IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	McGuckin, Jr. et al.	
U.S. Patent No.:	9,439,650	Attorney Docket No.: 11030-0060IP1
Issue Date:	Sept. 13, 2016	
Appl. Serial No.:	15/018,000	
Filing Date:	February 8, 2016	
Title:	APPARATUS AND METHOD FOR RESECTIONING GASTRO-ESOPHAGEAL TISSUE	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 9,439,650 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Pat. No. 9,439,650 to McGuckin Jr. et al. ("the '650 patent")
IS1002	File history of the '650 Patent ("the File History")
IS1003	Declaration of Dr. Bryan Knodel ("Knodel")
IS1004	U.S. Pat. No. 5,645,209 to Green et al. ("Green-209")
IS1005	U.S. Pat. No. 4,429,695 to Green et al. ("Green-695")
IS1006	U.S. Pat. No. 5,465,895 to Knodel et al. ("Knodel-895")
IS1007	U.S. Pat. No. 4,605,001 to Rothfuss et al. ("Rothfuss")
IS1008	U.S. Pat. No. 5,954,259 to Viola et al. ("Viola")
IS1009	U.S. Pat. No. 5,507,426 to Young et al. ("Young")
IS1010	U.S. Pat. No. 5,040,715 to Green et al. ("Green-715")
IS1011	U.S. Pat. No. 5,865,361 to Milliman et al. ("Milliman")
IS1012	U.S. Pat. No. 5,868,760 to McGuckin ("McGuckin")
IS1013	U.S. Pat. No. 5,307,976 to Olson et al. ("Olson")
IS1014	U.S. Pat. No. 5,389,098 to Tsuruta et al. ("Tsuruta")

I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 4-24 of U.S. Pat. No. 9,439,650 ("the '650 patent"). The '650 patent generally relates to a surgical stapler with a pair of jaws that open and close. According to the prosecution history, the allegedly novel and non-obvious feature of the vast majority of the claims is a beam configured to engage the first and second jaws **from within** the first and second jaws. However, such a beam was well-known at the time of the alleged invention. Had the examiner been aware of the relevant prior art, and, in particular, the references applied in this Petition, the challenged claims would not have issued. Petitioner therefore requests IPR of the challenged claims.

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

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

Intuitive Surgical, Inc. is the real party-in-interest. No other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation of, or 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 '650 patent. The '650 patent and U.S. Pat. No. 10,136,892, which is the great grandchild of the '650 patent, are the subject of Civil Action Nos. 1:19-cv-00005-MN and 1:19-cv-01092-MN, filed on January 2, 2019 and

June 13, 2019, respectively, in the United States District Court for the District of Delaware. Pending U.S. Pat. App. Nos. 16/185,506 and 16/564,543 claim priority to U.S. Pat. App. No. 15/018,000—the application from which the '650 patent issued.

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

Petitioner provides the following designation of counsel.

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D. Service Information

Please address all correspondence and service to the address listed above. Petitioner consents to electronic service by email at IPR11030-0060IP1@fr.com (referencing No. 11030-0060IP1 and cc'ing PTABInbound@fr.com, katz@fr.com, phillips@fr.com, and oconnor@fr.com).

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

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

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

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

Petitioner certifies that the '650 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

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

Petitioner requests an IPR of claims 4-24 of the '650 patent on the grounds listed below. A declaration from Dr. Bryan Knodel is included in support.

Ground	Claims	Basis for Rejection
Ground 1	**4-5, 9-18, 20, 22-24**	Obvious over **Green-209** (IS1004), **Green-695** (IS1005), and **Knodel-895** (IS1006) under pre-AIA 35 U.S.C. § 103.
Ground 2	**4-8, 10-24**	Obvious over **Rothfuss** (IS1007), **Green-209**, and **Knodel-895** under pre-AIA 35 U.S.C. § 103.
Ground 3	**4-24**	Obvious over **McGuckin** (IS1012) and **Green-695** under pre-AIA 35 U.S.C. § 103.

The '650 patent claims priority through a series of continuation applications

to U.S. Prov. Pat. App. No. 60/265,469, filed on January 31, 2001. Thus, the earliest possible date to which the '650 patent could claim priority (hereinafter the "earliest possible effective filing date") is January 31, 2001.

Green-209, Green-695, Knodel-895, Rothfuss, and McGuckin each qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(b) because they are all patents that issued more than one year before the earliest possible effective filing date.

Green-695, Knodel-895, and Rothfuss were not made of record during prosecution of the '650 patent. McGuckin was made of record during prosecution of the '650 patent, but never was discussed by the examiner or the applicant.

Green-209 was made of record during prosecution of the '650 patent. Grounds 1-3 should be considered notwithstanding 35 U.S.C. § 325(d) because they do **not** rely on substantially similar prior art and/or arguments as those already presented to the examiner. Specifically, the examiner did not consider whether the challenged claims would have been obvious in view of (1) Green-695, which is part of the combinations of Grounds 1 and 3, (2) Rothfuss, which is part of the combination of Ground 2, or (3) McGuckin, which is part of the combination of Ground 3. *See Edwards Lifesciences Corp. v. Boston Scientific SciMed, Inc*., Case IPR2017-01295, Paper 9, slip. op. at 25-27 (PTAB October 25, 2017) (institution not denied when Petition's and Examiner's reliance on a prior art reference was substantially different).

V. SUMMARY OF THE '650 PATENT

The '650 patent is directed to a surgical stapling apparatus 10. '650 patent, Abstract, 1:54-2:3, Figs. 1-3.

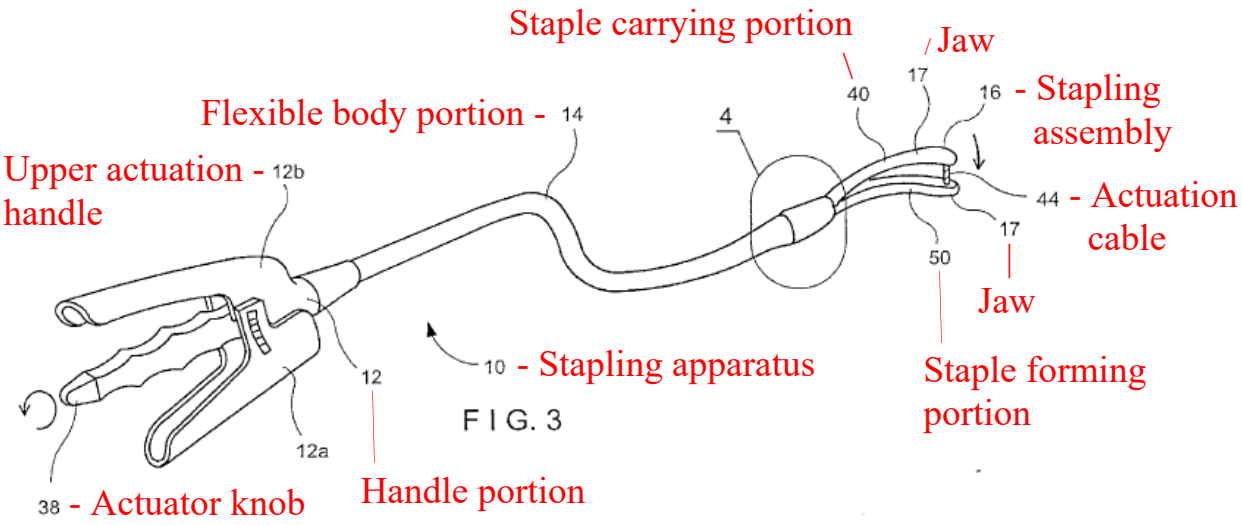


FIG. 3

"[S]tapling apparatus 10 includes a proximal handle portion 12, an elongated flexible body portion 14 extending from the handle portion 12 and a generally C-shaped stapling assembly 16 operatively associated with a distal end of the flexible body portion 14." *Id.*, 3:55-59, Fig. 3. Stapling apparatus 10 also includes "an actuation cable 44 to facilitate gross approximation of the jaws 17 via actuation of an actuator knob 38" (*id.*, 4:61-63), and, for one embodiment, an I-beam member 70 "for finely approximating the jaws in an initial position" via "actuation of [an] upper actuation handle 12b." *Id.*, 2:57-59, 6:21-26, Fig. 13. In this context, "approximation" of the jaws is the act of bringing the jaws together (so they are proximate to

one another). Gross approximation is a relatively large movement whereas fine approximation is a much smaller movement of the jaws.

"I-beam member 70 includes upper and lower beam portions 82a, 82b, respectively, connected by a central web portion 84." *Id.*, 5:36-50, Figs. 13-14. The "leading edge 84a of the central web portion 84 may preferably define a cutting blade for incising tissue as the I-beam member 70 is moved distally" by a flexible pusher 80. *Id.*

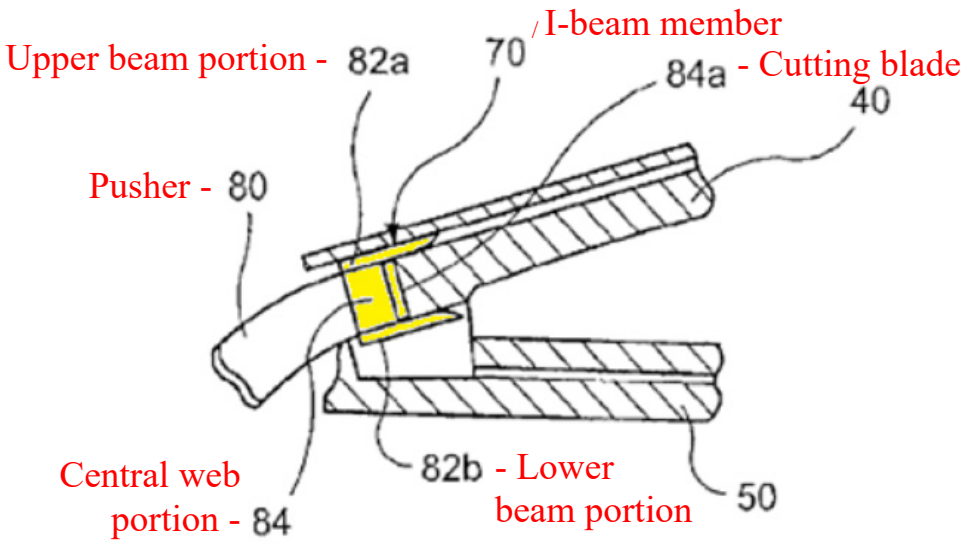


FIG. 13

The "I-beam" has a cross section similar to an "I-beam" used in building construction. *Id.* During operation, the jaws are first closed by a gross approximation motion (*e.g.*, by operation of actuation cable 44 shown at Figure 3). *Id.* Next, the I-beam is moved distally along the jaws of the device, during which the upper beam portion 82a rides in a channel in the upper jaw and the lower beam portion 82b

rides in a channel in the lower jaw. *Id*.

In one embodiment, "[w]hen the I-beam member 70 is driven by the pusher 80, the sloped leading edge of the upper beam portion 82a contacts sequentially each of a plurality of staple pushers 118 to drive them through their respective staple slots to drive the staples housed therein from each slot out of the staple carrying portion 40…." *Id*., 6:26-40, Fig. 15.

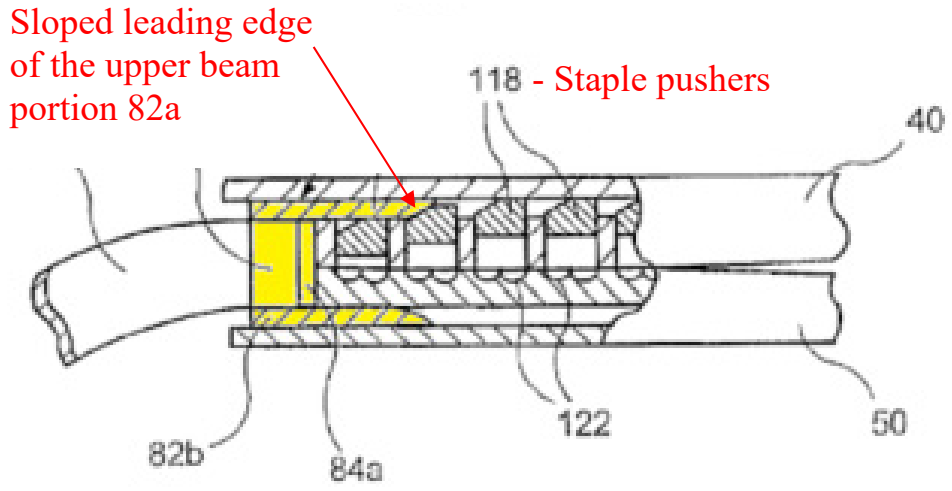


FIG. 15

VI. SUMMARY OF THE PROSECUTION HISTORY

The chain of applications to which the '650 patent claims priority is provided above. *See* Section IV.A, *supra*. Notably, the examiner of the '650 patent rejected original claims 24 and 29-31 (issued claims 4 and 9-11) as anticipated by Green-209. File History, 83-85. The examiner also rejected original claims 25-28,

33-44, and 47-50 as obvious over Green-209 in view of Young.[1] *Id.*, 86-90.

In response to these rejections, the applicants amended original claim 24 to require maintaining the distance and the alignment when the jaws of the stapler are clamped together "by a beam configured to engage the first and second jaws from within the first and second jaws" while the tissue is stapled. The applicants argued that this limitation was not disclosed or suggested by Green-209. File History, 60, 66.

Regarding independent claims 33 and 47, applicants argued that "Young discloses a web 52 with an upper cam plate 54 and a lower cam plate 56, each of which engages the ***outside*** of head 16 [and therefore] [n]o part of the 'upper portion' and 'lower portion' of the structure in Young engages the head 16 from therewithin as claimed." *Id*., 66 (emphasis original).

The examiner agreed with both of these arguments and subsequently issued a notice of allowance. *Id*., 10-18. Thus, applicants successfully distinguished the prior art of record on the basis that it disclosed an I-beam that engages the **outside** of the jaws while tissue is stapled, whereas the comparable claimed I-beam engages features on the **inside** of the jaws. *Id*.

[1] In addition, there was no prior art rejection of claims 21-23, and the remaining dependent claims (32, 45 and 46) were rejected over additional references.

VII. CLAIM CONSTRUCTION

In this proceeding, Petitioner submits that the challenged claims should be given their plain and ordinary meaning. Petitioner reserves the right to propose additional claim constructions and/or challenge the definiteness of any claim in the underlying litigation.

VIII. CLAIMS 4-24 ARE UNPATENTABLE

A. Ground 1: Claims 4-5, 9-18, 20, and 22-24 are obvious over Green-209 in view of Green-695 and Knodel-895, and also over Green-695 in view of Green-209 and Knodel-895

As explained above in Section VI, the examiner of the '650 patent found that Green-209 discloses every limitation of original claim 24 (issued claim 4) except "a beam configured to engage the first and second jaws from within the first and second jaws." However, it would have been obvious in view of Green-695 to modify Green-209's surgical stapler to include such a beam and jaws. It also would have been obvious in view of Green-209 to modify Green-695's surgical stapler for use in minimally invasive surgery to create essentially the same device (the Green-209/695 stapler). We discuss both options below.

Green-209 in view of Green-695

Like the '650 patent, Green-209 discloses an endoscopic surgical stapling instrument 50. Green-209, 11:17-20, Fig. 1; *see also* Fig. 90.

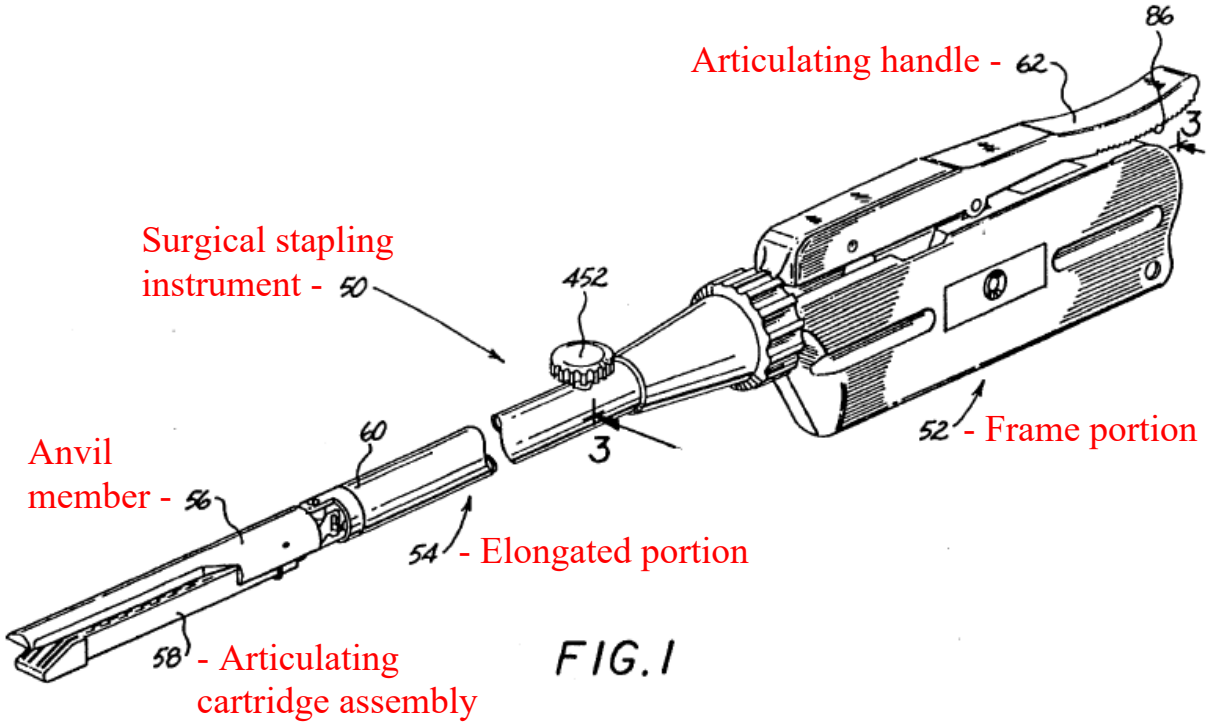


FIG. 1

Instrument 50 includes frame portion 52, elongated portion 54, anvil member 56, articulating cartridge assembly 58, and articulating handle 62. *Id.*, 11:21-35, Figs. 2, 15, 28. "Anvil member 56 and cartridge assembly 58 are manually controlled by … articulating handle 62 … by means of a linkage and cable assembly" (highlighted below) *Id.*

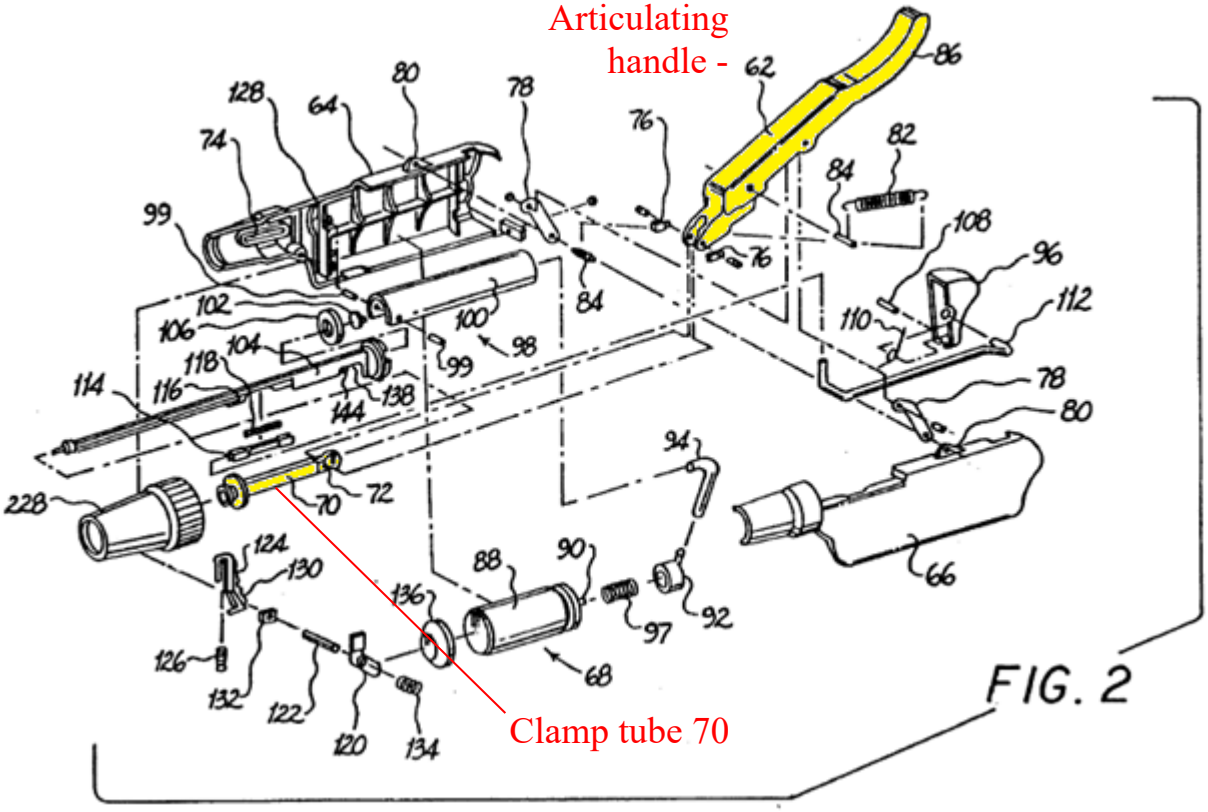
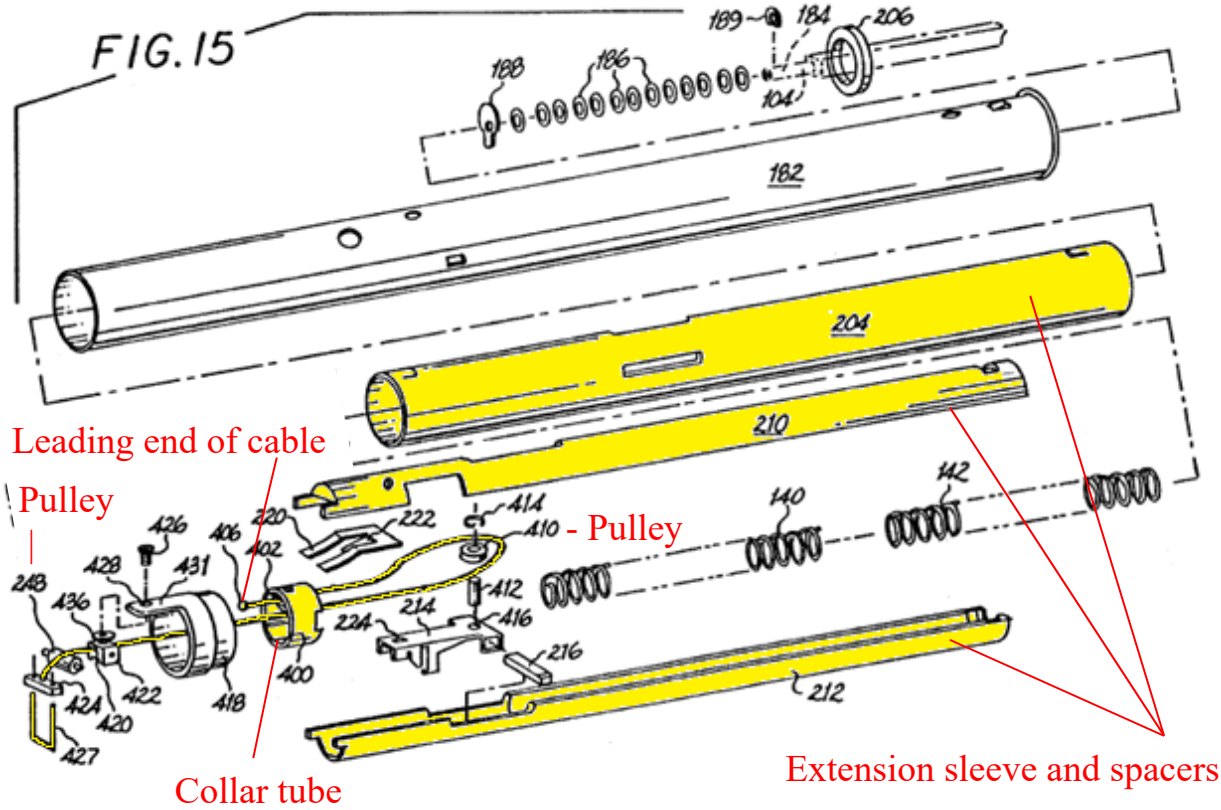

Articulating handle - 62
Clamp tube 70

FIG. 2

FIG. 15


Leading end of cable
Pulley
Pulley
Collar tube
Extension sleeve and spacers

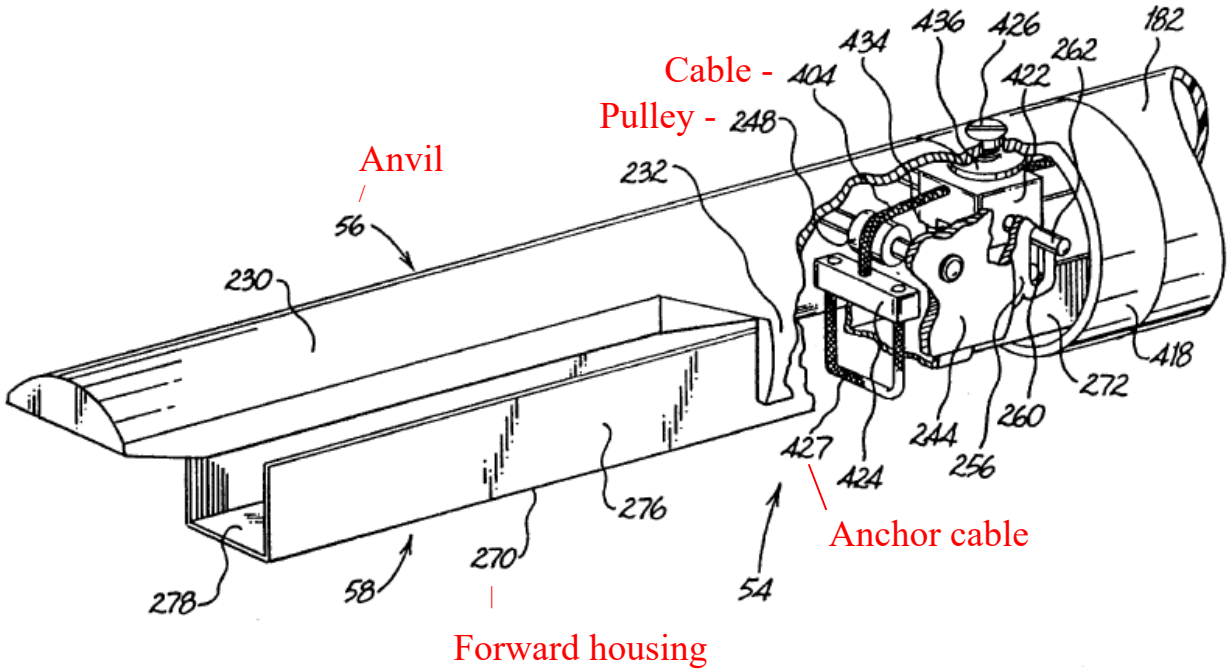


FIG. 28

In operation, the jaws are placed in the open position and then closed on tissue using cable 404. *Id*., 18:1-40, Figs 15-16. "Closure of the jaws is achieved as the surgeon presses down on articulating handle member 62…." *Id*., 19:50-20:2, Figs. 15-16, 29, 30. When tissue is clamped between the jaws, the instrument can be fired to staple and cut the tissue. Thus, instrument 50 also includes a firing trigger 96. *Id*., 12:40-42, Figs. 2-12. Depression of firing trigger 96 dispenses gas to propel surgical knife 240 in the distal direction. *Id*., 12:1-52, 13:16-27, 20:23-33, Figs. 9, 15-16.

FIG. 9

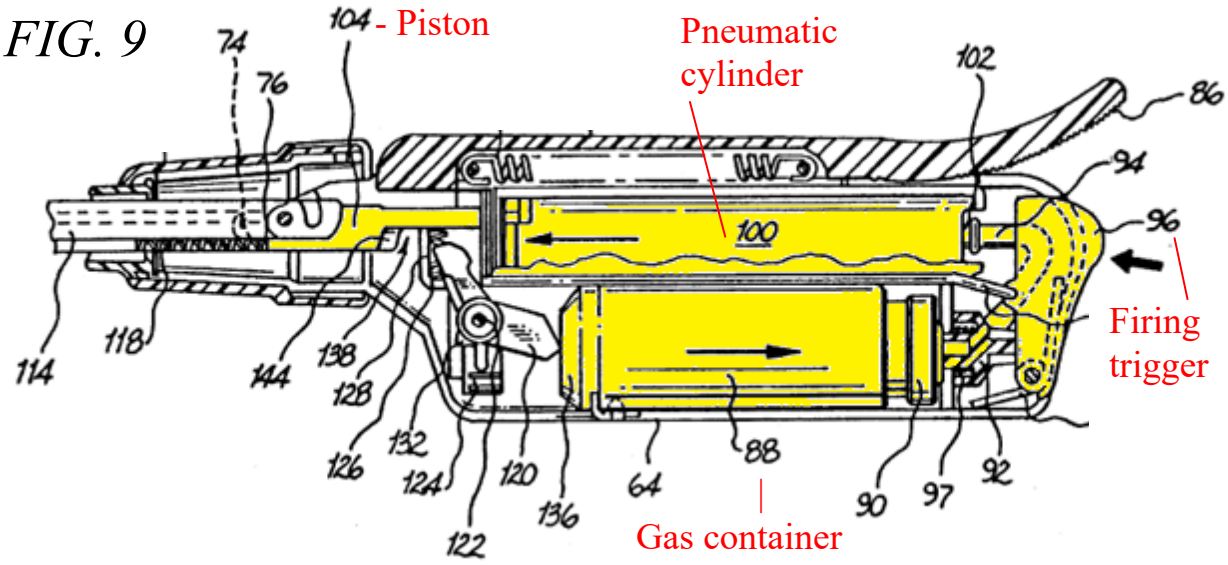
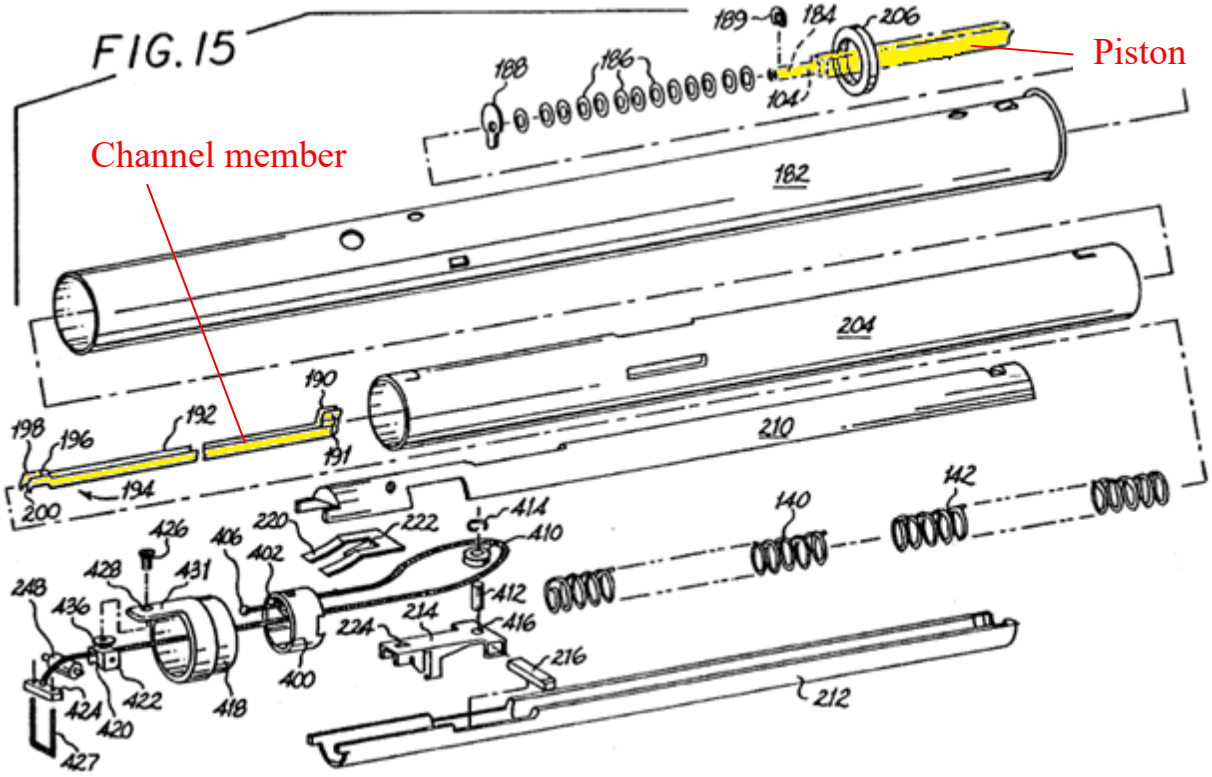

104 - Piston
Pneumatic cylinder
Firing trigger
Gas container
74
76
102
86
94
96
100
114
118
144
138
128
126
132
124
120
136
122
64
88
90
97
92

FIG. 15


Piston
Channel member
189
184
206
188
186
104
182
204
190
192
191
198
196
194
200
210
142
140
220
222
414
410
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214
416
216
400
424
422
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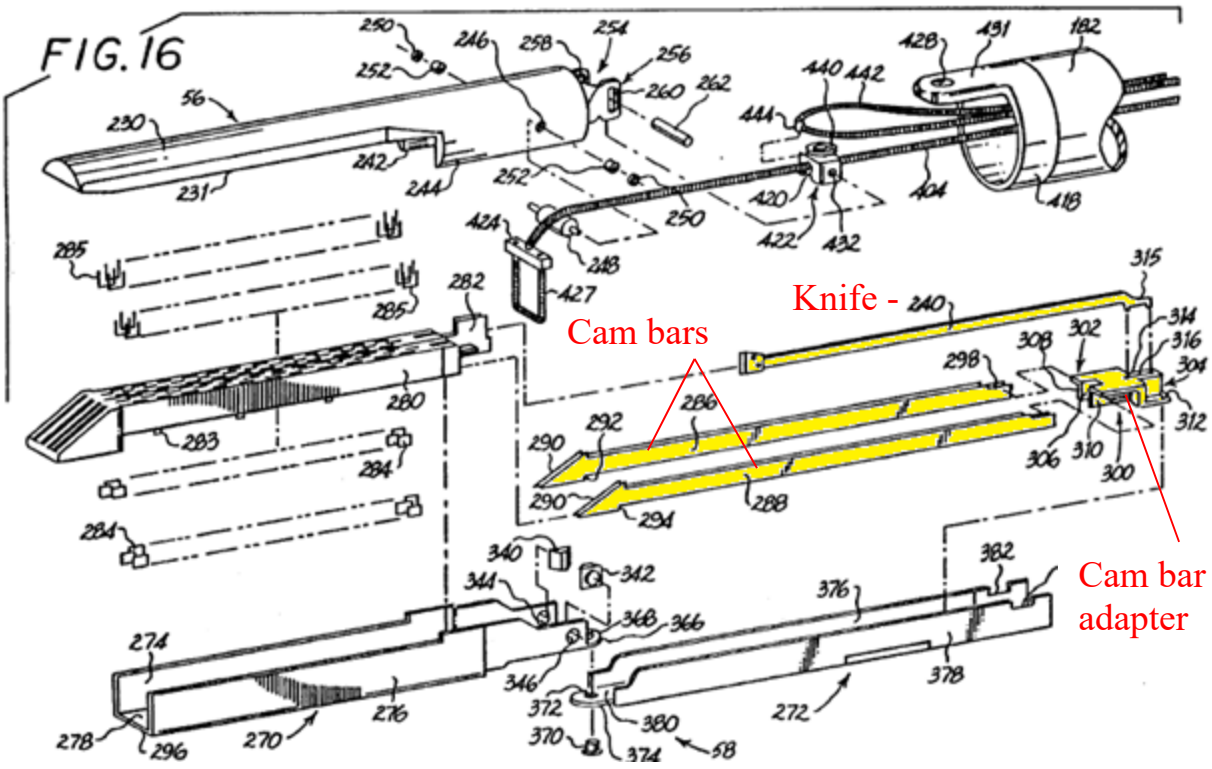
418
427
212

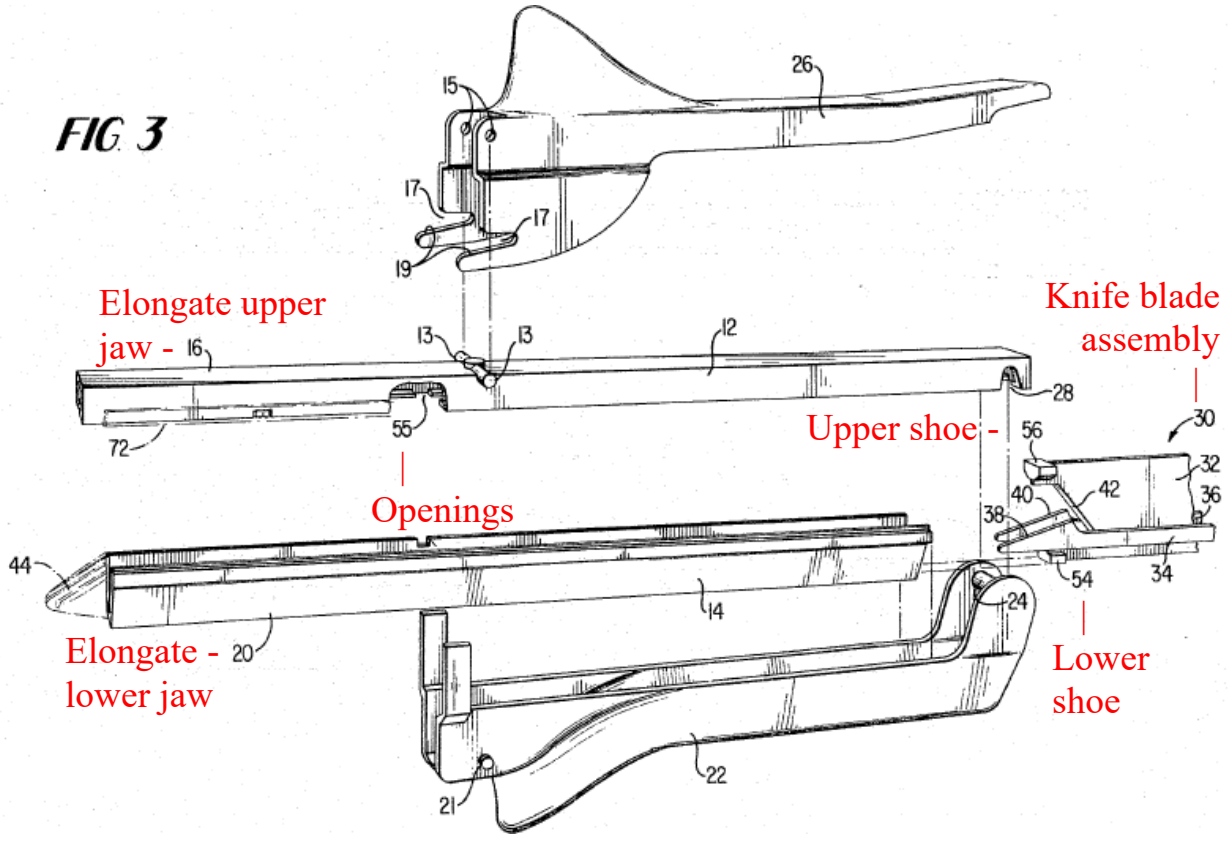


Knife 240 is not an I-beam. This is possibly because Green-209 is based on the design of hand-powered endoscopic staplers that did not use I-beams. Knodel, ¶53; *see also* Green-209, 2:7-17; Green-715, Fig. 1.

It would have been obvious in view of Green-695 to modify: (1) knife 240 to include an I-beam; (2) the jaws to include internal passageways; and (3) 209's anvil member 56 to include an opening that allows the I-beam to enter the channel as the instrument is closed. Knodel, ¶¶46-54, 59-61.

Green-695 discloses a surgical stapling instrument 10 that maintains the distance and the alignment between the jaws of the stapler using an I-beam (knife blade assembly 30) that engages the jaws 16, 20 of the stapler from within the jaws. Green-695, 4:37-60, 6:26-38, Figs. 1-12. Knife blade assembly 30 includes

"lower and upper shoes 54 and 56." *Id.*, 4:37-60, Figs. 3-6. "[L]ower shoe 54 … fits in passageway 48 … and upper shoe 56 is likewise shaped to fit in passageway 52." *Id.* Openings 55 are provided in upper jaw 16, which "allow shoes 56 to enter channel 52 as the instrument is closed." *Id.*, 6:14-17, Figs. 3, 6.



"[T]he vertical spacing between the shoes correspond[s] to the vertical spacing between the passageways 48 and 52 in the lower and upper frames when the frames are locked together." *Id.*, 4:37-60, Fig. 6.

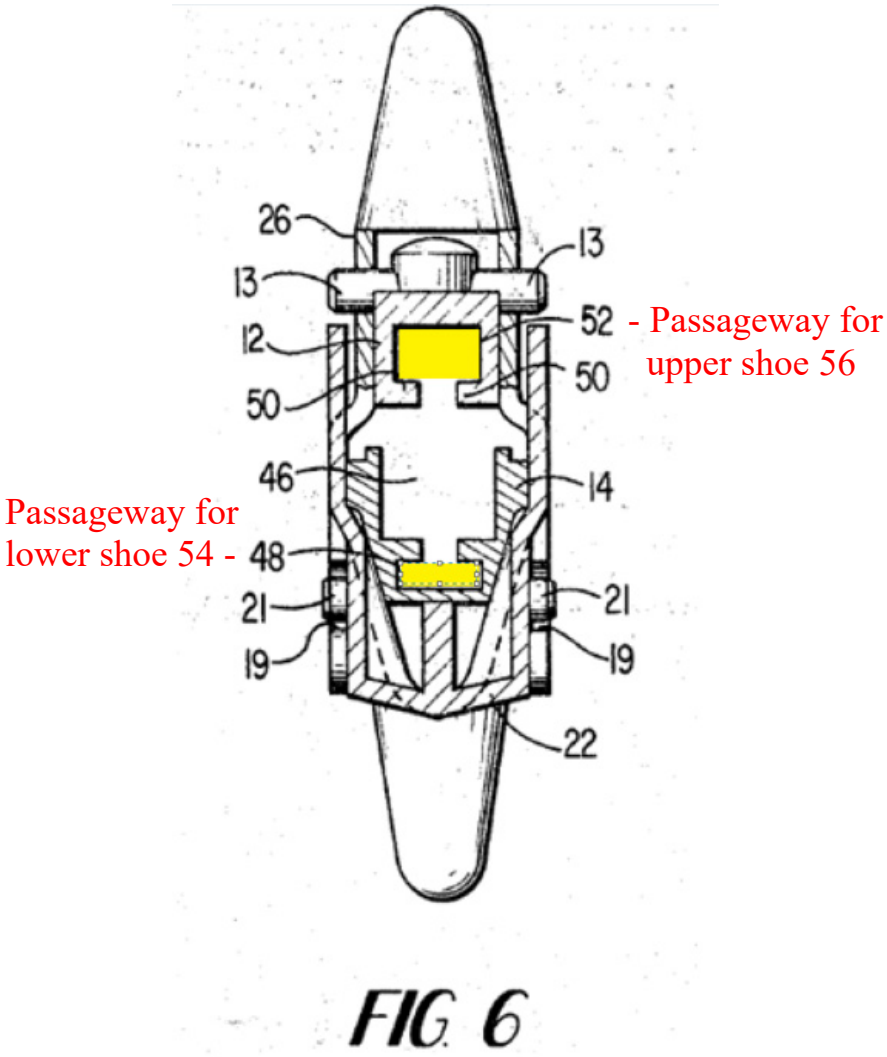
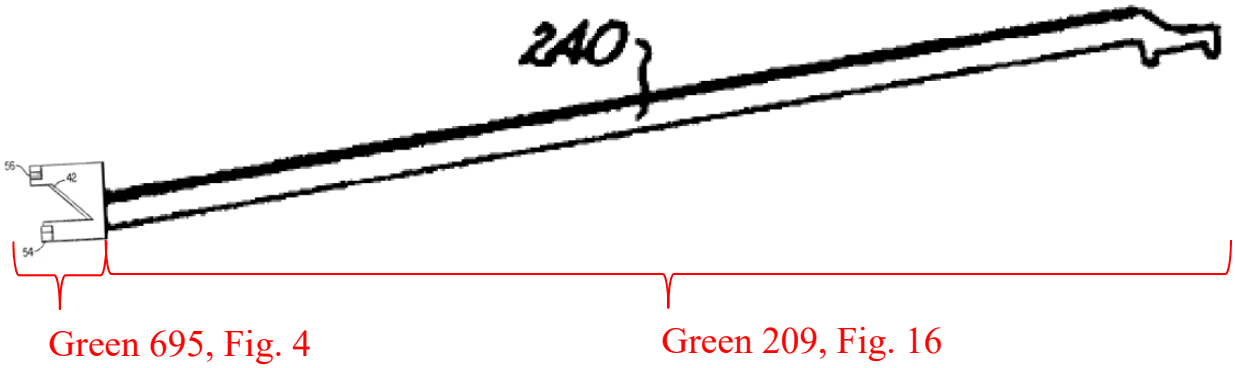


FIG. 6

The knife resulting from the modification of Green-209 in view of Green-695 is shown in the composite image below.



A POSITA would have been motivated to make these modifications for the reasons provided in Green-695—*e.g.*, "to provide … optimum alignment and stabilization of the jaws … during application and securing of the fasteners," and to enable the use of lightweight disposable materials for manufacture of the jaws. Green-695, 1:49-62, 2:48-56; Knodel, ¶51. A POSITA would have been further motivated because it enables the use of longer staple cartridges, which can reduce the number of cartridges used in a procedure. Knodel, ¶52.

Furthermore, a POSITA would have had good reason to pursue the known options within his or her technical grasp when, as here, "there are a finite number of identified, predictable solutions" for designing a knife bar for cutting tissue in a surgical stapler. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); Knodel, ¶54. Here, there are four identified, predictable options: (1) do not affirmatively space and align the jaws; (2) engage the jaws internally to affirmatively space and align the jaws; (3) engage the jaws externally to affirmatively space and align the jaws; and (4) engage one jaw internally and the other jaw externally to affirmatively space and align the jaws. *Id*.

Green-695 in view of Green-209

Green-695's instrument 10 does not include an elongated shaft and therefore could not be used for minimally invasive surgery ("MIS"). Nor does Green-695's instrument include a power source (separate from a hand-actuated mechanism) for

firing the stapling mechanism. However, it would have been obvious in view of Green-209 to modify Green-695's instrument for use in MIS to produce essentially the same device as discussed in the first combination. Knodel, ¶55. In one example of this combination, Green-695's handles 22, 26 are replaced with Green-209's frame 52 and elongated shaft portion 54. *Id*. Green-695's jaws 16, 20 are opened and closed using the linkage and cable assembly controlled by Green-209's handle 62. *Id*. And Green's 695's pusher bar and knife assembly 30 are driven by Green-209's pneumatic system 68. *Id*.

A POSITA would have been motivated to modify Green-695 for use in MIS, because the benefits of MIS compared to open surgery (*e.g*., faster recovery times, less pain, etc.) were well known. *See, e.g*., Green-715, 3:37-40; Green-209, 2:3-17; Knodel, ¶56. A POSITA would have been further motivated to combine Green-695 with Green-209 because Green-695's instrument requires "manually applied force … [which] can prove awkward or difficult…." Green-209, 2:18-39. And Green-209 addresses this difficulty with a pneumatic system to facilitate fastening and/or cutting tissue. *Id*., 12:1-39; *see also* Knodel, ¶58.

Reasonable expectation of success

A POSITA would have had a reasonable expectation of success when combining Green-209 and Green-695. Knodel, ¶¶59-60. Indeed, the proposed modifications would have required no more than ordinary mechanical skills to connect

the various moving and static structures. *Id*. Furthermore, each combination would have been merely the application of a known technique (*e.g*., using Green-695's I-beam) with a known system (*e.g.*, Green-209's instrument) in the same field of endeavor (surgical stapling). *Id*.; *KSR*, 550 U.S. at 417. And each component (*e.g.*, Green-695's I-beam, passageways, and opening) merely performs the same predictable function as it does separately (*e.g*., providing vertical and lateral stability to the jaws and allowing a shoe to enter a passageway as the instrument is closed) without significantly altering or hindering the functions performed by Green-209's instrument (*e.g*., clamping, stapling, and cutting). Knodel, ¶¶59-61.

The Green-209/695 stapler, which results from both combinations discussed above, in view of Knodel-895 discloses each limitation of challenged claims 4-5, 9-18, 20, and 22-24.

[4.0] An apparatus for stapling tissue, comprising:

If the preamble is deemed to be a limitation, then Green-209 discloses it. Knodel, ¶62; File History, 84. Green-209 discloses an apparatus for stapling tissue (surgical apparatus 50). *Id*.; Green-209, Abstract, 11:17-20, Fig. 1.

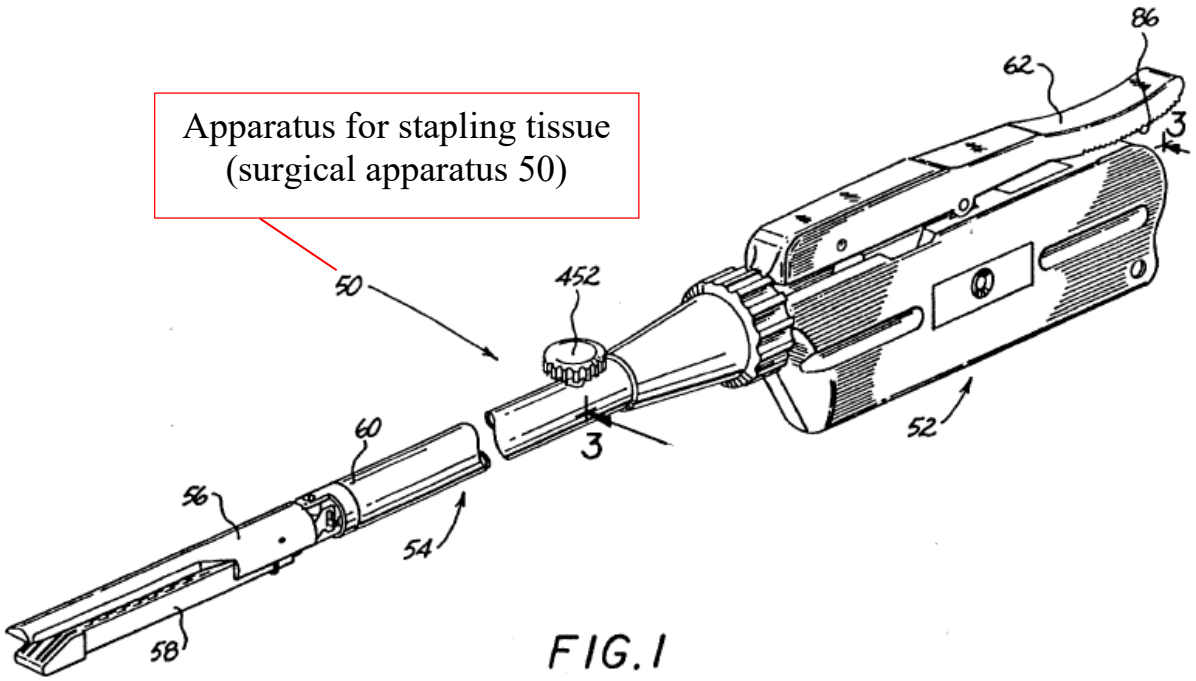


FIG. 1

[4.1] a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling,

Green-209 discloses this limitation. Knodel, ¶¶63-65; File History, 84.

Green-209 discloses a first jaw (forward housing portion 270 of cartridge assembly 58, highlighted yellow) and a second jaw (anvil member 56, highlighted blue). *Id.*, ¶64; Green-209, 11:18-35, 15:49-51, Fig. 1.

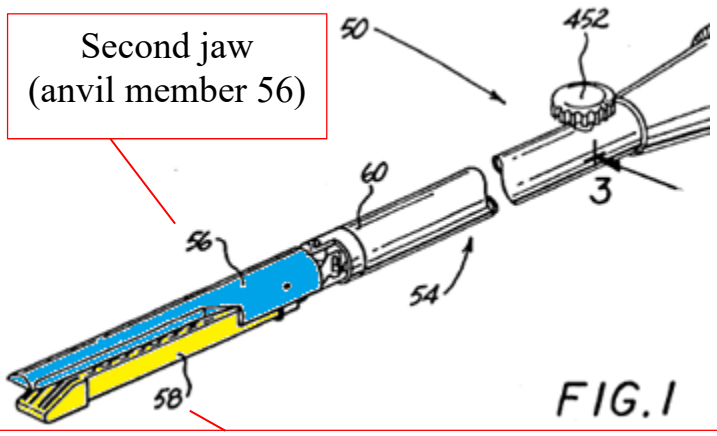


FIG. 1

At least one of the first jaw and the second jaw (anvil member 56) is movable with respect to the other of the first jaw and the second jaw (forward housing portion 270) from a first configuration (open) in which the first jaw and the second jaw are separated from each other at a first distance (shown in Figure 29) to receive tissue and a second configuration (closed) in which the first jaw and the second jaw are clamped together at a second distance (shown in Figures 1, 30) to hold tissue between them for stapling. Knodel, ¶65; Green-209, 11:18-35, 19:50-58, 20:23-24.

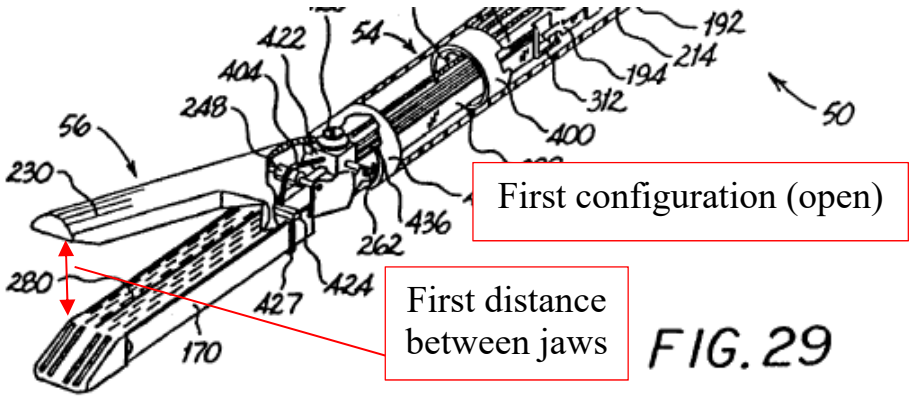


FIG. 29

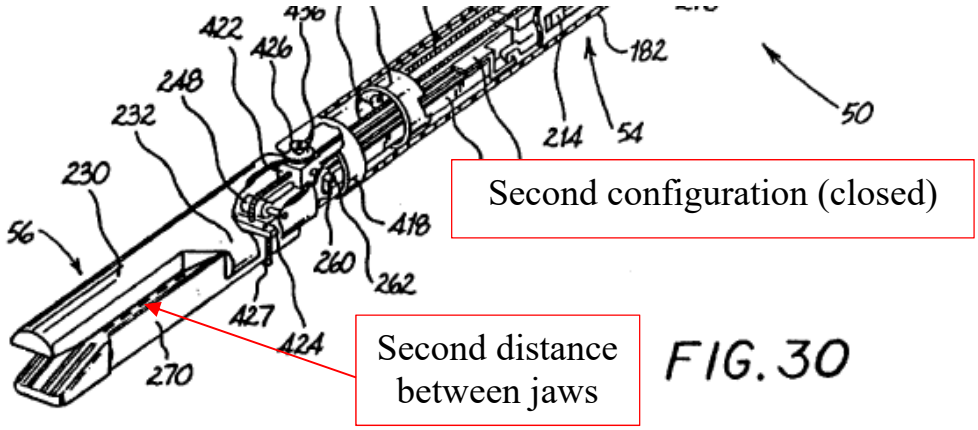
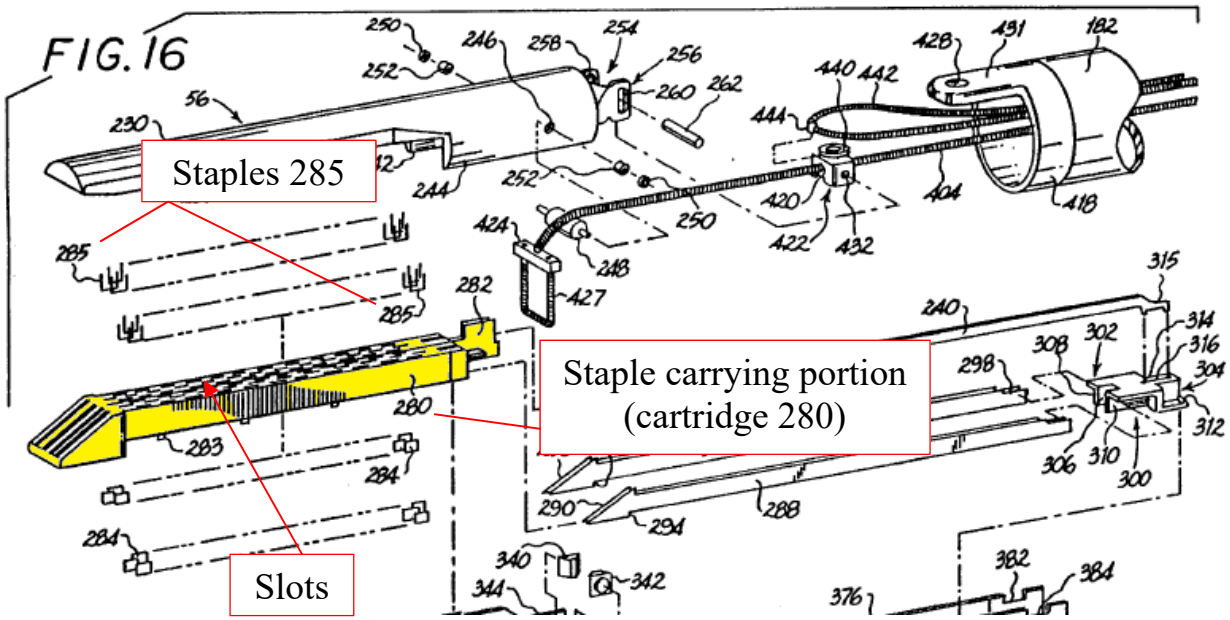


FIG. 30

[4.2] a staple carrying portion of the first jaw defining slots through which staples are configured to pass;

Green-209 discloses this limitation. Knodel, ¶66; File History, 84. Green-209 discloses a staple carrying portion (cartridge 280) of the first jaw defining slots (shown in Figures 16 and 18) through which staples (285) are configured to pass. *Id.*; Green-209, 15:49-16:5, Figs. 16, 18.



[4.3] an anvil surface defined on the second jaw opposing the first jaw;

Green-209 discloses this limitation. Knodel, ¶67; *see also* File History, 84.

Green-209 discloses an anvil surface (staple forming plate 234) defined on the second jaw opposing the first jaw. *Id.*; Green-209, 15:25-29, Figs. 17, 30.

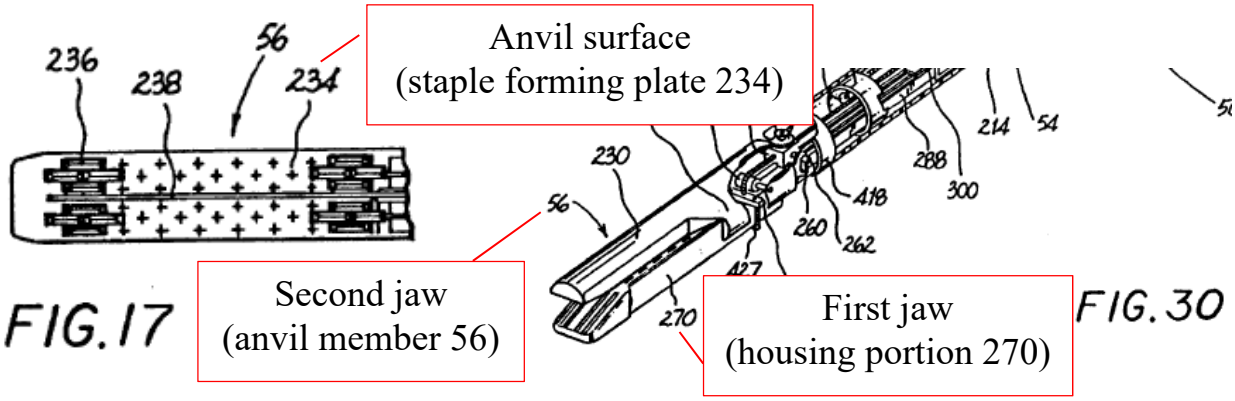
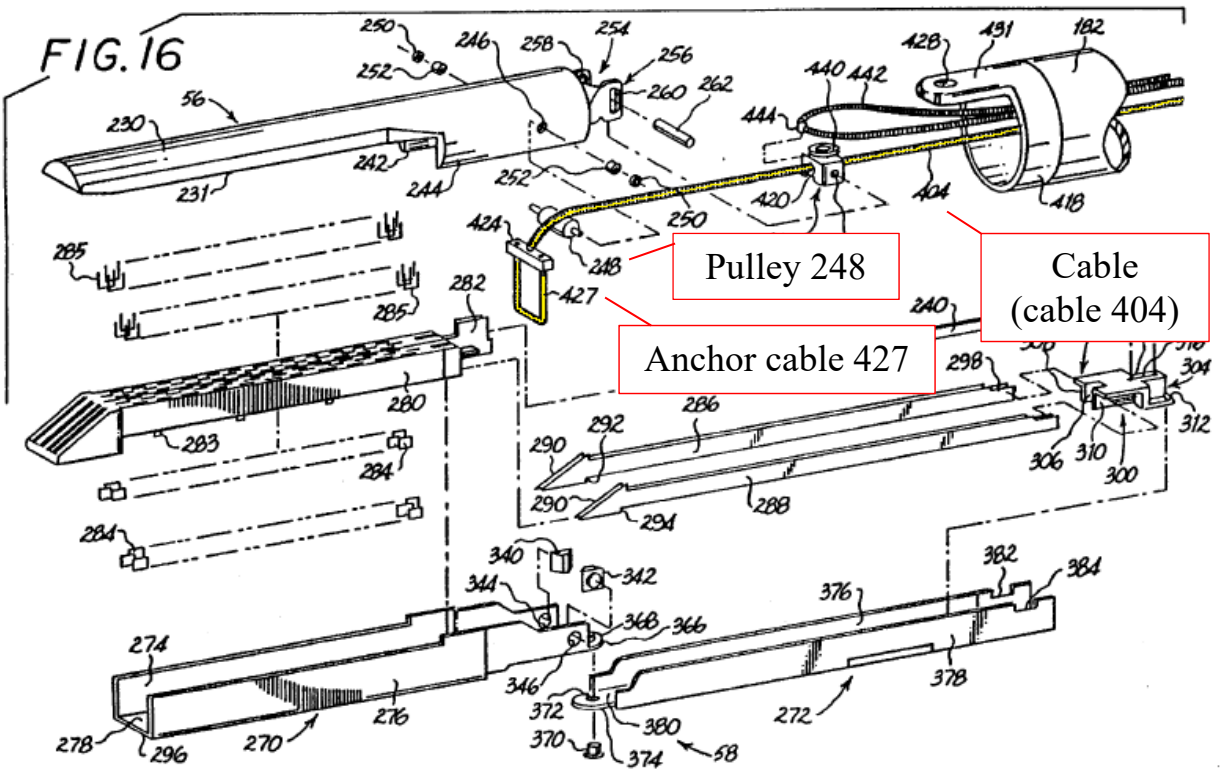


FIG. 17 FIG. 30

[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment; and

Green-209 in view of Knodel-895 discloses this limitation. Knodel, ¶¶68-76; File History, 84. Like the '650 patent (*see, e.g.*, Fig. 12), Green-209 discloses a cable 404 that is (1) operatively coupled to the first jaw by anchor cable 427, (2) operatively coupled to the second jaw by pulley 248, and (3) configured to move at least one of the first jaw and the second jaw (anvil member 56) from the first configuration (open) to the second configuration (closed) such that the first jaw and the second jaw are in alignment (the jaws are aligned in the closed position to allow stapling). *Id.*; Green-209, 18:1-41, Figs. 15-16.



In this embodiment of Green-209, the jaws are closed by pressing down on articulating handle member 62 to drive clamp tube 70 distally. Green-209, 19:54-58, Fig. 2.

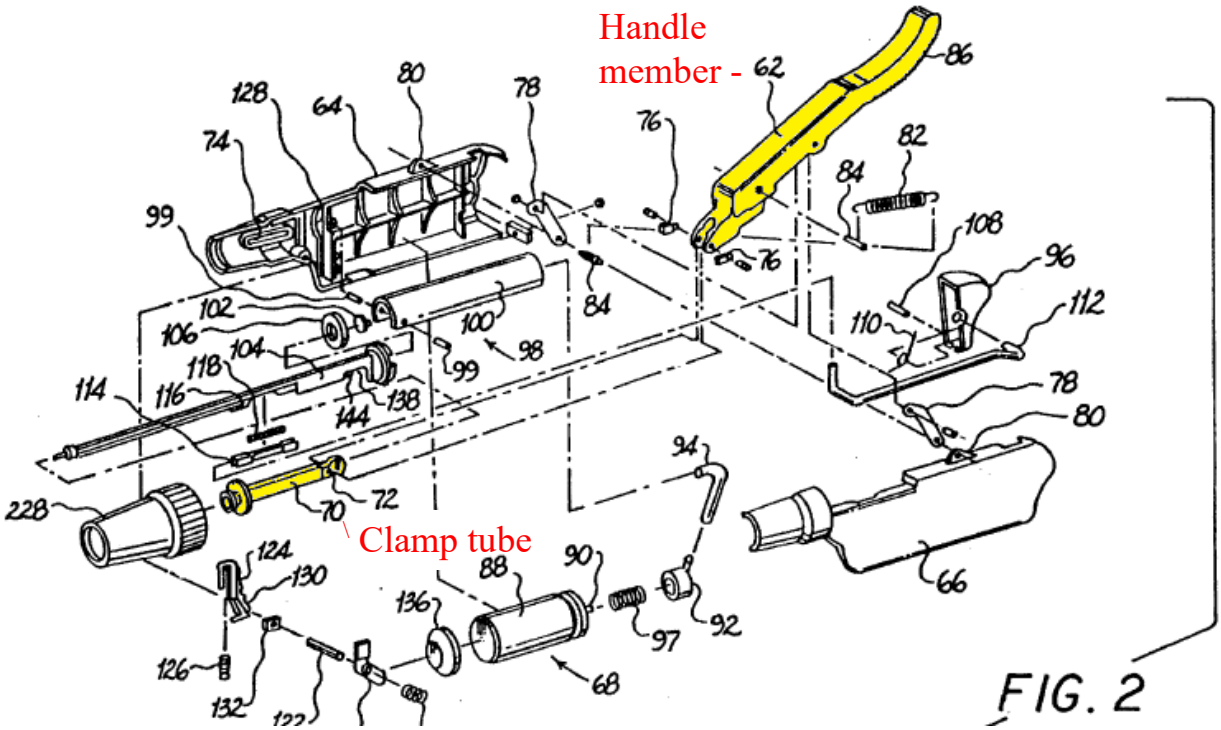


FIG. 2

Although the embodiment shown above uses a palm grip configuration, Green-209 confirms that the "handle portion … may have a palm grip configuration or a pistol grip configuration depending on the needs of the surgeon." Green-209, 5:53-56; *see also* 3:55-57, 36:14-35, Fig. 90. Green-209's exemplary pistol grip configuration and corresponding actuation handle 1018 are shown below.

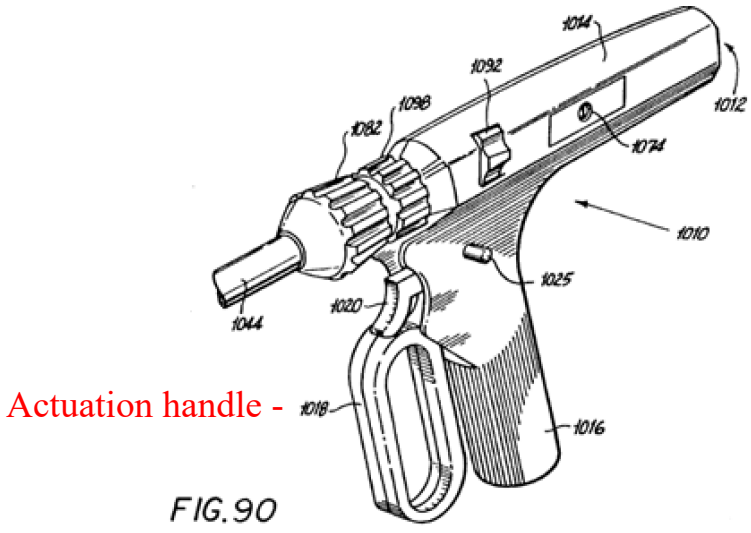
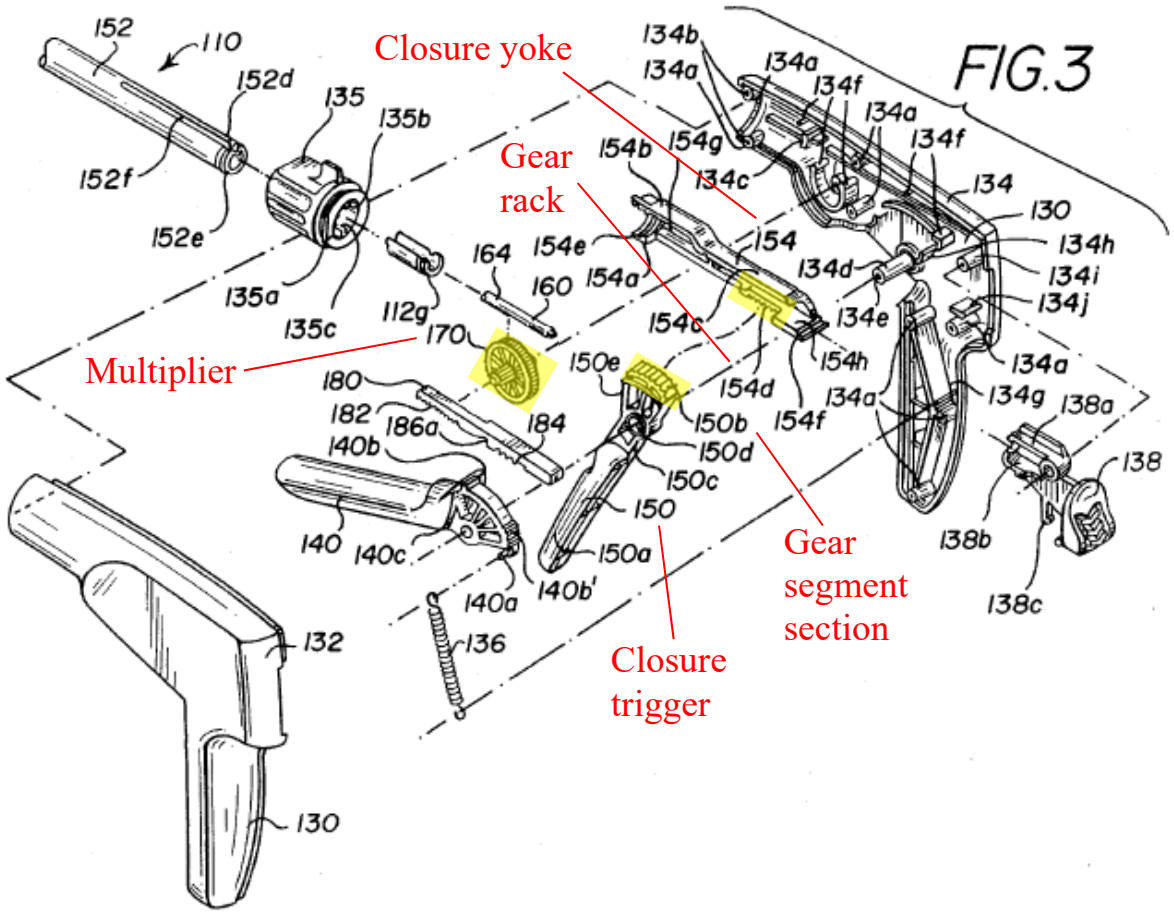


FIG. 90

A POSITA would have been motivated to use a pistol grip configuration instead of the palm grip configuration used in Figure 2 with a reasonable expectation of success for the reasons provided in Green-209 (*e.g.*, "needs of the surgeon" and "increased range of operability"). Knodel, ¶71; Green-209, 5:53-56, 36:14-35; *see also* Olson, 1:46-50, 2:7-17, 5:6-10 (confirming a pistol grip provides the benefit of one-handed use).

It would have been obvious in view of Knodel-895 to modify clamp tube 70 to include a gear rack and to modify closure handle 62 or 1018 to include a gear segment in meshing engagement with clamp tube 70's gear rack. Knodel, ¶¶72-76. The resulting device would include a gear and a cable operably coupled to the first jaw and the second jaw and configured to perform the claimed function. *Id*.

Like Green-209, Knodel-895 discloses a surgical stapler with a pistol grip configuration and a closure trigger 150. Knodel-895, Fig. 3, 7:50-65. Unlike Green-209, however, Knodel-895's closure trigger 150 has a gear segment section 150b in meshing engagement with a gear rack 154d of a closure yoke 154 (similar to Green-209's clamp tube 70). *Id*., 7:50-8:14. Knodel-895 further discloses the use of a firing multiplier 170 comprising first and second integral pinion gears 170a and 170b. *Id.*, 9:18-35, Figs 6, 12.



A POSITA would have been motivated to modify Green-209 to include Knodel 895's gears for several reasons. First, using gears provides increased design flexibility. Knodel, ¶74; Knodel-895, 11:16-25. For example, using gears to increase the drive system's mechanical advantage would permit a given input force to produce a larger output force, which may be advantageous for clamping certain tissues with a surgical stapler. *Id*.

Second, a POSITA would have recognized that both Green-209 and Knodel-895 concern endoscopic surgical staplers with drive features that advance distally

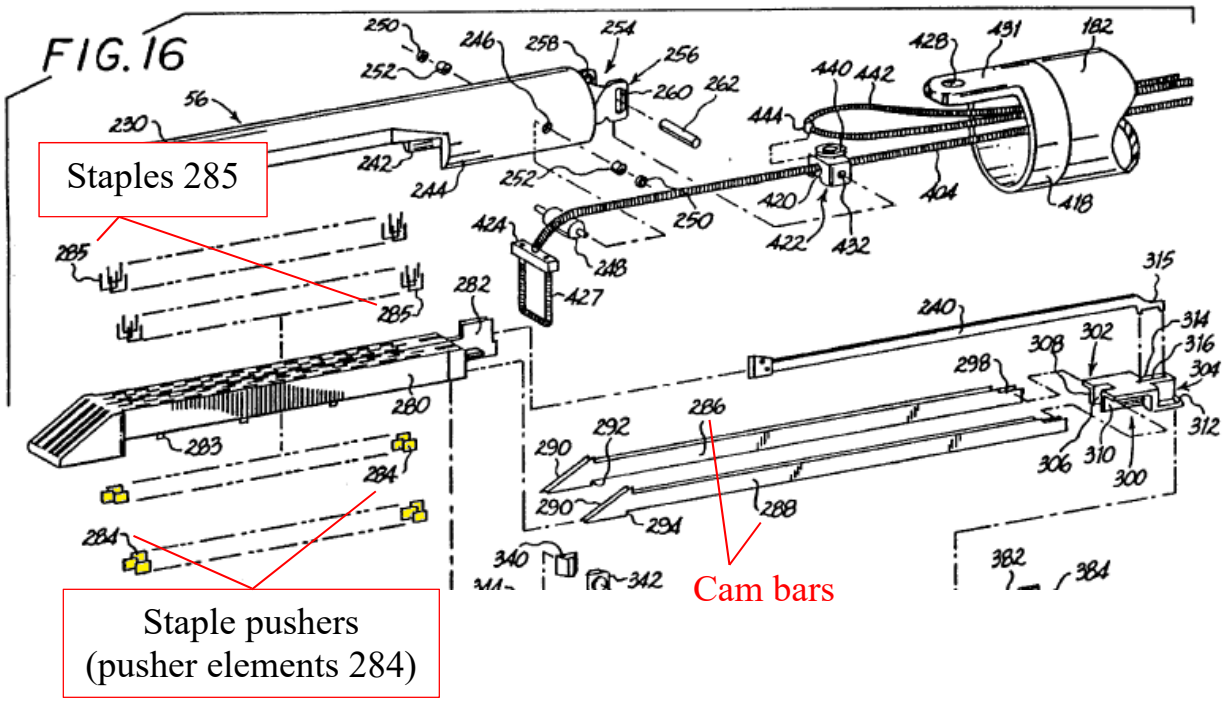
in response to actuation of a closure trigger and thus a POSITA would have looked to both references when designing a surgical stapler with a closure trigger. Knodel, ¶75.

Finally, a POSITA would have readily understood how to implement the combination based on the teachings of Green-209 and Knodel-895, and therefore would have had a reasonable expectation of success. *Id*., ¶76. Indeed, it would have been merely the application of a known technique (using gears to drive a closure mechanism) to a known system (Green-209's surgical stapler) ready for improvement to yield predictable results without significantly altering or hindering the functions performed by Green-209's stapler (*e.g*., clamping, cutting, and stapling). *Id*.; *see also* McGuckin, 17:57-18:9, Fig. 13.

[4.5] a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion,

Green-209 discloses this limitation. Knodel, ¶77; File History, 84. Green-209 discloses a staple pusher (pusher elements 284) configured to cause a staple (285) to move from a first position at least partially within the staple carrying portion (staple 285's first position is fully within cartridge 280) to a second (ejected) position entirely outside the staple carrying portion. *Id*.; Green-209, 4:39-42, 15:61-16:5, 16:56-59, Fig. 16. During staple firing, distal advancement of cam bars 286, 288 causes pusher elements 284 to push the staples out of the cartridge

through the tissue clamped between the two jaws and against the anvil, so as to form the staples to thus staple the tissue. *Id.*; *see also* Knodel, ¶77.



[4.6] the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location.

The Green-209/695 stapler discloses this limitation. Knodel, ¶¶78-79; *see also* Section VIII.A (explaining the combinations of Green-209 and Green-695). The Green-209/695 stapler includes a beam (Green-209's knife 240 modified to include an I-beam like Green-695's, which includes central knife blade carrier 32, lower shoe 54, and upper shoe 56) configured to engage the first and second jaws from within the first and second jaws when the jaws are in the second (closed) position and while tissue is stapled from a proximal location (*e.g.*, the proximal end

of the staple cartridge) to a distal location (*e.g.*, the distal end of the staple cartridge). *Id.*; Green-209, 20:23-34, Figs. 16, 20; Green-695, 4:10-60, Figs. 3-6. Specifically, during the firing operation, Green-695's shoes 56 and 54 move distally to engage Green-695's passageways 48, 52, which are formed within the jaws. *Id.*

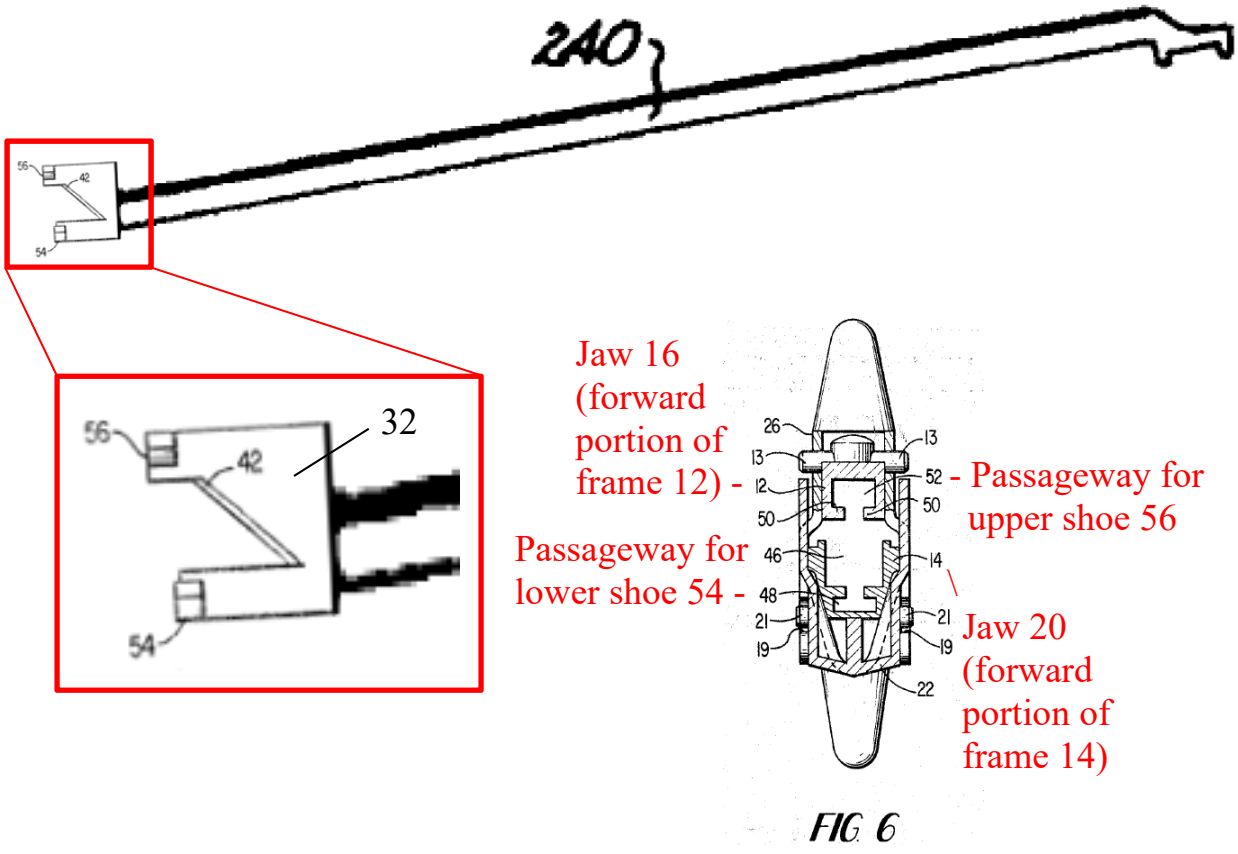


FIG 6

As explained in Green-695, central knife blade carrier 32, lower shoe 54, and upper shoe 56, "provide for lateral alignment and vertical stabilization of the jaws during stapling." Green-695, 2:12-21, 4:10-60.

[5.0] The apparatus of claim 4, wherein the beam is configured to engage the first and second jaws one of entirely or substantially from therewithin to maintain the second distance and the alignment.

Although the scope of this term is unclear, the Green-209/695 stapler discloses this limitation. *See* Ground 1, element [4.6] (confirming that shoes 56 and 54 maintain the closed (or clamped) distance between the jaws and the alignment by preventing deflection). Like the upper and lower portions of I-beam member 70 in the '650 patent, the upper and lower portions of the Green-209/695 stapler's beam are configured to engage the first and second jaws entirely or substantially from therewithin to maintain the second distance and the alignment. Knodel, ¶80. As shown in Ground 1, element [4.6], Green-695's shoes 56 and 54 engage Green-695's passageways 48, 52, which in the combination are formed within Green-209's first and second jaws, respectively. *Id*.

[9.0] The apparatus of claim 4, wherein the first jaw and the second jaw are pivotably coupled at a pivot point, a portion of the first jaw defining a flange that extends past a surface of the second jaw when the first jaw and second jaw are in the first configuration and the second configuration.

The Green-209/695 stapler discloses this limitation. Knodel, ¶¶81-86. Green-695's jaws 16, 20 are pivotably coupled at a pivot point (pivot bar 24) and a portion of the first jaw (20, which includes a staple carrying portion (staple cartridge 44)), defines a flange (shown in yellow) that extends past a surface (*e.g.*, the surface of anvil members 72) of the second jaw (16) when the first jaw and the second jaw are in the first configuration (open) and the second configuration (closed). *Id*.; Green-695; Figs. 1-3. A POSITA would understand that the flange shown in FIG. 2 will extend past the surface of the upper jaw while the instrument is still in

the first configuration once the handle lugs 21 engage the camming surfaces 19 (the position corresponding to the open position in the Green-209/695 stapler). Knodel, ¶81. To the extent Green-695's flange is deemed to not extend past a surface of the upper jaw in the open position, a POSITA would have been motivated to lengthen the flange so that it would overhang the opposite jaw from the moment of stapler assembly to provide even greater protection from pinching. *Id.*

FIG. 1

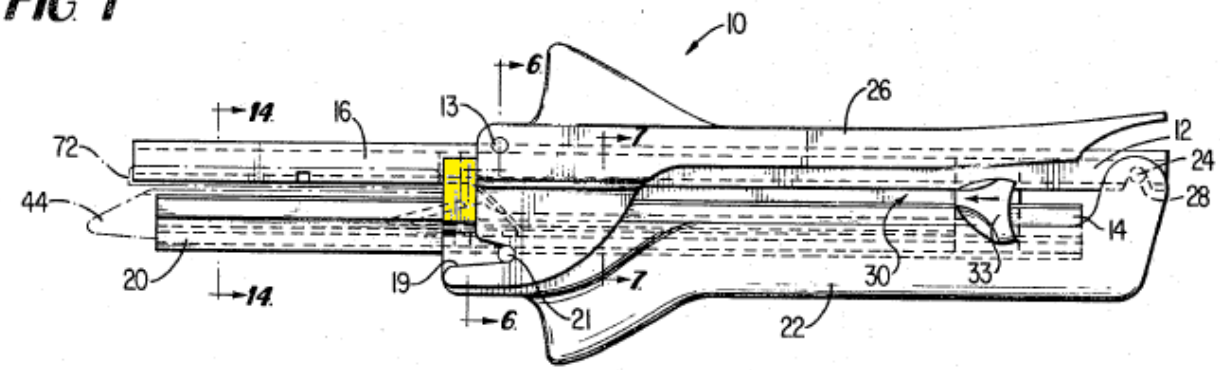
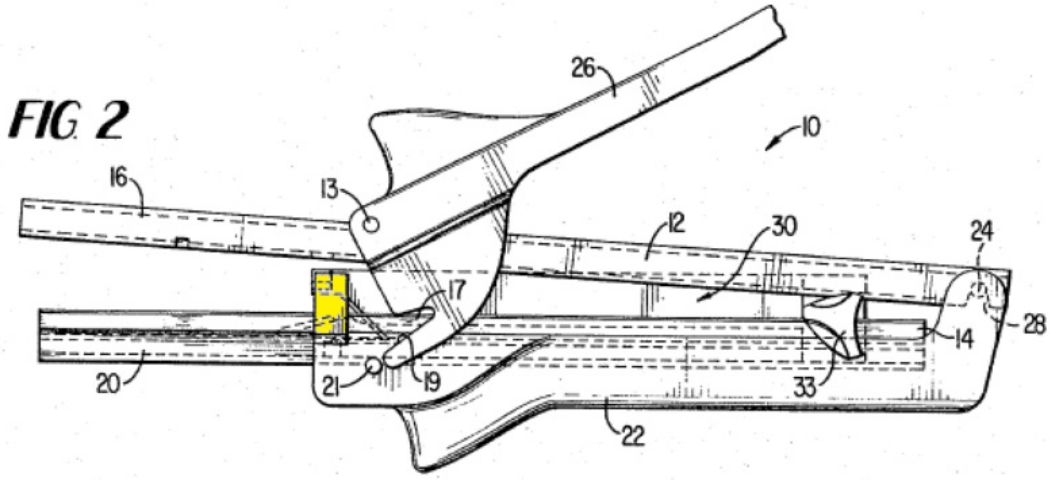
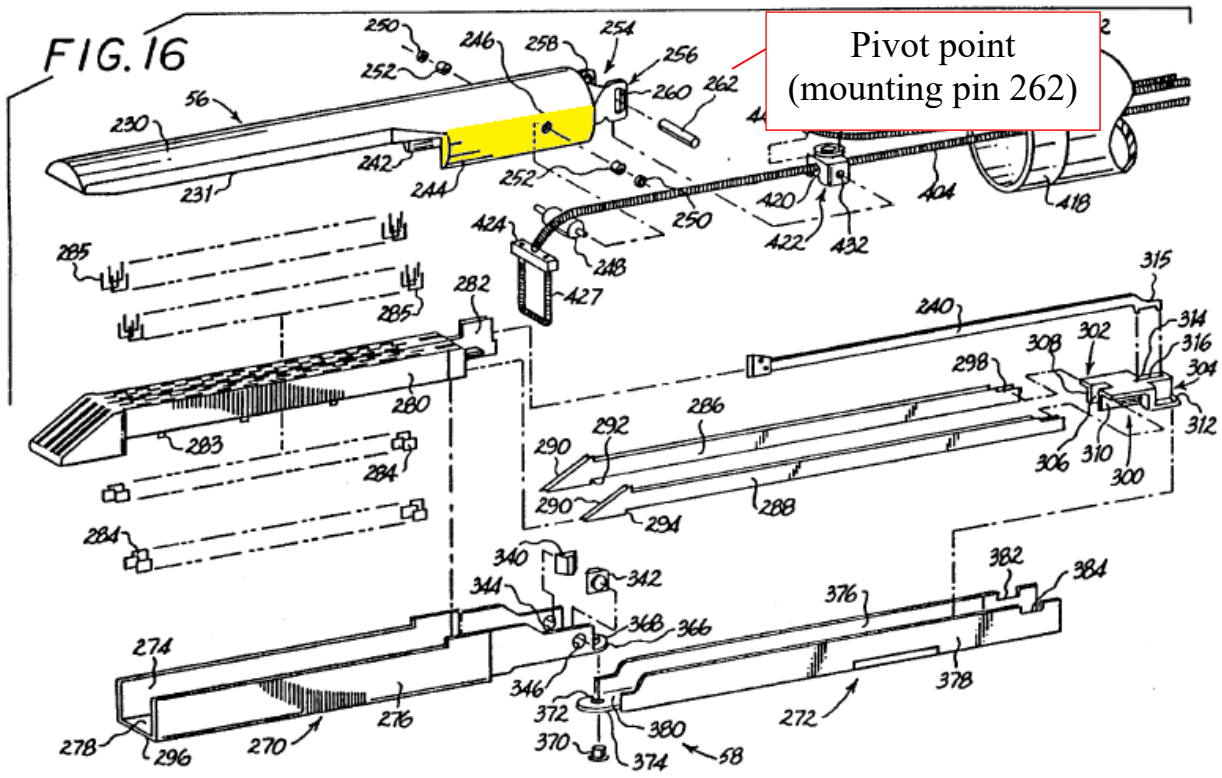


FIG. 2



Similarly, Green-209's jaws are pivotably coupled at a pivot point (mounting pin 262). *Id.*, ¶82; Green-209, 15:36-48, Fig. 16. Mounting slots 256 and 258 also enable anvil member 56 to adjust its vertical position relative to the pivot

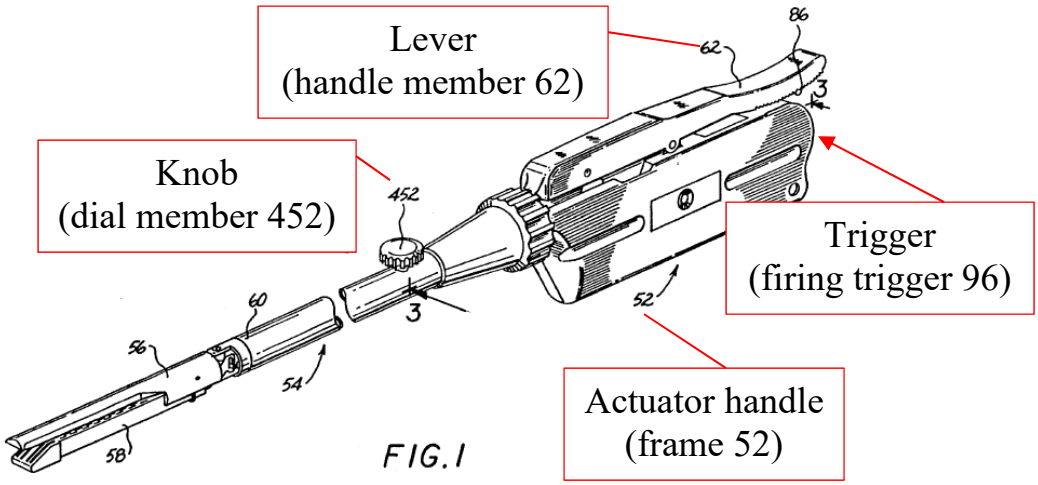
point upon engaging tissue. Green-209, 15:44-48. However, Green-209's second jaw defines the claimed flange (highlighted yellow), rather than the first jaw. *Id*.



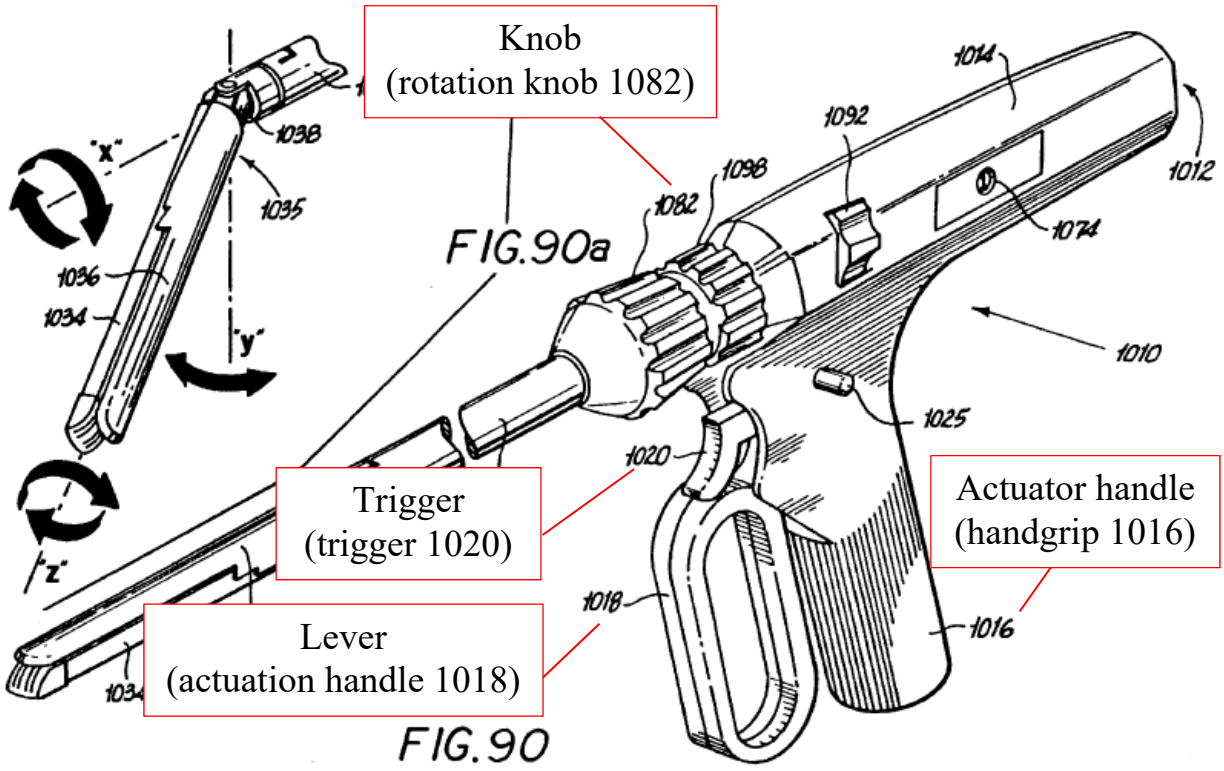
It would have been obvious to move Green-209's flange from the second jaw to the first jaw because there were a finite number of identified and predictable locations for the flange (*e.g.*, the first jaw, the second jaw, or the shaft housing). Knodel, ¶¶83-86; *KSR*, 550 U.S. at 421; Green-209, Fig. 16; Green-695, Fig. 1; Viola, Fig. 5. A POSITA making this modification would have reasonably expected to succeed because moving the location of the flange from one jaw to the other was well within the level of ordinary skill in the art. Knodel, ¶84.

[10.0] The apparatus of claim 4, further comprising one or more actuators including at least one of an actuator handle, a lever, a trigger, a knob or a cable.

Green-209 discloses this limitation. Knodel, ¶¶87-88. For example, the palm grip configuration includes an actuator handle (frame 52), a lever (handle member 62), a trigger (firing trigger 96), a knob (dial member 452), and a cable (*e.g.*, cable 404; not shown below). *Id.*; Green-209, 11:18-35, 12:40-42, 18:1-41, 19:25-28, 36:14-39:10, Figs., 1, 3, 15-16, 90.



Similarly, the pistol grip configuration includes an actuator handle (handgrip 1016), a lever (actuation handle 1018), a trigger (1020), and a knob (rotation knob 1082). *Id.*

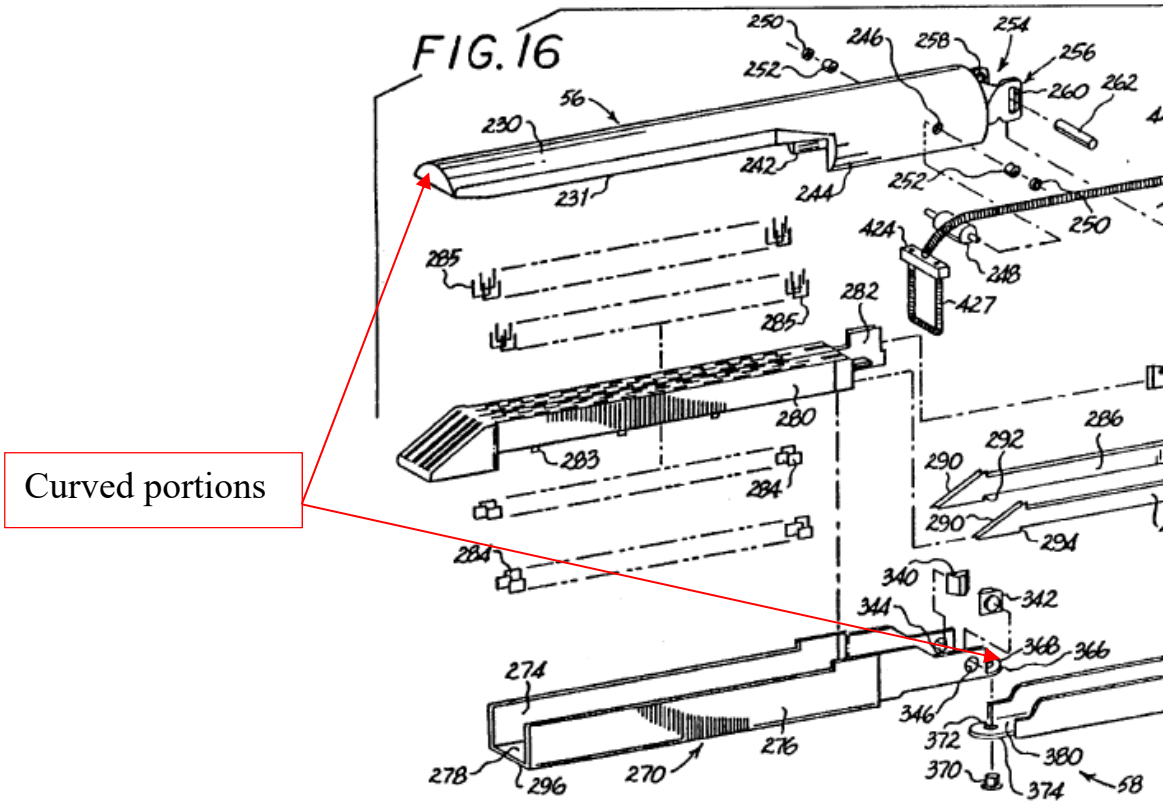


[11.0] The apparatus of claim 4, wherein at least a portion of the apparatus is powered.

Green-209 discloses this limitation. Knodel, ¶89. Green-209 discloses a portion of the apparatus (the firing portion) is pneumatically powered. *Id.*; Green-209, Abstract, 11:18-22, 12:1-42.

[12] The apparatus of claim 4, wherein at least a portion of the first jaw and the second jaw is curved.

Green-209 discloses this limitation. Knodel, ¶90. A portion of the first jaw and the second jaw (*e.g.*, the outer surface of anvil member 56 and flange 366 of forward housing 270) is curved. *Id.*, Green-209, Fig. 16.



[13.0] An apparatus, comprising:

See Ground 1, element [4.0].

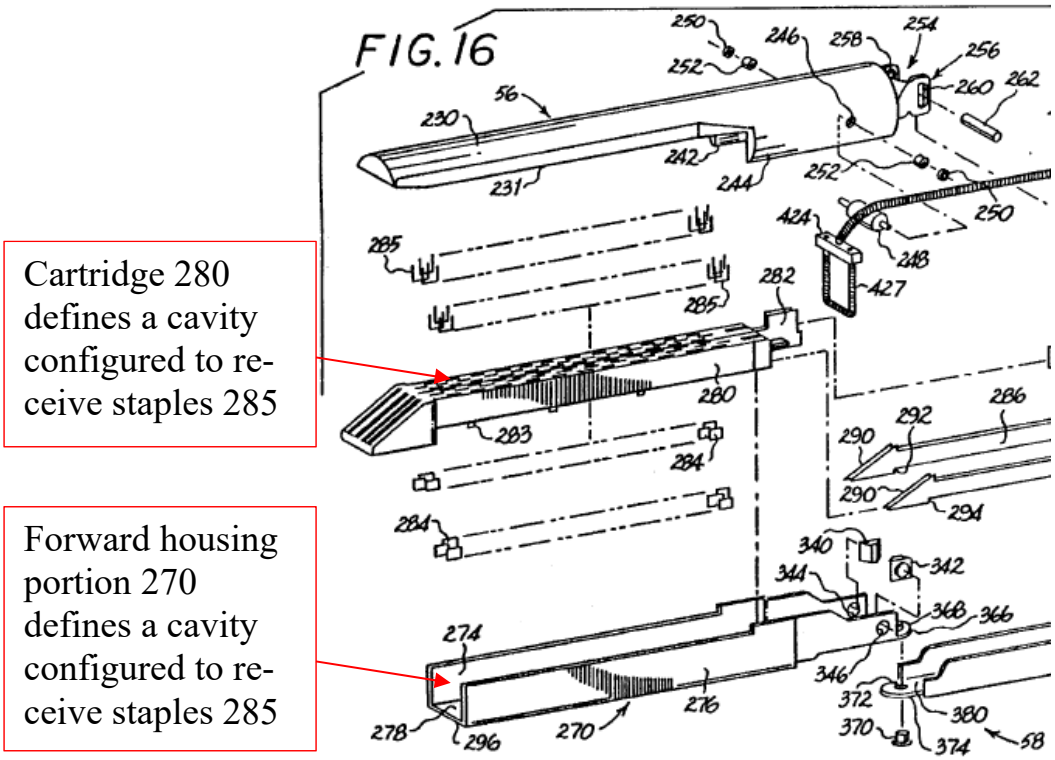
[13.1] a head portion having a first jaw and a second jaw configured to move between a first configuration for receiving tissue and a second configuration for stapling tissue,

See Ground 1, element [4.1]. The Green-209/695 stapler's jaws form a head portion. *Id*.; Knodel, ¶92. The first configuration (open) is for receiving tissue and the second configuration (closed) is for stapling tissue. *Id*.

[13.1.1] the first jaw defining a cavity configured to receive a plurality of staples and a plurality of slots configured to pass staples therethrough;

See Ground 1, elements [4.1]-[4.2] (confirming that cartridge 280 of the first jaw has a plurality of slots through which staples 285 pass). Furthermore, forward

housing portion 270 defines a cavity (channel) configured to receive the plurality of staples 285 and slots in cartridge 280. Green-209, Fig. 16; Knodel, ¶93. Similarly, the housing of cartridge 280 defines a cavity configured to receive the plurality of staples 285 and pusher element 284 within the housing. *Id*.



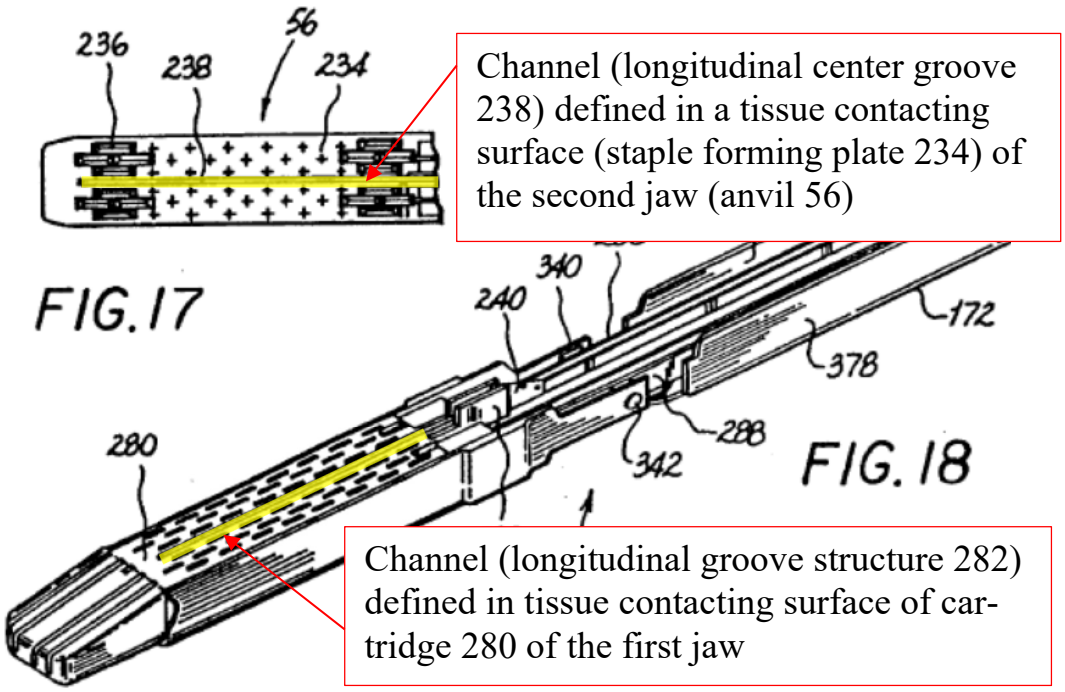
[13.1.2] the second jaw having a staple-forming surface; and

See Ground 1, element [4.3].

[13.2] a beam whose opposite end portions are connected by a central web portion and are configured to clamp and align the first and second jaws from therewithin when in the second configuration as the beam moves distally along a channel defined in a tissue contacting surface of each of the first and second jaws; and

See Ground 1, element [4.6] (confirming that the Green-209/695 stapler includes a beam configured to maintain the distance and alignment between the first

and second jaws from within the first and second jaws when the jaws are in the second (closed) position and while tissue is stapled from a proximal location to a distal location). As shown in Ground 1, element [4.6], opposite end portions (56 and 54, respectively) of the beam are connected by a central web portion (32) and are configured to clamp (to maintain a fixed distance between the jaws) and align the first and second jaws from therewithin (in the passageways 48 and 52) when the jaws are in the second (closed) configuration. Furthermore, the beam moves distally along a channel (longitudinal groove structure 282) defined in a tissue contacting surface of cartridge 280 of the first jaw. Green-209, 15:29-31, 15:55-57, Figs. 17-18; Knodel, ¶95. In addition, the beam moves distally along a channel (longitudinal center groove 238) defined in a tissue contacting surface (staple forming plate 234) of the second jaw. *Id*.



[13.3] a control handle configured to actuate receiving, clamping and stapling of tissue, and

See Ground 1, claim [10]. Green-209's control handle (frame 52 or handle assembly 1012) is configured to actuate receiving (via gross manipulation of frame 52/handle assembly 1012 to position the instrument jaws relative to tissue), clamping (via handle member 62 or actuation handle 1018) and stapling of tissue (via firing trigger 96 or 1020). Knodel, ¶96; Green-209, 11:25-35, 12:40-13:42, 19:50-58, 36:14-37:20.

[13.4] a shaft coupling the control handle to the head portion.

Green-209 discloses this limitation. Knodel, ¶97. Green-209 discloses a shaft (54 or 1044) coupling the control handle to the head portion. *Id.*; Green-209, 11:20-25, Figs. 1, 90.

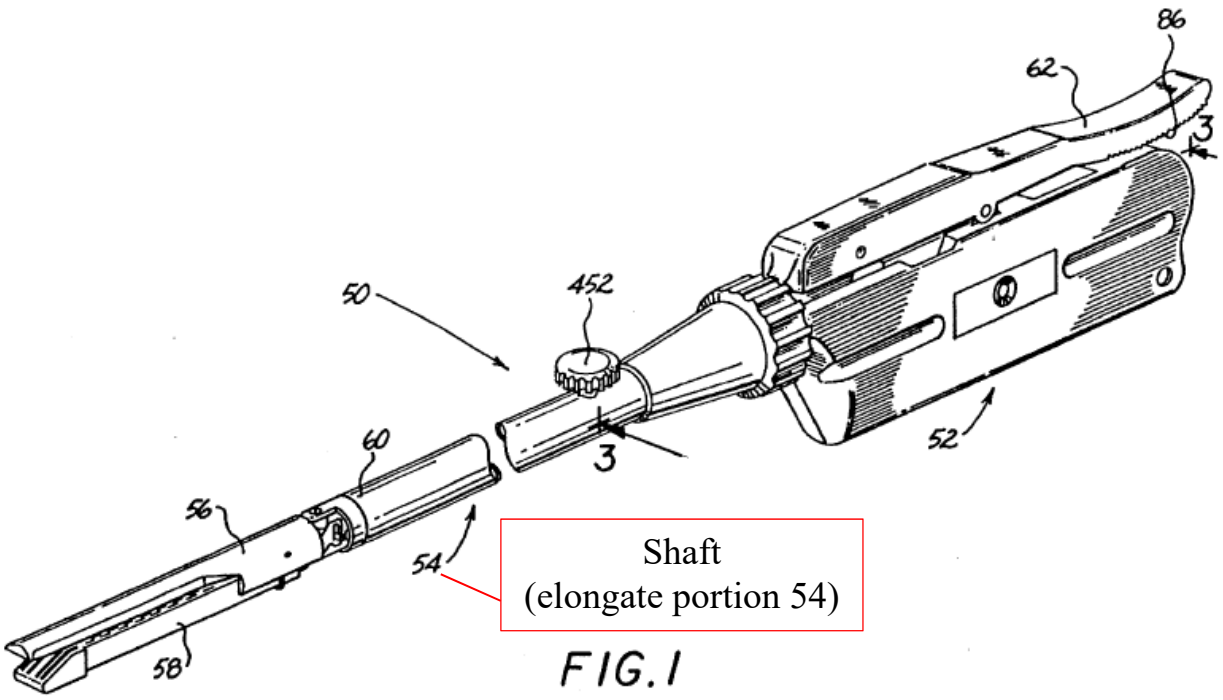

86
62
3
50
452
60
56
54
3
52
58
Shaft
(elongate portion 54)

FIG. 1

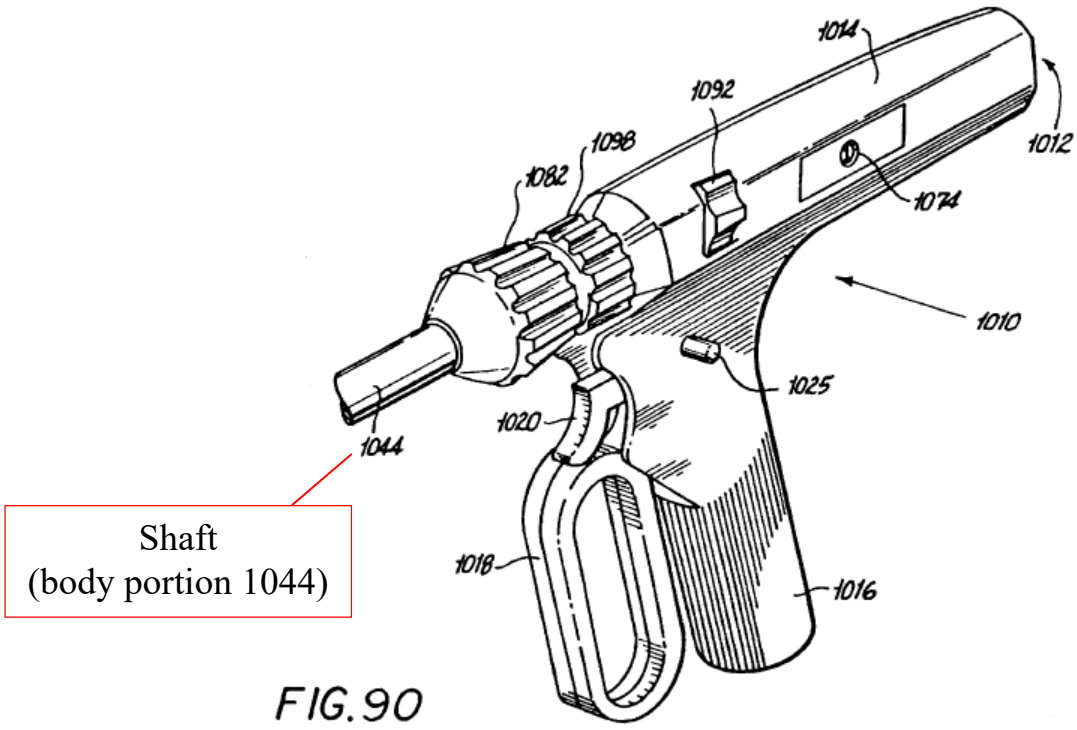
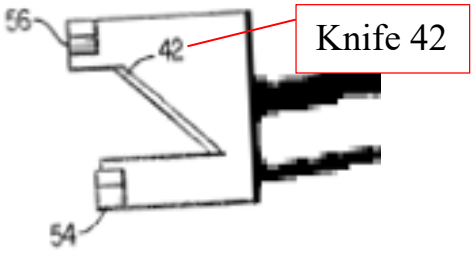

1014
1092
1012
1098
1082
1074
1010
1025
1020
1044
1018
1016
Shaft
(body portion 1044)

FIG. 90

[14.0] The apparatus of claim 13, wherein: the beam is configured to enable at least one of firing staples and cutting tissue.

See Ground 1, element [4.6]. The Green-209/695 stapler's beam supports Green-695's knife 42 and is therefore configured to enable cutting tissue. *Id*.; Green-695, 3:54-58, 4:6-9, 4:30-37; Knodel, ¶98.



[15.0] The apparatus of claim 13, wherein the slots through which staples are passed are arranged in a first row extending from a proximal end of the first jaw to a distal end thereof such that two or more staples are fired in a row orthogonal to a direction of movement of the beam one of simultaneously or serially.

Green-209 discloses this limitation. Knodel, ¶99. The slots through which staples (285) are passed are arranged in a first row (red line) extending from a proximal end of the first jaw to a distal end thereof such that two or more (*e.g.*, four) staples (285) are fired in a row (yellow line) orthogonal to a direction of movement of the beam (*e.g.*, along the longitudinal axis of the cartridge) one of simultaneously or serially (each row of staples orthogonal to the direction of movement of the beam is fired simultaneously and each subsequent row orthogonal to the direction of movement of the beam is fired serially to the preceding row). *Id*.; Green-209, Figs. 17-18, 15:63-67.

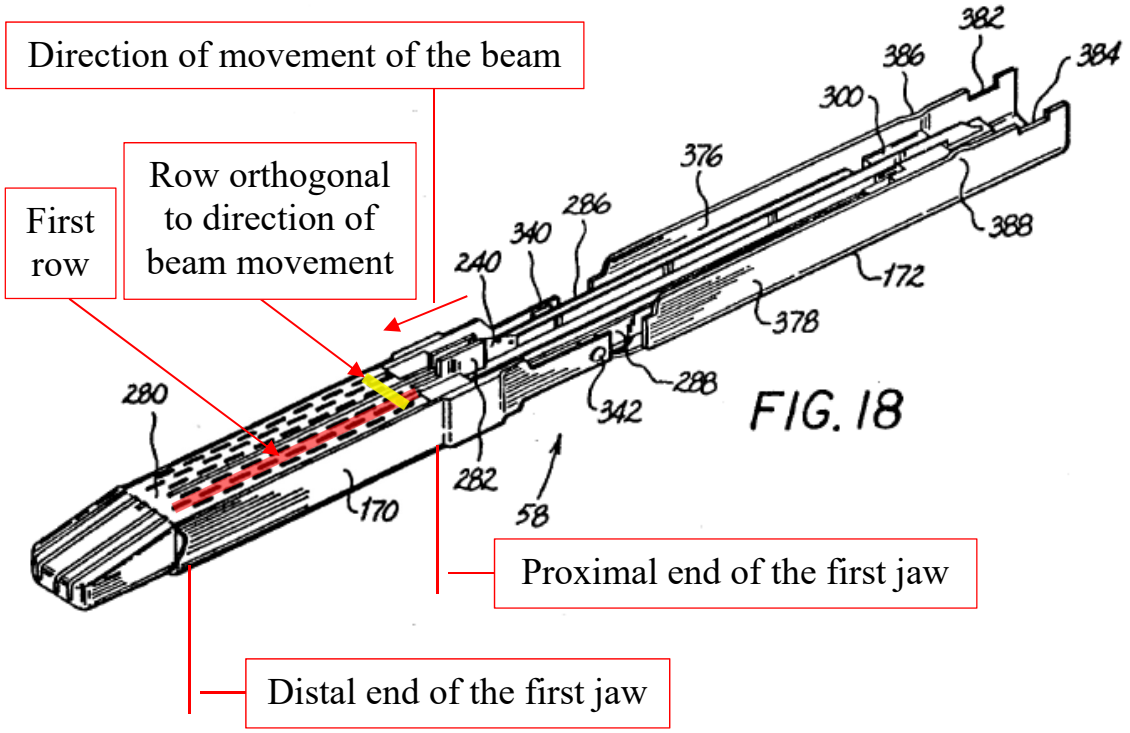


FIG. 18

[16.0] The apparatus of claim 15, wherein additional slots are arranged in a second row substantially parallel to the first row of slots.

See Ground 1, claim [15]. Additional slots are arranged in a second row substantially parallel to the first row of slots. Knodel, ¶100; Green-209, 15:63-67, Figs. 17-18.

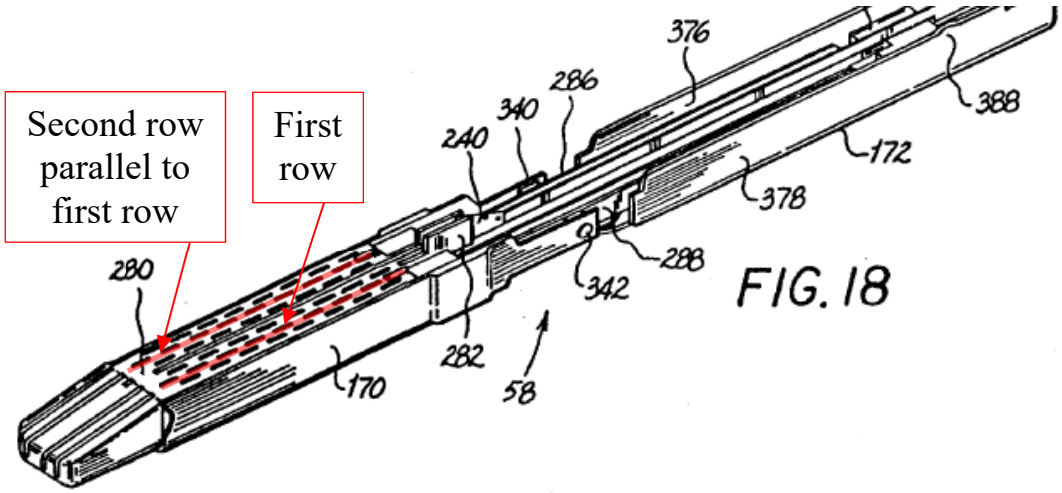


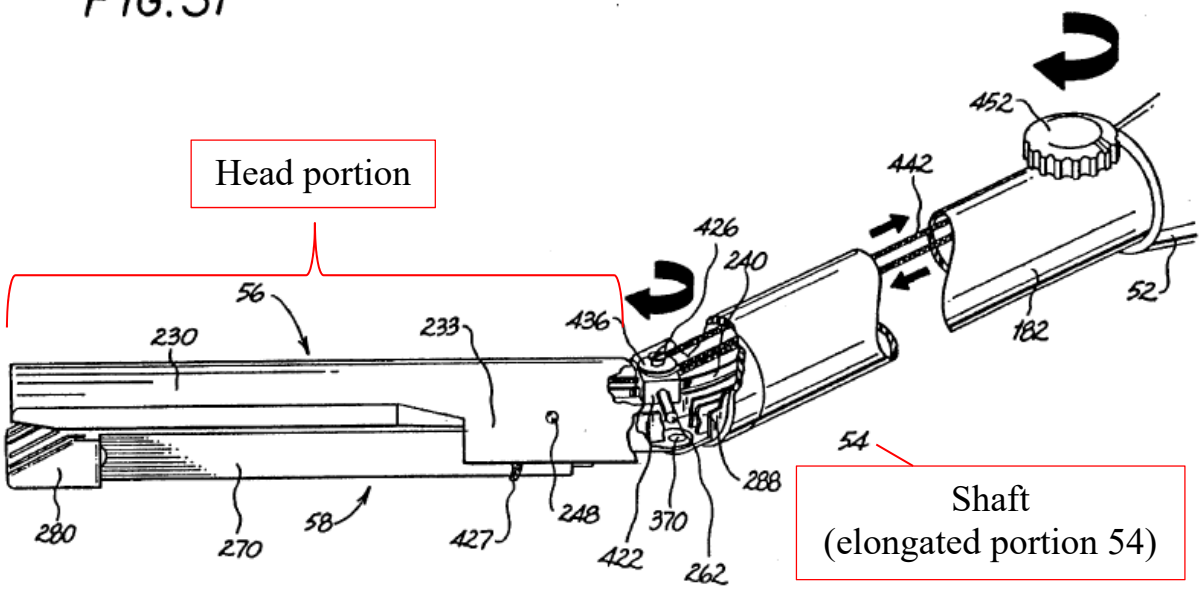
FIG. 18

[17.0] The apparatus of claim 13, wherein the head portion is one of fixedly coupled or movably coupled to the shaft.

Green-209 discloses this limitation. Knodel, ¶¶101-103. Green-209's head portion is movably coupled to the shaft because anvil member 56 is coupled such that it can rotate (*i.e.*, open/close) relative to the shaft and forward housing portion 270 of cartridge assembly 58. *Id.*, ¶101; Ground 1, element [4.1].

Green-209's head portion is also movably coupled to the shaft by rivet 370 and threaded fastener 426 for articulation. Knodel, ¶102; Green-209, 18:59-19:39, 20:3-22, Figs. 31-32.

FIG. 31



Finally, Green-209's head portion is movably coupled to the shaft because the head may be coupled to the shaft for rotation. Knodel, ¶103; Green-209, Fig. 52.

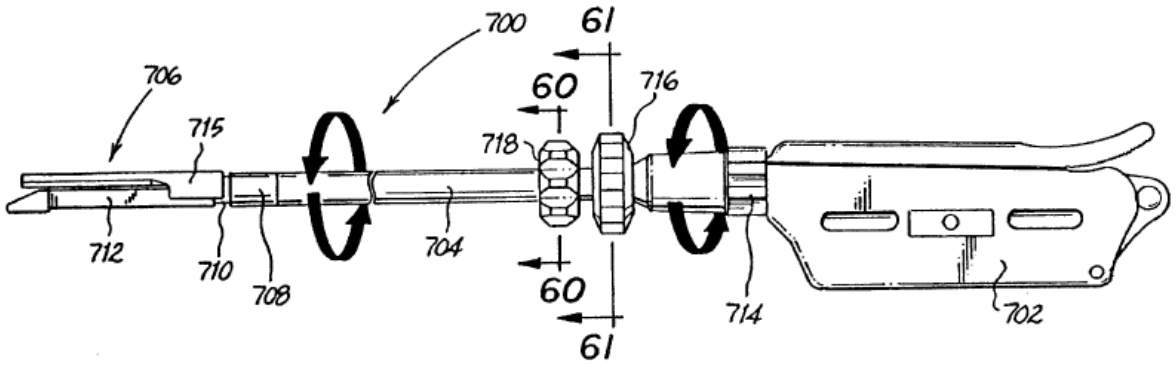


FIG. 52

[18.0] The apparatus of claim 13, wherein tissue is cut between the first row and the second row upon firing of one or more staples through the slots.

Although the scope of this claim is unclear, the Green-209/695 stapler discloses it. Knodel, ¶104. Upon firing the staples through the slots, Green-695's knife 42 cuts the stapled tissue between first and second rows of staples. *Id*.; *see also* Ground 1, elements [4.2], [4.6], claims [14], [16].

[20.0] The apparatus of claim 13, wherein the beam includes a cutting blade and is configured to clamp and align the first and second jaws one of entirely or substantially from therewithin.

See Ground 1, claim [14] (confirming the Green-209/695 stapler's beam includes a cutting blade), elements [4.6], [13.2] (confirming the Green-209/695 stapler's beam is configured to clamp and align the first and second jaws entirely or substantially from therewithin).

[22.0] The apparatus of claim 13, wherein the control handle includes at least one of an actuation handle, a lever, a trigger, a knob and a cable.

See Ground 1, claim [10].

[23.0] The apparatus of claim 13, wherein at least a portion of the apparatus is powered.

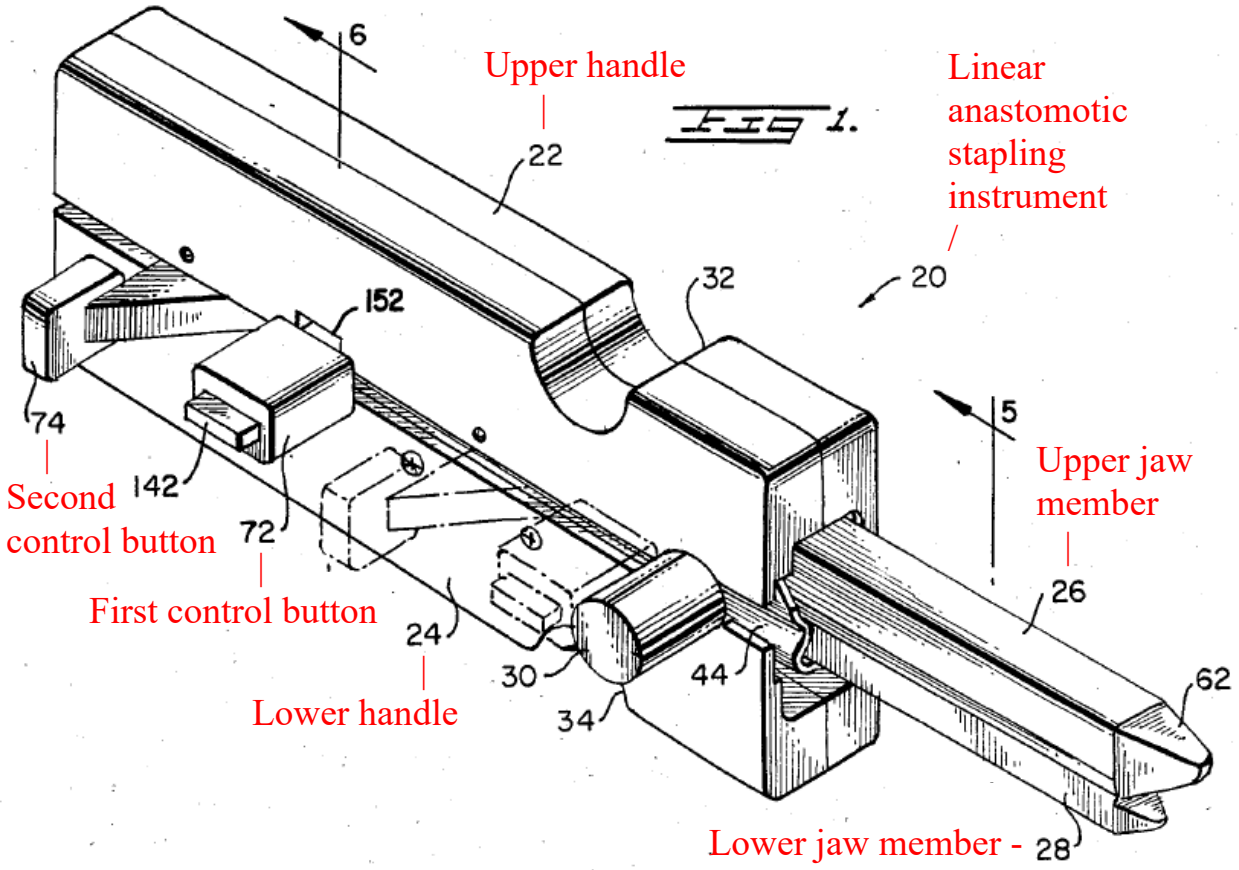
See Ground 1, claim [11].

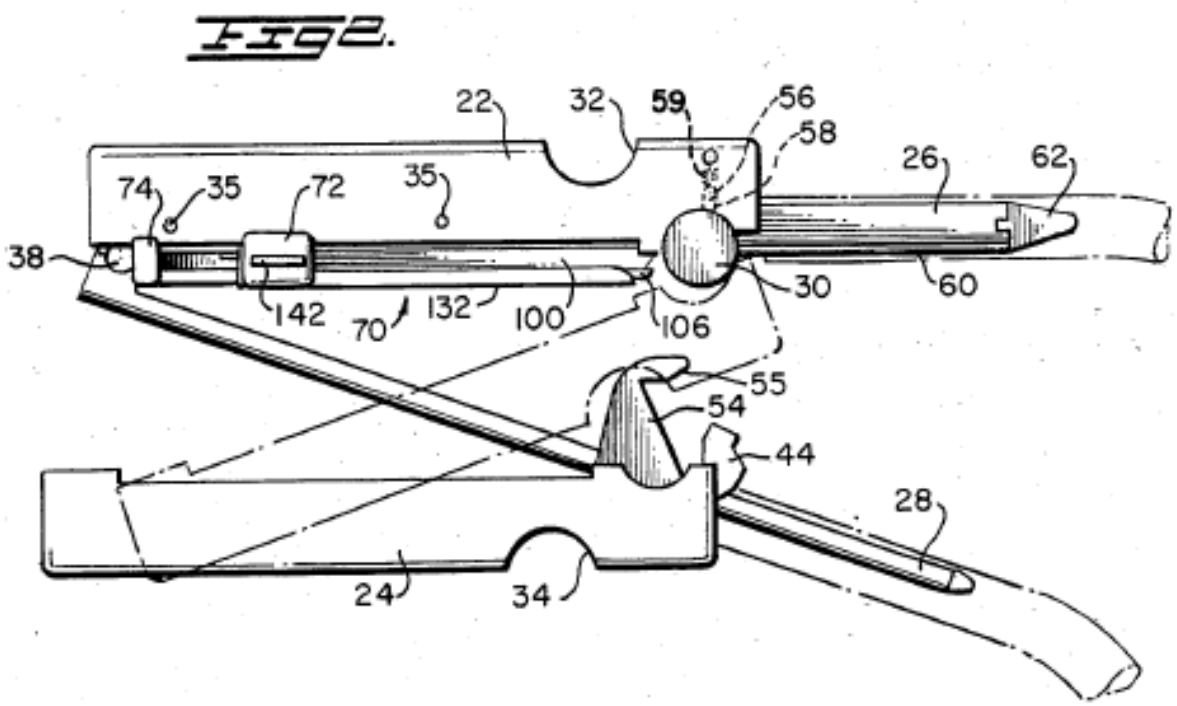
[24.0] The apparatus of claim 23, wherein the apparatus is powered electrically, hydraulically or pneumatically.

See Ground 1, claim [11].

B. Ground 2: Claims 4-8 and 10-24 are obvious over Rothfuss in view of Green-209 and Knodel-895

Rothfuss discloses a linear anastomotic stapling instrument 20, which includes upper and lower handles 22, 24, upper and lower jaw members 26, 28, and first and second control buttons 72, 74. Rothfuss, 6:8-14; 7:58-8:13, Figs. 1-2.





Two operations, performed sequentially, are required to complete the staple-firing operation. "After the tissue is clamped, first control button 72 is actuated to advance actuator assembly 70 [shown below in Figure 9] longitudinally along jaw members 26 and 28 into staple cartridge 60 [shown in Figure 8] and anvil 80 [shown in Figure 7]." *Id*., 12:37-40, Figs. 7-9; *see also* 11:38-52, 12:7-23, Fig. 2. When "actuator assembly 70 [is] advanced into staple cartridge 60 and anvil 80, its elongated I-beam structure provides support and alignment along the entire operating length of jaw members 26 and 28." *Id*., 12:66-13:2.

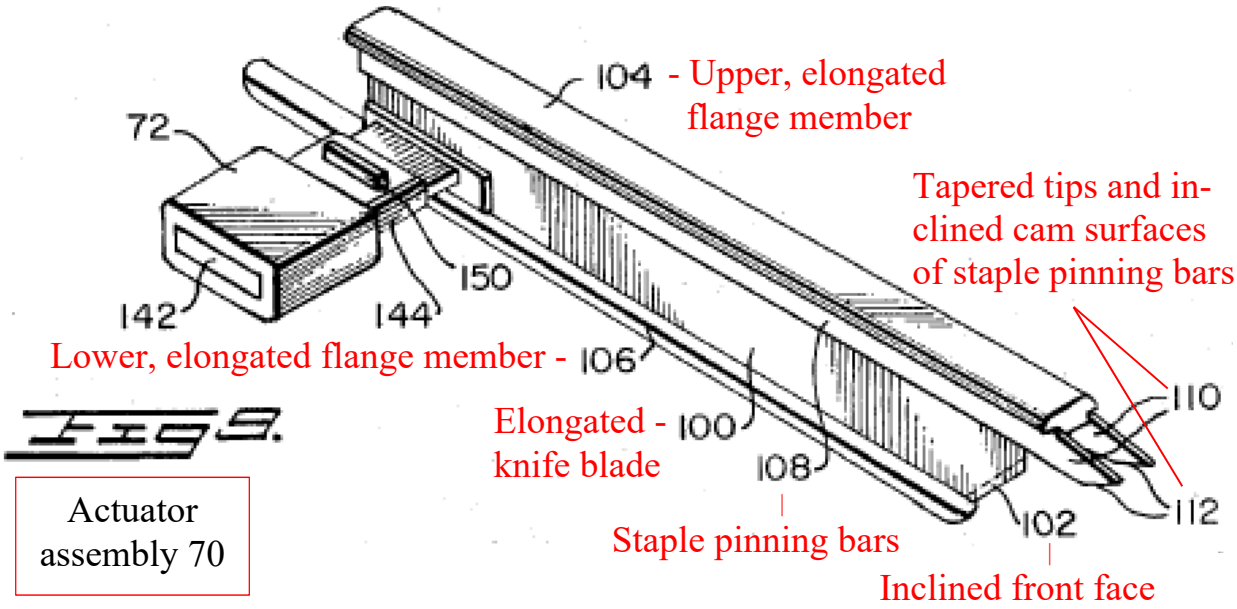
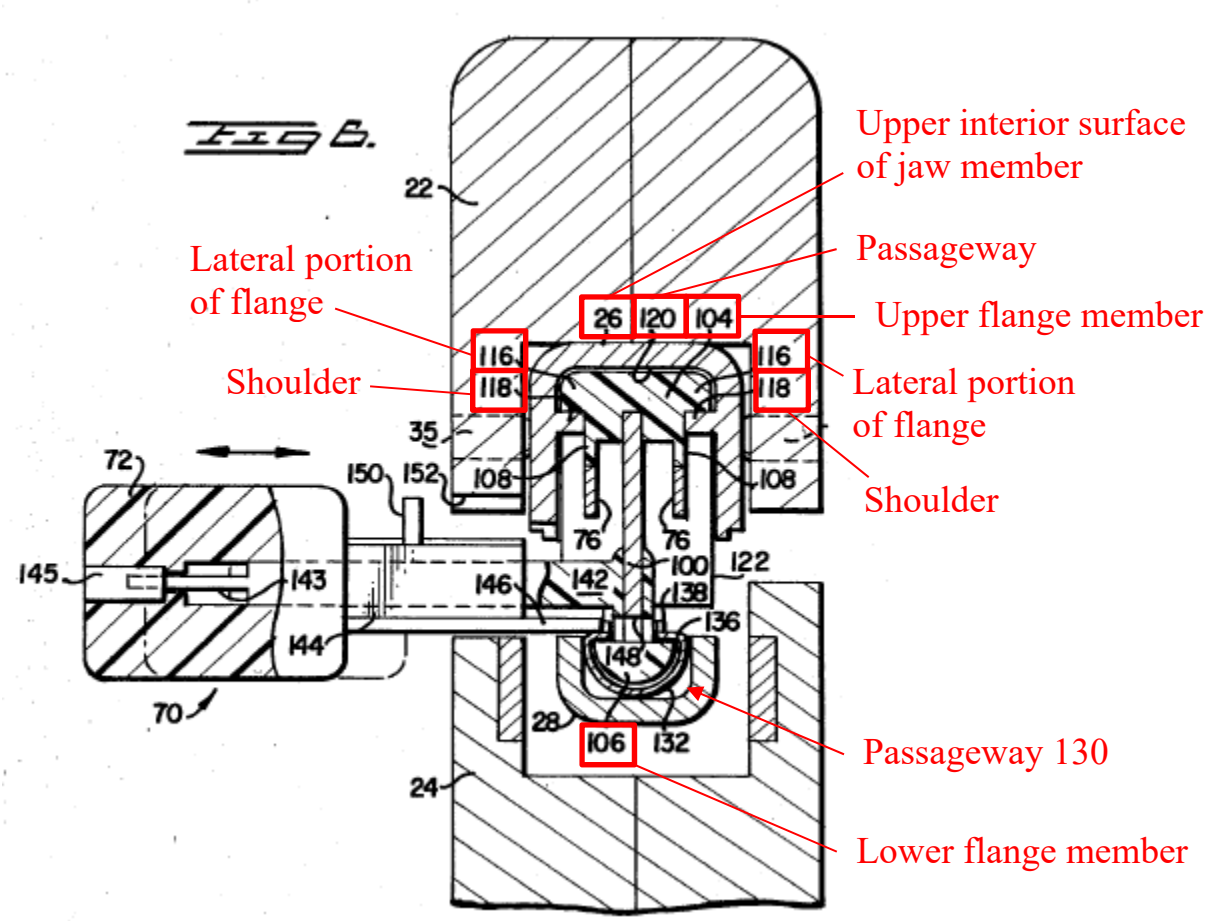


Fig 9.

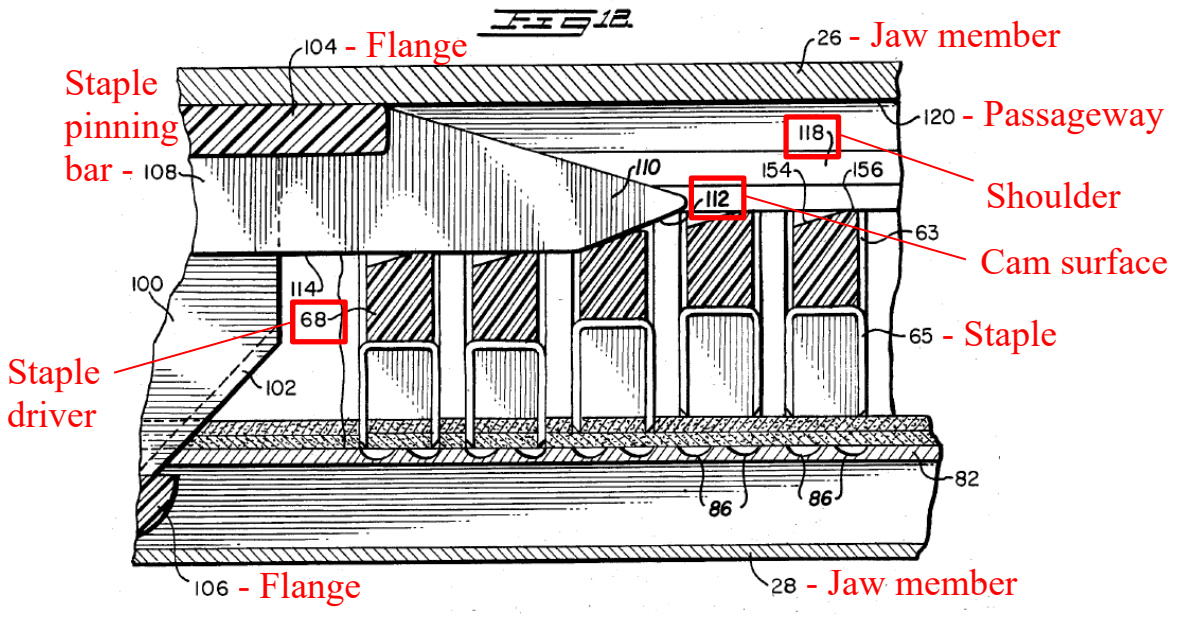
The I-beam includes "knife blade 100 having an inclined front face 102 which is beveled to provide a sharp cutting edge." *Id.*, 8:38-45, Fig. 9. "An upper, elongated flange member 104 extends along the top of knife blade 100 and a lower, elongated flange member 106 extends along the bottom of the knife blade to complete the I-beam structure." *Id.* "[U]pper I-beam flange member 104 is … provided with a pair of … staple pinning bars 108 which … [each] includes a forwardly projecting, tapered tip 110 … [and] an inclined cam surface 112." *Id.*, 8:45-56.

"[U]pper I-beam flange member 104 [also] includes a pair of elongated, lateral portions 116." *Id.*, 8:59-62, Fig. 6. "[J]aw member 26 includes a pair of … shoulders 118 which … together with the upper interior surface of jaw member 26[,] define a passageway 120 in which upper flange member 104 is slidably mounted for longitudinal movement relative to the jaw member." *Id.*, 8:62-9:3,

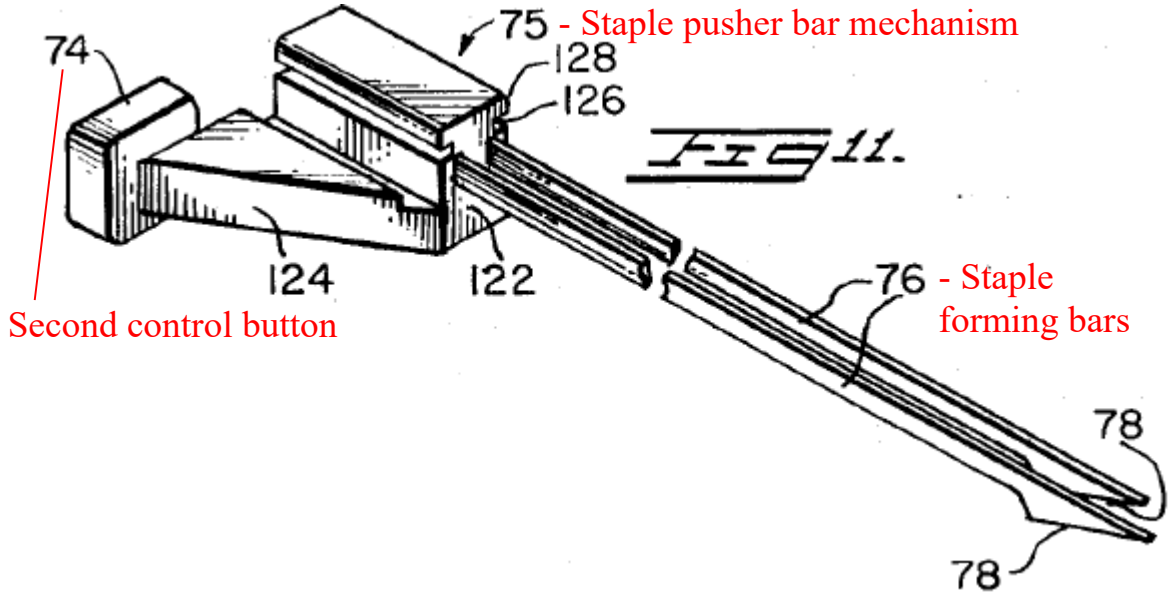
Fig. 6. Similarly, "anvil flanges 82 [shown in Figure 5] together with the interior walls of lower jaw member 28[,] define a passageway 130 for slidably receiving lower I-beam flange 106." *Id.*, 9:37-40, Figs. 5-6.



"[A]s the actuator assembly [70] is advanced, its upper I-beam flange 104 slides into passageway 120 … [and] [c]am surface 112 … sequentially engages the staple drivers 68…." *Id.*, 13:7-28, Fig. 12. "As a result, staple drivers 68 are sequentially pushed downward to partially drive each staple 65…." *Id.*

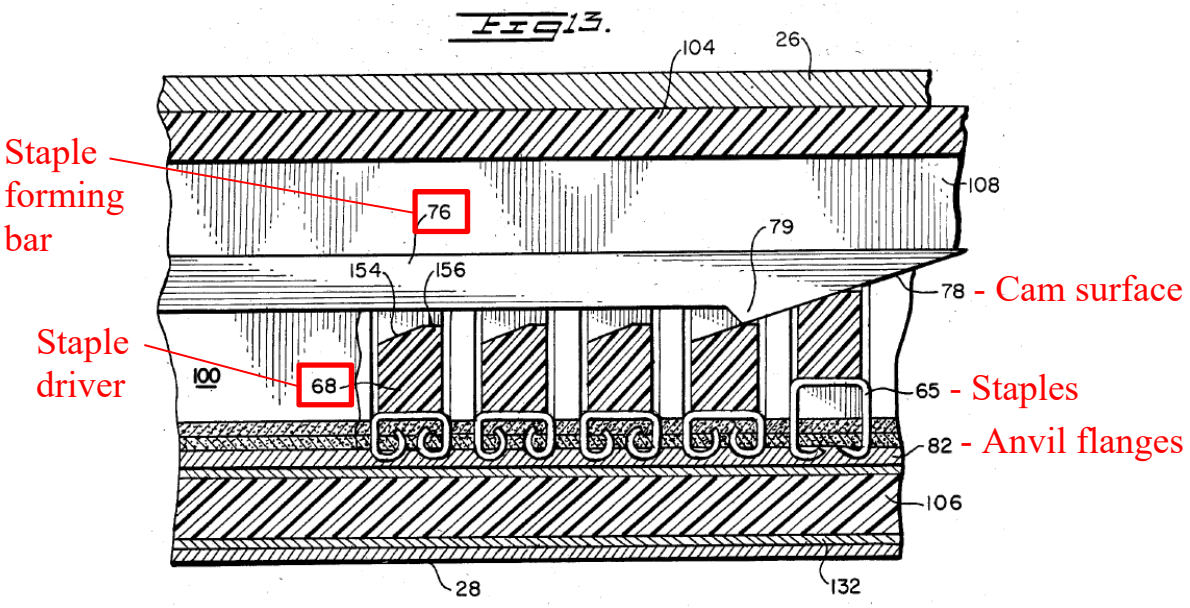


"Next, second control button 74 [of staple pusher bar mechanism 75] is actuated to advance staple forming bars 76 longitudinally into staple cartridge 60." *Id.*, 13:28-30, Fig. 11.



The "cam surfaces 78 of the staple forming bars 76 … push staple drivers 68

downward to complete the ejection of staples 65 from the cartridge and the formation of the staples into B-shaped configuration against anvil flanges 82." *Id.*, 13:29-38.



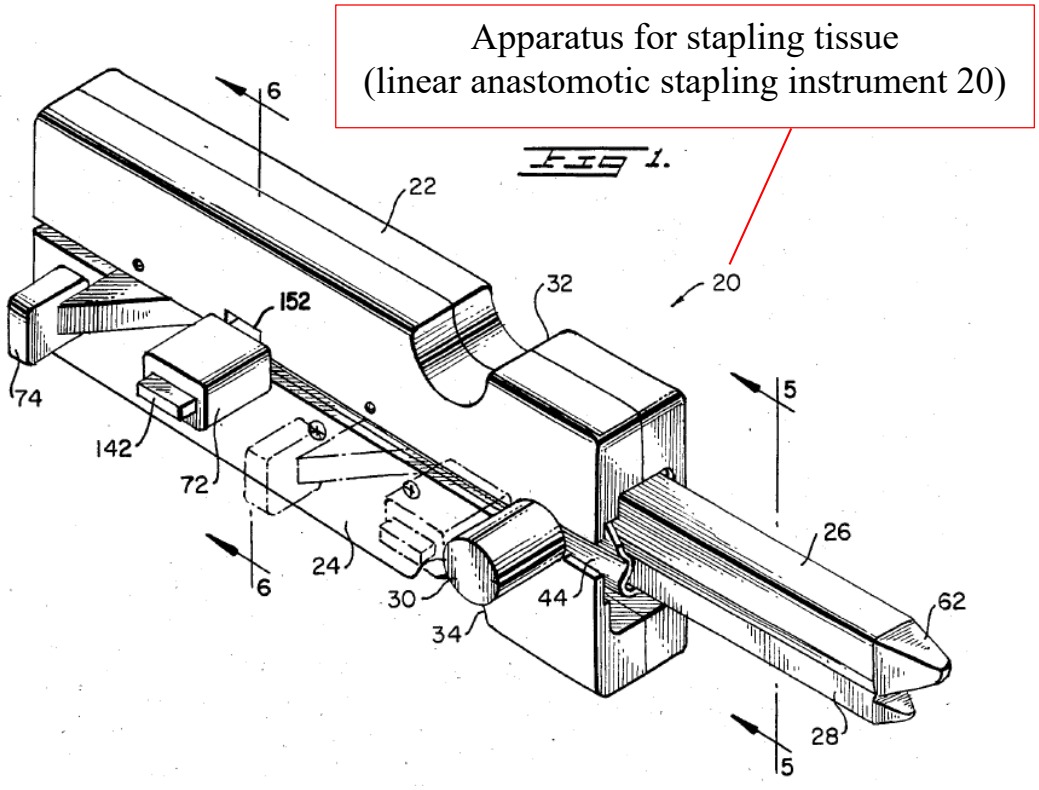
However, Rothfuss's surgical stapler was designed to be used in open surgery and required manually applied force to fasten tissue. Thus, a POSITA would have been motivated to modify Rothfuss's stapler for use in minimally invasive surgery (MIS) with a reasonable expectation of success for the same reasons a POSITA would have modified Green-695's stapler for use in MIS. Knodel, ¶117; Section VIII.A. In the resulting device (the Rothfuss/Green-209 stapler), Rothfuss's handles 22, 24 would be replaced with Green-209's frame portion 52 and elongated shaft portion 54 without or without Green-209's articulation and rotation functionality. Rothfuss's jaws 26, 28 (reduced in size and modified to resemble

Green-209's jaws) would be opened and closed using Green-209's linkage and cable assembly. And at least Rothfuss's staple pusher bar mechanism 75 would be driven by Green-209's pneumatic system 68 to gain the benefit of a powered firing mechanism.

The Rothfuss/Green-209 stapler, which results from this combination, in view of Knodel-895 discloses each limitation of challenged claims 4-8 and 10-24.

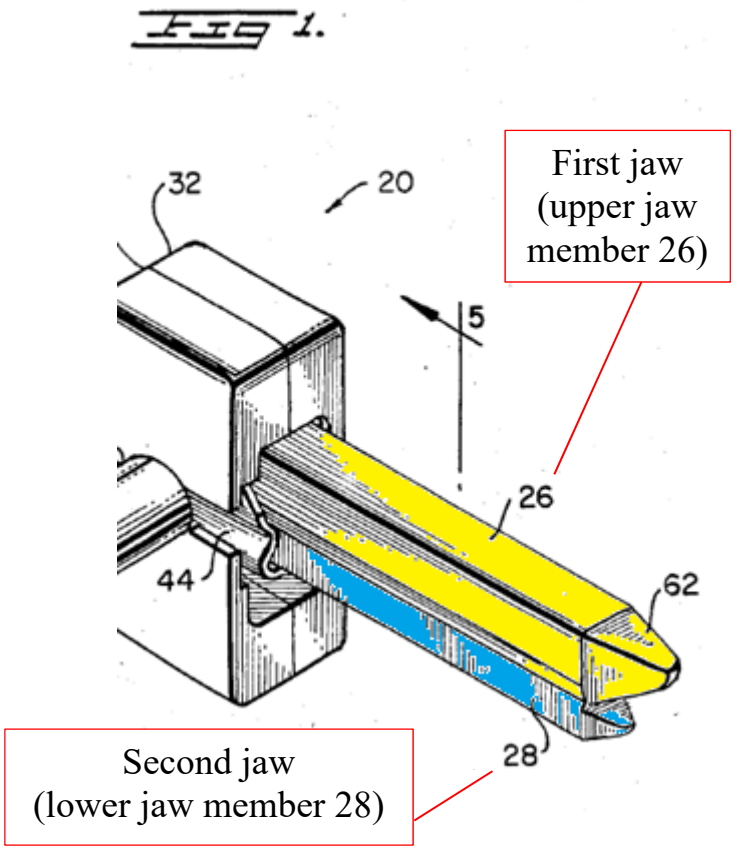
[4.0] An apparatus for stapling tissue, comprising:

If the preamble is deemed to be a limitation, then Rothfuss discloses it. Knodel, ¶119. Rothfuss discloses an apparatus for stapling tissue (linear anastomotic stapling instrument 20). *Id*., Rothfuss, 6:8-14, Fig. 1.



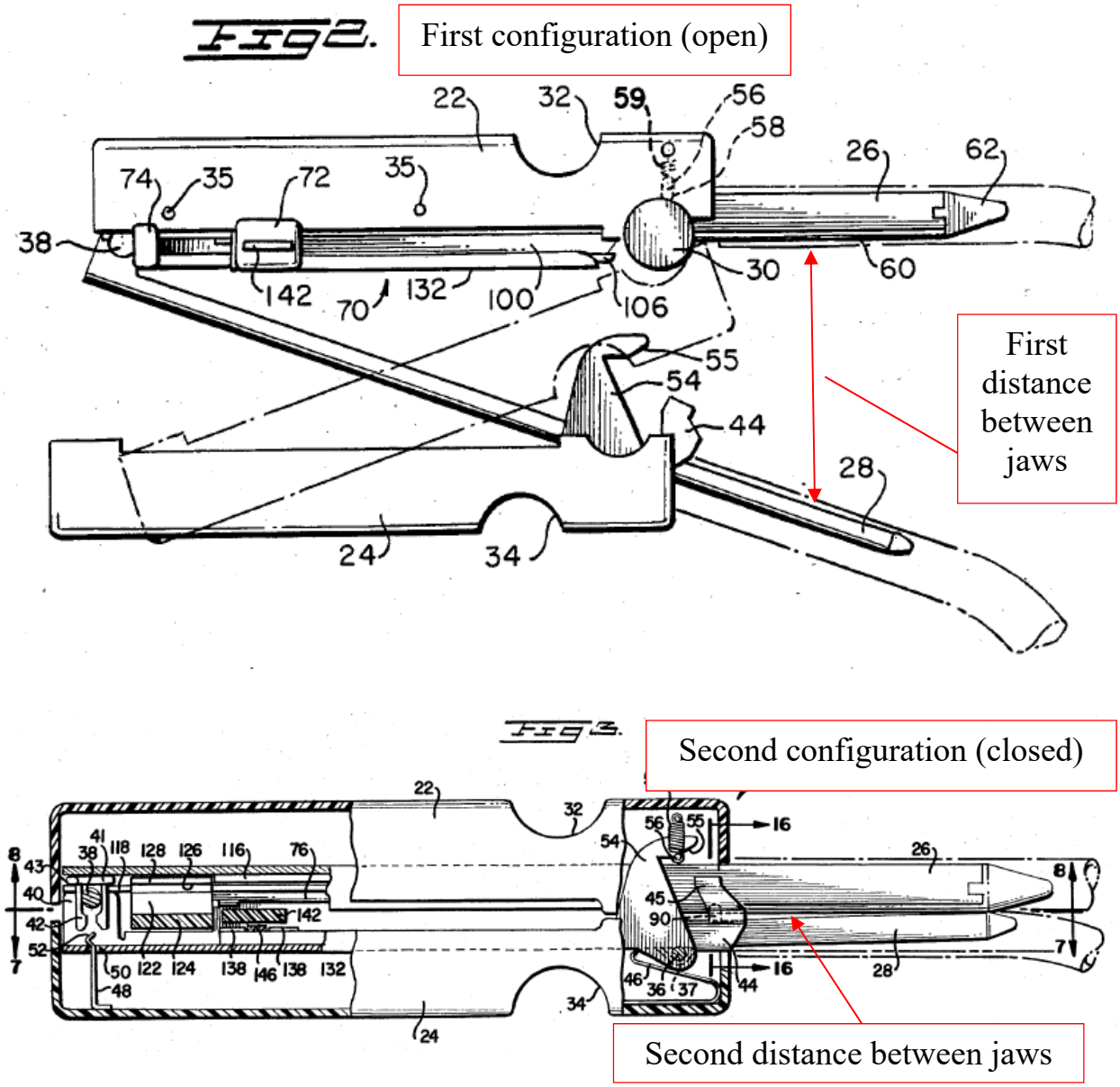
[4.1] a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling,

Rothfuss discloses this limitation. Knodel, ¶¶120-21. Rothfuss discloses a first jaw (upper jaw member 26, highlighted in yellow, which includes staple cartridge 60, which is not shown) and a second jaw (lower jaw member 28, highlighted in blue). *Id.*; Rothfuss, 6:8-46, Fig. 1.



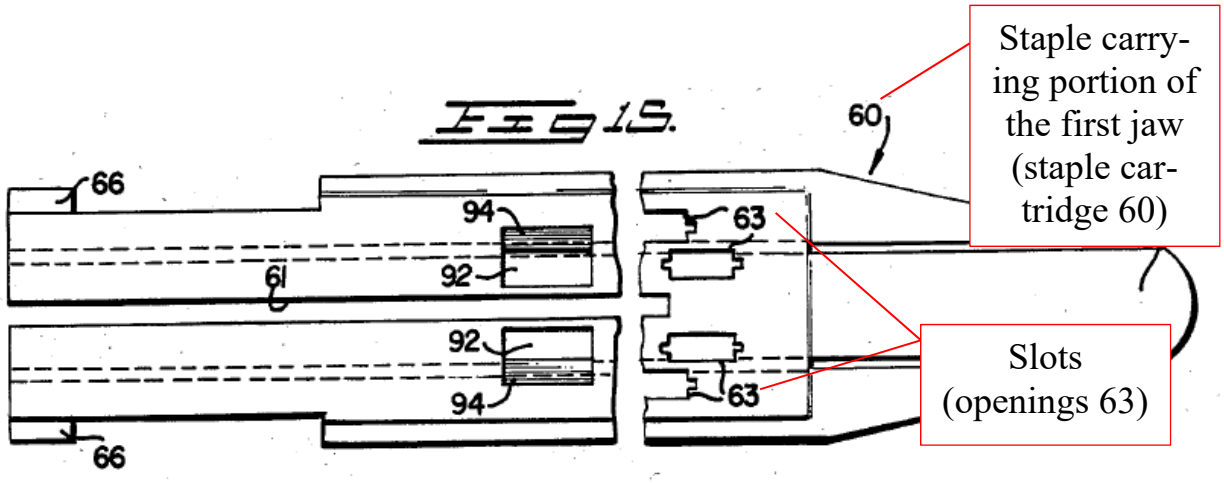
The two jaws are pivotally connected by pivot pin 38. Thus, at least one of the first jaw and the second jaw (lower jaw member 28) is movable with respect to the other of the first jaw and the second jaw (upper jaw member 26) from (i) a first

configuration (open) in which the first jaw and the second jaw are separated from each other at a first (longer) distance (shown in Figure 2) to receive tissue, to (ii) a second configuration (closed) in which the first and second jaws are clamped together at a second (shorter) distance (shown in Figure 3) to hold tissue therebetween for stapling. Knodel, ¶121; Rothfuss, 6:34-38, 11:38-12:36, Figs. 2-3.



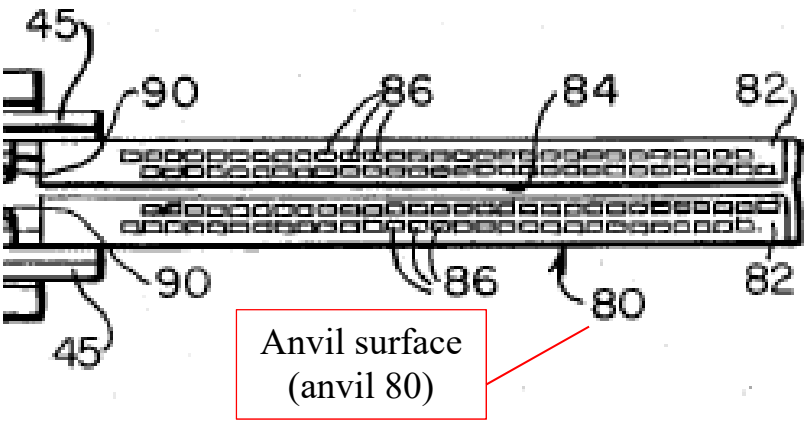
[4.2] a staple carrying portion of the first jaw defining slots through which staples are configured to pass;

Rothfuss discloses this limitation. Knodel, ¶122. Rothfuss discloses a staple carrying portion (staple cartridge 60) of the first jaw defining slots (openings 63) through which staples (65) are configured to pass. *Id*.; Rothfuss, 7:22-57, Figs. 2, 12, 15.



[4.3] an anvil surface defined on the second jaw opposing the first jaw;

Rothfuss discloses this limitation. Knodel, ¶123. Rothfuss discloses an anvil surface (anvil 80) defined on the second jaw opposing the first jaw. *Id*.; Rothfuss, 8:14-22, Fig. 7.

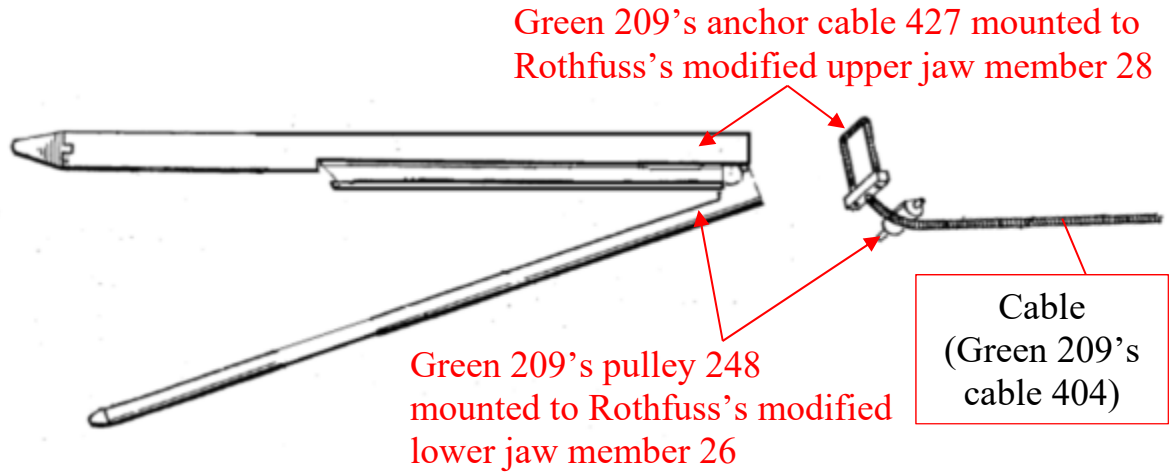


[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment; and

Rothfuss in view of Green-209 and Knodel-895 discloses this limitation. Knodel, ¶¶124-26. In the Rothfuss/Green-209/Knodel-895 stapler, Rothfuss's jaws 26, 28 (modified for use in MIS as taught by Green-209) would be opened and closed using Knodel-895's gear(s) and Green-209's cable, which are controlled by Green-209's handle 62 or 1012. *See* Ground 1, element [4.4]. Thus, the Rothfuss/Green-209/Knodel-895 stapler includes a gear (*e.g.*, Knodel-895's gears(s) 150b or 170a-b) and a cable (Green-209's cable 404) operatively coupled to the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration (open) to the second configuration (closed) such that the first jaw and the second jaw are in alignment. *See* Knodel, ¶124; Rothfuss, 8:23-37, Figs. 5-8; Ground 1, element [4.4].

A composite image of Rothfuss, Fig. 2 (modified to show only the jaws and

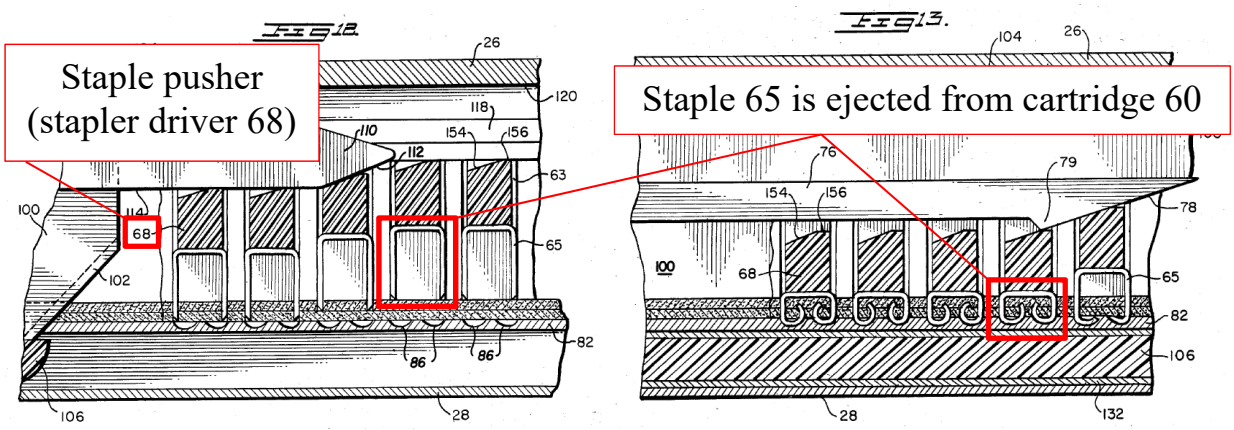
the I-beam) and a portion of Green-209, Fig. 16 (flipped vertically) illustrating an example of the proposed combination is shown below. Obviously many other implementations would have been apparent to a POSITA in view of the teaching of Green-209, Rothfuss, and Knodel-895. Knodel, ¶125.



[4.5] a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion,

Rothfuss discloses this limitation. Knodel, ¶127. Rothfuss discloses a staple pusher (stapler drivers 68) configured to cause a staple (65) to move from a first position at least partially within the staple carrying portion (shown below in Figure 12, staple 65's first position is fully within cartridge 60) to a second position entirely outside the staple carrying portion (shown below in Figure 13). *Id.*; Rothfuss, 8:52-56, 9:4-36, 11:4-37, 13:7-38, Figs. 12-13. As explained above, pinning bars 108 are driven distally via actuation of first control button 72, wherein cam

surfaces 112 engage staple drivers 68 to force staples 65 partially from staple cartridge 60. Rothfuss, 8:52-56, Fig. 12. Then, staple forming bars 76 are driven distally via actuation of second control button 74 to engage staple drivers 68 and "complete the ejection of the staples 65 from the staple cartridge [60]." *Id.*, 9:4-36, Fig. 13.



[4.6] the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location.

Rothfuss discloses this limitation. Knodel, ¶¶128-30. The second distance and the alignment between Rothfuss's jaws is maintained by a beam (I-beam structure including knife blade 100, flange members 104, 106, and staple pinning bars 108) configured to engage the first and second jaws from within the first and second jaws (via passageways 120, 130) while tissue is stapled from a proximal location (*e.g.*, the proximal end of staple cartridge 60) to a distal location (*e.g.*, the distal end of staple cartridge 60). *Id.*; Rothfuss, 8:38-9:3, 9:37-40, 12:66-13:2, 13:7-38, Figs. 5-6, 9-13.

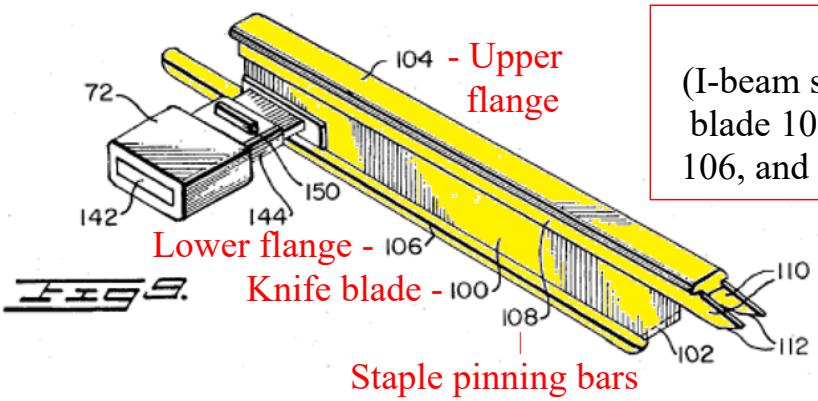


Fig 9.

Beam
(I-beam structure including knife blade 100, flange members 104, 106, and staple pinning bars 108)

"[J]aw member 26 includes a pair of … shoulders 118 which … together with the upper interior surface of jaw member 26[,] define a passageway 120 in which upper flange member 104 is slidably mounted for longitudinal movement…." *Id.*, 8:59-9:3, Fig. 6. Similarly, "anvil flanges 82 [Fig. 5] together with the interior walls of lower jaw member 28 define a passageway 130 for slidably receiving lower I-beam flange 106 of actuator assembly 70." *Id.*, 9:37-40, Figs. 5-6.

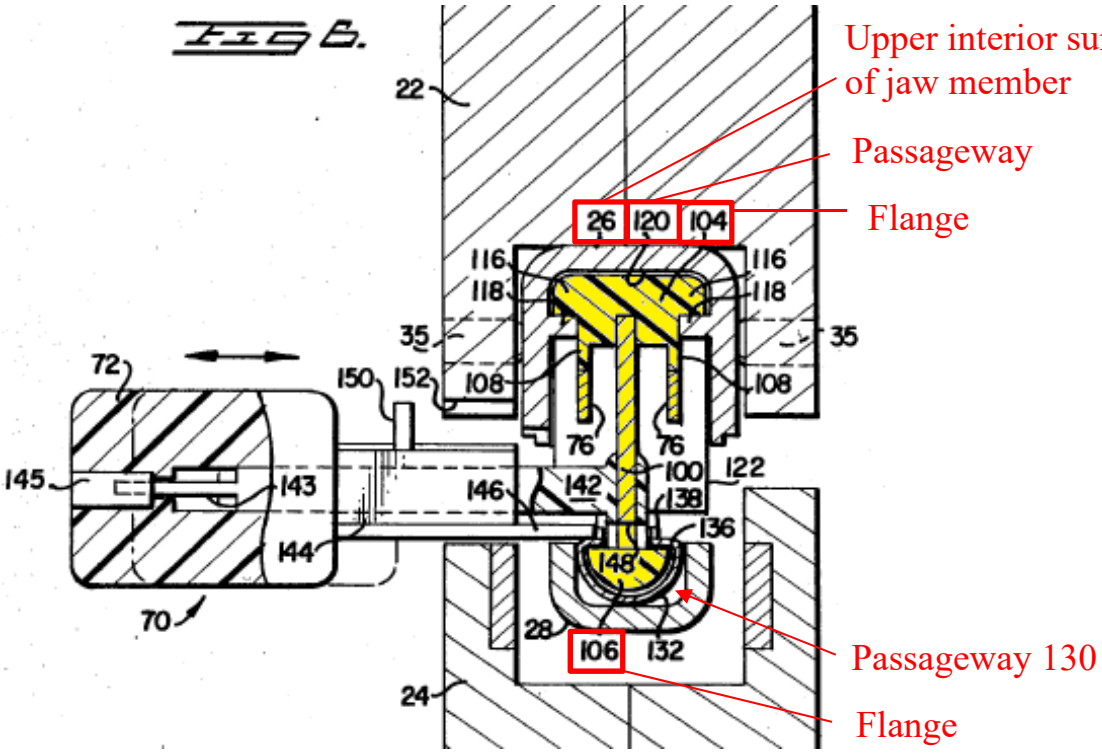
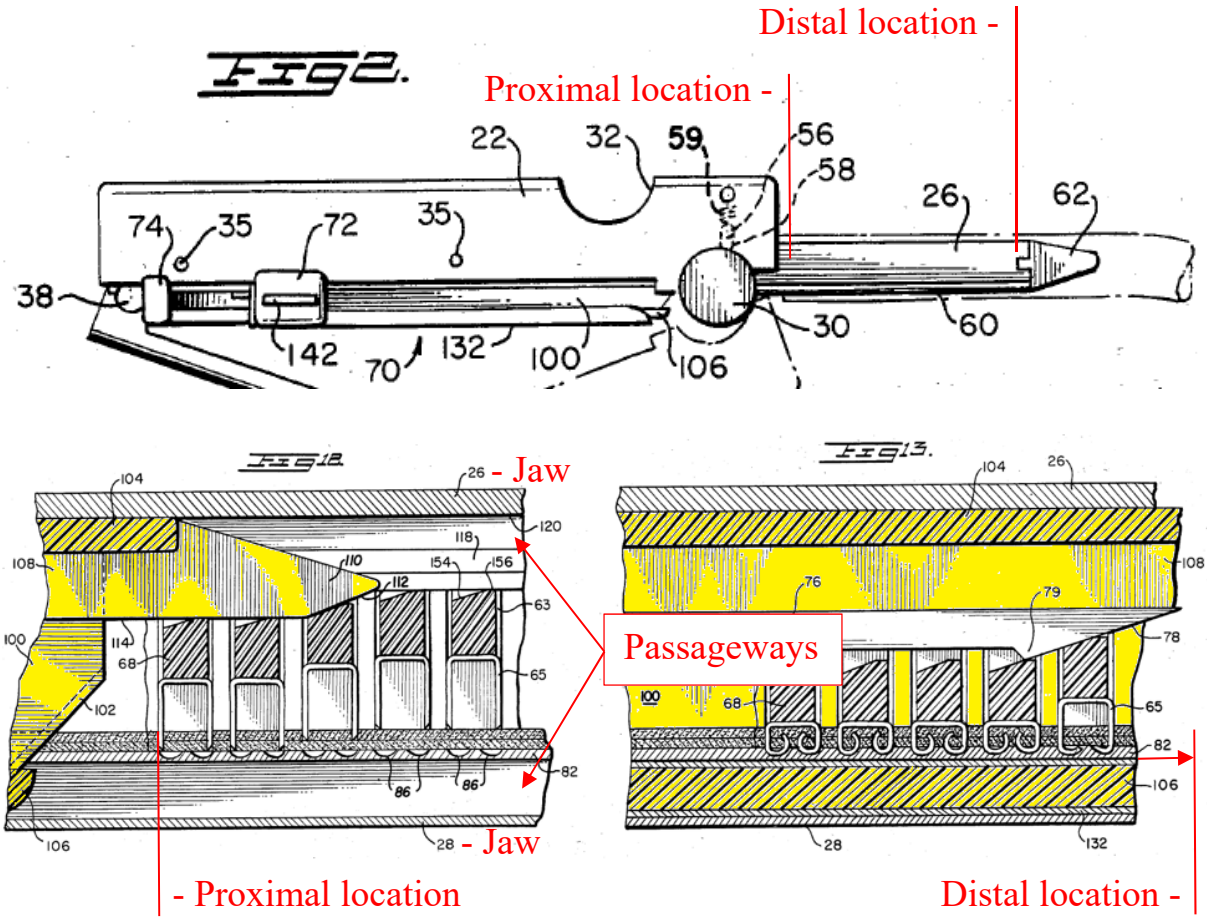


Fig 6.

The I-beam (highlighted yellow) engages jaws 26 and 28 via passageways 120, 130 within the jaws while tissue is stapled from a proximal location to a distal location (examples of both locations shown below). Knodel, ¶130; Rothfuss, 12:37-40, 13:7-38, Figs. 2, 5, 7-8, 12-13.



[5.0] The apparatus of claim 4, wherein the beam is configured to engage the first and second jaws one of entirely or substantially from therewithin to maintain the second distance and the alignment.

Although the scope of this term is unclear, the Rothfuss/Green-209 stapler discloses this limitation. *See* Ground 2, element [4.6]; *see also* Ground 1, element [4.6]. Like the upper and lower portions of I-beam member 70 in the '650 patent,

the upper and lower portions of the Rothfuss/Green-209 stapler's beam is configured to engage the first and second jaws entirely or substantially from therewithin to maintain the second distance and the alignment. *Id*.; Knodel, ¶131. As shown in Ground 2, element [4.6], Rothfuss's upper flange 104 and lower flange 106 engage Rothfuss's passageways 120 and 130, which are formed within Rothfuss's first and second jaws, respectively. *Id*.

[6.0] The apparatus of claim 5, wherein

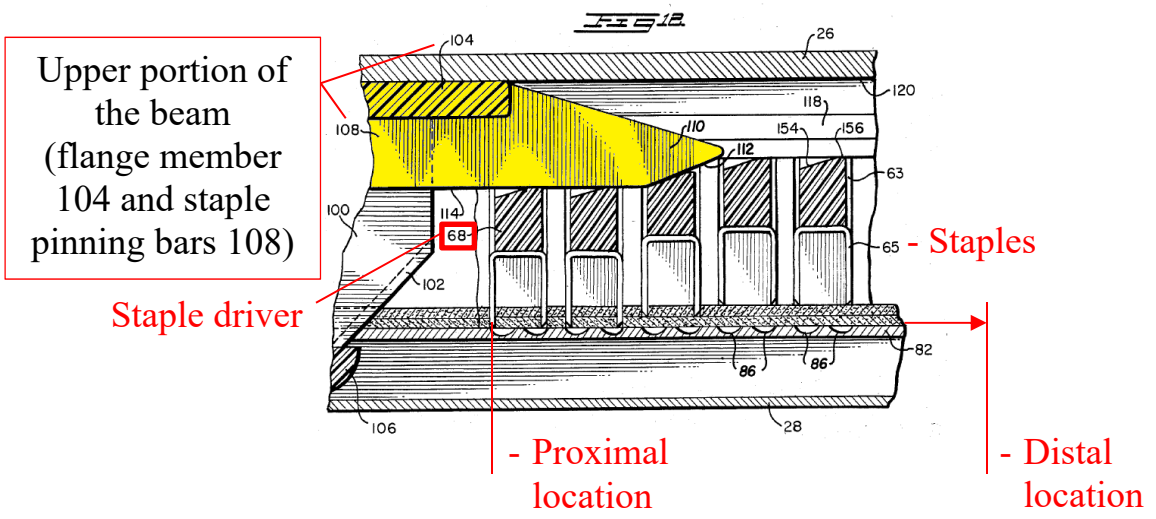
See Ground 2, claim [5].

[6.1] the beam comprises an upper portion and a lower portion and a web coupled between the upper portion and the lower portion,

As shown in Ground 2, element [4.6], the beam comprises an upper portion (upper flange 104 and staple pinning bars 108) and a lower portion (lower flange 106) and a web (elongated knife blade 100) coupled between the upper portion and the lower portion. Knodel, ¶133.

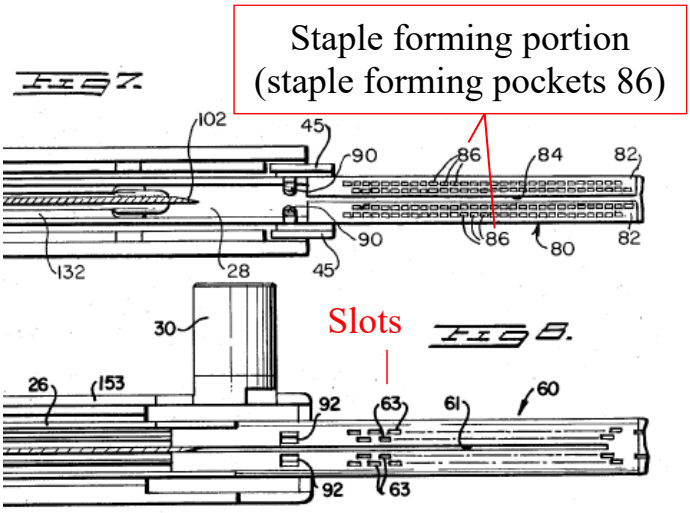
[6.2] at least one of the lower portion or the upper portion configured to cause the staple pusher to move a staple as the beam moves from a proximal location to a distal location,

Rothfuss discloses this limitation. Knodel, ¶134. Rothfuss discloses at least one of the lower portion or the upper portion (upper flange 104 and staple pinning bars 108) that is configured to cause the staple pusher to move a staple (65) as the beam moves from a proximal location to a distal location (examples of both locations shown below). *Id*.; Rothfuss, 8:45-56, 13:7-28, Figs. 6, 9, 12.



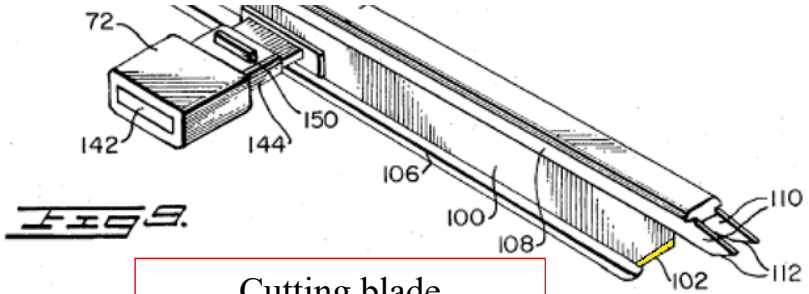
[6.3] the upper portion and the lower portion configured to cooperatively engage the first jaw and the second jaw to align the slots with a staple forming portion on the anvil surface.

See Ground 2, element [4.6] (confirming that the upper portion and the lower portion are configured to cooperatively engage the first and the second jaw). Rothfuss's I-beam also maintains the alignment of the slots with a staple forming portion (staple forming pockets 86) on the anvil surface. Knodel, ¶135; Rothfuss, 12:66-13:2; *see also* 12:11-21, 13:11-13, Figs., 7-8.



[7.0] The apparatus of claim 6, further comprising a cutting blade on the web.

Rothfuss discloses this limitation. Knodel, ¶136. Rothfuss's I-beam includes a cutting blade (face 102 of knife blade 100) on the web. *Id.*; Rothfuss, 8:38-41, Figs. 9, 12.



[8.0] The apparatus of claim 5, wherein the beam is configured as a cutting blade.

See Ground 2, claim [7].

[10.0] The apparatus of claim 4, further comprising one or more actuators including at least one of an actuator handle, a lever, a trigger, a knob or a cable.

The Rothfuss/Green-209 stapler discloses this limitation. Knodel, ¶138. The Rothfuss/Green-209 stapler includes Green-209's handle assembly, which includes at least one of an actuator handle, a lever, a trigger, a knob or a cable. *Id.*; Ground 1, claim [10].

[11.0] The apparatus of claim 4, wherein at least a portion of the apparatus is powered.

The Rothfuss/Green-209 stapler discloses this limitation. Knodel, ¶139. The Rothfuss/Green-209 stapler includes Green-209's handle assembly, which is pneumatically powered. *Id.*; Ground 1, claim [11].

[12] The apparatus of claim 4, wherein at least a portion of the first jaw and the second jaw is curved.

Rothfuss discloses this limitation. Knodel, ¶140. At least a portion of the first jaw and the second jaw (the distal portion) is curved. *Id*.; Rothfuss, Fig. 1.

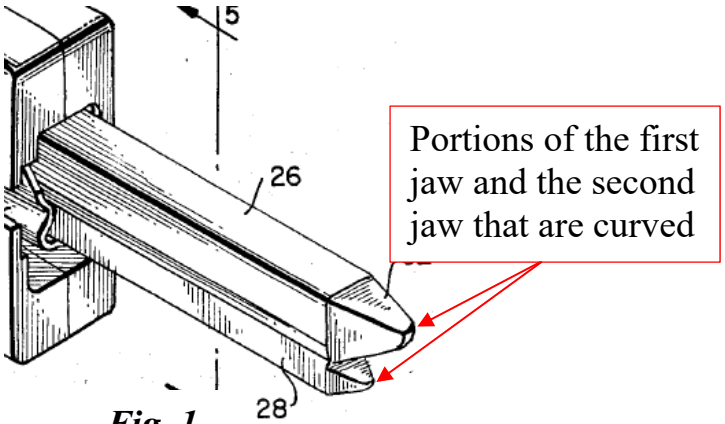


Fig. 1

[13.0] An apparatus, comprising:

See Ground 2, element [4.0].

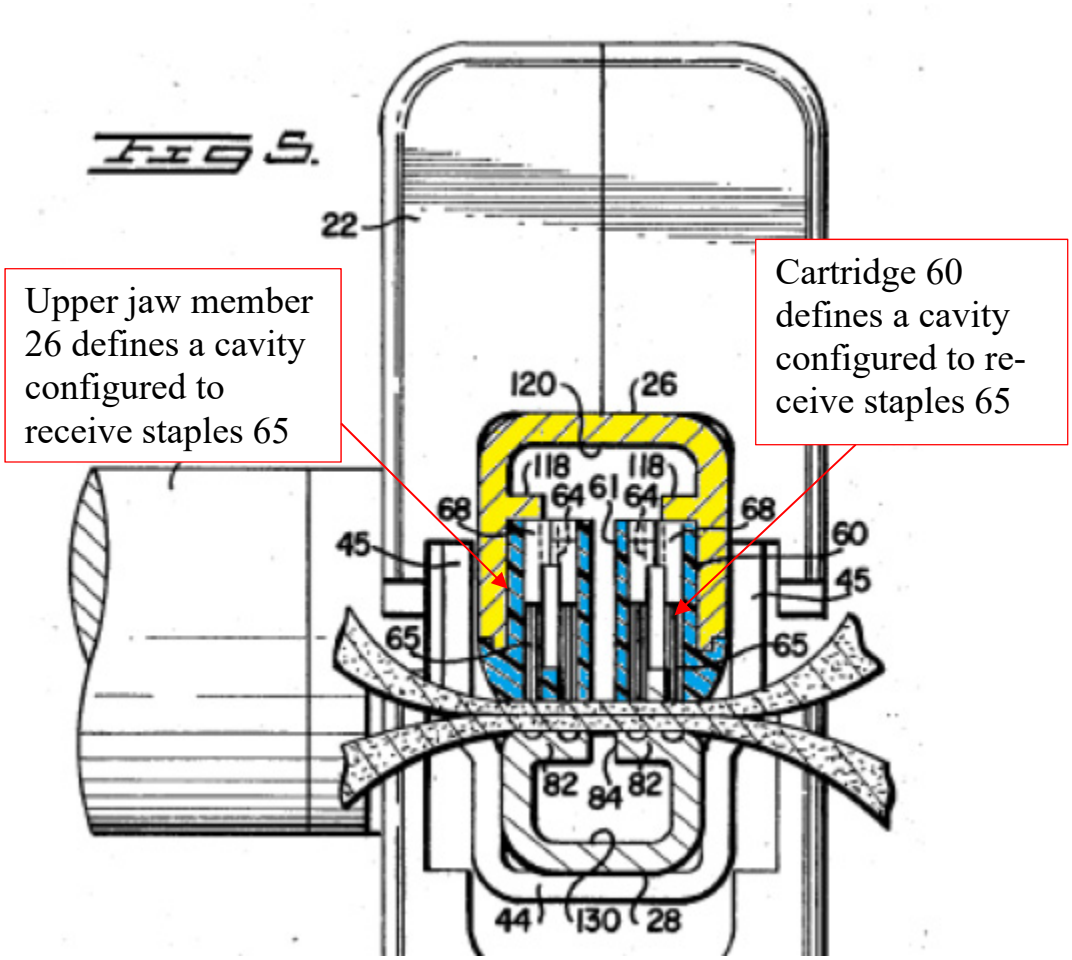
[13.1] a head portion having a first jaw and a second jaw configured to move between a first configuration for receiving tissue and a second configuration for stapling tissue,

See Ground 2, element [4.1]. The Rothfuss/Green-209 stapler's jaws form a head portion. *Id*.; Knodel, ¶142. The first configuration (open) is for receiving tissue and the second configuration (closed) is for stapling tissue. *Id*.

[13.1.1] the first jaw defining a cavity configured to receive a plurality of staples and a plurality of slots configured to pass staples therethrough;

See Ground 2, elements [4.1]-[4.2] (confirming that (1) upper jaw member 26 and staple cartridge 60 forms a first jaw, and (2) staple cartridge 60 has a plural-

ity of slots (openings 63) through which staples 65 pass during the stapling operation). Furthermore, upper jaw member 26 (highlighted yellow) defines a cavity (channel) configured to receive the plurality of staples 65 and slots in staple cartridge 60. Rothfuss, Fig. 5; Knodel, ¶143. Similarly, staple cartridge 60 (highlighted blue) defines a cavity configured to receive the plurality of staples 65. *Id*.

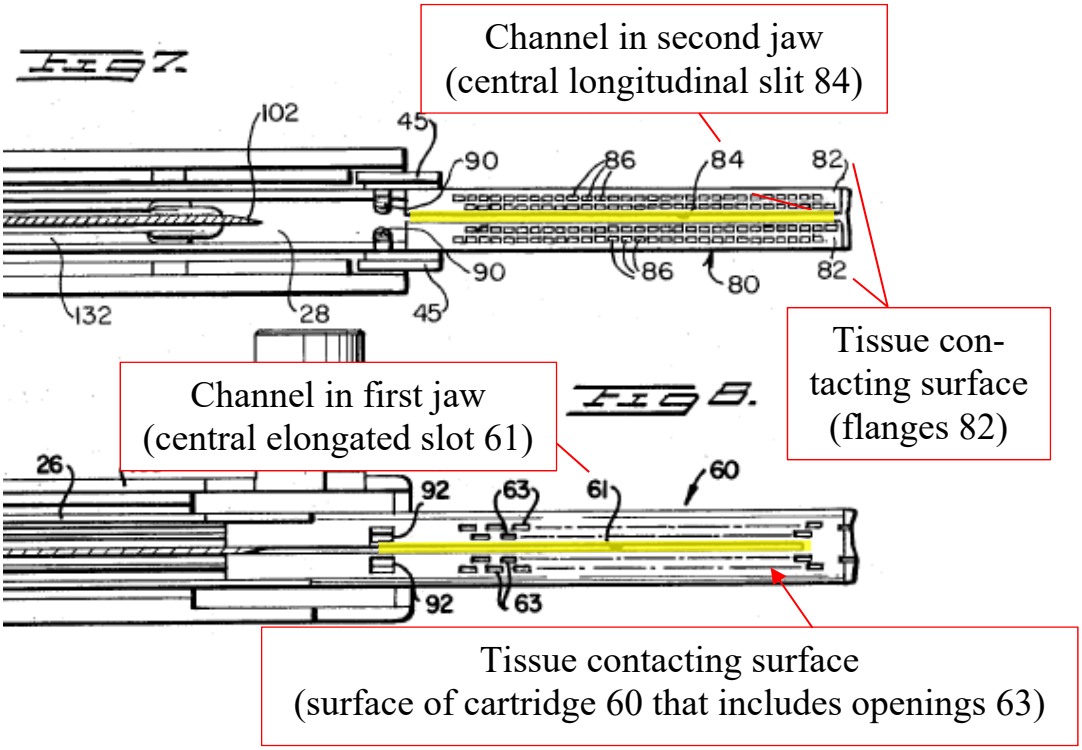


[13.1.2] the second jaw having a staple-forming surface; and

See Ground 2, element [4.3].

[13.2] a beam whose opposite end portions are connected by a central web portion and are configured to clamp and align the first and second jaws from therewithin when in the second configuration as the beam moves distally along a channel defined in a tissue contacting surface of each of the first and second jaws; and

See Ground 2, elements [4.6], [6.1], [6.3] (confirming that Rothfuss discloses a beam whose opposite end portions (i) are connected by a central web portion and (ii) are configured to clamp and align the first and second jaws from therewithin when in the second configuration as the beam moves distally). Rothfuss also discloses that the beam moves distally along: (1) a channel (central elongated slot 61) defined in a tissue contacting surface (the surface of cartridge 60 that includes openings 63) of the first jaw (26); and (2) a channel (central longitudinal slit 84) defined in a tissue contacting surface (flanges 82) of the second jaw (28). Knodel, ¶145; Rothfuss, 7:22-29, 8:14-22, Figs. 2, 7-8. Essentially, this limitation is met by an I-beam, which Rothfuss discloses; and, in Rothfuss, the I-beam travels within channels in the jaws, as previously discussed.



[13.3] a control handle configured to actuate receiving, clamping and stapling of tissue, and

See Ground 1, claim [13.3] (confirming that Green-209's control handle, which is included in the Rothfuss/Green-209 stapler, is configured to actuate receiving, clamping and stapling of tissue); Knodel, ¶146.

[13.4] a shaft coupling the control handle to the head portion.

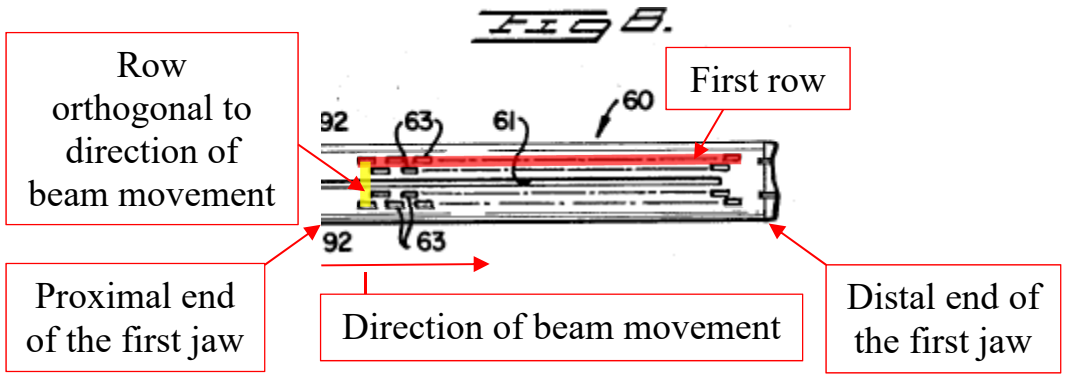
The Rothfuss/Green-209 stapler discloses this limitation. Knodel, ¶147. The Rothfuss/Green-209 stapler includes Green-209's shaft (elongate portion 54), which couples Green-209's control handle (frame 52) to Rothfuss's head portion (jaws 26, 28). *Id.*; Ground 1, claim [13.4].

[14.0] The apparatus of claim 13, wherein: the beam is configured to enable at least one of firing staples and cutting tissue.

See Ground 2, element [6.2] (confirming that Rothfuss's beam is configured to fire staples), claim [7] (confirming that Rothfuss's beam is configured to cut tissue); *see also* Knodel, ¶148.

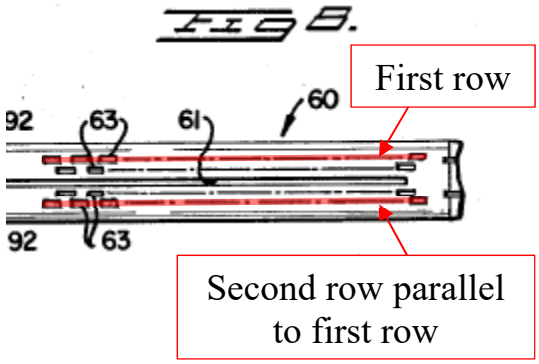
[15.0] The apparatus of claim 13, wherein the slots through which staples are passed are arranged in a first row extending from a proximal end of the first jaw to a distal end thereof such that two or more staples are fired in a row orthogonal to a direction of movement of the beam one of simultaneously or serially.

Rothfuss discloses this limitation. Knodel, ¶149. The slots (63) through which staples (65) are passed are arranged in a first row (red line) extending from a proximal end of the first jaw to a distal end thereof such that two or more (two) staples (65) are fired in a row (yellow line) orthogonal to a direction of movement of the beam (*e.g.*, along the longitudinal axis of the cartridge) one of simultaneously or serially (each row of staples that is orthogonal to the direction of movement of the beam is fired simultaneously and each subsequent row that is orthogonal to the direction of movement of the beam is fired serially to the preceding row). *Id.*; Rothfuss, Fig. 8.



[16.0] The apparatus of claim 15, wherein additional slots are arranged in a second row substantially parallel to the first row of slots.

See Ground 2, claim [15]. Additional slots are arranged in a second row substantially parallel to the first row of slots. Knodel, ¶150; Rothfuss, Fig. 8.



[17.0] The apparatus of claim 13, wherein the head portion is one of fixedly coupled or movably coupled to the shaft.

The Rothfuss/Green-209 stapler discloses this limitation. Knodel, ¶151. In the combination without Green-209's articulation or rotation assemblies, Rothfuss's head portion is fixedly coupled to the shaft because Rothfuss's jaw members are fixed to the shaft. *Id*. In that combination, Rothfuss's head portion is also movably coupled to the shaft because jaw member 28 is coupled such that it can rotate (*i.e*., open/close) relative to the shaft and jaw member 26. *Id*.; Ground 2, element [4.1]. Furthermore, a POSITA modifying Rothfuss for use in MIS may or may not have chosen to incorporate Green-209's articulation and/or rotation assemblies in the Rothfuss/Green-209 stapler. *Id*. If Green-209's articulation assembly and/or rotation assembly is included, then Rothfuss's head portion is movably coupled to the shaft for that reason as well. *Id*.; *see also* Ground 1, claim [17].

[18.0] The apparatus of claim 13, wherein tissue is cut between the first row and the second row upon firing of one or more staples through the slots.

Although the scope of this claim is unclear, Rothfuss discloses this limitation. Knodel, ¶152. As explained in Rothfuss, "the actuator assembly 70[, which includes knife blade 100,] is slidable longitudinally relative to the jaw members to partially eject the staples from cartridge 60 and force the staples into the tissue gripped between the jaw members and to cut the tissue along a line between the longitudinal rows of staples after the tissue is pinned." Rothfuss, 7:61-67.

[19.0] The apparatus of claim 13, wherein one of the opposite end portions of the beam is configured to enable firing of the plurality of staples.

See Ground 2, element [6.2].

[20.0] The apparatus of claim 13, wherein the beam includes a cutting blade and is configured to clamp and align the first and second jaws one of entirely or substantially from therewithin.

See Ground 2, claim 7 (confirming that the Rothfuss/Green-209 stapler's beam includes a cutting blade), elements [4.6], [6.3] (confirming that the Rothfuss/Green-209 stapler's beam is configured to clamp and align the first and second jaws entirely or substantially from therewithin).

[21.0] The apparatus of claim 13, wherein one end portion of the beam is configured to cause one or more staple pushers to be pushed for firing the plurality of staples as the beam travels towards a distal end of the head portion.

See Ground 2, element [6.2].

[22.0] The apparatus of claim 13, wherein the control handle includes at least one of an actuation handle, a lever, a trigger, a knob and a cable.

See Ground 2, claim [10].

[23.0] The apparatus of claim 13, wherein at least a portion of the apparatus is powered.

See Ground 2, claim [11].

[24.0] The apparatus of claim 23, wherein the apparatus is powered electrically, hydraulically or pneumatically.

See Ground 2, claims [11], [23].

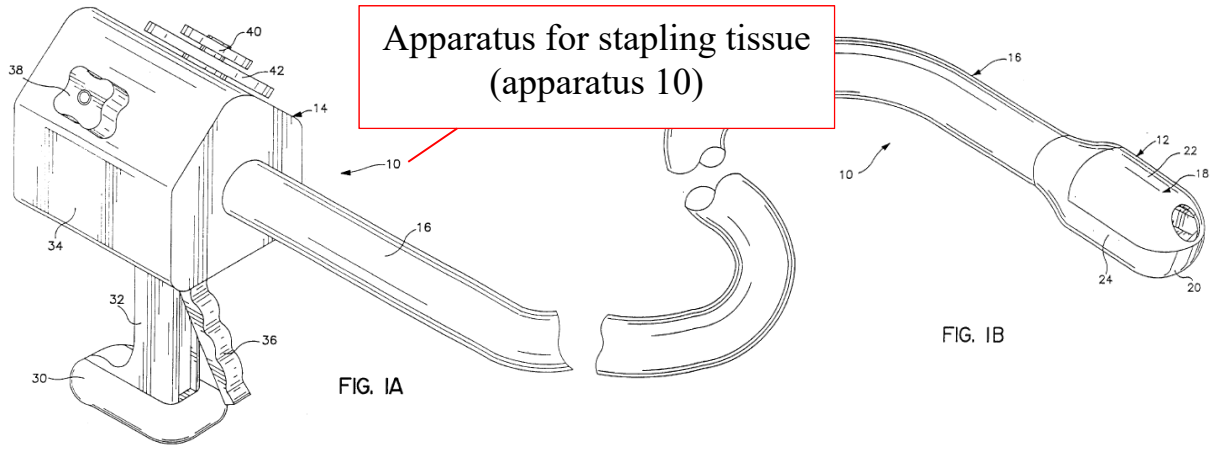
C. Ground 3: Claims 4-24 are obvious over McGuckin in view of Green-695 under Patent Owner's apparent construction

[4.0] An apparatus for stapling tissue, comprising:

If the preamble is deemed to be a limitation, then McGuckin discloses it.

Knodel, ¶159. McGuckin discloses an apparatus for stapling tissue (apparatus 10).

Id.; McGuckin, Abstract, 4:34-37, 4:63-65, 5:15-49, 6:51-64, 13:65-14:63, 21:8-24:25, Figs. 1A-B, 18-26, 30-31, claim 1.



[4.1] a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling,

McGuckin discloses this limitation. Knodel, ¶160. McGuckin discloses a first jaw (lower shell 24 alone or in combination with bulkhead 120 and, if necessary, transition portion 118) and a second jaw (upper shell 22), at least one of the first jaw and the second jaw (upper shell 22) being movable with respect to the other from a first configuration (open) in which the jaws are separated from each other at a first distance (shown in Figure 15) to receive tissue and a second configuration (closed) in which the jaws are clamped together at a second distance (shown in Figure 14) to hold tissue (208; shown in Fig. 31) therebetween for stapling. *Id*.; McGuckin, 5:4-15, 5:55-65, 10:41-52, 13:30-40, 25:21-28, 26:10-30, Figs. 14-15, 18, 28, 30-31, claim 1.

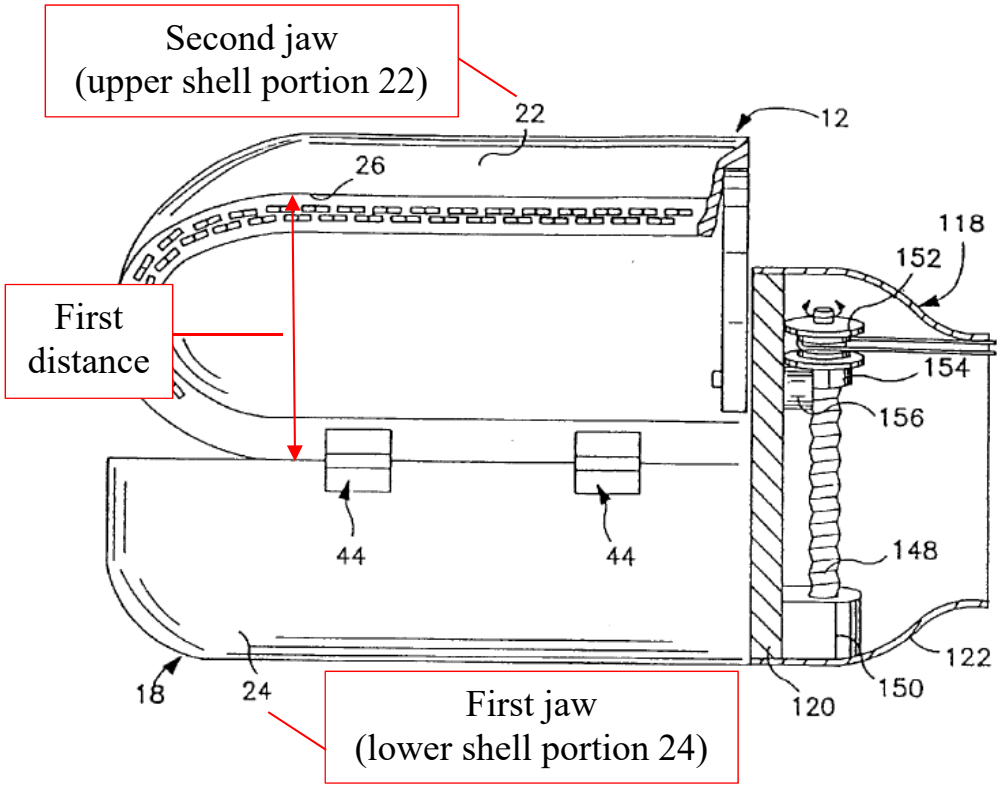

Second jaw
(upper shell portion 22)
22
12
26
118
152
First
distance
154
156
44
44
148
122
18
24
150
120
First jaw
(lower shell portion 24)

Fig. 15

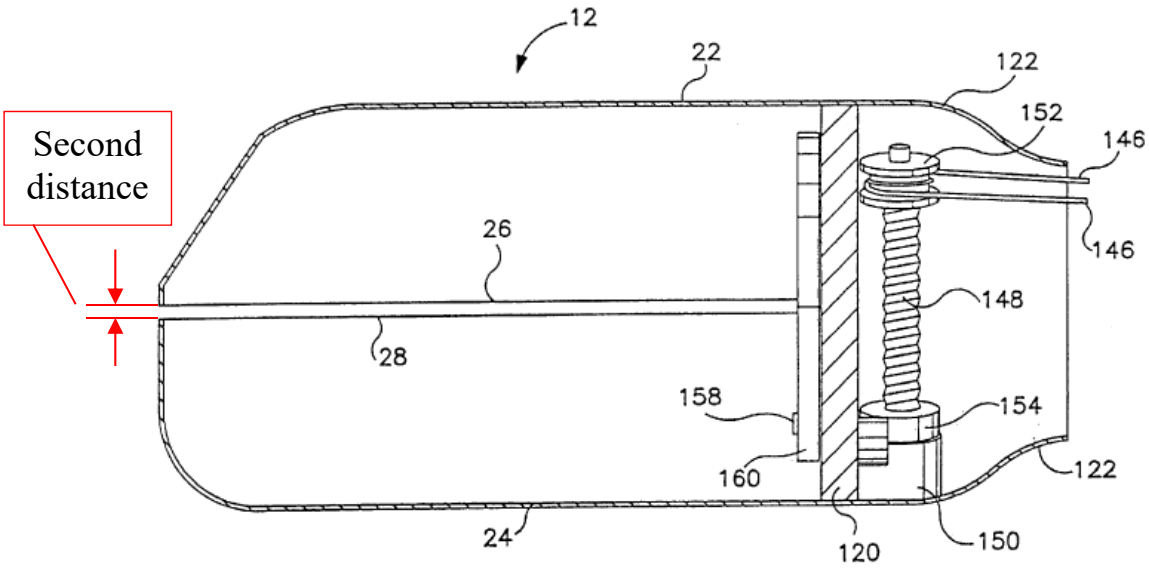
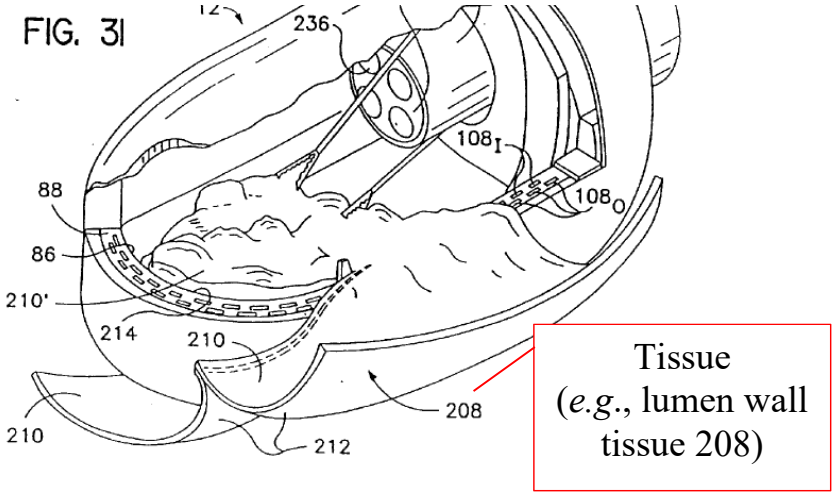
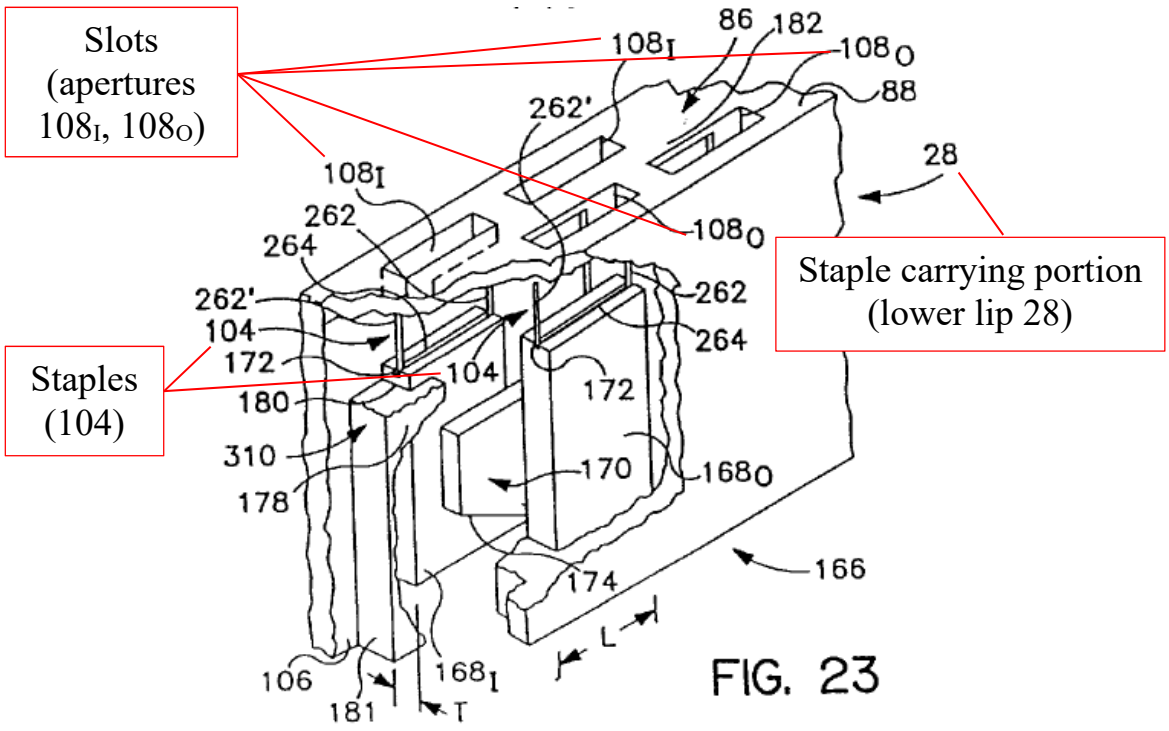

12
22
122
152
146
Second
distance
26
146
148
28
158
154
160
122
24
120
150

FIG. 14



[4.2] a staple carrying portion of the first jaw defining slots through which staples are configured to pass;

McGuckin discloses this limitation. Knodel, ¶161. McGuckin discloses a staple carrying portion (lower lip 28) of the first jaw defining slots (apertures 108_I, 108_O) through which staples (104) are configured to pass. *Id.*; McGuckin, 21:8-22:7, Figs. 18-25, 31.



[4.3] an anvil surface defined on the second jaw opposing the first jaw;

McGuckin discloses this limitation. Knodel, ¶162. McGuckin discloses an anvil surface (upper lip 26 having anvil surfaces 260 formed thereon) defined on the second jaw opposing the first jaw. *Id.*; McGuckin, 23:60-24:25, Figs. 24, 26.

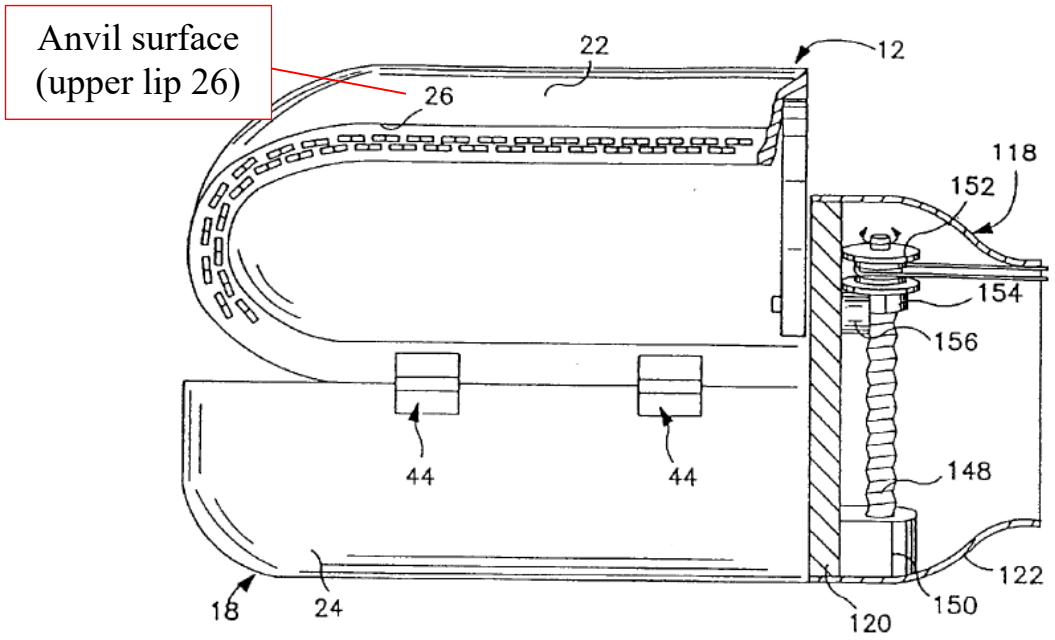


Fig. 15

[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment; and

Patent Owner appears to contend that this limitation is broad enough to cover a gear and a cable operatively coupled to the first jaw and the second jaw through a series of intermediary structures that ultimately move the first jaw and the second jaw from the first configuration to the second configuration. If so, McGuckin discloses this limitation under Patent Owner's apparent construction. Knodel, ¶¶163-67.

"at least one of a gear and a cable"

McGuckin discloses at least one of a gear (bevel gears 140 and 144) and a cable (146). *Id.*; McGuckin, 17:57-18:65, Figs. 13-14.

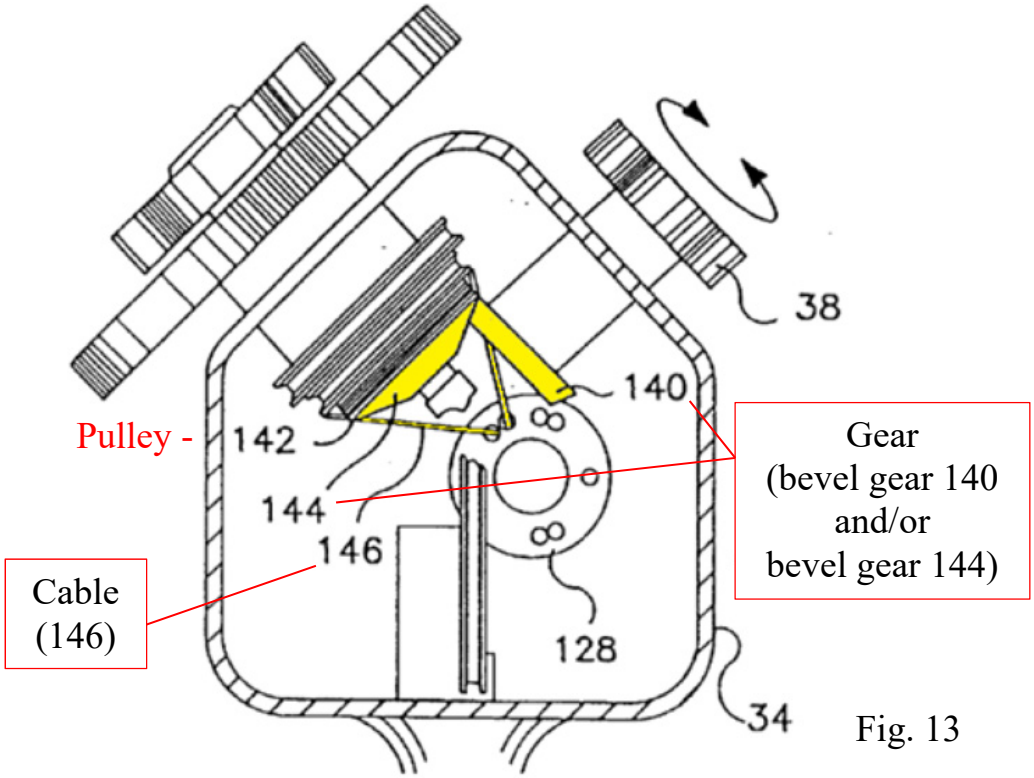


Fig. 13

"operatively coupled to at least one of the first jaw and the second jaw and"

Under Patent Owner's apparent construction, bevel gears 140, 144 and cable 146 are operatively coupled to the first and second jaws by pulley 142, threaded shaft 148, pedestal block 150, bulkhead 120, drive pulley 152, nut 154, arm 156, pin 158, and lift arm 160. *Id.*

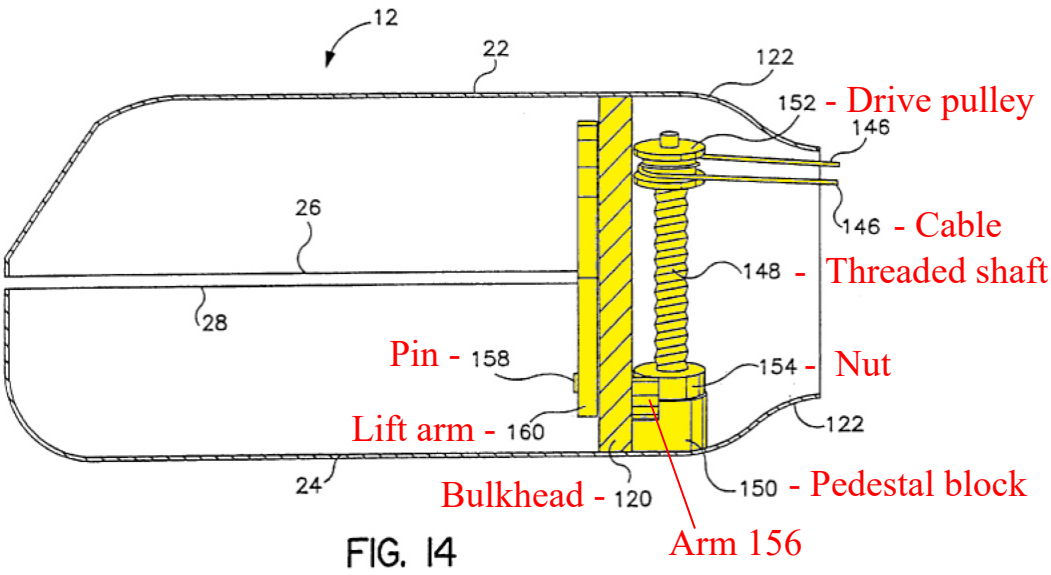


FIG. 14

"configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment"

Under Patent Owner's apparent construction, bevel gears 140, 144 and cable 146 are also configured to move at least one of the first jaw and the second jaw (upper shell portion 22) from the first configuration (open) to the second configuration (closed) such that the first jaw and the second jaw are in alignment. *Id.*; *see also* Ground 3, elements [4.1]. Specifically, rotation of bevel gear 140 rotates drive pulley 142, which advances cable 146, which rotates drive pulley 152, which rotates shaft 148, which moves the combination of nut 154, arm 156, pin 158, and lift arm 160. *Id.* Thus, "upper shell portion 22 … rotate[s] towards [and into alignment with] lower shell portion 24 … in response to rotation of capsule open/close control knob 38." *Id.*

[4.5] a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion,

McGuckin discloses this limitation. Knodel, ¶168. McGuckin discloses a staple pusher (staple support block 168) configured to cause a staple (104) to move from a first position (shown in Figures 23-24) at least partially (completely) within the staple carrying portion to a second position (shown in Figure 24) entirely outside the staple carrying portion. *Id*., McGuckin, 21:8-24:25, Figs. 23-24. The first and second positions shown below are representative of the first and second positions of each staple. *Id*.

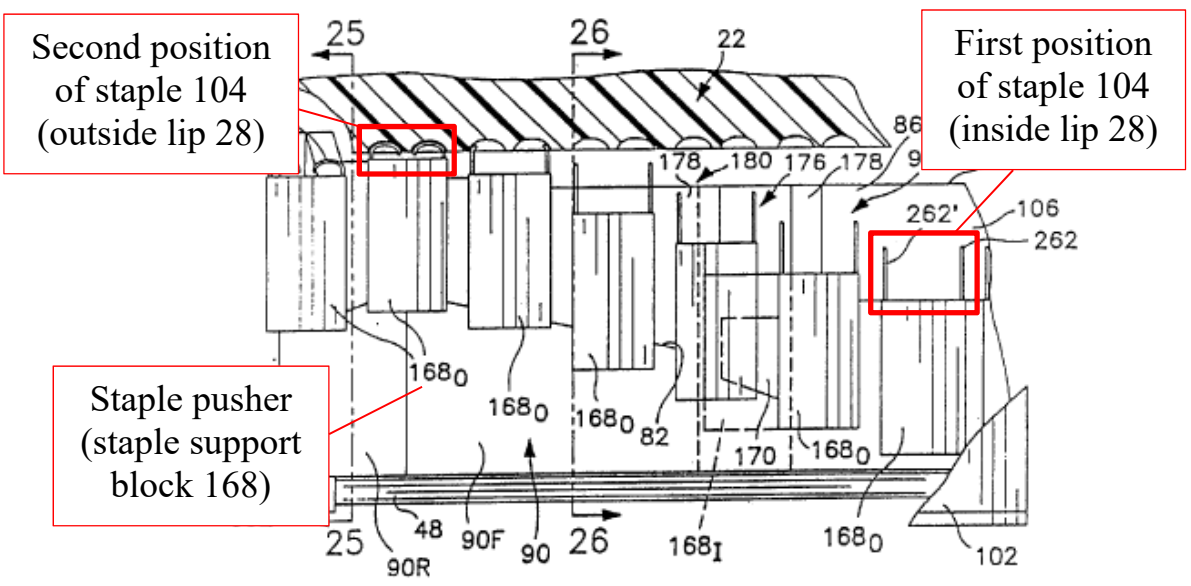


FIG. 24

[4.6] the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location.

McGuckin in view of Green-695 discloses this limitation. Knodel, ¶¶169-

72. It would have been obvious in view of Green-695 to modify: (1) McGuckin's knife portion 76 to include the upper portion of an I-beam; and (2) McGuckin's first and second jaws to include an internal passageway and an opening. *Id*. A POSITA would have been motivated to make these modifications with a reasonable expectation of success for the same reasons they would have modified Green-209 with a reasonable expectation of success. *Id*.; *see also* Ground 1.

An example of a resulting knife-ramp assembly ("the McGuckin/Green-695 beam") is shown below in the composite images of McGuckin, Figures 24 and 25 and Green-695, Figures 4 and 7. In this example, Green-695's upper shoe 56 (highlighted yellow) is mounted to the top of McGuckin's knife-ramp assembly 50 (highlighted blue) and engages a passageway formed in upper shell portion 22. Similarly, the lower portion of the modified knife-ramp assembly engages a passageway formed in lip portion 28 of lower shell portion 24. And the tissue-contacting surfaces of the first and second jaws each define a channel (highlighted green) that permits passage of the central web and knife of the beam. As shown below, the McGuckin/Green-695 beam is configured to engage the first and second jaws from within the jaws while tissue is stapled. Knodel, ¶170.

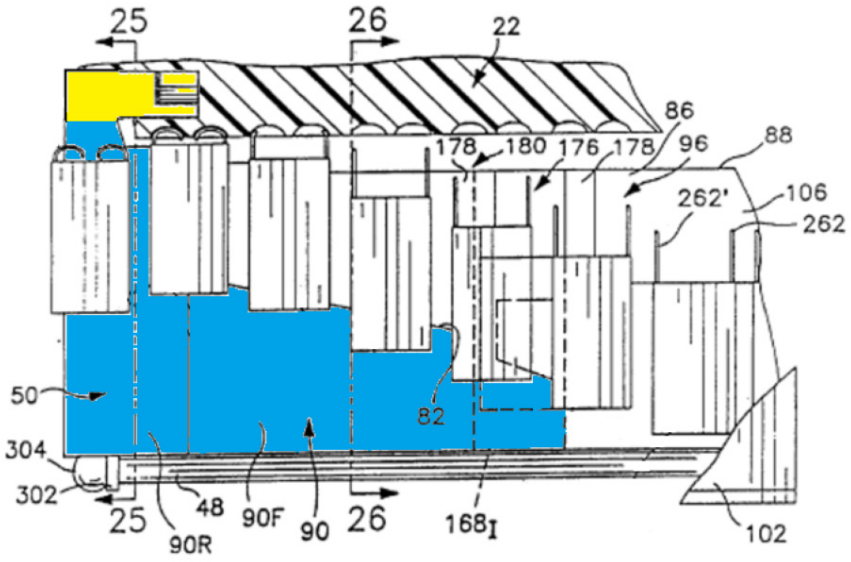


FIG. 24

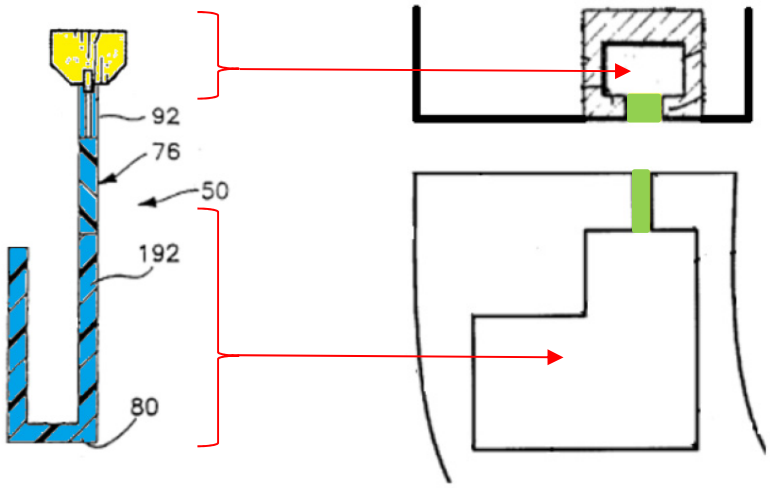
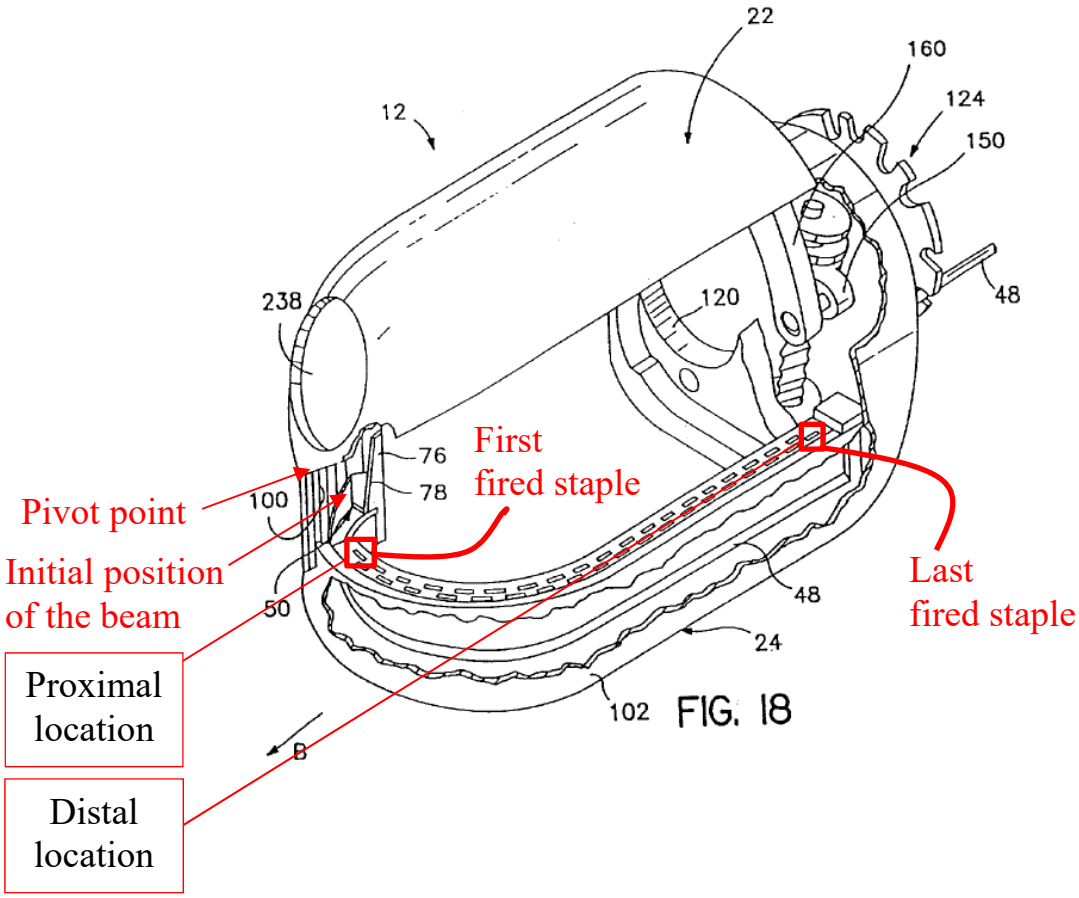


FIG. 25

The McGuckin/Green-695 beam also engages the jaws while tissue is stapled from a proximal location to a distal location. *Id.*, ¶¶171-75; *see also* McGuckin, Fig. 31. For example, relative to the jaw's pivot point and/or the initial

position of the beam, the locations of tissue fastened by the first fired staple and any subsequently fired staple (*e.g.*, the last fired staple) are proximal and distal locations, respectively. *Id.*, ¶172; McGuckin, Figs. 15, 18, 28, 30-31.



Similarly, relative to the handle assembly, the locations of tissue fastened by the inner row's first fired staple and the outer row's third fired staple are proximal and distal locations, respectively. Knodel, ¶171; *see also* McGuckin, 14:48-57 (confirming the beam need not move along the entire range of travel), Figs. 15, 18, 28, 30-31. Tissue in the curved portion is also stapled from the proximal inner row to the distal outer row. *Id.*

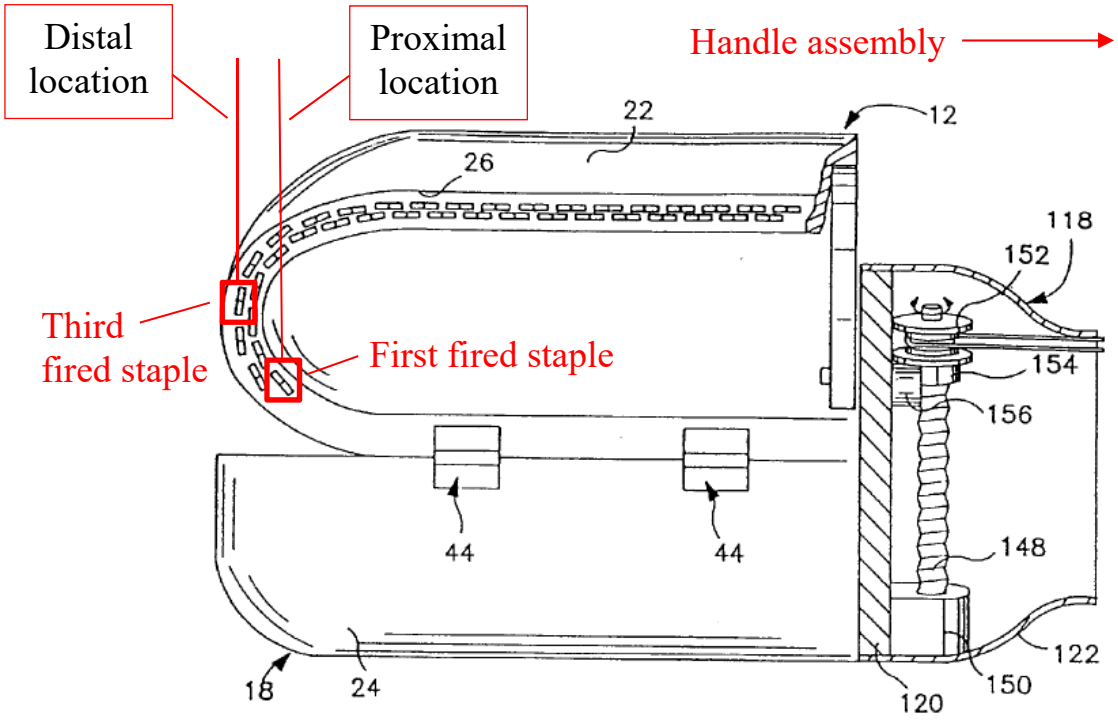


Fig. 15

Furthermore, if the claimed proximal and distal locations must be (1) relative to the handle assembly, and (2) at the beginning and end of the entire firing stroke, respectively, then it would have been obvious in view of Green-695 to move the beam in the opposite direction. Knodel, ¶¶173-75. Indeed, McGuckin confirms that it is "not limited to any particular or specific direction … of the incision." McGuckin, 3:35-40; *see also* 1:33-34. Moving the beam toward the pivot point could further limit deflection of the jaws at the end of the cutting stroke. Knodel, ¶173. And moving the beam in the opposite direction would have been the only other identified and predictable option. *Id.*; *KSR*, 550 U.S. at 421.

In the resulting the instrument, the claimed proximal and distal locations

would be the locations of tissue fastened by the first fired staple and any subsequently fired staple (*e.g.*, the last fired staple), respectively. *Id.*

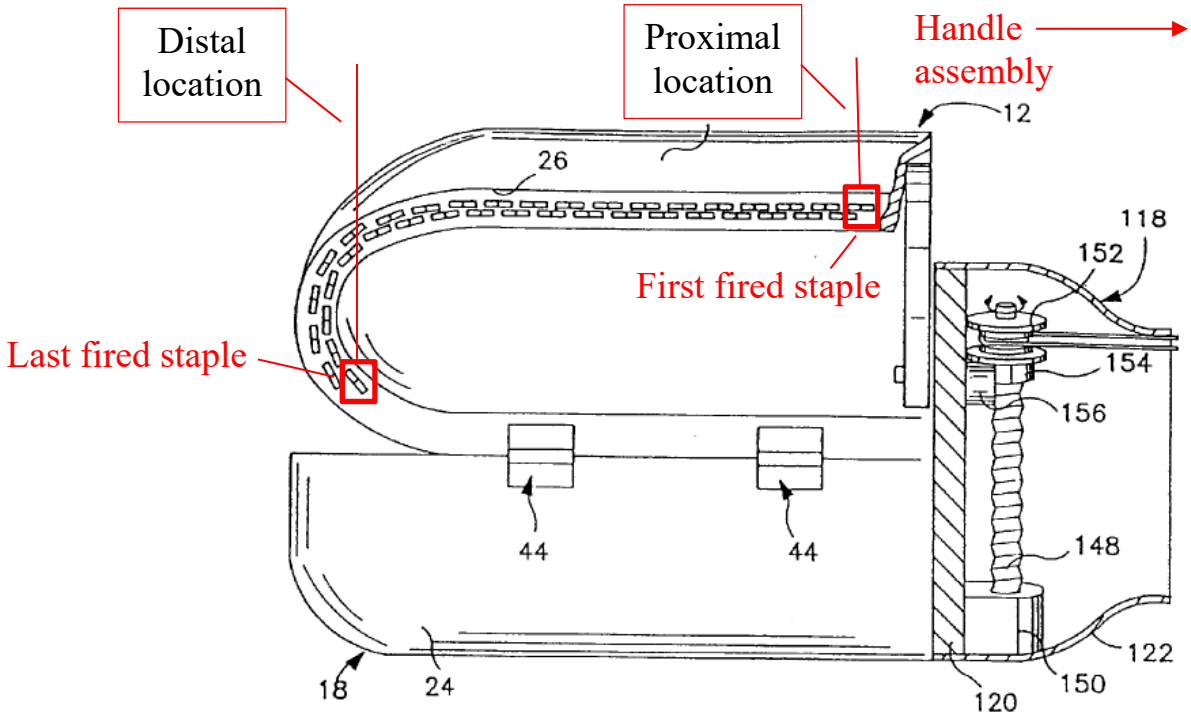


Fig. 15

A POSITA making this modification would have reasonably expected to succeed because it would have been merely the application of a known technique (moving the beam away from the handle assembly) with a known system (McGuckin's instrument) in the same field of endeavor (surgical staplers). *Id.*, ¶175; *KSR*, 550 U.S. at 417. McGuckin's instrument would have continued to perform the same predictable functions as it did separately (*e.g.*, cutting and stapling tissue). *Id.* And simply reversing the beam's direction of travel was well within a POSITA's skill. *Id.*

[5.0] The apparatus of claim 4, wherein the beam is configured to engage the first and second jaws one of entirely or substantially from therewithin to maintain the second distance and the alignment.

Although the scope of this term is unclear, the McGuckin/Green-695 stapler discloses this limitation. *See* Ground 3, element [4.6]; Knodel, ¶176; *see also* Ground 1, element [4.6]. Like the '650 patent's I-beam, the upper and lower portions of the McGuckin/Green-695 beam engage the first and second jaws entirely or substantially from therewithin to maintain the second distance and the alignment. *Id*. As shown in Ground 3, element [4.6], the lower portion of McGuckin's knife-ramp assembly 50 and Green-695's shoe 56 engage passageways formed within McGuckin's first and second jaws, respectively. *Id*.

[6.0] The apparatus of claim 5, wherein

See Ground 3, claim [5].

[6.1] the beam comprises an upper portion and a lower portion and a web coupled between the upper portion and the lower portion,

As shown in Ground 3, element [4.6], the McGuckin/Green-695 beam comprises an upper portion (Green-695's upper shoe 56) and a lower portion (McGuckin's horizontal base portion 80 and inclined staple advancing ramp portion 82) and a web (knife portion 76) coupled between the upper portion and the lower portion. Knodel, ¶¶178-79.

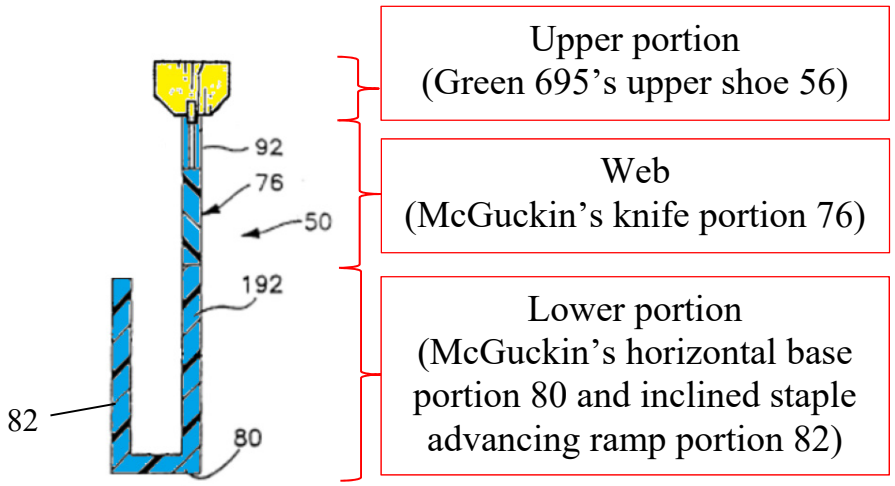


FIG. 25

[6.2] at least one of the lower portion or the upper portion configured to cause the staple pusher to move a staple as the beam moves from a proximal location to a distal location,

The McGuckin/Green-695 stapler discloses this limitation. Knodel, ¶180. The lower portion of the McGuckin/Green-695 beam (highlighted yellow) is configured to cause the staple pusher (168) to move a staple (104) as the beam moves from a proximal location to a distal location. *Id.*; McGuckin, 21:8-24:25, Figs. 18-26. The proximal and distal locations of the beam correspond to the proximal and distal locations where tissue is stapled, which are discussed above in Ground 3, element [4.6]. *Id.*

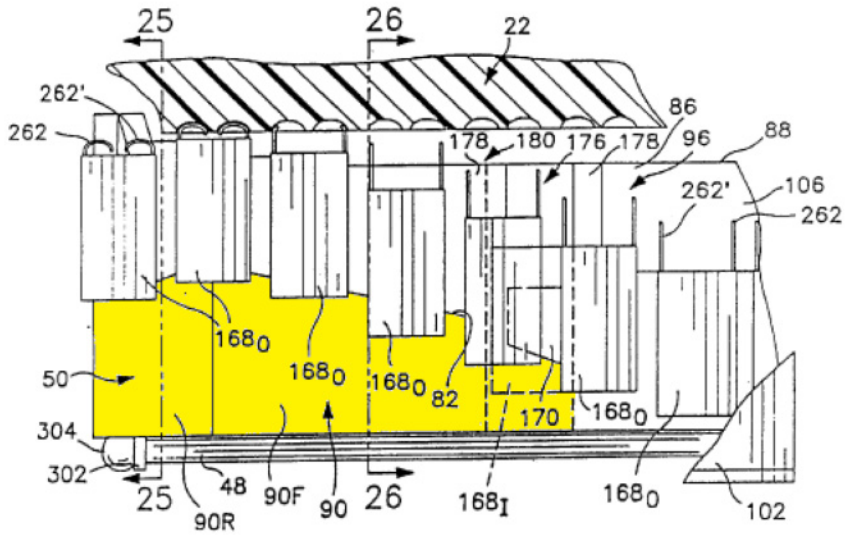


FIG. 24

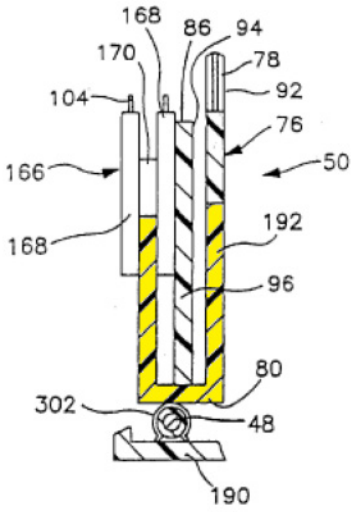


FIG. 25

[6.3] the upper portion and the lower portion configured to cooperatively engage the first jaw and the second jaw to align the slots with a staple forming portion on the anvil surface.

See Ground 3, element [4.6] (confirming the upper and lower portions are configured to cooperatively engage and align the jaws). Like Green-695's I-beam, the McGuckin/Green-695 beam also maintains the alignment of the slots with a staple forming portion (anvil surfaces 260) on the anvil surface. Knodel, ¶181; McGuckin, 23:53-24:25, Fig. 26.

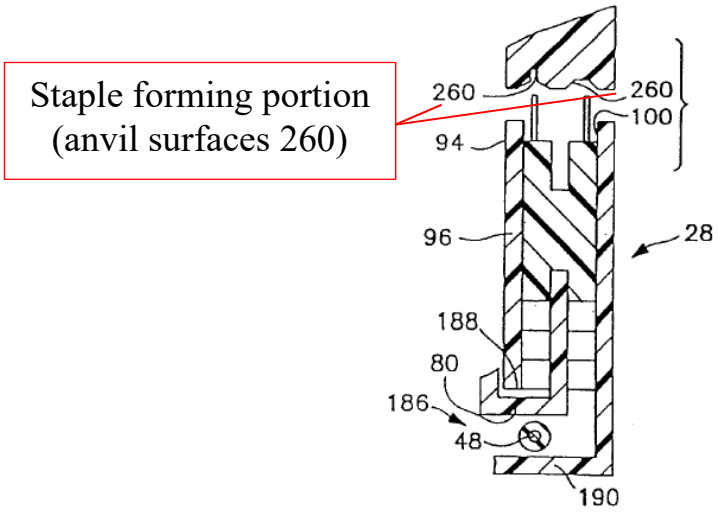


FIG. 26

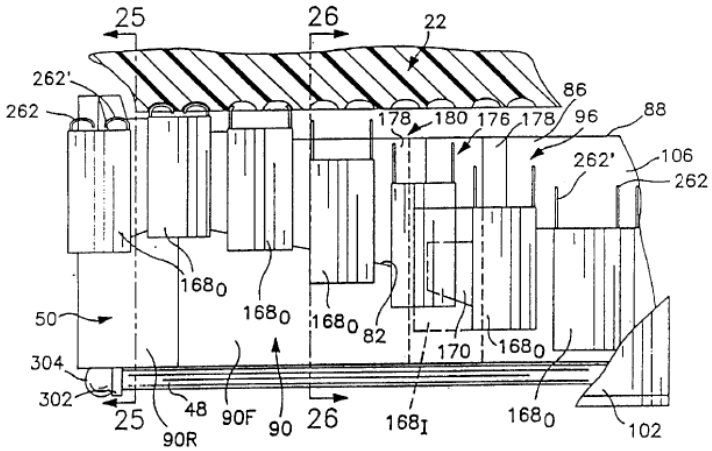


FIG. 24

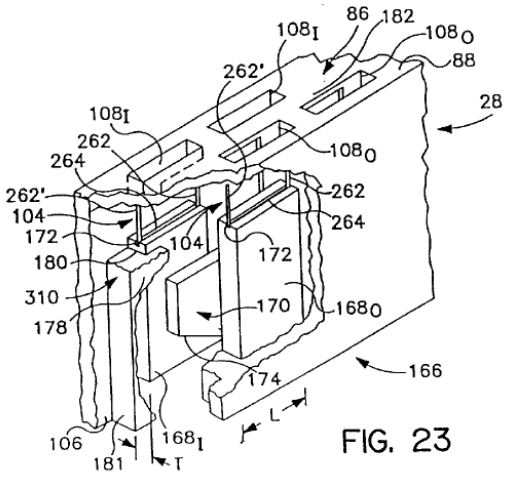


FIG. 23

[7.0] The apparatus of claim 6, further comprising a cutting blade on the web.

The McGuckin/Green-695 stapler discloses this limitation. Knodel, ¶182. The McGuckin/Green-695 stapler's beam includes a cutting blade (tissue cutting edge 78) on the web. *Id.*; McGuckin, 18:66-19:1, Fig. 25.

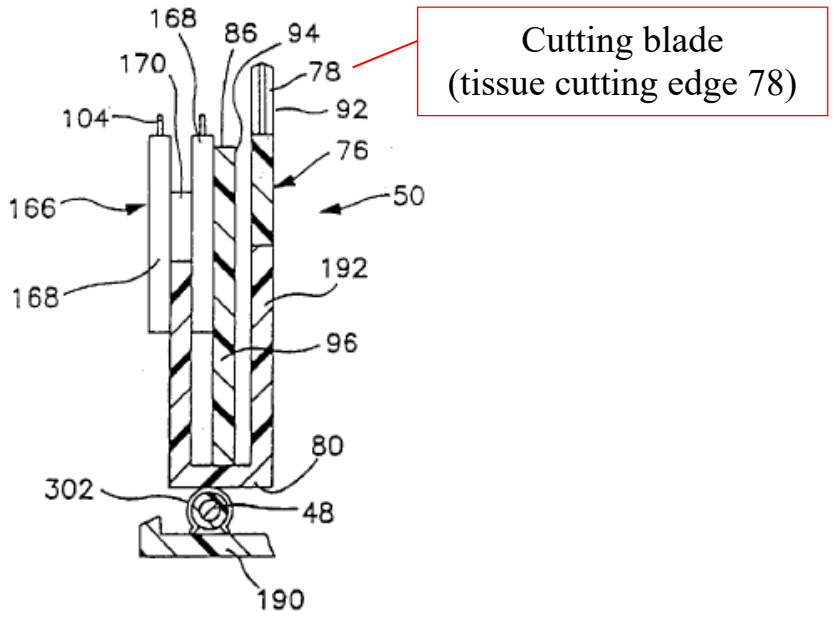


FIG. 25

[8.0] The apparatus of claim 5, wherein the beam is configured as a cutting blade.

See Ground 3, claim [7].

[9.0] The apparatus of claim 4, wherein the first jaw and the second jaw are pivotably coupled at a pivot point, a portion of the first jaw defining a flange that extends past a surface of the second jaw when the first jaw and second jaw are in the first configuration and the second configuration.

McGuckin discloses this limitation. Knodel, ¶184. McGuckin's jaws are pivotably coupled at a pivot point (hinges 44). *Id*.; McGuckin, 13:23-29, 16:42-67, Figs. 15, 30. Furthermore, a portion of the first jaw defines a flange (bulkhead 120) that extends past a surface (highlighted blue) of the second jaw when the first jaw and second jaw are in the first configuration (shown below) and the second configuration. *Id*.

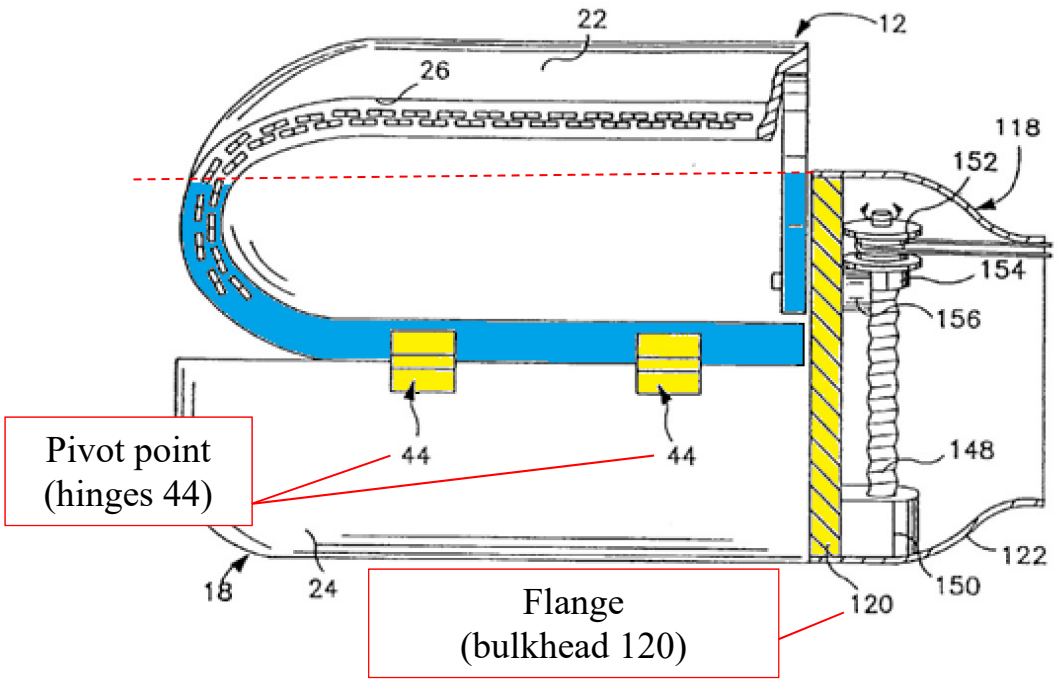
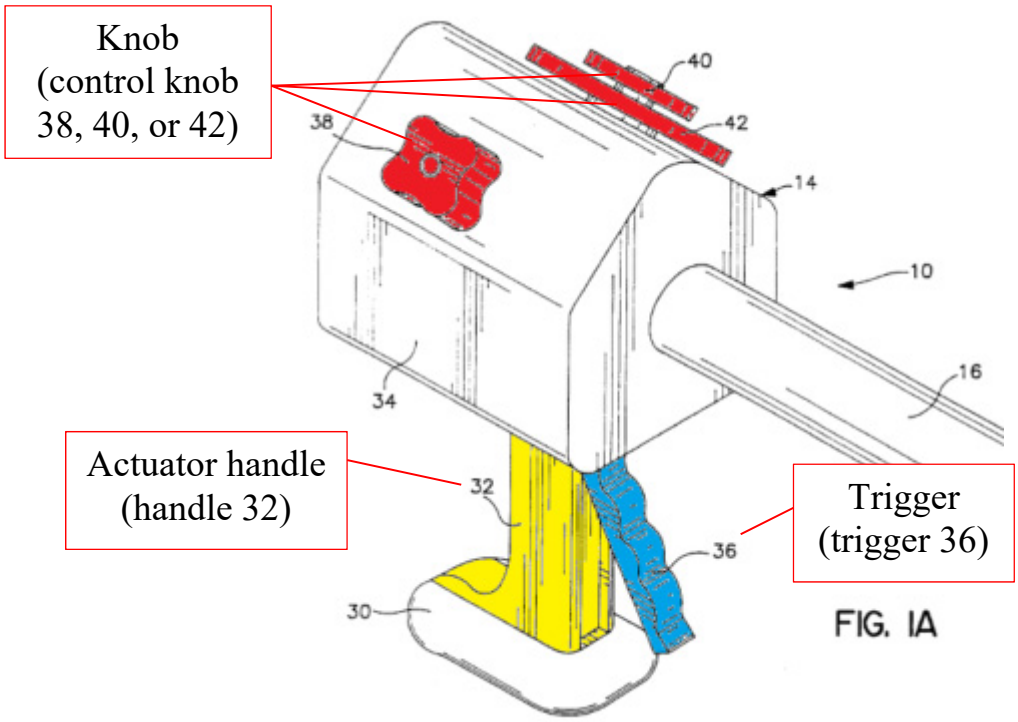


Fig. 15

[10.0] The apparatus of claim 4, further comprising one or more actuators including at least one of an actuator handle, a lever, a trigger, a knob or a cable.

McGuckin discloses this limitation. Knodel, ¶185. McGuckin discloses one or more actuators including at least one of an actuator handle (32, highlighted yellow), a trigger (36, highlighted blue), a knob (*e.g.*, control knob 38, 40, or 42, highlighted red), and a cable (*e.g.*, cables 48, 116, 134, and 146, not shown below). *Id.*; McGuckin, 13:41-56, Figs. 1A, 2, 10, 13, 16-17.



[11.0] The apparatus of claim 4, wherein at least a portion of the apparatus is powered.

McGuckin discloses this limitation. Knodel, ¶186. McGuckin discloses a portion of the apparatus ("the open/close mechanism") can be powered by "electric or hydraulic motors." *Id.*; McGuckin, 18:58-65.

[12] The apparatus of claim 4, wherein at least a portion of the first jaw and the second jaw is curved.

McGuckin discloses this limitation. Knodel, ¶187. At least a portion (the distal end) of the first jaw and the second jaw is curved. *Id.*; McGuckin, 4:66-5:4, 11:67-12:3, Fig. 15, Claim 1.

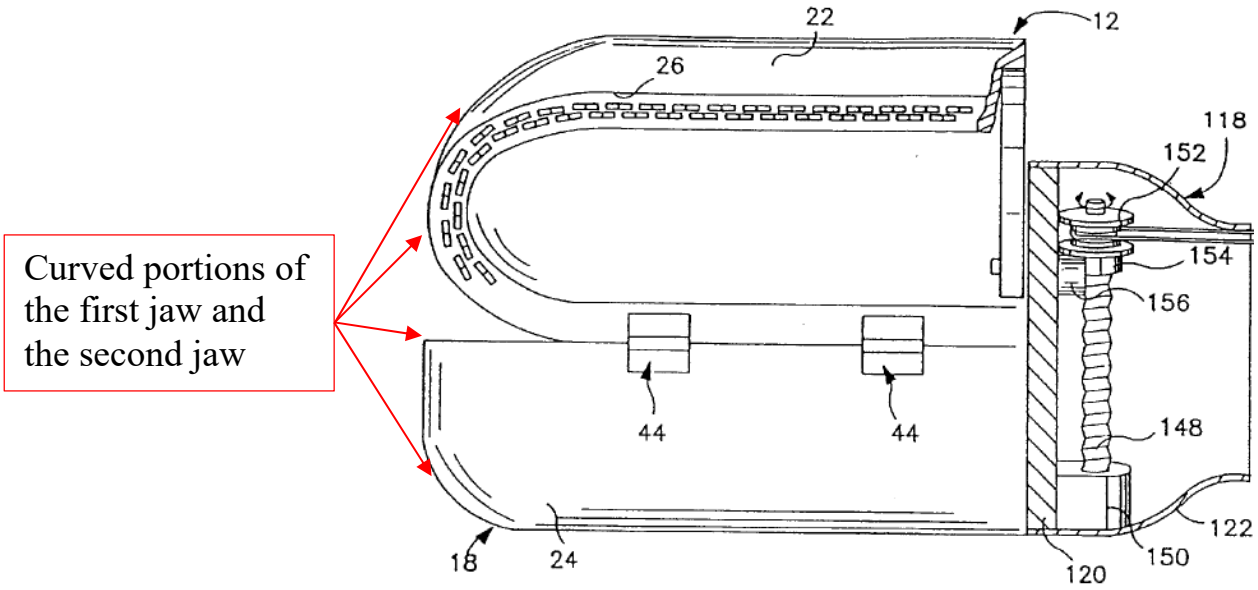


Fig. 15

[13.0] An apparatus, comprising:

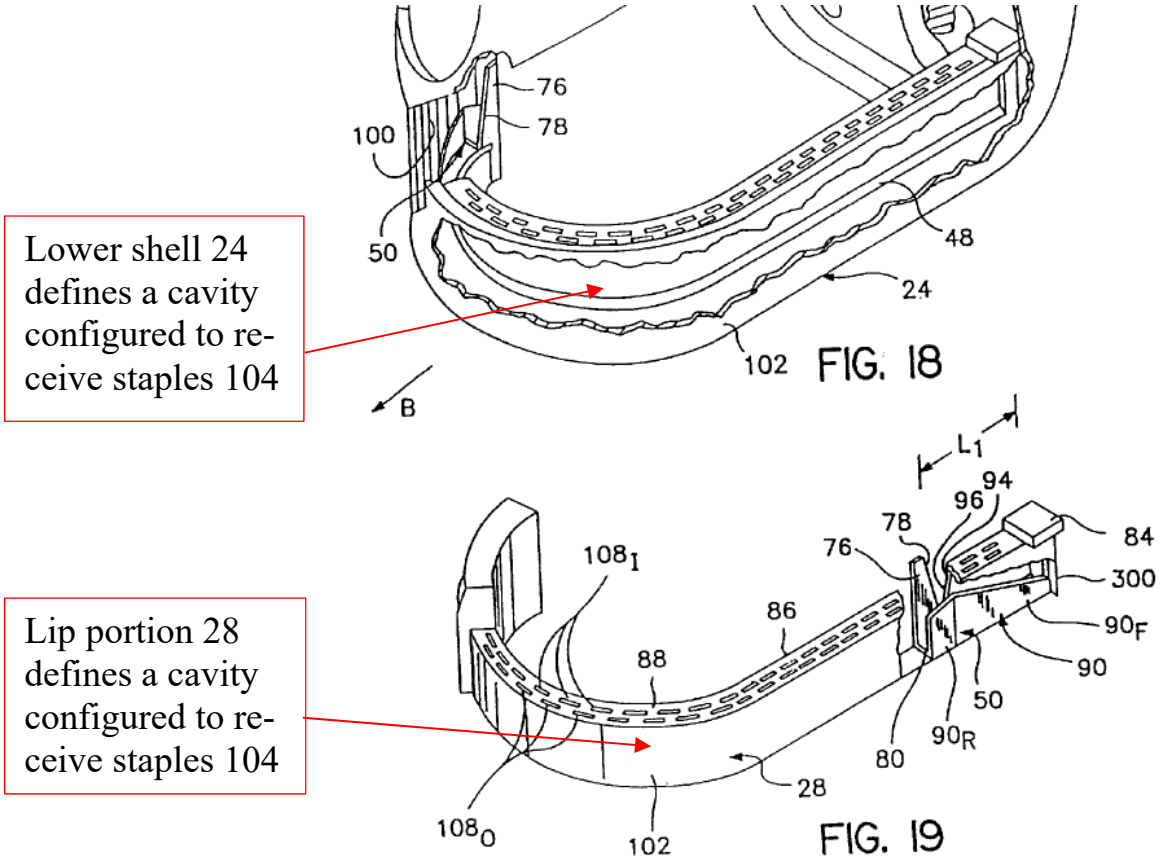
See Ground 3, element [4.0].

[13.1] a head portion having a first jaw and a second jaw configured to move between a first configuration for receiving tissue and a second configuration for stapling tissue,

See Ground 3, elements [4.1]-[4.2]. McGuckin's jaws form a head portion. *Id.*; Knodel, ¶189. The first configuration (open) is for receiving tissue and the second configuration (closed) is for stapling tissue. *Id.*

[13.1.1] the first jaw defining a cavity configured to receive a plurality of staples and a plurality of slots configured to pass staples therethrough;

See Ground 3, elements [4.1]-[4.2] (confirming the first jaw has a plurality of slots through which staples pass during the stapling operation). The first jaw also defines a cavity (shown below) configured to receive a plurality of staples (104). McGuckin, 19:35-24:25, Figs. 18-19, 23-26; Knodel, ¶190.



[13.1.2] the second jaw having a staple-forming surface; and

See Ground 3, element [4.3].

[13.2] a beam whose opposite end portions are connected by a central web portion and are configured to clamp and align the first and second jaws from therewithin when in the second configuration as the beam moves distally along a channel defined in a tissue contacting surface of each of the first and second jaws; and

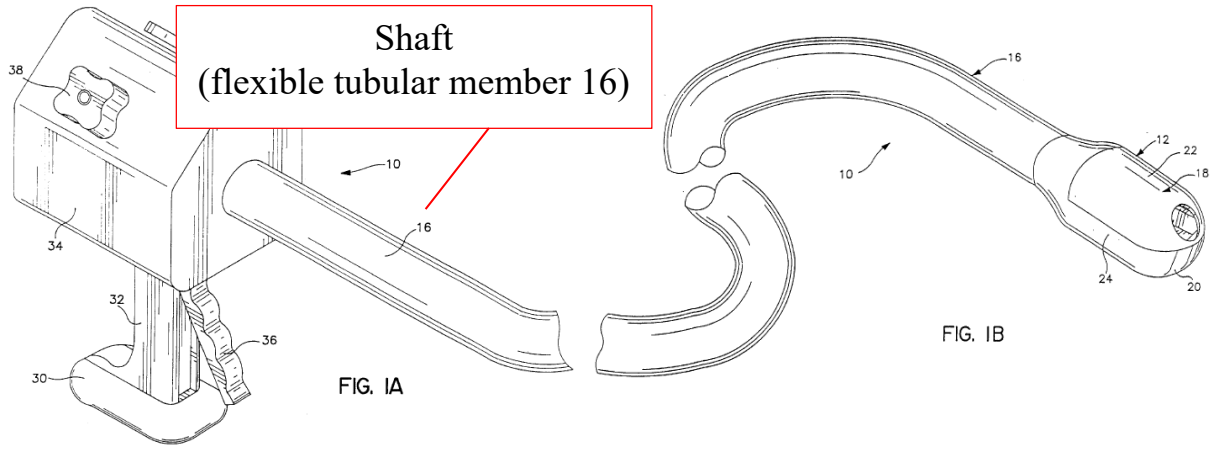
See Ground 3, element [4.6], element [6.1].

[13.3] a control handle configured to actuate receiving, clamping and stapling of tissue, and

See Ground 3, claim [10]; Knodel, ¶193; McGuckin, 13:41-56, Fig. 31.

[13.4] a shaft coupling the control handle to the head portion.

McGuckin discloses this limitation. Knodel, ¶194. McGuckin discloses a shaft (flexible tubular member 16) coupling the control handle to the head portion. *Id.*; McGuckin, 13:57-64, Figs. 1A-B.



[14.0] The apparatus of claim 13, wherein: the beam is configured to enable at least one of firing staples and cutting tissue.

See Ground 3, element [6.2], element [7].

[15.0] The apparatus of claim 13, wherein the slots through which staples are passed are arranged in a first row extending from a proximal end of the first jaw to a distal end thereof such that two or more staples are fired in a row orthogonal to a direction of movement of the beam one of simultaneously or serially.

McGuckin discloses this limitation. Knodel, ¶¶196-202. The slots through which staples are passed are arranged in a first row (highlighted below) extending from a proximal end of the first jaw to a distal end thereof such that two or more staples are fired in a row (identified below) orthogonal to a direction of movement of the beam (identified below) one of simultaneously or serially (each staple in the

row orthogonal to the direction of movement of the beam is fired serially). *Id.*, ¶196; McGuckin, 21:57-67, Figs. 18-19, 30-31.

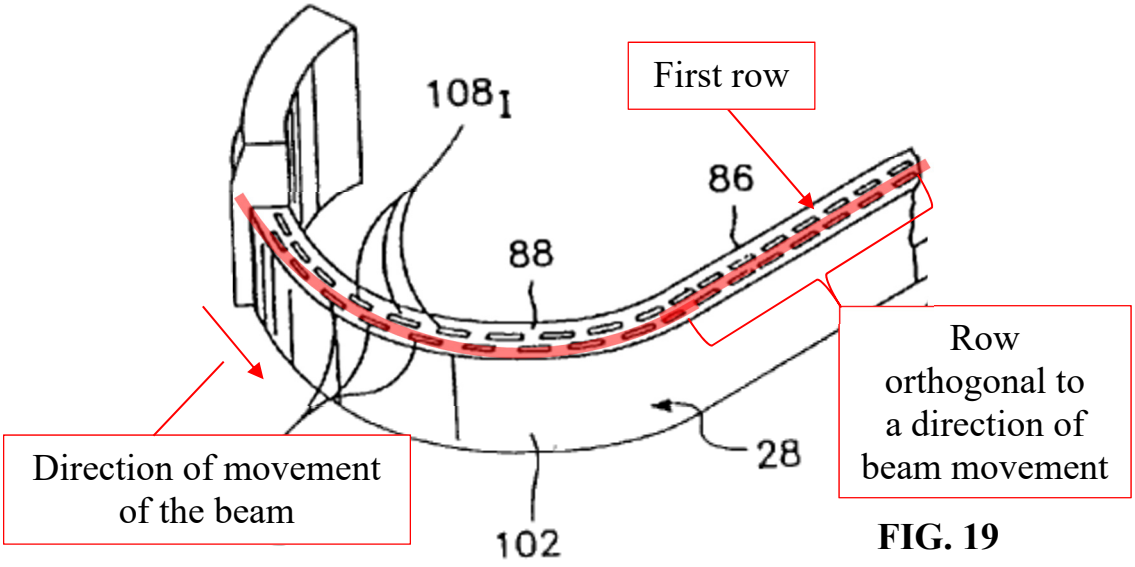


FIG. 19

The proximal and distal ends of the first jaw relative to the handle assembly are shown below. Knodel, ¶197; McGuckin, Fig. 15.

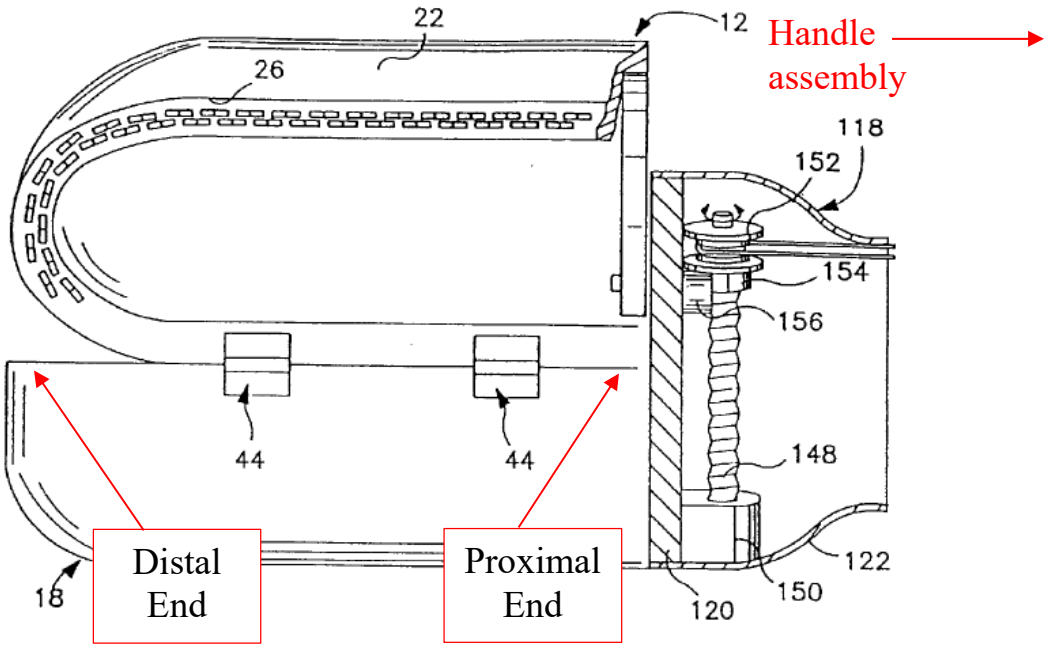
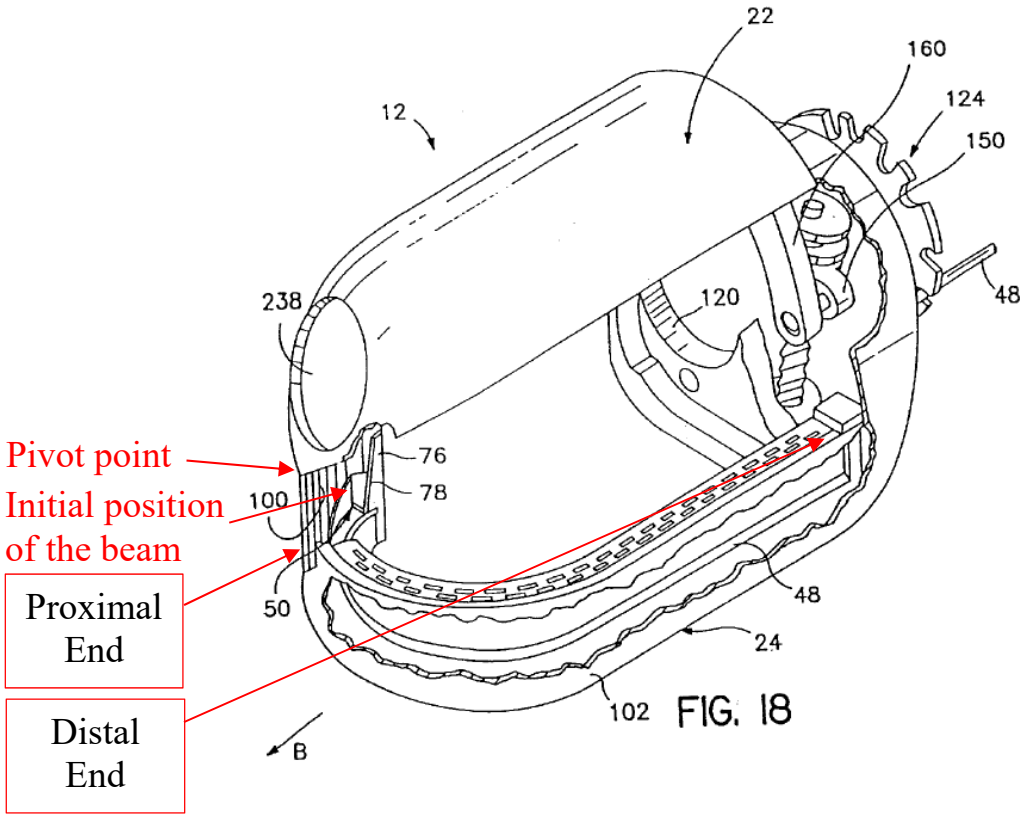


Fig. 15

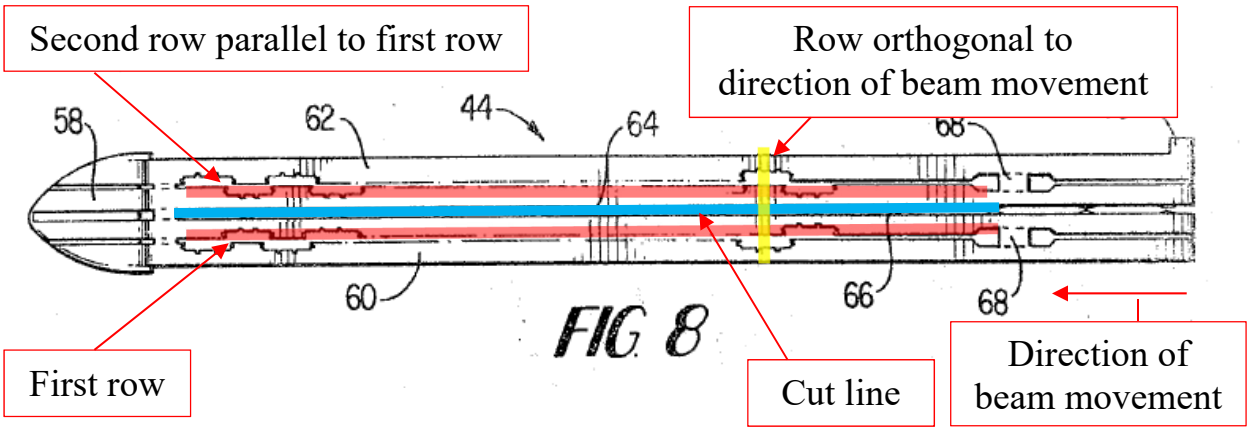
The proximal and distal ends of the first jaw relative to the pivot point and initial position of the beam are shown below. Knodel, ¶198, McGuckin, Fig. 18.



Furthermore, it would have been obvious in view of Green-695 to apply at least two rows of staples on each side of McGuckin's knife (presently, McGuckin applies staples only to one side of its knife) and therefore to cut tissue between a first row of staples on one side of the knife and a second row of staples on the other side of the knife, upon firing of one or more staples through the slots. Knodel, ¶¶199-202.

Like McGuckin, Green-695 discloses a "pusher bar and knife assembly … which is moved longitudinally along the jaws to sequentially eject staples …

thereby forming laterally spaced lines of staples in tissue gripped between the jaws." Green-695, 1:18-31. In Green-695, however, "the knife … cuts the tissue along a line [highlighted blue] between the staple rows." *Id*. And two or more staples are fired in a row (highlighted yellow) orthogonal to a direction of movement of the beam one of simultaneously or serially. Knodel, ¶200.



A POSITA would have been motivated to make this modification for several reasons. For example, Green-695 notes, and a POSITA would have understood, that such an arrangement was "typical" in the prior art because it minimizes contamination of surrounding healthy tissue by the malignant, diseased, or otherwise undesirable tissue resected with the knife. *See, e.g.*, Green-695, 1:8-31; Knodel, ¶201; *see also* Green-209, 1:26-61, 15:63-67, Figs. 17-18; Rothfuss, 1:37-45, 2:4-25, Figs. 5-8; Tsuruta, 8:39-42, 10:40-57, Fig. 2. Moreover, there were a finite number of identified and predictable solutions (*e.g.*, cutting tissue on either side of the rows or between the rows). *Id.*; *KSR*, 550 U.S. at 421.

A POSITA making this modification would have reasonably expected to succeed because it would have been merely the application of a known technique (applying rows of staples on both sides of a cut line) with a known system (McGuckin's instrument) in the same field of endeavor (surgical staplers). Knodel, ¶202; *KSR*, 550 U.S. at 417. The additional rows of staples perform the same predictable function (fastening tissue) as they do separately without significantly altering or hindering the functions performed by McGuckin's instrument (*e.g.*, cutting and stapling). Knodel, ¶202. Furthermore, the task of adding the stapling structures on the outside of McGuckin's knife to the inside of McGuckin's knife was well within the level of skill in the art. *Id*.

[16.0] The apparatus of claim 15, wherein additional slots are arranged in a second row substantially parallel to the first row of slots.

See Ground 3, claim [15] (McGuckin discloses slots arranged in a first row). Additional slots are arranged in a second row substantially parallel to the first row of slots. Knodel, ¶203; McGuckin, 21:57-67, Figs. 15, 18-19, 23.

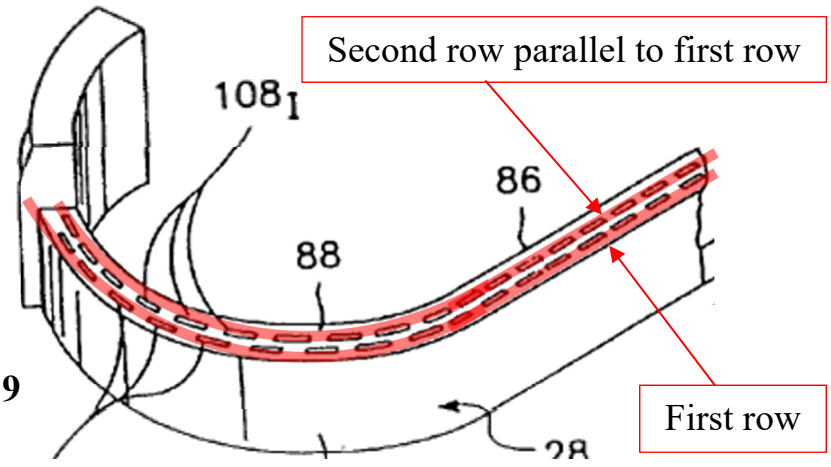


FIG. 19

[17.0] The apparatus of claim 13, wherein the head portion is one of fixedly coupled or movably coupled to the shaft.

McGuckin discloses this limitation. Knodel, ¶204. McGuckin's head portion is movably coupled to the shaft because upper shell 22 is coupled such that it can rotate relative to the shaft and lower shell 24. *Id*.; Ground 3, element [4.1]. McGuckin's head portion is also movably coupled to the shaft for left/right and up/down articulation. Knodel, ¶204; McGuckin, 15:7-16:33, Figs. 3-6.

[18.0] The apparatus of claim 13, wherein tissue is cut between the first row and the second row upon firing of one or more staples through the slots.

Although the scope of this claim is unclear, McGuckin in view of Green-695 discloses this limitation. *See* Ground 3, claim [15]. Upon firing the staples through the slots, McGuckin's knife cuts the stapled tissue between first and second rows. *Id*.

[19.0] The apparatus of claim 13, wherein one of the opposite end portions of the beam is configured to enable firing of the plurality of staples.

See Ground 3, element [6.2].

[20.0] The apparatus of claim 13, wherein the beam includes a cutting blade and is configured to clamp and align the first and second jaws one of entirely or substantially from therewithin.

See Ground 3, element [4.6], claim [14].

[21.0] The apparatus of claim 13, wherein one end portion of the beam is configured to cause one or more staple pushers to be pushed for firing the plurality of staples as the beam travels towards a distal end of the head portion.

See Ground 3, element [6.2].

[22.0] The apparatus of claim 13, wherein the control handle includes at least one of an actuation handle, a lever, a trigger, a knob and a cable.

See Ground 3, claim [10].

[23.0] The apparatus of claim 13, wherein at least a portion of the apparatus is powered.

See Ground 3, claim [11].

[24.0] The apparatus of claim 23, wherein the apparatus is powered electrically, hydraulically or pneumatically.

See Ground 3, claims [11], [23].

IX. CONCLUSION

Claims 4-24 of the '650 patent are unpatentable pursuant to the grounds presented in this Petition. Accordingly, Petitioner respectfully requests *Inter Partes* Review of these claims.

Respectfully submitted,

Dated: Nov. 19, 2019

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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 13,893 words, which is less than the 14,000 allowed under 37 C.F.R. § 42.24.

Dated: Nov. 19, 2019

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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 November 19, 2019, 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:

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