PETITIONER'S DEMONSTRATIVES

Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Life Sciences Limited

IPR2020-01341, -01342, -01343, -01344

November 18, 2021
ORAL HEARING

Conception and Reduction to Practice

New Issues: Method-of-Use Claims

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature,

25. A method, comprising:
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide cath-

'413 patent, claim 1; '116 patent, claim 25.

Teleflex cannot prove prior invention before Itou.

- No evidence corroborating assembly of RX prototypes.
- **No dispute that VSI did not perform the claimed methods.**
- **No evidence of required intended purpose testing.**
- Affirmative evidence showing VSI back-burnered RX and could not have reduced to practice—actually or constructively—before Itou.

Teleflex must prove prior invention.

Teleflex bears “the burden of **going forward with evidence** . . . and **presenting persuasive argument** based on” that evidence.

Dynamic Drinkware, LLC v. Nat’l Graphics, Inc., 800 F.3d 1375, 1379-80 (Fed. Cir. 2015).

-01341 Reply at 8; -01343 Reply at 3.

Reduction to Practice

Reduction to Practice

To prove reduction to practice, Teleflex must show:

(1) "**performance of a process** that met all the limitations of the [claimed method];

(2) **determination that the invention would work for its intended purpose**; and

(3) the existence of **sufficient evidence to corroborate inventor testimony** regarding these events."

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1169 (Fed. Cir. 2006).

"Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence . . . ."

Id. at 1171-72.

-01341 Reply at 8; -01343 Reply at 3-4.

Reduction to Practice: Performing + Demonstrating

1. **Perform a process that meets all limitations of the claimed invention.**

2. **Demonstrate that the invention would work for its intended purpose.**

Reduction to Practice: Performing + Demonstrating

1. Perform a process that meets all limitations of the claimed invention.

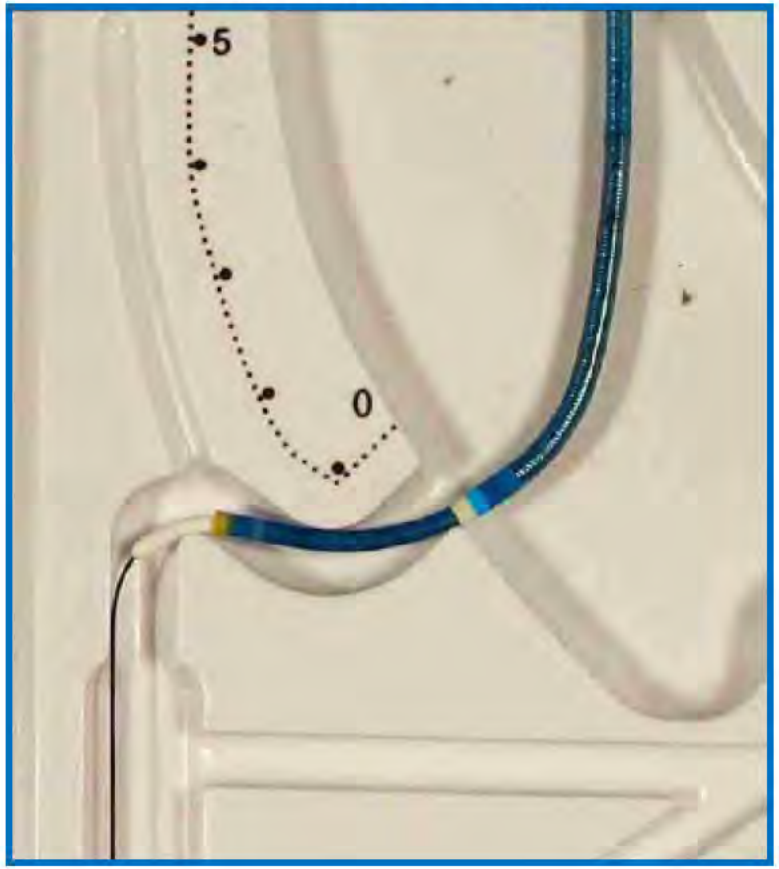
2. **Demonstrate that the invention would work for its intended purpose.**

VSI intended to develop an OTW GuideLiner (prior art).

OTW GEC:

- Full-length lumen
- Mother-and-child
- Prior art

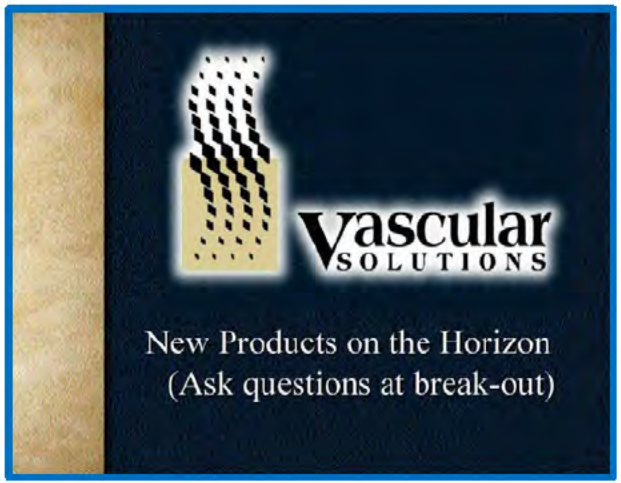
GuideLiner OTW Prototype

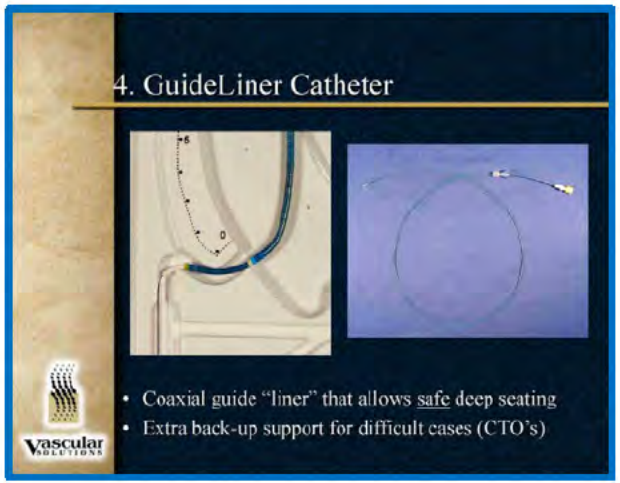


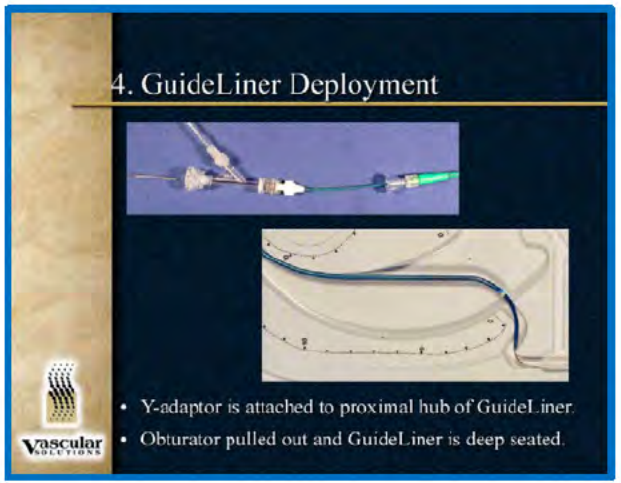
Ex-2129.

VSI intended to develop an OTW GuideLiner (prior art).

July 2005
GuideLiner OTW
"New Product[] on the Horizon"



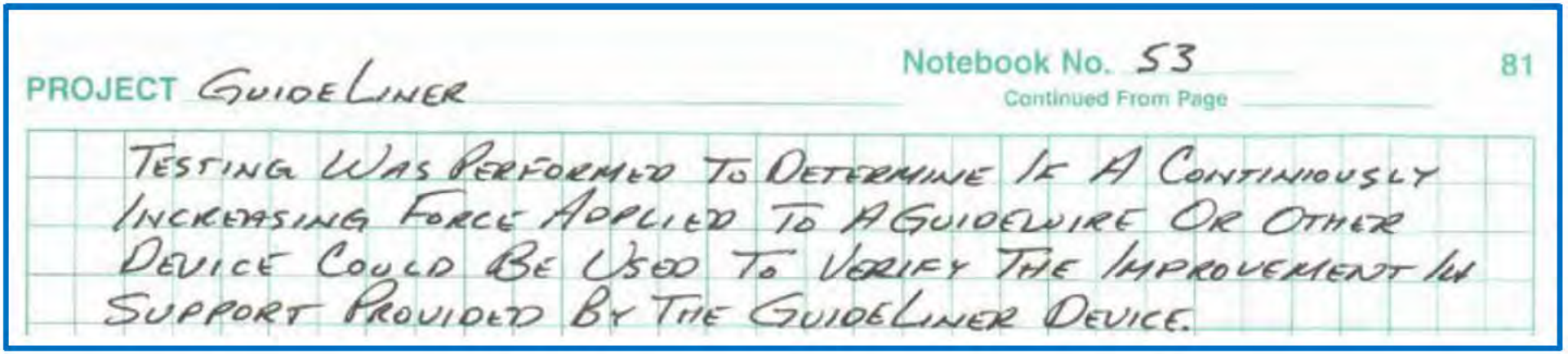




Ex-2129.

VSI intended to develop an OTW GuideLiner (prior art).

August / September / November 2005
GuideLiner OTW Testing



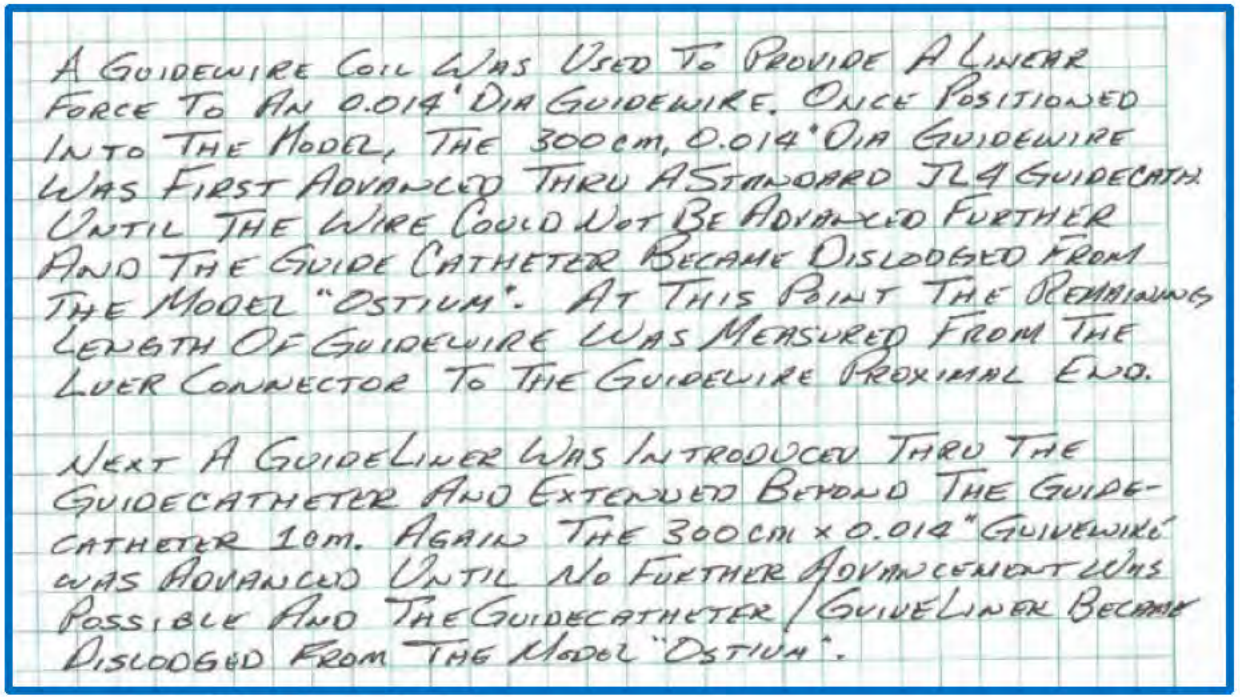
PROJECT GUIDELINER Notebook No. 53 81
Continued From Page

TESTING WAS PERFORMED TO DETERMINE IF A CONTINIOUSLY INCREASING FORCE APPLIED TO A GUIDEWIRE OR OTHER DEVICE COULD BE USED TO VERIFY THE IMPROVEMENT IN SUPPORT PROVIDED BY THE GUIDELINER DEVICE.

Ex-1760, 86-93; -01341 Reply at 10, 18; -01343 Reply at 5, 13.

VSI intended to develop an OTW GuideLiner (prior art).

August / September / November 2005
GuideLiner OTW Testing



A Guidewire Coil Was Used To Provide A Linear Force To An 0.014" Dia Guidewire. Once Positioned Into The Model, The 300cm, 0.014" Dia Guidewire Was First Advanced Thru A Standard JL4 Guidecath Until The Wire Could Not Be Advanced Further And The Guide Catheter Became Dislodged From The Model "Ostium". At This Point The Remaining Length Of Guidewire Was Measured From The Luer Connector To The Guidewire Proximal End.

Next A GuideLiner Was Introduced Thru The Guidecatheter And Extended Beyond The Guide-catheter 10m. Again The 300cm x 0.014" Guidewire was Advanced Until No Further Advancement Was Possible And The Guidecatheter / GuideLiner Became Dislodged From The Model "Ostium".

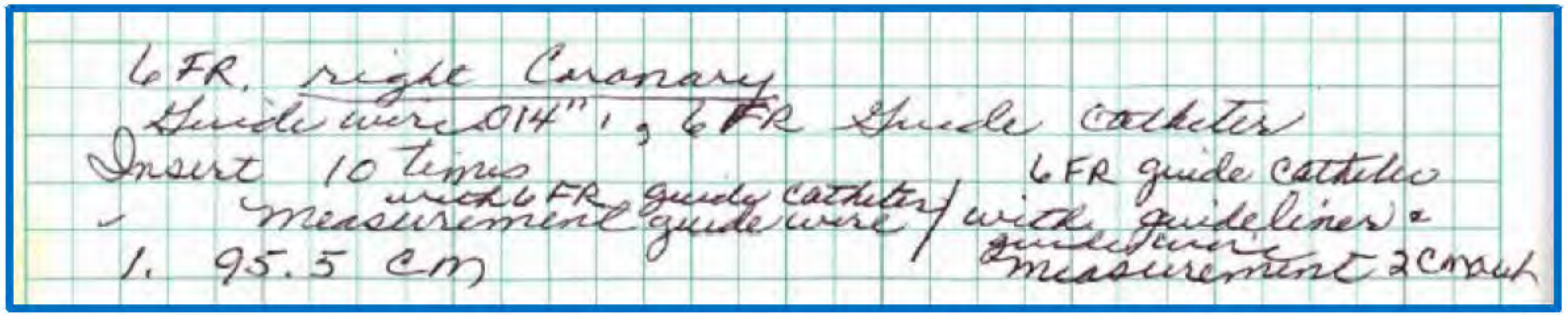
GC Backup Support Test

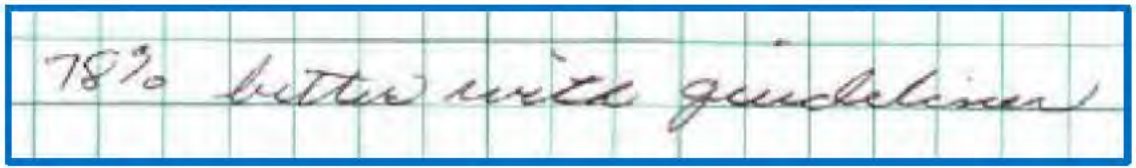
GEC Backup Support Test

Ex-1760, 86-93; -01341 Reply at 10, 18; -01343 Reply at 5, 13.

VSI intended to develop an OTW GuideLiner (prior art).

August / September / November 2005
GuideLiner OTW Testing


6 FR. right Coronary
Guide wire .014" / 6 FR Guide Catheter
Insert 10 times
with 6 FR guide catheter / with guideliner
Measurement guide wire
1. 95.5 cm
6 FR guide catheter
Guideliner
Measurement 2 cm each


78% better with guideliner

Ex-1761, 107; -01341 Reply at 10, 18; -01343 Reply at 5, 13.

VSI developed and tested GuideLiner OTW.

- **OTW** meetings.
- **OTW** photographs.
- **OTW** presentations.
- **OTW** laboratory notebook entries.
- **OTW** testing.

Ex-2129; Ex-1760; Ex-1761.

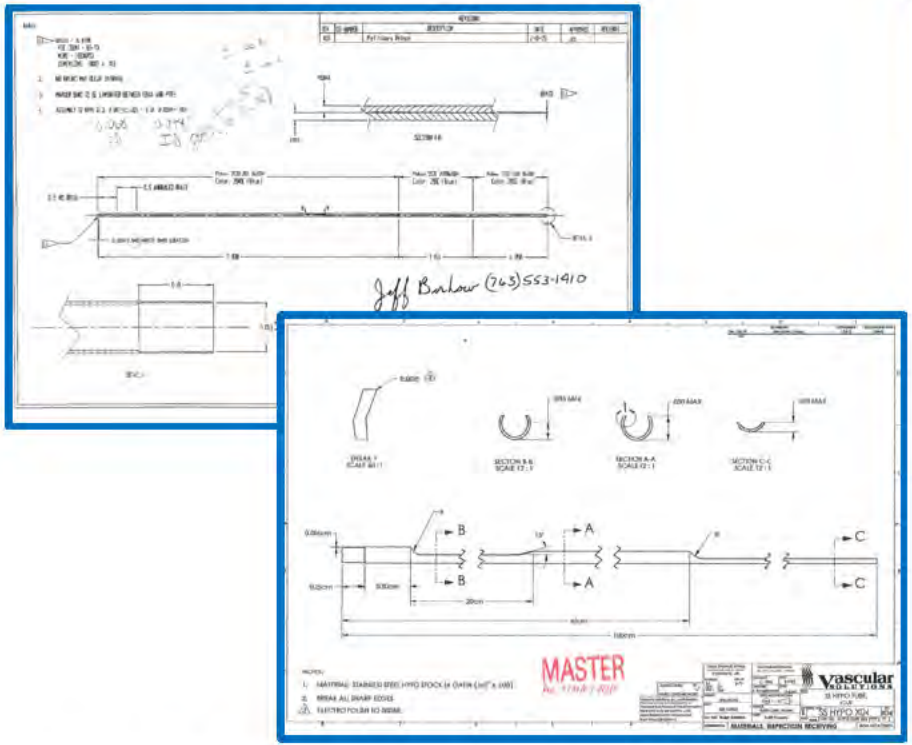
VSI did *not* perform critical RX work.

- **No** prototypes.
- **No** photographs.
- **No** assembly documents.
- **No** laboratory notebook entries.
- **No** testing protocols.
- **No** testing notes / data / results.

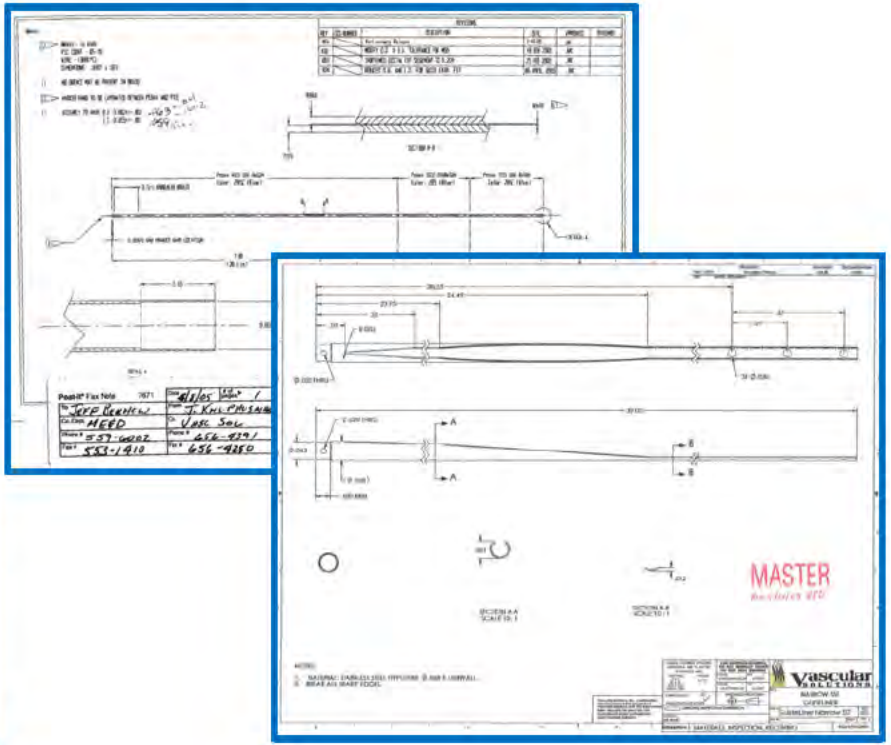
Ex-1796 (Sutton); Ex-1758 (Welch); Ex-1760 (Kauphusman); Ex-1761 (Mytty); -01341 Reply at 10; -01343 Reply at 5.

No document shows that VSI assembled an RX prototype.

"April Prototype"



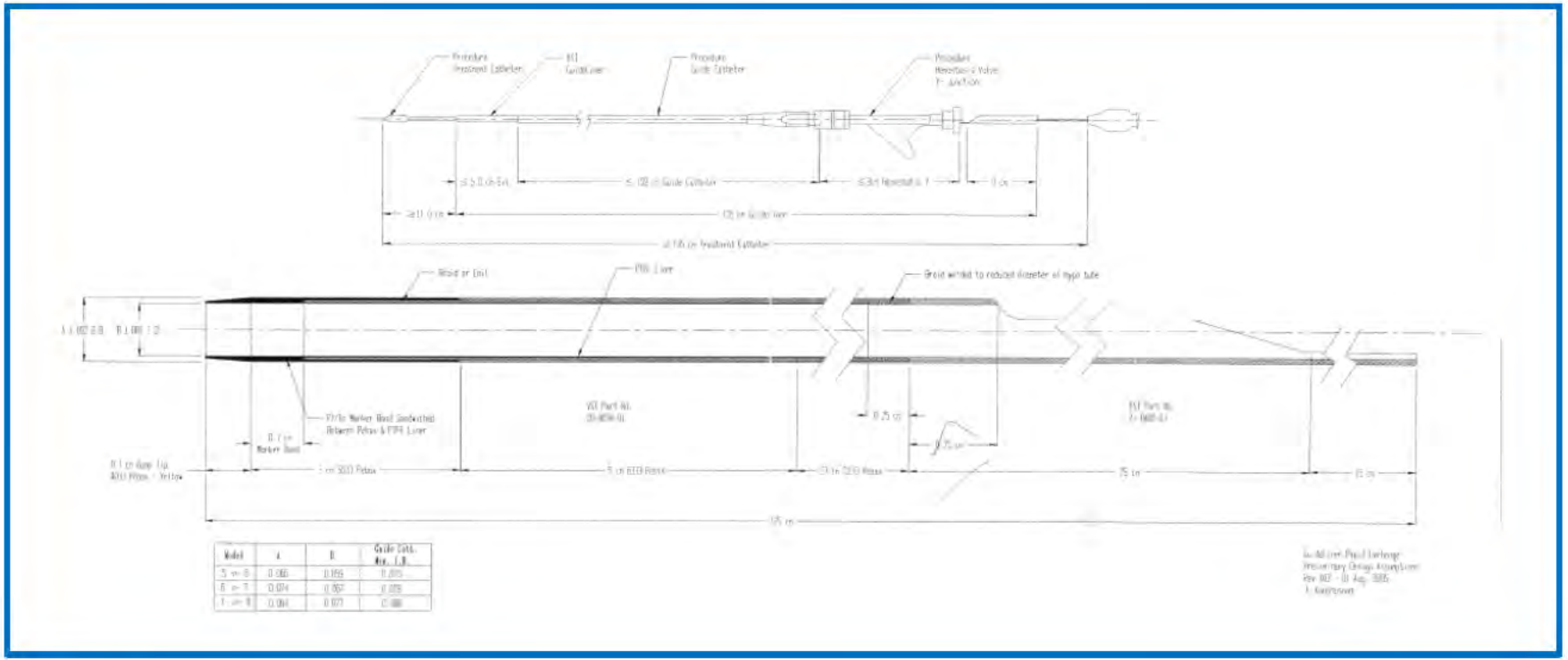
"July Prototype"



Ex-2089; Ex-2113; Ex-2092; Ex-2114; -01341 Reply at 10; -01343 Reply at 5.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Exhibit 2022 does not show that VSI assembled an RX prototype.



Ex-2022; -01341 Reply at 10 n.4; -01343 Reply at 5 n.2.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Exhibit 2022 does not show that VSI assembled an RX prototype.

Root:

Q. Okay. Now go back to my original question. In your declaration assessing reduction to practice, including your charts in Exhibit A, you do not contend that VSI built prototypes according to Exhibit 2022, prior to September 23rd, 2005; right?

A. **Not with that specific dimensions of the side opening, I'm not doing -- I'm not claiming that. I'm claiming it's built along the lines of 2114 for the July, and 2113 for the April.**

same answer. You do not contend in your reduction-to-practice analysis, that this Exhibit 2022 was tested and shown to work for its intended purpose prior to September 23, 2005; right?

A. **Not that specific dimension of the side opening, no.**

Ex-1798, 55:16-56:14; -01341 Reply at 10 n.4; -01343 Reply at 5 n.2.

Reduction to Practice: Performing + Demonstrating

1. Perform a process that meets all limitations of the claimed invention.

2. **Demonstrate that the invention would work for its intended purpose.**

The patents claim *methods of using* GECs.

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, 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, 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:

inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

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,

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;

advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery 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

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.

'413 patent, claim 1; -01341 Reply at 12-13.

The patents claim *methods of using* GECs.

25. A method, comprising:

advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;

advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and

while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.

'116 patent, claim 25; -01343 Reply at 7-8.

Teleflex must show that VSI performed the methods, as claimed.

Possibility or capability is not enough:

Though "a computer executing the algorithm . . . would perform all the method steps of claim 13, the thesis alone cannot show that the method was ever performed."

Lucent Techs., Inc. v. Gateway, Inc., No. 02-cv-2060-B(CAB), 2007 WL 2070346, at *2 (S.D. Cal. July 12, 2007).

-01341 Reply at 12; -01343 Reply at 7.

Teleflex must show that VSI performed the methods, as claimed.

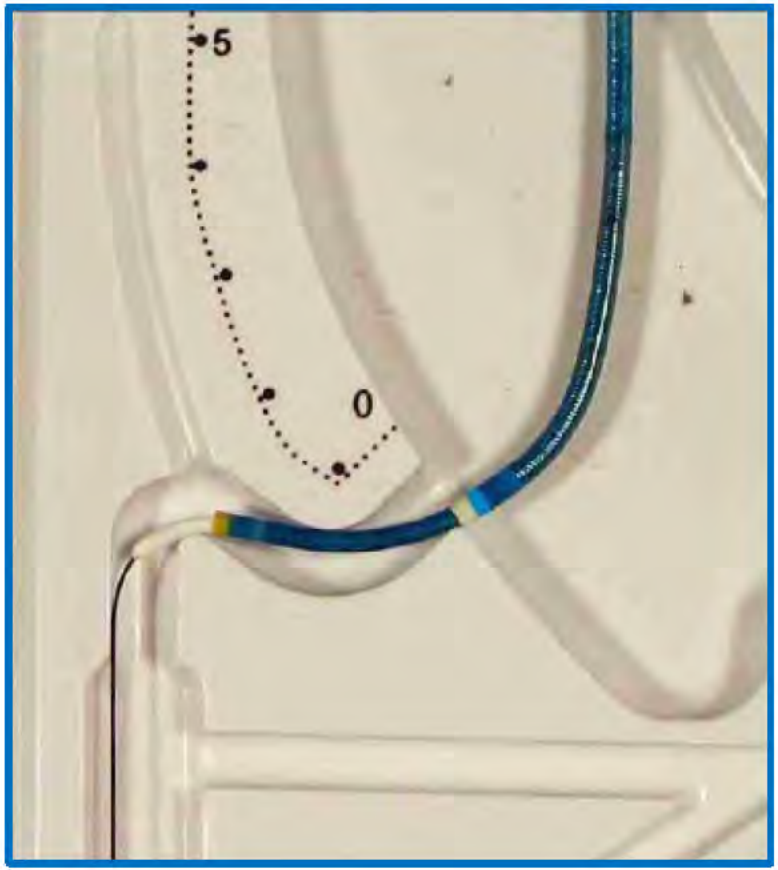
Simulating the claimed method is not enough:

"[C]omputer simulations could not meet all the limitations of the asserted claims, [thus] they are insufficient to show actual reduction to practice."

TC Tech. LLC v. Sprint Corp., 379 F. Supp. 3d 305, 319 (D. Del. 2019).

-01341 Reply at 13; -01343 Reply at 7-8.

Teleflex cannot show that VSI performed the methods, as claimed.



Ex-2129.

Teleflex cannot show that VSI performed the methods.

Root:

Q. Okay. And so you can't pinpoint for me when any particular confirmatory test occurred; is that right?

A. **I can give you a pretty good range of when it occurred, but I can't give you an exact date.**

Q. Okay. And you also don't say who would have performed a confirmatory test; is that right?

A. **I don't think I have names in this -- in this paragraph. I don't.**

Q. Okay. And sitting here today, you can't say for sure who performed some confirmatory test.

A. **Well I -- I know that I did some of that testing, along with Gregg Sutton and Jason Garrity and Jeff Welch, and there were other people, but I can't tell you exactly who.**

Q. Okay. And can you do that by reference to a specific date and/or prototype?

A. **Well I can't do it to a date. I can give you a range of when it occurred, but I can't give you a specific day that it happened. And the prototype -- the picture here in 17 is one of the prototypes we used. We also had a more three-dimensional model that we used in order to simulate the coronary anatomy.**

Q. Okay. So --

All right. The picture you've got there, you've mentioned this several times, but we all know that's not the rapid exchange version of GuideLiner; right?

A. **I -- I --**

Yeah, I think this is the over-the-wire version in this picture.

Ex-1798, 22:1-23:25; -01341 Reply at 13-14; -01343 Reply at 8-9.

Teleflex cannot show that VSI performed the methods.

Erb worked on separate, early prototypes that did not embody the inventions:

> 8. As a machinist for the group, I worked on the early GuideLiner prototypes. Specifically, I machined-down the hypotubes that were used to form the proximal end of the early prototypes of that device. I personally made a special jig to hold the hypotubes and then used a vertical milling machine to cut the tubes along their length.

Ex-2122 ¶ 8; -01341 Reply at 9; -01343 Reply at 4.

Teleflex cannot show that VSI performed the methods.

Erb could barely remember relevant components *when coached*:

Attempt #1

Q. Do you see the drawing that I'm looking at, Mr. Erb?
A. Yes.
Q. What is the date on that drawing? And you can zoom in with the tool.
A. Yeah.
Q. You can zoom in. There's a little magnifying glass with a plus sign.
A. Yes. Okay. It looks like 6/21/05.
Q. Do you recall seeing a prototype made using this part in 2005?
A. No, I do not.

Attempt #2

Q. So if you look at the drawing, it's dated June 21st, 2005?
A. Correct.
Q. Is this a Vascular Solutions drawing?
A. Yes.
Q. And if you look at the drawing, you can see that there's a -- I guess, does the drawing look to you to be a cut-down hypotube?
A. Yes, it does.
Q. And do you recall seeing a prototype like this that was made in 2005?
A. I do not remember.

Ex-2248, 93:14-95:12; -01341 Reply at 11; -01343 Reply at 6.

Teleflex cannot show that VSI performed the methods.

Erb reviewed the relevant component parts drawings only for this proceeding:

Q. When did you first review the engineering drawings that you discuss in paragraphs 14 to 18?

A. **It would have been when I did my declaration there, so. As far as I remember, okay, so that was...**

Q. Had you seen these engineering drawings before you created your declaration for these proceedings?

A. **Yeah, I don't -- I don't remember if I did or not.**

Ex-1799, 22:5-8, 23:21-24:1.

Teleflex cannot show that VSI performed the methods.

Erb "was not personally involved" in critical testing and only helped assemble unidentified "subsequent prototypes" subject to unidentified testing:

12. These prototypes were then tested, including for durability with basic pull-tests and for functionality in two-dimensional benchtop heart models to ensure that the device could get where it needed to go in the vasculature and to understand the forces involved in maneuvering the GuideLiner through the heart model. Although it goes without saying, as part of the testing, we also pulled the GuideLiner prototype back out of the heart models. I personally was involved in some of these tests on the GuideLiner prototypes. I also was aware of, though was not personally involved in, tests of the GuideLiner prototypes involving the delivery of stents and balloons in a benchtop heart model. Whenever a prototype

19. I primarily was involved in making prototypes before we started outsourcing the laser cutting to LSA and SPECTRAlytics. However, I did help assemble some of the subsequent prototypes. Additional testing, including testing of the kinds mentioned above, was performed on these subsequent prototypes. I recall watching Howard Root and others working in R&D test these subsequent prototypes, as well.

Ex-2122 ¶¶ 12, 19; -01341 Reply at 14-15 n.7; -01343 Reply at 9-10 n.6.

Reduction to Practice: Performing + Demonstrating

1. **Perform a process that meets all limitations of the claimed invention.**

2. **Demonstrate that the invention would work for its intended purpose.**

Intended Purpose

Intended purpose: “to increase backup support for delivery of interventional cardiology devices,” with “crossing tough or total occlusions [being] one noted benefit of the invention.”

IPR2020-00128 Final Written Decision (Paper 127), 55-56.

Intended Purpose

Intended purpose: "to increase backup support for delivery of interventional cardiology devices," with "crossing tough or total occlusions [being] one noted benefit of the invention."

Demonstrating that the invention would work for that intended purpose: comparative benchtop testing using simulated challenging anatomy.

IPR2020-00128 Final Written Decision (Paper 127), 55-56.

Demonstrating Intended Purpose

1. **Set up model simulating challenging anatomy, e.g., a lesion.**

Keith:

Q. Sure. So those -- and we've talked about those before, tight lesions, tortuous anatomy, et cetera.

Is it possible to test for those things in a benchtop model or to create those kinds of challenging coronary anatomy?

A. Yeah. I think one can simulate that fairly well in a bench model.

Q. What do you have to do -- I don't know how benchtop models work. I assume that they're pretty standard.

But how do you set up a benchtop model such that it's presenting challenging coronary anatomy?

A. Well, for example, I would set it up so that the simulated blood vessel has curvature in it versus being perfectly straight. And perhaps a restricted area that represents a lesion.

Ex-1764, 64:2-17; -01341 Reply at 18; -01343 Reply at 13.

Demonstrating Intended Purpose

1. Set up model simulating challenging anatomy, e.g., a lesion.

2. **Run prototype through and advance ICD to test accessing and crossing.**

Keith:

Q. Sure. And you could also make observations about whether a GuideLiner prototype, for instance, had any kinking problems?

A. If it kinked, that could be an observable thing, yes.

Q. And after you had used a prototype setup like we discussed in tortuous anatomy with a tight lesion, you could see whether there was any issue with the connection between the distal and proximal portions on the way in or on the way out, right?

A. Yeah, those are things that could be observed as part of that testing if one wanted to.

Ex-1764, 66:14-25, 67:4-10; -01341 Reply at 18; -01343 Reply at 13.

Comparative testing measures relative backup support.

1. Set up model simulating challenging anatomy, e.g., a lesion.
2. Run prototype through and advance ICD to test accessing and crossing.
3. **Compare the prototype's backup support to a standard GC.**

Keith:

Q. Okay. And so what you've said today is that even if you don't have tortuosity and even if you don't have a tight passageway or tough or chronic total occlusion, you could still perform comparative testing that would tell you something about how the device operates; right? I have that right?

A. Yes.

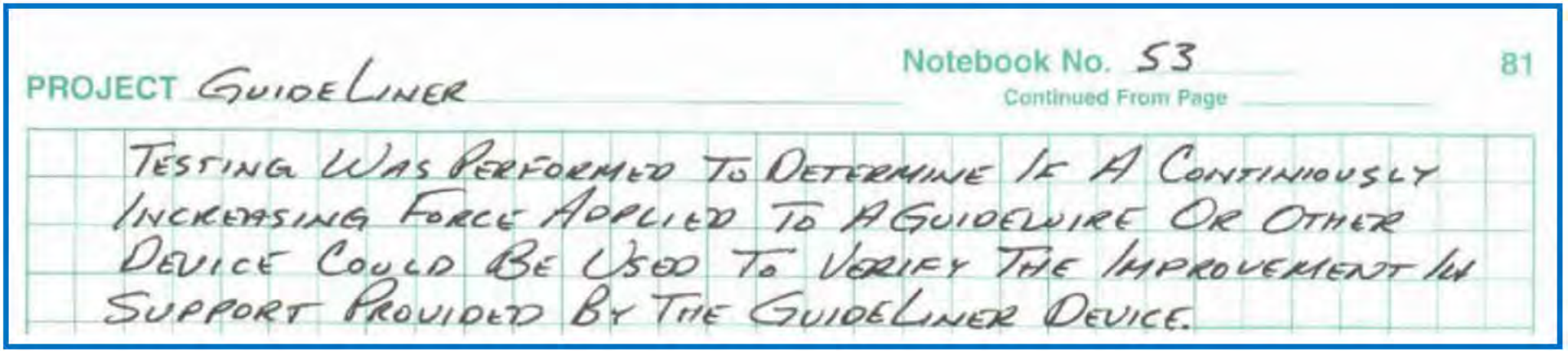
Q. And in that comparative testing I guess you would put two different devices through this same anatomy and -- and somehow see how they performed?

A. You could do that, or you could put -- you know, pass a -- a device without the assistance of a guide extension catheter, you could pass that down and then put the guide extension catheter in and observe the differences.

Ex-1797, 82:11-25; -01341 Reply at 18; -01343 Reply at 13.

VSI performed the requisite comparative testing—for OTW.

August / September / November 2005
GuideLiner OTW Testing



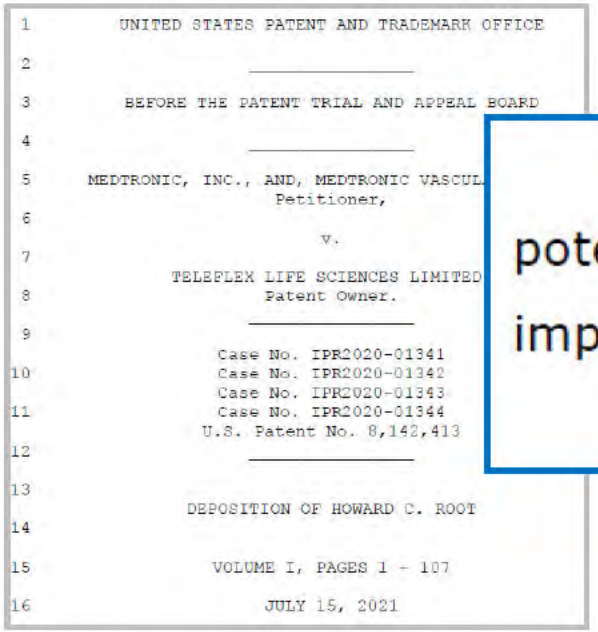
PROJECT GUIDELINER Notebook No. 53 81
Continued From Page

TESTING WAS PERFORMED TO DETERMINE IF A CONTINIOUSLY INCREASING FORCE APPLIED TO A GUIDEWIRE OR OTHER DEVICE COULD BE USED TO VERIFY THE IMPROVEMENT IN SUPPORT PROVIDED BY THE GUIDELINER DEVICE.

Ex-1760, 86-93; -01341 Reply at 10, 18; -01343 Reply at 5, 13.

VSI performed the requisite comparative testing—for OTW.

August / September / November 2005
GuideLiner OTW Testing



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND, MEDTRONIC VASCUL
Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED
Patent Owner.

Case No. IPR2020-01341
Case No. IPR2020-01342
Case No. IPR2020-01343
Case No. IPR2020-01344
U.S. Patent No. 8,142,413

DEPOSITION OF HOWARD C. ROOT

VOLUME I, PAGES 1 - 107

JULY 15, 2021

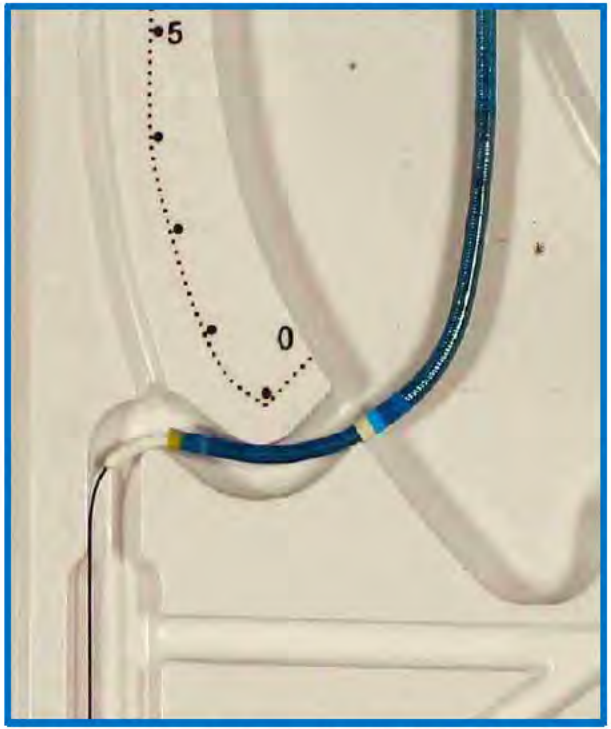
Q. Okay. So this test would actually potentially show the improvement or measure the improvement in back-up support?

A. **I'd say it measured the improvement.**

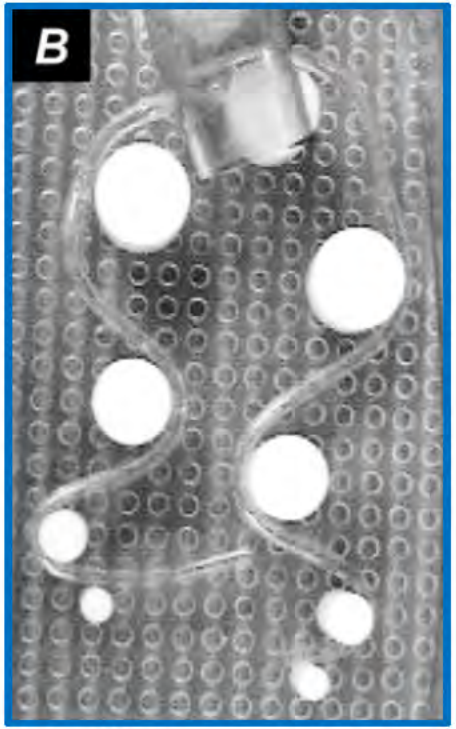
Ex-1798, 57:25-61:9; -01341 Reply at 18; -01343 Reply at 13.

Teleflex cannot show that VSI performed required testing.

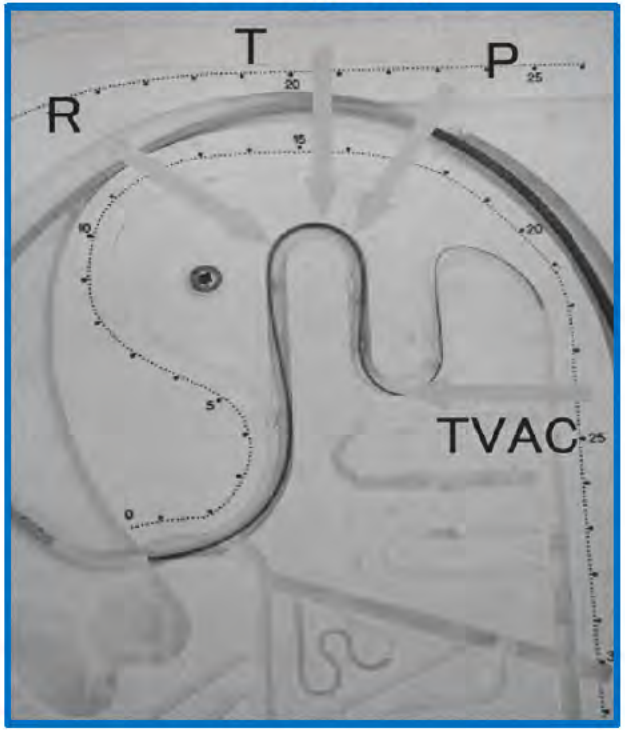
VSI Benchtop Model (with OTW)
July 2005



Takahashi
Demonstrating Increased
Backup Support



Sakurada
Demonstrating Improved
Crossing Ability



Ex-2129; Ex-1010; Ex-1055; -01341 Reply at 18-20; -01343 Reply at 13-15.

Teleflex cannot show that VSI performed required testing.

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12. These prototypes were then tested, including for durability with basic pull-tests and for functionality in two-dimensional benchtop heart models to ensure that the device could get where it needed to go in the vasculature and to understand the forces involved in maneuvering the GuideLiner through the heart model. Although it goes without saying, as part of the testing, we also pulled the GuideLiner prototype back out of the heart models. I personally was involved in some of these tests on the GuideLiner prototypes. I also was aware of, though was not personally involved in, tests of the GuideLiner prototypes involving the delivery of stents and balloons in a benchtop heart model. Whenever a prototype

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Ex-2122 ¶¶ 12, 19; -01341 Reply at 14-15 n.7; -01343 Reply at 9-10 n.6.

Teleflex cannot show that VSI performed required testing.

Schmalz
VSI VP of Regulatory

Q. Understood. Now, you did not conceive of the GuideLiner rapid exchange invention; is that correct?
A. That is correct.
Q. And you did not personally build prototypes of the GuideLiner rapid exchange device; is that correct?
A. That is correct.
Q. And you did not personally test any prototypes of the GuideLiner rapid exchange device; is that correct?
A. That is correct.

Ex-1766, 34:11-35:1; -01341 Reply at 14-16; -01343 Reply at 9-10.

The Board needs to be able to assess testing evidence.

The Board judges "[t]he adequacy of a reduction to practice . . . by **what one of ordinary skill in the art would conclude from the results of the tests**."

Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1265 (Fed. Cir. 2002).

The Board considers "**whether the testing in fact demonstrated a solution** to the problem intended to be solved by the invention."

Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994).

-01341 Reply at 20; -01343 Reply at 15.

Diligence

Teleflex cannot prove that VSI was diligent.

"[T]o antedate a reference, the applicant must not only have conceived the invention before the reference date, **but must have reasonably continued activity to reduce the invention to practice**."

ATI Techs. ULC v. Iancu, 920 F.3d 1362, 1369 (Fed. Cir. 2019).

"Reasonable diligence must be shown **throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice**."

Perfect Surgical Techniques, Inc. v. Olympus Am., Inc., 841 F.3d 1004, 1007 (Fed. Cir. 2016).

-01341 Reply at 21; -01343 Reply at 16.

Teleflex cannot prove that VSI was diligent.

Component Parts Drawings

Ex-2115; -01341 Reply at 22-23; -01343 Reply at 17-18.

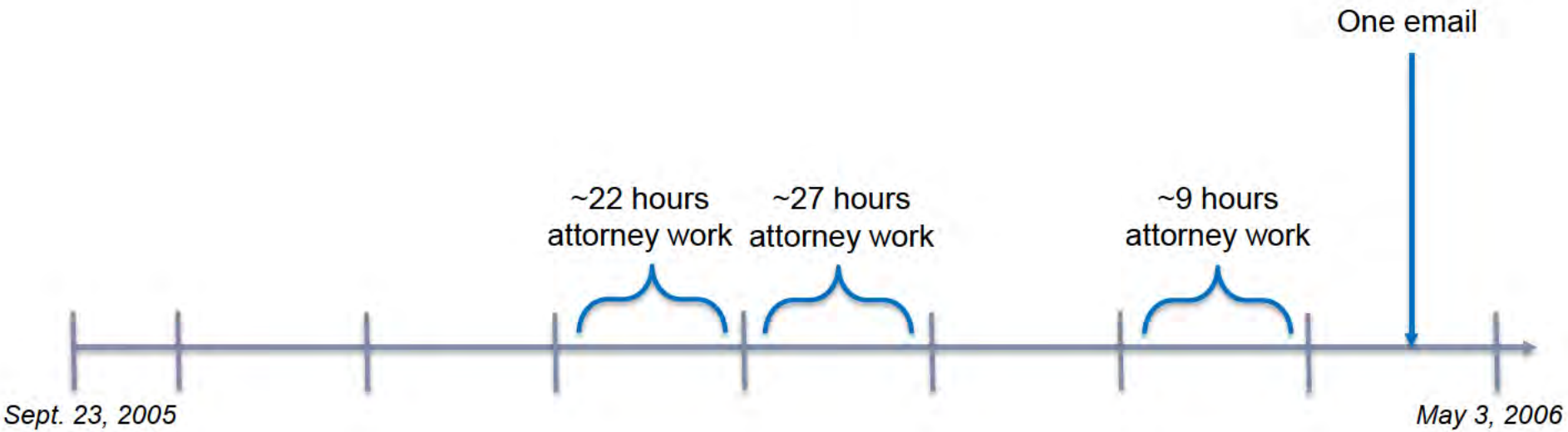
Teleflex cannot prove that VSI was diligent.

Parts Purchases

Ex-2104; Ex-2106; Ex-2107; Ex-2108; -01341 Reply at 22-23; -01343 Reply at 17-18.

Teleflex cannot prove that VSI was diligent.

Prosecution Work



Ex-2101; Ex-2102; Ex-2103; Ex-2117; -01341 Reply at 22-23; -01343 Reply at 17-18.

Teleflex cannot prove that VSI was diligent.

Root:

Q. Okay. And do you know specifically any of that activity you're talking about occurred between September of 2005 and May of 2006?

A. **I know that that work occurred during that period of time, but I can't specify what event happened at what date on that timeframe.** But it was a

Q. In order to meet that deadline that we know was not met, and not even close to being met; right?

A. **Well again, the work wasn't done, so therefore the deadline, or I would call it the goal, wasn't met.** **It took longer to get the work done, therefore the goal wasn't achieved.**

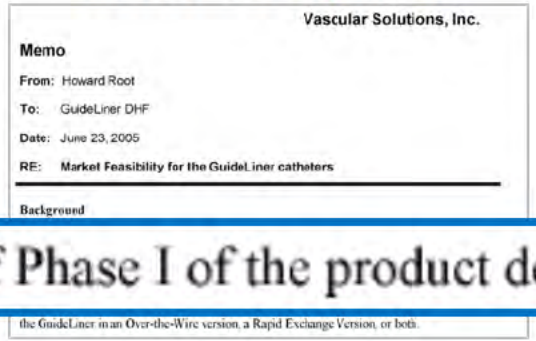
Ex-1798, 74:19-24, 87:3-8; -01341 Reply at 23; -01343 Reply at 18.

The Counter-Narrative

VSI did not reduce to practice—actually or constructively—before Itou.

2005

June 2005
Market Feasibility Memo



Vascular Solutions, Inc.

Memo

From: Howard Root

To: GuideLiner DHF

Date: June 23, 2005

RE: **Market Feasibility for the GuideLiner catheters**

Background

"As part of Phase I of the product development

the GuideLiner in an Over-the-Wire version, a Rapid Exchange Version, or both.

Zalesky:

172. Mr. Root discusses a market feasibility memo dated June 23, 2005, in which he discusses both an OTW and an RX version of the GuideLiner catheter. **Ex-2118** ¶ 37, citing **Ex-2017**. In my experience, assessing market feasibility is an early step in the Concept/Feasibility Phase, usually produced prior to any technical work. It provides justification for allocating resources to the prospective new project, and is usually among the very earliest entries into a DHF.

Ex-2128; Ex-1755 ¶ 172; -01341 Reply at 24; -01343 Reply at 19.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

VSI did not reduce to practice—actually or constructively—before Itou.

2005

July 2005
RX Design TBD

Vascular Solutions, Inc.
Research & Development Update
July 2005

GuideLiner Device
A device for providing extra guide catheter back-up support during PTCA procedures.

"rapid exchange version to follow."

Ex-2130; -01341 Reply at 24; -01343 Reply at 19.

VSI did not reduce to practice—actually or constructively—before Itou.

2005

August 2005 (?)

RX Product Requirements Incomplete

PRODUCT REQUIREMENTS:
GuideLiner Catheter System

Document Approvals

Reviewer	J. Kauphsman	8/24/05
Documentation	J. Kujawa	8/24/05

3. REQUIREMENTS/SPECIFICATIONS

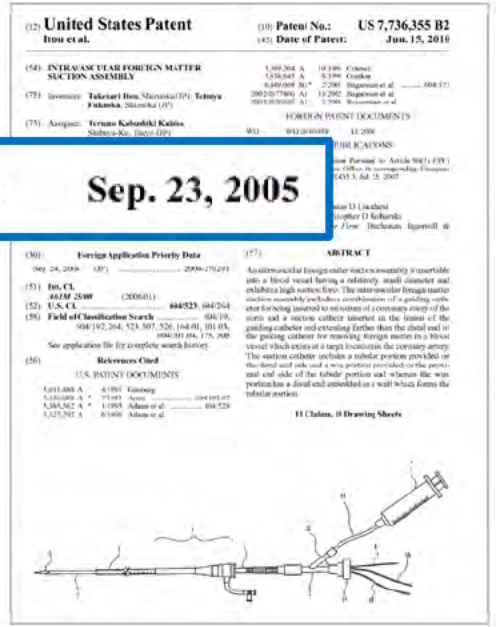
USER REQUIREMENTS	PRODUCT SPECIFICATIONS	TEST METHOD
3.1 Performance Requirements		
The catheter system must allow for advancement of the treatment catheter beyond (deeper) than using a guide catheter alone.		
The catheter system must be capable of withstanding normal insertion and removal forces through commonly used guide catheters and through the arterial system.		
The catheter system must slide inside the guide catheter and through the anticipated vasculature and be able to navigate the blood vessels without kinking.		
The catheter system must provide for an atraumatic entry into and travel through the blood vessel.		

Ex-2024; Ex-1755 ¶¶ 196-200; -01341 Reply at 24; -01343 Reply at 19.

VSI did not reduce to practice—actually or constructively—before Itou.

2005

September 2005
Itou



(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takeari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

FOREIGN PATENT DOCUMENTS

Filed: **Sep. 23, 2005**

(30) **Foreign Application Priority Data**

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 175, 508
See application file for complete search history.

(56) **References Cited**
U.S. PATENT DOCUMENTS

(57) **ABSTRACT**

11 Claims, 8 Drawing Sheets

Ex-1007.

VSI did not reduce to practice—actually or constructively—before Itou.

Vascular Solutions, Inc.
2006 Strategic Objectives

The over-the-wire version is expected to be launched in the U.S. and Germany [illegible]

"The rapid exchange version requires additional engineering and is not included in our 2006 forecasts."

Ex-2131; -01341 Reply at 25; -01343 Reply at 20.

VSI did not reduce to practice—actually or constructively—before Itou.

2005

December 2005
Additional Engineering Required

0370	12-2-2005	Guide liner DVT - Build	Jim K	N/A	R.S. 2-17-06 Design Change Not completed
0371	12-2-2005	Guide liner DVT - Build	Jim K	N/A	
0372	12-2-2005	Guide liner DVT - Build	Jim K.	N/A	
0373	12-2-2005	Guide liner DVT - Luer Assy.	Jim K.	N/A	
0374	12-2-2005	Guide liner DVT - Luer Assy	Jim K.	N/A	
0375	12-2-2005	Guide liner DVT - Luer Assy	Jim K.	N/A	

Sutton:

Q. What is design verification testing?

A. It's performance testing to verify the design works as intended.

Ex-1768, 14; Ex-1757, 77:16-18; -01341 Reply at 25; -01343 Reply at 20.

VSI did not reduce to practice—actually or constructively—before Itou.

2007

April 2007
RX Design In Progress

R&D Device Idea List	04-30-2007 page 1

Idea Name	Prior	Project Leader	Concept Drawing	Design Freeze	Status / Comments
Varilase Bright Tip Rail 5000-85000-05019	1	J. Welch	4/20/07	TBD	- Concept of ceramic 5mm rail samples - Coors Tec quoting price and lead time for mold - Project review scheduled for today
Guide-Liner A guide catheter support device to aid in delivery of treatment catheters 5000-85000-05005	2	J. Welch	TBD	5/30/07	- Assembly of polymer shaft to NiTi backbone repeatability issues - New adhesive with new LED light source being investigated - Assembly cost for GuideLiner with

Concept Drawing: TBD
Design Freeze: May 30, 2007

22. How strong is the bond between the metal collar and the guide extension on the GuideLiner?

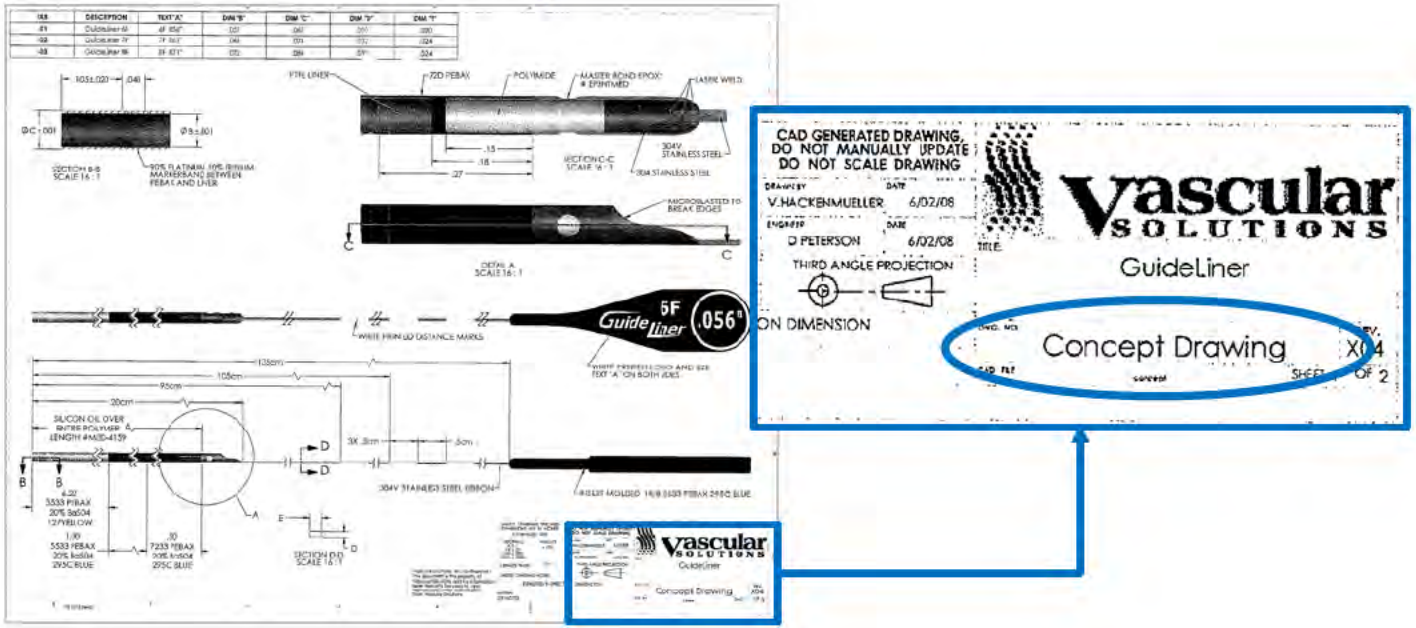
That is the part that took substantial engineering and testing. We did many pull tests on validation lots of the GuideLiner and the catheter would withstand at least a 3.5 lb. pull force. To give you some idea of what that feels like, that pull force is about the same as what it takes to lift a half-gallon of milk.

Ex-1769; Ex-1770; -01341 Reply at 25-26; -01343 Reply at 20-21.

VSI did not reduce to practice—actually or constructively—before Itou.

2008

June 2008
RX Concept Drawing



Ex-1765; -01341 Reply at 26; -01343 Reply at 21.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

VSI did not reduce to practice—actually or constructively—before Itou.

2008

July 2008
RX Design Pushed Out

Research & Development Update – July 2008
Jeff Welch (Devices) and Steve Penegor (Biologics)

GuideLiner
A coaxial liner for guide catheters to provide extra back-up support during PTCA procedures.

cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

"timelines have been pushed out due to drastic design changes"

Ex-2132; -01341 Reply at 26; -01343 Reply at 20-21.

VSI did not reduce to practice—actually or constructively—before Itou.

2009

May 2009
RX Product Requirements Complete

PRODUCT REQUIREMENTS:
GuideLiner

Document Approvals:

Reviewer	Dean Peterson	5/4/09
Documentation	Laura Thomas	5/5/09

3. REQUIREMENTS/SPECIFICATIONS

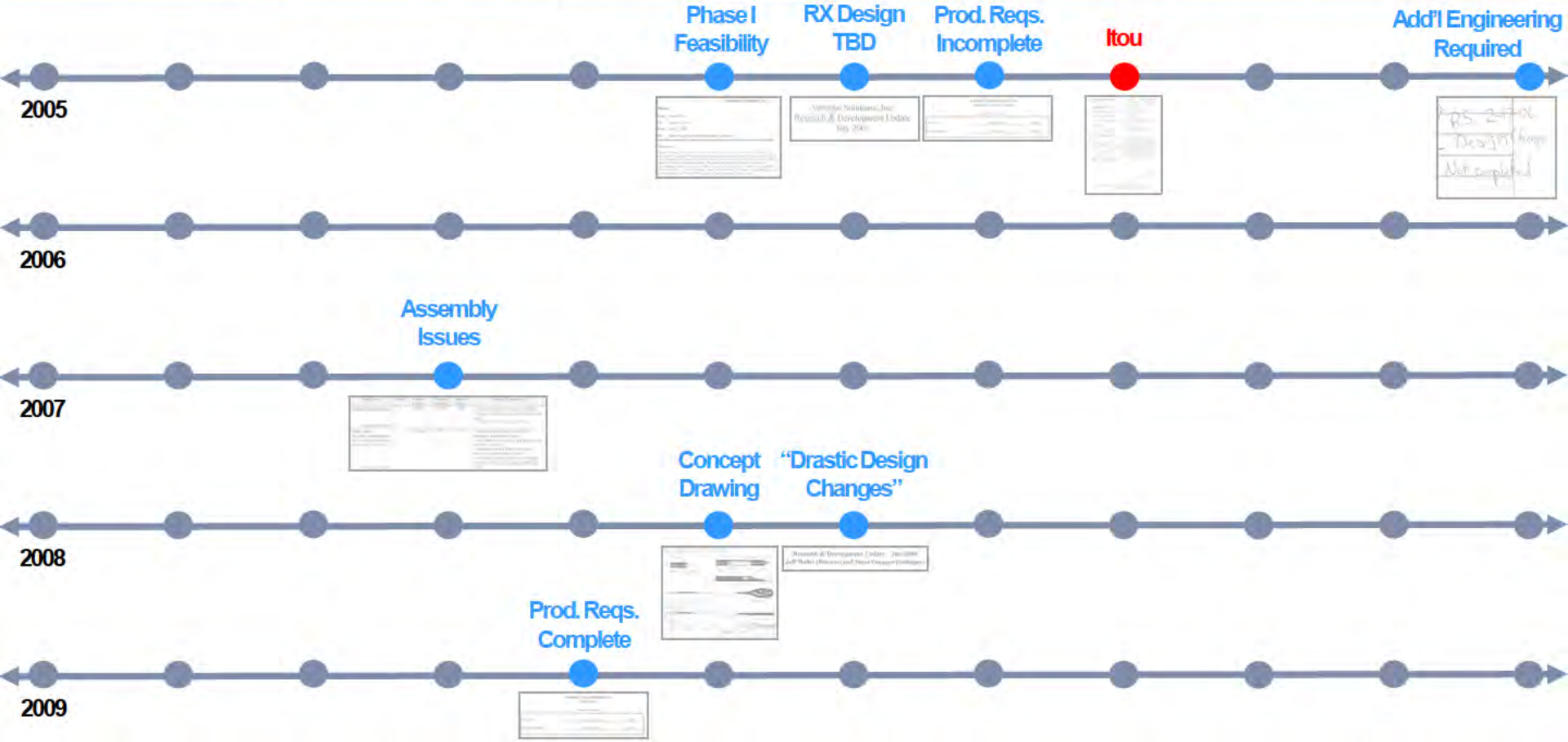
USER REQUIREMENTS	PRODUCT SPECIFICATIONS	TEST METHOD
3.1 Performance Requirements		
The device(s) must pass through a guide catheter and into the vasculature without kinking or seizing.	3.1.1 The GuideLiner (6Fr, 7Fr, & 8Fr) shafts' distal 15cm must have a coil, and be capable of a 1" bend radius without kinking.	Design Specification TP1182
	3.1.2 The GuideLiner (6Fr, 7Fr, & 8Fr) shafts' distal 15cm must have a silicone coating.	Design Specification
	3.1.3 The GuideLiner (6Fr, 7Fr, & 8Fr) must be capable of advancing through a guide catheter that is placed in simulated anatomy until 10cm of the GuideLiner have extended pass the tip of the guide catheter.	TP1276
The device(s) must have a lubricious inner with the largest possible I.D. while maintaining structural integrity.	3.1.4 The PTFE lined inner diameter of the GuideLiner must be:	Print Verification

GuideLiner Size	Minimum I.D.
6F	.056"
7F	.062"
8F	.071"

3.1.3 The GuideLiner (6Fr, 7Fr, & 8Fr) must be capable of advancing through a guide catheter that is placed in simulated anatomy until 10cm of the GuideLiner have extended pass the tip of the guide catheter.

Ex-1767; -01341 Reply at 24-25; -01343 Reply at 19.

VSI did not reduce to practice—actually or constructively—before Itou.



DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Teleflex cannot prove prior invention of its method claims.

- No evidence corroborating assembly of RX prototypes.
- **No dispute that VSI did not perform the claimed methods.**
- **No evidence of required intended purpose testing.**
- Affirmative evidence showing VSI back-burnered RX and could not have reduced to practice—actually or constructively—before Itou.

Introduction

’413, ’116 Patents

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

PATENT OWNER RESPON

Specifically, the claims are directed to methods of using guide extension catheters like GuideLiner in order to provide backup support during delivery of interventional cardiology devices ("ICDs").

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULA
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-01343
U.S. Patent No. RE 46,116

PATENT OWNER RESPONSE

Specifically, the claims are directed to methods of using a guide extension catheter like GuideLiner to deliver a stent or balloon catheter into a coronary artery.

IPR2020-01341, POR, 1; IPR2020-01343, POR, 1

Takahashi

Basic Science Review

New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter

Saeko Takahashi,[1]* MD, Shigeru Saito,[1] MD, Shinji Tanaka,[1] MD, Yusuke Miyashita,[1] MD, Takaaki Shiono,[1] MD, Fumio Arai,[1] MD, Hiroshi Domae,[1] MD, Shutaro Satake,[1] MD, and Takenari Itoh,[2] PhD

A 6 Fr guiding catheter is commonly used in the percutaneous coronary intervention (PCI). However, one of the limitations of the 6 Fr guiding catheter is its weak backup support compared to a 7 or an 8 Fr guiding catheter. In this article, we present a new system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv* 2004;63:452–456. © 2004 Wiley-Liss, Inc.

Key words: five-in-six system; backup support; 6 Fr guiding catheter; chronic total occlusion

INTRODUCTION

Currently, a 6 Fr guiding catheter is commonly used in percutaneous coronary intervention (PCI), since its use can decrease access site complication, enable early ambulation, and reduce the consumption of the contrast dye [1–4]. Major limitations of a 6 Fr guiding catheter are the inner lumen is not big enough to accommodate bulky atherectomy devices, and its backup support is not strong compared to a 7 or an 8 Fr catheter. In this report, we demonstrate a new technique for PCI called the five-in-six system, which increases a backup support of a 6 Fr guiding catheter.

MATERIALS AND METHODS

The Five-in-Six System

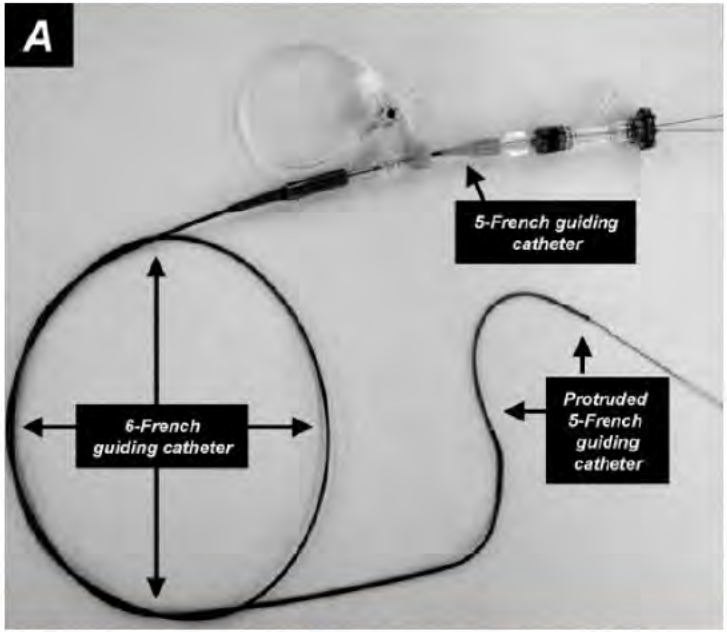
The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).

This 5 Fr Heartrail straight guiding catheter is 120 cm in length, whereas the 6 Fr guiding catheter is 100 cm. The 5 Fr Heartrail catheter has a very soft 13 cm distal portion. This soft end portion can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery. The inner lumen of the 5 Fr Heartrail catheter is 0.059″ in diameter; it can accept normal balloons or stent delivery systems less than 4.0 mm in diameter. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071″ in diameter to accommodate the 5 Fr Heartrail catheter; Launcher (Medtronic), Heartrail, and Radiguide (Terumo) guiding catheters can meet this inner lumen diameter.

In Vitro Experiments

We measured the backup support of this five-in-six system in vitro using an experimental system. The artery model had three curves simulating tortuous coronary arteries. It was filled with water that was kept at 37°C (Fig. 1B). A guiding catheter was engaged into the ostium of the artery model. Then a rapid-exchange balloon catheter (Ryujin 2.5 × 20 mm; Terumo) was pushed into

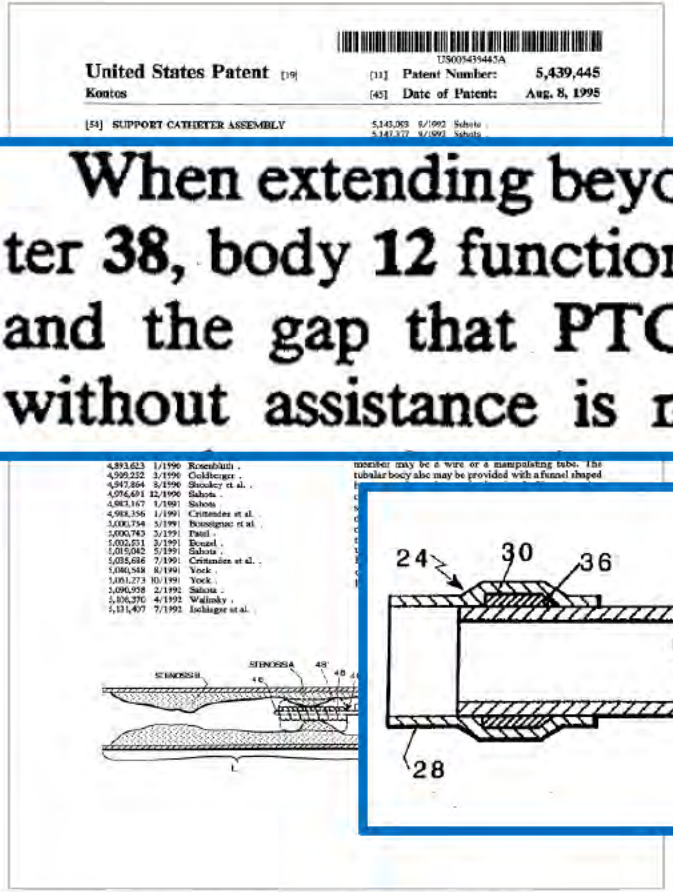
Published online in Wiley InterScience (www.interscience.wiley.com)



system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

IPR2020-01343, Pet. at 58, Ex-1010

U.S. Patent No. 5,439,445 (Kontos)



United States Patent [19]
Kontos

[11] Patent Number: 5,439,445
[45] Date of Patent: Aug. 8, 1995

[54] SUPPORT CATHETER ASSEMBLY

When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension, and the gap that PTCA catheter 40 must negotiate without assistance is made much shorter. It will be

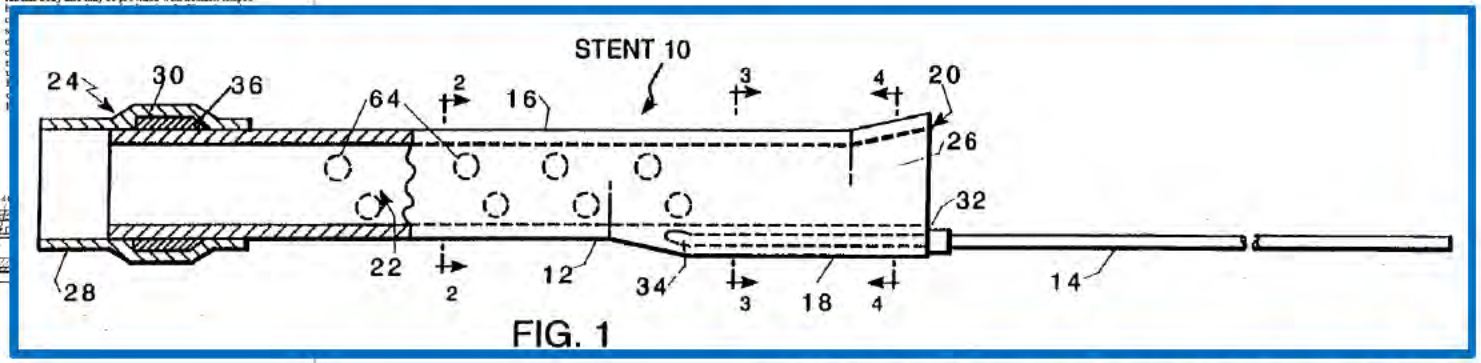


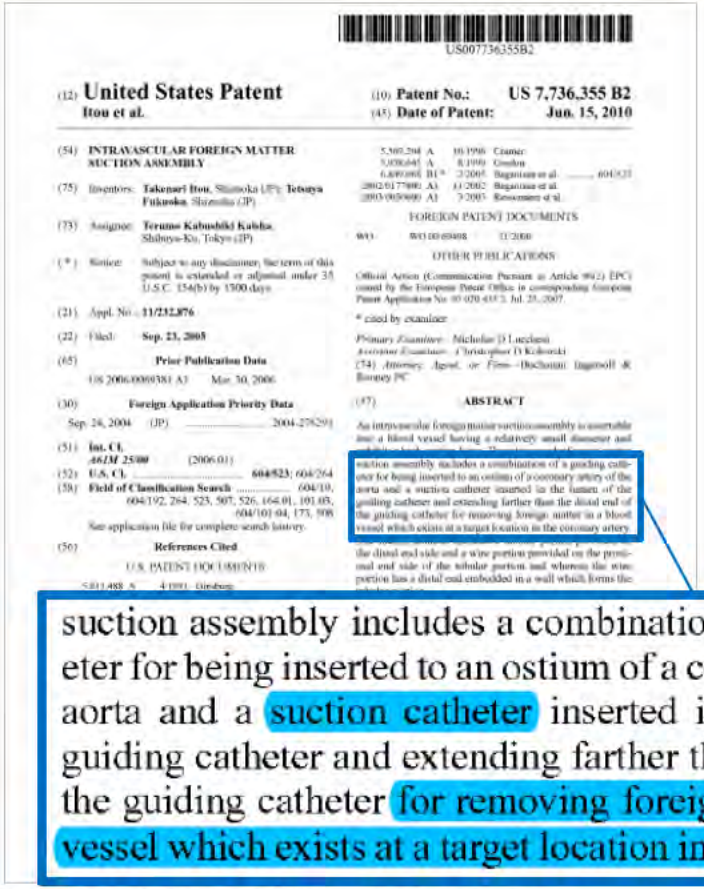
FIG. 1

IPR2020-01342, Pet. at 1, Ex-1409, Fig. 1; 5:49-52

Itou ANTICIPATES

IPR2020-01341 (Ground 1)

U.S. Patent No. 7,736,355 (Itou)



US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 28, 2004 (JP) 2004-278291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 175, 908

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,811,488 A 4/1991 Ginsburg

5,569,204 A 10/1996 Cramer
5,938,645 A 8/1999 Gordon
6,409,698 B1 * 2/2005 Bagaoisan et al. 604/523
2002/0177800 A1 11/2002 Bagaoisan et al.
2003/0050600 A1 3/2003 Rosenmayer et al.

FOREIGN PATENT DOCUMENTS

WO WO 03/03408 1/2003

OTHER PUBLICATIONS

Official Action (Communication Pursuant to Article 96(2) EPC) issued by the European Patent Office in corresponding European Patent Application No. 05 020 615.2, Jul. 23, 2007.

* cited by examiner

Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Christopher D Koharski
(74) *Attorney, Agent, or Firm*—Buchanan Ingersoll & Rooney PC

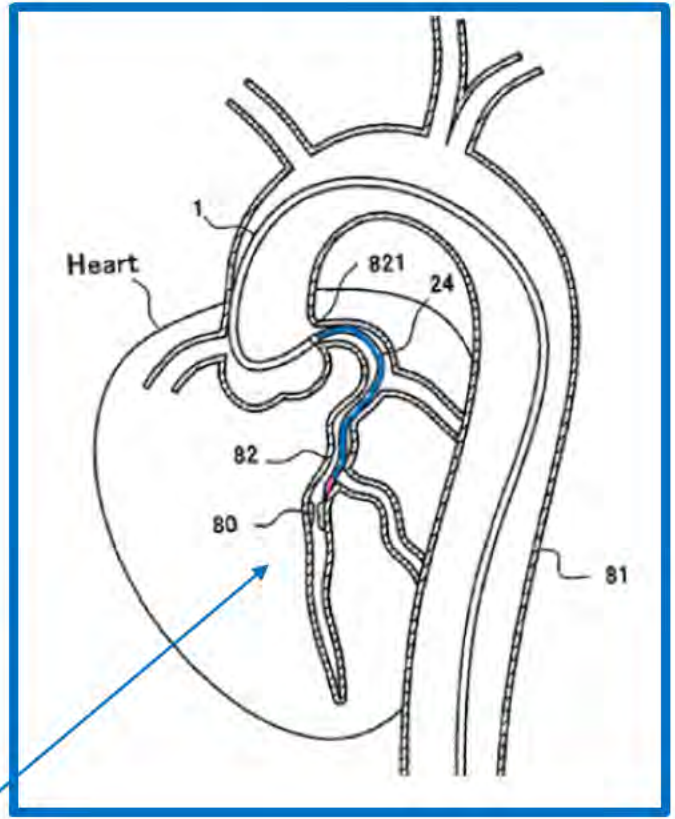
(57) **ABSTRACT**

An intravascular foreign matter suction assembly is operable into a blood vessel having a relatively small diameter and

suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery

the distal end side and a wire portion provided on the proximal end side of the tubular portion, and wherein the wire portion has a distal end embedded in a wall which forms the

suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a **suction catheter** inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter **for removing foreign matter in a blood vessel which exists at a target location in the coronary artery**.



Claim 1

’413 patent

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the **interventional cardiology device** being adapted to be passed through a standard guide catheter, . . . the method comprising:

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

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

order of steps

guide extension inserted into GC

1c. inserting a flexible tip portion of a coaxial guide catheter . . . into the continuous lumen of the standard guide catheter, and,

1d. further inserting a substantially rigid portion . . . into the continuous lumen of the standard guide catheter . . . ;

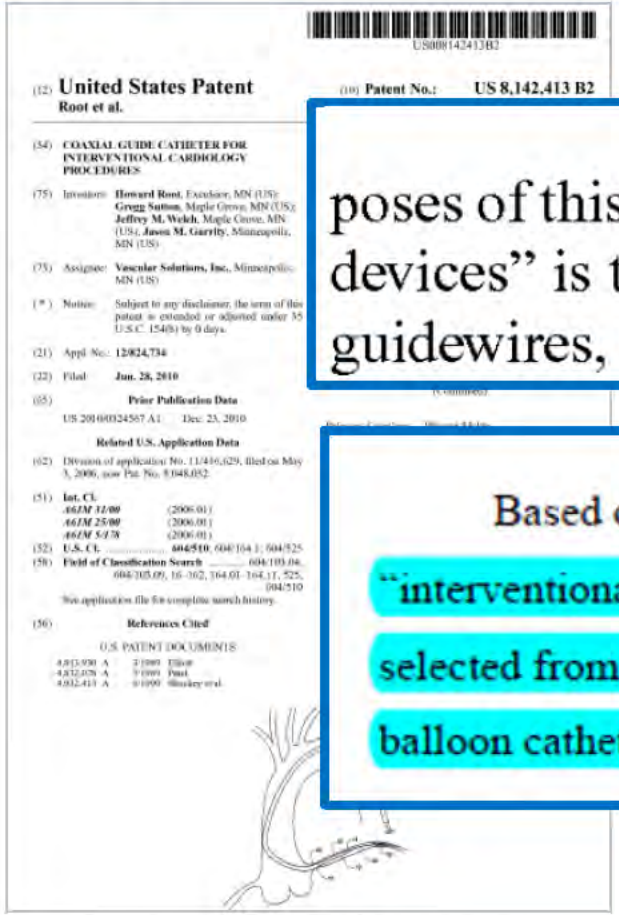
1e. advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends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

IVCD inserted into GC

1fi. inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and

1fii. 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.

"interventional cardiology device"



US008142413B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,142,413 B2**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/824,734**

(22) Filed: **Jun. 28, 2010**

(65) **Prior Publication Data**

US 2010/0324567 A1 Dec. 23, 2010

Related U.S. Application Data

(62) Division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,052.

(51) **Int. Cl.**
A61M 31/00 (2006.01)
A61M 25/00 (2006.01)
A61M 5/178 (2006.01)

(52) **U.S. Cl.** **604/510**; 604/164.1; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 16–102, 164.01–164.11, 525, 004/510

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,813,930 A 3/1989 Elliott
4,832,028 A 5/1989 Patel
4,932,413 A 6/1990 Shockey et al.

For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.

Based on the current record, we determine that the term "interventional cardiology devices" refers to at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters.

IPR2020-01341, Ex-1001, 1:23-26; Institution Decision at 16

"interventional cardiology device"

'413 claim 1	Teleflex Proposal
" . . . 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." IPR2020-01341, Ex-1001, col. 11, ll. 4-6	• " any other device delivered beyond the end of the device for use with a standard guide catheter to a location in the vasculature requiring treatment, **to provide treatment to that location**" IPR2020-01341, POR, 14.

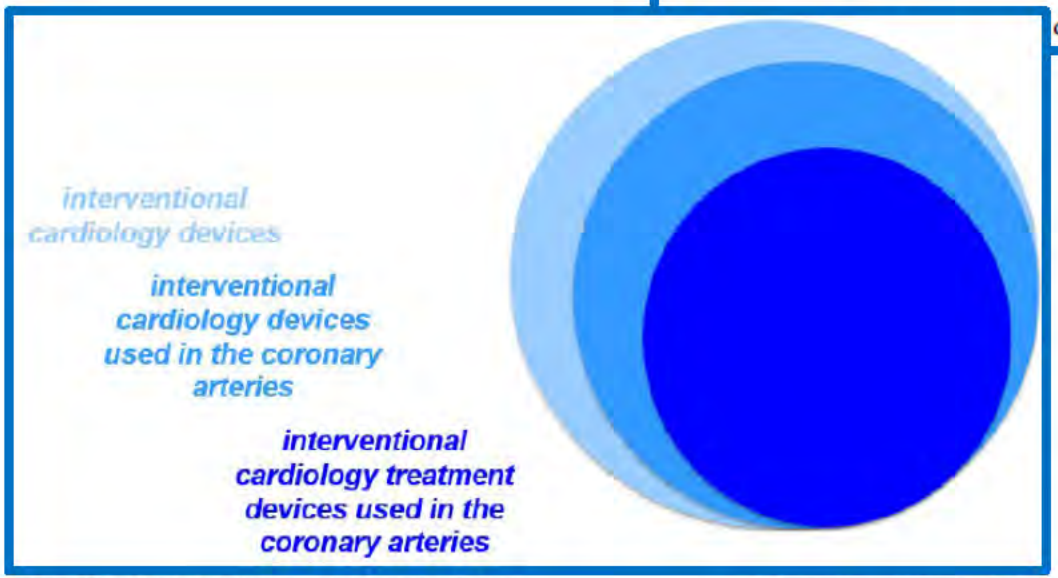
"interventional cardiology device"

'413 patent	'116 patent
1. A method of providing backup support for an ***interventional cardiology device*** . . . the ***interventional cardiology device*** being adapted to be passed through a standard guide catheter . . . and inserting the ***interventional cardiology device*** into and through the continuous lumen of the standard guide catheter	43. A method, comprising: advancing a distal end of a guide catheter . . . to an ostium of a coronary artery; advancing a distal end of a guide extension catheter through, and beyond . . . the guide catheter while a segment defining a side opening of the guide extension catheter and a proximal end of a tubular structure of the guide extension catheter remain within the guide catheter. . . advancing a ***treatment catheter*** at least partially through the guide catheter and the guide extension catheter and into the coronary artery . . . .

IPR2020-01341, Reply at 3

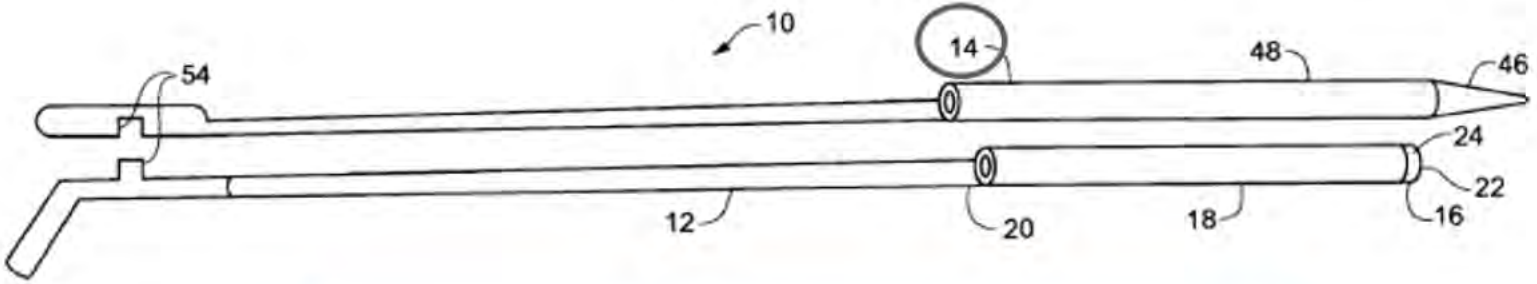
"interventional cardiology device"

10. I understand Teleflex's argument to be, in part, that the patent specification uses the terms "cardiac treatment device" and "interventional cardiology treatment device" interchangeably with "interventional cardiology device[s]." POR at 14-15. I disagree that the patent uses these three terms as synonyms. The specification does not limit its discussion to treatment devices, or catheters that deliver those devices.



"interventional cardiology device"

Fig. 1



. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

IPR2020-01341, Pet. at 10; POR at 15-16; Ex-1001, Fig. 1, 9:65-10:3

"interventional cardiology device"

- Distal end protective catheter (5) is inserted into catheter (2)

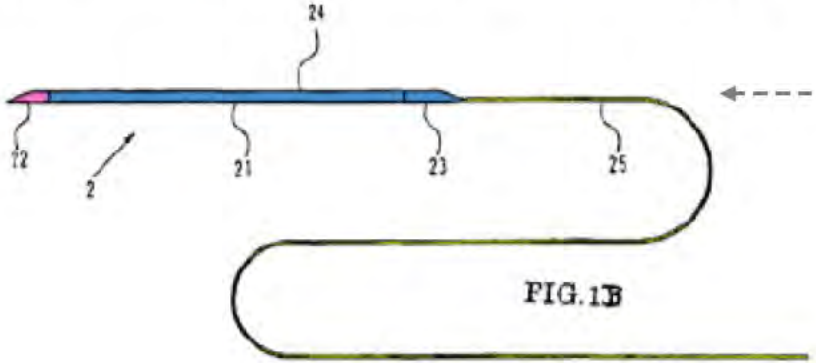


FIG.1B

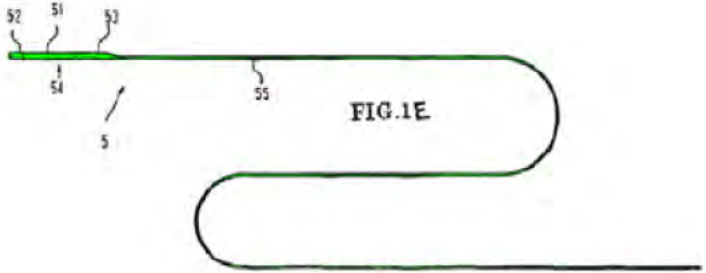
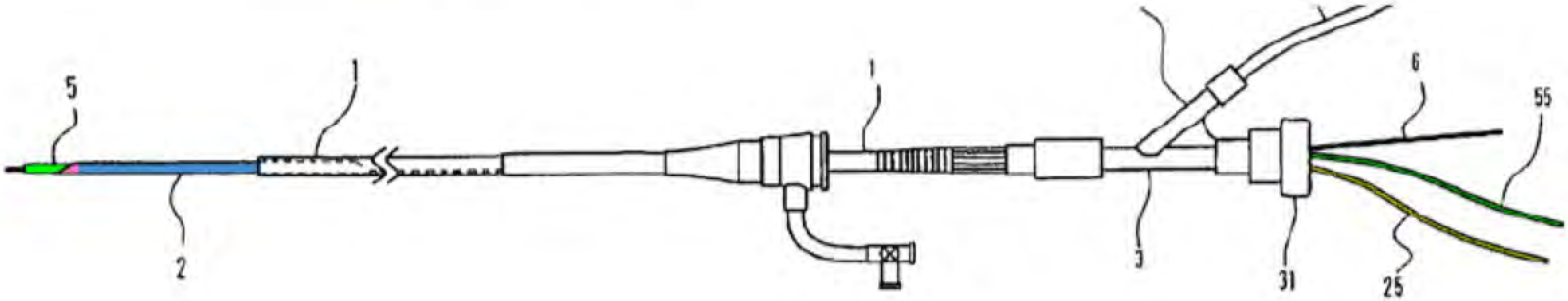


FIG.1E



Claim 1

’413 patent

1. A method of providing backup support for an **interventional cardiology device** for use in the coronary vasculature, the **interventional cardiology device** being adapted to be passed through a standard guide catheter, . . . the method comprising:

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

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

1c. inserting a flexible tip portion of a coaxial guide catheter . . . into the continuous lumen of the standard guide catheter, and,

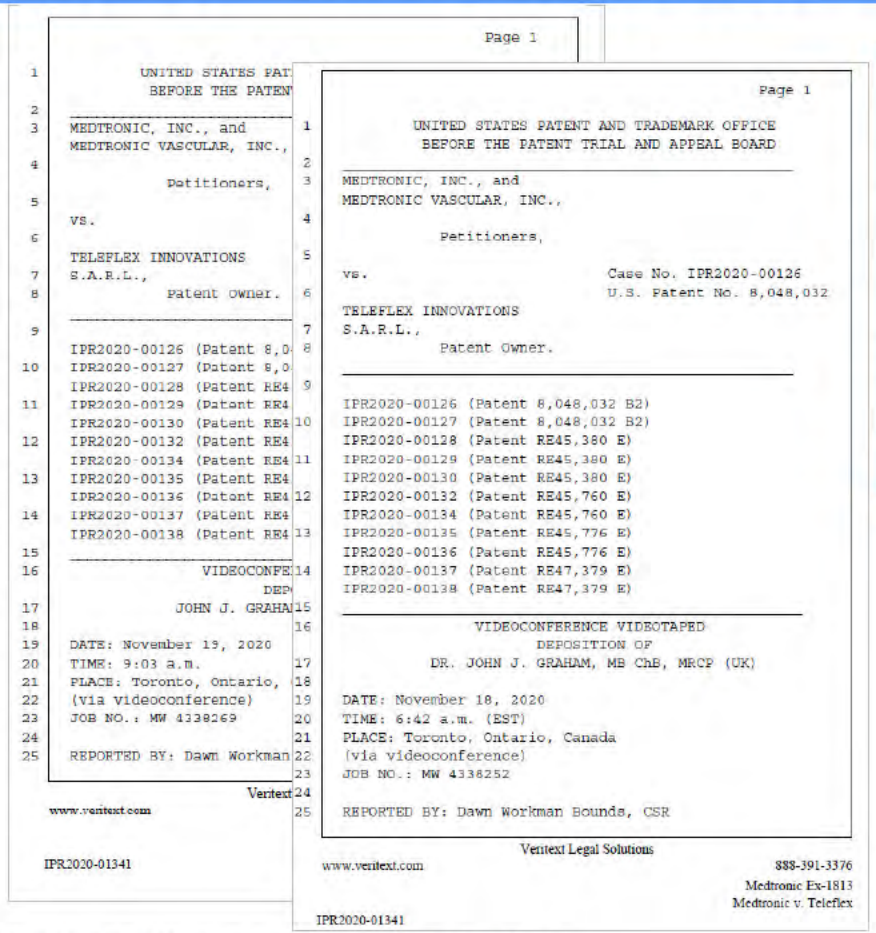
1d. further inserting a substantially rigid portion . . . into the continuous lumen of the standard guide catheter . . . ;

1e. advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery 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

1fi. inserting the **interventional cardiology device** into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and

1fii. 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.

"interventional cardiology device"



Page 1

UNITED STATES PAT
BEFORE THE PATEN

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,0
IPR2020-00127 (Patent 8,0
IPR2020-00128 (Patent RE4
IPR2020-00129 (Patent RE4
IPR2020-00130 (Patent RE4
IPR2020-00132 (Patent RE4
IPR2020-00134 (Patent RE4
IPR2020-00135 (Patent RE4
IPR2020-00136 (Patent RE4
IPR2020-00137 (Patent RE4
IPR2020-00138 (Patent RE4

VIDEOCONFE
DEP
JOHN J. GRAHA

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario,
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman

Veritext

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IPR2020-01341

Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

Case No. IPR2020-00126
U.S. Patent No. 8,048,032

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
DR. JOHN J. GRAHAM, MB ChB, MRCP (UK)

DATE: November 18, 2020
TIME: 6:42 a.m. (EST)
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338252

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex-1813
Medtronic v. Teleflex

IPR2020-01341

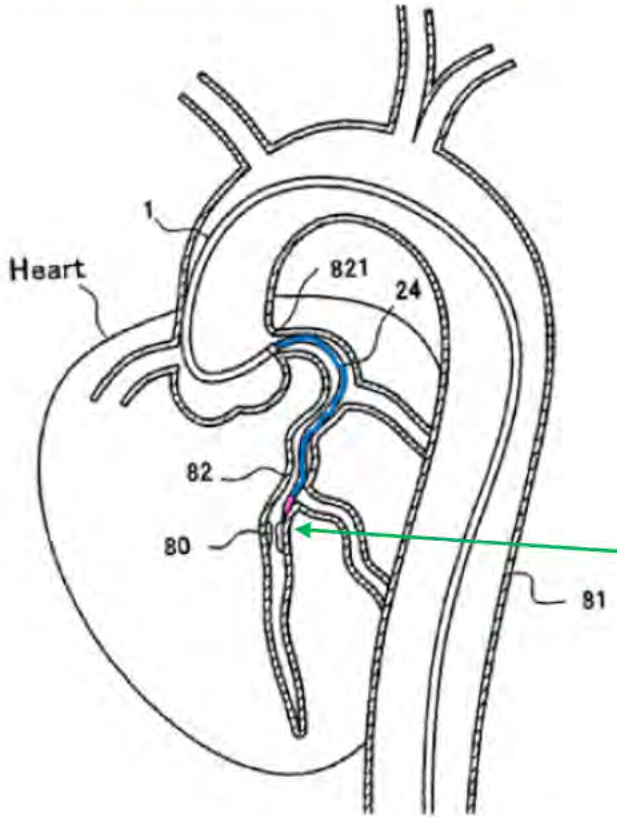
15 Q. So as you sit here today, you can't think of an
16 example where you've used just a guide wire in a
17 premeditative way to treat a lesion or occlusion, right?
18 A. As the sole treatment, no.
19 Q. And it's used in conjunction, the guide wire,
20 with a stent or a balloon --
21 A. True.
22 Q. -- usually, correct?
23 A. That is correct.

21 So I think that a guide wire is a device
22 which allows the delivery. It's an essential part of the
23 delivery

IPR2020-01341, Reply at 4, 27; Ex-1801 (Graham Tr.), 89:15-23; Ex-1813 (Graham Tr.), 108:21-24

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Catheter 5 is an interventional cardiology device



(4) A combination of the suction catheter **2** and the distal end protective catheter **5** is inserted into the guiding catheter **1** along the guide wire **6**.

(5) The distal end of the combination of the suction catheter **2** and the distal end protective catheter **5** is inserted to the target location **80**.

(6) The distal end protective catheter **5** is pulled out.

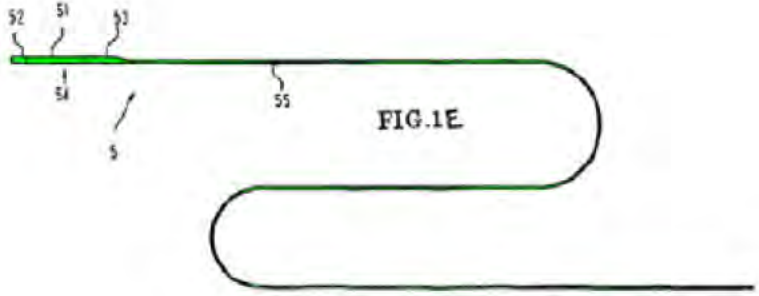


FIG.1E

IPR2020-01341, Pet. at 23, Reply at 26-29; Ex-1007, Figs. 1E, 6; 7:13-19

order of steps

necessarily a sequential insertion?

guide extension inserted into GC

IVCD inserted into GC

’413 patent

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, . . . the method comprising:

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

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

1c. inserting a flexible tip portion of a coaxial guide catheter . . . into the continuous lumen of the standard guide catheter, and,

1d. further inserting a substantially rigid portion . . . into the continuous lumen of the standard guide catheter . . . ;

1e. advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery 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

1fi. inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and

1fii. 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.

order of steps

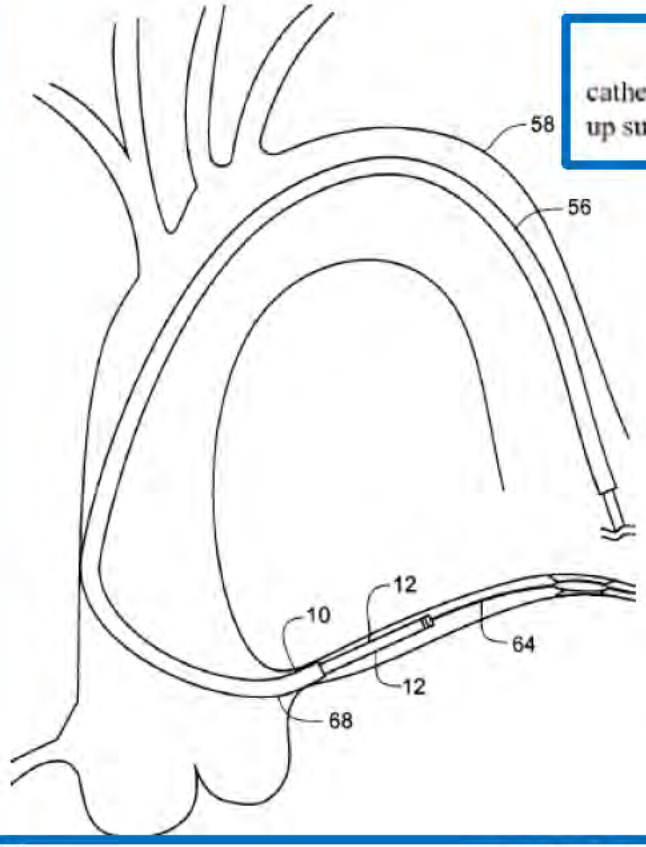
- *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) ("Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one.")

- *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1370-71(Fed. Cir. 2003) (reversing a claim construction in which the order of steps used by the sole, preferred embodiment was imported into the claims)

order of steps

- "backup support"

Fig. 9



The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone.

sequential insertion

simultaneous insertion

order of steps

1fi. inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion . . .

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX LIFE SCIENCES LIMITED,
Patent Owner.

Case No. IPR2020-01341
Case No. IPR2020-01342
Case No. IPR2020-01343
Case No. IPR2020-01344
U.S. Patent No. 8,147,418

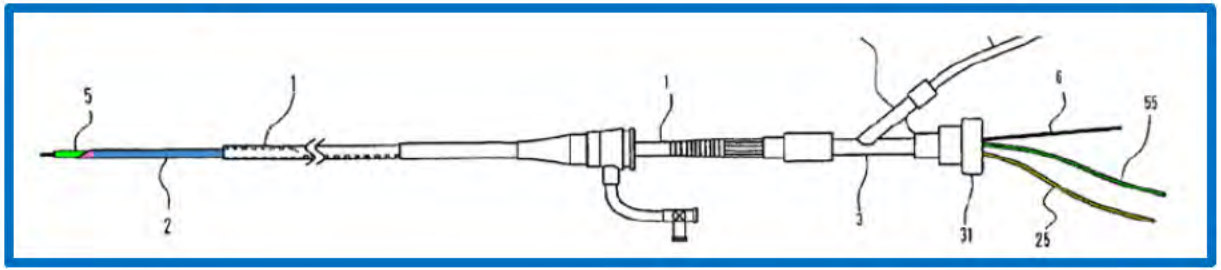
DEPOSITION OF PETER T. KEITH

VOLUME I, PAGES 1 - 94

JULY 8, 2021

(The following is the deposition of PETER T. KEITH, taken pursuant to Notice of Taking Deposition, via videotape, at Carlson Caspers Vandenburgh & Lindquist, P.A., 4200 Capella Tower, 225 South Sixth Street, in the City of Minneapolis, State of Minnesota, commencing at approximately 8:55 o'clock a.m., July 8, 2021.)

13 **Q.** So it's the same question we had earlier.
14 If those -- If that preloaded assembly is just lying
15 on the table here, the distal end protective catheter
16 is lying alongside the -- the pushrod of Itou's
17 catheter 2; right?
18 **A. In the context of just sitting there on the**
19 **table, yes.**



IPR2020-01341, Reply at 6, Ex-1007, Fig. 5; Ex-1797 (Keith Tr.), 31:13-19

order of steps

- sequential insertion ***required***?
  - *Mformation Tech. v. Research in Motion*, 764 F.3d 1392 (Fed. Cir. 2014) (agreeing that a connection is necessarily established between a wireless device and a server before there can be transmission from the latter to the former)
  - *Mantech Environmental Corp. v. Hudson Environmental Servs.*, 152 F.3d 1368 (Fed. Cir. 1998) (determining that wells must be provided before acid may be introduced through the wells into groundwater)

order of steps

- sequential insertion ***not*** required

> 19. As I have testified, claim 1 does not mandate insertion of an interventional cardiology device after insertion of a coaxial guide catheter. Ex-2245, 82:7-83:3. Premounted or preformed devices may be advanced within a catheter so long as the whole delivery system is de-aired, which guards against the danger of introducing an air embolism. *Id.*, 94:19-23; *see also* Ex-1846, 39:7-14, 44:5-14, 46:8-23, 48:21-49:14, 49:23-50:25; Ex-1797, 23:24-26:3.

IPR2020-01341, Reply at 6, Ex-1806 (Brecker Decl.); *and see* Ex-1846 (Graham Tr.), 50: 15-25 (admitting that preassembly is possible)

order of steps

sequential OR simultaneous insertion

guide extension inserted into GC

IVCD inserted into GC

’413 patent

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, . . . the method comprising:

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

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

1c. inserting a flexible tip portion of a coaxial guide catheter . . . into the continuous lumen of the standard guide catheter, and,

1d. further inserting a substantially rigid portion . . . into the continuous lumen of the standard guide catheter . . . ;

1e. advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery 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

1fi. inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and

1fii. 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.

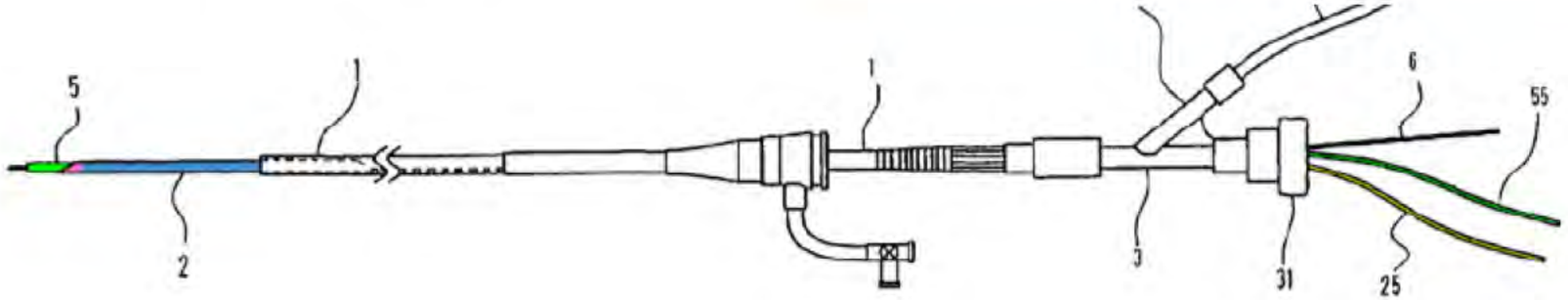
order of steps

- Itou discloses "inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion . . ."

(4) A combination of the suction catheter **2** and the distal end protective catheter **5** is inserted into the guiding catheter **1** along the guide wire **6**.

(5) The distal end of the combination of the suction catheter **2** and the distal end protective catheter **5** is inserted to the target location **80**.

(6) The distal end protective catheter **5** is pulled out.



IPR2020-01341, Pet. at 49-50; Reply at 27; Ex-1007, Fig. 5; 7:13-19

Claim 1

’413 patent

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, . . . the method comprising:

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

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

1c. inserting a flexible tip portion of a coaxial guide catheter . . . into the continuous lumen of the standard guide catheter, and,

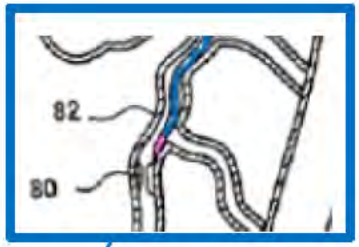
1d. further inserting a substantially rigid portion . . . into the continuous lumen of the standard guide catheter . . . ;

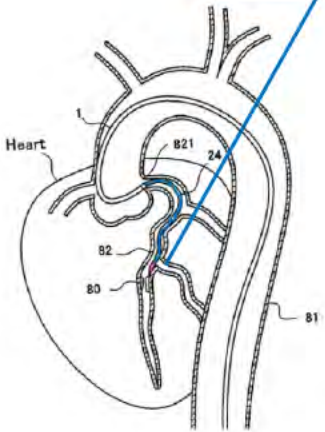
1e. advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends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

1fi. inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and

1fii. 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.

- Itou discloses a "lesion" at target location 80



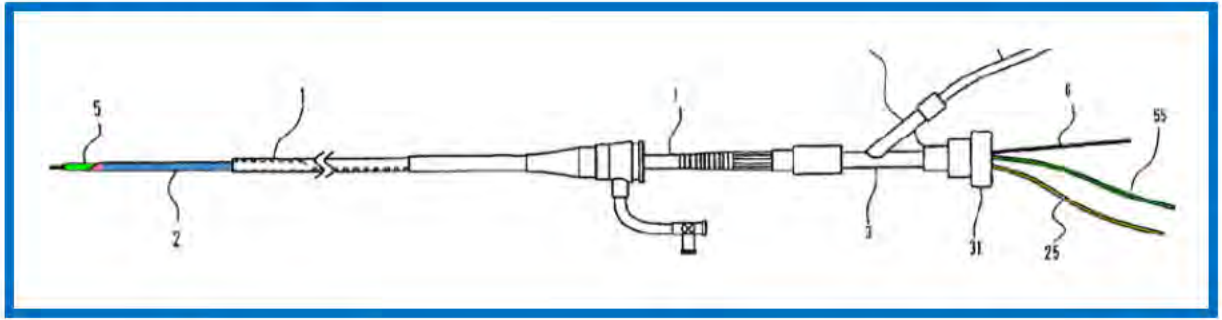


5 Q. So a thrombus develops from a lesion; is
6 that -- do I have that right?
7 A. **So this gets more nuanced. Normally in the**
8 **vast majority of heart attacks, yes, there is a lesion**
9 **that ruptures, a plaque that ruptures and causes a**
10 **thrombus. In a small proportion of patients, the**
11 **thrombus occurs de novo and is embolized from**
12 **somewhere else in the body.**

22 **Whereas a large thrombus, as is described in**
23 **Itou, is -- is sitting right there not being carried**
24 **downstream, or if it is it's not very far downstream**

IPR2020-01341 Pet., 50-51; Reply, 27-28;
Ex-1007, Fig. 6; 3:1-4; Ex-1846 (Graham Tr.), 100; Ex-1797 (Keith Tr.), 41:5-42:2

- Catheter (5) is longer than catheter (2)

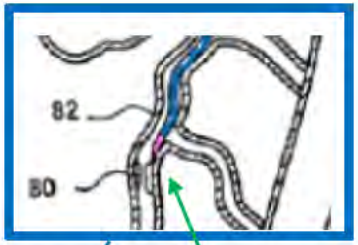


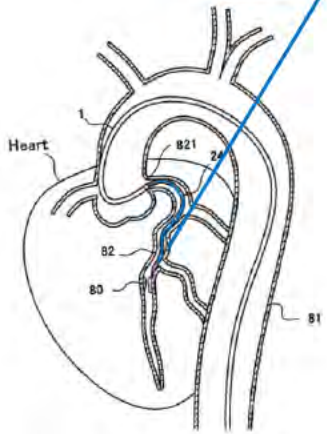
The distal end protective catheter **5** is inserted in the lumen of the suction catheter **2** and projects from the distal end of the suction catheter **2** such that it acts as a protective safety tip upon insertion into a blood vessel

TABLE 1

Name of device	Overall length (mm)	Outer diameter (mm)	Inner diameter (mm)
Guiding catheter 1	1000	2.06	1.8
Suction catheter 2 (tubular portion)	150	1.72	1.5
Suction catheter 2 (wire-like portion)	1100	0.45	—
Distal end protective catheter 5 (tubular portion)	20	1.35	0.5
Distal end protective catheter 5 (wire-like portion)	1300	0.45	—

- Catheter (5) is necessarily advanced into contact with the lesion at the target location





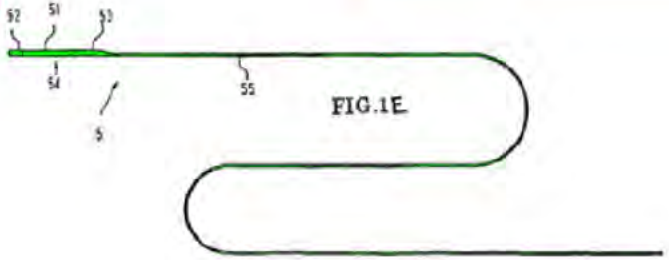


FIG.1E

(4) A combination of the suction catheter **2** and the distal end protective catheter **5** is inserted into the guiding catheter **1** along the guide wire **6**.

(5) The distal end of the combination of the suction catheter **2** and the distal end protective catheter **5** is inserted to the target location **80**.

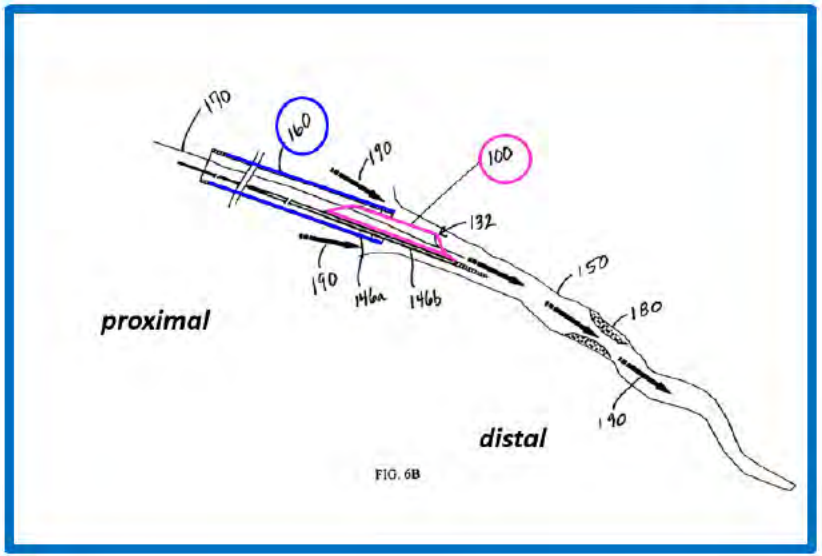
(6) The distal end protective catheter **5** is pulled out.

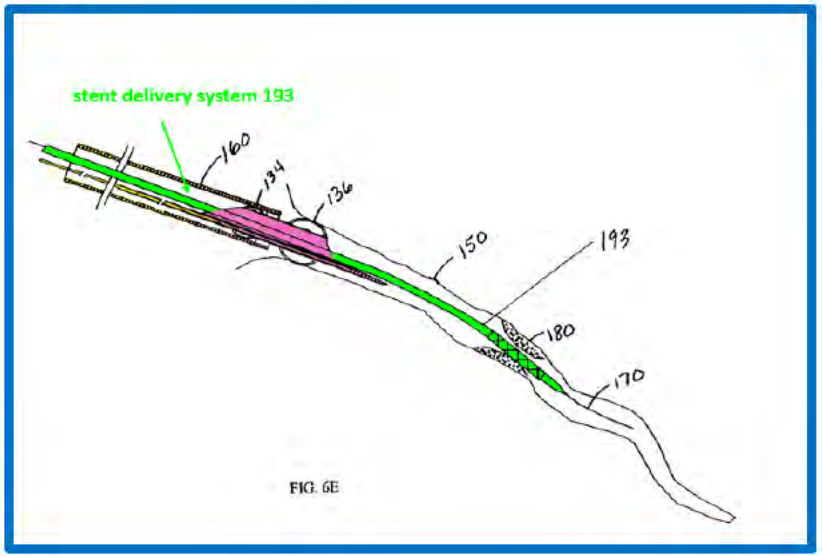
Itou RENDERS OBVIOUS

IPR2020-01341 (Grounds 2, 3)
IPR2020-01343 (Ground 2)

"Specifically, the claims are directed to methods of using a guide extension catheter like GuideLiner to deliver a stent or balloon into a coronary artery." POR, 1.

Ressemann





Would it have been obvious to use Itou's catheter (2) - - - with no modification to its structure - - - to deliver a balloon catheter or stent across a lesion?

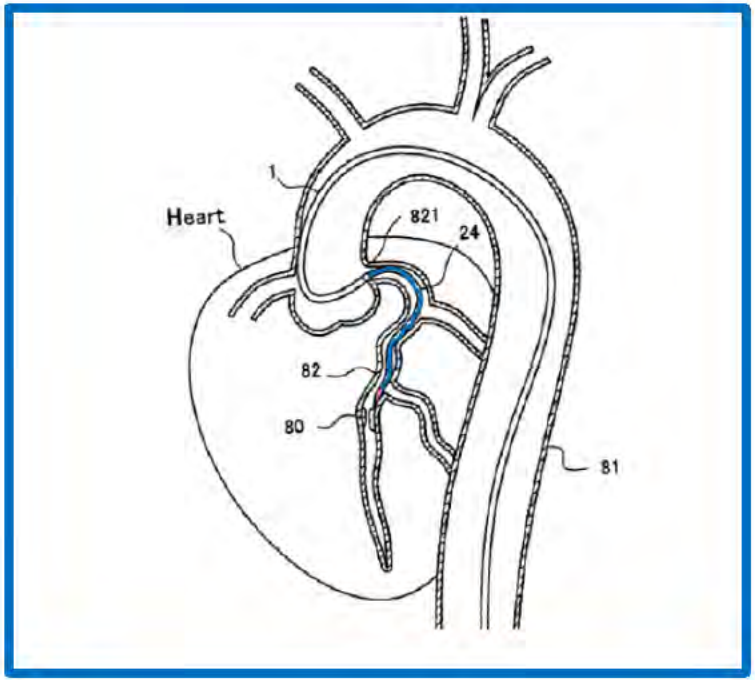
IPR2020-01341, Pet. at 23, Reply at 26-29; Ex-1007, Fig. 6; 7:13-19

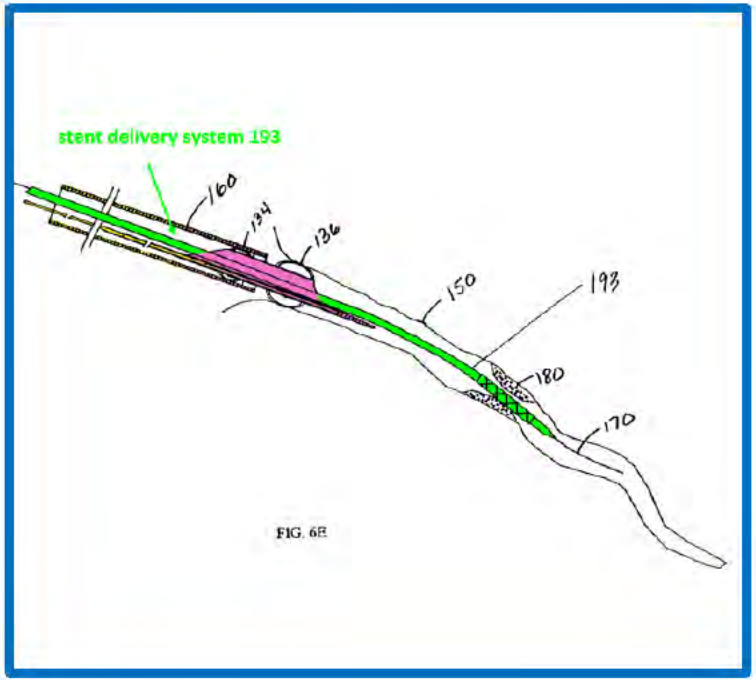
Patent Owner's arguments:

- Ressemann's embolic protection device and Itou's suction catheter are "very different." (POR at 39).
- A POSITA would not advance a balloon or stent through a suction catheter. (POR at 41-42).
- Itou's catheter (2) does not have a "'suitable structure' for delivering stents and balloon catheters." (POR at 34).

IPR2020-01341, -01343

- Itou and Ressemann both disclose catheters for removing coronary artery occlusions.

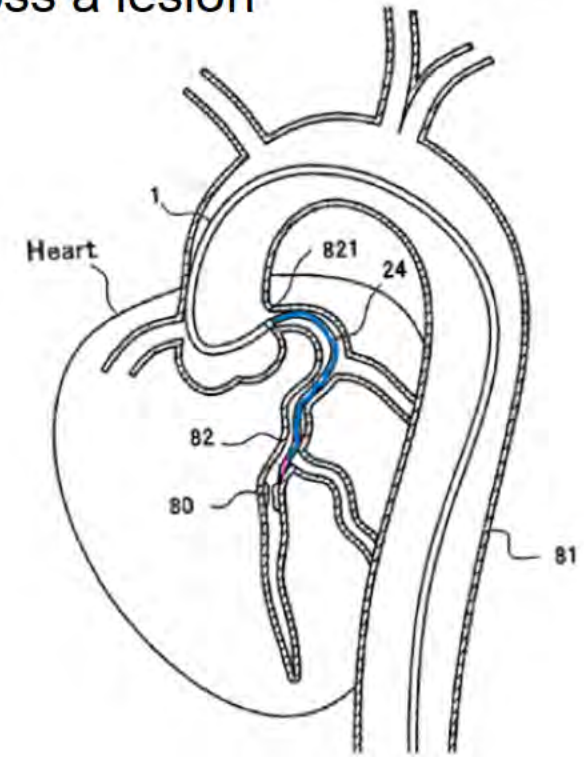




- An obviousness "analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (Fed. Cir. 2007).

- "A reference must be considered for everything that it teaches, not simply the described invention or a preferred embodiment." *In re Applied Materials, Inc.*, 692 F.2d 1289 (Fed. Cir. 2012)

Catheter (2) is in precisely the right place to deliver a balloon catheter or stent across a lesion



(4) A combination of the suction catheter **2** and the distal end protective catheter **5** is inserted into the guiding catheter **1** along the guide wire **6**.

(5) The distal end of the combination of the suction catheter **2** and the distal end protective catheter **5** is inserted to the target location **80**.

(6) The distal end protective catheter **5** is pulled out.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01341, Pet. at 23, Reply at 26-29; Ex-1007, Fig. 6; 7:13-19

Patent Owner's arguments:

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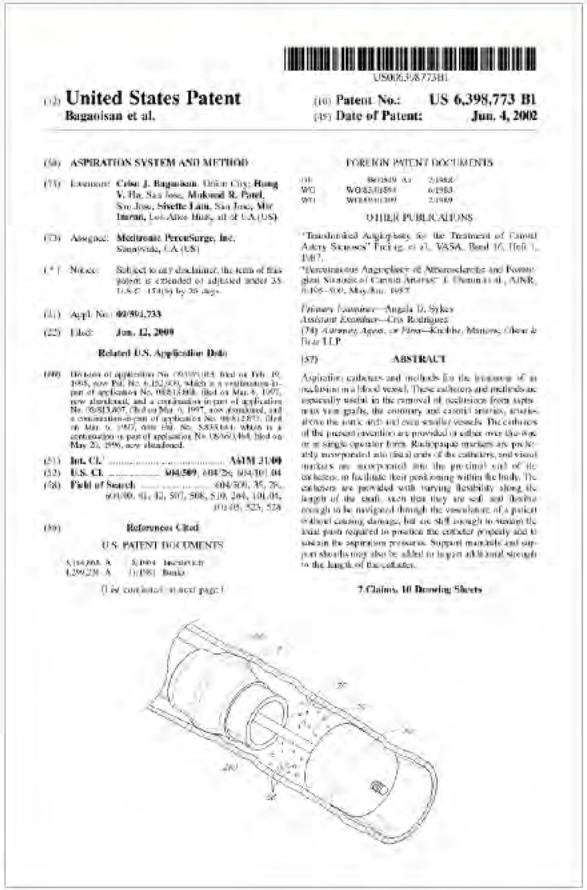
- Itou's catheter (2) does not have a "'suitable structure' for delivering stents and balloon catheters." (POR at 34).

IPR2020-01341, -01343



US006398773B1

(12) **United States Patent**
Bagaoisan et al.

(10) **Patent No.: US 6,398,773 B1**
(45) **Date of Patent: Jun. 4, 2002**

(54) **ASPIRATION SYSTEM AND METHOD**

(75) Inventors: **Celso J. Bagaoisan**, Union City; **Hung V. Ha**, San Jose, **Mahmud R. Patel**, San Jose, **Sivette Lain**, San Jose, **Mir Imran**, Los Altos Hills, all of CA (US)

(73) Assignee: **Medtronic PercuSurge, Inc.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 35 days.

(21) Appl. No.: **09/651,733**

(22) Filed: **Jun. 12, 2000**

Related U.S. Application Data

(60) Division of application No. 09/099,045, filed on Feb. 19, 1998, now Pat. No. 6,152,909, which is a continuation-in-part of application No. 08/815,808, filed on Mar. 6, 1997, now abandoned, and a continuation-in-part of application No. 08/813,807, filed on Mar. 6, 1997, now abandoned, and a continuation-in-part of application No. 08/812,873, filed on Mar. 6, 1997, now Pat. No. 5,833,644, which is a continuation-in-part of application No. 08/560,464, filed on May 22, 1996, now abandoned.

(51) **Int. Cl.**[7] **A61M 31/00**

(52) **U.S. Cl.** **604/509**; 604/26; 604/101.04

(58) **Field of Search** 604/509, 35, 26, 604/99, 93, 82, 507, 508, 510, 264, 101.04, 101.05, 523, 524

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(List continued on next page.)

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"Percutaneous Angioplasty of Atherosclerotic and Postsurgical Stenosis of Carotid Arteries" J. Theron et al., AJNR, 6:495-500, May/Jun. 1985.

Primary Examiner—Angela D. Sykes
Assistant Examiner—Cris Rodriguez
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Aspiration catheters and methods for the treatment of a stenosis in a blood vessel. These catheters are particularly useful in the removal of restenosis from saphenous vein grafts, the coronary and carotid arteries, arteries above the aortic arch and even smaller vessels. The catheters of the present invention are provided to either over the wire or in single operator form. Radiopaque markers are preferably incorporated into distal ends of the catheters, and visual markers are incorporated into the proximal end of the catheters to facilitate their positioning within the body. The catheters are provided with varying flexibility along the length of the shaft, such that they are soft and flexible enough to be navigated through the vasculature of a patient without causing damage, but are stiff enough to transfer the force applied to position the catheter properly and to maintain the aspiration pressures. Support materials and support sheaths may also be added to impart additional strength to the length of the catheters.

7 Claims, 10 Drawing Sheets

The catheters are preferably sized so as to allow the slidable insertion of a therapy catheter through the main aspiration lumen of the aspiration catheter.

In another embodiment not shown, the aspiration catheter can be configured such that the therapy catheter can be inserted through the lumen of the aspiration catheter. The lumen is made large enough to accommodate the desired therapy catheter. This allows the aspiration catheter and the therapy catheter to be delivered into the patient at the same time. When therapy is complete, the therapy catheter is removed while the aspiration catheter remains in place. This eliminates the need to separately deliver the aspiration catheter after removal of the therapy catheter, saving valuable time.

US 20140025143A1

(19) United States

(12) Patent Application Publication

Atkinson et al.

(10) Pub. No.: US 2014/0025143 A1

(43) Pub. Date: Jan. 23, 2014

(54) DEVICES AND METHODS TO REDUCE MYOCARDIAL REPERFUSION INJURY

(71) Applicant: Prospect Medical III, New Brighton, MN (US)

(72) Inventors: Robert Atkinson, White Bear Lake, MN (US); Jason Goldrath, Minneapolis, MN (US); Peter Keith, Lanesboro, MN (US); Paul McLean, North Oaks, MN (US)

(73) Assignee: Prospect Medical III, New Brighton, MN (US)

(21) Appl. No.: 13/941,605

(22) Filed: Jul. 16, 2013

Related U.S. Application Data

(60) Provisional application No. 61/672,528, filed on Jul. 17, 2012, provisional application No. 61/778,309, filed on Mar. 11, 2013.

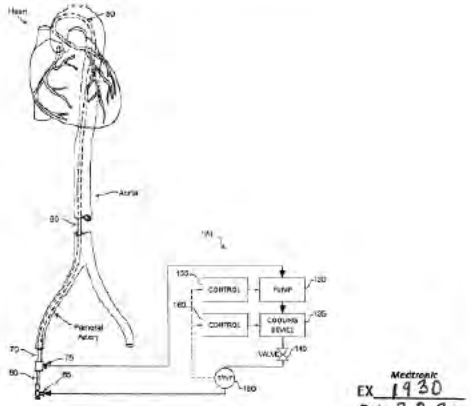
Publication Classification

(51) Int. Cl.
A61F 7/12 (2006.01)

(52) U.S. Cl.
CPC A61F 7/12 (2013.01)
USPC 607/105

(57) ABSTRACT

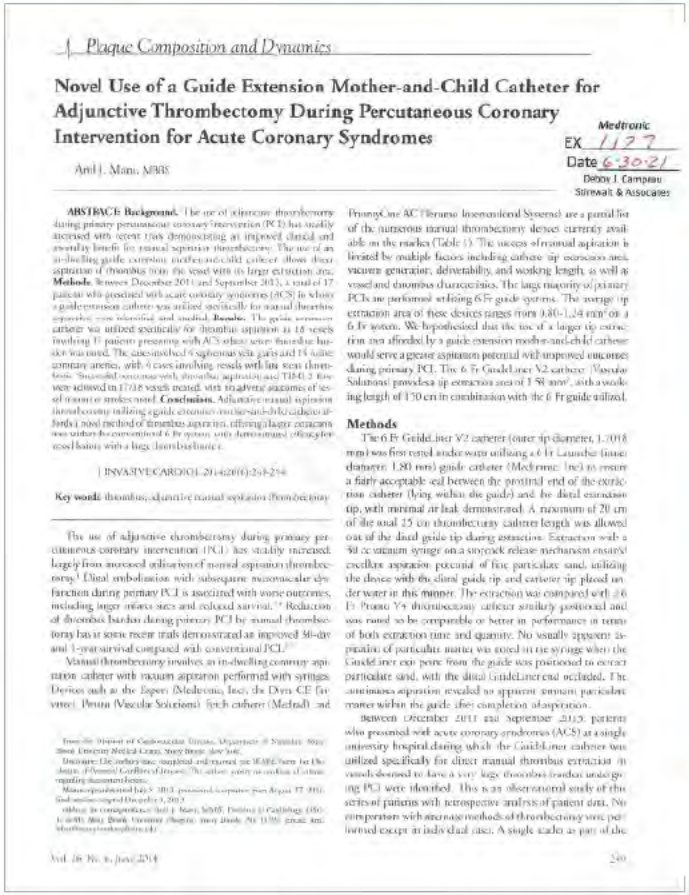
Devices and methods that mitigate reperfusion injury (RI) in a clinically practical manner so as to avoid significantly increasing time to reperfusion. In general, these systems and methods involve an adjunctive approach to deliver a fluid to the myocardium at risk of RI before, during and after reperfusion is established by a percutaneous coronary intervention such as aspiration and stenting.



[0084] Once the infusion wire **320** is across the blockage **296**, infusion of cooled fluid **297** may be initiated to the ischemic tissue distal of the blockage **296**. Thrombus may be then removed by utilizing the aspiration sheath **340** as a thrombectomy catheter, as shown in FIG. **28**. Cooling may be continued via the infusion wire **320** during this step. Once the thrombus is removed, it may be desirable to remove the infusion wire **320**. Thrombus may "hang up" within the lumen of the aspiration sheath **340**, but if the infusion wire **320** (or any device in the lumen) is removed while suctioning, any thrombus particulate will be removed. This can be important if the thrombectomy (aspiration) catheter is used subsequently for infusion.

[0085] Next, while the aspiration sheath **340** is positioned distally of the residual lesion **299**, a conventional guide wire **100** may be placed distally, thus preserving access for subsequent stent placement. Infusion of cooled fluid may be performed during this and following steps.

IPR2020-01341, -01343



Plaque Composition and Dynamics

Novel Use of a Guide Extension Mother-and-Child Catheter for Adjunctive Thrombectomy During Percutaneous Coronary Intervention for Acute Coronary Syndromes

Medtronic
EX 1127
Date 6-30-21
Debby J. Campau
Stinnett & Associates

Anil J. Maini, MBBS

ABSTRACT: Background. The use of adjunctive thrombectomy during primary percutaneous coronary intervention (PCI) has steadily increased with several trials demonstrating an improved clinical and mortality benefit for manual aspiration thrombectomy. The use of an in-dwelling guide extension mother-and-child catheter allows direct aspiration of thrombus from the vessel with its large extraction area. **Methods.** Between December 2011 and September 2013, a total of 17 patients who presented with acute coronary syndromes (ACS) in whom a guide extension catheter was utilized specifically for manual thrombus aspiration were identified and studied. **Results.** The guide extension catheter was utilized specifically for thrombus aspiration in 18 vessels involving 17 patients presenting with ACS where severe thrombus burden was noted. The cases involved 4 saphenous vein grafts and 14 native coronary arteries, with 4 cases involving vessels with late stent thrombosis. Successful outcomes with thrombus aspiration and TIMI-3 flow were achieved in 17/18 vessels treated, with no adverse sequelae of loss of transient strokes noted. **Conclusion.** Adjunctive manual aspiration thrombectomy utilizing guide extension mother-and-child catheter affords a novel method of thrombus aspiration, offering larger extraction area rather than conventional 6 Fr options with demonstrated efficacy for vessel patency with a large clot burden here.

J INVASIVE CARDIOL 2014;26(6):249–254

Key words: thrombus, adjunctive manual aspiration thrombectomy

The use of adjunctive thrombectomy during primary percutaneous coronary intervention (PCI) has steadily increased, largely from increased utilization of manual aspiration thrombectomy.[1] Distal embolization with subsequent microvascular dysfunction during primary PCI is associated with worse outcomes, including larger infarct sizes and reduced survival.[2,3] Reduction of thrombus burden during primary PCI by manual thrombectomy has in some recent trials demonstrated an improved 30-day and 1-year survival compared with conventional PCI.[4]

Manual thrombectomy involves an in-dwelling coronary aspiration catheter with vacuum aspiration performed with syringes. Devices such as the Export (Medtronic, Inc), the Diver CE (Invatec), Pronto (Vascular Solutions), Eject catheter (Medrad), and PrimaTone AC (Terumo Interventional Systems) are a partial list of the numerous manual thrombectomy devices currently available on the market (Table 1). The success of manual aspiration is limited by multiple factors including catheter tip extraction area, vacuum generator, deliverability, and working length, as well as vessel and thrombus characteristics. The large majority of primary PCIs are performed utilizing 6 Fr guide systems. The average tip extraction area of these devices ranges from 1.80–1.24 mm² or a 6 Fr system. We hypothesized that the use of a larger tip extraction area afforded by a guide extension mother-and-child catheter would serve a greater aspiration potential with improved outcomes during primary PCI. The 6 Fr GuideLiner V2 catheter (Vascular Solutions) provides a tip extraction area of 1.98 mm², with a working length of 130 cm in combination with the 6 Fr guide utilized.

Methods

The 6 Fr GuideLiner V2 catheter (outer tip diameter, 1.7018 mm) was first rinsed under water utilizing a 6 Fr Launcher (inner diameter, 1.80 mm) guide catheter (Medtronic, Inc) to ensure a fairly acceptable seal between the proximal end of the extraction catheter (lying within the guide) and the distal extraction tip, with minimal air leak demonstrated. A maximum of 20 cm of the total 25 cm thrombectomy catheter length was allowed out of the distal guide tip during extraction. Extraction with a 50 cc vacuum syringe on a stopcock release mechanism ensured excellent aspiration potential of clot particulate and, utilizing the device with the distal guide tip and catheter tip placed under water in this manner. The extraction was compared with a 6 Fr Pronto V4 thrombectomy catheter similarly positioned and was noted to be comparable or better in performance in terms of both extraction time and quantity. No visually apparent aspiration of particulate matter was noted in the syringe when the GuideLiner exit point from the guide was positioned to extract particulate and, with the distal GuideLiner end occluded. The continuous aspiration revealed no apparent remnant particulate matter within the guide after completion of aspiration.

Between December 2011 and September 2013, patients who presented with acute coronary syndromes (ACS) at a single university hospital during which the GuideLiner catheter was utilized specifically for direct manual thrombus extraction in vessels deemed to have a very large thrombus burden undergoing PCI were identified. This is an observational study of this series of patients with retrospective analysis of patient data. No comparison with alternate methods of thrombectomy were performed except in individual cases. A single reader as part of the

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Disclosure: The author has completed and returned the ICMJE form for disclosure of potential conflicts of interest. The author reports no conflicts of interest regarding the content herein.

Manuscript submitted July 9, 2013, provisional acceptance given August 27, 2013, final version accepted December 3, 2013.

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catheter was delivered to the thrombotic lesion. During aspiration, the distal tip of the GuideLiner was gradually advanced from the proximal edge of the thrombotic lesion, positioning it in gradual increments further distally. Care was taken to avoid any back and forth movement during actual thrombus aspiration in order to avoid clot dislodgment and distal embolization. The guide was aspirated prior to further contrast injection or device delivery with the guide extension catheter left within the coronary vessel. Lesions were then directly stented post aspiration with the avoidance of balloon dilation before or after stenting.

250

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01343, Reply at 21, Ex-1127, 250

Patent Owner's arguments :

- Ressemann's embolic protection device and Itou's suction catheter are "very different." (POR at 39).
- A POSITA would not advance a balloon or stent through a suction catheter. (POR at 41-42).
- Itou's catheter (2) does not have a "'suitable structure' for delivering stents and balloon catheters." (POR at 34).

- Catheter (2) has an inner diameter of 0.059 inches or 1.5 mm.

TABLE 1

Name of device	Overall length (mm)	Outer diameter (mm)	Inner diameter (mm)
Guiding catheter 1	1000	2.06	1.8
Suction catheter 2 (tubular portion)	150	1.72	1.5
Suction catheter 2 (wire-like portion)	1100	0.45	—
Distal end protective catheter 5 (tubular portion)	20	1.35	0.5
Distal end protective catheter 5 (wire-like portion)	1300	0.45	—

> And Itou's pushwire reduces the ***effective size*** of Itou's opening by about 22%, from 0.059 inches to around 0.046 inches. Ex-2138, ¶146; Ex-2145, ¶130.

IPR2020-01343, POR, 37

IPR2020-01341, -01343

29. Similarly, even if the "effective size" of the opening to the lumen of catheter (2) were 0.046 inches, angioplasty catheters were known to be insertable through catheters with lumen of 0.045 inches. Ex-1009, 4:48-64; Ex-1833, 1.

Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

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

Case IPR2020-01343
U.S. Patent No. RE 46,116

Case IPR2020-01344
U.S. Patent No. RE 46,116

SUPPLEMENTAL DECLARATI
MD, FR

IPR2020-01343

31. Baim explains that "[a]ll current slotted tube designs are 'bare mounted' on a delivery balloon, with deflated profiles smaller than 0.040-in. (1mm)." Ex-1015, 189.

And an article by Colombo described several balloon-expandable stents with crossing profiles well under 0.046 inches, including those with profiles of 0.99 mm (0.038 inch), 0.93 mm (0.036 inch) and 0.84 mm (0.033 inch). Ex-1804, Table 1, Fig. 3.

IPR2020-01341, -01343

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,
Petitioner,
v.
TELEFLEX LIFE SCIENCES LIMITED,
Patent Owner

DECLARATION OF MICHAEL JONES SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES AND PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO AMEND

IPR2020-01341
IPR2020-01342
U.S. Pat. No. 8,142,413

IPR2020-01343
IPR2020-01344
U.S. Pat. No. RE 46,116

IPR2020-01343

Medtronic Ex-1807
Medtronic v. Teleflex
Page 1 of 76

42. Moreover, even if Itou's proximal opening was obstructed by wire 25 so that the "effective size" of catheter 2's opening went from 0.059 inches (1.5mm) to 0.046 inches (1.16 mm) as Patent Owner and Mr. Keith allege (it is not), such an opening is still large enough to receive a standard coronary stent.

43. By the early 2000s, standard coronary stents, guidewires, balloon catheters, and stent catheters were available with an outer diameter sufficient to pass through Itou's allegedly constricted opening of 0.046 inches. *See* Ex-1015,

IPR2020-01343, Reply at 26, Ex-1807 (Jones Decl.)

IPR2020-01341, -01343

UNITED STATES PATENT AND TRADEMARK OFFICE

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IPR2020-01341
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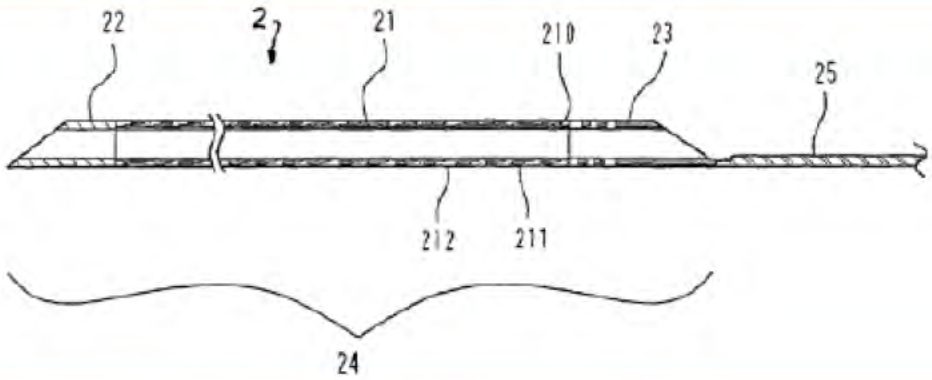
IPR2020-01343
IPR2020-01344
U.S. Pat. No. RE 46,116

IPR2020-01343

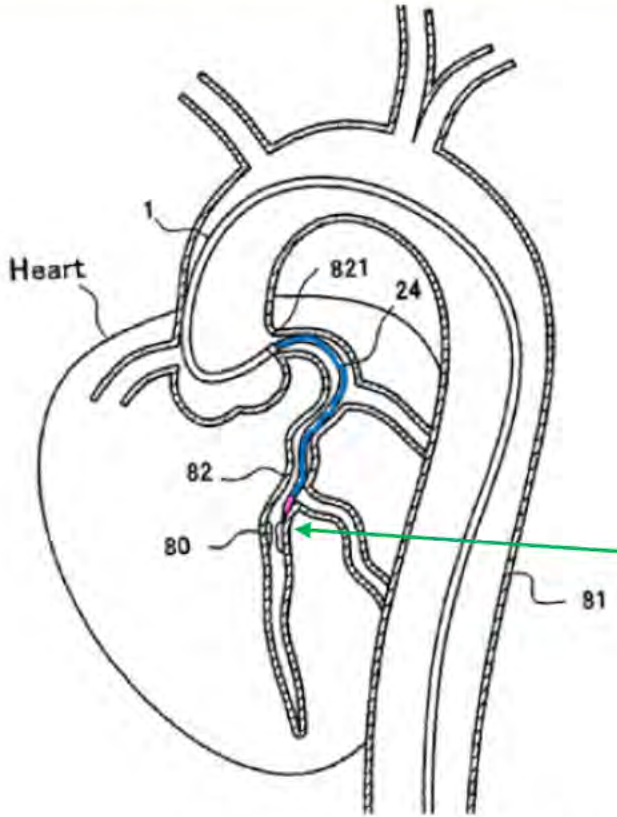
Medtronic Ex-1807
Medtronic v. Teleflex
Page 1 of 76

54. As mentioned above, Itou discloses that suction catheter 2's tubular body 24 comprises a body portion 21 that is lined with, *e.g.*, PTFE. *See* Ex-1007, Fig. 3, below. Itou is silent on the lining of portion 23 which also comprise tubular body 24. POSITA would understand that portion 23 would also include a lining having a sliding or lubricious property.



DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01343, Reply at 26, Ex-1807 (Jones Decl.); Ex-1007, Fig. 3



(4) A combination of the suction catheter **2** and the distal end protective catheter **5** is inserted into the guiding catheter **1** along the guide wire **6**.

(5) The distal end of the combination of the suction catheter **2** and the distal end protective catheter **5** is inserted to the target location **80**.

(6) The distal end protective catheter **5** is pulled out.

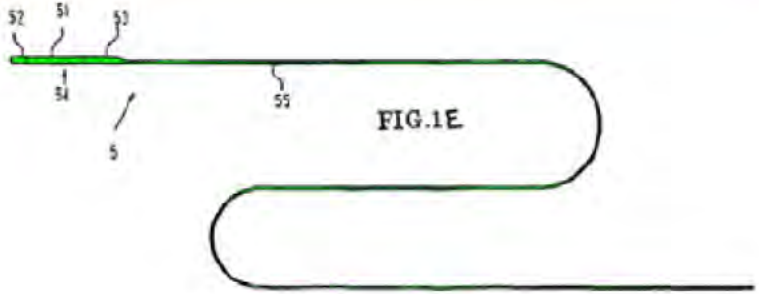


FIG.1E

IPR2020-01341, Pet. at 23, Reply at 26-29, Ex-1807 (Jones Decl.); Ex-1007, Figs. 1E, 6; 7:13-19

- Catheter (2)'s "effective size" cannot be 0.046 inches or 1.16 mm

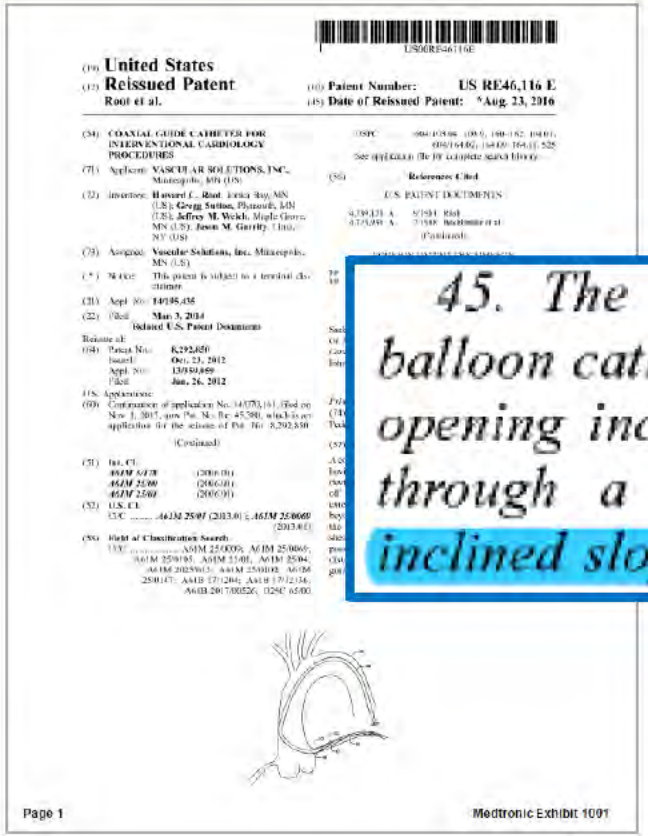
TABLE 1

Name of device	Overall length (mm)	Outer diameter (mm)	Inner diameter (mm)
Guiding catheter 1	1000	2.06	1.8
Suction catheter 2 (tubular portion)	150	1.72	1.5
Suction catheter 2 (wire-like portion)	1100	0.45	—
Distal end protective catheter 5 (tubular portion)	20	1.35	0.5
Distal end protective catheter 5 (wire-like portion)	1300	0.45	—

Double Incline claims

IPR2020-01343, -01344

Double Incline



(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE46,116 E**
(45) **Date of Reissued Patent: *Aug. 23, 2016**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **VASCULAR SOLUTIONS, INC.**, Minneapolis, MN (US)

(72) Inventors: **Howard C. Root**, Eden Prairie, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Utica, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/195,435**

(22) Filed: **Mar. 3, 2014**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,859**
Filed: **Jan. 26, 2012**

U.S. Applications:
(63) Continuation of application No. 14/070,161, filed on Nov. 1, 2013, now Pat. No. Re. 45,380, which is a reissue application of Pat. No. 8,292,850.

(Continued)

(51) Int. Cl.
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)
A61M 25/01 (2006.01)

(52) U.S. Cl.
CPC ***A61M 25/01*** (2013.01); ***A61M 25/0009*** (2013.01)

(58) Field of Classification Search
USPC 604/103.06, 103.09, 160–162, 164.01, 604/164.02, 164.03, 164.13, 525
See application file for complete search history.

(56) **References Cited**

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6,773,430 A 8/2004 Buchanan et al.
(Continued)

Page 1

Medtronic Exhibit 1001

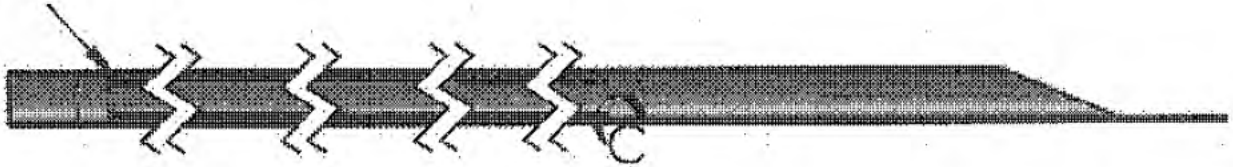
> 45. The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through a side-opening structure having at least two inclined slopes.

Ex-1001, ('116 patent), claim 45

PO's Inventor and Expert Agree: No Difference in Inclines

Guideliner V1

Guideliner V2



Guideliner V3

Ex-2138, Appendix B (citing Ex-2139, -2140, -2141)
See Paper No. 21 (PO's Response) at 61, IPR2020-01343

PO's Inventor and Expert Agree: No Difference in Inclines

And I'm trying to figure out, what is the angled side opening, like what's shown in Figure 4 -- what do you understand that that provides, other than a transition?

Does it have an advantage?

A. Not in my view.

Q. So it could -- the invention could be formed -- could be made with a perpendicular side opening, like Figure 1. And it would work just as well as an angled side opening, like Figure 4?

A. I believe so. If it's done right.

Ex-1794 (Inventor Sutton Dep. Tr.), 75:13-23

Q. Okay. And so the benefits that you talk about, stents catching, balloons tearing, as we discussed, are those benefits achieved with just a single angle or single incline side opening?
A. I think largely they are, yes.
Q. Are they achieved with a two-angled side opening, or two inclined side openings?
A. Certain two inclined side openings, I think, also provide that.
Q. Okay. So the issues that you mention, stent hang-up, balloon tear, et cetera, can you identify any difference in the improvement you discuss here for a single incline versus a double incline opening?
A. I think there are -- there may be some differences and some further advantages, but -- I mean, I certainly haven't elaborated on that in this part of my report.

Ex-1800 (Keith Dep. Tr.), 39:1-18

PO's Inventor and Expert Agree: No Difference in Inclines

As you sit here today, is there any reason you can think of, as an interventional cardiologist, that you would want to use a two incline proximal opening versus a one incline proximal opening.

MR. WINKELS: Objection, form. Objection, scope.

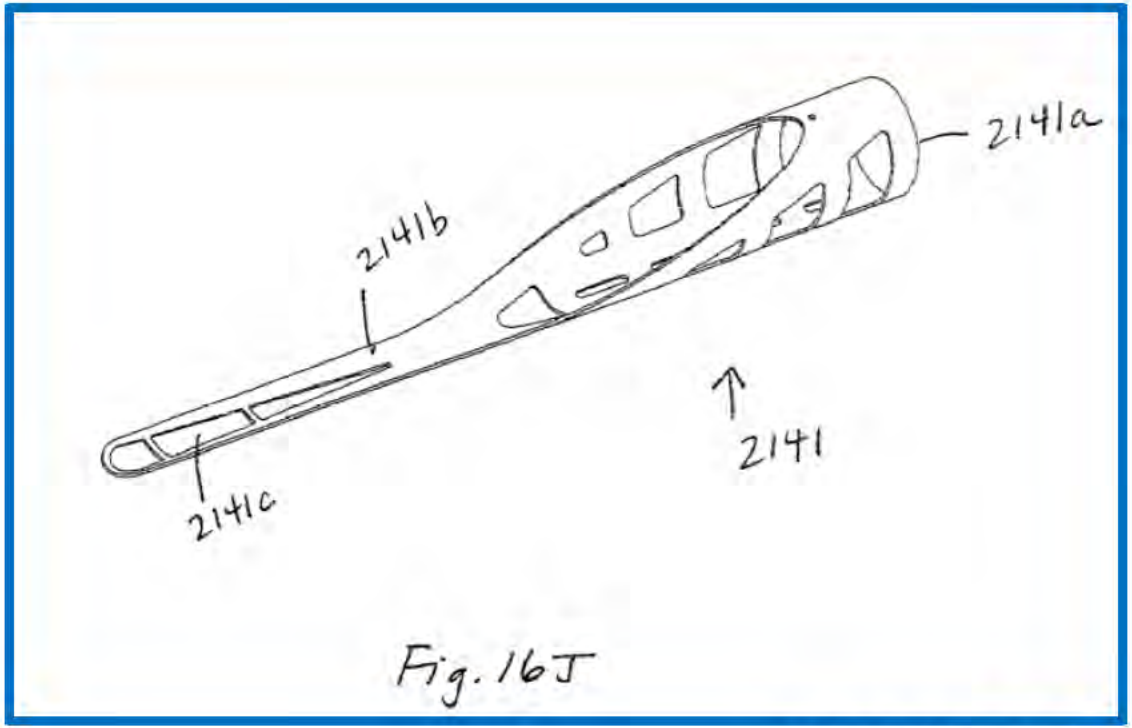
A. I have not considered it, so I -- I -- there may well be; and if I read up on it, I may come back and say, yes, there is. But at the moment, I have not considered it.

Ex-1813 (Graham Dep. Tr.), 98:6-15

Double Incline Claims

Ressemann Collar

Ressemann Collar



IPR2020-01343, Ex-1008

Incline – PO's Expert Says Incline is "Just Sort of By Eye"

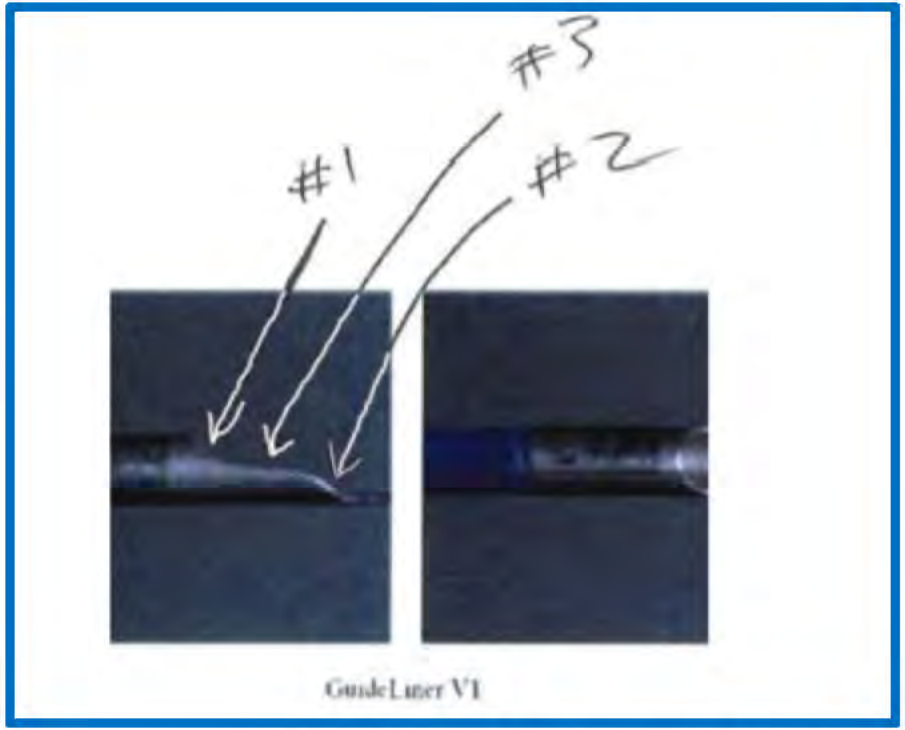
How do you know where incline 1 ends and incline 3 begins?

A. To me it's just sort of by eye, that incline 1 has a -- sort of a relatively steeper quality to it. Incline 3 has a shallower quality to it. So somewhere in between there is where that goes from one to the next.

Q. Okay. And so if you can identify an incline relative to the longitudinal axis, even if it's shallow, that constitutes an incline; is that fair?

A. I don't know if it's quite that specific. I think -- in this example, I think that works.

Ex-1800 (Keith Tr), 45:21-46:2; 47:3-8



Ex-1122 (color aded to arrows for visibility)

Incline – Petitioner's Expert Uses PO's Testimony

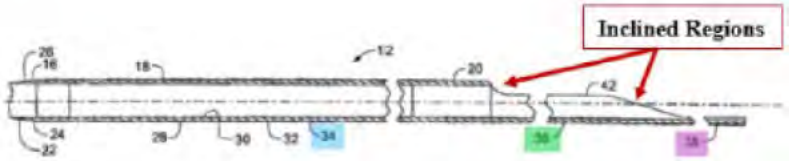
84. I have also reviewed the testimony of Mr. Root and Mr. Keith in Related IPRs. While Teleflex's position in its Response is that the first incline on collar 2141 is "extremely tiny," that position seems at odds with their testimony, as discussed below.

85. Mr. Keith did not opine that patent claims require an inclined slope of any particular size or shape. IPR2020-01343, Ex-2138; Ex-1805, 104:5-107:3, 176:10-177:16. An incline may be shallow. Ex-1800, 47:3-8. This was also the view of Mr. Root. Ex-1762, 91:24-93:25; Ex-1854. Based on Mr. Root's testimony, there are two inclines in the figure shown below.

Ex-1806 (Brecker Supplemental Decl.), ¶¶ 84-85

Incline – Petitioner's Expert Uses PO's Testimony

87. Mr. Keith has also opined that the curved area in Fig. 4 from the patent is also an incline.



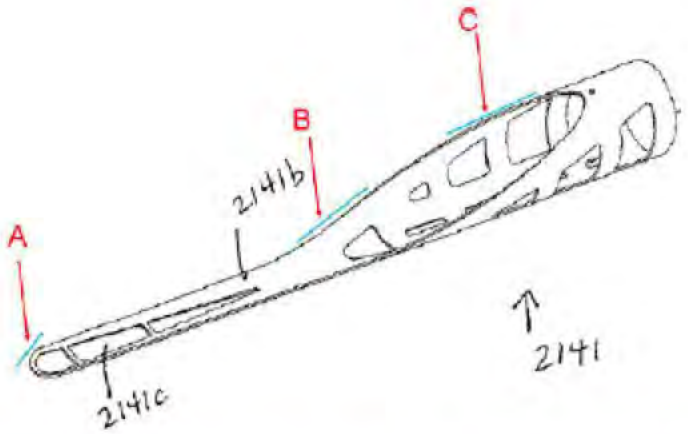
Ex-2138, ¶ 94.

89. Given the testimony of Teleflex's witnesses, it is my opinion that collar 2141 of Ressemann discloses more than two inclines. I understand that Mr. Keith has testified that collar 2141 has at least one incline leading up to its fully circumferential portion. Ex-1805, 173:14-174:3. He also admitted that collar 2141 has a second incline at the tip of tab 2141b. Ex-1800, 166:8-12, 168:9-19.

Ex-1806 (Brecker Supplemental Decl.), ¶¶ 87, 89

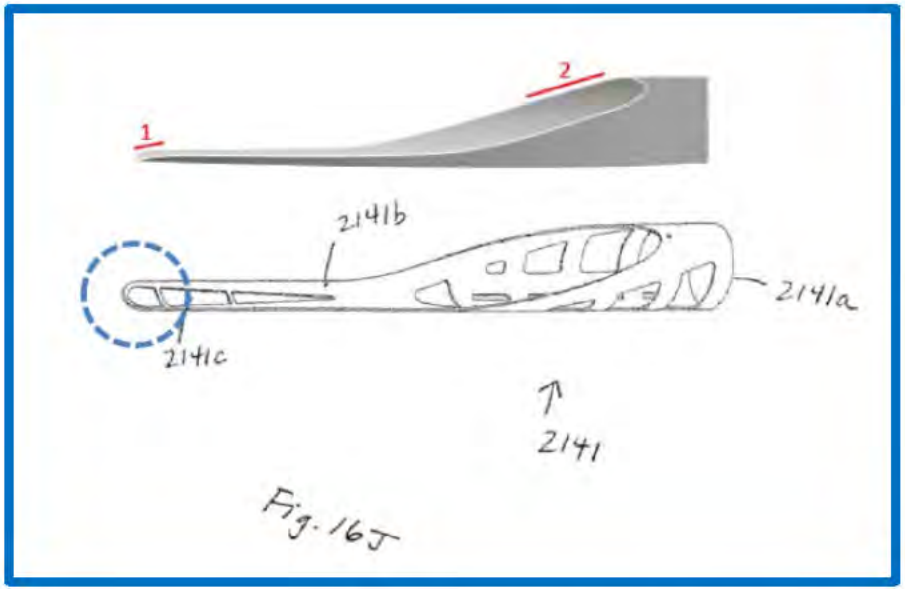
Incline – Ressemann Has More Than Two Inclines

90. In addition to two inclines, A and C, the collar has at least a third incline, at the transition between 2141a and 2141b, which is a curve shape similar to the curve that Mr. Keith identifies as an incline in Fig. 4 of the patent.



Ex-1806 (Brecker Supplemental Decl.) ¶ 90

Incline – PO's Expert Says Ressemann's Tip Has An Incline



IPR2020-00129, Ex-2138 ¶ 170

8 Q. Okay. That tip in the circle does show an
9 initial incline as you come into the collar,
10 right?
11 A. Yeah. I described that as a miniscule
12 incline. And this is looking at the collar, you

Ex-1800 (Keith. Dep. Tr.), 166:8-12

9 Q. And I just want to be clear; a miniscule
10 incline counts as an incline in the context of
11 these patent claims we're talking about, right?
12 A. I would argue that it counts as a -- it may
13 count as an incline in an abstract when we're just
14 trying to put labels on to this device in free
15 space, but in the context of an incline that would
16 be part of a side opening, you know, I don't --
17 certainly, when it's in the device as disclosed in
18 Ressemann, this does not form an incline that's
19 part of the side opening.

Ex-1800 (Keith. Dep. Tr.), 168:9-19

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry
2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top
2. Weld Collar Directly to Itou's Pushwire
3. Patent Owner's Interpretation of Tab

Ressemann's Proximal Opening Disclosure is Relevant to Itou

The first and preferably larger of the lumens, an evacuation lumen **140**, is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters. The evacuation lumen **140** is also designed to allow for fluid flow, such as blood, blood/solid mixtures, radiographic dye and saline, within the evacuation lumen **140**. This flow of fluid may occur regardless of whether an interventional device is within the evacuation lumen **140**. The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**. The larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly.

Ex-1008 (Ressemann), 6:45-61
see also Ex-1123 (Keith Patent), 7:54-60

Q. That's the identical passage we talked about earlier discussing that the proximal and distal ends are advantageous for smoother passage to the guide catheter, smoother passage of therapeutic devices and allowing for larger deformable particulate matter to pass through the lumen more smoothly, correct?
A. It looks to be the same, yeah.
Q. And, again, you would have had a chance to review this, and you agree with this passage as you sit here today, right?
A. Yes.
Q. And this patent where you have your name on it, nowhere in this patent is there anything about the use of a flare or a reverse bevel, correct?
A. I don't see it in any of the figures.

Ex-1800 (Keith Dep. Tr.), 149:3-18

Ressemann's Collar 2141 "Reinforces" And Is the Proximal Opening

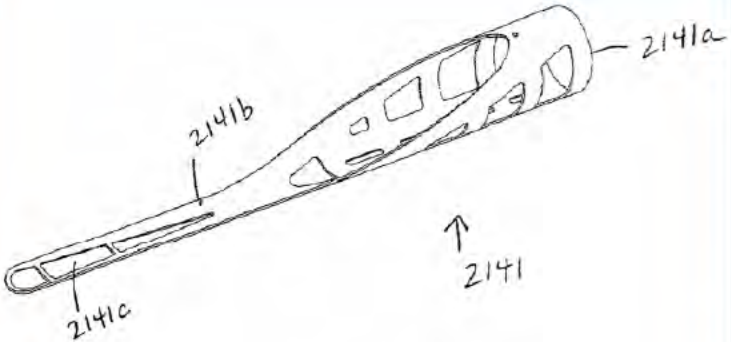


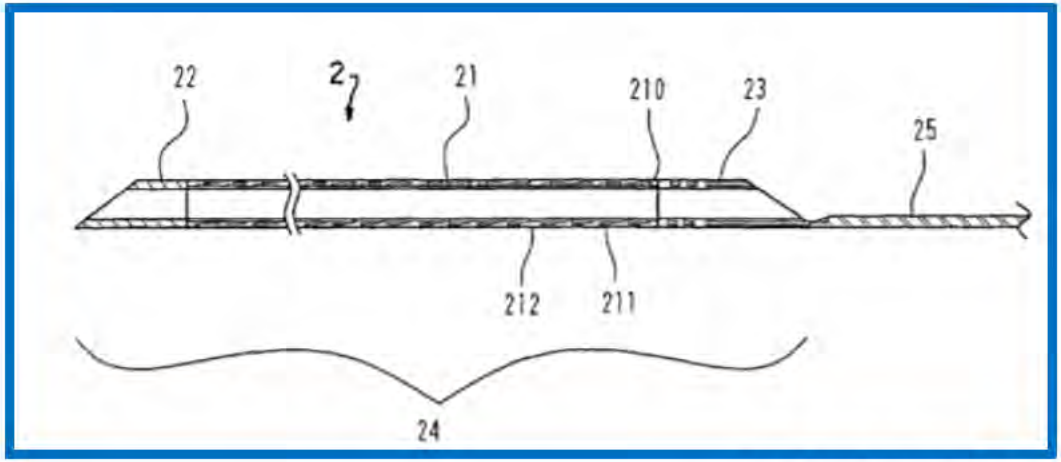
Fig. 16J

Ex-1008 (Ressemann) Fig. 16J

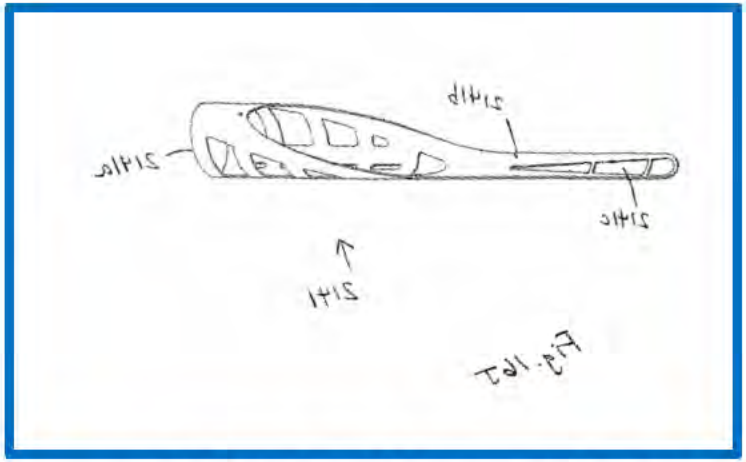
As embodied herein and shown in FIGS. **16**D and **16**J, the evacuation head **2132** may include a structure to reinforce the proximal opening of the multi-lumen tube **2138**. A support collar **2141** is positioned about the proximal end of the multi lumen tube **2138** and serves to reinforce the proximal opening of the evacuation lumen **2140** in the presence of deforming forces, particularly torsional stresses that may be created unintentionally by rotation of the catheter shaft near its proximal end. As shown in FIG. **16**J, the support collar **2141** includes a cylindrical portion **2141***a* that fits into the proximal opening of the evacuation lumen **2140** and provides hoop support to the opening of the multi-lumen tube **2138**. The cylindrical portion **2141***a* of the support collar **2141** tapers

Ex-1008 (Ressemann), 24:47-58

Modifying Itou with Ressemann Collar



Ex-1007 (Itou), Fig. 3



Ex-1008, Fig. 16J (orientatiion reversed)

IPR2020-00132

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann Collar

288. A POSITA had the motivation to modify the proximal end of the tubular structure of Itou's suction catheter (2), because s/he had the motivation to use catheter (2) to deliver a balloon catheter or stent for the reasons I discussed for claim 25.

289. Modifying the proximal opening of Itou's suction catheter (2) with Ressemann's collar 2141 would provide a larger area within which to receive the balloon catheter or stent.

Ex-1005 (Brecker Decl.), ¶¶ 288-89

87. The larger the opening area, the less coaxially aligned the interventional device (guidewire or balloon catheter) must be to enter the catheter lumen. By including features such as a concave track and angled opening, easier insertion of the interventional device is facilitated during a procedure.

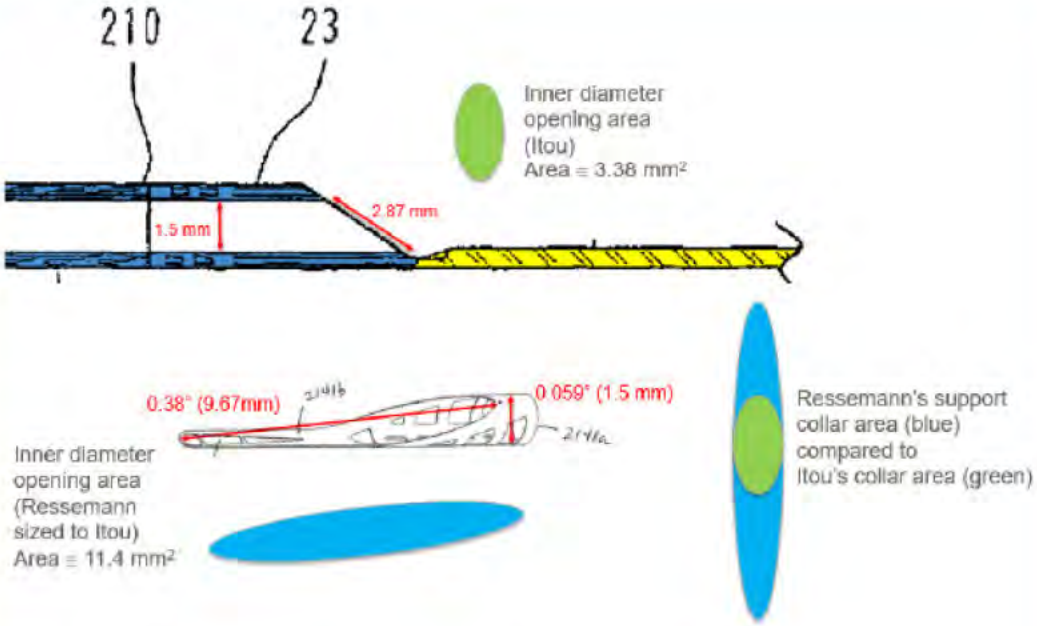
Ex-1042 (Hillstead Decl.), ¶ 87

Modifying Itou with Ressemann Collar

61. A POSITA would be motivated to modify Itou because the area of opening provided by the Ressemann collar creates a longer and more gradual entryway into the lumen of catheter 2. While Itou and Ressemann do not report the area of each of their angled side openings, these areas can be estimated based on the figures and dimensions reported in each patent. I compared what the area of the opening would be based on the inner diameter of Itou's catheter 2, which is 1.5 mm. Ex-1007, Table 1, 7:60. To compare to Ressemann's support collar, I scaled Ressemann's support collar such that it has the same inner diameter of Itou. Since Ressemann's support collar's inner diameter is ~0.067 inches (1.7mm) (Ex-1008, 23:4), I scaled Ressemann's collar down by 12% to achieve the same 1.5 mm inner diameter.

Ex-1807 (Jones Decl.), ¶ 61

Modifying Itou with Ressemann Collar



Schematic illustrating scaled comparison of Itou's collar area as compared to Ressemann's collar area.

Ex-1807 (Jones Decl.), ¶ 62

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

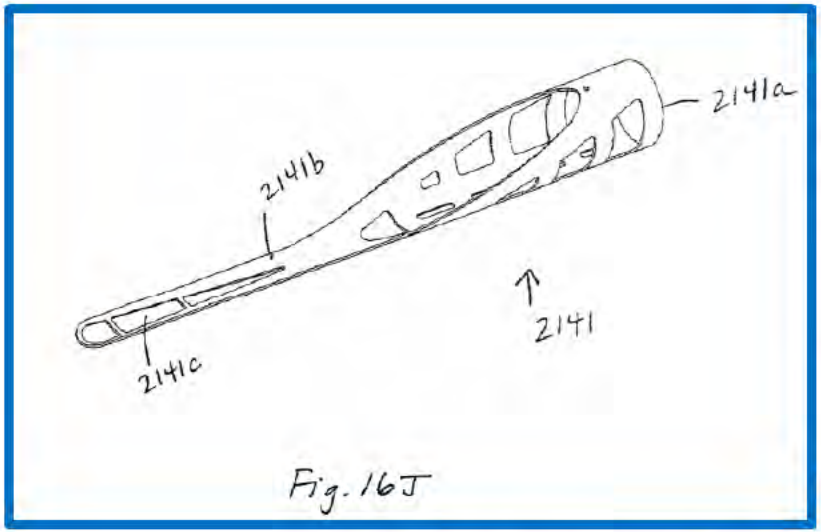
B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Ressemann's Collar 2141 Reinforces the Proximal Opening



Ex-1008 (Ressemann), Fig. 16J

The cylindrical portion **2141***a* of the support collar **2141** tapers into a tab portion **2141***b* that extends proximally and in a direction parallel to a longitudinal axis of the evacuation lumen **2140**. The tab portion **2141***b* lies adjacent the exterior walls of the multi-lumen tube **2138** which define the core wire lumen **2143** and the inflation lumen **2142** and provides a flexibility transition between the proximal end of the evacuation head **2131** and the shaft of the evacuation sheath assembly **2100**.

Ex-1008 (Ressemann), 24:58-67

Modifying Itou with Ressemann Collar

74. By the relevant time frame it was well known to a POSITA that a critical region where kinking and buckling can occur in coronary catheters was at the interface between the stiff proximal portion and the flexible distal portion of the catheter due to the change in stiffness at this interface." Ex-1829, 2:38-49.

Ex-1807 (Jones Decl.), ¶ 74

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann is Routine Engineering

70. A POSITA also appreciates that tab 2141b could be placed on top of a push rod, like wire-like portion (25), and the combination would have no catch points or ledge.

71. In the alternative, wire-like portion 25 could be flattened or tapered at its distal end, at the point at which it is affixed to collar 2141b. *See, e.g.*, Ex-1015, 551 ("The basic guidewire consists of a solid core (stainless steel or the superelastic alloy known as Nitinol) that is ground to a progressive taper in its distal portion."); Ex-1033, [0071], [0078]-[0079] (teaching tapering of the distal end of a pushwire attached to a distal tubular body). In addition to securing support collar 2141 to pushrod by adhesive and polymer encasement, the metal support collar could be spot-welded to the pushrod, as taught by both Itou and Ressemann.

Ex-1807 (Jones Decl.) ¶¶ 70-71

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann Collar

289. Modifying the proximal opening of Itou's suction catheter (2) with Ressemann's collar 2141 would provide a larger area within which to receive the balloon catheter or stent.

290. Tab 2141b of collar 2141 is concave. This would be an advantage, as adding it to the proximal opening of the tubular structure of Itou would not impede entry into the lumen.

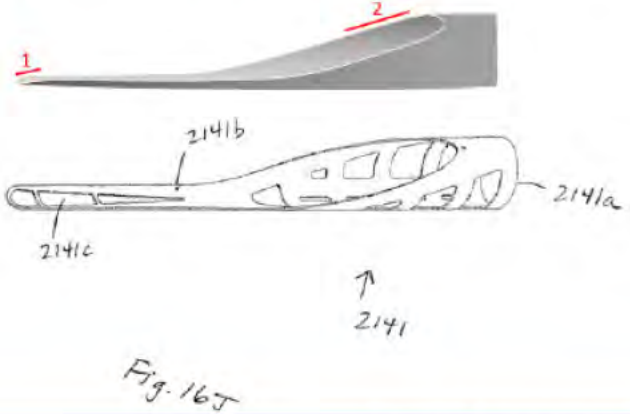


Fig. 16J

Ex-1005 (Brecker Decl.), ¶¶ 289-90, 92

Modifying Itou with Ressemann Collar

64. The second way that collar 2141 is an improvement over Itou's metal collar relates to the way that Itou teaches wire-like portion 25 should be attached to the proximal opening of the tubular portion of catheter (2). Itou teaches a weld point that is crushed flat. *See* Ex-1007, 4:35. This requires plastic deformation of the metal, resulting in work hardening and a decrease in the metal's ductility at that location. *See* Ex-1818, 117-18, 121-23. A reduction in ductility at a critical stiffness transition point is known in the art to be susceptible to kinking. Including tab 2141b on top of Itou's pushrod would decrease the risk that the device failed at the crushed weld point.

Ex-1807 (Jones Decl.), ¶ 64

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann is Routine Engineering

FIG. **4** is a view illustrating an example of a method of joining the wire-like portion **25** and the tubular portion **24** together. Referring to FIG. **4**, the proximal tip **23** includes a body which in turn includes a proximal end portion **231** formed by obliquely cutting one end of a metal pipe such as a pipe of stainless steel and a distal end portion **232** formed by working the other end portion of the metal pipe into a spiral shape. The inner and outer faces of the body are coated with a resin. The proximal end portion **231** is secured firmly by being welded to the distal end of the wire-like portion **25** crushed into a form of a flat plate so that it may not be broken during use. The resin layers which cover the inner and outer faces of the proximal tip **23** are secured to the tubular body portion **21** by fusion. Where the proximal tip **23** is formed from such a metal material as described above, the surface of the proximal tip **23** is plated with gold. The portion plated with gold functions as an X-ray contrast marker (radiopaque marker).

Ex-1007 (Itou), 4:33-36

Q. How is that rod attached to incline -- the area by incline 2?
A. I don't know the exact details of that, but I believe it's some sort of welding process.
Q. Okay. And that's something you would know how to do as an engineer?
A. Well, at a high level, yes. I mean, there may be particulars about this specific design, any design that you would need to do some work to -- you know, to perfect that, say. But, certainly, you know, welding is -- two metal components on a catheter, I think that's fairly well established as something that has been done.

Ex-1800 (Keith Dep. Tr.), 48:5-17

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

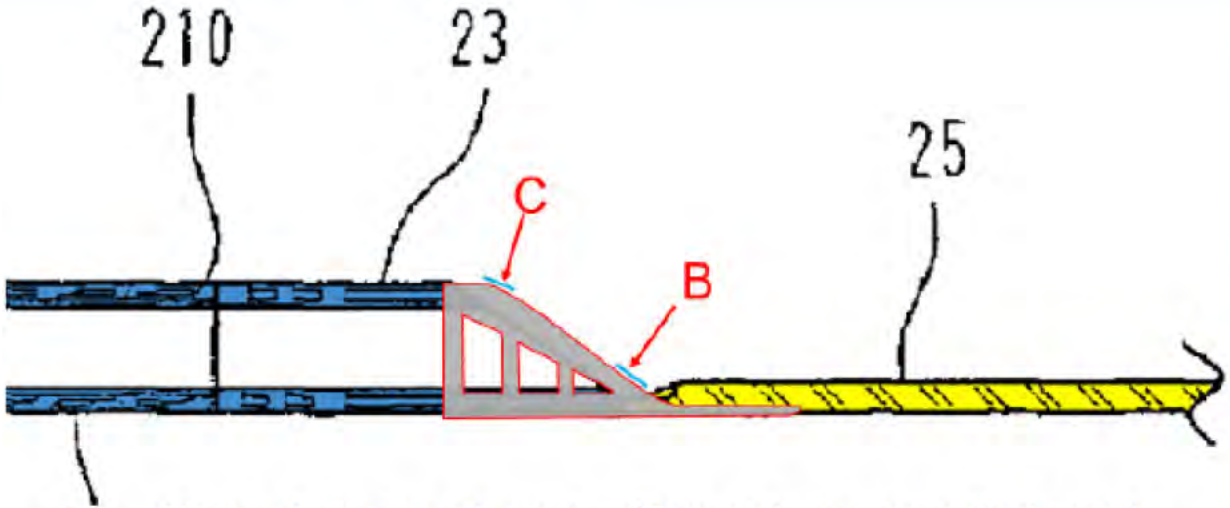
3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann Collar

72. I understand Patent Owner has argued that the collar of Ressemann, if combined with Itou, would be placed beneath pushrod wire 25, and not on top of wire 25. *See, e.g.*, IPR2020-00132, Paper 44, 38-43. If the collar were placed beneath pushrod wire 25, the collar would provide support at the proximal opening, improved flexibility transition and improved trackability. In such a scenario, the incline formed at the proximal end of the tab portion would be buried beneath wire 25. The inclines located at B and C of the collar (as shown schematically below) would still be present at the proximal opening as shown schematically below.

Ex-1807 (Jones Decl.), ¶ 72

Modifying Itou with Ressemann Collar



73. Shown above is a schematic of Itou with support collar located beneath pushrod wire 25, as argued by Patent Owner.

Ex-1807 (Jones Decl.), ¶¶ 72-73

Modifying Ressemann with Ressemann Collar

Fig. 16J

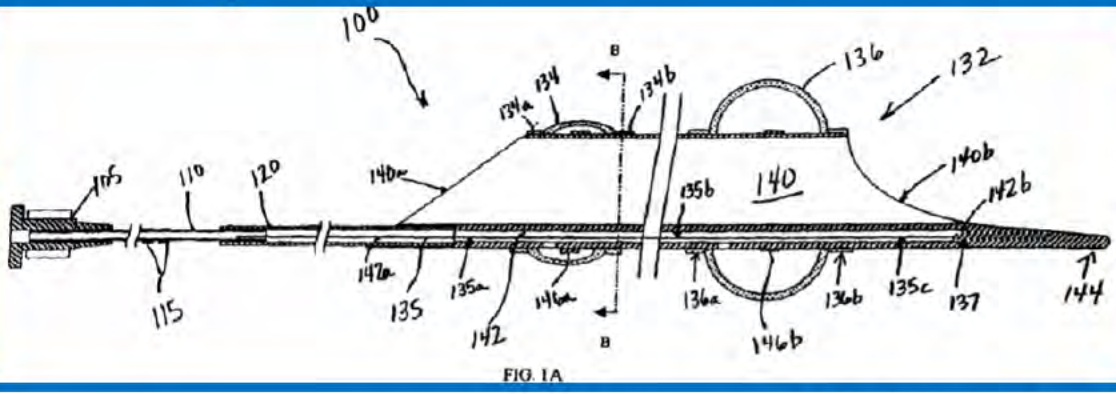
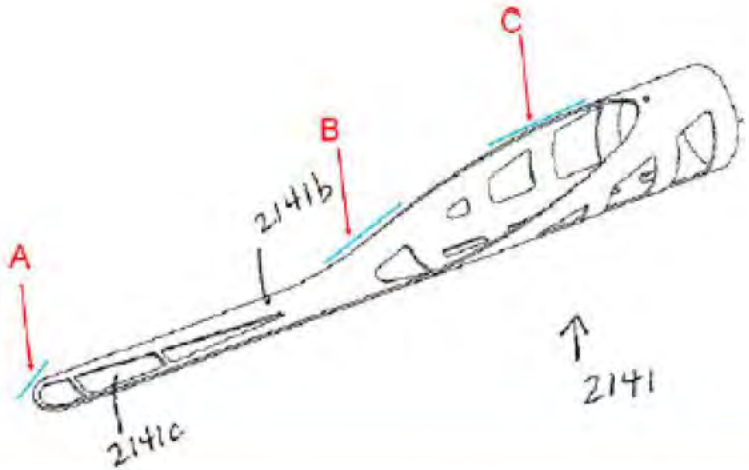


FIG. 1A

IPR2020-00138, Ex-1208

Incline – Ressemann Has More Than Two Inclines

90. In addition to two inclines, A and C, the collar has at least a third incline, at the transition between 2141a and 2141b, which is a curve shape similar to the curve that Mr. Keith identifies as an incline in Fig. 4 of the patent.



Ex-1806 (Brecker Supplemental Decl.) ¶ 90

Modifying Ressemann with Ressemann Collar

65. Additionally, the rigidity of catheter 2 transitions between wire 25 and tubular portion 24. Ex-1007, Figs. 1B, 3, 4, 2:5-26, 3:45-4:42, 5:26-51. A POSITA was aware that a region of flexibility transition could be improved upon by the addition of a stiffness transition member, as discussed below. *See* ¶¶ 74-88, *infra*.

Indeed, Ressemann explicitly teaches that its support collar, in particular its tab portion, functions as a flexibility transition. Ex-1008, 24:62-67. A POSITA would be motivated to include Ressemann's support collar due to the benefit of this flexibility transition.

Ex-1807 (Jones Decl.), ¶ 65

Double Incline Claims

Kataishi

Kataishi

US 20050015073A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0015073 A1

Kataishi et al. (43) Pub. Date: Jan. 20, 2005

(54) THROMBUS SUCTION CATHETER WITH IMPROVED SUCTION AND CROSSING

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(22) Filed: Jan. 22, 2004

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Publication Classification

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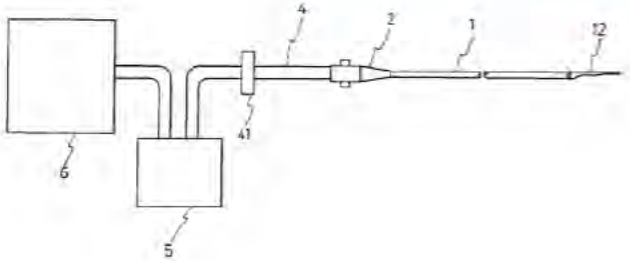
(52) U.S. Cl. 604/528

(57) ABSTRACT

A thrombus suction catheter which is a tube having a distal end opening formed by an angled cut surface. In the distal end opening, at least a part on the proximal end side of the cut surface is formed in a concave shape in an angled direction, and the distal end side of the cut surface is formed to be flat and flexible. With the distal end configuration, suction and crossing are significantly improved.



(57) ABSTRACT

A thrombus suction catheter which is a tube having a distal end opening formed by an angled cut surface. In the distal end opening, at least a part on the proximal end side of the cut surface is formed in a concave shape in an angled direction, and the distal end side of the cut surface is formed to be flat and flexible. With the distal end configuration, suction and crossing are significantly improved.

Ex-1025 (Kataishi)

Kataishi

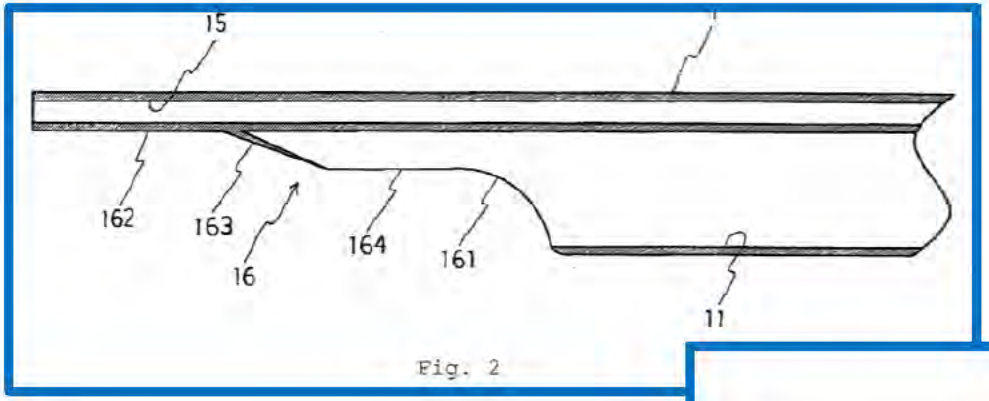


Fig. 2

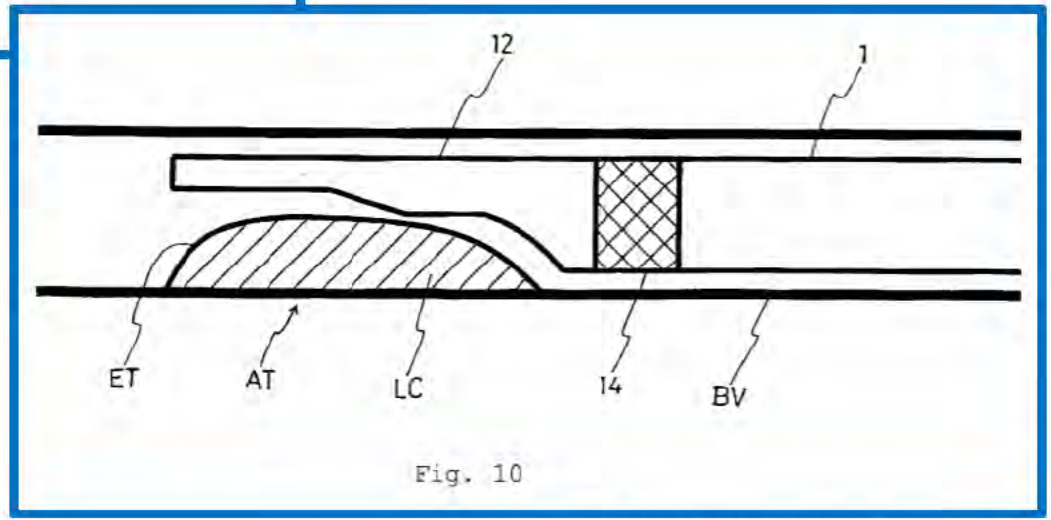


Fig. 10

Ex-1025 (Kataishi), Figs. 2 & 10

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry for Thrombus and Devices

2. Improved Trackability

B. Expectation of Success

Ressemann Discloses Benefits of Distal and Proximal Openings

The first and preferably larger of the lumens, an evacuation lumen **140**, is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters. The evacuation lumen **140** is also designed to allow for fluid flow, such as blood, blood/solid mixtures, radiographic dye and saline, within the evacuation lumen **140**. This flow of fluid may occur regardless of whether an interventional device is within the evacuation lumen **140**. The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**. The larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly.

Ex-1008 (Ressemann), 6:45-61
see also Ex-1123 (Keith Patent), 7:54-60

Q. That's the identical passage we talked about earlier discussing that the proximal and distal ends are advantageous for smoother passage to the guide catheter, smoother passage of therapeutic devices and allowing for larger deformable particulate matter to pass through the lumen more smoothly, correct?
A. It looks to be the same, yeah.
Q. And, again, you would have had a chance to review this, and you agree with this passage as you sit here today, right?
A. Yes.
Q. And this patent where you have your name on it, nowhere in this patent is there anything about the use of a flare or a reverse bevel, correct?
A. I don't see it in any of the figures.

Ex-1800 (Keith Dep. Tr.), 149:3-18

Kataishi – Motivation to Combine

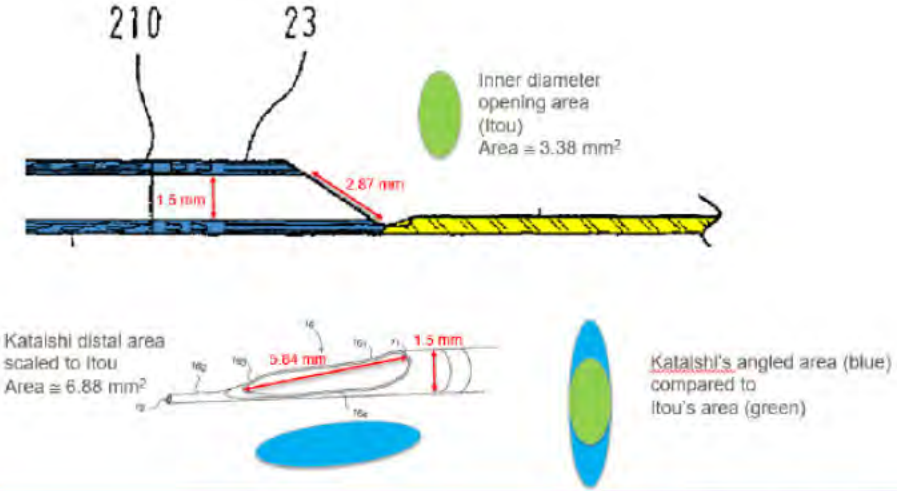
93. Thus, a POSITA knew that an angled opening was beneficial ***both*** for suctioning material out of the vasculature as well as for introducing a stent or balloon catheter. Patent Owner's expert witness, Mr. Keith, agrees. Ex-1800, 140:18-143:7; *see also id.*, 146:16-147:8, 148:21-149:14.

94. It follows that if the distal tip of Kataishi is more beneficial for allowing larger, deformable particulate matter to pass through the lumen more smoothly (i.e., suction thrombus), the same shape would be more beneficial for receiving a stent catheter of balloon catheter.

Ex-1807 (Jones Decl.), ¶¶ 93-94.

Kataishi – Motivation to Combine

100. Applying the shape of Kataishi to Itou's proximal opening also increase the effective are of the opening, as approximated by the following scaled comparison.



Ex-1807 (Jones Decl.), ¶ 100.

PO Ignores the Explicit Teaching in Ressemann as "Hindsight"

> Two, the cited passage is ambiguous at best—Ressemann's angled ends may serve more than one purpose, but that does not mean that each end serves ***both***. *See* Ex-1008, 6:52-57. Indeed, Ressemann later assigns only one of these functions to each angled portion. *Id.*, 7:48-53; 23:17-20.

IPR2020-01343, Paper 59 at 30.

PO's Expert on Ressemann's Benefits of Distal/Proximal Opening

Q. Okay. And you would agree with that, right, that the proximal and distal angles allow for smoother passage through the guide catheter?
A. I don't know that I formed an opinion on that, but I think that is probably true.
Q. Okay. And then it continues -- well, first it says that you then pass it into a blood vessel.
You see that, right?
A. Yep.
Q. And it also, in talking about the proximal and distal angles, it says that they "facilitate smoother passage of other therapeutic devices through the evacuation lumen 140 of the evacuation head 132," right?
A. Yes.
Q. And you would agree with that as well?
A. Yeah, I think that's probably true.

Q. Okay. And Ressemann also teaches that the larger area of the angled open ends -- again, referring to both ends -- also allows for larger deformable particulate matter to pass through the lumen more smoothly.
Do you see that?
A. Yes.
Q. And you would agree with that as well?
A. I think so, yes.

Ex. 1800 (Keith Dep. Tr.), 142:4-143:4

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry for Thrombus and Devices

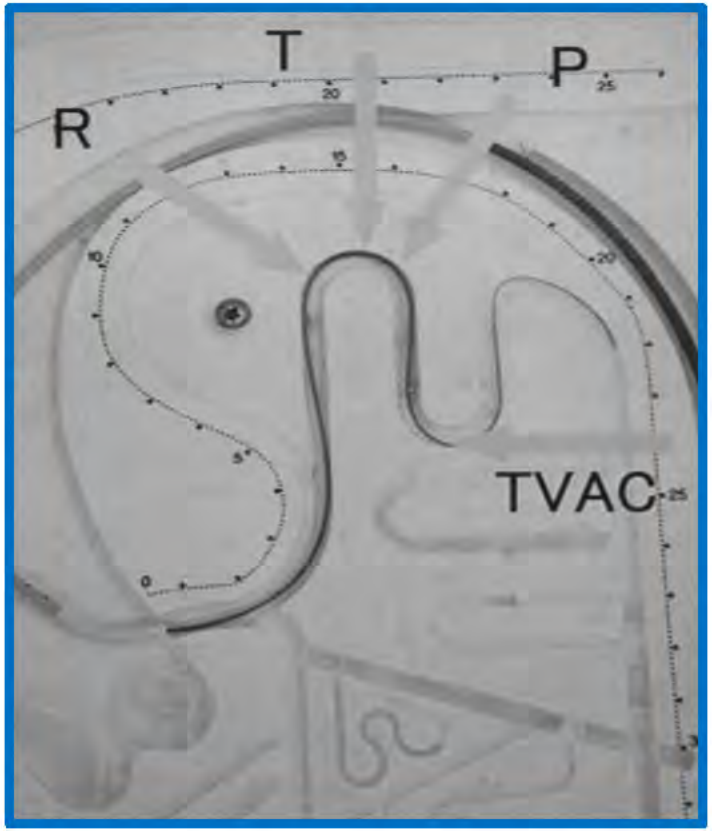
2. Improved Trackability

B. Expectation of Success

Sakurada Confirms Benefits of Kataishi's Shape

Passing Ability Test

Passing ability was measured using a PTCA training device (Medical Sense, Japan). A 7 Fr JL4 Wiseguide catheter (Boston Scientific) was inserted and a 0.014″ BMW guidewire (Guidant, Indianapolice, IN) was passed into a bending left anterior descending artery (LAD) of the training device. TVAC was pushed with a constant mechanical pressure until the guide catheter was dislodged from the coronary ostium. The length between the ostium and the distal tip of the aspiration catheters was measured. Other aspiration catheters such as Rescue, PercuSurge, and Thrombuster were compared under the same conditions. The experiment was repeated six times for each catheter.



Ex-1055, 6-7

Sakurada

TABLE I. Comparison of Aspiration Catheters for 7 Fr Guide Catheter

	TVAC	Thrombuster	PercuSurge	Rescue
Guide catheter	7 Fr	7 Fr	7 Fr	7 Fr
Larger outer diameter	4.5 Fr	5.7 Fr	5.6 Fr	4.5 Fr
Smaller outer diameter	4.5 Fr	4.5 Fr	3.7 Fr	4.5 Fr
Distal inner lumen (mm2)	0.9	1.13	0.95	0.65
Proximal inner lumen (mm2)	0.98	1.37	0.92	0.65
inner support	yes	no	no	yes
shape of distal tip	duckbill	oblique straight	oblique straight	oblique straight
original device for negative pressure	motor drive	30 ml syringe	20 ml syringe	motor drive
aspiration time in a test tube (sec)	20.35 ± 4.07	11.81 ± 1.13	39.50 ± 6.40	61.63 ± 2.73

Passing Ability

Quantitative measurements of passing ability is shown in Figure 2. Only TVAC was able to pass the third bend. PercuSurge and Thrombuster catheters were able to reach the second bend. The Rescue catheter was only able to pass the first bend.

Ex-1055, 6, 8

Kataishi's Shape Has Better Trackability

95. Kataishi also describes the shape of the distal tip of the catheter as improving crossing ability, which relates to the flexibility of the catheter. Ex-1025, [0009]-[0010]; Ex-1055, Figs. 1A, 2, 302 (explaining that the catheter with the unique shape performed quantitatively better when subjected to a "Passing Ability Test" in which the ability to navigate past multiple bends was assessed). Kataishi illustrates a "crossing test" in its patent application. Ex-1025, Fig. 8, [0020]. This is similar to Sakurada's "Passing Ability Test." Ex-1055, Figs. 1A, 2, 302. What Kataishi and Sakurada illustrate is how Kataishi's distal tip design improves, what is commonly referred to in the art as, "trackability."

Ex-1807 (Jones Decl.), ¶ 95.

Kataishi's Shape Has Better Trackability

Whether it is called trackability or crossability. Kataishi's distal tip design is such that increases the distance in which the device can navigate around bends. Whether the design of Kataishi is placed on a distal end of a device or at a proximal opening of a device, the design will improve trackability through a patient's vasculature.

96. Patent Owner has argued that having the shape of the Kataishi distal end on the proximal portion of a catheter like Itou's catheter (2) would have no benefit to catheter crossability because the proximal opening does not "'see' the vasculature." IPR2020-01343, Paper 21 at 58-59; *see also* IPR2020-00129, Paper 43 at 46, 59. This ignores the fact that the proximal opening of catheter (2) and evacuation lumen (140) "see" the inside of a guide catheter.

Ex-1807 (Jones Decl.), ¶¶ 95-96.

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry for Thrombus and Devices

2. Improved Trackability

B. Expectation of Success

Kataishi – Expectation of Success

tially equal to actual pump pressure when the cut surface **16** completely adsorbs the atheroma AT), and enables suction of the lipid core (LC) in a vascular endothelium (ET). Thus, the concave cut surface or portion **161** may have any shape, as long as it is angled in an angled direction, i.e., a proximal direction. Generally, the concave cut portion **161** is formed so as to be gently concave so that atheroma can be covered and the gap minimized. The concave cut portion **161** is provided at least partially on the proximal end side of the cut surface **16**. More specifically, the concave portion **161** may

Ex-1025 (Kataishi), ¶ [0027]

Secondary Considerations

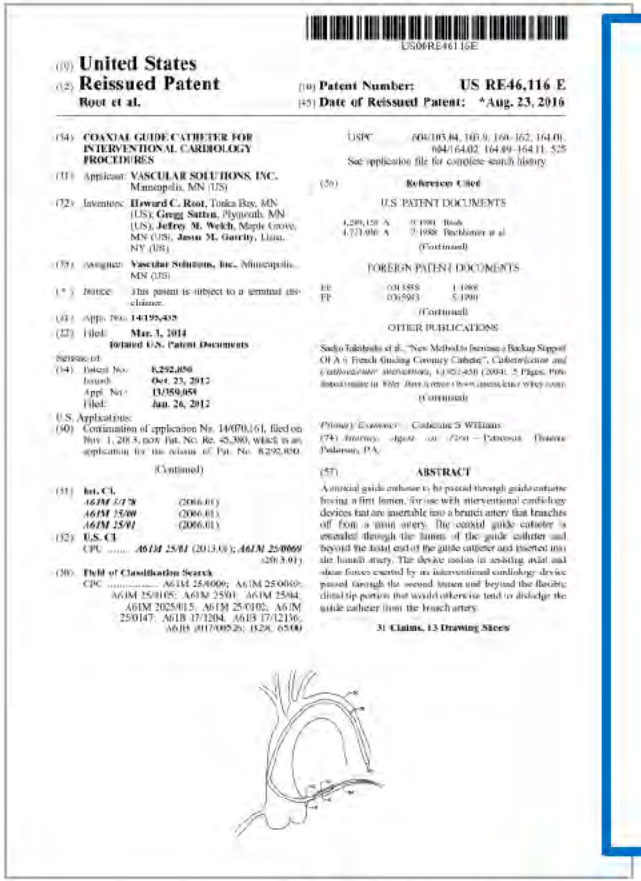
IPR2020-01341, -01342, -01343, -01344

Secondary Considerations – Copying

"Copying requires duplication of features of the patentee's work. . . . [M]ore is needed than merely showing that similarity exists between the patent and the competitor's accused product."

Liqwd, Inc. v. L'Oreal USA, Inc.,
941 F.3d 1133, 1137 (Fed. Cir. 2019)

Secondary Considerations – Copying



US00RE46116E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE46,116 E**
(45) **Date of Reissued Patent: *Aug. 23, 2016**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **VASCULAR SOLUTIONS, INC.**, Minneapolis, MN (US)

(72) Inventors: **Howard C. Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/135,435**

(22) Filed: **Mar. 3, 2014**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,054**
Filed: **Jan. 26, 2012**

U.S. Applications:
(60) Continuation of application No. 14/070,161, filed on Nov. 1, 2013, now Pat. No. Re. 45,380, which is an application for the reissue of Pat. No. 8,292,850.

(Continued)

(51) **Int. Cl.**
A61M 1/178 (2006.01)
A61M 25/00 (2006.01)
A61M 25/01 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/01*** (2013.01); ***A61M 25/0069*** (2013.01)

(58) **Field of Classification Search**
CPC A61M 25/0009; A61M 25/0069; A61M 25/0105; A61M 25/01; A61M 25/04; A61M 2025/015; A61M 25/0102; A61M 25/0147; A61B 17/1204; A61B 17/12136; A61B 2017/00526; B29C 65/00
USPC 604/103.04, 103.9, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

(56) **References Cited**

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(Continued)

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(Continued)

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(Continued)

Primary Examiner — Catherine S Williams
(74) *Attorney, Agent, or Firm* — Patterson Thuente Pedersen, P.A.

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is cannulated through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device 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 that would otherwise tend to dislodge the guide catheter from the branch artery.

31 Claims, 13 Drawing Sheets

25. *A method, comprising:*

advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;

advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure **having a cross-sectional inner diameter that is not more than one French size smaller** *than a cross-sectional inner diameter of the lumen of the guide catheter;*

'116 Patent, claim 25

Secondary Considerations – Copying

French Size (F)	GEC Name	I.D. (in)	O.D. (in)	Required GC I.D. (in)	Extension Length (cm)	Polymer Channel (cm)	Full Length (cm)
5.5	GuideLiner™* V3 GEC[1]	0.051	0.063	6 F ≥ 0.066	25	17	150
6	Telescope™ GEC	0.056	0.067	6 F ≥ 0.070	25	4	150
6	GuideLiner™* V3 GEC[1]	0.056	0.067	6 F ≥ 0.070	25	17	150
6	Guidezilla™* II GEC[2]	0.057	0.067	6 F ≥ 0.070	25	N/A, metal collar	150
7	Telescope™ GEC	0.062	0.075	7 F ≥ 0.078	25	4	150
7	GuideLiner™* V3 GEC[1]	0.062	0.075	7 F ≥ 0.078	25	17	150
7	Guidezilla™* II GEC[2]	0.063	0.073	7 F ≥ 0.078	25	N/A, metal collar	150

IPR2020-00132, Ex-1082 Ex-A at 39

Secondary Considerations – Copying: Guidezilla

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

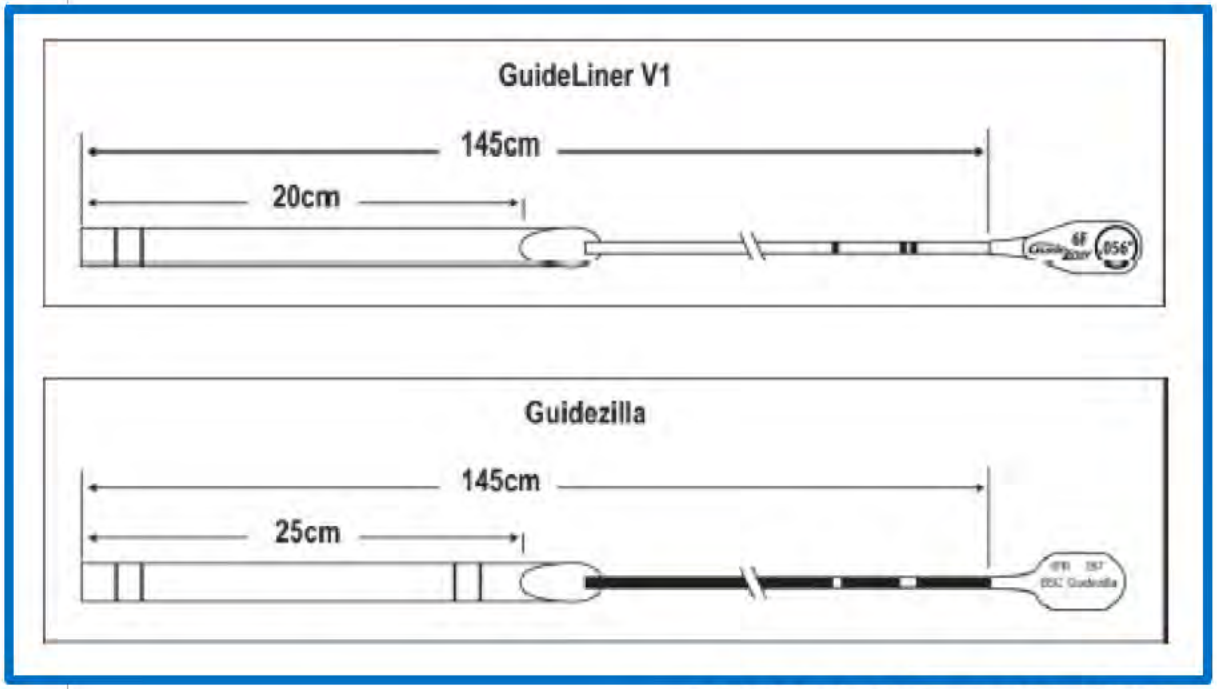
MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

PATENT OWNER RESPONSE



IPR2020-0141, Paper 23 at 65-66

Secondary Considerations – Copying: Guidezilla

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Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

PATENT OWNER RESPONSE

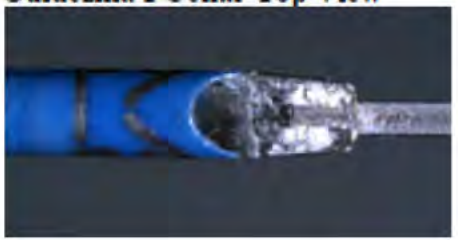
Guidezilla's side opening were essentially the same:

GuideLiner V1 collar side view

GuideLiner V1 collar top view

Guidezilla I Collar Side View

Guidezilla I Collar Top View



IPR2020-0141, Paper 23 at 66

Secondary Considerations – Ubiquitous Elements in the Art

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BEFORE THE PATENT TRIAL AND APPEAL BOAR

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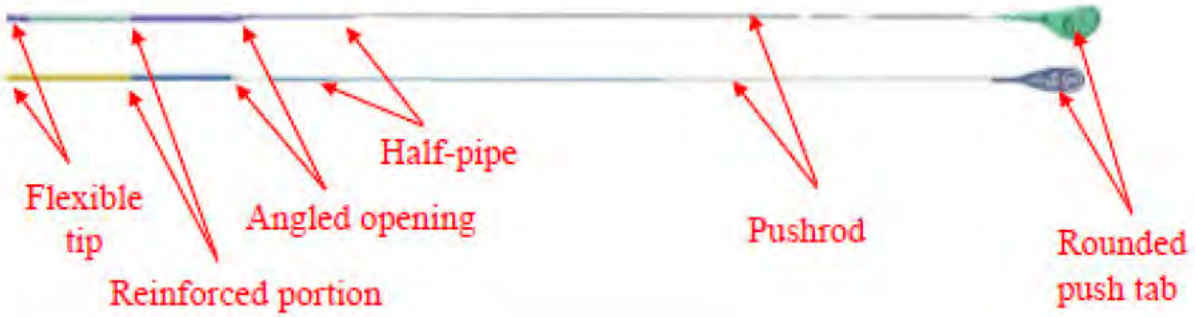
Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

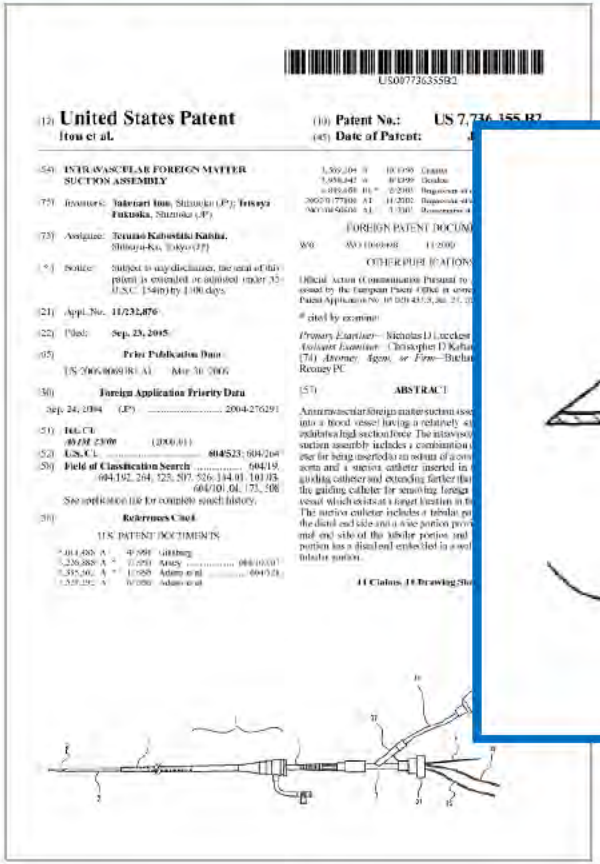
PATENT OWNER RESPONSE

Telescope is a striking copy of GuideLiner V3 both in terms of its instructions for use ("IFUs") and its structure:



IPR2020-0141, Paper 23 at 67

Ubiquitous Elements in the Art: Flexible Tip


US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent:**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Teisuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1100 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069383 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526-104.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

WO

OTHER PUBLICATIONS

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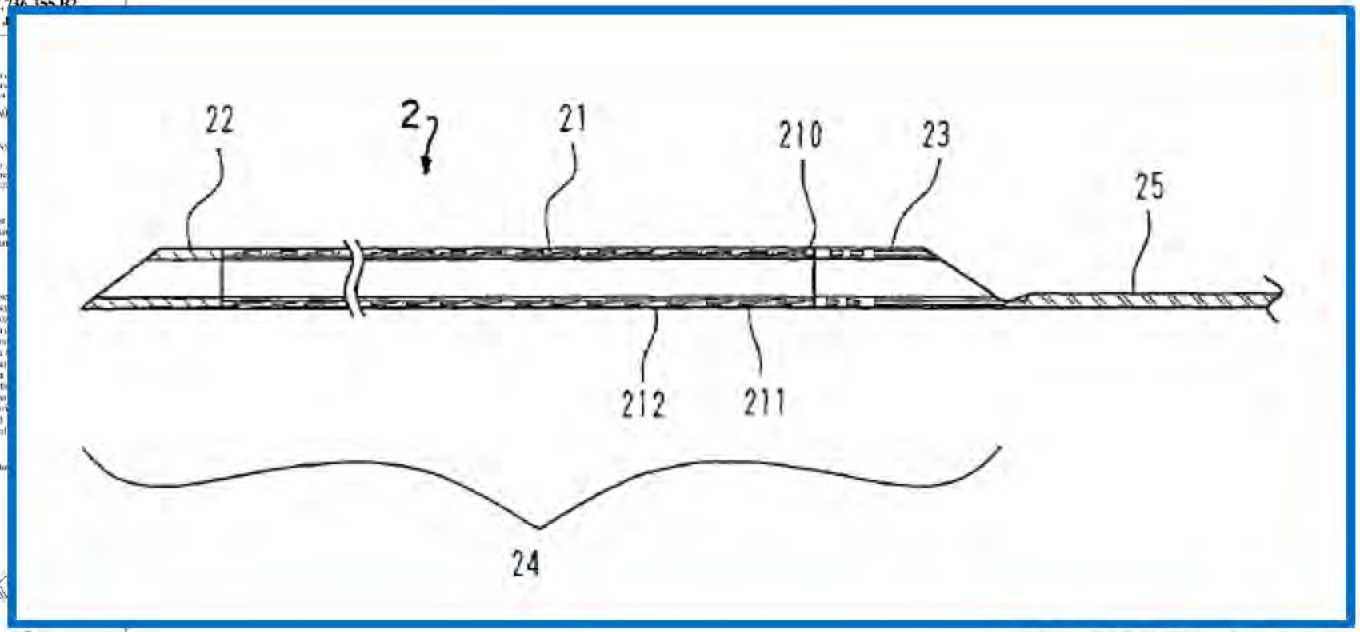
Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Christopher D Koha
(74) *Attorney, Agent, or Firm*—Buchanan Ingersoll & Rooney PC

(57) **ABSTRACT**

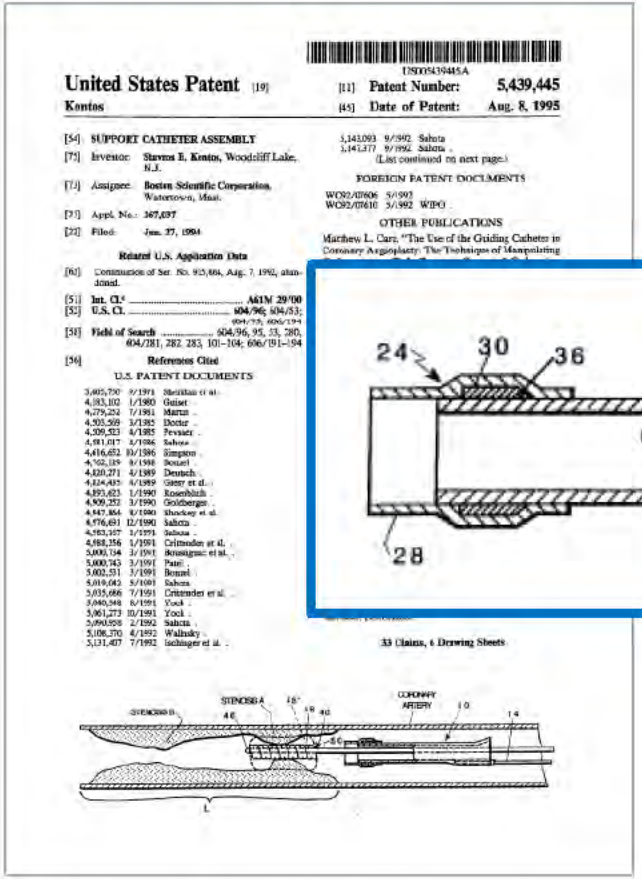
An intravascular foreign matter suction assembly is inserted into a blood vessel having a relatively small diameter and exhibits high suction force. The intravascular suction assembly includes a combination of a suction catheter for being inserted to a distal portion of a coronary artery and a suction catheter inserted in the guiding catheter and extending farther than the guiding catheter for sucking foreign matter in the blood vessel which exists at a target location in the blood vessel. The suction catheter includes a tubular portion having a distal end side and a wire portion provided on the distal end side of the tubular portion and the wire portion has a distal end embedded in a side wall of the tubular portion.

11 Claims, 14 Drawing Sheets



Ex-1007 (Itou), Fig. 3

Ubiquitous Elements in the Art: Flexible Tip



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Steven E. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **367,037**

[22] Filed: **Jan. 27, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 915,666, Aug. 7, 1992, abandoned.

[51] **Int. Cl.**[6] **A61M 29/00**
[52] **U.S. Cl.** **604/96**; 604/53; 604/175; 606/194
[58] **Field of Search** 604/96, 95, 53, 280, 604/281, 282, 283, 101–104; 606/191–194

[56] **References Cited**

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(List continued on next page.)

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33 Claims, 6 Drawing Sheets

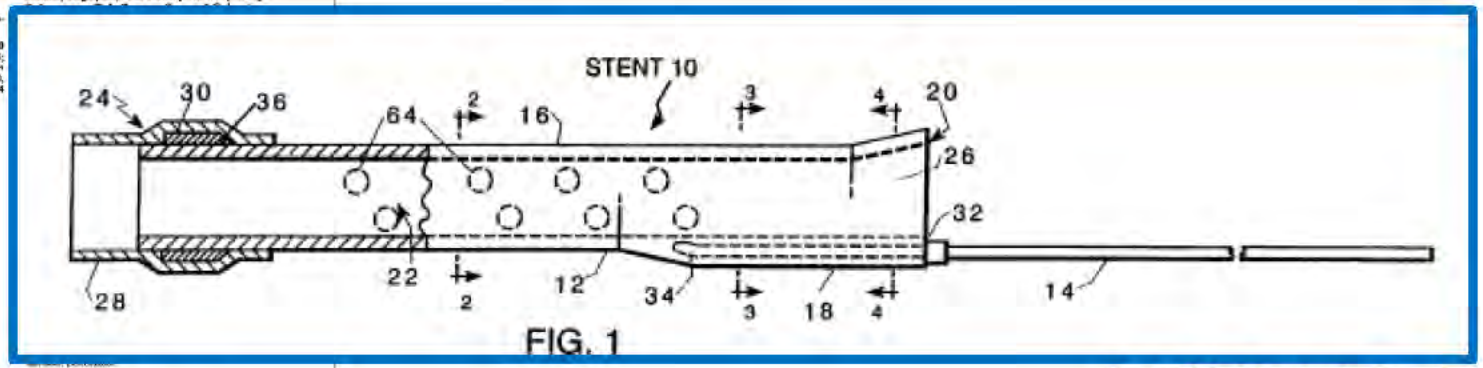

FIG. 1

Ex-1409 (Kontos), Fig. 1

Ubiquitous Elements in the Art: Reinforced Portion

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Petitio

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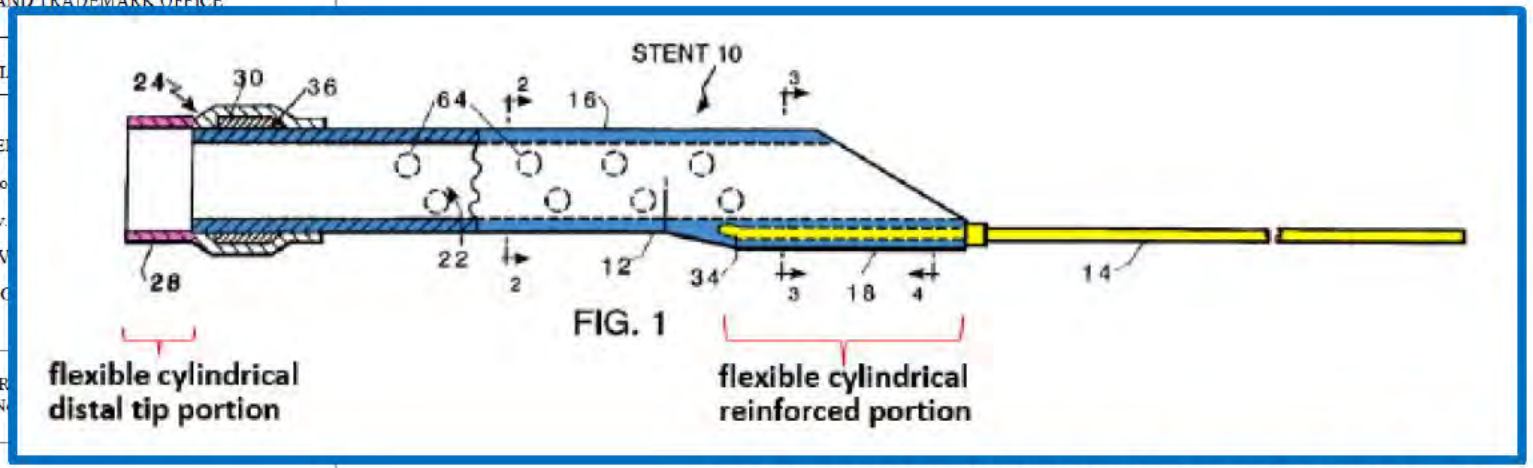
TELEFLEX INNOV

Patent C

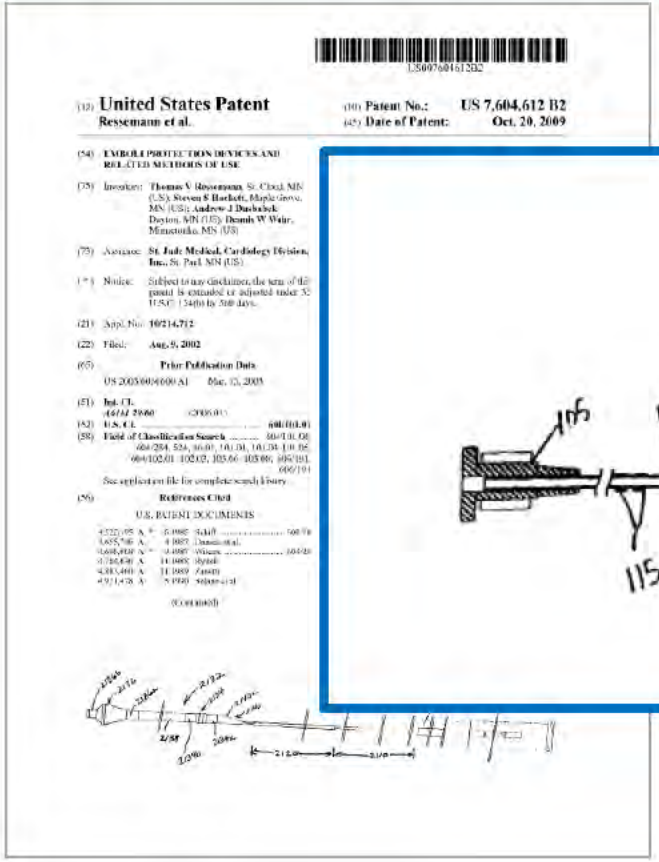
Case No.: IPR
U.S. Patent N

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC



Ex-1405 (IPR2020-01342), ¶ 236 (citing Ex-1409, Fig. 1)

Known Elements in the Art: Angled Openings



(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

(54) **EMBOLIC PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St. Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dushek**, Dayton, MN (US); **Dennis W Weir**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 508 days.

(21) Appl. No.: **10/214,712**

(22) Filed: **Aug. 9, 2002**

(65) **Prior Publication Data**

US 2005/0049600 A1 Mar. 03, 2005

(51) Int. Cl.
A61M 29/00 (2006.01)

(52) U.S. Cl. **606/108**

(58) Field of Classification Search 606/108, 606/200, 194, 159, 191, 198, 127, 128; 604/264, 524, 96.01, 101.01, 101.04, 101.05, 604/102.01, 102.02, 103.06, 103.09; 600/393, 600/191

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

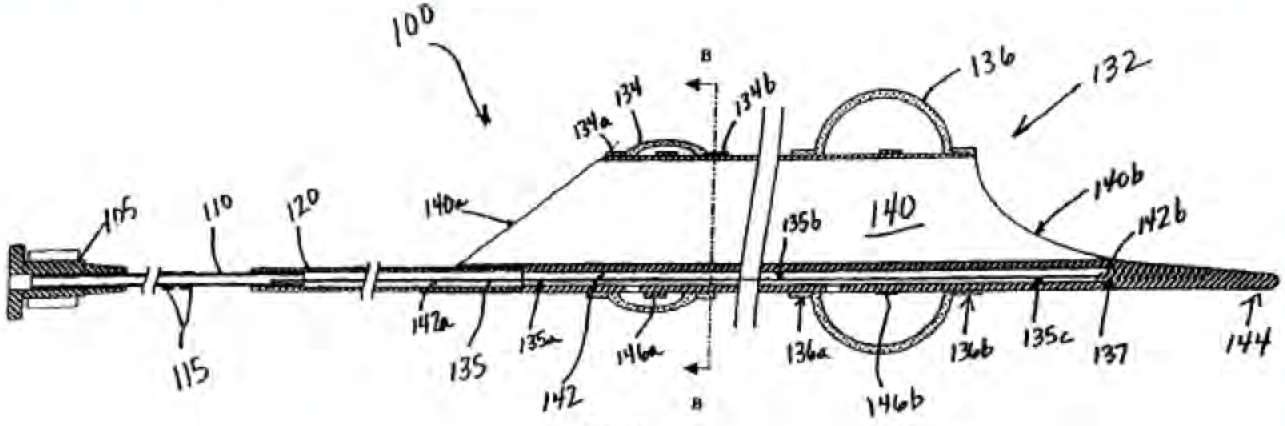
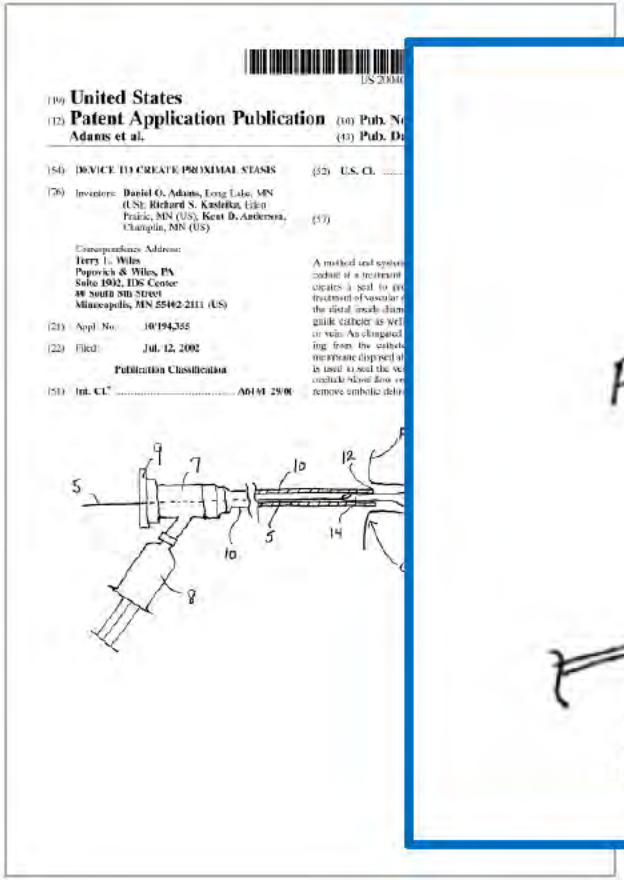
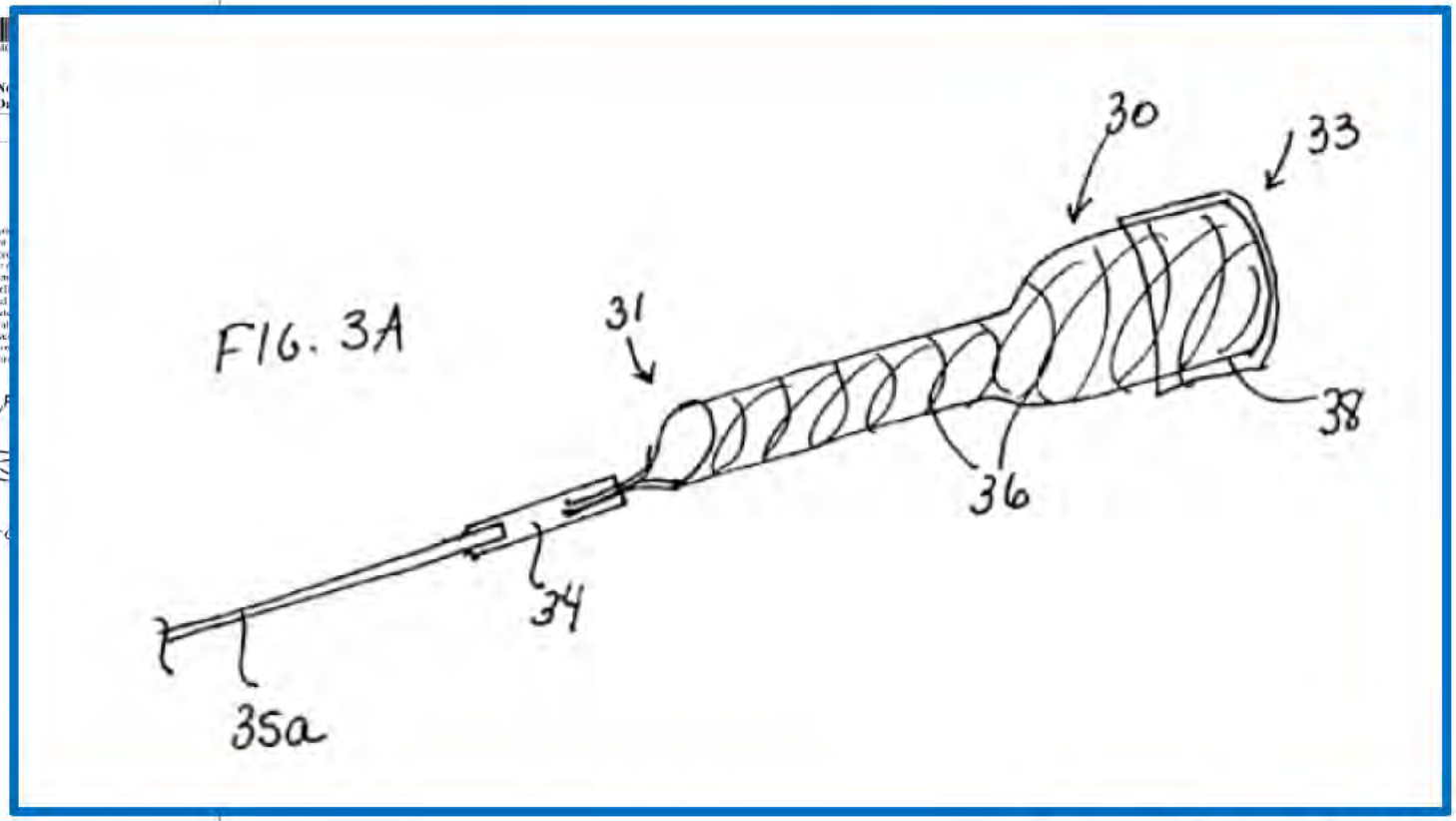


FIG. 1A

Ex-1008 (Ressemann), Fig. 1A

Known Elements in the Art: Angled Openings





Ex-1435 (Adams), Fig. 3A

Secondary Considerations – Copying: Half-pipe

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
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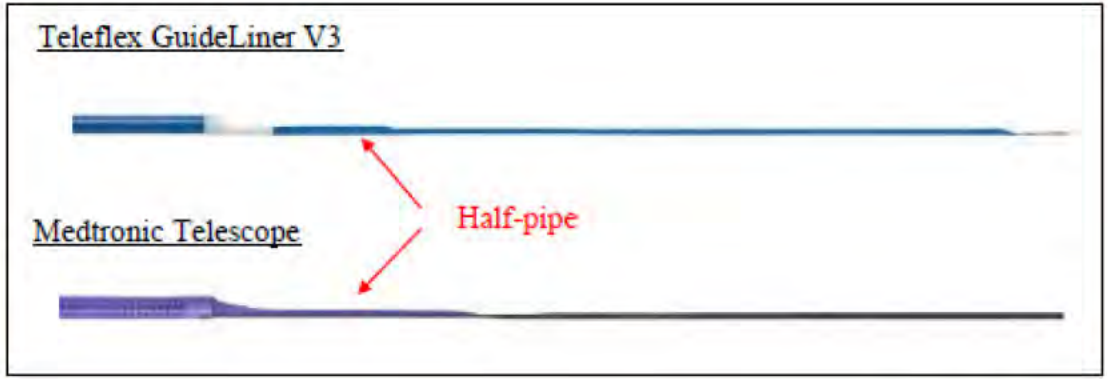
TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

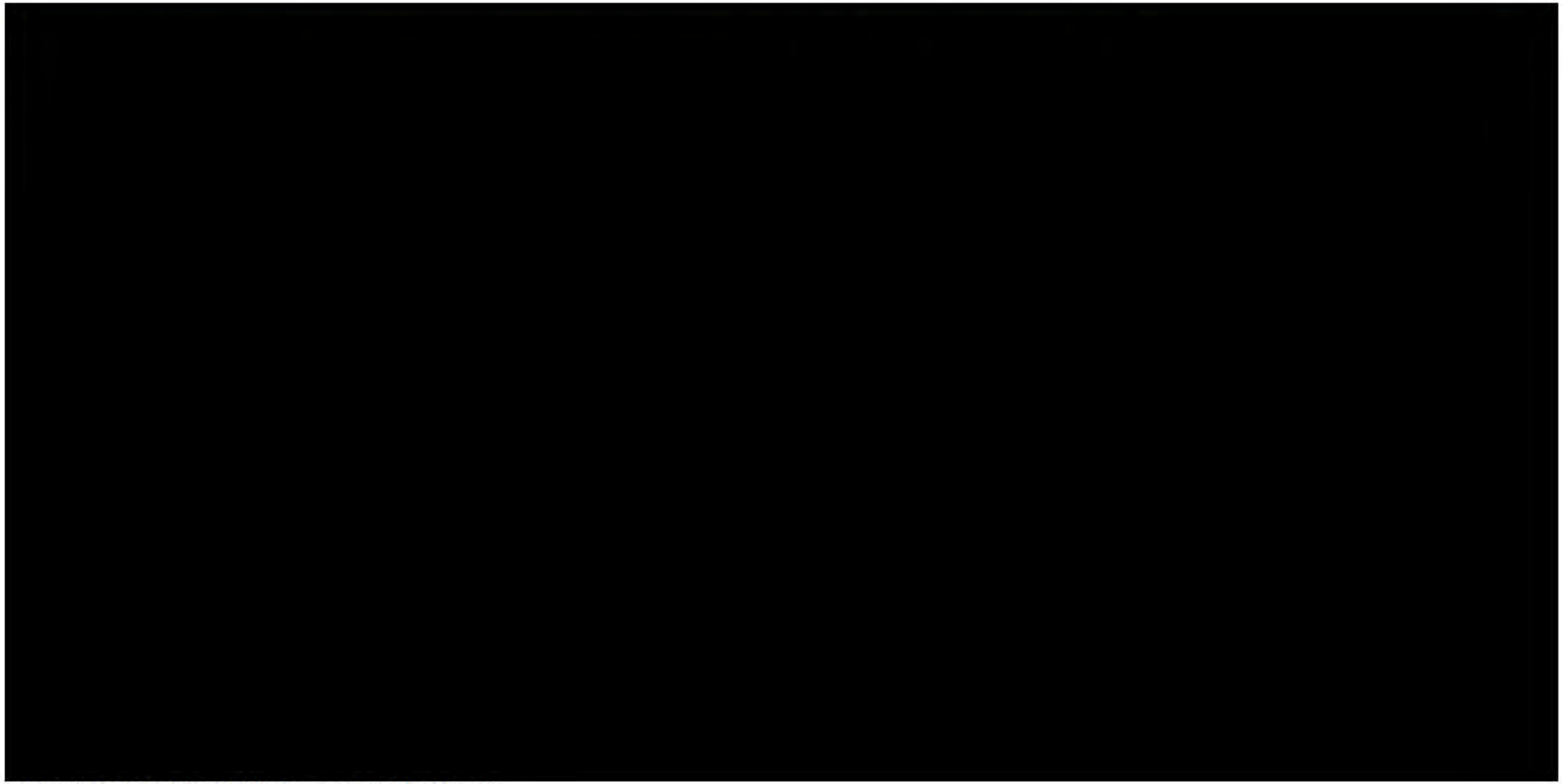
PATENT OWNER RESPONSE

Petitioner succeeded in its efforts to copy, incorporating the half pipe from the GuideLiner V3 product (top) into its Telescope product (bottom):



IPR2020-0141, Paper 23 at 69

Secondary Considerations – Copying: Half-pipe

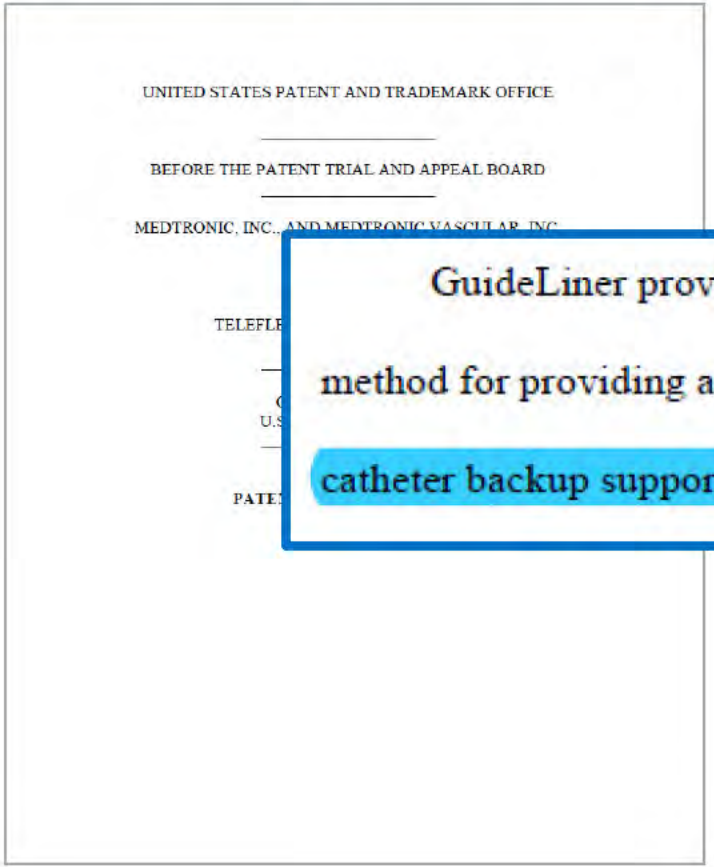


Secondary Considerations – Copying

"Not every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent. Rather, copying requires the replication of a specific product."

Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004)

Secondary Considerations – Nexus



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.

TELEFLE

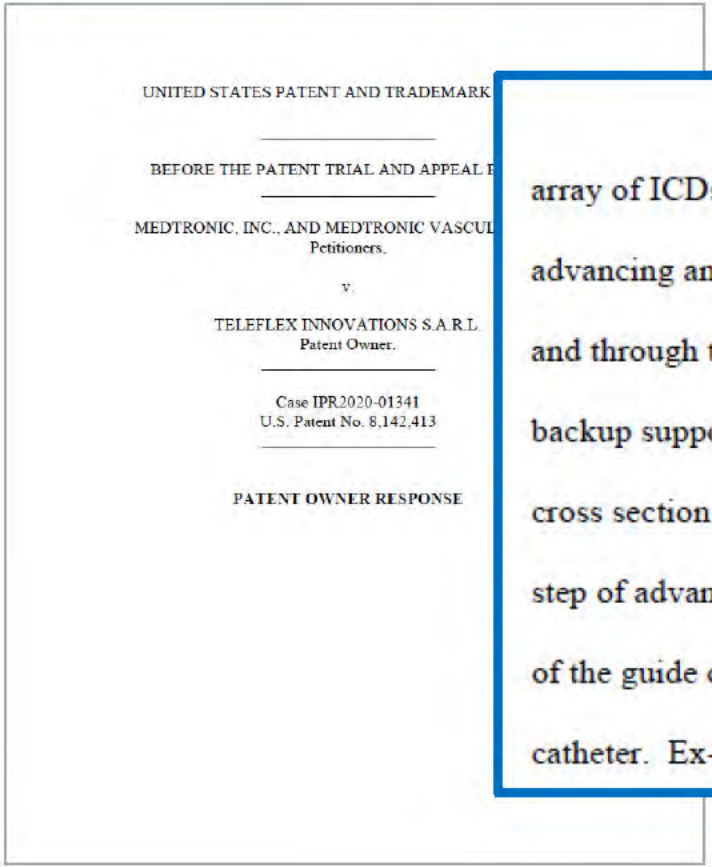
U.S

PATE

GuideLiner provided, for the first time, an elegant and highly effective method for providing a solution to the longstanding problem of insufficient guide catheter backup support in interventional cardiology procedures.

IPR2020-01341, Paper 23 (POR) at 56.

Secondary Considerations – Nexus



UNITED STATES PATENT AND TRADEMARK

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TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

PATENT OWNER RESPONSE

The ability to receive the full array of ICDs (including stents) is reflected in claims 4, 9, and 14's requirement of advancing an ICD through a side opening positioned deep within the guide catheter and through the flexible tip portion. Ex-2138, ¶336. And the benefit of improved backup support results from using a coaxial flexible tip portion having a circular cross section with a diameter that fits within the guide catheter and the claimed step of advancing the distal portion of the flexible tip portion beyond the distal end of the guide catheter while the remainder of the device remains inside the guide catheter. Ex-2138, ¶337.

IPR2020-01341, Paper 23 (POR) at 73.

Secondary Considerations – Nexus

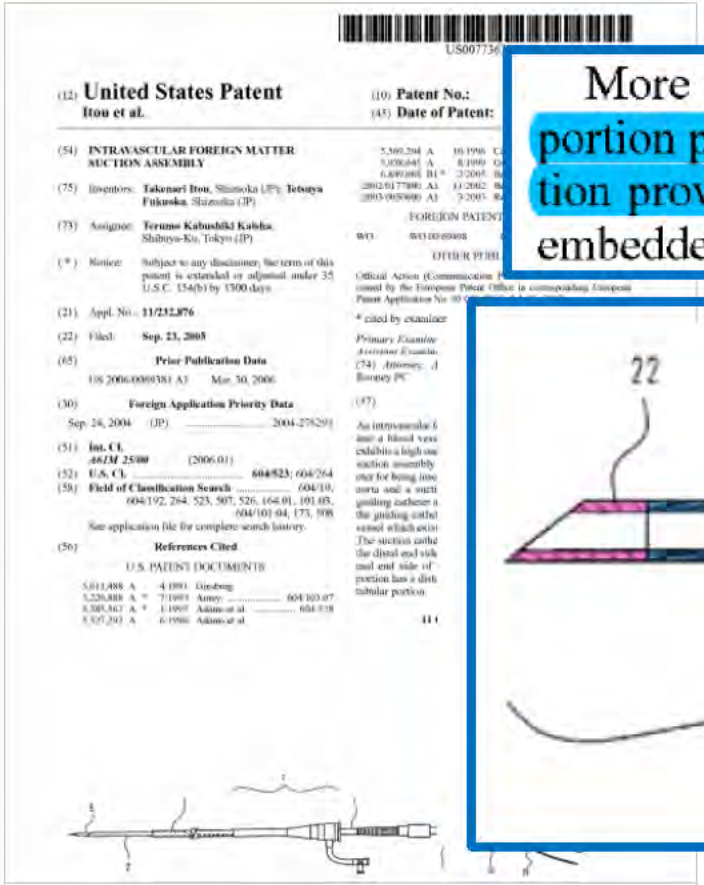
Q. Right. But in general, you didn't come up with guide extension; you didn't come up with rapid exchange. Your testimony is you came up with the combination of the two; is that right?

MR. VANDENBURGH: Objection; form.

THE WITNESS: Yeah. We did not invent rapid exchange, and we did not invent guide extension, but we invented rapid exchange guide extension.

IPR2020-01341, Ex-1762 (Root Tr), 39:14-22

Itou



(12) **United States Patent**
Itou et al.

(10) **Patent No.:**
(45) **Date of Patent:**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 28, 2004 (JP) 2004-278291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/10, 604/192, 264, 523, 507, 526, 164.01, 101.05, 604/101.04, 175, 908

See application file for complete search history.

(56) **References Cited**

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5,226,888 A * 7/1993 Arney 604/103.07
5,308,342 A * 5/1994 Adams et al. 604/538
5,527,293 A 6/1996 Adams et al.

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WO WO 03/039408

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Official Action (Communication
issued by the European Patent Office in corresponding European
Patent Application No. 05

* cited by examiner

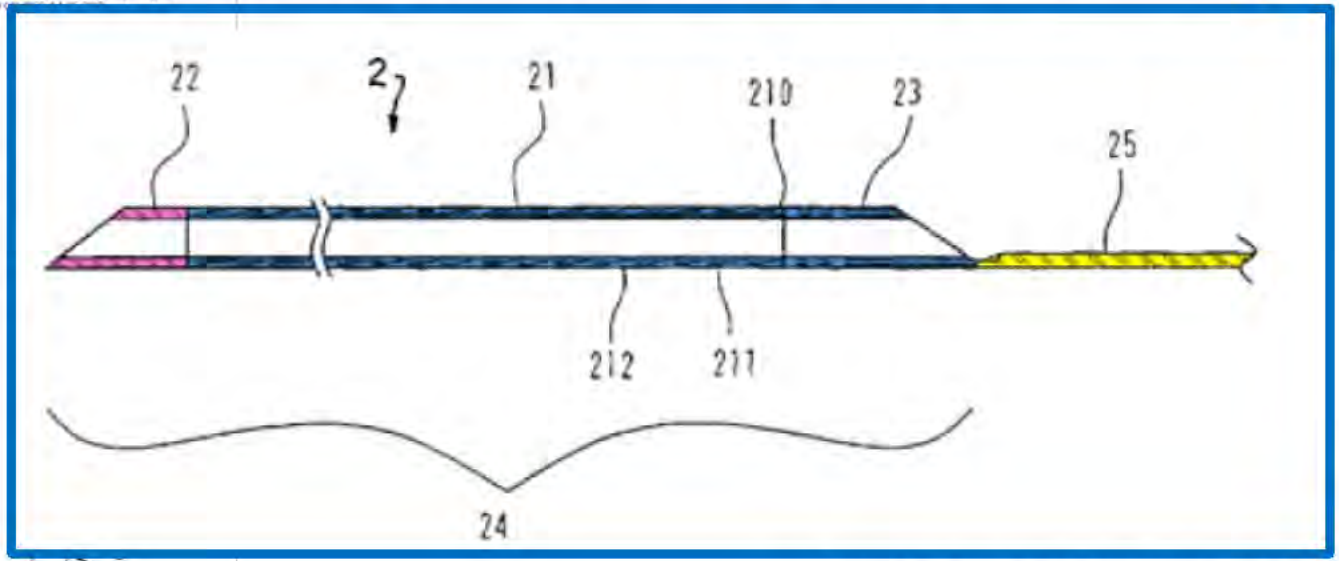
Primary Examiner
Assistant Examiner
(74) Attorney, A
Birney PC

(57)

An intravascular
and a blood vess
exhibits a high suc
suction assembly
ther for being inse
aorta and a suctio
guiding catheter a
the guiding cathe
vessel which exist
The suction cathe
the distal end vici
mal end side of
portion has a dist
tubular portion.

11

More preferably, the suction catheter includes a tubular portion provided on the distal side and a solid wire-like portion provided on the proximal side and having a distal end embedded in a wall which forms the tubular portion. Further,



Ex-1007, Fig. 3 (color added); 2:12-15

Itou

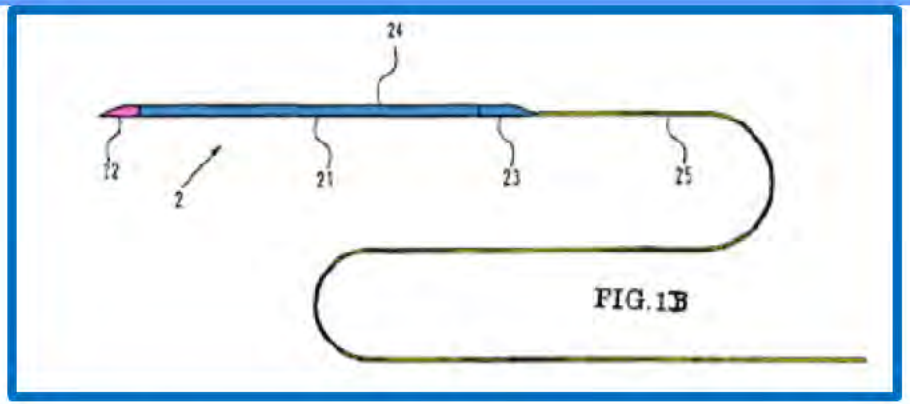
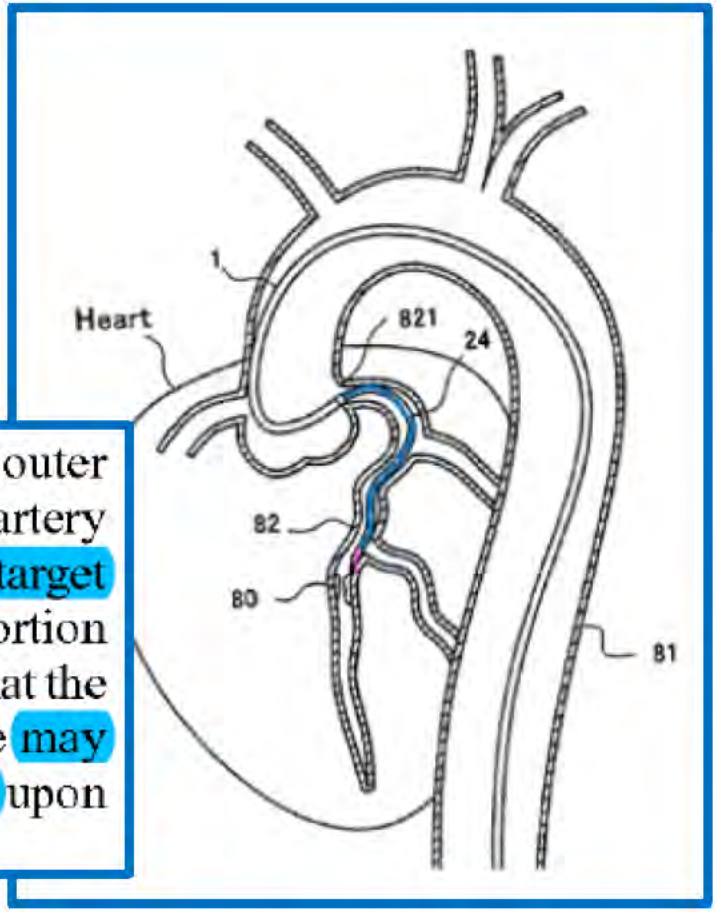
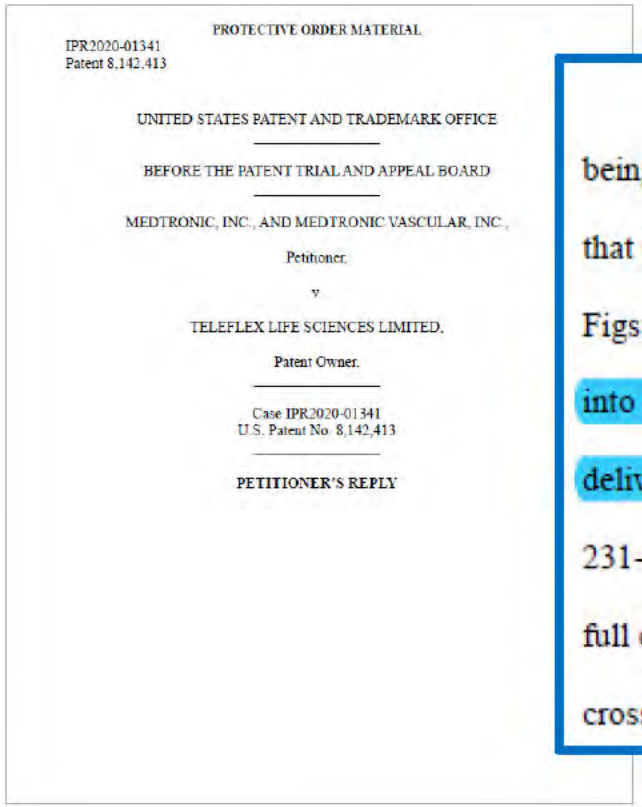


FIG. 1B

The tubular portion **24** of the suction catheter **2** has an outer diameter with which it can be inserted into the coronary artery **82** and is introduced along the guide wire **6** to the target location **80** positioned at a deep location. The tubular portion **24** is designed so as to have a sufficient axial length so that the proximal end of the tubular portion **24** in an open state may not leap out from the distal end of the guiding catheter **1** upon such introduction of the tubular portion **24**.



Itou



PROTECTIVE ORDER MATERIAL

IPR2020-01341
Patent 8,142,413

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED,

Patent Owner.

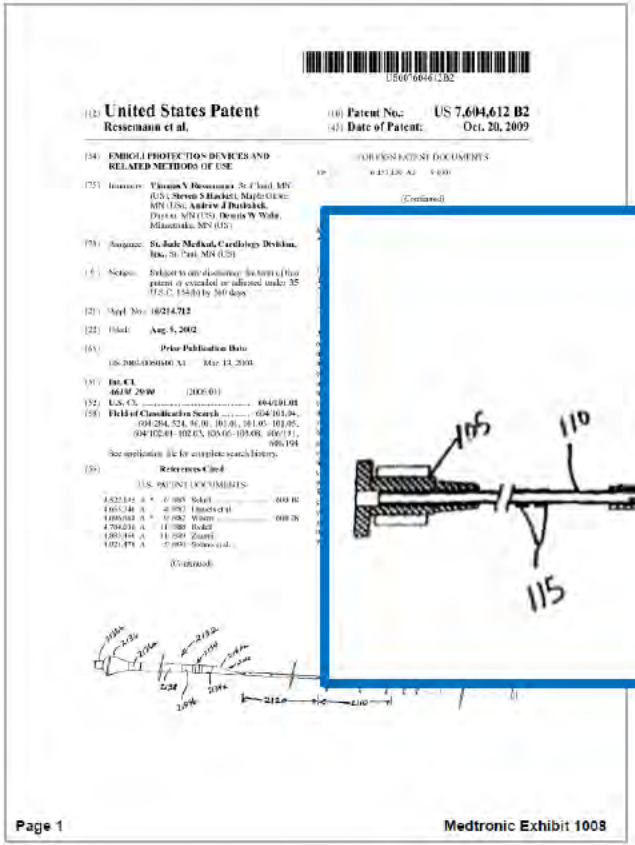
Case IPR2020-01341
U.S. Patent No. 8,142,413

PETITIONER'S REPLY

Teleflex does not dispute that Itou recites the necessary structure, despite being a suction catheter. POR, 41-42. Itou discloses a substantially rigid portion that comprises a partially cylindrical portion defining a side opening. Ex-1007, Figs. 3-4; Ex-1005 ¶227. Itou teaches that a protective catheter may be inserted into the lumen through the side opening and projected from its distal end, and delivered to the target location. Ex-1007, 4:48-52, 7:1-27, Fig. 5; Ex-1005 ¶¶195, 231-32. Itou's substantially rigid portion includes a cross-sectional shape having a full circumference portion, a hemicylindrical cross-sectional shape, and an arcuate cross-sectional shape. Ex-1005 ¶243.

IPR2020-01341, Paper 51 (Petitioner's Reply) at 37.

Ressemann



(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dudalski**, Dayton, MN (US); **Dennis W Wells**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 360 days.

(21) Appl. No.: **10/214,712**

(22) Filed: **Aug. 9, 2002**

(65) **Prior Publication Data**

US 2003/0050600 A1 Mar. 13, 2003

(51) **Int. Cl.**
A61F 2/90 (2006.01)

(52) U.S. Cl. 604/101.01

(58) **Field of Classification Search** 604/101.04, 604/264, 524, 96.01, 101.01, 101.05-101.05, 604/102.01-102.03, 103.05-103.08, 606/191, 198, 194
See application file for complete search history.

(56) **References Cited**
U.S. PATENT DOCUMENTS

(Continued)

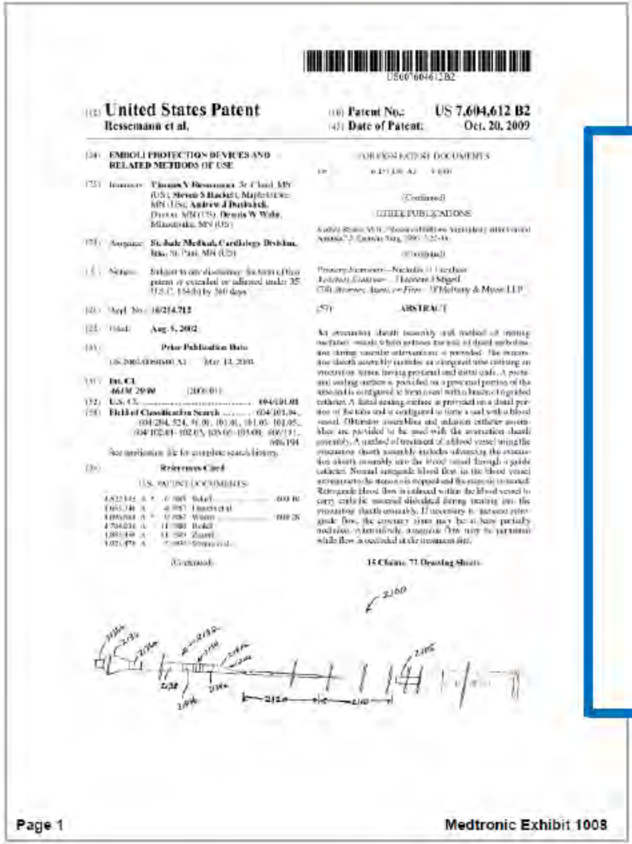
FIG. 1A

Page 1

Medtronic Exhibit 1008

Ex-1008, Fig. 1 A

Ressemann



(12) **United States Patent**
Ressemann et al.

(10) **Patent No.:** US 7,604,612 B2
(45) **Date of Patent:** Oct. 20, 2009

(54) EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE

(73) Assignee: St. Jude Medical, Cardiology Division, Inc., St. Paul, MN (US)

(21) Appl. No.: 10/214,712

(22) Filed: Aug. 9, 2002

Prior Publication Data

(51) Int. Cl.

(52) U.S. Cl. 604/101.01

(58) Field of Classification Search

References Cited

U.S. PATENT DOCUMENTS

(Continued)

FOREIGN PATENT DOCUMENTS

(Continued)

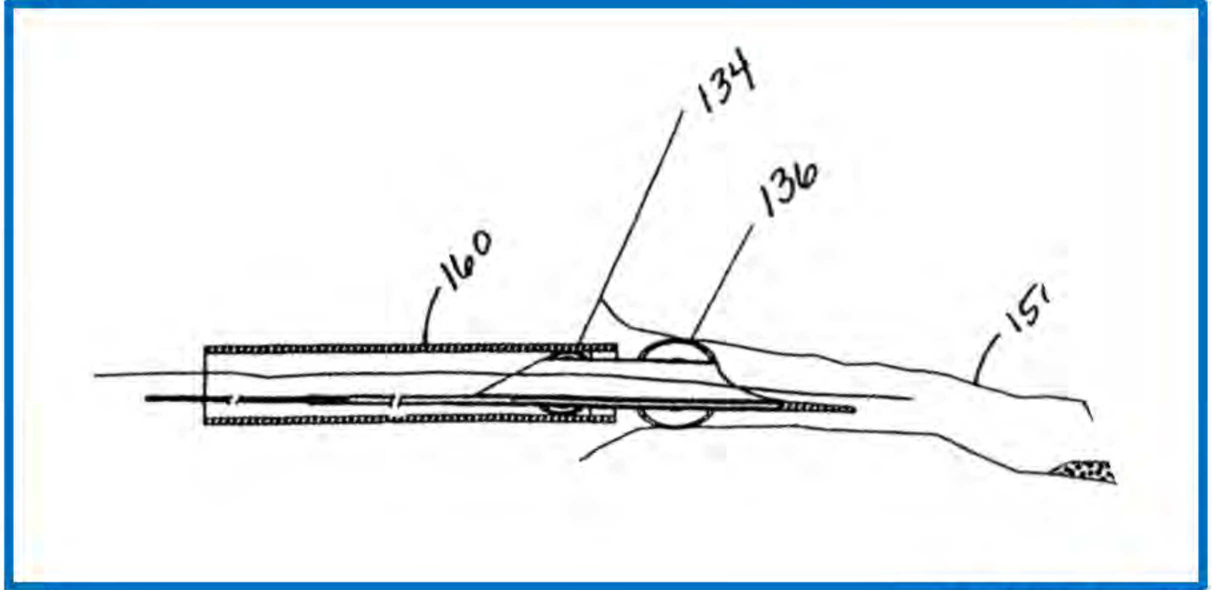
OTHER PUBLICATIONS

(Continued)

(57) ABSTRACT

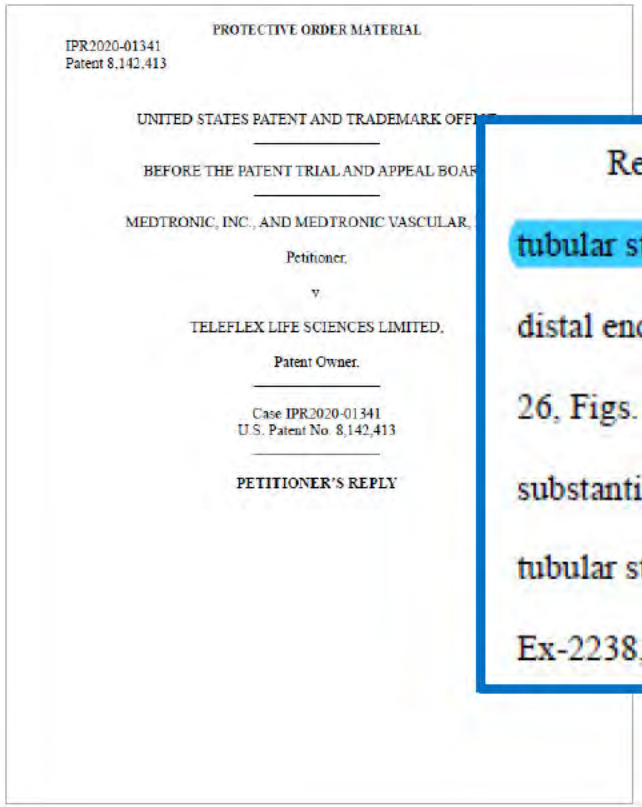
15 Claims, 71 Drawing Sheets

Page 1 Medtronic Exhibit 1008



Ex-1008, Fig. 6C

Ressemann



PROTECTIVE ORDER MATERIAL

IPR2020-01341
Patent 8,142,413

UNITED STATES PATENT AND TRADEMARK OFFI

BEFORE THE PATENT TRIAL AND APPEAL BOAR

MEDTRONIC, INC., AND MEDTRONIC VASCULAR,

Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED,

Patent Owner.

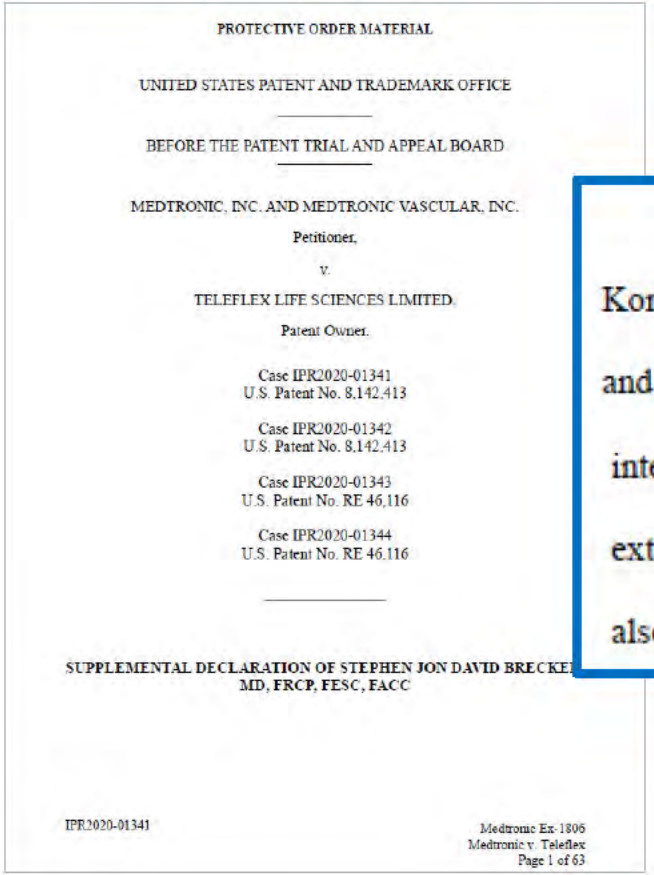
Case IPR2020-01341
U.S. Patent No. 8,142,413

PETITIONER'S REPLY

Ressemann similarly recites the claimed elements. Ressemann discloses a tubular structure defining a side opening that remains within the GC while the distal end is advanced beyond the distal end of the GC. Ex-1008, 6:18-24, 12:19-26, Figs. 1A, 6B. Before Ressemann delivers a stent, it is first advanced along the substantially rigid portion, through the side opening, and through Ressemann's tubular structure. *Id.*, 6:18-24, 10:47-53. Ressemann improves backup support. Ex-2238, 130:9-131:5.

IPR2020-01341, Paper 51 (Petitioner's Reply) at 37.

Secondary Considerations – Nexus



PROTECTIVE ORDER MATERIAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED

Patent Owner.

Case IPR2020-01341
U.S. Patent No. 8,142,413

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

Case IPR2020-01343
U.S. Patent No. RE 46,116

Case IPR2020-01344
U.S. Patent No. RE 46,116

SUPPLEMENTAL DECLARATION OF STEPHEN JON DAVID BRECKE
MD, FRCP, FESC, FACC

IPR2020-01341

Medtronic Ex-1806
Medtronic v. Teleflex
Page 1 of 63

148. The earliest rapid exchange guide extension catheter in the record is Kontos, followed by Ressemann and Itou. The devices disclosed in Itou, Kontos, and Ressemann are rapid exchange, configured to deliver a wide variety of interventional cardiology devices, and provide increased backup support when extended partially past the end of a guide catheter as intended. Ressemann and Itou also have a side opening.

IPR2020-01341, Ex-1806, ¶ 148.

Secondary Considerations – Nexus

"Where the offered secondary consideration actually results from something other than what is both claimed and *novel in the claim* there is no nexus to the merits of the claimed invention."

In re Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (emphasis added)

Kontos

IPR2020-01342, -01344

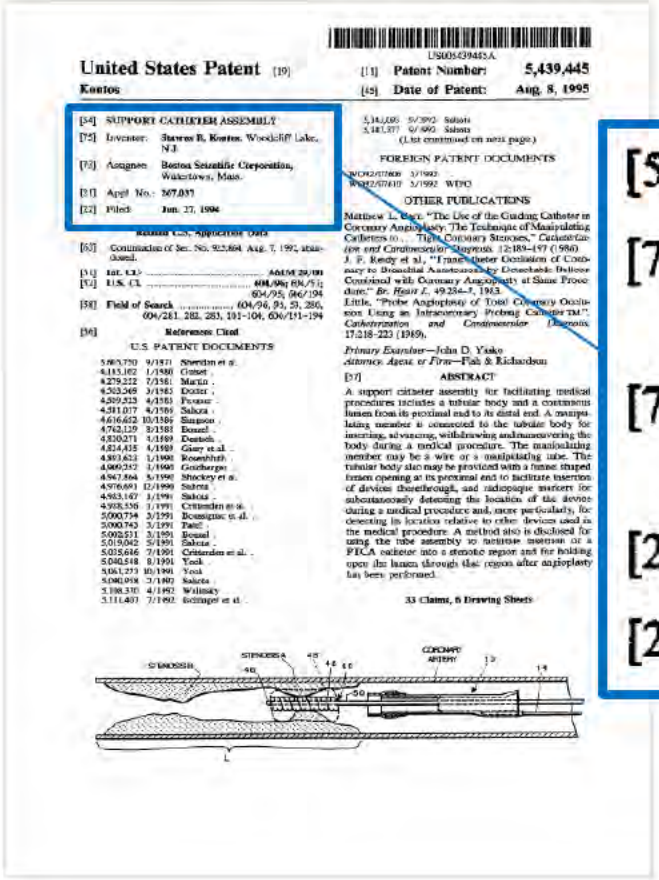
IPR2020-01342 & IPR2020-01344

8,142,413 claims	Instituted Ground	References
1, 2, 4, 5, 7-12, 14	1	Kontos, Adams
13	2	Kontos, Adams, Takahashi

RE46,116 claims	Instituted Ground	References
52, 53	1	Kontos, Ressemann
25-40, 42, 44-48	2	Kontos, Ressemann, Takahashi
45	3	Kontos, Ressemann, Takahashi, Kataishi
25-55	4	Root
45,46	5	Kontos, Ressemann, Takahashi, Root

1. Overview of Kontos
2. Kontos Teaches the "alongside" Limitation
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Issues Specific to -01344 IPR

U.S. Patent No. 5,439,445 (Kontos)



United States Patent [19]
Kontos

[11] Patent Number: 5,439,445
[45] Date of Patent: Aug. 8, 1995

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 923,869, Aug. 7, 1992, abandoned.

[51] Int. Cl.[6] A61M 29/00
[52] U.S. Cl. 604/96; 606/194
[58] Field of Search 604/96, 95, 93, 280, 604/281, 282, 283, 101-104; 606/191-194

[56] References Cited

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4,509,523 4/1985 Frazier .
4,581,017 4/1986 Sahota .
4,616,652 10/1986 Simpson .
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5,061,273 10/1991 Yock .
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(List continued on next page.)

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J. F. Reidy et al., "Transluminal Occlusion of Coronary to Bronchial Anastomosis by Detachable Balloon Catheter with Coronary Angioplasty at Same Procedure," *Br. Heart J.*, 49:236-7, 1983.
Little, "Probe Angioplasty of Total Coronary Occlusion Using an Intracoronary Probing Catheter™", *Catheterization and Cardiovascular Diagnosis* 17:218-223 (1989).

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Fish & Richardson

[57] ABSTRACT

A support catheter assembly for facilitating medical procedures includes a tubular body and a continuous lumen from its proximal end to its distal end. A manipulating member is connected to the tubular body for inserting, advancing, withdrawing and maneuvering the body during a medical procedure. The manipulating member may be a wire or a manipulating tube. The tubular body also may be provided with a funnel shaped lumen opening at its proximal end to facilitate insertion of devices therethrough, and radiopaque markers for substantially detecting the location of the device during a medical procedure and, more particularly, for detecting its location relative to other devices used in the medical procedure. A method also is disclosed for using the tube assembly to facilitate insertion of a PTCA catheter into a stenotic region and for holding open the lumen through that region after angioplasty has been performed.

33 Claims, 6 Drawing Sheets

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos, Woodcliff Lake, N.J.**

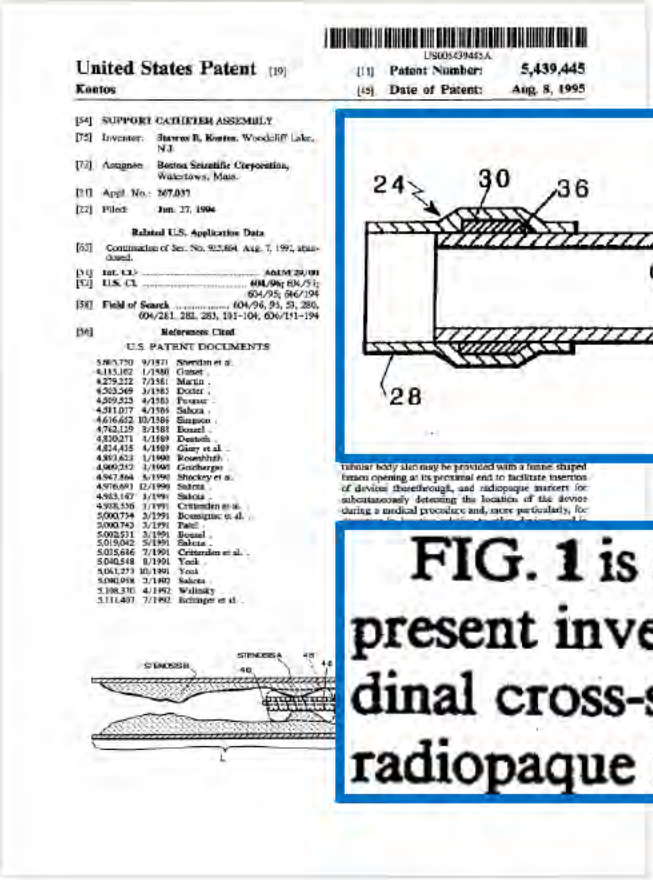
[73] Assignee: **Boston Scientific Corporation, Watertown, Mass.**

[21] Appl. No.: **267,037**

[22] Filed: **Jun. 27, 1994**

Ex-1409

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Steven B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 367,037

[22] Filed: Jan. 27, 1995

Related U.S. Application Data

[63] Continuation of Ser. No. 923,869, Aug. 7, 1992, abandoned.

[51] Int. Cl.[6] A61M 29/00
[52] U.S. Cl. 604/96; 606/194
[58] Field of Search 604/96, 95, 93, 280, 604/281, 282, 283, 101-104; 606/191-194

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4,279,252 7/1981 Martin .
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4,509,523 4/1985 Provost .
4,511,017 4/1985 Sahota .
4,616,652 10/1986 Simpson .
4,762,129 8/1988 Bonzel .
4,830,271 5/1989 Dentsch .
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4,893,613 1/1990 Rosenbluth .
4,900,252 1/1990 Goldberger .
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4,976,691 12/1990 Sahota .
4,983,167 1/1991 Sahota .
4,988,356 1/1991 Crittenden et al.
5,000,734 3/1991 Boussignac et al.
5,000,743 3/1991 Patel .
5,002,531 3/1991 Bonzel .
5,019,042 5/1991 Sahota .
5,035,686 7/1991 Crittenden et al.
5,040,548 8/1991 Yock .
5,047,273 10/1991 Yock .
5,080,958 2/1992 Sahota .
5,108,370 4/1992 Walinsky .
5,111,487 7/1992 Bettinger et al.

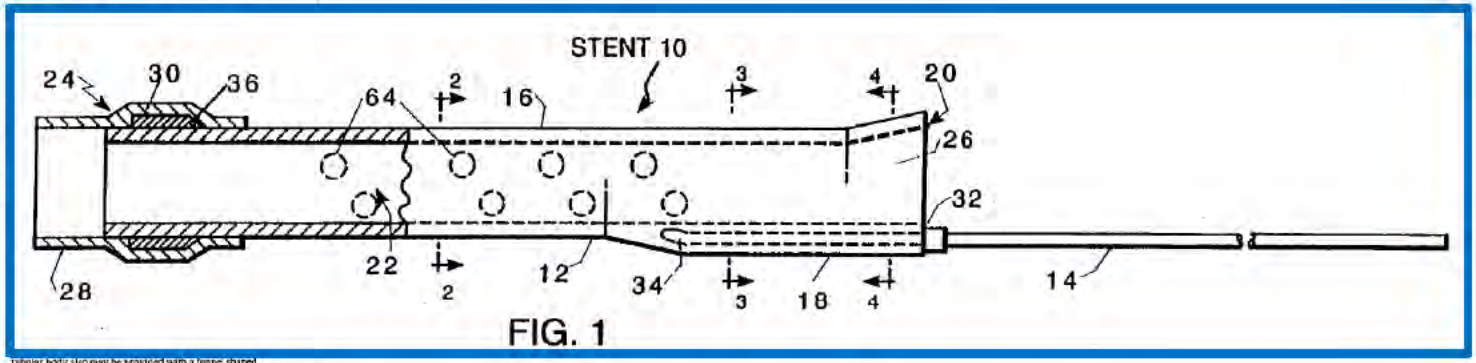


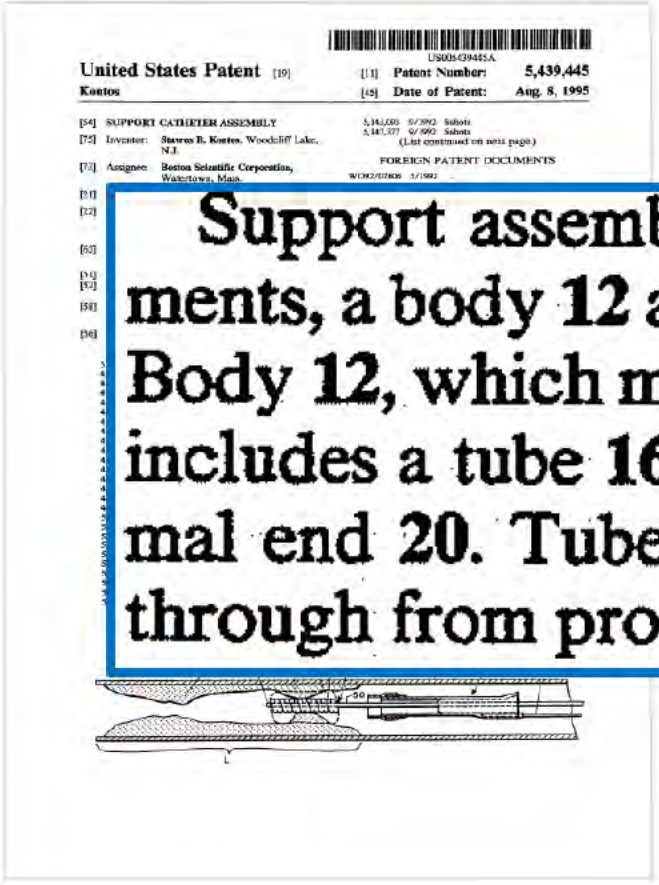
FIG. 1

tubular body sleeve may be provided with a funnel shaped lumen opening at its proximal end to facilitate insertion of devices therethrough, and radiopaque markers for substantially detecting the location of the device during a medical procedure and, more particularly, for

FIG. 1 is a side plan view of a support catheter of the present invention, cut-away in part to show in longitudinal cross-section a tubular body having a soft tip and radiopaque marker, and a manipulating wire.

Ex-1409, 2:51-54, Fig. 1

U.S. Patent No. 5,439,445 (Kontos)



United States Patent [19]
Kontos

[11] Patent Number: 5,439,445
[45] Date of Patent: Aug. 8, 1995

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Steven B. Kontos, Woodcliff Lake, N.J.

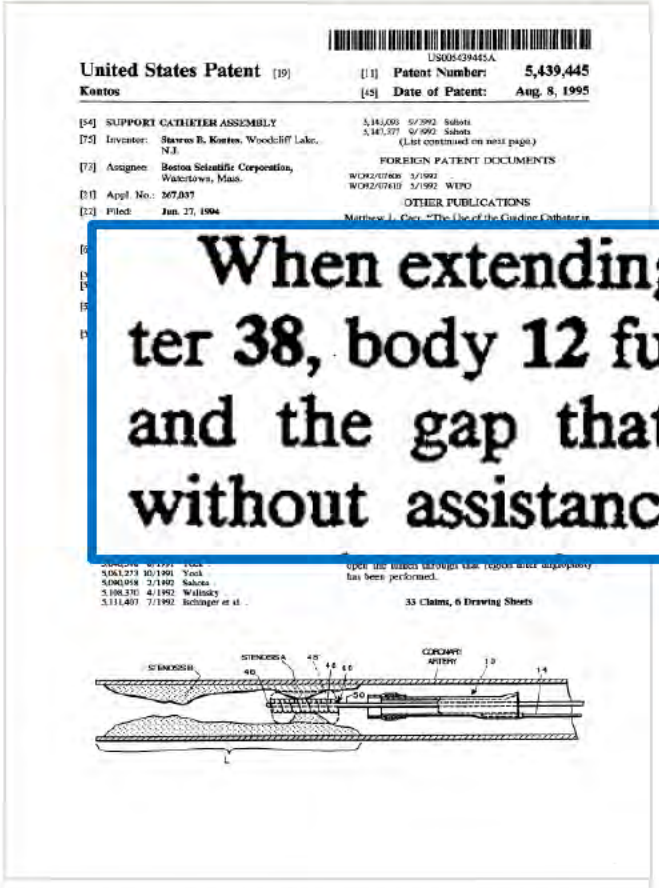
[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

FOREIGN PATENT DOCUMENTS

Support assembly **10** is composed of two major elements, a body **12** and an insertion/manipulation wire **14**. Body **12**, which may be viewed as a **mini guide catheter**, includes a tube **16** having a base portion **18** at its proximal end **20**. Tube **16** has a continuous lumen **22** therethrough from proximal end **20** to distal end **24**. Body **12**

Ex-1409, 3:45-49

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

5,143,093 9/1992 Sahota
5,147,377 9/1992 Sahota
(List continued on next page.)

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5,063,273 10/1991 Yock
5,090,958 2/1992 Sahota
5,108,370 4/1992 Walinsky
5,111,407 7/1992 Bellinger et al.

has been performed.

33 Claims, 6 Drawing Sheets

STENOSIS

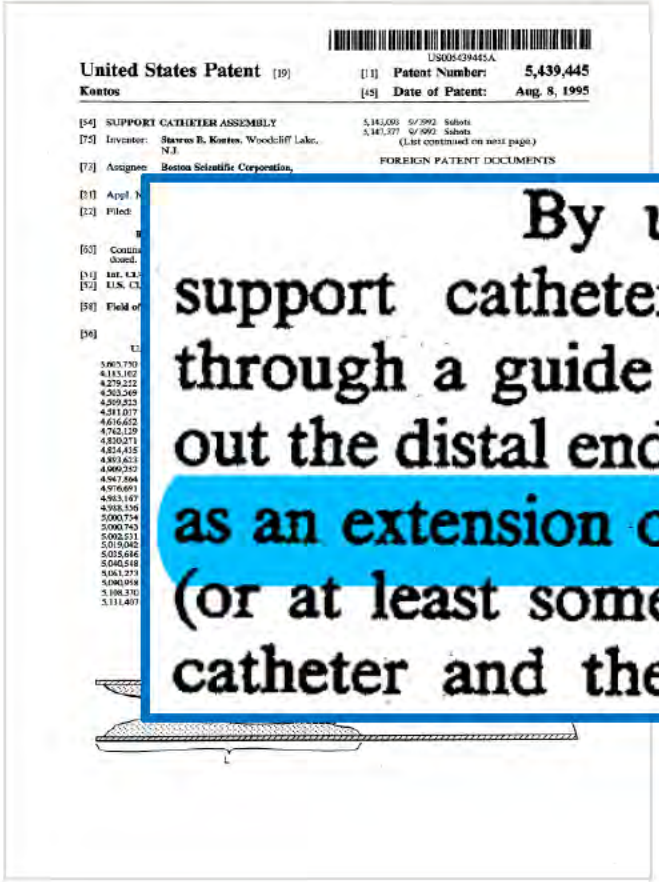
STENOSIS A

CORONARY ARTERY

When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension, and the gap that PTCA catheter 40 must negotiate without assistance is made much shorter.

Ex-1409, 5:49-52

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation,

5,143,093 9/1992 Sahota
5,147,377 9/1992 Sahota
(List continued on next page.)

FOREIGN PATENT DOCUMENTS

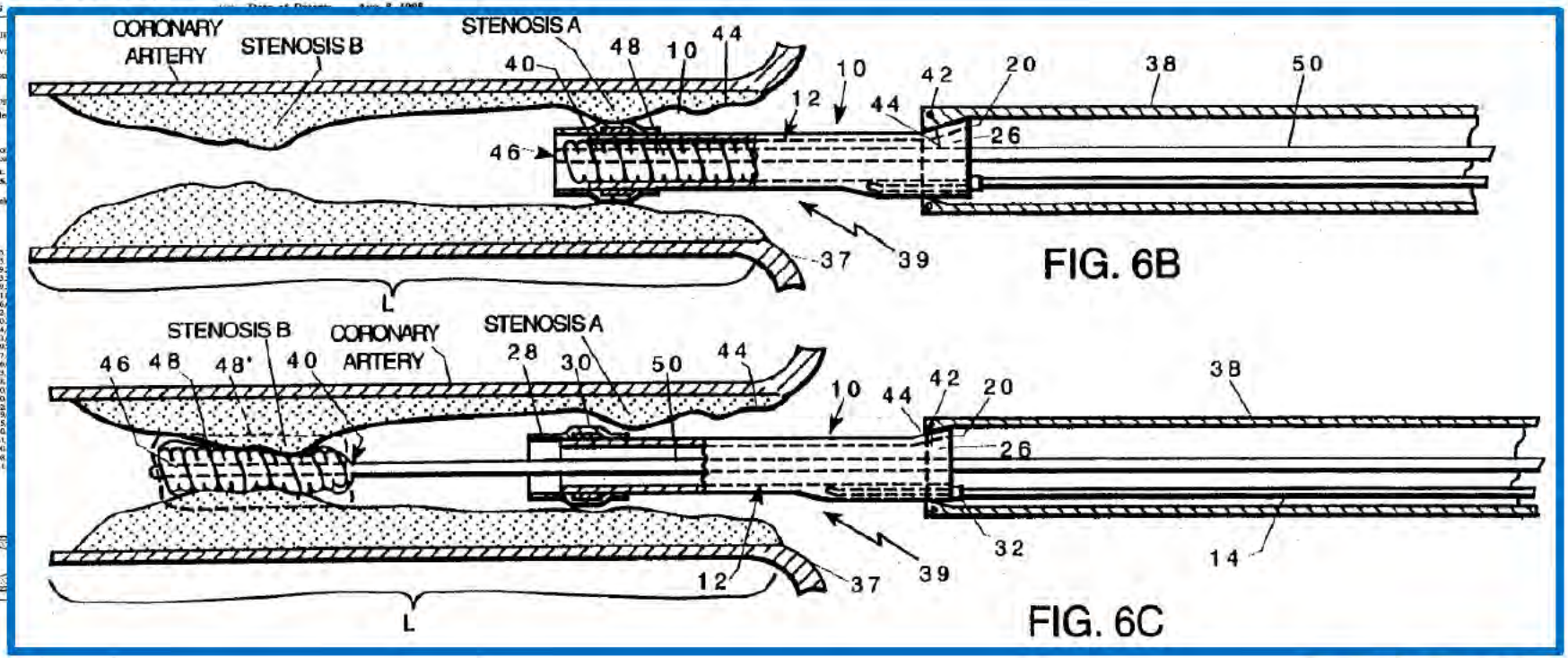
By use of such manipulating means, the support catheter can be inserted into and passed through a guide catheter, over a PTCA catheter, and out the distal end of the guide catheter so as to function as an extension of the guide catheter to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened.

Ex-1409, 2:16-32

U.S. Patent No. 5,439,445 (Kontos)

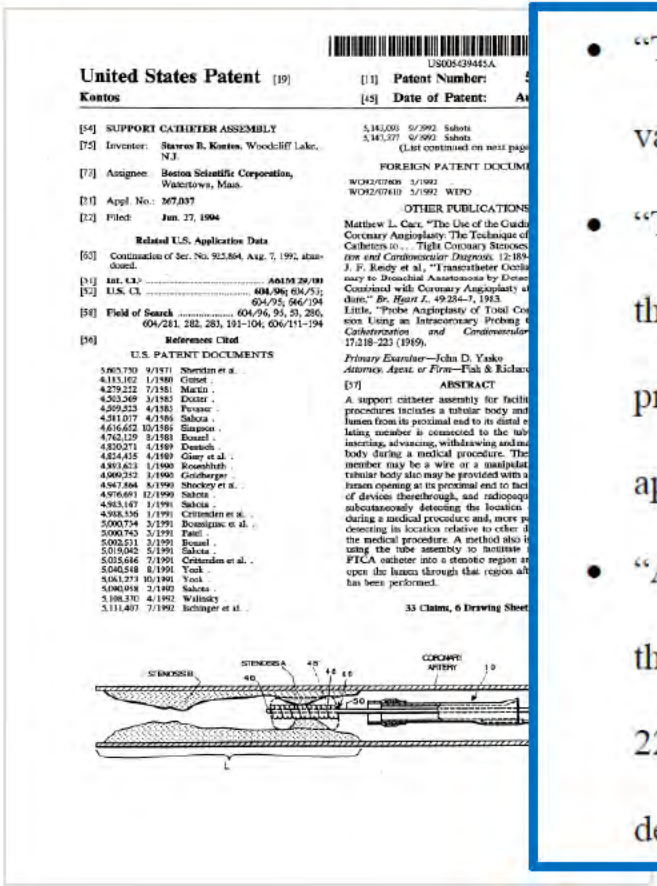
United States Patent [19] [11] Patent Number: 5,439,445

Kontos



Ex-1409, Figs. 6B-C

U.S. Patent No. 5,439,445 (Kontos)



United States Patent [19]
Kontos

[11] Patent Number: 5
[45] Date of Patent: Au

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 923,864, Aug. 7, 1992, abandoned.

[51] Int. Cl.[5] A61M 29/00
[52] U.S. Cl. 604/96; 606/194
604/95, 96; 606/194

[58] Field of Search 604/96, 95, 53, 280, 604/281, 282, 283, 101-104; 606/191-194

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5,000,743 3/1991 Patel .
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5,111,407 7/1992 Bottinger et al. .
5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.)

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WO92/07606 5/1992
WO92/07610 5/1992 WIPO

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Matthew L. Carr, "The Use of the Guidi Coronary Angioplasty: The Technique of Catheters 10 ... Tight Coronary Stenoses ... tion and Cardiovascular Diagnosis, 12:189- J. F. Reidy et al., "Transcatheter Occlu sary to Bronchial Anastomosis by Detac Combined with Coronary Angioplasty a duct," Br. Heart J., 49:284-7, 1983. Little, "Probe Angioplasty of Total Co ction Using an Intracoronary Probing Catheterization and Cardiovascular 17:218-223 (1969).

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Fish & Richar

[57] ABSTRACT

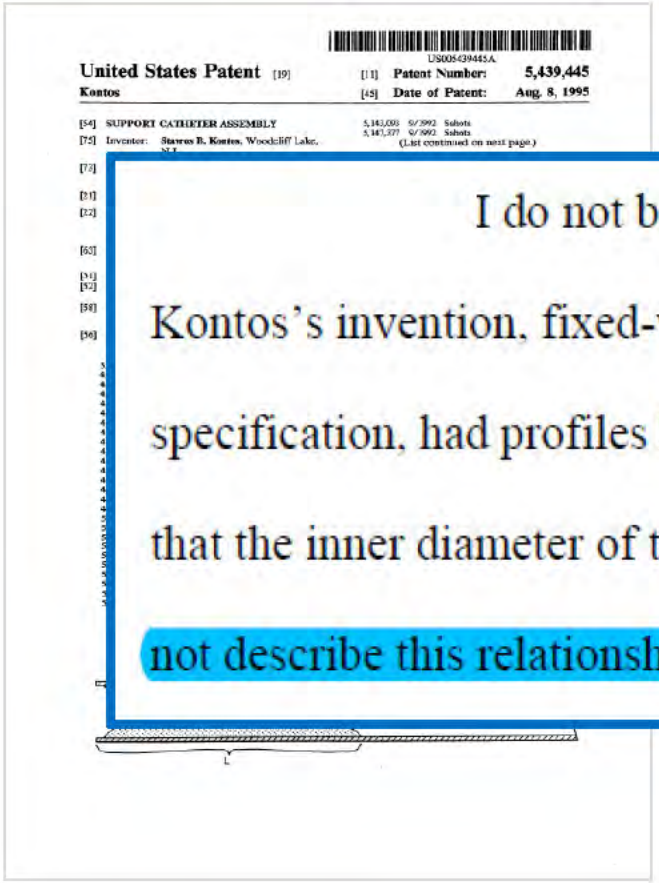
A support catheter assembly for facilit procedures includes a tubular body and lumen from its proximal end to its distal e lating member is connected to the tub inserting, advancing, withdrawing and ma body during a medical procedure. The member may be a wire or a manipulat tubular body also may be provided with a lumen opening at its proximal end to faci of devices therethrough, and radiopaqu subcutaneously detecting the location during a medical procedure and, more p detecting its location relative to other the medical procedure. A method also i using the tube assembly to facilitate FTCA catheter into a stenotic region a upon the lumen through that region aft has been performed.

33 Claims, 6 Drawing Sheet

- "The size and shape of the various elements of support assembly 10 may vary depending on the desired application." Ex-1009, 4:46-48.
- "These sizes generally are suitable for existing PTCA catheters, such as the INTEGRA catheter marketed by Datascope Corp., the assignee of the present invention. Of course, other sizes may be used for other applications." *Id.*, 4:61-65.
- "As noted, these sizes may vary depending upon the application to which the device is to be put. When it is to be used with a PTCA catheter, lumen 22 should be at least large enough to permit passage therethrough of the deflated PTCA balloon." *Id.*, 4:66-5:2.

Ex-1807, ¶ 115 (Jones)

U.S. Patent No. 5,439,445 (Kontos)



United States Patent [19]
Kontos

[11] Patent Number: 5,439,445
[45] Date of Patent: Aug. 8, 1995

[54] SUPPORT CATHETER ASSEMBLY

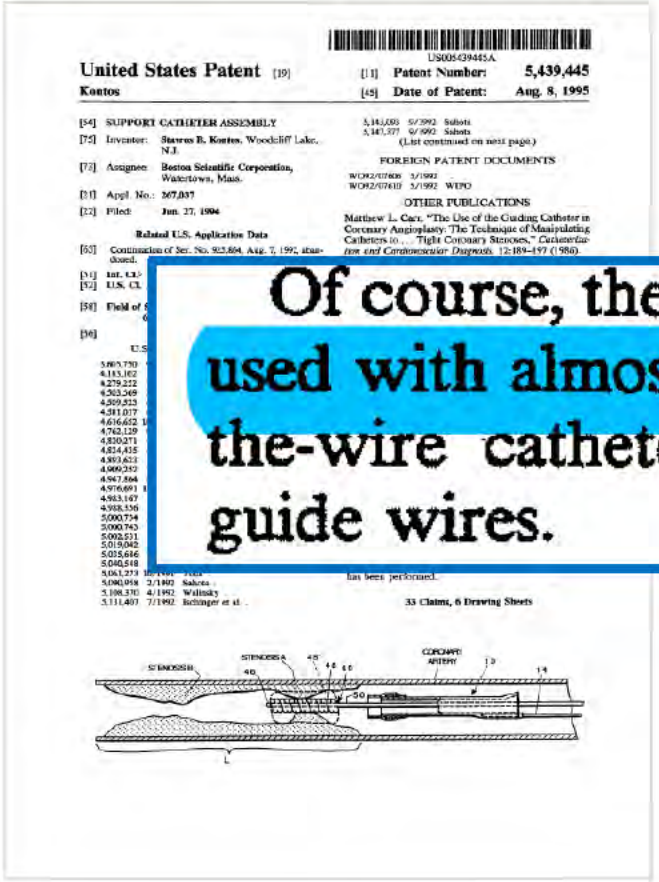
[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

(List continued on next page.)

I do not believe it would have resulted in a tight fit. At the time of Kontos's invention, fixed-wire balloons, including the Integra mentioned in the specification, had profiles less than 0.030 inches. Ex-1833, 113. Kontos teaches that the inner diameter of tube 16 can be 0.045 inches. Ex-1009, 4:48-50. I would not describe this relationship as being "snug."

Ex-1807, ¶ 116 (Jones)

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: **Steven B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **267,037**

[22] Filed: **Jun. 27, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 923,804, Aug. 7, 1992, abandoned.

[51] Int. Cl.
[52] U.S. Cl.
[58] Field of
[56]

U.S.

5,143,093 9/1992 Sahota
5,147,377 9/1992 Sahota
(List continued on next page.)

FOREIGN PATENT DOCUMENTS

WO92/07606 5/1992
WO92/07610 5/1992 WIPO

OTHER PUBLICATIONS

Matthew L. Carr, "The Use of the Guiding Catheter in Coronary Angioplasty: The Technique of Manipulating Catheters to ... Tight Coronary Stenoses," *Catheterization and Cardiovascular Diagnosis*, 12:189–197 (1986).

has been performed.

33 Claims, 6 Drawing Sheets

> Of course, the device of the present invention may be used with almost any type of catheter, including over-the-wire catheters as well as catheters with captive guide wires.

Ex-1409, 9:47-50

1. Overview of Kontos
2. Kontos Teaches the "alongside" Limitation
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Issues Specific to -01344 IPR

Kontos Teaches the Order of Insertion Proposed by Patent Owner

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

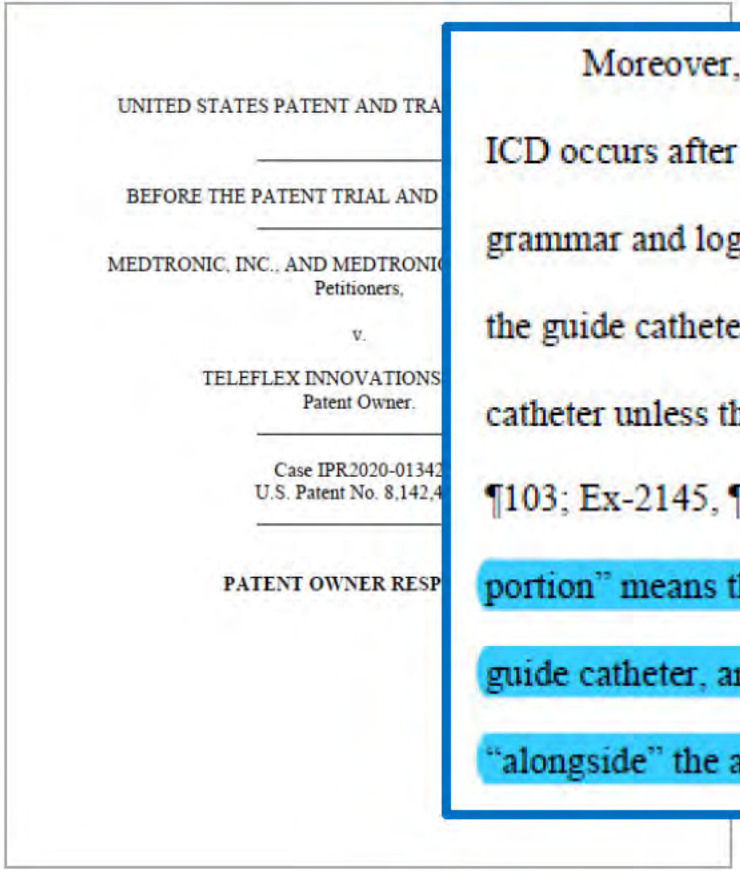
Case No.: IPR2020-01342
U.S. Patent No. 8,142,413

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

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.

IPR2020-01342 Petition at 48-49

Kontos Teaches the Order of Insertion Proposed by Patent Owner


UNITED STATES PATENT AND TRA

BEFORE THE PATENT TRIAL AND

MEDTRONIC, INC., AND MEDTRONI
Petitioners,

v.

TELEFLEX INNOVATIONS
Patent Owner.

Case IPR2020-0134
U.S. Patent No. 8,142,4

PATENT OWNER RESP

Moreover, step 1.f. itself contains language indicating that insertion of the ICD occurs after insertion of the coaxial guide catheter. As a matter of both grammar and logic, the ICD would not be inserted "into and through" the lumen of the guide catheter "alongside of" the substantially rigid portion of the coaxial guide catheter unless the coaxial guide catheter is already in the guide catheter. Ex-2138, ¶103; Ex-2145, ¶103. Inserting an ICD "alongside of the substantially rigid portion" means that the substantially rigid portion is already in place inside the guide catheter, and when the ICD is inserted into the guide catheter it moves "alongside" the already-positioned substantially rigid portion.

IPR2020-01342 Paper 24 (POR) at 14

Kontos Teaches the Order of Insertion Proposed by Patent Owner

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

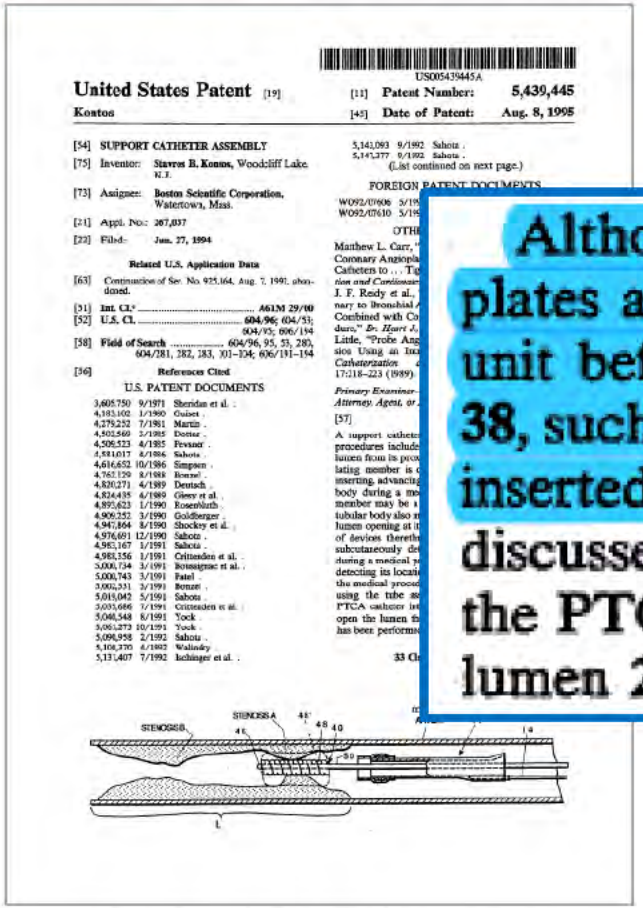
Case No.: IPR2020-01342
U.S. Patent No. 8,142,413

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

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).

IPR2020-01342 Petition at 48-49

Kontos Teaches the Order of Insertion Proposed by Patent Owner



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number:** 5,439,445
[45] **Date of Patent:** Aug. 8, 1995

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 925,164, Aug. 7, 1991, abandoned.

[51] **Int. Cl.**[6] A61M 29/00
[52] **U.S. Cl.** 604/96; 604/53; 604/93; 606/194
[58] **Field of Search** 604/96, 95, 53, 280, 604/281, 282, 283, 101-104; 606/191-194

[56] **References Cited**

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5,015,042	5/1991	Sahota .	
5,033,096	7/1991	Crittenden et al. .	
5,040,548	8/1991	Yock .	
5,061,273	10/1991	Yock .	
5,090,958	2/1992	Sahota .	
5,108,370	4/1992	Walinsky .	
5,131,407	7/1992	Ichinger et al. .	
5,141,093	9/1992	Sahota .	
5,147,377	9/1992	Sahota .	

(List continued on next page.)

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WO92/07610 3/19

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Matthew L. Carr, "
Coronary Angiopla
Catheters to ... Tr
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17:218-223 (1989)

Primary Examiner
Attorney, Agent, or

[57]

A support catheter
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33 Cl

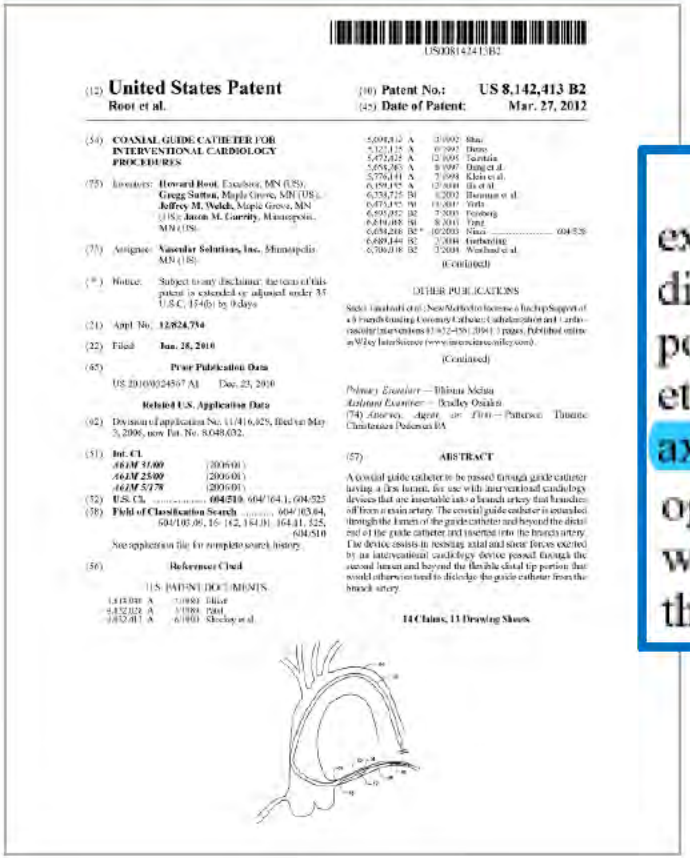
Although the procedure described above contemplates assembling body **12** and PTCA catheter **40** as a unit before passing them together into guide catheter **38**, such preassembly is not necessary. Body **12** could be inserted first, followed by the PTCA catheter **40**. As discussed above, funnel portion **26** facilitates passage of the PTCA catheter **40** from the guide catheter **38** into lumen **22** of body **12**.

Ex-1409 at 7:45-52

IPR2020-01342 & IPR2020-01344

1. Overview of Kontos
2. Kontos Teaches the "alongside" Limitation
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Issues Specific to -01344 IPR

IPR2020-01342, -01344: Representative Back-Up Claim



US008142413B2

(12) **United States Patent**
Root et al.

(10) Patent No.: US 8,142,413 B2
(45) Date of Patent: Mar. 27, 2012

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days

(21) Appl. No.: **12/824,794**

(22) Filed: **Jun. 28, 2010**

(65) **Prior Publication Data**

US 2010/0324567 A1 Dec. 23, 2010

Related U.S. Application Data

(62) Division of application No. 11/416,825, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 31/00 (2006.01)
A61M 25/00 (2006.01)
A61M 5/178 (2006.01)

(52) **U.S. Cl.** **604/510**; 604/164.1; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.06, 16, 142, 164.01, 164.11, 525, 604/510

See application file for complete search history.

(56) **References Cited**

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(Continued)

Primary Examiner — Bhisma Mehta
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente Christensen Pedersen PA

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. 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. The device 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 that would otherwise tend to dislodge the guide catheter from the branch artery.

14 Claims, 11 Drawing Sheets

> 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.

Ex-1401, claim 7 ('413 patent)

IPR2020-01342, -01344: Kontos Provides Back-Up Support

NON-PUBLIC VERSION – PROTECTIVE ORDER MATERIAL

Trials@uspto.gov
571-272-7822

Paper 105
Date: June 7, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and MEDTRONIC VASCULAR, INC.,
Petitioner,

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Before SHERIDAN K. SNEDDE
CHRISTOPHER G. PAULRAJ, A

SNEDDEN, *Administrative Patem*

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
Granting Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

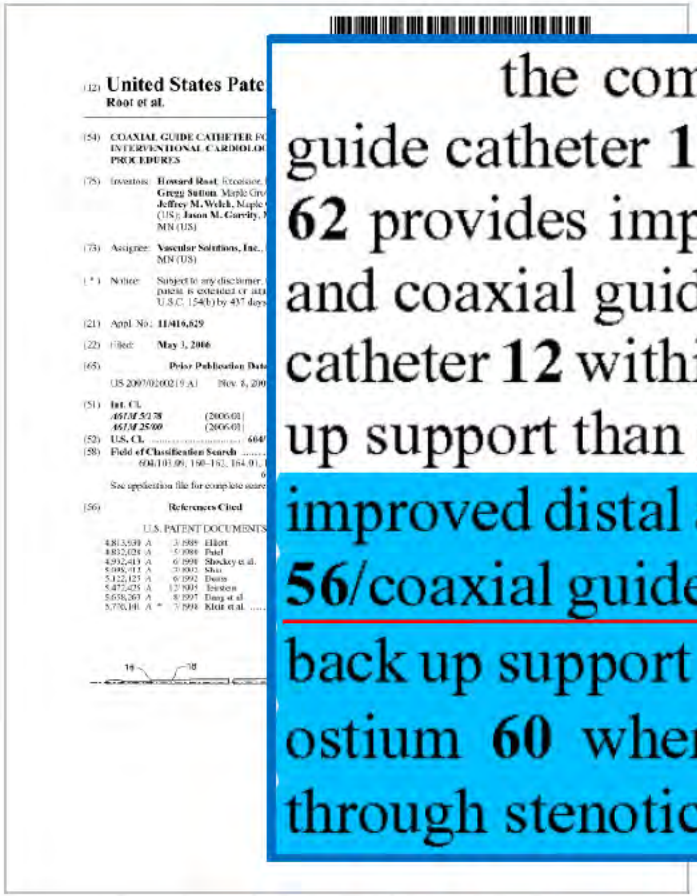
Petitioner and

Drs. Jones and Brecker present persuasive evidence, however, that the device of Kontos will resist axial and shear forces, at least to some extent, when extended into the ostium of a blood vessel.

IPR2020-00127, FWD (Paper 105) at 26

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

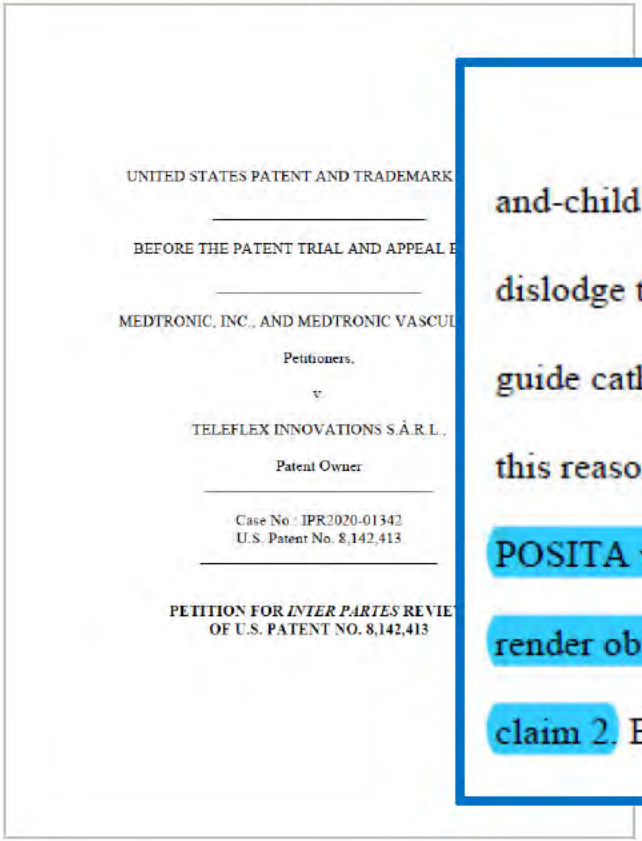
IPR2020-01342, -01344: What Patents Teach About Backup Support



the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion.

Ex-1401, 8:1-12 ('413 patent)

IPR2020-01342, -01344: How Patents Teach Backup Support



UNITED STATES PATENT AND TRADEMARK

BEFORE THE PATENT TRIAL AND APPEAL B

MEDTRONIC, INC., AND MEDTRONIC VASCUL

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

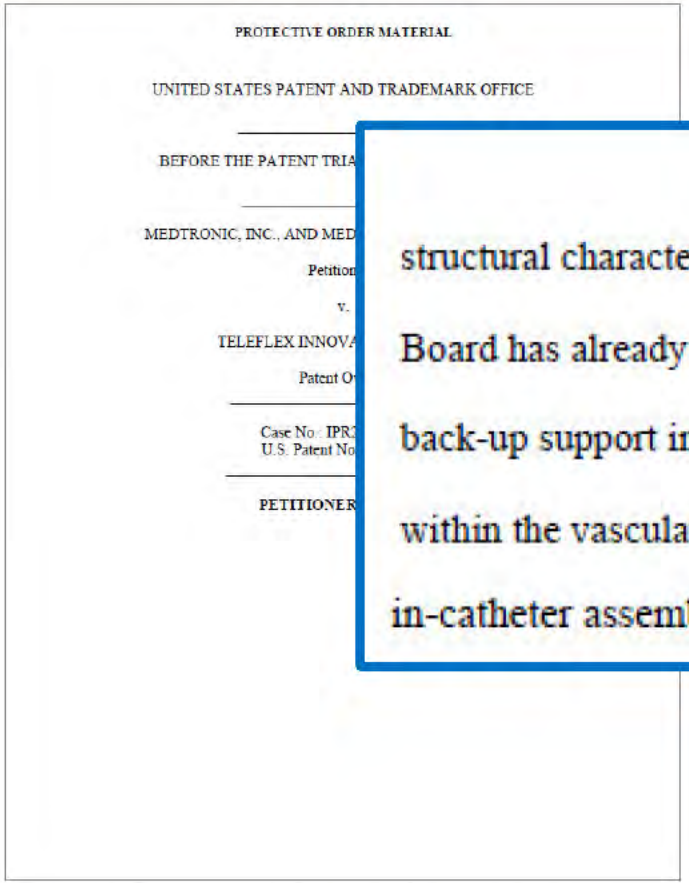
Case No.: IPR2020-01342
U.S. Patent No. 8,142,413

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

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*.

Paper 1 at 53 (-01342 IPR)

IPR2020-01342 & IPR2020-01344


PROTECTIVE ORDER MATERIAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIA

MEDTRONIC, INC., AND MED

Petition

v.

TELEFLEX INNOVA

Patent O

Case No.: IPR
U.S. Patent No

PETITIONER

But the structural characteristics of Kontos—which PO does not dispute, and which the Board has already found invalidated similar claims in a separate IPR—provide back-up support in two ways: (i) shortening the distance that the IVCD must travel within the vasculature and (ii) by increasing the moment of inertia of the catheter-in-catheter assembly. Ex-1806 ¶107-11; Ex-1807 ¶¶14-27, 106-12.

Reply at 7 (-01342)

IPR2020-01342, -01344: Shorter Distance

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

20. By using a catheter-in-catheter assembly, it is possible to extend the inner catheter (sometime referred to as the "child catheter") beyond the ostium of the coronary artery. In so doing, the interventional cardiology device has to travel a shorter distance in the vasculature, which in turn reduces the amount of force necessary to advance the interventional cardiology device to the target location. This is because the vasculature can be tortuous and/or calcified, thereby requiring more force to advance the interventional cardiology device.

IPR2020-01342, -01344: Increased Moment of Inertia

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

23. The moment of inertia, I_0, of the cross section of a catheter with respect to its neutral axis, is expressed by the following, and is proportional to flexural rigidity and buckling force. *Id.* at 12. The cross section of a catheter is a hollow circle with an outer diameter D and an inner diameter d. *Id.*

$$I_0 = \frac{\pi(D^4 - d^4)}{64}$$

Ex-1807, ¶ 23 (Jones)

IPR2020-01342, -01344: Increased Moment of Inertia

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

23. The moment of inertia, I_0, of the cross section of a catheter with respect to its neutral axis, is expressed by the following, and is proportional to flexural

hollow

24. The polar moment of inertia of a catheter shaft with outer diameter D and inner diameter d is expressed as follows, and is proportional to the torsional rigidity of a catheter. *Id.*, 12-15.

$$J_0 catheter = \frac{\pi(D^4 - d^4)}{32}$$

Ex-1807, ¶ 24 (Jones)

IPR2020-01342, -01344: Increased Moment of Inertia

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

23. The moment of inertia, I_0, of the cross section of a catheter with respect to its neutral axis, is expressed by the following, and is proportional to flexural

hollow

24. The polar moment of inertia of a catheter shaft with outer diameter D and inner dia

rigidity of a c

25. From these equations it is clear that when placing a catheter within a catheter, the outer diameter remains defined and the effective inner diameter decreases, which results in the following consequences:

a. Flexural rigidity increases;

b. Torsional rigidity increases; and

c. Resistance to buckling force increases.

Ex-1807, ¶ 25 (Jones)

IPR2020-01342, -01344: Teleflex's Argument

UNITED STATES PATENT

BEFORE THE PATENT TR

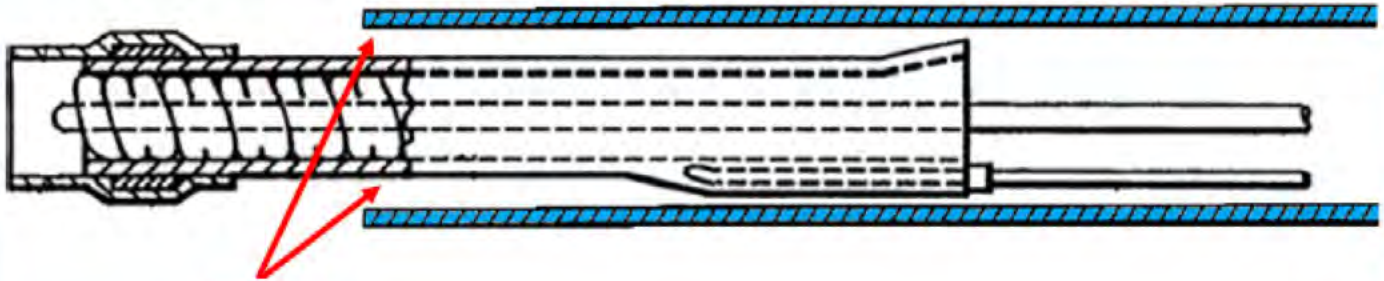
MEDTRONIC, INC., AND ME
Petit

TELEFLEX INNO
Patent Owner.

Case IPR
U.S. Patent

PATENT OWN

First, in contrast to the '413 patent. Kontos does *not* teach a method of resisting axial and shear forces or keeping the distal portion seated in the artery in response to opposing forces. Ex-2138, ¶¶216-22; Ex-2145, ¶148.



Paper 40 at 23-24 (-01342 IPR)

IPR2020-01342, -01344: Jones Addresses Teleflex's Argument

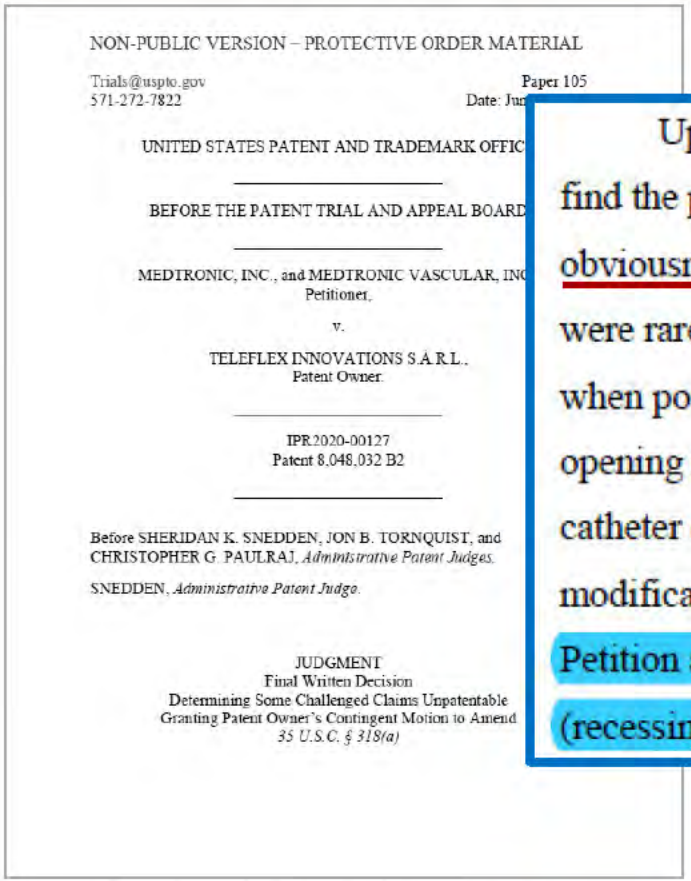
DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

108. By comparison to a single-catheter assembly, the use of Kontos's support assembly with a guide catheter will increase flexural rigidity, torsional rigidity, and increase resistance to buckling force. In reaching this conclusion, I have considered (i) the material that comprises tube 16, (ii) the dimensions, including the inner/outer diameter and length, and (iii) the relationship between tube 16 and the guide catheter, including that the inner diameters of the nested catheters is more than 1 French.

Ex-1807, ¶ 108 (Jones)

1. Overview of Kontos
2. Kontos Teaches the "alongside" Limitation
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Issues Specific to -01344 IPR

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New



NON-PUBLIC VERSION – PROTECTIVE ORDER MATERIAL

Trials@uspto.gov
571-272-7822

Paper 105
Date: Jun

UNITED STATES PATENT AND TRADEMARK OFFIC

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and MEDTRONIC VASCULAR, INC
Petitioner,

v.

TELEFLEX INNOVATIONS S.A.R.L.,
Patent Owner.

IPR2020-00127
Patent 8,048,032 B2

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
Granting Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

Upon review of the parties' arguments and supporting evidence, we find the parties' arguments present a close case on the question of obviousness. For example, while side openings were known in the art, they were rare in devices intended to receive an interventional cardiology device when positioned within a guide catheter. Moreover, switching to a side opening in Kontos to beneficially increase the available real estate within the catheter or to reduce the size of the guide catheter would require several modifications to the device, at least one of which was not mentioned in the Petition and may not have been possible in the relevant time period (recessing marker band 30).

IPR2020-00127, FWD (Paper 105) at 46

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

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

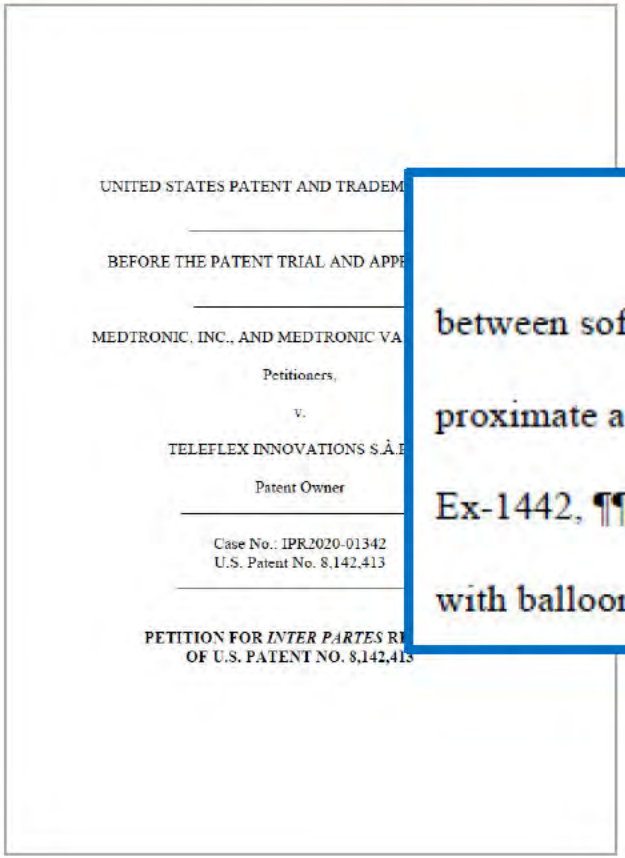
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,142,413

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.

IPR2020-01342, Petition at 57; *see also* Petition at 56-61, 63

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New


UNITED STATES PATENT AND TRADEM

BEFORE THE PATENT TRIAL AND APPE

MEDTRONIC, INC., AND MEDTRONIC VA

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.

Patent Owner

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

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

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.

IPR2020-01342, Petition at 63

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

BEFORE THE PATENT TRIAL

MEDTRONIC, INC., AND MEDT
Petitioner

v.

TELEFLEX INNOVAT
Patent Own

Case No.: IPR20
U.S. Patent No:

DECLARATION OF RICHARD A.

G. Kontos in combination with the common knowledge in the art teaches a marker band embedded in tube 16.

104. Kontos discloses a marker band 30 that is disposed in a recess 36 on the exterior of tube 16 as shown in the figure below. *See* Ex-1409, 4:19-21. Kontos also states that, "[o]f course, numerous other methods for disposing marker band 30 at distal end 24 will be readily apparent to those skilled in the art." *Id.*, 4:21-24.

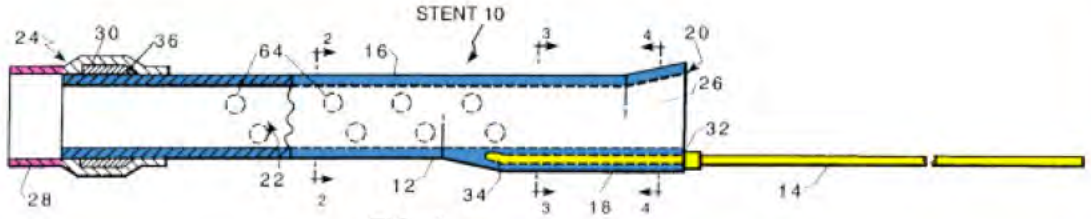


FIG. 1

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

Ex-1442, ¶ 104

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

BEFORE THE PATENT TRIAL

MEDTRONIC, INC., AND MEDT
Petitioner
v.
TELEFLEX INNOVAT
Patent Own

Case No.: IPR20
U.S. Patent No:

DECLARATION OF RICHARD A.

G. Kontos in combination with the common knowledge in the art teaches a marker band embedded in tube 16.

104.

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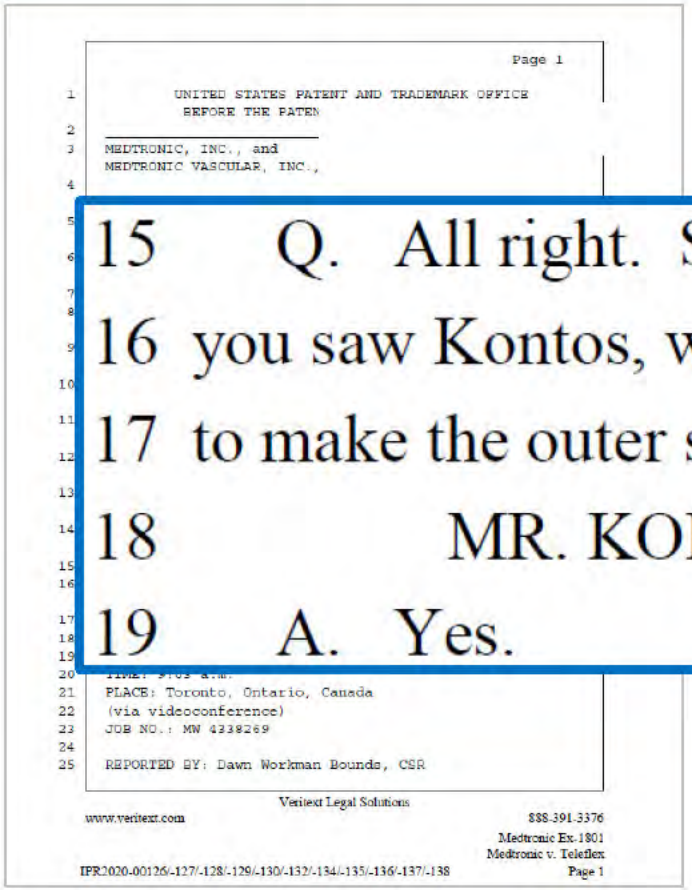
also state

30 at dist

Id., Fig.

105. Indeed, it is common knowledge in the art to dispose marker bands such that they are embedded within the tubular portion of the catheter instead of on the outside of the tubular portion. A POSITA understands that by embedding the marker band, the profile of the catheter can be reduced, thereby preventing the risk of damage to the vasculature when the extension catheter is advanced distal to the distal-most portion of the guide catheter. For example, the size of Kontos's marker band is 0.005 inches. Ex-1409, 4:54-58 (describing the marker band 30 as having an inner diameter of 0.055 inches and an outer diameter of 0.060 inches). By embedding the marker band into tube 16, 0.005 inches can be reduced from the diameter of the catheter.

IPR2020-01342, -01344: Graham Says Recess Marker Bands



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATEN

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

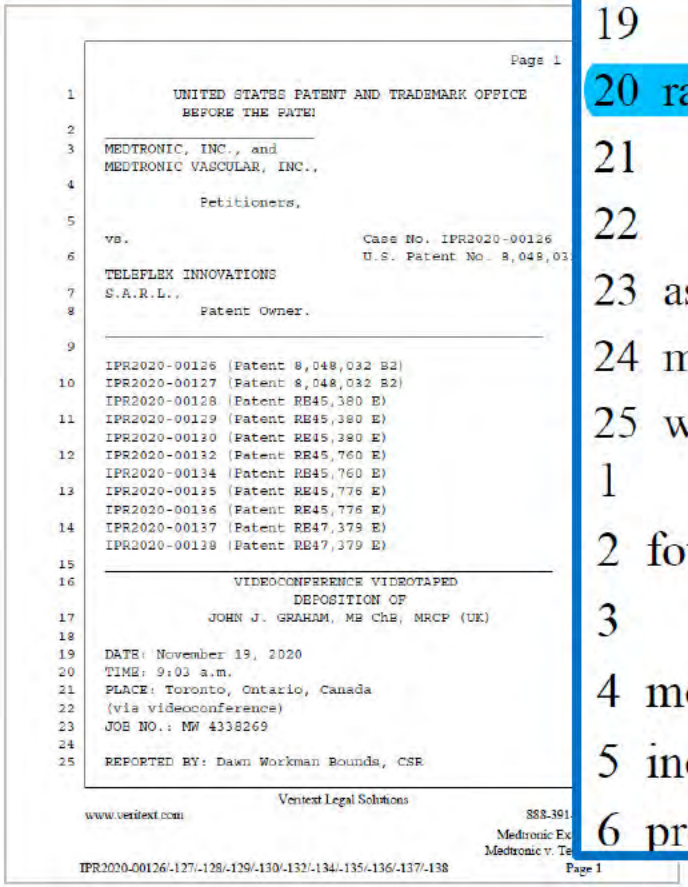
Veritext Legal Solutions
www.veritext.com 888-391-3376
Medtronic Ex-1801
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

15 Q. All right. So in the 2005, 2006 time frame, if
16 you saw Kontos, would you want to recess the marker bands
17 to make the outer surface smooth?
18 MR. KOHLHEPP: Objection, scope.
19 A. Yes.

Ex-1801, 75:15-19 (Graham)

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01342, -01344: Graham Never Used Raised Marker Bands



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATE

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,03

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (UK)

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

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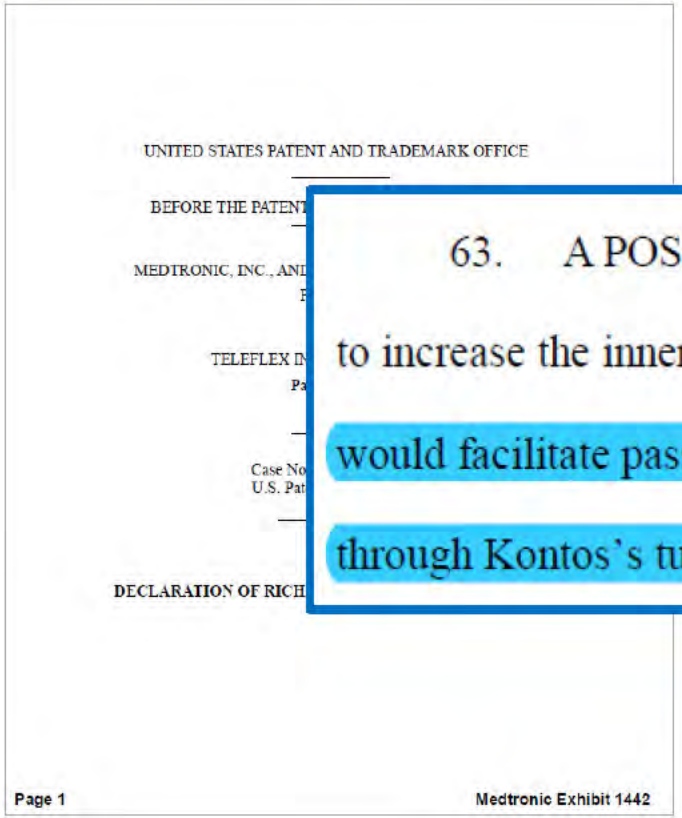
Medtronic Ex
Medtronic v. Te
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

19 Q. Have you ever used a catheter assembly with
20 raised marker bands as shown in Kontos?
21 A. No.
22 Q. In the 2005 to 2006 time frame, then, I'm
23 assuming you'd agree it was common practice to dispose
24 marker bands within the extension catheter such that they
25 weren't raised as shown in Kontos Figure 1?
1 MR. KOHLHEPP: Objection to form;
2 foundation.
3 A. The idea was to have a smooth outer profile, so
4 most marker bands were -- tried to -- the attempt was to
5 incorporate them into the catheter to try to minimize the
6 protuberance from the exterior surface.

Ex-1801, 66:19-67:6 (Graham)

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New


UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT

MEDTRONIC, INC., AND

TELEFLEX IN

Case No

U.S. Pat

DECLARATION OF RICH

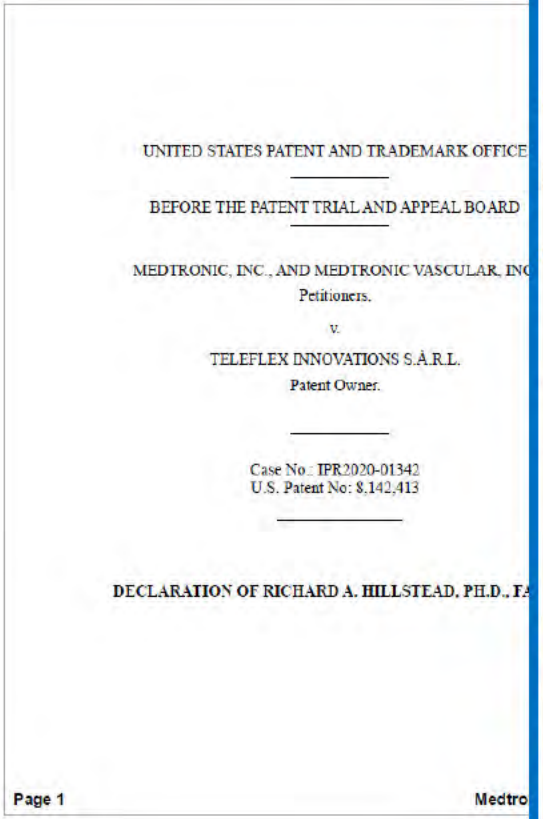
Page 1

Medtronic Exhibit 1442

63. A POSITA would have been motivated to combine Adams and Kontos to increase the inner diameter of Kontos's tube 16 because a larger inner diameter would facilitate passage of a greater variety of PCI catheters that are too big to pass through Kontos's tube 16.

Ex-1442, ¶ 63

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New



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

DECLARATION OF RICHARD A. HILLSTEAD, PH.D., FA

Page 1 Medtro

64. A POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success—including by removing Kontos's proximal funnel 26 and replacing it with Adams's proximal side opening—given the teachings of Kontos and Adams. *See* ¶¶ 69-88, *infra*. In particular, this design modification was well within the skill of a POSITA, as appropriately sized catheters were ubiquitous in the art. Ex-1410, 452. Indeed, combining the teachings of Kontos with Adams to permit the passage of an interventional cardiology device—including by removing proximal funnel 26 so that the inner diameter of Kontos's tube 16 could be made larger, thereby not requiring a corresponding increase in the inner diameter of guide catheter 38—would have been nothing more than combining prior art elements according to known methods to yield predictable results.

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, I
Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.
Patent Owner.

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

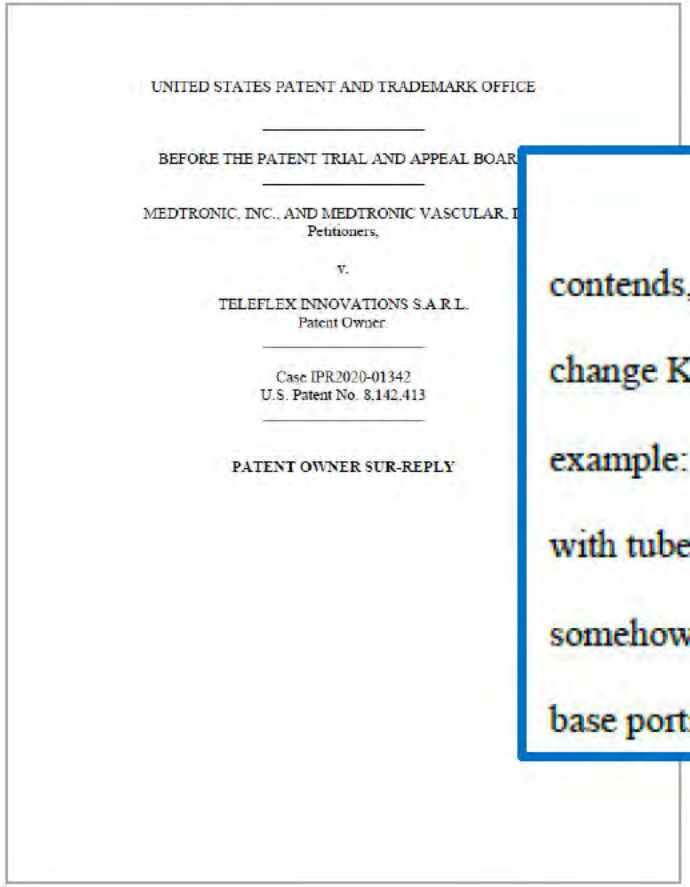
DECLARATION OF RICHARD A. HILLSTEAD, PH.D.

Page 1 Medtronic Exhibit 1442

Using a side opening (as opposed to a funnel) efficiently balances these considerations and optimizing the area of the point of entry into the extension catheter. That is, by replacing a funnel with an angled opening, the POSITA can either (i) reduce the outer diameter of the device while maintaining constant the area of the point of entry into the side opening (and the inner diameter of the extension catheter), or (ii) maintain constant the outer diameter of the device while increasing the area of entry into the side opening (and the inner diameter of the extension catheter).

Ex-1442, ¶ 84

IPR2020-01342, -01344: Patent Owner Again Argues "New" Evidence



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOAR

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, I
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner

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

PATENT OWNER SUR-REPLY

The Petitioner's Reply contends, for the first time, that a POSITA would be motivated to completely change Kontos, with numerous changes beyond those advocated in the Petition, for example: (1) "recess[ing]" Kontos's marker bands; (2) aligning distal soft tip 28 with tube 16; (3) removing Kontos's base portion 18; (4) "taper[ing]" the wire; (5) somehow "attach[ing]" the thin-tapered pushrod to Kontos's tube wall without base portion 18, and (6) "increas[ing]" the diameter of "tube 16."

Sur-Reply, at 3

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

UNITED STATES PATENT AND TRADEMARK OFFIC

BEFORE THE PATENT TRIAL AND APPEAL BOARI

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, I
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

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

PATENT OWNER SUR-REPLY

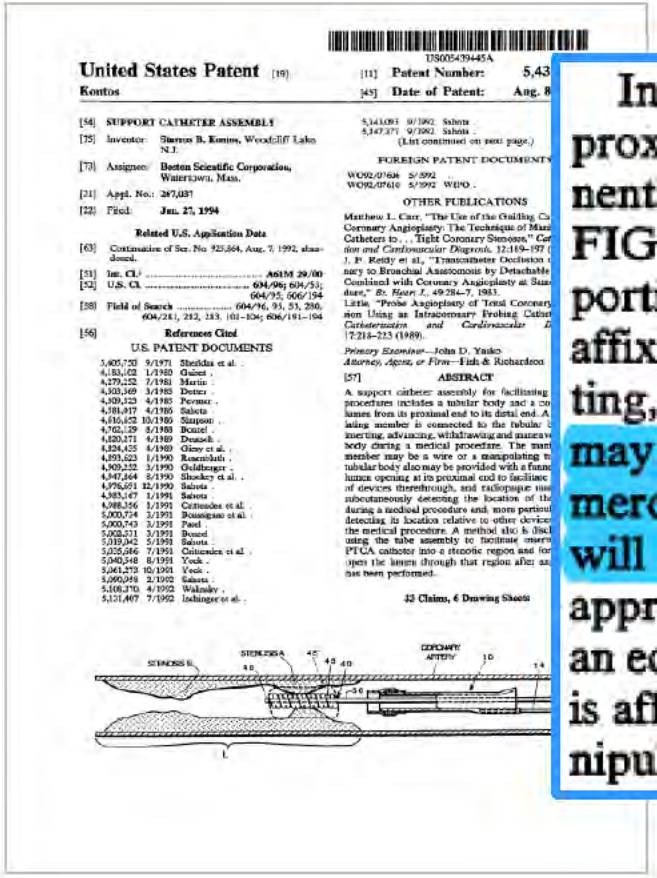
For example, the protruding base section 18 of Kontos's support catheter creates an "eccentric cross-section" that "provides leverage for facilitating manipulation of body 12." Ex-1409, 4:34-38. Similarly, Petitioner's new argument that a POSITA would be motivated to "taper" the relatively thick pushwire (Reply, 13 n.3, 19), contradicts Petitioner's argument in a related IPR that a POSITA would be motivated to modify Itou's pushwire because where it has been flattened created a "potential weakness point in the catheter." IPR2020-00135, Paper 82, 17.

IPR2020-01342, Paper 52 at 5-6

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

Patent Owner's Alleged "New Modifications"	Support or Responsive Argument Found in:	Other Support Offered by Petitioner
Removing Kontos's funnel	Petition at 56-61	Ex-1442 (Hillstead), ¶ 63-64; Ex-1405 (Brecker), ¶ 210-21
Aligning Kontos's distal tip with tube 16	Petition at 63	Ex-1405 (Brecker), ¶ 252; Ex-1807 (Jones), ¶ 128-30
Removing Kontos's base portion 18	POR at 26-31	Ex-1807 (Jones), ¶ 118-20
Tapering Kontos's pushwire	POR at 26-31	Ex-1807 (Jones), ¶ 131-32
Increasing the diameter of tube 16	Petition at 57; POR at 42-43	Ex-1807 (Jones), ¶ 134-35

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New



United States Patent [19]
Kontos

[11] Patent Number: 5,43
[45] Date of Patent: Aug. 8

[54] SUPPORT CATHETER ASSEMBLY
[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.
[73] Assignee: Boston Scientific Corporation, Watertown, Mass.
[21] Appl. No.: 267,037
[22] Filed: Jun. 27, 1994

Related U.S. Application Data
[63] Continuation of Ser. No. 925,864, Aug. 7, 1992, abandoned.
[51] Int. Cl.[6] A61M 29/00
[52] U.S. Cl. 604/96; 604/53; 604/95; 606/194
[58] Field of Search 604/96, 95, 53, 280, 604/281, 282, 283, 101-105; 606/191-194

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(List continued on next page.)

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Little, "Probe Angioplasty of Total Coronary ... sion Using an Intracoronary Probing Cathet... Catheterization and Cardiovascular D... 17:218-223 (1989).

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Fish & Richardson

[57] ABSTRACT
A support catheter assembly for facilitating ... procedures includes a tubular body and a co... lumen from its proximal end to its distal end. A... guiding member is connected to the tubular b... inserting, advancing, withdrawing and manipu... body during a medical procedure. The guid... member may be a wire or a manipulating t... tubular body also may be provided with a funne... lumen opening at its proximal end to facilitate ... of devices therethrough, and radiopaque mar... subcutaneously detecting the location of the ... during a medical procedure and, more particu... detecting its location relative to other devices ... the medical procedure. A method also is disc... using the tube assembly to facilitate inserti... PTCA catheter into a stenotic region and for... open the lumen through that region after an ... has been performed.

33 Claims, 6 Drawing Sheets

Insertion wire **14** is attached to base portion **18** at proximal end **20** of tube **16**, and preferably is permanently affixed thereto. For example, as best shown in FIGS. **1**, **3** and **4**, wire **14** may be connected to base portion **18** by inserting it into a receiving hole **34**, and affixing it therein by, for example, gluing, pressure fitting, shrink fitting, or the like. Alternatively, tube **16** may be molded directly onto application wire **14**. Numerous other methods of connecting wire **14** to body **12** will readily occur to those skilled in the art. It will be appreciated that this configuration, wherein tube **16** has an eccentric cross-section at base portion **18** and wire **14** is affixed thereto, provides leverage for facilitating manipulation of body **12**.

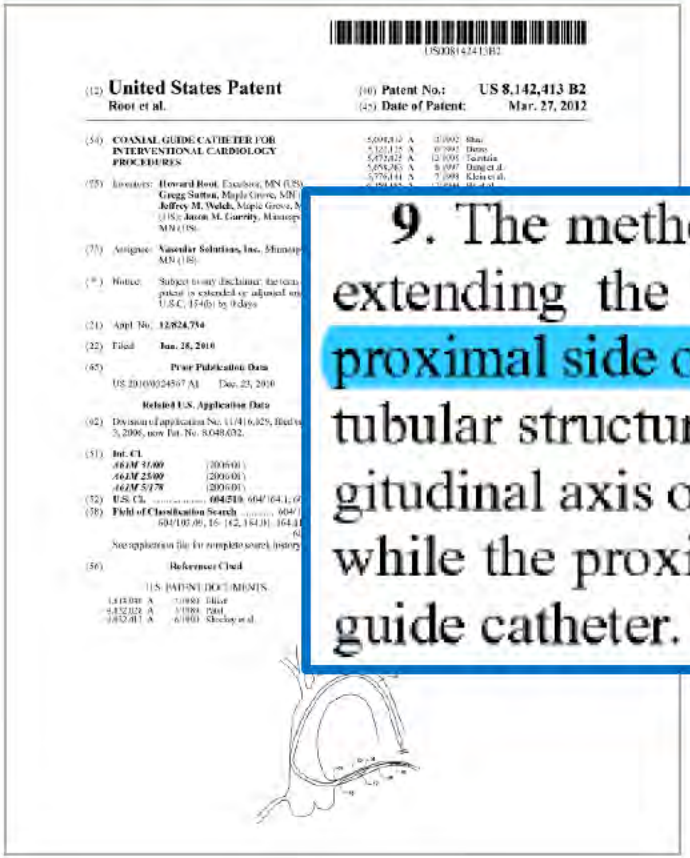
Ex-1409, 4:25-38

IPR2020-01342, -01344: Petitioner's Modifications to Kontos are Not New

"The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, but rather whether a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention."

Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (internal citations omitted)

IPR2020-01342, -01344: Representative Side Opening Claim



(12) **United States Patent**
Root et al.

(10) Patent No.: US 8,142,413 B2
(45) Date of Patent: Mar. 27, 2012

(54) COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

(75) Inventors: Howard Root, Excelsior, MN (US); Gregg Sutton, Maple Grove, MN (US); Jeffrey M. Welch, Maple Grove, MN (US); Jason M. Garrity, Minneapolis, MN (US)

(73) Assignee: Vascular Solutions, Inc., Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 12/824,754

(22) Filed: Jun. 28, 2010

(65) Prior Publication Data

US 2010/0324567 A1 Dec. 23, 2010

Related U.S. Application Data

(62) Division of application No. 11/416,625, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) Int. Cl.
A61M 31/00 (2006.01)
A61M 25/00 (2006.01)
A61M 5/178 (2006.01)

(52) U.S. Cl. 604/510; 604/164.1; 604/164.09; 604/164.13

(58) Field of Classification Search 604/164.01, 604/164.09, 164.13, 510; 606/108; 600/585
See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

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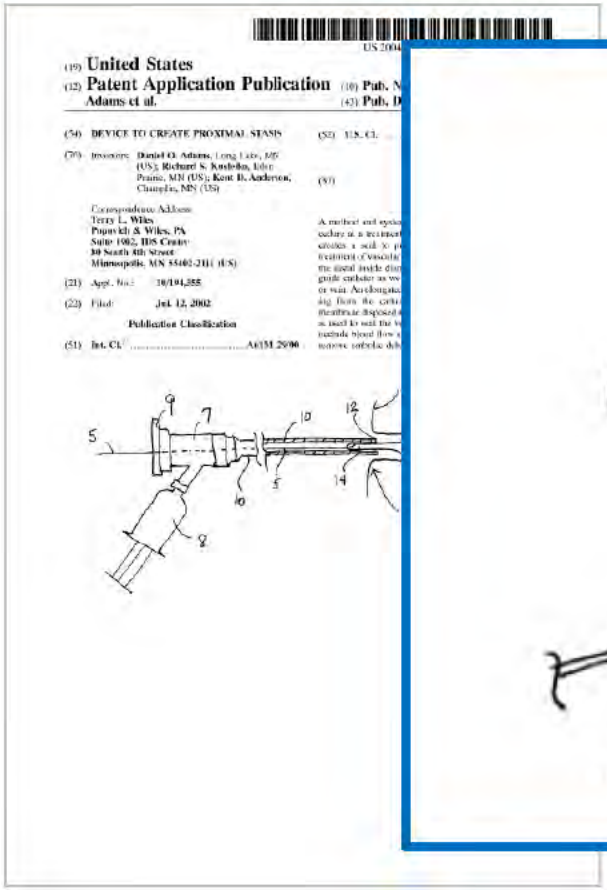
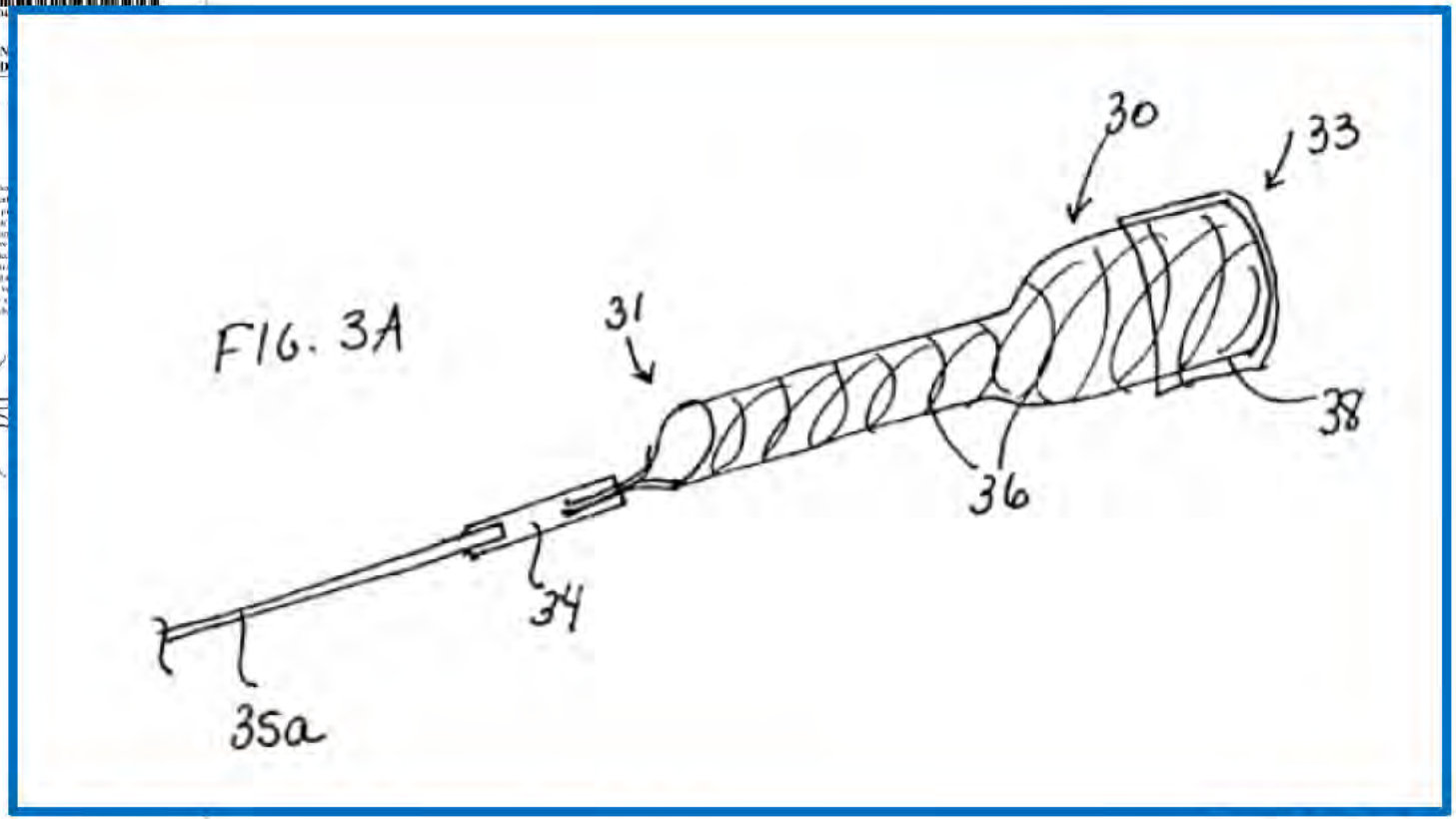
5,452,513 A 9/1995 Root
5,632,013 A 6/1997 Shockey et al.

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.

Ex-1401, claim 9 ('413 patent)

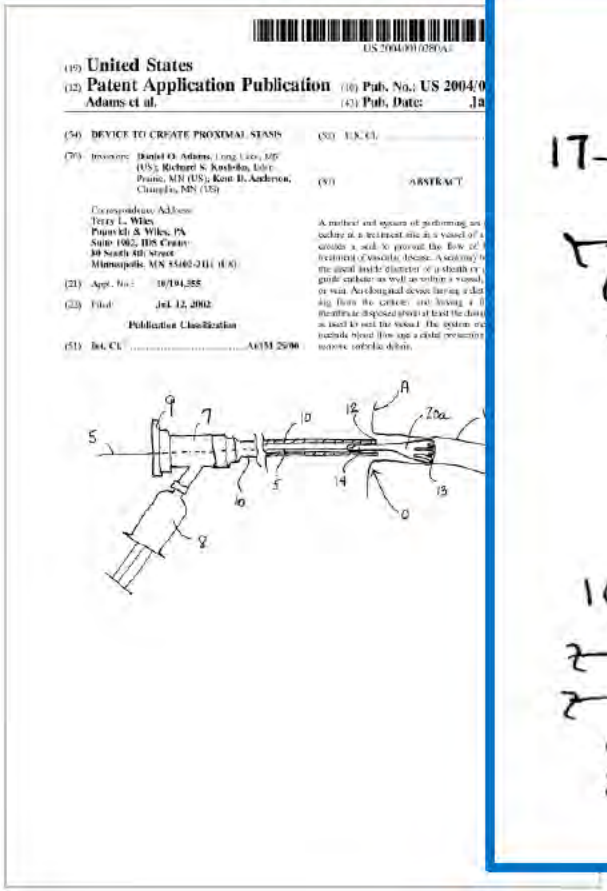
IPR2020-01342: Adams





Ex-1435, Fig. 3A

IPR2020-01342: Adams



(19) United States
(12) Patent Application Publication
Adams et al.
(10) Pub. No.: US 2004/0
(43) Pub. Date: Ja

(54) DEVICE TO CREATE PROXIMAL STASIS

(52) U.S. Cl. .....

(76) Inventors: Daniel O. Adams, Long Lake, MN (US); Richard S. Kaufeldt, Eden Prairie, MN (US); Kent D. Anderson, Champlin, MN (US)

(57) ABSTRACT

Correspondence Address:
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(21) Appl. No.: 10/194,355

(22) Filed: Jul. 12, 2002

Publication Classification

(51) Int. Cl. A61M 25/00

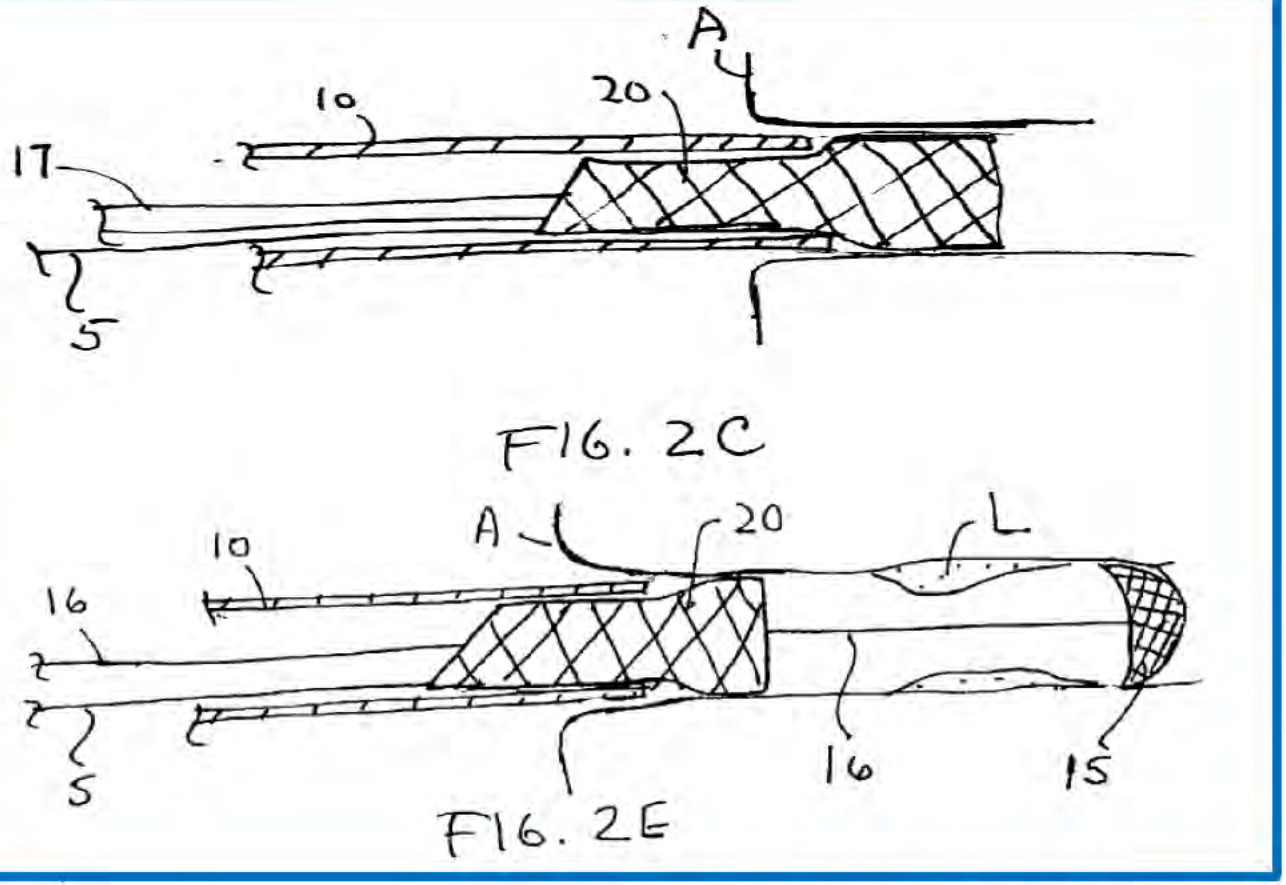


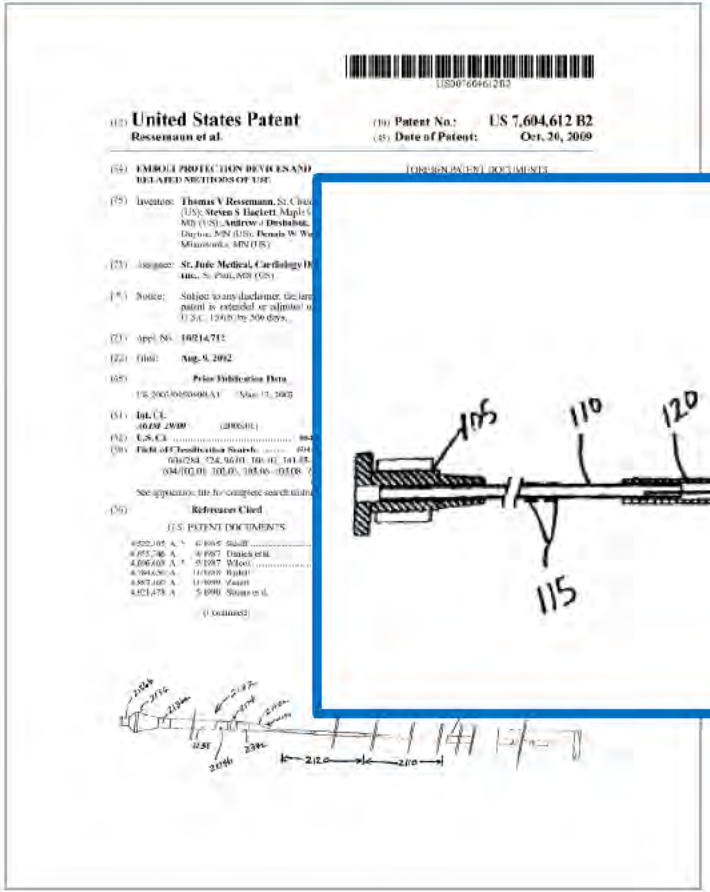
FIG. 2C

FIG. 2E

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Ex-1435, Figs. 2C, 2E

IPR2020-01344: Ressemann


US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) Patent No.: US 7,604,612 B2
(45) Date of Patent: Oct. 20, 2009

(54) EMBOLIC PROTECTION DEVICES AND RELATED METHODS OF USE

(75) Inventors: Thomas V Ressemann, St. Cloud (US); Steven S Hackett, Maple Grove, MN (US); Andrew J Denbraber, Dayton, MN (US); Pamela W Wong, Minnetonka, MN (US)

(73) Assignee: St. Jude Medical, Cardiology Division, Inc., St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 506 days.

(21) Appl. No.: 10/214,712

(22) Filed: Aug. 9, 2002

(65) Prior Publication Data

US 2003/0050660 A1 Mar. 13, 2003

(51) Int. Cl.
A61M 29/00 (2006.01)

(52) U.S. Cl. .....

(58) Field of Classification Search: .....
604/264, 524, 96.01, 101.01, 101.03, 104/102.01, 103.01, 103.06, 103.08, ...
See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

(continued)

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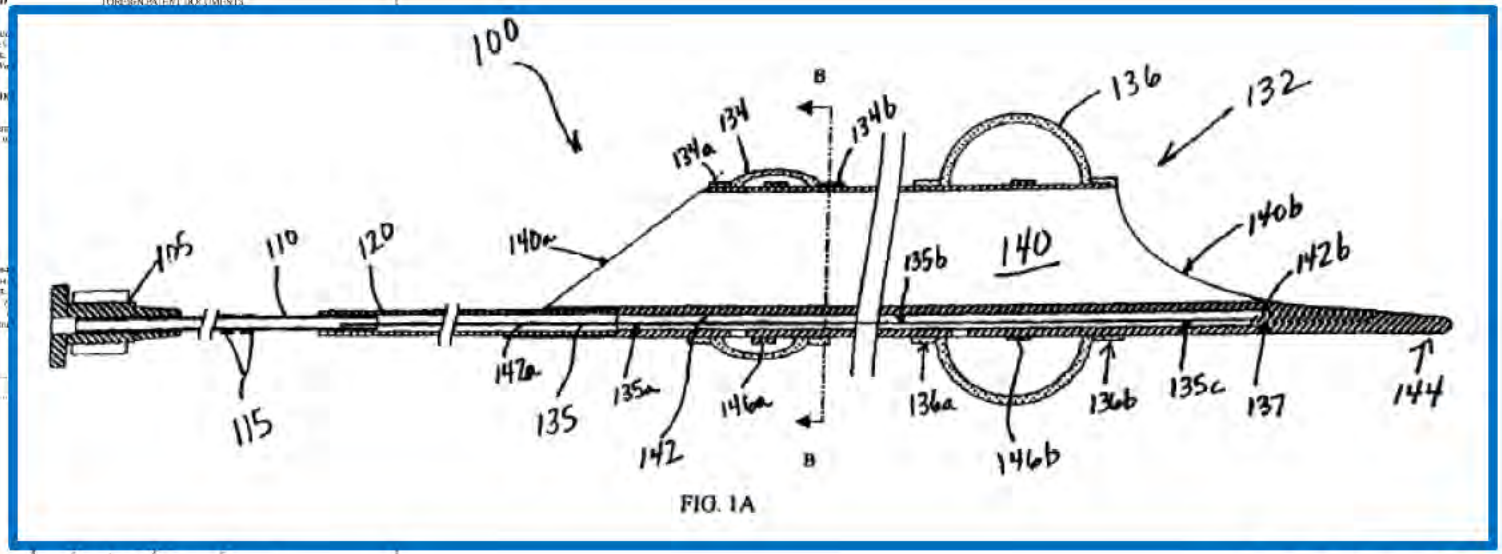


FIG. 1A

Ex-1408, Fig. 1A

IPR2020-01342, -01344: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize "Real Estate" Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

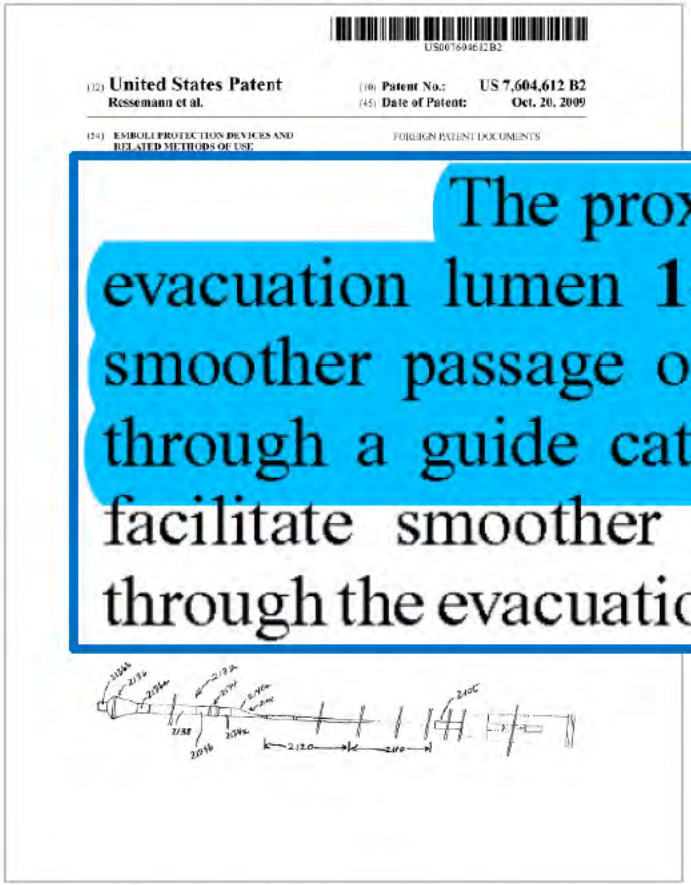
IPR2020-01342, -01344: Smooth Passage of Extension Catheter

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

217. Further, a POSITA would additionally have wanted to use a proximal side opening because such a design promotes "smoother passage" of the extension catheter as it is advanced through the guide catheter (i.e., navigates a patient's vasculature) from the side of insertion into the body to the occlusion site. Ex-1408, 6:52-57; Ex-1425, Abstract, [0034]. This is equally a concern when using a femoral or radial access point. Using an angled side opening can reduce the amount of force necessary to advance the catheter through tortuous vessels.

Ex-1405, ¶ 217 (-01342 IPR) (Brecker)

IPR2020-01342, -01344: Smooth Passage of Extension Catheter



US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

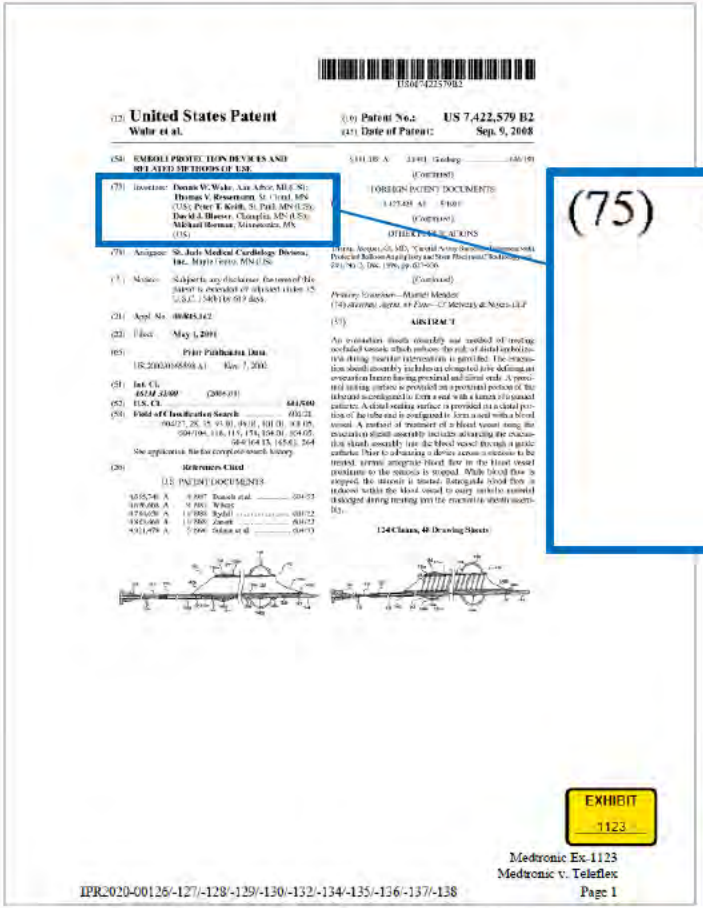
(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

FOREIGN PATENT DOCUMENTS

The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

Ex-1408, 6:52-57 (Ressemann)

IPR2020-01342, -01344: Smooth Passage of Extension Catheter



US007422579B2

(12) **United States Patent**
Wahr et al.

(10) Patent No.: US 7,422,579 B2
(45) Date of Patent: Sep. 9, 2008

(54) EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE

(75) Inventors: Dennis W. Wahr, Ann Arbor, MI (US); Thomas V. Ressemann, St. Cloud, MN (US); Peter T. Keith, St. Paul, MN (US); David J. Blaeser, Champlin, MN (US); Michael Berman, Minnetonka, MN (US)

(73) Assignee: St. Jude Medical Cardiology Divisi..., Inc., Maple Grove, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 869 days.

(21) Appl. No.: 10/845,342

(22) Filed: May 1, 2004

(65) Prior Publication Data

US 2005/0245968 A1 Nov. 3, 2005

(51) Int. Cl.
A61M 31/00 (2006.01)

(52) U.S. Cl. 604/500

(58) Field of Classification Search 606/127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200; 604/264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364 (13, 165-6), 364

See application file for complete search history.

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(Continued)

Primary Examiner—Mariam Meister
(74) Attorney, Agent, or Firm—O'Melveny & Myers LLP

(57) **ABSTRACT**

An embolism shield assembly and method of treating occluded vessels which reduces the risk of distal embolization during vascular intervention is provided. The embolism shield assembly includes an elongated wire defining an expansion frame having proximal and distal ends. A proximal sealing surface is provided on a proximal portion of the frame and configured to form a seal with a lumen of a vessel catheter. A distal sealing surface is provided on a distal portion of the frame and is configured to form a seal with a blood vessel. A method of treatment of a blood vessel using the embolism shield assembly includes advancing the embolism shield assembly into the blood vessel through a guide catheter. Prior to advancing a device across a stenosis to be treated, normal antegrade blood flow in the blood vessel proximate to the stenosis is stopped. While blood flow is stopped, the stenosis is treated. Retrograde blood flow is induced within the blood vessel to carry embolic material dislodged during treating into the expansion shield assembly.

124 Claims, 40 Drawing Sheets

EXHIBIT
1123

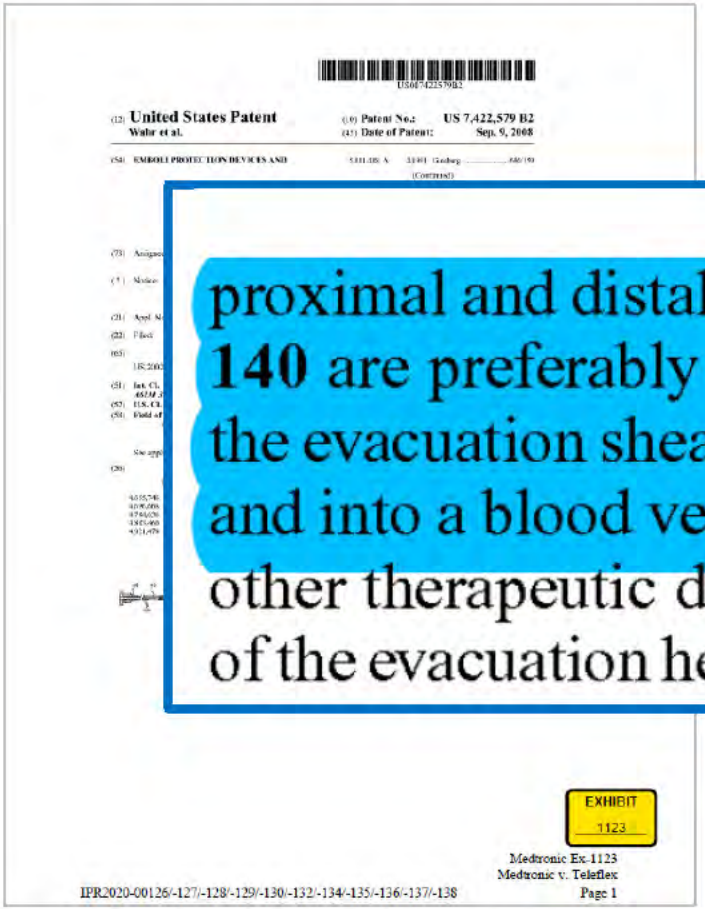
Medtronic Ex-1123
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

(75) Inventors: **Dennis W. Wahr**, Ann Arbor, MI (US); **Thomas V. Ressemann**, St. Cloud, MN (US); **Peter T. Keith**, St. Paul, MN (US); **David J. Blaeser**, Champlin, MN (US); **Michael Berman**, Minnetonka, MN (US)

Ex-1123 (Keith)

IPR2020-01342, -01344: Smooth Passage of Extension Catheter



(12) **United States Patent**
Wahr et al.

(10) Patent No.: US 7,422,579 B2
(45) Date of Patent: Sep. 9, 2008

(54) EMBOLI PROTECTION DEVICES AND

EXHIBIT
1123

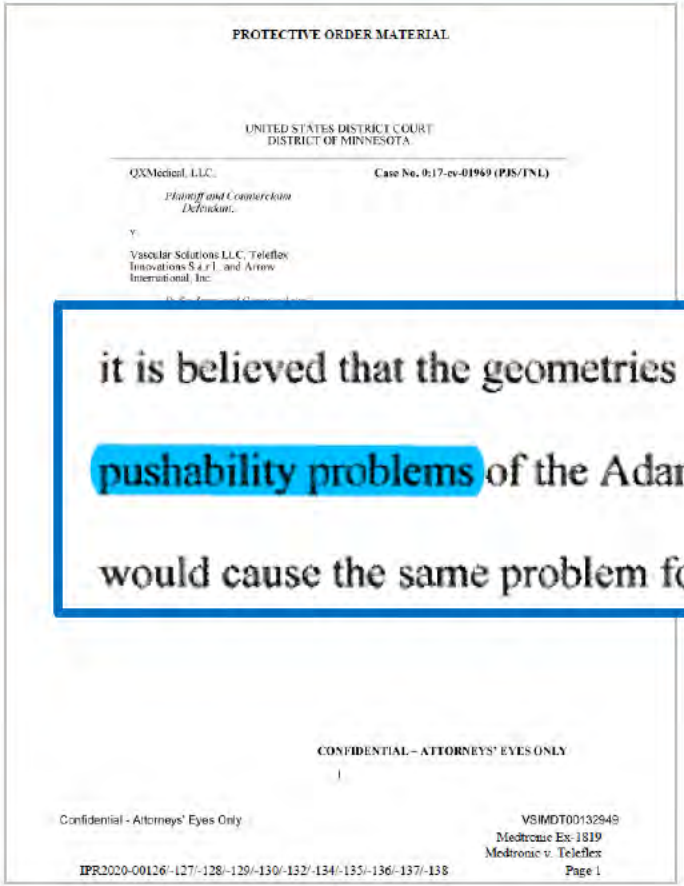
Medtronic Ex. 1123
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

Ex-1123, 7:54-60 (Keith)

IPR2020-01342, -01344: Smooth Passage of Extension Catheter



PROTECTIVE ORDER MATERIAL

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMedical, LLC,

Plaintiff and Counterclaim Defendant,

v.

Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc.

Case No. 0:17-cv-01969 (PJS/TNL)

it is believed that the geometries of the funnel and balloon embodiments contribute to the pushability problems of the Adams device, discussed above, and that the same configuration would cause the same problem for the Crittenden and Kontos devices.

CONFIDENTIAL – ATTORNEYS' EYES ONLY

Confidential - Attorneys' Eyes Only

VSIMDT00132849

Medtronic Ex. 1819
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

Page 1

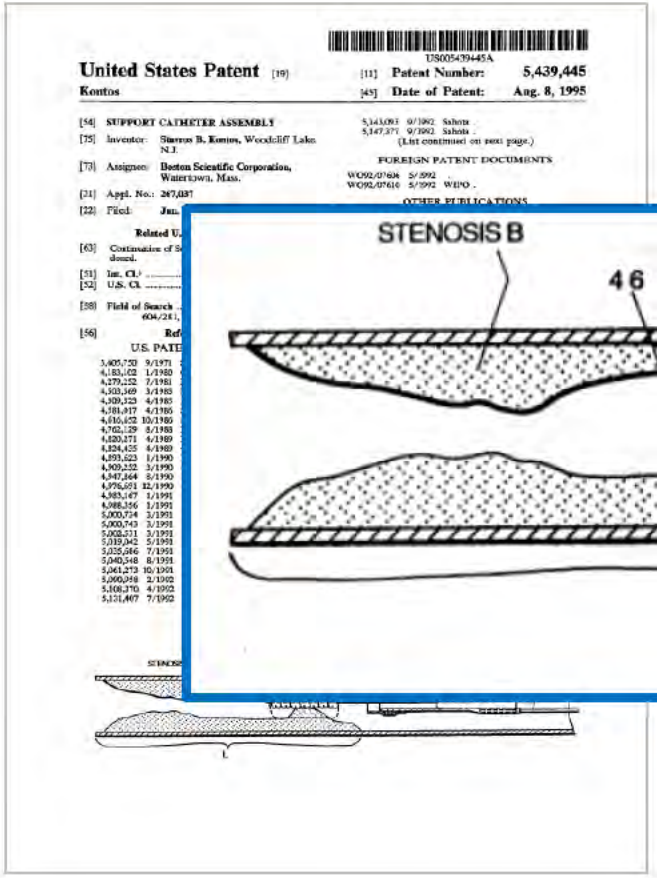
Ex-1819, ¶ 113 (Keith)

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01342, -01344: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize "Real Estate" Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

IPR2020-01342, -01344: Retrieval of Extension Catheter



United States Patent [19]
Kontos

[11] Patent Number: 5,439,445
[45] Date of Patent: Aug. 8, 1995

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun.

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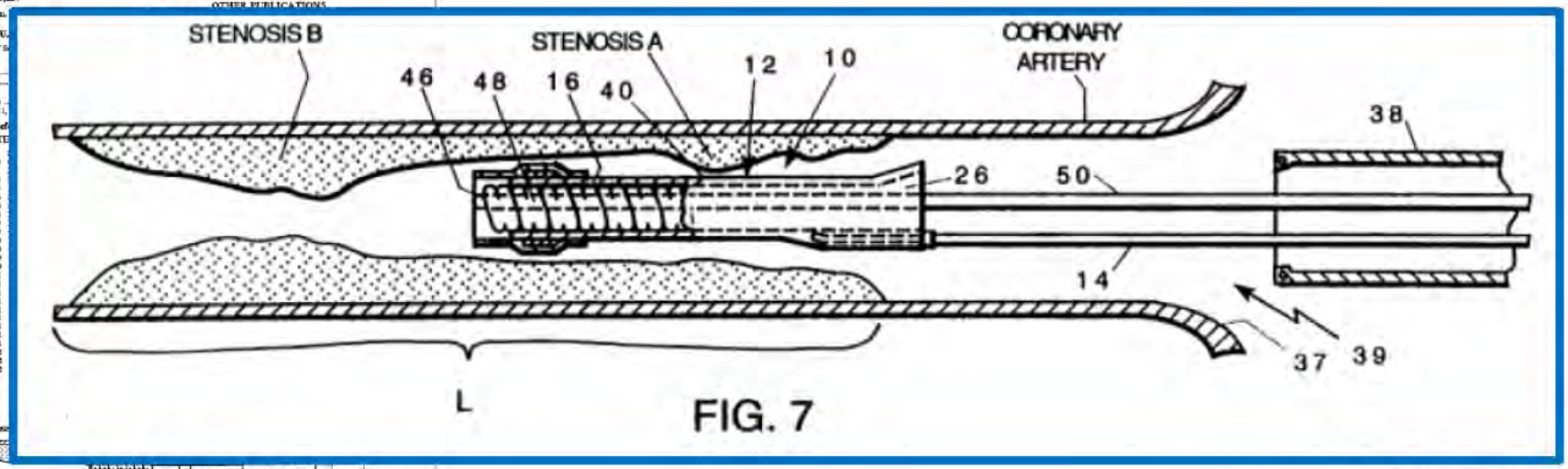


FIG. 7

Ex-1409, Fig. 7

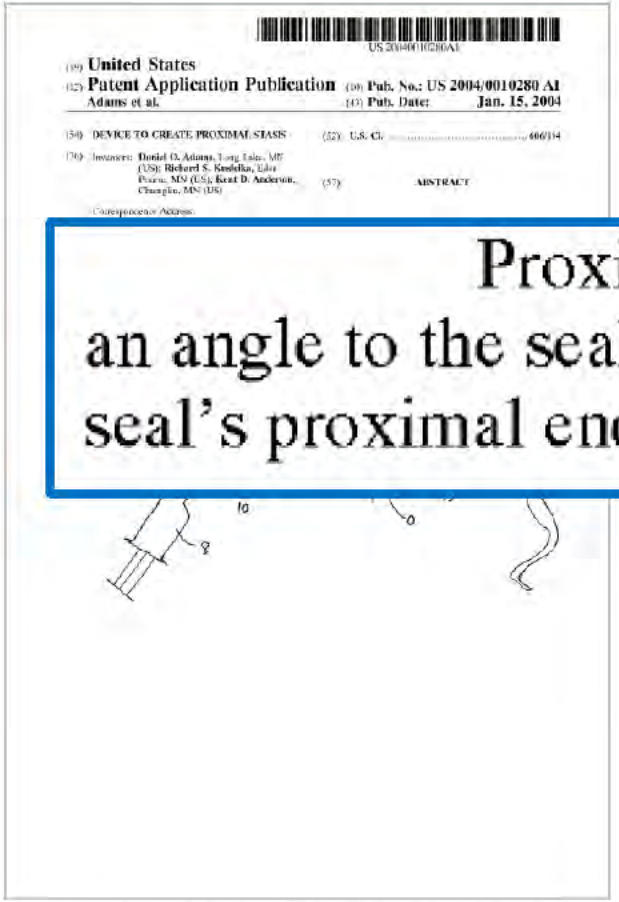
IPR2020-01342, -01344: Retrieval of Extension Catheter

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

219. In this embodiment, after the procedure, the support assembly 10 must return to the guide catheter 38. A POSITA would appreciate that the flared proximal opening of the tubular structure (body 12) was a poor design choice. This protrusion could damage the internal coronary wall (intimal lining) and hinder re-entry of the tubular structure into the guide catheter as the tubular structure travels proximally toward the guide catheter. The smaller cross-sectional diameter of an angled proximal opening would likely reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the guide catheter.

Ex-1405, ¶ 219 (Brecker)

IPR2020-01342, -01344: Retrieval of Extension Catheter



(19) **United States**
(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0010280 A1**
Adams et al. (43) **Pub. Date: Jan. 15, 2004**

(54) **DEVICE TO CREATE PROXIMAL STASIS** (52) **U.S. Cl.** 606/194

(76) Inventors: **Daniel O. Adams**, Long Lake, MN (US); **Richard S. Kusleika**, Eden Prairie, MN (US); **Kent D. Anderson**, Champlin, MN (US)

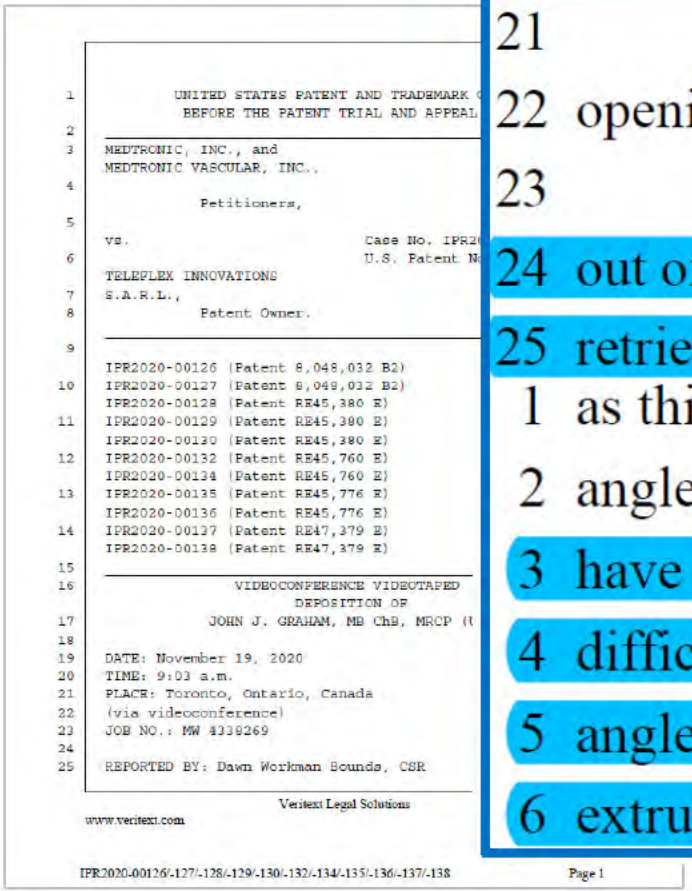
(57) **ABSTRACT**

Correspondence Address:

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.

Ex-1435, [0066]

IPR2020-01342, -01344: Retrieval of Extension Catheter



UNITED STATES PATENT AND TRADEMARK
BEFORE THE PATENT TRIAL AND APPEAL

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR
U.S. Patent N

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4339269

REPORTED BY: Dawn Workman Bounds, CSR

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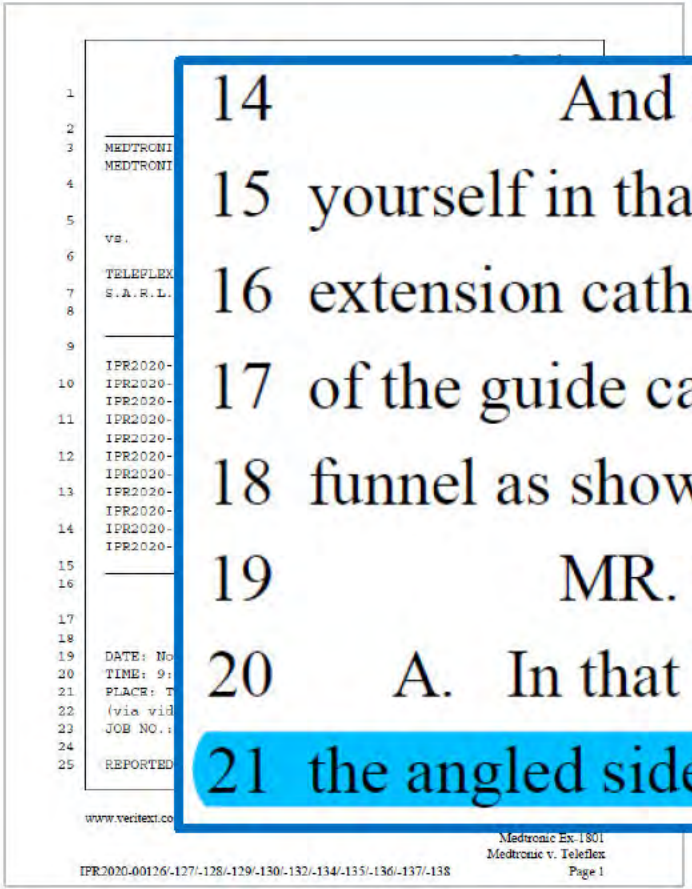
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

21 Your question is, would an angled side
22 opening be more easy to retrieve into the guide.
23 I have extruded angled guide extensions
24 out of a guide catheter, and I have been able to safely
25 retrieve them. But I have never extruded such a device
1 as this. So your question is, would it be easier for the
2 angled one? I have retrieved angled ones, yes; but I
3 have never used such a catheter. So it's going to be
4 difficult for me to say definitively, but I do know that
5 angled proximal catheters like the GuideLiner I have
6 extruded and have retrieved.

Ex-1801, 72:21-73:6 (Graham)

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01342, -01344: Retrieval of Extension Catheter



And so my question is if you found yourself in that situation, where the proximal end of the extension catheter was distal to the distal-most portion of the guide catheter, would you prefer to have the funnel as shown in Kontos or a proximal side opening?

MR. KOHLHEPP: Objection, form.

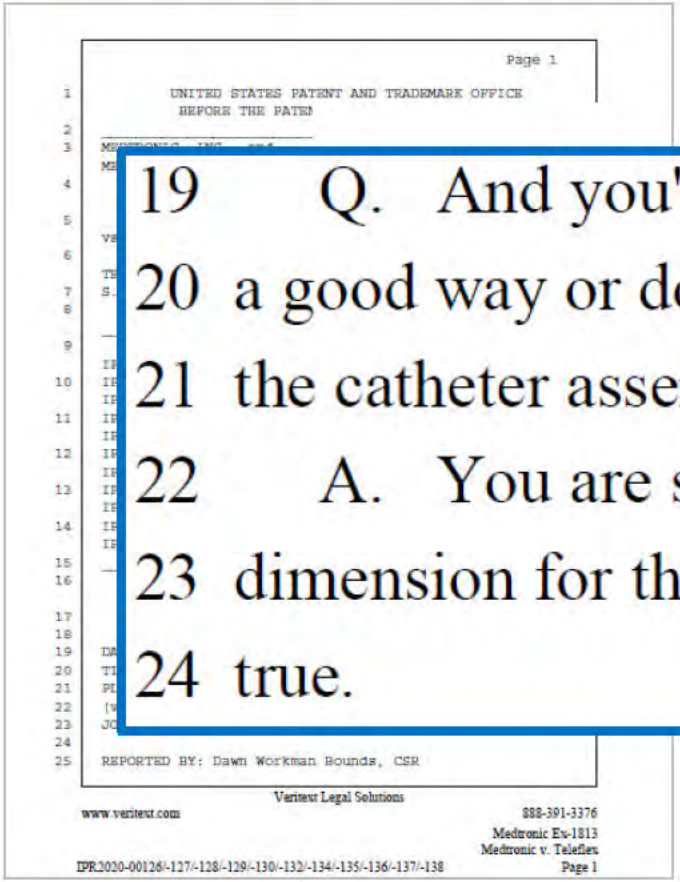
A. In that hypothetical situation, I would prefer the angled side opening.

Ex-1801, 79:14-21 (Graham)

IPR2020-01342 & IPR2020-01344: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize “Real Estate” Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

IPR2020-01342, -01344: Side Opening


Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
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REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex-1813
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138
Page 1

19 Q. And you'd agree that that type of funnel is not
20 a good way or does not maximize the usable real estate in
21 the catheter assembly, right?
22 A. You are sacrificing some of your inner
23 dimension for that funnel; so yes, what you are saying is
24 true.

Ex-1813, 92:19-24 (Graham)

IPR2020-01342, -01344: Transition from 7 French to 6 French GC

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

212. In 1995, when Kontos issued, the guide catheter was typically 7-8 French in diameter. *See* ¶ 46, *supra*. By 2006, a 6 French guide catheter had become more common. *Id*. These smaller guide catheters had several advantages: (i) permitted radial access of the catheter assembly[13] and (ii) reduced the size of the access point, regardless of whether femoral or radial access is used. But as the diameter of a guide catheter decreases, that also means that the diameter of the extension catheter must decrease. Because of this, the proximal opening 20 of the tubular structure 12 must decrease. *See* Ex-1409, Fig. 6B.

IPR2020-01342, -01344: Transition from 7 French to 6 French GC

DECLARATION OF STEPHEN JON DAVID BRECKER,
MD, FRCP, FESC, FACC

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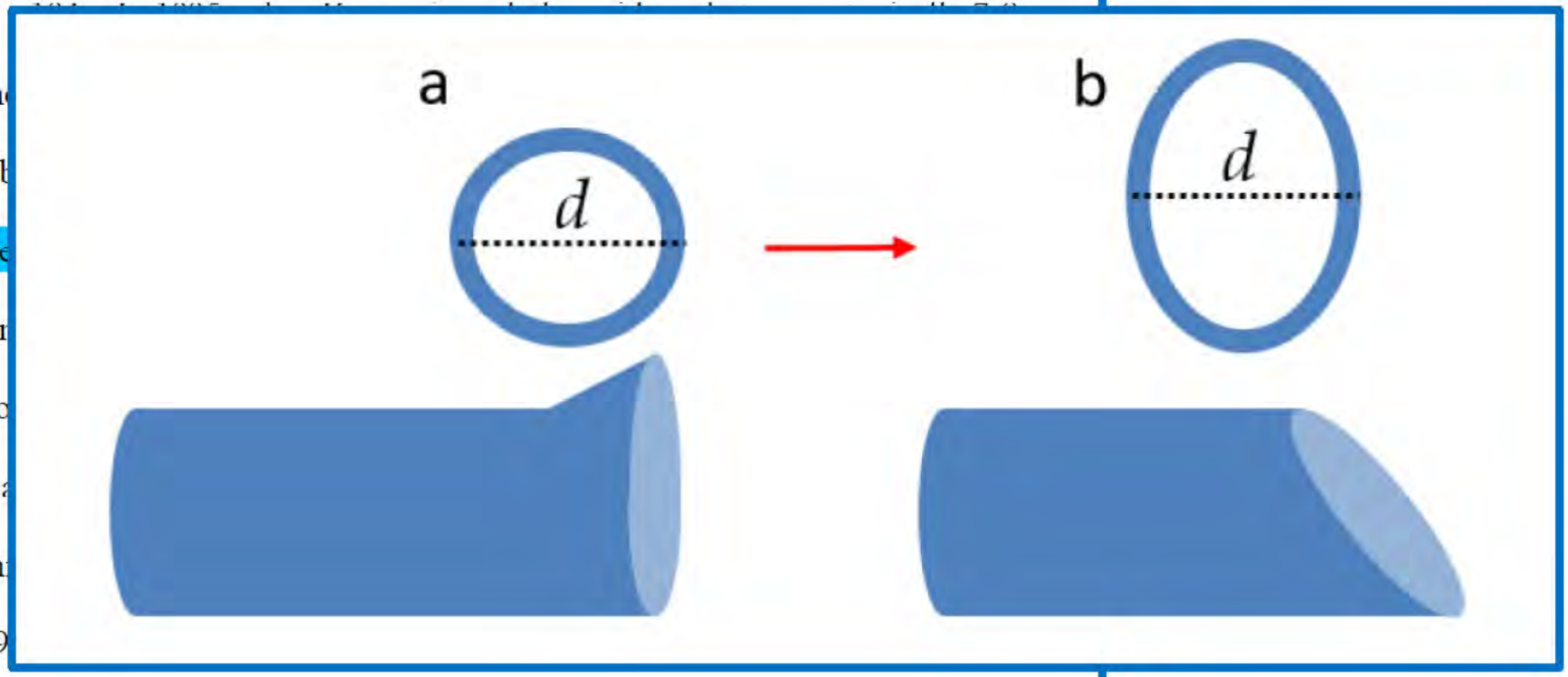


IPR2020-01342, -01344: Teleflex Argues Kontos Already Used in 6 French GC

DECLARATION OF PETER T. KEITH

253. In my opinion, a POSITA would not have been motivated to reduce the outer diameter of Kontos's device because I believe that the Kontos device as disclosed would already have been expected to fit inside a 6 French guide catheter.

Ex-2138, ¶ 253 (-01342 IPR) (Keith)

IPR2020-01342, -01344: Funnel Height is 0.005 Inches in 6 French GC

DECLARATION OF MICHAEL JONES SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

If Kontos is deployed in, for example, a 6 French guide catheter[4] with in inner diameter of 0.070 inches[5], the maximum the outer diameter of the funnel's apex can be is 0.070 inches. This means the maximum height that the funnel adds to catheter 10's outer diameter is 0.005 inches. This is schematically represented in the figure below.

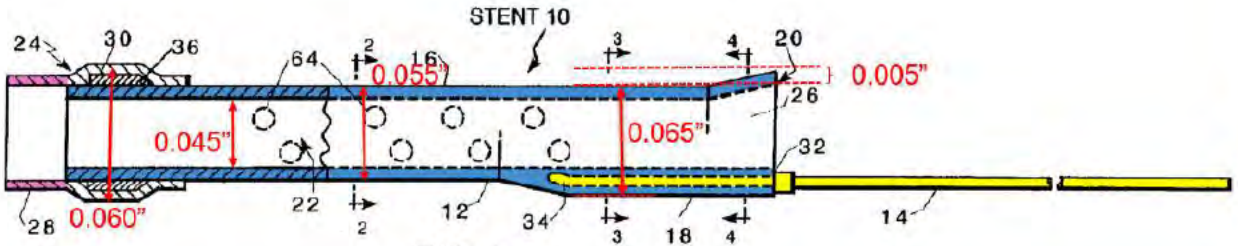


FIG. 1

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Ex-1807, ¶ 120 (Jones)

IPR2020-01342, -01344: No Funnel Function in 6 French GC

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

121. A funnel with only a maximum inclination of 0.005 inches over a longitudinal distance of 0.1 inches provides a less than 3-degree angle of inclination. Such a small angle would provide minimal funneling function.

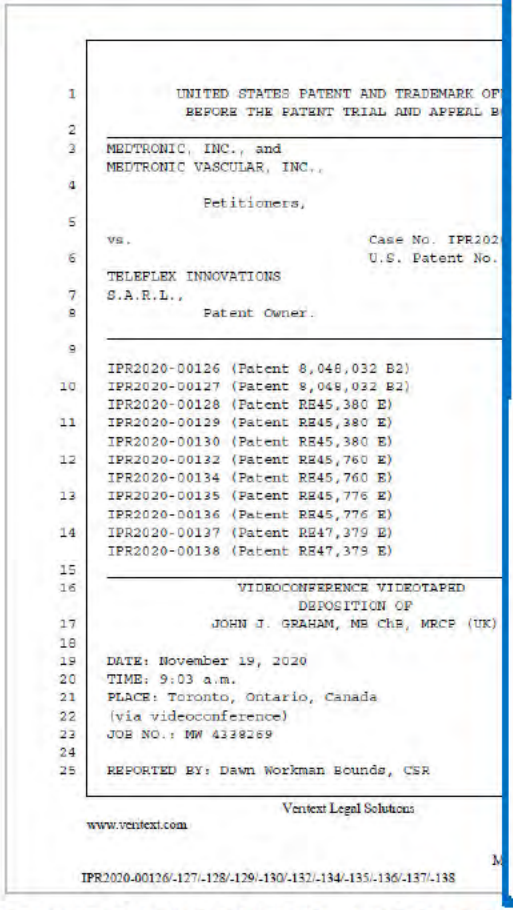
Ex-1807, ¶ 121 (Jones)

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

Any actual funneling function would be outwieghed by the potential danger of advancing a catheter assembly that "rubbed" against the guide catheter during passage from the hemostatic valve to a location distal the distal-most portion of the guide catheter.

Ex-1806, ¶ 116 (Brecker)

IPR2020-01342, -01344: Graham "would not expect it to go" in 6 French GC



UNITED STATES PATENT AND TRADEMARK OF
BEFORE THE PATENT TRIAL AND APPEAL B

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR202
U.S. Patent No.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

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JOHN J. GRAHAM, MB ChB, MRCP (UK)

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REPORTED BY: Dawn Workman Bounds, CSR

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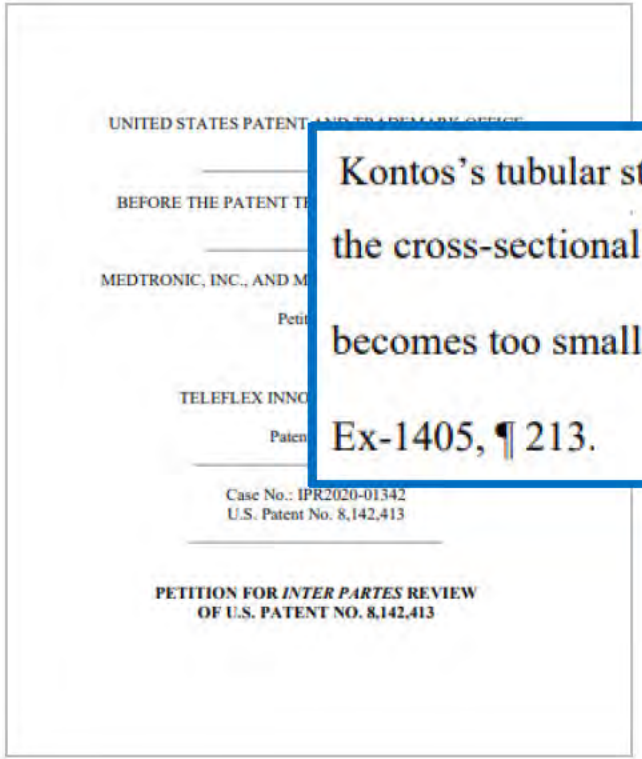
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

20 If the outer diameter of Kontos' funnel at
21 the proximal end was 0.070 inches, that would at least --
22 or that would hinder the ability to facilitate smooth
23 passage of the catheter through the guide catheter?
24 A. I would expect it to be a not easy insertion.
25 It depends on the deformability of it.
1 You may be able to compress it down and
2 crimp it down on get in that way. But you -- for your
3 argument, .07 inside .07 doesn't -- doesn't equate. I
4 would not expect it to go or go easily.
5 Q. And smooth passage is something that you prefer
6 to have if possible as an interventional cardiologist?
7 A. Agreed, yes.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Ex-1801, 116:20-117:7 (Graham)

IPR2020-01342, -01344: Small Extension Catheter can Hinder Entry of Therapy Catheter


UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TR

MEDTRONIC, INC., AND M

Petit

TELEFLEX INNO

Paten

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

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

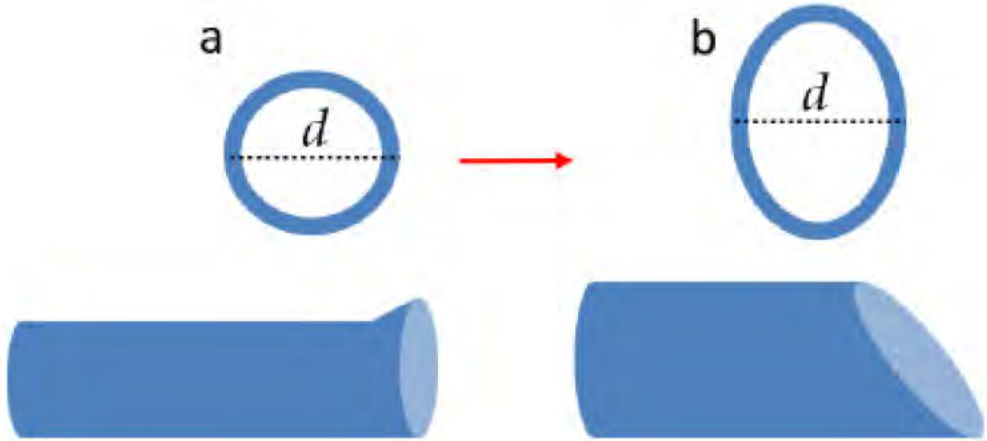
Kontos's tubular structure (tube 16) must decrease. *Id.*; Ex-1409, Fig. 6B. And if the cross-sectional diameter of the proximal opening of the tubular structure becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex-1405, ¶ 213.

Paper 1 at 56-57 (-01342 IPR)

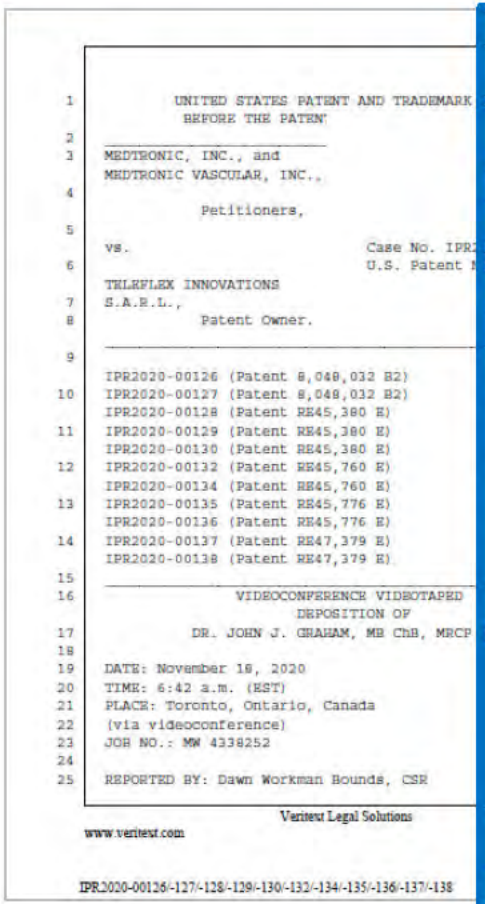
IPR2020-01342, -01344: Small Extension Catheter can Hinder Entry of Therapy Catheter

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

For example, as shown below, I have demonstrated how the cross-sectional inner diameter of the tubular structure must be reduced when using a funnel as opposed to a side opening.



IPR2020-01342, -01344: Motivation to Increase ID of Extension Catheter



UNITED STATES PATENT AND TRADEMARK
BEFORE THE PATEN

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR
U.S. Patent

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
DR. JOHN J. GRAHAM, MB ChB, MRCP

DATE: November 18, 2020
TIME: 6:42 a.m. (EST)
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338252

REPORTED BY: Dawn Workman Bounds, CSR

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www.veritext.com

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

18 Q. All right. So is another way to think about
19 that, that you want to try to have the largest possible
20 inner diameter of the extension catheter without having
21 to increase the outer diameter of the guide catheter?
22 A. Yes. You want to -- you want to maximize the
23 usable inner diameter without having to compromise with a
24 bigger outer diameter or catheter it goes in, yes.
25 Q. And that goal is similarly important in the
1 2005-2006 time frame as it is today?
2 A. Real estate is -- we are more aware of real
3 estate. The phrase hadn't really been described then.
4 It's used more often now, but the concept would have been
5 similar.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Ex-1813, 91:18-92:5 (Graham)

IPR2020-01342, -01344: Kontos's Diameter Greatest at Funnel

Schematic Based on Patent Owner Argument that Kontos Used with 6 French GC

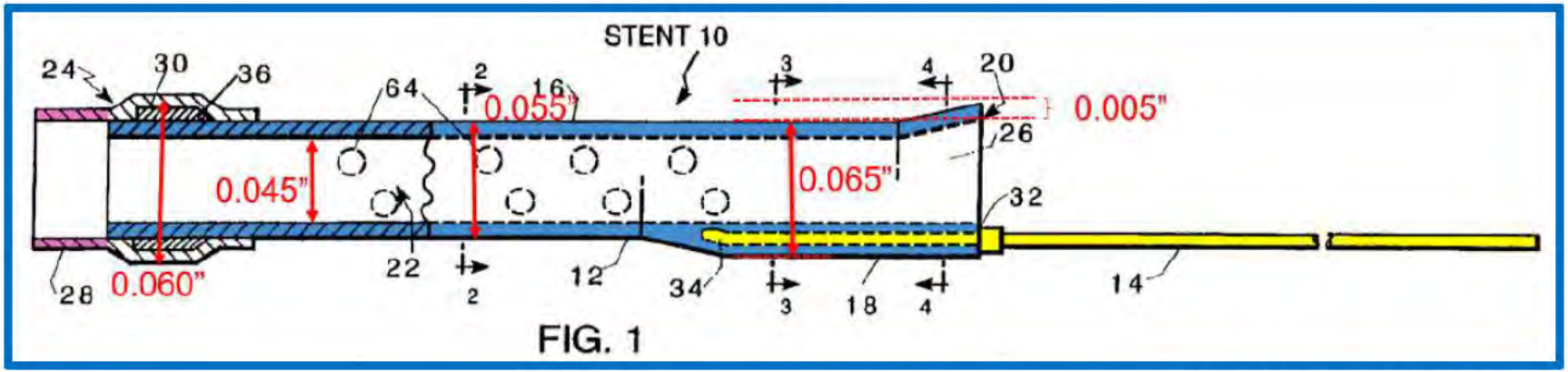


FIG. 1

Ex-1807, ¶ 120 (Jones)

IPR2020-01342, -01344: 7 French or 6 French GC

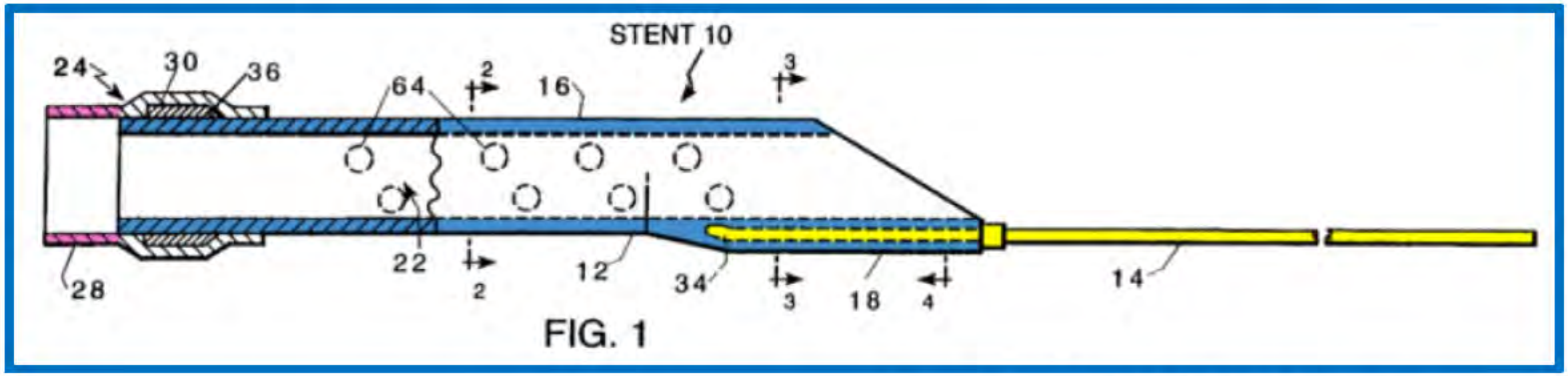


FIG. 1

Ex-1405, ¶ 193 (-01342 IPR) (Brecker)

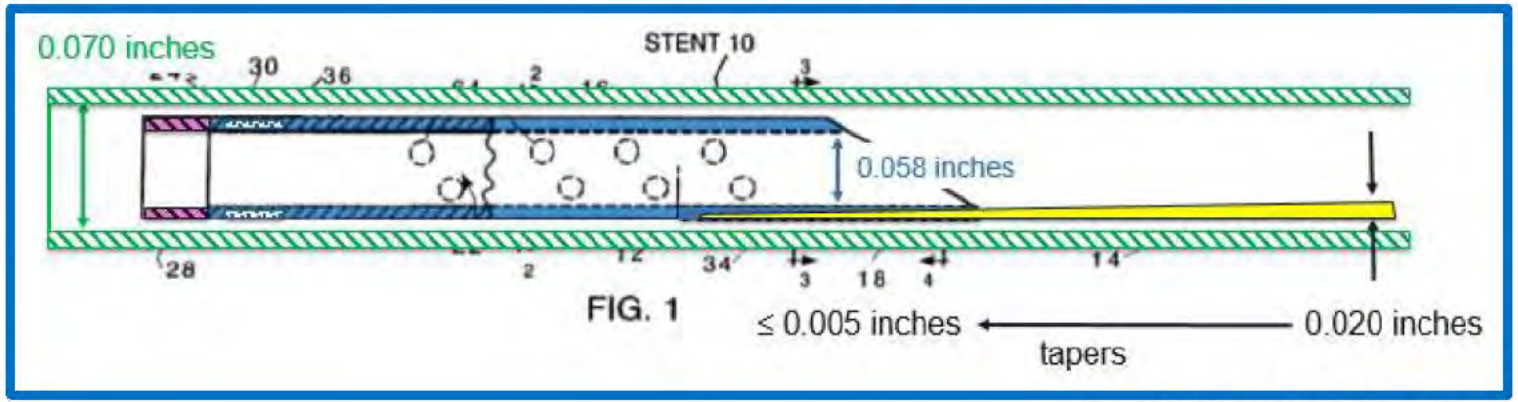
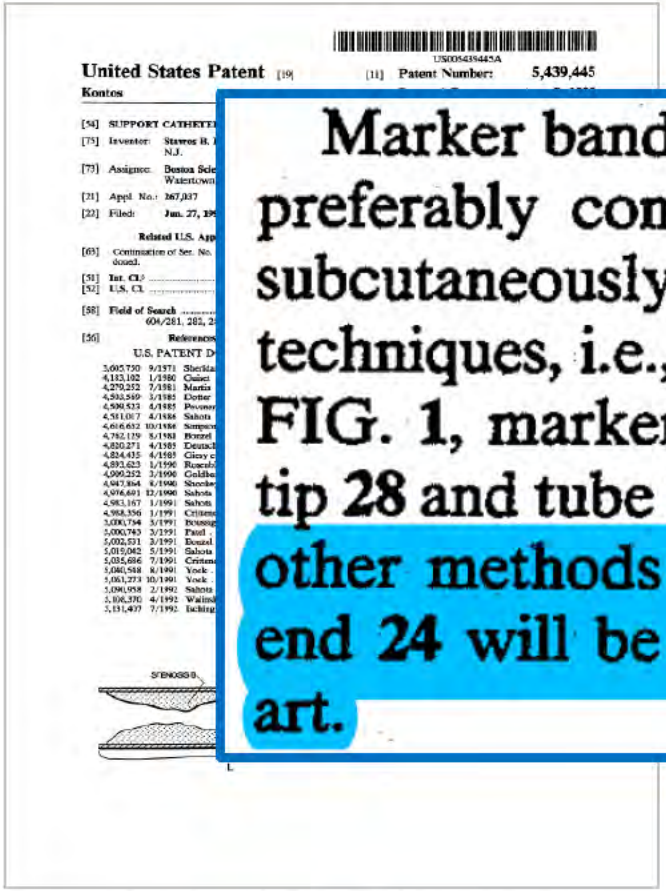


FIG. 1

Ex-1806, ¶ 128 (Brecker)

IPR2020-01342, -01344: Kontos's Marker Bands



United States Patent [19]

Kontos

[11] Patent Number: 5,439,445

[54] SUPPORT CATHETE

[75] Inventor: Stavros H. [illegible] N.J.

[73] Assignee: Boston Sci[illegible] Watertown

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 19[illegible]

Related U.S. App[illegible]

[63] Continuation of Ser. No. [illegible] doned.

[51] Int. Cl.[illegible]

[52] U.S. Cl.[illegible]

[58] Field of Search[illegible] 604/281, 282, 2[illegible]

[56] References

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5,131,407 7/1992 Itching

STENOSIS

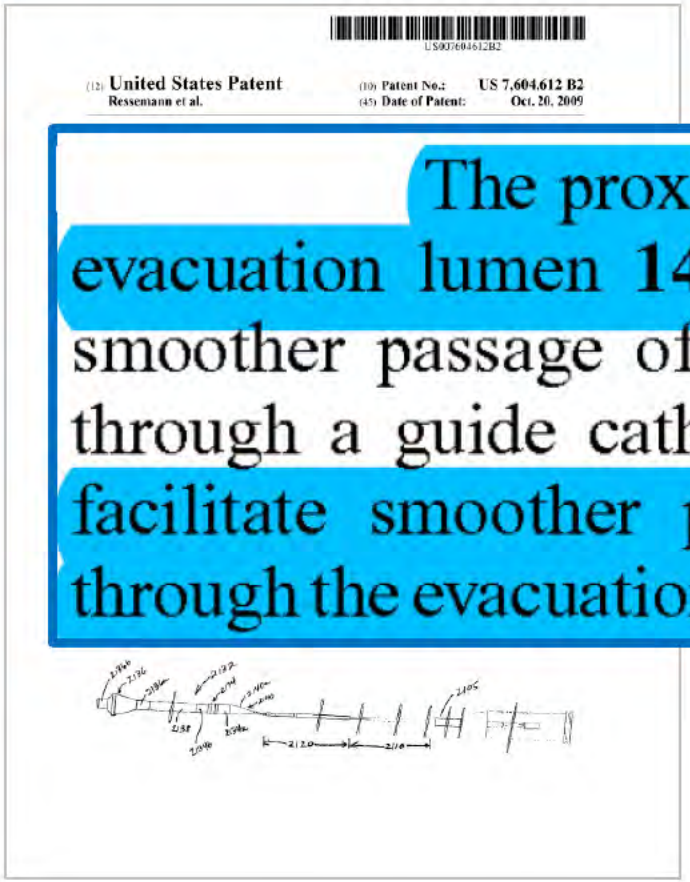
Marker band **30**, which is disposed at distal end **24**, is preferably composed of a material that is detectable subcutaneously through the use of X-ray or fluoroscopy techniques, i.e., it is preferably radiopaque. As shown in FIG. **1**, marker band **30** may be retained between soft tip **28** and tube **16** within recess **36**. Of course, numerous other methods for disposing marker band **30** at distal end **24** will be readily apparent to those skilled in the art.

Ex-1409, 4:16-24

IPR2020-01342 & IPR2020-01344: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize "Real Estate" Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

IPR2020-01342, -01344: Ressemann Teaches Smooth Receipt of IVCD



(12) **United States Patent**
Ressemann et al.

(10) Patent No.: US 7,604,612 B2
(45) Date of Patent: Oct. 20, 2009

The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

Ex-1408, 6:52-57 (Resseamnn)

IPR2020-01342, -01344: Keith Teaches Smooth Receipt of IVCD

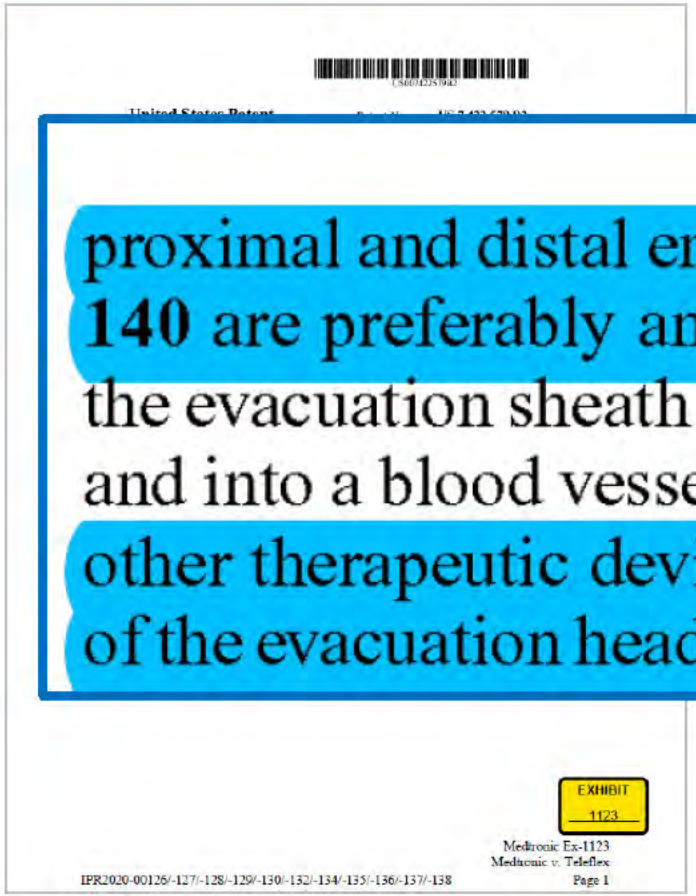


EXHIBIT
1123

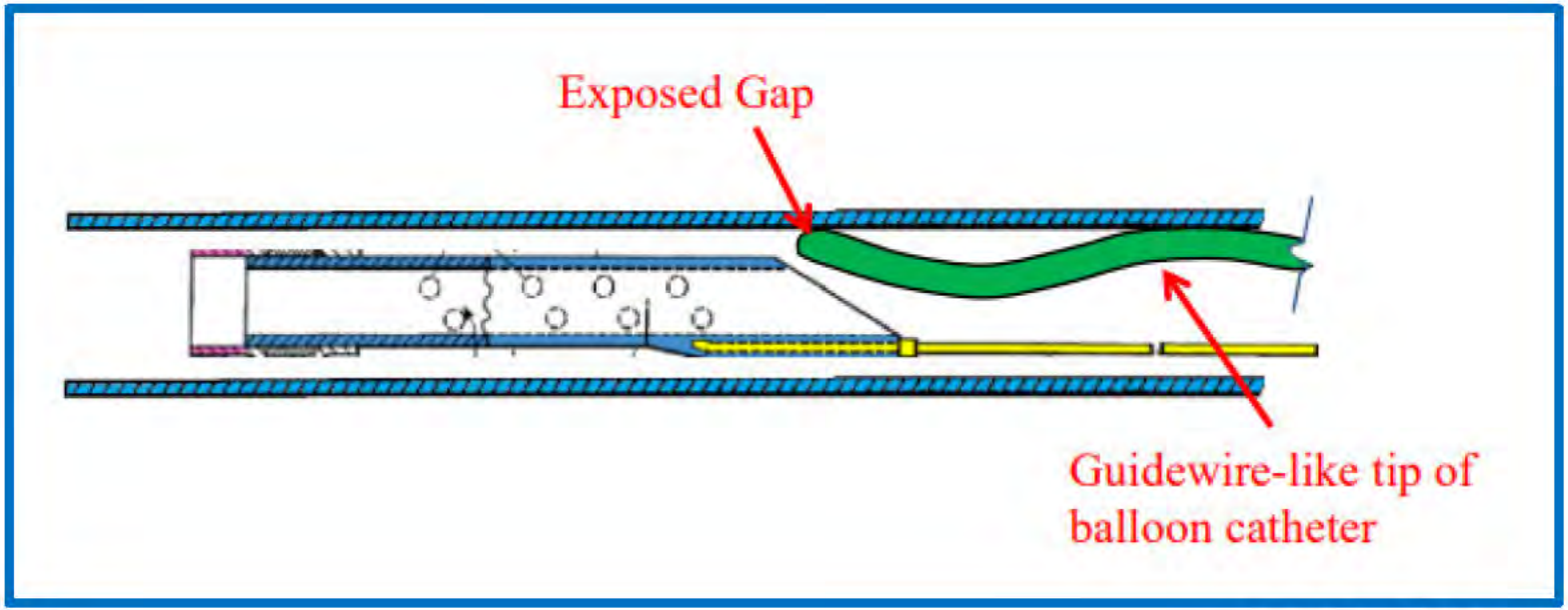
Medtronic Ex-1123
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

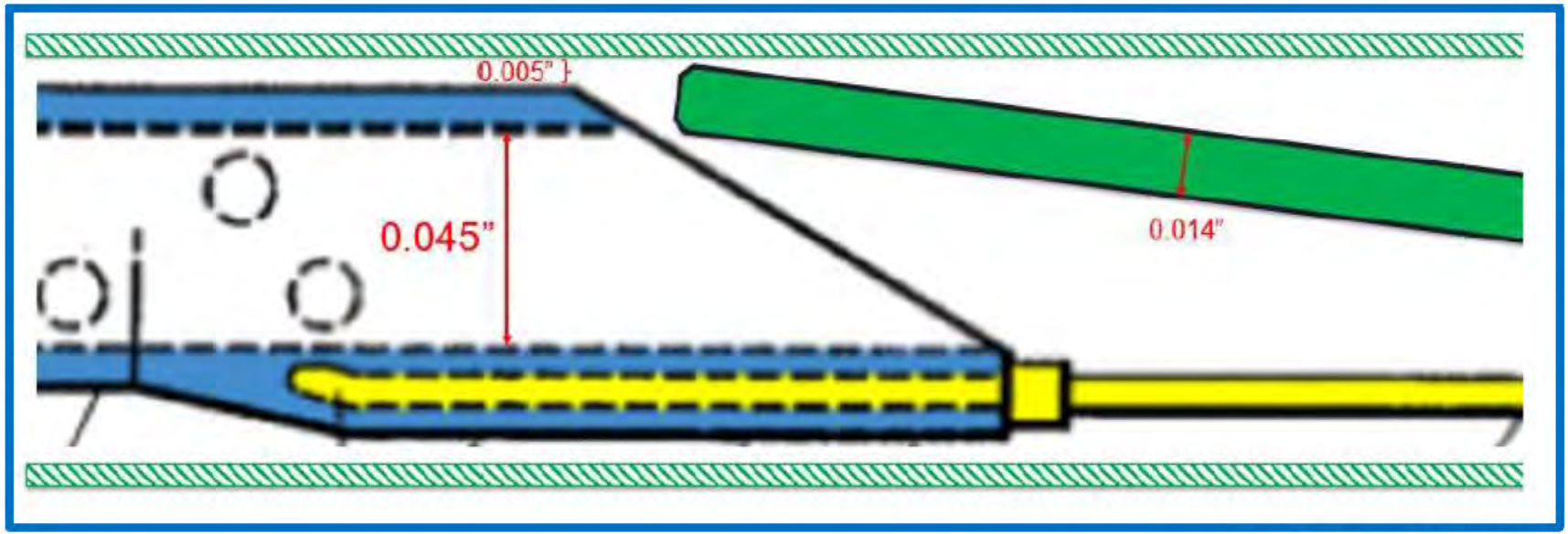
Ex-1123, 7:54-60 (Keith)

IPR2020-01342, -01344: Teleflex's Catch-Point Argument



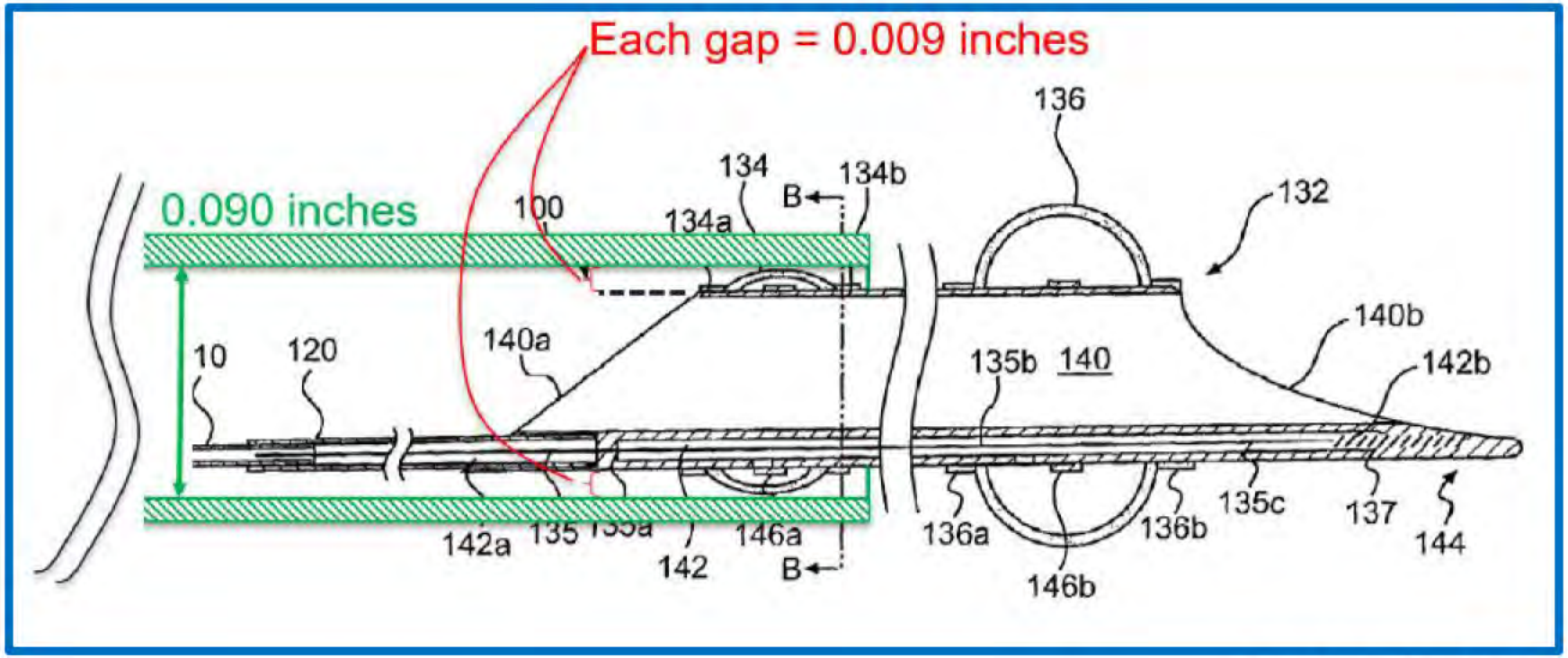
Ex-2145, ¶ 201 (Keith)

IPR2020-01342, -01344: Brecker Shows no Catch Point



Ex-1806, ¶ 122 (Brecker)

IPR2020-01342, -01344: Ressemann/Keith Gap is Larger



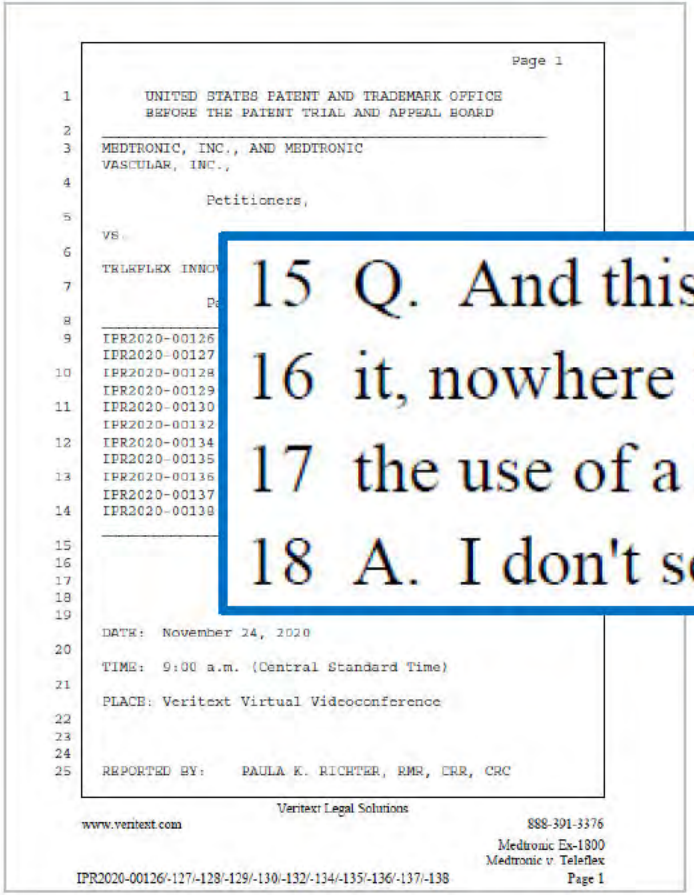
Ex-1806, ¶ 125 (Brecker)

IPR2020-01342, -01344: Brecker Testimony

Not only do Ressemann and Keith not suggest that the relationship between guide catheter and extension catheter will cause device hang-up, but both teach that their proximal opening will "facilitate smoother passage of the other therapeutic devices through the evacuation lumen 140 of the evacuation head 132." Ex-1008, 6:52-60; Ex-1123, 7:54-60. Because Ressemann and Keith's gap is nearly twice as big as the alleged problematic gap in Kontos, I do not believe that replacing Kontos's funnel with a side opening (and making no further modification) will cause device hang-up.

Ex-1806, ¶ 125 (Brecker)

IPR2020-01342, -01344: Keith Patent Has No Funnel/Bevel



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

VS.

TELEFLEX INNO

Pa

IPR2020-00126
IPR2020-00127
IPR2020-00128
IPR2020-00129
IPR2020-00130
IPR2020-00132
IPR2020-00134
IPR2020-00135
IPR2020-00136
IPR2020-00137
IPR2020-00138

DATE: November 24, 2020

TIME: 9:00 a.m. (Central Standard Time)

PLACE: Veritext Virtual Videoconference

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC

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www.veritext.com 888-391-3376

Medtronic Ex-1800
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

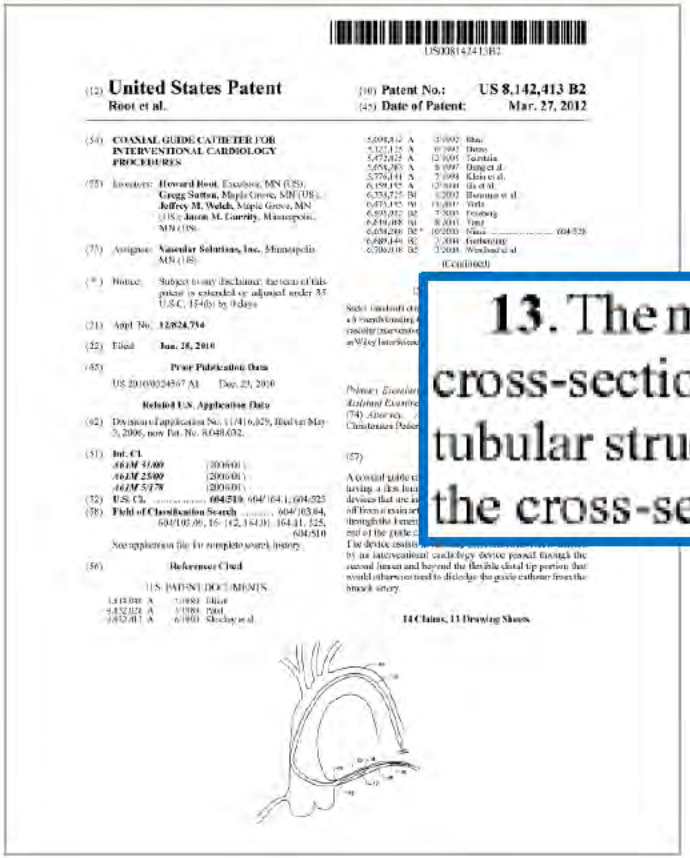
15 Q. And this patent where you have your name on
16 it, nowhere in this patent is there anything about
17 the use of a flare or a reverse bevel, correct?
18 A. I don't see it in any of the figures.

Ex-1800, 149:15-18 (Keith)

IPR2020-01342 & IPR2020-01344

1. Overview of Kontos
2. Kontos Teaches the "alongside" Limitation
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Issues Specific to -01344 IPR

IPR2020-01342, -01344: 1 French



(12) **United States Patent**
Root et al.

(10) Patent No.: US 8,142,413 B2
(45) Date of Patent: Mar. 27, 2012

(54) COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

(75) Inventors: Howard Root, Excelsior, MN (US); Gregg Sutton, Maple Grove, MN (US); Jeffrey M. Welch, Maple Grove, MN (US); Aaron M. Garrity, Minneapolis, MN (US)

(73) Assignee: Vascular Solutions, Inc., Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 12/824,754

(22) Filed: Jun. 28, 2010

(65) Prior Publication Data

US 2010/0324567 A1 Dec. 23, 2010

Related U.S. Application Data

(62) Division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) Int. Cl.
A61M 31/00 (2006.01)
A61M 25/00 (2006.01)
A61M 5/178 (2006.01)

(52) U.S. Cl. 604/510; 604/164.1; 604/525

(58) Field of Classification Search 604/103.04, 604/103.06, 16, 142,164.01, 164.11, 525, 604/510

See application file for complete search history.

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6,706,018 B2 3/2004 Westlund et al.

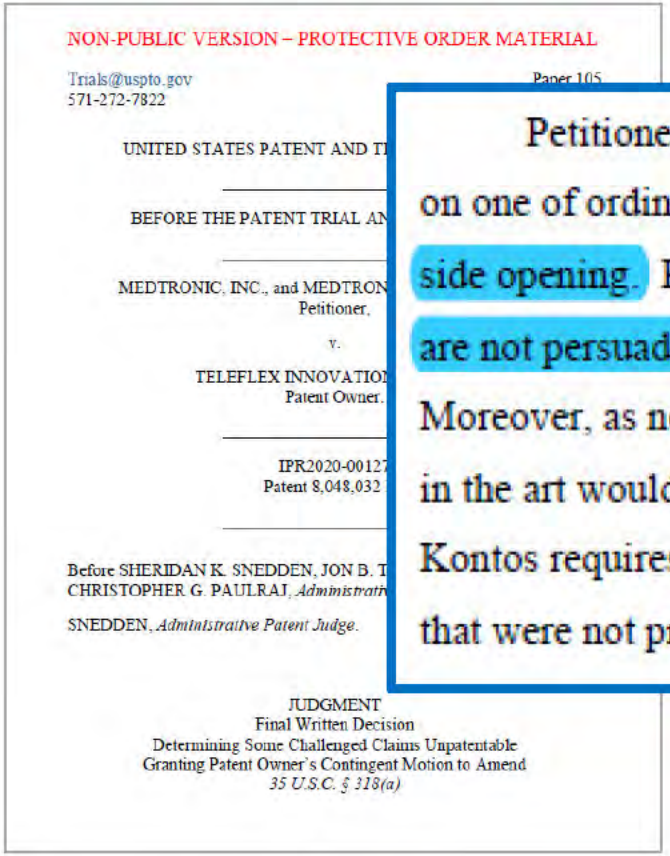
(Continued)

14 Claims, 11 Drawing Sheets

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.

Ex-1401, claim 13 ('413 patent)

IPR2020-01342, -01344: 1 French



NON-PUBLIC VERSION – PROTECTIVE ORDER MATERIAL

Trials@uspto.gov
571-272-7822

Paper 105

UNITED STATES PATENT AND T

BEFORE THE PATENT TRIAL AN

MEDTRONIC, INC., and MEDTRON
Petitioner,

v.

TELEFLEX INNOVATIO
Patent Owner.

IPR2020-0012
Patent 8,048,032

Before SHERIDAN K. SNEDDEN, JON B. T
CHRISTOPHER G. PAULRAJ, *Administrati*

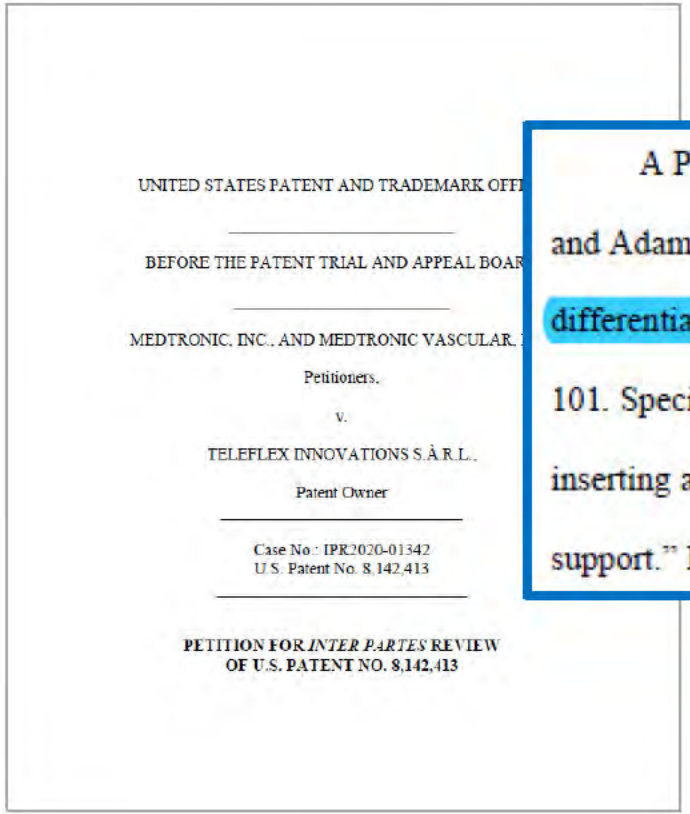
SNEDDEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
Granting Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

Petitioner's arguments with respect to claims 8 and 18 are premised on one of ordinary skill in the art removing Kontos's funnel in favor of a side opening. Pet. 71–72. As discussed above with respect to claim 3, we are not persuaded that this modification to Kontos would have been obvious. Moreover, as noted by Patent Owner, the argument that one of ordinary skill in the art would recess the marker bands and modify the pushrod structure of Kontos requires significant modifications of Kontos's device, modifications that were not proposed in the Petition. Sur-Reply 23–24; Pet. 71–72. The

FWD (Paper 105) at 51 (-01342)

IPR2020-01342, -01344: 1 French



UNITED STATES PATENT AND TRADEMARK OFFI

BEFORE THE PATENT TRIAL AND APPEAL BOAR

MEDTRONIC, INC., AND MEDTRONIC VASCULAR,

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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

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.

Petition (Paper 1) at 73 (-01342)

IPR2020-01342, -01344: Takahashi Teaches Improved Back-Up Support

Basic Science Review

New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter

Saeko Takahashi,[1*] MD, Shigeru Saito,[1] MD, Shinji Tanaka,[1] MD, Yusuke Miyashita,[1] MD, Takaaki Shiono,[1] MD, Fumio Arai,[1] MD, Hiroshi Domae,[1] MD, Shutaro Satake,[1] MD, and Takenari Itoh,[2] PhD

A 6 Fr guiding catheter is commonly used in the percutaneous coronary intervention (PCI). However, one of the limitations of the 6 Fr guiding catheter is its weak backup support compared to a 7 or an 8 Fr guiding catheter. In this article, we present a new system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv* 2004;63:452–456. © 2004 Wiley-Liss, Inc.

Key words: five-in-six system; backup support; 6 Fr guiding catheter; chronic total occlusion

INTRODUCTION

Currently, a 6 Fr guiding catheter is commonly used in percutaneous coronary intervention (PCI), since its use can decrease access site complication, enable early ambulation, and reduce the consumption of the contrast dye [1–4]. Major limitations of a 6 Fr guiding catheter are the inner lumen is not big enough to accommodate bulky atherectomy devices, and its backup support is not strong compared to a 7 or an 8 Fr catheter. In this report, we demonstrate a new technique for PCI called the five-in-six system, which increases a backup support of a 6 Fr guiding catheter.

MATERIALS AND METHODS

The Five-in-Six System

The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).

This 5 Fr Heartrail straight guiding catheter is 120 cm in length, whereas the 6 Fr guiding catheter is 100 cm. The 5 Fr Heartrail catheter has a very soft 13 cm end portion. This soft end portion can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery. The inner lumen of the 5 Fr Heartrail catheter is 0.059″ in diameter; it can accept normal balloons or stent delivery systems less than 4.0 mm in diameter. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071″ in diameter to accommodate the 5 Fr Heartrail catheter; Launcher (Medtronic), Heartrail, and Radiguide (Terumo) guiding catheters can meet this inner lumen diameter.

In Vitro Experiments

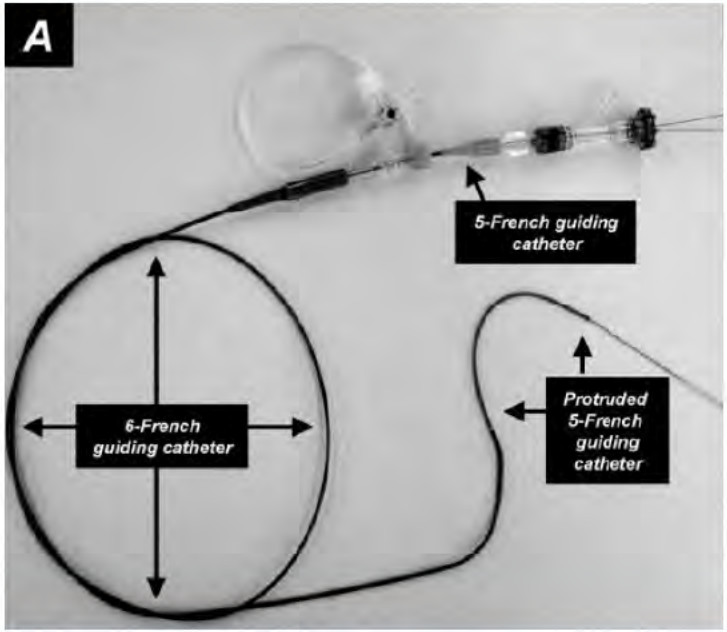
We measured the backup support of this five-in-six system in vitro using an experimental system. The artery model had three curves simulating tortuous coronary arteries. It was filled with water that was kept at 37°C (Fig. 1B). A guiding catheter was engaged into the ostium of the artery model. Then a rapid-exchange balloon catheter (Ryujin 2.5 × 20 mm; Terumo) was pushed into

[1]Division of Cardiolog… Center of Shonan Kam… Japan [2]Research and … tory, Terumo Corporat…

*Correspondence to: Dr. … Catheterization Laborato… onal Hospital, 1202-1 Y… E-mail: saekot@wa2.so…

Received 8 October 200…

DOI 10.1002/ccd.20223 Published online in Wiley InterScience (www.interscience.wiley.com)

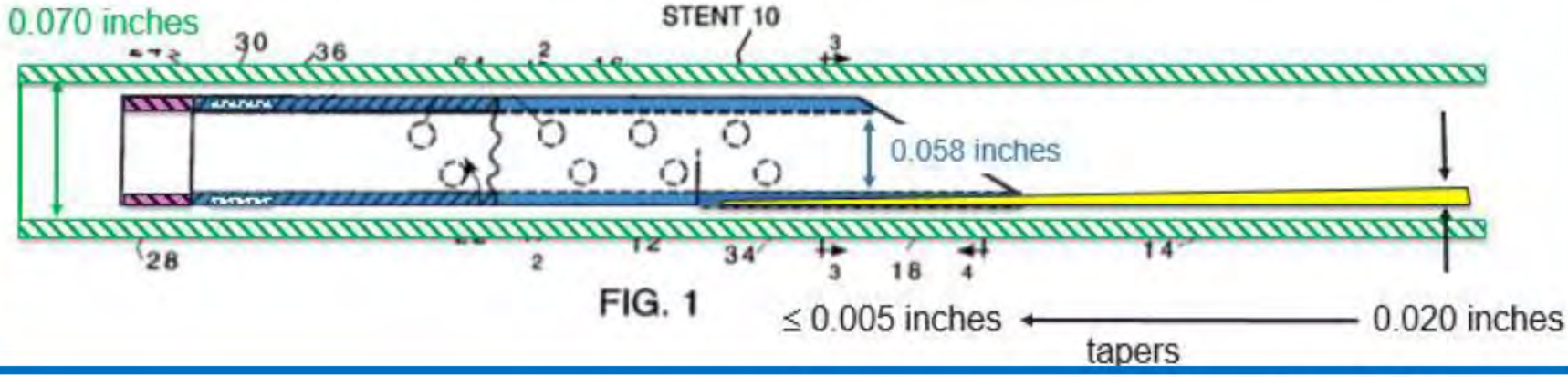


system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

IPR2020-01342, Ex-1410

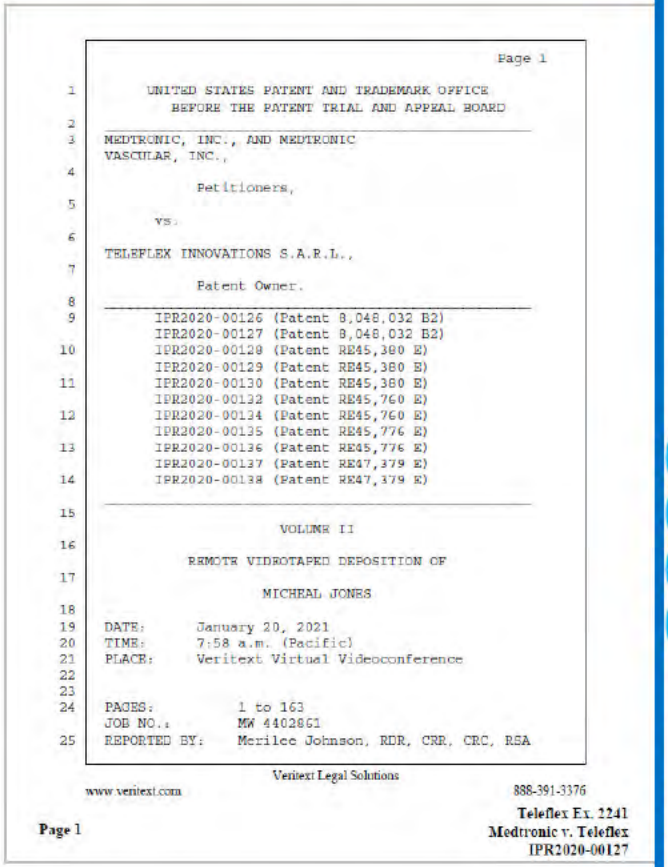
DECLARATION OF MICHAEL JONES SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

133. Making these straightforward modifications results in a configuration schematically represented below.



Ex-1807, ¶ 133 (Jones)

IPR2020-01342, -01344: Jones Testimony



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
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Petitioners,

vs.

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Patent Owner.

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IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VOLUME II

REMOTE VIDEOTAPED DEPOSITION OF

MICHEAL JONES

DATE: January 20, 2021
TIME: 7:58 a.m. (Pacific)
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PAGES: 1 to 163
JOB NO.: MW 4402861
REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA

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Page 1

Teleflex Ex. 2241
Medtronic v. Teleflex
IPR2020-00127

6 Q. Okay. And you don't see any
7 inconsistencies by saying that one of ordinary
8 skill in the art would pound Kontos's wire flat,
9 even though with respect to another piece of prior
10 art, you criticized that prior art because that
11 prior art pounds the wire flat.
12 A. Yeah. Because the -- again, I stand by
13 that statement. The difference in producing a flat
14 spot in a very short distance, as shown in Itou,
15 and the difference between creating a flat
16 cross-section in -- as shown in the Figure 179 is
17 rather substantial.
18 There's a whole lot less work -- or
19 work-hardening in the relatively large size that's
20 been flattened versus the very end that's
21 flattened.

Ex-2241, 133:6-21 (Jones)

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

IPR2020-01342 & IPR2020-01344

1. Overview of Kontos
2. Kontos Teaches the "alongside" Limitation
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Issues Specific to -01344 IPR

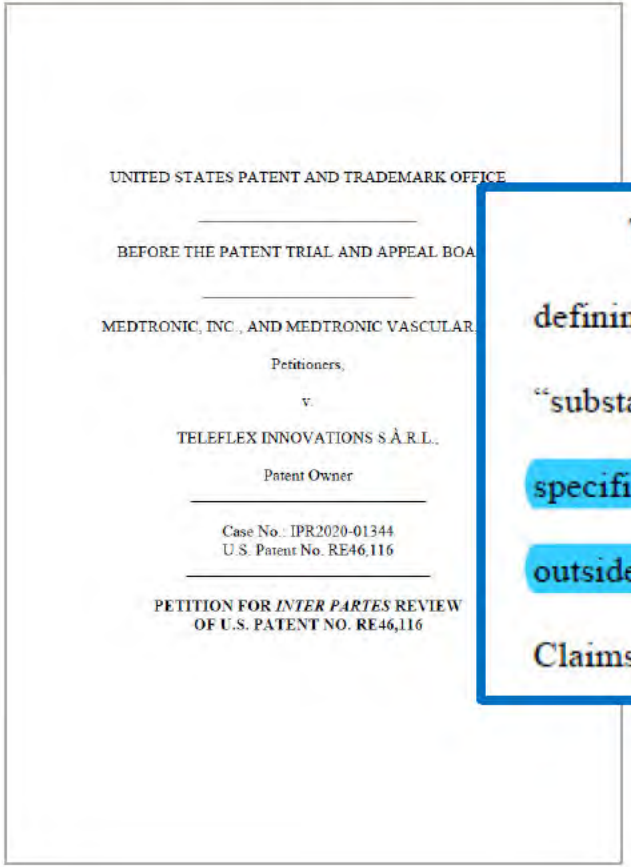
Issues Specific to IPR2020-01344

1. Root is Prior Art

2. Kontos's Tube 16 is Coaxial to Guide Catheter

3. Stents are Deliverable Through Kontos

IPR2020-01344: Obviousness Under Root



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOA

MEDTRONIC, INC., AND MEDTRONIC VASCULAR,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-01344
U.S. Patent No. RE46,116

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. RE46,116

The Challenged Claims recite an extension catheter having a "segment defining a side opening" that is in a separate and distinct region from the claimed "substantially rigid segment." Ex-1442, ¶¶ 35-40. There is no support in any specification in the priority chain or the original claims for a side opening that is outside the substantially rigid segment. *Id.*, ¶¶ 41-63. Therefore, the Challenged Claims are not entitled to their claim of priority.

IPR2020-01344, Petition at 62

IPR2020-01344: Obviousness Under Root

CASE 0:19-cv-01760-PJS-TNL Document 247 Filed 04/09/20 Page 1 of 17

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

VASCULAR SOLUTIONS LLC; ARROW INTERNATIONAL, INC.; TELEFLEX LLC; and TELEFLEX LIFE SCIENCES LIMITED;

Plaintiffs,

v.

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,

Defendants.

Case No. 19-CV-1760 (PJS/TNL)

ORDER

J. Derek Vandenburgh, Tara C. Norgard, Joseph W. Winkels, Alexander S. Rinn, and Shelleaha L. Jonas, CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A., for plaintiffs.

Kurt J. Niederluecke, Lora M. Friedemann, Laura L. Myers, and Anne E. Rondoni Tavernier, FREDRIKSON & BYRON, P.A., for defendants.

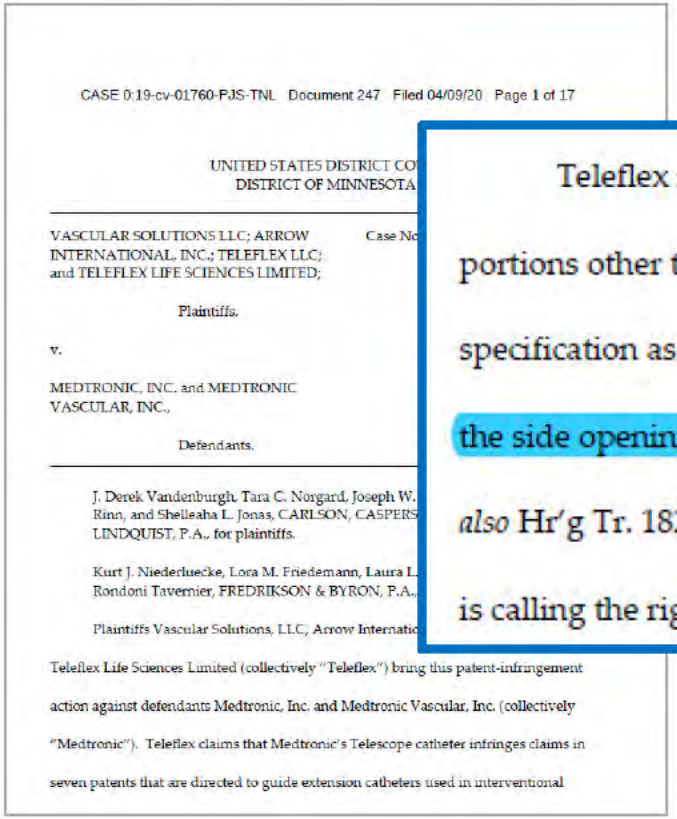
Plaintiffs Vascular Solutions, LLC, Arrow International, Inc., Teleflex LLC, and Teleflex Life Sciences Limited (collectively "Teleflex") bring this patent-infringement action against defendants Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Medtronic"). Teleflex claims that Medtronic's Telescope catheter infringes claims in seven patents that are directed to guide extension catheters used in interventional

Teleflex mischaracterizes the law. While predictability and criticality can be relevant to the adequacy of the written description, the focus is on what the disclosure conveys to persons of ordinary skill in the art. *Ariad*, 598 F.3d at 1351. This inquiry—which, again, is a question of fact for the jury, *id.* at 1355—"will necessarily vary depending on the context," *id.* at 1351, and "the precedential value of cases in this area is extremely limited," *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) (citation and quotation marks omitted). As the Federal Circuit stated in *Ariad*,

> [W]e do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.

Ariad, 598 F.3d at 1351.

IPR2020-01344: Obviousness Under Root



CASE 0:19-cv-01760-PJS-TNL Document 247 Filed 04/09/20 Page 1 of 17

UNITED STATES DISTRICT CO
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Teleflex next argues that the specification explicitly discloses side openings in portions other than the "substantially rigid" portion, pointing to Figure 1 of the specification as an example. As can be seen in Figures 4 and 12 through 16, however, the side opening is actually in the rigid portion. Am. Compl. Ex. G Figs. 1, 4, 12-16; *see also* Hr'g Tr. 182 ("All of the embodiments disclose [the side opening] in what the patent is calling the rigid portion.").

IPR2020-01344, Ex-1488 at 7

IPR2020-01344: Obviousness Under Root

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPE

MEDTRONIC, INC., AND MEDTRONIC VAS

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TELEFLEX INNOVATIONS S.À.R

Patent Owner.

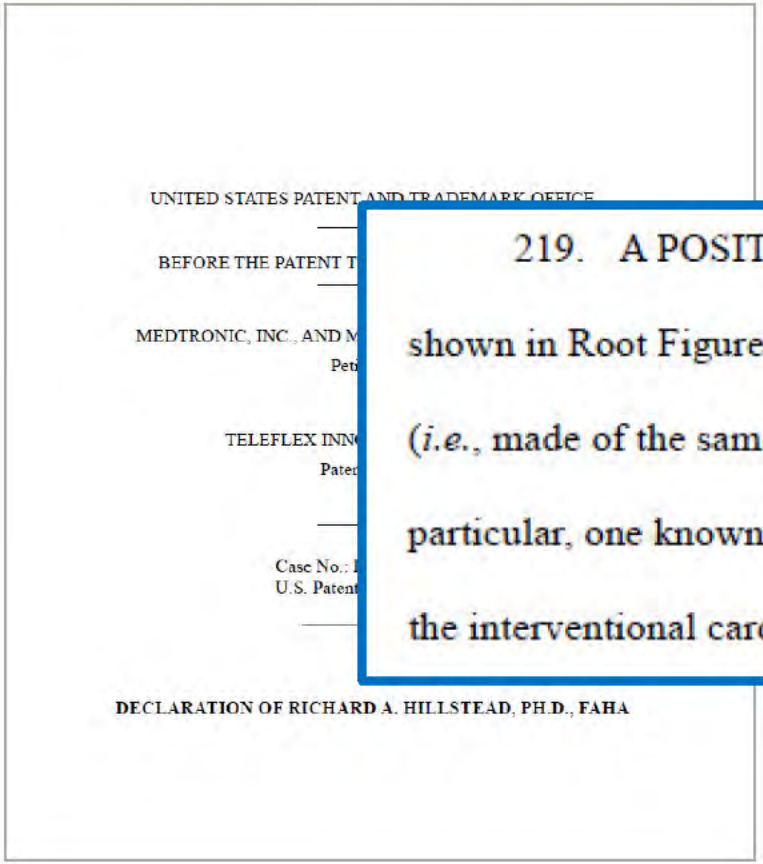
Case No.: IPR2020-01344
U.S. Patent No: RE46,116

DECLARATION OF STEPHEN JON DAVI
MD, FRCP, FESC, FACC

249. A POSITA would have been motivated to locate the side opening outside of the substantially rigid segment because it was known that "stents can get damaged entering [a] metal collar." Ex-1509 at 10. For example, a "main limitation" of Teleflex's original GuideLiner product was that the metal collar (side opening in the substantially rigid portion) could damage a stent upon entry into the extension catheter and the prior art suggested "[f]uture catheter design modifications" to eliminate this risk. *Id.*

IPR2020-01344, Ex-1405 (Brecker), ¶ 249

IPR2020-01344: Obviousness Under Root


UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT T

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TELEFLEX INN
Pate

Case No.:
U.S. Patent

DECLARATION OF RICHARD A. HILLSTEAD, PH.D., FAHA

219. A POSITA would have been motivated to modify the side opening shown in Root Figure 4 to change this portion from substantially rigid to flexible (*i.e.*, made of the same material used for the tube of the extension catheter). In particular, one known drawback of using a rigid side opening is that it can damage the interventional cardiology device upon entry into the extension catheter.

IPR2020-01344, Ex-1442 (Hillstead), ¶ 219

Issues Specific to IPR2020-01344

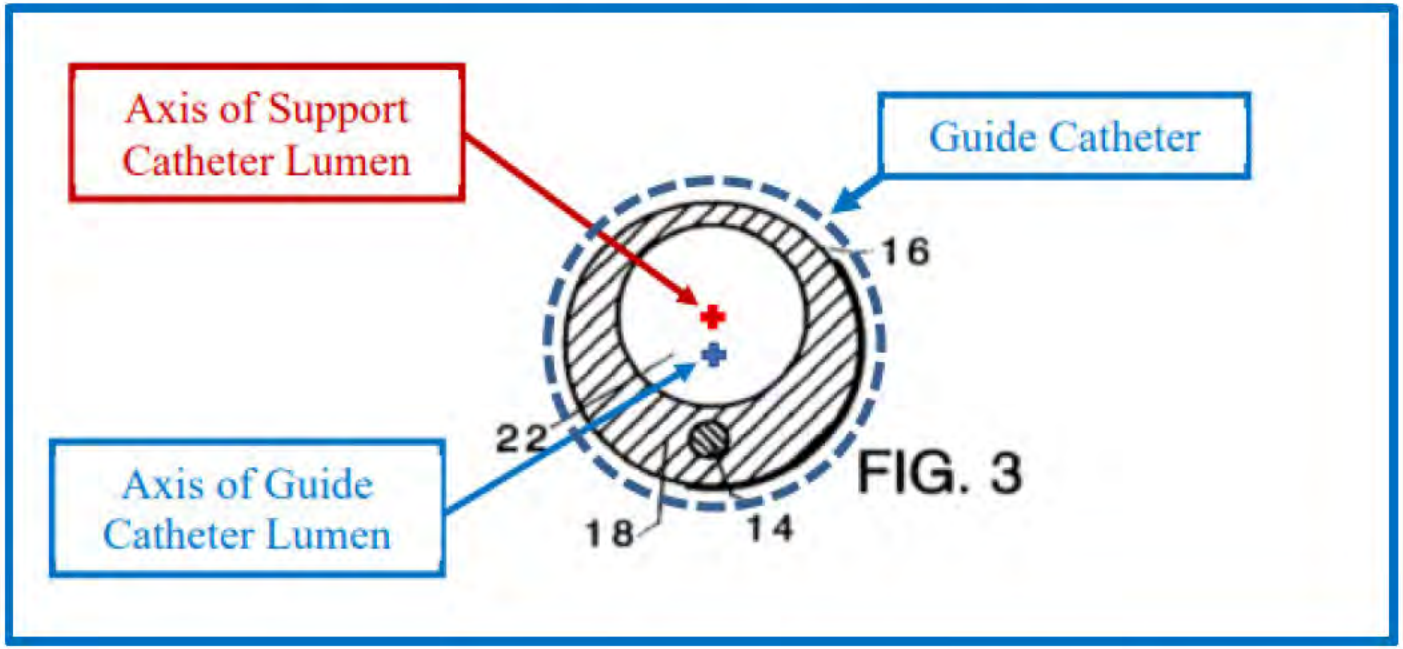
1. Root is Prior Art

2. Kontos's Tube 16 is Coaxial to Guide Catheter

3. Stents are Deliverable Through Kontos

IPR2020-01344: Coaxial

DECLARATION OF PETER T. KEITH



Ex-2138, ¶ 256 (Keith)

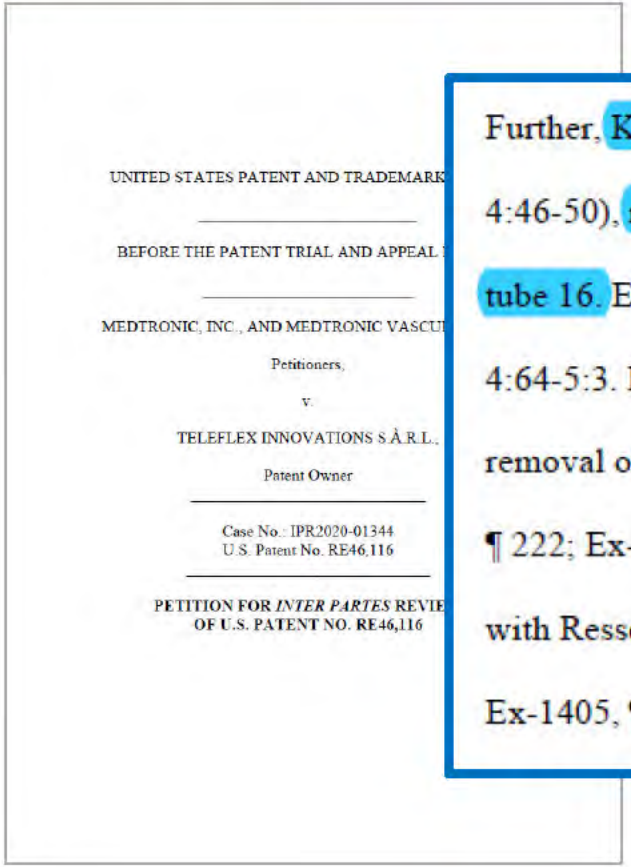
Issues Specific to IPR2020-01344

1. Root is Prior Art

2. Kontos's Tube 16 is Coaxial to Guide Catheter

3. Stents are Deliverable Through Kontos

IPR2020-01344: Kontos Teaches Delivering a Stent



UNITED STATES PATENT AND TRADEMARK

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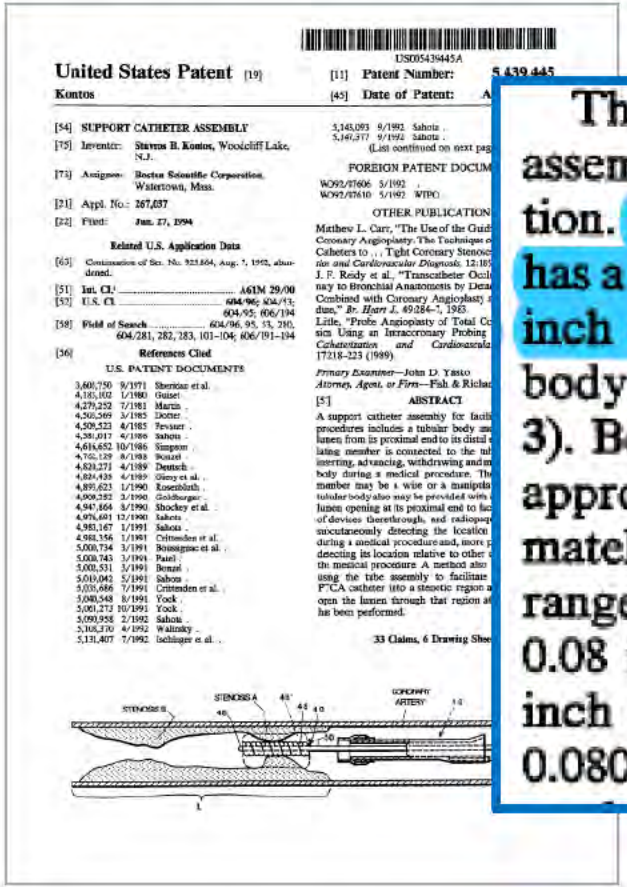
OF U.S. PATENT NO. RE46,116

Further, Kontos teaches that tube 16 has a 0.045 inch inner diameter (Ex-1409, 4:46-50), meaning stent and stent catheters could be advanced through Kontos's tube 16. Ex-1405, ¶ 221; Ex-1428, 641; Ex-1497, 104, 269, 274, 280; Ex-1409, 4:64-5:3. Regardless, the Ground II combination modifies Kontos's tube 16 (e.g., removal of funnel), such that it was possible to deliver larger sized stents. Ex-1405, ¶ 222; Ex-1442, ¶¶ 186-90. Stent delivery was common and combining Kontos with Ressemann would have required no creativity, experimentation, or invention. Ex-1405, ¶ 222; Ex-1442, ¶ 201.

IPR2020-01344, Petition at 46

IPR2020-01344: Kontos Teaches Delivering a Stent



United States Patent [19]

Kontos

US005439445A

[11] Patent Number: 5,439,445

[45] Date of Patent: A

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Steven B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 923,864, Aug. 3, 1992, abandoned.

[51] Int. Cl.[5] A61M 29/00

[52] U.S. Cl. 604/96; 604/53; 604/95; 606/194

[58] Field of Search 604/96, 95, 53, 280, 604/281, 282, 283, 101-104; 606/191-194

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sis Using an Intracoronary Probing
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17:218-223 (1989).

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Fish & Richar

[57] ABSTRACT

A support catheter assembly for facili
procedures includes a tubular body a
lumen from its proximal end to its distal
lating member is connected to the tu
inserting, advancing, withdrawing and m
body during a medical procedure. Th
member may be a wire or a manipula
tubular body also may be provided with
lumen opening at its proximal end to fac
of devices therethrough, and radiopaq
unconventionally detecting the location
during a medical procedure and, more p
detecting its location relative to other
the medical procedure. A method also
using the tube assembly to facilitate
PTCA catheter into a stenotic region a
open the lumen through that region a
has been performed.

33 Claims, 6 Drawing Shee

The size and shape of the various elements of support assembly **10** may vary depending on the desired application. In the application depicted in FIGS. 1 to 4, tube **16** has a 0.055 inch outer diameter and lumen **22** has a 0.045 inch diameter. (See, e.g., FIG. **2**). At base portion **18**, body **12** has a 0.065 inch outer diameter. (See, e.g., FIG. **3**). Body **12** is approximately 1 foot in length including approximately 1 inch of base portion **18** and approximately 0.1 inch of funnel portion **26**. Soft tip **28** is arranged to extend coaxially from distal end **24** for about 0.08 inch, and marker band **30** is approximately 0.055 inch inner diameter by 0.060 inch outer diameter by 0.080 inch long.

Ex-1409 at 4:46-58

IPR2020-01344: Kontos Teaches Delivering a Stent

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DECLARATION OF STEPHEN JON DAVID
MD, FRCP, FESC, FACC

As an initial matter, stent delivery was common by well before 2006. Further, tube 16 of body 12 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 extension catheter of Kontos. Ex-1415, 641 ("All current slotted tube designs are 'bare mounted' on a delivery balloon, with deflated profiles smaller than 0.040-in. (1mm) . . . ."); Ex-1497, 104 (Genic® stent with less than 0.9 mm (0.035 inch) profile), 143 (Lunar stent with 0.0382 inch profile), 269 (Spiral Force stent with 0.039 to 0.042 inch profile), 274 (Tsunami stent with 0.95 mm (0.038 inch) profile). The lumen of body 12 of Kontos was sufficiently sized to permit such delivery of the balloon catheter or stent.

Ex-1405 (Brecker Opening Declaration), ¶ 221