IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Peter M. Bonutti		
U.S. Patent No.:	10,368,953	Attorney Docket No.:	11030-0064IP1
Issue Date:	August 6, 2019		
Appl. Serial No.:	16/132,159		
Filing Date:	September 14, 2018		
Title:	ROBOTIC SYSTEM FOR FASTENING LAYERS OF BODY TISSUE TOGETHER AND METHOD THEREOF		

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PETITION FOR *INTER PARTES* REVIEW
OF UNITED STATES PATENT NO. 10,368,953
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 1-4, 6-20, 22-25, 27, and 29-30 of the '953 patent, entitled "Robotic System For Fastening Layers of Body Tissue Together And Method Thereof." The challenged claims relate generally to methods of using well-known surgical fasteners with well-known robotic surgical systems to clamp two portions of body tissue together and fasten the tissue when the clamping force has a predetermined magnitude. *See, e.g.*, '953 patent, claims 1-2. Petitioner submits these methods were obvious at the time of the alleged invention. Petitioner therefore requests IPR of the challenged claims. IPR is appropriate under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (PTAB May 13, 2020) because the co-pending district court litigation is stayed.

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 '953 patent. The '953 patent is the subject of Civil Action No. 1:19-cv-525-RGA, filed on March 15, 2019, in the United States District Court for the District of Delaware, as amended on October 2, 2019, to add the '953 patent. U.S. Pat. Nos. 9,149,281 and 9,192,395—which are assigned to Patent Owner, share the same disclosure as the '953 patent, and have been asserted against Petitioner in Civil Action No. 1:19-cv-525-RGA—are the subject of co-pending petitions for IPR. Patent Owner is also prosecuting U.S. Pat. App. Nos. 16/412,008 and 16/674,970, both of which claim the benefit of the application from which the '953 patent matured. The district court litigation was stayed on March 24, 2020, pending resolution of this IPR and the related IPRs.

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: 617-542-5070 / 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 Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence and service to the address listed above. Petitioner consents to electronic service by email at IPR11030-0064IP1@fr.com (referencing No. 11030-0064IP1 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 – 37 C.F.R. § 42.104

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

Petitioner certifies the '953 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 IPR of claims 1-4, 6-20, 22-25, 27 and 29-30 of the '953 patent on the grounds listed below. A declaration from Dr. Gregory Fischer (IS1003) is included in support.

Ground	Claims	Basis for Rejection
1	**1-2, 4, 6, 8-20, 22-25, 27, and 29-30**	Obvious over **Bonutti-'234** (IS1004) in view of **Tierney** (IS1005) under 35 U.S.C. § 103.[1]
2	**1-4, 6-8, and 24**	Obvious over **Hooven** (IS1006) in view of **Tierney** (IS1005) under 35 U.S.C. § 103.
3	**1-2, 4, 6, 8-20, 22-25, 27, and 29-30**	Obvious over **Bonutti-'234** (IS1004) in view of **Tierney** (IS1005) and **Cooper-'666** (IS1007) under 35 U.S.C. § 103.
4	**24**	Obvious over **Bonutti-'234** (IS1004) in view of **Tierney** (IS1005) and **Bonutti-'986** (IS1008) under 35 U.S.C. § 103.

[1] The AIA applies to the '953 patent (*see* MPEP § 2159.02). However, because references cited herein are prior art under the AIA and pre-AIA statute, whether the AIA applies is immaterial.

The ’953 patent issued from U.S. App. No. 16/132,159, filed on September 14, 2018, and claims priority through a series of continuations to U.S. App. No. 10/102,413, filed on March 20, 2002, the earliest possible priority date.

Bonutti-’234, Tierney, Cooper-’666, Hooven, and Bonutti-’986 qualify as prior art under AIA 35 U.S.C. §§ 102(a)(1)-(2).[2] Bonutti-’234, Tierney, Hooven, and Bonutti-’986 were made of record during prosecution, but not discussed by the Examiner or Applicant.[3]

Section 325(d) is inapplicable here. The arguments presented herein differ from those presented during prosecution. For example, the Examiner did not consider whether the claims were patentable over the combinations presented herein. *Edwards Lifesciences Corp. v. Boston Scientific SciMed, Inc.*, IPR2017-01295, Paper 9 (PTAB October 25, 2017) (declining to deny institution under 325(d) where examiner did not consider whether the claims were patentable over the proposed

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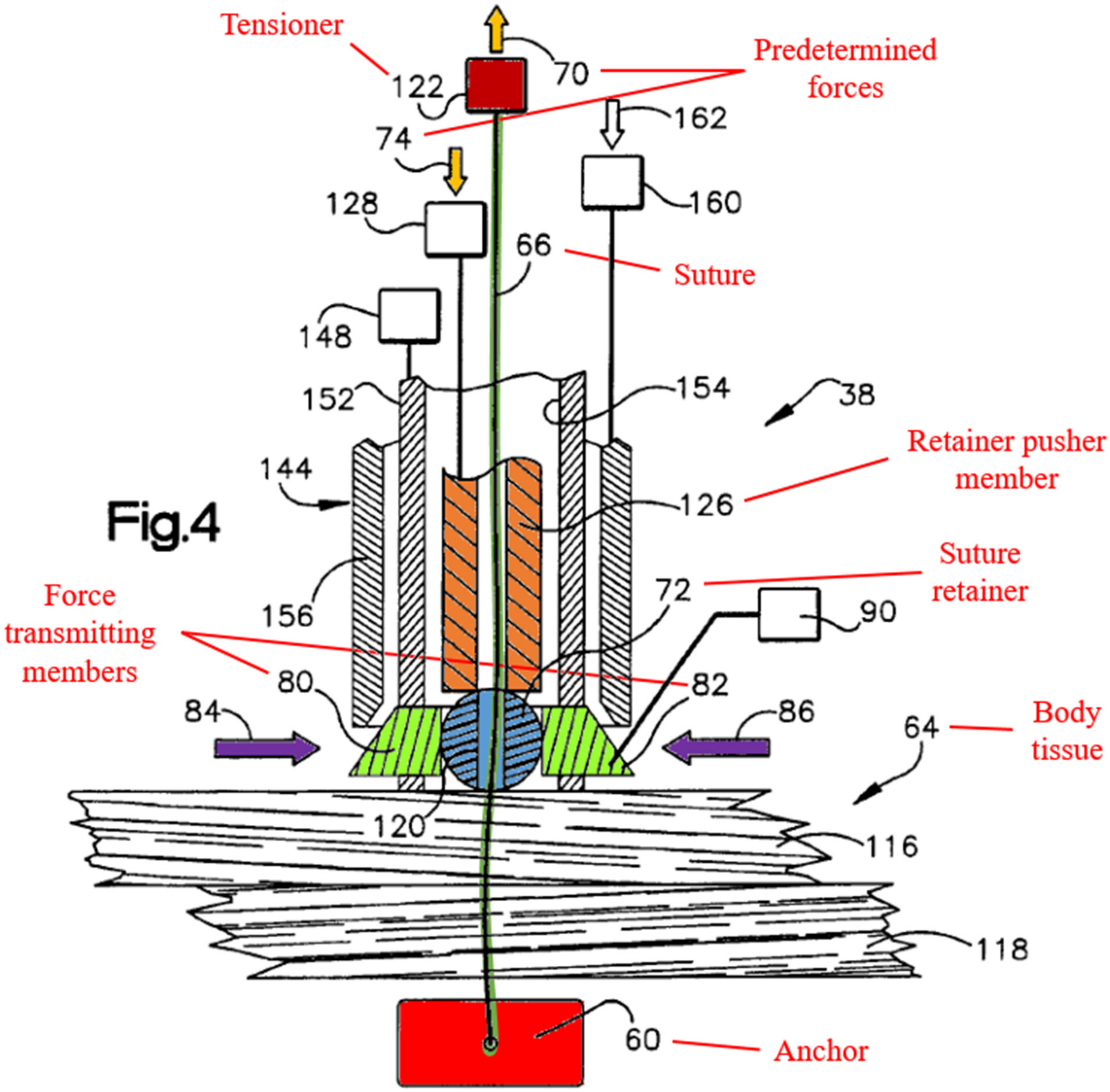
[2] Bonutti-’234, Cooper-’666, Hooven, and Bonutti-’986 are also prior art under at least pre-AIA § 102(b). Tierney is also prior art under at least pre-AIA §§ 102(a) & (e).

[3] Bonutti-’234, Tierney, Hooven, and Bonutti-’986 were among hundreds of references cited by the Applicant.

combinations presented in the petition); *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00486, Paper 10 (PTAB July 15, 2015) at 15 (declining to deny institution under 325(d) where there was no evidence the Examiner considered the particular disclosures cited in the petition). And the Examiner lacked the benefit of Patent Owner's infringement allegations implicitly based on broad claim constructions. *See* Complaint (IS1022). Thus, the factors identified in *Becton, Dickinson and Company v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-28 (PTAB Dec. 15, 2017 (informative)) do not weigh heavily in favor of denying institution.

V. SUMMARY OF THE '953 PATENT

The '953 patent is generally directed to "a method of securing either hard or soft body tissue" using "[a] robotic mechanism … to position a fastener relative to the body tissue." '953 patent, 1:41-45. In one embodiment, the patent describes a mechanism 38 for applying "a fastener assembly formed by [an] anchor 60, suture 66 and retainer 72." *Id.*, 8:65-9:3, Fig. 4.



The mechanism 38 comprises "a tensioner 122[,] which grips the suture 66" and tensions it "with a predetermined force [70]." *Id.*, 11:10-38. "While the suture 66 is tensioned…, a retainer pusher member 126 is pressed against the retainer 72 with a predetermined force [74]," which "presses the retainer 72 against the upper layer 116 of body tissue 64." *Id.*, 11:47-56. The combination of these forces "results in the two layers 116 and 118 of body tissue being clamped between the [anchor] 60 and retainer 72 with a predetermined force." *Id.*, 11:57-67. Also, tensioner 122 includes a "pezielectric [sic] cell which detects when the tension transmitted from the gripper to the suture 66 has reached the predetermined magnitude." *Id.*, 11:30-38. After the predetermined magnitude is reached and "[w]hile anchor 60 and retainer 72 are being pressed against their respective body tissues, the robotic mechanism 38 is effective to plastically deform the retainer 72 to grip the suture 66." *Id.*, 12:24-37. In particular, "force transmitting members 80 and 82" of mechanism 38 press "radially inward against the suture retainer 72," causing "the passage 120 … to collapse and the material of the suture retainer 72 to move into engagement with and grip the suture 66." *Id.*, 12:45-13:6.

The '953 patent concedes that most of these structures and steps were known at the time of filing. *See id.*, 1:24-37 (method of fastening body tissue using a suture), 5:40-49 (robotic mechanism 38).

VI. SUMMARY OF THE PROSECUTION HISTORY

The prosecution history demonstrates that every structural element of the challenged claims was disclosed in the prior art, and a prior art system was at least "capable of" performing every claimed method step. The Examiner nonetheless allowed the claims without explanation.

At the outset, the Applicant canceled all claims from the parent applications and added a new set of claims reciting both apparatus (claims 32-41 and 49-51) and methods (claims 42-48). File History, 447-451. The apparatus claims described a robotic surgical system "configured to" perform certain functions. *See id.* The method claims merely restated the apparatus claims in method form, with each structural limitation of the method claims corresponding to a limitation of the apparatus claims. *See id.*; Fischer, ¶44. In the first and only office action, the Examiner rejected ***all*** the apparatus claims as anticipated by U.S. Pat. No. 5,762,458 ("Wang"). File History, 419-420. For claim 35, which introduced the limitation "wherein the computer is configured to determine if the clamping force imparted by the clamp has a predetermined magnitude," the Examiner found the Wang apparatus was capable of performing the claimed function, and thus met the limitation. *Id.*, 420. Without any explanation, however, the Examiner found the method claims allowable even though they merely restated, in method form, the same structural limitations as the (unpatentable) apparatus claims. *Id.*

The Applicant then canceled the apparatus claims. *Id.*, 407. Proceeding with the method claims only, the Examiner issued a Notice of Allowance. *Id.*, 75.

VII. CLAIM CONSTRUCTION

A. determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude (claim 1); determining, using the computer and the received fastening signal, that the first and second portions of body tissue are suitable for being fastened to one another (claim 6)

There are two claim construction issues pertaining to these limitations. **First**, although the limitations require "using the computer," they do not specify that the computer performs the "determining," and thus do not exclude the situation where the surgeon, using the computer to display a force readout, performs the "determining" step. The patent's specification confirms this reading: "Alternatively, the tensioner 122 and computer 44 may have a visual readout which enables a surgeon to determine the magnitude of the tension in the suture 66 and to maintain the tension in the suture at a desired magnitude." '953 patent, 11:20-29. Accordingly, these limitations encompass mental steps that are not entitled to patentable weight. *See In re Venner*, 262 F.2d 91, 95 (C.C.P.A. 1958) ("Patentability cannot be predicated upon a mental step."); *see also Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1378 (Fed. Cir. 2016) (mental step of "detect[ing] the allele" did not supply inventive concept necessary for patent-eligibility under § 101).

Second, the patent's only embodiment that practices this step is a *suture* securing system that determines whether the clamping force has a specific value that is known or selected before performing the recited method and is sufficient to accomplish the intended function. The patent does not disclose **<u>any</u>** *stapler* embodiment that practices this step. *See* '953 patent, 27:32-32:11. In the related litigation, however, Patent Owner reads this limitation as covering a robotic linear staple applier that allegedly determines, using a computer and clamping force signal, if the force applied to tissues when the staple applier jaws are closed is less than a predetermined magnitude indicative of the tissue being too thick. Petitioner relies on this apparent construction in Ground 2.

B. fastening, after said determining and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude, the first and second portions of body tissue together using the adaptive arm (claim 1)

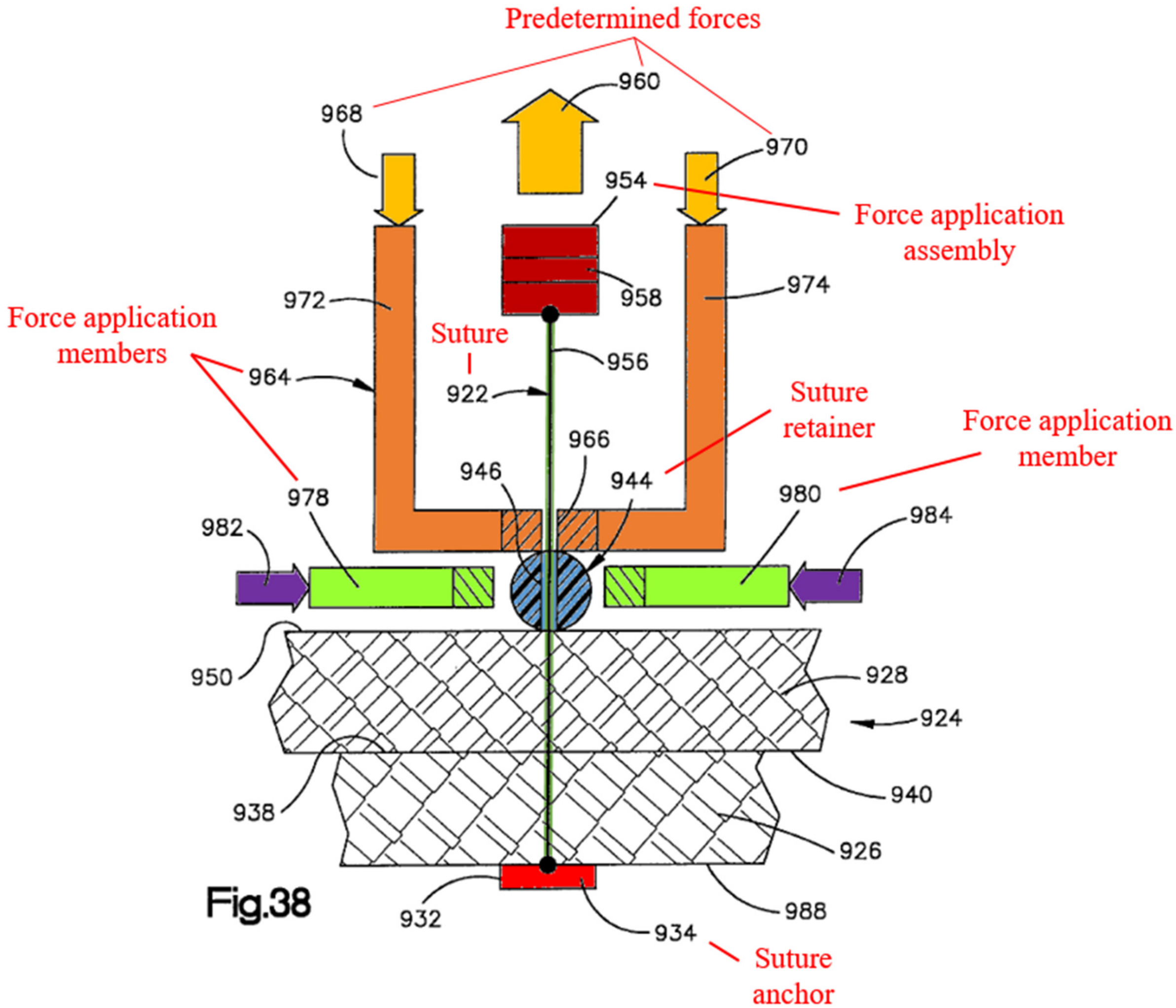
The patent's only embodiment that practices this step is a *suture* securing system, which deforms the suture retainer to fasten the tissues simultaneously with the clamping forces having the predetermined magnitude (*e.g.*, a specific value) to maintain the desired tension on the suture. *See* '953 patent, 27:32-32:11. The patent does not disclose **<u>any</u>** *stapler* embodiment that practices this step.

In the related litigation, however, Patent Owner reads this limitation as covering a linear stapler that allegedly fastens, after determining that the clamping force applied when the stapler jaws are closed is less than a predetermined magnitude and simultaneously with the application of that clamping force, the first and second portions of body tissue together using the adaptive arm. Petitioner relies on this apparent construction in Ground 2.

VIII. SUMMARY OF THE PRIOR ART

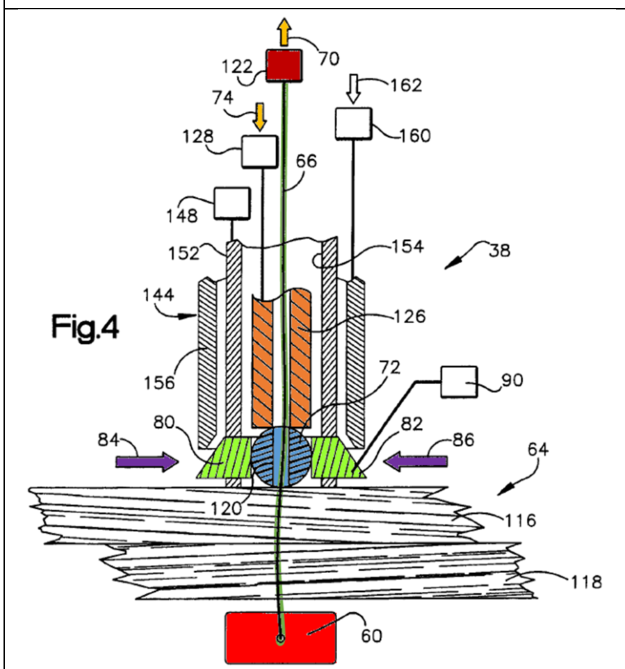
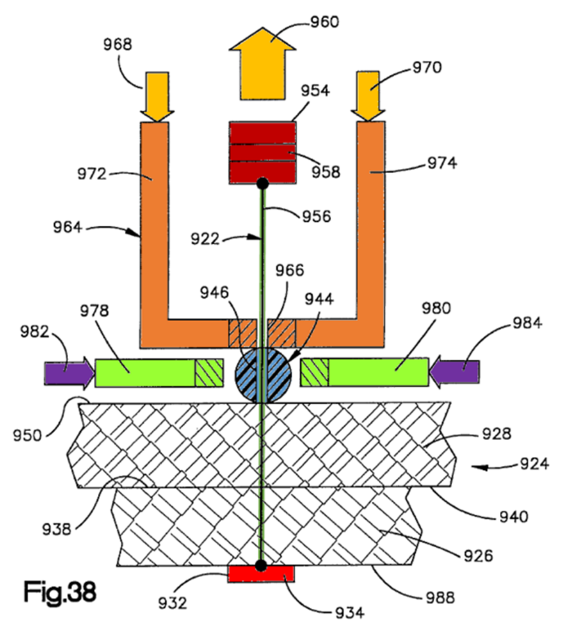
A. Bonutti-'234

The '953 patent acknowledges that Bonutti-'234 discloses a system for securing body tissue using a fastener, in particular a suture and suture retainer. '953 patent, 1:29-31, 10:42-45, 13:3-6, 20:65-67, 26:61-27:2. Indeed, Bonutti-'234's system is virtually identical to the '953 patent embodiment described in Section V. Specifically, Bonutti-'234 discloses a system for securing a suture 922, suture anchor 934, and suture retainer 944 to interconnect layers of body tissue 924. Bonutti-'234, 40:33-60, 43:59-64, Fig. 38; *see also* 34:17-64, 35:8-23, 37:38-64, 38:16-32, 39:33-55, Figs. 34-36.



Bonutti-'234's suture securing system comprises "force application assembly 954," which applies "predetermined" force 960 on suture 922, causing it to become "tensioned" and pull up on suture anchor 934. *Id.*, 41:41-53, 42:28-45. The suture securing system further comprises "force application member 964," which applies "predetermined" forces 968 and 970 to the top of suture retainer 944 so it "slides downward … along the suture 922," whereby the suture retainer is "pressed against" outer layer 928 of body tissue 924. *Id.*, 41:54-42:45. These opposing forces clamp the body tissue layers between suture anchor 934 and suture retainer 944. After forces 968 and 970 reach the "predetermined" magnitude (which is based on suture strength), "the suture retainer 944 is plastically deformed to firmly grip the suture 922." *Id.*, 42:33-43:5. To perform this step, the suture securing system includes "a pair of force application members 978 and 980," which are "pressed against opposite sides of the suture retainer 944," causing "the material of the suture retainer 944 to bond to and obtain a firm grip on the suture 922." *Id.*, 43:6-14.

A side-by-side comparison of Figure 4 of the '953 patent and Figure 38 of Bonutti-'234 illustrates their similarities:

<table>
<tr><th>'953 patent, Fig. 4</th><th>Bonutti-'234, Fig. 38</th></tr>
<tr><td>
</td><td>
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B. Tierney

Tierney discloses a surgical system 10, which "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.

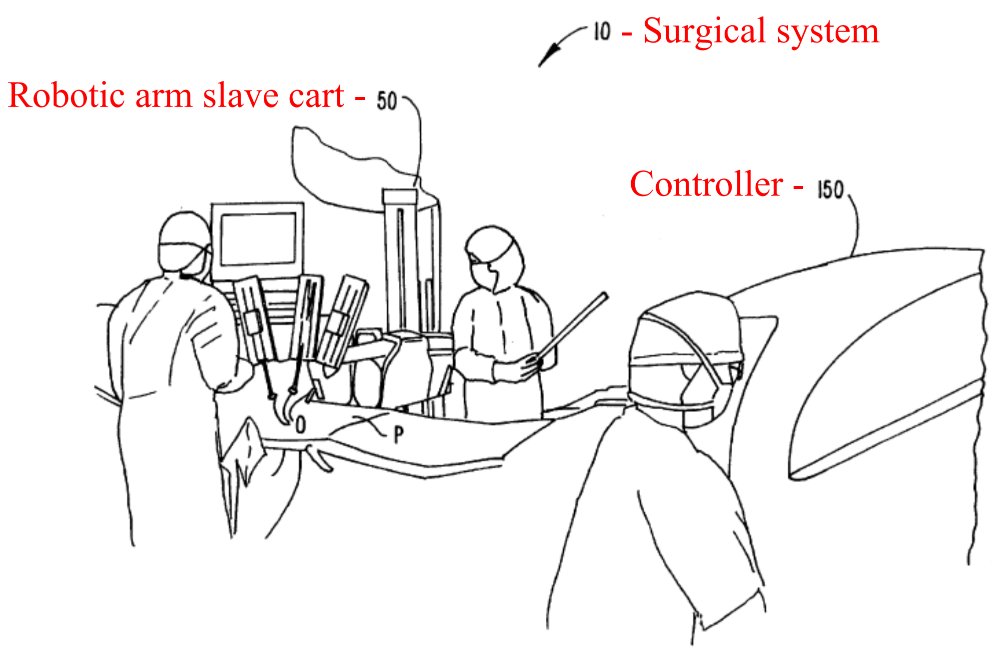


FIG. 1.

Master controller 150 includes "processor 152." Tierney, 12:29-32. "Cart 50 includes a base 52 from which three surgical tools 54 are supported." *Id.*, 7:16-18, Fig. 2. "Tool 54 generally includes a … surgical end effector 112." *Id.*, 9:8-15, Fig. 4.

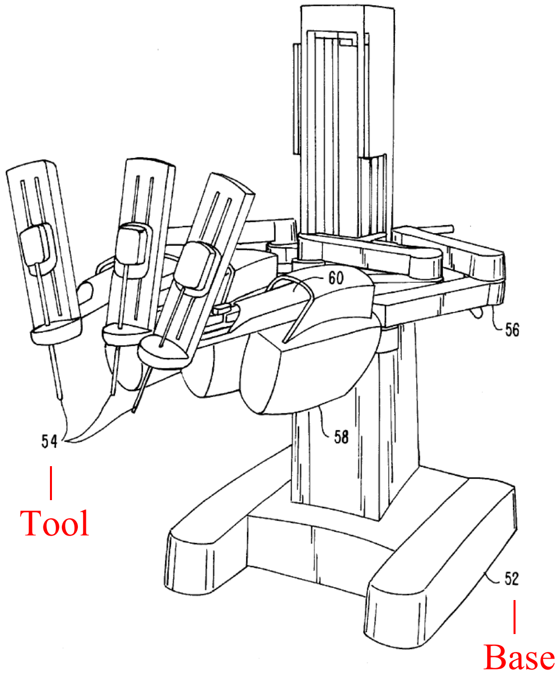
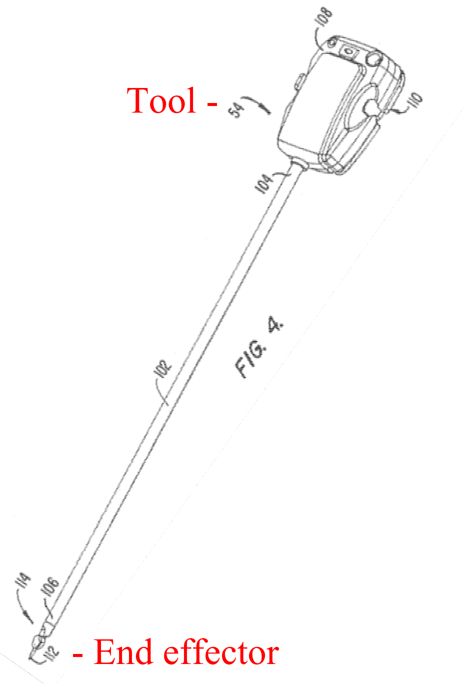


FIG. 2.



"Motors 70 are … coupled to tool 54 … to rotate the tool[,] … articulate a wrist at the distal end of the tool[,] …. [and] actuate an articulatable end effector of the tool." *Id.*, 7:65-8:10, Figs. 2A-B. As explained in Cooper-'666, which Tierney incorporates by reference, the drive motors "preferably include … force sensors (not shown) for transmitting force and torque feedback to the surgeon." Cooper-'666, 16:38-17:3; Tierney, 1:60-66; Fischer, ¶59; *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011) (application incorporated by reference the entire disclosure of two co-pending applications); *see also* Cooper-'666, 5:32-35, 8:19-23; Madhani, 5:10-19, 5:62-67, 7:23-28, 7:38-39, 9:66-10:1, 10:28-30.

Tool 54 "may incorporate any … end effector [112] which is useful for surgery." Tierney, 10:5-11. The tools are controlled, in part, by drive elements 119 on the robot arms. *E.g.*, Tierney, Figs. 7C, 7J.

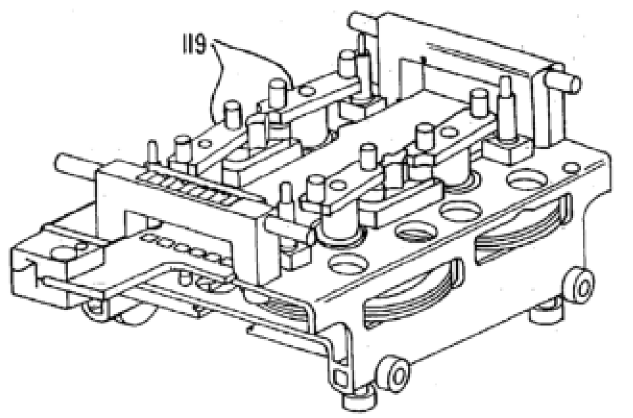
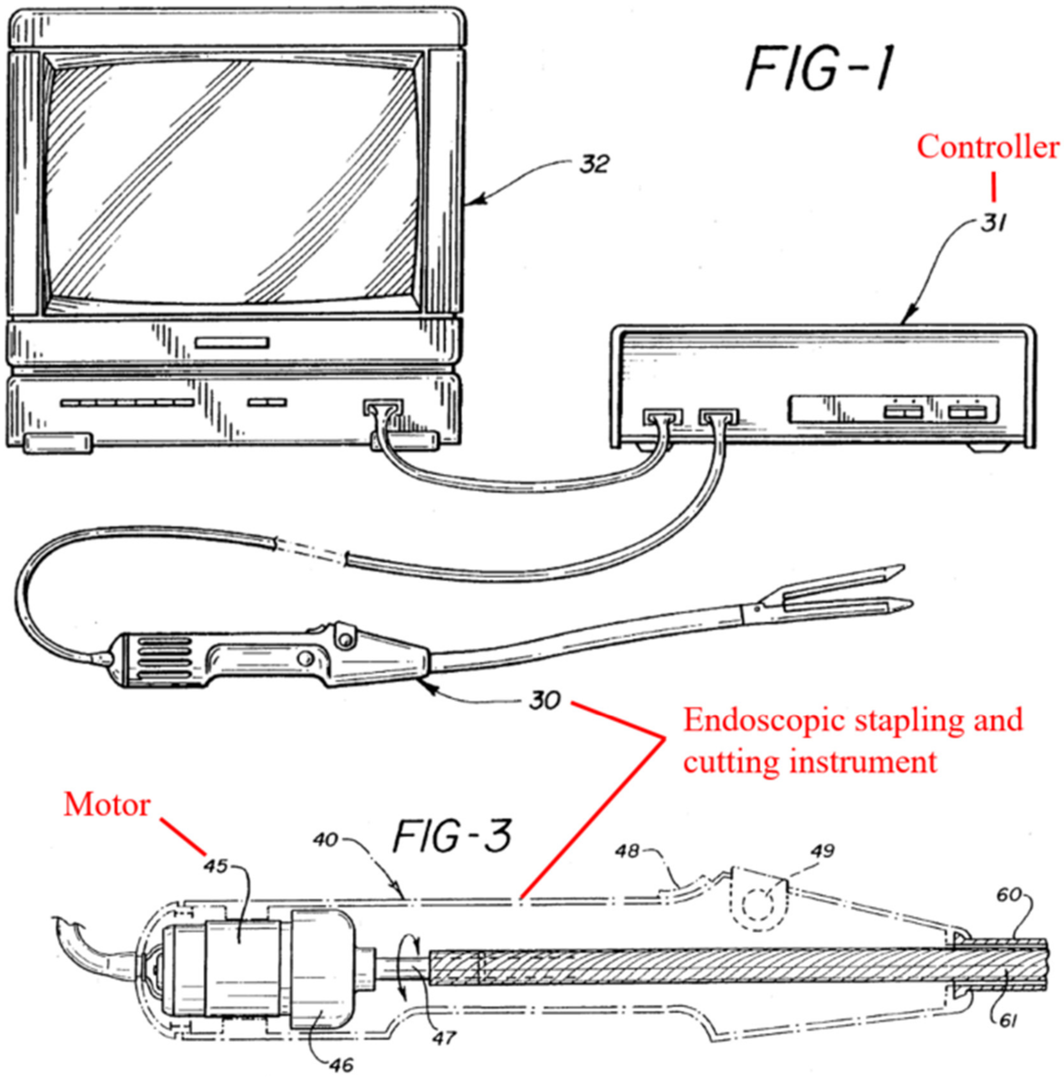


FIG. 7J.

C. Hooven

Hooven discloses a controller 31 removably connected to an endoscopic surgical cutting and stapling instrument 30. *E.g.*, Hooven, Figs. 1, 3, 6; 4:3-62, 5:9-6:47; *see also* Fischer, ¶61.



As shown below, Hooven's instrument 30 includes a closure nut 77, firing nut 86, and wedge member 83 that are driven by a motor-powered threaded rod 71. Hooven, 5:9-6:47. To prepare the instrument for firing, motor 45 rotates threaded rod 71 to advance closure nut 77, causing anvil 75 to close against staple portion 74. *Id.* Once anvil 75 is closed, threaded rod 71 engages firing nut 86 to drive wedge member 83 along the length of staple portion 74, thereby pushing staple drivers 84 and staples 81 toward anvil 75 to secure the body tissue. *Id.*

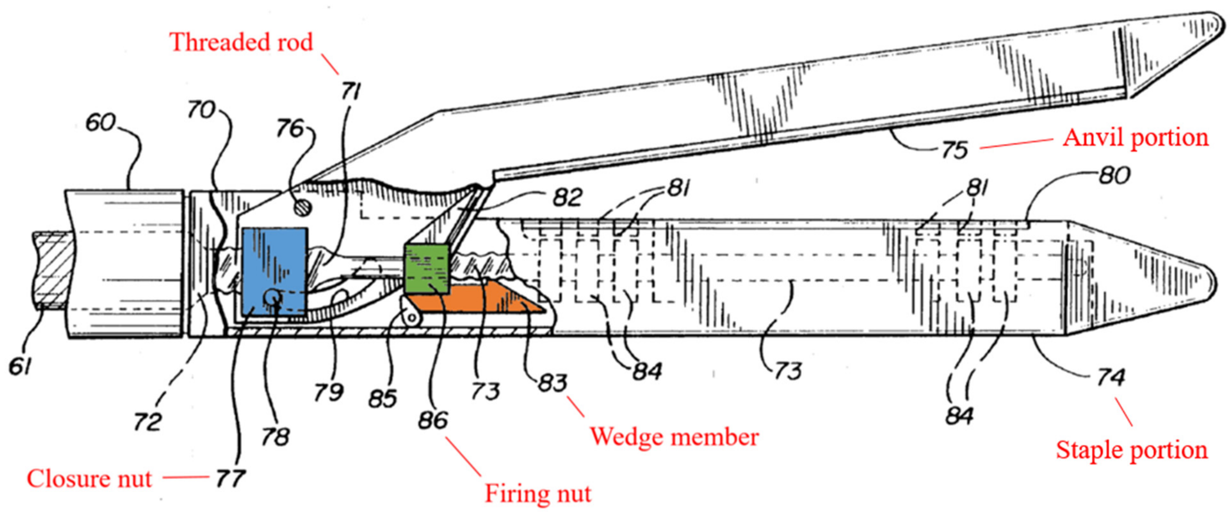
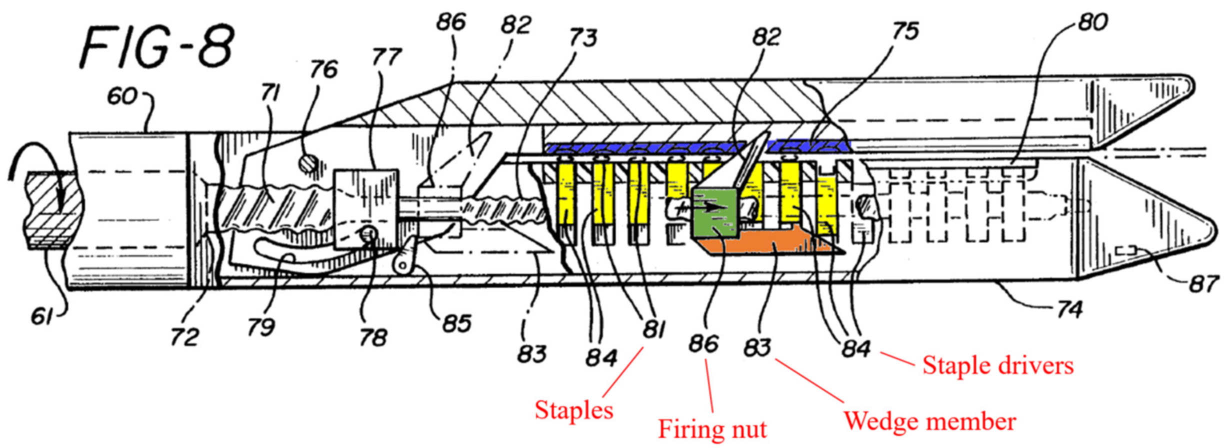
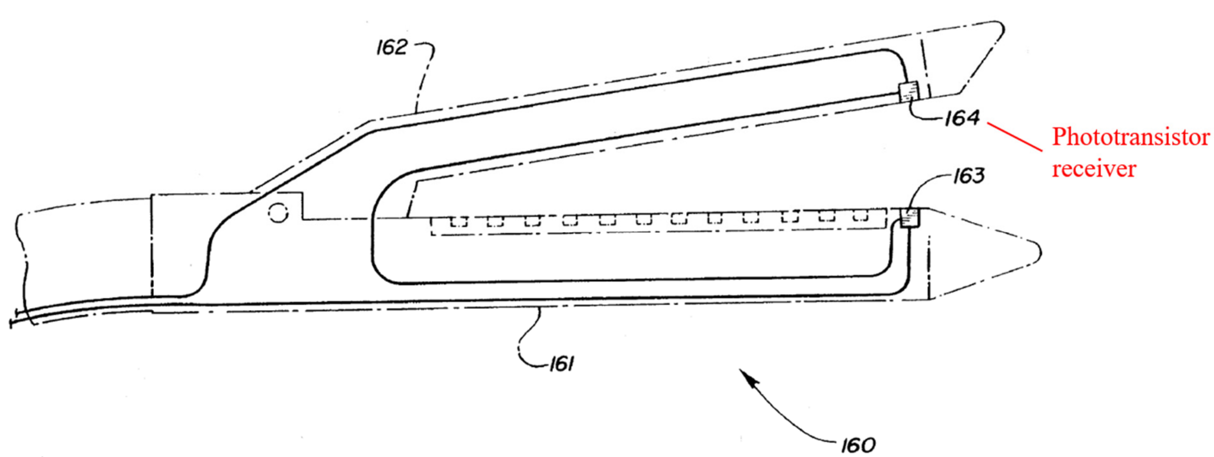


FIG-8



Hooven's staple applier also "includes miniature sensors to detect the power and/or force being used" by the motor. Hooven, 8:18-9:17, Fig. 19; *see also* 3:2-8, 4:15-20, 5:39-50, 9:21-22. These sensors are connected to controller 31, which "acts to supply power to the instrument at the appropriate level, frequency, timing, etc." Hooven, 4:4-20. "[I]nformation is fed to a video display screen" so "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." Hooven, 6:33-47, 8:45-49. Accordingly, controller 31 may determine "the thickness of tissue between the anvil and the staple portion" and then "inform the surgeon as to whether or not he has the appropriate amount of tissue between the anvil portion and the staple portion … or whether he has too much or too little tissue and should re-manipulate the instrument." Hooven, 5:39-48. Also, with regard to closing the anvil, Hooven notes "the force required to close the instrument may be measured by monitoring motor current." Hooven, 5:48-50.

Hooven's instrument also includes "phototransistor receiver 164," which measures "a desired property of the tissue [between the jaws] such as oxygen content." Hooven, 7:43-8:17, Fig. 17. Controller 31 uses this information to "determine proper positioning of the instrument or other procedure related manipulations" and "control desired operations of the instrument," such as "the firing of the staples." *Id.*



D. Bonutti-'986

Bonutti-'986 discloses the use of a suture securing system similar to Bonutti-'234's to interconnect two bone segments using a plurality of linearly aligned "bone suture assemblies 32." Bonutti-'986, Abstract, 2:28-67, 6:8-7:20, Figs. 1-3.

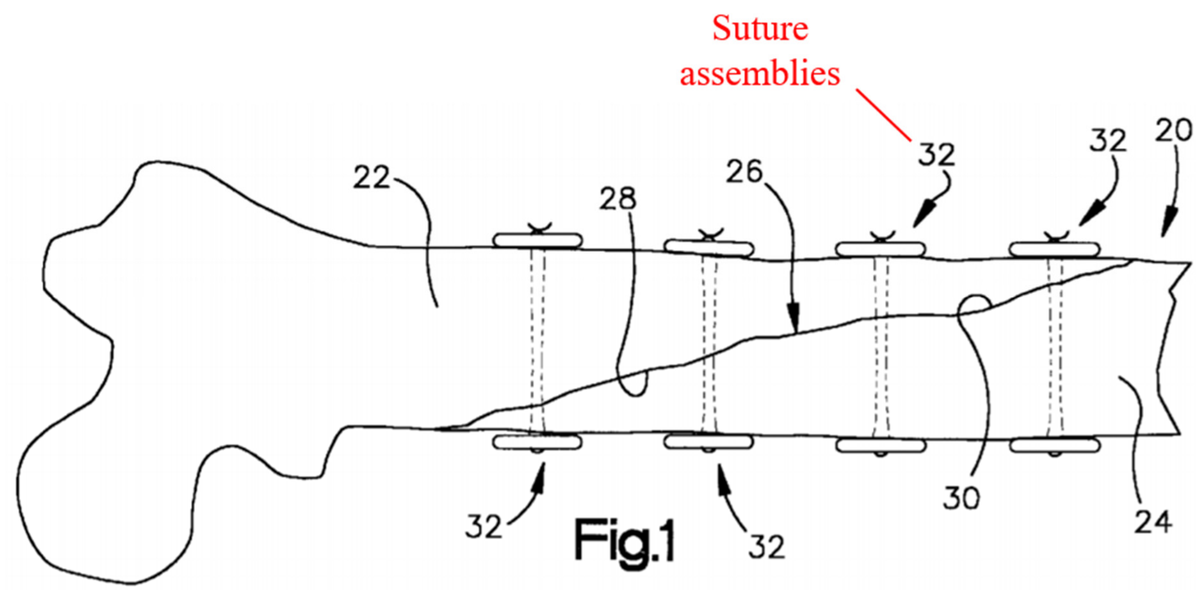


Fig.1

IX. THE CHALLENGED CLAIMS ARE INVALID

A. Ground 1: Claims 1, 2, 4, 6, 8-20, 22-25, 27, and 29-30 are obvious over Bonutti-'234 in view of Tierney

[1.1] A method of fastening at least first and second portions of body tissue together, the method comprising:

Bonutti-'234 discloses a method of fastening together at least first and second portions of body tissue (*e.g.*, inner layer 926 and outer layer 928 of body tissue 924). Fischer, ¶66; Bonutti-'234, 40:33-37; *see also* 4:16-20, 44:48-52, 47:19-21; Figs. 1, 35-36, 38-39.

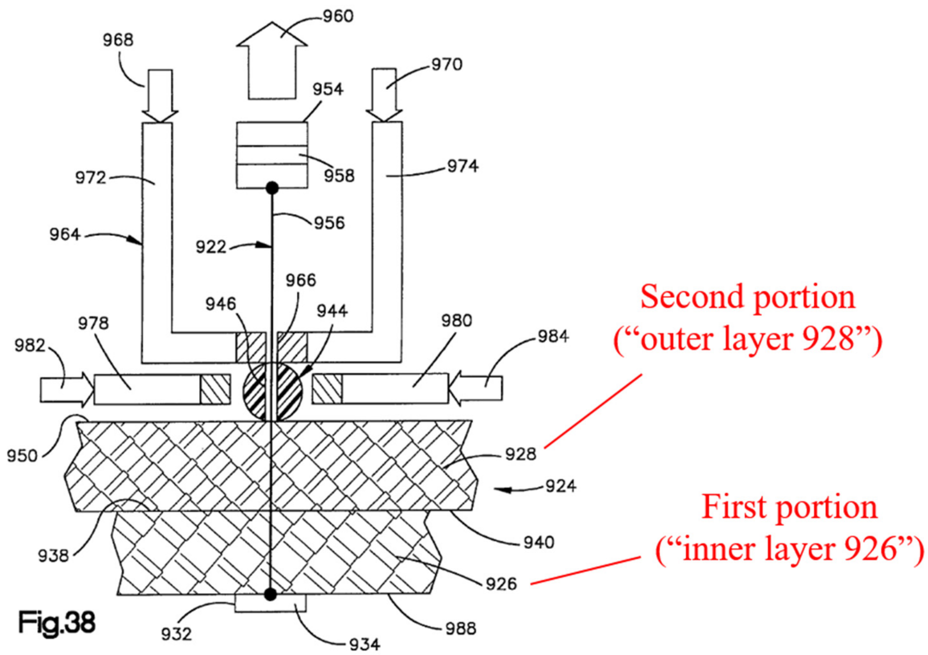


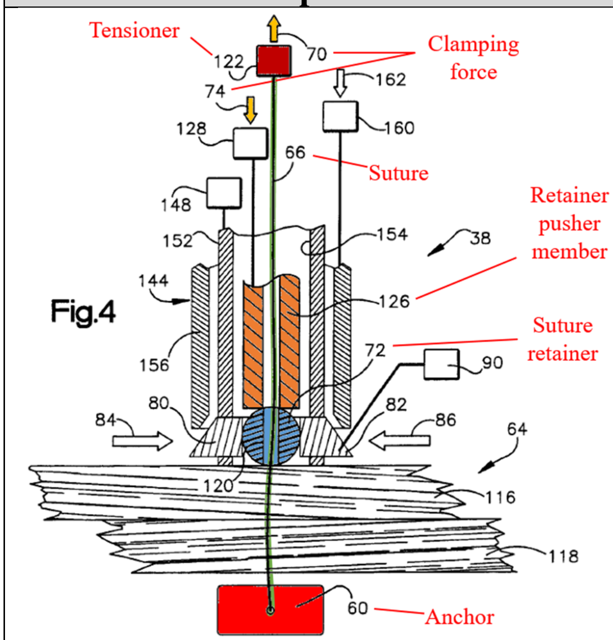
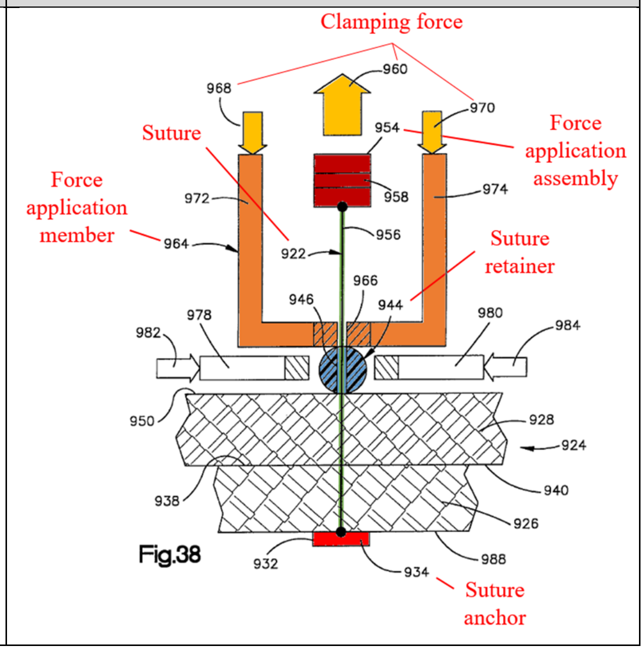
Fig.38

[1.2] imparting, using an adaptive arm of a robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another;

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶67. Bonutti-'234 discloses imparting a clamping force (combination of upward force 960 and opposing downward forces 968 and 970) to the first and second portions of body tissue suitable to press the first and second portions against one another between suture anchor 934 and suture retainer 944. Bonutti-'234, 39:62-40:32, 41:41-42:59, 43:59-64, Fig. 38; Fischer ¶67. Force 960 pulls suture anchor 934 up against the bottom portion (inner layer 926) of the body tissue, and forces 968 and 970 push suture retainer 944 down against the top portion (outer layer 928) of the body tissue, thus clamping the body tissue portions together between the suture anchor and suture retainer. *Id.* Bonutti-'234's suture securing system applies force

960 using force application assembly 954, and it applies forces 968 and 970 using force application member 964. *Id.*

Significantly, Bonutti-'234 discloses essentially the same method and structure for applying the clamping force as the '953 patent. *Compare* '953 patent, 11:57-67, Fig. 4 *with* Bonutti-'234, 42:28-45, Fig. 38; Fischer, ¶68.

'953 patent	**Bonutti-'234**
	

It would have been obvious in view of Tierney to convert Bonutti-'234's suture securing system from a handheld device to the form factor of Tierney's robotic system (and modify Tierney's robotic system as necessary to accommodate Bonutti-'234) so Bonutti-'234's movable components are controlled by Tierney's driven elements 118. Fischer, ¶70; *see also Venner*, 262 F.2d at 95 (holding that broadly providing automatic means to replace manual activity which accomplished same result is insufficient to distinguish prior art).

Tierney discloses a robotic system (surgical system 10) comprising a controller (controller 150) and a robotic mechanism (robotic arm slave cart 50). Fischer, ¶71; Tierney, 6:61-63, 7:16-28, Figs. 1-4.

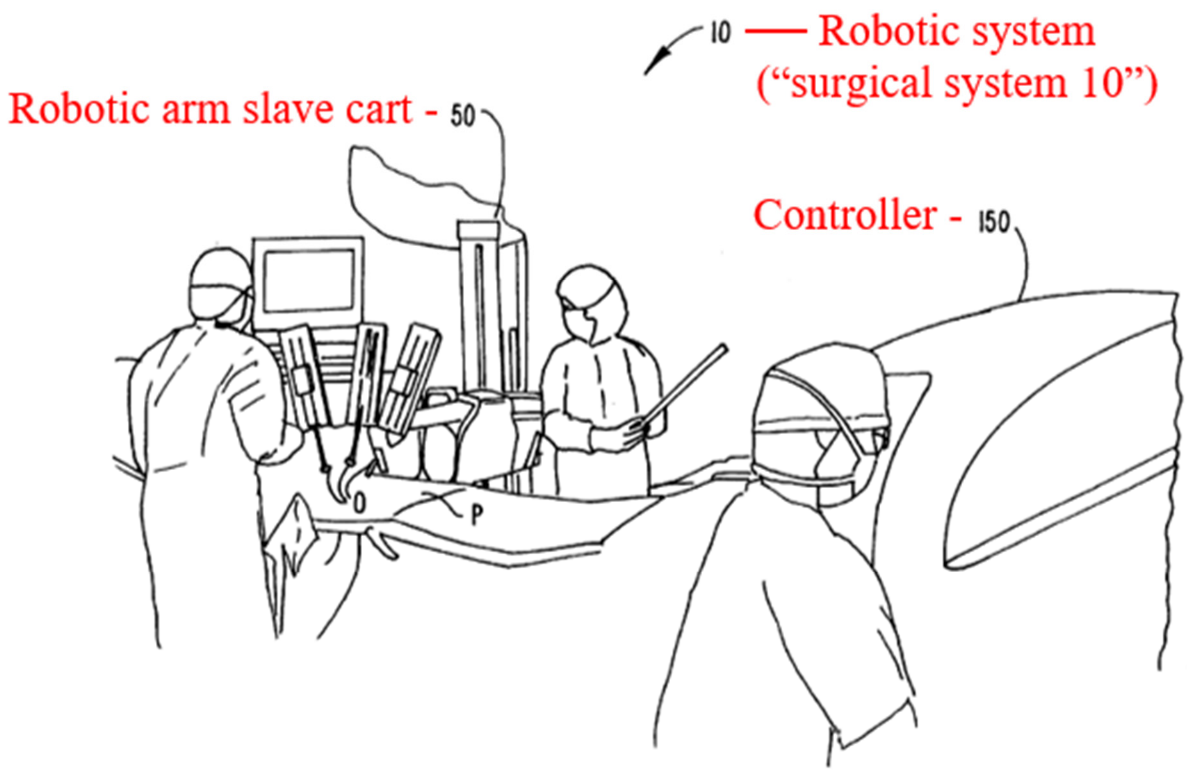


FIG. 1.

Although the scope of the term "adaptive arm" is unclear, Tierney discloses that its robotic arm slave cart 50 includes an adaptive arm (combination of set-up joint 56, robotic manipulator 58, and surgical tool 54). Tierney, 7:16-18, 6:49-60, 7:16-8:1, 11:65-12:1, Figs. 2, 3A, 4, 5F. That is, whatever the full scope of the term "adaptive arm" may be, based on the disclosure of the '953 patent, Tierney's arm must qualify as an "adaptive arm." Fischer, ¶72. There is no pertinent feature of the arms in the '953 patent that Tierney's arms lack. *Id*.

Tierney further discloses that surgical tool 54 "may incorporate any … end effector [112] which is useful for surgery." Tierney, 6:22-28, 9:8-15, 10:5-11.

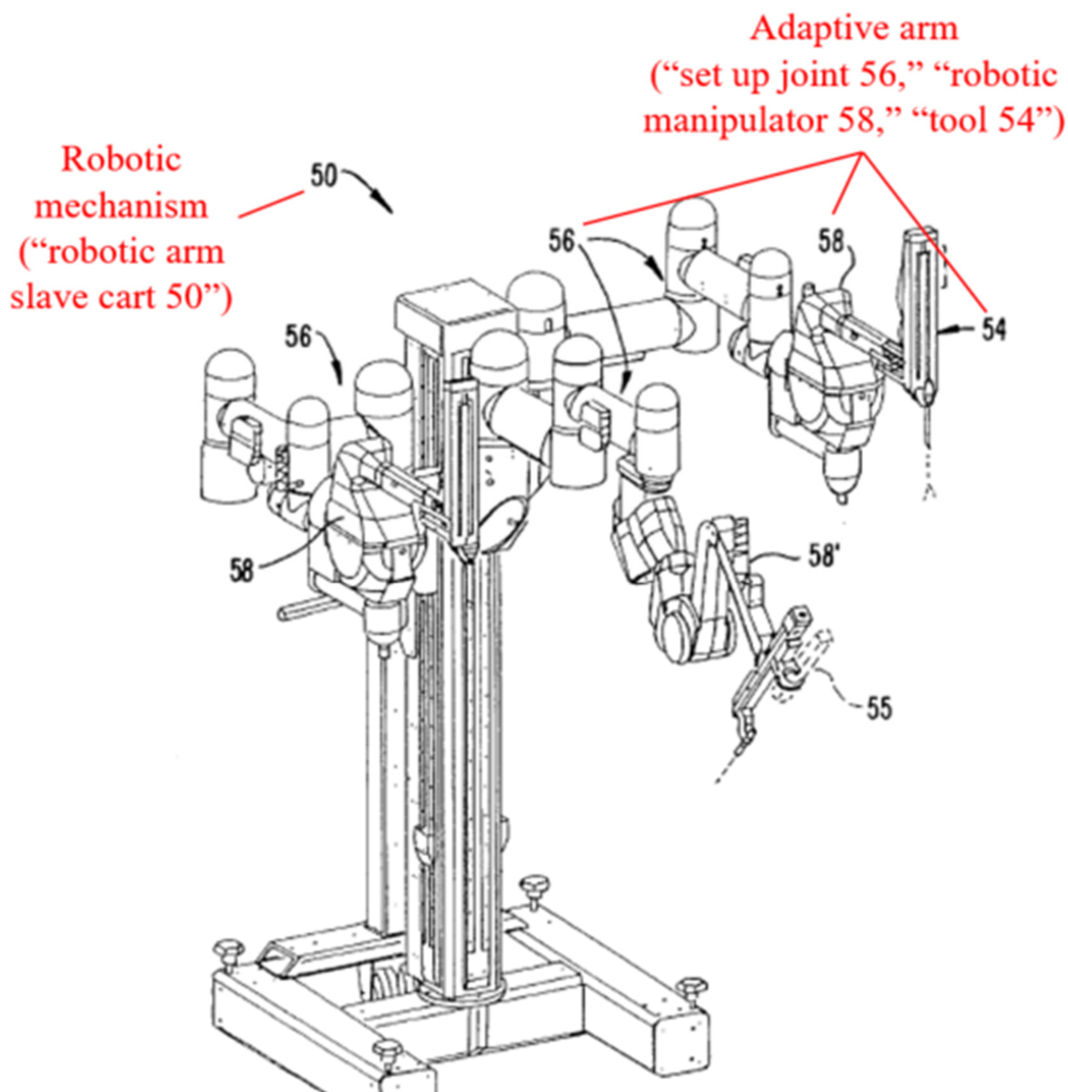


FIG. 3A.

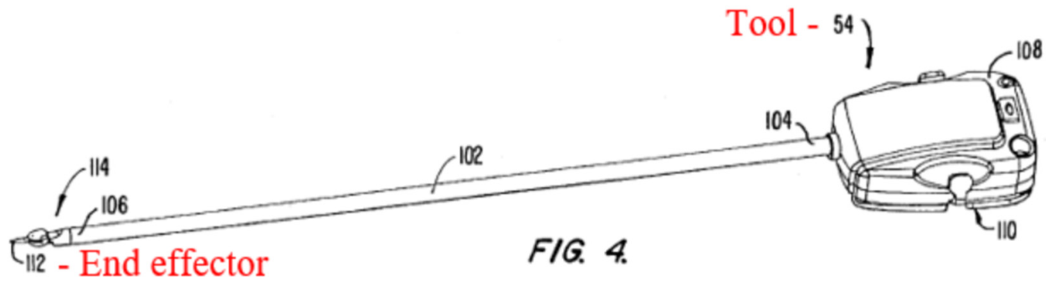
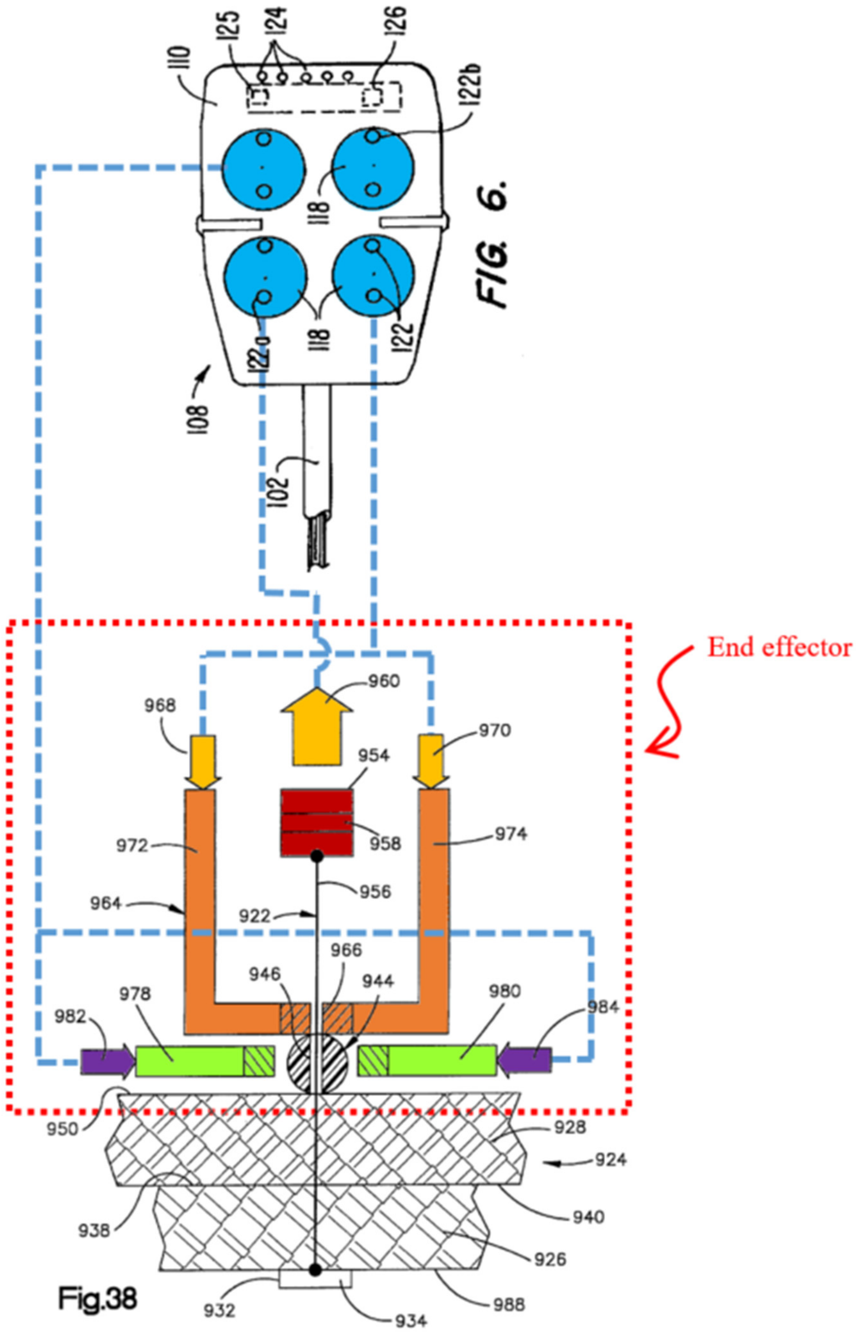


FIG. 4.

As shown in Figure 3A (above), tool 54 is "supported by a series of manually articulatable linkages, generally referred to as set-up joints 56, and a robotic manipulator 58." *Id.*, 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] 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 64." *Id.*, 7:55-58.

The composite figure below shows one possible way Bonutti-'234's movable components would be integrated into Tierney's tool 54, with blue lines denoting mechanical linkages.[4]

[4] Other obvious configurations exist, including one where Bonutti-'234's movable components are integrated into separate end effectors 112 and tools 54 of Tierney's robotic system. Fischer, ¶77.



These mechanical linkages would couple each movable component of Bonutti-’234’s instrument to one or more of Tierney’s driven elements 118, which transmit torque from motors 70. Fischer, ¶75; Tierney, 7:65-8:10, 10:12-24, Figs.

2A-B, 4A-B, 6. To make these mechanical linkages, Tierney teaches using "cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like." Tierney, 9:16-45; *see also* 8:4-7 (disclosing "cables" and incorporating "the full disclosure" of Madhani), Figs. 4A-B (disclosing pulleys and capstans). A POSITA would have known how to use such linkages to convert rotary motion of Tierney's driven elements into linear motion of Bonutti-'234's movable components. Fischer, ¶¶104-07.

Although the above figure depicts Bonutti-'234's movable components as mere "black boxes," a POSITA would have readily envisioned specific physical structures based on Bonutti-'234's other embodiments. Regarding force application member 964 and force application assembly 954, a POSITA would have envisioned, *e.g.*, a plunger and plunger housing similar to those shown in Figures 34-36 of Bonutti-'234. Fischer, ¶76; Bonutti-'234, 43:59-64, 34:26-55, 35:16-36:4, 37:7-64, 38:24-39:43, Figs. 34-36. In operation, the suture would be secured (*e.g.*, by tying) to the portion of the instrument (*e.g.*, the plunger housing) that would be pulled upward to tension the suture while the plunger is pushed downward to press the suture retainer against the body tissue. *Id.* Regarding force application members 978 and 980, a POSITA would have envisioned, *e.g.*, a "gripper" like in Figure 35. Fischer, ¶76; Bonutti-'234, 35:32-45, Fig. 35. Notably, Tierney also discloses a gripper. Tierney, 2:38-3:6, 6:20-37.

The resulting robotic system ("the Bonutti-'234/Tierney robotic system") enables a surgeon to fasten at least first and second portions of body tissue (layers 926, 928) together with Bonutti-'234's suture securing assembly (including suture 922, suture anchor 934, and suture retainer 944) using an arm of Tierney's robotic system. Fischer, ¶85.

A POSITA would have been motivated to combine Bonutti-'234 with Tierney for several reasons. *Id*., ¶86. **First**, Tierney contemplates using its robotic system with "any … end effector which is useful for surgery, particularly at an internal surgical site," including end effectors that a POSITA would have understood are for suturing (*i.e.*, "needle drivers," "needle graspers," and "needle holders"). *Id*., ¶87; Tierney, 10:5-11, 1:30-37, 2:47-52, 6:22-28. A POSITA therefore would have turned to Bonutti-'234 for details on how to implement Tierney's robotic system with a suture securing system such as Bonutti-'234's to increase the number of uses for Tierney's robotic system. Fischer, ¶¶87-88.

Second, a POSITA would have known the benefits of using Tierney's robotic system. Fischer, ¶89. For example, a POSITA would have understood 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 perform minimally invasive surgical procedures in an intuitive manner. Fischer, ¶¶89-91; Anderson, 2:16-55. Unsurprisingly, Tierney notes its robotic system will "have applications for surgical procedures which are difficult to perform using existing minimally invasive techniques." Tierney, 6:38-60. And Tierney confirms "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*. Thus, a POSITA would have been motivated to modify Bonutti-'234's suture securing system for use with Tierney's robotic system to enable surgeries that were previously too difficult or impossible to perform using Bonutti-'234's handheld suture securing system. Fischer, ¶91. A POSITA further would have been motivated to make this modification because they would have understood it could be useful in *any* surgery performed using Tierney's robotic system and requires suturing (even if Bonutti-'234's handheld suture securing system could have also been used), as it would allow the surgeon to continue using Tierney's robotic system throughout the surgery, rather than switching to Bonutti-'234's handheld suture securing system mid-surgery. *Id.*

Additionally, Tierney incorporates Madhani, and Madhani provides further motivation to adapt a surgical instrument such as Bonutti-'234's for use with a surgical robot. Tierney, 8:4-10, 9:18-20. For example, Madhani states, "Telesurgery 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 confirms robotic systems (particularly "telesurgical systems") can provide a 3D image wherein "[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, 2:33-38. As such, robotic systems can give a surgeon performing minimally invasive surgery a visual sensation similar to (and perhaps better than) open surgery. Fischer, ¶92. Thus, a POSITA would have been motivated to modify Bonutti-'234's suture securing system for use with Tierney's robotic system to obtain the benefits taught by Madhani. *Id*.

Third, the adaptation of surgical tools like Bonutti-'234's for use with robotic systems like Tierney's was well known in the art. Fischer, ¶93; *see* Anderson, 1:52-2:55, 3:44-61, 7:6-25, 15:3-29, 18:25-38, Figs. 10-36 (disclosing the modification of a handheld ultrasonic instrument for use with a robotic system); Tovey, 3:37-48, 5:26-6:15, Figs. 4-5 (disclosing a variety of surgical instruments, each existing in non-robotic form, for coupling to a surgical robot). In fact, Anderson taught that robotic surgical tools "may include OEM parts" from handheld surgical tools, like Bonutti-'234's suture securing system, "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 Bonutti-'234's suture securing system for use with Tierney's robotic system would have been motivated to use Bonutti-'234's components to the extent practicable to reduce costs and increase manufacturing convenience. Fischer, ¶94.

Fourth, a POSITA would have been motivated to modify Bonutti-'234's suture securing system for use with Tierney's robotic system to obtain the safety benefits of Tierney's force limitation mechanism. Fischer, ¶97. A POSITA would have been aware of the safety concerns associated with a suture securing system applying excessive force to a patient, which could injure the patient and/or damage the suture assembly. *Id.*; Bonutti-'234, 42:1-16 (recognizing the magnitude of forces 960, 968, and 970 should be "a function of the size and strength of the suture 922," *e.g.*, "0.80 times the strength of the suture 922"), 4:25-27, 9:11-14, 10:51-55, 44:57-59 (recognizing the system may be used with "soft body tissue"). A POSITA also would have known 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. Fischer, ¶97; Tierney, 15:59-66; *see also* Gardiner, 17:57-64; Whitman, 17:41-60, 18:4-13.

And **finally**, there was a design need to provide a mechanism for operating Bonutti-'234's suture securing system and "a finite number of identified, predictable solutions" to that problem. Fischer, ¶100. Bonutti-'234 does not explicitly describe how to generate the forces necessary to operate its suture securing system. *Id.* Tierney discloses a predictable solution—using a robotic arm. Thus, a POSITA had good reason to pursue Tierney's known option, and the device resulting from the combination of Tierney and Bonutti-'234 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 Bonutti-'234 to be successful. Fischer, ¶101. Indeed, a POSITA would have had a greater expectation of success combining Bonutti-'234 with Tierney than they would have had attempting to implement the '953 patent's robotic suturing tool. *Id.* Tierney, for example, discloses multiple means of coupling its robotic system to Bonutti-'234's suturing tool (*e.g.*, "cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like"). Tierney, 9:16-45. But the '953 patent fails to explain how its robotic system and suturing tool would be coupled. Instead, the '953 patent merely states it could be done and leaves the details to conventional wisdom and knowledge. *See* '953 patent, 8:64-14:62, Figs. 1-4 (providing no details on how tensioner 122, pusher assembly 128, and retainer deformation assembly 144 are integrated with the robotic system)[5]; *see also SRI Int'l, Inc. v. Internet Sec. Systems, Inc.*, 511 F.3d 1186, 1193-94 (Fed. Cir. 2008) (prior art need not disclose more details than challenged patent to meet "lower enablement standard for prior art"); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988) (same).

Furthermore, Dr. Fischer confirms combining Bonutti-'234 and Tierney would have been merely the application of a known technique (adapting a manually operated surgical instrument for use with a robotic system) with known devices (Bonutti-'234's suture securing system and Tierney's surgical robot) in a common field of endeavor (the development of surgical instruments). Fischer, ¶102; *KSR*, 550 U.S. at 417. As illustrated by Anderson and Tovey, adapting a surgical instrument, like Bonutti-'234's suture securing system, for use with a robotic system, like Tierney's, was well within the level of skill in the art. Fischer, ¶102; Anderson, 1:52-2:55, 3:44-61, 7:6-25, 15:3-29, 18:25-38, Figs. 10-36; Tovey, 3:37-48, 5:26-6:15, Figs. 4-5. Tierney even discloses "needle drivers," which a POSITA would have understood is for suturing, and which would have bolstered a POSITA's expectation of success in combining Bonutti-'234's suture

[5] The '953 patent does mention the tensioner "may include a gripper," but Tierney also discloses a gripper. '953 patent, 11:30-38; Tierney, 2:38-3:6, 6:20-37.

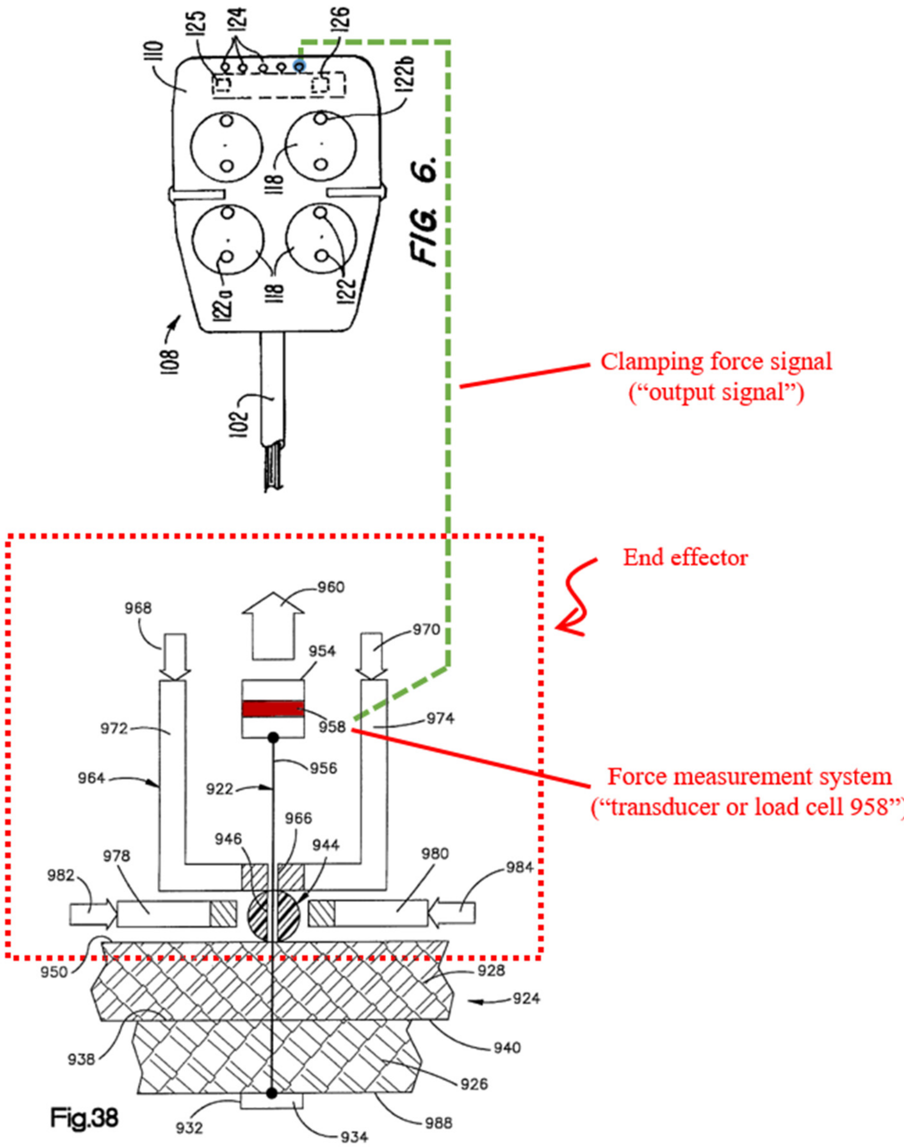
securing system and Tierney's robotic system. Fischer, ¶102: Tierney, 1:30-37, 2:47-52, 6:22-28; IS1029, 6. Similarly, Tovey discloses a "suturing" tool coupled to a surgical robot, which would have further bolstered a POSITA's expectation of success in combining Bonutti-'234's suture securing system and Tierney's robotic system. Tovey, 3:42-46, Fig. 8. And, in the Bonutti-'234/Tierney robotic system, Tierney's robot and Bonutti-'234's suture securing system both continue to work as they always have. Fischer, ¶108. Thus, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by Bonutti-'234's suture securing system (securing a suture) or Tierney's robotic system (positioning the tool, providing mechanical controls to the tool, and receiving feedback signals from the tool). *Id.*

[1.3] generating, using a force measurement system associated with the adaptive arm, a clamping force signal indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue;

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶109. The Bonutti-'234/Tierney robotic system generates, using a force measurement system (Bonutti-'234's "transducer or load cell 958") associated with Tierney's adaptive arm, a clamping force signal ("output signal" of Bonutti-'234's transducer or load cell 958) indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue. *Id.* As explained in Bonutti-'234, "transducer or load cell 958 … provides an output signal indicative of [force 960]," which applies the upward component of the clamping force and "is contemplated" to be equal to forces 968 and 970, which apply the downward component of the clamping force. Bonutti-'234, 41:41-42:16; Fischer, ¶110.

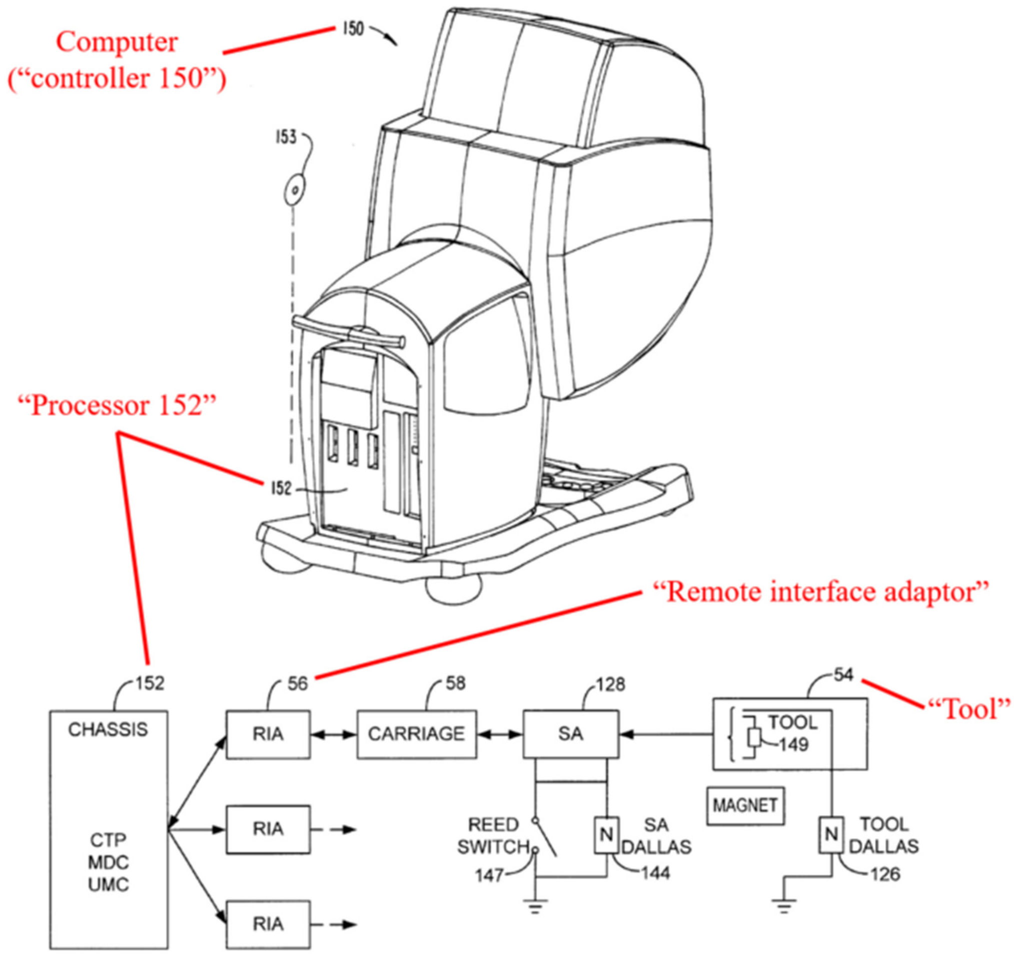
The composite figure below shows one possible configuration of the Bonutti-'234/Tierney robotic system, with the green line denoting an electrical connection between Bonutti-'234's transducer 958 and one of Tierney's "electrically connecting pins 124," which "transmit[] electrical signals between the tool[,] holder" and, ultimately, controller 150. Tierney, 10:12-24, 11:20-35, 12:29-64, Figs. 6, 9; Fischer, ¶112.[6]

[6] Other obvious configurations exist, including one where Tierney's "force sensors" are used instead of Bonutti-'234's transducer 958. Fischer, ¶113-14.



[1.4] receiving, using a computer in communication with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system;

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶115. The Bonutti-'234/Tierney robotic system receives, using a computer (Tierney's controller 150) in communication (via the "remote interface adaptor") with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system. *Id.* Tierney discloses a controller 150 comprising “processor[] 152” that communicates with tool 54 of the robotic mechanism via a “remote interface adaptor.” Tierney, 11:61-12:64, Figs. 8A, 9.



Tierney further renders obvious “receiving … the clamping force signal from the force measurement system.” Tierney discloses that a memory of controller 150 stores information (“tool-type data”) about the tool attached to the robotic mechanism, such as “the maximum force to be applied via driven element 118.”

Tierney, 15:59-16:19. A POSITA would understand that to make use of this information about the limits of the tool, the controller must know the force being applied via driven element 118 so it can prevent the surgeon from exceeding those limits or alert the surgeon when he/she is doing so. And, as explained in Ground 1, element [1.3], the robotic mechanism of the Bonutti-'234/Tierney robotic system includes a force measurement system (*e.g.,* Bonutti-'234's transducer 958) that generates a clamping force signal. Thus, in the Bonutti-'234/Tierney robotic system, Tierney's controller 150 would receive the clamping force signal from the force measurement system. Fischer, ¶117; *see also* Bonutti-'234, 38:44-51, Fig. 36 (disclosing the transducer output signal can be sent to a display unit, which a POSITA would understand involves a computer for signal processing).

[1.5] determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude; and

If this term is entitled to patentable weight, Bonutti-'234 in view of Tierney discloses it. Fischer, ¶118. Either the surgeon or the Bonutti-'234/Tierney robotic system would determine, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude ("predetermined function of the strength of the suture 922," *e.g.*, "0.80 times the strength of the suture 922").

Bonutti-'234 discloses that after the suture retainer 944 is positioned against outer layer 928 of body tissue 924, the suture securing system increases the clamping force until it is determined, using the clamping force signal, that the clamping force is "equal to a predetermined function of the strength of the suture 922" (*e.g.*, "0.80 times the strength of the suture 922"). *Id.*, ¶119; Bonutti-'234, 42:28-45, 42:1-16, 41:41-53. Thus, in the Bonutti-'234/Tierney robotic system, the computer (Tierney's controller 150) would store information about the strength of the suture and the predetermined function, and it would either determine on its own whether the clamping force is equal to the predetermined function or display the necessary information so the surgeon could make this determination mentally. Fischer, ¶119.

A POSITA would have used Tierney's computer in either of these ways for several reasons. Fischer, ¶120. **First**, Bonutti-'234 teaches using a display unit to display the output signal of a force sensor indicative of the force applied to the suture retainer, and Tierney discloses a computer with a display unit. Bonutti-'234, 38:44-51, Fig. 36; Tierney, 6:61-7:6. **Second**, Bonutti-'234 teaches using a clamping force signal to activate an "indicator" that the clamping force has reached a predetermined value, and a POSITA would recognize this indicator could be displayed by Tierney's computer. *Id.*, 35:24-31; Fischer, ¶121. **Third**, Bonutti-'234 teaches using its display unit and received sensor signals to make similar determinations concerning the application of force to the suture retainer—*i.e.*, that a predetermined force has been applied to the suture retainer for a predetermined length of time sufficient to plastically deform the suture retainer. Bonutti-’234, 7:2-7, 10:17-26, 19:57-65, 33:27-34, 38:44-51. **Fourth**, Tierney incorporates Cooper-’666 by reference, and Cooper-’666 discloses Tierney’s computer includes “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, 9:22-26. **Fifth**, a POSITA would understand Bonutti-’234’s “predetermined function of the strength of the suture 922” is what Tierney considers “tool-type data” (*i.e.*, information about the tool attached to the robotic mechanism, such as “the maximum force to be applied via driven element 118”), and Tierney discloses storing such data in the computer. Fischer, ¶124; Tierney, 15:59-16:19. And **finally**, like Bonutti-’234, Tierney teaches using the computer and received sensor signals to make similar determinations concerning the system’s operation—*i.e.*, the “position and orientation” of the end effector 112. Tierney, 8:25-42.

[1.6] fastening, after said determining and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude, the first and second portions of body tissue together using the adaptive arm.

Bonutti-’234 in view of Tierney discloses this limitation. Fischer, ¶126. The Bonutti-’234/Tierney robotic system fastens the first and second portions of body tissue together using a pair of force application members 978 and 980 on the adaptive arm that are “pressed against opposite sides of the suture retainer 944” so "the suture retainer 944 is plastically deformed to firmly grip the suture 922." Bonutti-'234, 42:46-59.

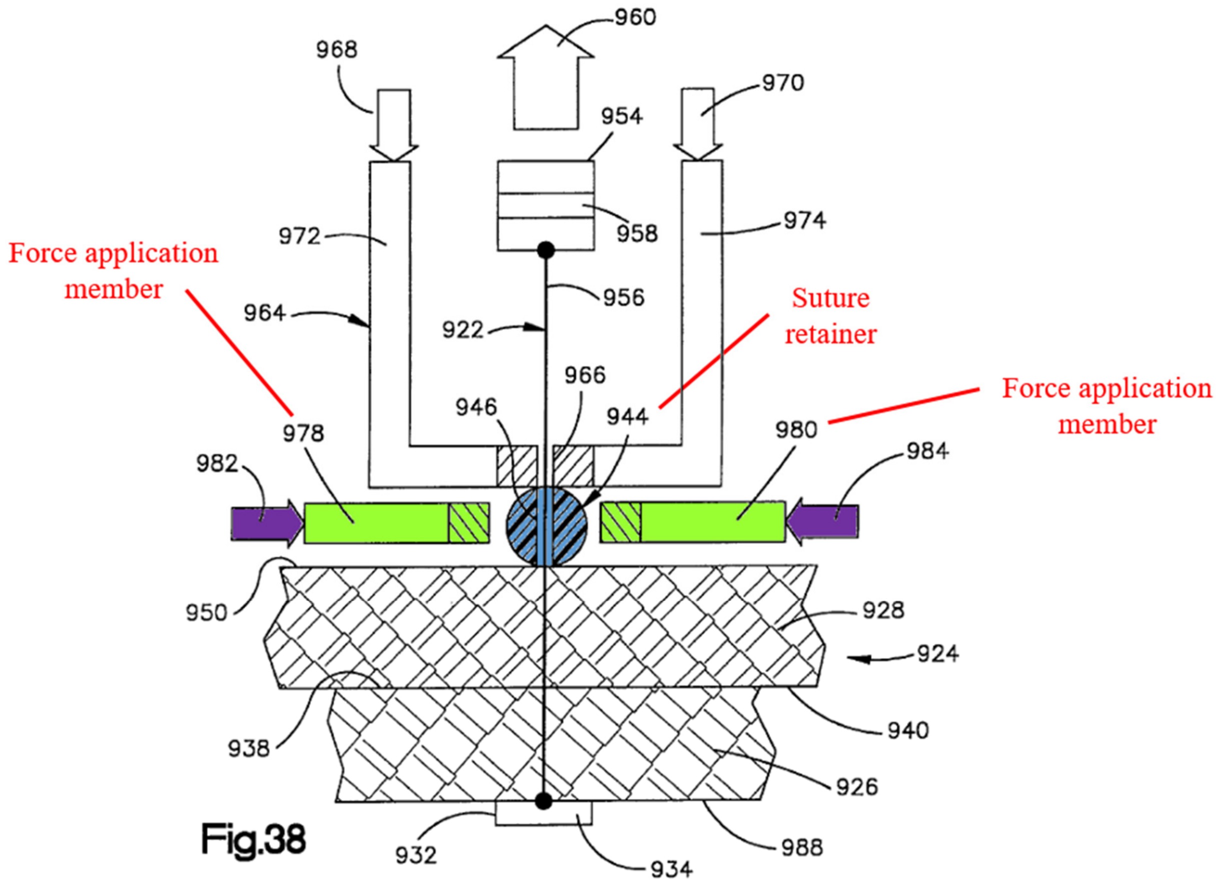


Fig.38

The fastening also occurs after the determining step and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude. Fischer, ¶127; Bonutti-'234, 42:28-59; Tierney, 15:59-16:19. As Bonutti-'234 explains, determining whether the clamping force has a predetermined magnitude occurs before deforming suture retainer 944 to fasten outer layer 928 and inner layer 926 of body tissue 924 together. Bonutti-'234, 42:28-59. Moreover, the suture retainer is deformed "[w]hile the suture is tensioned" with the predetermined clamping force so it "maintain[s] the tension in the suture [922]." Bonutti-'234, 2:5-10, 42:46-59, Fig. 38. Thus, at the time of fastening, the adaptive arm simultaneously imparts the predetermined clamping force. Fischer, ¶127; Bonutti-'234, 42:1-59, 40:18-25, 41:28-67.

2. The method of fastening at least first and second portions of body tissue together as set forth in claim 1, wherein said fastening comprises inserting at least one fastener into the first and second portions using the adaptive arm.

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶128. The Bonutti-'234/Tierney robotic system inserts the suture portion of at least one fastener (combination of suture 922, suture anchor 934, and suture retainer 944) into the first and second portions of body tissue using an adaptive arm of Tierney's robot. *Id*. Bonutti-'234 discloses threading suture 922 through the body tissue portions using a "needle or similar device." Bonutti-'234, 43:59-64; *see also* 40:33-34, 40:46-47, Fig. 38. In the example of the Bonutti-'234/Tierney robotic system described in claim 1, this step would be performed using a "needle holder[]" mounted to one of Tierney's other adaptive arms. Tierney, 6:20-37; Fischer, ¶129. The surgeon would use *that* adaptive arm to position the suture and suture anchor, and then they would use the adaptive arm incorporating Bonutti-'234's suture securing system to tension the suture, impart the downward clamping force, and plastically deform the suture retainer. Fischer, ¶129.

If Patent Owner contends the adaptive arm in this limitation must be the same adaptive arm as in claim 1, this configuration would have been obvious as well. Fischer, ¶130. As previously noted in Ground 1, element [1.2], another obvious combination of Bonutti-'234 and Tierney is one where Bonutti-'234's movable components are integrated into separate tools that cooperate to perform the claimed functions. In that alternative configuration, Bonutti-'234's force application assembly 954, which applies the upward component of the clamping force (force 960) to the bottom side of the body tissues, would be separated from Bonutti-'234's other movable components and incorporated into or performed by Tierney's needle holder—*i.e.*, the tool that inserts the suture into the body tissue portions. Accordingly, one adaptive arm would both insert the suture and impart the upward component of the clamping force (force 960), thus satisfying claim 2, and another adaptive arm would impart the downward component of the clamping force (forces 968 and/or 970) and the forces that plastically deform the suture retainer (forces 982, 984). Fischer, ¶130.

A POSITA would have been motivated to pursue this alternative for at least three reasons. Fischer, ¶131. **First**, using the same tool to both insert and tension the suture would obviate the need to detach the suture from one tool and secure it to another mid-surgery (as is the case with the configuration we presented in element [1.2]). *Id*. **Second**, incorporating Bonutti-'234's movable components into separate tools would free up driven elements 118 for other uses, such as providing additional degrees of freedom to the tools or supplying additional torque as needed. *Id.* And **third**, each tool would have fewer moving parts, thus reducing their individual size, complexity, likelihood of mechanical failure, and cost, all of which are well-known design considerations. *Id.*

Furthermore, a POSITA making this alternative configuration would have reasonably expected to succeed for the same reasons they would have reasonably expected to succeed when making the modifications proposed in claim 1, and because Tierney's needle holder already has force sensing capabilities. *Id.*, ¶132; Cooper-'666, 16:38-17:3 (drive motors "include … force sensors … for transmitting force and torque feedback to the surgeon").

4. The method of fastening at least first and second portions of body tissue together as set forth in claim 1, wherein said fastening comprises applying at least one fastener to the first and second portions of body tissue.

Bonutti-'234 discloses this limitation. Fischer, ¶133. Bonutti-'234's suture securing system applies at least one fastener (combination of suture 922, suture anchor 934, and suture retainer 944) to the first and second portions of body tissue that extends through both the first and second portions of body tissue to fasten them together. *Id.*; Bonutti-'234, 40:33-37, 40:46-55, 43:59-64, Fig. 38.

[6.1] A method of fastening at least first and second portions of body tissue together, the method comprising:

See Ground 1, element [1.1].

[6.2] applying, using a robotic mechanism, a force to the first and second portions of body tissue suitable to press the first and second portions against one another;

See Ground 1, element [1.2] (confirming the Bonutti-'234/Tierney robotic system applies, using a robotic mechanism (robotic arm slave cart 50) modified to include Bonutti-'234's suture securing system, a force (forces 960, 968, and 970) to the first and second portions of body tissue (inner layer 926 and outer layer 928 of body tissue 924) suitable to press (and thus clamp) the first and second portions against one another). Fischer, ¶135.

[6.3] generating, using a sensor associated with the robotic mechanism, a fastening signal indicative of the first and second portions being suitable for being fastened to one another during said applying a force to the first and second portions of body tissue;

See Ground 1, element [1.3] (confirming the Bonutti-'234/Tierney robotic system generates, using a sensor (*e.g.*, Bonutti-'234's "transducer or load cell 958") associated with the robotic mechanism, a clamping force signal (*e.g.*, "output signal" of Bonutti-'234's transducer or load cell 958) indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue).

Bonutti-'234 further discloses fastening the first and second portions to one another when the clamping force reaches a predetermined magnitude (*e.g.*, "0.80 times the strength of the suture 922"). Bonutti-'234, 42:28-59; *see also* 35:24-31 (disclosing the activation of an "indicator" to inform the surgeon when the clamping force has reached the predetermined magnitude), 19:57-65, 6:62-7:9, 10:17-29, 38:44-51, 33:27-34 (disclosing other indicators); Fischer, ¶137. This disclosure parallels that of the ’953 patent with respect to the claimed fastening signal. ’953 patent, 6:19-23, 12:1-6, 12:24-27. Thus, if the ’953 patent discloses a fastening signal, Bonutti-’234 does too. Fischer, ¶137.

[6.4] receiving, using a computer in communication with the sensor and the robotic mechanism, the fastening signal from the sensor;

See Ground 1, element [1.4] (confirming the Bonutti-’234/Tierney robotic system receives, using a computer (Tierney’s controller 150) in communication with the sensor and the robotic mechanism, the clamping force signal from the sensor); Ground 1, element [6.3] (confirming the clamping force signal is a fastening signal when it indicates the clamping force has reached a predetermined magnitude).

[6.5] determining, using the computer and the received fastening signal, that the first and second portions of body tissue are suitable for being fastened to one another; and

See Ground 1, element [1.5] (confirming the surgeon or the Bonutti-’234/Tierney robotic system determines, using the computer and the received clamping force signal, that the clamping force has a predetermined magnitude); Ground 1; element [6.3] (confirming the Bonutti-’234/Tierney robotic system deems the first and second portions suitable for being fastened to one another when the clamping force has the predetermined magnitude).

[6.6] fastening, after said determining, the first and second portions of body tissue together using a fastener applied by the robotic mechanism.

See Ground 1, element [1.6] (confirming the Bonutti-'234/Tierney robotic system fastens, after the determining step of claim 1, the first and second portions of body tissue together using a fastener (combination of suture 922, suture anchor 934, and suture retainer 944) applied by the robotic mechanism); Ground 1, element [6.5] (confirming the determining steps in claims 1 and 6 are equivalent).

8. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue comprises applying, using the robotic mechanism, a compressive force to the first and second portions of body tissue.

See Ground 1, element [1.2] (confirming the Bonutti-'234/Tierney robotic system applies, using the robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another). A POSITA would understand the clamping force is a compressive force. Fischer, ¶143.

9. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said fastening comprises inserting, using the robotic mechanism, the fastener through each of the first and second portions of body tissue.

See Ground 1, claim 2.

10. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said fastening includes engaging, using the robotic mechanism, an outer surface of the first portion of body tissue with a

first part of the fastener, and engaging, using the robotic mechanism, an outer surface of the second portion of body tissue with a second part of the fastener.

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶145. The Bonutti-'234/Tierney robotic system engages, using the robotic mechanism, an outer surface of the first portion of body tissue (outer side surface 988) with a first part of the fastener (suture anchor 934), and engages, using the robotic mechanism, an outer surface of the second portion of body tissue (outer side surface 950) with a second part of the fastener (suture retainer 944). *Id.*; Bonutti-'234, 41:28-40, 44:17-28, Fig. 38; *see also* 41:54-58.

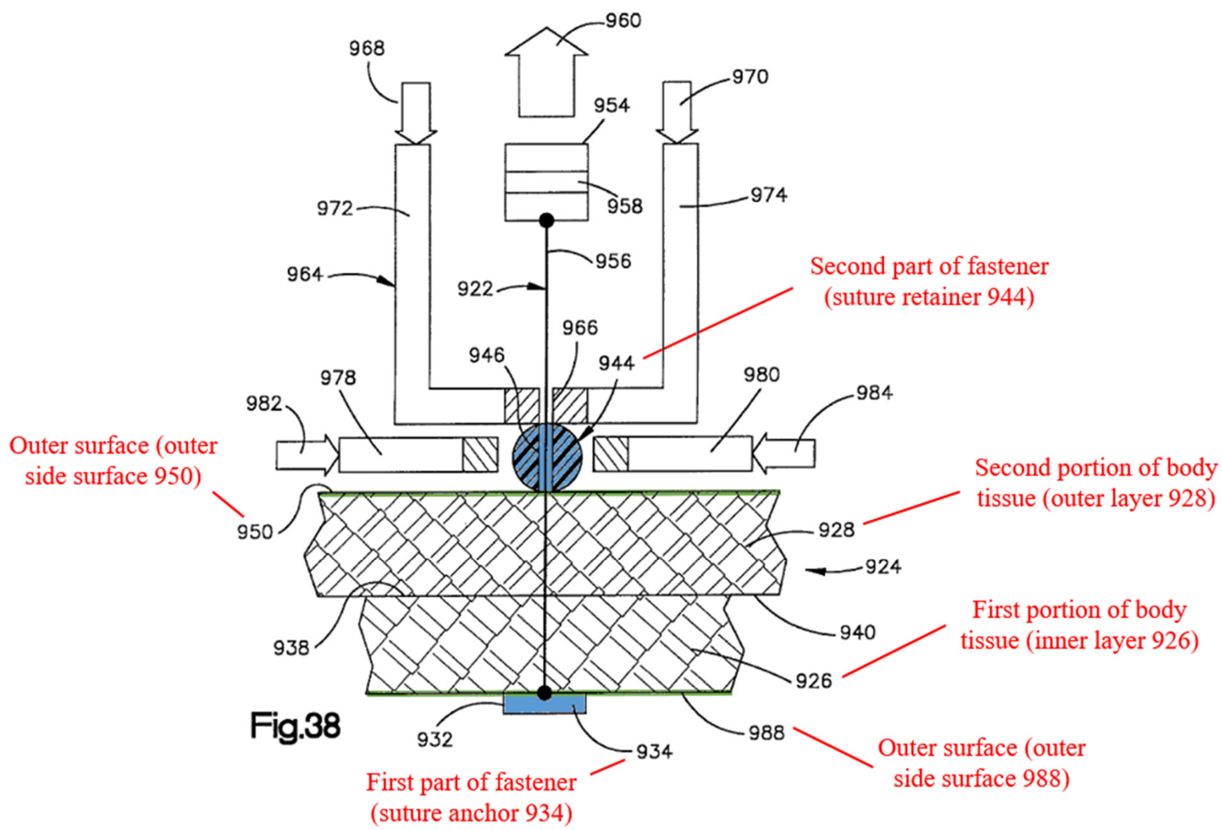


Fig.38

11. The method of fastening at least first and second portions of body tissue together as set forth in claim 10, wherein said engaging, using the robotic mechanism, an outer surface of the second portion of body tissue with a second part of

the fastener comprises deforming, using the robotic mechanism, the second part of the fastener.

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶146. The Bonutti-'234/Tierney robotic system deforms, using the robotic mechanism, the second part of the fastener (suture retainer 944). As Bonutti-'234 explains, "the suture retainer 944 is plastically deformed to firmly grip the suture 922." Bonutti-'234, 42:46-59, Fig. 38.

12. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said fastening, after said determining, the first and second portions of body tissue together comprises deforming, using the robotic mechanism, a part of the fastener.

See Ground 1, claim 11.

13. The method of fastening at least first and second portions of body tissue together as set forth in claim 12, wherein the deformed part of the fastener engages an outer surface of the second portion of body tissue.

See Ground 1, claims 10 and 11.

14. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue and said fastening are performed using a single adaptive arm of the robotic mechanism, wherein said single adaptive arm is received in a cannula in a patient's body.

See Ground 1, element [1.2] (confirming the Bonutti-'234/Tierney robotic system integrates Bonutti-'234's movable components, which apply the force (forces 960, 968, and 970) to the body tissue and perform the fastening (by plastically deforming the suture retainer), into a single adaptive arm). Tierney also discloses the adaptive arm is received in a cannula 72 in a patient's body. Fischer,

¶149; Tierney, 8:10-13, Fig. 2B.

15. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said fastening is performed during said applying a force to the first and second portions of body tissue.

See Ground 1, element [1.6].

16. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue and said fastening are performed using a single adaptive arm of the robotic mechanism.

See Ground 1, claim 14.

17. The method of fastening at least first and second portions of body tissue together as set forth in claim 16, wherein said applying a force to the first and second portions of body tissue is performed using a first drive mechanism of the robotic mechanism, wherein said fastening is performed using a second drive mechanism of the robotic mechanism.

See Ground 1, element [1.2] (confirming the Bonutti-'234/Tierney robotic system applies a force to the first and second portions of body tissue using a first drive mechanism of the robotic mechanism (combination of Bonutti-'234's force application assembly 954 and force application member 964)); Ground 1, element [1.6] (confirming the Bonutti-'234/Tierney robotic system fastens tissue using a second drive mechanism of the robotic mechanism (Bonutti-'234's force application members 978 and 980)).

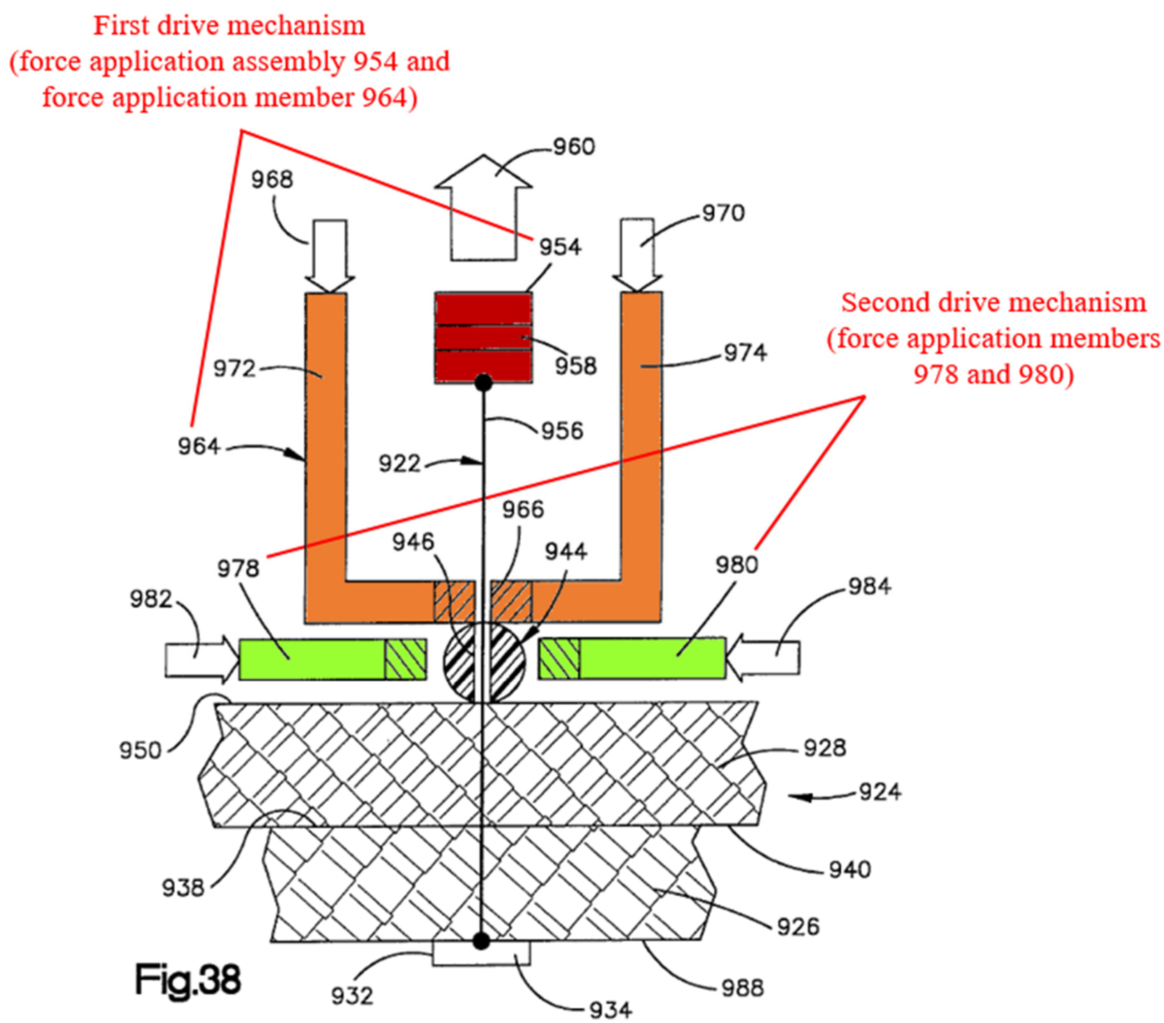
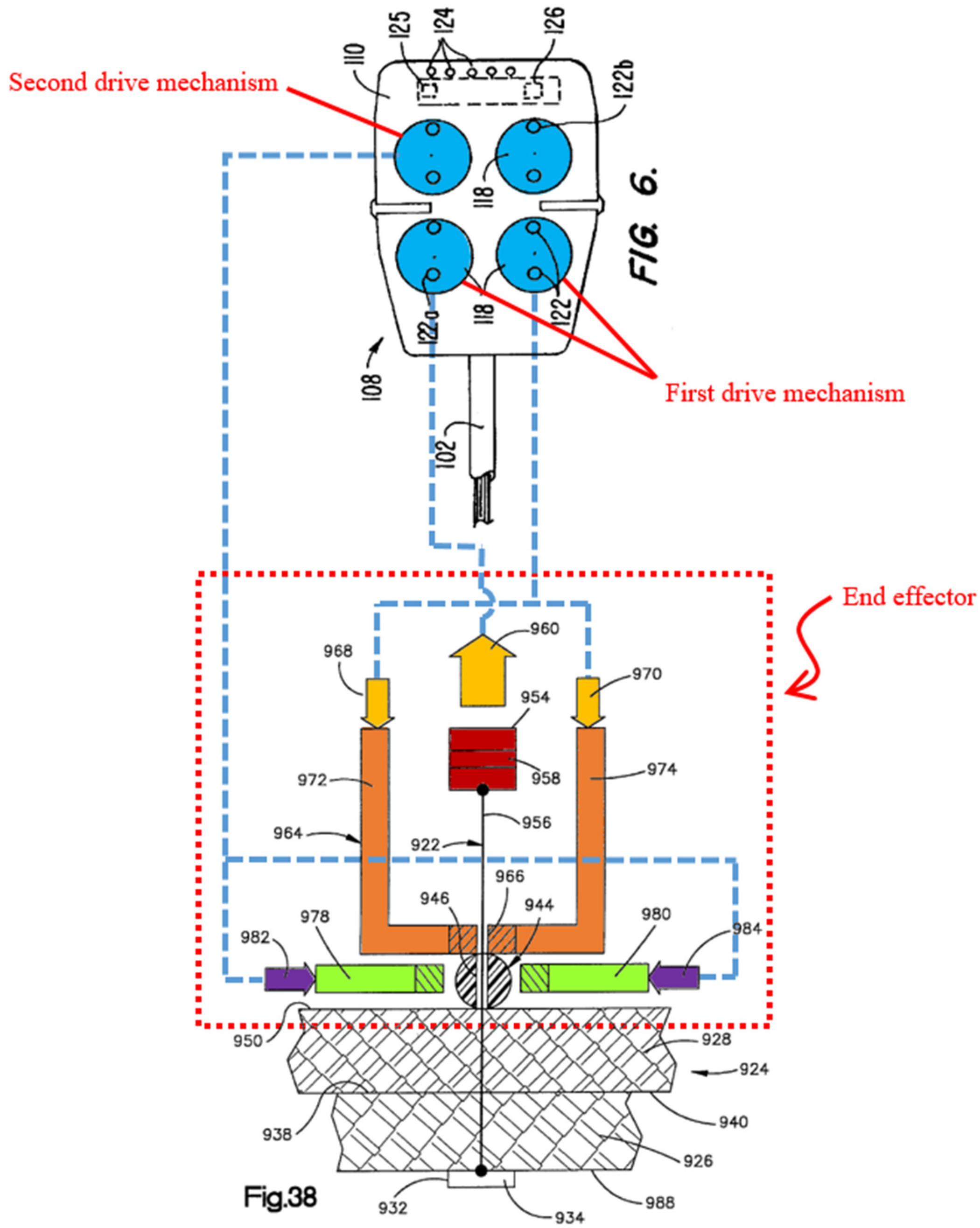


Fig.38

If the claimed drive mechanisms must drive the force application members and be distinct from the force application members, then the first drive mechanism is the combination of Tierney's driven elements 118 (and corresponding motors 70) that drive the combination of Bonutti-'234's force application assembly 954 and force application member 964. And the second drive mechanism is the driven element 118 (and corresponding motor 70) that drives Bonutti-'234's pair of force application members 978 and 980. As Tierney explains, "driven elements 118 provide mechanical coupling of the end effector to drive motors [70]" that are "coupled to tool 54 … to actuate an articulatable end effector of the tool." Tierney, 7:65-8:10, 10:12-24, Figs. 2A-B, 4A-B, 6. Moreover, Tierney discloses a "one to one correspondence between driven elements 118 and motion of an end effector element about an axis." Tierney, 9:35-37; *see also* Ground 1, elements [1.2], [1.6].



18. The method of fastening at least first and second portions of body tissue together as set forth in claim 17, wherein the first drive mechanism and the second drive mechanism are operated independently of one another.

Bonutti-’234 in view of Tierney discloses this limitation. Fischer, ¶156. As Figure 38 of Bonutti-’234 shows, the first drive mechanism (combination of force application assembly 954 and force application member 964) and second drive mechanism (pair of force application members 978 and 980) are not coupled to one another, but rather are separate components. *Id*. Additionally, Bonutti-'234 explains these components are actuated independently during the fastening process. Bonutti-'234, 41:41-67, 42:28-59. The first drive mechanism is actuated to press the body tissues together, and the second drive mechanism is actuated separately to plastically deform the suture retainer 944 while the body tissues are pressed together. *Id.*; *see also* Fig. 35.

Furthermore, in the Bonutti-'234/Tierney robotic system, Bonutti-'234's movable components are driven by Tierney's driven elements 118, and Tierney discloses that these elements are operated independently. Specifically, Tierney's incorporation of Madhani discloses that the drive system provides multiple degrees of freedom to the end effector "independently of each other." Tierney, 9:18-20; Madhani, 4:10-16, 9:44-48; *see also* Tierney, 9:16-45, Figs. 4A-B, 6. Furthermore, it would have been obvious in view of Madhani to operate Tierney's driven elements 118 independently to give the surgeon control over each motion of Bonutti-'234's movable components. Fischer, ¶157.

For the same reasons, the alternative first drive mechanism (combination of Tierney's driven elements 118 that drive Bonutti-'234's force application assembly/member 954 and 964) and second drive mechanism (Tierney's driven element

118 that drives Bonutti-'234's pair of force application members 978 and 980) described in Ground 1, claim 17, are also operated independently. *Id.*, ¶158

19. The method of fastening at least first and second portions of body tissue together as set forth in claim 17, wherein the first drive mechanism is actuated independently of and before the second drive mechanism so that the first and second portions of body tissue are suitably pressed against one another before and during said fastening.

See Ground 1, claim 1 (confirming the Bonutti-'234/Tierney robotic system fastens the body tissues together after determining that the clamping force suitable to press the body tissue portions against one another has a predetermined magnitude, and simultaneously with said clamping force having the predetermined magnitude); Ground 1, claim 18 (confirming the Bonutti-'234/Tierney robotic system independently actuates the first and second drive mechanisms, which apply the clamping force and perform the fastening).

20. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue is performed using a first drive mechanism of the robotic mechanism, wherein said fastening is performed using a second drive mechanism of the robotic mechanism.

See Ground 1, claim 17.

22. The method of fastening at least first and second portions of body tissue together as set forth in claim 20, wherein the first drive mechanism is actuated independently of and before the second drive mechanism so that the first and second portions of body tissue are suitably pressed against one another before and during said fastening.

See Ground 1, claim 19.

23. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein the first and second portions of body tissue are fastened together in linear apposition.

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶162. The Bonutti-'234/Tierney robotic system fastens the first and second portions of body tissue together in linear apposition ("flat apposition"). *Id.*; Bonutti-'234, 40:46-55, Fig. 38.

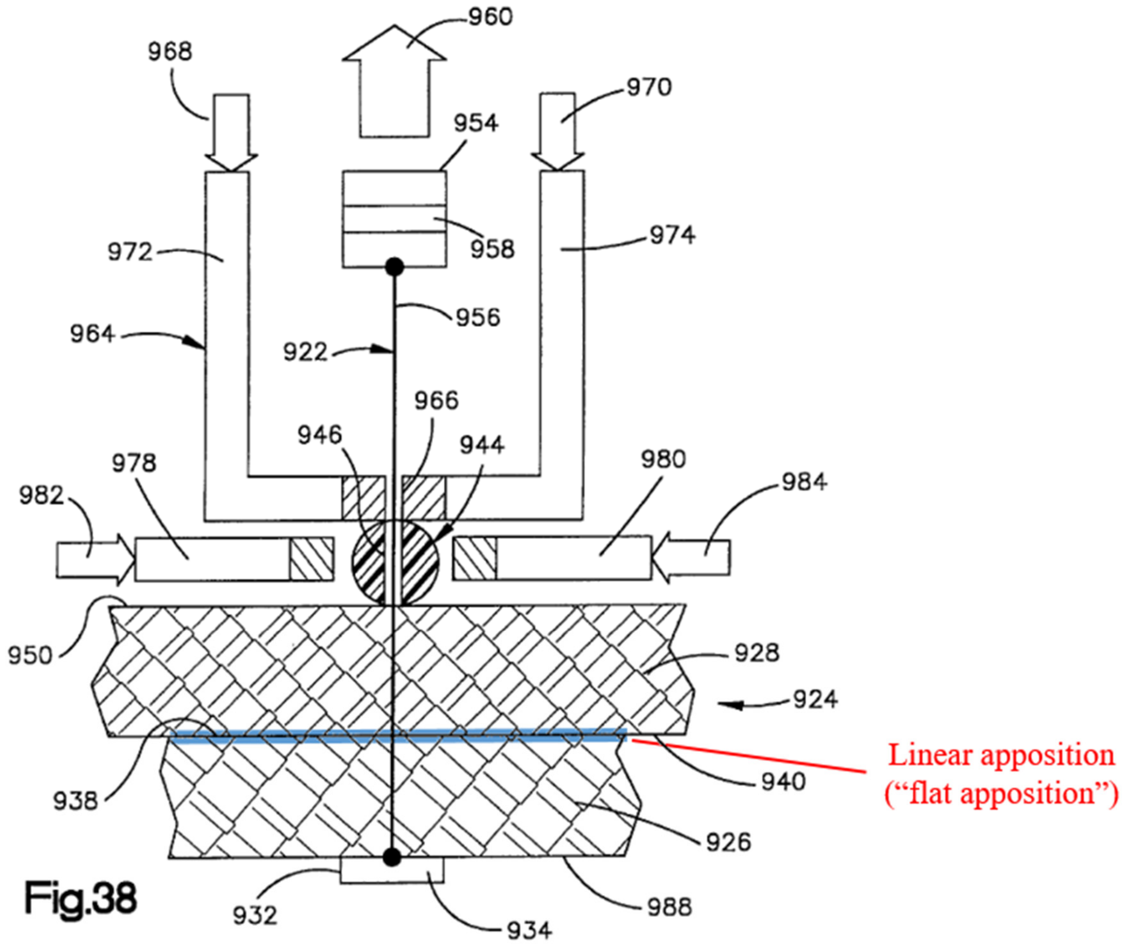


Fig.38

24. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein the first and second portions of body tissue are fastened together in linear apposition using a plurality of linearly aligned fasteners applied by the robotic mechanism.

It would have been obvious to use the Bonutti-'234/Tierney robotic system to fasten the first and second portions of body tissue together in linear apposition using a plurality of linearly aligned fasteners applied by the robotic mechanism. Fischer, ¶163. Humans have been manually fastening body tissue together in linear apposition using a plurality of linearly aligned fasteners (*e.g.*, sutures) for thousands of years. *Id*.

Bonutti-'234 also discloses using its suture securing system to interconnect "stomach or intestinal tissue," and a POSITA would have understood a single one of Bonutti-'234's fasteners would rarely, if ever, be used to suture an incision in stomach or intestinal tissue. Bonutti-'234, 40:14-17; Fischer, ¶164.

25. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said fastening comprises applying a fastening force to the fastener.

Bonutti-'234 in view of Tierney discloses this limitation. Fischer, ¶165. The Bonutti-'234/Tierney robotic system applies a fastening force (forces 982 and 984) to suture retainer 944 of the fastener. *Id.*; Bonutti-'234, 42:46-59, Fig. 38.

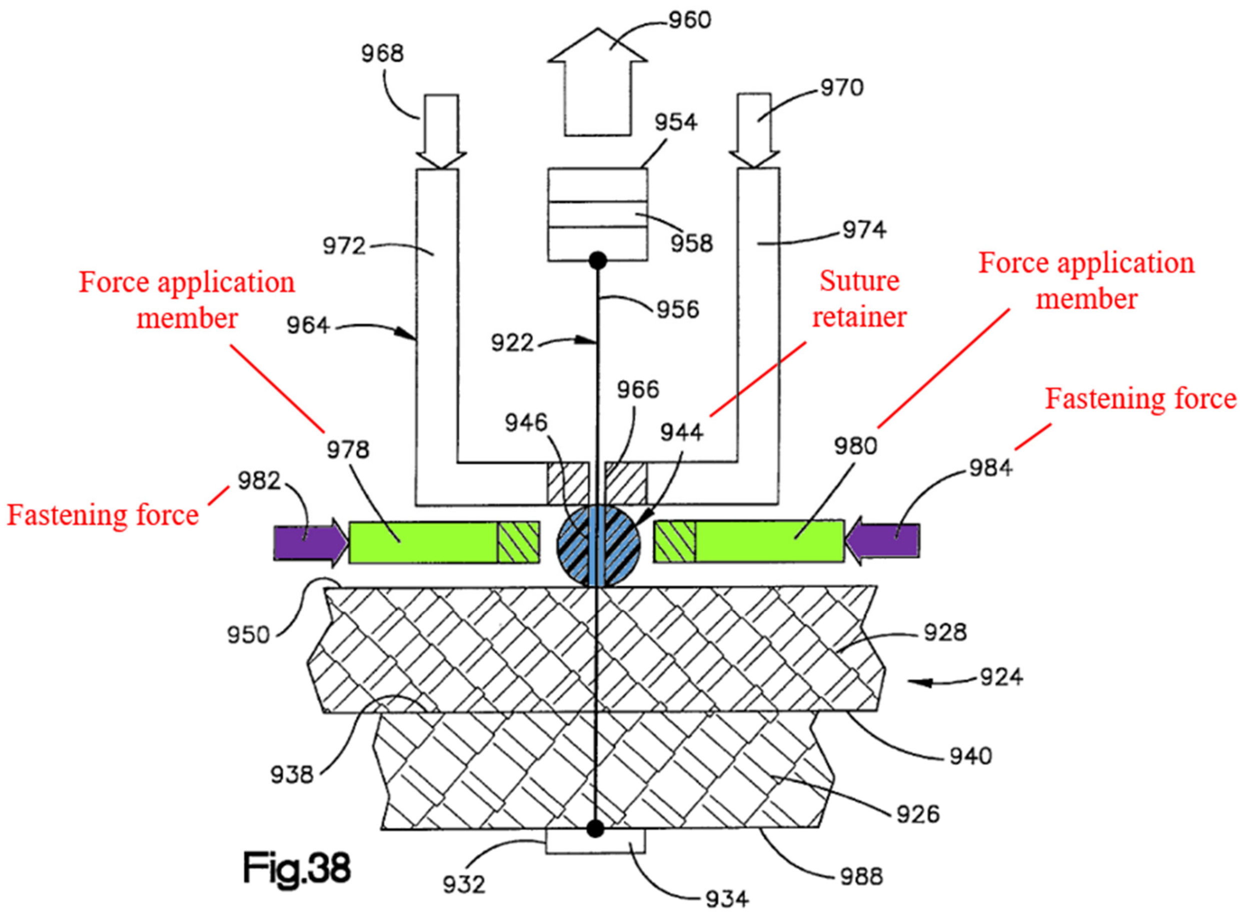


Fig.38

27. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue comprises applying a predetermined force to the first and second portions of body tissue.

See Ground 1, element [1.5].

29. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein the first and second portions of body tissue include one or more of a colon and a stomach.

Bonutti-'234 discloses this limitation. Fischer, ¶167. Bonutti-'234 discloses using its suture securing system to interconnect "stomach or intestinal tissue." Bonutti-'234, 40:14-17.

30. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue and said fastening are performed using a single adaptive arm of the robotic mechanism, wherein the single adaptive arm is inserted in an abdomen of a patient.

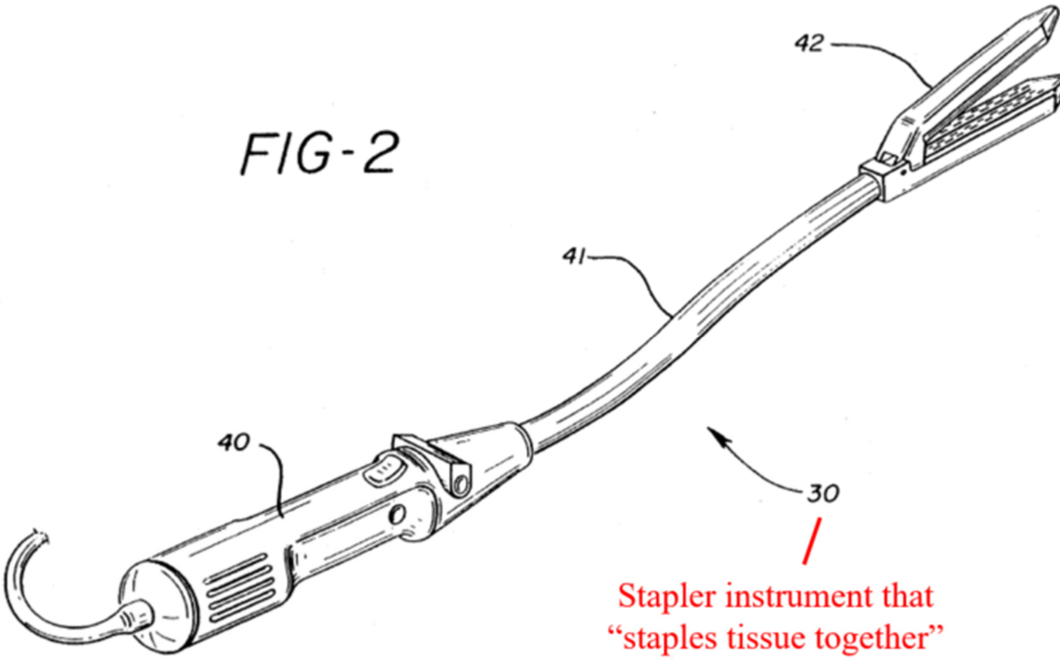
See Ground 1, claim 14 (confirming the Bonutti-'234/Tierney robotic system applies a force to the first and second portions of body tissue and fastens the tissue using a single adaptive arm of the robotic mechanism, wherein said single adaptive arm is received in a cannula in a patient's body); Ground 1, claim 29 (confirming the Bonutti-'234/Tierney robotic system would be used to apply a force to stomach tissues). A POSITA would understand stomach tissues are in the abdomen, and therefore the single adaptive arm of the robotic mechanism would be inserted into the abdomen of a patient's body via the cannula. Fischer, ¶168.

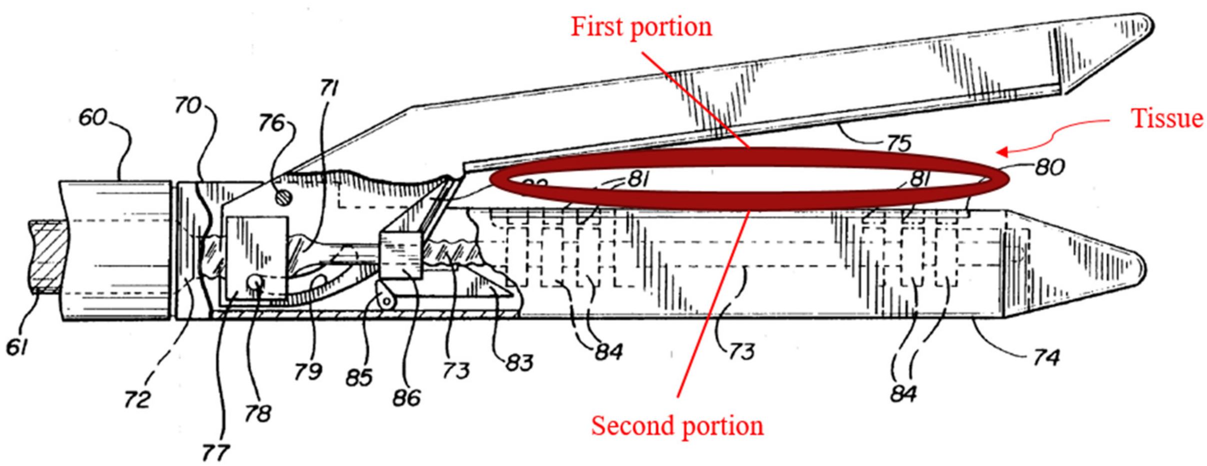
B. Ground 2: Claims 1-4, 6-8, and 24 are obvious over Hooven in view of Tierney under Patent Owner's apparent construction

[1.1] A method of fastening at least first and second portions of body tissue together, the method comprising:

Hooven discloses a method of fastening at least first and second portions of body tissue ("stapled portions"). Fischer, ¶169; Hooven, 4:33-41, Figs. 1-2, 6-10.

FIG-2


42
41
40
30
Stapler instrument that
"staples tissue together"


First portion
Tissue
Second portion
60
70
71
76
75
80
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81
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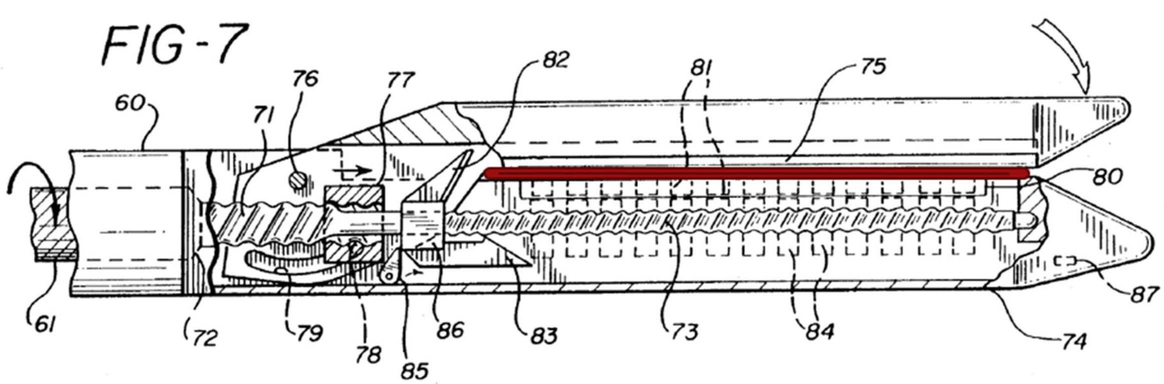
74

FIG-7


82
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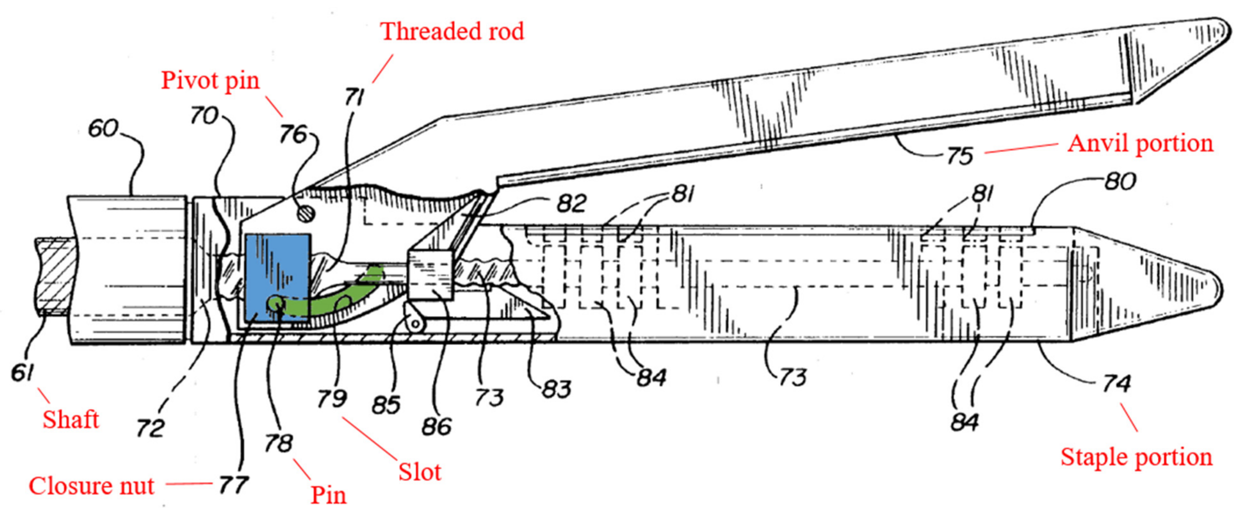
74

[1.2] imparting, using an adaptive arm of a robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another;

Hooven in view of Tierney discloses this limitation. Fischer, ¶170. Hooven discloses imparting a clamping force (force applied by closing anvil portion 75 against staple portion 74) to the first and second portions of body tissue suitable to press the first and second portions against one another. *Id.*; Hooven, 5:9-6:47. Hooven's staple portion 74 and anvil portion 75 are "pivotally connected to each other" to form a jaw. *Id.* In operation, "[t]issue to be treated or manipulated is placed between the anvil portion and the staple portion … when in the open position." *Id.* And closing the jaw imparts a clamping force to the body tissues suitable to press them against one another. Fischer, ¶170. The amount of force required to close the jaw is measured to determine whether "the appropriate amount of tissue [is] between the anvil portion and the staple portion." Hooven, 5:39-48.



It would have been obvious in view of Tierney to use an adaptive arm of a robotic mechanism to control Hooven's staple applier. Fischer, ¶171. As explained in Ground 1, element [1.2], Tierney discloses an adaptive arm of a robotic mechanism, which "may incorporate any … end effector [112] which is useful for surgery," such as a "staple applier[]." Tierney, 6:22-28, 6:49-63, 7:16-8:1, 8:14-24, 9:8-15, 9:66-10:11, 11:65-12:29, Figs. 1-4, 5F; Fischer, ¶171.

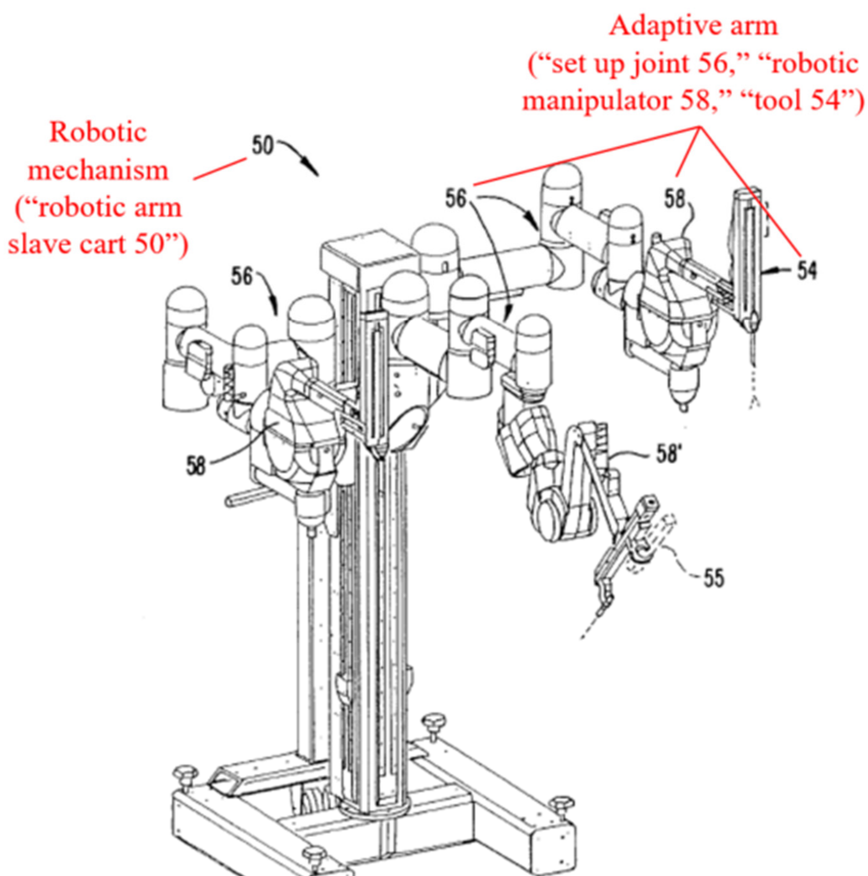


FIG. 3A.

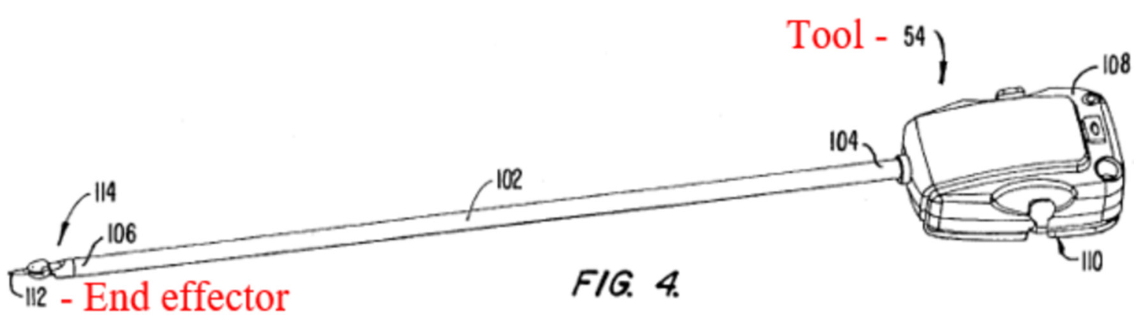
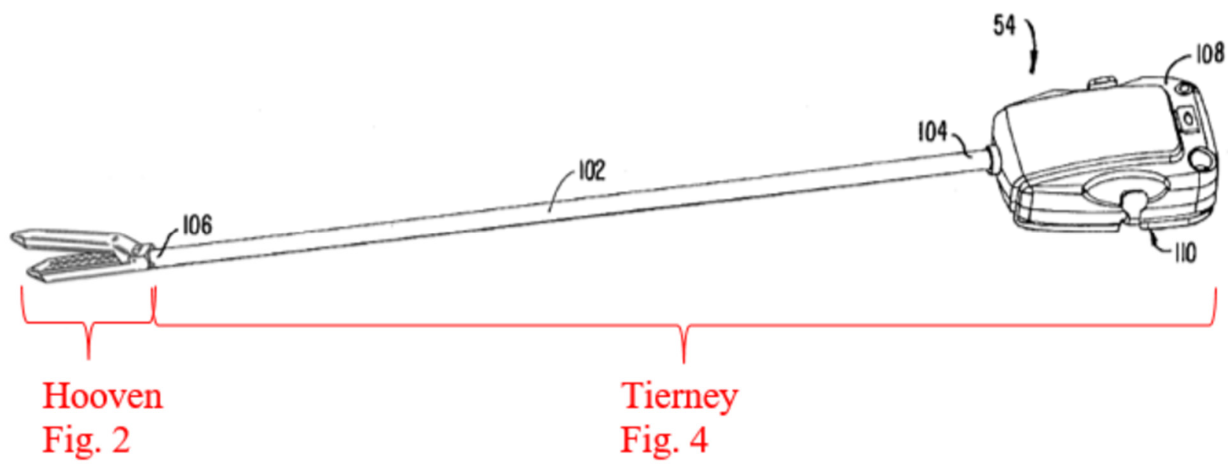


FIG. 4.

An example of the tool portion of the resulting system ("the Hooven/Tierney robotic system") is shown below in the composite image of Tierney, Figure 4 and Hooven, Figure 2:[7]



In this example, the components inside Hooven's handle 40 (*e.g.*, motor 45) would be incorporated into the proximal housing 108 of Tierney's tool 54 to supply rotational motion to Hooven's shaft 61. Hooven's motor 45 would be controlled by Tierney's controller 150 via Tierney's "electrically connecting pins 124," which "transmit[] electrical signals between the tool[,] holder" and, ultimately, controller

[7] Other obvious configurations exist, including one where the forces required to operate the staple applier are provided by Tierney's driven elements 118 and motors 70. Fischer, ¶174. Another obvious configuration would be to use Hooven's flexible shaft instead of Tierney's rigid shaft. *Id.*

150. Tierney, 10:12-24, 11:20-35, 12:29-64, Figs. 6, 9; Fischer, ¶173. And Tierney's controller 150 and "remote interface adaptor" would replace Hooven's controller and interface cable 205, respectively. Fischer, ¶173.

A POSITA would have been motivated to combine Hooven with Tierney. Indeed, the same reasons to combine Bonutti-'234 with Tierney apply to Hooven, including the benefits robotic systems offer for handheld surgical tools. *See* Ground 1, element [1.2]. The motivations do not change even though Bonutti-'234 and Hooven disclose different types of fastening tools. Fischer, ¶¶176-88. A POSITA would have recognized that both instruments would have benefited from adaption for use with Tierney's robot.

A POSITA would have been further motivated to combine Tierney and Hooven because Tierney specifically contemplates using its robotic system with "staple appliers" but does not disclose the details of any specific staple appliers. *Id.*, ¶¶176-77; Tierney, 6:20-28; *see also* Tovey, 5:26-45, Fig. 4. Thus, a POSITA would have looked to references, like Hooven, that disclose how to make and use staple appliers. Fischer, ¶177.

Additionally, 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 staple applier into Tierney's robotic system to obtain a high degree of control over the resulting robotic surgical staple applier. Fischer, ¶¶189-90. A POSITA would have also seen the clear safety benefits (*e.g.*, preventing the staple applier 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. *Id.*; *KSR*, 550 U.S. at 424.

Not surprisingly, the USPTO has already found a POSITA would have had reason to combine essentially the same staple applier as Hooven's with essentially the same robotic system as Tierney's, and has instituted IPR on two other Patent Owner patents based upon the combination of Hooven and Tierney. IS1025, 5-6; IS1026, 34-37; IS1027, 27-29; IS1028, 30.

Moreover, a POSITA would have reasonably expected the combination of Tierney and Hooven to be successful. Fischer, ¶191. Indeed, a POSITA would have had a greater expectation of success combining Hooven with Tierney than they would have had attempting to implement the '953 patent's robotic staple applier. *Id.* Tierney, for example, discloses multiple means of coupling its robotic system to Hooven's staple applier (*e.g.*, "cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like"). Tierney, 9:16-45. But the '953 patent fails to explain how its robotic system and staple applier would be coupled. Instead, the '953 patent merely states it could be done and leaves the details to conventional wisdom and knowledge. *See* '953 patent, 30:3-32:11, Figs. 1, 23-26; *see also SRI*, 511 F.3d at 1193-94; *Constant*, 848 F.2d at 1569.

Furthermore, Dr. Fischer confirms combining Hooven and Tierney would have been merely the application of a known technique (adapting a manually operated surgical instrument for use with a robotic system) with a known system (Tierney's surgical robot) in a common field of endeavor (the development of surgical instruments). Fischer, ¶192; *KSR*, 550 U.S. at 417. As illustrated by Anderson and Tovey, the adaptation of a handheld instrument, like Hooven's staple applier, for use with a robotic system, like Tierney's, was well within the level of skill in the art. Fischer, ¶192; Anderson, 1:52-2:55, 3:44-61, 6:21-36, 7:6-25, 15:3-29, 18:25-38, 23:31-45, Figs. 10-36; Tovey, 3:37-48, 5:26-6:15, Figs. 4-5. And, in the Hooven/Tierney robotic system, Tierney's robot and Hooven's staple applier continue to work as they always have. Fischer, ¶¶195-96. Thus, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by Hooven's staple applier (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] generating, using a force measurement system associated with the adaptive arm, a clamping force signal indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue;

Hooven in view of Tierney discloses this limitation. Fischer, ¶197. The

Hooven/Tierney robotic system generates, using a force measurement system (*e.g.*, Hooven's "miniature sensors") associated with the adaptive arm, a clamping force signal (sensor output signal) indicative of the clamping force ("the power and/or force being used" by Hooven's motor 45 to close anvil portion 75) imparted by the adaptive arm to the first and second portions of body tissue. *Id.*; Hooven, 8:18-49, 5:9-53; *see also* 9:21-22; 3:2-8. For example, Hooven discloses "the amount of torque required to pivot the anvil portion about the pivot pin can be sensed [to determine] the thickness of the tissue between the anvil and the staple portion." Hooven, 5:39-43; *see also* Figs. 6-10. A POSITA would have understood the force used by motor 45 to close anvil portion 75 against staple portion 74 is indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue. Fischer, ¶198; *see also* Hooven, 5:43-48.

[1.4] receiving, using a computer in communication with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system;

Hooven in view of Tierney discloses this limitation. Fischer, ¶201. The Hooven/Tierney robotic system receives, using a computer (Tierney's controller 150) in communication (via the "remote interface adaptor") with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system. *Id.*; *see also* Ground 1, element [1.4] (confirming Tierney discloses a computer (controller 150) in communication (via a "remote interface adaptor") with the robotic mechanism).

Hooven, for example, discloses its staple applier "is interconnected with a controller," which "includes a microprocessor,… sensor interface and motor drive circuits." Hooven, 4:3-20; *see also* 8:18-49. "All sensors [of the staple applier] are connected to the controller via [an] interface cable 205" so "the controller can accept, store, manipulate, and present data." *Id.*, 4:3-20, 8:18-49, Figs. 1, 18, 19, 20A.

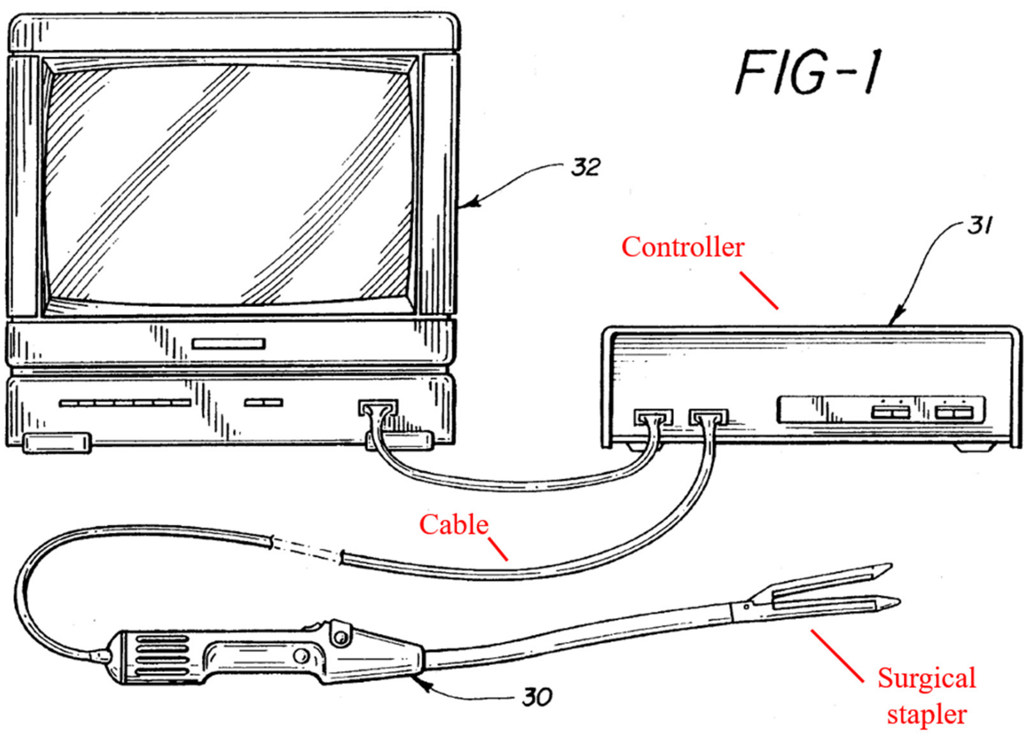
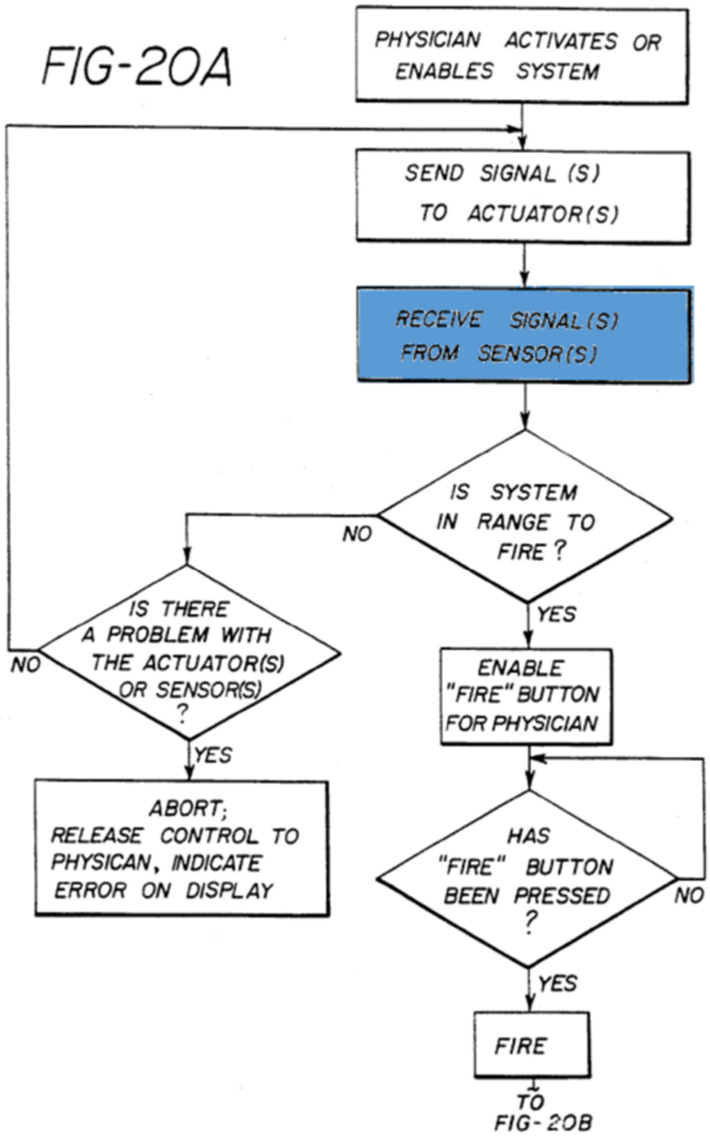


FIG-20A



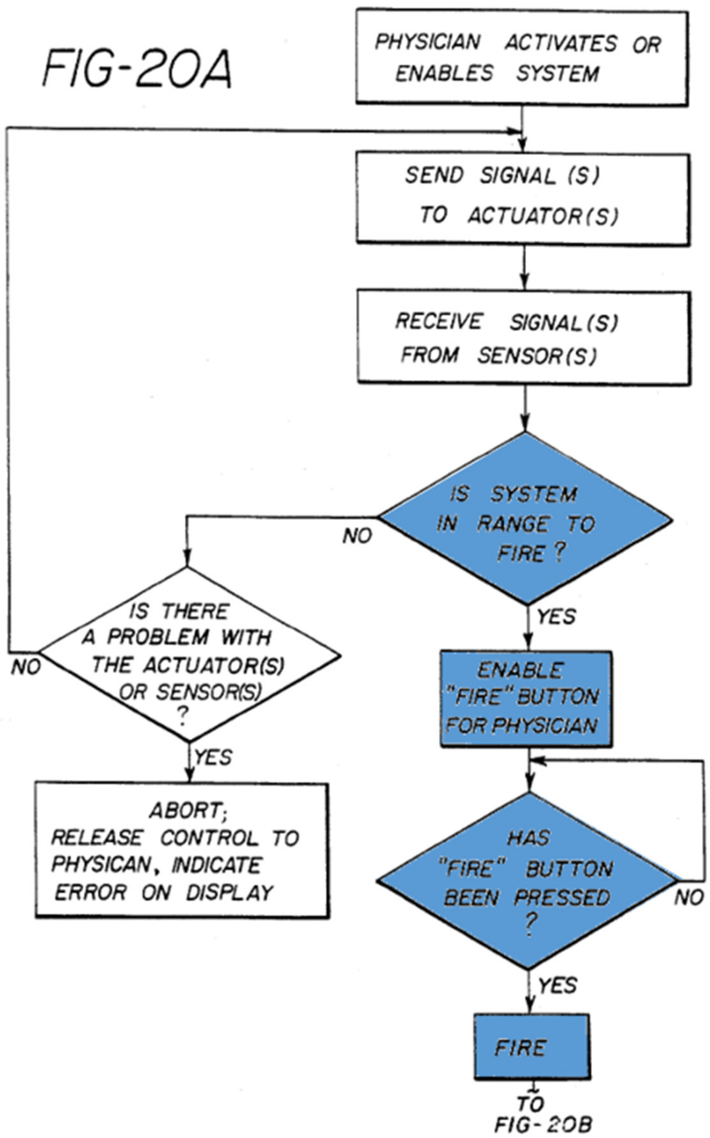
In the Hooven/Tierney robotic system, Tierney's computer (controller 150) and "remote interface adaptor" replace Hooven's computer (controller) and interface cable 205, respectively. Fischer, ¶204.

[1.5] determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude; and

Under Patent Owner's apparent construction, Hooven in view of Tierney discloses this limitation if it is entitled to patentable weight. Fischer, ¶205. Hooven, for example, discloses determining, using the computer and the received clamping force signal, if the force applied to tissues when the staple applier jaws are closed is less than a predetermined magnitude indicative of the tissue being too thick (*e.g.*, an amount indicating the surgeon "has too much … tissue [between the anvil and staple portions] and should re-manipulate the instrument"). Hooven, 5:9-53; *see also* 7:43-46. As Hooven explains, "the amount of torque required to pivot the anvil portion about the pivot pin can be sensed and the thickness of tissue between the anvil and the staple portion determined." *Id.* From there, "[i]t is a simple matter for a controller to manipulate this information and inform the surgeon as to whether or not he has the appropriate amount of tissue … upon closure or whether he has too much or too little tissue and should re-manipulate the instrument." *Id.* A POSITA would understand the controller "inform[s] the surgeon as to whether or not he has the appropriate amount of tissue" by determining if the force applied to tissues when the jaws are closed is less than a predetermined magnitude indicative of there being "too much" tissue. Fischer, ¶205.

[1.6] fastening, after said determining and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude, the first and second portions of body tissue together using the adaptive arm.

Under Patent Owner's apparent construction, Hooven in view of Tierney discloses this limitation. Fischer, ¶206. The Hooven/Tierney robotic system fastens, after performing the determining step (*see* Ground 2, element [1.5]) and simultaneously with the application of the clamping force, the first and second portions of body tissue together using the adaptive arm. *Id.* Specifically, Hooven discloses the system must be "in range to fire" before the system will "enable [the] 'fire' button for [the] physician," which when pressed will "fire" the staples (*e.g.*, "plural parallel rows of staples") to secure the body tissues together. Hooven, 2:40-45, 4:33-41, 5:9-16, 5:43-48, 6:9-47, 8:33-36, 8:52-56, Fig. 20A. And Hooven confirms the controller "inform[s] the surgeon as to whether or not he has the appropriate amount of tissue between the anvil portion and the staple portion of the head of the instrument upon closure or whether he has too much or too little tissue and should re-manipulate the instrument." *Id*., 5:43-48. Thus, a POSITA would have understood tissue is fastened only after it is determined the jaws are in "the closed position ready for firing" and the force applied to tissues by the jaws is less than a predetermined magnitude. *Id*.; Fischer, ¶206.



Hooven also discloses the firing (*i.e.*, fastening) occurs simultaneously with the jaws being closed and applying the clamping force. Fischer, ¶207. Indeed, firing nut 86 does not engage threaded rod 71 until closure nut 77 fully closes the anvil, thereby applying the clamping force, and closure nut 77 does not "retract and open the anvil" until after firing nut 86 has "drive[n] and form[ed] all of the staples." Hooven, 6:9-47, Fig. 20B. Thus, the fastening step occurs simultaneously with the jaws in the closed position and the application of the clamping force.

Fischer, ¶207.

2. The method of fastening at least first and second portions of body tissue together as set forth in claim 1, wherein said fastening comprises inserting at least one fastener into the first and second portions using the adaptive arm.

Hooven in view of Tierney discloses this limitation. Fischer, ¶208. The Hooven/Tierney robotic system inserts at least one fastener (a staple) into the first and second portions of tissue using the adaptive arm. *Id.* Hooven discloses that "[t]he staples pass through the tissue and against the anvil to form the staples in the tissue." Hooven, 6:1-3.

3. The method of fastening at least first and second portions of body tissue together as set forth in claim 2, wherein the at least one fastener comprises at least one staple.

See Ground 2, claim 2.

4. The method of fastening at least first and second portions of body tissue together as set forth in claim 1, wherein said fastening comprises applying at least one fastener to the first and second portions of body tissue.

See Ground 2, claim 2.

[6.1] A method of fastening at least first and second portions of body tissue together, the method comprising:

See Ground 2, element [1.1].

[6.2] applying, using a robotic mechanism, a force to the first and second portions of body tissue suitable to press the first and second portions against one another;

See Ground 2, element [1.2] (confirming the Hooven/Tierney robotic system applies, using a robotic mechanism (Tierney's robotic arm slave cart 50), a force (the clamping force applied by Hooven's anvil portion 75 and staple portion 74) to the first and second portions of body tissue suitable to press the first and second portions against one another); Fischer, ¶212.

[6.3] generating, using a sensor associated with the robotic mechanism, a fastening signal indicative of the first and second portions being suitable for being fastened to one another during said applying a force to the first and second portions of body tissue;

See Ground 2, element [1.3] (confirming the Hooven/Tierney robotic system generates, using a sensor (Hooven's "miniature sensors") associated with the robotic mechanism, a clamping force signal (output of the sensors) indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue).

Hooven further discloses fastening the first and second portions to one another when the output signals of Hooven's miniature sensors indicate the surgeon "has the appropriate amount of tissue between the anvil portion and the staple portion." Hooven, 5:9-53, 8:29-32; Fischer, ¶214; *see also* Ground 2, element [1.5]. This disclosure parallels that of the '953 patent with respect to the claimed fastening signal. '953 patent, 6:19-23, 12:1-6, 12:24-27. Thus, if the '953 patent discloses a fastening signal, Hooven does too. Fischer, ¶214.

Hooven also discloses using phototransistor receiver 164 to measure "a desired property of the tissue [between the jaws] such as oxygen content." Hooven, 7:43-8:17. The controller uses this information to "determine proper positioning of the instrument or other procedure related manipulations" and "control desired operations of the instrument," such as "the firing of the staples." *Id.* A POSITA would have understood that when the output signal of phototransistor receiver 164 indicates "a desired property of the tissue[,] such as oxygen content," it would be used in determining whether the first and second portions of body tissue are suitable for being fastened to one another. Fischer, ¶216.

[6.4] receiving, using a computer in communication with the sensor and the robotic mechanism, the fastening signal from the sensor;

See Ground 2, element [1.4] (confirming the Hooven/Tierney robotic system receives, using a computer (Tierney's controller 150) in communication with the sensors and the robotic mechanism, the clamping force signal from the sensor); Ground 2, element [6.3] (confirming: (1) the clamping force signal is a fastening signal when it indicates the surgeon "has the appropriate amount of tissue between the anvil portion and the staple portion"; and (2) the output signal from phototransistor receiver 164 is a fastening signal when it indicates "a desired property of the tissue[,] such as oxygen content").

[6.5] determining, using the computer and the received fastening signal, that the first and second portions of body tissue are suitable for being fastened to one another; and

See Ground 2, element [1.5] (confirming the surgeon or the Hooven/Tierney robotic system determines, using the computer and the received clamping force signal, if the force applied to tissues when the jaws are closed is less than a predetermined magnitude indicative of the tissue being too thick); Ground 2; element [6.3] (confirming the first and second portions are suitable for being fastened to one another when the output signals from Hooven's miniature sensors indicate the surgeon "has the appropriate amount of tissue between the anvil portion and the staple portion").

Hooven also discloses determining, using the computer and the received fastening signal from phototransistor receiver 164, that the first and second portions of body tissue are suitable for being fastened to one another because they have a desired property such as blood oxygen content or tissue density. Hooven, 7:43-8:17; Fischer, ¶221.

[6.6] fastening, after said determining, the first and second portions of body tissue together using a fastener applied by the robotic mechanism.

See Ground 2, element [1.6] (confirming the Hooven/Tierney robotic system fastens, after the determining step of claim 1, the first and second portions of body tissue together using a fastener ("plural parallel rows of staples") applied by the robotic mechanism); Ground 1, element [6.5] (confirming the determining steps in claims 1 and 6 are equivalent under Patent Owner's apparent construction); *see also* Hooven, 4:33-41, 5:9-6:8, 7:43-8:17, 8:50-56, Fig. 20A; Fischer, ¶222.

Hooven also discloses fastening, after said determining, the first and second portions of body tissue together using a fastener ("plural parallel rows of staples") applied by the robotic mechanism, when phototransistor receiver 164 is used to determine whether the tissues are suitable for being fastened. Indeed, a POSITA would have understood a surgeon would not fire the staple applier to perform the fastening step until after the Hooven/Tierney robotic system performs the determining step to ensure the staples are formed in suitable tissue. Fischer, ¶223. Hooven, 8:7-17; *see also* Figs. 19, 20A.

7. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein the fastener comprises at least one staple.

See Ground 2, element [6.6].

8. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein said applying a force to the first and second portions of body tissue comprises applying, using the robotic mechanism, a compressive force to the first and second portions of body tissue.

See Ground 2, element [1.2] (confirming the Hooven/Tierney robotic system imparts, using an adaptive arm of a robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another). A POSITA would understand the clamping force is a compressive force. Fischer, ¶225.

24. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein the first and second portions of body tissue are fastened together in linear apposition using a plurality of linearly aligned fasteners applied by the robotic mechanism.

Hooven discloses this limitation. Hooven's staple applier applies four rows of staples each comprising a plurality of staples to staple tissue in linear apposition.

Hooven, 4:33-41, Figs. 1-2, 6-10; Fischer, ¶226.

C. Ground 3: Claims 1, 2, 4, 6, 8-20, 22-25, 27, 29, and 30 are obvious over Bonutti-'234 in view of Tierney, Cooper-'666, and Madhani

As discussed in Ground 1, claims 1, 2, 4, 6, 8-20, 22-25, 27, 29, and 30 are obvious over Bonutti-'234 in view of Tierney based in part on Tierney's incorporation of Cooper-'666 and Madhani by reference. If Tierney is deemed not to include Cooper-'666's or Madhani's disclosures, it would have been obvious to combine Tierney with those references to arrive at the same subject matter. Fischer, ¶227.

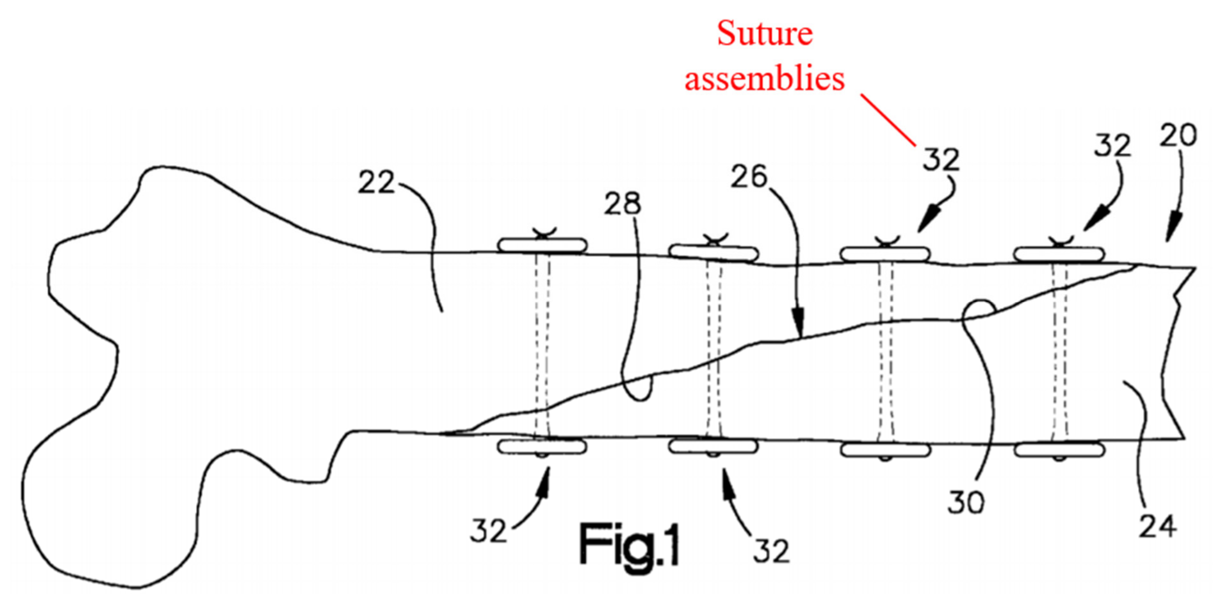
A POSITA would have been motivated to combine Tierney with Cooper-'666 and Madhani for at least two reasons. Fischer, ¶228. First, Tierney alone does not fully disclose the structure of motors 70, robotic system 10, or drive system 116. *Id*. Accordingly, a POSITA would have turned to references such as Cooper-'666, which discloses examples of motors 70 and robotic system 10, and Madhani, which discloses examples of drive system 116. *Id*. Second, Tierney explicitly cites Cooper-'666 and Madhani for a more fulsome disclosure of the structures Tierney builds upon. *Id.*; Tierney, 1:60-66, 9:18-20.

D. Ground 4: Claim 24 is obvious over Bonutti-'234 in view of Tierney and Bonutti-'986

24. The method of fastening at least first and second portions of body tissue together as set forth in claim 6, wherein the first and second portions of body tissue are fastened together in linear apposition using a plurality of linearly aligned fasteners applied by the robotic mechanism.

Bonutti-'234 in view of Tierney and Bonutti-'986 discloses this limitation. Fischer, ¶229. It would have been obvious in view of Bonutti-'986 to use the Bonutti-'234/Tierney robotic system to fasten the first and second portions of body tissue together in linear apposition using a plurality of linearly aligned fasteners applied by the robotic mechanism. *Id.*

Bonutti-'986 discloses using a suture securing system similar to Bonutti-'234's to interconnect two bone segments using a plurality of linearly aligned "bone suture assemblies 32." Bonutti-'986, Abstract, 2:28-67, 6:8-7:20, Figs. 1-3.



A POSITA would have been motivated to use the Bonutti-'234/Tierney robotic system this way for several reasons. Fischer, ¶231. **First**, Bonutti-'234 discloses using its suture securing system to interconnect bone, and Bonutti-'986 discloses treating bone fractures using essentially the same fastener as Bonutti-'234 (combination of a suture, suture anchor, and suture retainer). Bonutti-'234, 44:24-28. A POSITA therefore would have looked to Bonutti-'986 to understand the possible uses of the Bonutti-'234/Tierney robotic system. Fischer, ¶231. **Second**, a POSITA would have recognized using the Bonutti-'234/Tierney robotic system to apply a single fastener would not be effective in most (if not all) surgeries, including the treatment of bone fractures, but Bonutti-'234 does not disclose how to apply multiple fasteners. Thus, a POSITA would have looked to Bonutti-'986 to understand possible methods for applying a plurality of fasteners. *Id.*, ¶232. **Third**, a POSITA would have recognized fasteners have finite strength and can therefore fail under excessive strain. Accordingly, a POSITA would have been motivated to apply a plurality of fasteners as Bonutti-'986 teaches to ensure a sufficiently strong (and therefore safe) interconnection between the body tissues. *Id.*, ¶233. And **finally**, a POSITA would have known using a plurality of fasteners provides redundancy, which reduces the likelihood of failure of an interconnection. *Id.*, ¶234.

Moreover, a POSITA would have reasonably expected success in using the Bonutti-’234/Tierney robotic system this way. Fischer, ¶235. Indeed, it would have been merely the combination of a suturing robot (the Bonutti-’234/Tierney robotic system) with a basic suturing technique (using a plurality of linearly aligned sutures). *Id.*; *KSR*, 550 U.S. at 417. And, in using the Bonutti-’234/Tierney robotic system as Bonutti-’986 teaches, Tierney’s robot and Bonutti-’234’s suture securing system continue to work as they always have. Fischer, ¶235. Thus, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by Bonutti-’234’s suture securing system (securing a suture) or Tierney’s robotic system (positioning a surgical tool, providing mechanical controls to the tool, and receiving feedback signals concerning forces on the tool). *Id.*

X. CONCLUSION

Claims 1-4, 6-20, 22-25, 27, 29, and 30 of the ’953 patent are invalid as set forth above. Accordingly, Petitioner requests IPR.

Respectfully submitted,

Dated: October 1, 2020

/Ryan P. O’Connor/
Ryan P. O’Connor, Reg. No. 60,254
Fish & Richardson P.C.

(Control No. IPR2020-01687)

Attorney for Petitioner

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 13,868 words, which is less than the 14,000 allowed under 37 C.F.R. § 42.24.

Dated: October 1, 2020

/Ryan P. O'Connor/
Ryan P. O'Connor, Reg. No. 60,254
Fish & Richardson P.C.

Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on October 1, 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