UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMédical, LLC,

Plaintiff and Counterclaim Defendant,

v.

Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc.,

Defendants and Counterclaim Plaintiffs.

Case No. 0:17-cv-01969 (PJS/TNL)

DECLARATION OF PETER T. KEITH IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

I, Peter T. Keith, state as follows:

1. I have been retained by Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc., whom I will refer to collectively in this declaration as VSI, to provide my expert opinions in this matter. I make this declaration in support of VSI's Opposition to the motion filed by QXMédical's ("QXM") for summary judgment, and further in support of VSI's cross-motion for summary judgment. If called to testify, I could and would testify to the following facts and opinions.

I. INTRODUCTION

2. I summarize my educational background and career history in the following paragraphs. My curriculum vitae is attached as Exhibit A to this report.

3. I received a Bachelor of Science degree with High Distinction from the University of Minnesota in 1987. During my undergraduate training, I began working as an engineering intern in the research and development (R&D) department at SCIMED, which was later acquired by Boston Scientific Corporation. I joined SCIMED full-time after graduation, and I remained with the company until 1996. During this time I rose from engineering intern to full-time R&D engineer to Director of R&D. Throughout my various roles at SCIMED, the focus of my work was on medical devices in the field of interventional cardiology, particularly catheter design.

4. Since 1997, I have served as an independent consultant for early stage medical device companies in the areas of product design and intellectual property development. Several of my consulting clients have developed successful products that are on the market and in hospitals today. A number of the products have been in the field of interventional cardiology, particularly catheters.

5. In addition to my work as an independent consultant, since 2000 I have engaged in a number of entrepreneurial ventures in the field of medical devices. In many of these, I held

chief responsibility for product design and development. Several of these products have been in the area of interventional cardiology. I have also done considerable work outside the area of interventional cardiology, including in treatments for chronic sinusitis, orthopedics for extremities such as feet and ankles, and treatment of spinal disorders.

6. Between my work at SCIMED, my independent consulting, and my entrepreneurial ventures, I have been named as an inventor on over 100 issued U.S. patents, as well as many corresponding patents in foreign countries. Numerous patent applications on which I am a named inventor are still pending.

II. OVERVIEW OF THE VSI PATENTS

7. The VSI patents teach methods, systems, and devices for guide extension. One important purpose of the VSI devices is to provide backup support to a guide catheter when interventional cardiology devices, including stent delivery catheters, are inserted into the guide catheter for delivery to a treatment site. As the VSI patents explain, crossing tough lesions with an interventional cardiology device can create enough backward force to dislodge the guide catheter from the ostium of the artery to be treated. Increasing backup support for the guide catheter helps prevent that dislodgement, allowing for successful advancement of the treatment device to treat the lesion. Doc. 8-1, Ex. D, at 1:59-64.

8. There are a variety of factors that can create the need for additional guide catheter backup support, and while devices and techniques have changed somewhat over time, the need for stable backup support has existed since the beginning of interventional cardiology. The VSI patents describe several prior art techniques and devices that were designed to increase backup support, none of which proved effective or successful. *Id.* at 1:64-3:5. A couple of the backup support-related prior art references cited in the VSI patents date back to the late ’80s.

9. First were guide catheters that were provided with a particular shape and stiffness profile to "draw backup support from engaging the wall of the aortic arch opposing the ostium." *Id.* at 2:3-5. However, such catheters are potentially more traumatic to the aorta. *Id.* at 2:6-15.

10. Second, certain prior art catheters included an extension or appendage that could be deployed against the opposing wall of the aortic arch in order to provide backup support. *Id.* at 2:16-21. These devices were considered unwieldy and were not adopted for use. Similarly, prior art devices that sought to "expand laterally to grip the interior wall of the ostium of the coronary artery to provide a force acting in opposition to the backward forces" were considered "mechanically complex" and ran the risk of completely occluding the ostium. *Id.* at 2:26-39. For those reasons, such devices were not widely adopted.

11. Finally, one technique advocated placement of one long guide catheter within a larger-diameter standard-length guide catheter so that the inner catheter could be extended beyond the outer catheter. As with other techniques, however, increasing backup support through this "mother-and-child" approach was limited by several factors, including the cumbersomeness of needing to utilize an exchange-length guidewire. *Id.* at 2:51-55.

12. Prior to the invention of the VSI patents, procedures requiring improvement in guide catheter support were left untreated, or otherwise implemented other less optimal ways of increasing guide catheter support. The design of the VSI patents overcame the challenges and shortcomings in the prior art to provide a guide extension device that was capable of simply and safely providing backup support to a guide catheter during interventional device delivery. For example, the VSI inventions provide improved support with a 6F (six French size) guide catheter, which allows a physician to reach further into narrower vessels and perform procedures that would have been difficult or impossible by switching to a larger diameter (and therefore

stiffer) guide catheter or other device with enhanced backup support. It is my opinion that none of the prior art references cited by QXM, alone or in combination, provide the safety, ease of use, and versatility that was captured in VSI's patented design.

III. INFRINGEMENT BY THE BOOSTING CATHETER

13. I understand that VSI is asserting the following claims in this litigation:

- Claims 3 and 8 of U.S. Patent No. 8,048,032 (the '032 Patent, Doc. 8-1, Ex. H)
- Claim 9 of U.S. Patent No. 8,142,413 (the '413 Patent, Doc. 8-1, Ex. I)
- Claims 1, 3, and 8 of U.S. Patent No. RE45,380 (the '380 Patent, Doc. 8-1, Ex. D)
- Claims 25, 30, 31, 32, and 48 of U.S. Patent No. RE45,760 (the '760 Patent, Doc. 8-1, Ex. E)
- Claims 25, 32, 36, 52, and 53 of U.S. Patent No. RE45,776 (the '776 Patent, Doc. 8-1, Ex. F), and
- Claims 25, 34, and 53 of U.S. Patent No. RE46,116 (the '116 Patent, Doc. 8-1, Ex. G).

14. I further understand that VSI is moving for summary judgment of infringement of claims 25, 36, 52, and 53 of the '776 patent.

15. In this part of my declaration, I first address QXM's assertion that it does not infringe the "without a lumen" limitation of the '032, '413, and '380 patents.

16. I then address VSI's motion for summary judgment that the Boosting Catheter infringes claims 25, 36, 52, and 53 of the '776 patent. In addressing VSI's motion for summary judgment of infringement of the '776 patent, I will address elements of the '776 patent that QXM contends are not present in the Boosting Catheter that QXM does not raise in its motion. I will also address the "one French" argument that QXM makes in its motion, which relates to claims 30 and 53 of the '776 patent and also to claim 8 of the '032 patent, claim 8 of the '380 patent, claims 25 and 48 of the '760 patent, and claim 25 of the '116 patent. I will also address QXM's

argument that it does not infringe the various claims that require that the segment that defines a side or partially cylindrical opening be more rigid than the tubular structure or the distal end portion of the tubular structure, which relates to claims 25 and 52 of the '776 patent, and also to claims 25 and 48 of the '760 patent and claim 52 of the '116 patent.

A. The Boosting Catheter Meets the "Without a Lumen" Limitation of the '032, '413, and '380 Patents.

17. The asserted claims of the '032, '413, and '380 patents recite "a substantially rigid portion … defining a rail structure without a lumen."

18. I understand that the Court has construed "lumen" to mean "the cavity of a tube." Doc. 102 at 25. I further understand that a "cavity" is a hollow or unfilled space.

19. I understand that QXM contends that the rail structure of the Boosting Catheter's substantially rigid portion does not meet the "without a lumen" limitation because the interior of the shrink-wrap over the Boosting Catheter's substantially rigid portion is the "cavity of a tube." It is my opinion that the shrink-wrap over the Boosting Catheter's substantially rigid portion does not define the cavity of a tube. The shrink-wrap is essentially filled, by the two wires and adhesive, with only a minute void between the side-by-side wires and the shrink-wrap surrounding them. In other words, it is my opinion that the inside of the Boosting Catheter's wrap is not "the cavity" of the tube, because the tube's cavity is not hollow, and instead is essentially solid. Therefore, the Boosting Catheter's substantially rigid portion literally meets the "without a lumen" limitation.

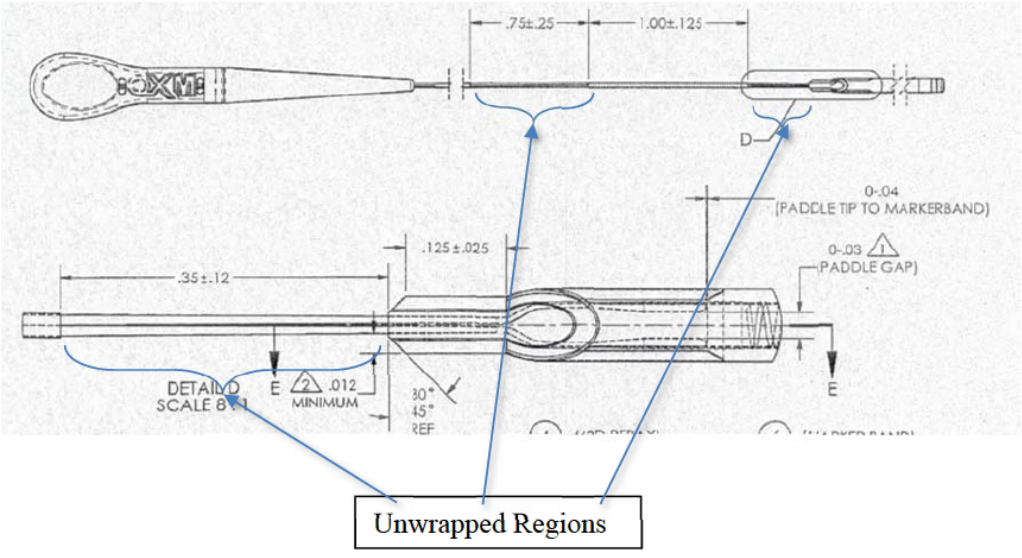
20. By my calculation, the void inside the shrink-wrap is only about 6% of the cross-sectional area of the shaft inside the wrap.

21. I understand that QXM contends that "a 'lumen' is a lumen regardless of whether it has something occupying it or not," Merrill Dec., Ex. 1, ¶146, and that even a tube that is

"completely filled" with another material has a lumen, O'Rear Ex. 2 (Brown Dep. at 81-83). Under QXM's interpretation of the Court's construction of "lumen," a shrink-wrapped solid wire would have a lumen; it is my opinion that such a reading of "lumen" is inconsistent with how those of skill in the art of interventional cardiology would understand the term as construed.

22. I understand that QXM also contends that the void inside some portions of the shrink-wrap is a lumen. It is my opinion that that remaining space is neither a tube nor "the cavity of a tube."

23. First, I note that the shrink-wrap does not cover the entire length of the Boosting Catheter's substantially rigid portion. Instead, the shrink-wrap stops and starts over the length of the substantially rigid portion and thus is discontinuous, i.e., there are two segments where there is no shrink-wrap and the wires are exposed, including where the wires approach the distal tubular section. The two gaps in the shrink-wrap can be felt with one's fingers, such as on the Boosting Catheter sample being submitted with VSI's response and cross-motion, and can be seen in the figures below, where the gap on the bottom figure is a magnified view of the gap on the right of the top figure:



24. The irregular, triangular-like void that is left in the shrink-wrap that QXM applies over the wires and adhesive is not itself a lumen, because the periphery surrounding it is not a tube, nor is it the cavity of a tube. It is not even round or circular, as a "tube" is in normal parlance. Instead, it is residual minor space left by the shrink-wrapped wires and adhesive.

25. It is my opinion that the rail structure of the Boosting Catheter's substantially rigid portion also meets the "without a lumen" limitation under the doctrine of equivalents. Having a tiny, non-functional void between the side-by-side stainless steel rods and the surrounding wrap is insubstantially different from having no void at all. I note that the void lacks many of the characteristics of a lumen. It is tiny, and blocked at its proximal end by the handle. The shrink-wrap does not cover the entire length of the wires, and instead leaves a portion of the wires uncovered. Because the pushrod is embedded into the handle, nothing can enter or pass through the void between the stainless steel rods and the wrap of the Boosting Catheter. It serves no meaningful purpose or function.

26. I understand that QXM confirms that nothing can pass through the void that it claims is a lumen:

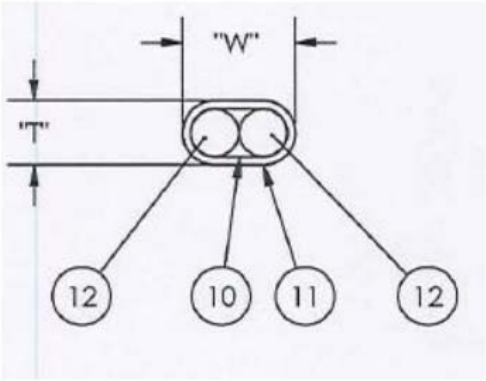
> Q. At the end of the day when the final shaft is embedded into the strain relief and the handle, is there any access from the outside to that space that is inside the shaft?
> A. No.
>
> Q. If you wanted to put something through there, you couldn't?
> A. Obviously not.

Exhibit B at 12.

27. I understand that QXM argues that the gap in the lumen's pushrod can be used to pass fluid, in reliance on work done by its expert, Mr. Brown, discussed at Merrill Dec., Ex. 1, ¶147. To pass the fluid, Mr. Brown had to alter the device. QXM "cut off the [Boosting

Catheter's] handle, … and put on a luer fitting." O'Rear Ex. 2 (Brown Dep. at 86). Because the wrap on the Boosting Catheter's substantially rigid portion is discontinuous, *id.*, the balloon was placed "quite a bit further back from where … the sheath ended," *id.* at 88, and a hole had to be made in the sheath, *id.* Without these modifications, it would not be possible even to attempt to pass a fluid down the interior of the substantially rigid portion. The device as it is currently fabricated cannot perform the function that Mr. Brown seems to imply that it can perform

28. The small void in the Boosting Catheter's rail structure does not increase the outside dimensions of the substantially rigid portion and does not at all change the space that the substantially rigid portion takes up within the guide catheter, as can be seen in the following depiction of the cross-section of the Boosting Catheter's rail structure; specifically, dimension "T" is not at all affected by what QXM is referring to as a "lumen":



Br. at 14.

29. It is my opinion that the void does not have any function in the Boosting Catheter. I have reviewed QXM's FDA submissions, and while those documents repeatedly refer to the Boosting Catheter's flexible tip portion as having a lumen, they make no reference to a lumen in the Boosting Catheter's rail structure. Exhibit B at 13.

30. I understand that QXM argues that the configuration of its device's substantially rigid portion "makes the shaft more flexible in the axial, angular and longitudinal directions, minimizes stress concentration at the joint between the shaft and the tube, and enhances safety by making the device less prone to breakage and separation." Br. at 17. I understand from Mr. Brown's noninfringement report that QXM is comparing its commercial device to earlier versions of the patented GuideLiner device (Versions 1 and 2). Merrill Dec., Ex. 21, ¶152 (cited in QXM's brief at 17). This argument is based on an exaggerated criticism by QXM of the GuideLiner Version 1 and 2 devices. My understanding from VSI is that a small number of GuideLiner Version 1 and 2 devices experienced "device separation," where the tubular section separated from the pushrod at the juncture between the two. (GuideLiner Version 3 has not had these separation problems.) QXM argues that the twin-wire design reduces the likelihood of device separation by allowing the pushrod to twist more easily than the GuideLiner's pushrod. I have not seen data to support that assertion, and I do not believe the Boosting Catheter has been used enough to assess its performance and safety. In any event, the relevant claim language is "a substantially rigid portion … defining a rail structure without a lumen," and to the extent the Boosting Catheter's substantially rigid portion is more able to twist, that is not attributable to the supposed "lumen." O'Rear Ex. 2 (Brown Dep. at 91-92).

31. In summary, it is my opinion that the Boosting Catheter's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside).

32. I have been asked to consider QXM's statement, at page 17 of its brief, that "Nothing passes through Solar's 'lumen' in Figure 1." It is my opinion that Solar teaches that fluid can be administered through the device's hypotube pushrod embodiment. Solar states: "Advancement member 5 may be hollow to provide an alternative means for fluid administration to the treatment site." Merrill Dec., Ex. 18, ¶51.

B. The Boosting Catheter Infringes the '776 Patent

33. For the reasons set forth below, it is my opinion that each model of the Boosting Catheter infringes claims 25, 36, and 52 of the '776 patent. I understand that counsel for VSI is submitting a 6F Boosting Catheter as evidence.

34. Claim 53 of the '776 patent requires that the inner diameter of the guide extension catheter be "not more than one French" size smaller than the inner diameter of the guide catheter. For the reasons set forth below, it is my opinion that the 6F Boosting Catheter, Model No. BC57-150, infringes this claim when QXM makes or sells its 6F Boosting Catheter.

35. I understand that QXM does not contest that its Boosting Catheter meets many of the elements of the asserted VSI claims. Specifically, I understand that QXM only contests those elements listed as disputed in its expert's report, Merrill Dec., Ex. 1.

36. I have reproduced below the claims of the '776 patent for which VSI seeks a ruling of summary judgment of infringement, with the claim elements that are contested in the report of QXM's expert Brian Brown bolded:

- Claim 25 of the '776 patent:

> 25. A guide extension catheter for use with a guide catheter, comprising:
>
> **a substantially rigid segment;**
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and

> **a segment defining a partially cylindrical opening** positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, **formed from a material more rigid than a material or material combination forming the tubular structure**, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,
>
> wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

- Claim 36 of the '776 patent:

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

- Claim 52 of the '776 patent:

> 52. A guide extension catheter for use with a guide catheter, comprising:
>
> **a substantially rigid segment;**
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and
>
> **a segment defining a partially cylindrical opening** positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, **formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure**, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,
>
> wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;
>
> wherein **the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions**.

- Claim 53 of the '776 patent:

> 53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:
>
> **a substantially rigid segment;**
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment, **the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter**; and
>
> a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;
>
> wherein **the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions**.

37. As to the elements that QXM does not contest, the bases for my opinions that QXM meets these elements are set forth in detail in claims charts that I prepared for my expert report, when I analyzed infringement by the Boosting Catheter. These charts, which were submitted as Merrill Dec., Ex. 23, Appendix I, are attached to this declaration as Exhibit B for the Court's ease of reference.

38. As to the elements that QXM disputes are met by the Boosting Catheter, either in QXM's motion for summary judgment of noninfringement or as relevant to VSI's cross-motion for summary judgment of infringement, my opinions are set forth in the following sections.

1. The Boosting Catheter Meets the "Substantially Rigid Segment" Limitation of the '776 Patent Claims.

39. Asserted independent claims 25, 52, and 53 of the '776 patent, and thereby also asserted claim 36, which depends from claim 25, recite a "substantially rigid segment."

40. I understand that the Court has construed "substantially rigid" to mean "rigid enough to allow the device to be advanced within the guide catheter." Doc. 102 at 15.

41. I understand that QXM does not dispute that the Boosting Catheter meets the substantially rigid portion/segment, as that term has been construed, O'Rear Ex. 2 (Brown Dep. at 10), though QXM's expert report continues to contest the claim construction, Merrill Dec., Ex. 1 at ¶ 120.

42. It is my opinion, based on my physical examination of the Boosting Catheter, and for the reasons set forth in Exhibit B, that all models of the Boosting Catheter meet the substantially rigid segment claim element because the pushrod is rigid enough to allow the Boosting Catheter to be advanced within the guide catheter.

2. QXM Directly Infringes the '776 Patent's "One French" Limitation

43. Several asserted claims recite that the inner diameter of the guide extension catheter is "not more than one French" size smaller than the inner diameter of the guide catheter:

- "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter," as recited in claim 8 of the '032 patent and claim 8 of the '380 patent;
- "the lumen of the tubular structure … having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter," as recited in claims 25 and claim 48 of the '760 patent;
- "a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter," as recited in claim 30 of the '776 patent;
- "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," as recited in claim 25 of the '116 patent; and
- "a tubular structure … having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter," as recited in claim 53 of the '776 patent.

44. I note that the claims listed above from the '032 and '776 patents are directed to the guide extension catheter device itself; the claims from the '380 and '760 patents are directed to a system that includes the guide extension catheter; and the claims of the '413 and '116 patents are directed to methods that include use of the guide extension catheter.

45. It is my opinion that QXM directly infringes the device claims of the '032 and '776 patents when it makes and sells its 6F Boosting Catheter, Model No. BC57-150. It is also my opinion that a physician who uses QXM's 6F Boosting Catheter with a guide catheter with an inner diameter of .070 inches is directly infringing all of the "one French" claims. I understand that VSI alleges that QXM is inducing infringement of these claims. Because I understand that the question of inducement relates to QXM's intent, I do not express an opinion on inducement.

46. I understand that VSI is moving for summary judgment of claim 53 of the '776 patent. I also understand that VSI is moving for summary judgment regarding claim 8 of the '032 patent.

47. Standard 6F guide catheters typically have inner diameters of .070 or .071 inches. Based on my analysis of market data, about 52.5% of 6F guide catheters sold from 2016 to 2018 had an inner diameter of .070 inches, and about 44% had an inner diameter of .071 inches. *See* Merrill Dec., Ex. 23, Appendix S.

48. Mathematically, those of ordinary skill in the art define one French as .0131 inches. Thus, the .057-inch inner diameter of the 6F Boosting Catheter is within one French size of the standard .070 6F guide catheter. As such, it is my opinion that QXM directly infringes the claim 8 of the '032 patent and claim 53 of the '776 patent when it makes and sells its 6F Boosting Catheter.

3. The Boosting Catheter Meets The Claim Limitations Requiring The "Segment Defining A Side/Partially Cylindrical Opening" To Be More Rigid Than The Tubular Structure Or The Distal End Portion Of The Tubular Structure.

49. Certain asserted claims require that the device have a segment that defines a side or partially cylindrical opening that is more rigid than the tubular structure or the distal end portion of the tubular structure:

- "a material forming the segment defining the side opening is more rigid than the tubular structure," as recited in claim 25 of the '760 patent;
- "the segment defining the partially cylindrical opening … formed from a material more rigid than a material or material combination forming the tubular structure," as recited in claim 25 of the '776 patent;
- "the segment defining the partially cylindrical opening … formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure," as recited in claim 52 of the '776 patent; and
- "the segment defining the side opening … is more rigid than the [a] distal end portion of the tubular structure," as recited in claim 52 of the '116 patent and claim 48 of the '760 patent.

50. I understand that the Court has adopted the following constructions, which I have applied:

- (1) "wherein a material forming the segment defining the side opening is more rigid than the tubular structure" means "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure";
- (2) "formed from a material more rigid than a material or material combination forming the tubular structure" means "formed from matter that is more rigid than the matter forming the tubular structure"; and
- (3) "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure" means "formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure."

a. The Boosting Catheter Meets the Requirement of Claim 25 of the '760 Patent that "A Material Forming the Segment Defining the Side Opening Is More Rigid Than the Tubular Structure."

51. To form opinions regarding whether the Boosting Catheter meets certain claim elements, including the various rigidity comparisons, I performed laboratory testing on samples

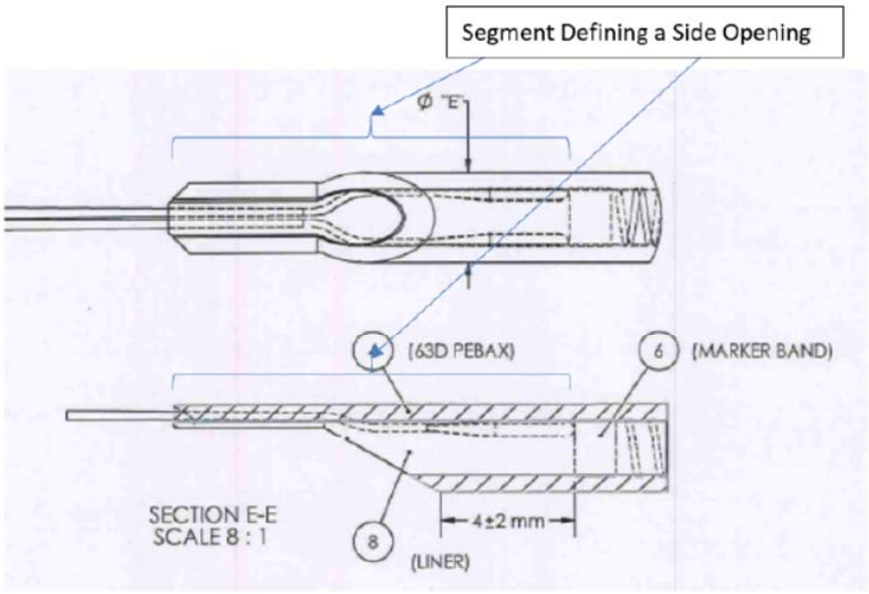
of the Boosting Catheter. My testing methods and results are set forth in my expert report, Merrill Dec., Ex. 23, Appendices C-H.

52. For purposes of analyzing whether the Boosting Catheter meets the requirement of claim 25 of the '760 patent that the segment defining a side opening is more rigid than the tubular structure, I identified the segment defining a side opening, as shown below.[1] This is consistent with my opinion that the "segment defining a side opening" would be understood by those of ordinary skill in the field of interventional cardiology to potentially include a portion of the full circumference tube. It is my opinion that one of ordinary skill in the art of interventional cardiology devices would interpret the "segment defining a side opening" language to include structures that overlap in the side opening region. Functionally, these structures serve to impart the necessary structural integrity to this side opening region. Without these elements and the transition in rigidity, the catheter would be prone to kinking and other deformities.

53. As such, I identified the segment as extending from where the stainless steel rods are embedded in the Boosting Catheter's polymer segment (where the side opening begins) to where the segment defining the side opening transitions into the tubular structure, near the marker band and the beginning of the coil-reinforced portion. I identified the distal endpoint of the segment as being where materials specific to the segment terminate, including laminated materials, and the embedded stainless steel rods. This segment also includes a patch of Teflon (PTFE) material, which ends at the marker band, that QXM adds specifically to further reinforce the segment defining a side opening. The Teflon material has a flexural modulus of 72,000 psi

[1] The claims quoted above from the '760 and '116 patents recite "a segment defining a side opening," while the claims quoted above from the '776 patent recite "a segment defining a partially cylindrical opening." For the reasons set forth in this paragraph, I treat the two phrases as the same, and my analysis of the Boosting Catheter applies equally to both phrasings.

(Merrill Dec., Ex. 23, Appendix Q), which is greater than the flexural modulus of the PEBAX 6333 used in the polymer just distal to the side opening segment (flexural modulus of 41,300 psi) (Merrill Dec., Ex. 23, Appendix R), and greater than the even "softer" and more flexible PEBAX formulations used further distally in the tubular shaft portion.



Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

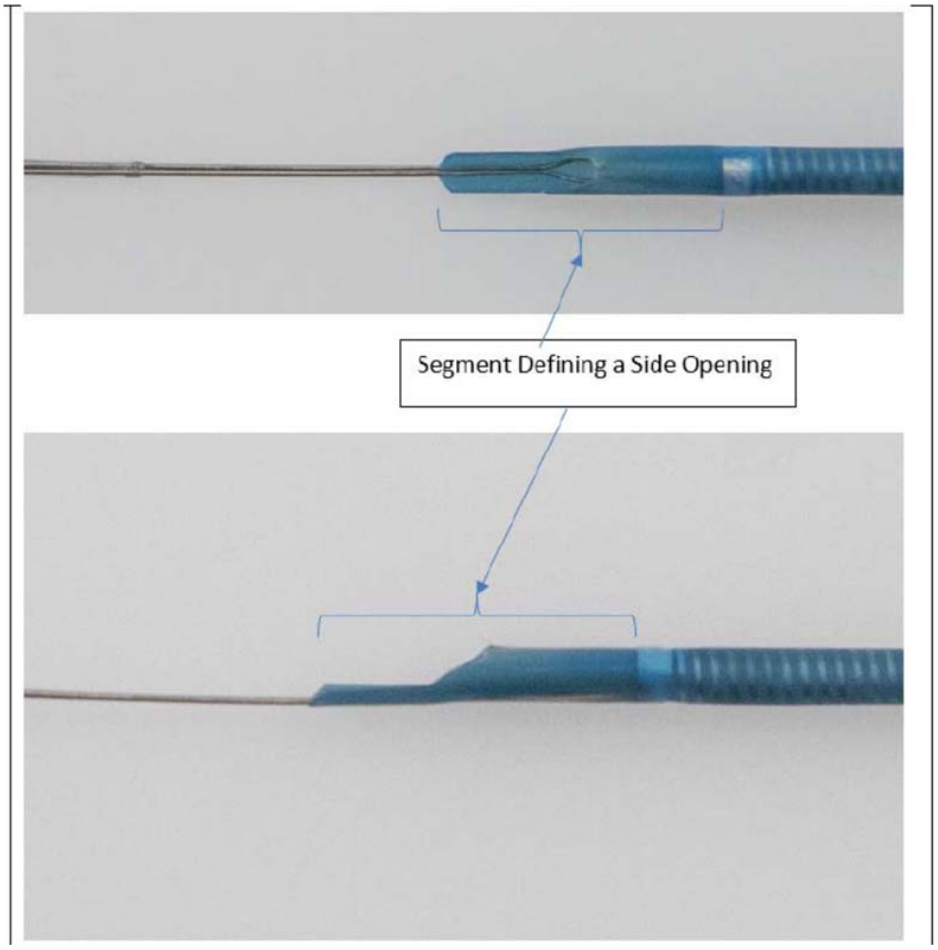


Exhibit B at 30-31.

54. QXM's assembly drawings show the Teflon patch, marked with reference number 16 below:

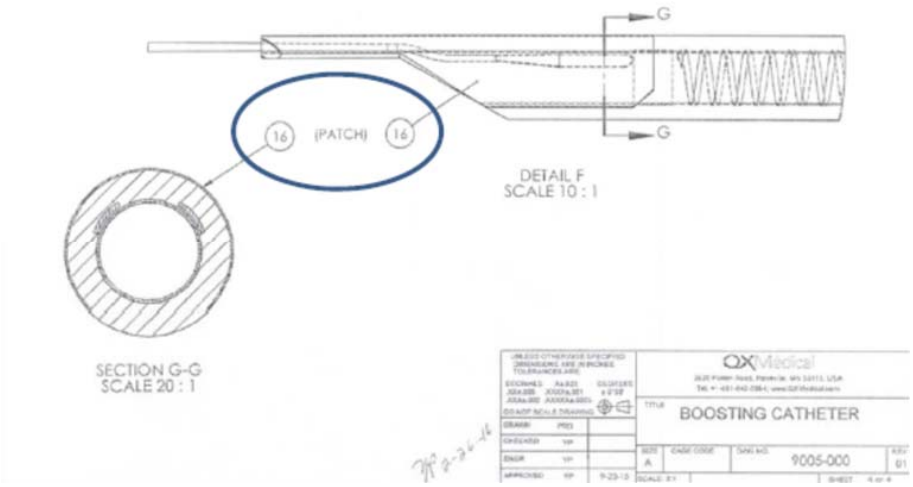


Exhibit B at 37.

55. In order to determine whether this segment was more rigid than the tubular section of the Boosting Catheter, I tested each segment in a two-point bend test using standard engineering test equipment. *See* Merrill Dec., Ex. 23, Appendix C. I used the entire segment defining the side opening as my test sample for that segment.

56. The tubular section and the segment defining the side opening together total about 25 cm in length. The tubular section has a 1-mm marker band immediately distal to the segment defining a side opening; a blue section, less rigid than and distal to the segment defining a side opening; and a green section, less rigid than and distal to the blue section. The tubular section also has a second 1 mm marker band and a 2 mm bumper tip. The yellow and blue sections are reinforced with a coil; the bumper tip is not. For my analysis of the tubular section, I measured two different samples of equivalent length, one taken from each of the main portions of the distal tubing, both blue and green, because the blue and green segments make up nearly the entire length of the tubular portion, and thus impart the tubular portion with its bending and rigidity characteristics.

57. My test results chart, submitted previously as Merrill Dec., Ex. 23, Appendix D, shows that the matter forming the segment defining the side opening of the Boosting Catheter is more rigid than the Boosting Catheter's tubular structure. The two point bend testing of the Boosting Catheter shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment (denoted "Flex 3 up" and "Flex 3 down" in my test results chart) are all higher than the maximum load values for the tubular structure, both the proximal (blue) section of the tubing ("Flex 2" in my test results chart) and the distal green section of the tubing ("Flex 1" in my test results chart). Merrill Dec., Ex. 23, Appendix D, at 1.

b. The Boosting Catheter Meets the Requirement of Claim 25 of the '776 Patent that the "Segment Defining the Partially Cylindrical Opening [Is] Formed from a Material More Rigid than a Material or Material Combination Forming the Tubular Structure."

58. My testing further shows that the Boosting Catheter's segment defining a partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure. The two point bend testing of the Boosting Catheters shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values both the proximal (blue) section of the tubing ("Flex 2" in my test results chart) and the distal green section of the tubing ("Flex 1" in my test results chart). Merrill Dec., Ex. 23, Appendix D, at 1.

c. The Boosting Catheter Meets the Requirement of Claim 52 of the '776 Patent that the "Segment Defining the Partially Cylindrical opening [Is] Formed from a Material Having a Greater Flexural Modulus than a Flexural Modulus of the Tubular Structure."

59. I understand that the parties have agreed that "flexural modulus," as used in claim 52 of the '776 patent, means "a numeric, dimension-independent material property that captures the tendency of a material to bend." Doc. 36 at 2. I further understand that the Court has construed "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure" to mean "formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure." Doc. 102 at 32.

60. In view of the Court's claim construction, it is my opinion that the Boosting Catheter's partially cylindrical opening is formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure. My two point bend testing of the Boosting Catheters shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than both the proximal (blue) section of the tubing ("Flex 2" in my test results chart) and the distal green section of the tubing ("Flex 1" in my test results chart). Merrill Dec., Ex. 23, Appendix D, at 1.

d. The Boosting Catheter Meets the Requirement of Claim 52 of the '116 Patent and Claim 48 of the '760 Patent that the "Segment Defining the Side Opening … Is More Rigid than the [a] Distal End Portion of the Tubular Structure."

61. Test results confirm that the segment defining the side opening of the Boosting Catheter comprises a portion of the Boosting Catheter that is more rigid than a distal end portion of the tubular structure. The claims define the distal end portion as the portion of the tubular structure that extends past the distal end of the guide catheter. (See claim 48 ("the distal end of

the guide extension catheter extends beyond the distal end of the guide catheter") and claim 52 ("maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter"). I note that, in use, not more than about 15 cm of the Boosting Catheter's tubular structure is advanced beyond the guide catheter's distal end. Exhibit B at 45.

62. Specifically, two point bend testing of the Boosting Catheters shows that the side opening segment is more rigid than distal end portion of the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal end portion, which is the distal green section of the tubing ("Flex 1" in my test results chart). Merrill Dec., Ex. 23, Appendix D, at 1.

e. Response to QXM's Marker Band Argument

63. I understand that QXM takes the position that it does not meet any of the limitations discussed above because the Boosting Catheter's marker bands are more rigid than the side opening segment. QXM essentially argues that the claims should be interpreted as having no slice of the distal tube that has a stiffness that is greater than the side opening segment, notwithstanding that the vast majority of the distal tube is very flexible. This is functionally and factually flawed.

64. It is my opinion that the rigidity of the 1 mm marker bands is not relevant to the design and function of the catheter device. Because the marker bands are so short, they do not significantly affect (if it all) the ability of the device to bend and flex as it passes through the patient's vasculature. Simply running the device through one's hands confirms that the marker bands have little if any effect on the flexibility of the catheter. Indeed, a tiny sliver of the hardest material in the universe could be used in a catheter without having any impact on the device's pushability, trackability, or performance. Accordingly, I do not believe it is representative of the

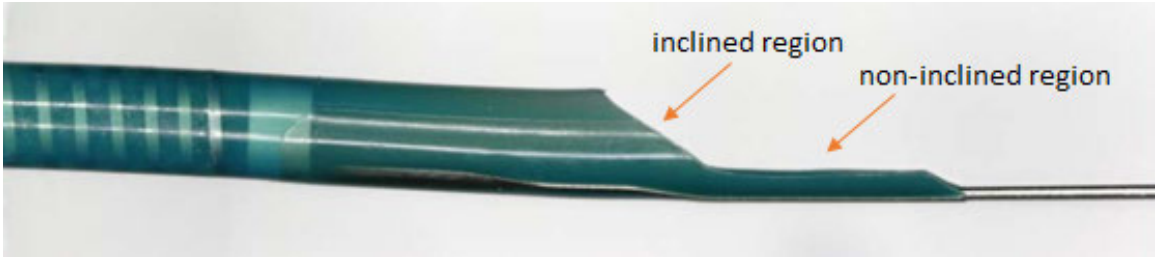
"tubular structure" or the "distal end portion of the tubular structure" recited in the claim language to measure only the rigidity of a very short portion of those structures.

65. Mr. Brown did not test the actual device, but instead tested a much longer marker band test sample (e.g., 2 cm), which is a poor way of characterizing the performance of a short segment. As Mr. Brown agreed, no one would ever put a 2 cm-long segment of marker band into a guide extension catheter. O'Rear Ex. 2 (Brown Dep. at 129). The 2 cm metal segment bears no relationship to the actual Boosting Catheter, and Mr. Brown did not test the actual device. If the testing were done on an actual Boosting Catheter, one would not see the sharp spikes and dips in the charts at pages 28 and 29 of QXM's brief, which purport to show that certain portions of the catheter are radically stiffer than others.

4. "Inclined Region that Tapers into a Non-Inclined Region"

66. Dependent claim 36 of the '776 patent recites that the "segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region."

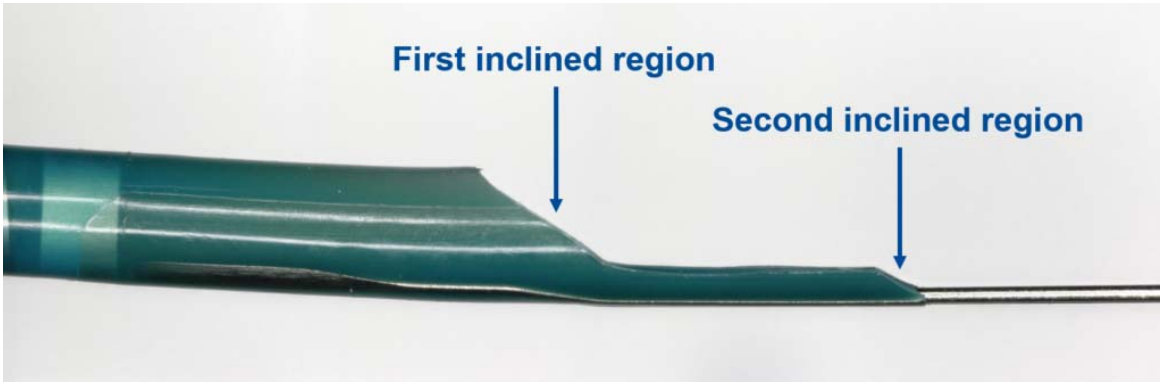
67. It is my opinion that the Boosting Catheter's segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region, as illustrated below:



5. "At Least Two Inclined Regions"

68. Independent claims 52 and 53 of the '776 patent recite that "the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions."

69. It is my opinion that the Boosting Catheter's segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions, as illustrated below:



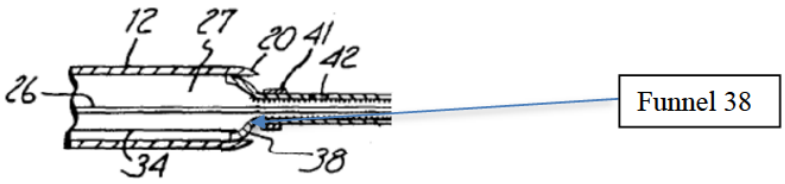
IV. CLAIM 53 OF THE '116 PATENT IS NOT ANTICIPATED BY ADAMS

A. Background on Adams

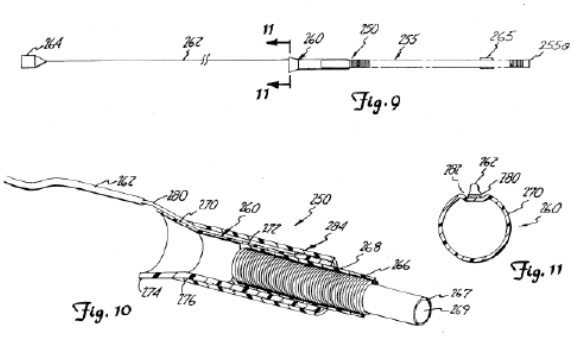
70. Adams describes three types of devices. One has a pushrod that connects to a funnel on the proximal end of a distal tube; a second has a pushrod connected to a balloon on the proximal end of a distal tube; and a third has a slitted tube, with no pushrod, that is longer than a guide catheter. Because QXM does not rely on the third (slitted tube) embodiment, I do not express any opinions on it.

71. In the funnel embodiment, an elongated wire is attached to a funnel positioned at the proximal end of a flexible distal tube. This embodiment is shown in Figures 1, 2, and 9-13 of Adams.

72. Figure 2 of Adams, below, shows the flared proximal end 38 (the funnel) on the proximal end of elongated flexible tube 32, positioned in the guide catheter 12:



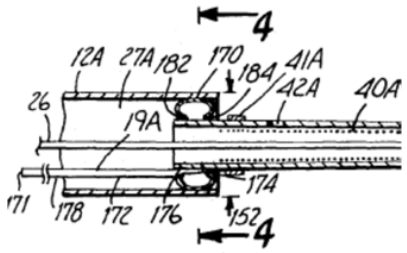
73. Figures 9-11 of Adams, below, show the proximal funnel 260 positioned on the flexible tube 255:



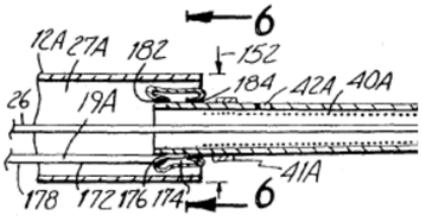
74. In use, the Adams funnel "pilot[s]" the coil tip of a guidewire or a fixed-wire balloon catheter (which had a "built in" guidewire for steering/navigation and stiffening support, and thus did not use a separate guidewire) into the flexible tube. Merrill Dec., Ex. 29, at 6:24-31.

75. In the balloon embodiment, a hypotube is attached to a balloon that encircles the proximal end of the flexible tube. This embodiment is shown in Figures 3 and 4, where the balloon is inflated, and Figures 5 and 6, where the balloon is deflated, of Adams.

76. The excerpt of Adams Figure 3 below shows an inflated balloon 170 pressing against the internal wall of the guide catheter 12A:



77. The excerpt of Adams Figure 5 below shows a deflated balloon inside the guide catheter:



78. Both the funnel and balloon embodiments of Adams are used to fill the space between the guide catheter's cross-sectional inner diameter and the flexible tube's cross-sectional inner diameter, as can be seen in Figure 4 of Adams, which depicts flexible tube 32A inside guide catheter 12A in the balloon embodiment:

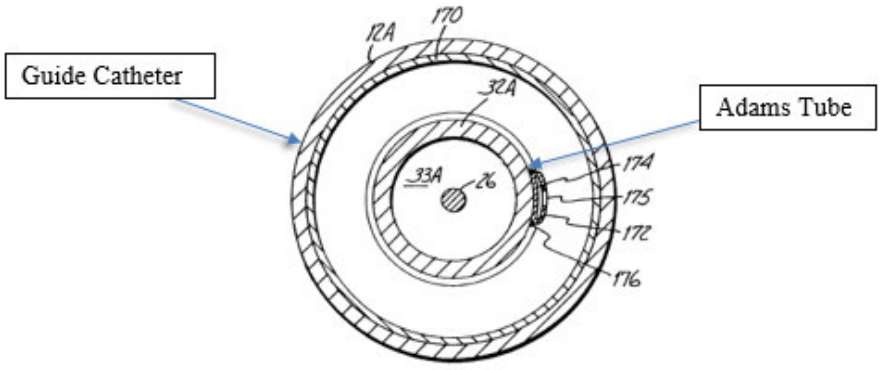


Fig. 4

79. The balloon and funnel also form a seal with the guide catheter, for drug delivery and thrombus aspiration, Merrill Dec., Ex. 29, at 6:31-35, 7:52-65, as Mr. Brown confirms, O'Rear Ex. 2 (Brown Dep. at 248-50).

80. Adams describes the pushrod as an "elongated wire 34 … of small diameter, preferably 0.010 to 0.016 of an inch in diameter," Merrill Dec., Ex. 29, at 6:14-18, *see id.* at 7:19-21; 15:17-18). At least at the smaller end of the diameter ranges provided, e.g., a 0.010 inch diameter pushrod, the pushrod would be pretty flexible. Further, the distal end of the pushrod is flattened, regardless of whether it attaches to the funnel, *id.* at 15:17-24, or the balloon, *id.* at 7:22-24.

B. Adams Does Not Disclose "A Segment Defining A Side Opening."

81. Unasserted claim 52 of the '116 patent, from which asserted claim 53 depends, recites "a segment defining a side opening."

82. I understand that the Court has ruled that the phrase "segment defining a side opening" should have its plain and ordinary meaning. It is my opinion that the plain meaning of the phrase "segment defining a side opening" is that the opening has some amount of side exposure where the opening transitions into the fully circumferential portion, and that that phrase should not be read to refer to a segment that consists only of full circumference structure with an opening that is fully perpendicular to the axis of the device.

83. The proximal opening for each of Adams's funnel and balloon embodiments is oriented perpendicularly to the longitudinal axis of a guide catheter. Adams has no disclosure that the proximal end of the flexible tube is oriented in any other manner. It is my opinion that, because the Adams's funnel and balloon have no side exposure where the opening transitions into the fully circumferential portion, and instead are perpendicular to the device's axis, it is

unreasonable to call them side openings. For the same reason, Adams does not disclose a segment defining a side opening.

C. Rigidity Comparisons

84. Claim 53 of the '116 patent recites that "the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure."

85. Because the Adams device was never commercialized, there is no actual device to test. Accordingly, any such comparison must rely on the patent's disclosure. Adams discloses that its funnel is flexible: "[T]he funnel 260 is sufficiently flexible to allow the extension 250 to be slidably advanced through the guide catheter without significant friction." Merrill Dec., Ex. 29, at 16:10-12. This implies that the funnel may be quite thin, thinner than the tube, which would add to flexibility no matter how it was measured. Adams says nothing about the funnel being rigid or more rigid than anything, such as the flexible tube, nearby. I note that the funnel is not reinforced with a coil, while the flexible tube is. The coil runs the entire length of Adams's distal tube, including over the end tip 255a shown in Figure 9 above:

> An end tip *255a* is formed by wicking cyanoacrylate adhesive between the inner and outer layers 267 and 268 and coil spring 266 to assure that the inner and outer layers 267 and 268 of the tip do not separate from the coil spring 266 as the extension 250 is advanced for use and treatment.

Id. at 14:48-52. The distal tube of Adams would be more rigid with that coil than without it. It is unclear how much rigidity the flattened pushrod's distal end would add to the funnel, especially in comparison to the tube's coil.

86. Adams provides no information regarding the flexibility or rigidity of the funnel, coil, distal tube, and the flattened portion of the pushrod embedded in the funnel and in the tube, nor does Adams provide any information as to their relative flexibilities or rigidities. Thus, it is

not possible to reach a definitive conclusion as to the relative flexibilities of these portions of the device.

V. INDEFINITENESS

87. I have been informed that a patent claim is indefinite and therefore invalid if the language of the claim, when read in light of the specification of the patent and the prosecution history, fails to inform a person of ordinary skill in the art with reasonable certainty about the scope of the claim.

88. The asserted VSI patents contain claim language that requires a transition in rigidity from the more rigid proximal end to the more flexible distal end of the guide extension catheter. It is my opinion that a person of ordinary skill would have understood the teachings in the VSI patents regarding the portions of, and transitions between the portions of, the guide extension catheters described and claimed by VSI. In the field of interventional cardiology, devices may have discrete parts, but the materials and structures that make up each part often overlap. Abrupt transitions from one material to another, or from one structure to another, are typically undesirable because they can form weak points where the device may kink or break under stress. It is preferable to have a smooth transition and a more uniform distribution of strain. For example, a standard coronary guidewire has a more flexible tip than the rest of the guidewire, with the transition taking place gradually over several centimeters. Similarly, a person of ordinary skill in the art might describe the device as having a more rigid part and a more flexible part even though it is difficult to pinpoint precisely where the device goes from "rigid" to "flexible."

89. I understand that the Court has construed "substantially rigid" to mean "rigid enough to allow the device to be advanced within the guide catheter." Doc. 102 at 15. It is my opinion that this phrase is not indefinite because a person of ordinary skill would understand the

phrase and its construction, and could test a device to evaluate whether the "substantially rigid portion" of the device meets this limitation. I understand that Mr. Brown agrees that a person of ordinary skill can test a device to see if it meets the Court's construction, and that Mr. Brown does not contest that the Boosting Catheter meets this limitation. O'Rear Ex. 2 (Brown Dep. at 10, 51).

90. I understand that QXM argues the claims of VSI's patents are invalid because the term "substantially rigid" is indefinite, and that QXM's argument rests on the factual premise that the Boosting Catheter's tubular section is rigid enough to allow the device to be advanced within the guide catheter, thus meeting the Court's construction of "substantially rigid."

91. It is my opinion that, in the field of interventional cardiology, the terms "substantially rigid" and "flexible" are not mutually exclusive. I disagree with the notion that no device or material can be both substantially rigid and also flexible. As the Court noted in its claim construction order, the substantially rigid portion "must have a considerable degree of flexibility" or else it would be unable to navigate safely through a patient's vascular system. Doc. 102 at 13. This would be readily apparent to a person of ordinary skill in the art of designing and manufacturing interventional cardiology devices. Any such person would understand that a device must be flexible enough not to harm the patient when used, even if it is substantially rigid for some purposes.

92. The claim language itself states both that the substantially rigid portion is only "substantially" rigid, which means that it has some flexibility, as the Court recognized previously. Doc. 102 at 13-14.

93. My opinion on this point is supported by the testing I did to determine whether the Boosting Catheter infringes the asserted claims. In that testing, I determined that the

Boosting Catheter's pushrod is considerably more rigid (less flexible) than its tubular structure. For example, in a two-point bend test with fixed parameters, the distal tubing of the six French Boosting Catheter measured 19.38-29.10 gf (grams force) in the proximal section and 12.5-16.41 gf in the distal section. The pushrod of the Boosting Catheter measured 53.33-69.33 gf in the same tests, somewhat more than twice the rigidity of the proximal section of tubing and almost four times as rigid as the distal section. *See* Merrill Dec., Ex. 23, Appendix D. These tests confirm that there is a significant difference in rigidity between the "substantially rigid" and "flexible" portions of the Boosting Catheter.

94. I understand that QXM's expert, Mr. Brown, performed two tests regarding the pushability of the Boosting Catheter's distal tubing to support his view that the claims are indefinite. In the first test, he constructed a full-length child catheter by linking together several segments of the distal tubing over a PTFE liner. He then pushed the full-length device down a guide catheter inside a heart model. In the second test, Mr. Brown removed the proximal end of a Boosting Catheter including the handle, strain relief, and the first 30 centimeters of the pushrod. Mr. Brown then reversed the device and, gripping the distal tubing, pushed the pushrod down the guide catheter inside a heart model. As I understand it, Mr. Brown intended these tests to show that the distal tubing section of the Boosting Catheter is both "flexible" and "substantially rigid."

95. Mr. Brown's tests are contrary to the description of VSI's invention in the specification and the prosecution history. The context of the invention makes clear that it is a rapid-exchange guide extension catheter—a tubular section attached at the distal end of a pushrod, which (as the Court explained in its claim construction order) is the "substantially rigid" portion referred to by the claims. The invention is not a full-length child catheter for a

mother catheter, or a reversed rapid-exchange catheter to be advanced pushrod-first into a guide catheter.

96. Mr. Brown's tests are also contrary to the claim language. All of the asserted claims contain limitations making clear that the claimed device is neither a child catheter nor a reversed rapid-exchange catheter, as in Mr. Brown's tests. The independent claims of the VSI patents contain numerous limitations that relate to the claimed substantially rigid portion or segment that the tubular structure fabricated and tested by Mr. Brown does not meet.

97. For example, Mr. Brown's fabricated tubular structure does not meet the limitations of claim 1 of the '032 patent, claim 1 of the '413 patent, or claim 1 of the '380 patent that recite that the substantially rigid portion:

- be "proximal of [and] operably connected to … the flexible tip portion";
- be "more rigid along a longitudinal axis than the flexible tip portion ";
- "defin[e] a rail structure without a lumen"; and
- "hav[e] a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion."

98. In particular, Mr. Brown's test devices specifically contradict the requirement in the '032, '413, and '380 patents that the substantially rigid portion define "a rail structure without a lumen." In both examples, the would-be "substantially rigid portion" is the distal tubing section of the Boosting Catheter. Even though the parties disagree about what constitutes a lumen and whether the Boosting Catheter's substantially rigid portion has one, I do not understand either party to believe that the distal tubing section of the Boosting Catheter lacks a lumen. Accordingly, Mr. Brown's test devices contradict that requirement of the claims.

99. Similarly, the asserted claims of the '760 require that the "substantially rigid" portion of the device be located proximal of a "segment defining a side opening" and a "tubular

structure" and the side opening and tubular structure must be "configured to receive" interventional cardiology devices.

100. The '776 claims require a similar structure, with the "substantially rigid segment" proximal to a "partially cylindrical opening" and a "tubular structure" with the partially cylindrical opening "configured to receive" interventional cardiology devices while positioned inside the guide catheter.

101. The '116 claims also call out a "substantially rigid segment," a "segment defining a side opening," and a "tubular structure," and further require that a balloon catheter or stent pass "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."

102. Mr. Brown's full-length child catheter and reversed rapid-exchange catheter do not meet the required elements of the claims. The substantially rigid portion cannot *be* the tubular section if it also must be located proximal of the side opening and tubular section. And the interventional cardiology devices must pass alongside the "substantially rigid segment" and then pass into and through the side opening and tubular structure, which again is not possible in Mr. Brown's modified devices.

103. In addition, I had an opportunity to examine the device that Mr. Brown constructed as a full-length child catheter. I noted several differences between the device and the representation that the device was of the same structure as the current distal tubular portion of QXM's Boosting Catheter. First, it appears that the test device contains an additional tubular element inside the Boosting Catheter's Teflon (PTFE) liner. As noted above, QXM adds a Teflon patch to its segment defining a side opening to stiffen that segment. This additional

PTFE layer would increase Mr. Brown's device's longitudinal stiffness, and renders his test inapplicable. Second, the segments joined appeared to be heat-fused in some manner, resulting in a dimensional increase. Third, the device presented to me had been destroyed in a tensile manner (pulled apart), making it difficult to discern any other differences that may have been present. The full-length catheter Mr. Brown constructed is not representative of the Boosting Catheter. My review of the device was relatively brief, so it is possible there may have been other differences as well between the structure of the tested device and the structure of the distal tubular portion of QXM's Boosting Catheter.

104. That Mr. Brown was able to advance his full-tube devices through a slightly bigger guide catheter proves little. A fully tubular device has less room to buckle and gains support from the walls of the guide catheter, whereas a more slender pushrod would need more rigidity to provide pushing power without buckling. And even though Mr. Brown used an 8F guide catheter for his test, the guide catheter was a much closer fit around the Boosting Catheter tubing—and provided more support—than a 6F guide catheter around the pushrod of a Boosting Catheter or GuideLiner.

105. Ultimately, neither of Mr. Brown's tests show that something described or claimed in the patents as "flexible" is rigid enough to form a pushrod that can advance a rapid exchange catheter through a guide catheter. Mr. Brown's attempts to show that the Boosting Catheter's distal tubing section is "substantially rigid" contradict the whole thrust of the patents, which is to provide a rapid-exchange guide extension catheter having a distal tubing section and a pushrod.

VI. RECAPTURE

106. I understand that QXM argues the asserted claims of the '760, '776, and '116 patents are invalid for recapture of surrendered subject matter because they do not contain the

"without a lumen" limitation that is present in the original '032 and '413 patents and was present in the '850 patent, from which the reissue patents descend. I disagree that the asserted claims of the '760, '776, and '116 patents are invalid for recapture of surrendered subject matter.

107. QXM argues that the "without a lumen" requirement was added to the claims of the original patents during prosecution in order to avoid prior art. I disagree. Prior to the addition of "without a lumen," the "substantially rigid portion" element read as follows:

> a substantially rigid portion proximal of and operably connected to the flexible tip portion and defining a non-tubular structure having a maximal cross-sectional dimension at a proximal portion that is non-circular and smaller than the cross-sectional outer diameter of the flexible tip portion . . . .

Merrill Dec., Ex. 13, at 3. The examiner rejected the claims over the Solar and Niazi prior art and on the grounds that the "non-tubular" and "non-circular" limitations lacked written description support. Merrill Dec., Ex. 14, at 2-4. VSI then amended the claims to remove the "non-tubular" and "non-circular" limitations and added the requirement that the substantially rigid portion be "more rigid along a longitudinal axis than" the flexible tip portion:

> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a ~~non-tubular~~ structure having a maximal cross-sectional dimension at a proximal portion that is ~~non-circular and~~ smaller than the cross-sectional outer diameter of the flexible tip portion . . . .

Merrill Dec., Ex. 15, at 3. Following an examiner's amendment to add "rail structure without a lumen," the examiner withdrew the rejections and allowed the claims to issue. Merrill Dec., Ex. 16, Notice of Allowance at 2. The "substantially rigid portion" in the allowed claims reads, with the language added by the Examiner underscored:

> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and 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 . . . .

108. I do not believe the "without a lumen" requirement was added to avoid prior art. The pending rejection over prior art was based on a combination of Solar with Niazi. Niazi teaches a full-length over-the-wire catheter that lacks a pushrod or rail structure of any kind. To meet the "substantially rigid portion" limitation, the examiner relied on Solar, which describes a catheter having an "advancement member" that is "formed of a flexible wire or, alternately, of spring hollow hypotubing." Merrill Dec., Ex. 18, at ¶25; *see* Merrill Dec., Ex. 14, at 3-4.

109. The Solar Publication generally describes the invention as follows:

> According to the invention, an enhanced balloon dilatation delivery system comprises an elongated advancement member which optionally terminates in a tubular tracking member, an inflatable dilatation balloon having proximal and distal ends and being in fluid communication with an inflation channel, and means for aligning the advancement member and the inflation channel.

Merrill Dec., Ex. 18, at ¶14. Figures 1 (annotated) and 12 below illustrate the invention of the Solar Publication:

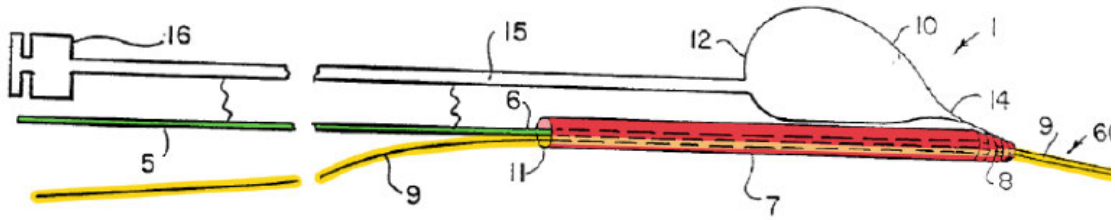


FIG. 1

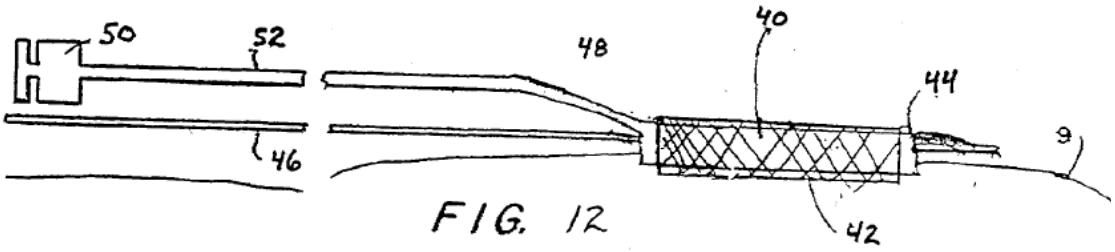


FIG. 12

110. The apparatus disclosed by the Solar Publication includes an "advancement member 5" (in green above) attached at its distal end to a tubular tracking member 7 that acts as

a pushrod. *Id.* at ¶¶25-27. "Preferably advancement member 5 is formed of a flexible wire or, alternately, of spring hollow hypotubing" and has a "diameter of from about 0.008" to 0.035." *Id.* at ¶ 25. The "advancement member 5 has sufficient column strength and flexibility" to be able to advance the device through tortuous anatomy. *Id.* Moreover, the advancement member 5 is "rigid at its proximal end and becomes increasingly more flexible as it extends distally." *Id.* The solid wire that Solar discloses for use as a pushrod does not have a lumen, under any interpretation of that term.

111. Because Solar discloses that its advancement member may be made of "a flexible wire"—i.e., a solid structure—the addition of "without a lumen" would not have been intended by VSI or understood by the examiner to avoid the Solar prior art. This is supported by the examiner's statement of the reasons for allowance, which states that "the arrangement of a claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art." Merrill Dec., Ex. 16, Notice of Allowance at 2. The examiner made no mention of the "without a lumen" requirement.

112. It is my opinion that the "rail structure without a lumen" requirement was added to make clear that the device is a rapid-exchange catheter, with a tubular section forming a lumen large enough to pass interventional cardiology devices and a substantially rigid portion that does not have such a lumen because it is merely a pushrod.

113. Because the "without a lumen" requirement was not added to avoid prior art, it is my opinion that VSI's reissue patents lacking that limitation do not improperly recapture any surrendered claim scope, and therefore are not invalid for improper recapture.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 29, 2019

Peter T. Keith