UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AURIS HEALTH, INC.
Petitioner,

v.

INTUITIVE SURGICAL OPERATIONS, INC.
Patent Owner.

Patent No. 6,800,056

Inter Partes Review No. IPR2019-01189

Petition for *Inter Partes* Review of
U.S. Patent No. 6,800,056

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Petitioner's Mandatory Notices

I. REAL PARTY IN INTEREST (§42.8(B)(1))

Auris Health, Inc. is a real party in interest pursuant to § 42.8(b)(1). Auris Health, Inc. is a wholly owned subsidiary of Ethicon, Inc., which is a wholly owned subsidiary of Johnson & Johnson. Both Ethicon, Inc. and Johnson & Johnson also are real parties in interest.

II. OTHER PROCEEDINGS (§42.8(B)(2))

A. Patents and Applications

U.S. Patent No. 6,800,056 ("the '056 patent" (Ex.1001)) is related to the following issued patents or pending applications:

- U.S. Patent No. 6,610,007
- U.S. Patent No. 6,468,203
- U.S. Patent No. 6,837,846
- U.S. Patent No. 6,858,005
- U.S. Patent No. 6,869,396
- U.S. Patent No. 6,890,297
- U.S. Patent No. 6,974,411
- U.S. Patent No. 6,984,203
- U.S. Patent No. 7,044,907
- U.S. Patent No. 7,087,013

- U.S. Patent No. 8,062,212
- U.S. Patent No. 8,226,546
- U.S. Patent No. 8,517,923
- U.S. Patent No. 8,641,602
- U.S. Patent No. 8,721,530
- U.S. Patent No. 8,827,894
- U.S. Patent No. 8,834,354
- U.S. Patent No. 8,845,524
- U.S. Patent No. 9,138,132
- U.S. Patent No. 9,427,282
- U.S. Patent No. 9,808,140
- U.S. Patent No. 10,105,036
- U.S. Appl. No. 14/833,921
- U.S. Appl. No. 14/833,921
- U.S. Appl. No. 15/229,177

B. Related Litigation

The '056 patent has been asserted in the following litigations:

- *Intuitive Surgical, Inc. v. Auris Health, Inc.*, Action No. 18-1359-MN (D. Del.) (pending).

C. Patent Office Proceedings

The '056 patent is not subject to any proceedings filed in the Patent Office.

I. LEAD AND BACKUP LEAD COUNSEL (§42.8(B)(3))

Lead Counsel is: Ching-Lee Fukuda (Reg. No. 44,334), clfukuda@sidley.com, (212) 839-7364. Back-Up Lead Counsel are: Thomas A. Broughan III (Reg. No. 66,001), tbroughan@sidley.com, (202) 736-8314, Sharon Lee, sharon.lee@sidley.com, (202) 736-8510) and Ketan Patel, ketan.patel@sidley.com, (212) 839-5854.[1]

II. SERVICE INFORMATION (§42.8(B)(4))

Service on Petitioner may be made by e-mail (at the email addresses above & SidleyAurisTeam@sidley.com). Petitioner's mail or hand delivery address is: Sidley Austin LLP, 1501 K Street, N.W., Washington, D.C. 20005. The fax number for lead and backup lead counsel is (202) 736-8711.

[1] Petitioner will file motions for Sharon Lee and Ketan Patel to appear *pro hac vice* according to the Board's orders and rules.

I. INTRODUCTION

The '056 patent is directed to a well-known method and apparatus for advancing a medical instrument, such as an endoscope, along an arbitrary path in the human body by using a slidable tracking rod or guide within a channel of the instrument. In its normal state, the guide is flexible and can follow a curve or path in the body as defined by a steerable distal portion of the instrument. The guide can also be selectively rigidized to adopt a curve or path such that the instrument can be advanced over the rigidized guide in a monorail or "piggy-back" fashion. This process allows the instrument to navigate around bends without exerting excessive or potentially dangerous forces on the patient's body.

This type of apparatus for advancing a medical instrument was well known before the priority date of the '056 patent. For example, a near identical instrument was first described in a 1993 paper by Robert H. Sturges and Schitt Laowattana titled "A Flexible, Tendon-Controlled Device for Endoscopy." ("Sturges" (Ex.1004)). Sturges describes a flexible instrument that uses a selectively rigidized spine to guide the instrument through a passageway. The spine and the flexible instrument are incrementally advanced relative to one another by repeatedly (1) advancing the flexible spine, (2) rigidizing the spine, (3) advancing the instrument using the rigid spine as a guide, and (4) relaxing the spine. This "slide motion" scheme teaches or renders obvious all of the elements of the independent claims of the '056 patent (as

well as most dependent claims) and was not considered during prosecution of the '056 patent.

A similar apparatus was also described in U.S. Patent No. 5,251,611 to Zehel ("Zehel" (Ex.1005)). Zehel describes a flexible steerable medical instrument, such as an endoscope, containing an inner and outer conduit, which are used to insert the instrument into a patient. Like Sturges, insertion of the Zehel instrument comprises a repeating process comprising (1) advancing a flexible conduit, (2) rigidizing that conduit, (3) advancing a second flexible conduit using the rigidized first conduit as a guide, and (4) relaxing the first conduit. To the extent Sturges does not teach or render obvious every independent claim of the '056 patent, those claims would have been obvious to a person of ordinary skill in the art ("POSA") based on Sturges in view of Zehel. To the extent Sturges does not teach every limitation of the dependent claims, the claims would have been obvious to a POSA based on Sturges (with or without Zehel) in view of additional references.

Petitioner respectfully requests the Board to institute *inter partes* review of the '056 patent claims.

II. REGULATORY INFORMATION

A. Certification that Petitioner May Contest the '056 Patent (§ 42.104(a))

Petitioner certifies that the '056 patent is available for IPR, and that Petitioner is not barred or estopped from requesting an IPR of the '056 patent claims. Neither

Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '056 patent. The '056 patent has not been the subject of a prior IPR by Petitioner or a privy of Petitioner.

Petitioner also certifies this petition for *inter partes* review is timely filed as this petition was filed less than one year after September 4, 2018, the date Petitioner was first served with a complaint alleging infringement of a claim of the '056 patent. *See* 35 U.S.C. § 315(b); Ex.1001.

B. Identification of Claims Being Challenged (§ 42.104(b))

Claims 1, 3-8, 11-12, 14, 16-17, 22-26 and 32 are unpatentable based on the following art and grounds.

Prior Art Reference	Abbreviation
R.H. Sturges, Jr. and S. Laowattana, "A Flexible, Tendon-Controlled Device for Endoscopy," The International Journal of Robotics Research, Vol. 12, No. 2 (April 1993)	"Sturges" (Ex.1004)
U.S. Patent No. 5,251,611 to Zehel et al.	"Zehel" (Ex.1005)
R.H. Sturges, Jr. and S. Laowattana, "A Voice-Actuated Tendon-Controlled Device for Endoscopy," Computer-Integrated Surgery, Technology and Clinical Applications (1996)	"Sturges II" (Ex.1006)

Ground	35 U.S.C. §	Claims	Prior Art Reference(s)
1	103(a)	1, 5-8, 11-12, 14, 16-17, 22-26, 32	Sturges and Zehel
2	103(a)	3, 4	Sturges and Sturges II

Petitioner's positions are supported by the Declaration of Blake Hannaford Ph. D. (Ex.1003), an expert in telerobotic surgery who has over 20 years of experience in the field. Ex.1003, ¶¶2-8.

C. Fee for *Inter Partes* Review (§ 42.15(a))

The Director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 50-1597.

III. BACKGROUND

A. Background Technology

Steerable medical instruments such as endoscopes have long been used in a variety of diagnostic and interventional procedures, including colonoscopies, bronchoscopies, thoracoscopies, laparoscopies, and video endoscopies. *See, e.g.*, Ex.1001, 1:20-21-25; *see also id.*, 1:57-63 (describing art known at time of the invention); *id.*, Fig. 1; Ex.1004, 121 (citing art known in 1993); Ex.1003, ¶47. These instruments typically employ a flexible hose or conduit through which a variety of diagnostic and therapeutic tools can be deployed. Ex.1001, Fig. 1; Ex.1004, 122; Ex.1003, ¶47.

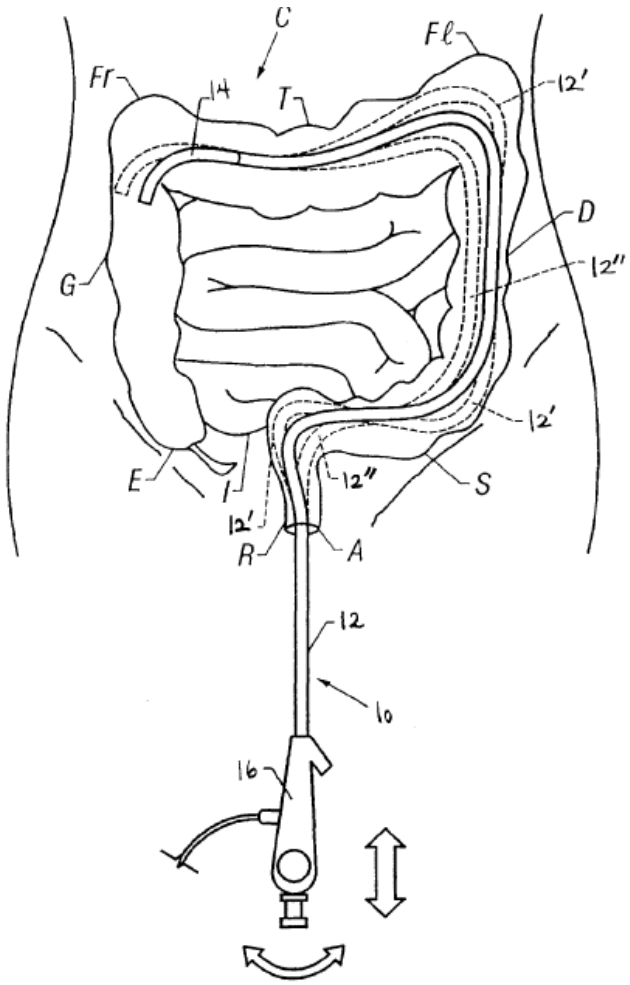

FIG. 1
(Prior Art)

During use, these instruments may be inserted into a patient's mouth, colon, or surgically prepared opening and can be steered in multiple directions (up/down and left/right) using a set of proximally-mounted manual controls or via an automatic steering system. Ex.1001, Fig. 1; Ex.1005, 1:14-21; Ex.1004, 122; Ex.1003, ¶48.

When inserted, the instrument can often be impeded by the peristaltic action of the body (the radial and symmetrical contraction of muscles in the esophagus, stomach, small intestine and colon for pushing food or other objects through the

digestive tract), which may attempt to expel the instrument. Ex.1004, 122; Ex.1003, ¶49. To prevent damage to any internal diagnostic and therapeutic tools, the instrument must be sufficiently stiff to avoid unwanted buckling/bending when inserted against the resistive forces of the body. Ex.1005, 2:41-45; Ex.1003, ¶49.

However, the instrument can itself apply unwanted and sometimes dangerous pressure to the patient, especially when advanced longer distances and when following curves of the body lumens. Ex.1005, 2:16-20; Ex.1003, ¶49. When traversing a curve, any forward or backward motion of the instrument can exert pressure on the cavity wall. Ex.1005, 2:21-23. As a result, a certain degree of mechanical flexibility is desired to prevent injury to patients because of these potentially damaging interacting forces. *Id*. One well-known technique for maintaining the necessary flexibility of the instrument while also providing sufficient structural support is the use of guides or spines. Ex.1004, 123; Ex.1005, 3:9-17; Ex.1003, ¶50. These guides can selectively be made flexible or stiff to provide support against which flexible portions of the instrument may push in order to prevent dangerous pressure from or on the instrument. Ex.1004, 123; Ex.1005, 3:9-17; Ex.1003, ¶50. Accordingly, the instrument can be fed into a patient by alternately relaxing, sliding, and stiffening the conduit and the guide with respect to one another while directing the distal end of the instrument toward the target location. Ex.1004, 123-24; Ex.1005, 3:33-38; Ex.1003, ¶50.

B. Summary of the '056 Patent

The '056 patent is directed to a guiding apparatus for a steerable instrument. As shown below in Figure 2, the steerable instrument (20) comprises an elongate body (21) (identified in green below) with a manually or selectively steerable distal portion (24) (in red) and an externally controlled and manipulatable tracking rod or guide (36) (in blue). Ex.1001, 7:17-24.

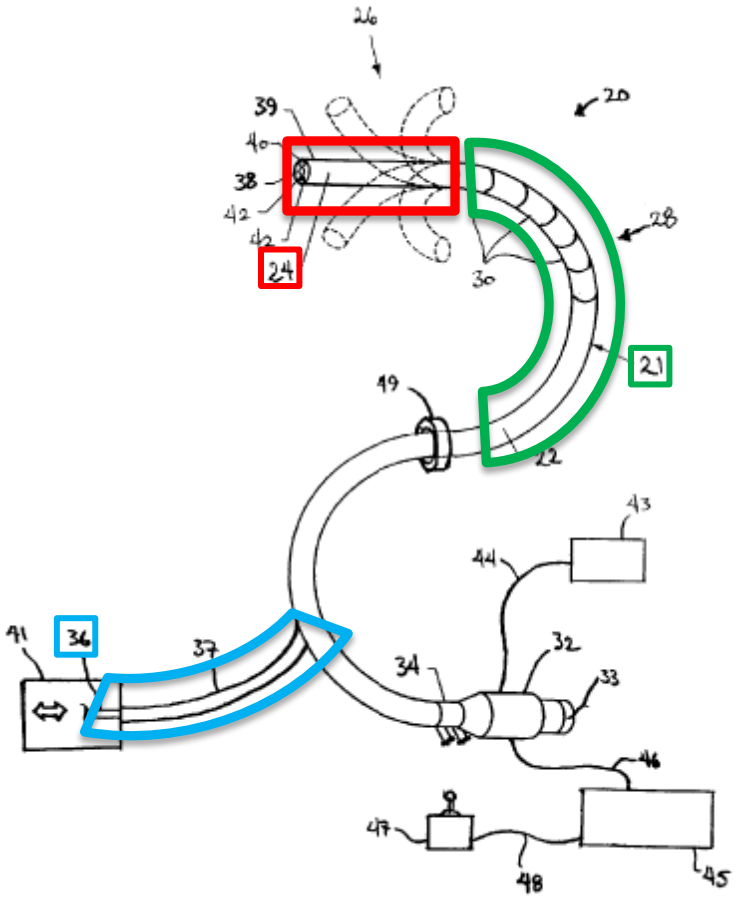

FIG. 2

As shown below in Figure 3A, the '056 patent describes that this guide (36) may be slidably positioned within a guide channel or lumen (50) (in green) of a

medical instrument or externally such that the guide (36) and the instrument may slide relative to one another along a rail or channel located along the external surface of the instrument. Ex.1001, Abstract; *id.*, 2:8-13.

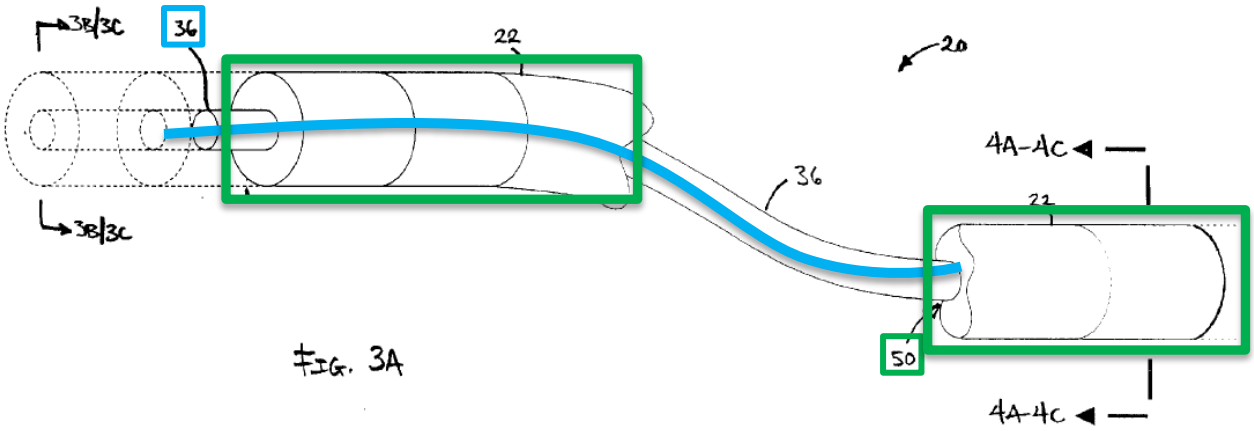

FIG. 3A

When the guide (36) is in a flexible state, it can follow a curve or path defined by the steerable distal portion (24). *Id*. The guide (36) can then be selectively rigidized to adopt and maintain that curve or path. *Id*. Once it has been made rigid, the guide (36) imparts the desired curvature initially defined by the steerable distal portion (24) onto the elongate body. Ex.1001, 9:25-28. Figure 9C, reproduced below, shows that the guide may be comprised of individual segments having a uniform sleeve section (102, 104) in combination with an integrated curve or hemispherical section (106).

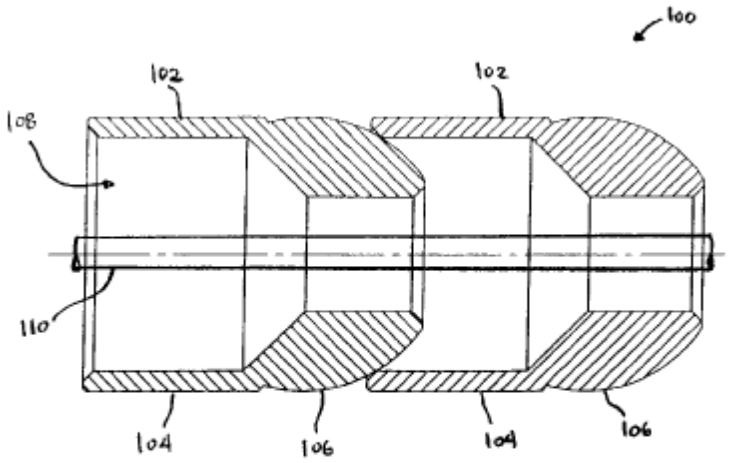

Fig 9C

Alternatively, Figure 10, reproduced below, illustrates an alternate construction of the guide wherein the individual segments are comprised of spherical bead segments (122) alternating with sleeve segments (124).

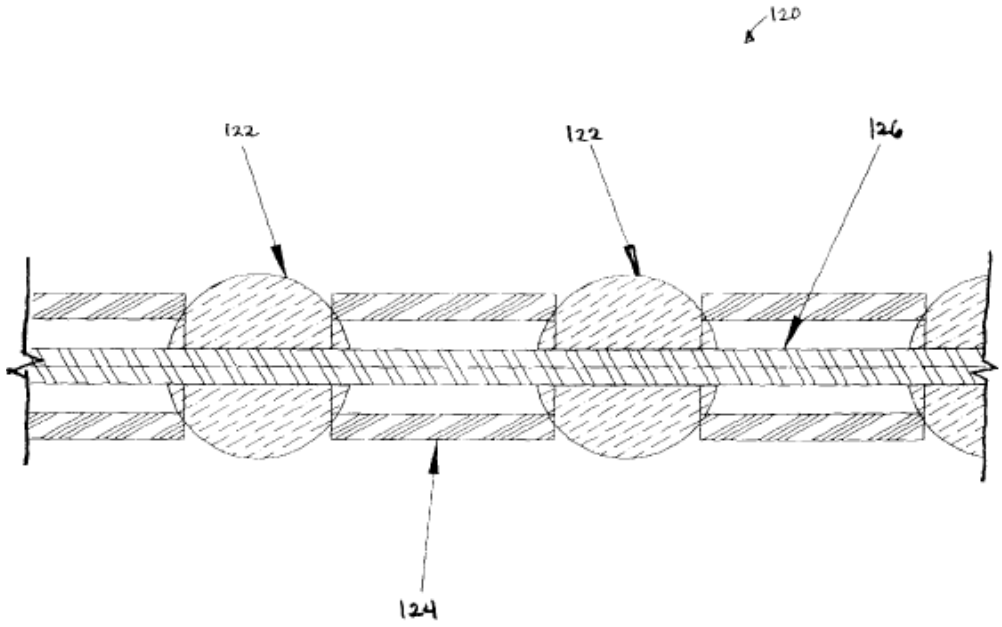

FIG. 10

The specification describes the operation of the claimed medical instrument as follows. First, the steerable distal portion (24) of the instrument (20) may be advanced into a patient's body cavity (*e.g.* rectum), either manually or automatically by a motor, until a first curvature is reached. Ex.1001, 14:15-20. At this stage, the physician or surgeon can control the steerable distal portion to attain an optimal curvature or shape to navigate around the curve. Ex.1001, 14:20-23. Once this curvature has been determined, physician may advance the guide in its flexible state along the instrument until it reaches a distal position. Ex.1001, 14:34-39. Prior to advancing the instrument (20) over the guide (36), the guide (36) may be left in its flexible state or it may be optionally rigidized. Ex.1001, 14:45-47. When rigidized, the guide maintains its position such that the instrument may then be advanced over the guide in a "piggy-back" fashion where the flexible proximal portion follows the curve formed by the guide until the instrument reaches the next point of curvature. Ex.1001, 14:52-56. This operation can be repeated to incrementally advance the instrument to the target location.

To withdraw the instrument, the procedure described above may be reversed to minimize unnecessary contact with the cavity walls. Ex.1001, 15:57-60. Alternatively, the guide may simply be removed while leaving the instrument within the cavity. Ex.1001, 15:60-62.

C. Prosecution History

The ’056 patent issued from Application No. 10/087,100, filed on March 1, 2002. In a June 25, 2003 Office Action, the Examiner rejected both independent claims (1 and 14) and dependent claims 5-12, 16-17, 22-26, 31 and 32 as being anticipated by U.S. Patent No. 5,759,151 to Sturges (“the Sturges ’151 Patent”) (Ex.1007)). Ex.1002, 149-152. The sole named inventor of the Sturges ’151 Patent is also one of the co-authors of the Sturges article (Ex.1004) and textbook chapter (Ex.1006) at issue in this Petition. Both of the Sturges references at issue in this Petition, however, disclose variations on the instrument and procedure described in the Sturges ’151 Patent.

In response to the Office Action, the applicant attempted to traverse the rejection arguing that, while the claims of the ’056 patent require a guide which is “**freely slidable through the device**,” the distal end of the guide described in Sturges ’151 Patent has a maximum and minimum limit of travel which restricts the movement of the guide through the instrument. Ex.1002, 167-68. Citing Figure 1 of the Sturges ’151 Patent (reproduced below), the applicant noted that “the distal end 4 [of the guide in the Sturges ’151 Patent (identified in blue below)] has a **maximum limit of travel** wherein the distal end 4 is inserted into the steerable tip 12 [(in red) and] a **minimum limit of travel** wherein the distal end 4 [can only be] retracted

from the steerable tip 12 into the conduit 10 [(in green)]." Ex.1002, 167-68 (emphasis in original).

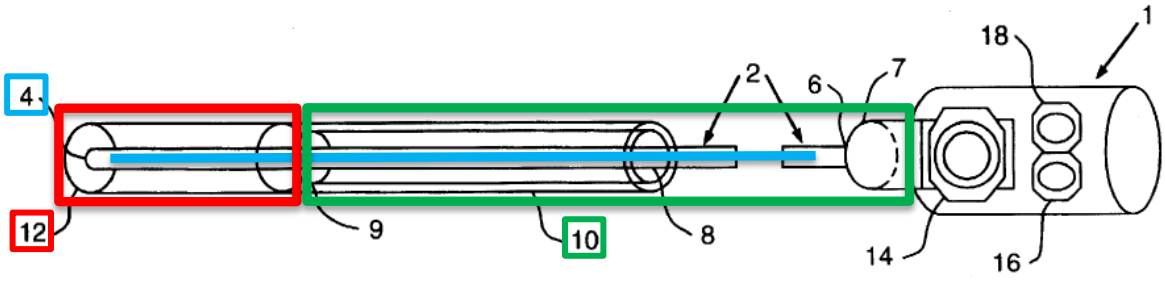

FIG. 1

As a result, the applicant argued, the "Sturges ['151 Patent] fails to recite the feature of having a guide which is freely slidable through the device, as recited in the claims." Ex.1002, 167.

Following an interview, the Examiner allowed the claims after the applicant authorized an amendment to further differentiate the '056 patent invention over the Sturges '151 Patent by clarifying that "the guide of the instant invention [is] freely slidable and [is] capable of unconstrained movement along the entire length of the instrument, rather than in a particular area, as in the device of [the Sturges '151 Patent]." Ex.1002, 174-76 (amending claim 1 to recite "wherein the elongate guide is freely slidable along the length of the instrument" and claim 14 to recite "the guide being slidably disposed without constraint within the lumen along the length for selectively supporting the body") (amended language underlined). In the reasons for allowance, the Examiner noted that the "spine 2 [of the Sturges '151 Patent] was

contained within the distal portion of the device (the steerable tip 12) as depicted in the Figures and as described at col. 3, lines 52-57 of [the Sturges '151 Patent]. However, as broadly as claimed, although the spine 2 of [the Sturges '151 Patent] was confined to a particular area of the device, it appeared to be able to move freely within that area or, in other words, was unconstrained within that area." Ex.1002, 174-76. The Examiner concluded that, with the clarifying amendment, "independent claims 1 and 14 define the instant invention over the prior art of record." Ex.1002, 176.

D. Person of Ordinary Skill in the Art

A POSA would have been a person with a good working knowledge of robotics and medical devices such as endoscopes. That knowledge would have been gained by an undergraduate education in electrical engineering, mechanical engineering, robotics, biomedical engineering, or a related field of study, along with about two years of experience in academia or industry studying or developing robotics or medical devices such as robotic surgical systems or endoscopes. Ex.1003, ¶30. This description is approximate; varying combinations of education and practical experience also would be sufficient. *Id.*

IV. CLAIM CONSTRUCTION

Claims "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b),

including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Claim construction requires consideration of "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314 (citations omitted); *see also Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015). The specification is "usually" dispositive and "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (citations omitted). Absent any special definitions, claim terms receive their "ordinary and customary meaning" as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

A. "freely slidable along the length of the instrument"/"guide being slidably disposed without constraint within the lumen along the length"

The terms "*freely slidable along the length of the instrument*" in independent claim 1 and "*guide being slidably disposed without constraint within the lumen along the length*" in independent claim 14 should be construed to mean that the

elongate guide is freely slidable and is capable of unconstrained movement along the entire length of the instrument.

The '056 patent states that "the guide is slidably disposed within the length of the endoscope body and may freely slide entirely through the passive proximal portion, through the controllable portion, and the steerable distal portion." Ex.1001, 4:64-67. Further, as described above, the applicant authorized the Examiner to amend the claims specifically to differentiate the instant invention over the Sturges '151 Patent because "the guide of the instant invention [is] freely slidable and [is] capable of unconstrained movement along the entire length of the instrument, rather than in a particular area, as in the device of [the Sturges '151 Patent]." Ex.1002, 174-176. The applicant noted that, in contrast to the alleged invention of the '056 patent, the distal tip of the Sturges '151 Patent's guide was restricted to a specific area. Ex.1002, 167 (citing Ex.1007, 3:52-57). This amendment reflects both the applicant's and the Examiner's shared understanding that the claimed guide of the '056 patent is freely slidable and is capable of unconstrained movement along the entire length of the instrument.

V. ANALYSIS OF THE PATENTABILITY OF THE CLAIMS

A. Ground 1 – Sturges and Zehel Render Claims 1, 5-8, 11-12, 14, 16-17, 22-26 and 32 Obvious

1. Summary of Sturges

Sturges was first published on April 1, 1993 in The International Journal of Robotics Research, Volume 12, Issue 2 as indicated on the document's face. Ex.1004, 121. Sturges is therefore prior art to the '056 patent under at least 35 U.S.C. § 102(b).[2] Sturges was published by The MIT Press, a reputable, well-known publisher of textbooks and academic articles affiliated with the Massachusetts Institute of Technology. Ex.1004, 2; Ex.1003, ¶61; *see Ericsson Inc. v. Intellectual Ventures I LLC*, IPR2014-00527, Paper 41, at 11 (May 18, 2015) (relying on statements in a document regarding its publication, where document was published by a well-known, reputable organization); *see also Oracle Am., Inc. v. Netapp, Inc.*, No. 2012-009493, 2012 WL 5387671, at *8 (P.T.A.B. Oct. 31, 2012) (affirming rejection of claims based on textbook published by The MIT Press). Additionally, a representative from the University of Wisconsin has attested that the College of Engineering Library, University of Wisconsin-Madison received a copy of the

[2] The '056 patent's earliest effective priority date is April 3, 2000, which is over a year after Sturges was published.

article on March 29, 1993 and that it was made available to library patrons shortly thereafter. Ex.1008, 2.

Sturges is directed to apparatus and methods for traversing a medical instrument, like the endoscope shown below in Figure 2, through a patient's anatomy. Ex.1004, Abstract.

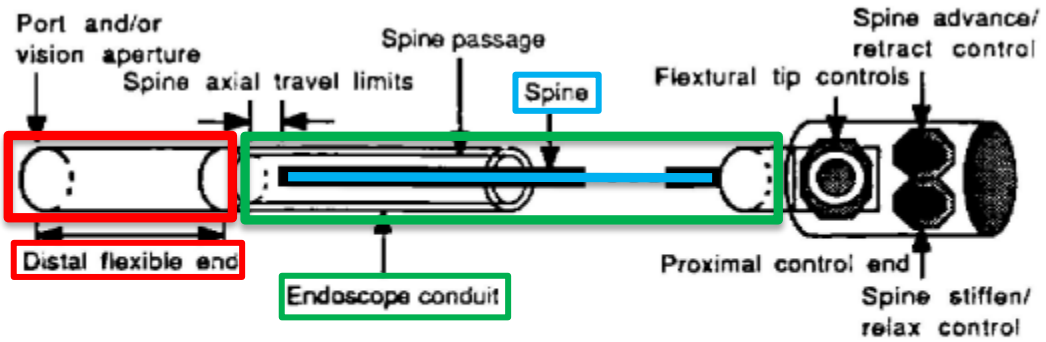

Fig. 2. Cross section of an endoscope with controllable stiffness spine.

Sturges describes that this proposed endoscope implements a "slide motion" scheme that allows for the advancement of an endoscope with a flexible distal end (identified in red above). Ex.1004, Abstract. This advancement is implemented via a series of relative motions between flexible outer conduit ("Endoscope conduit") (in green) and one or more intermittently stiff spines (in blue) inside the outer conduit. Ex.1004, Abstract.

Sturges notes that, at the time of publication, there were two general types of endoscopes: rigid and flexible. Ex.1004, 121. Rigid endoscopes are limited in the depth to which they can penetrate a curved lumen such as the colon. *Id.*; Ex.1003,

¶65. To obtain longer lengths of operation, more flexible endoscopes are required. *Id*. However, the stems of most flexible endoscopes are positionally uncontrollable over most of their length and, without modification, are unable to account for resistive forces in the body. *Id*.

Use of an endoscope is often impeded by the peristaltic action of the body, which is continuously attempting to expel the device. Ex.1004, 122. Further, involuntary motions of the body can create difficulties in acquiring a target and in using the array of diagnostic/therapeutic tools that are deployed through a channel in the stem. *Id*. The required flexibility, however, makes maneuvering the endoscope around bends extremely difficult. *Id*. The endoscope must be twisted and retracted to traverse these loops. *Id*. These twisting and retracting actions can cause high interacting forces between the endoscope and the surrounding tissue, and require great proficiency from the operator as well as a great deal of time. *Id*.

As described above, Sturges proposes a "slide motion" scheme comprising an endoscope stem with two major parts: (1) one or two spines, and (2) an endoscope conduit which acts as a covering tube for the spine(s). *Id*. Using a variety of control methods, the spine—which is comprised of a tendon bead chain—can be made temporarily flexible or temporarily rigid. In its rigid state, the spine can maintain the shape it held prior to being rigidized. Ex.1004, 123-24 ("the curve commanded by the master is copied by one or the other locking spines."). While the spine is in a

rigid state, the endoscope conduit can be advanced along the passageway while any reactive forces from the conduit are applied to the spine rather than the surrounding tissue. Ex.1004, 124 ("While the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine . . . using the spine as a guide.").

The controllable spine "consists of a set of cylindrical beads strung on a flexible cable." Ex.1004, 125. As shown in Figure 4, reproduced below, the bead chain contains a continuous cable through its center. All beads are free to rotate on adjacent beads around their centers but, in the presence of a cable tension force, these beads are compressed axially along the cable. Ex.1004, 125. As a result, "increasing the cable tension force creates friction forces between beads and ultimately increases the apparent stiffness of the entire bead chain." Ex.1004, 125.

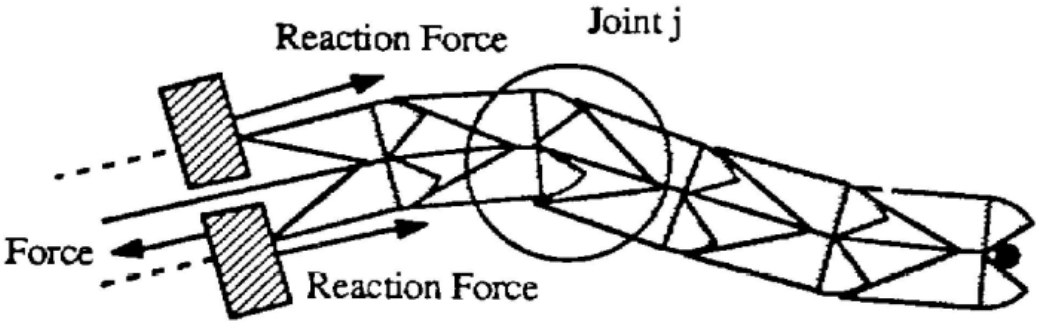

Fig. 4. Bead chain with a continuous cable.

Additionally, Figure 12, reproduced below, shows exemplary arrangements of a single spine instrument and a double spine instrument wherein the spines (identified in blue below) are arranged within or adjacent to the endoscope conduit (in green).

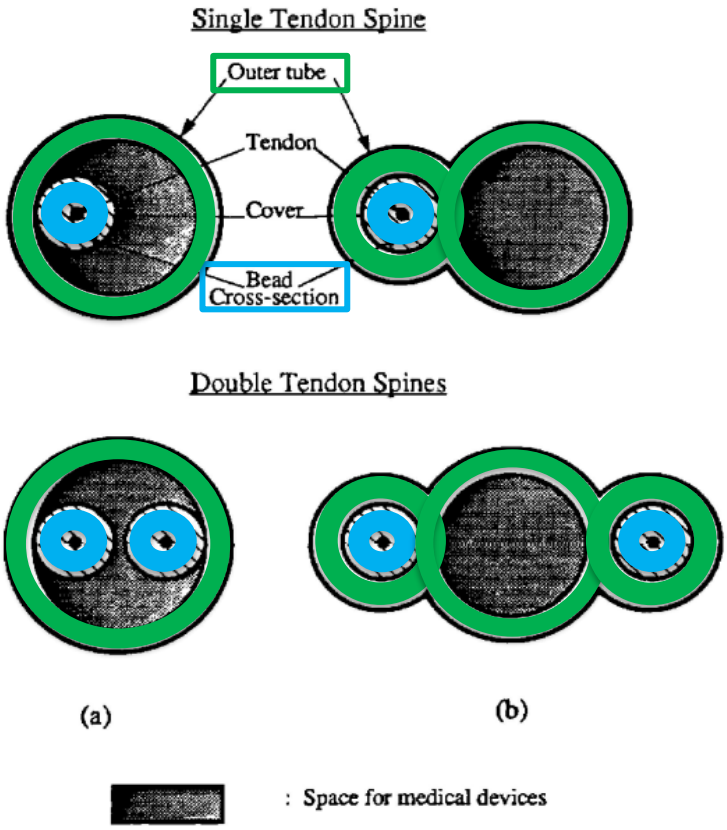

Fig. 12. Two arrangements for the single and double spines.

Ex.1004, 129.

The "distal end [of the endoscope] is flexed by the endoscopist to observe and point [the instrument] in the desired directions." Ex.1004, 123. To operate the device, Sturges describes that:

> [1] the spine is advanced manually or automatically to its maximum limit (about 5cm) and made rigid. [2] The conduit is then inserted manually into the colon up to the first substantial curve. [3] While the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine and within certain pre-determined axial travel

> limits, using the spine as a guide. [4] The flexible conduit is inserted further (again, either manually or automatically) at the same forward rate that the spine is retracted; thus, the spine is relatively stationary with respect to the patient's [anatomy]. When the incremental forward motion of the flexible conduit is complete, the spine is relaxed and pushed forward to its maximum limit.

Ex.1004, 124.

Thus, the spine is first advanced to its maximum limit while the flexible conduit remains stationary with respect to the patient, and then the flexible conduit is advanced while the spine remains stationary with respect to the patient. *Id*. In this manner, the relative advancement of the conduit and the spine can be repeated until the target location is achieved. *Id*. When the target location is acquired, the spine can be removed and replaced by other therapeutic/diagnostic tools, if the stable platform allowed by the stiffened spine is no longer required. *Id*. Further, the instrument can be removed by reversing the procedure described above. *Id*.; Ex.1003, ¶71.

2. Summary of Zehel

Zehel was filed on May 7, 1991 and published on October 12, 1993, more than one year before the '056 patent's earliest effective priority date. Zehel is therefore prior art to the '056 patent under at least 35 U.S.C. § 102(b).

Zehel is directed to methods and apparatus for conducting exploratory medical procedures using a flexible steering device. Ex.1005, Abstract. Specifically,

Zehel describes an apparatus which includes "a flexible steerable device which may alternately be stiffened along its entire length or a portion thereof and relaxed in order to effect movement of the device through a subject, such as the gut of a patient." *Id*. The apparatus comprises a pair of concentric conduits, either of which can be selectively rigidized to act as a guide for the other conduit. *Id*.

Zehel identifies the same problem in the prior art identified by Sturges. Zehel notes that "[e]ndoscopes apply pressure to the walls of the gut, especially when inserted to lengths of 50 cm or more, since some portion of the instrument will be following a relatively sharp curve around an angle of at least 90 degrees." Ex.1005, 2:16-20. In these conditions, "any forward or backward motion of the endoscope will necessarily cause pressure to be exerted on the gut walls at these points." Ex.1005, 2:20-22. This forward or backward motion of the endoscope "can result in relatively large and potentially dangerous forces being applied to the walls of the gut at its points of contact with the conduit." Ex.1005, 2:32-35. Zehel suggests that "an advance in the art could be realized if there existed an exploratory instrument which, though flexible, could be stiffened along its entire length, providing a stable platform for the deployment of exploratory instruments." Ex.1005, 2:63-67.

Zehel proposes a steerable endoscope in which "an inner flexible conduit is slidably and concentrically engaged with an outer flexible conduit." Ex.1005, 3:18-20. Figure 1, reproduced below, shows a preferred embodiment of this endoscope.

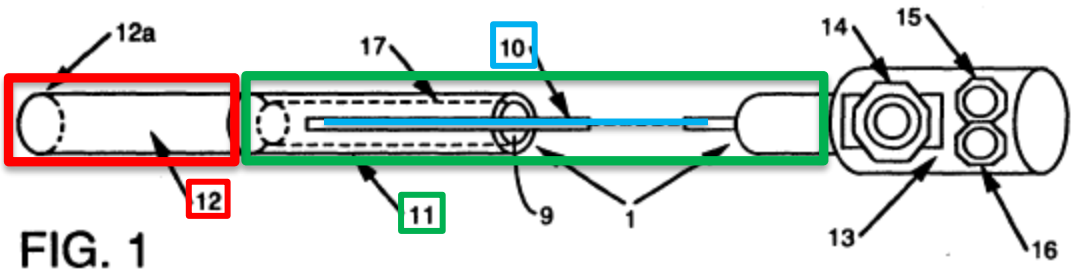

FIG. 1

Zehel describes that either the inner conduit (10) (identified in blue above) or the outer conduit (11) (in green) may be made rigid along its entire length by a stiffening device. Ex.1005, 3:18-23. The stiffening device is preferably comprised of a series of segments that are aligned with one another and strung on flexible cables which lock the segments together when pulled taught. Ex.1005, 3:24-28.

Zehel further describes that the device may be fed into the cavity of a subject "by alternately relaxing, sliding, and stiffening the inner and outer conduit with respect to each other while directing the distal end of the device [(12) (in red)] toward the target point of interest." Ex.1005, 3:33-38; *see also id*., 4:59-5:32 (describing the process by which (1) the flexible inner conduit is advanced within the outer conduit; (2) the inner conduit is rigidized; (3) the inner conduit is inserted into the body cavity up to the first substantial curve; (4) the distal end is flexed using the control apparatus to determine the appropriate forward direction; (5) the outer conduit is inserted, using the rigid inner conduit as a guide until it experiences appreciable resistance from the subject; (6) the outer conduit is stiffened; (7) the inner conduit is relaxed and, using the outer rigid conduit as a guide, advanced until it reaches the distal end

of the flexible device).

Zehel additionally discloses that the inner flexible conduit consists of a plurality of cylindrically shaped beads or segments strung on flexible cables such that "applying tension to the cables 20 causes friction forces between the spherical surfaces 24 and 25 of the male end 22 and female end 23, respectively, rendering the segments immovable with respect to each other and rendering the inner flexible conduit 10 rigid along its entire length." Ex.1005, 6:59-7:7.

3. A POSA Would Have Considered Sturges and Zehel Together

A POSA following his or her ordinary design process would consider and evaluate techniques used in analogous systems that could improve the performance of the system that was being designed. Ex.1003, ¶80. A person implementing a steerable instrument would have looked to other references describing processes for steering a medical instrument within a patient without exerting undue force on patient or on the instrument to determine whether any features of those systems could improve Sturges's operation. Ex.1003, ¶80. A POSA reading Sturges would have considered Zehel as one such reference and would have considered its teachings together with Sturges. Ex.1003, ¶80. When implementing the various features of Sturges, the POSA would have refined those feature's implementation based on Zehel's implementation of analogous features, particularly where Zehel

identifies particular benefits for its particular implementation of the feature. Ex.1003, ¶80.

A POSA at the time of the invention considering Sturges would have been motivated to look to other references to identify additional designs for the individual segments of the guide. Ex.1003, ¶81. Sturges notes that "bead design affects spine performance requirements, which include spine curvatures, diameter, stiffness and stability." Ex.1004, 125. Sturges further states that "[t]o improve the locking ability [of adjacent beads] over the entire rotational range, the geometry can be varied to reduce the turning moment." Ex.1004, 127. As a result, a POSA would have looked to Zehel as it discloses "a plurality of cylindrically shaped beads or segments 19 strung on flexible cable 20" to further experiment with the spine performance. *See* Ex.1005, 6:41-45; *see also id.*, Figs 2 & 3; Ex.1003, ¶81. After reviewing Zehel, a POSA would have been motivated to combine the endoscope of Sturges with the endoscope of Zehel at least because:

- Both instruments are directed to the same subject matter of guiding a flexible steerable device through the body cavity of a patient. Ex.1004, 121; Ex.1005, Abstract; Ex.1003, ¶81.

- Both instruments sought to solve the same problem: minimizing the force exerted on the walls of a patient's body cavity during endoscopic procedures. Ex.1004, 121-122; Ex.1005, 2:16-67; Ex.1003, ¶81.

- Both instruments are depicted using nearly identical pictures which each identify (1) a steerable distal tip; (2) a flexible outer conduit; (3) an internal mechanism that can be selectively rigidized; and (4) a control mechanism located at the proximal end of the device. Ex.1004, Fig. 2; Ex.1005, Fig. 1; Ex.1003, ¶81.

- Both references disclose nearly identical solutions using a repeating process in which (1) the inner segment of the device is rigidized; (2) the outer conduit is advanced relative to the rigidized segment using the rigidized segment as a guide so as not to exert pressure on the patient's body; (3) the rigidized segment is relaxed and advanced relative to the outer conduit, using the outer conduit as a guide. Ex.1004, 123-124; Ex.1005, 9:61-10:4; Ex.1003, ¶81.

- Both instruments are comprised of a selectively rigidizable guide(s) that are freely slidable along the length of the device. Ex.1004, 124; Ex.1005, 4:59-5:32; Ex.1003, ¶81.

- Both references describe similar rigidizing methods in which a tensioning force applied to a cable causes friction forces to be applied to adjacent beads or segments, rendering the beads or segments immovable with respect to one another. Ex.1004, 125; Ex.1005, 6:59-7:7; Ex.1003, ¶81.

- Zehel states that the disclosed "device can be an add-on device for an existing endoscope" due to the hollow, concentric nature of the invention which allows standard endoscopic instruments to occupy the center section. Ex.1005, 10:20-29; Ex.1003, ¶82.

As Dr. Hannaford explains, flexible endoscopes were well known at the time and components of one could have readily been integrated into another, especially where, as in Zehel, the second endoscope is specifically designed to integrate with existing instruments. Ex.1003, ¶82.

4. Claims 1, 5-8, 11-12, 14, 16-17, 22-26 and 32 Based on Sturges and Zehel

a) Claim 1

(1) "method of advancing an instrument along an arbitrary path"

Sturges describes that the human colon "is comprised of a set of labyrinthine and reverse bends." Ex.1004, 121. Figure 1, reproduced below, shows a diagram of the human colon.

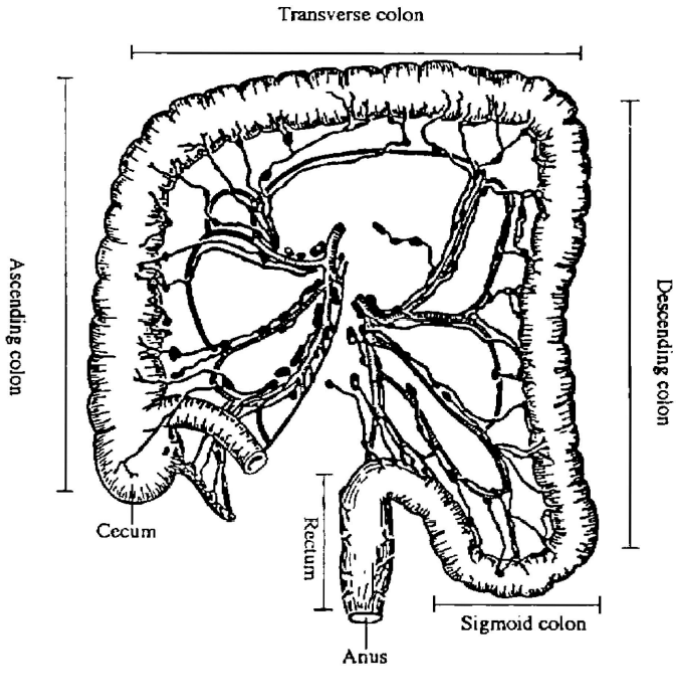

Fig. 1. Diagram of human colon.

Sturges discloses a "slide motion" scheme for navigating an endoscope ("*an instrument*") through the colon and other similar passageways. Ex.1004, 124 ("The conduit is then inserted manually into the colon up to the first substantial curve.").

Thus, to the extent the preamble is limiting, Sturges discloses a "*method of advancing an instrument along an arbitrary path.*" Ex.1003, ¶¶85-86.

(2) "selectively steering a distal portion of the instrument to assume a selected shape along an arbitrary path"

As shown in Figure 2, reproduced below, Sturges describes an instrument with a distal flexible end that can be selectively steered along an arbitrary path. Ex.1004, 123 ("The distal end (Figure 2) is flexed by the endoscopist to observe and point [the device] in the desired directions.").

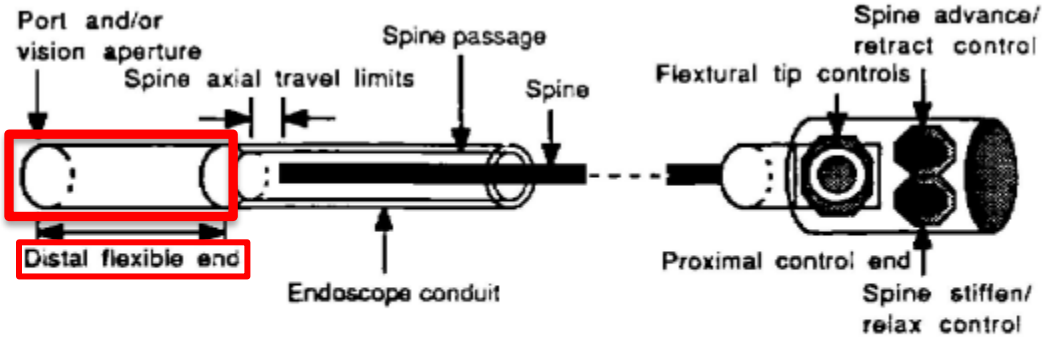

Fig. 2. Cross section of an endoscope with controllable stiffness spine.

Thus, Sturges discloses "*selectively steering a distal portion of the instrument to assume a selected shape along an arbitrary path.*" Ex.1003, ¶¶88-89.

(3) "advancing an elongate guide along the instrument such that a portion of the guide conforms to and assumes the selected shape;"

Sturges "slide motion" scheme uses a spine (and in a second embodiment, two spines) which, when rigidized, acts as an elongate guide for the instrument's flexible conduit. Ex.1004, 124 ("While the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine and within the predetermined axial travel limits, using the spine as a guide."). In its flexible state, however, this elongate guide can be advanced to its maximum limit ("*advancing an elongate guide*") along the endoscope conduit ("*along the instrument*") such that the guide conforms to the shape formed by the conduit. *Id.* ("When the incremental forward motion of the flexible conduit is complete, the spine is relaxed and pushed forward to its maximum limit."). This maximum limit is obtained because the flexible conduit "***serve[s] as a guide for the relaxed spine***." *Id*. (emphasis added). Once the spine has been advanced, it "is then stiffened in its new position" and thus assumes the selected shape. *Id*.

Accordingly, Sturges discloses "*advancing an elongate guide along the instrument such that a portion of the guide conforms to and assumes the selected shape*." Ex.1003, ¶¶90-91.

(4) "maintaining a position of the guide while advancing the instrument along the guide such that a proximal portion of the instrument

assumes the selected shape defined by the guide;"

After the spine is advanced along the conduit to its maximum limit, it "is then stiffened in its new position." *Id.*, ¶90. When the spine is rigidized, "the flexible conduit [can be moved] ***incrementally relative to the spine*** and within the predetermined axial travel limits, using the spine as a guide." *Id.* (emphasis added). Because the flexible conduit moves relative to the rigidized spine (*advancing the instrument along the guide*), the endoscope conduit retains the shape defined by the spine (*proximal portion of the instrument assumes the shape defined by the guide*). Further, as the flexible conduit is advanced, the spine is retracted at the same rate as the forward insertion rate of the flexible conduit (*maintaining a position of the guide*). *Id.*, ¶ 92 ("The flexible conduit is inserted further . . . at the same forward rate that the spine is retracted; thus, the spine is relatively stationary with respect to the patient's gut.").

Thus, Sturges discloses "*maintaining a position of the guide while advancing the instrument along the guide such that a proximal portion of the instrument assumes the selected shape defined by the guide*." Ex.1003, ¶¶92-93.

(5) "wherein the guide is freely slidable along the length of the instrument such that advancing of

the instrument along the guide is unconstrained;"

Sturges discloses a spine that is freely slidable and is capable of unconstrained movement along the entire length of the instrument. First, Sturges teaches a spine that is freely slidable from any point within the instrument to the distal tip of the instrument (as indicated below in blue) because Sturges teaches that the spine axial travel limits can be "adjusted to meet the specific requirements of the curvature at each bend of the colon" and the maximum limit motion "includes the distal tip." Ex.1004, 124 ("The total forward insertion distance of the endoscope is equal to the spine axial travel limits. Such limits would be adjusted to meet the specific requirements for the radius of curvature at each bend of the colon."); *id*. ("Because ***the maximum limit motion includes the steerable tip***, the curve commanded by the master is copied by one or the other locking spines."); Ex.1003, ¶94.

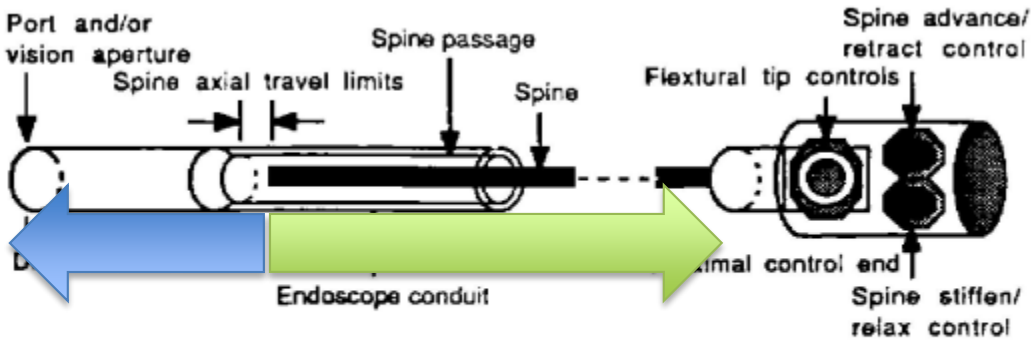

Fig. 2. Cross section of an endoscope with controllable stiffness spine.

Sturges further discloses that the steerable tip is freely slidable through the distal tip because it states that prior to insertion "the spine is advanced manually or

automatically to its maximum limit (about 5 cm) and made rigid." Ex.1004, 124. As Dr. Hannaford explains, a POSA would have understood that this 5 cm limit can extend to the distal tip of the instrument because during the initial steps of insertion, "the flexible conduit moves incrementally relative to the spine . . . using the spine as a guide." *Id*.; Ex.1003, ¶95.

Second, Sturges discloses a spine that is also freely slidable from any point within the instrument to the proximal end of the instrument (as indicated above in green). Sturges teaches this limitation because, as referenced above, it does not place any limit on the forward insertion distance of the endoscope conduit (*i.e.*, the proximal travel limit of the guide). Ex.1004, 124 ("The total forward insertion distance of the endoscope is equal to the spine axial travel limits [and that such] limits would be ***adjusted to meet the specific requirements for the radius of curvature at each bend of the colon***.") (emphasis added). Because Sturges places no limitation on the forward insertion distance of the endoscope conduit (relative to the position of the guide), it necessarily places no limit on how far the guide can be retracted from the endoscope conduit. Ex,1003, ¶96.

As evidence, that Sturges places no restraint on the spine axial travel limits, Sturges provides that the spine can be removed from the conduit entirely and be replaced by other therapeutic/diagnostic devices. Ex.1004, 124 (noting "[t]he stiffened spine … resists the involuntary motions of the colon [it] provides [a] stable

platform required for visual and therapeutic procedures in the colon" and, "***when the stable platform is not required, the spine can be removed and replaced by other therapeutic/diagnostic devices***." (emphasis added)); Ex.1003, ¶97. A similar process is described in the '056 patent specification. Ex.1001, 15:60-62 ("[G]uide 36 may simply be removed from device 20 . . . while leaving device 20 within colon C.").

Unlike the Sturges '151 Patent identified during prosecution of the '056, the Sturges reference at issue here describes a spine that is freely slidable and capable of unconstrained movement along the entire length of the instrument. During the prosecution of the '056 patent, the patentee successfully traversed the Examiner's §102(b) rejection based on the Sturges '151 Patent. Ex.1002, 175-76. The Examiner noted that the spine taught by the Sturges '151 Patent (which described a different invention, by a different set of authors, and which was submitted to the Patent Office ***two years after*** the publication of the Sturges reference at issue here), "was confined to a particular area of the device." Ex.1002, 176. Specifically, the Examiner agreed with the applicant's argument that the spine in the Sturges '151 Patent was confined to the distal tip of the instrument. *See* Ex.1002 at 167 ("Sturges shows and describes a device in which . . . '[t]he distal end 4 of the spine 2 has a **maximum limit of travel** wherein the distal end 4 is inserted into the steerable tip 12 [and a] **minimum limit of travel** wherein the distal end 4 is retracted from the steerable tip 12 into the

conduit 10.'"); *id.*, 175-76 ("spine 2 [of the Sturges '151 Patent] was contained within the distal portion of the device (the steerable tip 12)); *id.*, ("although the spine 2 of [the Sturges '151 Patent] was confined to a particular area of the device").

The Examiner agreed that, in contrast to the Sturges '151 Patent, the '056 patent "indicate[s] that the guide of the instant invention was freely slidable and was capable of unconstrained movement along the entire length of the instrument, rather than in a particular area, as in the device of [the Sturges '151 Patent]." Ex.1002, 176. Like the guide of the '056 patent, the Sturges article ***places no restriction*** on the "minimum limit of travel" of the spine(s) (*i.e.*, the distance which the spine can be withdrawn from the flexible conduit) and, instead, expressly teaches that "[s]uch limits would be adjusted to meet the specific requirements for the radius of curvature at each bend of the colon" without defining or restraining those limits in any way. Ex.1004, 124.

Accordingly, a person of ordinary skill in the art would understand that Sturges discloses or renders obvious "*wherein the guide is freely slidable along the length of the instrument such that advancing of the instrument along the guide is unconstrained*." Ex.1003, ¶¶94-98.

To the extent Patent Owner contends that Sturges does not disclose or render obvious the step of "*wherein the guide is freely slidable along the length of the instrument such that advancing of the instrument along the guide is unconstrained*,"

a POSA would understand that the disclosures in Sturges could readily be combined with the disclosure in Zehel to create a guide that "is freely slidable along the length of the instrument such that advancing of the instrument along the guide is unconstrained." Ex.1003, ¶99.

Zehel describes both an "inner flexible conduit system 10," which corresponds to the claimed "*elongate guide*" and an "outer flexible conduit system 11," which corresponds to the claimed "*instrument*." Ex.1005, 4:4-13. Zehel recognizes, however, that this mapping may be switched such that the outer "flexible conduit system 11" may be rigidized and used as the claimed "*elongate guide*." Ex.1005, 5:38-42 ("Other methods and apparatus are possible in accordance with this invention. For example, it would be possible to use a flexible device in which the outer flexible conduit is not stiffenable, but the inner flexible conduit is stiffenable, or vice versa."). In operation, "[t]he inner flexible conduit system 10 is [first] advanced within the outer flexible conduit 11 [and then] made rigid by the stiffen/relax control." Ex.1005, 4:62-64. Next, "the distal end 12 of the exploratory device 1 is inserted into the gut or other cavity of the subject up to the first substantial curve or point of substantial resistance by the subject on the device 1." Ex.1005, 4:64-68. After the distal end of the device is inserted into the subject and used to determine the necessary direction, "the outer conduit is inserted, maintaining the inner flexible conduit system 10 in the rigid state." Ex.1005, 5:1-6.

Like the flexible conduit of Sturges, the forward insertion distance of the ***outer conduit 11*** is not limited by any physical or mechanical barrier. Ex.1003, ¶101. Unlike Sturges, however, it also cannot be restricted by any pre-determined minimum or maximum axial travel limit. Instead, the flexible outer conduit of Zehel "continues ***until the flexible [outer] conduit 11 experiences appreciable resistance from the subject***." Ex.1005, 5:8-11 (emphasis added). Accordingly, only the physical limitations of the patient (as opposed to any limits of the device itself) can hinder the forward insertion distance of the instrument. *See* Ex.1005, 11:63-65 ("the inner flexible conduit and outer flexible conduit being disposed for sliding axial movement relative to each other"). Because Zehel allows the *instrument* to freely slide forward relative to the *elongate guide*, it necessarily allows the *elongate guide* to freely slide backwards relative to *instrument*. Ex.1003, ¶101.

Zehel further teaches that after the outer conduit 11 has been advanced, it "is stiffened, the inner conduit 10 is then relaxed and, using the stiffened outer flexible conduit 11 as a guide, inner conduit 10 is advanced while the outer conduit 11 remains axially stationary with respect to the gut." Ex.1005, 5:16-20. "The inner conduit 10 is again stiffened, for example, ***after reaching the distal end 12 of the flexible device***." Ex.1005, 5:25-27 (emphasis added). Accordingly, Zehel allows the "inner conduit 10" (*elongate guide*) to freely slide forward relative to "outer flexible conduit 11" (*instrument*). Ex.1003, ¶102.

As further evidence that inner conduit 10 is capable of unconstrained movement along the entire length of the instrument, Zehel provides that the instrument "may alternately be stiffened ***along its entire length*** or a portion thereof." Ex.1005, Abstract (emphasis added); *id*., 3:14-17 ("The device is capable of becoming rigid ***along its entire length when a stiffening actuator . . . is actuated***.") (emphasis added). A POSA would understand that because inner conduit 10 provides the stiffening means, in order to stiffen the Zehel instrument "along its entire length," inner conduit 10 must be freely slidable relative to the *instrument* in both directions. Ex.1003, ¶103.

A POSA would thus understand that Sturges, with or without Zehel, renders claim 1 obvious. Ex.1003, ¶¶94-104.

b) Claim 5

Claim 5 depends from claim 1 and specifies that the claimed method further includes "*releasing the position of the guide and further advancing the guide along the instrument.*"

As discussed above, Sturges describes an iterative process for advancing the instrument to the target comprising alternating steps (1) advancing a flexible spine (Ex.1004, 124 ("In its initial position, the spine is advanced . . . to its maximum limit . . . and made rigid")); (2) rigidizing the spine (*id*. ("In its initial position, the spine is advanced . . . and made rigid")); (3) advancing the flexible conduit while using

the spine as a guide (*id*. ("[w]hile the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine")); (4) relaxing the spine (*id*. ("[w]hen the incremental forward motion of the flexible conduit is complete, the spine is relaxed and pushed forward to its maximum limit")); and (5) advancing the flexible spine while using the flexible conduit as a guide (*id*. ("The maximum limit [of the spine] can be obtained because [the conduit] serve[s] as a guide for the relaxed spine.")). This process can be repeated to further advance the instrument. *Id*. ("Advancement of the conduit and spine is now repeated cyclically;").

Steps 4 and 5 identified above disclose this limitation as they describe (a) relaxing the spine from its rigidized state and (b) advancing the now flexible spine along the instrument. Sturges, with or without Zehel (for claim 1), renders claim 5 obvious. Ex.1003, ¶107.

c) Claim 6

Claim 6 depends from claim 1 and specifies that the claimed method further includes "*withdrawing the guide from the instrument.*"

After the spine is used to navigate the endoscope to the target, Sturges discloses that the stiffened spine can "provide[] the stable platform required for visual or therapeutic procedures in the colon." Ex.1004, 124. As a result, in situations where this stable platform is not required, "the spine can be removed and replaced by other therapeutic/diagnostic devices." *Id*. Accordingly, Sturges, with or without

Zehel (for claim 1), renders claim 6 obvious. Ex.1003, ¶110.

d) Claim 7

Claim 7 depends from claim 1 and specifies that "*the elongate guide is advanced along the instrument through a lumen defined within the instrument*."

Sturges discloses a number of different potential arrangements for the spine(s). Figure 12, reproduced below, illustrates a first embodiment in a single tendon spine shares the same "[s]pace for medical devices" as other diagnostic and therapeutic tools. Ex.1004, 129.

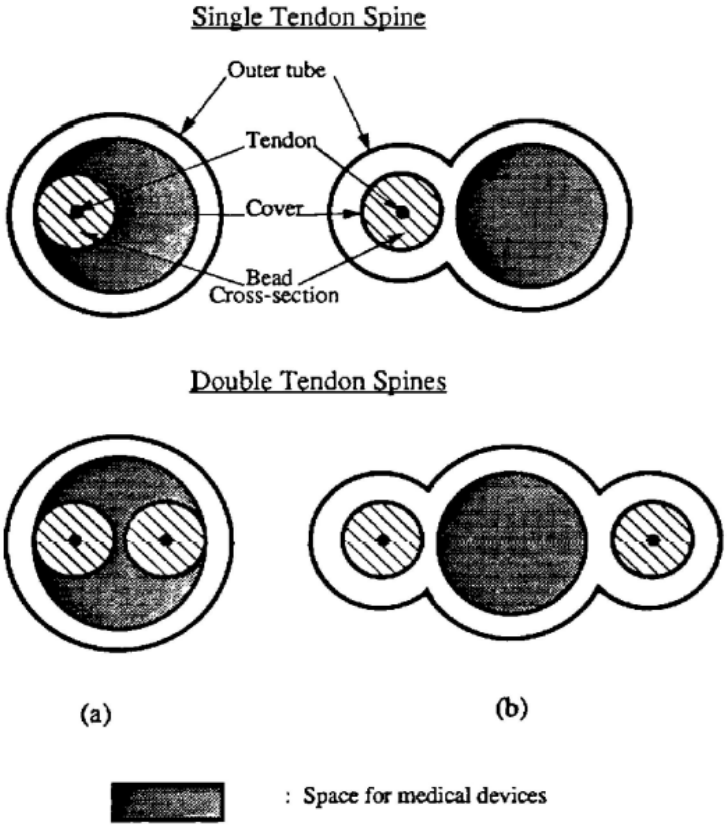

Fig. 12. Two arrangements for the single and double spines.

Accordingly, Sturges, with or without Zehel (for claim 1), renders claim 7

obvious. Ex.1003, ¶113.

e) Claim 8

Claim 8 depends from claim 1 and specifies that "*the distal portion of the instrument selectively assumes a second shape when the instrument is advanced along the guide*."

As discussed above in claim 5, Sturges describes an iterative process for advancing a medical instrument to the target. *See* §V.A.2.b, above. Repetition of step 3 (advancing the flexible conduit while using the spine as a guide (Ex.1004, 124 ("[w]hile the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine")) teaches claim 8 because, in order to advance the conduit in the described direction, the "distal end (Figure 2) is flexed by the endoscopist to observe and point in the desired directions." Ex.1004, 123. Because the endoscopist can direct the flexible distal end around a second curve, Sturges, with or without Zehel (for claim 1), renders claim 8 obvious. Ex.1003, ¶116.

f) Claim 11

Claim 11 depends from claim 1 and specifies that the claimed method further includes "*maintaining the position of the guide comprises rigidizing the guide such that the guide rigidly assumes a position of the selected shape*."

Sturges repeatedly discloses that the spine can be made rigid to assume a selected position. Ex.1004, 124 ("In its initial position, the spine is advanced . . . and

made rigid."); *id*. ("While the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine . . . using the spine as a guide."); *id*. ("The spine is then stiffened in its new position."); *id*. ("The stiffened spine inside the flexible conduit resists the involuntary motions of the colon."). Additionally, the spine can be made rigid after it assumes a position of the selected shape. *Id*. ("Because the maximum limit motion includes the steerable tip, the curve commanded by the master is copied by one or the other locking spines. Once the second spine has reached its maximum limit, it can be stiffened . . . .").

Accordingly, Sturges, with or without Zehel (for claim 1), renders claim 11 obvious. Ex.1003, ¶120.

g) Claim 12

Claim 12 depends from claim 11 and specifies that "*rigidizing the guide comprises applying tension to a tensioning member disposed within the guide such that a plurality of adjacent segments comprising the guide are compressed*."

Sturges teaches that the "central tendon locking spine consists of a set of cylindrical beads strung on a flexible cable." Ex.1004, 125. In a relaxed state, "[a]ll beads are free to rotate on adjacent beads around their centers [but in] the presence of a cable tension force, these beads slide axially along the cable until the positional constraints at both ends of the bead chain are satisfied." *Id*. "Consequently, increasing the cable tension force creates friction forces between beads and

ultimately increases the apparent stiffness of the entire bead chain." *Id*. "Therefore, pulling the cable stiffens the bead chain, and relaxing the cable tension force loosens it." *Id*. Figure 4, reproduced below, shows the central tendon locking spine described above and demonstrates how the spine is rigidized by applying a tensioning force to a cable within the spine such that the adjacent segments are compressed. Sturges, 125.

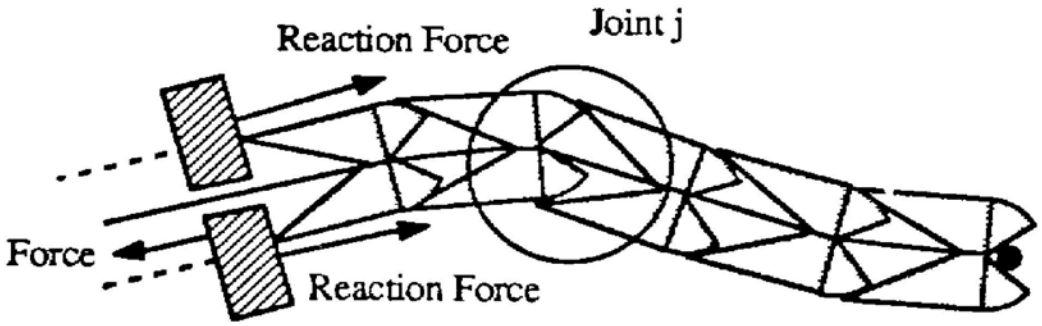

Fig. 4. Bead chain with a continuous cable.

Accordingly, Sturges, with or without Zehel (for claim 1), renders claim 12 obvious. Ex.1003, ¶123.

h) Claim 14

(1) "An apparatus for insertion into a body cavity"

Sturges discloses the preamble of claim 14 for the same reasons as claim 1. *See* §V.A.2.a.1, *above*.

(2) "an elongate body having a proximal portion and a selectively steerable distal portion and defining a lumen therebetween"

Sturges discloses "*a selectively steerable distal portion*" for the same reasons

as the corresponding element of claim 1. *See* §V.A.2.a.2, *above*. Further, Sturges discloses a lumen between the proximal portion of the device and the selectively steerable distal portion. Ex.1004, 123 ("In this scheme, the stem consists essentially of two major parts: one or two *spines* and an endoscope *conduit*, which is a covering tube for the spine."); *see also id.*, Figs. 2 & 12.

(3) "the steerable distal portion being configurable to assume a selected shape along an arbitrary path"

Sturges discloses this element for the same reasons as the corresponding element of claim 1. *See* §V.A.2.a.2, *above*.

(4) "an elongate guide having a proximal section, a distal section, and a length therebetween"

As shown in Figure 2, reproduced below, Sturges describes an instrument that contains a spine with a proximal and distal section with a length therebetween.

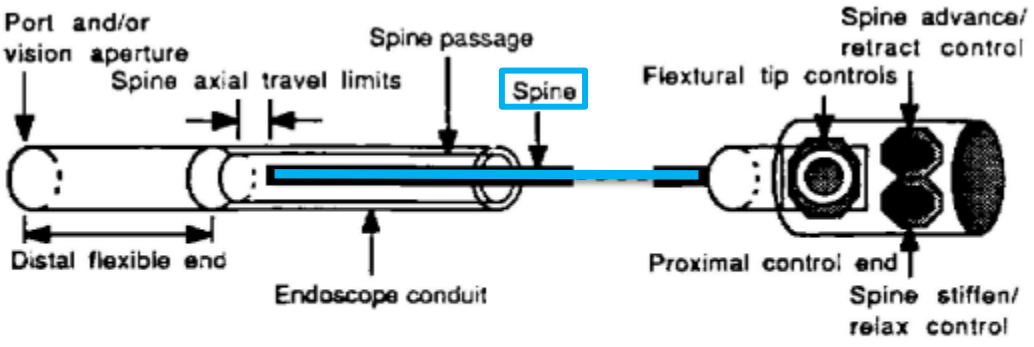

Fig. 2. Cross section of an endoscope with controllable stiffness spine.

Further, Sturges discloses that the spine is a "flexible tendon bead chain" comprised of a "set of cylindrical beads strung on a flexible cable." Ex.1004, 122; *id.*, 125; *see*

also Figs. 2 & 4. Accordingly, a person of ordinary skill in the art would understand that Sturges teaches "*an elongate guide having a proximal section, a distal section, and a length therebetween.*" Ex.1003, ¶129.

(5) "the guide being slidably disposed without constraint within the lumen along the length for selectively supporting the body"

Sturges discloses this element or renders this element obvious for the same reasons as identified in the corresponding element of claim 1. *See* §V.A.2.a.5, *above.* Sturges also discloses that the spine can support the lumen body of the instrument because it teaches that "[t]he stiffened spine inside the flexible conduit resists the involuntary motions of the colon [and thus], the distal end of the endoscope can be positionally supported. This support provides the stable platform required for visual or therapeutic procedures in the colon." Ex.1004, 124; Ex.1003, ¶130. To the extent that Sturges by itself does not disclose this limitation or render this limitation obvious, Sturges in view of Zehel teaches this limitation for the same reasons as the corresponding element of claim 1. *See* §V.A.2.a.5

(6) "wherein the guide is configured to conform to and selectively maintain the selected shape assumed by the steerable distal portion"

Sturges discloses this element for the same reasons as the corresponding element of claim 1. *See* §V.A.2.a.3, *above*.

(7) "wherein the proximal portion of the elongate body when advanced distally is configured to

conform to the selected curve maintained by the guide"

Sturges discloses this element for the same reasons as the corresponding element of claim 1. *See* §V.A.2.a.4, *above*.

Accordingly, Sturges, with or without Zehel, renders claim 14 obvious. Ex.1003, ¶133.

i) Claim 16

Claim 16 depends from claim 14 and specifies that "*the selectively steerable distal portion is configurable via a control located externally of the body cavity.*"

As shown in Figure 2, reproduced below, Sturges describes a medical instrument with a controllable portion, an endoscope conduit and a distal flexible end, which can be used to steer the instrument along an arbitrary path.

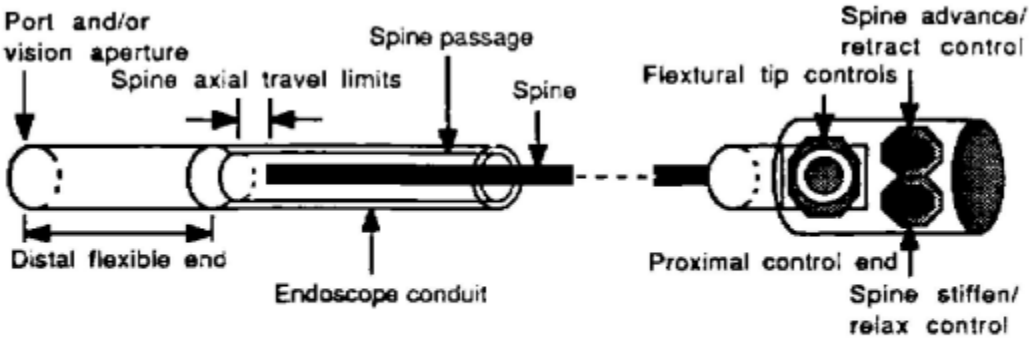

Fig. 2. Cross section of an endoscope with controllable stiffness spine.

"The distal end (Figure 2) is flexed by the endoscopist to observe and point [the device] in the desired directions." Ex.1004, 123. This "steering system is driven by two pairs of cables through a series of bent washers [and] provides for four

directions of steering (*i.e.*, up/down and left/right), as shown in Figure 3 [reproduced below]." *Id.*

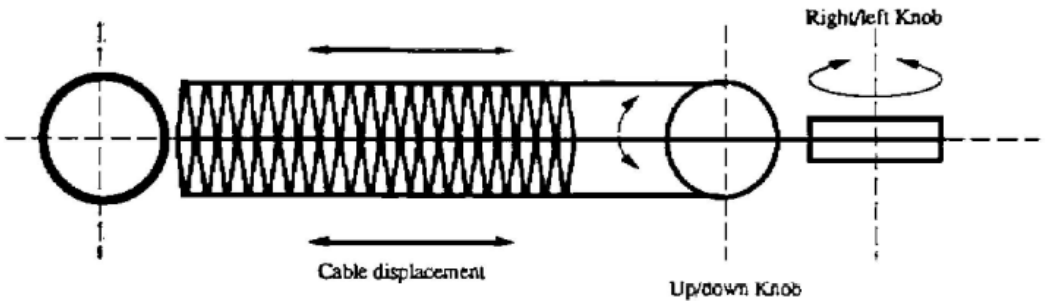

Fig. 3. Tip-steering system.

Sturges further notes that "[t]hese applications will most likely require indirect control from a master station, such as that used with modern teleoperators." Ex.1004, 124.

Accordingly, Sturges, with or without Zehel (for claim 14), renders claim 16 obvious. Ex.1003, ¶138.

j) Claim 17

Claim 17 depends from claim 14 and specifies that "*the proximal portion comprises a flexible tubular member*."

As discussed above, Sturges discloses a spine that acts as a guide for a flexible conduit. Ex.1004, 124 ("While the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine and within the predetermined axial travel limits, using the spine as a guide."); *id.* ("[w]hen the incremental forward motion of the flexible conduit is complete, the spine is relaxed and pushed forward to its

maximum limit."); *id*. (describing the advancement of the spine "while the flexible conduit remains stationary with respect to the patient."). The flexible conduit is comprised of a proximal portion and a distal portion. *See* Ex.1004, Figure 2 (disclosing an "endoscope conduit" with a section near a "proximal control" and a second section near the "distal flexible end.").

Accordingly, Sturges, with or without Zehel (for claim 14), renders claim 17 obvious. Ex.1003, ¶142.

k) Claim 22

Claim 22 depends from claim 14 and specifies that "*the elongate guide is configured to assume the selected shape when the guide is in a flexible state and wherein the guide is further configured to maintain the selected shape when the guide is in a rigidized state.*"

Sturges discloses this element for the same reasons as the corresponding element of claim 1. *See* §V.A.2.a.3, *above*. Sturges teaches that the spine can assume a selected shape while in a flexible state and subsequently retain that shape when rigidized. Ex.1004, 124 ("Because the maximum limit motion includes the steerable tip, the curve commanded by the master is copied by one or the other locking spines. Once the second spine has reached its maximum limit, it can be stiffened and the first spine relaxed so that the process can be repeated.").

Accordingly, Sturges, with or without Zehel (for claim 14), renders claim 22

obvious. Ex.1003, ¶145.

l) Claim 23

Claim 23 depends from claim 22 and specifies that "*the elongate guide is configured to selectively rigidize along the length of the guide to maintain the selected shape in the rigidized state.*"

Sturges discloses this limitation for the same reasons it anticipates claim 11. *See* §V.A.2.f, *above*. Sturges further teaches that the "central tendon locking spine consists of a set of cylindrical beads strung on a flexible cable." Ex.1004, 125. In a relaxed state, "[a]ll beads are free to rotate on adjacent beads around their centers [but in] the presence of a cable tension force, these beads slide axially along the cable until the positional constraints at both ends of the bead chain are satisfied." *Id.* "Consequently, increasing the cable tension force creates friction forces between beads and ultimately ***increases the apparent stiffness of the entire bead chain***." *Id.* (emphasis added). "Therefore, pulling the cable stiffens the bead chain, and relaxing the cable tension force loosens it." *Id*. As a result, Sturges teaches that the elongate guide is configured to selectively rigidize along the length of the guide.

Further, this rigidizing process maintains the selected shape while in a rigidized state. Ex.1004, 124 ("Because the maximum limit motion includes the steerable tip, the curve commanded by the master is copied by one or the other locking spines. Once the second spine has reached its maximum limit, it can be

stiffened and the first spine relaxed so that the process can be repeated.").

Accordingly, Sturges, with or without Zehel (for claim 14), renders claim 23 obvious. Ex.1003, ¶149.

m) Claim 24

Claim 24 depends from claim 22 and specifies that "*the proximal section of the elongate guide is in communication with a guide controller for selectively rigidizing the guide along its length.*"

As shown in Figure 2, reproduced below, Sturges describes a medical instrument with a controllable portion, an endoscope conduit and a distal flexible end, which can be used to steer the instrument along an arbitrary path. Figure 2 further shows a "Spine stiffen/relax control" located on the proximal portion of the device.

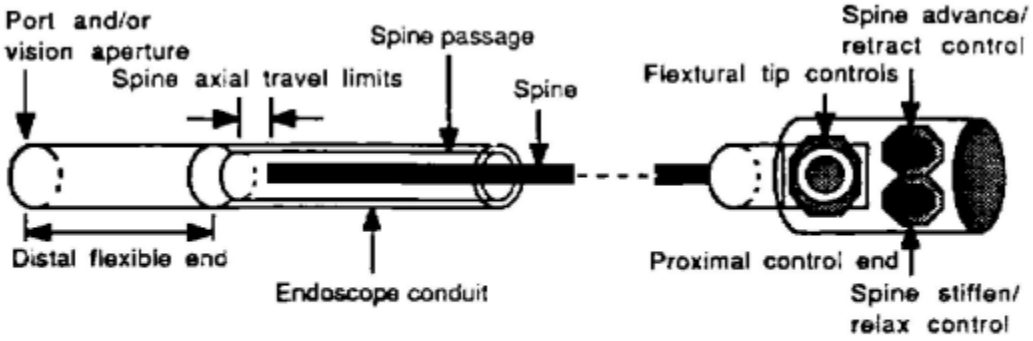

Fig. 2. Cross section of an endoscope with controllable stiffness spine.

Sturges further notes that once a "spine has reached its maximum limit, it can be stiffened." Ex.1004, 124. These functions are controlled from a remote master

station. *Id*. ("These applications will most likely require indirect remote control from a master station, such as that used with modern teleoperators."). Accordingly, Sturges with or without Zehel (for claim 14), renders claim 24 obvious. Ex.1003, ¶154.

n) Claim 25

Claim 25 depends from claim 22 and specifies that "*the elongate guide comprises a plurality of adjacent segments each defined through the length of the guide.*"

Sturges states that its controllable spine "consists of a set of cylindrical beads strung on a flexible cable." Ex.1004, 125. As shown in Figure 4, reproduced below, the bead chain contains a continuous cable through its center. All beads are free to rotate on adjacent beads around their centers but in the presence of a cable tension force, these beads slide axially along the cable until the positional constraints at both ends of each bead are satisfied. *Id*. As a result, "increasing the cable tension force creates friction forces between beads and ultimately increases the apparent stiffness of the entire bead chain." *Id*.

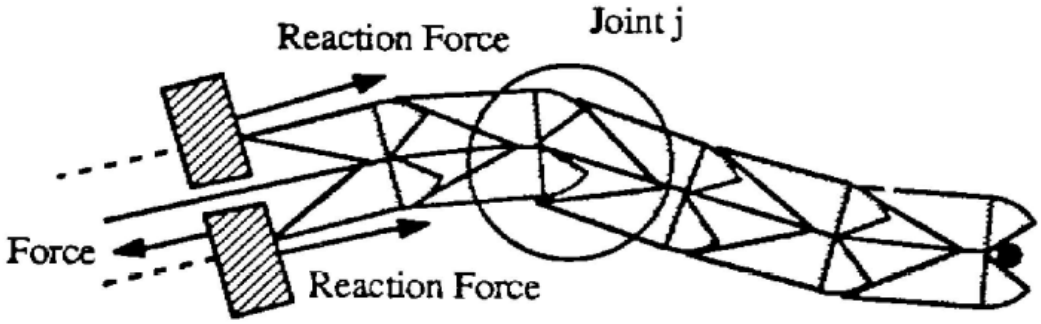

Fig. 4. Bead chain with a continuous cable.

Further, Zehel teaches that "[t]he stiffening device preferably comprises a series of segments, aligned with one another and strung on flexible cables which lock the segments together when the cables are pulled taut." Ex.1005, 3:25-29. Further, "[t]he stiffening mechanism of the inner conduit may be an integral unit comprising an endoscopic device and a stiffenable hollow conduit combined within the same protective sheath or coating." *Id.*, 3:29-32.

Accordingly, Sturges, with or without Zehel, renders claim 25 obvious. Ex.1003, ¶158.

o) Claim 26

Claim 26 depends from claim 25 and specifies that "*a tensioning member disposed within the common channel such that applying a force to the tensioning member compresses the adjacent segments together*."

Sturges teaches that the "central tendon locking spine consists of a set of cylindrical beads strung on a flexible cable." Ex.1004, 125. In a relaxed state, "[a]ll beads are free to rotate on adjacent beads around their centers [but in] the presence

of a cable tension force, these beads slide axially along the cable until the positional constraints at both ends of the bead chain are satisfied." *Id*. "Consequently, increasing the cable tension force creates friction forces between beads and ultimately increases the apparent stiffness of the entire bead chain." *Id*. "Therefore, pulling the cable stiffens the bead chain, and relaxing the cable tension force loosens it." *Id*.

Likewise, Zehel teaches that "[t]he stiffening device preferably comprises a series of segments, aligned with one another and strung on flexible cables which lock the segments together when the cables are pulled taut." Ex.1005, 3:25-29. Further, "[t]he stiffening mechanism of the inner conduit may be an integral unit comprising an endoscopic device and a stiffenable hollow conduit combined within the same protective sheath or coating." *Id.*, 3:29-32.

Accordingly, Sturges, with or without Zehel, renders claim 26 obvious. Ex.1003, ¶162.

p) Claim 32

Claim 32 depends from claim 14 and further comprises "*a tubular covering disposed over at least a majority of the length of the elongate guide.*"

Sturges teaches that the "locking spine and other diagnostic/therapeutic tools lie together inside the outer tube." Ex.1004, 128. Further, Sturges notes that "[t]o allow the spine to move easily, another cover sleeve wrapped around the spine is

required." *Id*. Further, Sturges discloses an "alternative arrangement [which] separates the cover sleeve from the outer tube while maintaining a parallel… mechanical interaction between the spine and the medical equipment in the stem." *Id*. Finally, Figure 12 illustrates multiple embodiments in which a spine is contained entirely within an "Outer tube."

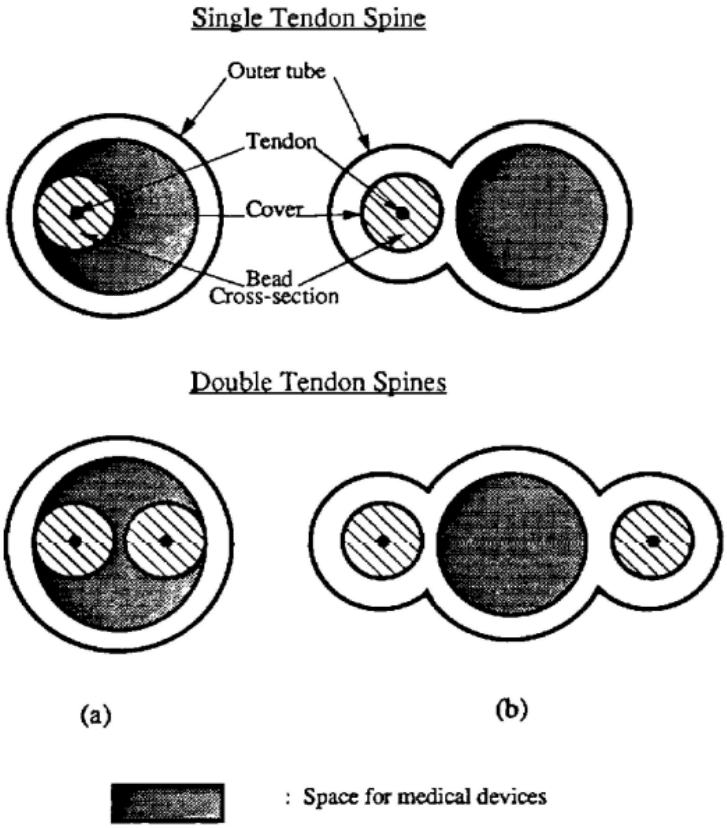

Fig. 12. Two arrangements for the single and double spines.

Accordingly, Sturges, with or without Zehel (for claim 14), renders claim 32 obvious. Ex.1003, ¶165.

B. Ground 3 – Sturges and Sturges II, With or Without Zehel, Render Claims 3 and 4 Obvious

1. Summary of Sturges II

Sturges II, titled "A Voice-Actuated, Tendon-Controlled Device for Endoscopy" was first published in a 1996 textbook ("Computer-Integrated Surgery, Technology and Clinical Applications," edited by Russel H. Taylor, Stephane Lavallee, Grigore C. Burdea, and Ralph Mosges) by the Massachusetts Institute of Technology, more than one year before the '056 patent's earliest effective priority date. Sturges II is therefore prior art to the '056 patent under at least 35 U.S.C. § 102(b). Sturges II was published by the Massachusetts Institute of Technology, a reputable, well-known publisher of academic articles. Ex.1006, 2; *see Ericsson Inc. v. Intellectual Ventures I LLC*, IPR2014-00527, Paper 41, at 11 (May 18, 2015) (relying on statements in a document regarding its publication, where document was published by a well-known, reputable organization). Additionally, a representative from the University of Michigan has attested that the University of Michigan Taubman Health Sciences Library received a copy of the Sturges II textbook and made it available to library patrons by at least June 12, 1998. Ex.1009, 2.

Sturges II provides supplements to the Sturges reference discussed above and is similarly directed to apparatus and methods for traversing a medical instrument, like an endoscope, through a patient's anatomy. Ex.1006, 603. It contains a near-verbatim recitation of the disclosures in the Sturges reference discussed above but

also includes a supplemental section directed to integrating a voice control system for advancing and retracting the endoscope. *See* Ex.1006, 614 ("Integrating voice control for endoscopic control"). This supplemental section teaches a method by which an "endoscopist determines advancing direction by giving voice commands to the steering mechanism (*i.e.*, Up-down or Left-right) together with specified values of angular displacement (0-180°)." Ex.1006, 615.

2. A POSA Would Have Considered Sturges and Sturges II Together, With or Without Zehel

A POSA following his or her ordinary design process would consider and evaluate techniques used in analogous systems that could improve the performance of the system that was being designed. Ex.1003, ¶83. A person implementing a steerable instrument would have looked to other references describing processes for steering a medical instrument within a patient without exerting undue force on patient or on the instrument to determine whether any features of those systems could improve Sturges's operation. Ex.1003, ¶83. A POSA reading Sturges would have considered Sturges II as one such reference and would have considered its teachings together with Sturges. Ex.1003, ¶83. When implementing the various features of Sturges, the POSA would have refined those feature's implementation based on Sturges II's implementation of analogous features, particularly where Sturges II identifies particular benefits for its particular implementation of the feature. Ex.1003, ¶83.

A POSA at the time of the invention considering Sturges would have been motivated to look to other references to identify control strategies for steering and moving. Sturges notes that "[a]lthough the acquisition of such feedback is routine, control strategies for steering and moving remain the subject for future research." Ex.1004, 125; Ex.1006, 607. Further, Sturges notes "details of the implementation of teleoperatortype controls are beyond the scope of this article." *Id*. As a result, a POSA would have looked to Sturges II as it discloses a control strategy for steering and moving. *See* Ex.1006, 614 ("Integrating voice control for endoscopic control"); Ex.1003, ¶84. After reviewing Sturges II, a POSA would have been motivated to combine the endoscope of Sturges with the endoscope of voice control of Sturges II at least because:

- Both references share authors; Ex.1003, ¶84.
- The disclosures are nearly identical but for the supplemental voice-control material provided in Sturges II; Ex.1003, ¶84.
- Sturges specifically indicated that additional research regarding teleoperator type controls remained outstanding, which Sturges II then provides. Ex.1003, ¶84.

3. Claims 3 and 4 Are Obvious in View of Sturges in view of Sturges II, with or without Zehel

a) Claim 3

Claim 3 depends from claim 1 and specifies that the claimed method further

includes "*measuring a depth change of the instrument while advancing the instrument distally*."

As discussed above in Ground 1, Sturges (with or without Zehel) renders claim 1 obvious. *See* §V.A.2.a. Further, Sturges II discloses a method for "giving voice commands to the steering mechanism [by which] the conduit is commanded to move forward." Ex.1006, 615. Sturges II implements this steering mechanism using a "coordinate frame at each image [as] shown in figure 48.16," which is reproduced below.

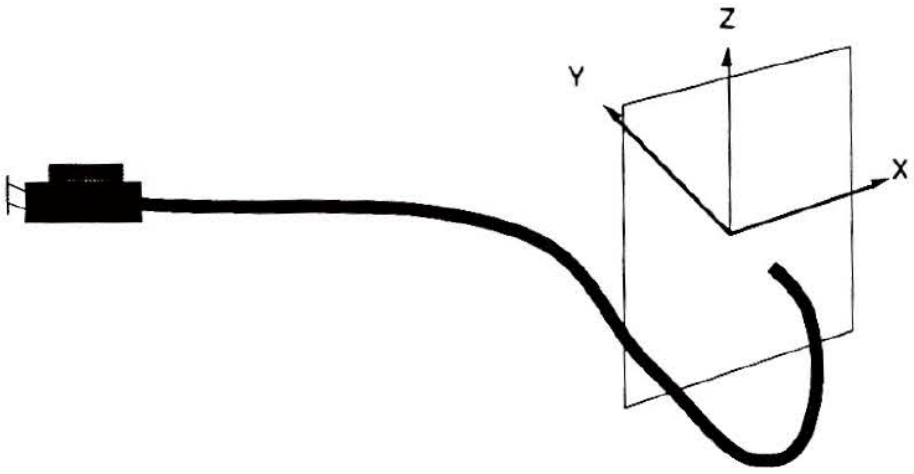

FIGURE 48.16 Coordinates at the image.

Using these coordinate frames, "the angular displacement is measured by the angle difference between the steering axis and the x-z plane and y-z plane, respectively, in the counterclockwise direction. With this set of coordinate frames, the initial position of the tip is at 90° of angular displacement in both planes. It also is possible to transform the angular displacement into the 2D Cartesian coordinates

of the image such that the user can specify directly the desired location of the endoscope tip." Ex.1006, 615.

Sturges II states that the automatic steering system controls the insertion distance of the endoscope conduit. Ex.1006, 616 ("The process of moving the conduit (which consists of stiffening the locking spine, incrementally advancing the conduit over the stiff spine, and relaxing and pushing the spine to catch up to the tip of the conduit), can be achieved automatically by a single voice command, Forward."). In certain modes, "the movement of the endoscope into the colon is accomplished by voice command only. Conduit insertion distance is estimated by the positioning of the prismatic joint drive. Such information approximates the location of the endoscope tip with reference to the colon [and] [t]he incremental step size in moving backward or forward subsequently is selected based on the current position of the tip with respect to the GI tract." *Id*.

A POSA would understand that, in order to estimate the insertion distance and approximate the location of the endoscope tip, the Sturges II system must "measur[e] a depth change of the instrument while advancing the instrument distally" as information regarding depth change is critical to prevent injury when advancing an endoscope. Ex.1003, ¶171. Technology for incrementing the depth of an endoscope was well known at the time. *Id.*; *see also* Ex.1010, Abstract ("The penetration depth of an intraluminal device, such as a transesophageal probe or a vascular catheter, is

monitored by totalizing incremental advancement and withdrawal of the device over time."); *id.*, 3:7-11 ("By continuously totalizing the incremental distances advanced and the incremental distances withdrawn, a value is produced which corresponds to the net penetration distance of the device in the body lumen over real time."). Further, a person of ordinary skill in the art at the relevant time would have been aware that many traditional endoscopes had depth markings for visual readings of instrument insertion distance. Ex.1003, ¶171.

Accordingly, Sturges and Sturges II (with or without Zehel for claim 1) render claim 3 obvious. Ex.1003, ¶172.

b) Claim 4

Claim 4 depends from claim 3 and specifies that the claimed method further includes "*incrementing a current depth by the depth change.*"

Sturges II discloses this claim for the same reasons it teaches claim 3. *See* §V.B.3.a.

VI. CONCLUSION

For the reasons set forth above, Auris respectfully asks the Board to initiate *inter partes* review and find claims 1, 3-8, 11-12, 14, 16-17, 22-26 and 32 to be unpatentable.

Dated: June 13, 2019

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CERTIFICATE OF COMPLIANCE

I hereby certify that this petition complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,742 words (as determined by the Microsoft Word word-processing system used to prepare the petition), excluding the parts of the petition exempted by 37 C.F.R. § 42.24.

Dated: June 13, 2019

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CERTIFICATE OF SERVICE
(37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by Federal Express on the Patent Owner at the correspondence address indicated for U.S. Patent No. 6,800,056.

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