IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Peter M. Bonutti	
U.S. Patent No.:	9,149,281	Attorney Docket No.: 11030-0059IP1
Issue Date:	October 6, 2015	
Appl. Serial No.:	13/912,730	
Filing Date:	June 7, 2013	
Title:	ROBOTIC SYSTEM FOR ENGAGING A FASTENER WITH BODY TISSUE	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 9,149,281 PURSUANT TO 35 U.S.C. §§311–319, 37 C.F.R. §42

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I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1-20 of U.S. Pat. No. 9,149,281 ("the '281 patent") (IS1001). The '281 patent relates to a "robotic system for engaging a fastener with body tissue." '281 patent, Title. The claimed system performs the well-known functions of applying at least one of an axial force and a transverse force relative to the fastener and limiting a magnitude of the at least one axial force and transverse force. *E.g., id.*, Claim 1.

The Applicant did not invent the fastening mechanism that applies axial and transverse forces, and, in fact, directs the reader to the prior art McGarry patent (and essentially copies the McGarry structure into the '281 patent). As noted in the '281 patent: "The stapling mechanism 332 has a general construction and mode of operation which is similar is [sic] to the construction and mode of operation of a known stapling mechanism disclosed in [McGarry]." *Id.* at 30:53-56.

The Applicant's IDS did not cite McGarry, but the Examiner nonetheless found that the prior art taught every limitation in the claims except "wherein the magnitude of the axial and transverse force applied to the fastener is limited by the computer." However, that feature (a force limiter) was also known in the prior art. Had the Examiner known about the references applied in this Petition, the claims would not have issued.

Petitioner therefore seeks review of the challenged claims.

II. MANDATORY NOTICES UNDER 37 C.F.R §42.8

A. Real Party-In-Interest Under 37 C.F.R. §42.8(b)(1)

Intuitive Surgical, Inc. is the real party-in-interest. No other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation of, or the filing of the present Petition.

B. Related Matters Under 37 C.F.R. §42.8(b)(2)

Petitioner is not aware of any disclaimers, reexamination certificates, or petitions for IPR of the '281 patent. The '281 patent is the subject of Civil Action No. 1:19-cv-00525-RGA, filed on March 15, 2019, in the United States District Court for the District of Delaware. A co-pending petition is directed to U.S. Patent No. 9,192,395, a patent assigned to Patent Owner which shares the same disclosure as the '281 patent and which has also been asserted against Petitioner in Civil Action No. 1:19-cv-525-RGA. U.S. Pat. No. 10,368,953 is also assigned to Patent Owner, shares the same disclosure as the '281 patent, and has been asserted against Petitioner in Civil Action No. 1:19-cv-525-RGA. Patent Owner is also prosecuting U.S. Pat. App. Nos. 16/272,650 and 16/412,008, which each claim the benefit of U.S. Pat. App. No. 13/888,957.

C. Lead And Back-Up Counsel Under 37 C.F.R. §42.8(b)(3)

Petitioner provides the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
Steven R. Katz, Reg. No. 43,706 3200 RBC Plaza, 60 South Sixth Street Minneapolis, MN 55402 Tel: 858-678-5070 / Fax 877-769-7945	John C. Phillips, Reg. No. 35,322 Ryan P. O'Connor, Reg. No. 60,254 3200 RBC Plaza, 60 South Sixth Street Minneapolis, MN 55402 Tel: 858-678-5070

D. Service Information

Please address all correspondence and service to the address listed above. Petitioner consents to electronic service by email at IPR11030-0059IP1@fr.com (referencing No. 11030-0059IP1 and cc'ing PTABInbound@fr.com, katz@fr.com, phillips@fr.com, and oconnor@fr.com).

III. PAYMENT OF FEES – 37 C.F.R. §42.103

Petitioner authorizes the Office to charge Deposit Account No. 06-1050 for the petition fee set in 37 C.F.R. §42.15(a) and for any other required fees.

IV. REQUIREMENTS FOR IPR UNDER 37 C.F.R. §42.104

A. Grounds for Standing Under 37 C.F.R. §42.104(a)

Petitioner certifies that the '281 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

B. Challenge Under 37 C.F.R. §42.104(b) and Relief Requested

Petitioner requests an IPR of claims 1-20 of the '281 patent on the grounds listed below. A declaration from Dr. Gregory S. Fischer (IS1003) is included in support.

Ground	Claims	Basis for Rejection
Ground 1	**1-3, 8-12, 16-20**	Obvious over **Tierney** (IS1004) in combination with **McGarry** (IS1005) under pre-AIA 35 U.S.C. § 103
Ground 2	**4-8, 13-15**	Obvious over **Tierney** (IS1004) in combination with **McGarry** (IS1005) and **Hooven** (IS1007) under pre-AIA 35 U.S.C. § 103
Ground 3	**1-20**	Obvious over **Tierney** (IS1004) in combination with **Hooven** (IS1007) under pre-AIA 35 U.S.C. § 103
Ground 4	**1-20**	Obvious over **Tierney** (IS1004) in combination with **McGarry** (IS1005) and **Gardiner** (IS1020) under pre-AIA 35 U.S.C. § 103
Ground 5	**1-20**	Obvious over **Tierney** (IS1004) in combination with **Hooven** (IS1007) and **Gardiner** (IS1020) under pre-AIA 35 U.S.C. § 103

The '281 patent issued from U.S. App. No. 13/912,730, which is a continuation of Application No. 13/888,957, filed on May 7, 2013, which is a continuation of Application No. 10/102,413, filed on March 20, 2002. Thus, March 20, 2002 is the earliest possible date to which the '281 patent can claim priority.

Tierney qualifies as prior art under at least 35 U.S.C. §§ 102(a) & (e). McGarry, Gardiner, and Hooven each qualifies as prior art under at least pre-AIA 35 U.S.C. §102(b). McGarry[1] was not considered during prosecution. Tierney,

[1] McGarry is referenced in the '281 patent specification but was not disclosed in an IDS. *See* MPEP 6.49.06 ("The listing of references in the specification is not a

Gardiner, and Hooven were made of record during prosecution, but were not discussed by the Examiner or the applicant.[2] Madhani and Cooper ’666, each incorporated into Tierney, were not considered during prosecution.

During prosecution, the Examiner relied on Wang for the robotic disclosure. Here, Petitioner relies on Tierney, a disclosure that is more extensive than Wang, and the arguments presented in this Petition are different from the arguments presented during prosecution concerning Wang. Therefore, Section 325(d) is inapplicable. Furthermore, the Examiner did not consider whether the claimed subject matter was patentable over the proposed combinations of Tierney, McGarry, Hooven, Gardiner, Madhani, and Cooper ’666 presented in this Petition. *Edwards Lifesciences Corp. v. Boston Scientific SciMed, Inc.*, IPR2017-01295, Paper 9 (PTAB October 25, 2017); *Microsoft Corp. v. Parallel Networks Licensing*, LLC, PR2015-00486, Paper 10 (PTAB July 15, 2015) at 15 (declining to deny institution under 325(d) where there was no evidence that the Examiner considered the partic-

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proper information disclosure statement. … [U]nless the references have been cited by the Examiner on form PTO-892, they have not been considered.”)

[2] Gardiner and Hooven were two of hundreds of references cited by the Applicant after the Examiner issued a notice of allowance.

ular disclosures cited in the petition). Furthermore, the Examiner lacked the benefit of Patent Owner's broad infringement allegations.[3] *See* IS1021 (Complaint), IS1022 (Preliminary Infringement Contentions, Ex. B-1), IS1023 (Preliminary Infringement Contentions, Ex. B-2). Thus, not one of the six factors identified in *Becton, Dickinson and Company v. B. Braun Melsungen AG* weighs heavily in favor of denying institution. IPR2017-01586, Paper 8 at 17-28 (PTAB Dec. 15, 2017 (informative)).

V. OVERVIEW OF THE TECHNOLOGY

Robots entered the surgical world more than 30 years ago. In 1985, the Programmable Universal Machine for Assembly (PUMA) 200 robot was used in a surgical theater for manipulating surgical instruments in a brain biopsy. IS1011, e4. In 1994, FDA cleared the first version of AESOP®, a robotic arm equipped with an endoscope created by Computer Motion, Inc. *Id.* In 1997, a prototype of the *da Vinci* robotic surgical system from Petitioner was used to perform the first robot-assisted cholecystectomy. *Id.* During the same period, Computer Motion, Inc. developed a teleoperating robotic system, ZEUS®. On September 7, 2001, a surgeon

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[3] To be clear, Petitioner's unpatentability arguments in Grounds 3, 4, and 5 concerning the combination of Tierney and Hooven are based solely on Patent Owner's infringement allegations, with which Petitioner does not agree.

operating in New York successfully completed a robot-assisted surgery on a patient in Paris using the ZEUS® system. *Id.*, e5.

In the prior art, it was common for robots to use force and position sensors. In fact, a consideration in designing robotic surgical systems is patient safety, including the risk of the robot exerting excessive force on the patient. IS1012 at 269; Cooper '666 (IS1010). Well before the priority filing date of the '281 patent, surgical robotic systems included sensors to compute end effector movement and imparted force. *Id.*; *see also* IS1013, 61 (disclosing a "force sensor [that] automatically pauses the cutting action and robot motion if the force applied by the cutter exceeds a certain limit"). Mechanisms for informing the surgeon of the applied forces through force feedback or a variety of display modalities were ubiquitous by the earliest possible priority filing date of the '281 patent. *See, e.g.* Niemeyer, IS1014; Hooven, IS1007; Spetzler, IS1015; Cooper '666, IS1010; *see also* Mizuno, IS1016, at 3:63-68; McCormick, IS1017, at 11:60-65; Madhani, IS1009, at 6:25-53, 7:33-44; 9:60-10:6; Fischer, ¶¶32-38.

VI. SUMMARY OF THE '281 PATENT

The '281 patent is directed to "an improved apparatus and method of securing body tissue [that] may be performed with a robotic mechanism." '281 patent, Abstract. The apparatus 30 for use in securing tissue in a patient's body includes a robotic mechanism 38 to position a fastener (suture, threaded fastener, or staple), a programmable computer 44, a robotic arm interface 46, and a monitor or display 48. *Id.*, 4:55-5:41; Fig. 1. "The body tissue may be secured with a staple." *Id.*

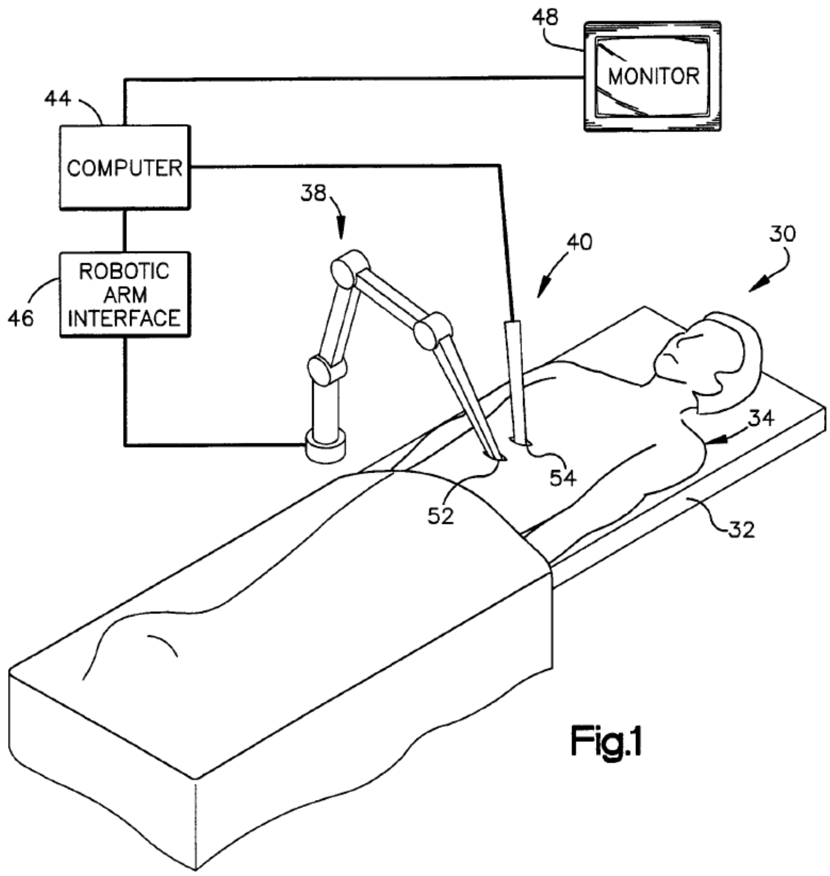

Fig.1

The '281 patent describes structures of the claimed system with reference to prior art patents, conceding these structures were known at the time of filing. For example:

- **Robotic Mechanism**: "The robotic mechanism 38 may have many different constructions, including constructions similar to those **disclosed in U.S. Pat. Nos. 5,078,140; 5,572,999; 5,791,231; 6,063,095; 6,231,565; and/or U.S. Pat. No.**

6,325,808. The specific robotic mechanism 38 illustrated in FIG. 1 has a construction and mode of operation generally similar to that **disclosed in U.S. Pat. No. 5,876,325**." '281 patent, 5:32-38.

- **Stapling mechanism**: "The stapling mechanism 332 has a general construction and mode of operation which is similar is [*sic*] to the construction and mode of operation of a known stapling mechanism **disclosed in U.S. Pat. No. 5,289,963 [to McGarry]**." *Id.*, 30:53-56. McGarry, discussed *infra*, discloses first and second force transmitting portions configured to apply at least an axial force and a transverse force to move the first and second legs of the staple toward each other.

As described in the '281 Patent (and likewise in McGarry from which the structure was taken), the robotic mechanism 38 moves staple mechanism 332 to a desired position relative to body tissue 334. '281 Patent, 29:33-35. Next, a pusher plate 338 with lands 356 and 358 advances the staple into the body tissue and bends the legs of the staple. *Id.*, 29:38-30:9; Figs. 24-26, Fischer, ¶¶39-41.

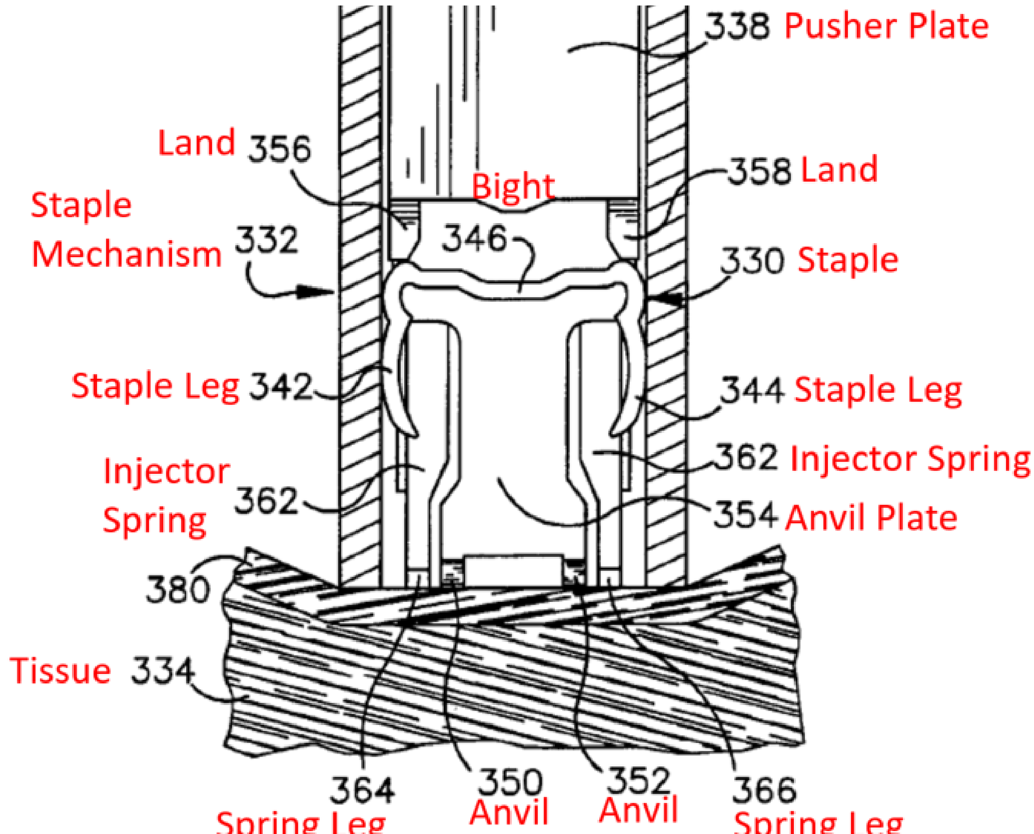
338 Pusher Plate
Land 356
358 Land
Bight
Staple
Mechanism 332
346
330 Staple
Staple Leg 342
344 Staple Leg
Injector
Spring 362
362 Injector Spring
354 Anvil Plate
380
Tissue 334
364
Spring Leg
350
Anvil
352
Anvil
366
Spring Leg

Fig.24

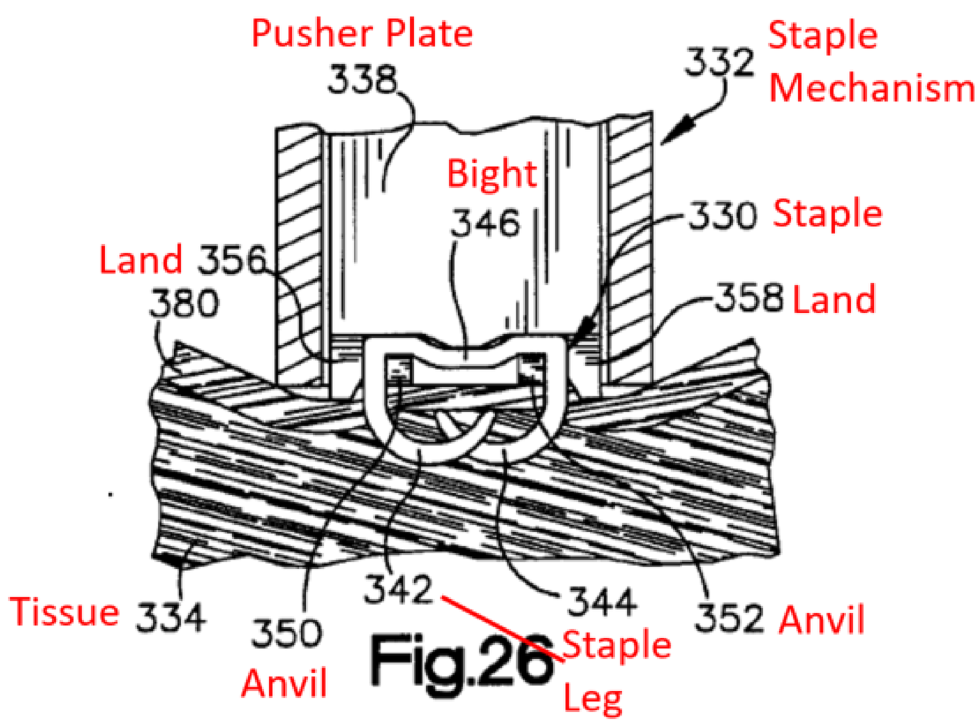
Pusher Plate
338
332
Staple
Mechanism
Bight
346
330 Staple
Land 356
380
358 Land
Tissue 334
342
344
Staple
Leg
350
Anvil
352 Anvil

Fig.26

VII. SUMMARY OF THE PROSECUTION HISTORY

During the prosecution of the '281 patent, the Examiner found that every limitation in the independent claims except one was disclosed by the combination of Wang et al. (5,762,458) and Tsuruta et al. (5,467,911). In an Office Action dated September 12, 2014, the Examiner concluded that "[i]t would have been obvious to one having ordinary skill in the art to have provided the Tsuruta's fastening device and robotic system, with these features as taught by Wang in order to control Tsuruta's device from a remote surgical site and/or room." IS1002 at 140.

To overcome the rejection, the Applicant added the requirement that the computer "limit a magnitude of the at least one axial force and transverse force" to all of the independent claims of the patent. The Examiner stated: "The prior art cited as record shows the use a robotic system for engaging a fastener with a body tissue comprising a computer, wherein the computer receive signals from the surgical site to provide feedback to the user of the tool, but fails to disclose wherein the magnitude of the axial and transverse force applied to the fastener is limited by the computer." IS1002 at 84. *See also* Interview Summary, IS1002 at 97 (February 18, 2014 Interview).

The claims were then allowed.

VIII. CLAIM CONSTRUCTION

For purposes of this proceeding only, Petitioner submits the following constructions. The remaining limitations should be afforded their plain and ordinary meaning.

A. "at least one of an axial force and a transverse force" (claims 1, 10, and 18)

"For claims written in the format of 'at least one of A and B,' the Federal Circuit made clear in *SuperGuide* that the plain and ordinary meaning is the conjunctive phrase 'at least one of A and at least one of B.'" *Ex parte Jung*, 2016-008290 (PTAB Mar. 22, 2017) (discussing *SuperGuide Corp. v. DirecTV Enters., Inc*., 358 F.3d 870 (Fed. Cir. 2004). Thus, "at least one of an axial force and a transverse force" means the conjunctive phrase "at least one of an axial force and at least one of a transverse force."[4] *Id*.

The prosecution history confirms this reading. On September 12, 2014, the Examiner rejected claims reciting that the transverse force was limited by the computer. IS1002 at 139-140. The Examiner then allowed the amended claims which the Examiner understood to require the limiting of both the axial force and transverse force. IS1002 at 84 ("the magnitude of the axial **and** transverse force applied

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[4] Of course, the invalidity analyses presented in this Petition be would be equally applicable under broader constructions than those presented here.

to the fastener is limited by the computer”).

B. “first and second force transmitting portions…” (claims 1, 10, and 18)

These terms invoke pre-AIA 35 U.S.C. § 112, ¶ 6 because they each claim a function without also reciting sufficient structure for performing that function. Fischer, ¶¶47-51. The term “portion” is a nonce word. *Id*. The prefix “force transmitting” does not impart any structure; it merely confirms that the structure transmits force. *Id*. The phrase “configured to” is analogous to “for” in a traditional means-plus-function limitation. *E.g.*, MPEP, § 2181. And the specification does not provide a structural definition for the claimed “force transmitting portions.” *Id*.

Claims 1, 10, and 18 explicitly recite the function(s) performed by the force transmitting portions—“***apply*** at least one of an axial force and [at least one of] a transverse force”: (1) “relative to the fastener” (claim 1); (2) “***to move*** the first and second legs toward each other” (claim 10); or (3) “***to urge*** the first and second body tissue sections together” (claim 18).

The plain language of the claims requires each force transmitting portion to perform each claimed function. Fischer, ¶¶47-51. Thus, in claim 1, for example, the first force transmitting portion must apply an axial force and a transverse force relative to the fastener and the second force transmitting portion must also apply an axial force and a transverse force relative to the fastener.

The corresponding structures disclosed in the specification are "force transmitting members or lands 356 and 358." Fischer, ¶50; '281 patent, 29:60-30:2, 30:19-32, Figs. 23-26.

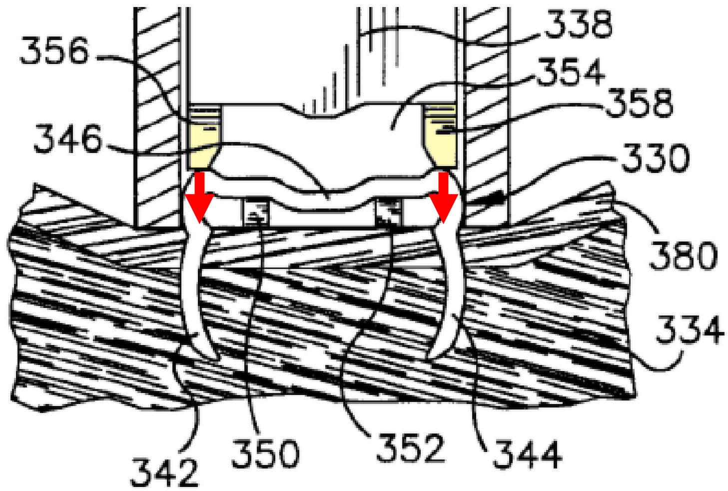


Fig.25

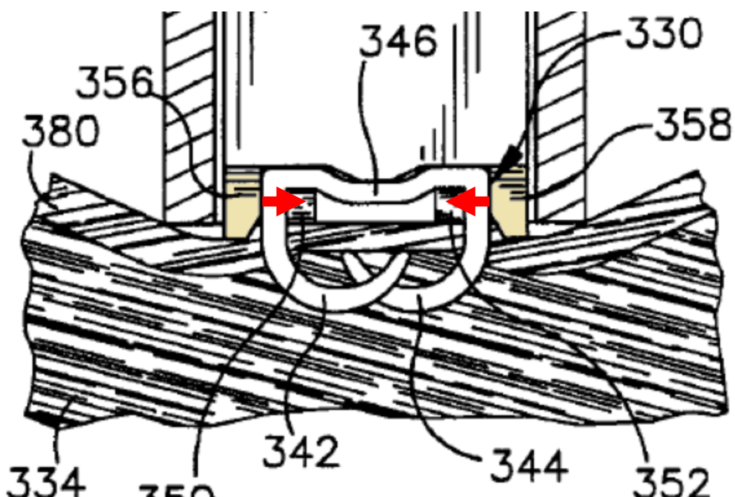


Fig.26

As shown above, each land 356, 358 applies an axial force (illustrated by the red arrows in Figure 25) and a transverse force (illustrated by the red arrows in

Figure 26): to the fastener (330); to move the first and second legs (342, 344) toward each other; and to urge the first and second body tissue sections (the sections of tissue engaged by the staple legs) together. '281 patent, 27:30-32; 29:33-30:2.

IX. SUMMARY OF THE PRIOR ART

A. Tierney

Tierney discloses a surgical system 10, which "generally includes master controller 150 and robotic arm slave cart 50." Tierney, 6:61-63, 7:16-18, 9:8-15, 9:66-10:11, 11:66-12:29, Figs. 1-4, 5F; Fischer, ¶¶52-57.

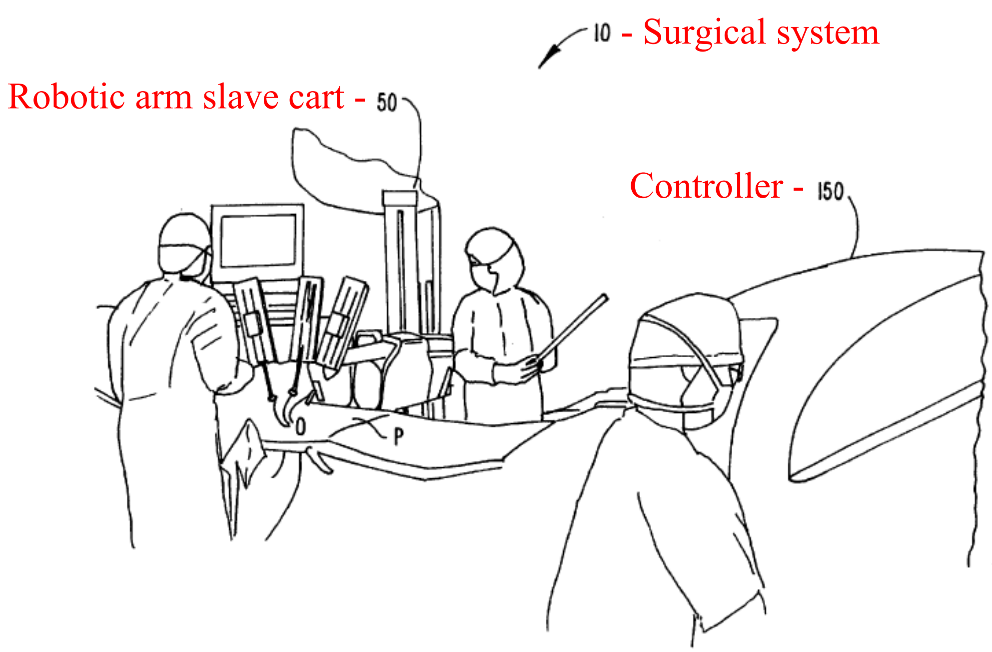


FIG. 1.

"Cart 50 includes a base 52 from which three surgical tools 54 are supported." Tierney, 7:16-18, Fig. 2. And "[t]ool 54 generally includes a … surgical end effector 112." *Id.*, 9:8-15, Fig. 4.

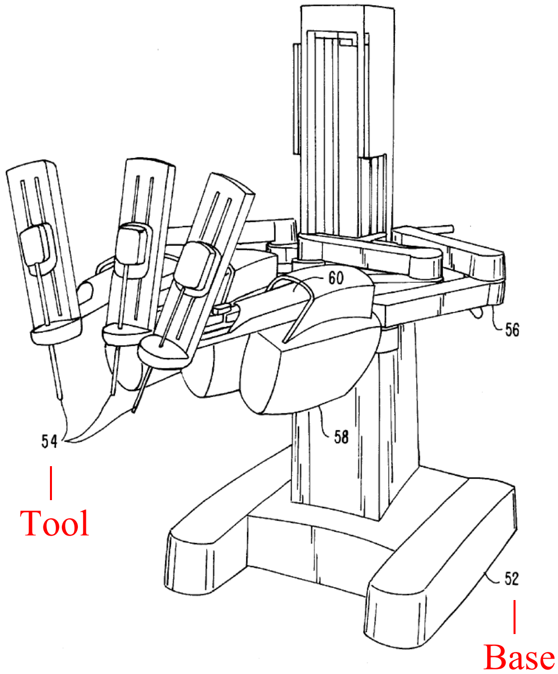
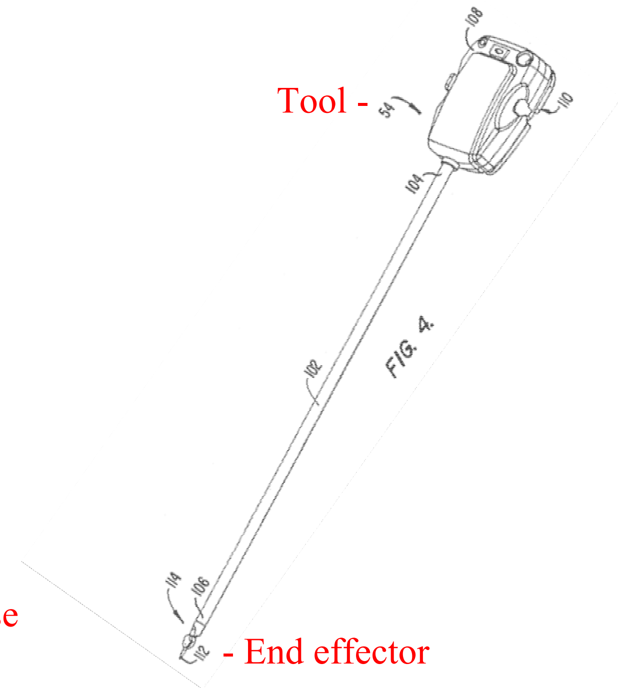


FIG. 2.



"Motors 70 are … coupled to tool 54 … to rotate the tool … to articulate a wrist at the distal end of the tool …. [and] to actuate an articulatable end effector of the tool." *Id.*, 7:65-8:10, Figs. 2A-C. Motors 70 may be coupled to at least some of the joints of tool 54 using cables, as more fully described in [Madhani], the full disclosure of which is also incorporated … by reference" into Tierney. *Id.*8:4-12; *see also* Fischer, ¶54 (confirming that this statement incorporates all of Madhani into Tierney as if recited by Tierney itself as a single reference); *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). As explained in Madhani, "[e]ach drive motor … includes a respective encoder … for providing [the] computer … with the rotational position of their respective drive shafts." Madhani, 8:35-39; *see also*

5:15-19, 5:62-67, 7:23-28, 7:38-39, 9:66-10:1, and 10:28-30.

Tierney also incorporates by reference “the full disclosure” of Cooper ’666. Tierney, 1:60-66; Fischer, ¶56 (confirming that this statement incorporates all of Cooper ’666 into Tierney as if recited by Tierney itself as a single reference); *Harari*, 656 F.3d at 1335; *Advanced Display Sys*., 212 F.3d at 1282. As explained in Cooper ’666, “servomechanism 16 will include a safety monitoring controller (not shown) that may freeze or at least inhibit all robot motion in response to recognized conditions (e.g., exertion of excessive force on the patient, ‘running away’ of the manipulator assemblies 4, etc.).” Cooper ’666 at 9:22-26.[5]

Tool 54 “may incorporate any … end effector [112] which is useful for surgery.” Tierney, 10:5-11. The tools are controlled, in part, by rotatable driven discs that receive rotary motion from drive elements 119 on the robot arms and use those rotary motions to control the movement of various surgical tools. *E.g.*, Tierney, 11:3-35, Figs. 7C-7J.

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[5] Madhani and Cooper ’666 are fully incorporated by reference and thus are considered part of the Tierney disclosure. To the extent the incorporation is found insufficient, it would have been obvious to a POSITA to combine Tierney with each because Tierney expressly refers the reader to those references.

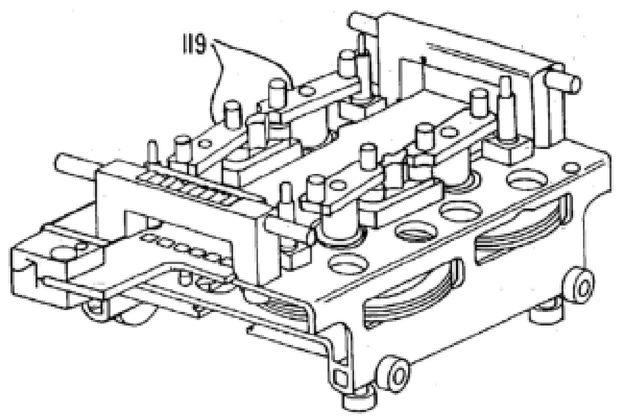


FIG. 7J.

Notably, "processor 152 changes the operating state of the robotic system based on tool signals from … tool memory 126." *Id.*, 14:1-6. "More specifically, data stored in tool memory 148 may be transmitted to the processor. In the exemplary embodiment, the data from the tool memory will include a character string indicating tool compatibility with the robotic system. Additionally, the data from the tool memory will often include a tool-type." *Id.*, 15:48-53. "For example, the tool-type data might indicate … tool strengths, grip force, [and] … ***the maximum force to be applied*** via driven elements 118." *Id.*, 15:59-16:40. "This data may be provided from the tool memory 148 in response to a request signal from the processor 152." *Id.*, 15:55-57.

B. McGarry

McGarry is acknowledged by the ’281 patent to be an embodiment of the claimed fastener applicator.[6] ’281 patent, 30:56-61; Fischer, ¶¶58-59. McGarry describes a stapler with a pusher plate 104 that contains “distally advancing lands 104R and 104L … at the distal end to facilitate transmission of advancing force to the two rounded or arcuate bridge portions of the staple.” McGarry, 17:16-25; Figs. 17-24.

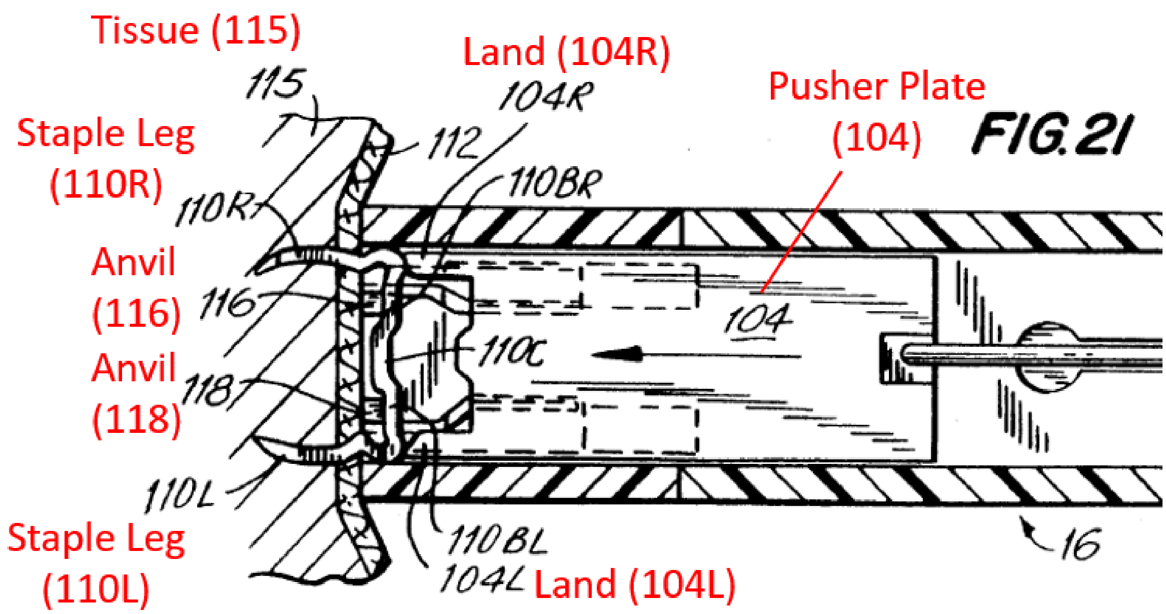
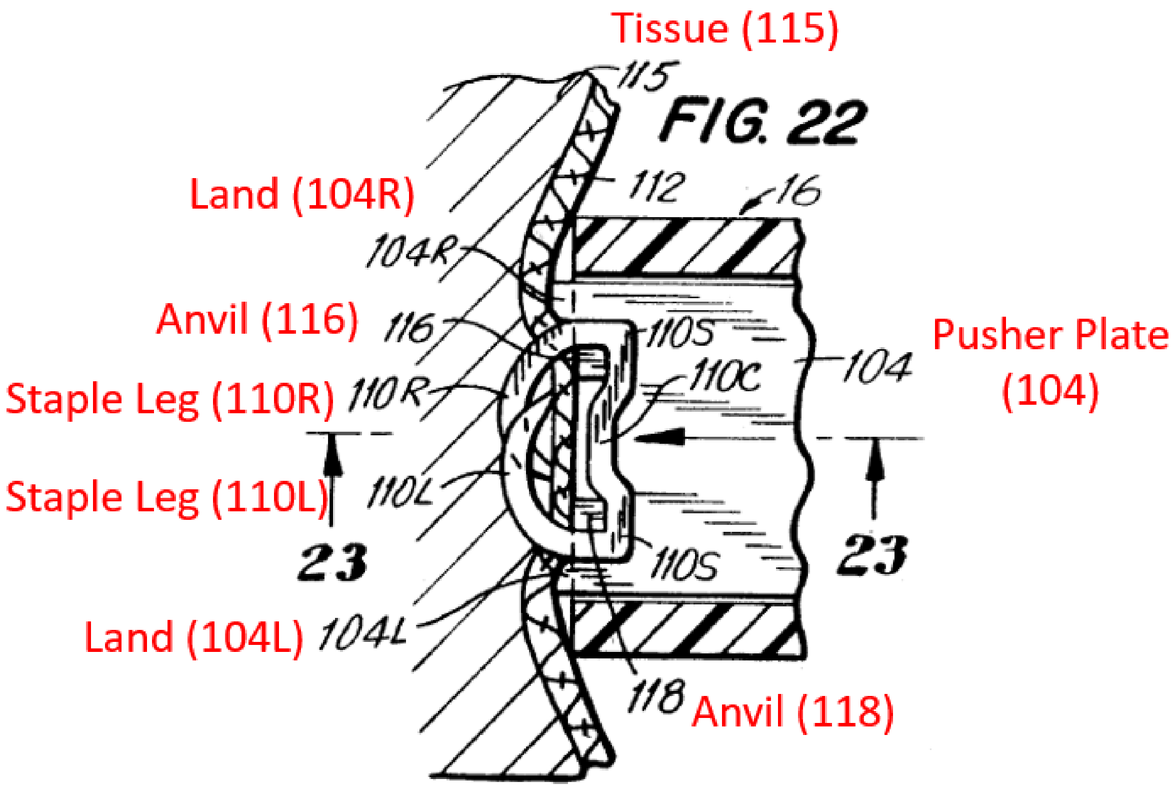


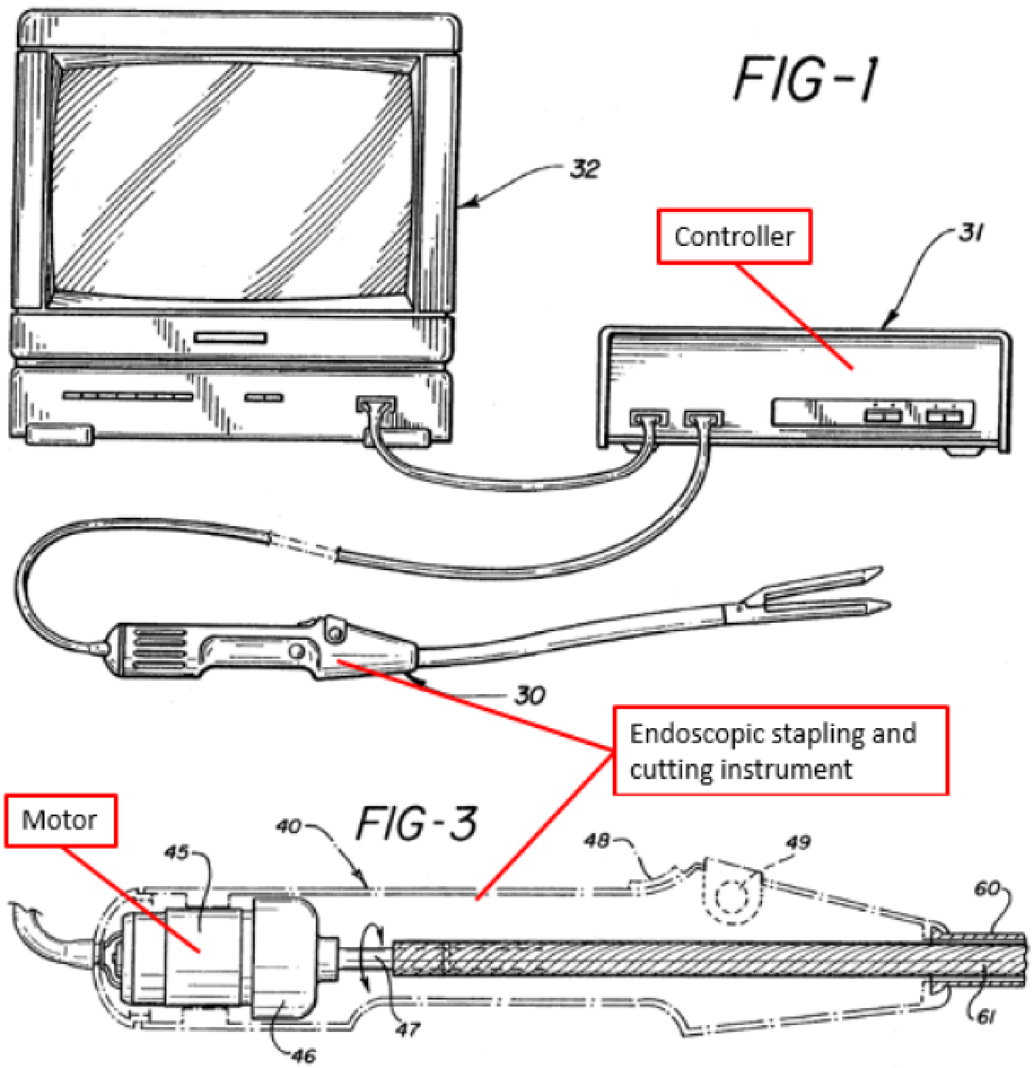
FIG. 21

[6] The ’281 Patent states, however, that McGarry lacks the “bonding” feature described in the patent. This “bonding” feature, which requires heating of polymeric staples, is not a limitation of the challenged claims.



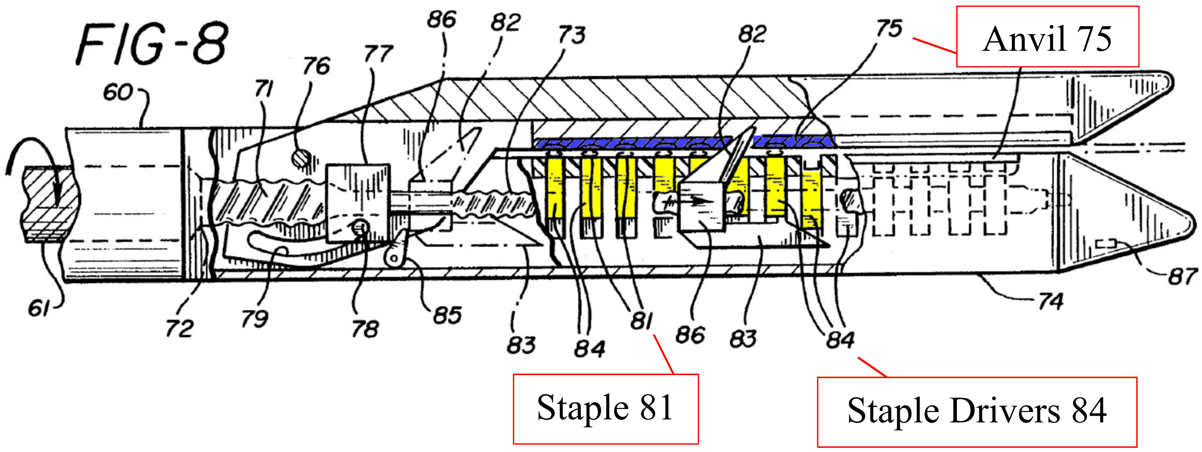
C. Hooven

Hooven discloses a controller 31 removably connected to an endoscopic surgical cutting and stapling instrument 30 that is capable of applying lines of staples to tissue while cutting the tissue between those staple lines. *E.g.*, Hooven, Figs. 1, 3, 6, 6;4:3-62, 5:9-6:47; Fischer, ¶¶60-62.



As shown below, Hooven's surgical cutting and stapling instrument 30 includes a firing nut 86 and a driving wedge 83 that are driven by a motor-powered threaded rod 71. Hooven, 5:9-6:47. When the instrument 30 is fired, driving wedge 83 is driven along the length of stapler 30 by motor 45, threaded rod 71, and firing nut 86 to move staple drivers 84 and staples 81 toward anvil 75. *Id*. As a result, staples are sequentially ejected and formed against the recesses located on the anvil, causing the two legs of each staple 81 to be forced toward each other, securing the body tissue. *Id*.

FIG-8



Hooven's stapler also "includes miniature sensors to detect the power and/or force being used" by the motor. *Id.,* 8:62-9:17, Fig. 19; *see also* 4:15-326:55-7:2. These sensors are connected to the controller 31, which stores and manipulates the information received from the sensors and controller 31 "acts to supply power to the instrument at the appropriate level, frequency, timing, etc." *Id*. "[T]he processed and manipulated information is fed to a video display screen" so that "the surgeon using the instrument will instantaneously receive information as to the placement of the staples, the cutting of the tissue, the presence of staples in the cartridge, etc." *Id*.

D. Gardiner

Gardiner discloses a robotically controlled surgical stapler wherein the robotic system's computer limits the magnitude of the axial and transverse forces applied to the staple. Gardiner, 10:30-16:22, 17:57-18:11; Figs. 4A-4I. More specifically, Gardiner discloses "force limiters [that] … limit the force with which the motors and/or actuators drive the drive rods and tube [for forming and releasing a completed staple]. The force limiters may be … electrical, such as closed loop feedback signals which monitor the amount of force exerted on the drive rods and/or distal end assemblies." *Id.*, 17:57-64. And "the assemblies in the working end of the instrument may be actuated and controlled by a surgical robot…. In [this robotic] embodiment, motors, actuators, pneumatic/hydraulic systems and/or other force transmission mechanisms … for driving the drive rods and assemblies in the working end of the instrument for forming and releasing a completed staple [are] controlled remotely by a computer." Gardiner, 18:4-11.

X. CLAIMS 1-20 OF THE '281 PATENT ARE INVALID

A. Ground 1: Claims 1-3, 8-12, and 16-20 are obvious over Tierney in view of McGarry

[1.1] A robotic system for engaging a fastener with a body tissue, the system comprising:

If the preamble is deemed to be a limitation, Tierney discloses it. Fischer, ¶¶63-65. Tierney discloses a robotic system (surgical system 10, which "generally includes master controller 150 and robotic arm slave cart 50") for engaging a fastener (clip or staple) with a body tissue. *Id.*; Tierney, 6:61-63, 7:16-18, 9:8-15, 9:66-10:11, 11:66-12:29, Figs. 1-4, 5F.

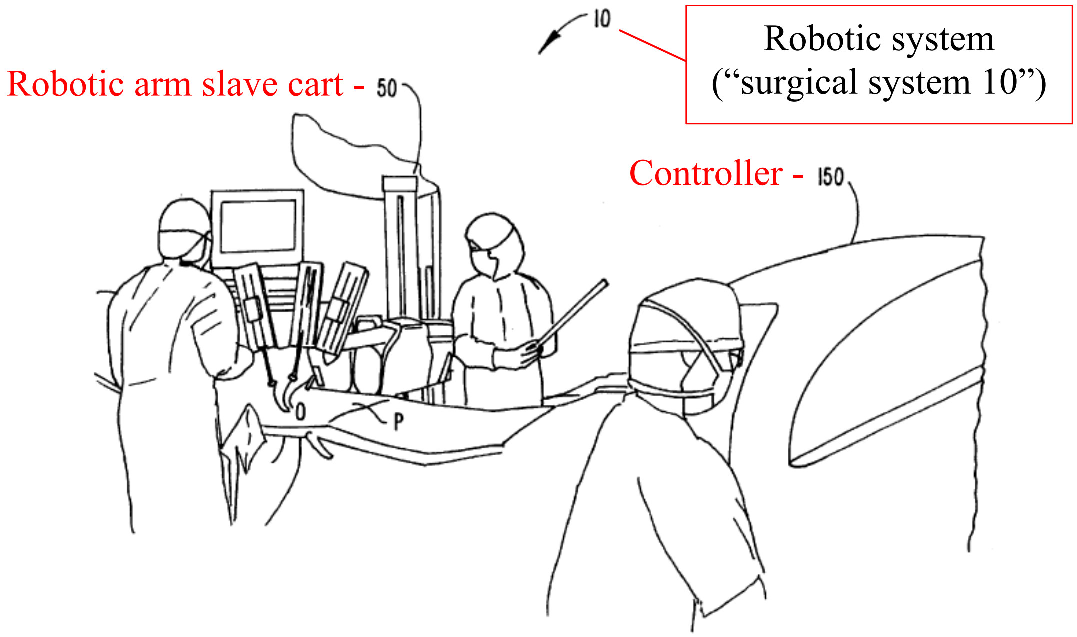


FIG. 1.

"Cart 50 includes a base 52 from which three surgical tools 54 are supported." Tierney, 7:16-18, Fig. 2. And "[t]ool 54 generally includes a … surgical end effector 112." *Id.*, 9:8-15, Fig. 4.

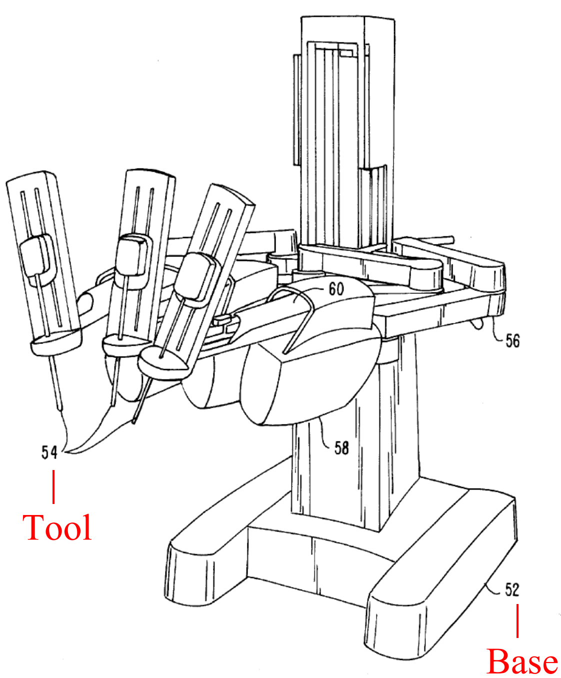


FIG. 2.

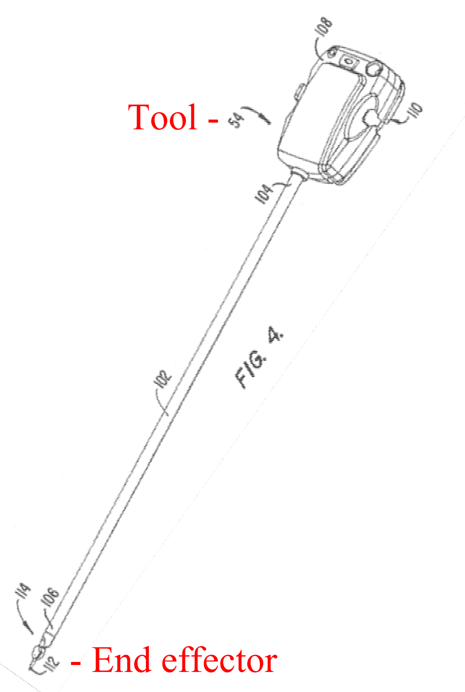


FIG. 4.

As explained in Tierney, tool 54 "may incorporate any … end effector [112] which is useful for surgery." *Id.*, 10:5-11. As one example, Tierney discloses an end effector 112 that is a robotically-controlled clip applier used to engage a fastener (clip) with a body tissue. *Id.*, 9:66-10:3, 11:66-12:29; Fig. 5F.

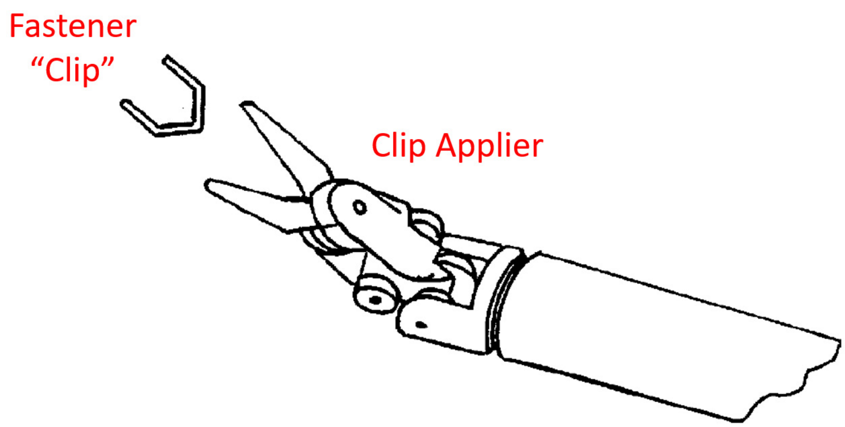


FIG. 5F

[1.2.1] a robotic mechanism including an adaptive arm, the robotic mechanism configured to position a fastener relative to the body tissue,

Tierney discloses this limitation. Fischer, ¶66-67. Although the scope of the term "adaptive arm" is unclear, Tierney discloses a robotic mechanism (robotic arm slave cart 50) including an adaptive arm (combination of set up joint 56 and robotic manipulator 58) configured to position a staple relative to the body tissue (*e.g.*, "tissue undergoing physiological movement (such [as] a beating heart)," etc.) of a patient. *Id.*, Tierney, 6:49-60, 7:16-8:1, 11:65-12:1, Figs. 3A, 5F. That is, whatever the full scope the term "adaptive arm" may be, based on the disclosure of the ’281 patent, Tierney’s arm must qualify as an “adaptive arm.” There is no pertinent feature of the arms in the ’281 patent that Tierney’s arms lack.

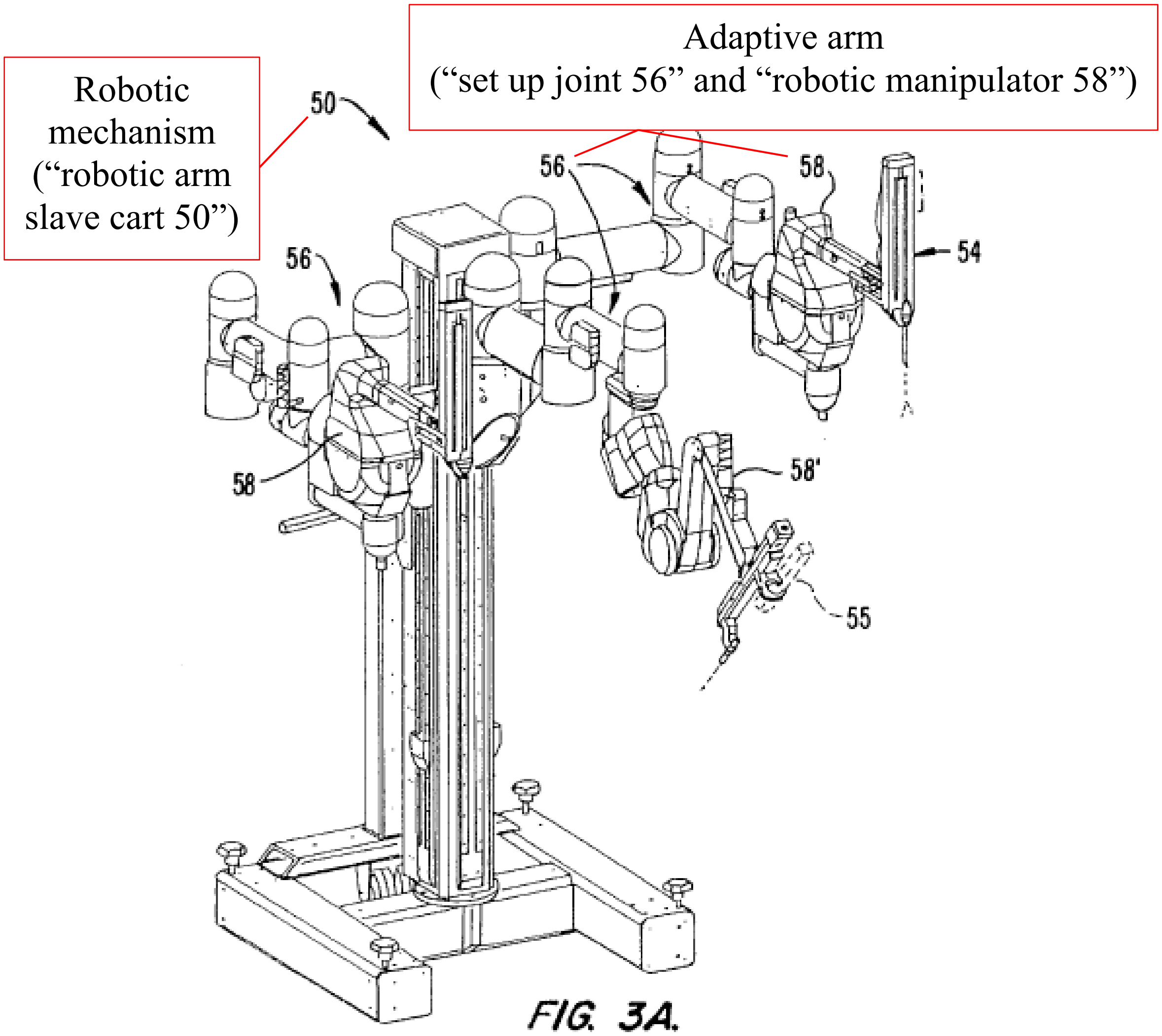
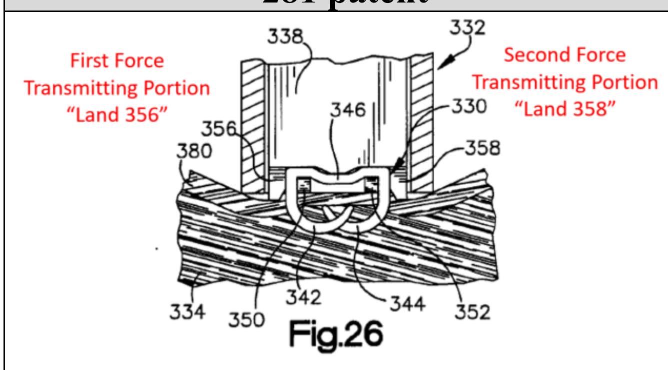
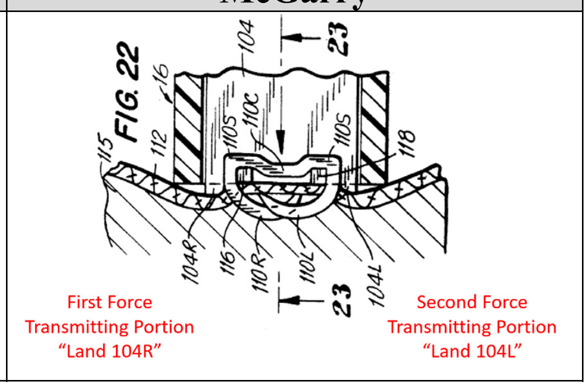


FIG. 3A.

As explained in Tierney, tool 54 (“staple applier”) is “supported by a series of manually articulatable linkages, generally referred to as set-up joints 56, and a robotic manipulator 58.” *Id.*, 6:24-25, 7:16-20, Fig. 3A. Furthermore, “robotic manipulator[] 58 preferably include[s] a linkage 62 … coupled to tool 54 so as to rotate the tool … and often to articulate a wrist at the distal end of the tool.” *Id.*, 7:40-8:1. "Tool 54 has still further driven degrees of freedom as supported by manipulator 58, including sliding motion of the tool along insertion axis." *Id.*, 7:55-58. "The surgeon will generally manipulate tissues using the robotic system by moving the controllers within a three dimensional controller work space of controller station 150." Id., 11:65-12:1.

[1.2.2] the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force relative to the fastener;

As explained above in the claim construction section, the phrase "first and second force transmitting portions" invokes 35 U.S.C. § 112, ¶ 6 and the corresponding structures are force transmitting lands 356, 358. McGarry discloses the same force transmitting lands as the '281 Patent. McGarry, 17:26-19:68, Figs. 17-24; Fischer, ¶¶68-70.

<table>
<tr><th>'281 patent</th><th>McGarry</th></tr>
<tr><td>
</td><td>
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To the extent there are any dissimilarities between McGarry's lands 104R, 104L and the '281 patent's lands 356, 358, the structures are at least equivalent because there are no substantial differences between them. Fischer, ¶69. Indeed, McGarry's lands 104R, 104L perform the claimed function of applying an axial force (red arrows in the annotated Figure 21 of McGarry and Figure 25 of the '281 patent) and a transverse force (red arrows in the annotated Figure 22 of McGarry and Figure 26 of the '281 patent) relative to the fastener in substantially the same way as the '281 patent's lands 356, 358 (physically contacting the legs of the staple and moving axially to initially apply an axial force and then a transverse force as the staple bends around the anvil) to produce substantially the same result (closing the staple). *Id.*

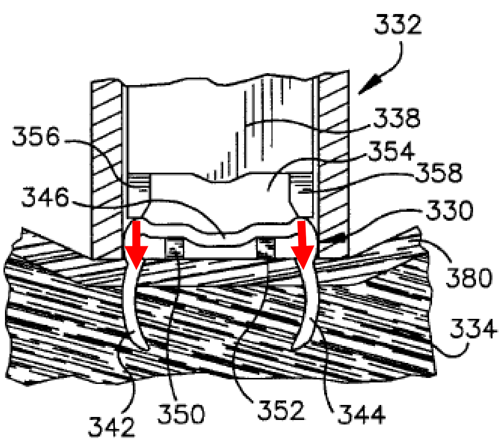
<table>
<tr><th>'281 patent</th><th>McGarry</th></tr>
<tr><td>


Fig.25
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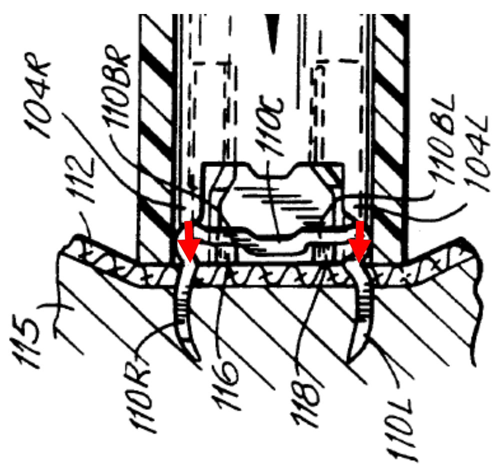

Fig. 21
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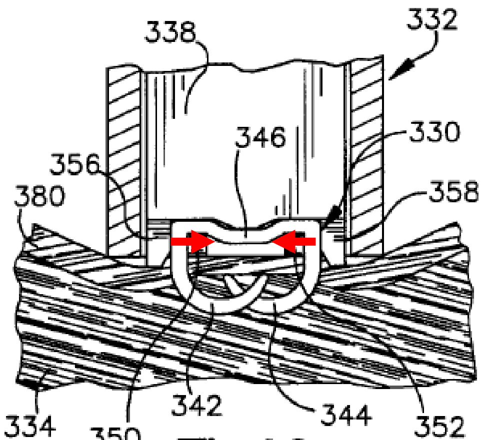
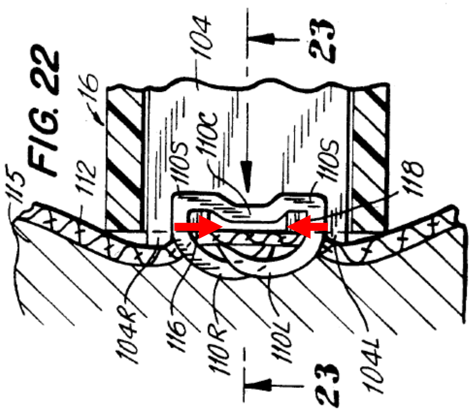
'281 patent	**McGarry**
 Fig.26	

If the Board does not agree that the term "first and second force transmitting portions" invokes 35 U.S.C. § 112, ¶ 6, then, as shown above, McGarry's lands 104L, 104R are nonetheless first and second force transmitting portions that are configured to apply an axial force and a transverse force relative to the fastener (staple 110). Fischer, ¶70.

A POSITA would have been motivated to combine McGarry's stapler applier with Tierney's robotic system for several reasons. *Id*. **First**, a POSITA would have recognized that Tierney contemplates use of its robotic system with "stapler appliers." Tierney, 6:20-27. And Tierney confirms that "[i]t should be understood that a wide variety of alternative end effectors for differing tool-types may be provided, and that … the tools of [Tierney's] invention may incorporate any … end effector which is useful for surgery, particularly at an internal surgical site." *Id*., 10:5-11. A POSITA therefore would have turned to McGarry for details on how to implement a robotic tool with a surgical stapler applier to increase the number of uses for Tierney's robotic system. Fischer, ¶¶71-90.

Second, Tierney discloses the benefits of the use of surgical robots. For example, Tierney notes that its robotic system will "have applications for surgical procedures which are difficult to perform using existing minimally invasive techniques." Tierney, 6:38-60. Tierney confirms that "it [was] anticipated that [Tierney's robotic] systems [would] find uses in entirely new surgeries that would be difficult and/or impossible to perform using traditionally open or known minimally invasive techniques." *Id*. And Tierney teaches that its robotic system provides for more rapid tool changes, leading to enhanced safety and reliability, and thus further suggests that multiple tools will be adapted for coupling to the Tierney robot. *Id*., 2:28-35. Furthermore, a POSITA would have understood that Tierney's robotic system increases accuracy (*e.g.*, tremor reduction and more precise movements) and surgical dexterity compared to manually operated instruments and permits a surgeon to operate on a patient in an intuitive manner. Fischer, ¶¶74-77; Anderson, 2:37-55. In addition, Tierney incorporates Madhani and Madhani provides further motivation to adapt a manual instrument such as McGary for use with a surgical robot. For example, Madhani states "[t]elesurgery systems for use in surgery are being developed to increase a surgeon's dexterity as well as to allow a surgeon to operate on a patient from a remote location." Madhani, 2:24-26.

Madhani also states that the robotic ("telesurgical systems" in particular) can provide a 3D image such that "[t]he surgeon's hands and the master device are positioned relative to the image of the operation site in the same orientation as the instrument is positioned relative to the act." Madhani, 2:35-38. In other words, robotic systems can give a surgeon performing laparoscopy a visual sensation similar to (and perhaps better than) open surgery. Thus, a POSITA would have been motivated to modify McGarry's stapler for use with Tierney's robotic system to obtain the myriad benefits of Tierney's robotic system. Fischer, ¶¶76-77.

Third, the adaptation of handheld tools like McGarry's for use with robotic systems like Tierney's was well known in the art. Fischer, ¶¶78-80; *see* Anderson (IS1019), 1:52-2:55, 3:44-61, 7:6-25, and Tovey (IS1018), 3:37-48 (disclosing a variety of surgical instruments, each existing in non-robotic form, for coupling to a surgical robot). And the prior art taught a POSITA that robotic surgical tools "may include OEM parts" from handheld tools, like McGarry's stapler, "to reduce costs and for manufacturing convenience." Anderson, 7:6-7; *see also* 15:8-13. Thus, like the inventors in Anderson, a POSITA modifying McGarry's stapler for use with Tierney's robotic system would have been motivated to use McGarry's components to the extent practicable to create the staple applier tool described in Tierney to reduce costs and increase manufacturing convenience. Fischer, ¶80.

Fourth, a POSITA would have been aware of the safety concerns associated with a surgical stapler applying excessive force to a patient or a staple, which could injure the patient or damage the tool. A POSITA also would have been aware that force limitation mechanisms, like Tierney's tool memory 148, which stores "the maximum force to be applied via driven element 118," and the safety monitoring controller disclosed by Tierney's incorporation of Cooper '666, were ubiquitous in the art by 2002. Tierney, 15:59-66; Fischer, ¶¶83-85; Gardiner, 17:57-64; Whitman, 17:41-60, 18:4-13. Thus, a POSITA would have been motivated to modify McGarry's stapler for use with Tierney's robotic system to obtain the safety benefits of Tierney's force limitation mechanism.

And **finally**, there was a design need to include a mechanism for manipulating surgical staplers and "a finite number of identified, predictable solutions" to that problem. Fischer, ¶86. McGarry discloses one predictable solution for manipulating a staple applier—by hand. *Id.*; McGarry, FIG.1 and throughout. And Tierney discloses the other predictable solution—using a robotic arm. Tierney, 6:20-37, FIGs 1-3A, 7A-J, and 14A-C (and accompanying text). Thus, a person of ordinary skill had good reason to pursue Tierney's known option and the device resulting from the combination of Tierney and McGarry would have been the product not of innovation, but of ordinary skill and common sense. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Moreover, a POSITA would have reasonably expected the combination of

Tierney and McGarry to be successful. Fischer, ¶87. Indeed, it would have been merely the application of a known technique (use of a surgical stapler end effector) with a known system (Tierney surgical robot) in a common field of endeavor (the development of surgical instruments). *Id.*; *KSR*, 550 U.S. at 417. As shown in Anderson and Tovey, the adaptation of a handheld instrument, like McGarry's stapler, for use with a robotic system, like Tierney's, was well within the level of skill in the art. *Id.*; Anderson (IS1019), 1:52-2:55, 3:44-61, 7:6-25; Tovey (IS1018), 3:37-48. And, in the Tierney/McGarry system, Tierney's robotic system and McGarry's stapling mechanism both continue to work as they always have. Fischer, ¶¶87-90. Thus, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by McGarry's stapler (stapling) or Tierney's robotic system (positioning the tool, providing mechanical controls to the tool, and receiving feedback signals from the tool). *Id.*

[1.3] a computer configured to control the robotic mechanism; and

Tierney in view of McGarry discloses this limitation. Fischer, ¶¶92-92. The Tierney/McGarry robotic system includes a computer (Tierney's processor 152) configured to control the robotic mechanism (Tierney's robotic arm slave cart 50 and the Tierney/McGarry stapler). *Id.*; Tierney, 11:37-16:61, Figs. 8-13.

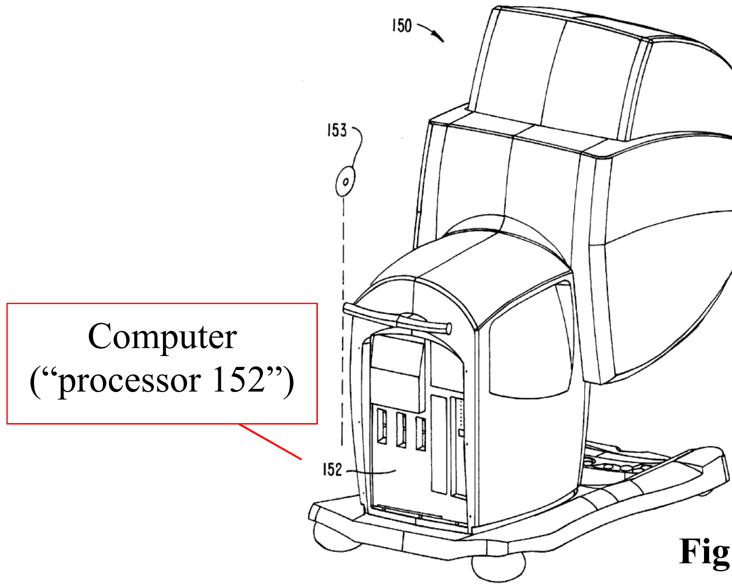


Fig. 8a

As explained in Tierney, "***[p]rocessor 152*** can calculate an image capture coordinate system via the sensors in setup joints 56 and manipulator 58 supporting the laparoscope, and can perform coordinate system transformations so as to ***generate signals to the drive motors of the manipulator*** that maintain alignment between the three dimensional image of the end effectors and the hand controllers within the controller work space." Tierney, 12:2-8. Tierney incorporates Cooper '666 and Manhani and Cooper '666's "controller (not shown)" and Manhani's "controller" would correspond to Tierney's processor 152. Cooper '666, 9:5-11, 22-26; Manhani, 4:51-65.

[1.4] an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer,

Tierney discloses this limitation. Fischer, ¶93. Although the scope of the term "adaptive arm interface" is unclear, Tierney discloses an adaptive arm interface, which are the ("master controllers") configured to operate the adaptive arm of the robotic mechanism. *Id.*; Tierney, 6:63-7:6, 11:66-12:64. Alternatively, to the extent the "adaptive arm interface" is considered to be the low-level control system that controls arm movement, Tierney likewise discloses processor 152 which receive signals from the "master controllers" and based on those signals generate control signals for the robot arms and instruments. Tierney, 12:1-64. As explained in Tierney, "[m]aster controller 150 generally includes master controllers (not shown), which are manual input devices which preferably move with six degrees of freedom, and which often further have an actuatable handle for actuating tools." Tierney, 6:63-7:6. "The surgeon will generally manipulate tissues using the robotic system by moving the controllers within a three dimensional controller work space of controller station 150." *Id.*, 11:66-12:1; *see also* 12:2-14 (confirming that the master controllers are electrically coupled to processor 152, setup joints 56, and manipulator 58); 12:43-45 (confirming that a "processor is used as the user interface master controller UMC to handle the input and output to and from the surgeon seated at the console" manipulating the master controllers), 12:59-60 (confirming that a "remote interface adaptor RIA … couples the processor 152 to … manipulator 58").

[1.5] wherein a magnitude of the at least one axial force and transverse force applied to the fastener is limited by the computer.

Tierney in view of McGarry discloses this limitation. Fischer, ¶¶94-97. In the Tierney/McGarry robotic system, the magnitude of the axial and transverse forces applied to the fastener (McGarry's staple 110) by McGarry's lands 104R, 104L is limited by Tierney's computer (processor 152) because Tierney's processor limits the magnitude of the forces that can be applied to operate McGarry's stapler. Tierney, 15:42-16:61.

Tierney, for example, describes storing tool-type data such as "the maximum force to be applied via driven elements" of the robotic system to drive each surgical tool. Tierney, 15:53-57; *see also* 6:20-26, 9:66-10:3, 11:66-12:29, 15:59-66, Fig. 5F. The tool-type date may be stored in tool memory 148 or in memory of the robotic system. *Id.*, 15:48-50, 16:5-7. The tool-type data is sent to software running on processor 152 to operate the tool. *Id.,* 16:53-61. And processor 152 limits the magnitude of the force applied via the driven elements of the robotic system accordingly. *Id.*; Fischer, ¶96. In the proposed combination the force applied by the driven disks 118 of Tierney's instrument interface is coupled via the staple pusher in McGarry and thus to the two lands 104R and 104L of McGarry's stapler, and thus to the staple itself, which applies a force to the body tissue. If the force applied to the driven disks 118 is limited, the force applied by the staple to the body tissue will be accordingly limited. And, because the McGarry lands 104R and 104L transmit both axial and transverse forces, both forces would be limited when the force exerted by the motor driving the lands is limited. Fischer, ¶96.

Thus, in the Tierney/McGarry robotic system, the force required to operate McGarry's stapler is supplied by the driven elements of Tierney's robotic system. *Id*. (explaining how an increase in the magnitude of the force applied via the driven elements increases the magnitude of the axial and transverse forces applied to staple 110 by each land 104R, 104L and vice versa). In the combination, the tool-type data (*e.g.*, "the maximum allowable force to be applied via the driven elements") is transferred from memory (tool memory 148 or robotic system memory) to the computer (Tierney's processor 152), and the computer uses that information to limit the magnitude of the forces applied via the driven elements. By limiting the magnitude of the forces applied via the driven elements of the robotic system to operate McGarry's stapler, Tierney's processor 152 limits the magnitude of the axial and transverse forces that can be applied to McGarry's staple 110 by each of McGarry's lands 104R, 104L.

[2] The system of claim 1, wherein the fastener includes a clip.

See Ground 1, element [1.2.1] (confirming that the fastener in the Tierney/McGarry robotic system is staple 110, which is a type of clip, as is clear from claim 3); Fischer, ¶98.

[3] The system of claim 2, wherein the clip includes a staple.

See Ground 1, claim [2].

[8] The system of claim 1, further comprising a position sensor configured to indicate a distance moved by the fastener.

Tierney in view of McGarry discloses this limitation. Fischer, ¶¶100-102. The Tierney/McGarry robotic system includes a position sensor (*e.g.*, motor encoder(s) E1, E2, E3, E4, and/or E5) configured to indicate a distance moved by the fastener (*e.g.*, the distance between staple 110's initial and fired positions) by providing an output which is indicative of the (rotational) position of the drive shaft, given that there is a direct relationship between the movement of the drive shaft and the fastener (*e.g.*, each rotation of the drive shaft corresponds to predetermined advancement of the pusher plate lands). In the combination, the drive shaft causes McGarry's pusher plate and lands to move downward, pushing the staple into the anvil and tissue. *Id.*; Tierney, 8:4-7 (incorporating by reference the entirety of Manhani); Madhani, 8:35-39, 10:22-30, Fig. 3; McGarry, FIGs. 15, 21, 17:50-18:7.

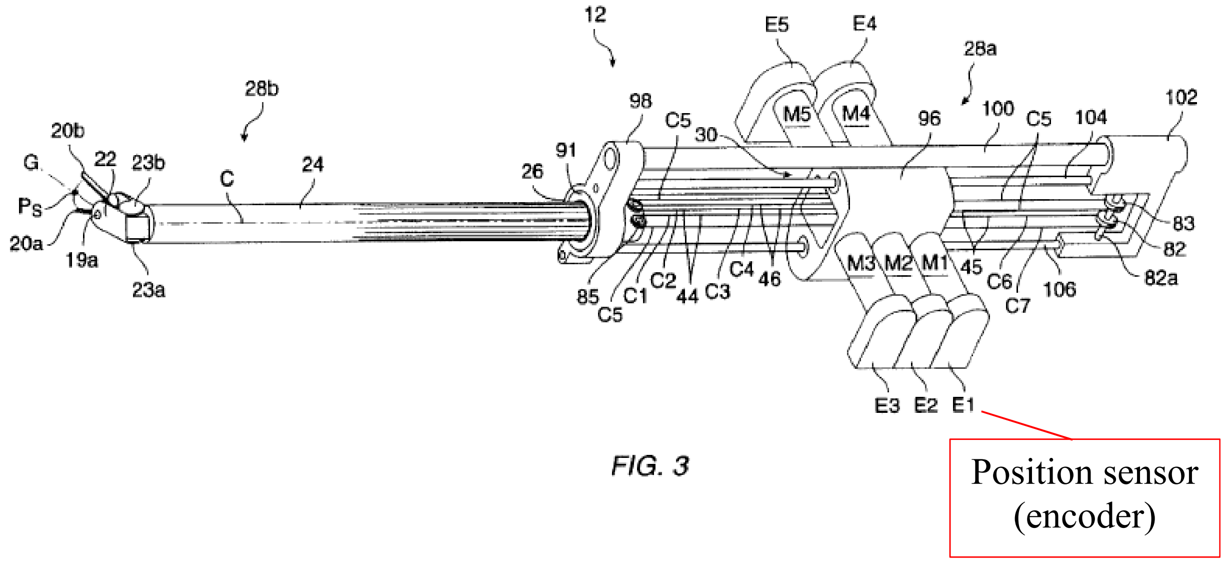
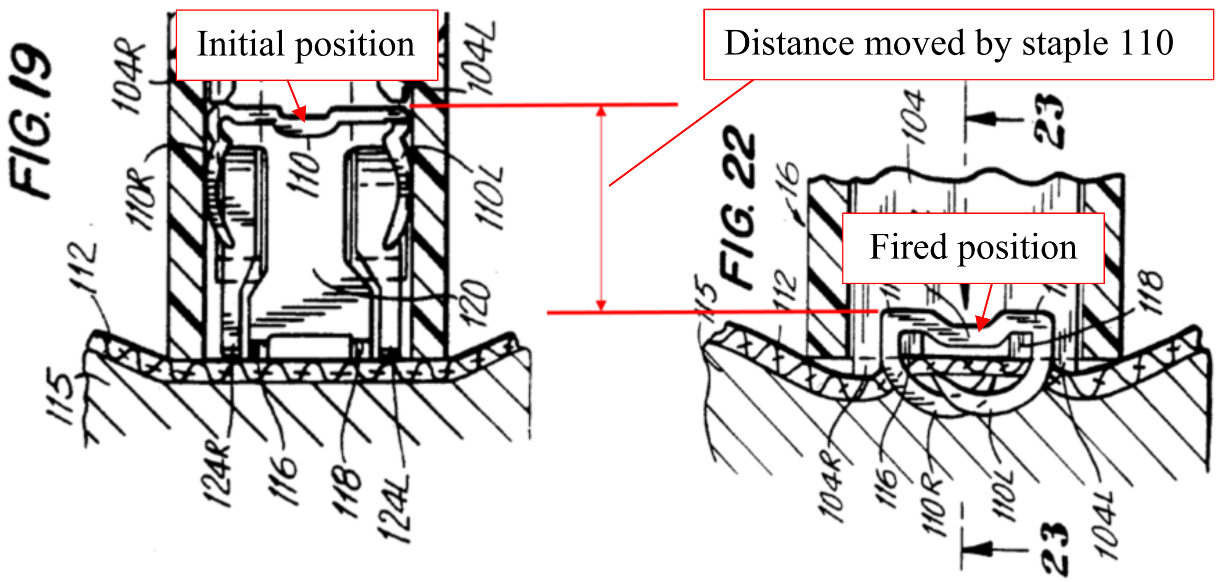


FIG. 3



The Tierney/McGarry robotic system uses at least one of Tierney's drive motors to drive McGarry's stapler. A POSITA would understand that the power to drive the staple may increased in a variety of ways. For example, the motor may be coupled via gears to the staple pusher of McGarry, and a POSITA would know that gears can be used to increase or decrease torque based on the gear ratio used.

Additionally, a POSITA would understand that cables may be used to drive the staple, and that by using pulleys with different diameters, torque may be increased or decreased. Additionally, multiple motors may be used to increase the power provided to the staple applier. Tierney, 9:31-45. Furthermore, Tierney's incorporation of Madhani discloses that "[e]ach drive motor … includes a respective encoder E1, E2, E3, E4 and E5 for providing [processor 152] with the rotational position of their respective drive shafts." Madhani, 8:35-39; *see also* Madhani, 10:22-30, Fig. 3. Tierney also incorporates Cooper '666 and Cooper '666 confirms that the drive motors "will preferably include encoders." Cooper '666, 16:38-17:1. Thus, like position sensor 452 in the '281 patent, which "has an output [that] is indicative of the position of the fastener drive member" and therefore "indicates the depth or distance to which the threaded fastener is moved into body tissue," Tierney's encoder has an output which is indicative of the position of the drive shaft that moves the fastener drive member (McGarry's pusher plate 104) and therefore indicates the distance that the fastener (staple 110) is moved. Fischer, ¶102; '281 patent, 36:54-59; *see also* '281 patent, 20:4-6 (confirming that "[a]n encoder connected with a drive assembly in the robotic mechanism 38 may be utilized to indicate the depth to which the long thin member 202 is moved into the patient's body"); Whitman, 7:63-9:8; Fig. 9 (confirming that encoders can be used to determine the absolute position of the staple driver).

[9] The system of claim 1, further comprising a force measurement device configured to indicate a resistance required to move the fastener relative to the body portion.

The Tierney/McGarry system includes a force measurement device (*e.g.*, "force sensors" alone or in combination with the servomechanism 16 and the "safety monitoring controller") configured to indicate a resistance (force) required to move the fastener relative to the body portion. Fischer, ¶¶103-108.; Tierney, 13:40-53, 15:62-16:4 (discussing variable force limits), 1:60-66; Cooper '666, 16:38-17:3. As explained above, the Tierney/McGarry system uses at least one of Tierney's drive motors to drive McGarry's stapler. Furthermore, Tierney's incorporation of Manhani discloses that the system in which "the surgical instrument detects forces for force reflection" and "only the instrument is used to reflect forces to the master." Tierney, 8:4-7; Manhani, 5:64-47, 7:38-44, 9:66-10:1; Fischer, ¶103. And "[s]ervomechanism 16 will usually provide force and torque feedback from the surgical instruments 20 to the hand-operated controllers 12. In addition, servomechanism 16 will include a safety monitoring controller (not shown) that may freeze or at least inhibit all robot motion in response to recognized conditions (*e.g.*, exertion of excessive force on the patient …)." Cooper '666, 9:16-26.

Thus, like force measurement assembly 450 in the '281 patent, which "has an output … indicating the magnitude of resistance encountered by the fastener drive member 446 to rotation of the fastener," Tierney's force sensor has an output indicating the magnitude of the resistance encountered by the fastener drive member (Tierney's drive motor) to movement of McGarry's staple 110 relative to the body portion. Fischer, ¶105;. Furthermore, the Tierney/McGarry system's servomechanism 16 and safety monitoring controller indicate that the resistance required to move McGarry's lands 104L, 104R, and thus staple 110, relative to the body portion is excessive by freezing or at least inhibiting robotic control of the stapler. This teaching informs a POSITA that the forces are being sensed, measured, and reported the system so that the system can implement the safety protocol if forces are exceeded. Fischer, ¶¶105-107.

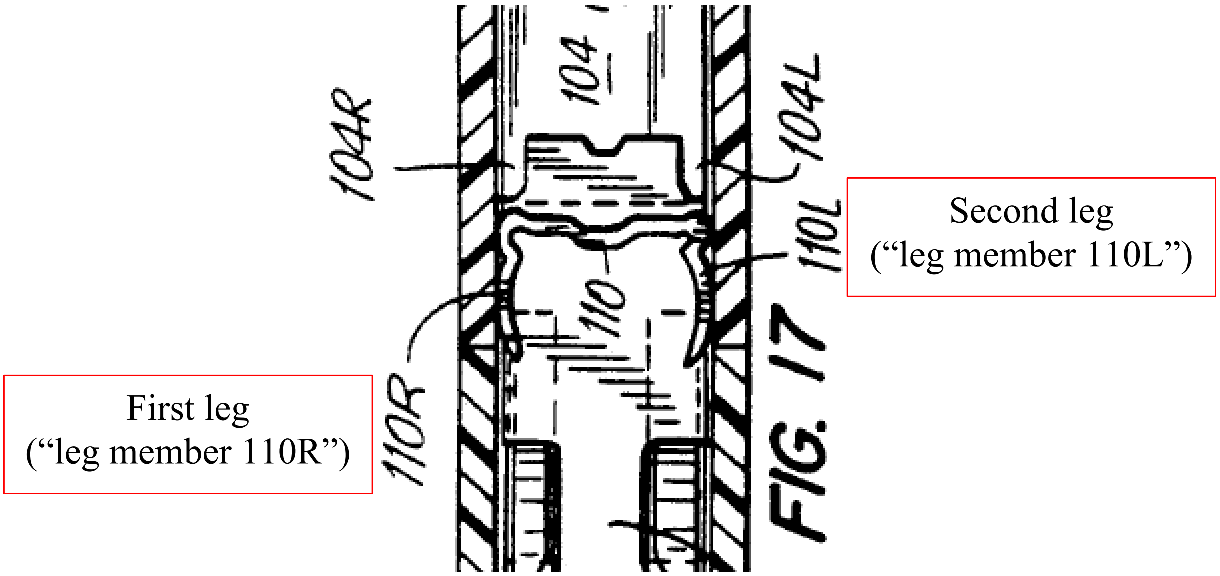
Finally, Tierney/McGarry system also includes "a force measurement device configured to indicate a resistance required to move the staple relative to the body portion" under Patent Owner's apparent construction. Patent Owner, for example, appears to believe that this limitation reads on a robotic stapling system that measures the torque output of the drive motor and changes the torque limit of the drive motors based on the type of instrument installed. *See* Preliminary Infringement Contentions, Ex. B-1, p. 15. As explained above, however, the Tierney/McGarry system includes force sensors for measuring the torque output of the drive motors. Furthermore, like the robotic stapling system accused of infringement in the related district court case, Tierney discloses that tool memory 148 stores tool-type data, including "the maximum force to be applied via driven element 118," and that the tool-type data is transmitted to Tierney's processor 152. Tierney, 15:43-16:14. Thus, a POSITA would understand that, in the Tierney/McGarry system, the tool-type data includes the maximum torque to be applied via Tierney's driven element 118 to operate the Tierney/McGarry stapler, which, under Patent Owner's apparent construction, indicates a resistance required to move the staple relative to the body portion. Fischer, ¶108.

[10.1] A robotic system for engaging a fastener with a body tissue, the system comprising:

See Ground 1, elements [1.1], [1.2.2].

[10.2.1] a robotic mechanism including an adaptive arm, the robotic mechanism configured to position the fastener having first and second legs,

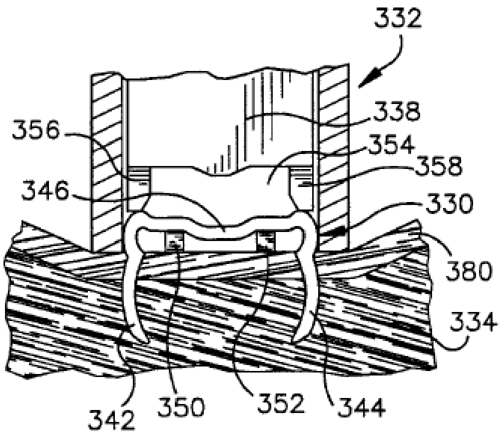
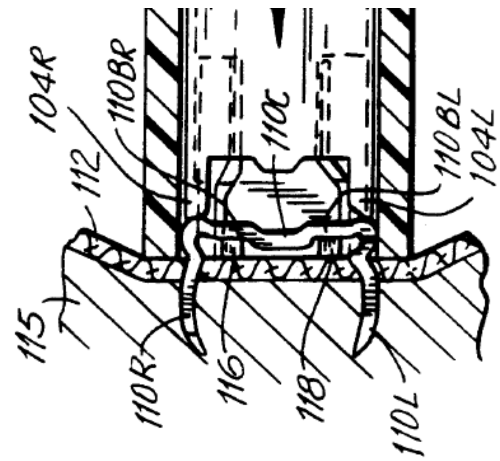
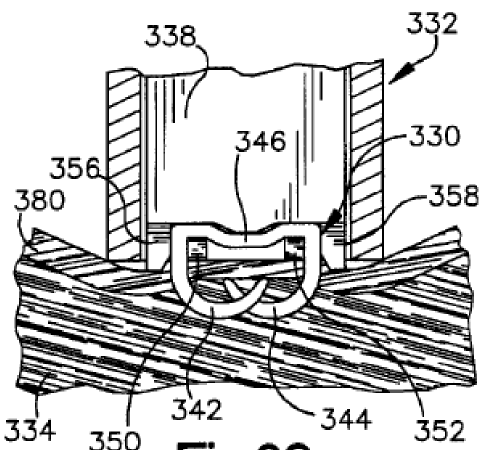
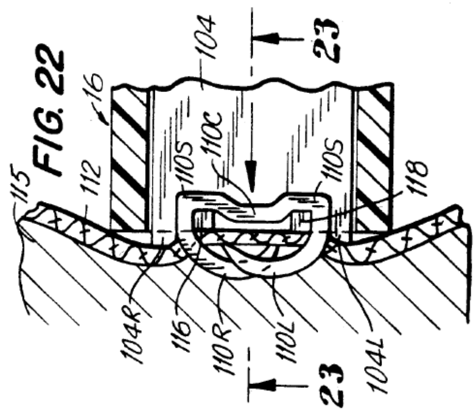
See Ground 1, elements [1.2.1]-[1.2.2] (confirming that the Tierney/McGarry robotic system includes a robotic mechanism including an adaptive arm and that the robotic mechanism is configured to position the fastener). As shown below, McGarry's fastener (staple 110) also has first and second legs (leg members 110R and 110L, respectively). McGarry, Fig. 17; Fischer, ¶110.



[10.2.2] the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force to move the first and second legs toward each other;

See Ground 1, element [1.2.2] (confirming that McGarry's lands 104L, 104R are the claimed first and second force transmitting portions configured to apply at least one of an axial force and at least one of a transverse force to the fastener).

Although element [10.2.2] recites additional details—namely that the first and second force transmitting portions move the first and second legs toward each other, McGarry's lands 104L, 104R perform this function with the identical, or at least equivalent, structure. The differences (if any) between McGarry's lands and the '281 patent's lands 356, 358 are not substantial. Fischer, ¶¶111-112. Like the '281 patent's lands 356, 358, McGarry's lands 104L, 104R performs the additional function of moving the first and second legs of the staple (leg members 110R and 110L, respectively) toward each other in the same way (physically contacting the legs and moving to apply the forces) to produce substantially the same result (closing the staple). McGarry, 19:51-68; Fischer, ¶112.

’281 patent	**McGarry**
 Fig.25	 Fig. 21
 Fig.26	

If the Board does not agree that the term “first and second force transmitting portions” invokes 35 U.S.C. § 112, ¶ 6, then, as shown above, McGarry’s lands (104L and 104R) are nonetheless first and second force transmitting portions that are configured to apply at least one of an axial force and a transverse force to move the first and second legs (leg members 110R and 110L, respectively) toward each other. Fischer, ¶113.

[10.3] a computer configured to control the robotic mechanism and limit a magnitude of the at least one axial force and transverse force; and

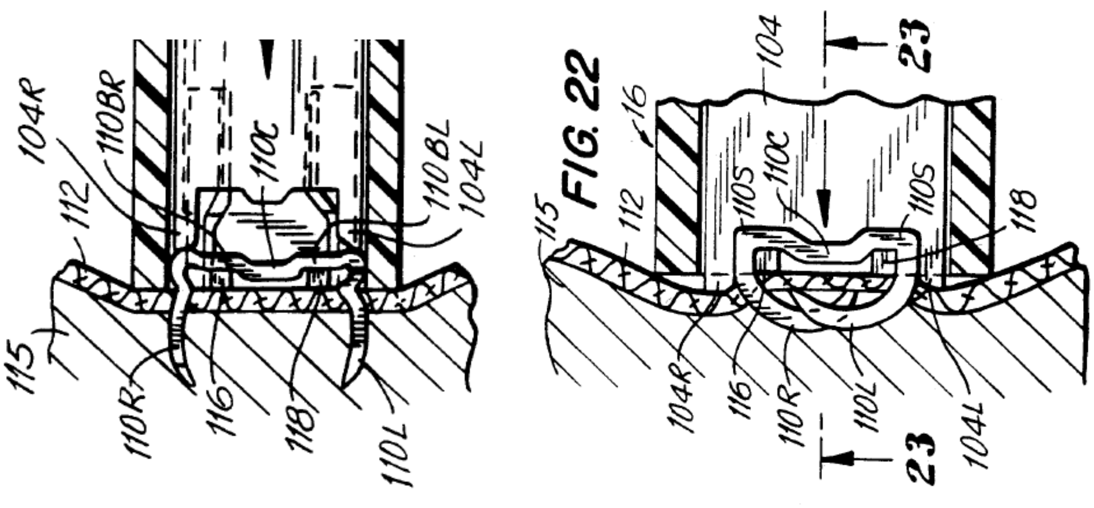
See Ground 1, elements [1.3], [1.5].

[10.4] an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer,

See Ground 1, element [1.4].

[10.5] wherein the first and second legs are configured to engage the fastener with the body tissue.

McGarry discloses this limitation. Fischer, ¶116. As shown below, the first and second legs of McGarry's fastener (leg members 110R and 110L of staple 110) engage body tissue (115). *Id.*; McGarry*,* Figs. 21-22.



[11] The system of claim 10, wherein the fastener includes a clip.

See Ground 1, claim [2].

[12] The system of claim 11, wherein the clip includes a staple.

See Ground 1, claim [3].

[16] The system of claim 10, further comprising a position sensor configured to indicate a distance moved by the fastener.

See Ground 1, claim [8].

[18.1] A robotic system for engaging a fastener with first and second body tissue sections, the system comprising:

See Ground 1, element [1.1] (confirming that Tierney in view of McGarry discloses a robotic system for engaging a fastener with a body tissue). McGarry explains that staples have traditionally been used to fasten first and second body tissue sections. "The staple is applied to two pieces of body tissue on opposite sides of the opening which are gripped, approximated and held together by a tissue positioning assembly." McGarry, 2:26-29 (discussing prior art). Although McGarry is focused on attaching mesh to tissue, it would have been obvious to a POSITA based on McGarry's prior art discussion of tissue-to-tissue stapling to apply McGarry's staples to first and second body tissue sections on opposite sides of an opening. Fischer, ¶121-122; *see also* McGarry, 18:57-60, 19:7-10.

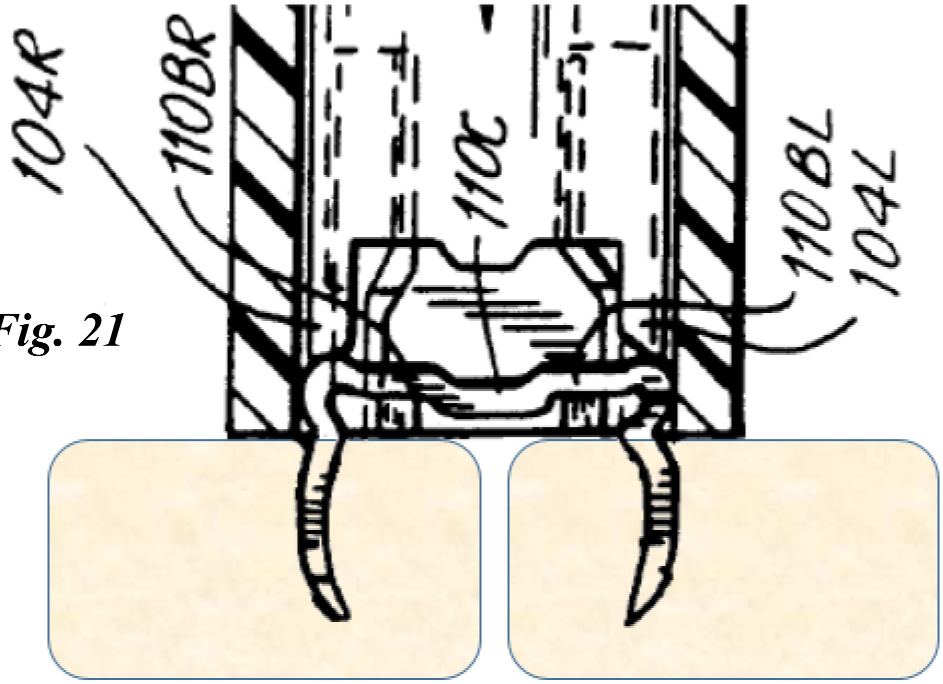


Fig. 21

In addition, it was well-known in the art that surgical staples stapled two sections of tissue stacked one on top of the other, wherein each staple leg passes through both sections of tissue, and a POSITA would have understood that when the staple is closed, the staple urges the two stacked sections together. In fact, McGarry discloses stacking a material on tissue and a POSITA would have understood that instead of material, two sections of tissue could be stapled together. Fischer, ¶122.

[17] The system of claim 10, further comprising a force measurement device configured to indicate a resistance required to move the fastener relative to the body portion.

See Ground 1, claim [9].

[18.2.1] a robotic mechanism including an adaptive arm, the robotic mechanism configured to position the fastener relative to first and second body tissue sections,

See Ground 1, elements [1.2.1], [18.1].

[18.2.2] the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force to urge the first and second body tissue sections together;

See Ground 1, elements [1.2.2], [10.2.2] (confirming that McGarry's lands 104L, 104R are the claimed first and second force transmitting portions configured to apply at least one of an axial force and at least one of a transverse force to the fastener to move the first and second legs toward each other). As shown below, moving the first and second legs of staple 110 together also urges the first and second body tissue sections together (exemplary body tissue sections illustrated with yellow blocks). Alternatively, the sections of tissue could be stacked one on top of the other *Id.*; Fischer, ¶¶124-125; McGarry, Figs. 21-22.

Fig. 21

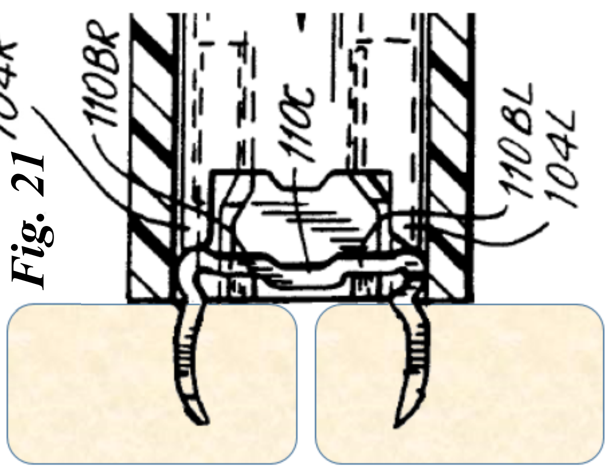
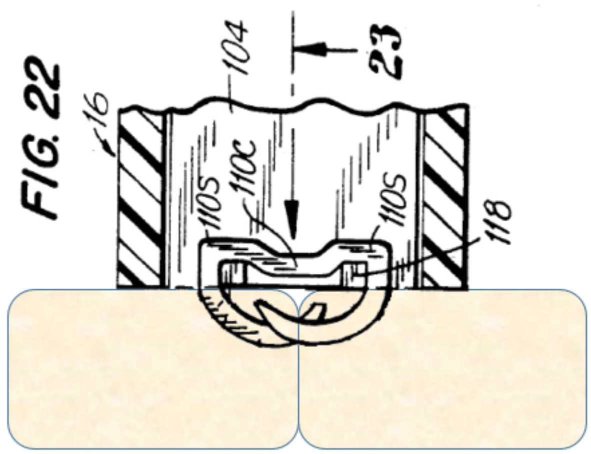


FIG. 22



Although element [10.2.2] recites an additional function performed by the first and second force transmitting portions (urging the first and second body tissue sections together), McGarry's lands 104L, 104R and the '281 patent's lands 356, 358 are still equivalent structures because the differences between them (if any) are not substantial. Fischer, ¶125. Like the ’281 patent’s lands 356, 358, McGarry’s lands 104L, 104R performs the additional function of moving the first and second legs of the staple (leg members 110R and 110L, respectively) toward each other in the same way (physically contacting the legs and moving to apply the forces) to produce substantially the same result (closing the staple and urge the body tissue sections together). McGarry, 19:51-68; Fischer, ¶126.

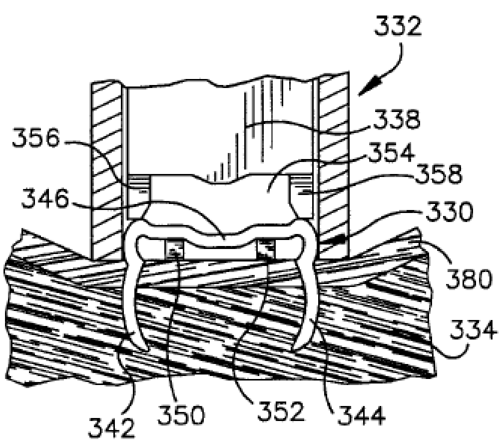
<table>
<tr><th>’281 patent</th><th>McGarry</th></tr>
<tr><td>

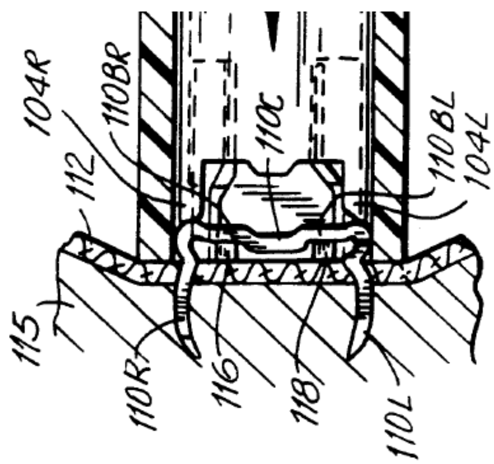
Fig.25</td><td>

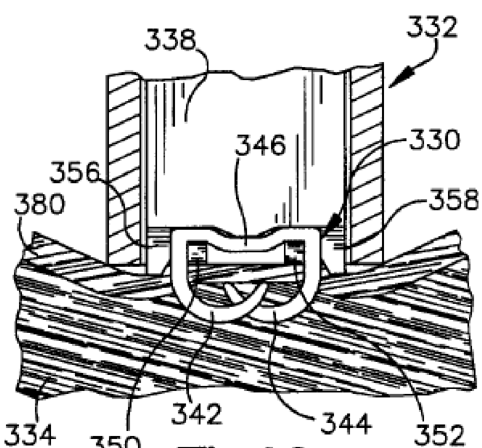
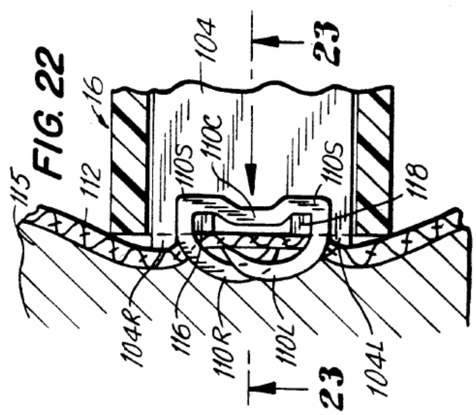
Fig. 21</td></tr>
<tr><td>

Fig.26</td><td>
</td></tr>
</table>

If the Board does not agree that the term "first and second force transmitting portions" invokes 35 U.S.C. § 112, ¶ 6, then, McGarry's lands (104L and 104R) are nonetheless first and second force transmitting portions that are configured to apply at least one of an axial force and a transverse force to urge the first and second body tissue sections together. Fischer, ¶127.

[18.3] a computer configured to control the robotic mechanism and limit a magnitude of the at least one axial force and transverse force; and

See Ground 1, element [10.3].

[18.4] an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer.

See Ground 1, element [1.4].

[19] The system of claim 18, wherein the fastener includes a clip.

See Ground 1, claim [2].

[20] The system of claim 19, wherein the clip includes a staple.

See Ground 1, claim [3].

B. Ground 2: Claims 4-8 and 13-15 are obvious over Tierney in view of McGarry and further in view of Hooven

[4] The system of claim 1, further comprising a display configured to indicate the magnitude of the transverse force.

Tierney in combination with McGarry and Hooven renders this limitation obvious. Fisher, ¶¶132-139. The Tierney/McGarry system includes a display ("stereo display [154] and/or assistance monitor"). Tierney, 14:57-61, Fig. 1.

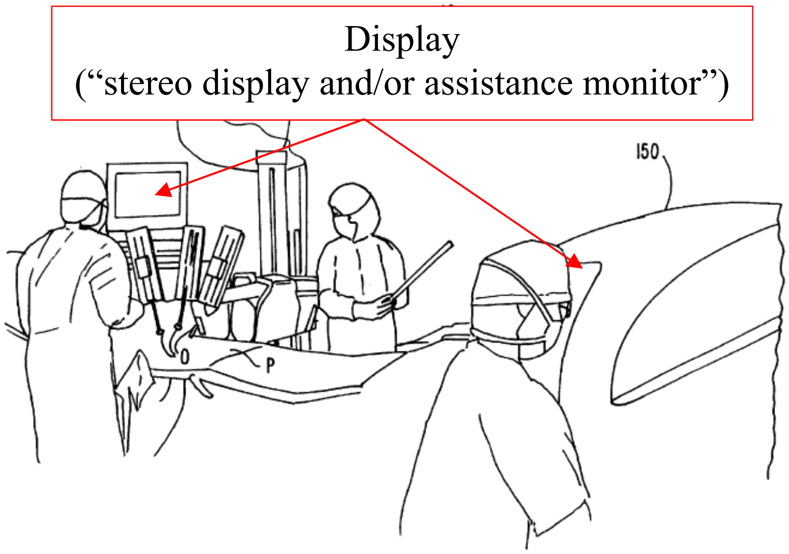


FIG. 1.

It would have been obvious in view of Hooven to modify McGarry's lands 104R, 104L to include a force sensor that measures the transverse force and to display information indicating the magnitude of the transverse force. Fischer, ¶133.

For example, Hooven discloses an endoscopic ligating system comprising jaws 111 (highlighted in yellow below) that apply a transverse force to close surgical clip 120 (highlighted in blue below). Hooven, Figs. 11-16.

FIG-14

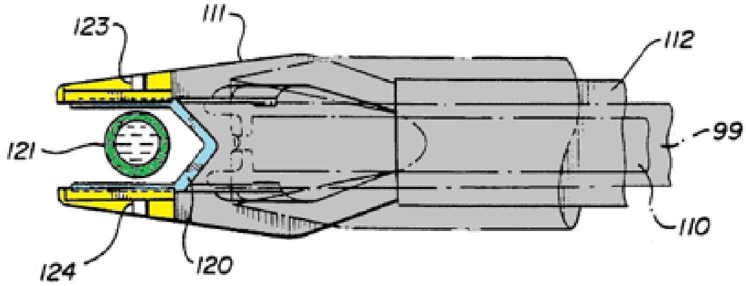


FIG-15

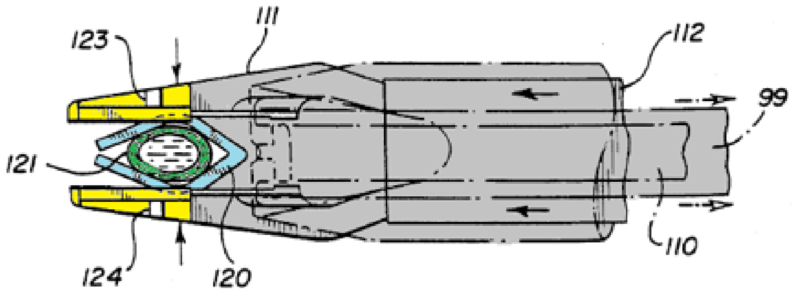
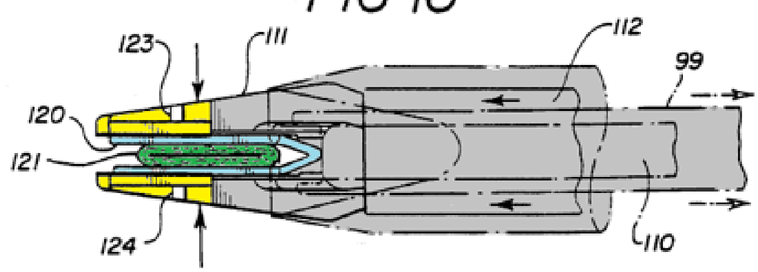
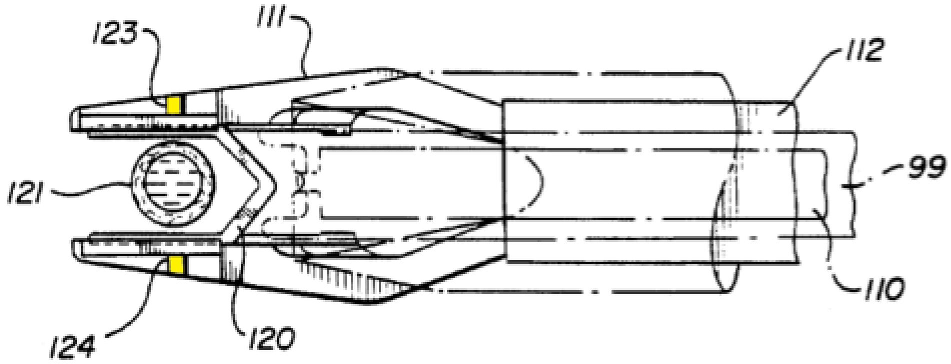


FIG-16

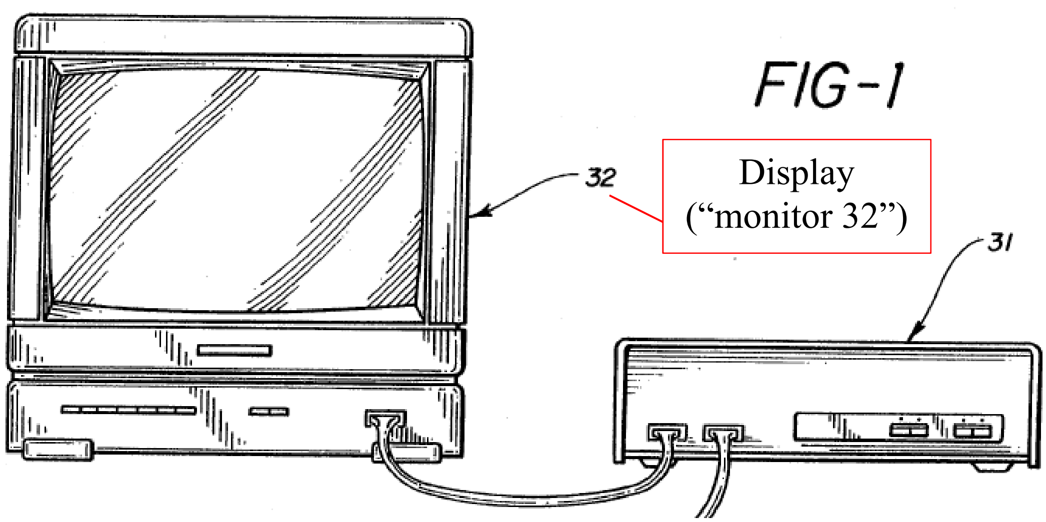


Importantly, jaws 111 include "[s]uitable sensing means 123 and 124 [that] can determine whether or not there is an appropriate clip in the jaws, whether or not the clip is appropriately closed and when the stack of clips is empty." Hooven, 7:54-63, Figs. 14-16. Hooven further explains that "[a]ll of this information may be fed back to a controller for storage and manipulation and appropriate information reported to the operator of the instrument." Hooven, 7:32-33. And Hooven confirms that the "sensing means" can be a force sensor. *Id.*, 3:5-8. Thus, because a "force sensor" is an option disclosed in Hooven, sensors 123 and 124 are disclosed as being "force sensors". Alternatively, at the very least it would have been obvious to implement sensors 123 and 124 as force sensors given Hooven's teachings.

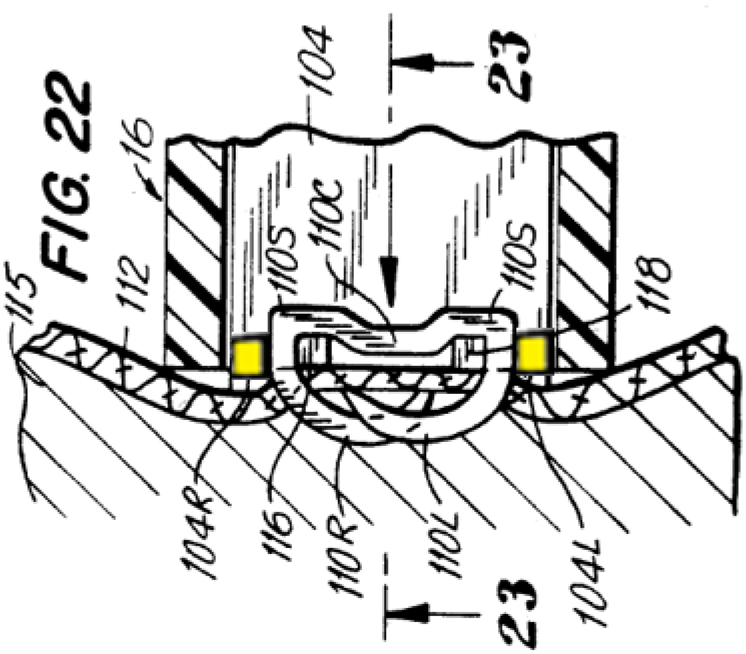
FIG-14



Furthermore, Hooven discloses "a display screen to present the data [controller 31] has received from" sensors 123 and 124. *Id.*, 4:30-32; 8:62-9:17 (confirming the sensors are "connected to the controller," and the corresponding information processed by the controller "is fed to a video display screen").



Thus, in the proposed combination, Hooven's sensing means 123 and 124 are added to McGarry's lands 104R, 104L and Tierney's display is configured to indicate information derived from the sensors, including, for example, whether or not there is an appropriate staple 110 at the distal end of McGarry's stapler, whether or not the staple is appropriately closed. Fischer, ¶135. The composite image below of McGarry, Figure 23 and Hooven, Fig. 14 shows an example of the resulting stapler.



A POSITA would have been motivated to include Hooven's sensing means 123 and 124 in McGarry's lands 104R, 104L and to display the corresponding information on Tierney's display(s) for the reasons provided in Hooven, and in particular, as Hooven teaches, an operator would want to know if a staple is present and whether it has been appropriately closed. A POSITA would have been further motivated to make this modification because Hooven explicitly teaches that sensing means 123 and 124 "can be used with other endoscopic instruments," like McGarry's stapler. Hooven, 7:64-67. And Hooven confirms that the use of sensors to control the operation of an endoscopic instrument provides "a high degree of control and reliability while expanding the scope of the actions that can be accomplished by any specific instrument to provide improved endoscopic procedures." Hooven, 9:34-39. Fischer, ¶¶135-137.

A POSITA would have reasonably expected the combination of Hooven's sensing means 123 and 124 with McGarry's stapler to be successful because it is merely the application of a known technique (using Hooven's sensing means to measure the transverse force) with a known system (McGarry's stapler) in a common field of endeavor (surgical fasteners). *Id.*; *KSR*, 550 U.S. at 417. Furthermore, each element (Hooven's sensing means and stapler) merely performs the same predictable function as it does separately (*e.g.*, sensing and stapling, respectively), without significantly altering or hindering the functions performed by the other. Fischer, ¶138.

Likewise, a POSITA would have reasonably expected the combination of the McGarry/Hooven stapler with Tierney's robotic system to be successful for the same reasons that a POSITA would have reasonably expected the combination of

McGarry and Tierney to be successful. *See* Ground 1, element [1.2.2]. A POSITA also would have reasonably expected the combination of the McGarry/Hooven stapler with Tierney's robotic system to be successful because it is merely the application of a known technique (displaying the information received from Hooven's sensors) with a known system (Tierney's robotic system) in a common field of endeavor (computer-controlled surgical fasteners). *Id.*; KSR, 550 U.S. at 417. Indeed, the task of moving the functionality of Hooven's microprocessor and display to Tierney's microprocessor and display would have been trivial. *Id*. Not surprisingly, each element (Tierney's robotic system, McGarry's stapler, and Hooven's sensing means) merely performs the same predictable function as it does separately (*e.g.*, providing remote control of various surgical instruments and displaying relevant information to the surgeon, stapling, and sensing the transverse force, respectively), without significantly altering or hindering the functions performed by the other. Fischer, ¶139.

[5] The system of claim 1, wherein the robotic mechanism includes a force sensor configured to measure the transverse force.

See Ground 2, claim [4] (confirming that the combination of Tierney, McGarry, and Hooven discloses, or at least renders obvious, a force sensor (Hooven's sensing means 123 and 124) configured to measure the transverse force). Fischer, ¶140.

[6] The system of claim 5, wherein the force sensor includes a piezoelectric cell.

Tierney in view of McGarry and Hooven discloses this element in combination with general knowledge in the art. Fischer, ¶141. As explained in Ground 2, claim [4], the combination includes "suitable" force sensors (sensing means 123 and 124). A POSITA would have understood that a piezoelectric cell is a suitable force sensor. *See, e.g.*, File History, 165 (1-10-2014 Office Action) ("[A] piezoelectric cell is a well-known art-recognized equivalent of a detector at the time the invention was made, and the Examiner takes **Official Notice** that is [sic] use is common knowledge in the art and would have found it obvious to substitute one type of detector for another.") (emphasis original).

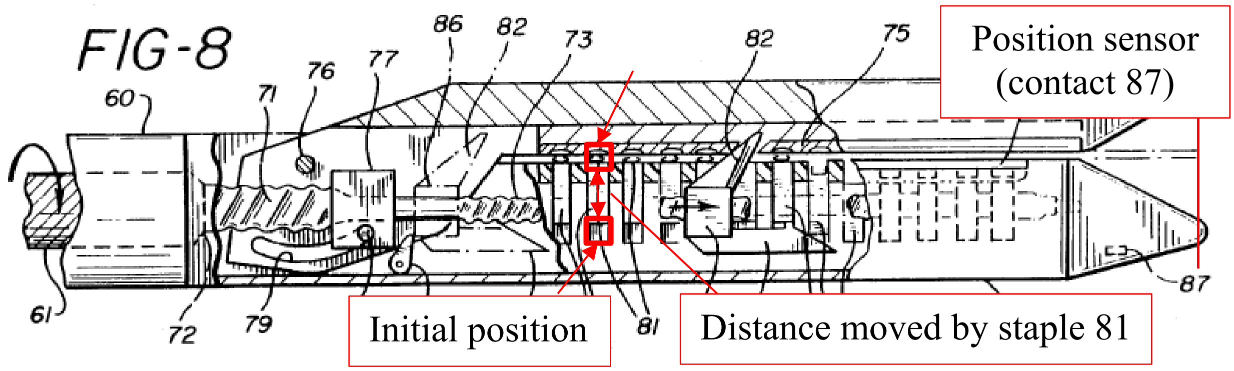
[7] The system of claim 1, further comprising a visual read out configured to enable a user to determine a magnitude of the transverse force.

See Ground 3, claim [4]. A read out, for example, indicating that the staple is appropriately closed enables a user (the surgeon) to determine a magnitude of the transverse force (*e.g.*, that McGarry's lands applied sufficient transverse force to close the staple). *Id.*; Fischer, ¶142.

[8] The system of claim 1, further comprising a position sensor configured to indicate a distance moved by the fastener.

Tierney in view of McGarry discloses this element. *See* Ground 1, claim [8] (confirming that Tierney's motor encoder is the claimed position sensor). Fischer, ¶¶143-147.

In addition, Hooven itself discloses a position sensor that would render this element obvious. It would have been obvious to a POSITA in view of Hooven to modify the Tierney/McGarry system to include a position sensor on the end effector configured to indicate a distance moved by the fastener. *Id*. Hooven discloses a position sensor (*e.g.*, contact 87) configured to indicate a distance moved by a fastener (*e.g.*, the distance Hooven's staple 81 moves from its initial position inside the cartridge to its driven position). *Id*.; Hooven, 6:16-18.



As explained in Hooven, "[o]nce the firing nut has moved to its most forward position to drive and form all of the staples and cut the tissue, it engages a suitable contact 87." Hooven, 6:16-18. Thus, this sensor is configured to indicate the position of the staples because, when the firing nut reaches the end of its firing stroke and activates the sensor, all staples have been fired and are thus in their fired position. Fischer, ¶144.

When combined with McGarry's stapler, Hooven's contact 87 is placed near the end of the firing stroke of McGarry's pusher plate 104. *Id*. Thus, like position sensor 452 in the ’281 patent, which “has an output which is indicative of the position of the fastener drive member” and therefore “indicates the depth or distance to which the threaded fastener is moved into body tissue,” Hooven’s contact 87 has an output which is indicative of the position of the fastener drive member (McGarry’s pusher plate 104) and therefore indicates the distance which the fastener (McGarry’s staple 110) is moved. Fischer, ¶145; ’281 patent, 36:54-59.

A POSITA would have been motivated to make this modification for the reasons provided in Hooven. “For example, the surgeon may be informed as to the position of the instrument in the procedure [and] the operation of the instrument….” Hooven, 2:44-48. Similarly, Hooven’s contact 87 may provide another way for Tierney’s computer to accurately and safely control the operation of McGarry’s stapler. Fischer, ¶146.

A POSITA combining Hooven’s contact 87 with the Tierney/McGarry system would have reasonably expected to succeed because it is merely the application of a known technique (using Hooven’s contact 87 to measure the position of a staple driver) with known systems (McGarry’s stapler and Tierney’s robotic system) in a common field of endeavor (computer-controlled surgical fasteners). *Id.*; *KSR*, 550 U.S. at 417. Furthermore, each element (Tierney’s robotic system, McGarry’s stapler, Hooven’s contact 87) merely performs the same predictable function as it does separately (*e.g.*, providing remote control of various surgical instruments, stapling, and sensing the position of a staple driver, respectively), without significantly altering or hindering the functions performed by the other.

Fischer, ¶147.

[13] The system of claim 10, further comprising a display configured to indicate the magnitude of the transverse force.

See Ground 2, claim [4]

[14] The system of claim 10, wherein the robotic mechanism includes a force sensor configured to measure the transverse force.

See Ground 2, claim [5]

[15] The system of claim 14, wherein the force sensor includes a piezoelectric cell.

See Ground 2, claim [6]

C. Ground 3: Claims 1-20 are obvious over Tierney in view of Hooven under Patent Owner's apparent construction

[1.1] A robotic system for engaging a fastener with a body tissue, the system comprising:

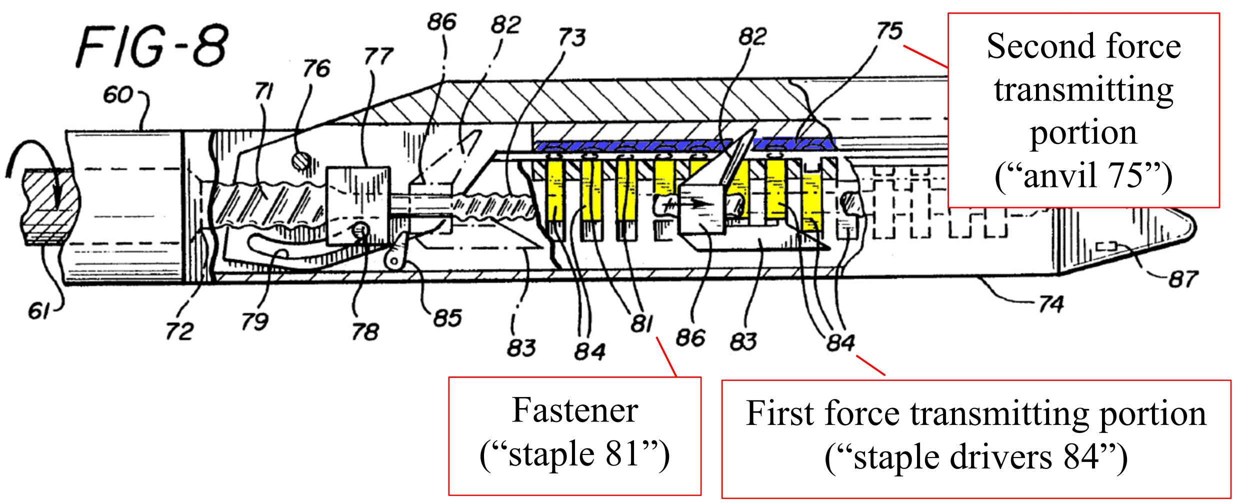
See Ground 1, element [1.1].

[1.2.1] a robotic mechanism including an adaptive arm, the robotic mechanism configured to position a fastener relative to the body tissue,

See Ground 1, element [1.2.1].

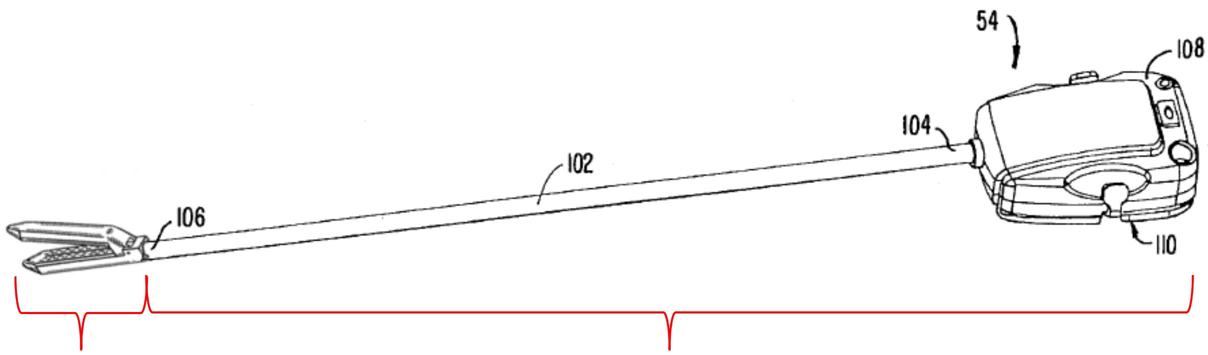
[1.2.2] the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force relative to the fastener;

Tierney in view of Hooven discloses this element under Patent Owner's apparent construction. Fischer, ¶¶153-161. Like Petitioner's EndoWrist stapler accused of infringing claim 1, Hooven discloses a linear surgical stapler 30 comprising a wedge-shaped sliding mechanism (driving wedge 83) that drives staple drivers 84 (shown below in yellow) and an anvil (item 75, shown below in blue). *Id.*; Hooven, 5:9-6:47, Figs. 6-10; Complaint, ¶¶51-55.



When stapler 30 is fired, driving wedge 83 is driven along the length of the stapler by a motor 45 and a drive screw (*e.g.*, threaded rod 71) to move staple drivers 84 and staples 81 toward anvil 75. *Id.* As a result, the two legs of the open end of each staple 81 are forced toward each other by the features of the anvil (recesses shown above in Figure 8) that form the staples to secure the body tissue. *Id.* Under Patent Owner's apparent construction, the staple drivers 84 are one of the first and second force transmitting portions, even though they do not apply a transverse force.

It would have been obvious to modify Hooven's stapler for use with Tierney's robotic system. Fischer, ¶155-158. An example of the resulting tool ("the Tierney/Hooven stapler") is shown below in the composite image of Tierney, Figure 4 and Hooven, Figure 2:



Hooven
Fig. 2

Tierney
Fig. 4

In this tool, the forces required to operate Hooven's end effector are either provided by Hooven's motor 45, which would be incorporated into the proximal housing 108 of Tierney's tool 54, or by the driven discs 118 of Tierney's robotic system, which are driven by Tierney's motors 70. In either case, the forces used to operate the tool would be controlled by Tierney's processor 152. *Id.*

Furthermore, like Tierney's robotic system, the Tierney/Hooven system is a robotic system for engaging a fastener (*e.g.*, Hooven's staple 81) with a body tissue (*e.g.*, bowel or lung tissue) and Tierney's robotic mechanism (cart 50) is configured to position Hooven's staple 81 relative to the body tissue. Thus, the Tierney/Hooven system still satisfies elements [1.1] and [1.2.1]. *Id.*

A POSITA would have been motivated to modify Hooven's stapler for use with Tierney's robotic system for the same reasons that a POSITA would have been motivated to modify McGarry's stapler for use with Tierney's robotic system, including for the benefits robotic systems can offer for surgical tools traditionally used by hand. *See* Ground 1, element [1.2.2]. A POSITA would have been further motivated to combine Tierney and Hooven because, like Tierney, one of Hooven's objectives is "allowing for a high degree of control in the manipulation of the active part or business head of an endoscopic instrument." Hooven, 2:24-27. Given those overlapping concerns, a POSITA would have been motivated to implement the computer-control features of Hooven's stapler into Tierney's robotic system to obtain a high degree of control over the resulting robotic surgical stapler. Fischer, ¶158. A POSITA would have also seen the clear safety benefits (*e.g.,* preventing the stapler from firing when no staple cartridge is present or too much tissue is clamped between the jaws) of such a routine and common-sense modification. Fischer, ¶158; *KSR*, 550 U.S. at 424.

Moreover, a POSITA would have reasonably expected the combination of Tierney and Hooven to be successful. Fischer, ¶¶159-161. Indeed, it would have been merely the application of a known technique (use of a surgical stapler end effector) with a known system (Tierney's surgical robot) in a common field of endeavor (the development of surgical instruments). *Id.*; *KSR*, 550 U.S. at 417. As shown in Anderson and Tovey, the adaptation of a handheld instrument, like

Hooven's stapler, for use with a robotic system, like Tierney's, (*e.g.*, by incorporating the components inside Hooven's tool into Tierney's proximal housing 108 and shaft 102 and, if desired, replacing Hooven's motor 45 with one or more of Tierney's rotary driven discs) was well within the level of skill in the art. *Id.*; Anderson (IS1019), 1:52-2:55, 3:44-61, 7:6-25, and Tovey (IS1018), 3:37-48. And, in the Tierney/Hooven robotic system, Tierney's robot and Hooven's stapler end effector both continue to work as they always have. Fischer, ¶¶159-161. Thus, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by Hooven's stapler (stapling) or Tierney's robotic system (positioning the tool, providing mechanical controls to the tool, and receiving feedback signals from the tool). Fischer, ¶161.

[1.3.] a computer configured to control the robotic mechanism; and

See Ground 1, element [1.3].

[1.4] an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer,

See Ground 1, element [1.4].

[1.5] wherein a magnitude of the at least one axial force and transverse force applied to the fastener is limited by the computer.

Tierney in view of Hooven discloses this limitation under Patent Owner's apparent construction. Fischer, ¶¶164-168. In the Tierney/Hooven system, the magnitude of the forces applied relative to the fastener (Hooven's staple 110) by

Hooven's driving wedge 83 and anvil 75 are limited by Tierney's computer (processor 152) because Tierney's processor limits the magnitude of the force applied by the driving wedge 83 of Hooven and thus limits the magnitude of the axial and transverse forces that can be generated by the forward movement of the driving wedge 83 when Hooven's stapler is operated. Tierney, 15:42-16:61. The force applied by Hooven's driving wedge 83 is prescribed and controlled by the computer (processor 152) of the Tierney/Hooven system by prescribing and controlling the force applied by the motor. Fischer, ¶164; *See* Complaint, ¶49 (reading claims on a linear stapler that uses a driving wedge and anvil on opposite side of staple).

As explained above in Ground 1, element [1.5], Tierney describes storing tool-type data such as "the maximum force to be applied via driven elements" of the robotic system to drive each surgical tool. Tierney, 15:43-16:14; 6:20-26, 9:66-10:3, 11:66-12:29, Fig. 5F. The tool-type data from memory is sent to software running on processor 152 to operate the tool. *Id.,* 16:53-61. And processor 152 limits the magnitude of the force applied via the driven elements of the robotic system accordingly. *Id.*; Fischer, ¶165; *see* Ground 1, element [1.5]. Thus, a POSITA would understand that, in the Tierney/Hooven system, the tool-type data includes the maximum torque to be applied via Tierney's driven element 118 to operate the Tierney/Hooven stapler (and which provides the torque for the axial force applied by the staple drivers 84 and at least the transverse force applied by the anvil against the staple), and thus the magnitude of the axial force and transverse force applied to the fastener is limited by the computer. Fischer, ¶165.

Like Tierney, Hooven discloses a computer that controls the force used to operate the surgical tool and therefore limits the magnitude of the alleged axial and transverse forces that can be applied relative to the fastener. Fischer, ¶166; Hooven, 2:6-3:8. More specifically, Hooven discloses "sensing means attached to [Hooven's stapler] to measure the force used in carrying out the [clamping and firing] step[s] in the procedure, and control means, interconnected with [the] sensing means, to control the operation of [Hooven's stapler] while carrying out the step[s] in the procedure." Hooven, claim 1; *see also* 3:2-4, 4:20-32, 8:18-49, Fig. 18. Thus, Hooven's control means (*e.g.*, controller 31) "acts to supply power to the instrument at the appropriate level." *Id.*, 4:20-32.

As noted above in Ground 3, element [1.2.2], in the Tierney/Hooven system, Hooven's control mechanism is incorporated into Tierney's processor 152 and the forces required to operate Hooven's stapler are supplied by the driven elements of Tierney's robotic system or Hooven's motor. In the combination, "the maximum allowable force to be applied via the driven elements" information is provided to the computer (Tierney's processor 152), and the computer uses that information to limit magnitude of the force applied via the driven elements. Fischer, ¶¶167-168. Thus, by limiting the magnitude of the force that can be applied to operate

Hooven's stapler, Tierney's processor 152 limits the magnitude of the axial and transverse forces that can be applied by Hooven's driving wedge 83 and anvil 75 relative to Hooven's staple 81. *Id*. Tierney's processor also limits the magnitude of the axial and transverse forces by receiving information from Hooven's sensors and supplying power to the instrument at the appropriate level. *Id*.

[2] The system of claim 1, wherein the fastener includes a clip.

See Ground 3, element [1.2.1] (confirming that the fastener in the Tierney/Hooven system is staple 81, which is a type of clip); Fischer, ¶169.

[3] The system of claim 2, wherein the clip includes a staple.

See Ground 3, claim [2].

[4] - [7]

See Ground 2, claims [4]-[7]. Tierney in view of Hooven discloses these claims for the same reasons provided for the Tierney, McGarry, Hooven combination, except that Hooven provides the stapler rather than McGarry. For each of these claims, Hooven's clip applier embodiment provides the teaching of using a force sensor to sense a transverse force and a system that provides an indication of that transverse force to the surgeon. Ground 3 primarily relies on Tierney in combination with Hooven's linear stapler (rather than McGarry's stapler), and for claims 4-7, and it would have been obvious to a POSITA to use the teachings regarding transverse force measurement from the clip applier embodiment in the linear stapler embodiment. A POSITA would have recognized the benefits of transverse force measurement to ensure staple closure integrity and there is no "teaching away" in Hooven that would dissuade a POSITA from applying the transverse force measurement teaching from the clip applier embodiment to the linear stapler embodiment. In particular, given Tierney's teaching of monitoring forces and having a "safety monitoring controller," a POSITA would be motivated to add transverse force sensors to the linear stapler's anvil to monitor the forces exerted in bending the staples and stop the operation if the forces are excessive. Fischer, ¶171.

[8] The system of claim 1, further comprising a position sensor configured to indicate a distance moved by the fastener.

Tierney in view of Hooven discloses this limitation. Fischer, ¶172. The Tierney/Hooven robotic system would include the same position sensor provided in Tierney's servo-mechanism (the encoders) as described in Ground 1. *See* Ground 1, claim [8] for a discussion of the position sensor. That analysis applies except that instead of the motor driving McGarry's staple pusher, the motor drives Hooven's wedge and staple drivers and the position of the motor is indicative of the position of the staples. In addition, Hooven discloses a position sensor to determine when all staples have been fired, and under Patent Owner's apparent construction, that position sensor would indicate a distance moved by the fastener (it would indicate that each fastener moved from the unfired to fired position).

Hooven, 6:9-25.

[9] The system of claim 1, further comprising a force measurement device configured to indicate a resistance required to move the fastener relative to the body portion.

Tierney in view of Hooven discloses this limitation under Patent Owner's apparent construction. Fischer, ¶¶173-177. Hooven discloses a force measurement device (*e.g.*, the sensor circuits in Hooven's controller 31) configured to indicate (via signals sent to the "logic circuits" in controller 31) a resistance required to move the fastener relative to the body portion ("the power and/or force being used" by drive motor 45 to move driving wedge 83 and fire staples 81). *Id.*; Hooven, 8:62-63, Figs. 1, 18; *see also* 4:20-32. As explained in Hooven, the sensors are "connected to the controller," which processes and manipulates the information from the sensors. *Id.*; *see also* 9:1-17 (noting that the information from the sensors "may also be fed back to the instrument controller to control some or all of the instrument function"). In the embodiment of the Tierney/Hooven system that uses Hooven's motor 45 to actuate the stapler, Hooven's sensor circuits are incorporated into Tierney's processor 152 to measure the resistance required to move staple 81. Fischer, ¶173; *see also* Ground 3, claim [4].

And Tierney's incorporation of Cooper '666 teaches "[s]ervomechanism 16 will usually provide force and torque feedback from the surgical instruments 20 to the hand-operated controllers 12. In addition, servomechanism 16 will include a safety monitoring controller (not shown) that may freeze or at least inhibit all robot motion in response to recognized conditions (*e.g.*, exertion of excessive force on the patient …).” Cooper ’666, 9:16-26, 16:38-17:3; *see also* Cooper ’666, 5:32-35, 8:19-23. Tierney’s force sensor has an output indicating of the magnitude of the force and torque encountered by Tierney’s drive motor to move Hooven’s staple 81 relative to the body portion. This resistance includes, among other sources of resistance, the resistance required to move the fastener relative to the body portion. Fischer, ¶¶175-176; ’281 patent, 36:49-52. Under Patent Owner’s apparent construction, this is sufficient to disclose a force measurement device configured to indicate a resistance required to move the fastener relative to the body portion.

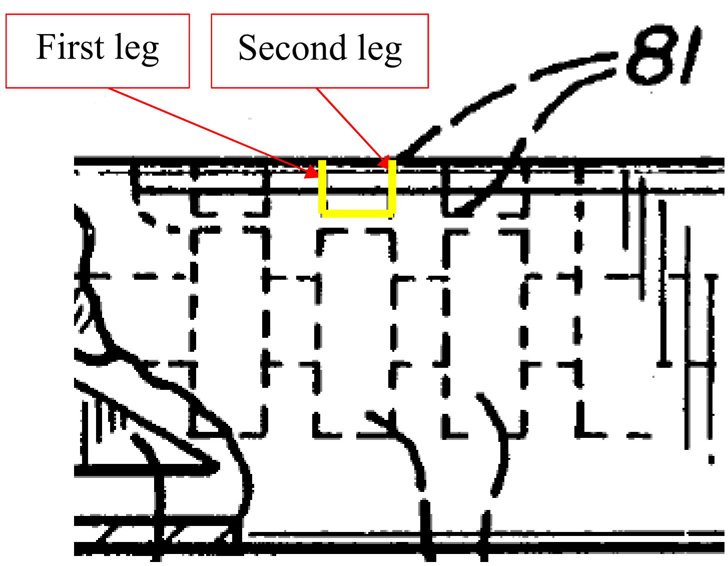
Finally, as explained above in Ground 3, claim [4], it also would have been obvious to add Hooven’s clip applier sensing means to Hooven’s stapler to determine staple positions, to determine whether or not the staples are appropriately closed, and to report that information to the operator of the instrument. Thus, the resulting device also includes a force measurement device (the combination of Hooven’s sensing means and Tierney’s processor 152) configured to indicate a resistance required to move the fastener relative to the body portion. Fischer, ¶177. Indeed, an indication from Tierney’s processor that staple 81 is appropriately closed clearly indicates that a magnitude of the force required to moved staple 81 relative to the body portion has been applied. *Id*.

[10.1] A robotic system for engaging a fastener with a body tissue, the system comprising:

See Ground 3, element [1.1].

[10.2.1] a robotic mechanism including an adaptive arm, the robotic mechanism configured to position the fastener having first and second legs,

See Ground 3, element [1.2.1]-[1.2.2] (confirming that the Tierney/Hooven system includes a robotic mechanism including an adaptive arm and that the robotic mechanism is configured to position the fastener). As shown below, Hooven's fastener (staple 81) also has first and second legs. Hooven, Fig. 6; Fischer, ¶179.



[10.2.2] the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force to move the first and second legs toward each other;

See Ground 3, element [1.2.2] (confirming that Hooven's staple drivers 84 and anvil 75 are the claimed first and second force transmitting portions configured to apply at least one of an axial force and at least one of a transverse force to the fastener to move the first and second legs toward each other under Patent Owner's apparent construction). Fischer, ¶180.

[10.3] a computer configured to control the robotic mechanism and limit a magnitude of the at least one axial force and transverse force; and

See Ground 3, elements [1.3], [1.5].

[10.4] an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer,

See Ground 1, element [1.4].

[10.5] wherein the first and second legs are configured to engage the fastener with the body tissue.

Hooven disclose this limitation. Fischer, ¶183. The first and second legs of Hooven's staple 81 are configured to engage the fastener with the body tissue (e.g., bowel or lung tissue). *Id.*; Hooven, 4:38-41.

[11]-[14]

See Ground 3, claims [2]-[5]. The analysis for these claims is the same as for claims 2-5 respectively.

[15] The system of claim 14, wherein the force sensor includes a piezoelectric cell.

Tierney in view of Hooven discloses this element in combination with general knowledge in the art. Fischer, ¶188. A POSITA would have understood that a piezoelectric cell is a suitable force sensor. *See, e.g.*, File History, 165 (1-10-2014

Office Action) ("[A] piezoelectric cell is a well-known art-recognized equivalent of a detector at the time the invention was made, and the Examiner takes **Official Notice** that is [sic] use is common knowledge in the art and would have found it obvious to substitute one type of detector for another.") (emphasis original).

[16]-[17]

See Ground 3, claims [8]-[9].

[18.1] A robotic system for engaging a fastener with first and second body tissue sections, the system comprising:

See Ground 1, element [1.1] (confirming that Tierney in view of Hooven discloses a robotic system for engaging a fastener into body tissue). Furthermore, Hooven confirms that its stapler may "staple tissue together" and may be "used in various types of surgical procedures such as bowel and lung resections." Hooven, 4:50-53. And a POSITA would have understood that such procedures involve engaging staples with first and second body tissue sections to attach the first body tissue section to the second body tissue section. Fischer, ¶191.

[18.2.1] a robotic mechanism including an adaptive arm, the robotic mechanism configured to position the fastener relative to first and second body tissue sections,

See Ground 3, elements [1.2.1], [18.1].

[18.2.2] the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force to urge the first and second body tissue sections together;

See Ground 3, elements [1.2.2], [10.2.2], [18.2.1]. Like the first and second legs of the ’281 patent’s staple 346, the first and second legs of Hooven’s staple move toward each other to urge the first the first and second body tissue sections (the sections of body tissue that are engaged by a leg of the staple) together. *Id.*; Fischer, ¶193.

[18.3] a computer configured to control the robotic mechanism and limit a magnitude of the at least one axial force and transverse force; and

See Ground 3, element [10.3].

[18.4] an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer.

See Ground 1, element [1.4].

Claims [19], [20]

See Ground 3, claims [2], [3] respectively.

D. Ground 4: Claims 1-20 are obvious over Tierney in view of McGarry and further in view of Gardiner

As explained above, the Tierney/McGarry system discloses each limitation of challenged claims 1-3, 8-12, and 17-20, and with the addition of Hooven, the Tierney/McGarry/Hooven combination discloses the remainder of the claims. If, however, this prior art is deemed not to sufficiently disclose a computer limiting a magnitude of the axial and transverse forces applied to the fastener (*see* elements [1.5], [10.3], and [18.3]), then it would have been obvious in view of Gardiner to perform this function. Fischer, ¶¶198-202.

Like the ’281 patent, Gardiner discloses a surgical stapler and the use of a computer in a robotic system to limit the magnitude of the axial and transverse forces applied to a staple. *Id.*; Gardiner, 17:57-64, 18:4-11. In the Gardiner stapler, "force limiters may be provided to limit the force with which the motors and/or actuators drive the drive rods and tube [for forming and releasing a completed staple]. The force limiters may be … electrical, such as closed loop feedback signals which monitor the amount of force exerted on the drive rods and/or distal end assemblies." *Id.*, 17:57-64. And "the assemblies in the working end of the instrument may be actuated and controlled by a surgical robot…. In [this] embodiment, motors, actuators, pneumatic/hydraulic systems and/or other force transmission mechanisms … for driving the drive rods and assemblies in the working end of the instrument for forming and releasing a completed staple [are] controlled remotely by a computer." Gardiner, 18:4-11.

In the proposed combination, Tierney's computer (processor 152) is modified to include Gardiner's electrical force limiter (to the extent it is deemed not already present in Tierney) and to therefore limit the magnitude of the axial and transverse forces applied by McGarry's lands 104R, 104L to McGarry's staple 110 as taught by Gardiner. Fischer, ¶200.

A POSITA would have been motivated to make this modification because, as explained above in Ground 1, element [1.2.2], a POSITA would have been aware of the safety concerns associated with a surgical stapler applying excessive force to a patient or surgical tool, which could injure the patient or damage the tool. Fischer, ¶201; *see also* Gardiner, 17:46-64 (discussing force limiters to control the movement of the stapler), 9:10-18 (discussing importance of distributing staple forces).. A POSITA would have also been aware that force limitation mechanisms, like Gardiner's, were ubiquitous in the art by 2002. Fischer, ¶201; *see also* Ground 1, element [1.5]. Thus, a POSITA would have been motivated to modify the Tierney/McGarry robotic system to include Gardiner's electrical force limiter to obtain the safety benefits of Gardiner's force limitation mechanism. *Id*. In addition, a POSITA would have seen the clear safety benefits from such a routine and common sense modification. *Id.*; *KSR*, 550 U.S. at 424; *In re Magna Elec., Inc.,* 611 Fed. Appx. 969, 974 (Fed. Cir. 2015); *Perfect Web Techs., Inc. v. InfoUSA, Inc.,* 587 F.3d 1324, 1329 (Fed. Cir. 2009).

Moreover, a POSITA would have reasonably expected the combination of Tierney, McGarry, and Gardiner to be successful. Fischer, ¶202. Indeed, it would have been merely the application of a known technique (Gardiner's force limiter) with a known system (Tierney surgical robot) in a common field of endeavor (the development of surgical instruments). *Id.*; *KSR*, 550 U.S. at 417. And, in the proposed combination, Tierney's robot, McGarry's stapler end effector, and Gardiner's force limiter all continue to work as they always have. Thus, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by Tierney's robotic system (positioning the tool, providing mechanical controls to the tool, and receiving feedback signals from the tool), McGarry's stapler (stapling), or Gardiner's force limiter (limiting the force with which the motors and/or actuators drive the components that form and release a completed staple). Fischer, ¶202.

E. Ground 5: Claims 1-20 are obvious over Tierney in view of Hooven and further in view of Gardiner

As explained above, Tierney in view of Hooven discloses each limitation of challenged claims 1-20 under Patent Owner's apparent construction. If, however, the combination is deemed not to disclose Tierney's computer limiting a magnitude of the axial and transverse forces applied to the fastener (*see* elements [1.5], [10.3], and [18.3]), then it would have been obvious in view of Gardiner to modify Tierney's computer to limit the magnitude of the axial and transverse forces applied by Hooven's staple drivers 84 and anvil 75 for reasons explained Ground 4. Fischer, ¶203.

XI. CONCLUSION

Claims 1-20 of the '281 patent are invalid pursuant to Grounds 1-5 set forth above. Accordingly, Petitioner requests *Inter Partes* Review of these challenged claims.

Respectfully submitted,

Dated February 26, 2020

/*Steven R. Katz*/
Steven R. Katz, Reg. No. 43,706
Fish & Richardson P.C.
Attorney for Petitioner

(Control No. IPR2020-00650)

CERTIFICATION UNDER 37 C.F.R. § 42.24

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,874 words, which is less than the 14,000 allowed under 37 CFR §42.24.

Dated February 26, 2020

/Steven R. Katz/
Steven R. Katz, Reg. No. 43,706
Fish & Richardson P.C.
Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on February 26, 2020, a complete and entire copy of this Petition for *Inter Partes* Review, Power of Attorney, and all supporting exhibits were provided via Federal Express to the Patent Owner by serving the correspondence address of record as follows:

STINSON LEONARD STREET*
7700 Forsyth Boulevard, Suite 1100
St. Louis, MO 63105

/Christine Rogers/
Christine Rogers
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(650) 839-5092