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.: IPR2020-01342
U.S. Patent No. 8,142,413

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,142,413

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I. PRELIMINARY STATEMENT

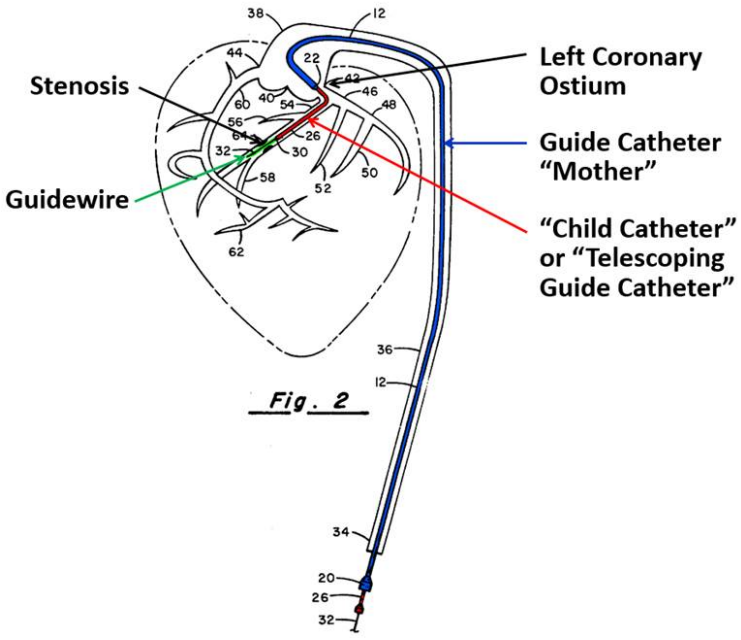
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 1-2, 4-5, and 7-14 ("Challenged Claims") of U.S. Pat. No. 8,142,413 ("the '413 patent," Ex-1401). The '413 patent is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures*. *Id*., [54].

The '413 patent describes a catheter assembly that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. *Id*., Abstract. The purported invention requires a guide catheter ("GC") and a coaxial guide catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*.,

[1] Unlike the other patents in this family—that explicitly claim a "guide extension catheter" or, more vaguely, claim a device/system "for use" with a guide catheter—the '413 patent claims a "coaxial guide catheter." Ex-1405, ¶ 116. A POSITA knew, however, that the "coaxial guide catheter" of the '413 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id*., ¶ 71; *see also* Ex-1409, 5:49-52 (referring to body 12 "as a guide catheter extension"). For ease of discussion, and to match the terminology of the '413 patent, Petitioner uses "coaxial guide catheter" when referring to the extension catheter of the '413 patent.

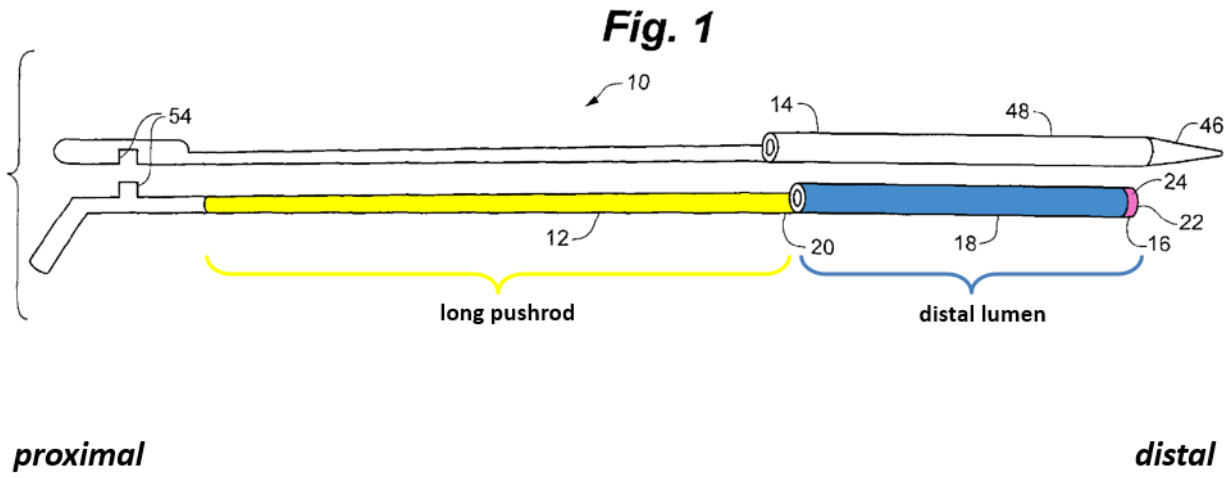
Abstract, Figs. 8-9. In so doing, the coaxial guide catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id.*, 2:51-55, 7:66-8:12.

The '413 patent admits that the use of a coaxial guide catheter inside an outer guide catheter was known. *Id.*, 2:23-39 (describing the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-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 coaxial guide 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. *Id.*, ¶ 70.



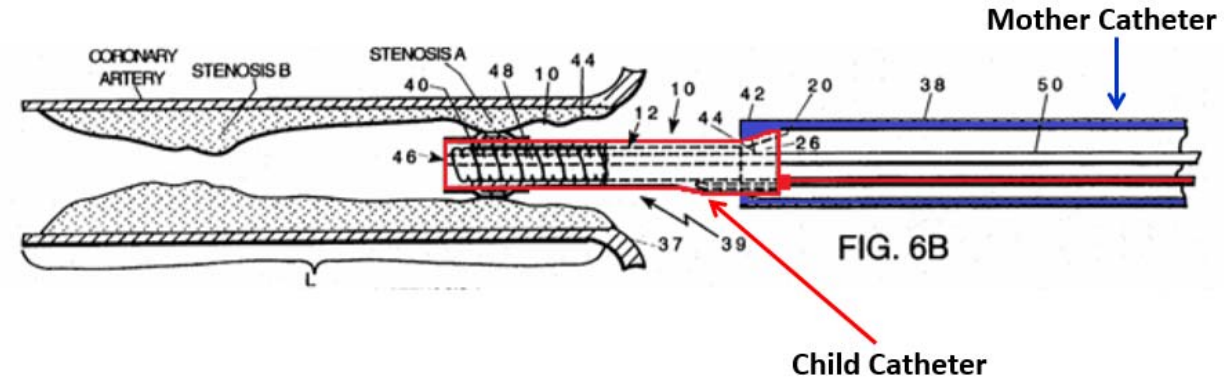
Ex-1454, Fig. 2 (annotations and color added).

The child catheter in the mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id.*; Ex-1405, ¶ 70. The '413 patent alleges that such a design had certain drawbacks (Ex-1401, 2:40-50; 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., a tube) that is highly flexible so it can extend deep into the coronary artery.



Id., Fig. 1 (annotation and color added).

But such child catheters that served as coaxial guide 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 '413 patent. Ex-1409, [45].



Id., 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 ’413 patent are unpatentable. Accordingly, Petitioner respectfully requests institution of a trial and cancellation/invalidation of the Challenged Claims.

II. MANDATORY NOTICES UNDER 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 ’413 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)[2]; and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) ("QXMedical Litigation").

The '413 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.*, IPR2014-00759 (P.T.A.B., terminated Aug. 13, 2014).

The '413 patent shares a common specification with and is related to several patents that, as shown in the below table, are currently subject to IPR:

IPR No.	U.S. Patent No.	Status
IPR2020-00126	8,048,032	Trial Instituted
IPR2020-00127	8,048,032	Trial Instituted
IPR2020-00128	RE45,380	Trial Instituted
IPR2020-00129	RE45,380	Trial Instituted
IPR2020-00130	RE45,380	Trial Instituted
IPR2020-00132	RE45,760	Trial Instituted
IPR2020-00134	RE45,760	Trial Instituted
IPR2020-00135	RE45,776	Trial Instituted
IPR2020-00136	RE45,776	Trial Instituted
IPR2020-00137	RE47,379	Trial Instituted
IPR2020-00138	RE47,379	Trial Instituted
IPR2020-01341	8,142,413	Pending
IPR2020-01342	8,142,413	Pending (Present Petition)

[2] The '413 patent was not originally asserted. The '413 patent was added by Amended Complaint on February 14, 2020. Ex-1514.

IPR2020-01343	RE46,116	Pending
IPR2020-01344	RE46,116	Pending

C. Lead and Backup Counsel

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

Lead Counsel	**Back-Up Counsel**
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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 '413 patent is available for IPR and that Petitioner is not barred or estopped from requesting such review on the identified grounds.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 1-2, 4-5, and 7-14 of the '413 patent and cancellation of these claims as unpatentable in view of the following grounds:[3]

No.	Grounds
1	Claims 1-2, 4-5, 7-12, 14 are rendered obvious by Kontos in view of Adams and/or the common knowledge of a POSITA.
2	Claim 13 is rendered obvious by Kontos in view of Adams, Takahashi, and/or the common knowledge of a POSITA.

[3] This petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1405) and Richard A. Hillstead, PhD (Ex-1442), as experts in the field of the '413 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1478) to support the authenticity and public availability of the documents cited herein.

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, and thus can treat CAD without the need for open-heart surgery. *Id*., ¶¶ 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, a physician uses a hollow needle to gain access to the patient's vasculature. *Id*., ¶ 34. A guidewire is then introduced through the needle and into the vasculature. *Id*. After removal of the needle, an introducer sheath is placed and then the guidewire and guide catheter can be advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id*., ¶¶ 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*.

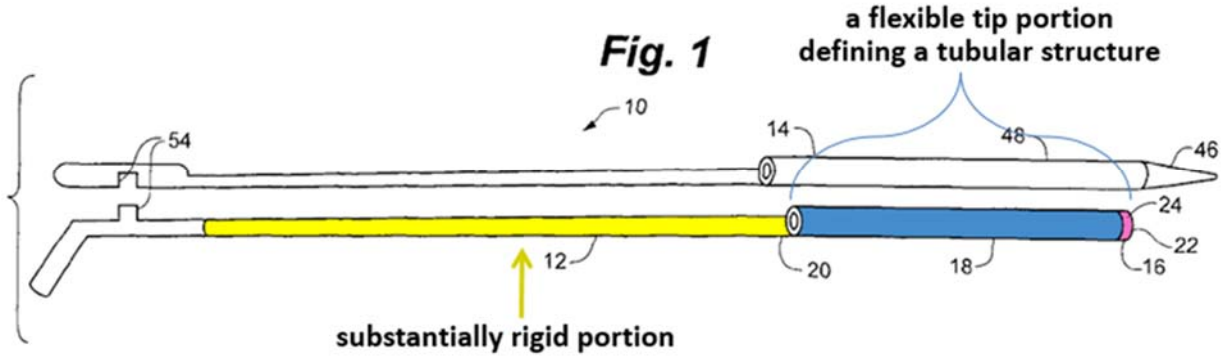
Another small diameter flexible guidewire can then be threaded through the

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 ’413 Patent

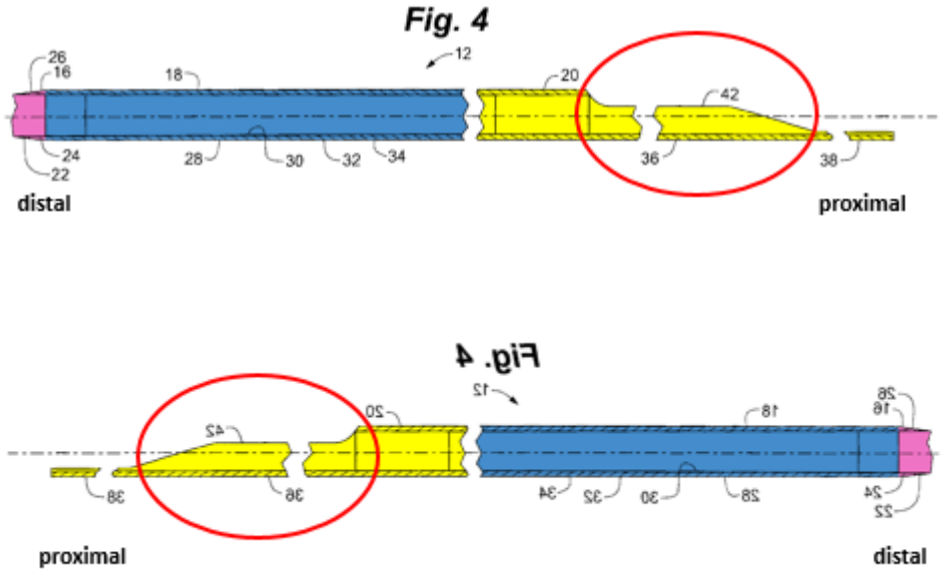
The ’413 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1401, 1:13-17. In particular, the ’413 patent discloses a coaxial guide catheter that extends “beyond the distal end of the guide catheter, and … into [a] branch artery.” *Id*., Abstract. The catheter assembly 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*., 5:4-8; Ex-1405, ¶¶ 115-17.

The ’413 patent claims a coaxial guide catheter 12 that includes a substantially rigid segment (yellow) and a tubular structure (blue). Ex-1405, ¶ 118.



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

The patent also addresses structural characteristics of the transition at or near the extension catheter's reinforced and rigid portions, sometimes referred to as a "partially cylindrical portion" or a "side opening," (red circle), which may have an "inclined slope." *Id*., Figs. 4, 13-16; *see also id*., 6:44-60, 8:40-46; 12:7-13; Ex-1405, ¶ 119.

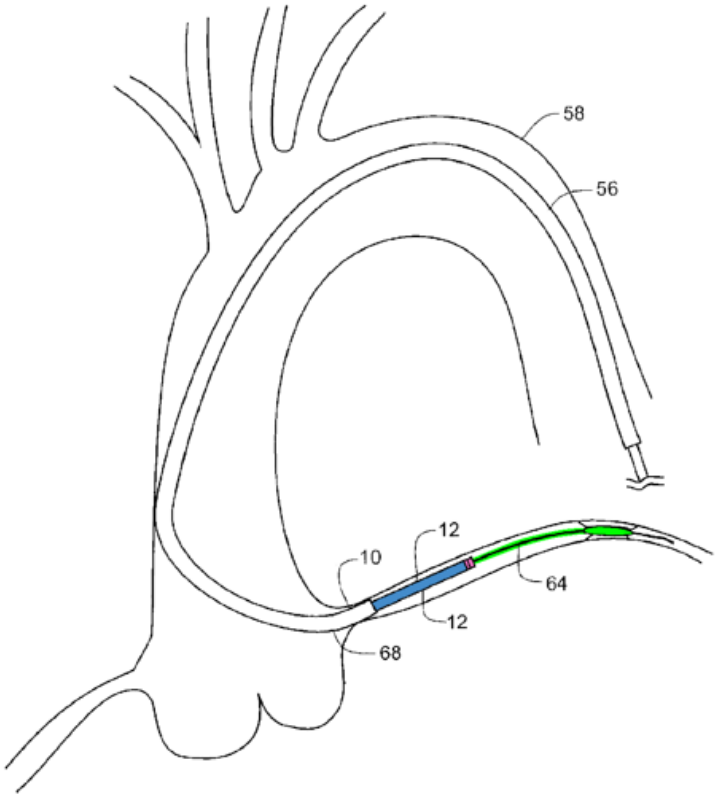


Ex-1401, Fig. 4 (annotations and color added) (bottom figure inverted by

Petitioner).

As shown below, the ’413 patent describes that coaxial guide 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 distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter 56. Ex-1405, ¶ 120.

Fig. 9



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

V. 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

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 advanced, 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 6-8; Ex-1413, at 15)
- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1413, at 20).

Additionally, the district court provided the following construction:

- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (*Id.*, 26)
- "lumen": "the cavity of a tube" (*Id.*, 25).

Further, Patent Owner stipulated that the claim term "reinforced portion" means "portion made stronger by additional material or support." Ex-1412, at 2. Petitioner agrees with the above constructions for purposes of this IPR[4] (Ex-1405, ¶¶ 121-26) and proposes the following additional constructions:

A. "interventional cardiology device(s)"

In the QXMedical litigation, Patent Owner stipulated that "interventional cardiology device(s)" means "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters." *Compare* Ex-1412, at 25 (Dkt. 36-1), *with* Ex-1464, at 1 n.1. Then in co-pending IPRs involving patents sharing a common specification with the '413 patent, Patent Owner argued, in the context of the patent claims, that this stipulated construction requires the guide catheter to be sized such "that at least **all four enumerated devices** (guidewires, balloon catheters, stents, and stent catheters) be insertable into the lumen." Ex-1513, at 19 (emphasis in original). The Board disagreed, explaining that "the term

[4] Petitioner reserves the right to raise different constructions in other forums.

'interventional cardiology device**s**' refers to at least two types of devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters." *Id*., at 19-20 (citing Ex-1401, 7:36-40, 7:42-8:7, Figs. 7-8).[5] Petitioner applies that construction for purposes of this IPR. Ex-1405, ¶¶ 127-28.

B. "standard guide catheter"

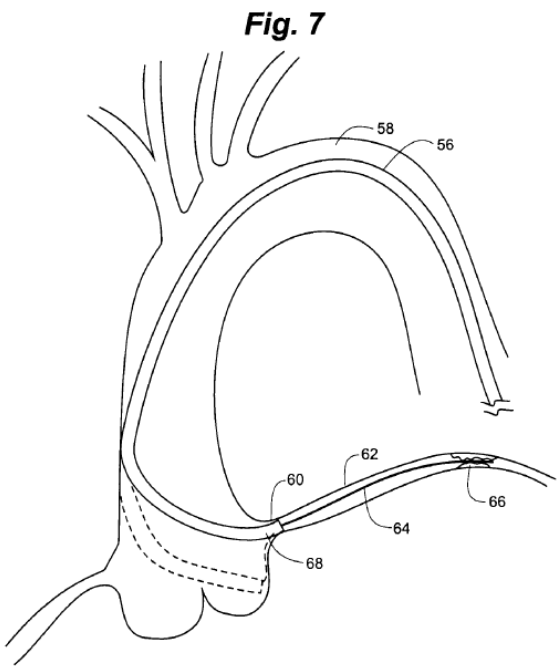
All challenged claims recite the use of a "standard guide catheter." As of the purported priority date, "standard guide catheter" did not refer to a guide catheter of a specified length (although 100 cm was common (Ex-1401, 2:41-43; Ex-1415, 549)), inner or outer diameter, or rigidity. Ex-1405, ¶ 129; Ex-1410, 454 (showing various "guiding catheter systems"). Further, the patent does not define "standard guide catheter," and, in fact, only uses this term (outside of the claims) once in the background when describing the drawbacks of previous catheter assemblies. Ex-1401, 2:40-41. Finally, in other parts of the patent, the specification instead refers to "typical guide catheter" or references, more simply, "guide catheters." *Id*., 7:32-

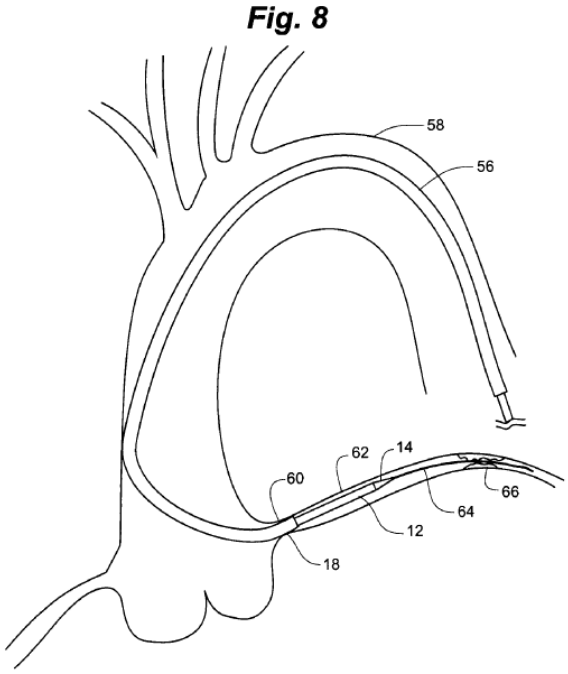
[5] The Board's prior Institution Decisions addressed only the plural version of this claim term. Ex-1513, at 20 (construing "interventional cardiology devices"). Accordingly, "interventional cardiology device," which is singular, will require only one of the enumerated devices. Ex-1405, ¶¶ 127-28.

33. Thus, "standard guide catheter" does not reference a specific guide catheter and means "one of a variety of catheters used to guide devices or smaller catheters from the site of insertion into the coronary vasculature." Ex-1405, ¶ 129.

C. "placed in a branch artery"

Claim 1 recites, *inter alia*, "positioning the distal end of the standard guide catheter in a branch artery." In the context of the '413 patent, "positioning in a branch artery" includes "placement in the ostium of a coronary artery." *Id*., ¶¶ 134-35. For instance, the '413 patent notes, in its background, the well-understood fact that a "guide catheter is inserted … into the ostium of the coronary artery." Ex-1401, 1:35-41. This is further shown in figures 7 and 8 (reproduced below), and confirmed by other description in the '413 patent. The patent describes that a GC is "inserted into the ostium of a branch artery where it branches off from a larger artery." *Id*., 4:46-52, Figs. 7, 8.





It is more common in the art to refer to arteries branching off from the coronary artery as branch arteries, rather than the coronary arteries themselves. Ex-1405 ¶¶ 130-33. However, the patent explicitly states that "guide catheter 56 is brought into proximity of ostium 60 of a smaller branch blood vessel, such as coronary artery 62." Ex-1401, 9:51-55. Thus, to the extent Petitioner's construction deviates from the plain meaning, the inventors acted as their own lexicographers. *Laryngeal Mask Co. v. Ambu, A/S*, 618 F.3d 1367, 1371-72 (Fed. Cir. 2010).

VII. THE BOARD SHOULD NOT DECLINE TO INSTITUTE UNDER 35 U.S.C. § 314(A).

When granting institution of related patents, the PTAB declined to exercise its discretion under § 314(a). Ex-1513, at 9-16. As set forth below, the relevant

Fintiv factors dictate a similar result for this Petition:

Fintiv Factors 1 & 2: On July 7, 2020, the district court stayed the litigation pending final resolution of the already-filed IPRs. Ex-1515 (Dkt 276). Given Judge Schiltz's past practice (Ex-1493), it is unlikely he will lift the stay prior to resolution of this IPR. Ex-1513, at 12-14. Therefore, these factors support Petitioner.

Fintiv Factor 3: When Petitioner filed IPR Petitions against related patents in Fall 2019, Patent Owner had not yet asserted the '413 patent. As a result, Petitioner did not file an IPR against the '413 patent at that time. Then, on February 14, 2020, Patent Owner filed an Amended Complaint that asserted the '413 patent. Ex-1514. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly five months later and more than seven months before the statutory deadline. For the same reasons provided in its prior Institution Decisions, the PTAB should find that this factor favors Petitioner. Ex-1513, at 14-15.

Fintiv Factor 4: In the District Court, Patent Owner asserts only 3 of the 12 claims challenged in this IPR. Ex-1495, at 3. This factor favors Petitioner.

Fintiv Factors 5 & 6: For the same reasons set forth in the prior Institution Decisions, the PTAB should find that factors 5 & 6 do not warrant discretionary denial. Ex-1513, at 15-16.

VIII. GROUND 1: KONTOS RENDERS CLAIMS 1-2, 4-5, 7-12, 14 OBVIOUS IN VIEW OF ADAMS AND/OR THE KNOWLEDGE OF A POSITA.

A. Prior Art

1. Kontos

Kontos issued on August 8, 1995 and is prior art under at least pre-AIA § 102(b). During prosecution of the ’413 patent, Kontos was neither disclosed by Patent Owner, nor cited by the Examiner. Exs-1401-1403.

Kontos is entitled “Support Catheter Assembly.” Ex-1409, [54]. As the title suggest, 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 ’413 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 ’413 patent; namely, it serves as a coaxial guide catheter for providing backup support, such that it prevents dislodgment of the guide catheter from the coronary ostium. Ex-1405, ¶¶ 138-39.

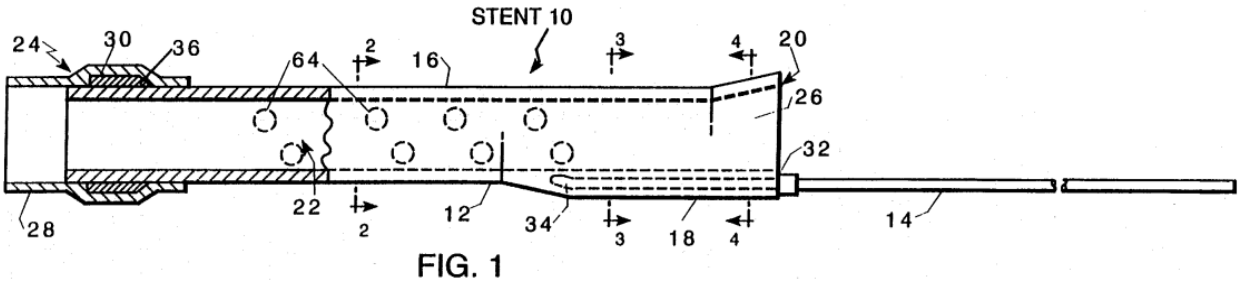


FIG. 1

Ex-1409, Fig. 1.

Kontos explains that 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, Fig. 6B. This way, "the gap that PTCA catheter 40 must negotiate without assistance is made much shorter." *Id.*, 5:49-52.

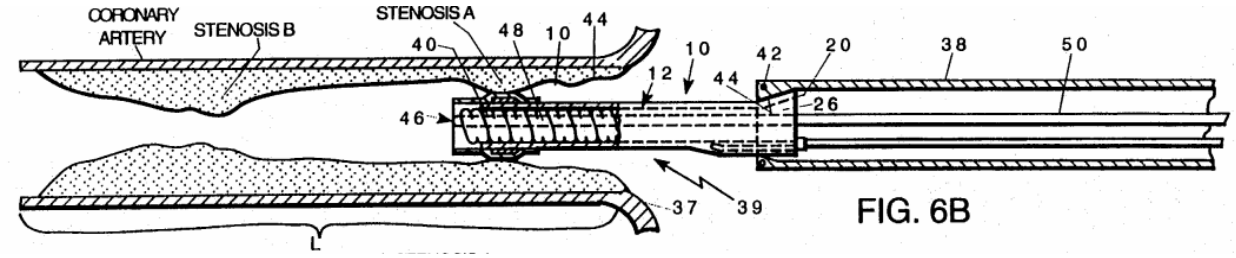


FIG. 6B

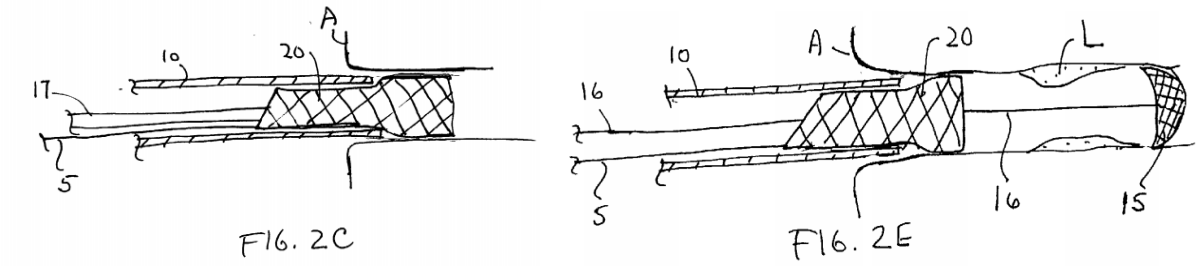
A POSITA would appreciate that Kontos's support catheter 10 operates no differently than coaxial guide catheter 12 of the '413 patent. Ex-1405, ¶¶ 136-41. The support catheter 10 extends further into the coronary artery than the guide catheter, while permitting a therapeutic device (e.g., PTCA catheter) to be passed therethrough and provides backup support for the guide catheter, thereby preventing its dislodgment from the ostium. Ex-1405, ¶¶ 138-39.

2. Adams

U.S. Patent Publication 2004/0010280 ("Adams") published on January 15, 2004 and is prior art under pre-AIA § 102(b). Ex-1435, [43]. Adams is not listed on the "References Cited" portion of the '413 patent (Ex-1401, [56]) and was not the basis of an Examiner rejection during prosecution of the '413 patent. Exs-1401-03. Thus, the Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (P.T.A.B. Jan. 17, 2019).[6]

[6] During prosecution of a related (child) patent, Adams formed the basis of an Examiner rejection. Ex-1469, at 4. The "presentation of [a reference] during prosecution of a child patent application, not the application that matured into the [patent-in-question,] has less relevance to the challenged claims." *Microsoft Corp. v. Parallel Networks Licensing LLC*, IPR2015-00483, Paper 10 at 15 (P.T.A.B. July 15, 2015). Regardless, "the present Petition relies primarily on [Kontos], not [Adams], and the combinations presented [here] were not before the Examiner or applied by the Examiner during prosecution." *Synaptic Medical Inc. v. Karl Storz-Endoscopy-America, Inc.*, IPR2018-00462, Paper 6 at 10 (P.T.A.B. July 16, 2018). "As such, the Examiner did not consider the combination and argument … presented" in this Petition, and the Board should not invoke § 325(d). *Id*.

Adams discloses an apparatus and method for removing a coronary stenosis. Ex-1435, Abstract. More particularly, Adams describes a catheter assembly with (i) a guide catheter, (ii) a sealing device (extension catheter) sized to fit within the lumen of, and advance distal to, the guide catheter, and (iii) a protection device (interventional cardiology device) that is advanced distal to both the guide catheter/sealing device assembly and the occlusion to be treated. *Id.*, [0045], [0064]; *see also* Ex-1405, ¶¶ 142-46.



Ex-1435, Figs. 2A-2F.

B. Claim 1

1. [1.pre.I] "A method of providing backup support for an interventional cardiology device for use in the coronary vasculature,"[7]

Long before the '413 patent, those working in the field knew that to advance

[7] The preamble is not limiting when, as here, the claim "defines a structurally complete invention … and uses the preamble only to state a purpose or intended use for the invention." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

an interventional cardiology device through a GC and into the coronary vasculature, the GC had to have "sufficient stiffness to offer 'backup' support." Ex-1415, 548; Ex-1405, ¶ 154. As Dr. Brecker explains, and as taught in *Grossman's*, the support came from the GC's shape, and the intrinsic stiffness of its material, as well as from its "deep engagement" with the coronary ostia. Ex-1405, ¶¶ 155-57; Ex-1415, 549-50; Ex-1441, 20.

The '413 patent admits that because the disclosed, coaxial extension catheter is "extended through the lumen of the guide catheter and beyond the distal end of the guide 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; 5:4-27. The '413 patent explains that, essentially, it is the combination of a GC and an

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Regardless, even if limiting, as set forth herein, the Kontos-Adams combination teaches the preamble. Section VIII.B.1-10, *infra*. Importantly, neither the claims nor the specification quantify the amount of "backup support" necessary to satisfy this claim limitation, and as explained, a POSITA would appreciate that Kontos's support catheter 10 necessarily teaches a method of providing backup support. Ex-1405, ¶ 153 n.9. Here, claim [1.pre.I] is non-limiting, reciting only the purpose of providing backup support.

extension catheter inserted into a coronary ostium that improves distal anchoring of the system, and provides "stiffer backup support" than a GC alone. *Id*., 7:65-67. This combination is what allows the claimed method to resist dislodgement, but this is no different than what was already known in the prior art, and disclosed in Kontos. Ex-1405, ¶¶ 160-61.

For example, Kontos discloses "[a] support catheter assembly for facilitating medical procedures, [that] includes a tubular body and a continuous lumen from its proximal end to its distal end." Ex-1409, 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. 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. Support catheter 10 serves as a coaxial guide catheter for providing backup support, such that dislodging of the guide catheter from the coronary ostium is prevented. Ex-1405, ¶¶ 158-59.

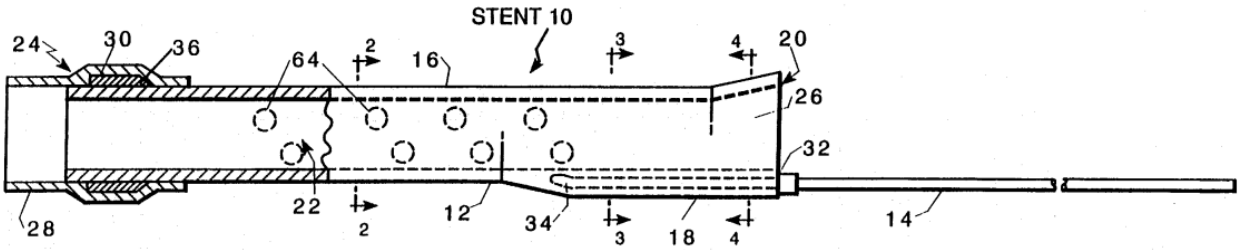


FIG. 1

Ex-1409, Fig. 1.

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.

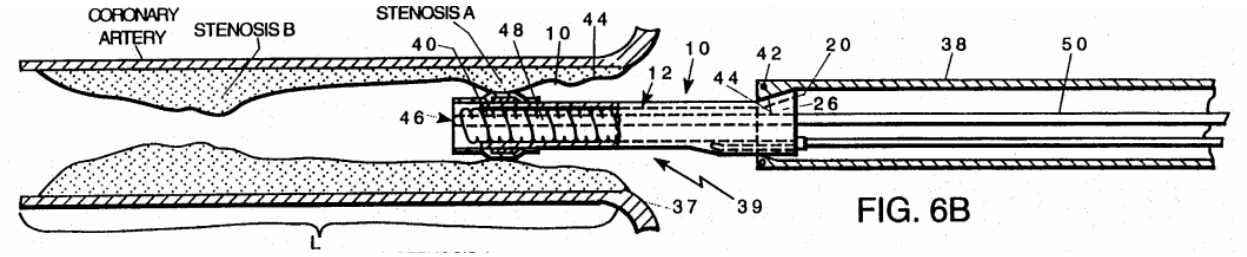


FIG. 6B

Id., Fig. 6B.

In sum, Kontos describes a support catheter assembly 10 that is capable of being inserted into the coronary artery while delivering a balloon catheter to treat a lesion in the same. Ex-1409, Abstract, 1:46-48, 5:40-44, Fig. 6B; Ex-1405, ¶ 153; Section VIII.A.1, *supra*. The support catheter assembly 10 is used in conjunction with a guide catheter 38 (Ex-1405, ¶ 157), and the combination of the two discloses the claimed "method of providing backup support." *Id*., ¶ 153; Ex-1442, ¶¶ 54-59; Section VIII.B.2-10, *infra* (analysis and citations for remaining elements of claim 1). For this reason, because Kontos and the '413 patent contain the same teachings, to the extent the '413 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, this limitation of claim 1. Ex-1405, ¶ 161.

2. [1.pre.II] "the interventional cardiology device being adapted to be passed through a standard guide catheter,"

Kontos teaches an "interventional cardiology device being adapted to be passed through a standard guide catheter." Ex-1405, ¶ 162. In particular, Kontos teaches that PTCA catheter 40 with balloon 48 can be passed through guide catheter 38. Ex-1409, Figs. 6A-C; Section VI.B, *supra* (construing "standard guide catheter"). Therefore, because this claim limitation recites the singular tense "interventional cardiology device," Kontos's PTCA catheter 40 with balloon 48 satisfies this claim element. Ex-1405, ¶ 162; Section VI.A (construing "interventional cardiology device" to include balloon catheters).

Patent Owner may nevertheless argue that "interventional cardiology device" requires Petitioner to show that guide catheter 38 is adapted to receive all four devices exemplified in the specification of the '413 patent. As an initial matter, the Board already rejected this interpretation of "interventional cardiology device(s)." Ex-1513, at 19-20. Further, given the specification's use of the language "include but not be limited to," the claim only requires that one interventional cardiology device be adapted to pass through the standard guide catheter. *Fed. Land Bank of St. Paul v. Bismarck Lumber Co.*, 314 U.S. 95, 99–100

(1941) ("[T]he term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle.").

Kontos teaches that tube 16 of body 12, which is positioned within guide catheter 38, has a 0.045 inch inner diameter. Ex-1409, 4:46-50. It was known that stent and stent catheters could be advanced through the guide catheter of Kontos. Ex-1405, ¶ 162; Ex-1415, 641; Ex-1497, 103-04, 143, 269, 274. The lumen of body 12, which is positioned within guide catheter 38, of Kontos was sufficiently sized to permit delivery of the all four interventional devices. Ex-1405, ¶ 162.

To the extent not taught, it would have been obvious to modify Kontos, as taught by Adams, to permit the passage of additional interventional cardiology devices. *Id*., ¶ 163. Adams 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 '413 patent. *Id*.

For example, Adams discloses a device and method for using PTCA and stenting to treat vascular disease. Ex-1435, [0001]-[0002]; Ex-1405, ¶ 164. Adams discloses, just like Kontos, a guide catheter 10 that is located in the ostium of the coronary artery and a sealing device 20 (extension catheter) that is longer than and sized to fit into the guide catheter. Ex-1435, [0012], [0022], [0059].

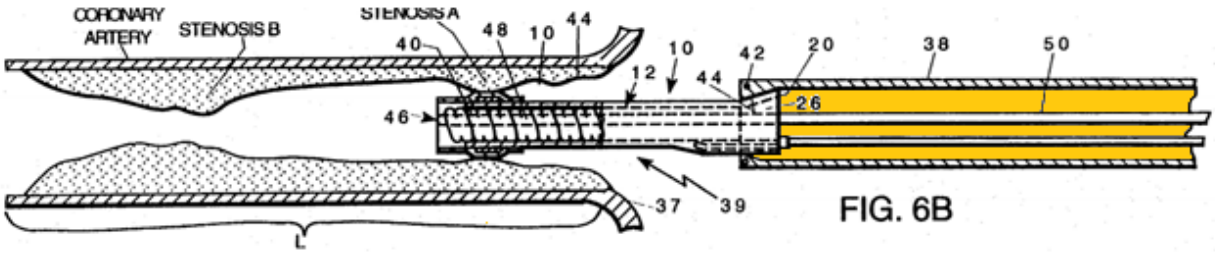
Adams further teaches an inner diameter of guide seal 20 (extension catheter) from between 1.27 mm to about 2.8 mm (0.050 inch to 0.110 inch). Ex-

1435, [0048]; Ex-1405, ¶ 165. As explained by Adams, the guide seal 20 is sufficiently sized to permit "a treatment device of choice (i.e., a balloon, atherectomy device, stent) or a combination thereof … to the treatment site." Ex-1435, [0064].

A POSITA would have been motivated to combine Adams and Kontos to re-size the inner diameter of tube 16, which is positioned inside guide catheter 38, because doing so would permit the delivery of a greater variety of PCI catheters, including those that were too large to pass through Kontos's tube 16. Ex-1405, ¶ 166; Ex-1442, ¶¶ 60-63. Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. In particular, this design modification was well within the skill of a POSITA, as appropriately sized catheters were ubiquitous in the art. Ex-1442, ¶ 64; Ex-1409, 4:61-5:2; Ex-1410, at 452. Indeed, combining the teachings of Kontos with Adams to permit the passage of an interventional cardiology device would have been nothing more than combining prior art elements according to known methods to yield predictable results. Ex-1405, ¶ 167; Ex-1442, ¶ 64; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

3. [1.pre.III] "the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,"

Kontos discloses a guide catheter 38 having a continuous lumen that is identified in yellow below. Ex-1405, ¶ 168. The guide catheter 38, and thus the continuous lumen, necessarily has a predefined length.



Ex-1409, Fig. 6B (color added).

In characterizing Figure 6B, Kontos states that "a physician inserts a guide catheter 38 through the aorta 37 and into a patient's coronary ostia 39 using known medical procedures." *Id*., 5:11-15. The distal end of the guide catheter 38 that is placed in the coronary ostia 39 is identified in green in Figure 14 below. Therefore, Kontos discloses a "standard guide catheter having … a distal end adapted to be placed in a branch artery." Section VI.C, *supra*.

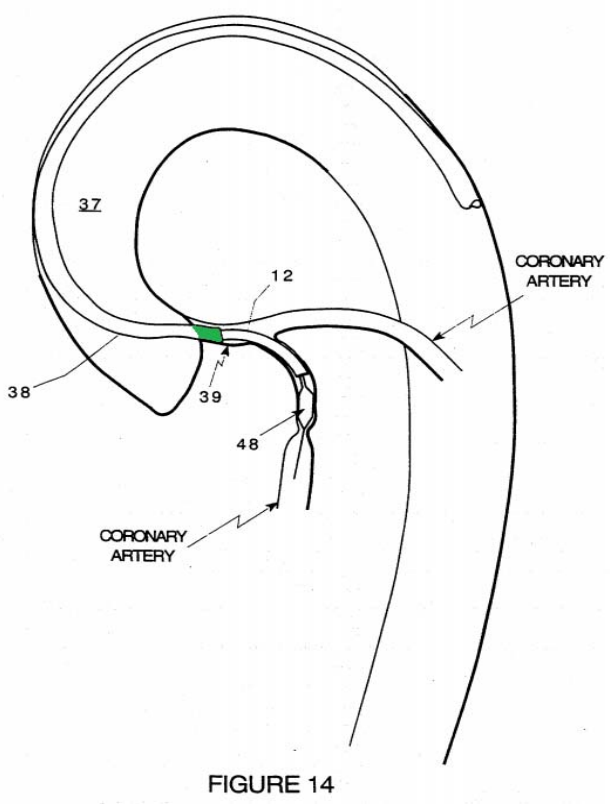


FIGURE 14

Ex-1409, Fig. 14 (color added).

Although not specifically enumerated in Kontos, the knowledge of a POSITA combined with Kontos would have taught that the proximal end of the continuous lumen of guide catheter 38 is connected to a hemostatic valve.[8] Ex-1405, ¶ 169. Indeed, without the proximal end being connected to a hemostatic valve, the catheter assembly would be exposed to the ambient environment, meaning the patient would risk excessive blood loss and/or develop an air

[8] The ’413 patent admits as much. Ex-1401, 3:4-7 (describing “commonly existing hemostatic valves used with guide catheters”).

embolism. *Id*. (testifying no responsible physician would forego a hemostatic valve); Ex-1412, ¶ 13 (Dkt. 36-2) (inventor, Mr. Root, admitting same); Ex-1401, 3:4-7; Ex-1477, 43:2-15.

To the extent Patent Owner contends that the use of a hemostatic valve is not obvious in view of Kontos and the knowledge of a POSITA, it would have been obvious to modify Kontos to add a hemostatic valve in view of Adams. Ex-1405, ¶¶ 170-72. Adams 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 ’413 patent. Ex-1405, ¶ 170.

Adams teaches that “[a] Y connector with hemostasis valve typically is attached to the proximal end of the guide catheter for ease of device passage and reduced blood loss.” Ex-1435, [0060], Fig. 1A; Ex-1405, ¶ 171. Adams states that “[h]emostasis valve 9 is at the proximal end of Y connector 7.” Ex-1435, [0060], Fig. 1A.

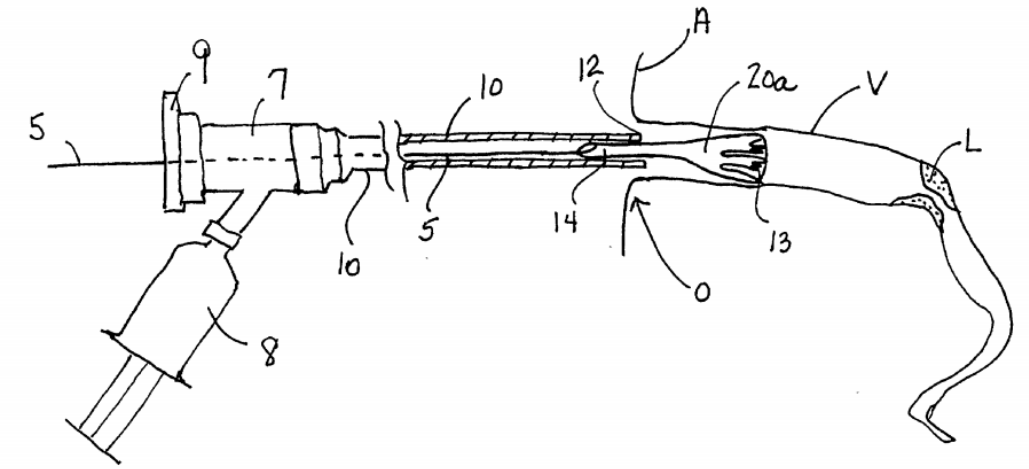


FIG. 1A

If not already obvious based on the knowledge of a POSITA and Kontos, a POSITA would have been motivated to add a hemostatic valve, as taught by Adams, for the dual purpose of easing device passage and reducing blood loss. Ex-1405, ¶ 172; Ex-1435, [0060]. A POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success, as combining Adams with Kontos to provide a hemostatic valve at the proximal end of the guide catheter lumen would have been nothing more than combining prior art elements according to known methods to yield predictable results. Ex-1405, ¶ 173; *KSR*, 550 U.S. at 417.

4. [1.pre.IV] "the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:"

As shown in Kontos Figure 6A, the continuous lumen of the guide catheter

38 (yellow) has a cross section that is sized to allow interventional cardiology devices, such as a guidewire or PTCA catheter 40 with balloon 48, to be inserted into and travel through the lumen of guide catheter 38 and to the branch artery.[9] Ex-1409, 5:16-20, Fig. 6A-C; Ex-1405, ¶ 174.

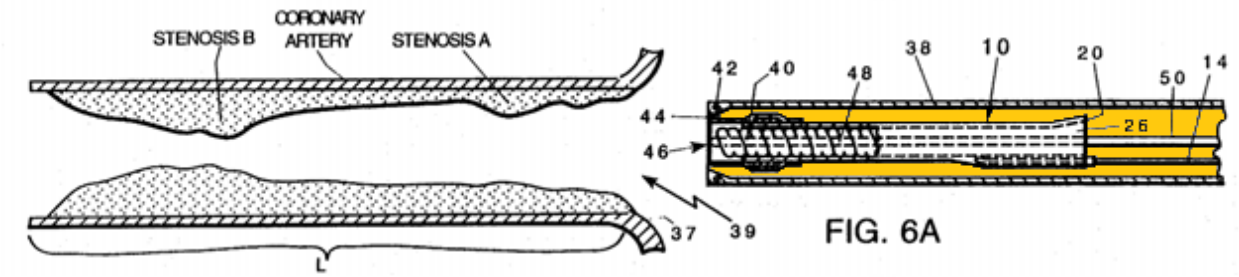


FIG. 6A

A POSITA would recognize that the guide catheter 38 has a circular cross-

[9] Because Kontos's support assembly 10 is sufficiently sized to receive guidewires, balloon catheters, stents, and stent catheters (Section VIII.B.2, *supra*), to the extent an overly-expansive interpretation of "interventional cardiology devices" is applied, this claim limitation nevertheless is met. Ex-1405, ¶ 174. Regardless, Kontos in combination with Adams and/or the knowledge of a POSITA satisfies this claim limitation. As explained for claim [1.pre.II], a POSITA would have been motivated, with a reasonable expectation of success, to increase the size of Kontos's tube 16, such that the "guide catheter ha[d] a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through [its] lumen." Section VIII.B.2, *supra*.

sectional inner diameter. Kontos describes both that the extension catheter has a "tubular body" and that a proximal portion may remain within the guide catheter 38. Ex-1409, Abstract, 3:56-59, 5:57-62. As a result, because a tubular structure has a circular cross-section, a POSITA would expect that the continuous lumen of the guide catheter—which is coaxial to the extension catheter—also has a circular cross-sectional diameter. Ex-1405, ¶¶ 4-8, 175.

To the extent Patent Owner argues that Kontos does not explicitly teach that guide catheter 38 has a circular cross-sectional diameter, it would have been obvious to modify Kontos to add this design feature in view of Adams. *Id*., ¶ 176. Adams 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 '413 patent. *Id.* Further, Adams specifically teaches the use of a guide catheter with a circular cross-sectional inner diameter. Ex-1435, [0052], Fig. 1C. A POSITA would have been motivated to use a guide catheter with a circular inner diameter, as doing so would provide better seating between Kontos's guide catheter 38 and support catheter 10, thereby minimizing the outer diameter of the catheter assembly. Ex-1405, ¶¶ 176-78.

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. *Id*., ¶ 179. Indeed, combining Adams with Kontos to provide a guide catheter with a circular cross-

sectional diameter would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id*.; *KSR*, 550 U.S. at 416-21.

5. [1.a] "inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;"

In characterizing Figure 6B, Kontos states 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. As explained by Dr. Brecker, "known medical procedures" include inserting a GC into the vasculature (i.e., a first artery) over a guidewire. Ex-1405, ¶ 180; Ex-1428, 1285-86. The distal end of the guide catheter 38 that is placed in the coronary ostia 39 is identified in green in Figure 14 below. Therefore, a POSITA would understand that Kontos necessarily discloses a method of "inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end." Ex-1405, ¶ 181.

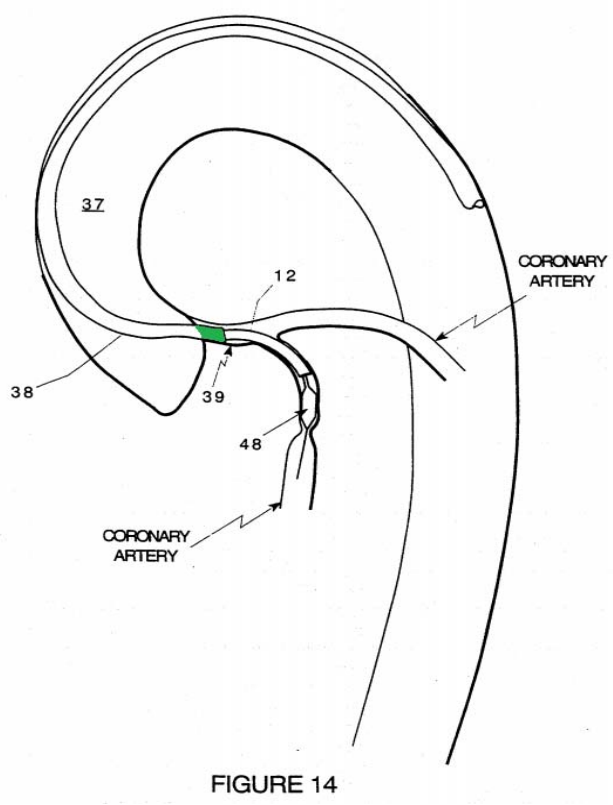


FIGURE 14

Ex-1409, Fig. 14 (color added).

To the extent not taught by Kontos and the knowledge of a POSITA, it would have been obvious to modify Kontos to teach inserting a GC over a guidewire in view of Adams. Ex-1405, ¶ 182. Adams 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 '413 patent. *Id.*, ¶ 183. Further, Adams specifically teaches that "[a] guidewire is … advanced through the femoral artery into the aorta," and then "[t]he guide catheter is … advanced over the guidewire until the distal tip of the guide catheter is in the ostium of the vessel." Ex-1435, [0061].

A POSITA would be motivated to apply Adams' teachings to Kontos (to the extent not already obvious) because s/he knew that a guidewire is always inserted first and that then the guide catheter is advanced over the guide wire. Ex-1405, ¶ 183; Ex-1415, 69. Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. Ex-1405, ¶ 184. Indeed, combining Adams with Kontos to provide a method of inserting the GC, with a distal end, into a first artery and over a guidewire would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id.*; *KSR*, 550 U.S. at 416-21.

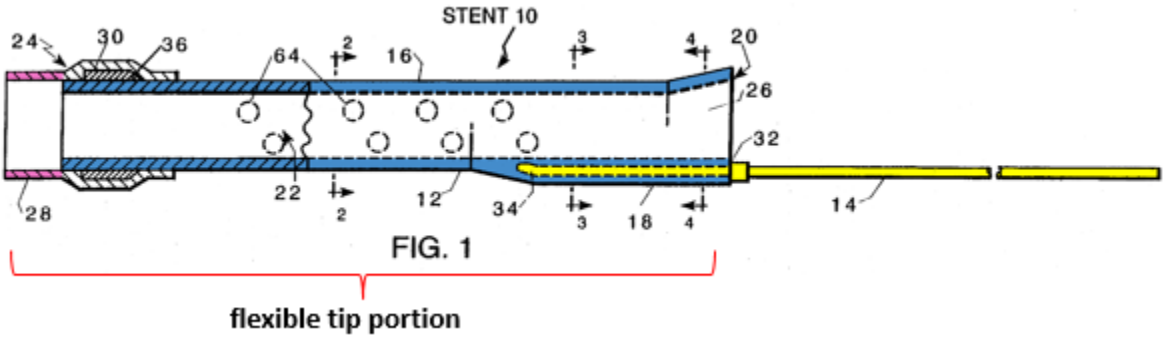
6. [1.b] "positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;"

As shown in Kontos Figure 14, the guide catheter is advanced through the aorta 37 until its distal end is placed in the ostia 39, which is part of the coronary artery. Ex-1409, Fig. 14. As a result, Kontos discloses a method of "positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery." Ex-1405, ¶ 185; Section VI.C, *supra*.

7. [1.c] "inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,"

As discussed for claim [1.pre.I], Kontos's support catheter 10 is the coaxial

guide catheter.[10] Section VIII.B.1, *supra*. Body 12 is the "flexible tip portion." Ex-1405, ¶ 186; Ex-1409, 4:1-11. Body 12 is a tubular structure with a circular cross-section. Ex-1405, ¶ 186; Ex-1409, 2:51-54, 3:47-57, 4:5-7.

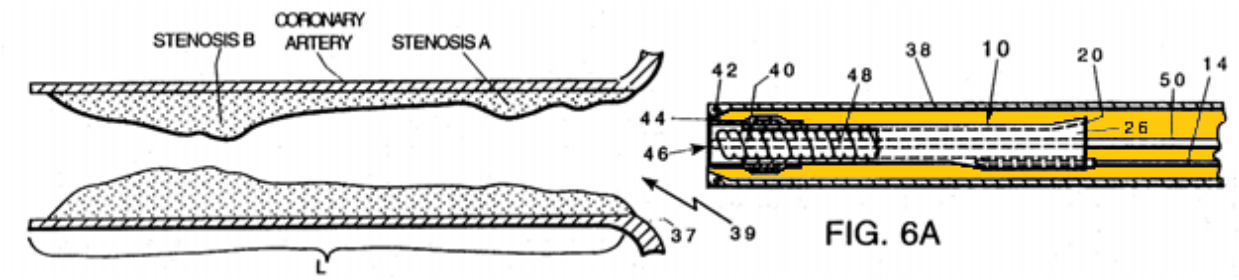


Ex-1409, Fig. 1 (annotation and color added).

The flexible tip portion is shorter in length than the predefined length of the continuous lumen of the guide catheter. Ex-1405, ¶ 186. As shown in Figure 6A, Kontos expressly discloses to a POSITA that the length of body 12 is shorter than

[10] The '413 patent recites a "coaxial guide catheter," but does not explain what the extension catheter is coaxial to. Ex-1405, ¶ 186 n.11. To the extent the "coaxial guide catheter" is somehow found to recite structure—despite not providing what the extension catheter is coaxial to—Kontos's support assembly 10 is "coaxial." *Id.*, ¶ 186. Indeed, the inner surface of tube 16 is coaxial with the outer surface of tube 16, and body 12 is coaxial to guide catheter 38. *Id.*; Ex-1409, 3:56-59, 4:48-50, Figs. 2, 6A-B.

the length of the guide catheter 38. *Id.*; Ex-1409, 4:52-54, Fig. 6A.



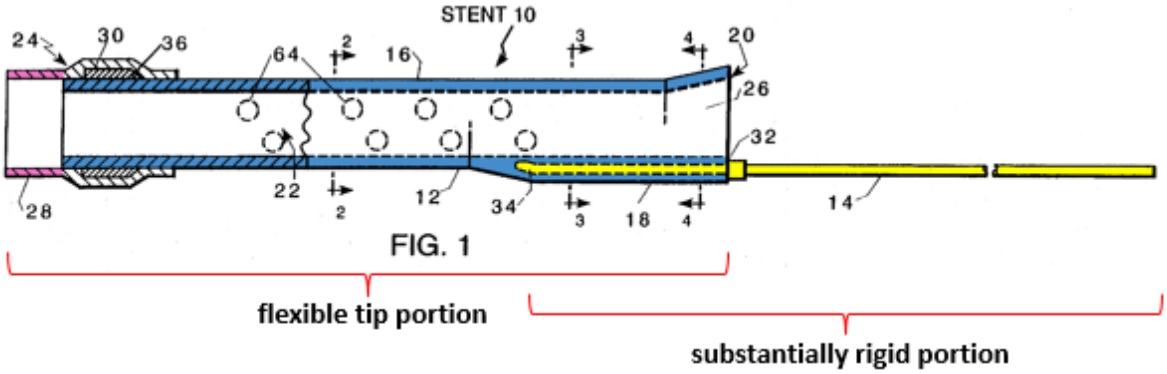
Ex-1409, Fig. 6A (color added).

The cross-sectional outer diameter of the tubular structure is sized to be insertable into and travel through the continuous lumen of the guide catheter. Ex-1405, ¶ 186. As shown in Figure 6A, the tubular, flexible tip portion (body 12) is insertable through the continuous lumen in yellow of the guide catheter 38. *Id*.

8. [1.d] "further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;"

In Kontos's support catheter 10, the insertion/manipulation wire 14 is the "substantially rigid portion." Ex-1405, ¶ 187; Section VI, *supra* (construing "substantially rigid"). Wire 14 is used to advance support catheter 10 within the guide catheter, thus providing a structure that facilitates monorail or sliding

delivery. Ex-1409, 5:25-30, Figs. 6A-C. As shown in Figure 1, the substantially rigid portion (yellow) is located proximal of and "operably connected to" the flexible tip portion (body 12), and is inserted into the continuous lumen of the GC. *Id.*, 4:25-38, Figs. 6A-C.



Id., Figure 1 (annotations and color added).

Based on the known properties of the materials, Kontos expressly discloses to a POSITA that the substantially rigid portion is "more rigid along [the] longitudinal axis than the flexible tip portion." Ex-1405, ¶ 187; Ex-1442, ¶¶ 65-68. Wire 14 (substantially rigid portion) is stainless steel, whereas the tube 16 and soft tip 28 of body 12 (flexible tip portion) are made of polyethylene and copolymer of polyethylene and ethylvinylacohol ("PVA"), respectively. Ex-1409, 4:1-11, 4:58-61; Ex-1419, 9:30-50.

As demonstrated in Figure 1, the substantially rigid portion defines a rail

structure without a lumen.[11] Ex-1405, ¶ 187; Ex-1409, 3:45-46, Figs. 3-4 (showing wire 14 as a solid material (i.e., no lumen)). Further, wire 14 has a smaller cross sectional diameter (0.020 inches) than the outer diameter of the tube 16 (0.055 inches) (and therefore, of body 12).[12] Ex-1405, ¶ 187; Ex-1409, 4:48-50, 4:58-61.

Kontos discloses a "combined length" of the flexible tip portion and the substantially rigid portion that is longer than the guide catheter. Ex-1405, ¶ 187. The flexible tip portion (body 12) is approximately twelve inches in length, and the substantially rigid portion (wire 14) "is generally at least about 50 inches long and

[11] Claim 1 recites numerous limitations on the substantially rigid portion, including "defining a rail structure without a lumen." Thus, while the substantially rigid portion includes a rail structure without a lumen, the claim does not say it is limited to only that structure (Ex-1477, 138:24-139:10), particularly where it is "operably connected to … the flexible tip portion." Dependent claims 4 and 14 confirm this reading and require the side opening, which necessarily includes a lumen, to be part of the substantially rigid portion.

[12] The claim language "maximal cross-sectional dimension" permits, but does not require, the rail structure to vary in cross-sectional dimension. All the claim requires is that the proximal rail structure cannot have a larger outer diameter than the flexible tip portion (body 12).

preferably about 53 inches long." Ex-1409, 4:52-61. Kontos does not disclose the length of the guide catheter, but a POSITA would appreciate that the combined length of the flexible tip portion in combination with the substantially rigid portion is longer than the length of guide catheter. Ex-1405, ¶ 187 (explaining that the typical guide catheter is 100 cm[13] in length, which is shorter than the combined length of the flexible tip portion and substantially rigid portion—approximately 62 inches or 157 cm—as taught by Kontos).

Moreover, Kontos teaches that the "proximal member [(substantially rigid portion)] is connected to said tubular body [(flexible tip portion)] and extend[s] proximally therefrom for providing communication between said tubular body and a region outside of the body of the patient." Ex-1409, 10:12-15, 11:35-39 (same). And not only does Kontos specifically teach that the substantially rigid portion extends outside of the body, but it also teaches in Figure 6B that body 12 of the support catheter 10 extends distally to guide catheter 38 while advancing the PTCA catheter 40 with balloon 48. Ex-1405, ¶ 187. In other words, the combined length of the flexible tip portion and the substantially rigid portion must be longer than the guide catheter 38. Ex-1405, ¶ 188 (explaining that a physician cannot treat

[13] The background of the '413 patent admits that GCs are "one hundred centimeter[s]" in length. Ex-1401, 2:41-43.

a stenosis unless s/he can maintain physical contact with the extension catheter, meaning that it must be longer than the GC).

Even if it would not have been obvious—in light of Kontos and the knowledge of a POSITA—for the flexible tip portion and substantially rigid portion to have a combined length that is greater than the length of the guide catheter, it would have been obvious to modify Kontos to add these design features in view of Adams. Ex-1405, ¶ 189. Adams and Kontos are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem face by the inventors of the '413 patent. *Id.* Further, as shown in Fig. 1A, Adams specifically teaches that the combined length of the guide seal 20 (flexible tip portion) and control wire 5 (substantially rigid portion) are greater than that of the guide catheter. Ex-1435, [0060], Figs. 1A-B; Ex-1405, ¶ 190.

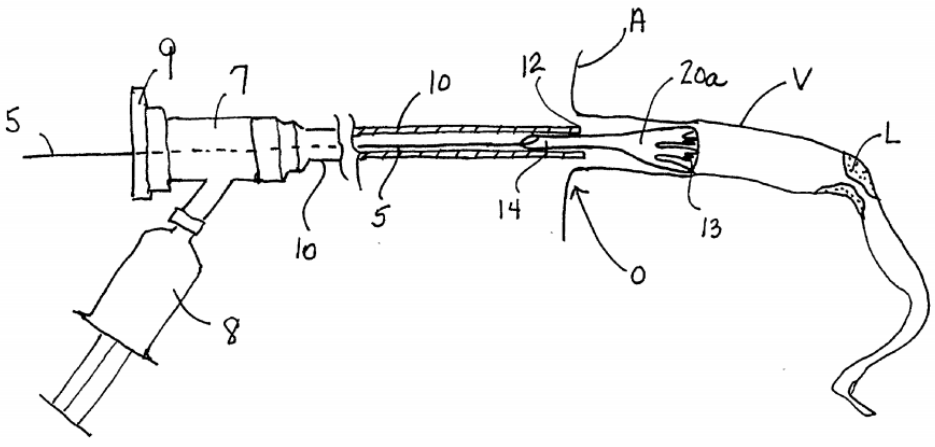
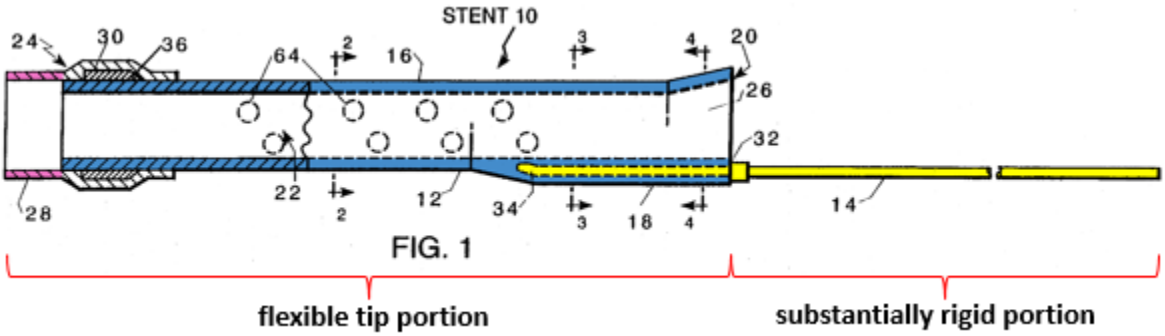


FIG. 1A

A POSITA would have been motivated to combine these well-known

aspects from interventional cardiology, as disclosed by Adams, with Kontos's disclosure given the latter's teaching that the catheter assembly should "us[e] known medical procedures." Ex-1409, 5:11-15; Ex-1405, ¶ 191. A POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. Ex-1405, ¶ 192. Indeed, combining Adams with Kontos to provide a flexible tip portion and substantially rigid portion that is longer than the guide catheter would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id*.

Finally, out of an abundance of caution, Petitioner notes that claim 1 requires the substantially rigid portion to be "proximal of" the flexible tip portion, and recites a combined "total length" of both portions. Should Patent Owner argue that these limitations require the entirety of the substantially rigid portion to be proximal of the entirety of flexible tip portion (Ex-1477, 123:14-17, 124:19-25, 127:24-128:14, 129:20-130:4), such that one structure does not overlap with the other, the results do not change. Ex-1405, ¶ 193. First, that interpretation is wrong. The two structures are "operably connected" as claimed and clearly two structures can overlap to connect. Ex-1401, 6:35-36, 9:26-28 (describing welding bonding or adhesive). Second, even if they cannot overlap, Kontos can also be applied under that interpretation. Ex-1405, ¶ 194.



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

Mapping the portion of wire 14 that does not overlap with body 12 to the "substantially rigid portion" does not affect the analysis of the other claim limitations of claim 1. The substantially rigid portion, that is solely a rail structure without a lumen, would still be more rigid along the longitudinal axis and have a maximal cross-sectional dimension at a proximal portion that is less than the flexible tip portion. Ex-1405, ¶ 194; Ex-1442, ¶¶ 65-68. Moreover, the "combined length" of these portions (i.e., body 12 and portion of wire 14 outside of body 12) would be longer than that of the guide catheter. Ex-1405, ¶ 194; Ex-1409, 4:52-61.

9. [1.e] "advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery[14] such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and"

Kontos teaches "advancing a distal portion of the flexible tip portion distally

[14] Claim 1 refers to "first" and "second" arteries, but provides no antecedent basis for the latter. The specification also provides no direction as to these claim terms, as it never refers to a "first" or "second" artery. Because claim 1 also states that the distal end of the GC is "position[ed] … in a branch artery that branches off from the first artery," the "first artery" must be the aorta. Ex-1405, ¶ 195; Ex-1401, 1:35-39, Figs. 7-9 (showing that GC is placed in the ostium of the coronary artery); Section VI.C, *supra* (construing "placed in a branch artery). Therefore, the "second artery" must be an artery that is located downstream of the aorta. It is unclear, however, if it is the same as the claimed branch artery (coronary artery), or refers to a further branch (which is not described or shown in the specification). In other words, it is unclear whether the second artery is the initial portion of the coronary artery before any further branch, or if it must be a further branch. Regardless, this limitation is taught by Kontos. Ex-1405, ¶ 195; Ex-1409, Fig. 14.

beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery." Ex-1405, ¶ 195. Specifically, Kontos teaches that the body 12 is "advanced … out of the distal end of guide catheter 38" and into the second artery. Ex-1409, 5:31-39, Figs. 6B-C, 14.

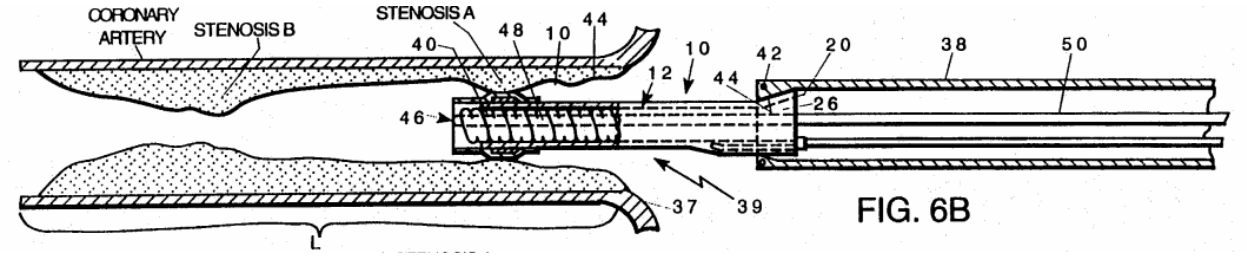


FIG. 6B

Further, a POSITA would expect that the proximal end of the substantially rigid portion of Kontos extends proximally through the hemostatic valve even when body 12 extends into the second artery, as shown above in Figure 6B. Ex-1405, ¶ 195. Specifically, a POSITA would have understood that wire 14 would need to extend proximally through the hemostatic valve regardless of the position of body 12 within the guide catheter 38 because the physician needs to have physical access to wire 14 to control the movement of body 12. Ex-1405, ¶ 195; Ex-1409, 9:62-10:21, 11:15-43.

Even if Kontos and the knowledge of a POSITA does not teach that the flexible tip portion advances distal of guide catheter 38 and into the second artery while the substantially rigid portion extends proximally through the hemostatic valve, it would have been obvious to add these design features in view of Adams.

Ex-1405, ¶ 196. Adams 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 '413 patent. *Id.* Further, as shown in Figure 1A, Adams specifically teaches that the combined length of the guide seal 20 (flexible tip portion) and control wire 5 (substantially rigid portion) (i) are greater than that of the guide catheter and (ii) extend proximal to the hemostatic valve 9 when the guide seal extends beyond the distal end of guide catheter 10. Ex-1405, ¶ 197; Ex-1435, Figs. 1A-B.

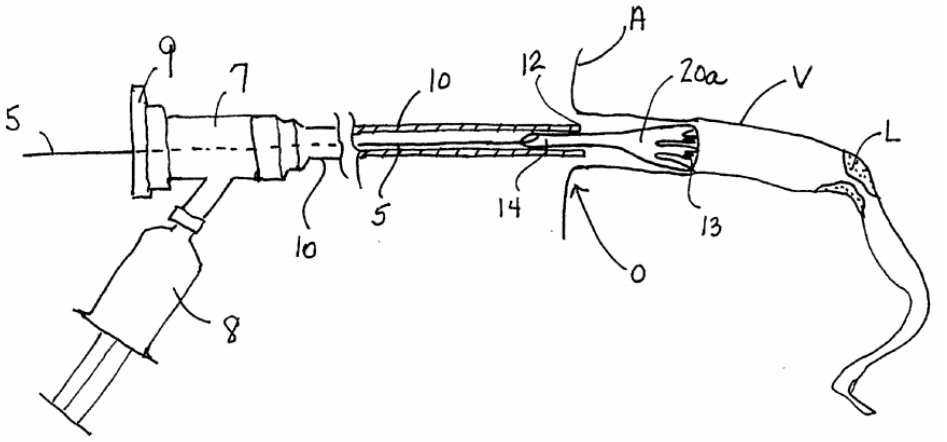


FIG. 1A

Ex-1435, Fig. 1A.

A POSITA would have been motivated to combine these well-known aspects from interventional cardiology, as disclosed by Adams, with Kontos's disclosure given the latter's teaching that the catheter assembly should "us[e] known medical procedures." Ex-1409, 5:11-15; Ex-1405, ¶ 198. It would have been obvious to a

POSITA to modify Kontos (to the extent not obvious based on a POSITA's knowledge) to add these claimed design features. Ex-1405, ¶ 198.

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. *Id*., ¶ 199. Indeed, combining Adams with Kontos to provide that the substantially rigid portion extends through a hemostatic valve, while the flexible tip portion extends into the second artery, would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id.*

10. [1.f] "inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery."

Kontos or Kontos in combination with Adams teaches this limitation of the '413 patent. Ex-1405, ¶¶ 200-05. Figure 6 of Kontos shows that in one embodiment, the PTCA catheter and support catheter are advanced together into the guide catheter. Ex-1409, Figs. 6A-C. In particular, Kontos explains that "[t]he balloon 48 of PTCA catheter 40 [can] be captured within the confines of body 12 and then "the PTCA catheter/support catheter assembly combination … is fed into []guide catheter 38, and advanced through guide catheter 38 to the distal end thereof." *Id*., 5:16-28, 7:45-49. Therefore, insertion of PTCA catheter 40 occurs

"alongside" of the substantially rigid portion of Kontos's wire 14.[15] Ex-1405, ¶ 200.

To the extent claim [1.f] is interpreted to require insertion of the "interventional cardiology device" *after* insertion of a "coaxial guide catheter," Kontos still teaches this claim limitation. *Id*., ¶ 201. Indeed, Kontos explains that support assembly 10 can be advanced first, followed by PTCA catheter 40. Ex-1409, 7:45-52. In other words, Kontos teaches that body 12 is advanced distal to guide catheter 38, and then the PTCA catheter 40 with balloon 48 is advanced into the guide catheter/extension catheter assembly. Ex-1405, ¶ 203 (explaining that when separately inserting extension catheter and therapy catheter, a POSITA extends the extension catheter distal to the guide catheter prior to insertion of the therapy catheter).

Regardless of the interpretation of claim [1.f], Kontos satisfies the remainder

[15] There is nothing in the claim language that requires the coaxial guide catheter to be inserted first, followed (separately) by the interventional cardiology device. The devices are inserted "alongside" one another. *Interactive Gift Express, Inc. v. Compuserve Inc*., 256 F.3d 1323, 1342 (Fed. Cir. 2001) ("Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one.").

of this claim limitation. As shown in Figure 6, the interventional cardiology device is advanced through the continuous lumen of the guide catheter 38, along the substantially rigid portion 14, through the flexible tip portion 12, and into contact with or past a lesion in the second artery. *Id*., ¶ 200.

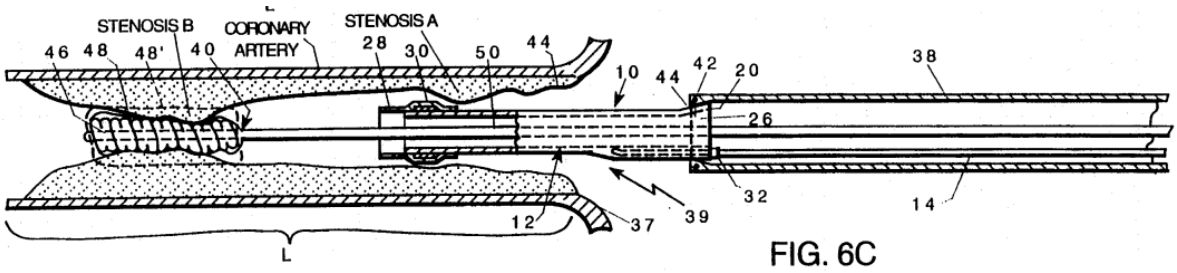


FIG. 6C

Ex-1409, Fig. 6C.

To the extent patent owner argues that Kontos and the knowledge of a POSITA does not teach this claim element, it is rendered obvious in light of Adams. Adams teaches advancing guide catheter 10 to the ostium, whereupon the sealing device 20 (extension catheter) is advanced until the distal portion extends beyond the guide catheter. Ex-1405, ¶ 202; Ex-1435, [0012], [0061], [0064], Figs. 2D-E. Thereafter, the distal protection device 15 (interventional device) is advanced through the lumen of the sealing device 20 and to a location distal to the treatment site.

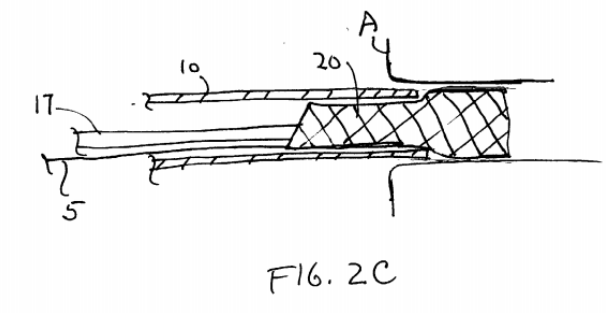


FIG. 2C

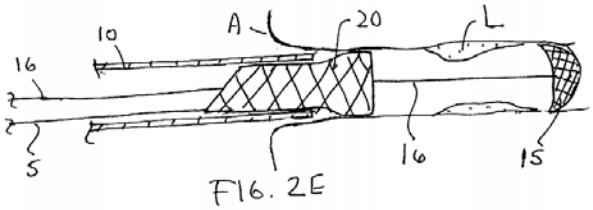


FIG. 2E

Ex-1435, Figs. 2C, 2E.

To the extent not taught by Kontos, a POSITA would have been motivated to, as provided by Adams, maintain the distal end of the extension catheter beyond the distal end of the guide catheter, and then advance the interventional device into the coronary artery alongside the substantially rigid portion. Ex-1405, ¶ 203. Adams 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 '413 patent. *Id*. As explained by Dr. Brecker, a physician will wait to advance the interventional device until after positioning the extension catheter for multiple reasons. *Id*., ¶ 204.

The extension catheter is easier to manipulate in the vasculature if the interventional device is not pre-loaded in its lumen. *Id*. In other words, an extension catheter will have greater trackability (i.e., greater flexibility) while traversing to the patient's vasculature if its lumen does not contain the therapy catheter. *Id*. Additionally, there is greater risk of an air embolism if the extension catheter is advanced contemporaneous to the therapy catheter. *Id*. Physicians

routinely perform PCI in a step-wise process and combining Kontos with Adams to perform the steps of inserting the interventional cardiology device into and through the continuous lumen of the GC, alongside the substantially rigid portion, through and beyond a lumen of the flexible tip portion, and into contact with or past a lesion in the second artery would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id*., ¶ 205; *KSR*, 550 U.S. at 417.

C. Claim 2: The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal portion of the coaxial guide catheter remains seated in the second artery in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.

The ’413 patent provides that because the coaxial guide catheter is “extended through the lumen of the guide catheter and beyond the distal end of the guide 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, 4:55-5:8. The ’413 patent explains that it is essentially the combination of a GC 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 GC alone. *Id*., 7:66-8:12. This combination

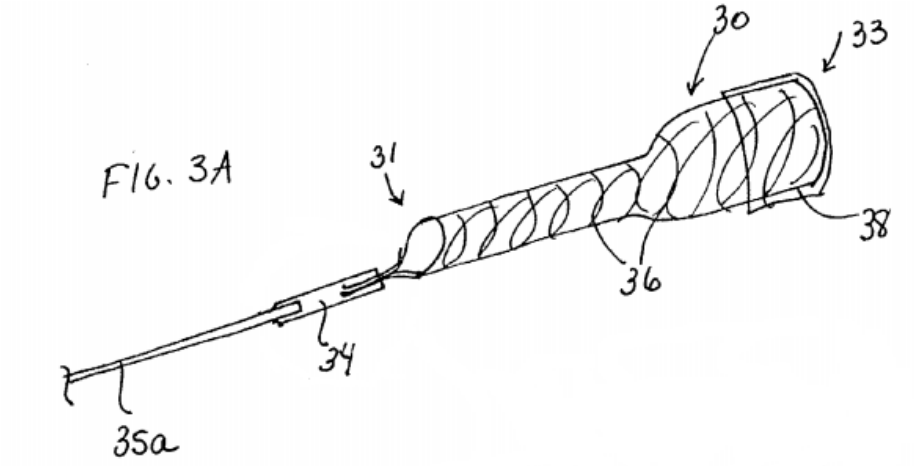
permits the claimed assembly to resist dislodgement. Ex-1405, ¶ 206.

Claim 2 is obvious over Kontos in view of the knowledge of a POSITA. 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, at 5:11-15. Feeding the coaxial guide catheter is "most effectively accomplished by exerting axial force on wire 14 and on catheter tube 50 simultaneously." *Id*., 5:28-30. 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." *Id.*, 2:16-22, Figs 6A-C (showing proximal end of body 12 within guide catheter 38). As discussed above, a mother-and-child catheter assembly ameliorates the backwards force that can otherwise dislodge the GC in the ostium where the child catheter acts as an extension of the guide catheter into the coronary artery. Section IV.A, *supra*; Ex-1405, ¶ 206. For this reason, because Kontos and the '413 patent contain the same teachings, 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 2. Ex-1405, ¶ 206; Section VIII.B.1, *supra*.

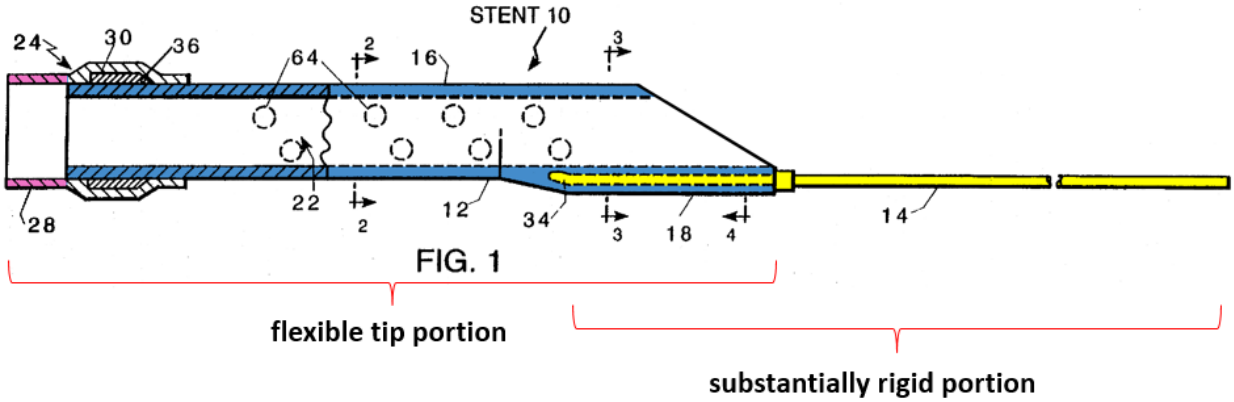
D. Claim 4: The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.

Kontos in combination with Adams teaches the method of claim 4. Kontos teaches that the interventional cardiology device is insertable into the coaxial lumen of the tubular structure (body 12). Ex-1405, ¶ 207. Kontos does not teach, however, that the substantially rigid portion of the extension catheter comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof. As seen in Figure 1, the proximal opening of tube 16 does not extend along the longitudinal axis of the tubular structure, meaning it is not a side opening with a cylindrical and a partially cylindrical portion. Proximal side openings falling within the scope of claim 4 were, however, well-known in the art. Ex-1405, ¶¶ 95-108, 208; Ex-1407, 4:10-15; Ex-1408, 12:9-13:60, Figs. 6A-E; Ex-1418, Fig. 7; Ex-1432, 119, Fig. 1; Ex-1433, [0035], [0049], Fig. 2; Ex-1435, [0066]; Ex-1450, Fig.7; Ex-1461, 6:9-11, Fig. 1B.

Adams is one such catheter assembly that uses a proximal side opening. Ex-1405, ¶¶ 207-09. In particular, Adams teaches a guide seal 30 (tubular portion) with proximal end 31 that is "preferably cut or formed at an angle." Ex-1435, [0066].



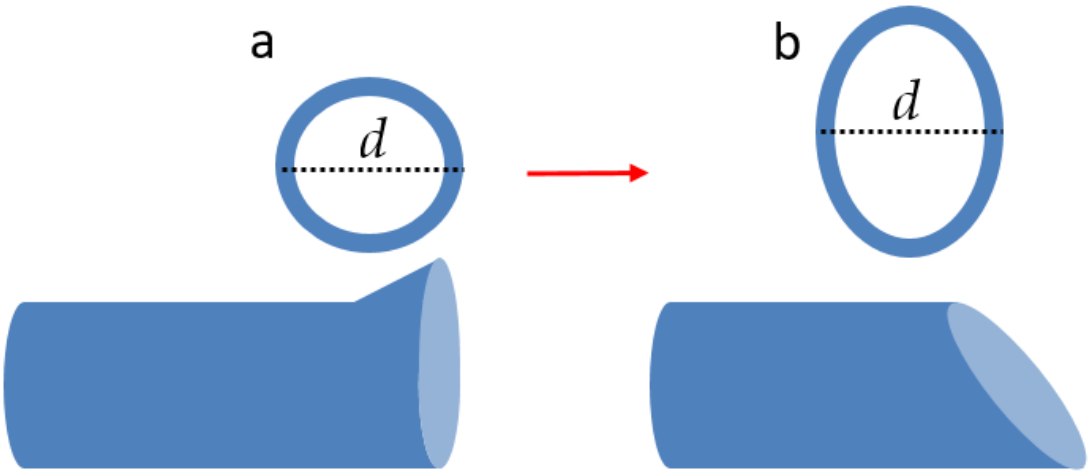
Id., Fig. 3A. A POSITA would have been motivated, with a reasonable expectation of success, to add Adams's proximal side opening to Kontos's tube 16, as shown below:



Ex-1409, Fig. 1 (annotations and color added) (modified by Petitioner).[16]

[16] As discussed above, the "substantially rigid portion" may include more than just the rail structure. Specifically, the substantially rigid *portion* of support catheter 10 overlaps with and may include tube 16. Ex-1405, ¶ 210.

A POSITA would have been motivated to modify Kontos to add a side opening at the proximal end of tube 16 of body 12, as taught by Adams, for multiple reasons. Ex-1405, ¶¶ 90-108, 210; Ex-1442, ¶¶ 72-74, 81-87. First, a POSITA would have known, as shown in the below figure, that use of a side 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.



Ex-1405, ¶ 211; Ex-1442, ¶¶ 83-84.

In 1995, when Kontos issued, GCs were typically 7-8 French in diameter. Ex-1405, ¶ 212. But by the purported priority date of the '413 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, ¶ 213. 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 side 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. Ex-1405, ¶ 213; Ex-1442, ¶ 84. Alternatively, a POSITA would have been motivated to remove Kontos's proximal funnel, as it would permit the inner diameter of the extension catheter to be increased without causing a commensurate increase in the outer diameter of the guide catheter. Ex-1405, ¶ 213; Ex-1442, ¶ 84.

Second, a POSITA would have been motivated to use a proximal side opening because doing so facilitates "smoother" reception of the interventional cardiology device as it enters the lumen of the child catheter. Ex-1408, 6:52-57; *see also* Ex-1405, ¶¶ 214-15; Ex-1442, ¶¶ 85-86; Ex-1426, 3:6-9. 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, ¶ 214; Ex-1442, ¶¶ 85-86. A proximal side opening reduces the likelihood—by comparison to a vertical opening—meaning it promotes better advancement of the therapy catheter

as it travels to the occlusion.[17] Ex-1405, ¶ 216; Ex-1442, ¶¶ 85-86.

Third, a POSITA additionally would have been motivated to use a proximal side opening 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, ¶ 217; Ex-1442, ¶ 87; Ex-1425, Abstract, [0034]. In other words, adding a side opening to the distal lumen of the extension catheter reduces the amount of force that a physician must exert to advance the catheter through winding vasculature. Ex-1405, ¶ 217; Ex-1442, ¶ 87.

Fourth, a POSITA was motivated to add a proximal side 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,

[17] Kontos itself reflects the same concern, and provides funnel 26 to aid insertion of a therapy catheter. Ex-1409, 3:66-68. A side 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 between funnel 26 and ridge 44 is an alternative, and therefore unnecessary, embodiment. *Id*., 5:57-6:8.

¶ 218; Ex-1442, ¶¶ 81-83. 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, stenosis B." Ex-1409, 6:22-25.

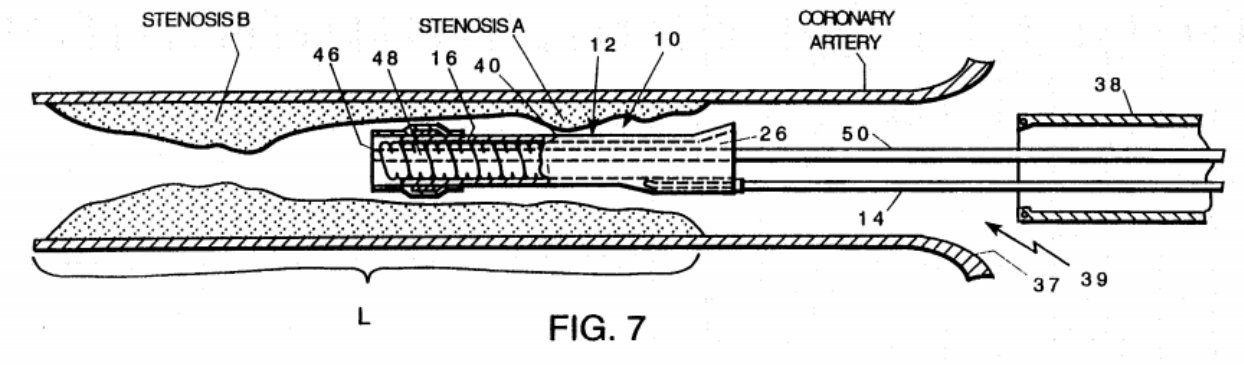


FIG. 7

Id., Fig. 7. In such an embodiment, after the angioplasty is performed, the support catheter 10 must return to the guide catheter 38. Ex-1405, ¶ 219; Ex-1442, ¶ 81. A POSITA would recognize, however, that a flared proximal opening of the tubular structure (body 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, ¶ 219; Ex-1442, ¶ 82. The smaller cross-sectional diameter of a proximal side opening would reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the GC. Ex-1405, ¶ 219; Ex-1442, ¶ 83.

In fact, Adams provided this exact rationale for using a proximal side opening on the guide seal. 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."). Given this explicit motivation in the reference Petitioner seeks to combine, a POSITA would have been motivated to use a proximal side opening at the proximal end of the tubular structure to aid in the retraction and re-insertion of the tubular structure into the guide catheter, if it were necessary to do so. Ex-1405, ¶ 220.

The prior art, including Adams, shows that the use of a proximal side opening was well-known. *Id*., ¶ 221. Employing a proximal side opening with a cylindrical and a partially cylindrical portion (as opposed to an opening perpendicular to the longitudinal axis) to 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. *Id*., ¶ 221; Ex-1442, ¶ 88.

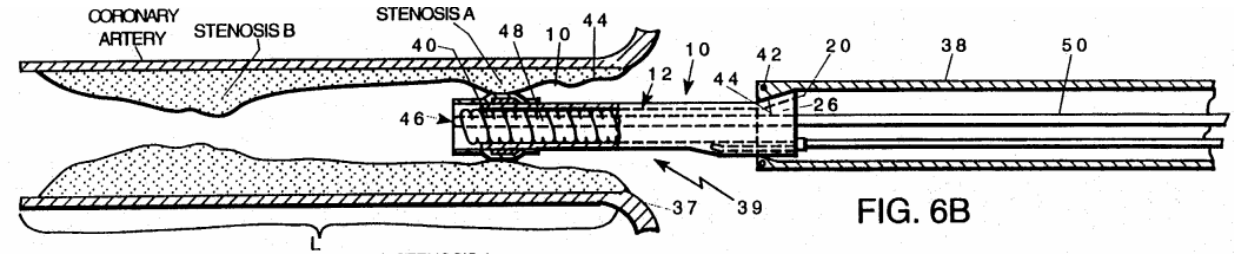
E. Claim 5: The method as claimed in claim 1, further comprising selecting the standard guide catheter to further comprise a Y-adapter and the method further comprising injecting a fluid through the Y-adapter into the standard guide catheter.

Kontos in combination with Adams and/or the knowledge of a POSITA teaches claim 5. Ex-1405, ¶ 222. In particular, Adams teaches "facilitat[ing] fluoroscopic visualization during injection of contract through the sidearm of the Y connector." Ex-1435, [0077]; Fig. 9.

A POSITA would have been motivated to configure Kontos (to the extent not already taught) to permit the injection of one or more fluids through a y-adaptor and into the coronary artery. Ex-1405, ¶ 223. Adams 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 '413 patent. *Id*. Further, the tubular portion of Kontos's support assembly 10 and Adams's guide seal both have radiopaque markers. Ex-1409, 4:16-19; Ex-1435, [0056]. X-ray or fluoroscopy techniques permit the subcutaneous detection of these radiopaque markers in the vasculature after the addition of contrast dye. Ex-1405, ¶ 224. Because Kontos teaches the inclusion of marker band 30, a POSITA would have been motivated to include a y-adapter with hemostatic valve at the proximal end of guide catheter 38 to permit one or more fluids (e.g., contrast dye) to be injected into the coronary artery via the guide catheter. *Id*. (explaining that without injecting contrast dye, a physician would not be able to locate the radiopaque markers vis-à-vis the vasculature). Employing Adams's hemostatic valve on the proximal end of Kontos's guide catheter 38 and injecting one or more fluids, as taught by Adams, 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. *Id*., ¶ 225.

F. Claim 7: The method as claimed in claim 1, further comprising extending a distal portion of the tubular structure beyond the distal end of the standard guide catheter while a proximal portion remains within the lumen of the standard guide catheter, such that the coaxial guide catheter 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 standard catheter from the branch artery.

Kontos discloses the method of claim 7. Kontos discloses that a distal portion of the tubular structure of the flexible tip portion (body 12) is insertable through and extends beyond the continuous lumen of guide catheter 38. Ex-1409, 3:50-52, 5:31-59, Figs. 6A-C. When the distal end of body 12 extends into the coronary artery (i.e., beyond the distal end of guide catheter 38), the proximal end remains within guide catheter 38. *Id.* In so doing, the combination of body 12 and wire 14 (support catheter 10) assists in resisting axial and shear forces as claimed. Ex-1405, ¶ 226.



Ex-1409, Fig. 6B.

Indeed, Kontos 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." *Id*., 2:16-22, Figs. 6A-C (showing proximal end of body 12 within guide catheter 38). This is the same teaching found in the specification of the '413 patent. Section VIII.B.1, *supra.* For this reason, because Kontos and the '413 patent contain the same teachings, to the extent the '413 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 7. Ex-1405, ¶ 226.

G. Claim 8: The method of claim 7, further comprising extending the interventional cardiology device past a radiopaque marker proximate a distal tip of the coaxial guide catheter.

As discussed for claim 1, Kontos's flexible tip portion is body 12. Section VIII.B.7, *supra*. Kontos further discloses that "marker band 30 may be retained between soft tip 28 and tube 16" of body 12, and thus the radiopaque marker is proximate a distal tip of the extension catheter. Ex-1409, 4:19-21; Ex-1405, ¶ 227; Ex-1442, ¶¶ 103-06. Further, as shown in Kontos Figure 6, the PTCA catheter 40 with balloon 48 is extended past (distal) the marker band 30.

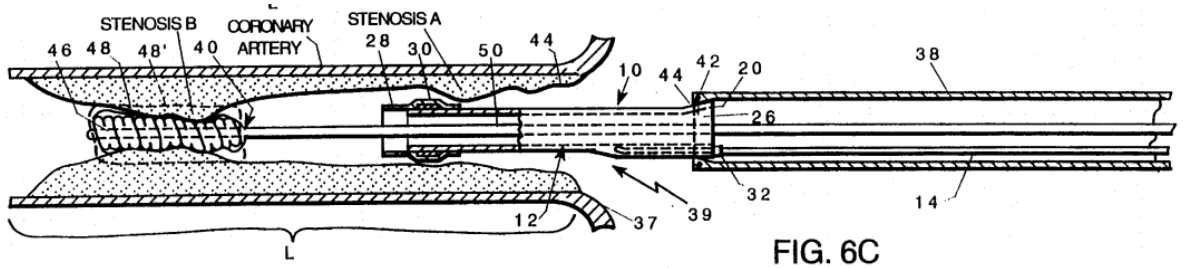


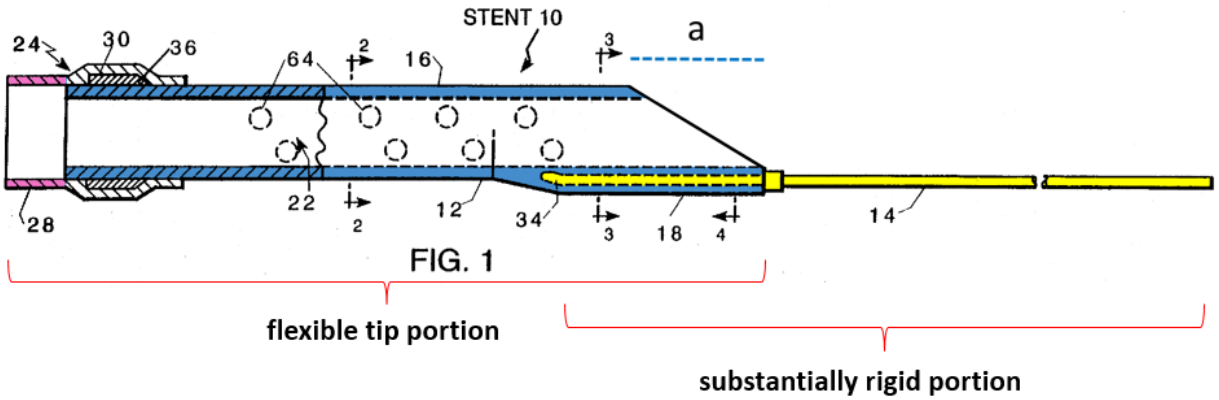
FIG. 6C

Ex-1409, Fig. 6C.

H. Claim 9: The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.

Kontos in combination with Adams and/or the knowledge of a POSITA teaches claim 9. Ex-1405, ¶ 228; Ex-1442, ¶¶ 69-88. As discussed for claim [1.f], a POSITA would be motivated, with a reasonable expectation of success, to first position the extension catheter and then insert the interventional cardiology device through the hemostatic valve and beyond the distal-most portion of the extension catheter. Section VIII.B.10, *supra*.

Further, as discussed for claim 4, a POSITA would have been motivated, with a reasonable expectation of success, to add a side opening to Kontos's tube 16. Section VIII.D, *supra*. In so doing, the side opening would necessarily "extend[] for a distance along the longitudinal axis [(shown by dashed line "a")] of the proximal portion of the tubular structure." Ex-1405, ¶ 229.



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

Further, a POSITA would be motivated to keep the side opening of the tubular structure within the guide catheter. Ex-1405, ¶ 230. For example, anytime the proximal end of the coaxial guide catheter is extended beyond the distal-most portion of the guide catheter, there is risk that it can scrape against and cause damage to the vasculature. *Id*. Additionally, when retracted, it is possible for the proximal end of the coaxial guide catheter to "hang up" or get stuck on the distal-most portion of the guide catheter. *Id*., ¶ 231; Ex-1442, ¶ 82.

A POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. Ex-1405, ¶ 232; Ex-1442, ¶¶ 69-71. Indeed, both Kontos and Adams teach that the proximal portion of the tubular structure can remain within the lumen of the guide catheter. Ex-1409, Figs. 6A-C; Ex-1435, Figs. 2A-D. Performing the method of keeping the proximal side opening of the tubular portion within the lumen of the guide catheter would have required no substitution, experimentation, or invention. Ex-1405, ¶ 232; *KSR*, 550 U.S. at

417. As a result, Kontos in combination with Adams and/or the knowledge of a POSITA teaches the method of sending the interventional cardiology device through a proximal side opening, which extends for a distance along the longitudinal axis of the proximal end of the tubular structure that remains within the lumen of the guide catheter. Ex-1405, ¶ 233.

I. Claim 10:

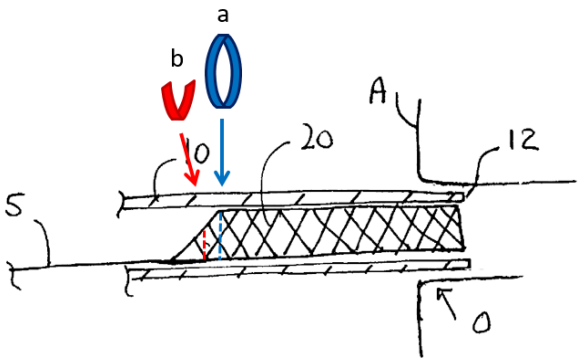
1. [10.a] "The method of claim 9, further comprising extending the interventional cardiology device through the proximal side opening;"

As discussed for claim 9, Kontos in combination with Adams and/or the knowledge of a POSITA discloses this claim limitation. Section VIII.H, *supra*; Ex-1405, ¶ 234.

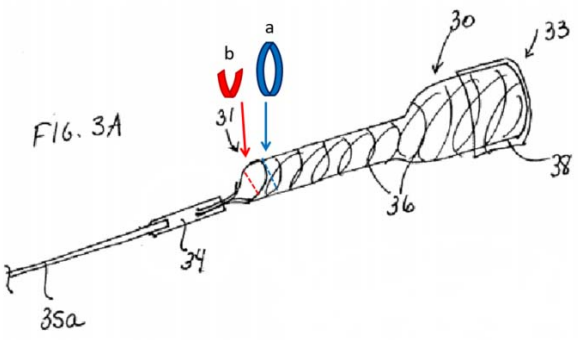
2. [10.b] "advancing the interventional cardiology device through structure defining a full circumference portion; and advancing the interventional cardiology device through structure defining a partially cylindrical portion."

As discussed for claim 9, a POSITA would have been motivated, with a reasonable expectation of success, to design the tubular structure of Kontos with a proximal side opening. Section VIII.H, *supra*. In so doing, when advancing the interventional cardiology device into the coronary artery, it necessarily would pass through a structure defining a full circumference portion and a partially cylindrical portion. Ex-1405, ¶ 235. Indeed, a cross-section of the circular guide catheter 10 and guide seal 20 (extension catheter) of Adams shows the partially cylindrical

portion (red) and a full circumference portion (blue). *Id.*



F16. 2A



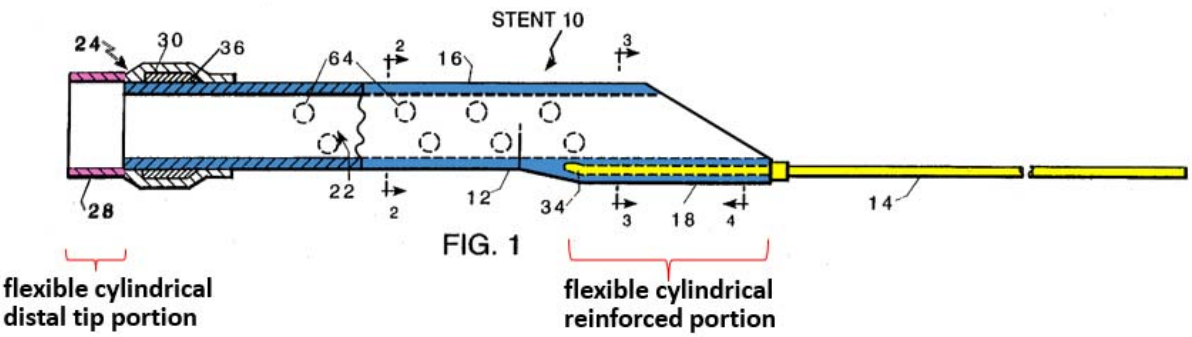
F16. 3A

Ex-1435, Figs. 2A, 3A (annotations and color added).

J. Claim 11: The method of claim 9, further comprising extending the interventional cardiology device through a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion of the tubular structure proximal to the flexible distal tip portion.

This claim is rendered obvious by Kontos in combination with Adams. In Kontos's support catheter 10, body 12 is the "flexible tip portion … defining a tubular structure." Ex-1405, ¶ 236. The tubular structure (body 12) must also have a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion. As construed above, "reinforced portion" means a "portion made stronger by additional material or support." Section VI, *supra*.

This limitation is satisfied by comparing the portion of body 12 that is coextensive with receiving hole 34 ("flexible cylindrical reinforced portion") to the portion of body 12, including soft tip 28, that is distal to the distal-most portion of tube 16 ("flexible cylindrical distal tip portion"). *Id.*



Ex-1409, Fig. 1 (annotations and color added) (modified by Petitioner). The proximal end of body 12 is the attachment location for the substantially rigid portion (wire 14).[18] Ex-1409, 4:25-27, Fig. 1. One way to attach the substantially rigid portion, as shown in Figure 1, is to insert wire 14 into a receiving hole 34 that is located on the proximal end of body 12. *Id*., 4:27-31. Thus, the proximal end of body 12—that is located proximal to soft tip 28—constitutes the "flexible cylindrical portion" because it has more material and more support. Ex-1405, ¶ 236.

Even if Kontos does not disclose a "flexible cylindrical reinforced portion,"

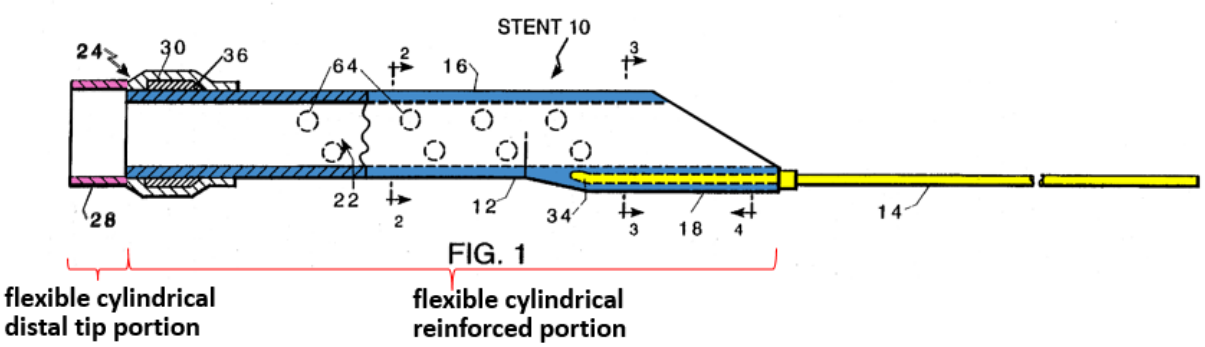
[18] As discussed, wire 14 is the substantially rigid portion. Section VIII.B.8, *supra*. This does not mean, however, that wire 14 cannot also satisfy the limitation reciting a "flexible cylindrical reinforced portion." Indeed, "a single element, feature, or mechanism can ordinarily satisfy multiple claim limitations." *Google LLC v. Pers. Audio, LLC*, 743 F. App'x 978, 985 (Fed. Cir. 2018).

it would have been obvious based on the knowledge of a POSITA to modify Kontos by adding metallic coiling or braiding (i.e., reinforcement) to tube 16. Ex-1405, ¶ 237; Ex-1442, ¶¶ 89-96. 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, ¶¶ 237-43; Ex-1442, ¶¶ 92-96; Ex-1408, 6:66-7:7; Ex-1446, Abstract; Ex-1447, Abstract.

Should the Board require a reference to combine, Adams discloses braiding/coiling. Ex-1405, ¶ 244. Adams 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 ’413 patent. *Id.*, ¶ 245. In Adams, guide seal 30 is the device adapted for use with the guide catheter as taught by the ’413 patent. *Id.*; Ex-1435, Fig. 3A. Adams discloses stainless steel or nitinol braiding in a polymer of the guide seal 30. Ex-1435, [0066]. A POSITA would have been motivated to add this design feature to tube 16 of Kontos because s/he knew that metallic braiding/coiling in a polymer promoted pushability and prevented kinking during advancement of the catheter. Ex-1405, ¶ 245; Ex-1442, ¶¶ 90-91, 93; Ex-1435, [0075] (explaining that when coiling is used as an alternative to braiding, then “the guide seal may not be sufficiently rigid to be pushed through the lumen of the guide catheter”); 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, ¶ 246; Ex-1442, ¶¶ 95-96.

If Kontos was reinforced with metallic braiding/coiling, then tube 16 would be the proximally-located, "flexible cylindrical reinforced portion." Ex-1405, ¶ 247. The portion of body 12 that is distal to tube 16, including soft tip 28, would remain the distally-located "flexible cylindrical distal tip portion." *Id*.



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

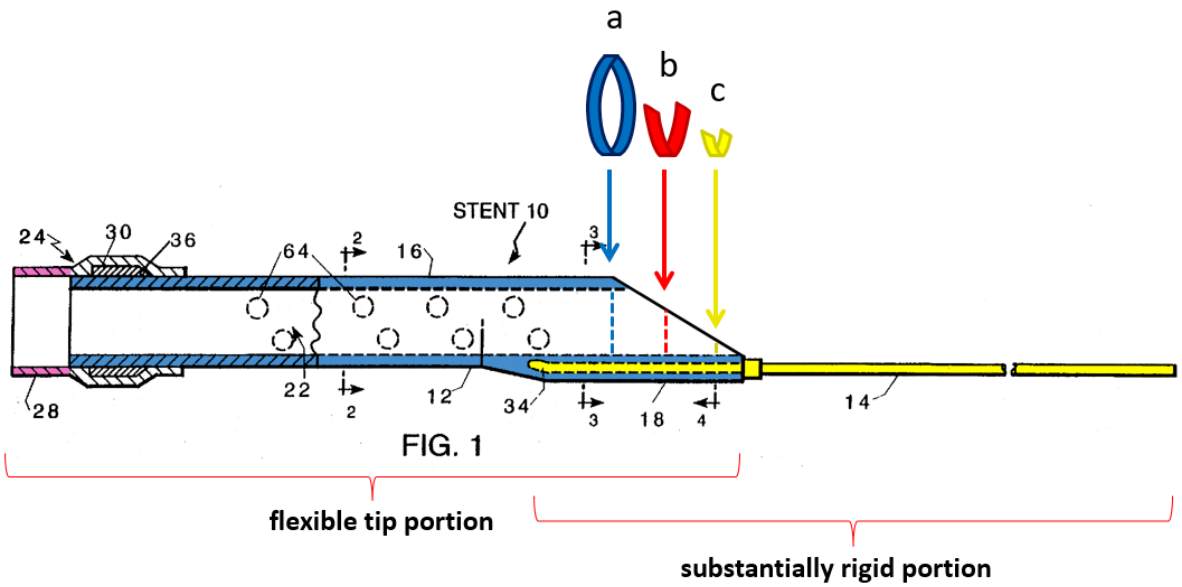
K. Claim 12: The method of claim 11 further comprising extending the interventional cardiology device through the flexible cylindrical reinforced portion that is reinforced with metallic elements in a braided or coiled pattern.

As discussed for claim 11, Kontos discloses that the portion of body 12 that is coextensive with receiving hole 34 is the "flexible cylindrical reinforced portion," or, alternatively, braiding/coiling can be added, such that tube 16 of Kontos becomes the "flexible cylindrical reinforced portion." Section VIII.J, *supra*. In the latter scenario, Adams teaches the use of metallic elements in a braided or coiled pattern. Ex-1435, [0066] ("The guide seal is substantially tubular

and comprises stainless steel or nitinol braid 36 ….”); *see also id.* [0049], Fig. 3A. For the same reasons discussed for claim 11, it would have been obvious to add metallic elements in a braided or coiled pattern to tube 16 of Kontos in view of Adams. Section VIII.J, *supra*; Ex-1405, ¶ 248.

L. Claim 14: The method of claim 1, further comprising extending the interventional cardiology device through the substantially rigid portion from proximal to distal through a cross-sectional shape having an arcuate portion, a hemicylindrical portion and a full circumference portion.

The combination of Kontos and Adams teaches the method recited by claim 14. As discussed for claim 4, a POSITA would have been motivated, with a reasonable expectation of success, to design the tubular structure of Kontos with a proximal side opening. Section VIII.D, *supra*. Further, tube 16 is cylindrical with “a continuous lumen 22 therethrough.” Ex-1409, 3:49-50; 3:56-57, Fig. 6C.



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

As shown above in Figure 1, the extension of wire 14 into body 12 creates a substantially rigid portion with a side opening at the distal end of tube 16. Ex-1405, ¶ 253. As a result, the substantially rigid portion necessarily includes from a proximal to distal direction, a cross-sectional shape having an arcuate portion (yellow), a hemicylindrical portion (red), and a full circumference portion (blue). The treating physician would insert the interventional cardiology device into the substantially rigid portion and extend it from a proximal to distal direction. Ex-1405, ¶ 253.

IX. GROUND 2: KONTOS RENDERS CLAIM 13 OBVIOUS IN VIEW OF ADAMS AND TAKAHASHI.

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, ¶ 52. Takahashi is cited in the Background of the '413 patent, but was not the basis of an Examiner rejection during prosecution of the '413 patent (Exs-1401-03), and thus the Board should decline to exercise its discretion under 35 U.S.C. § 325(d).

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, respectively (*id.*), which is less than a 1 French difference in inner diameters. Ex-1405, ¶¶ 147-52; Ex-1442, ¶ 98.

B. Claim 13: The method of claim 1, further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

This claim is rendered obvious by Kontos in view of Adams, Takahashi, and/or the knowledge of a POSITA. Ex-1405, ¶ 249. 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. At base portion 18 (i.e., funnel) of body 12, Kontos discloses a 0.065 inch outer diameter. *Id*., 4:50-52. Kontos does not disclose the cross-sectional inner diameter of the guide catheter. Ex-1405, ¶ 249. 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 catheter. Ex-1405, ¶¶ 77-80, 250; Ex-1442, ¶¶ 97-98; Ex-1410, at 452.

It would have been obvious to modify Kontos in light of Adams and Takahashi to achieve the not-more-than-one French differential. Indeed, Kontos, Adams, 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 '413 patent. Ex-1405, ¶ 251.

A POSITA would have been motivated to combine Takahashi with Kontos and Adams, given the former teaches that the not-more-than-one French differential improved backup support of its catheter assembly. *Id.*; Ex-1442, ¶¶ 99-101. 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.

In particular, as discussed for claim 4, a POSITA would have had a reasonable expectation of success when removing Kontos's funnel in favor of a side opening. Section VIII.D, *supra*. Doing so would permit a POSITA to achieve the not-more-than-one-French differential as taught by Takahashi. Ex-1442, ¶ 101 (describing that use of side opening permits close seating of child and mother catheters). 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, ¶¶ 101-02; Ex-1409, 4:21-24, 4:31-34, 4:61-5:2; 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, ¶ 252; Ex-1442, ¶ 103; *KSR*, 550 U.S. at 417.

X. SECONDARY CONSIDERATIONS

Any purported secondary indicia should not preclude institution. As a threshold matter, the PTAB already addressed this issue in its institution decision for related patents, explaining that, "as in most cases, an analysis of objective evidence of nonobviousness is best made on a complete trial record, and not upon the incomplete record presented at the institution stage." Ex-1513, at 27. That rationale aligns with the PTAB's prior practice of not—absent a previous finding at the Patent Office or by a Court that such evidence exists—addressing secondary indicia of non-obviousness until the trial phase. *Lowe's, Cos., Inc. v. Nichia Corp.*, IPR2017-02011, Paper 13 at 18 (P.T.A.B. Mar. 12, 2018); *C&D Zodiac, Inc. v. b/e Aerospace, Inc.*, IPR2017-01275, Paper 12 at 15 (P.T.A.B. Oct. 31, 2017); *Arctic Cat, Inc. v. Polaris Industries Inc.*, IPR2017-00433, Paper 17 at 9-10, 19 (P.T.A.B. July 5, 2017).

Even if a pre-institution obligation existed, the PTAB explained in its institution decisions for related patents that Patent Owner has identified no secondary indicia for Petitioner to prebut in this Petition. Indeed, Patent Owner attempted to identify secondary indicia in prior IPRs, but the PTAB held that the purported evidence of non-obviousness lacked any nexus to the alleged invention. Ex-1513, at 27-29. In other words, because Patent Owner has not provided any "persuasive analysis" demonstrating a nexus between the alleged secondary indicia

and the claims of this patent (or any related patents), there is nothing for Petitioner to respond to in this Petition. *Id.*

Regardless, even if secondary indicia existed, they cannot overcome Petitioner's strong showing of obviousness. *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1374 (Fed. Cir. 2018) (holding that "a strong showing of obviousness may stand even in the face of considerable evidence of secondary considerations"). Accordingly, even if Patent Owner advances evidence of secondary indicia in its preliminary response, this Board should grant institution.

XI. CONCLUSION

Petitioner respectfully requests institution of a trial and invalidation of claims 1-2, 4-5, and 7-14 of the '413 patent.

Date: July 30, 2020

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I hereby certify that the Petition for *inter partes* review consists of 13,930 words in 14 point Times New Roman font as calculated by the word count feature Microsoft Office 2016, in compliance with 37 C.F.R. § 42.24(a)(i). This word count is inclusive of all text and footnotes but not including a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence was served on July 30, 2020, by Federal Express mail to the USPTO correspondence address of record listed below:

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