

A. Claim 53

As explained in Section IX.A, *supra*, Kataishi teaches a two-inclined, partially cylindrical opening. To the extent Patent Owner contends that the Kontos-Ressemann combination does not teach two-inclined regions, Kataishi teaches this limitation, and claim 53 is obvious. Ex. 1405, ¶ 251.

A POSITA would have been motivated, with a reasonable expectation of success, to add the two-inclined regions of Kataishi to the combination of Kontos, Ressemann, and Takahashi for the same reasons just discussed in claim 52. *See* Section IX.B, *supra*; Ex. 1405, ¶ 252; Ex. 1442, ¶ 160. Kontos in view of Ressemann, Takahashi, and Kataishi renders obvious each of the limitations of claim 53 for the reasons stated in Ground 2. Section VIII.B.1-9, *supra*; Ex. 1405,

¶ 252. Accordingly, Kontos in view of Ressemann, Takahashi, Kataishi, and/or the knowledge of a POSITA also renders claim 53 obvious. Ex. 1405, ¶ 252.

B. Claims 54-56

Kataishi renders obvious each of the remaining limitations of claim 54-56 for the reasons stated in Ground 2. Section VIII.C-E, *supra*; Ex. 1405, ¶ 253; Ex. 1442, ¶ 160. Accordingly, Kontos in view of Ressemann, Takahashi, Kataishi and/or the knowledge of a POSITA also render claims 54-56 obvious. Ex. 1405, ¶ 253.

XI. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex. 1473. The "Facts" section of the memorandum in support states that Patent Owner's catheters solved a long-standing problem, are successful, and that Petitioner launched a "copycat" product. *Id.*, 2, 5, 9. Patent Owner does not, however, allege secondary considerations in the section on validity and makes no attempt to satisfy any of the requirements for establishing secondary considerations, including nexus. Thus, Patent Owner cannot assert that it has met its burden of production, and secondary considerations—should they be raised later—are a matter for the trial phase.

XII. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests institution of a trial and cancellation/invalidation of claims 25-27, 29-33, 35-37, 39, 41-49, and 52-56 of the ’776 patent as unpatentable under 35 U.S.C. § 103.

XIII. PAYMENT OF FEES

Pursuant to 37 C.F.R. §§ 42.15 and 42.103, the required fees are submitted herewith. If additional fees are due during this proceeding, the Office is authorized to charge Deposit Account No. 600615.

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 14, 2019
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WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 12,695 words, excluding any Mandatory Notices. I further certify that, in preparation of this Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

Dated: November 14, 2019

/ Cyrus A. Morton /

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence. was served on November 14, 2019, by Federal Express mail to the USPTO correspondence address of record listed below:

Paul Onderick
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Courtesy copies were also sent to the following address of record for counsel in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al*., No. 19-cv-01760 (D. Minn., filed July 2, 2019):

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