IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	McGuckin, Jr. et al.	
U.S. Patent No.:	10,136,892	Attorney Docket No.: 11030-0061IP1
Issue Date:	November 27, 2018	
Appl. Serial No.:	15/617,835	
Filing Date:	June 8, 2017	
Title:	APPARATUS AND METHOD FOR RESECTIONING GASTRO-ESOPHAGEAL TISSUE	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 10,136,892 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Pat. No. 10,136,892 to McGuckin Jr. et al. ("the '892 patent")
IS1002	File history of the '892 Patent ("File History")
IS1003	Declaration of Dr. Bryan Knodel for the '892 Patent ("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	Reserved
IS1008	Reserved
IS1009	U.S. Pat. No. 5,507,426 to Young et al. ("Young")
IS1010	Reserved
IS1011	U.S. Pat. No. 5,865,361 to Milliman et al. ("Milliman")
IS1012	Reserved
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IS1015	U.S. Pat. No. 5,312,023 to Green et al. ("Green 023")
IS1016	American Heritage Dictionary of the English Language, 3rd Ed. 2000 ("American Heritage Dictionary")
IS1017	U.S. Patent No. 5,647,526 to Green et al. ("Green 526")

I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1-15 of U.S. Pat. No. 10,136,892 ("the '892 patent"), entitled "Apparatus and Method for Resectioning Gastro-Esophageal Tissue." The '892 patent generally relates to a hand-held 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" (emphasis added throughout unless otherwise specified). However, such a beam was well-known in the surgical stapler prior art at the time of the alleged invention. Had the Examiner been aware of the relevant prior art, and, in particular, the secondary 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 '892 patent. The '892 patent and U.S. Pat. No. 9,439,650,

which is the great-grandparent of the '892 patent, are the subject of Civil Action No. 1:19-cv-00005-MN filed on January 2, 2019 against Intuitive Surgical, Inc. et al. and Civil Action No.1:19-cv-01092-MN filed on June 13, 2019 against Medtronic PLC et al., both in the United States District Court for the District of Delaware. Petitioner filed an *Inter Partes* Review petition against the '650 Patent on November 19, 2019 in IPR2020-00152. Pending U.S. Pat. App. No. 16/185,506 claims priority to U.S. Pat. App. No. 15/617,835—the application from which the '892 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 IPR11030-0061IP1@fr.com (referencing No. 11030-0061IP1 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 '892 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

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

Petitioner requests an IPR of claims 1-15 of the '892 Patent on the grounds listed below. A declaration from Dr. Bryan Knodel is included in support.

Ground	Claims	Basis for Rejection
Ground 1A	**1-15**	Obvious over **Young (USP 5,507,426)** (IS1009) in view of **Milliman (USP 5,865,361)** (IS1011) under pre-AIA 35 U.S.C. § 103
Ground 1B	**1-3, 5-15**	Obvious over **Young** in view of **Green 695 (USP 4,429,695)** (IS1005) under pre-AIA 35 U.S.C. § 103
Ground 2	**4**	Obvious over **Young** in view of **Green 695** and **Knodel 895 (USP 5,465,895)** (IS1006) under pre-AIA 35 U.S.C. § 103
Ground 3	**1-15**	Obvious over **Green 209 (USP 5,645,209)** (IS1004) in view of **Green 695** and **Alesi (USP 5,779,130)** (IS1014) under pre-AIA 35 U.S.C. § 103

The '892 patent issued from U.S. App. No. 15/617,835, filed on June 8, 2017, which is a continuation of U.S. App. No. 15/475,438, which is a

continuation of U.S. App. No. 15/241,659, filed on August 19, 2016, which is a continuation of U.S. App. No. 15/018,000, filed on February 8, 2016, now U.S. Pat. No. 9,439,650, which is a continuation of U.S. App. No. 13/856,819, filed on April 4, 2013, now U.S. Pat. No. 9,271,727, which is a continuation of U.S. App. No. 11/471,126, filed on June 20, 2006, now U.S. Pat. No. 8,424,741, which is a continuation of U.S. App. No. 10/855,908, filed on May 27, 2004, now U.S. Pat. No. 7,090,684, which is a continuation of U.S. App. No. 10/062,760, filed on January 31, 2002, now U.S. Pat. No. 6,835,199, which claims priority to U.S. Prov. Pat. App. No. 60/265,469, filed on January 31, 2001. Thus, the earliest possible date to which the '892 patent could claim priority (hereinafter the "earliest possible effective filing date") is January 31, 2001.

Young, Milliman, Green 695, Green 209, Alesi, and Knodel 895 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.

Young and Knodel 895 were made of record during prosecution of the '892 Patent and were used as the basis for rejection of the original claims.

Green 209 and Green 695 were made of record during prosecution, but were not discussed by the Examiner or Applicant.

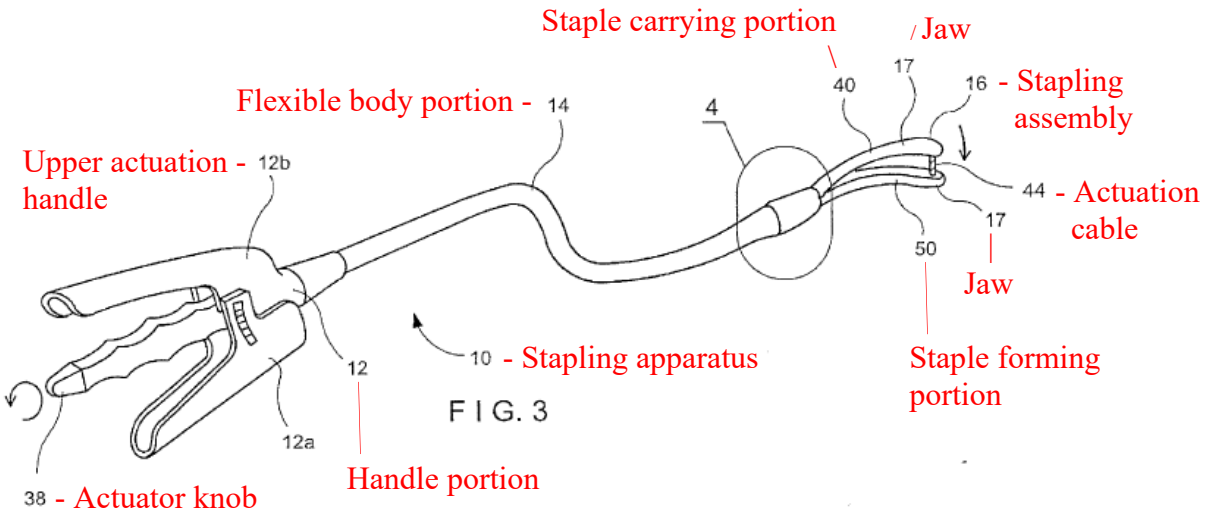
Milliman and Alesi were not made of record during prosecution of the '892

Patent.

Grounds 1A, 1B, and 2, which rely in part on Young, should be considered notwithstanding 35 U.S.C. § 325(d) because those grounds 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 Milliman or Green 695, as presented in Grounds 1A and 1B, respectively, and the Examiner likewise did not consider the combination presented in Ground 2. Ground 3 relies on references made of record, but not discussed by the Examiner, and therefore the Examiner did not rely on the specific combination of references, and did not consider the specific arguments presented in this Petition. S*ee 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 were substantially different).

V. SUMMARY OF THE '892 PATENT

The '892 patent is directed to a surgical stapling apparatus 10. '892 patent, Abstract, 1:62-2:13, Figs. 1-3.



F I G. 3

As shown above in Figure 3, "stapling 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.*, 3:63-67, 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" (i*d.*, 4:63-5:14), 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.*, 2:65-67, 4:63-67, 6:29-48, Fig. 13. In this context, "approximation" of the jaws is the act of bringing the jaws together (so they are proximate to one another). For a given control motion or signal, gross approximation is a relatively large movement whereas fine approximation is a much smaller movement of the jaws.

As shown below in Figure 13, "I-beam member 70 includes upper and lower

beam portions 82a, 82b, respectively, connected by a central web portion 84." *Id.*, 5:53-67, 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.*

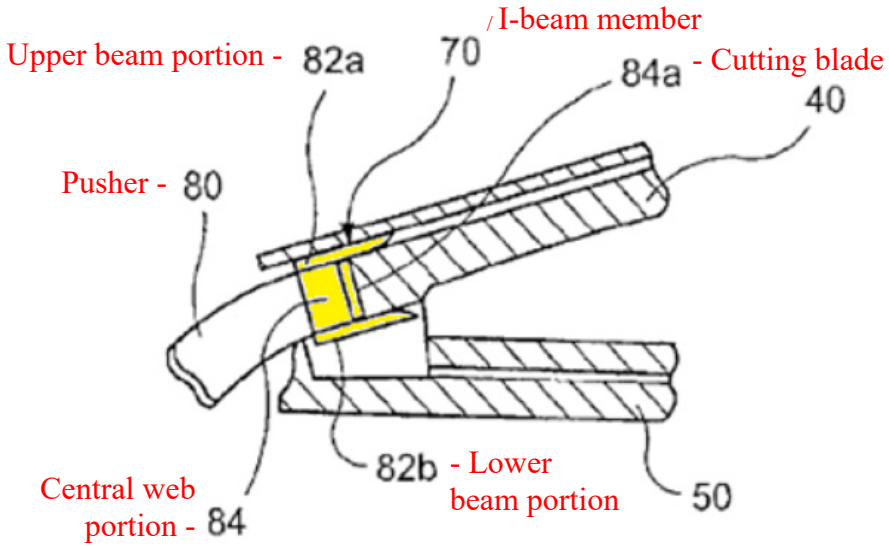


FIG. 13

As shown above in Figure 13 (and also in Figure 14), the "I-beam" has a cross section like the capital letter "I," similar to the cross section of a structural "I-beam" used in building construction. *Id.* During operation of the device shown in Figure 13, 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 travels in a channel in the upper jaw and the lower beam portion 82b travels in a channel in the lower jaw. *Id.* The distal movement of the I-beam results in the fine

approximation of the jaws, and the cutting of tissue and ejection of staples from the stapling apparatus. '892 Patent, 6:29-48. *See* Knodel,¶¶30-34.

VI. SUMMARY OF THE PROSECUTION HISTORY

Following a restriction requirement, Applicant elected to pursue application claims 21-50. IS1002, 114-115. However, claims 21-22, 25-47, and 49 were rejected as anticipated by Young (the primary reference used in Grounds 1A, 1B, and 2). Claims 23 and 48 were rejected as obvious over Young. And claims 24 and 50 were rejected as obvious over Young in view of Knodel 895. *Id*., 88-102.

In response to these rejections, Applicant amended application claim 21 (issued claim 1) to provide that "at least one of the upper beam portion and the lower beam portion … is configured to engage the first jaw or the second jaw ***entirely from within*** the first jaw or the second jaw for clamping and alignment." *Id*., 59-70 (emphasis original). Applicant similarly amended application claim 34 (issued claim 5) to provide that the upper and lower beam portions clamp and align "partially from within the first jaw and the second jaw." Applicant also added the requirement to both application claims 21 and 34 (issued claims 1 and 5) that the pusher and central web portion be "coplanar." *Id*. Applicant then argued that Young's beam did not engage the jaws from "**within**" the jaws and that Young's "pusher 58 … is not **coplanar** with the central web portion and the channel." IS1002, 68.

The Examiner subsequently allowed application claims 21-24 and 34-44, (issued claims 1-15) finding that Young disclosed a coplanar pusher, central web portion, and channel, but failed to disclose at least one of the upper beam portion and the lower beam portion engaging the "the first jaw or the second jaw **entirely from within**" the respective jaw. IS1002, 49-50 (emphasis added); *See* Knodel,¶¶35-37.

VII. CLAIM CONSTRUCTION

For purposes of this proceeding only, Petitioner submits that the following terms requires construction and the remaining terms in the challenged claims should be given their plain and ordinary meaning.

A. "the pusher and the central web portion are coplanar with a channel" (claim 1) and "the pusher is coplanar with the central web portion and the channel" (claim 5)

The '892 Patent describes "flexible pusher 80" that is coupled to the "central web portion 84" of "I-beam member 70" as depicted in FIGs. 13 and 14. '892 Patent, 5:49-52.

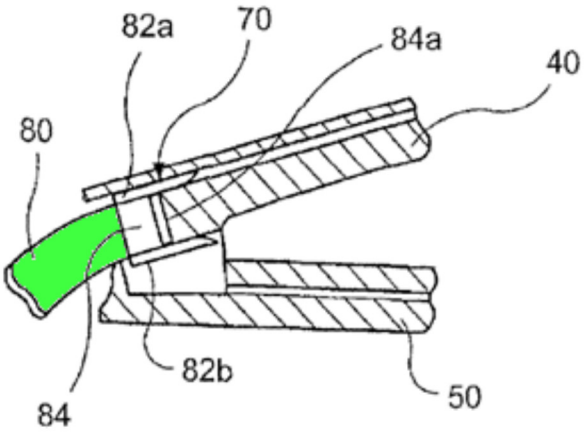


FIG. 13

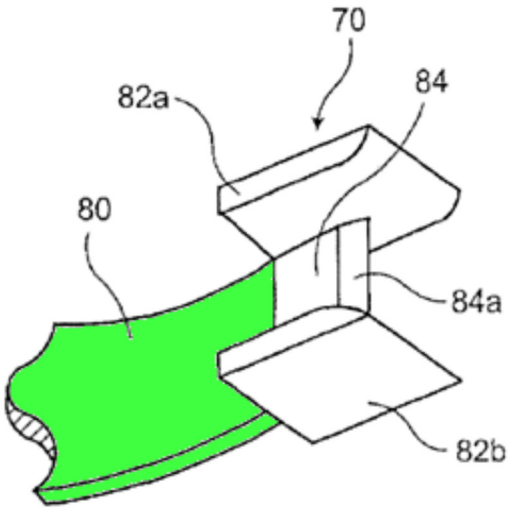
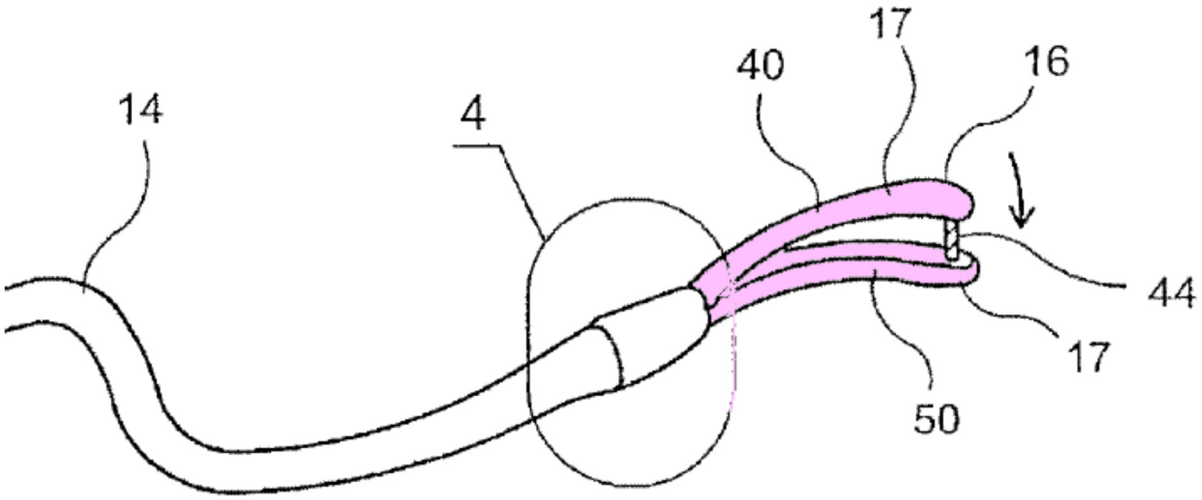


FIG. 14

As seen in Figure 13 and Figure 14, the flexible pusher 80 can bend so that the I-beam may move through a curved end effector, as depicted in, e.g., FIGS 2C, 3, 5, and 8, 11, 16, 19, and 20:



'892 Patent, FIG. 3 (excerpt).

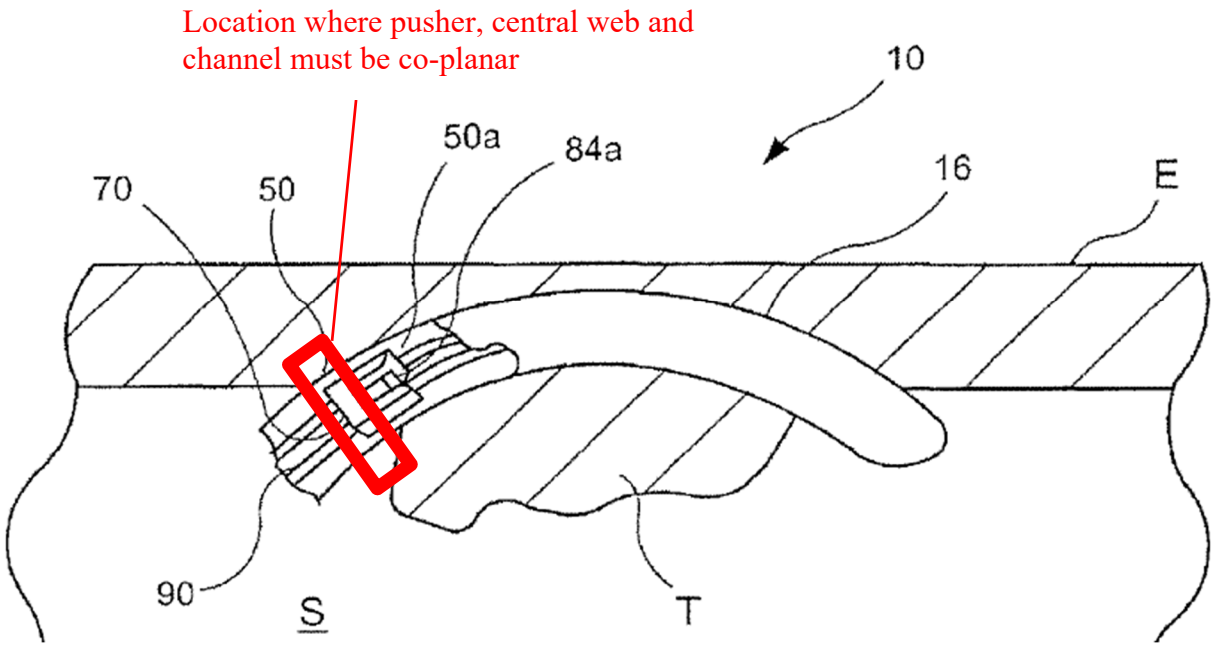
As can be seen in FIGs. 13 and 14, at the point where pusher 80 connects to the central web portion 84 of the I-beam, the pusher is flat and inline with the central web portion of the I-beam. That is, the central web portion 84 resides in a plane, and the pusher **at the connection point** is likewise flat and lies in the same plane. Thus, **at the connection point**, the pusher is co-planar with the central web portion 84 of I-beam 70. In fact, the '892 Patent does not even describe the entire pusher. Rather, only the distal portion of the pusher 80 is shown in FIGs. 13 and 14. The patent would thus not support a contruction requiring the entire pusher to be co-planar with another structure.

In addition, because the pusher is flexible so that it bends around curved end effectors, the entirety of the pusher cannot be "co-planar" with anything. Likewise the channel through which the central web portion moves is likewise depicted exclusively as a curved channel, and is thus not in its entirely "planar" nor "co-planar" with anything. "As shown in FIG. 11, an **arcuate** channel 90 within which the central web portion 84 travels . . . ." '892 Patent, 5:53-67. A "plane" is a "flat or level surface." American Heritage Dictionary, 1341. And two structures are "coplanar" if they are "lying or occurring in the same plane." Id. Thus, for two structures to be "co-planar," they must necessarily both be flat.

Accordingly, for the claims to make sense and have adequate written description, the phrase "the pusher and the central web portion are coplanar with a

channel" refers to the area of the channel, pusher, and central web portion where the pusher and central web portion are joined. This construction makes sense because the "co-planar" feature of the '892 Patent ensures that the pusher and central web portion are able to travel through the vertical channel through the center of the staple carrying portion 40.

This construction is also consistent with other language in the claim. The claim states that the "co-planar" aspect applies "when the beam moves distally." This suggests that the channel, pusher, and central web portion may not be co-planar at all times, but at discrete locations as the beam moves distally. If all three structures were "co-planar" all the time, then this temporal language would be superfluous. *Id.* Thus, the relevant location of the "co-planar" feature moves as the beam moves distally:



Accordingly, the "co-planar" terms should be construed to mean "at the location where the pusher and the central web portion are joined, each are flat and lie in the same plane as the channel." *See* Knodel,¶¶38-44.

VIII. THERE IS A REASONABLE LIKELIHOOD THAT THE CLAIMS OF THE '892 PATENT ARE UNPATENTABLE

For the reasons explained below, claims 1-15 of the '892 patent are unpatentable.

A. GROUND 1A – Claims 1-15 Would Have Been Obvious over Young in view of Milliman

Like the '892 Patent, Young discloses a surgical stapling apparatus 10.

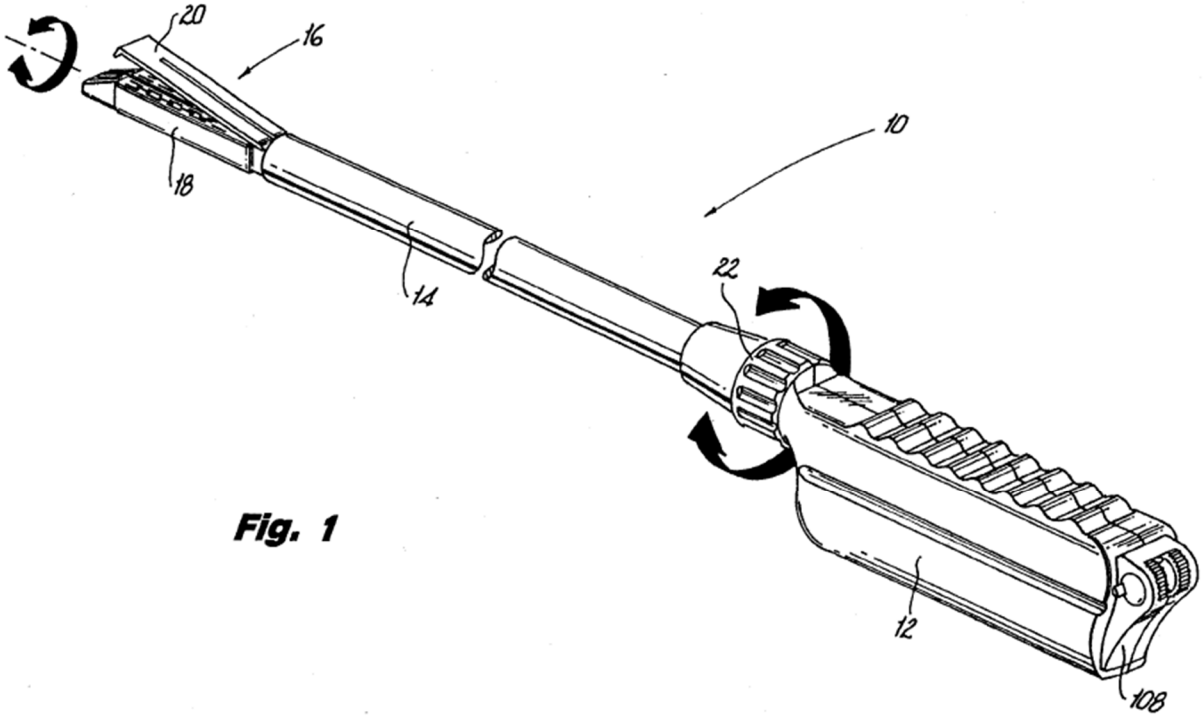


Fig. 1

Young, Fig. 1. As the Examiner already found during prosecution, Young discloses every limitation of the independent claims except the limitation requiring that at least one of the upper beam portion and the lower beam portion be configured to engage the first jaw or the second jaw entirely from ***within*** the first jaw or the second jaw. IS1002, 11-13, 37-51. As shown below, Young's upper and lower beam portions are outside the jaws.

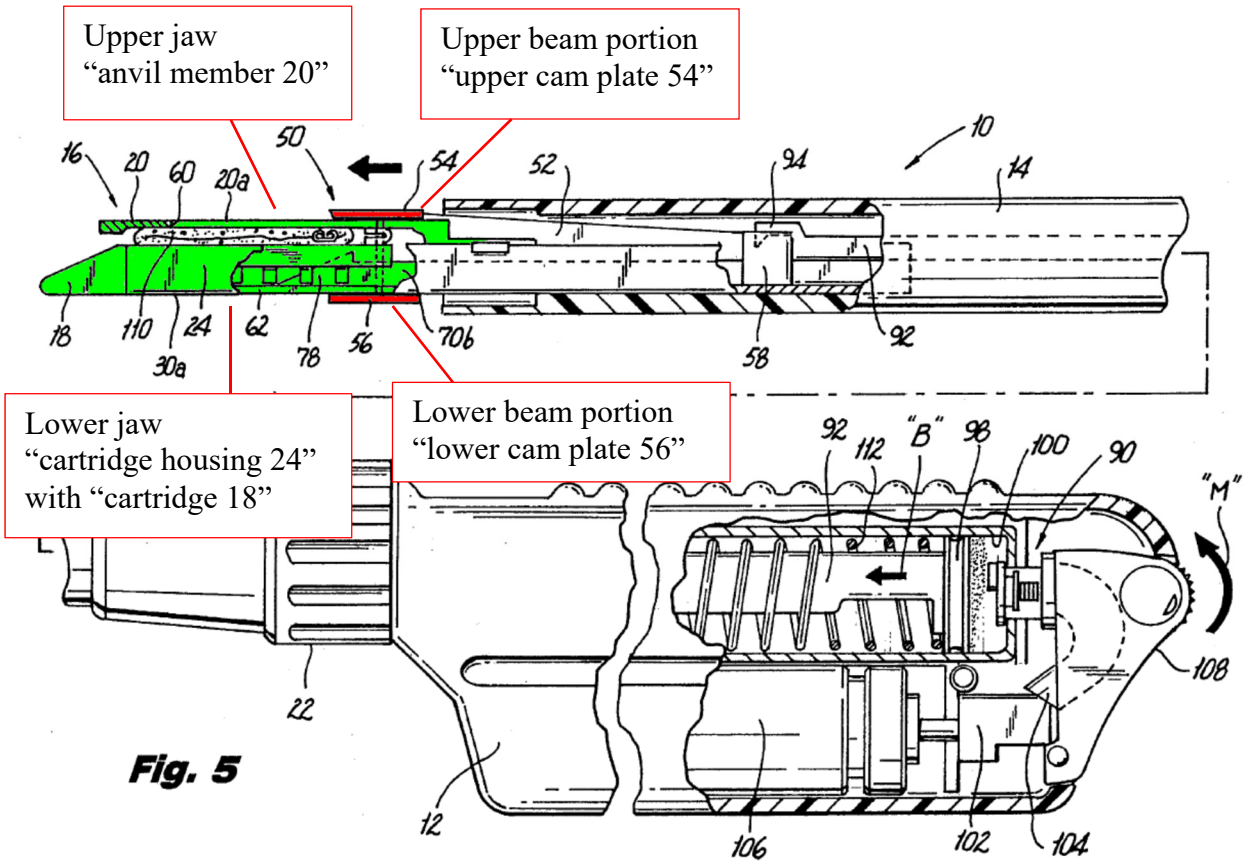


Fig. 4 of Young depicts "the surgical apparatus of FIG. 1 prior to a staple applying operation." The instrument has been positioned such that body tissue 100 is between the jaws.

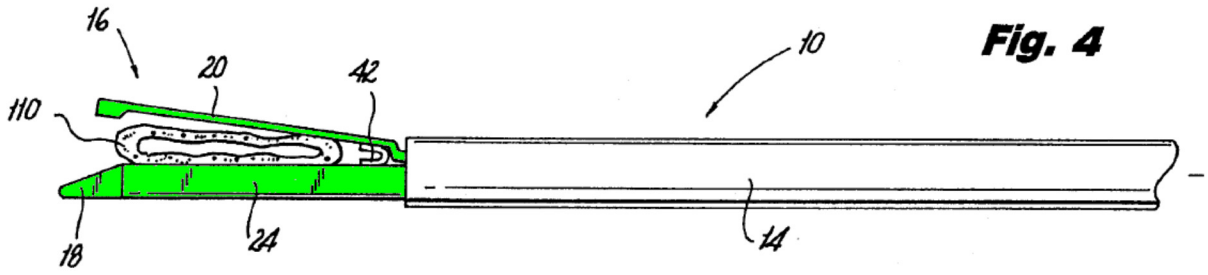
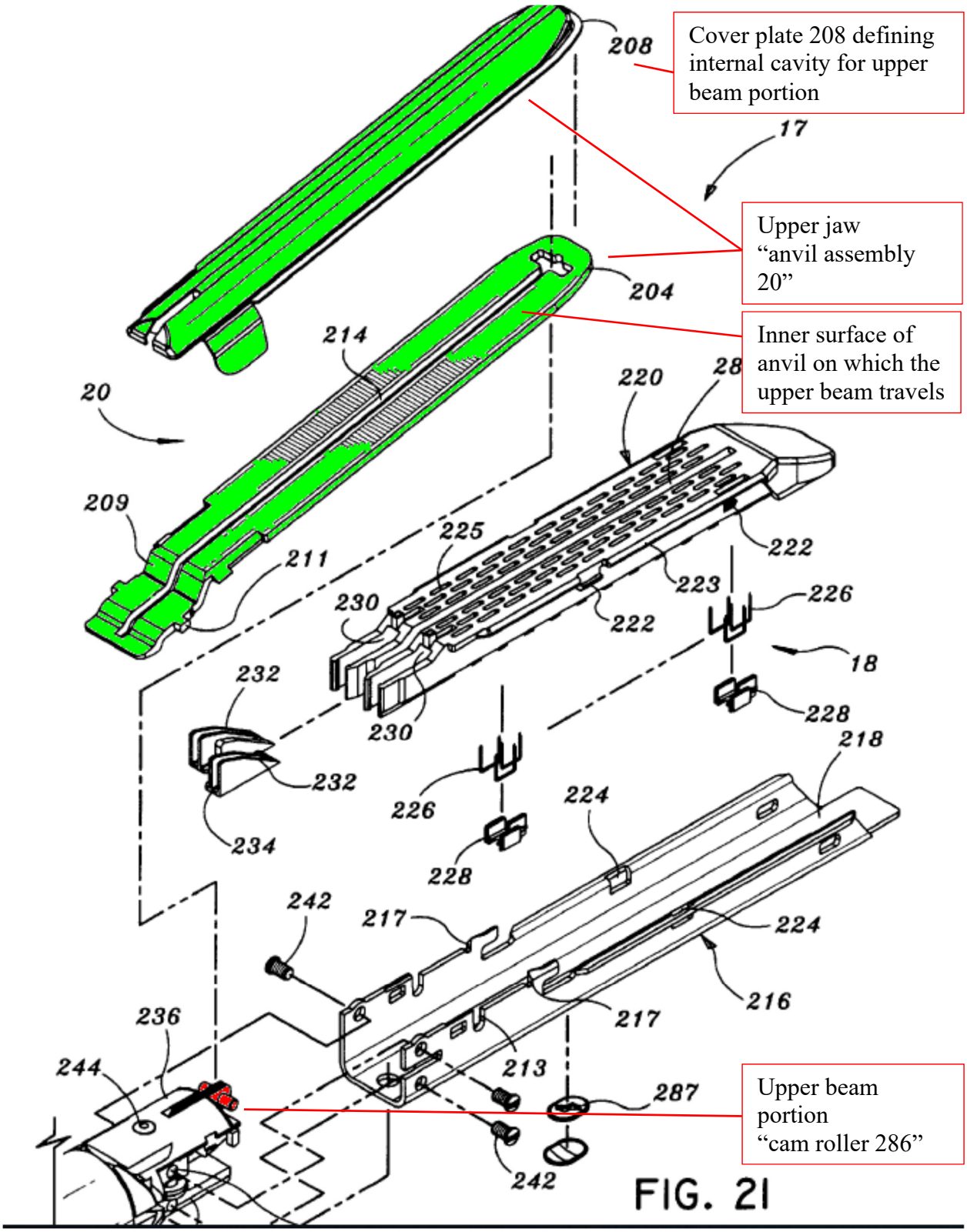


Fig. 4

Young, Fig. 4 (excerpt). Then, firing the instrument "causes cam plate 54 to urge anvil member 20 toward cartridge 18 to bring the fastener forming surface of anvil member 20 into closer cooperative alignment with the tissue contacting surface of cartridge 18, clamping the body tissue 110 disposed therebetween." Young, 5:26-36 (See Fig. 5, above).

In addition to clamping, Young staples and cuts the body tissue 100: "Concomitantly, staple drivers 35 are activated by the wedged cam surface 78 on each of the staple firing bars 70a-70d, driving staples 34 through the captured body tissue 110. In addition, cutting blade 80 travels behind the staple firing bars to incise the stapled tissue. *Id.,* 5:26-36, 4:18-32.

Although Young's upper and lower beam portions travel outside the jaws, upper and lower beam portions traveling **within** the jaws was known in the prior art. For Ground 1, for example, Milliman discloses a surgical stapler with an anvil cover such that the upper beam portion travels within the upper jaw:



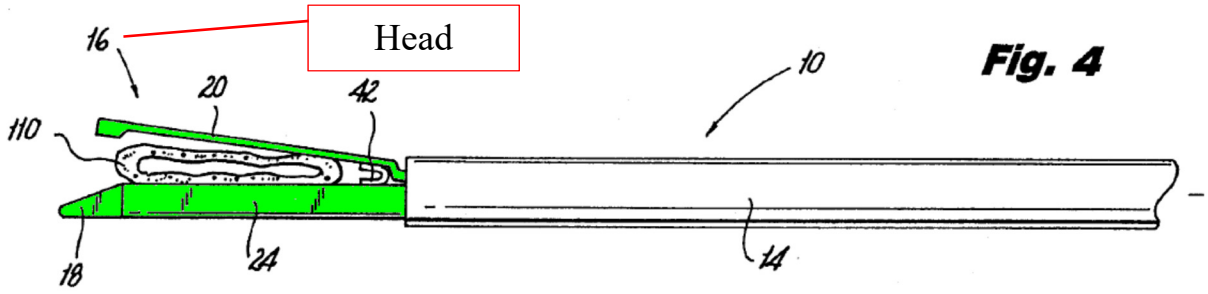
Milliman, FIG. 21, 11:24-44, 12:53-67, 14:3-13; *see* Knodel,¶¶45-51.

[1.pre] An apparatus, comprising:

Young discloses an apparatus, and in particular discloses an "Apparatus for Applying Surgical Fasteners." Young, Title; Knodel,¶52.

[1.1] a head having

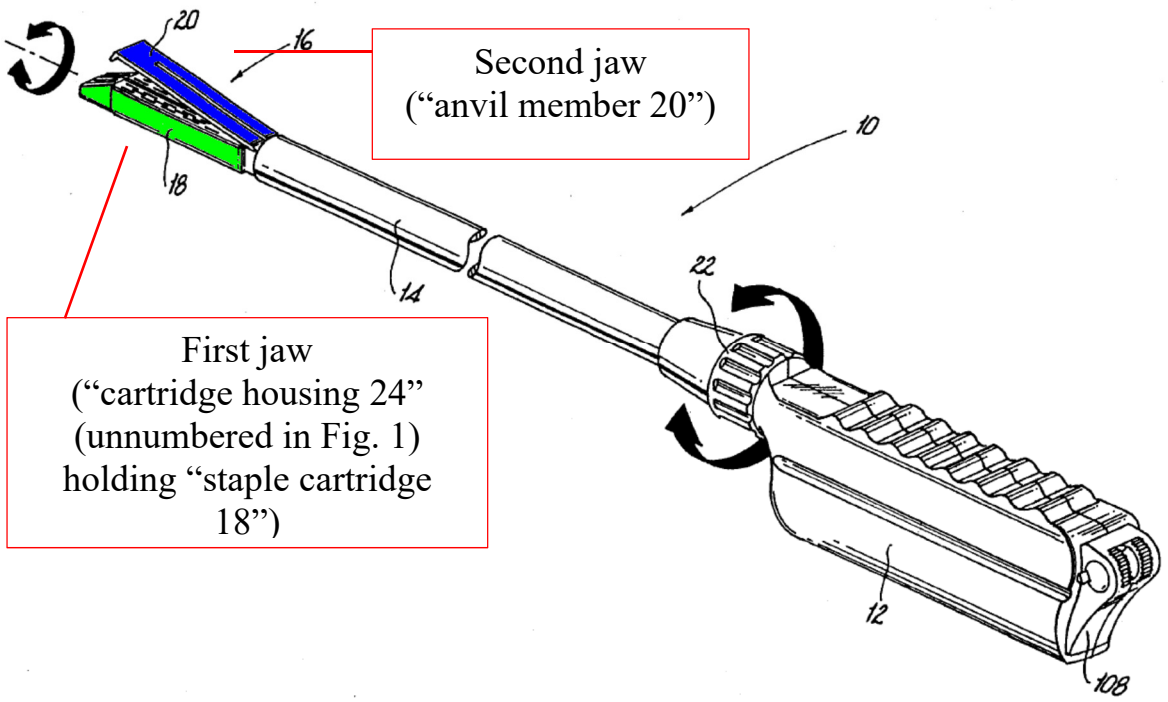
As the Examiner already found, Young discloses this limitation. Knodel,¶53; IS1002, 45. Young discloses a head (fastener applying assembly 16). *Id.*; Young, 3:35-49, Figs. 1, 4.



[1.1.1] 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 spaced apart at a first distance and a second configuration in which the first jaw and the second jaw are spaced apart at a second distance,

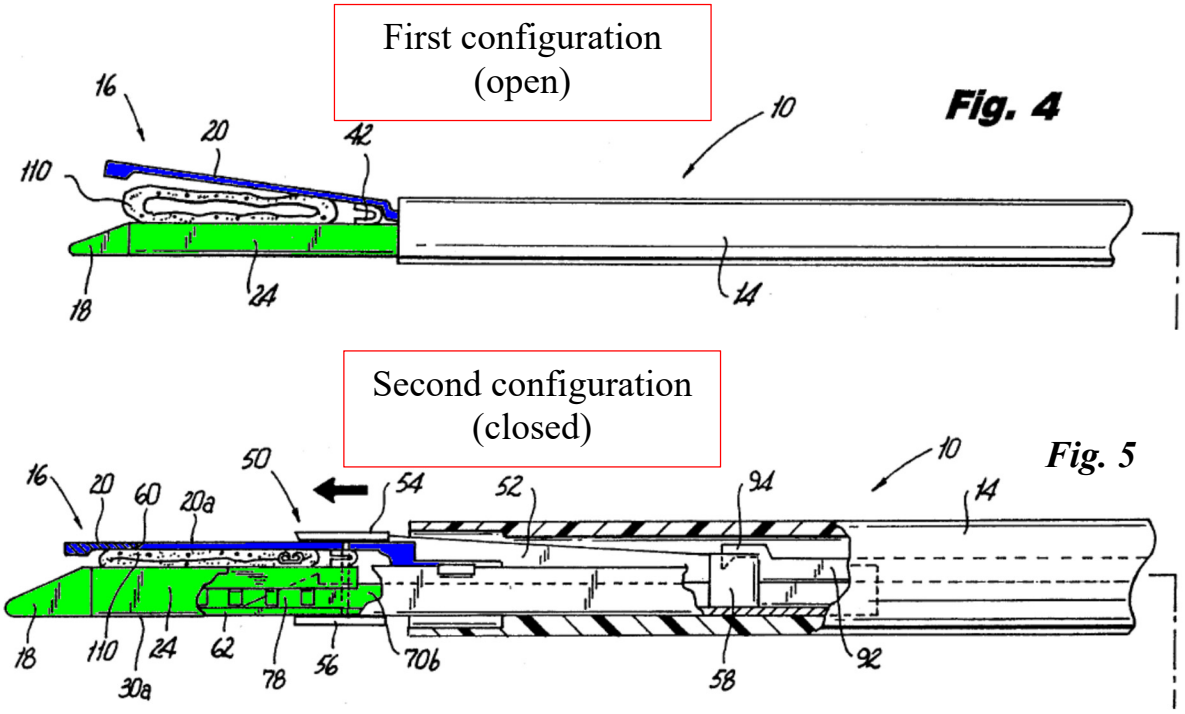
As the Examiner already found, Young discloses this limitation. Knodel,¶¶54-56; IS1002, 41, 92.

Young's head has a first jaw (combination of cartridge housing 24 and cartridge 18 shown below in green) and a second jaw (anvil member 20 shown below in blue). *Id.*; Young, Fig. 1.



Young's second jaw (anvil member 20) is movable with respect to the first jaw (cartridge housing 24 and staple cartridge 18) from a first configuration (open) in which the jaws are spaced apart at a first distance (*see* Young, FIGS. 1, 3, and 4) to a second configuration (closed) in which the jaws are spaced apart at a second distance (*see* Young, FIGS. 5 and 6). Knodel Decl., ¶¶54-56; Young, 3:8-9, 3:36-5:3. "The ***anvil member*** is mounted at a location spaced from the handle portion and ***is movable between a first position*** wherein the fastener forming surface is spaced from the tissue contacting surface ***and a closed position*** wherein the fastener forming surface and the tissue contacting surface are in closer cooperative alignment." Young, 2:8-13, *see also* 3:10-12, FIGS. 4-5. As can be seen from

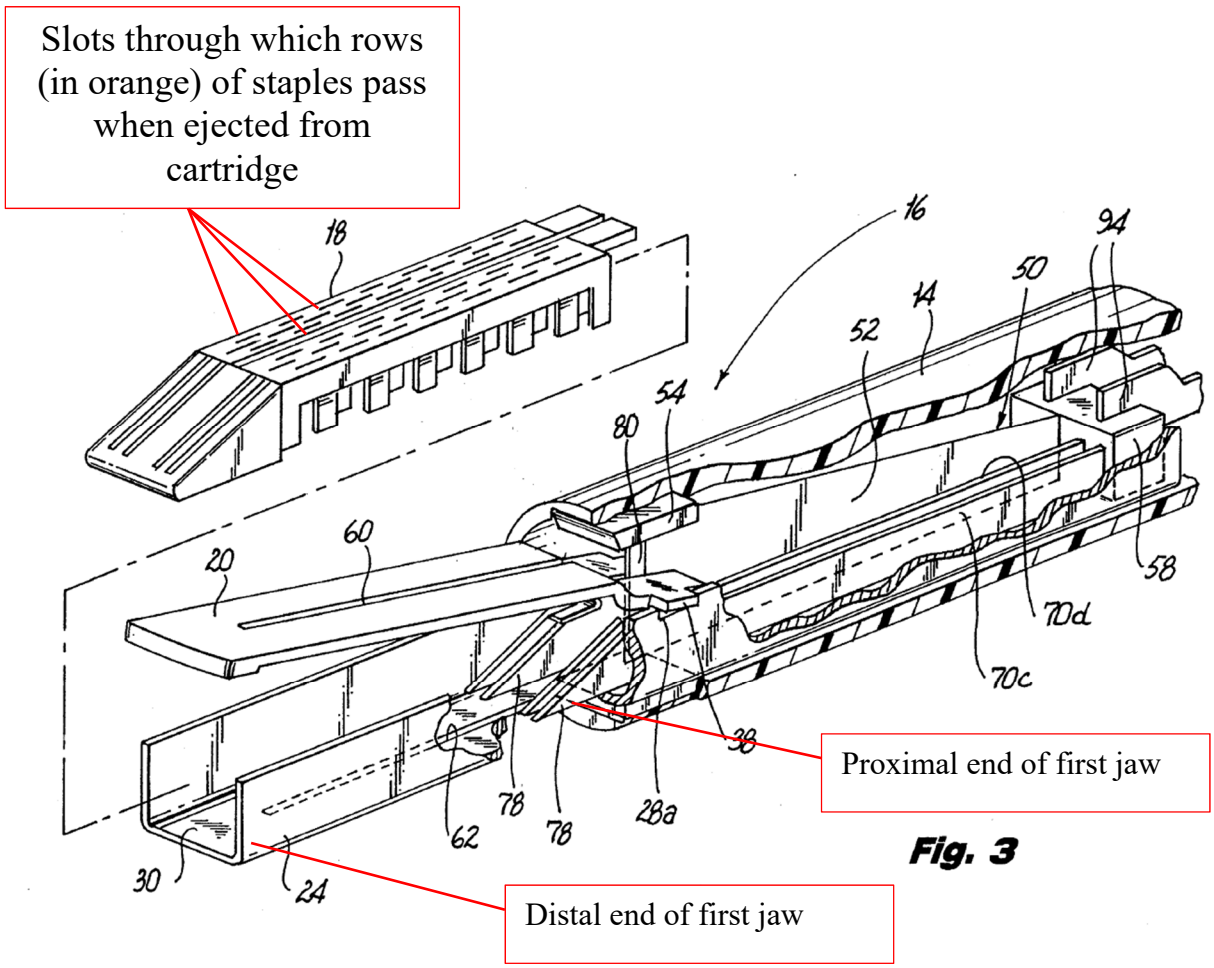
Figures 4 and 5, the distance between the jaws in the first configuration and second configuration are different.



[1.1.2] a stapling assembly of the first jaw having slots through which staples are configured to be passed in one or more rows extending from a proximal end of the first jaw to a distal end of the first jaw,

As the Examiner already found, Young discloses this limitation. Knodel,¶¶57-59; IS1002, 40-41. Young's head includes a stapling assembly (cartridge 18) of the first jaw (cartridge housing 24 with cartridge 18) having slots through which staples are configured to be passed in one or more rows extending from a proximal end of the first jaw to a distal end of the first jaw. *Id.*; Young, 1:21-29, FIG. 3. Young, 1:21-29.

As shown in Figure 3 of Young, the cartridge 18 is inserted into the cartridge housing 24 such that the slots form rows extending from the proximal to distal end of the lower jaw (first jaw):



[1.1.3] and an anvil surface of the second jaw being configured to form a staple

As the Examiner already found, Young discloses this limitation. Knodel,¶60; IS1002, 41, 45-46. Young discloses an anvil surface ("fastener forming surface;" highlighted in yellow below in Young, FIG. 6) in the second jaw ("anvil member 20") being configured to form a staple (34). *Id.*; Young, 1:21-25,

2:5-17, FIGs. 5-6. As explained in Young, "anvil member [20] defin[es] a fastener forming surface against which fasteners ejected from the cartridge assembly are driven." Young, 2:5-7.

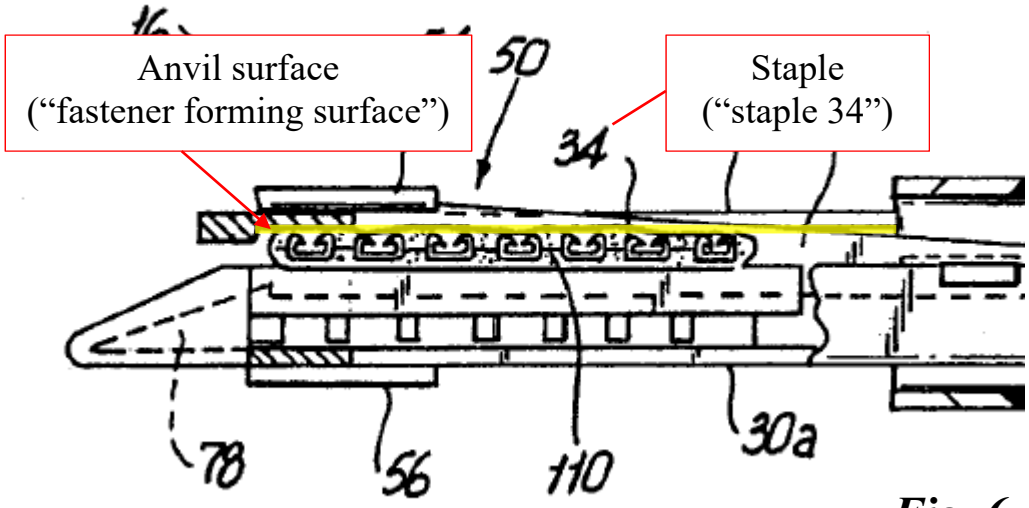
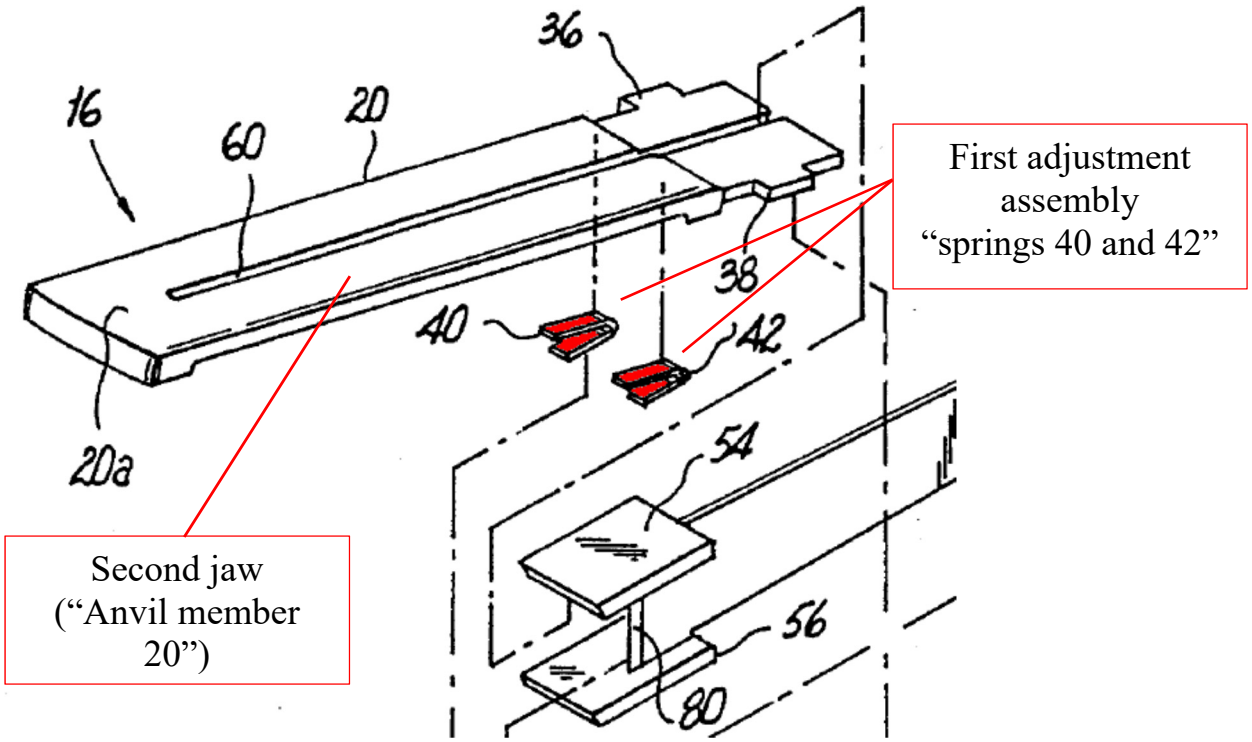


Fig. 6

[1.2] a first adjustment assembly configured for gross movement of the first jaw or the second jaw

As the Examiner already found, Young discloses this limitation. Knodel,¶¶61-63; IS1002, 92-93. Young discloses a first adjustment assembly (springs 40 and 42) configured for gross movement of the first jaw or the second jaw (anvil member 20, the second jaw). *Id*. "As shown in FIGS. 2 and 4, springs 40 and 42 are associated with anvil member 20 to bias the anvil into an open position with respect to cartridge 18." Young, 4:1-3. After the firing operation is complete, the actuation mechanism 50 is returned to its proximal-most position by a return spring 112. Then springs 40 and 42 move anvil member 20 from the substantially closed position to the open position. Knodel,¶61.



The gross movement in Young is comparable to the gross movement in the '892 Patent. The device of the '892 Patent uses an "actuation cable 44 to facilitate gross approximation [gross movement closer together] of the jaws 17" from an open position to a substantially closed position. '892 Patent, 5:2-3. Young's springs facilitate the same magnitude of gross movement, except that Young's gross movement is in the opposite direction. Young uses springs to provide a gross movement of the jaws further apart, from from a substantially closed position to an open position. Knodel,¶62.

Similarly and additionally, Young discloses that its springs may be biased in a closed position such that the initial closing would alternately be the gross movement. Young, 4:9-17; Knodel,¶63.

[1.3] a second adjustment assembly including a beam configured for fine movement of the first jaw or the second jaw to maintain a fixed distance there between, wherein the beam is operatively coupled to a pusher and includes a central web portion connecting an upper beam portion and a lower beam portion, the central web portion including a cutting blade which is generally more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion, and the pusher being configured to cause a staple pusher to move for firing as the beam moves distally

As the Examiner already found, Young discloses this limitation. Knodel,¶¶64-69; IS1002, 92-93.

"a second adjustment assembly including a beam configured for fine movement of the first jaw or the second jaw to maintain a fixed distance there between"

Young discloses a second adjustment assembly (distal end of "actuation mechanism 50") including a beam (the I-beam; distal end of "elongated support beam 52", which is similar to the structure of '892 Patent's "I-beam member 70") configured for fine movement of the second jaw (anvil member 20), which takes place after the initial downward rotation of the second jaw. Both Young and the '892 patent disclose an I-beam for performing the fine movement function of the second adjustment assembly. Knodel,¶65.

’892 Patent Fig. 14 Second Adjustment Assembly	Young Fig 2 (Excerpt) Second Adjustment Assembly

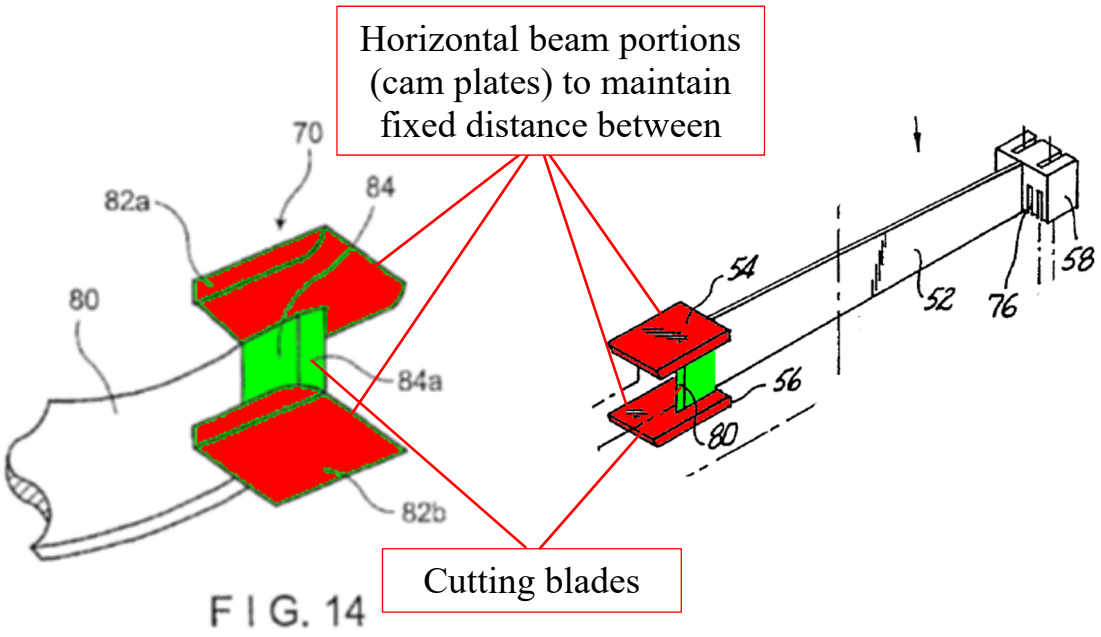
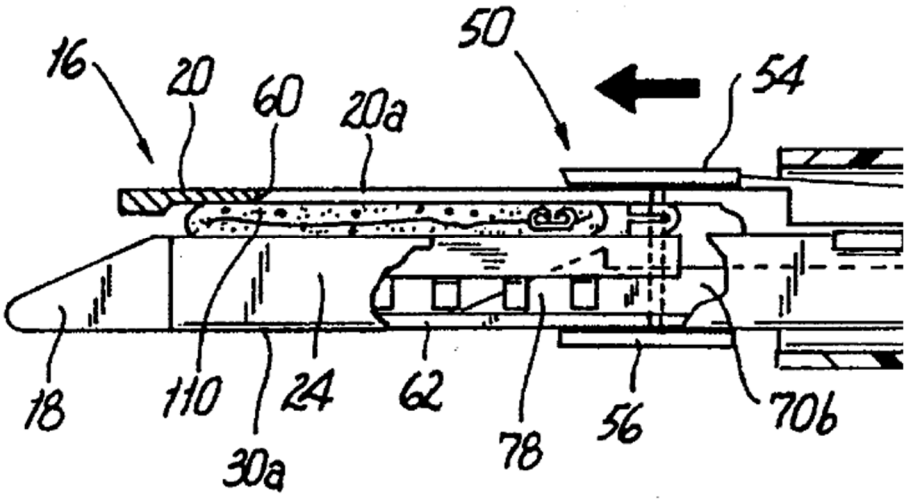


FIG. 14

Young, 4:33-57, ’892 Patent, 5:56-57. *See also* Young, 2:24-27; Knodel,¶¶65-66.

The fine movement motion begins with the jaws in the configuration shown at Young’s Fig. 5, in which the jaws are in a close configuration. When tissue grasped between the jaws causes a slight upward deflection of at least the second jaw (anvil member 20), the distal movement of the second adjustment assembly’s beam (the I-beam) will counteract this upward deflection, producing a fine, closing movement of the second jaw. The second adjustment assembly’s counteracting of jaw deflection constitutes a fine movement of the second jaw (anvil member 20) for at least for the reason that the second jaw moves a small distance (jaw

deflection distance) in relation to the control motion of the I-beam. The second adjustment assembly accomplishes this fine movement of the second jaw using its I-beam, which maintains a fixed distance between the first and second jaws. The I-beam is used "to gradually cam anvil member 20 into a closed (or fully clamped) position and, at the same time, activate a plurality of staple drivers 35 to urge staples 34 from cartridge 18." Young, 4:23-29; Knodel,¶67.



"wherein the beam is operatively coupled to a pusher ... configured to cause a staple pusher to move for firing as the beam moves distally"

Young's beam (distal portion of elongated support beam 52, shown below in red and green) is operatively coupled (coupled for operation) to a pusher (the combination of "wedged cam surface 78," "firing bars 70a-70d," "mounting block 58," and the proximal portion of "support beam 52", shown in blue), which is configured to cause a staple pusher ("staple driver 35") to move for firing as the

beam moves distally. Young, 4:48-56, 6:48-59, FIGs. 2-3. As the wedged cam surface 78 moves distally, it contacts the staple pushers and moves the staple pushers upward to eject the staples out of the cartridge. Knodel,¶68.

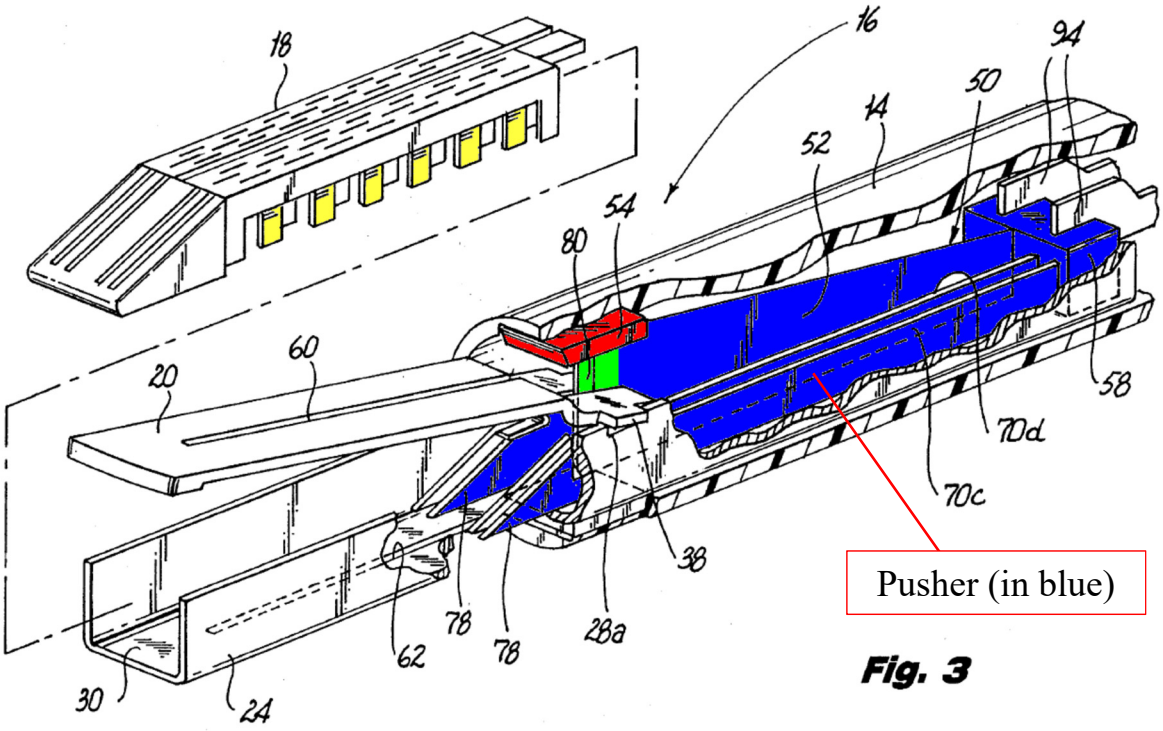
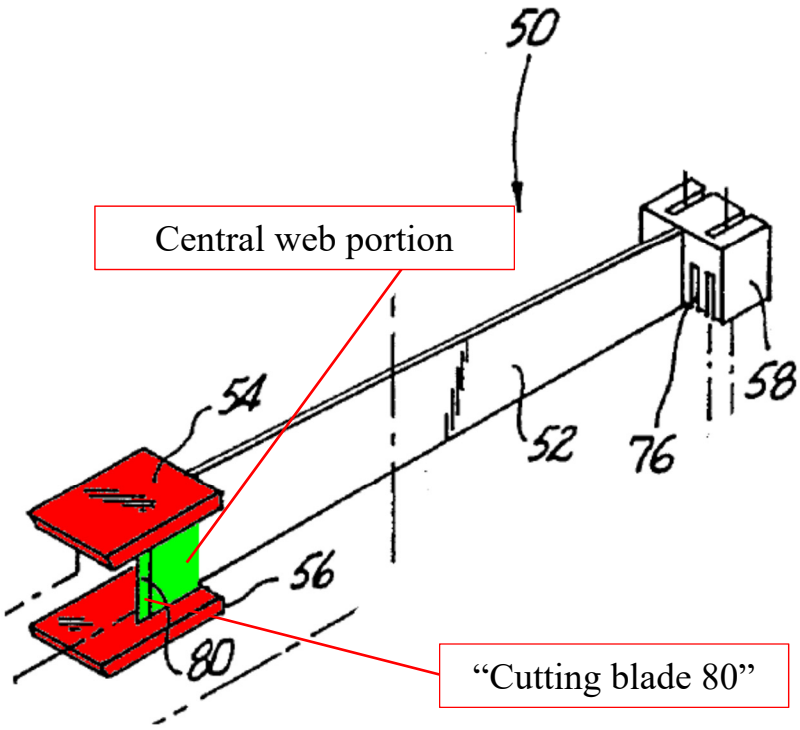


Fig. 3

"wherein the beam … includes a central web portion connecting an upper beam portion and a lower beam portion, the central web portion including a cutting blade which is generally more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion,"

As shown below in Figure 3, Young's beam includes a central web portion (vertical part of the distal portion of "elongated support beam 52", in green) connecting an upper beam portion ("cam plate 54", in red) and a lower beam

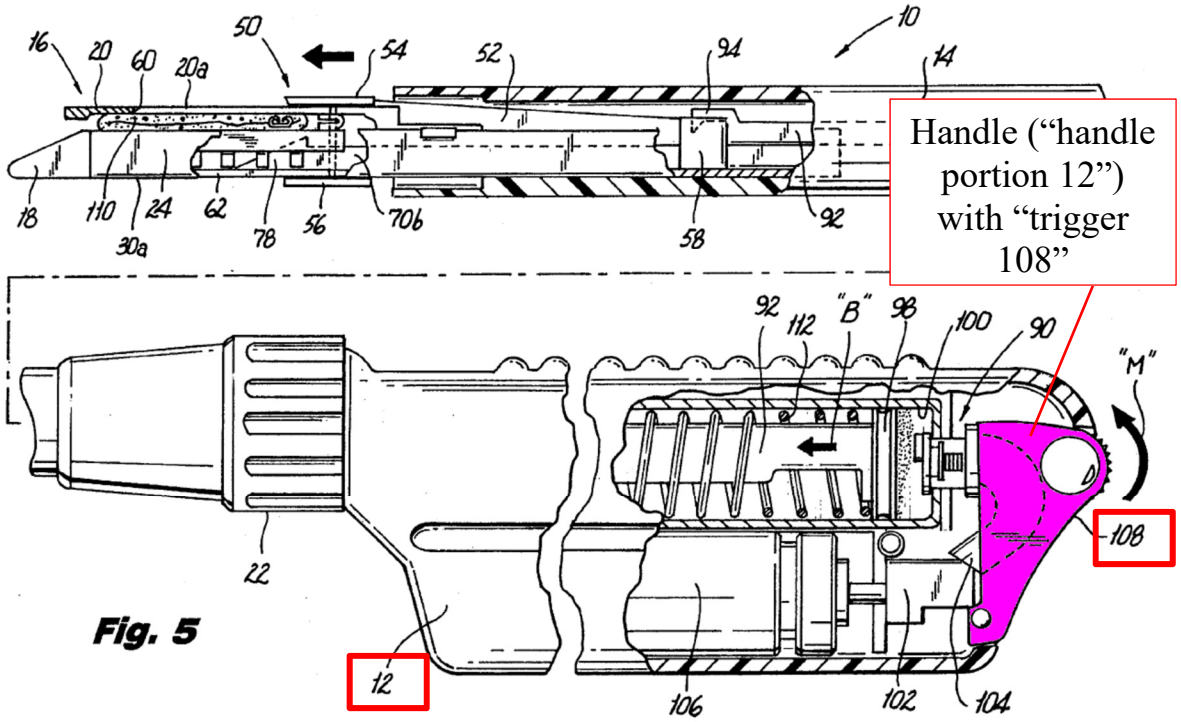
portion ("cam plate 56", in red). IS1002, 41-42, Knodel,¶69; Young, 2:21-36, FIG. 2. The central web portion includes a cutting blade ("cutting blade 80", in green), which is generally more distal (more forward; in the figure below, more to the left of) than the trailing (right-facing) edges of both the upper and lower beam portions (cam plates 54 and 56). *Id*.



[1.4] a handle having one or more actuators configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration, and to actuate the stapling assembly

As the Examiner already found, Young discloses this limitation. Knodel,¶70; IS1002, 92-93. Young discloses a handle ("handle portion 12") having one or more actuators ("trigger 108") to move at least one of the jaws from the first configuration (open position) to the second configuration (closed position),

and to actuate the stapling assembly (fire the staples). *Id.*; Young, 2:37-50, 3:40-43.



"In operation, as illustrated in FIG. 5, upon manipulation of trigger 108…drive shaft 92 is urged distally, driving actuation mechanism 50 into fastener assembly 16…[and] caus[ing] cam plate 54 to urge anvil member 20 toward cartridge 18 to bring the fastener forming surface of anvil member 20 into closer cooperative alignment with the tissue contacting surface of cartridge 18, clamping the body issue 110 disposed therebetween." Young, 5:18-31. Once the anvil is initially closed, the actuation mechanism 50 causes further clamping to proceed alongside staple firing: "Concomitantly, staple drivers 35 are activated by the

wedged cam surface 78 on each of the staple firing bars 70a-70d, driving staples 34 through the captured body tissue." Young, 5:31-36.

[1.5] and a shaft coupling the handle to the head;

As the Examiner already found, Young discloses this limitation. Knodel,¶¶71-73; IS1002, 92-93. Young discloses a shaft ("body portion 14" shown in purple) coupling the handle (handle portion 12) to the head (fastener applying assembly 16). *Id.*; Young, 3:36-44.

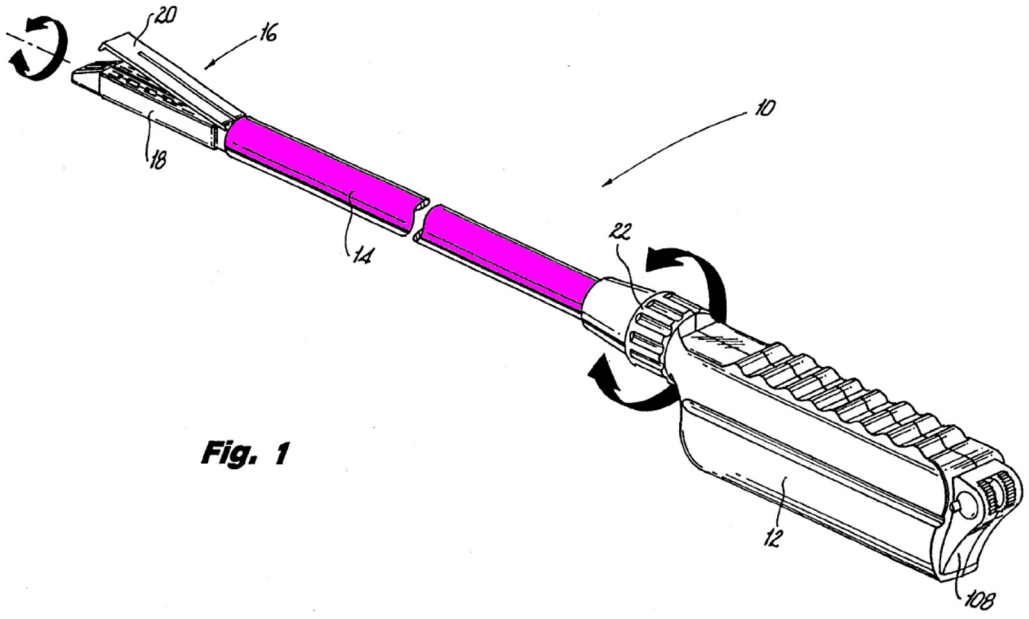


Fig. 1

Alternatively, Young discloses "a drive shaft 92 which extends from handle portion 12, through body portion 14, to fastener applying assembly 16." Young, 4, 65-67; Knodel,¶72.

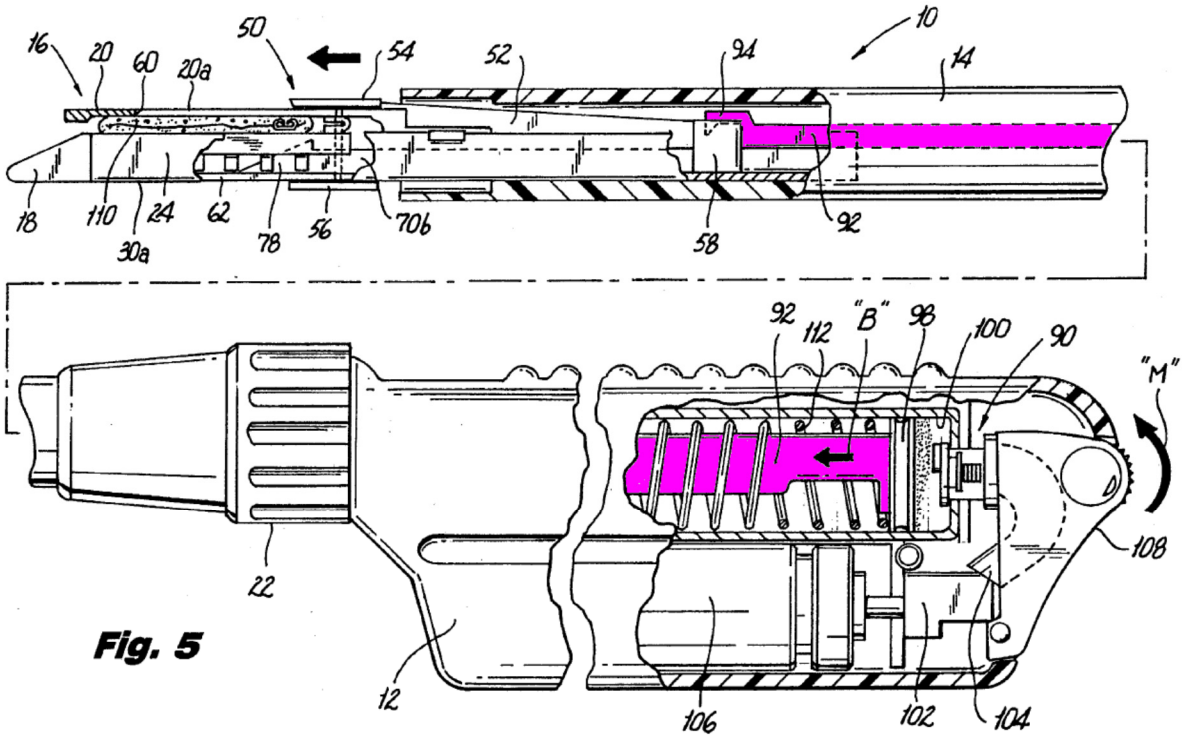
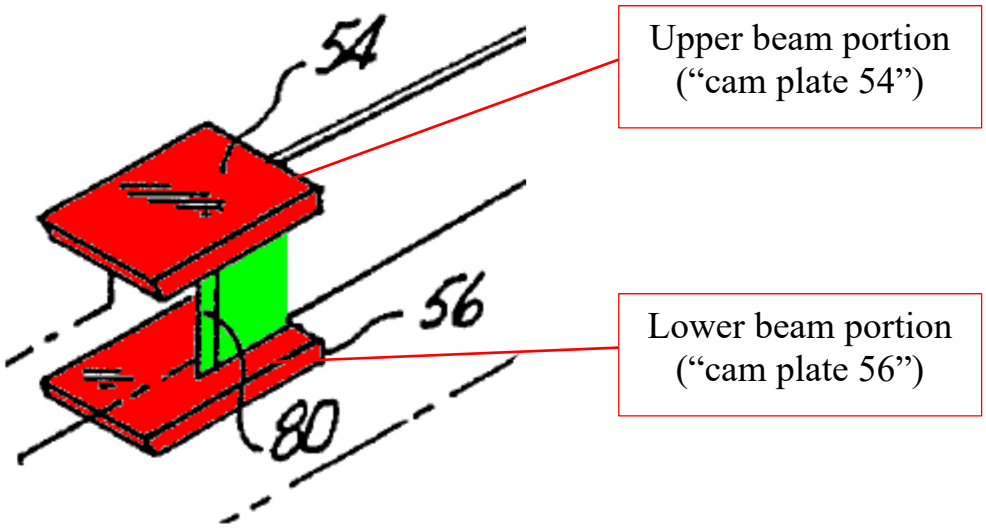


Fig. 5

Young, FIG. 5 ("drive shaft 92" shown in purple). The recited "shaft" can correspond to either "drive shaft 92" or the elongated "body portion 14."

[1.6.1] wherein at least one of the upper beam portion and the lower beam portion is a generally flat plate orthogonally attached to an end of the central web portion

Young discloses this limitation. Knodel,¶74. Young discloses an upper beam portion ("upper cam plate 54") and a lower beam portion ("lower cam plate 56"), which are each generally flat plates orthogonally attached to the end of the central web portion. *Id*.; Young, 4:32-47, Fig. 2.



Young, Fig. 2 (excerpt).

[1.6.2] and is configured to engage the first jaw or the second jaw entirely from within the first jaw or the second jaw for clamping and alignment

This limitation is missing from Young, but is readily found in Milliman. Knodel,¶¶75-79. It would have been obvious in view of Milliman to modify Young such that at least one of the upper and lower beam portions (cam plates 54 and 56) engages a jaw entirely from within the respective jaw for clamping and alignment. The I-beam of Young provides clamping and alignment. As the I-beam moves distally, its upper and lower cam plates provide clamping by ensuring a fixed distance between the jaws to hold the tissue being cut and stapled. Likewise, the cam plates align the upper and lower jaws by ensuring a substantially parallel jaw configuration and further provide lateral alignment via the central web portion as well.

Specifically, it would have been obvious to modify Young by adding a cover to form an enclosed passageway through which the upper beam portion (cam plate 54) travels, as taught by Milliman. Knodel,¶¶80-86.

Milliman discloses an upper beam portion ("cam roller 286") of an I-beam structure (distal end of "axial drive assembly 212"). Milliman, 11:24-28; 12:40-67; Figs. 21, 31-34. As shown in FIG. 21, Milliman discloses an endoscopic surgical stapler having an anvil with a "cover plate 208" that forms an internal passage or cavity through which an upper beam portion travels. Milliman, 11:24-28; Figs. 21, 49.

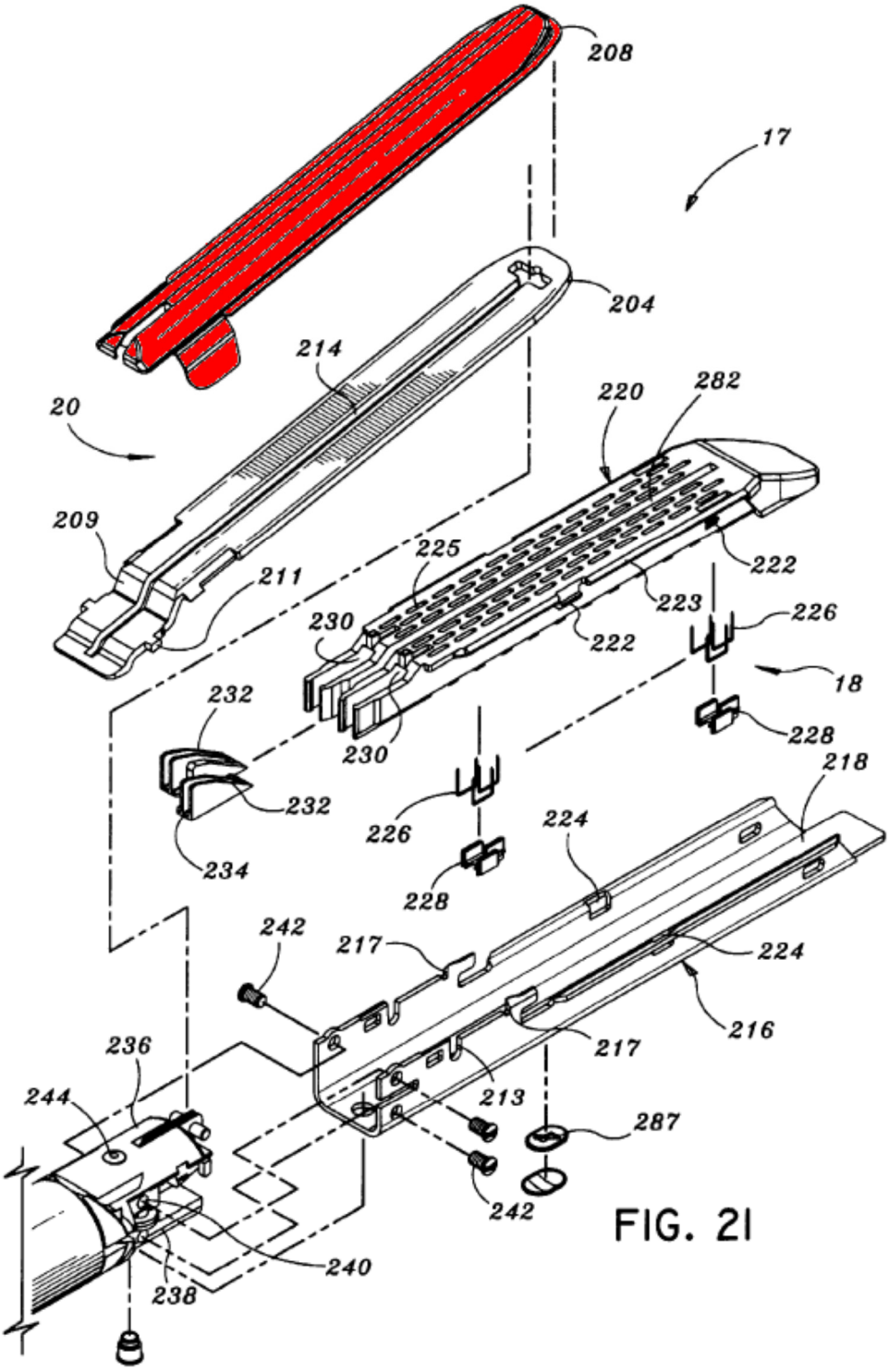


FIG. 21

Milliman, FIG. 21.

Figure 24 of Milliman depicts cavity 210 (shown below in blue) formed by the cover plate secured to the top surface of the anvil. The upper beam portion ("cam roller 286") (shown in red) of Milliman's I-beam (remainder shown in green) travels distally through the cavity 210 when the instrument is fired.

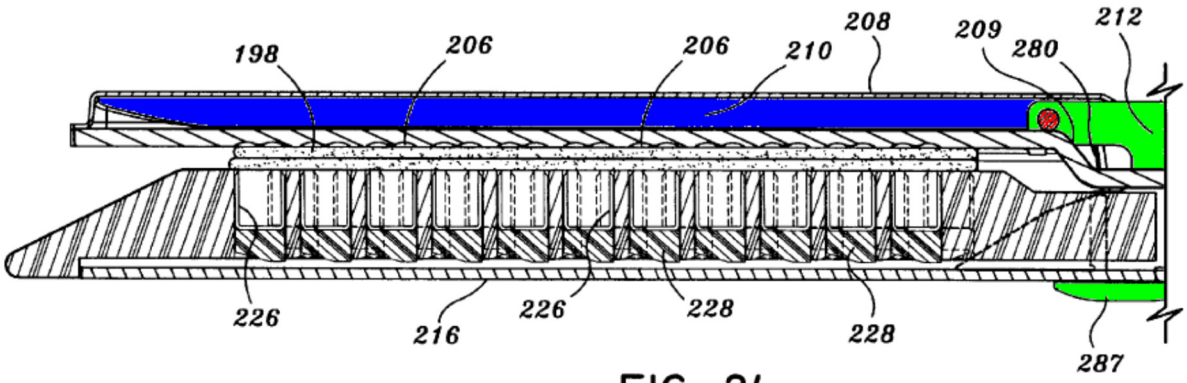


FIG. 24

Milliman, FIG. 25. *See also* Milliman, FIGs.19, 27, 32-34, 12:53-56, 11:55-67.

It would have been obvious to a POSITA at the time of the '892 Patent to modify Young to add a cover plate to Young's anvil member 20, based on the teachings of Milliman. Both Young and Milliman employ I-beams and thus have similar structures in that regard. Knodel,¶¶80-81. The particular shape of the I-beam components differ between Young and Milliman, but these differences are not material to the function of the anvil cover taught by Milliman. Milliman discloses the upper beam portion as "cylindrical cam roller 286" whereas Young discloses the upper beam portion as the flat "cam plate 54". Nonetheless, both serve the same jaw-approximation function when traversing along the length of the

head —to close the anvil and maintain a fixed distance between the jaws. Knodel,¶¶79-81.

Young teaches applying the cam plate to the "outer" surface of the anvil because the anvil of Young is a single layer structure with only a top and bottom surface. To cam the anvil to a closed position, the upper beam portion engages the top surface rather than the bottom surface. Knodel,¶82.

Milliman, however, teaches that an anvil with an additional cover plate may be used, which provides a benefit of enclosing the travel path of the upper beam portion and thereby avoid pinching tissue adjacent the anvil. Milliman, 11:24-33; Knodel,¶83. A POSITA would have understood from the teachings of Milliman that that the anvil of Young could be modified to add a cover, thereby transforming the outer surface (top surface) of the anvil of Young into part of an interior passageway or cavity. *Id.*

A POSITA would have been motivated to enclose the travel path of the upper beam portion of Young to obtain the benefits of an anvil cover identified by Milliman. *Id*. Milliman explains that the cover plate forms a protective internal cavity for the upper beam portion to travel within: Anvil assembly 20 includes "a cover plate 208 secured to a top surface of anvil portion 204 to define a cavity 210 (FIG. 24) therebetween. Cover plate 208 is provided to prevent pinching of tissue during clamping and firing of stapling apparatus 10. Cavity 210 is dimensioned to

receive a distal end of an axial drive assembly 212 (See FIG. 27)." *Id.* In addition, a POSITA would have understood that the cover provides additional benefits, including providing additional support structure to the anvil to increase its rigidity and providing a physical barrier that helps keep tissue and foreign objects away from the path along which the upper beam portion travels. Knodel,¶84.

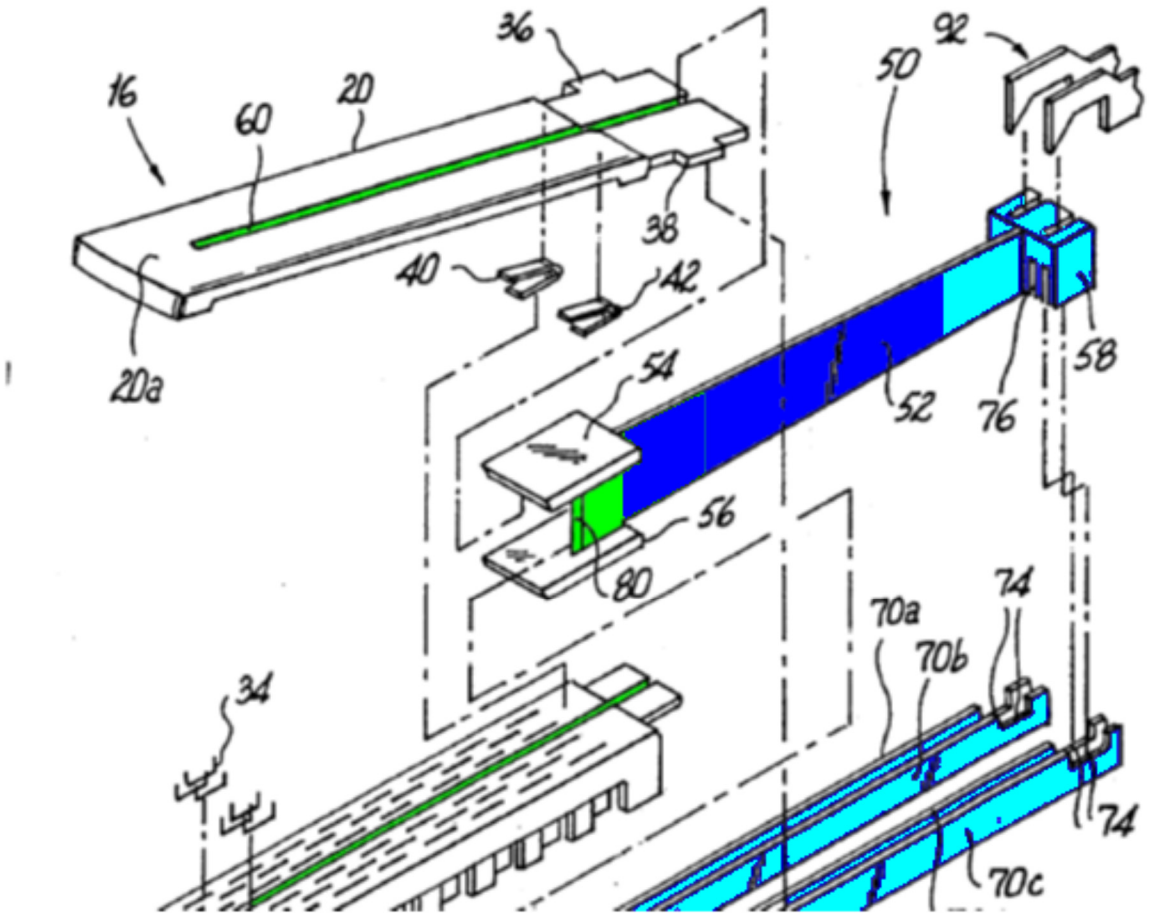
A POSITA would have had a reasonable expectation of success because adding a cover plate to an anvil is a simple mechanical step. This is confirmed by Milliman, which does not discuss any challenges with enclosing the upper beam portion in the anvil (and nor does the '892 Patent suggest it "solved" any problem associated with a covered anvil). Knodel,¶85.

Moreover, all elements of the claim were known in the prior art, as taught by Young and Milliman and the addition of the cover of Milliman to the instrument of Young would have been accomplished by simple and known mechanical methods with no change in the respective functions of the cover of Milliman or the instrument of Young. A POSITA would readily have understood that the combination yields predictable results (a cover on the anvil of the Young device provides the same benefits as would be provided by the cover on the anvil of the Milliman device). *See KSR Int'l Co. v. Teleflex Inc.*,550 U.S. 398, 416 (2007). Knodel,¶86. Application of the cover of Milliman to the instrument of Young is

nothing more than the application of a known technique (adding a cover to a part of a surgical stapler end effector) to a similar device in the same way. *Id*.

[1.7] and the pusher and the central web portion are coplanar with a channel defined in a tissue contacting surface of each of the first jaw and the second jaw when the beam moves distally.

As the Examiner already found, Young discloses this limitation. Knodel,¶87-88; IS1002, 42. As shown below in an excerpt from FIG. 2, the relevant portions of Young's pusher (which includes "support beam 52" shown in dark blue) and central web portion (distal portion of "support beam 52" shown in light green) are coplanar with: (1) a channel (slot 62 shown in dark green) defined in a tissue contacting surface (the top surface of cartridge 18) of the first jaw; and (2) a channel (slot 60 also shown in dark green) defined in a tissue contacting surface (lower surface of anvil member 20) of the second jaw. *Id*.; Young, 4:35-40.



Like the ’892 Patent, Young’s central web portion and pusher are coplanar with the channels defined in the tissue contacting surfaces of the upper and lower jaws (lower surface of upper jaw and upper surface of lower jaw) at the connection point of the pusher and central web portion so that the central web and pusher can function to cut tissue as they travel along the length of the jaws. Knodel,¶¶87-88 Accordingly, this limitation is met under the proper construction of the “co-planar” phrase.

This analysis is likewise consistent with the prosecution history. During prosecution, the Applicant argued that Young did not disclose a “coplanar” pusher.

IS1002, 68 ("The pusher 58 of the Young patent identified by the Examiner is not coplanar with the central web portion and the channel as the beam moves distally.") Notably, the Examiner did not agree with Applicant, and found that Young discloses a "coplanar" pusher as claimed. IS1002, 42. Applicant's arguments are based on a misidentification of Young's "pusher." Applicant only identified mounting block 58 as the pusher. However, the pusher is more than mounting block 58, and Young in fact does disclose an elongated support beam 52 located immediately proximal of the I-beam of Young; the elongated support beam 52 is coplanar with the central web portion of the I-beam and with the channels through which the I-beam travels. Knodel,88.

In addition and also in the alternative (should the claim not be construed as Petitioner suggests), a POSITA would have been motivated to build a stapler that not only used Milliman's cover, but also Milliman's articulation mechanism and therefore drive beam and wedge sled (for ejecting staples). In this combination, the entire pusher would be co-planar with the entire channel and central web portion.

Specifically, a POSITA would have understood that articulation provides greater control and maneuverability of a surgical instrument, and would have been motivated by the teachings of Milliman to develop both articulating and non-articulating surgical instruments in the combination. Milliman, Abstract,

Knodel,¶90. Milliman discloses a "drive beam 266" that is in a single plane when not articulated. Milliman, 12:40-67; FIGs. 29, 57, 60, and 61; Knodel,¶90.

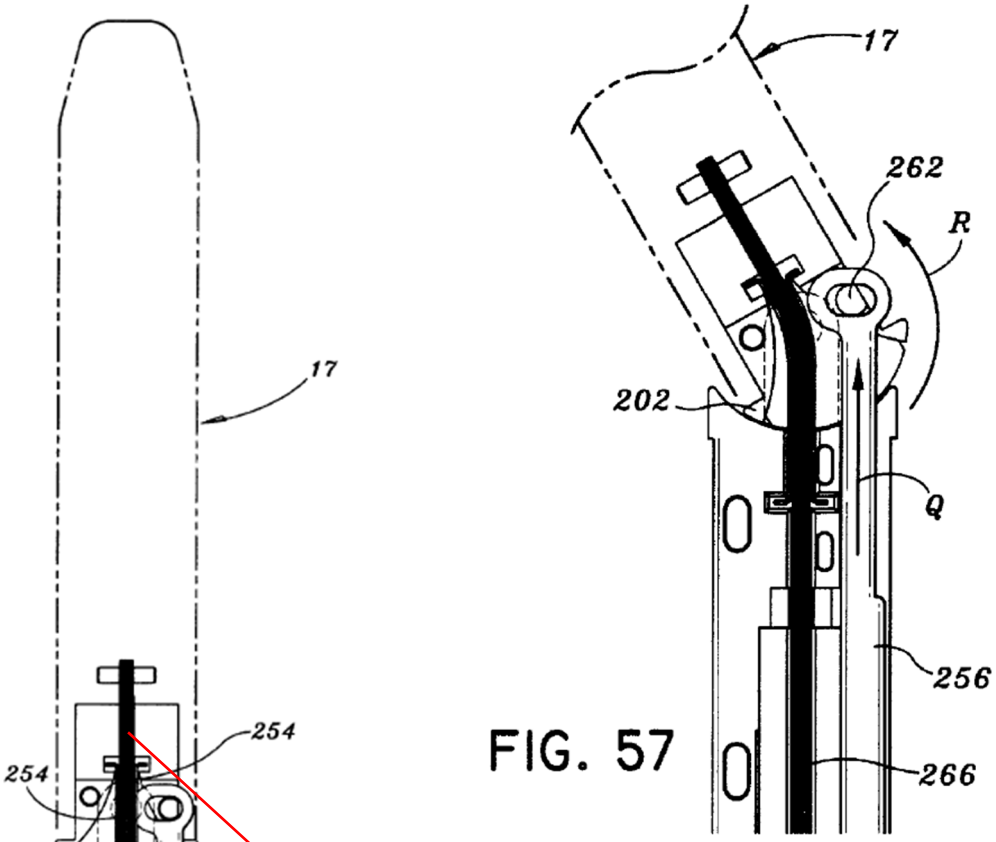


FIG. 57

FIG. 60

Pusher ("drive beam 266") is in a single plane and coplanar with central web portion (distal portion of "drive beam 266")

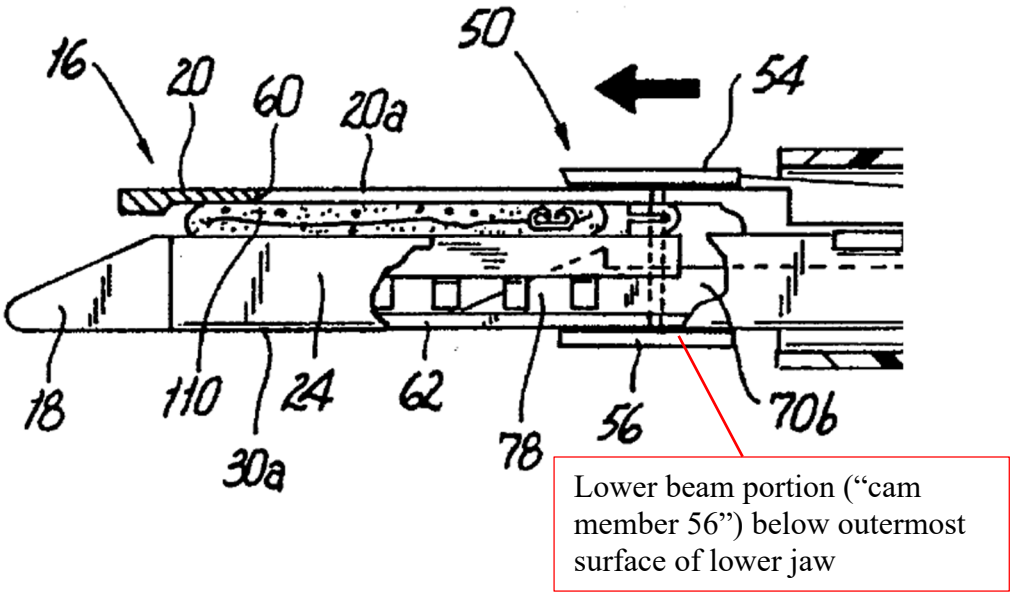
Milliman, FIGs. 57 and 60.

A POSITA would be motivated to use Milliman's articulation joint, and therefore also Milliman's compatible drive beam and wedge sled, to get the benefits of articulation, which Young does not disclose. A POSITA would be motivated to use the I-beam of Young (including cam plates 54 and 56) in the combination rather than substituting in the Milliman I-beam in order to get the benefits of the flat cam plates in Young. The benefits include having a larger surface area for improved clamping and surface area that applies clamping pressure throughout the length of the central web. Knodel,¶¶89-92. A POSITA would have a reasonable expectation of success in modifying Young to use Milliman's articulation mechanism, drive beam, and wedge sled. Both Young and Milliman have coplanar drive beams at the attachment point to the I-beam. Accordingly, based on the teachings of Milliman, a POSITA would readily be able to make the pusher substitution, and would possess the basic mechanical design skills necessary to alter the mechanical device to include an articulation joint and an I-beam-driven wedge sled. Knodel,_¶93.

[2.] The apparatus of claim 1, wherein a second one of the upper beam portion and the lower beam portion is configured to engage the first jaw below an outermost surface of the first jaw or the second jaw below an outermost surface of the second jaw for clamping and alignment.

Young in view of Milliman discloses this limitation. As discussed, Young's upper beam portion ("cam plate 54") would travel within the covered second jaw (anvil member 20) of the combination in view of the teachings of a cover plate in

Milliman. *See* Ground 1, limitation [1.6]. Young disclose a second one of the beam portions, namely lower beam portion ("cam plate 56"), which is configured to engage the first jaw (the lower jaw) below an outermost surface of the first jaw.



To the extent that the Board determines that "below" means "within" (a construction Petitioner contends would be incorrect because it would impermissibly redraft the claim), it would have been obvious to move the lower beam portion within the lower jaw based on Milliman's disclosure of the upper beam portion traveling within the upper jaw. To avoid pinching and to avoid tissue from interfering with the operation of the lower beam portion, a POSITA would have been motivated to modify Young to cover the cam plates in both jaws based on the teachings of Milliman. Knodel,¶94. This would be especially true if the POSITA's design constraints permitted a thicker lower jaw. Accordingly,

Milliman does not "teach away" from this modification, but merely discloses an alternate approach with its own benefits and drawbacks. *See Meiresonne v. Google,* 849 F.3d 1379, 1382 (Fed. Cir. 2017) (reference that provides "alternative invention, but does not criticize" the claimed invention "does not teach away.")

[3.] The apparatus of claim 1, wherein the pusher and the beam are coupled together as one piece.

Young discloses this limitation. Knodel,¶95. Young's pusher and beam are formed from "elongated support beam 52," and are thus coupled together as one piece. *Id*.; Young, 4:32-47. Likewise, Milliman's pusher and beam are similarly coupled together as one piece ("drive beam 266") (each laminate portion forms a portion of both the pusher and I-beam). Milliman, 12:53-67, FIGs. 29-34.

[4.] The apparatus of claim 1, further comprising a gear or a cable for controlling the gross movement or the fine movement.

In the combination, the pneumatic components of Young responsible for driving the fine movement of the Young device's jaws are replaced with the hand-powered components of Milliman responsible for driving the fine movement of the Milliman device's jaws. A POSITA would be motivated to make this combination in order to provide an instrument having the benefits of Young's end effector (*e.g.*, strong clamping) and that does not require compressed gas to operate. Knodel,¶96. This would allow for repeated stapling operations without having to change the gas canister or change the instrument (in the case of a single use or limited use gas-

powered instrument), which could potentially result in a more cost-effective device. *Id.*, Young, 5:14-17 (incorporating Green 023), Green 023. In fact, Young specifically teaches that a manual alternative may be used. Young, 2:46-50. In this combination, the Milliman drive components discloses a gear or cable (e.g., gear 94, gear 98, gear plate 106, and/or actuation shaft 46 with gear teeth 110a and 110b, all of which provide the fine movement of the I-beam in Milliman) (see components in green below) for controlling the gross movement or the fine movement (in this example, the fine movement) of the jaws. Milliman, FIGS. 4, 6, and 7; 8:1-57, 14:26-36; FIGs 46-49 and related text. Knodel,¶¶97-98.

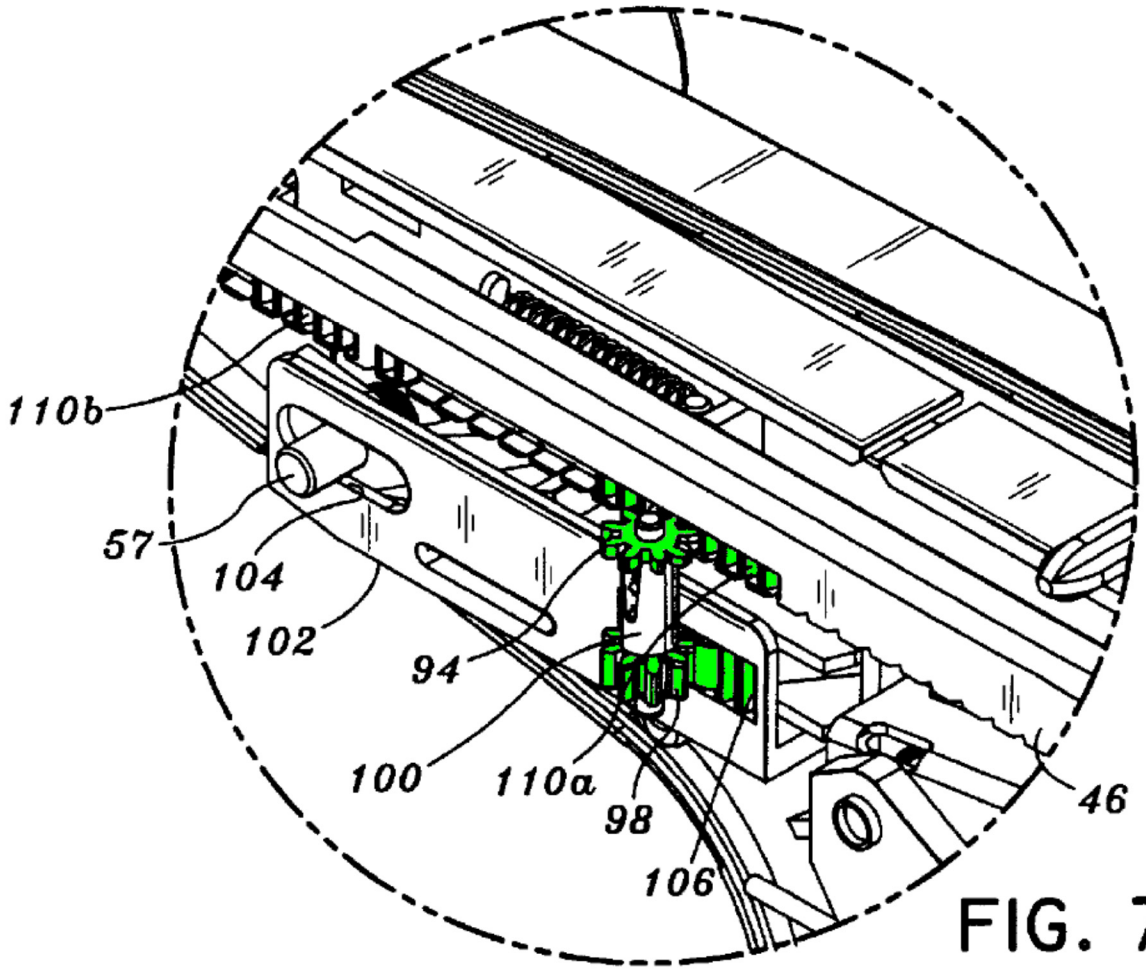


FIG. 7

A POSITA would have a reasonable expectation of success in making the modification because it is merely combining mechanical features in similar tools in a predictable manner and in a way well within the skill of a POSITA based on the teachings of the prior art references. Knodel,¶100.

[5.pre]. An apparatus, comprising:

As the Examiner already found, Young discloses an apparatus. *See* Ground 1A, [1pre].

[5.1] 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 sealing tissue;

As the Examiner already found, Young discloses a head portion having a first jaw (cartridge housing 24 and cartridge 18) and a second jaw (anvil member 20) configured to move between a first configuration (open position) for receiving tissue and a second configuration (closed position) for sealing tissue. *See* Ground 1A, [1.1]. Tissue is sealed when the instrument is fired and the staples are ejected out of the cartridge and into the tissue. Young, 3:45-60 ("…tissue is captured between cartridge 18 and anvil 20, and staples are applied to the tissue."); 5:31-36.

[5.2] a beam having an upper beam portion and a lower beam portion connected by a central web portion having a leading edge including a cutting blade that is more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion, wherein the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw at least partially from within the first jaw and the second jaw when in the second configuration as the central web portion moves distally along a channel defined in a tissue contacting surface of each of the first jaw and the second jaw;

Although the ordering of the elements in this limitation is different than claim 1 it is largely co-extensive with claim 1 and the analysis for claim 1 applies equally here. Young in view of Milliman discloses a beam having an upper beam portion and a lower beam portion where the two beam portions are connected by a central web portion having a leading edge including a cutting blade that is more distal than at least one of a trailing edge of the upper beam portion and a trailing

edge of the lower beam portion, (*see* Ground 1A, [1.3]) and wherein the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw at least partially from within the first jaw and the second jaw when in the second configuration (*see* Ground 1A, [1.6.2]) as the central web portion moves distally along a channel defined in a tissue contacting surface of each of the first jaw and the second jaw (*see* Ground 1A, [1.7]). Knodel,¶103.

[5.3] a pusher operatively coupled to the beam and configured to move the beam distally;

As the Examiner already found, Young discloses this limitation. Young discloses a pusher operatively coupled to the beam. *See* Ground 1A, [1.3]. The pusher of Young is also configured to move the beam distally. Actuation mechanism 50 "translate[s] distally until each of the staples are ejected from the cartridge," Young, 5:37-40, and "[a]ctuation mechanism 50 includes an elongated support beam 52 …." Young, 4:32-36. Because "elongated support beam 52" makes up at least part of the pusher and part of the beam, distal movement of the pusher (one part of elongate support beam 52) will likewise cause distal movement of the beam (another part of elongate support beam 52). Knodel,¶104.

[5.4] a control handle configured to actuate receiving, clamping and sealing of tissue; and

As the Examiner already found, Young discloses this limitation. IS1002, 45-46. Young has a control handle ("handle portion 12") configured to actuate the receiving of tissue, which would be the act of positioning the instrument with the handle so that the instrument jaws are adjacent to the tissue in question. The control handle (via actuation of trigger 108) actuates clamping by triggering the pneumatic drive to cause the I-beam of Young to clamp the tissue. "[A] pneumatic drive system 90 is operatively associated with handle portion 12 to control the translation of actuation mechanism 50 through fastener applying assembly 15 during a stapling procedure." Young, 4:60-63. The "distal translation of actuation mechanism 50 causes" the "clamping the body tissue 110" between the jaws. Young, 5:26-31. Likewise, the control handle actuates the sealing of tissue because actuation of trigger 108 also cause firing of staples to seal the tissue. The "staple drivers 35 are activated by the wedged cam surface 78 on each of the staple firing bars 70a-70d driving staples through the captured body tissue 110." Young, 5:32-36. Knodel,¶105-107.

[5.5] a shaft coupling the control handle to the head portion; wherein at least one of the upper beam portion and the lower beam portion is orthogonally attached to an end of the central web portion, and the pusher is coplanar with the central web portion and the channel.

Young discloses this limitation. IS1002, Knodel,¶108.

"a shaft coupling the control handle to the head portion"

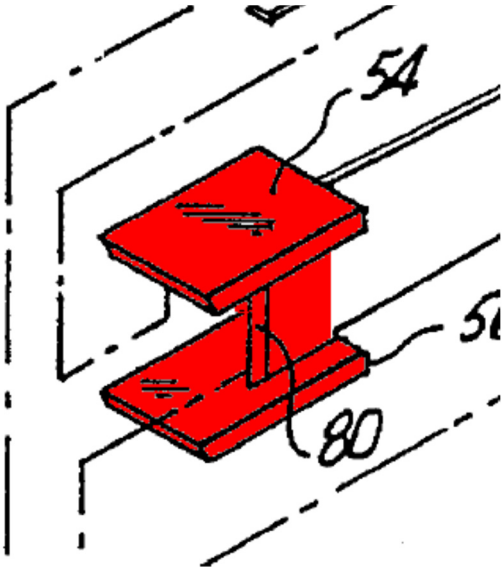
See Ground 1A, [1.5].

"wherein at least one of the upper beam portion and the lower beam portion is orthogonally attached to an end of the central web portion, and the pusher is coplanar with the central web portion and the channel"

See Ground 1A, [1.7]. As shown in the figures from Young, the central web is orthogonally attached to the upper and lower portions of Young's I-beam.

[6.] The apparatus of claim 5, wherein the beam is an I-beam and the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw entirely from therewithin.

Young in view of Milliman discloses this claim. Young discloses an I-beam. *Id.*; Young, 4:33-35, Fig. 2 (excerpt).



In Young, the upper and lower portions of the I-beam are configured to clamp and align the jaws from outside the jaws by keeping the jaws at a fixed distance during staple firing. *See* Ground 1A, [1.6.1 and 1.6.2]. It would have been obvious in view of Milliman to modify Young by adding a cover to each of the first and

second jaws. In the resulting combination, the upper and lower portions of the I-beam would travel within enclosed passagways within the second and first jaw, respectively, enabling the I-beam to clamp and align the jaws entirely from within both jaws. *See* Ground 1A, [1.6.1, 1.6.2], [2], Knodel,¶¶109-110.

[7.1] The apparatus of claim 5, wherein the first jaw defines a cavity configured to receive a plurality of staples and a plurality of slots configured to pass said plurality of staples therethrough;

Young discloses this limitation. Knodel,¶111. Young's first jaw (cartridge housing 24 and cartridge 18) defines a cavity (the volume defined in cartridge 18 that holds the staples) configured to receive a plurality of staples. Young, 1:21-23; FIG. 3.

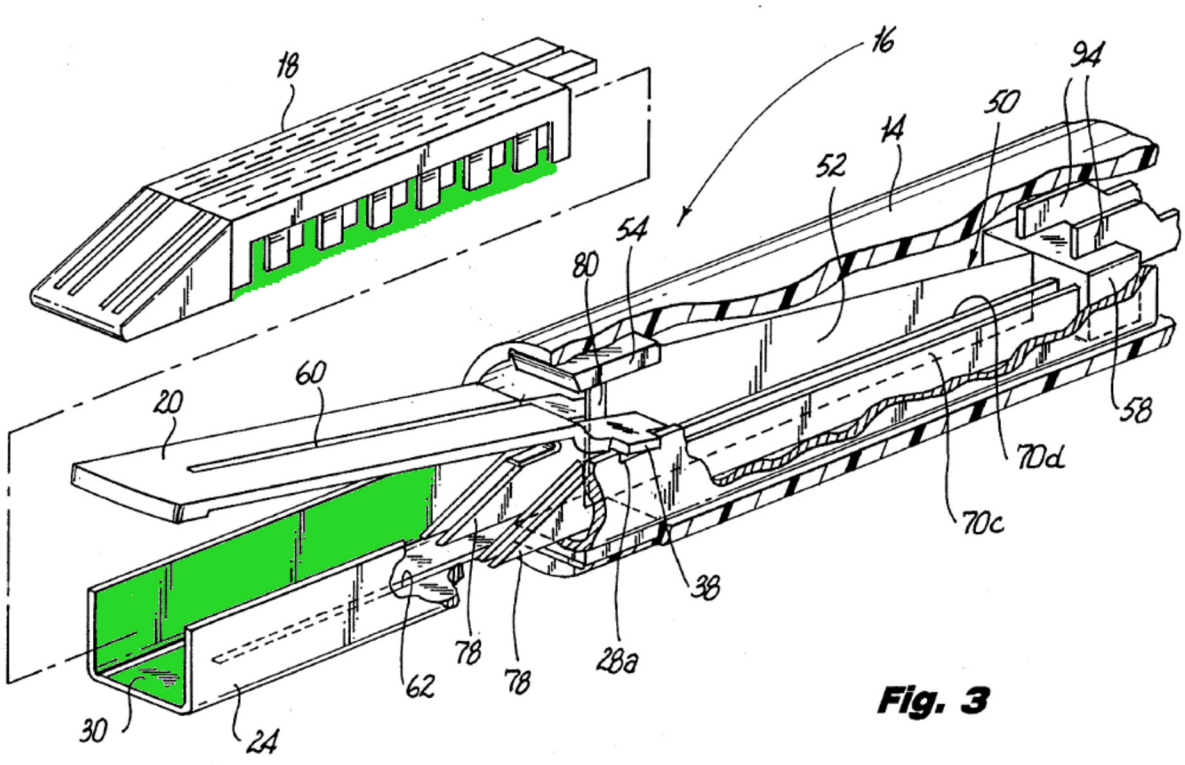
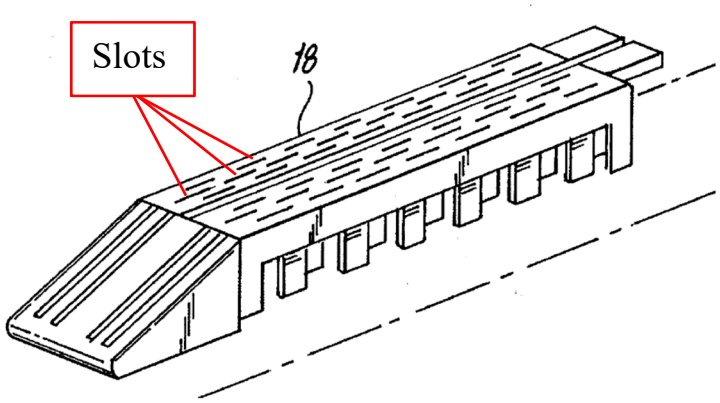


Fig. 3

Cartridge 18 further has a plurality of slots configured to pass the plurality of staples (the staples are ejected through the slots and into the tissue). Young, 2:12-17.



Young, FIG. 3 (excerpt) (the volume is at least the space in which the staples sit below the slots at the top surface of the cartridge). *See* Ground 1A, [1.1.2].

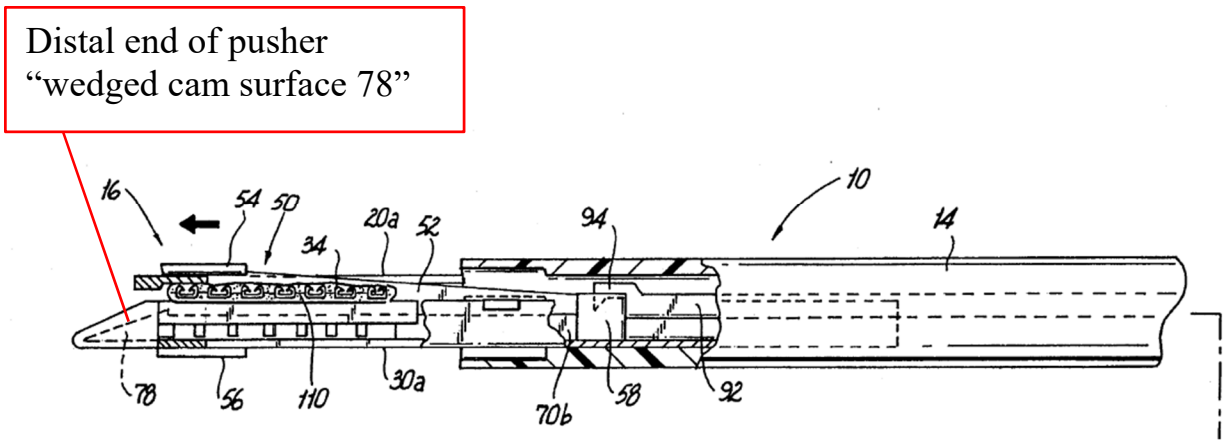
[7.2] the second jaw has a staple-forming surface;

See Ground 1A, [1.1.3].

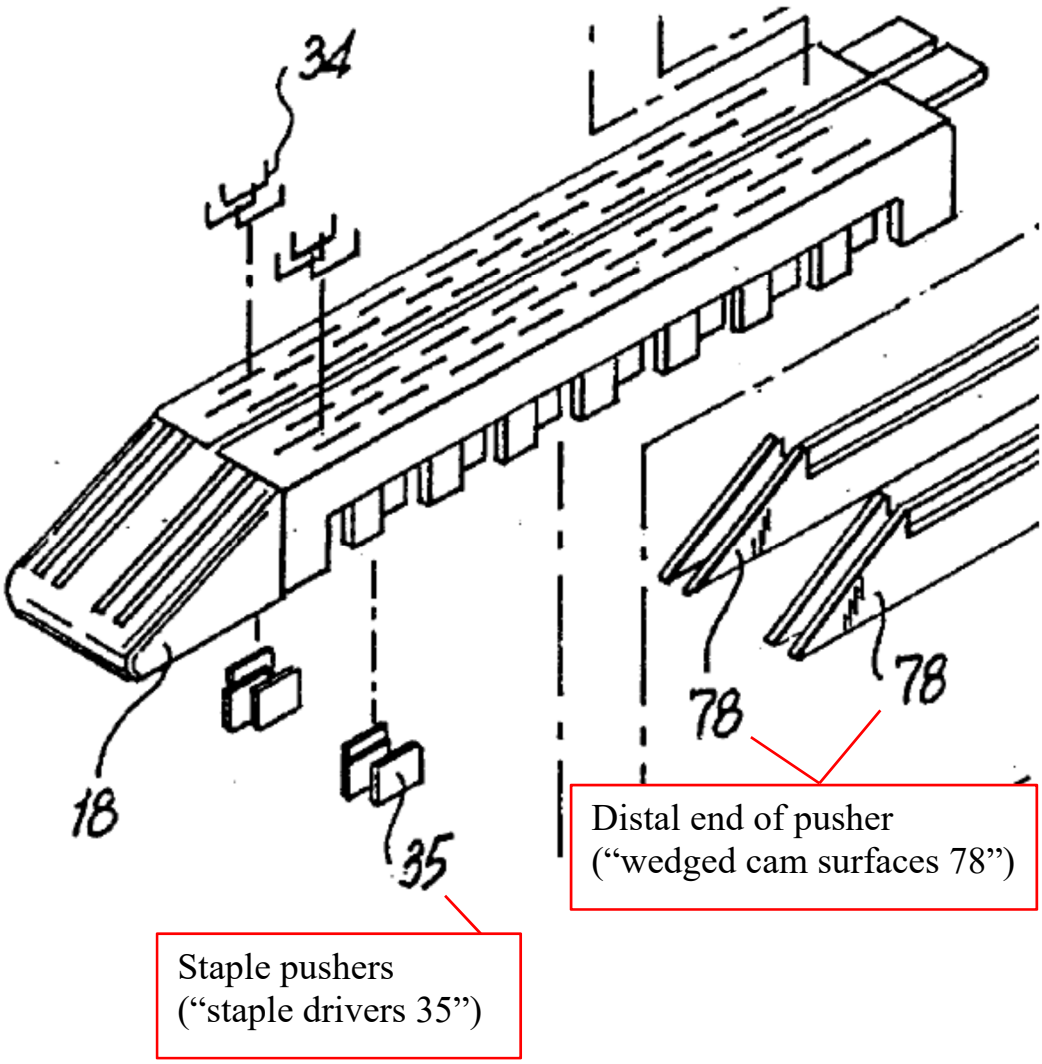
[7.3] and the pusher is configured to cause a staple pusher to move for firing a staple as the beam moves distally.

The distal end (wedged cam surface 78) of Young's pusher is configured to cause a staple pusher (35) to move for firing a staple (34) as the beam moves distally. "A plurality of spaced apart cam plates [defining wedged cam surface 78] are provided on the actuator [50] and are configured to engage a plurality of staple pushers [35] disposed within the cartridge housing to effect the ejection of surgical fasteners [34] therefrom." Young, 2:27-31. Actuation mechanism 50 "translate[s]

distally until each of the staples are ejected from the cartridge 18." Young, 5:37-40, Figs. 2, 5-6, Knodel,¶¶113-114.

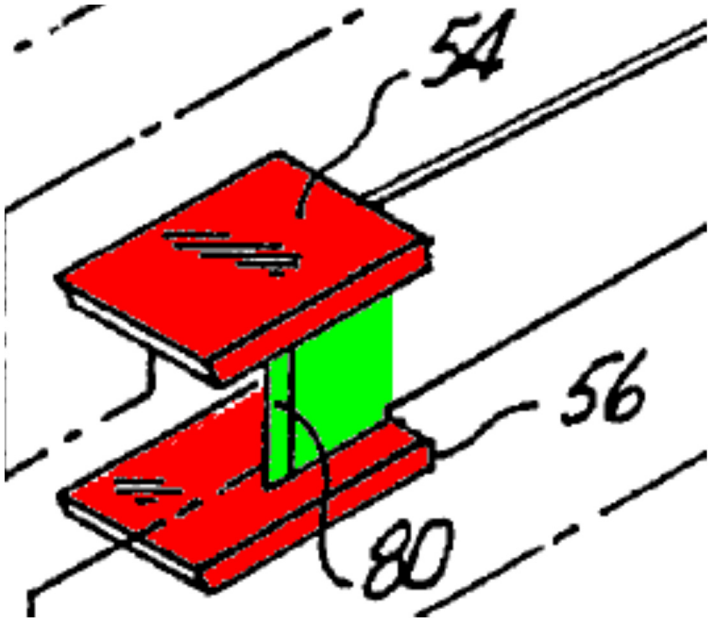


Young, FIG. 6.



[8.] The apparatus of claim 7, wherein each of the upper beam portion and the lower beam portion is substantially wider than the central web portion in cross section, and the head portion is rotatably coupled to the shaft.

Young discloses this limitation. Knodel,¶¶115-118. Each of Young's upper beam portion and lower beam portion ("cam plates 54 and 56") is substantially wider in cross section than the central web portion (the vertical part of the distal portion of "elongated support beam 52" supporting the cam plates). *Id.*; Young, Fig. 2.



In addition, Young's head is rotatably coupled to the shaft in two different ways. First, the anvil member 20, which together with cartridge housing 24 and cartridge 18 form Young's head, is rotatably coupled to the shaft ("body portion 14") because anvil member 20 can rotate relative to the shaft and cartridge housing 24 when it opens and closes. Young, 2:8-13, FIGs 3-6 (depicting structure that permits pivoting (rotation) of anvil).

Second, Young's head is coupled to the shaft ("body portion 14") for rotation; rotation of the shaft will cause rotation of the head. "As best seen [below] in FIG. 1, a rotation control knob. 22 is provided at the proximal end of body portion 14 and is mounted in such a manner so as to facilitate rotation of body portion 14 and fastener applying assembly 16 about a longitudinal axis defined by the body portion 14." Young, 3:49-54.

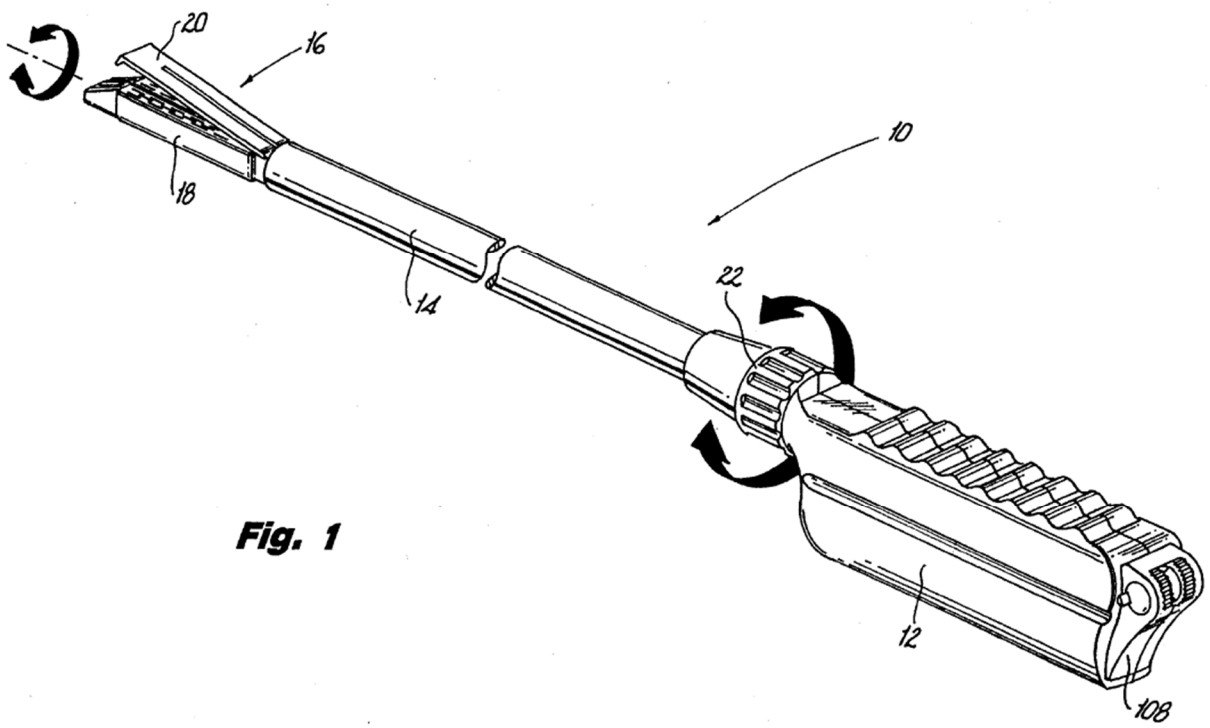


Fig. 1

Finally, in the alternative combination where the resulting instrument articulates, *see* Ground 1A, claim 1, the articulation joint provides a rotatable coupling between the shaft and the head. Knodel,¶118.

[9.] The apparatus of claim 5, wherein the head portion is movably coupled to the shaft, and the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw entirely from within the first jaw and the second jaw when in the second configuration.

Young in view of Milliman discloses this limitation. *See* Ground 1A, [1.6.2] and claims [2], [6], and [8], Knodel,¶¶119-120. The head of Young is movably coupled to the shaft ("body portion 14") because, as discussed, its anvil member 20 can open and close relative to the shaft. Additionally or in the alternative, the head is movably coupled to the shaft because rotation of the shaft along its longitudinal

axis produces a rotation of the head. Additionally or in the alternative, the head being movably coupled to the shaft is disclosed in the Young/Milliman combination, because in at least one articulating embodiment, the head articulates relative to the shaft. And, as discussed previously, in the Young/Milliman combination, the I-beam clamps and aligns the jaws entirely from within the two jaws when the jaws are closed because the Young/Milliman combination involves adding covers would be added to both of Young's jaws. The upper and lower portions of the I-beam would travel within enclosed passagways within the second and first jaw, respectively, enabling the I-beam to clamp and align the jaws entirely from within both jaws when the jaws are closed.

[10.] The apparatus of claim 5, wherein the head portion is sized for laparoscopic surgery.

Young discloses this limitation. Knodel,¶121. Young's instrument is a laparoscopic instrument and thus has a head portion sized for laparoscopic surgery. Young, 3:26-34.

[11.] The apparatus of claim 5, wherein the control handle includes at least one of an actuation handle, a lever, a trigger, a knob and a cable.

Young discloses this limitation. Knodel,¶122. Young's control handle (12) includes a trigger ("pivoting trigger 108") and a knob ("rotation control knob 22"). *Id*.; Young, 5:11-17; Young, 3:49-54; Ground 1A, [1.4].

[12.] The apparatus of claim 5, wherein the apparatus is powered.

Young discloses this limitation. Knodel,¶123. Young's instrument is powered pneumatically. *Id*.; Young, 4:60-67.

[13.] The apparatus of claim 12, wherein the apparatus is powered electrically, hydraulically or pneumatically.

Young discloses this limitation. Young is powered pneumatically. *See* Ground 1A, claim [12].

[14.] The apparatus of claim 5, wherein one of the first jaw and the second jaw includes an overhanging flange at a proximal end that extends past a surface of the other of the first jaw and the second jaw when the first jaw and second jaw are in the first configuration and the second configuration.

Young in view of Milliman discloses this limitation. Knodel,¶¶125-126. In the combination, a modified anvil is created by adding Milliman's anvil cover ("cover plate 208") to the anvil member 20 of Young. This modified anvil will include all of the features of Milliman's anvil cover, including the overhanging flanges (left-side flange show in red below) that, in Milliman, extends past the top surface of the cartridge in both the first (open) configuration and the second (closed) configuration. In the combination, the modified anvil's flanges would similarly extend past the top surface of Young's first jaw (combination of "cartridge housing 24" and "cartridge 18") when the first jaw and the second jaw (modified anvil) are in the first (open) configuration and the second (closed) configuration.

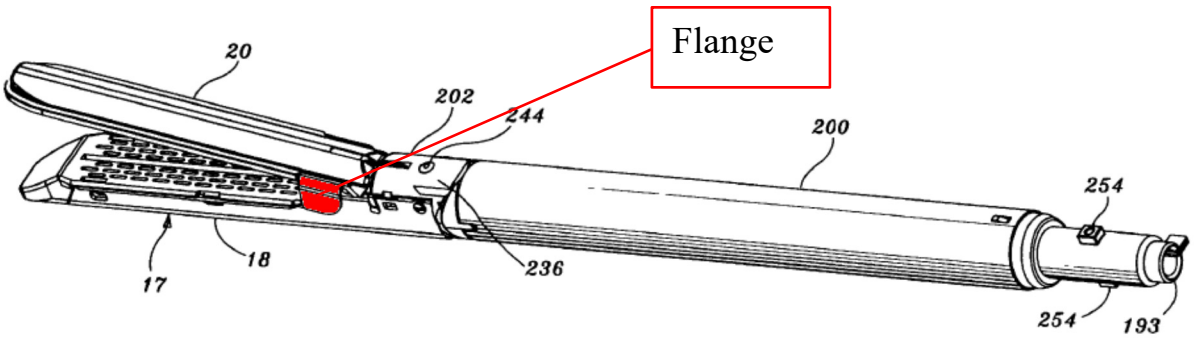
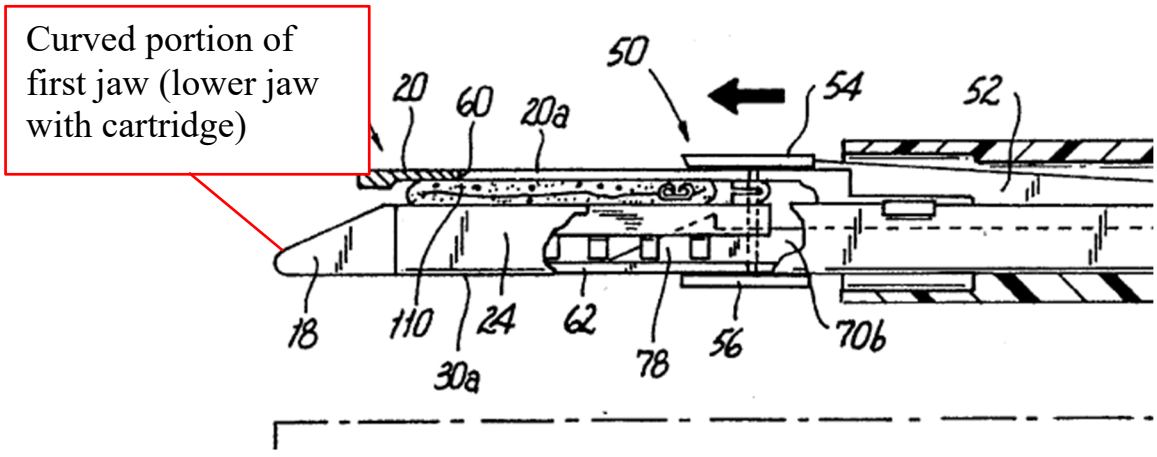


FIG. 20

[15.] The apparatus of claim 5, wherein at least a portion of the first jaw and the second jaw is curved.

Young discloses this limitation. Knodel,¶¶127-128. Young discloses a curved lower jaw and also a curved upper jaw. *Id.*; Young Fig. 5.



Furthermore, Young in view of Milliman discloses this limitation. In the Young/Milliman combination, Milliman's anvil cover ("cover plate 208") is added to Young's anvil member 20 to form a modified anvil. In the combination, this modified anvil makes up the recited "second jaw." Because Milliman's cover plate

208 includes a curved portion, at least a portion of the second jaw of the Young/Milliman combination is curved. Milliman, Fig. 19 (excerpt)

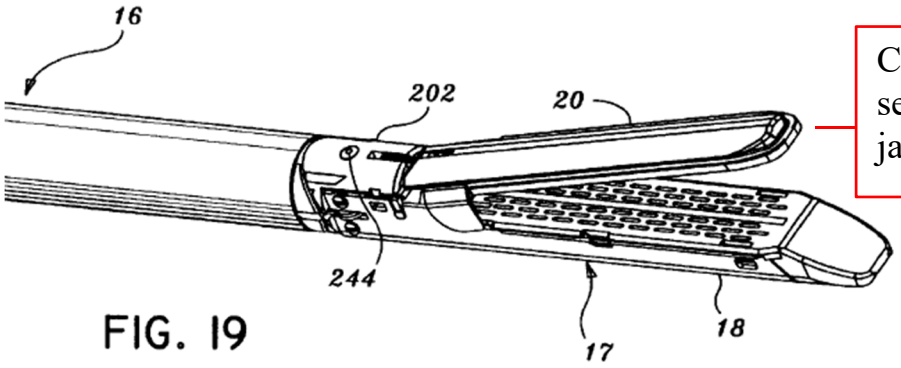


FIG. 19

B. GROUND 1B: Claims 1-3 and 5-15 Would Have Been Obvious over Young in View of Green 695

[1pre] – [1.5] and [1.7]

See Ground 1A, [1pre]-[1.5], [1.7]. Young discloses each of these limitations.

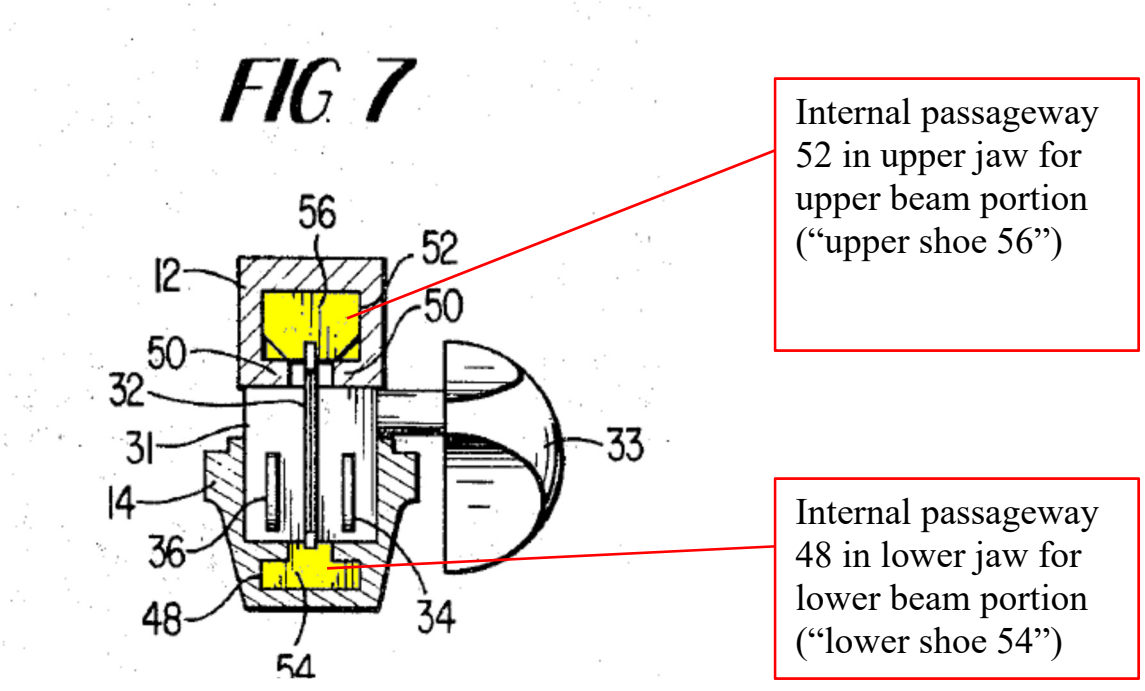
[1.6.2] at least one of the upper beam portion and the lower beam portion … is configured to engage the first jaw or the second jaw entirely from within the first jaw or the second jaw for clamping and alignment; and

Young in view of Green 695 discloses this limitation.

It would have been obvious in view of Green 695 to move both Young's upper beam portion and lower beam portion ("cam plates 54 and 56") "within" the jaws. Knodel,¶¶129-137; Green 695, 1:49-57, 4:10-19, 4:50-60, 6:26-41, FIGs 3-7. Green 695 discloses a surgical stapler designed for open surgeries (as opposed to laparoscopic surgeries). Nonetheless, the functional architecture of the stapler head portion (end effector) is common to both Young and Green 695. Similar to

Young, Green has a first jaw ("lower jaw 20") that holds a staple cartridge 44 and second jaw ("upper jaw 16") that holds anvil members 72. Green 695, 3:23-54. Like Young, Green has an I-beam formed by a "central knife carrier 32" and "upper and lower shoes 54 and 56." Green 695, 4:30-60, FIGs. 3-5. Like Young, Green's I-beam provides vertical alignment, and clamps and cuts tissue as the tissue is stapled (alignment and clamping provided by the "shoes" of Green 695. Knodel,¶129.

Unlike Young, however, Green 695 discloses upper and lower beam portions ("lower and upper shoes 54 and 56") that travel inside passageways within the upper and lower jaws:



Green 695, FIG. 7; 4:30-60; 6:26-40

Green 695 teaches specific benefits of its internal passageways, thus providing a motivation to use the internal passageways in other surgical stapler designs. Knodel,¶¶131-137.

First, a POSITA would have been motivated by the teaching of Green 965 to modify Young to provide travel paths for the Young's upper and lower beam portions ("cam plates 54 and 56") located within the jaws to get the benefit of greater vertical and lateral alignment. *Id*. Green 695 teaches that "by locating the [upper and lower beam portions] both laterally and vertically in the respective passageways, both lateral alignment of the jaws and resistance to vertical jaw opening during stapling is obtained." Green 695, 4:57-60, 2:12-22.

Second, a POSITA would have been motivated by the teaching of Green 695 to modify Young to provide internal passageways in order to provide a more rigid device with greater structural stability. Green 695 describes "vertical stabilization" as well as alignment. Green 695, 2:7-56.

Third, Green 695 explains that the cross sectional shape of its internal passageways are particularly well suited to resist bending and twisting forces: "Due to the cross-sectional shape of the shoes and passageways, such support resists forces tending both laterally to distort the jaws and to open the jaws vertically, and accordingly the present construction lends itself to manufacturing the jaws in relatively lightweight disposable materials. It is to be understood,

however, that the construction can also be used in in instruments manufactured from more conventional materials." Green 695, 6:33-41.

Fourth, Green 695 explains that its invention is applicable to devices other than the specific embodiments shown: "The invention may be applied to other fastening instruments having opposed jaws which require stabilization while fastening means are applied to living tissue gripped between the jaws." Green 695, 6:49-52. Thus, even though Young is a laparoscopic surgical stapler, a POSITA would understand that Green's structure has general applicability to surgical jaws requiring stabilization and would have been motivated to modify Young's structure to provide that stabilization.

In the combination for Ground 1B, a POSITA would have been motivated to apply Green 695's teaching of internal passageways to the jaws of Young and would have reason to keep the relative dimensions of Young's upper and lower beam portions ("cam plates 54 and 56") as disclosed in Young. These cam plates offer a relatively larger surface area with which to apply clamping forces and thus allow those forces to be distributed over the cam plate. Compared to the upper shoe 56 and lower shoe 54 of Green 695, the mechanical stress to Young's cam plates 54 and 56 will be lower. In addition, as the number of rows of staples increases, a POSITA would have found it desirable to increase the surface area of

the cam plates to apply the increased forces necessary to fire the additional staples. *Id,*

A POSITA would have had a reasonable expectation of success in making this relatively simple mechanical modification given the similarities of the references. For example, adding cover plates to stapler jaws or otherwise modifying jaws to include internal passageways is well within the skill of a POSITA. Knodel,¶137.

[2] The apparatus of claim 1, wherein a second one of the upper beam portion and the lower beam portion is configured to engage the first jaw below an outermost surface of the first jaw or the second jaw below an outermost surface of the second jaw for clamping and alignment.

Young in view of Green 695 discloses this additional limitation. In the combination, both upper beam portion and lower beam portion engage the jaws from within the first jaw ("lower jaw 20") and second jaw ("upper jaw 16"). Because the upper beam portion is configured to engage the second jaw ("upper jaw 16") from within the second jaw, the upper beam portion engages the second jaw below an outermost (top) surface of the second jaw for clamping and alignment. Knodel,¶138. Green 695, 1:49-62, 2:7-56. *See* Ground 1B, [1.6.2].

[3.] The apparatus of claim 1, wherein the pusher and the beam are coupled together as one piece.

See Ground 1A, [3].

[5.pre]-[5.1]

See Ground 1A, [5.pre]-[5.1].

[5.2] a beam having an upper beam portion and a lower beam portion connected by a central web portion having a leading edge including a cutting blade that is more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion, wherein the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw at least partially from within the first jaw and the second jaw when in the second configuration as the central web portion moves distally along a channel defined in a tissue contacting surface of each of the first jaw and the second jaw;

Young in view of Green 695 discloses a beam having an upper beam portion and lower beam portion (the "cam plates" of Young) where the two beam portions are connected by a central web portion having a leading edge including a cutting blade that is more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion. *See* Ground 1A, [1.3]; Ground 1B, [1.6.2].

In the combination, because jaws of Young are modified so that the cam plates of Young are relocated from outside the jaws to inside the jaws, the clamping and alignment is at least partially from within the first jaw and the second jaw (see Ground 1B, [1.6.2]) as the central web portion moves distally (*see* Ground 1A, [1.7]). Knodel,¶¶141-142.

[5.3]-[5.5]

See Ground 1A, [5.3]-[5.5].

[6.] The apparatus of claim 5, wherein the beam is an I-beam and the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw entirely from therewithin.

Young in view of Green 695 discloses this limitation. Young discloses an I-beam with upper and lower beam portions. *See* Ground 1A, [6]. In the combination, Young's upper and lower beam portions are moved within their respective jaws so as to be configured to clamp and align the first jaw and second jaw entirely from therewithin. *See* Ground 1B, [1.6.1 and 1.6.2], [2.]. Knodel,¶144.

[7]-[8]

See Ground 1A, [7]-[8].

[9.] The apparatus of claim 5, wherein the head portion is movably coupled to the shaft, and the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw entirely from within the first jaw and the second jaw when in the second configuration.

Young in view of Green 695 discloses this limitation. Young's head is movably coupled to Young's shaft (including being rotatably coupled). *See* Ground 1A, [9]. Young in view of Green 695 would have the upper beam and lower beam portions clamping and aligning entirely from within the two jaws. *See* Ground 1B, [1.6], [2], [6]. Knodel,¶146.

[10]-[13]

See Ground 1A, [10]-[13].

[14.] The apparatus of claim 5, wherein one of the first jaw and the second jaw includes an overhanging flange at a proximal end that extends past a surface of the other of the first jaw and the second jaw when the first jaw and second jaw are in the first configuration and the second configuration.

Young in view of Green 695 discloses this limitation. Knodel,¶¶148-149. Green 695 discloses a first jaw ("lower jaw 20") that includes an overhanging flange (shown in green) at a proximal end. FIG. 2 shows the position of the flange just before the first configuration (open position) and FIG. 1 shows the position of the flange in the second configuration (closed position). A POSITA would understand that the purpose of the flange at the pivot point of the jaws is to keep tissue out of the pivot area (which creates a pinch point).

FIG. 1

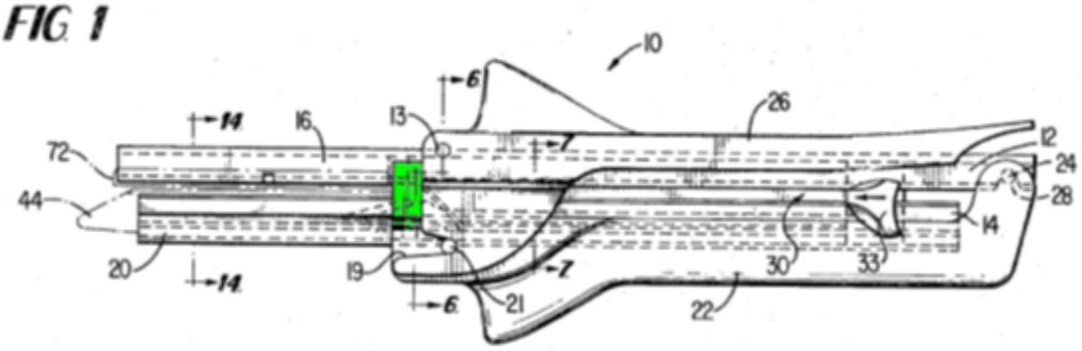
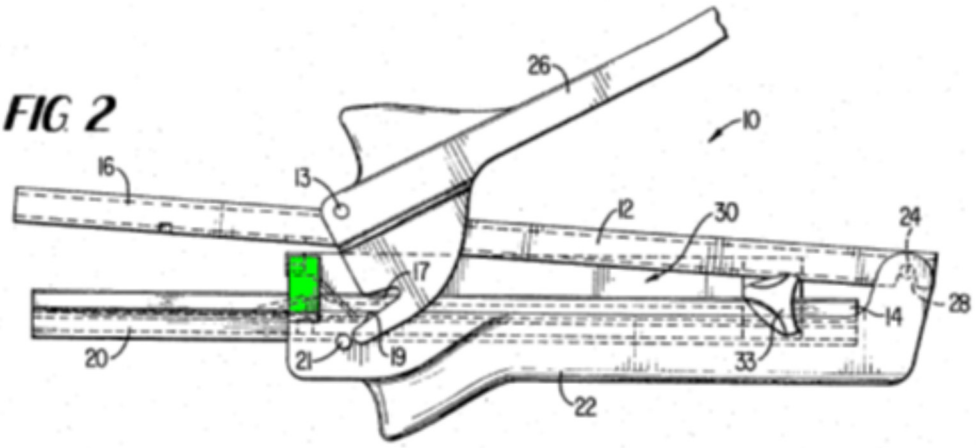


FIG. 2



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 (open position) once the handle lugs 21 engage the camming surfaces 19. A POSITA would be motivated to use the flange in the combination to avoid pinching tissue during operation at the pivot point. Knodel,¶149. A POSITA would likewise be motivated to increase the length of the flange so that it would overhang the opposite jaw from the moment of stapler assembly (e.g., overhanging in the FIG. 2 position) to provide even greater protection from pinching. *Id.*

[15.] The apparatus of claim 5, wherein at least a portion of the first jaw and the second jaw is curved.

See Ground 1A, [15].

IX. GROUND 2: Claim 4 would have been obvious over Young in view of Green 695 and further in view of Knodel 895

[4.] The apparatus of claim 1, further comprising a gear or a cable for controlling the gross movement or the fine movement.

Young in view of Green 695 discloses all elements of claim 1. *See* Ground 1B, claim [1.] Young's instrument is powered pneumatically and Green 695's instrument is powered manually. As the Examiner already found, it would have been obvious to modify Young to include gears in the drive mechanism as taught by Knodel 895. IS1002, 49. A POSITA would have been motivated to add gears to the drive mechanism for the purpose of increasing the mechanical advantage of the drive system as taught by Knodel and as explained by the Examiner. *Id.*, Knodel 895, 10:65-11:12. Increasing the drive system's mechanical advantage

would, for example, permit a given input force to produce a larger output force, which may be advantageous for treatment of certain tissues with a surgical stapler. Knodel,¶¶151-153.

X. GROUND 3: Claims 1-15 would have been obvious over Green 209 in view of Green 695 and Alesi

[1.pre] *(To avoid redundancy, the brackets refer to the same claim elements recited in the preceding grounds).*

If the preamble is deemed to be a limitation, Green 209 discloses an apparatus ("endoscopic surgical stapling instrument 50"). Knodel,¶¶154-155; Green 209, 11:17-20, Figs. 1, 90.

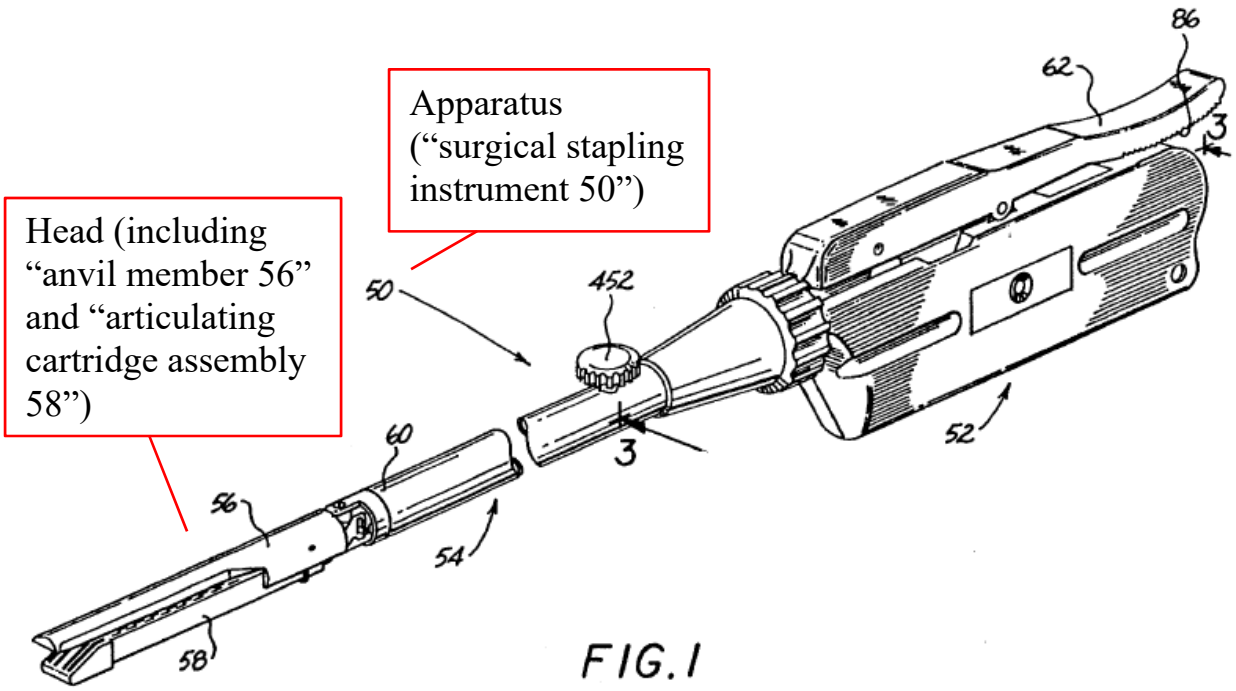


FIG. 1

[1.1]

Green 209 discloses this limitation. Knodel,¶155. Green 209 discloses a head (combination of "anvil member 56" and "articulating cartridge assembly 58"). *Id.*; Green 209, 11:21-35.

[1.1.1]

Green 209 discloses this limitation. Knodel,¶156. Green 209's head includes a first jaw ("forward housing portion 270" of "articulating cartridge assembly 58" with "cartridge 280") (shown in yellow) and a second jaw ("anvil member 56") (shown in blue), wherein the second jaw is movable relative to the first jaw from a first configuration (open) in which the jaws are spaced apart at a first distance (shown below in Figure 29) and a second configuration (closed) in which the jaws are spaced apart at a second distance (also shown below in Figure 30). *Id.*; Green 209, 11:18-35, 15:49-16:17, 18:1-40, 19:50-20:24, Figs 1, 15-16, 29, 30.

Second jaw (anvil member 56)

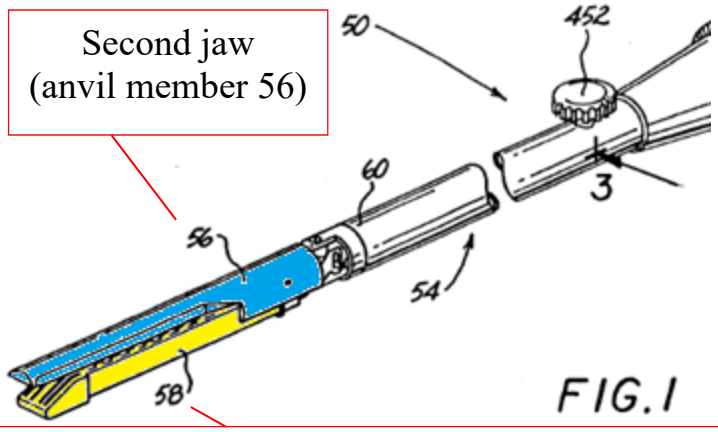


FIG. 1

First jaw (forward housing portion 270 of cartridge assembly 58)

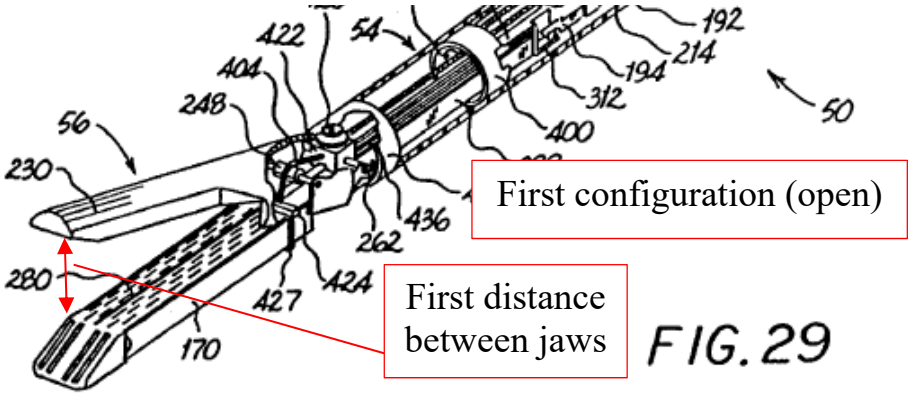


FIG. 29

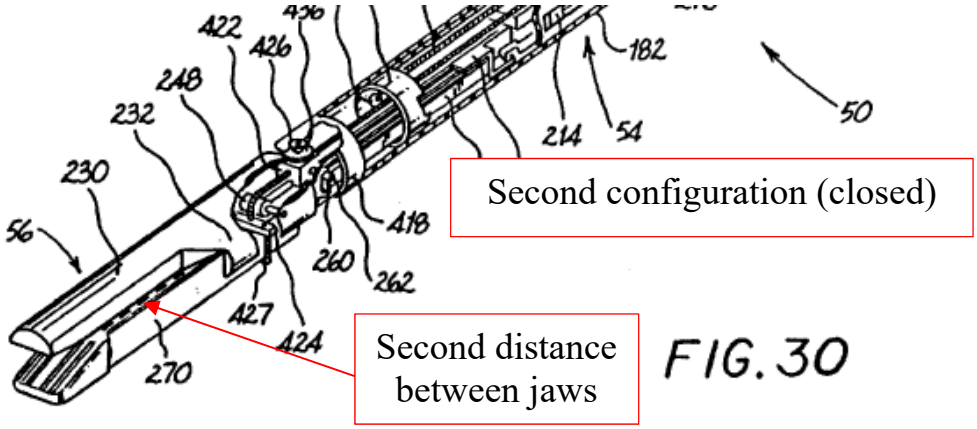
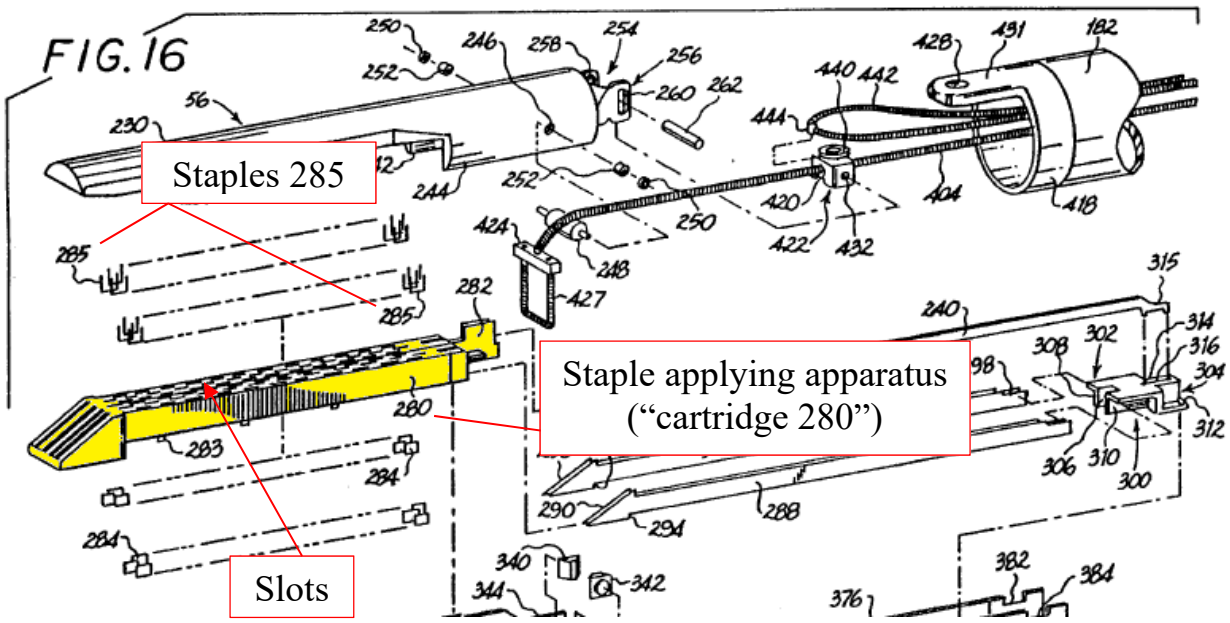


FIG. 30

[1.1.2]

Green 209 discloses this limitation. Knodel,¶157. Green 209's head includes a stapling assembly ("cartridge 280") of the first jaw defining slots (shown in Figures 16 and 18) through which "staples 285" are configured to pass in one or more rows extending from the proximal end to the distal end of the cartridge jaw. *Id.*; Green 209, 15:49-16:5, Figs. 16, 18.

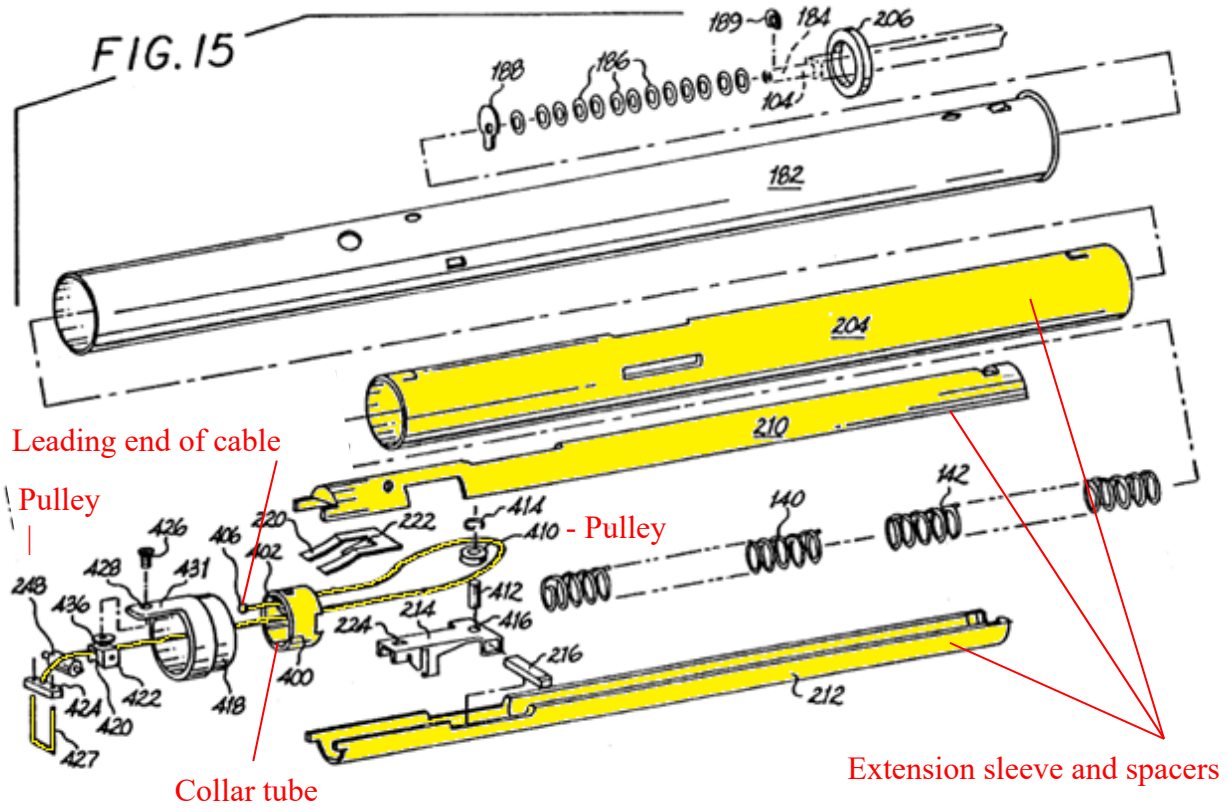


[1.1.3]

Green 209 discloses this limitation. Knodel,¶158. Green 209's head includes an anvil surface ("staple forming plate 234") of the second jaw being configured to form a staple (285). *Id.*; Green 209, 20:23-34, 25:2-17, 29:36-30:4, Figs. 17, 30.

[1.2]

Green 209 includes a first adjustment assembly (including "tube collar 400", "anchor ball 406," "cable 404," "anchor cable 427," "clamp tube 70," "extension sleeve 204," "pulley 410," "pulley 428," and "extension spacers 210, 212") configured for closure of the first jaw using a gross movement. Knodel,¶159; Green 209, 19:54-20:2; *see also id.,* 11:21-34, 60-67, 15:23-47, 19:50-20:22, 21:55-57, FIGs. 15, 16, 28-30.

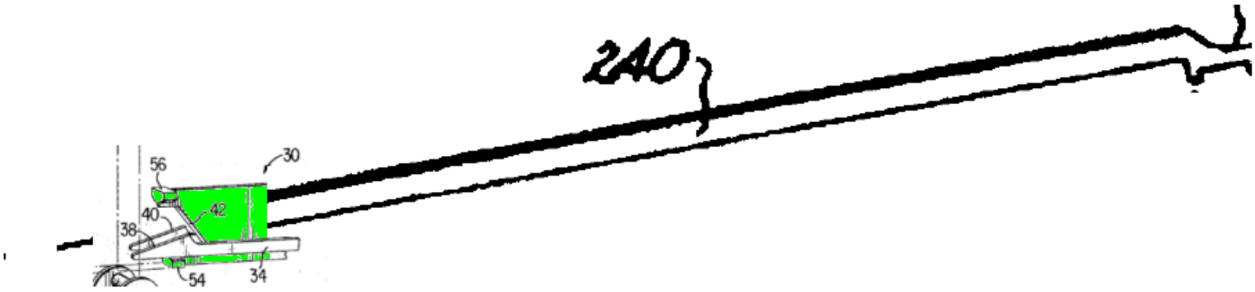


Green 209, FIG. 15.

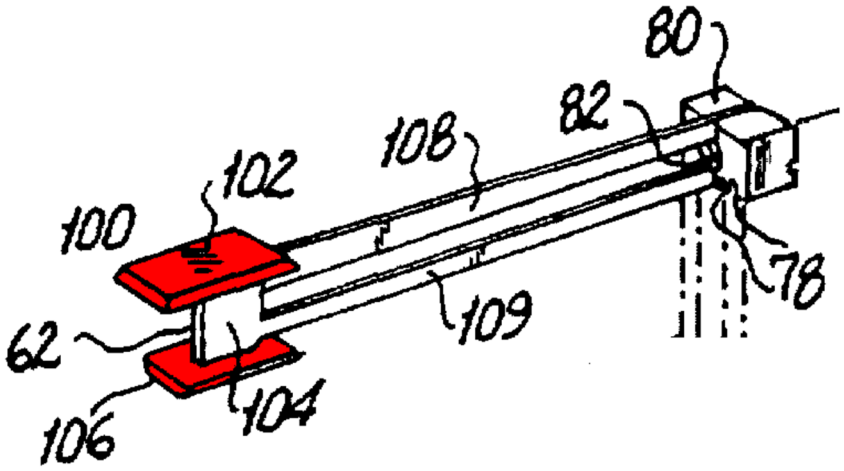
[1.3]

Green 209 in view of Green 695 and Alesi discloses this limitation. Knodel,¶¶160-169. In the combination, the instrument of Green 209 is modified to include an I-beam as taught by Green 695, where the upper and lower portions of Green 695's I-beam are further modified to take the form of large, flat plates, as taught by Alesi.

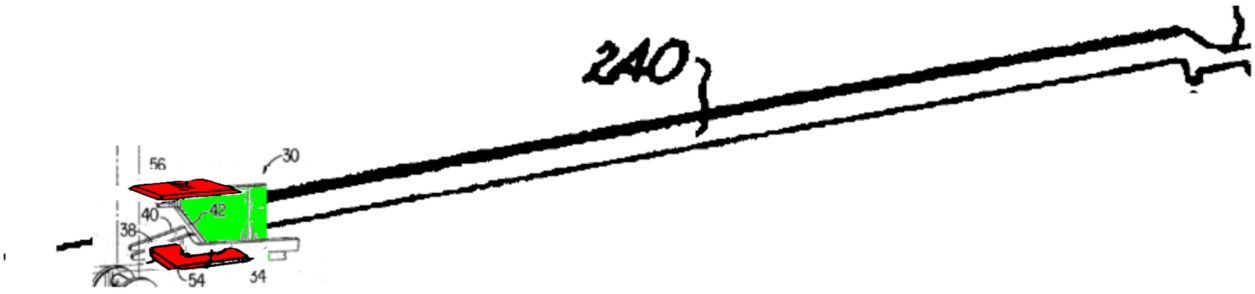
A composite of Green 209 (FIG. 16) and Green 695 (FIG. 3) is shown here:



Alesi's drive beam and I-beam are shown here (FIG. 4):



A composite applying the teachings of Alesi to the Green 209/695 stapler is shown here:



The combination has a second adjustment assembly with a beam configured for fine movement of the second jaw (anvil member 56 of Green 209) and to

maintain a fixed distance between the first and second jaws by virtue of the upper and lower beam portions (shoes of Green 695 as modified by the upper beam portion 102 and lower beam portion 106 of Alesi) connected by a central web portion ("central knife carrier 32" of Green 695 or alternatively "central web portion 104" of Alesi"). Green 695, 2:12-22, 4:56-60, FIG. 6; Alesi, 6:55-7:8.

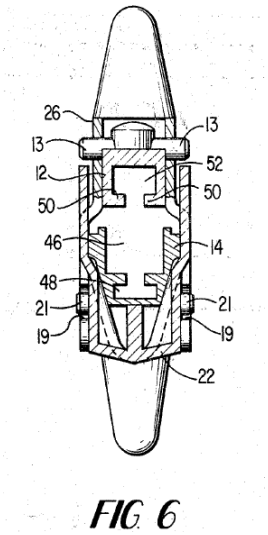


FIG. 6

Green, FIG. 6.

In the combination, a POSITA would have expanded the shoes of Green 695 into larger flat plates as taught by Alesi, and the resulting larger flat plates would extend proximally past the knife; in the resulting structure, the knife would be more distal than the trailing edges of both the upper and lower beam portions. Alesi, 6:55-7:21, FIG. 4, Knodel,¶¶164, 173. A POSITA would be motivated to make these modifications to obtain the benefits of shoes with a larger area for increased stability and to reduce stresses applied to the shoes. *Id*. In addition, a

POSITA would be motivated to use the larger surface area where additional rows of staples are used to greater distribute the increased stapling forces. *Id.*

In the combination, the I-beam is operatively coupled to a pusher (proximal end of Green 209's "knife 240", "cam bar adapter 300", dual "cam bars 286 and 288") and the pusher is configured to cause a staple pusher (pusher elements 284) to move for firing as the beam moves distally, and thereby eject staples into the clamped tissue. Green 209, 4:39-42, 15:61-16:5, 16:56-59, 20:23-34, Fig. 16. Knodel,¶165.

A POSITA would have been motivated to modify Green 209 to include the Green 695 I-beam for the reasons provided in Green 695—"to provide … optimum alignment and stabilization of the jaws … during application and securing of the fasteners." Green 695, 1:58-62. *Id.*, 1:49-57; 2:48-56. Green 209 recognizes the importance of proper alignment. Green 209, 4:30-36. A POSITA reading both Green 209 and Green 695 would have been motivated to improve the alignment and clamping capability of Green 209 by using the I-beam disclose in Green 695.

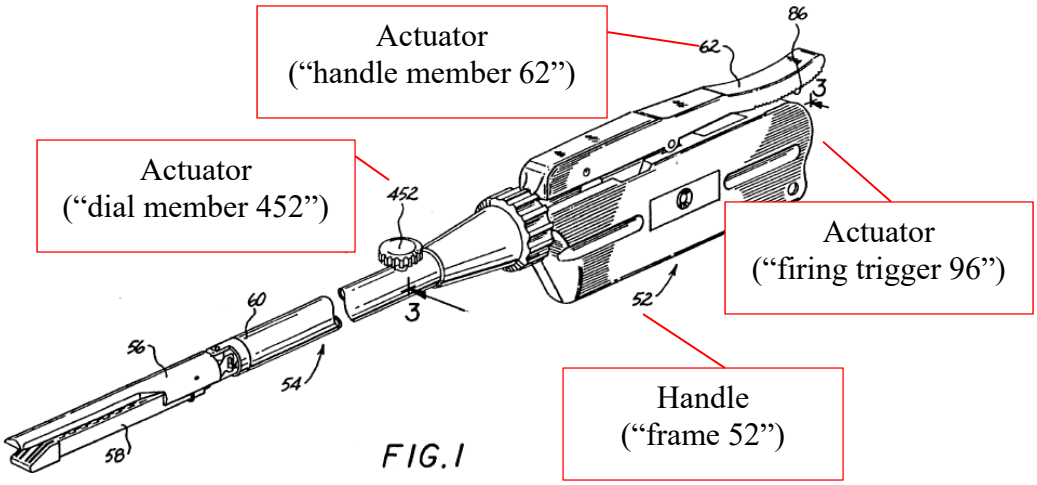
A POSITA would have understood that in the combination, the Green 209 components perform their same functions and the I-beam from Green 695 would perform the same function in the combination as it did in Green 695. Because the combination comprises known structures with known functions where each component performs its respective function in the same manner in which it did so

prior to the combination, a POSITA would have had a reasonable expectation of success in making the combination. Knodel,¶168.

A POSITA would further have been further motivated to enlarge the shoes of Green 695 based on the teachings of Alesi, which adopts the use of relatively large flat plates for its I-beam upper and lower beam portions that provide more surface area for distributing the clamping forces. Alesi, 6:55-7:21; 8:57-9:7. A POSITA would have had a reasonable expectation of success in making the combination given that the references have similar structures and the modifications are merely mechanical modifications well within the skill of a POSITA. Knodel,¶169. Moreover, a POSITA would have known how to size Alesi's upper and lower beam portions in conjunction with the passageways in Green 695. *Id*.

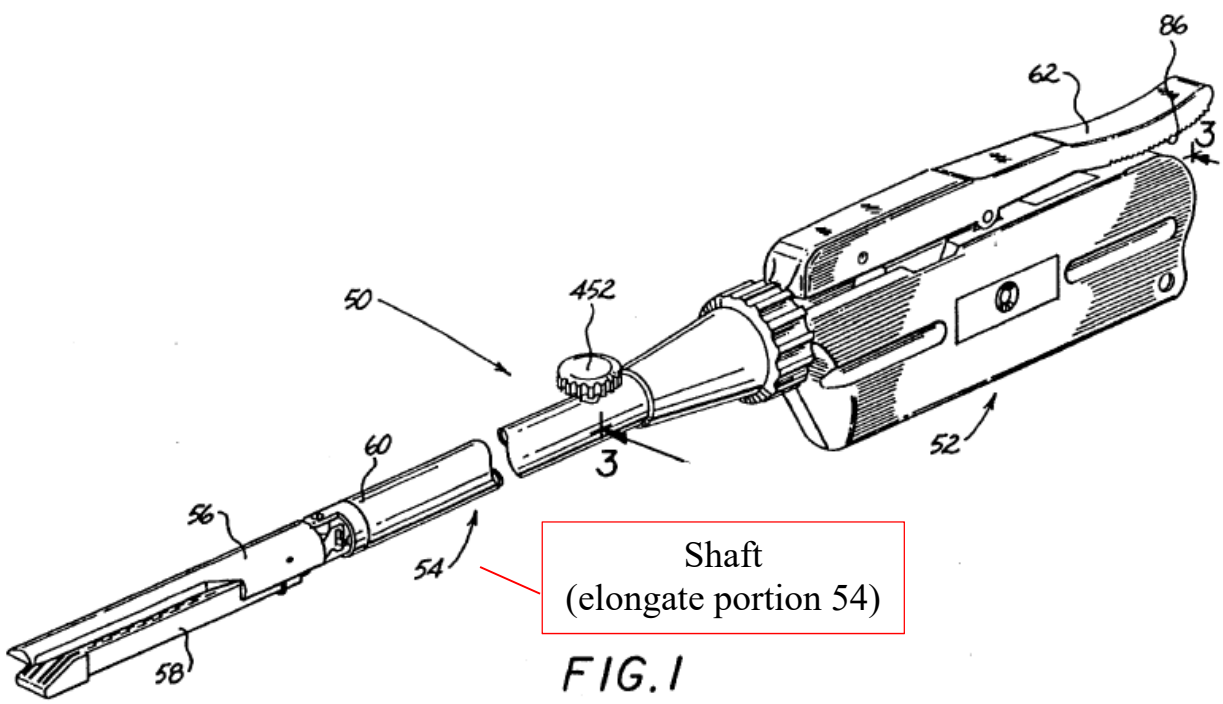
[1.4]

Green 209 discloses this limitation. Knodel,¶170. Green 209 discloses a handle (frame 52) having one or more actuators (e.g., handle member 62, firing trigger 96, and dial member 452). *Id*.; Green 209, 11:18-35, 12:40-42, 18:1-41, 19:25-28, Figs., 1, 3, 15-16.



[1.5]

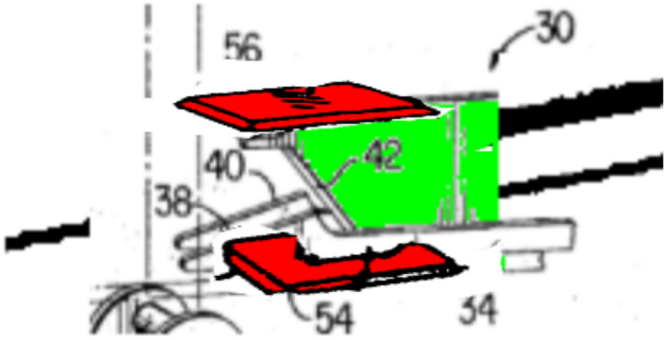
Green 209 discloses this limitation. Knodel,¶171. Green 209 discloses a shaft ("elongate portion 54") coupling the "control handle 52" to the head portion (jaws 56 and 58). *Id.*; Green 209, 11:20-25, Fig. 1.



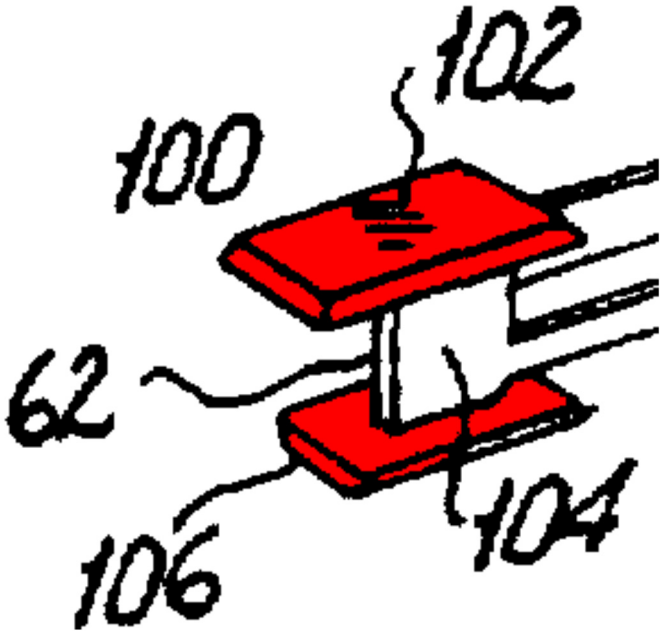
[1.6.1]

Green 209 in view of Green 695 and Alesi discloses this limitation. Knodel,¶¶172-173.

See Ground 3, [1.3] (describing the beam resulting from the proposed combination). As shown below, each of the upper beam portion (Alesi's "upper beam portion 102") and the lower beam portion (Alesi's "lower beam portion 106") in the proposed combination is a generally flat plate orthogonally attached to an end of the central web portion (Green 695's "central knife carrier 32" or Alesi's "central web portion 104"). *Id*.



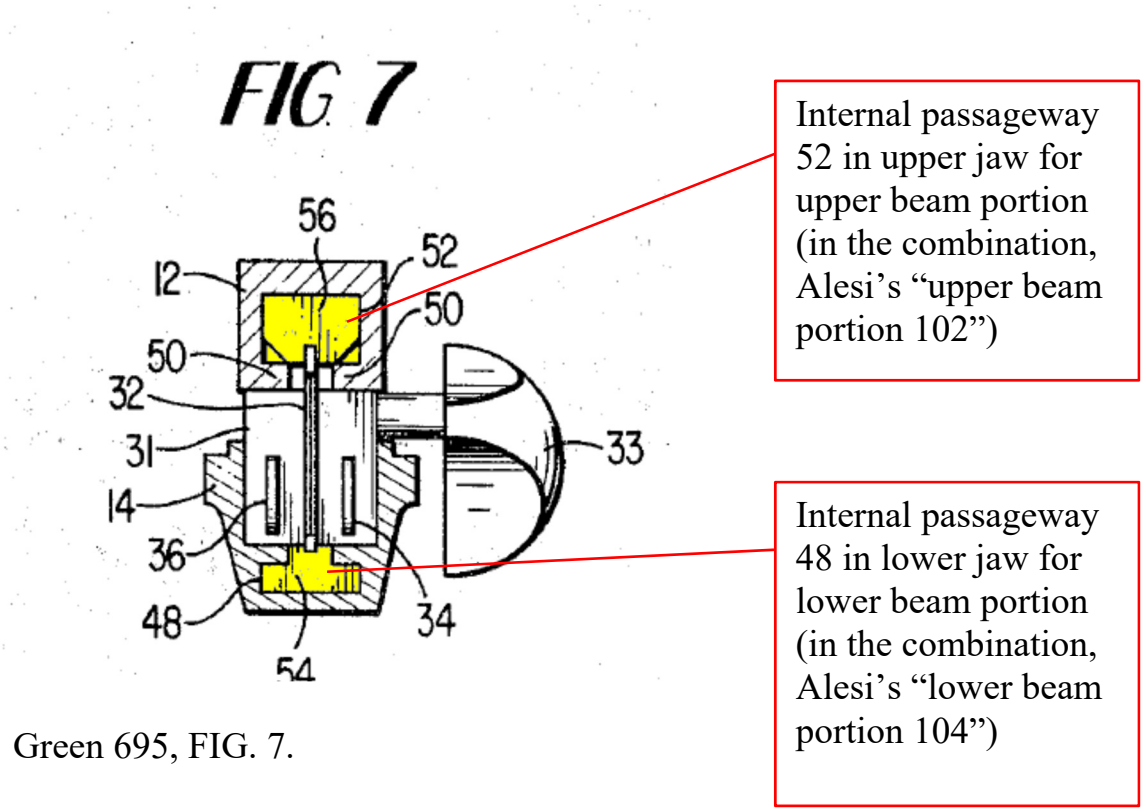
Composite of Green 209, FIG, 16, Green 695, FIG. 3, Alesi, FIG. 4. Alternatively, a POSITA would be motivated to use Alesi's central web portion 104 with its straight knife (as shown in Alesi, FIG. 4) in addition to Alesi's upper and lower beam portions:



Alesi, Fig. 4.

[1.6.2]

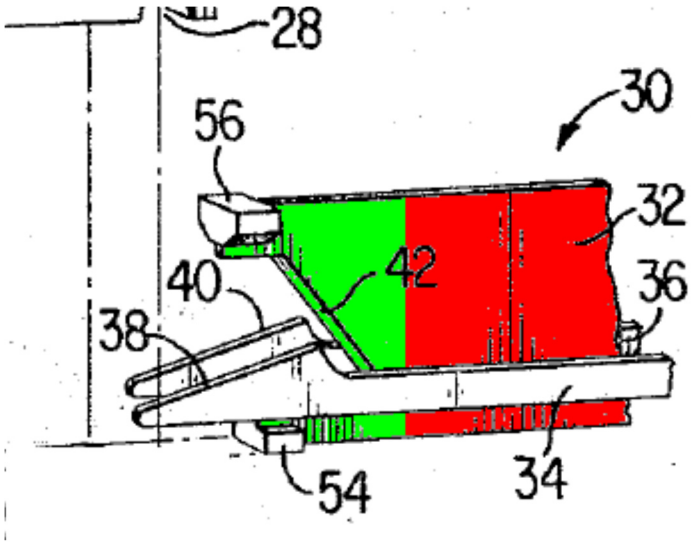
The combination discloses this limitation. Knodel,¶174. In the combination, the Alexi upper/lower beam portions 102,104 would engage their respective jaws entirely from within each jaw (via the appropriately redimensioned internal passageways 48 and 52 of Green 695) for clamping and alignment. Green 695, 1:49-57; 4:10-19; 4:50-60. *See* Ground 1B, [1.6.2].



Green 695, FIG. 7.

[1.7]

Green 209 in view of Green 695 and Alesi discloses this limitation. Knodel,¶¶175-178. In the combination, the pusher and I-beam of Green 695, with the upper and lower beam portions as modified by the teachings of Alesi, (or alternatively, the pusher and I-beam of Alesi) are used within the Green 209 instrument. The pusher (shown in red below) and the central web portion of the I-beam (shown in green below) are coplanar with a channel defined in the tissue contacting surface of each jaw so that the I-beam and pusher can cut the tissue as the I-beam is pushed distally.



Green 695, FIG. 3 (excerpt). The top view of the channel is shown in green below in annotated Green 209 FIG. 8:

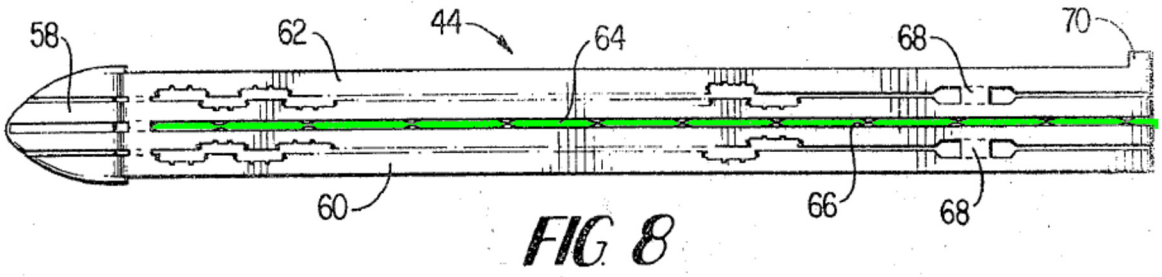
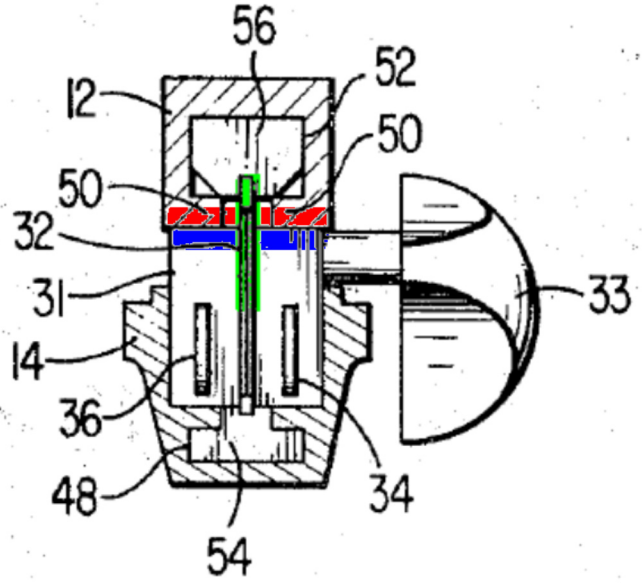


FIG 8

A front view of the stapler is shown below in FIG. 7 with the tissue contacting surface of the anvil in red, tissue contacting surface of cartridge in blue and the vertical channels through each surface in green:

FIG. 7



In the combination, the pusher and I-beam of Green 695, with the upper and lower beam portions as modified by the teachings of Alesi, (or alternatively, the pusher and I-beam of Alesi) will be coplanar with the above-illustrated channels defined in the tissue contacting surfaces of the two jaws when the pusher/I-beam combination moves distally.

[2]

In the combination, the I-beam of Green 695 has an upper beam portion and lower beam portion (as modified by the teachings of Alesi) configured to engage the upper and lower jaws respectively from within each jaw, for clamping and alignment. *See* Ground 3, [1.3], [1.6.1], [1.6.2]; Ground 1B, claim 2. The upper

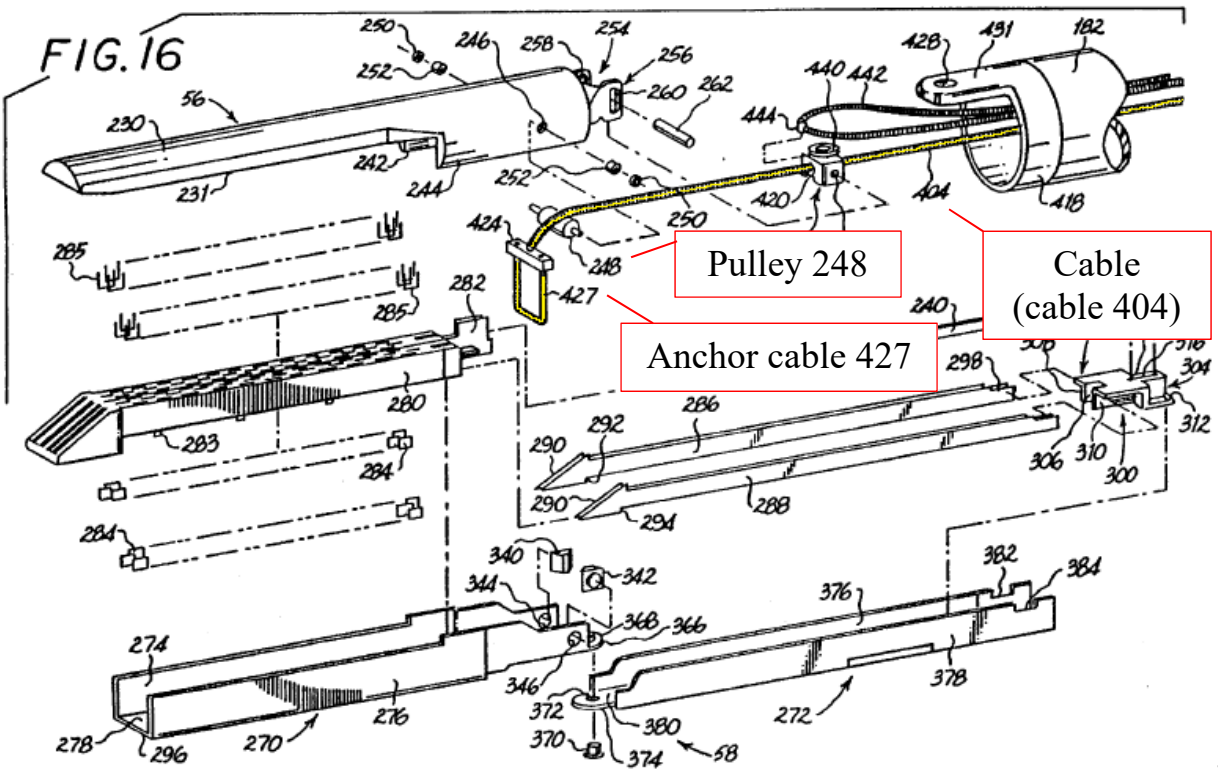
beam portion engages the second jaw (the upper jaw, the anvil) from within the second jaw, which is by definition below an outermost surface of the second jaw. Accordingly, the upper beam portion engages the second jaw from below an outermost surface of the jaw for clamping and alignment. Knodel,¶179.

[3.]

In the combination, the pusher and beam are coupled together as one piece. In Green 695 and Alesi, the central web portion of the I-beam and a portion of the pusher are the same physical component. *See* discussion of I-beam and pusher in Ground 3, [1].

[4.]

In the combination, the pusher and I-beam of Green 695, with the upper and lower beam portions as modified by the teachings of Alesi, (or alternatively, the pusher and I-beam of Alesi) are used within the Green 209 instrument. Green 209 discloses this limitation. Knodel,¶181. Green 209 discloses a cable (cable 404) for controlling the gross movement. *Id*.; Green 209, 18:1-41, Figs. 15-16. Cable 404 operatively coupled to the first jaw ("forward housing portion 270" of cartridge assembly 58 and "cartridge 280") by anchor cable 427, operatively coupled to the second jaw (anvil member 56) by pulley 248, and configured to move 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 (to allow stapling). *Id*.



[5.pre].

See Ground 3, [1.pre].

[5.1]

See Ground 3, [1.1]. The first configuration (open) is for receiving tissue and the second configuration (closed) is for sealing tissue. Knodel,¶183; Green 209, 1:26-29, 3:19-24, 4:37-63. Tissue is sealed when Green 209 is fired and the staples are ejected out of the cartridge and into the tissue. *Id*.

[5.2]

Green 209 in view of Green 695 and Alesi discloses a beam having an upper beam portion and a lower beam portion connected by a central web portion having a leading edge including a cutting blade that is more distal than the trailing edges

of the upper beam portion and a trailing edge of the lower beam portion (*see* Ground 3, [1.3]) and the beam portions are configured to clamp and align the first jaw and the second jaw at least partially from within the first jaw and the second jaw when in the second configuration (*see* Ground 3, [1.6.2]) as the central web portion moves distally along a channel defined in a tissue contacting surface of each of the first jaw and the second jaw (*see* Ground 3, [1.7]). Knodel,¶184.

[5.3]

Green 209 in view of Green 695 and Alesi discloses this limitation. Knodel,¶185. In the combination, the pusher of Green 695 is operatively coupled to the central portion of the beam because they are the same component ("pusher bar and knife assembly 30"). Green 695, 4:30-60. In the combination, Green 695's I-beam and pusher (or alternatively, Alesi's I-beam and pusher ("camming beam 100" and "upper and lower beam extensions 108 and 109"), Alesi, 6:55-65, would be coupled to, and driven distally by, the pneumatic drive of Green 209. *See* Ground 3, [1.3]; Green 209, 12:32-39, Green 695, 1:18-31, 6:16-41.

[5.4]

In the combination, the pusher and I-beam of Green 695, with the upper and lower beam portions as modified by the teachings of Alesi, (or alternatively, the pusher and I-beam of Alesi) are used within the Green 209 instrument, and Green 209 discloses this limitation. Knodel,¶186; *see also* Ground 3, [1.4]. Green 209

discloses a control handle (frame 52) that includes a handle member 62 configured to actuate the receiving and clamping of tissue and a firing trigger 96 configured to actuate the sealing of tissue. *Id.*; Green 209, 11:18-35, 12:40-42, 18:1-41, 19:25-28, Figs., 1, 3, 15-16.

[5.5]

Green 209 in view of Green 695 and Alesi discloses this limitation. Knodel,¶¶187-188.

Green 209 discloses a shaft (elongated shaft portion 54), which couples the control handle to the head. Id.; Green 209, Fig. 1.

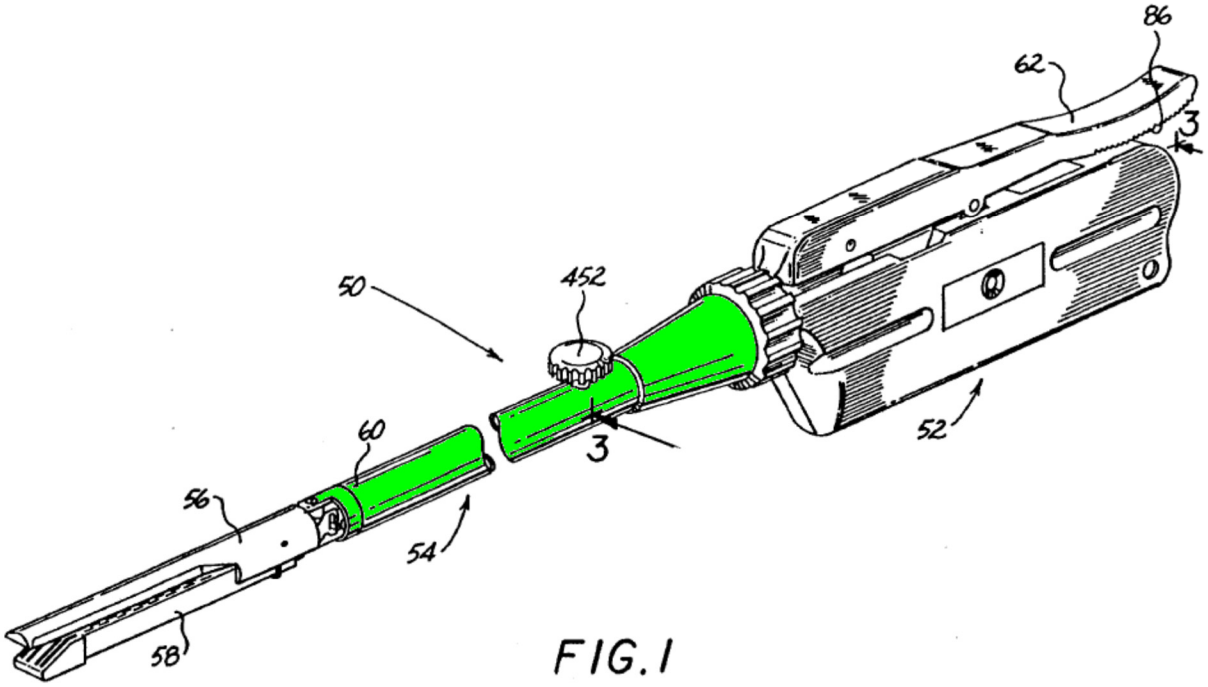


FIG. 1

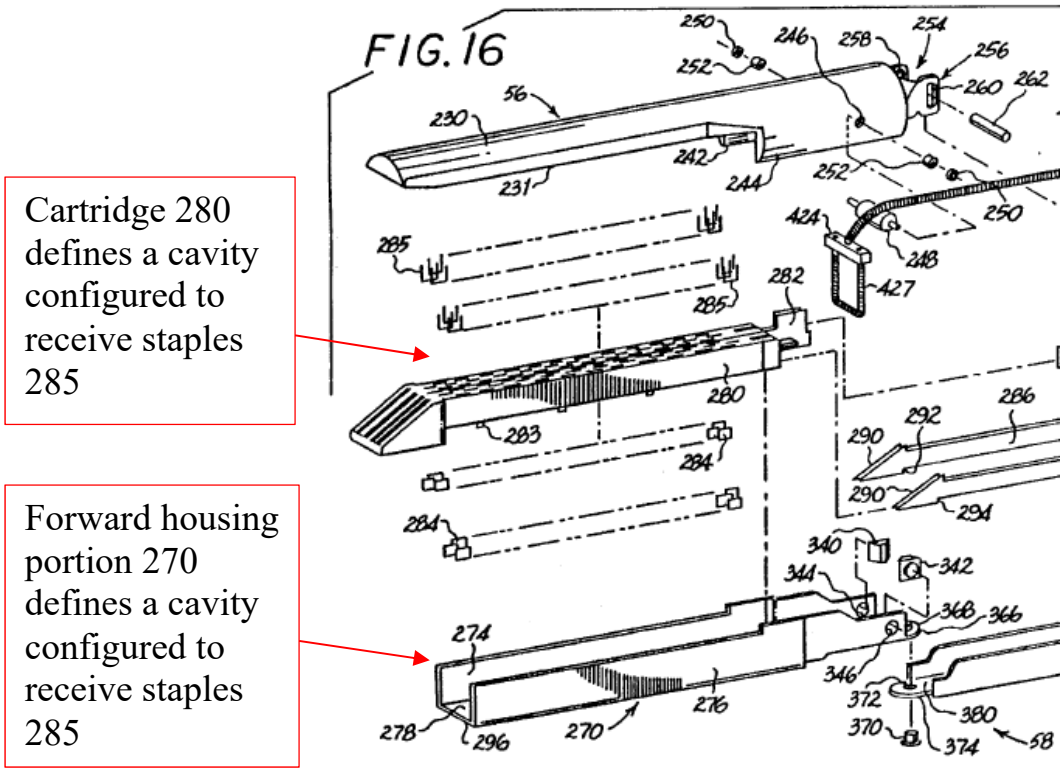
In the combination, the upper and lower beam portions (from Alesi) are orthogonally attached to the ends of the central web portion (the center of the I-beam from Green 695 or alternatively, from Alesi), and the pusher is coplanar with the central web portion and the channel through which the central web portion moves. *See* Ground 3, claim [1]. See also Ground 1, [1.7] regarding the relevant portion of the pusher that must be "coplanar."

[6.]

The combination discloses this limitation. Green 695 discloses an I-beam, which would be used in the combination. The Green 695 I-beam (modified by the teachings of Alesi) has upper and lower beam portions configured to clamp and align the jaws. Green 695 discloses that the upper and lower beam portions are configured to clamp and align the jaws from entirely within the jaws. *See* Ground 3, [1.6.2] and [2.], Knodel,¶189.

[7.1]

Green 209 has a first jaw ("forward housing portion 270" and "cartridge 280"), and cartridge 280 defines a cavity to hold a plurality of staples and includes a plurality of slots through which staples 285 pass during the stapling operation. In addition, the "forward housing portion 270" also defines a cavity configured to receive the plurality of staples 285 when it receives cartridge 280. Green 290, Fig. 16; Knodel,¶190.



[7.2]

Green 209 discloses this limitation. See Ground 3, [1.1.3].

[7.3]

The combination discloses this limitation. In the combination, the Green 209 pusher is coupled Green 695's I-beam. The pusher includes dual cam bars 286 and 288 which cause staple pushers to fire the staples as the I-beam moves distally. *See* Ground 3, [1.7], Knodel,¶192.

[8.]

In the combination, the Green 695 I-beam (as modified by the teachings of Alesi to include the upper and lower beam portions of Alesi) has an upper and

lower beam portion each substantially wider than the central web portion in cross section. Further, the I-beam would be connected to the Green 209 pusher embodiments, which include the shank portion 315 of knife 240 and cam bars 286 and 288. Green 209, 15:49-16:38; FIGs. 16-24. The Green 209 structure articulates, and therefore is rotatably coupled to the shaft. Replacement of the distal end of the knife with the Green 695 I-beam would not interfere with the operation of the articulation joint. Knodel,¶193.

[9.]

The Green 209/Green 695 disclose this limitation. *See* Ground 3, [6.], Ground 3, [8.]. Because the head portion is rotatably coupled, as shown for claim 8, it is likewise movably coupled (rotation is a movement). Knodel,¶194.

[10.]

The combined instrument would generally adopt the form factor of Green 209 which has a head portion sized for laparoscopic surgery. Green 209, 2:3-17, Knodel,¶195.

[11.]

In the combination, the device has a control handle with an actuation handle, a lever, a trigger, and a cable. *See* Ground 3, [1.4].

[12.]

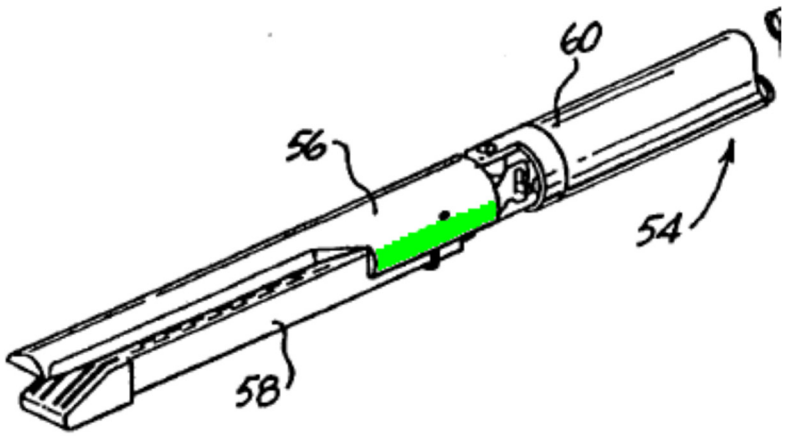
In the combination, the device is powered as taught by Green 209. Green 209 discloses a portion of the apparatus (the firing portion) is pneumatically powered. *Id.*; Green 209, Abstract, 11:18-22, 12:1-42.

[13.]

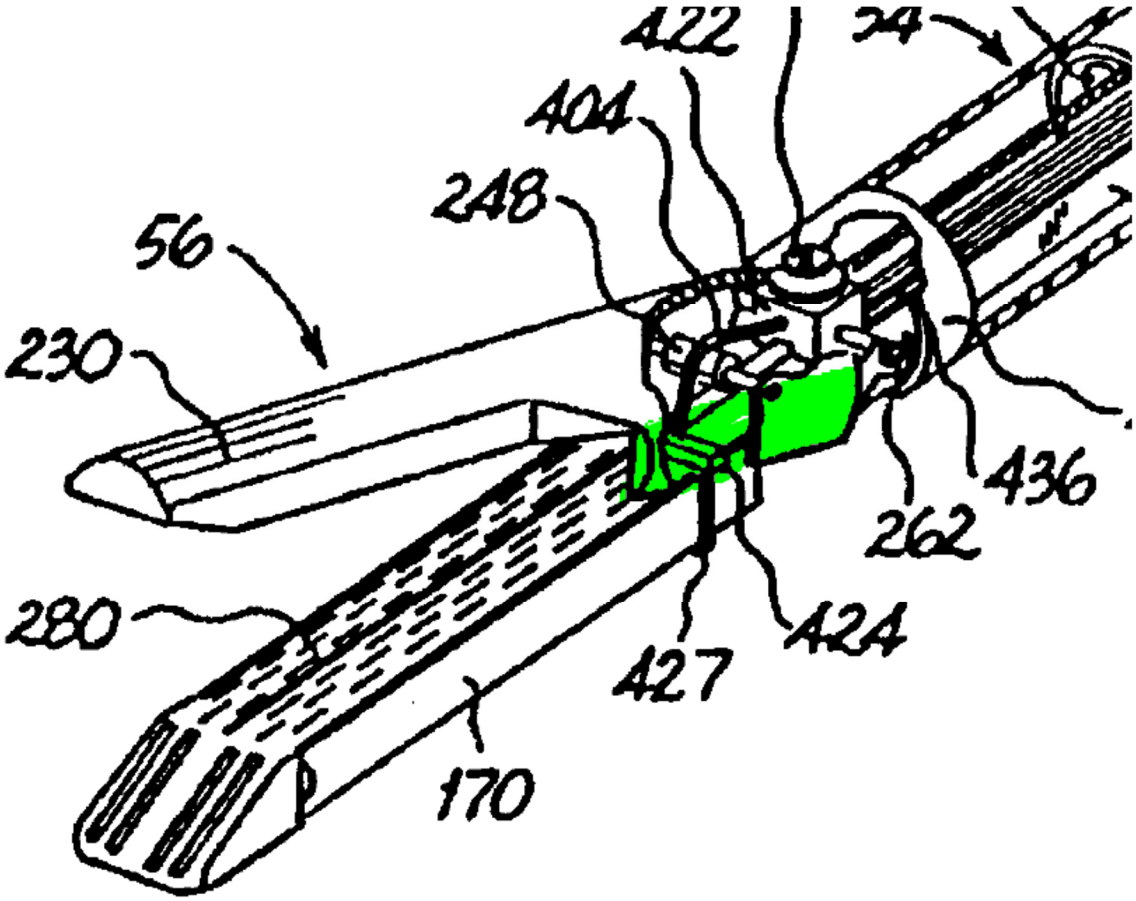
In the combination, the device is powered pneumatically as taught by Green 209. *See* Ground 3, [12.].

[14.]

Green 209 also discloses the claimed flange (opposite side walls 242 and 244). *See* Green 209, FIGs. 1, 16. Knodel,¶199.



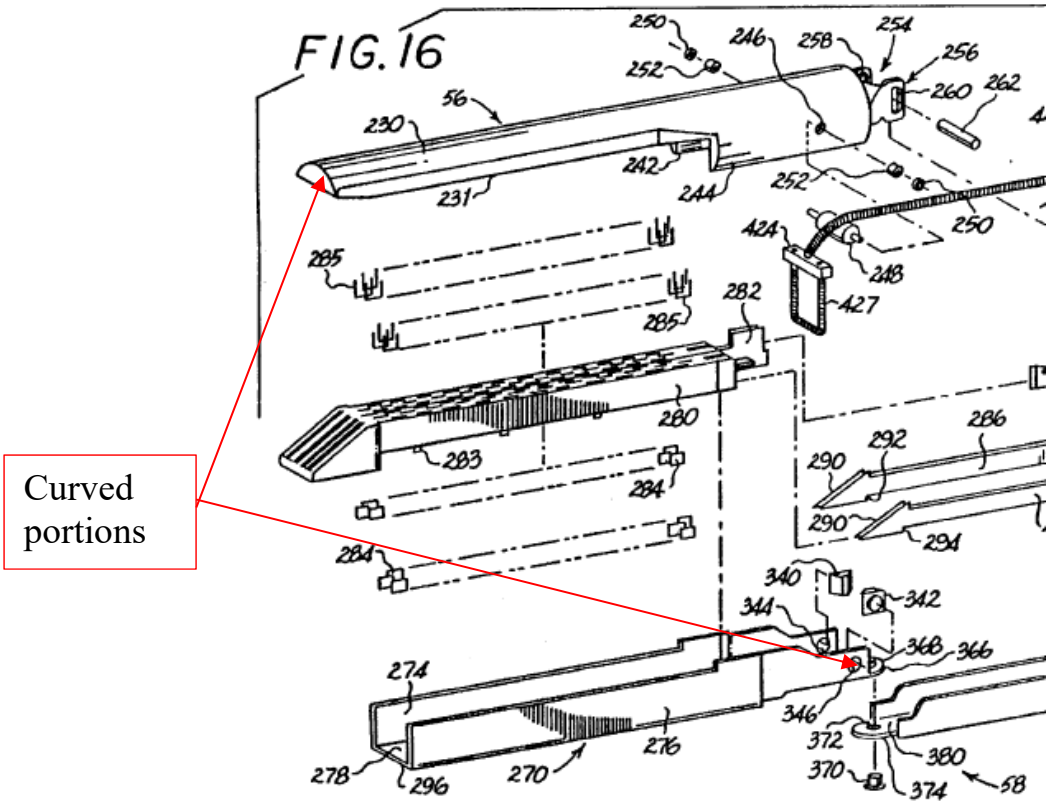
Green 209, FIG. 1 (excerpt).



Green 209, FIG. 29 (excerpt) (overhanding flange in green).

[15.]

Green 209 discloses this claim. Knodel,¶200. 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.



XI. CONCLUSION

Claims 1-15 of the '892 Patent are unpatentable pursuant to the grounds presented in this Petition. Accordingly, Petitioner respectfully requests *Inter Partes* Review of these claims.

Respectfully submitted,

Dated January 3, 2020

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Attorney for Petitioner

(Control No. IPR2020-00375)

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 13,996 words, which is less than the 14,000 allowed under 37 C.F.R. § 42.24.

Dated January 3, 2020

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

Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on January 3, 2020, a complete and entire copy of this Petition for *Inter Partes* Review, Power of Attorney, and all supporting exhibits were provided via Federal Express to the Patent Owner by serving the correspondence address of record as follows:

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