IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Thomas W. Huitema, et al.	
U.S. Patent No.:	9,844,369	Attorney Docket No.: 11030-0056IP1
Issue Date:	December 19, 2017	
Appl. Serial No.:	14/319,004	
Filing Date:	June 30, 2014	
Title:	SURGICAL END EFFECTORS WITH FIRING ELEMENT MONITORING ARRANGEMENTS	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 9,844,369 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Patent No. 9,844,369 to Huitema et al. ("the '369 Patent")
IS1002	Excerpts from the Prosecution History of the '369 Patent ("the Prosecution History")[1]
IS1003	Declaration of Dr. Bryan Knodel ("Knodel")
IS1004	U.S. Patent No. 7,380,696 to Shelton et al. ("Shelton")
IS1005	U.S. Patent No. 4,429,695 to Green ("Green")
IS1006	U.S. Published Patent Application 2011/0036891 A1 to Zemlok et al. ("Zemlok")

[1] Copies of foreign patent references removed.

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1, 15, 22, and 23 ("the Challenged Claims") of U.S. Patent No. 9,844,369 ("the '369 Patent").

I. MANDATORY NOTICES—37 C.F.R § 42.8

A. Real Party-In-Interest—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 or filing of the present Petition.

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

Petitioner is not aware of any disclaimers, reexamination certificates, or petitions for IPR of the '369 Patent. The '369 Patent is the subject of Civil Action No. 1:18-cv-01325-LPS, filed on August 27, 2018, in the United States District Court for the District of Delaware. The following IPRs involve patents that belong to Patent Owner and have been asserted against Petitioner in the United States District Court for the District of Delaware: *Intuitive Surgical, Inc. v. Ethicon LLC*, Case Nos. IPR2018-00933, -934, -935, -936, -938, -1247, -1248, -1254, -1703, and IPR2019-00880.

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 IPR11030-0056IP1@fr.com (referencing No. 11030-0056IP1 and cc'ing PTABInbound@fr.com, katz@fr.com, phillips@fr.com, and oconnor@fr.com).

II. 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.

III. REQUIREMENTS FOR IPR—37 C.F.R. § 42.104

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

Petitioner certifies that the '369 Patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

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

Petitioner requests IPR of claims 1, 15, 22, and 23 of the '369 Patent on the grounds listed below. A declaration from Dr. Bryan Knodel (IS1003) is included in support.

Ground	Claims	Basis
Ground 1	22, 23	Obvious under § 103 over **Shelton** (US 7,380,696) in view of **Green** (US 4,429,695)
Ground 2	22, 23	Obvious under § 103 over **Shelton** in view of **Green** and further in view of **Zemlok** (US 2011/0036891)
Ground 3	1, 15	Obvious under § 103 over **Shelton** in view of **Green** and further in view of **Zemlok**

The '369 Patent issued from U.S. Appl. No. 14/319,004, which was filed on June 30, 2014, and claims priority to Provisional Application No. 61/980,293, filed on April 16, 2014. Thus, the earliest possible effective filing date is April 16, 2014.

Shelton (US 7,380,696) issued on June 3, 2008, and is thus prior art under 35 U.S.C. §§ 102(a)(1) and 102(a)(2). Shelton was made of record during prosecution of the '369 patent, but was never discussed by the Examiner or the Applicants.[2]

Green (US 4,429,695) issued on February 7, 1984, and is thus prior art under 35 U.S.C. §§ 102(a)(1) and 102(a)(2). Green was made of record during prosecution of the '369 patent, but was never discussed by the Examiner or the

[2] Applicants cited more than 4000 references during prosecution of the '369 patent after receiving a Notice of Allowance, including the three references relied upon here.

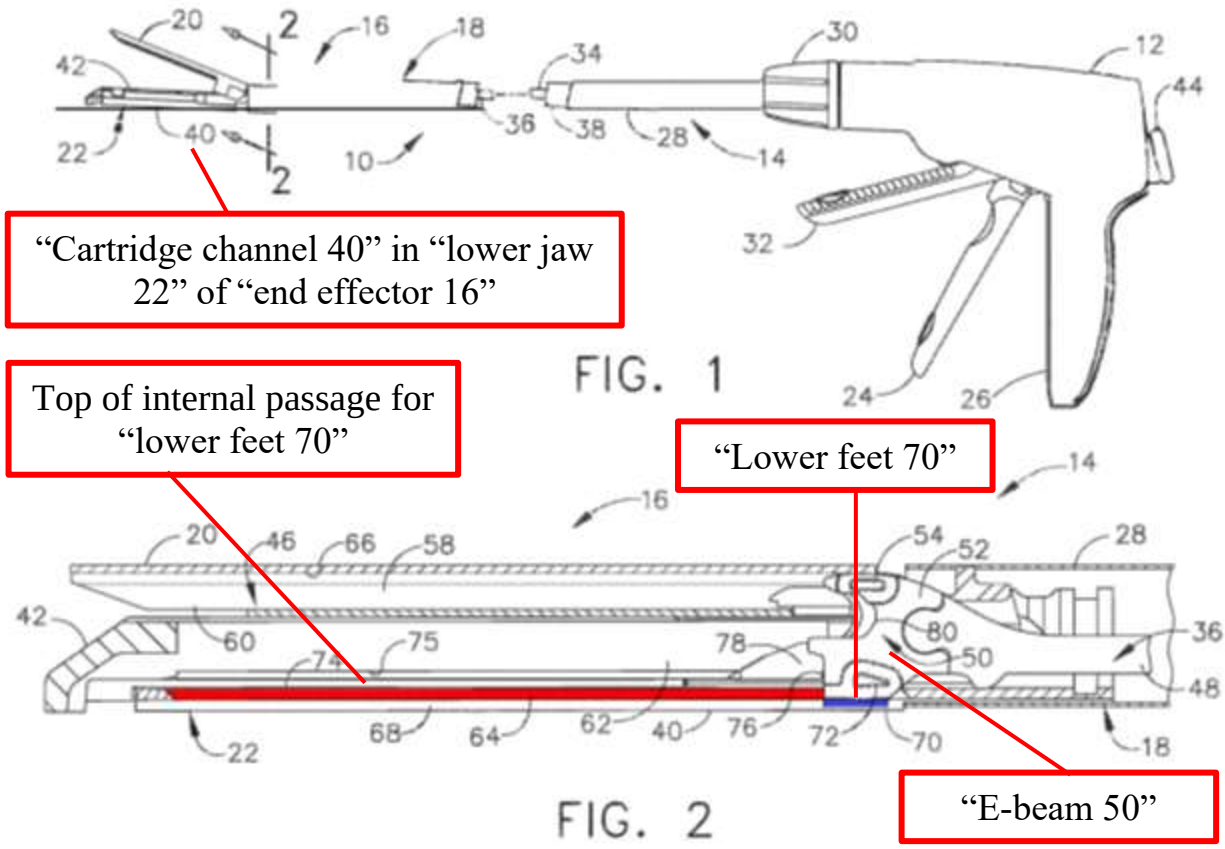
Applicants.

Zemlok (US Published Application No. 2011/0036891 A1) was published on February 17, 2011, and is thus prior art under 35 U.S.C. § 102(a)(2). Zemlok was made of record during prosecution of the '369 patent, but was never discussed by the Examiner or the Applicants.

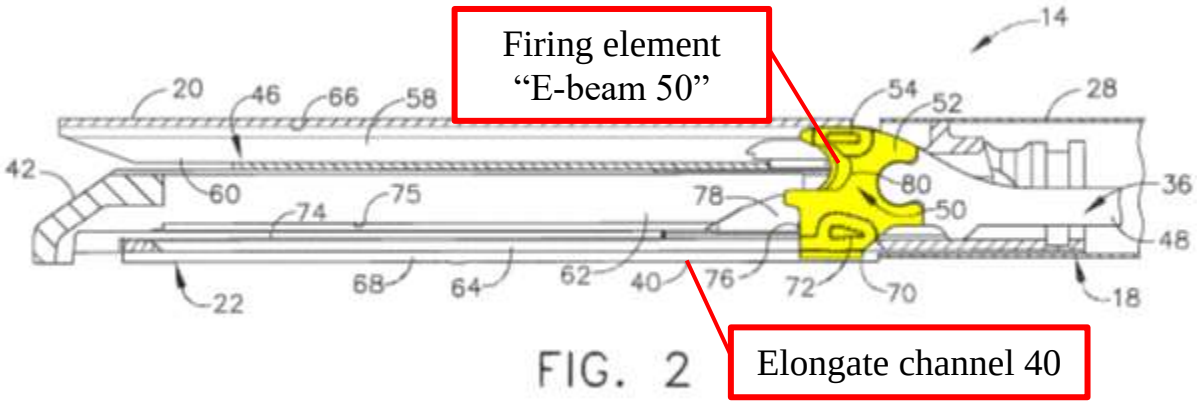
IV. OVERVIEW OF THE '369 PATENT

The '369 Patent is directed to a surgical stapling instrument with a particular style of end effector. In the relevant embodiments, the end effector has an elongate channel that holds a staple cartridge and also has an "E-beam" firing member with a "foot" that rides in an "internal passage" below the cartridge floor and above the bottom surface of the elongate channel. '369 Patent, 72:36-55. As explicitly set forth in each of the Challenged Claims, the internal passage has a "proximal channel opening."

Figure 1 depicts an embodiment of the overall stapler and Figure 2 depicts a side view of the internals of the end effector, including "cartridge channel 40" within "lower jaw 22" of "end effector 16." '369 Patent, 16:11-25. Also within the end effector is "E-beam 50" with one or more "lower feet 70." '369 Patent, 16:58-17:15.

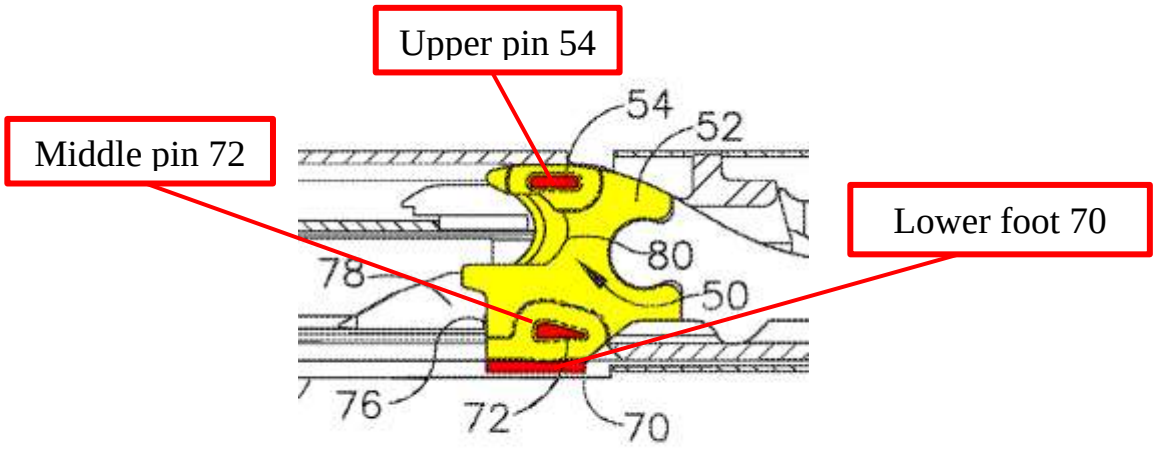


Referring to FIG. 2, the patent explains that when the instrument is fired "an E-beam 50 [] can translate within the end effector 16." '369 Patent, 16:59-67.



The "E-beam" is called an "E-beam" because it has three lateral structures

so that the "E-beam" resembles the letter "E" (at least to the extent it has an upper, middle, and lower structure): "upper pin 54," "middle pin(s) 72," and a "lower foot portion" (labeled 70). '369 Patent, 17:1-20; 71:57- 72:18.



The patent further explains that "[t]he E-beam 50 can comprise a vertical portion 52 which can pass through a narrow longitudinal anvil slot 58 extending through a tissue-contacting surface 60 in the anvil 20, a narrow vertical slot 62 in the staple cartridge 42, and a narrow longitudinal channel slot 64 in the elongate staple channel 40 when the E-beam is advanced distally." '369 Patent, 16:59-67; *see also* '369 Patent, 72:11-15. In the claimed embodiments, the channel slot is not exposed, but connects to the internal passageway through which the E-beam feet travel through. *See, e.g.*, channel slot 6026 coupling to internal passageway 6030 as depicted in FIGs. 32-39. *See also* '369 Patent, 72:31-68; Knodel, ¶¶32-35.

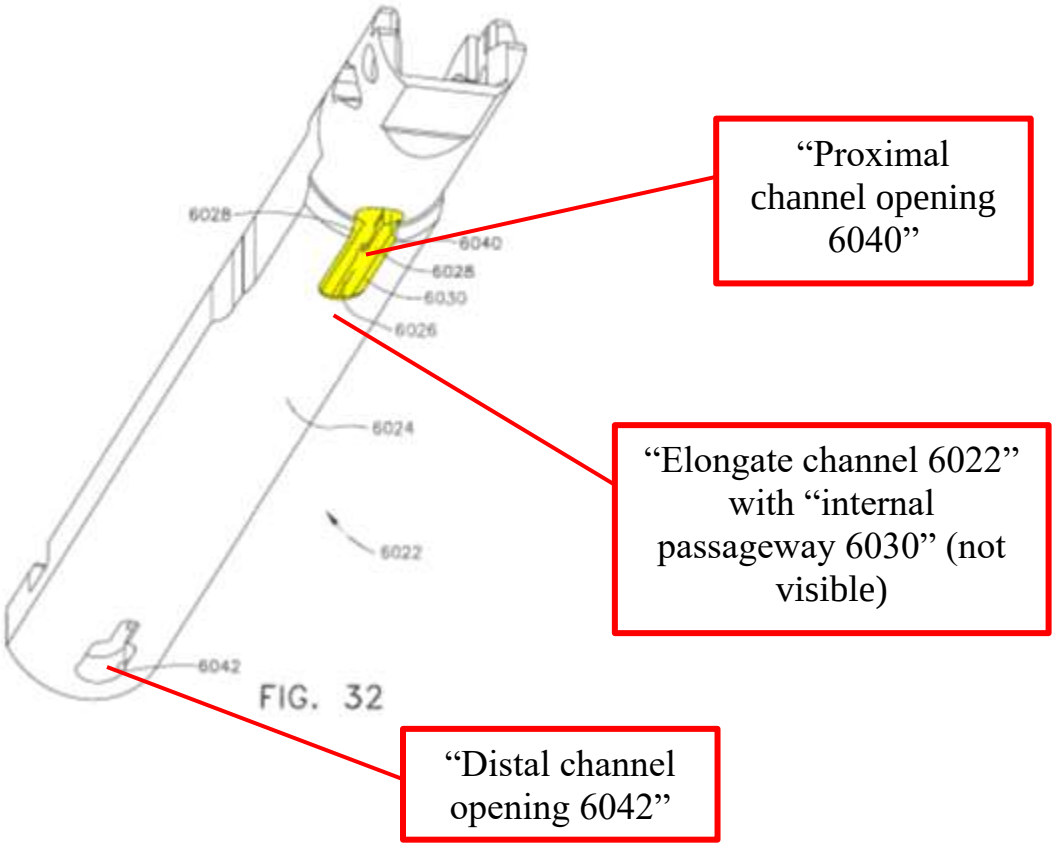
The "upper pin 54" (also identified as "upper tab 6058") is "configured to be slidably received within an upper passageway within an anvil that is operably

mounted to the elongate channel." '369 Patent, 76:36-38. The "middle pins 72 can be configured to seat the staple cartridge 42, or assure that the staple cartridge 42 remains seated, in the channel 40." '369 Patent, 72:5-8. Finally the "foot portion may help affirmatively space the anvil relative to the elongate channel." '369 Patent, 72:19-23; Knodel, ¶32-35.

In the prior art (and also in various embodiments disclosed in the specification), the foot of the E-beam rides in an exposed longitudinal slot. One benefit of the slot is that it can "serve as convenient means for the clinician to ascertain the position of the cutting head in the elongate channel." '369 Patent, 72:19-23.

The '369 Patent allegedly improves upon these prior art E-beam staplers by providing an "internal passageway"[3] along the bottom portion of the elongate channel, the passageway having a "proximal channel opening." *Id.*, 73:1-8; 72:50-55. Figure 32 depicts such an embodiment. The lower jaw of the end effector has "elongate channel 6022" having an "internal passageway 6030" and a "proximal channel opening 6040." The figure also depicts a "distal channel opening 6042." '369 Patent, 73:1-4, 11-12; Knodel, ¶¶27-30.

[3] The term "passageway" and "passage" are used interchangeably in the '369 Patent and we use the terms interchangeably here.



The proximal channel opening purports to provide two functions: (1) the proximal channel opening serves as part of a lockout mechanism by allowing the cutting head to descend into the opening such that it cannot enter the internal passageway; and (2) the proximal channel opening provides a visible indicator that the E-beam is in either the proximal or locked position. *Id.*, 72:1-15, 76:51-62; Knodel, ¶¶27-31.

The '369 Patent explains that the "internal passageway" provides increased stiffness to the elongate channel so that it resists twisting and spreading. '369 Patent, 72:11-55. Because the internal passageway blocks (or at least partially blocks) the clinician's view of the foot, the "proximal channel opening" ensures

that the clinician can at least determine if the cutting head is in the starting or locked position. '369 Patent, 72:1-8. The '369 Patent further explains that the "proximal channel opening" is made large enough to permit "the downward movement of the cutting head to a locked position." '369 Patent, 72:31-34.

V. PROSECUTION OF THE '369 PATENT

The patent application issuing as the '369 Patent was filed on June 30, 2014. On November 14, 2016, the Examiner issued a non-final rejection finding application claims 19 and 20 anticipated by Bombard et al., US Published Application No. 2011/0101069, and Zemlok et al., US Published Application No. 2009/0114701 (a different Zemlok reference than the reference used in this petition), and finding application claims 23 and 24 anticipated by Olson et al., US Published Application No. 2006/0011699. The Examiner allowed claims 1-18 and 22 over the prior art of record and found claim 21 allowable if rewritten in independent form.

In that Office Action, the Examiner stated that the "means for guiding" limitation in Application claim 23 was a means-plus-function limitation and identified the corresponding structure as: "Firing bar." IS1002, 798-799 (11/14/2016 Office Action at 2-3). The Examiner further stated that if Applicants disputed the Examiner's interpretation of the corresponding structure, then

Applicants must specifically identify the correct structure. Id. at 799.

On February 14, 2017, the Applicants responded and questioned whether the Examiner had properly identified the corresponding structure, but did not affirmatively state what they believed to be the corresponding structure. IS1002 at 782 (2/14/2017 Response at 10). The Applicant also cancelled claims 19 and 20, and argued that that Olson did not anticipate claims 23 and 24 because whereas the claims recited an "internal passage," the Olson reference disclosed a flange that "**is positioned <u>external to</u>** the channel assembly 120." Prosecution History at 783-784 (emphasis in original). The Applicants also added new claim 25.

On April 3, 2017, the Examiner allowed claims 1-18 and 21-25.

On June 23, 2017, the Applicants amended claims 1 and 23 "to correct minor clerical errors." Prosecution History at 547.

<u>After</u> receiving a Notice of Allowance, Applicant filed a RCE and submitted a 170-page Information Disclosure Statement listing over 4,000 references. Less than one month later, the Examiner stated that all the art had been "considered," and one month after that, the Notice of Allowance issued.

Notably, the Examiner did not discuss any of the 4,000+ references or state that any combination of the 4,000+ references was applied in an obviousness analysis. Knodel, ¶¶36-42.

Although not mentioned by the Examiner, the Shelton reference used in this

Petition is buried on page 81 of the IDS.

Although not mentioned by the Examiner, the Green reference used in this Petition is buried on page 37 of the IDS.

Although not mentioned by the Examiner, the Zemlok reference used in this Petition is buried on page 154 of the IDS.

VI. CLAIM CONSTRUCTION

For the purpose of assessing invalidity in view of the prior art discussed in this petition, the following terms in the Challenged Claims should be construed. Given the similarities between the prior art and disclosure of the '369 Patent, no further constructions are necessary to assess the arguments in this petition.

A. Firing Element

All of the Challenged Claims include "firing element" as a limitation. The term "element" is a nonce term and the purely functional nature of the modifier "firing" would not have connoted structure to a POSITA. Knodel, ¶¶46-48. In addition, for each of the Challenged Claims, "firing element" recites function without reciting sufficient structure for performing that function. Knodel, ¶¶46-48. As such, the negative presumption against Section 112(f) treatment under *Williamson v. Citrix Online*, LLC, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (*en banc* in relevant portion) is overcome.

The claimed functions performed by the "element" are "firing" and

"translat[ing] between a [starting/first] position adjacent the proximal end of the bottom of the elongate channel and an ending position adjacent the distal end of the bottom of the elongate channel." '369 Patent, claims 1 and 22; Knodel, ¶47.

Claim 1 is devoid of structure for this element, but claims 15 and 22 recite some structure, namely, "a vertical portion and at least one laterally extending lower foot." However, this structure is not ***sufficient*** structure to avoid application of 112(f) because a "vertical portion" and at least one "foot" does not itself perform the firing or translating functions. Knodel, ¶¶45-51.

Turning to the specification, the corresponding structure in the patent is an "E-beam." The E-beam is substantially identical throughout the various embodiments of the '369 Patent's specification and it is first introduced in reference to FIG. 2. With regard to that figure, the patent explains that "an E-beam 50 [] can translate within the end effector 16" and that "[t]he E-beam 50 can comprise a vertical portion 52 which can pass through a narrow longitudinal anvil slot 58 extending through a tissue-contacting surface 60 in the anvil 20, a narrow vertical slot 62 in the staple cartridge 42, and a narrow longitudinal channel slot 64 in the elongate staple channel 40 when the E-beam is advanced distally." '369 Patent, 16:59-67; Knodel, ¶49. Essentially the same E-beam is shown in FIGs. 32-42, which specifically relate to embodiments with the internal passageway rather than an exposed slot for the E-beam feet.

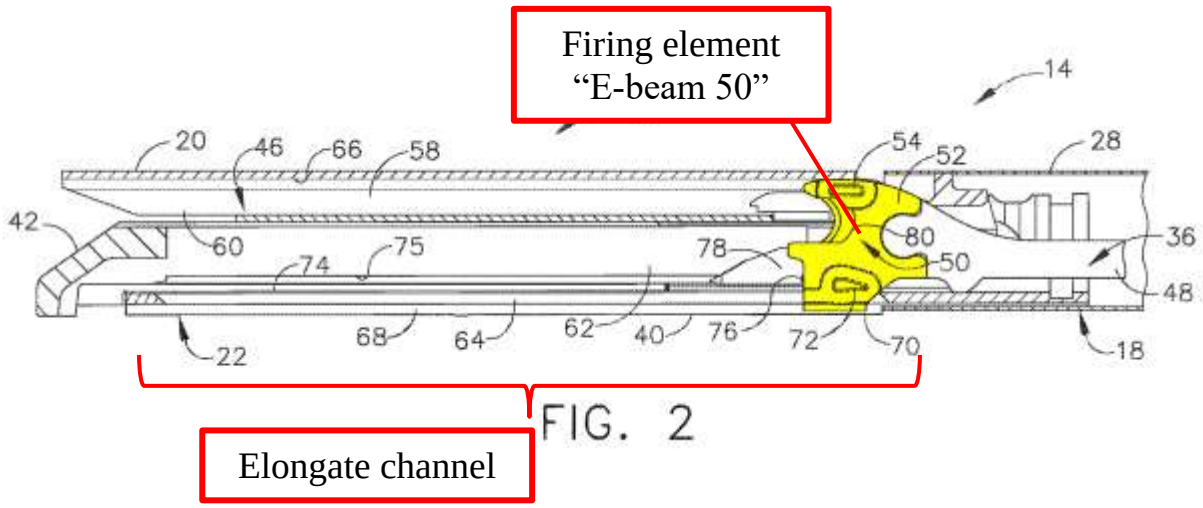


FIG. 2

The "E-beam" is called an "E-beam" because it has three lateral structures (like the letter "E"). Knodel, ¶¶33, 49-50.

B. Means for guiding . . .

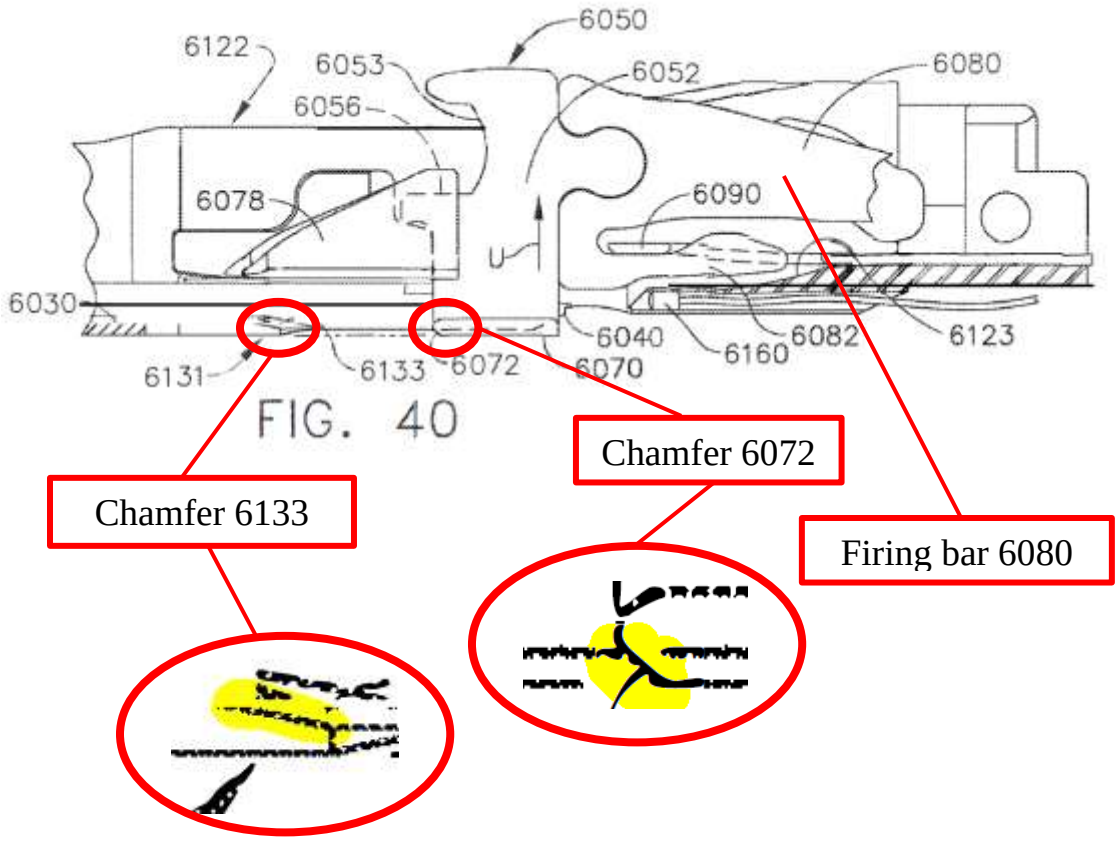
The final limitation of claim 22 is a "means for guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element."

This limitation uses the term "means" and is recited as a function rather than structure. Accordingly, it is a "means plus function" term that should be construed according to 35 U.S.C. 112(f). *Williamson*, 792 F.3d at 1347-49. The function is as claimed: "guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element."

The corresponding structure is that structure from the specification that is "clearly linked" to the function. *Medtronic, Inc. v. Advanced Cardiovascular Sys.,*

Inc., 248 F.3d 1303, 1311 (Fed. Cir. 2001). The Examiner identified the "firing bar" as the corresponding structure. IS1002, 798-799. However, in the specification, the structures disclosed for "guiding" the lower foot are either "chamfers 6072" on the foot of the firing element, "chamfer 6133" on the channel, or both (Knodel, ¶¶52-55):

> As can be seen in FIGS. 40 and 41, for example, the distal end of **each foot 6070 may have a chamfer 6072 formed thereon**. The chamfer 6072 is configured to engage corresponding portions of the elongate channel 6122 as the cutting head 6050 is advanced distally to cause the feet 6070 to enter the internal passage 6030. Thus the **chamfers 6072 form small "lead-in" ramps which help to guide the feet 6070 into the passage 6030**. As can also be seen in FIGS. 40 and 41, the portion of the elongate channel 6122 defining the proximal end 6131 of the **internal passage 6030 may have a chamfer 6133 thereon or otherwise be sloped as shown**. In alternative arrangements, the feet 6070 (or single foot) may be provided with the chamfer 6072 or the proximal end portion 6131 of the internal passage 6030 may be provided with the chamfer 6133 or both chamfer arrangements may be provided as shown in FIGS. 40 and 41.
>
> ('369 Patent, 77:24-39)



In addition, the Examiner identified the "firing bar" as corresponding structure. Accordingly, the corresponding structure includes the chamfers on the foot (6072) or on the channel (6131), or both, in combination with the firing bar. Knodel, ¶¶52-55.

VII. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art at the time of the claimed invention ("POSITA") would have had the equivalent of a bachelor's degree or higher in mechanical engineering, or a related field directed towards medical mechanical systems, and at least 3 years working experience in research and development for

surgical instruments. Knodel, ¶56.

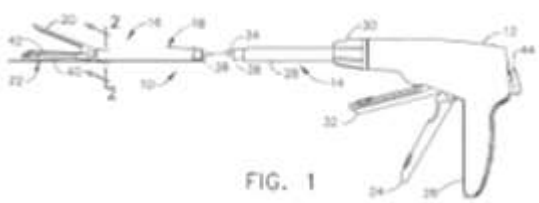
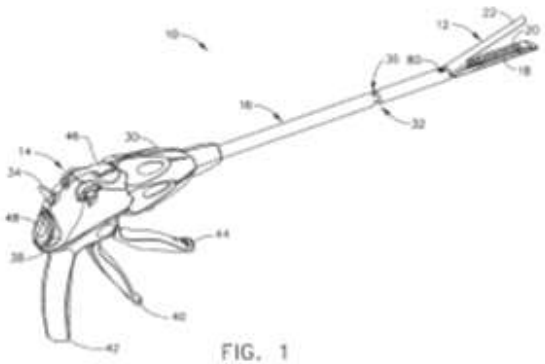
VIII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. [GROUND 1]—Shelton in View of Green Renders Obvious the Claims 22-23

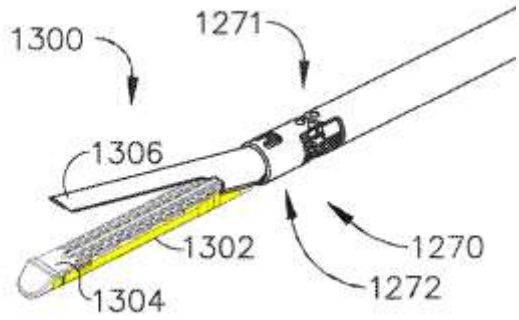
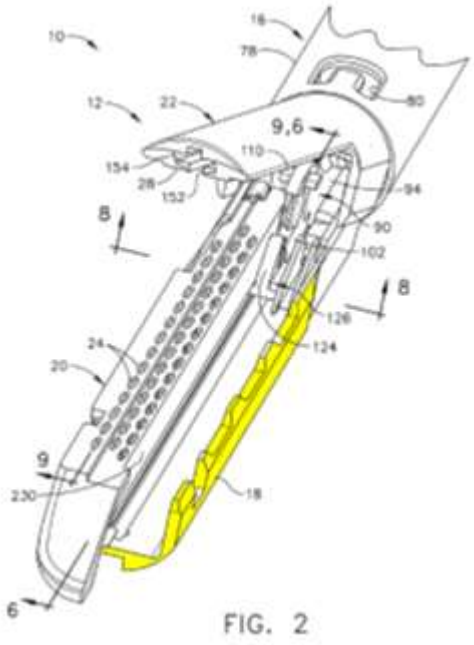
Overview of Shelton

Shelton is an Ethicon patent that issued more than one year before the earliest possible effective filing date of the ’369 Patent. It discloses a surgical stapler very similar to the embodiments of the ’369 Patent with one notable exception: The lower passageway (called the “lower track 132”) of the Shelton elongate channel is not enclosed as taught in the ’369 Patent. Instead, it is open along much of the length of the elongate channel. Knodel, ¶¶57-58.

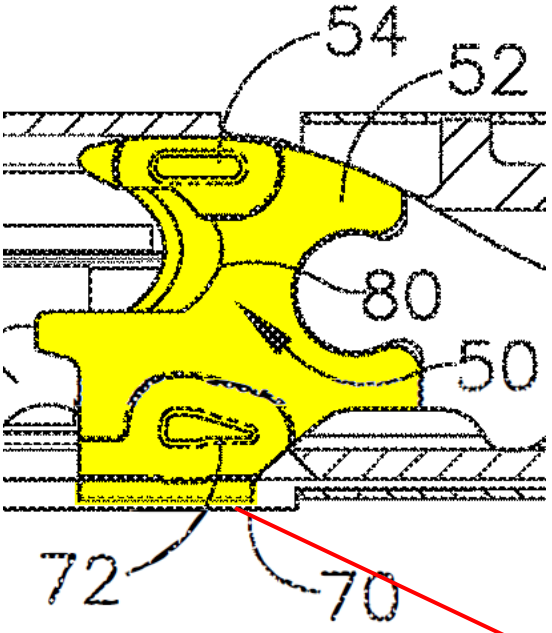
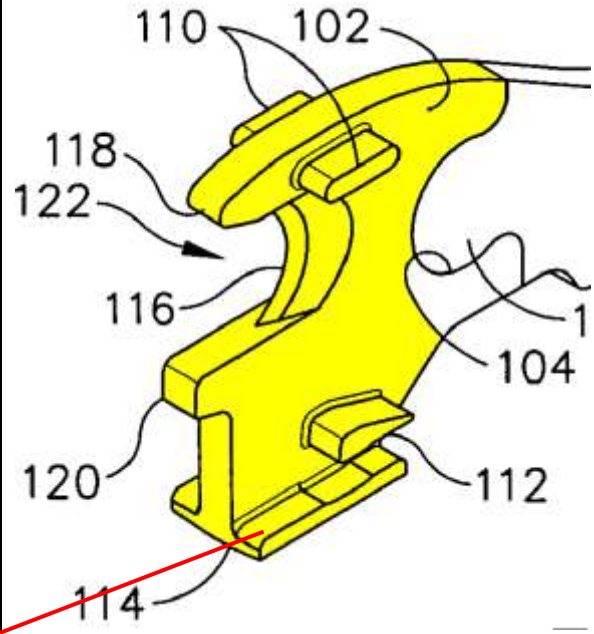
Like the ’369 Patent, Shelton discloses a surgical stapler. ’369 Patent at 16:11-44; Shelton at 4:54-67:

The ’369 Patent (FIG. 1)	Shelton (FIG. 1)
 FIG. 1	 FIG. 1

Like the ’369 Patent, Shelton discloses an end effector with an elongate channel ’369 Patent at 65:25-30, 72:11-75:58; Shelton at Abstract, 2:45-65, 3:20-24; 9:38-14:15:

The ’369 Patent (FIG. 20 showing elongate channel 1302)	**Shelton (FIG. 2 showing elongate channel 18)**
	

Like the ’369 Patent, Shelton discloses an E-beam firing element with a laterally extending foot. ’369 Patent at 72:11-30, 56-67; Shelton at 6:36-57:

The '369 Patent (FIG. 2 showing E-beam 50 with foot 70)	Shelton (FIG. 4 showing E-beam 102 with foot 114)
	

Foot

Like the '369 Patent, Shelton has a lower passageway for accommodating the translation of the foot from the proximal end to the distal end of the elongate channel, except that Shelton's passageway is not covered, but instead forms a "lower track 132 formed in the staple channel 18." Shelton, 6:62-64. The lower track 132 "includes a narrow slot 133 that opens up as a widened slot 134 on an undersurface of the staple channel 18 to form an inverted T-shape in lateral cross section, as depicted particularly in FIGS. 7 and 8, which communicates with the widened hole 130." Shelton, 6:65-7:1. Knodel, ¶59.

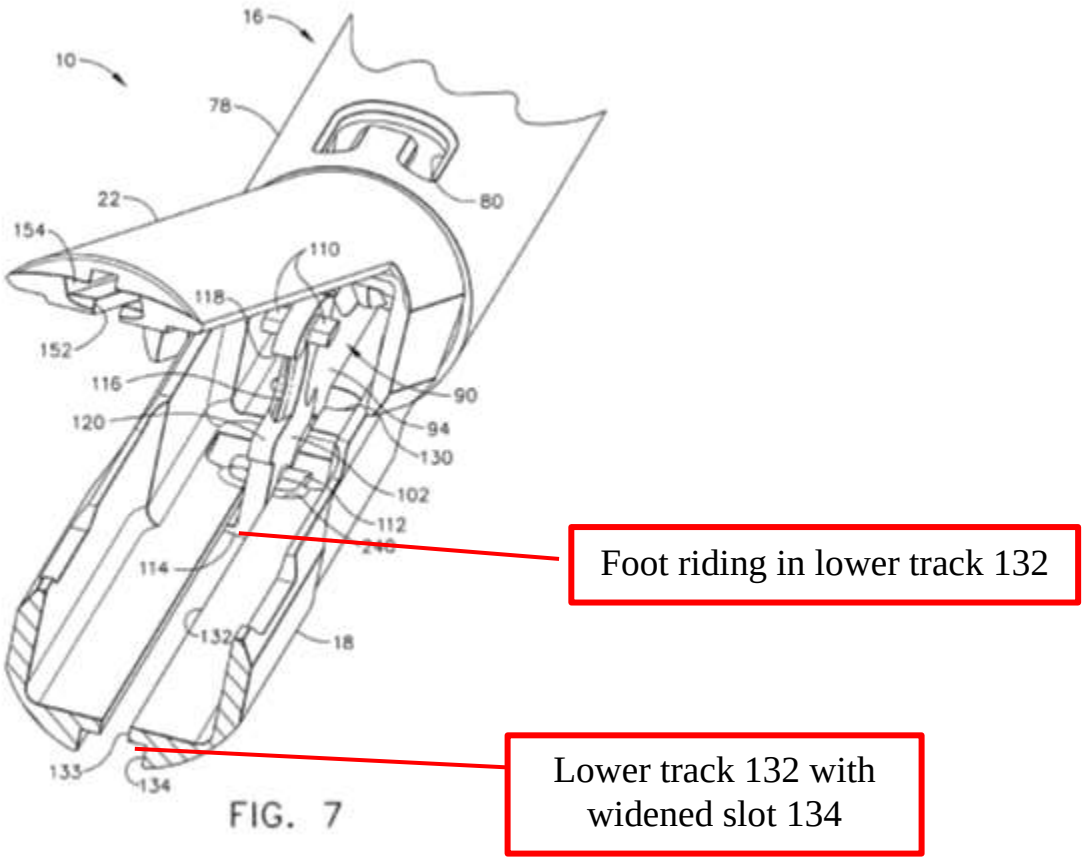


FIG. 7

Shelton, FIG. 7.

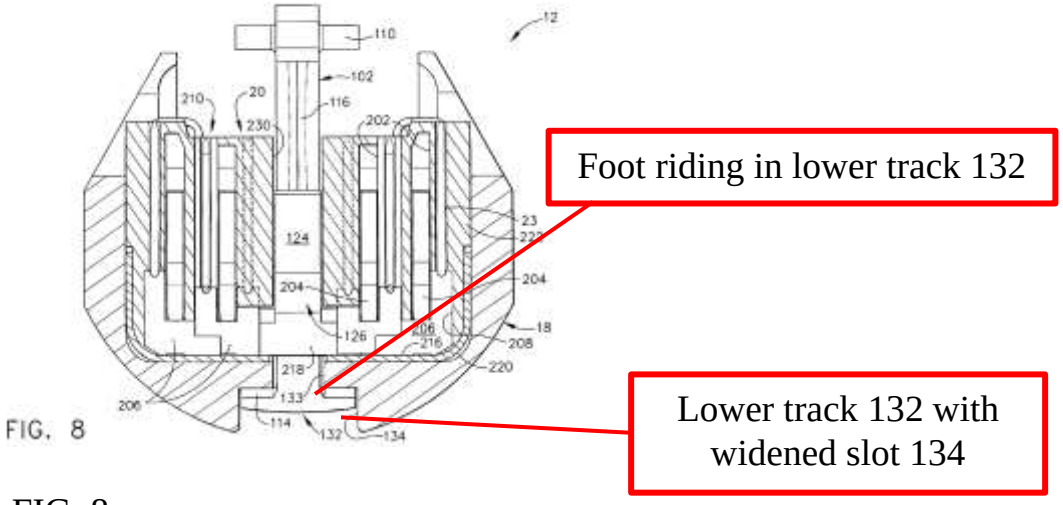


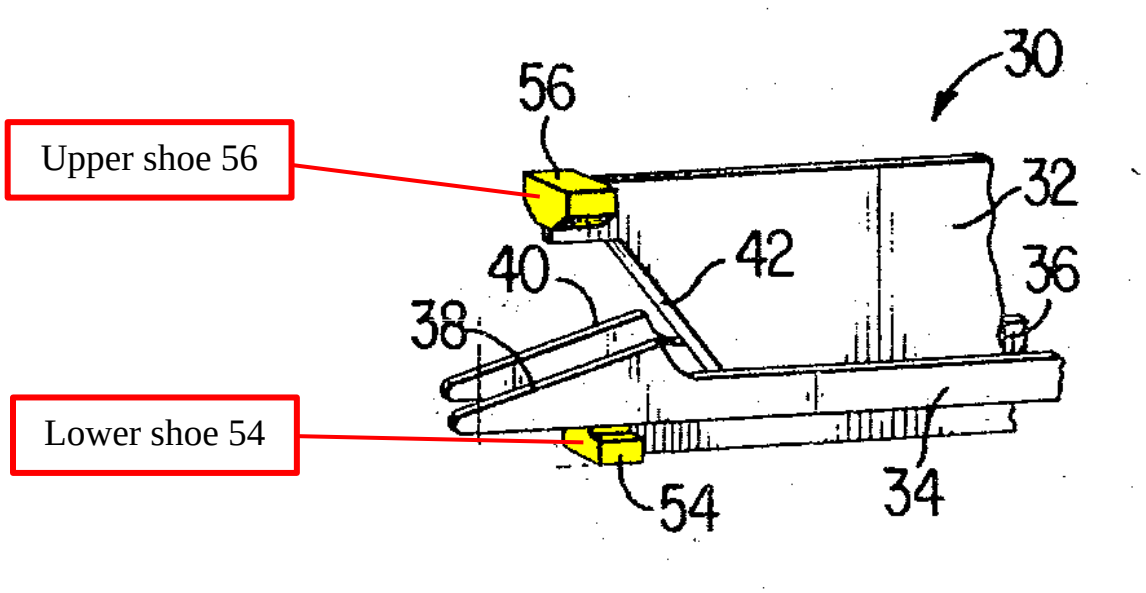
FIG. 8

Shelton, FIG. 8.

Overview of Green

Like the ’369 Patent and Shelton, Green discloses a “surgical stapling instrument” that “has upper and lower elongate jaws for receiving a staple cartridge and anvil respectively.” Green, Abstract. However, the Green surgical stapling instrument is a device designed for use in open surgery. Green, FIGS. 1 and 2. In contrast, the devices disclosed in Shelton and in the ‘369 patent are designed for use in laparoscopic surgery. However, these differences are not relevant to the issues presented in this Petition. Green also uses an “I-beam” rather than an “E-beam” to provide a localized maximum separation between the instrument jaws. The I-beam lacks the middle pin provided by the E-Beam of Shelton and the ’369 Patent. Knodel, ¶¶61-63. As discussed below, a POSITA would apply the teachings concerning I-beams identified in this Petition to E-beams as well.

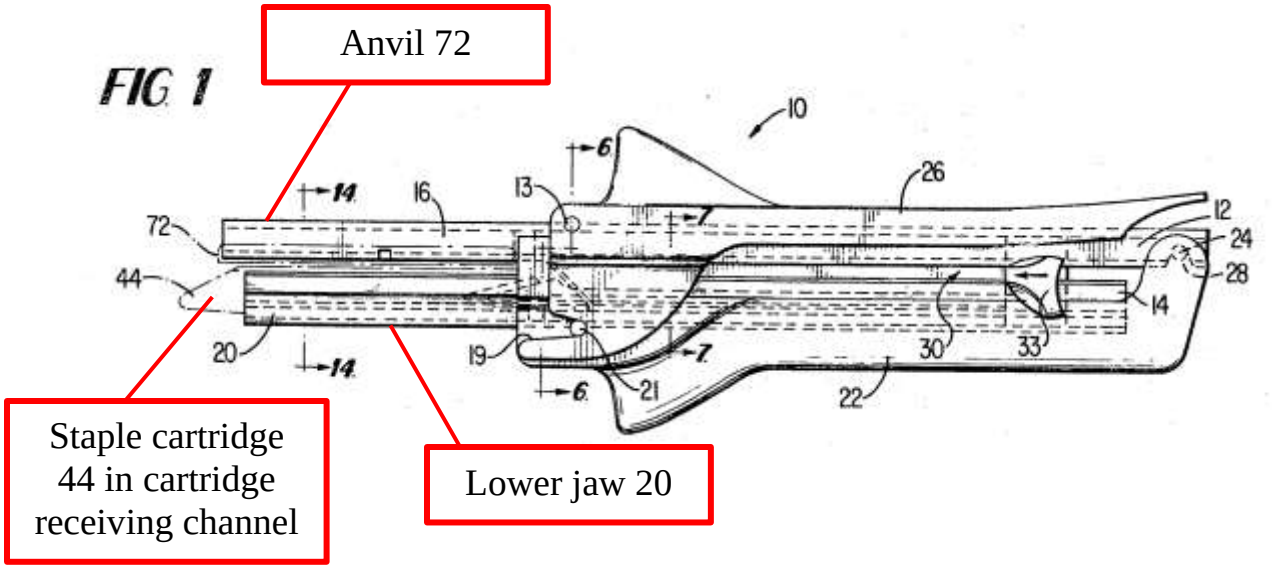
Green’s I-beam has an upper pin (“upper shoe 56”) that rides in a passageway in the anvil and a lower foot (“lower shoe 54”) that rides in a longitudinal passageway in the lower jaw that holds the staple cartridge. Green, 4:30-60.



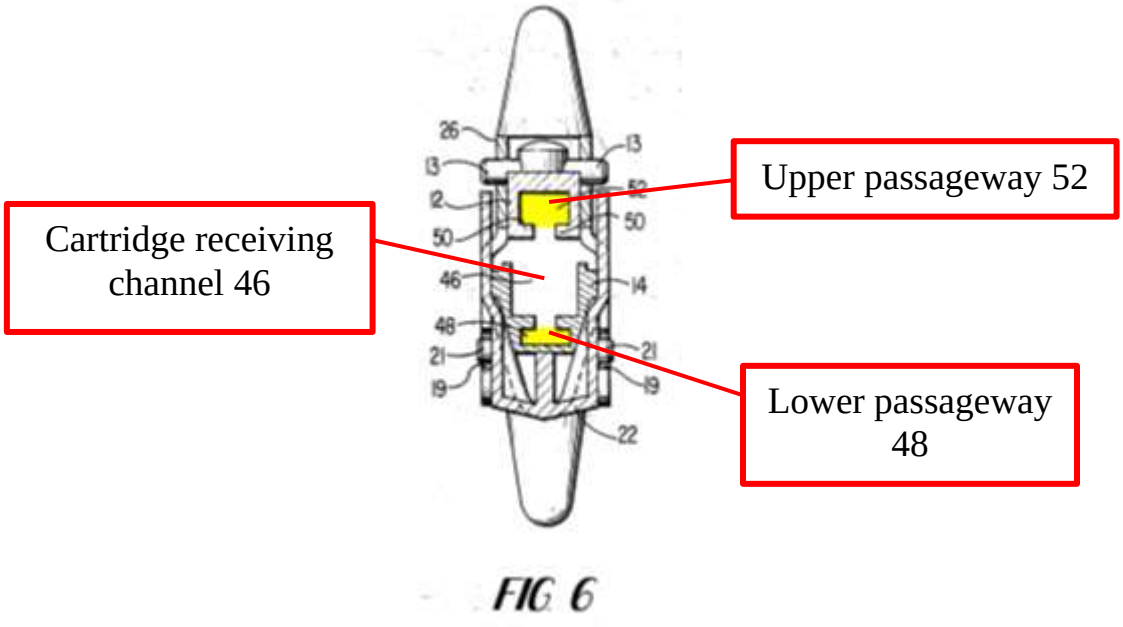
Green, FIG. 3.

A head-on view of the stapler is depicted in Figure 6 of Green (below). As shown in Figure 6, when the stapler is prepared for use, there is an upper "longitudinally extending passageway 52 of generally rectangular section" in the anvil and a lower "passageway 48." The upper shoe 56 rides in the upper "passageway 52" and the lower shoe 54 rides in the lower "passageway 48." The lower shoe "fits in passageway 48 with minimal clearance to allow substantially friction-free passage of the shoe along the passageway." Green, 4:24-50. In between the upper and lower passageways is "cartridge-receiving channel 46." Green, 4:20-24. Accordingly, as the knife and staple pushers ride through channel 46, upper shoe 56 rides in passageway 52 and lower shoe 54 rides in passageway 48. Knodel, ¶¶62-63.

Side View:



Front View:



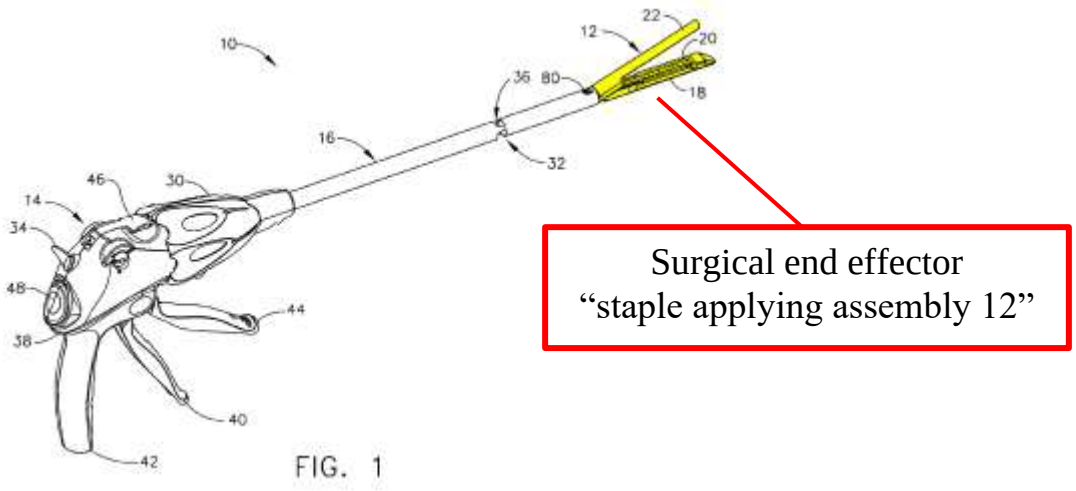
Green explains that passageways 48 and 52 help resist lateral forces as well as forces tending to open the jaws:

> It will be appreciated, since the shoes 54 and 56 are accurately laterally aligned and carried by a relatively rigid member, that during stapling, as the shoes move along the passageways 48 and 52 with minimal clearance, they provide adequate localized support to the jaws in the region of operation of the pusher bar cams and the particular individual staple pushers being actuated. 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** . . . .

Green, 6:26-36 (emphasis added).

22[Pre]: A surgical end effector, comprising:

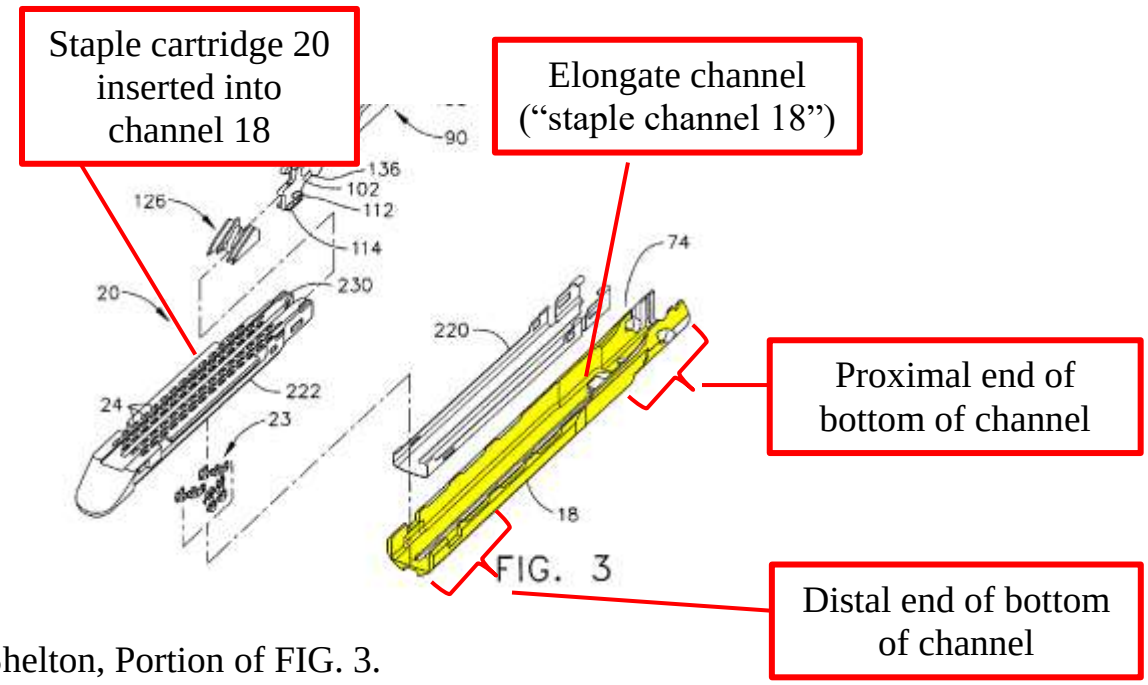
Whether the preamble is limiting or not, Shelton discloses it. Knodel, ¶68. Shelton discloses a "surgical instrument 10 [that] has at its distal end an end effector, depicted as a staple applying assembly 12." Shelton, 4:54-56.



Shelton, FIG. 1.

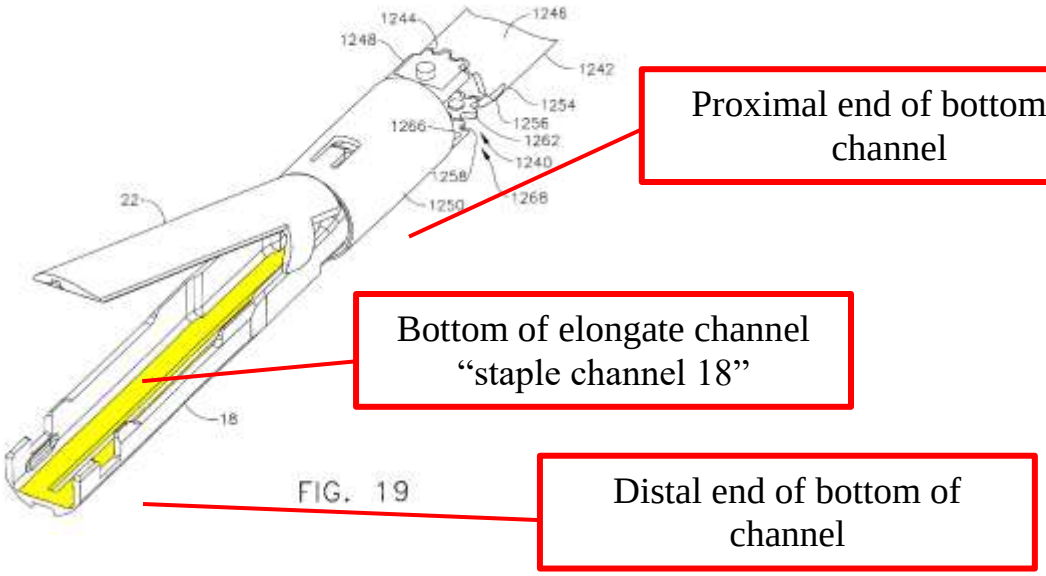
22[a]: an elongate channel including a bottom including a proximal end and a distal end, the elongate channel being configured to operably support a staple cartridge therein;

Shelton discloses this limitation. Knodel, ¶¶69-70. Shelton discloses an elongate "staple channel 18." Shelton, 4:56-58. As shown in FIGs. 3 and 19, the bottom of the elongate channel 18 has a proximal end and a distal end. A POSITA would have readily understood based on the disclosure of the '369 Patent that the proximal and distal "ends" are not the edges of the channel, but the areas at either "end" of the channel (for lack of a better word). Knodel, ¶¶61-67.



Shelton, Portion of FIG. 3.

Another view of the elongate channel with just the bottom highlighted is shown here:



Shelton, FIG. 19. The staple channel of Shelton is configured to operably support a staple cartridge therein, as shown above in FIG. 3 ("staple cartridge 20" is shown being inserted into elongate channel 18.). *See* Shelton, 8:1-4.

22[b]: a firing element configured to translate between a first position adjacent the proximal end of the bottom of the elongate channel and an ending position adjacent the distal end of the bottom of the elongate channel, the firing element including a vertical portion and at least one laterally extending lower foot;

Shelton discloses this limitation. Knodel, ¶¶71-79.

"a firing element configured to translate between a first position adjacent the proximal end of the bottom of the elongate channel and an ending position adjacent the distal end of the bottom of the elongate channel."

Like the '369 Patent, Shelton discloses an "E-beam" firing element. "FIG. 4 is a perspective view of a two-piece knife and firing bar ('E-beam') of the staple applying assembly of FIG 2." Shelton, 3:59-62. "An E-beam 102 is the distal

portion of the two-piece knife and firing bar 90, which facilitates separate closure and firing as well as spacing of the anvil 22 from the elongate staple channel 18 during firing." Shelton, 6:25-28.

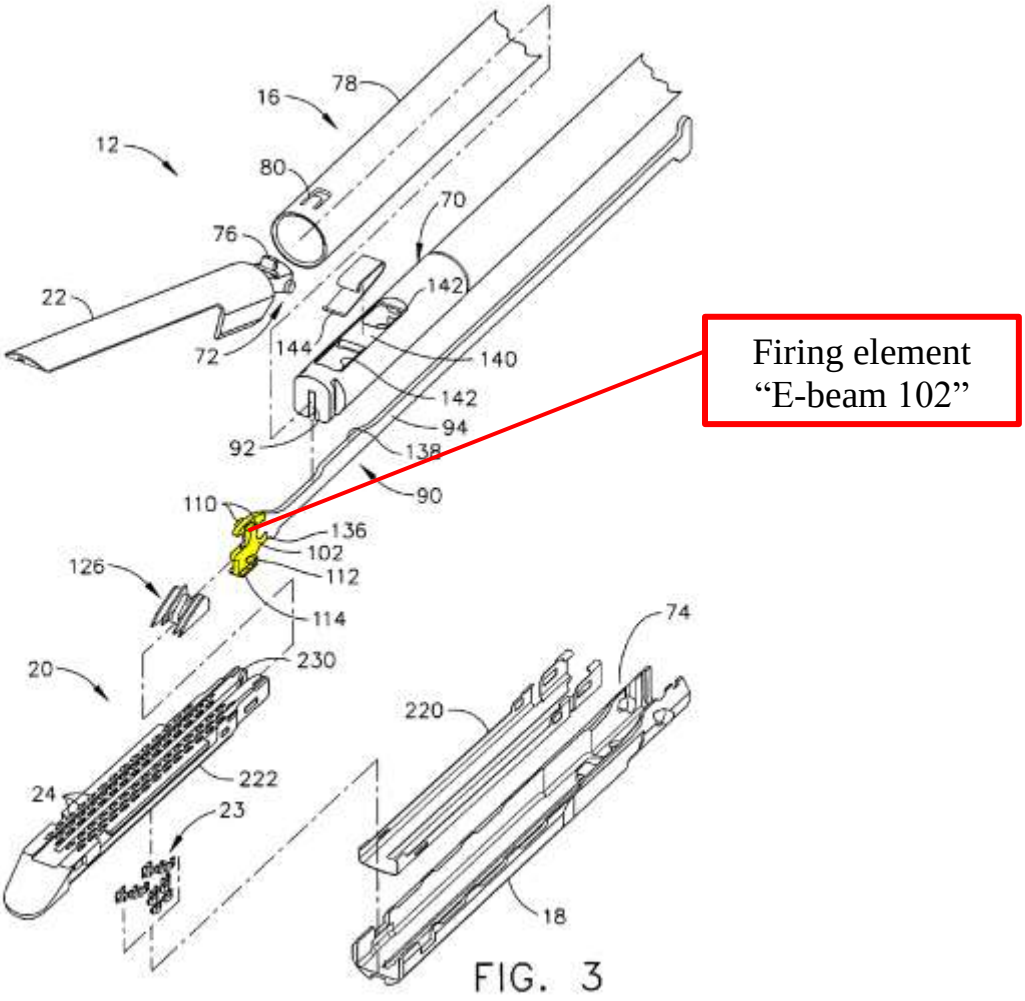


FIG. 3

In the exploded view of FIG. 3, above, the firing element is shown at the first position, which is adjacent the proximal end of the bottom of the elongate channel. This first position is also shown in FIGs. 6 and 7 of Shelton. Shelton, 6:58-59.

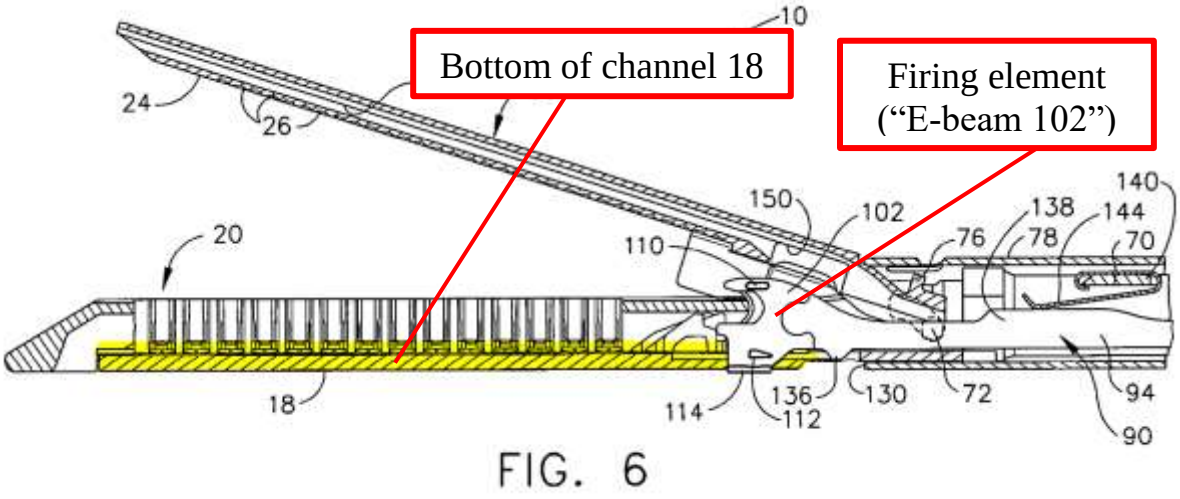


FIG. 6

FIG. 12 of Shelton depicts the firing element at the ending position, which is adjacent the distal end of the bottom of channel 18. *See* Shelton, 8:14-15 ("In FIG. 12, the two-piece knife and firing bar 90 has been distally fired . . . ."):

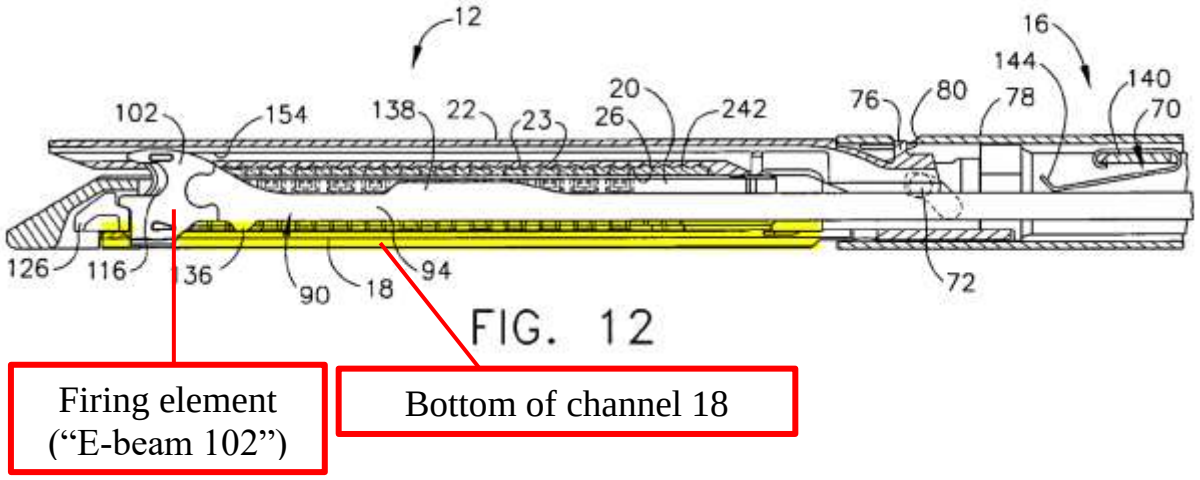
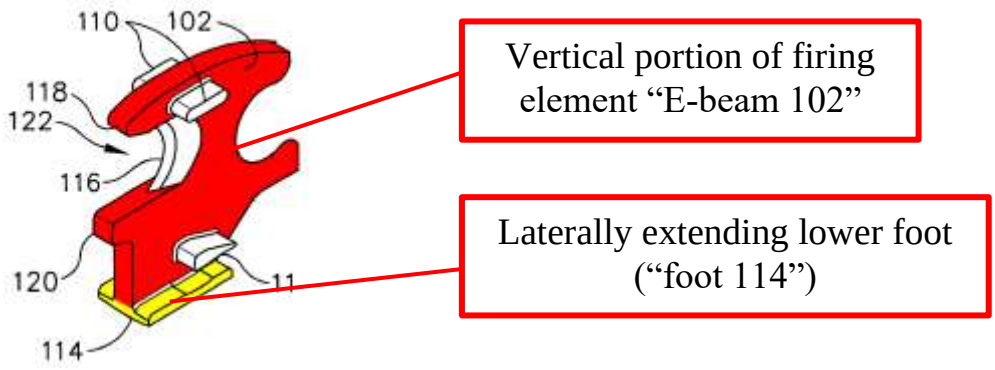


FIG. 12

"the firing element including a vertical portion and at least one laterally extending lower foot"

The firing element of Shelton, "E-beam 102," has a vertical portion to which is attached laterally extending lower foot ("bottom pin or foot 114"), Shelton, 6:36-41:



22[c]: an internal passage extending within the elongate channel and configured to receive the at least one laterally extending lower foot when the firing element moves between the first position and ending position;

Shelton in view of Green discloses this element. Knodel, ¶¶80-97.

"*an internal passage extending within the elongate channel*"

Shelton discloses an *exposed* passage extending within the elongate channel—"lower track 132 formed in the staple channel 18." Shelton, 6:62-64. The lower track 132 "includes a narrow slot 133 that opens up as a widened slot 134 on an undersurface of the staple channel 18 to form an inverted T-shape in lateral cross section, as depicted particularly in FIGS. 7 and 8, which communicates with the widened hole 130." Shelton, 6:65-7:1.

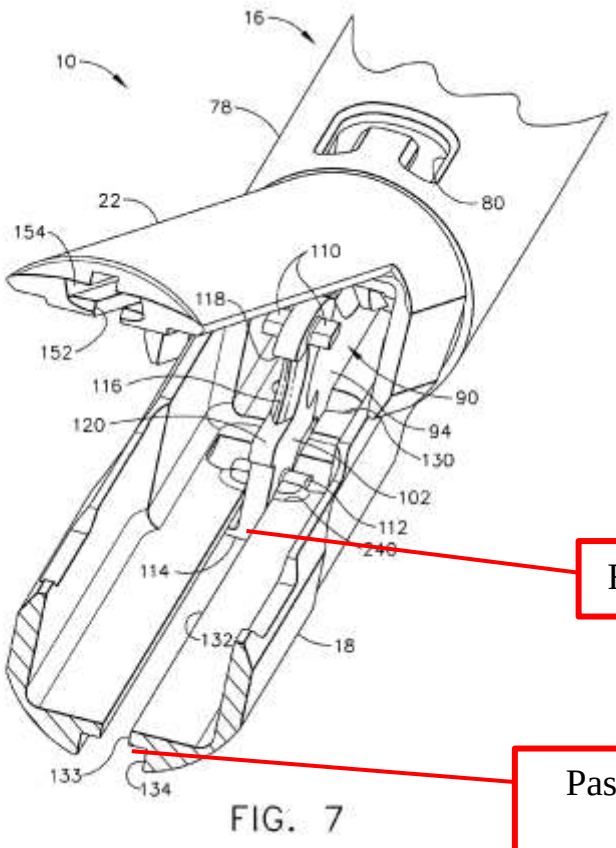


FIG. 7

Foot riding in lower track 132

Passage extending within the elongate channel "lower track 132"

Shelton's passage is not "internal," in that the passage is exposed. In the '369 Patent, the "internal" passageway is shown as having a bottom portion, such as "solid bottom portion 6024." (IS1001, 72:45-55). The exposed slot embodiment of the '369 Patent, as shown in Fig. 4 of the '369 Patent, is not described as an "internal" passage.

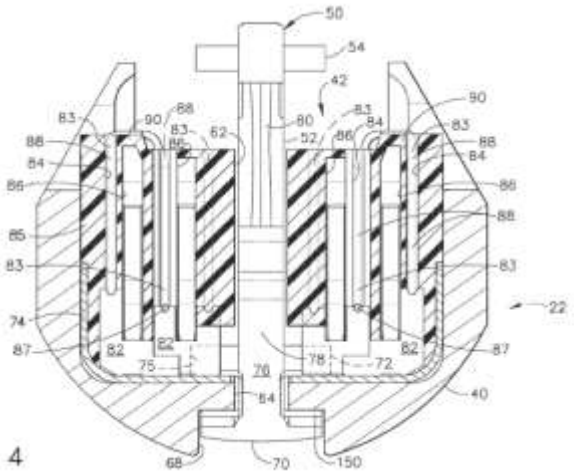


FIG. 4

'369 Patent, Fig. 4. The '369 Patent specifically mentions a potential problem with the exposed slot: "such arrangement does employ a longitudinal slot in the elongate channel which may reduce the channel stiffness as well as the channel's resistance to twisting and spreading"—which is the very problem discussed by Green and solved by Green's internal passageway. *Compare* '369 Patent, 72:25-30 *with* Green, 6:26-36; Knodel, ¶¶84-85.

Clearly, it would have been obvious to a POSITA at the time of the alleged invention of the '369 Patent (no earlier than April 2014) based on the teachings of Green to cover at least part of the passage so that it would be internal to the elongate channel (the stapler jaw that houses a removable staple cartridge). Knodel, ¶¶86-89. For example:

First, Green discloses a surgical stapler with an internal passage in the elongate channel jaw that houses the staple cartridge, the internal passage accommodating the lower foot of a firing element. Thus, the use of a lower

internal passage for a firing element foot was not new at the time of the alleged invention of the ’369 Patent. Although Green uses an “I-beam” instead of an “E-beam,” a POSITA looking to improve an E-beam design would turn to “I-beam” designs for inspiration. Knodel, ¶¶89-93. In particular, a POSITA would have recognized that both an E-beam and an I-beam have lower feet, which work in conjunction with upper pins to provide local support to the stapler jaws to resist the opening of the jaws, and a POSITA would have recognized that an improvement to a lower foot passage in an I-beam would be applicable to an E-beam as well. Knodel, ¶89. In particular, Green discloses an I-beam with an upper pin (“upper shoe 56”) that rides in an internal passage in the anvil and a lower foot (“lower shoe 54”) that rides in an internal passage in the lower jaw that holds the staple cartridge. Green, 4:30-60.

Figure 6 of Green depicts both these internal passages, which accommodate the upper and lower “shoes” of Green’s I-beam, Green, 4:20-50.

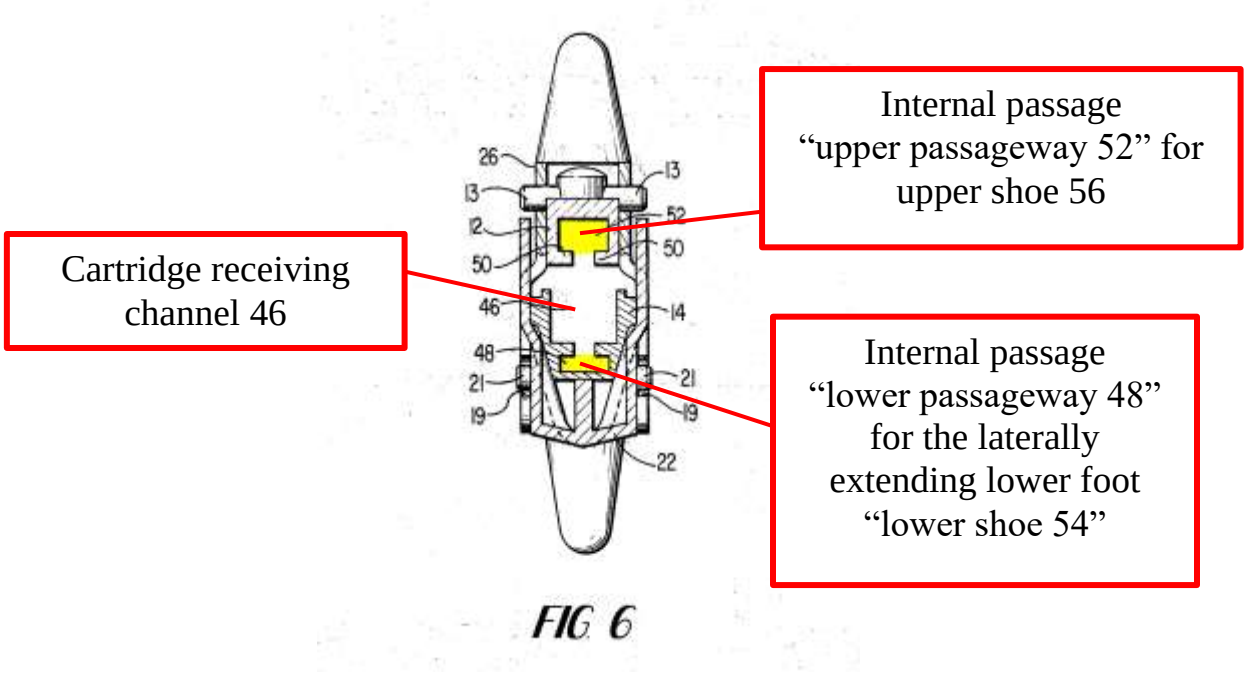


FIG 6

Green also discloses another cross section of the stapler near the distal end of the stapler with the cartridge installed:

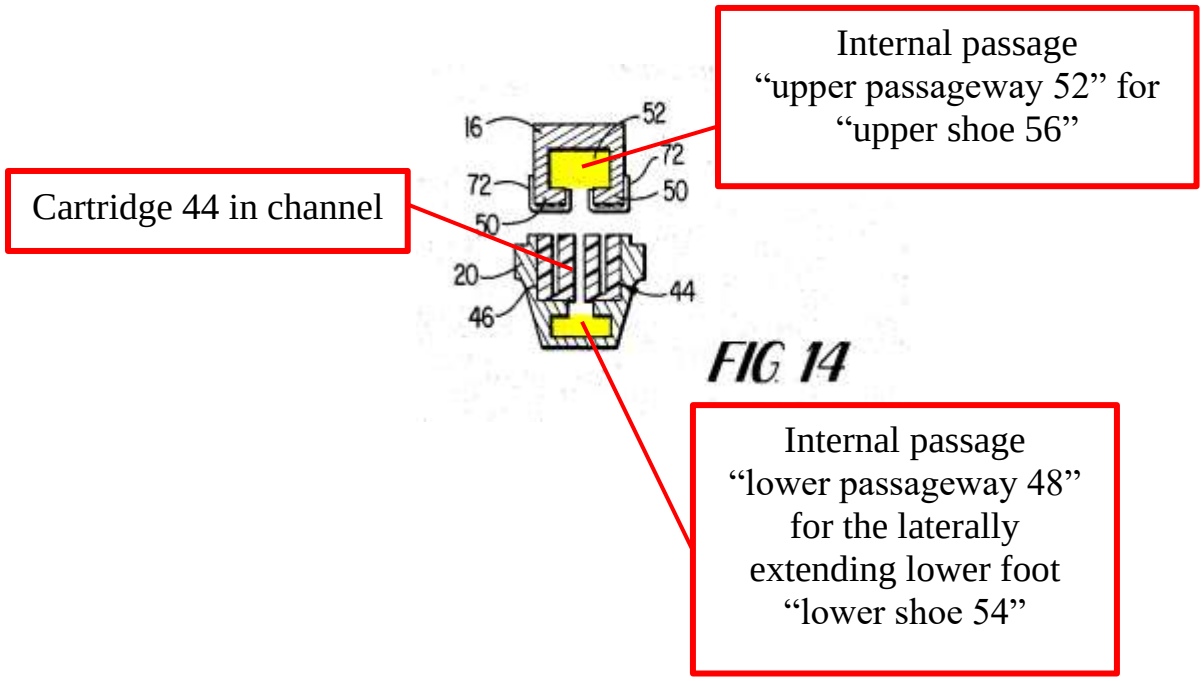
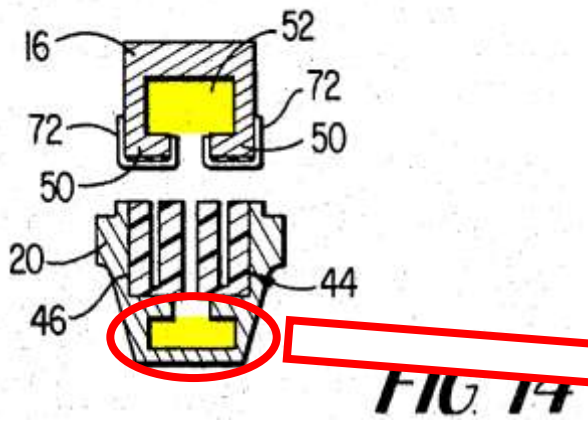
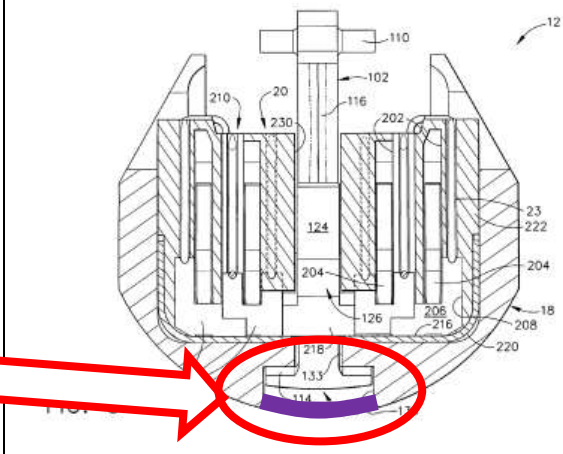


FIG 14

Thus, Green taught those of ordinary skill in the art that the foot of a firing element in a surgical stapler should travel within an internal passage below the staple cartridge-holding channel. Knodel, ¶¶91-93

Second, Green explains that the internal passage design offers structural integrity, and a POSITA would thus have been motivated to apply the teaching of Green to Shelton, and would have a reasonable expectation of success doing so. Knodel, ¶94. A POSITA would have readily understood and have seen the value in applying this specific teaching of Green to the Shelton stapler:

Green, Fig. 14	**Shelton, FIG. 8 (Purple channel bottom added to figure to illustrate modification)**
	

Green provides an explicit motivation to provide a lower internal passage for the laterally extending lower foot as the firing element moves through the channel during firing. Green explains that the internal passages "provide[s] adequate

localized support to the jaws in the region of operation of the pusher bar cams and the particular individual staple pushers being actuated. Due to the cross-sectional shape of the shoes and passages, such support resists forces tending both laterally to distort the jaws and to open the jaws vertically . . . ." Green, 6:26-36. Thus, a POSITA reading Green would have understood the benefit of using an internal passage for the foot of either an "I-beam" or "E-beam" structure, as the internal passage provides for improved clamping support when firing the stapler. Knodel, ¶95.

Third, a POSITA at the time of the alleged invention would have readily appreciated that enclosing the passage to create an internal passage would provide more protection from external tissue and other material than that provided by an open passage. Knodel, ¶96. A POSITA would have understood the benefits of enclosing passages (thus making them internal passages) based on the teachings of Green and/or based on general knowledge in the art, and/or knowledge generally. Knodel, ¶¶96-97.

To be clear, Petitioner is not suggesting that a POSITA would have tried to physically combine Green with Shelton, which have different physical structures. Rather, a POSITA would have understood from Green the teaching that the lower passage may be an internal passage, and that there are benefits to using an internal passage, as discussed in Green. This teaching would have led a POSITA to modify

Shelton to obtain the benefits of using an internal passage for Shelton's lower foot as the foot moves from the starting position to the ending position. *See Allied Erecting and Dismantling Co., Inc. v. Genesis Attachments, LLC*, 825 F.3d 1373 (Fed. Cir. 2016) (references need not be physically combinable in obviousness analysis).

Modified FIG. 9 from Shelton illustrating the passage being modified from an exposed passage to an internal passage (Knodel, ¶97):

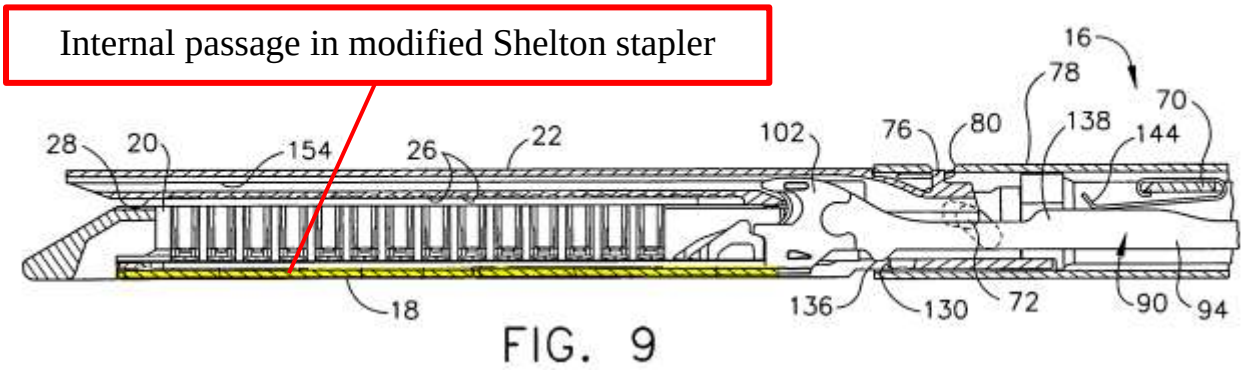


FIG. 9

22[d]: a proximal channel opening through the proximal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the first position, the proximal channel opening sized to receive therein the at least one laterally extending lower foot on the firing element;

"*a proximal channel opening through the proximal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the first position,*"

Shelton alone, and Shelton in view of Green, disclose this limitation. Knodel, ¶¶97-99. Shelton's "widened slot 134" provides a channel opening which includes a "proximal channel opening through the proximal end of the bottom of the elongate channel." Specifically, Shelton discloses that its passage is formed from "a widened slot 134 on an undersurface of the staple channel 18 to form an inverted T-shape in lateral cross section, as depicted particularly in FIGS. 7 and 8." Shelton, 6:65-7:1. The widened slot runs from the proximal end of the bottom of the channel to the distal end, as shown in Fig. 7:

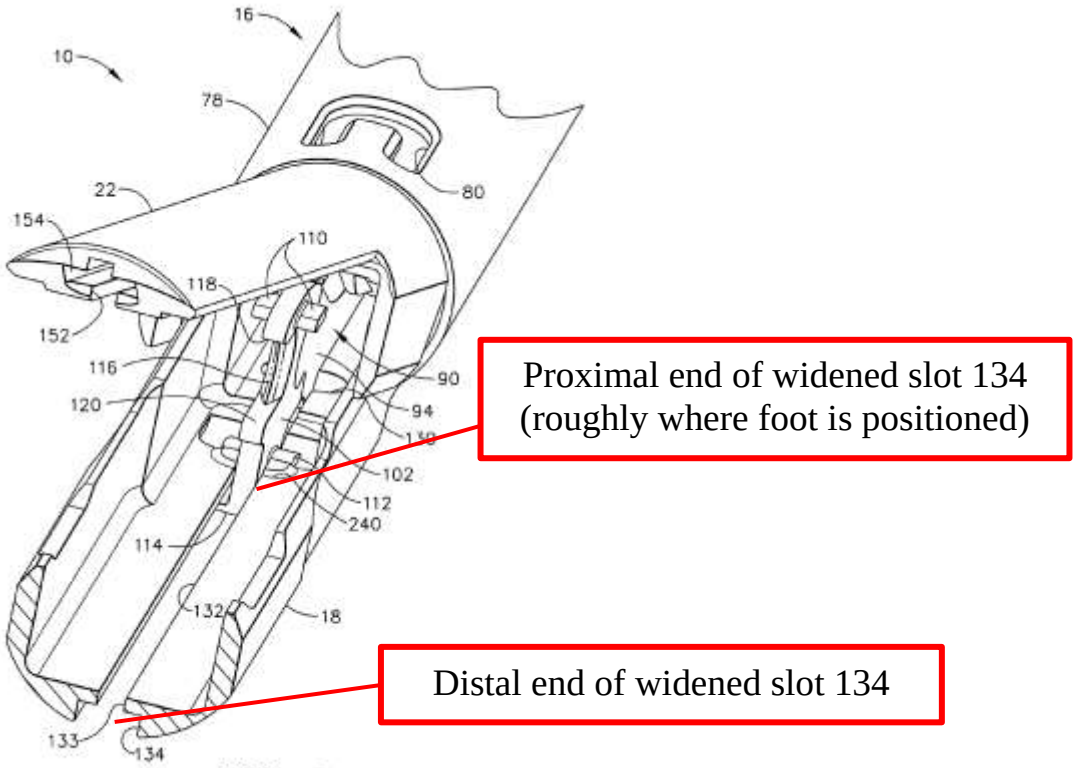
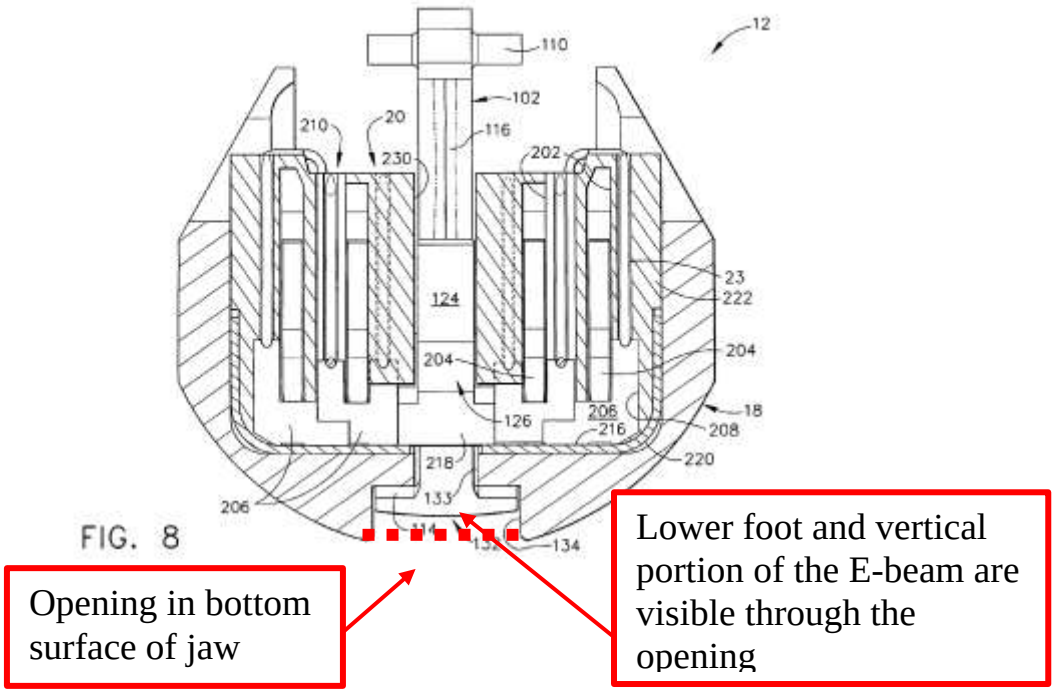


FIG. 7

Viewing of the firing element "therethrough" (through the proximal channel opening) is disclosed by the combination of Shelton and Green. The "opening" would be the two dimensional surface on the bottom of the lower jaw that has no material—and thus creates a hole into the jaw. In Shelton, the "opening" is formed by the lower track 132. Because the foot 114 is riding in the track, the foot (which is part of the E-beam firing element 102) is visible "through" the opening, which allows a user to look "inside" the bottom surface of the lower jaw. Knodel, ¶101.



Alternatively, a user can look through the lower track (including the slot connecting the lower track to the elongate channel) before or behind the foot and into the elongate channel of the lower jaw and see the vertical portion of the firing element above the foot.

A POSITA would have been motivated to make the combination for a number of reasons.

First, A POSITA would have understood that the widened slot 134 provides a visual indication of the location of the lower foot, and therefore the firing element of the stapler, as is apparent from FIGs. 7, 8 and 9 of Shelton. Knodel, ¶101. Accordingly, when modifying Shelton in view of Green, a POSITA would have wanted to maintain the benefit of Shelton's exposed widened slot (providing a visual indication and allow for a mechanical lockout) and additionally obtain the benefit of Green (providing a more rigid and stable structure). Thus, a POSITA would have modified Shelton to provide an internal passage as taught by Green while leaving exposed portions as taught by Shelton. In the combination, it would have been obvious to leave proximal (and distal) ends of an internal passage exposed, so that the user could visually see if the firing element was at the beginning or end of the firing stroke. Knodel, ¶¶101-106. A POSITA would have readily understood, based on general knowledge, that when an open passage is enclosed, it would be obvious to place openings in the enclosing structure to maintain visual observation of elements traveling in the passage, including placing observation points at least at the beginning and ending positions of travel. Knodel, ¶106.

Second, a POSITA would have recognized that Shelton discloses a lockout feature that prevents advancement of the E-beam beyond a proximal or starting position if an unspent staple cartridge is absent from the elongate channel. In the absence of an unspent staple cartridge, the E-beam is prevented from advancing beyond its proximal or starting position by middle pins 112 that fall into lockout recess 240. Shelton, 8:21-23. In order for this lockout mechanism of the combination to work, the widened slot 134 must remain open below the proximal portion of the elongate channel so that vertical movement of the E-beam is not impeded. Otherwise, the presence of a cover would interfere with and prevent vertical movement of the E-beam, and thus prevent the lockout from working. Knodel, ¶¶100, 107. Accordingly, a POSITA would have understood that when combining Shelton and Green, an outer surface of Green's internal passage would not extend over the proximal portion of Shelton's widened slot so that the Shelton lockout is able to function. Knodel, ¶108.

"The proximal channel opening sized to receive therein the at least one laterally extending lower foot on the firing element"

Shelton teaches that the "widened slot 134" is wide enough to receive the laterally extending lower foot 114 on the firing element, as depicted in FIG. 8:

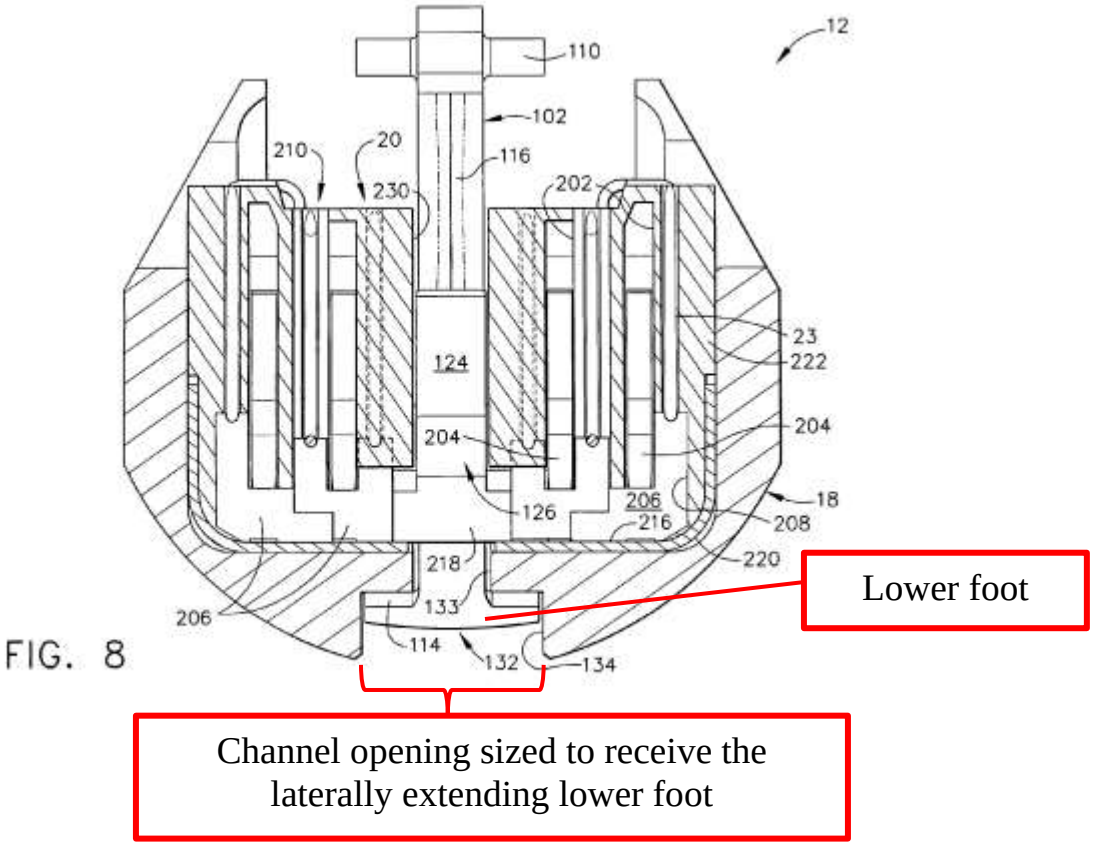
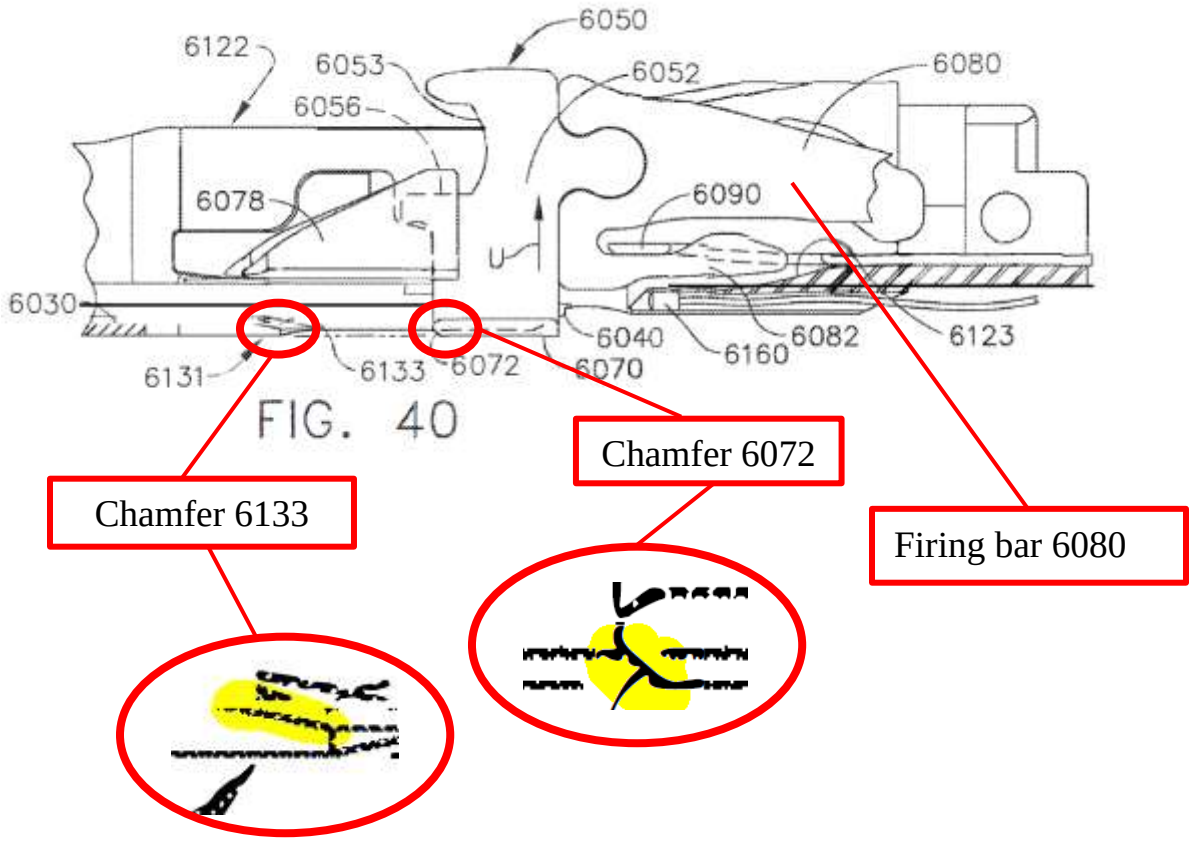


FIG. 8

In the combination with Green, the outer surface of the Green internal passage would not extend into the most proximal area of the elongate channel and thus the proximal channel opening would retain its width. In addition, a POSITA would be motivated to preserve the lockout in Shelton and would thus be led to leave an exposed portion at the proximal end of Shelton's widened slot 134 long enough so that the foot could descend to engage the lockout. Thus, in the combination the proximal channel opening would be sized to receive therein the laterally extending lower foot. Knodel, ¶¶109-110.

22[e]: and means for guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element.

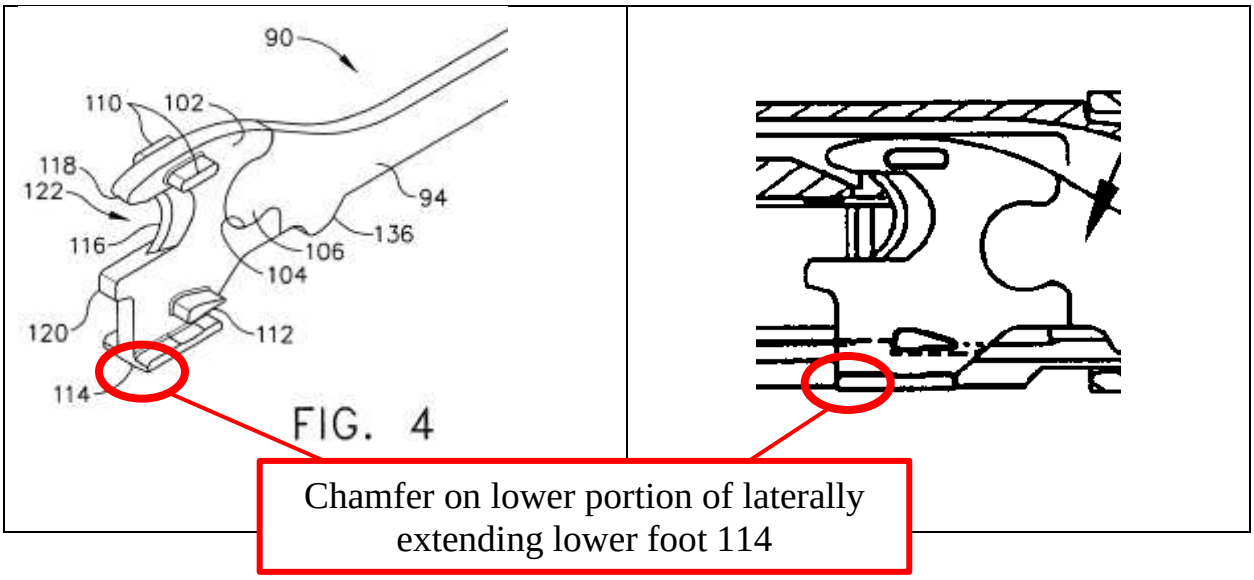
The corresponding structure for the "means for guiding . . ." limitation has been identified in the claim construction section as either "chamfers 6072" on the foot of the firing element or corresponding "chamfer 6133" on the channel or both, in combination with the firing bar 6080.



'369 Patent, FIG. 40.

Shelton's E-beam discloses such a chamfer as the lower foot is depicted as rounded on both the leading upper edge and the leading lower edge. Shelton's E-

beam is also connected to a firing bar 94, which is similar to the firing bar 6080 depicted in the '369 Patent. Knodel, ¶¶111-112.

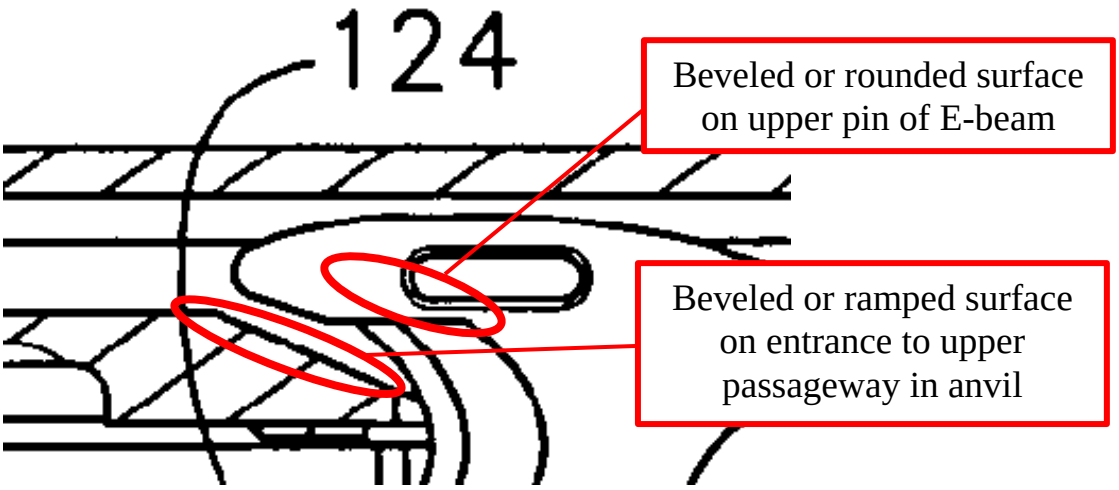


Shelton, FIG. 4 (excerpt) and FIG. 13 (excerpt).

In addition, even if Shelton did not disclose a chamfer on the lower portion of the foot, it would nonetheless have been obvious to a POSITA to add a chamfer to the lower portion of the foot. In the combination, the lower foot at the starting position is co-located with the proximal channel opening. When the foot is moved into the internal passage, the lower foot may have a tendency to contact the bottom portion of the internal passage. It would have been obvious to a POSITA to add a chamfer to the lower foot or to the entrance to the internal passage or both in order to provide smoother operation of the instrument. It would have been well-known

to a POSITA to add chamfers, ramped edges, where a component is guided into another component. Knodel, ¶1113.

In fact, a POSITA would have recognized the complementary ramped surfaces (or chamfers) on the top portion of the E-beam of Shelton. In Shelton, the E-beam has an upper pin, which slides into an internal passageway of the anvil. To facilitate ease of sliding, the upper pin has a ramped surface that contacts and interacts with the ramped surface of the anvil. As depicted in FIG. 11, the closure tube has closed the anvil and the E-beam is advancing forward from its retracted position. As the E-beam moves forward, the upper pin may touch the lower surface of the upper passageway and be eased into the upper passageway in the anvil, Knodel, ¶114:



Shelton, FIG. 11.

23. The surgical end effector of claim 22, wherein said means for guiding comprises at least one ramped surface provided on at least one of the at least one lower foot and a portion of the elongate channel defining the proximal channel opening.

This claim is met by the combination of Shelton and Green. In the combination of Green and Shelton, the composite stapler would have the ramped surface (or chamfer) on the foot of the E-beam, as disclosed in Shelton and would also have a corresponding ramped surface of an edge of the proximal channel opening leading into the internal passageway. A POSITA would have immediately recognized that a ramped surface on the foot of the E-beam would operate more smoothly with a corresponding ramped surface of an edge of the proximal channel opening leading into the internal passageway. Knodel, ¶¶115-116. A POSITA would have recognized that the ramped surface on the foot without a corresponding ramped surface on the elongate channel would potentially cause jerky movement of the E-beam as its foot moves into the internal passageway from the proximal channel opening, and that a smoother gradual transition could be accomplished by smoothing an edge of the proximal channel opening leading into the internal passageway. *Id.*

As discussed with regard to element 22[e], a POSITA would have readily recognized that on the anvil end of the Shelton E-beam, both the E-beam and anvil passage are chamfered to allow ease of entry of the E-beam into the anvil

passageway. *Id.* A POSITA would have readily adopted a similar interface for ease of entry of the lower foot into an internal passageway on the elongate channel.

B. [GROUND 2]—Shelton in View of Green and Further in View of Zemlok Renders Obvious Claims 22-23

Even if Shelton in view of Green did not disclose a proximal channel opening through which a firing element can be viewed, such a structure is suggested by Zemlok. Like Shelton and Green, Zemlok discloses a surgical stapler: "Surgical stapling devices wherein tissue is first grasped or clamped between opposing jaw structure and then joined by means of surgical fasteners are well known in the art." Zemlok, ¶5. Zemlok asserts that his patent is directed to a surgical stapling instrument that "has visual indicators that provide the operator with information relating to the position of a movable part." Zemlok, ¶10.

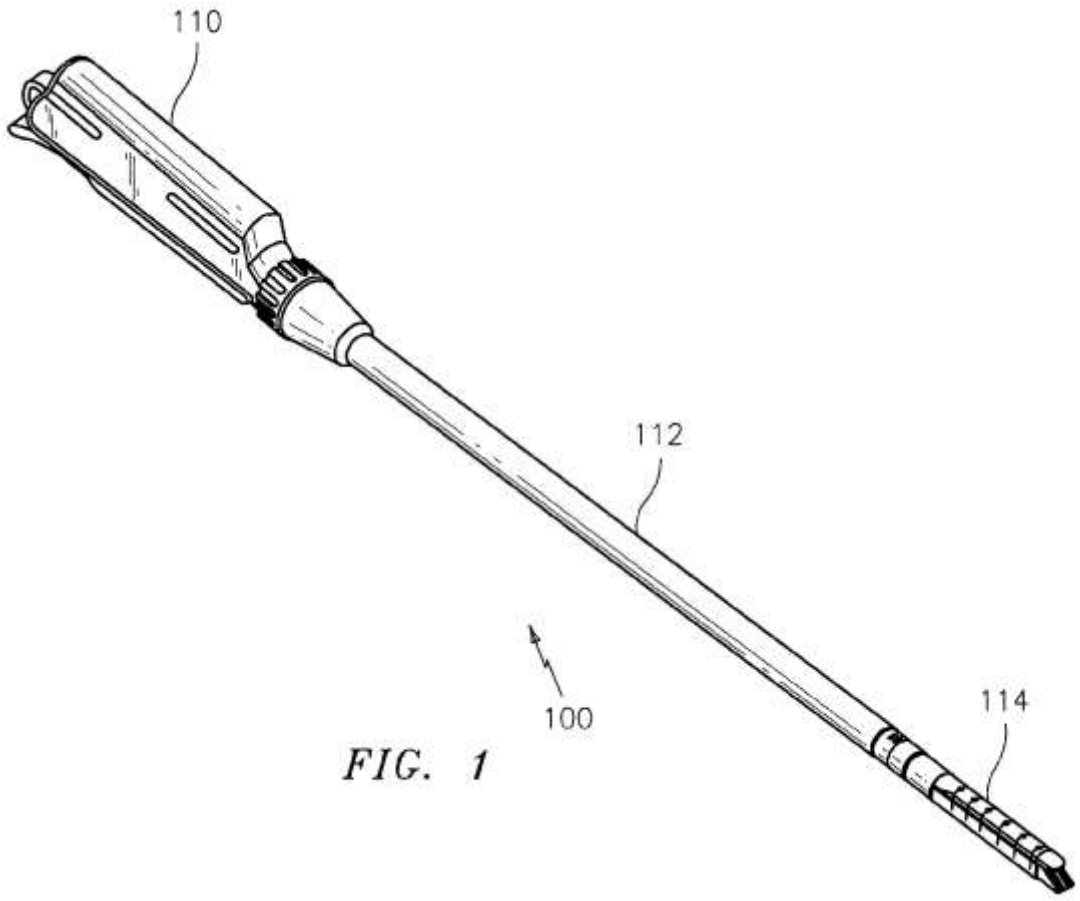


FIG. 1

Zemlok states that the visual indicators may be visible from the top of the end effector (through the anvil) or from the bottom of the end effector (through the cartridge): "In one embodiment, the surgical stapling instrument has a cartridge, an anvil, a drive assembly, and the visual indicator. The cartridge contains a plurality of fasteners and is mounted adjacent the anvil. The drive assembly moves through the cartridge to eject the fasteners from the cartridge. The visual indicator has a material that provides an optical contrast to the body of either, or both, the cartridge and the anvil." Zemlok, ¶11; Knodel, ¶¶64-67, 117, 118.

22[Pre]: A surgical end effector, comprising:

See Ground 1, element 22[pre].

22[a]: an elongate channel including a bottom including a proximal end and a distal end, the elongate channel being configured to operably support a staple cartridge therein;

See Ground 1, element 22[a].

22[b]: a firing element configured to translate between a first position adjacent the proximal end of the bottom of the elongate channel and an ending position adjacent the distal end of the bottom of the elongate channel, the firing element including a vertical portion and at least one laterally extending lower foot;

See Ground 1, element 22[b].

22[c]: an internal passage extending within the elongate channel and configured to receive the at least one laterally extending lower foot when the firing element moves between the first position and ending position;

See Ground 1, element 22[c].

22[d]: a proximal channel opening through the proximal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the first position, the proximal channel opening sized to receive therein the at least one laterally extending lower foot on the firing element;

See Ground 1, element 22[d].

In addition, Zemlok discloses a proximal channel opening (in addition to other channel openings along the length of the channel) to facilitate viewing of the firing element therethrough. Zemlok discloses a firing element with a visual indicator that can be located on the anvil side (top surface) or the cartridge side (bottom surface): "As best shown in FIG. 7, the blade 124 includes a visual

indicator 138 located on the outermost surface within the anvil or top surface. This configuration allows the operator to observe the location of the visual indicator 138 as the drive mechanism 122 and knife blade 124 travel distally along the fastener applying assembly 114 as observed from the top of the surgical stapler 100. As best seen in FIG. 6, an additional visual indicator 138 may be placed on the outermost surface within the cartridge housing 116, ***or bottom surface***. This configuration allows the operator to observe the location of the visual indicator 138 as the drive mechanism 122 and knife blade 124 travel distally along the fastener applying assembly 114 as observed from the bottom of the surgical stapler 100." Zemlok, ¶27; Knodel, ¶¶124-129.

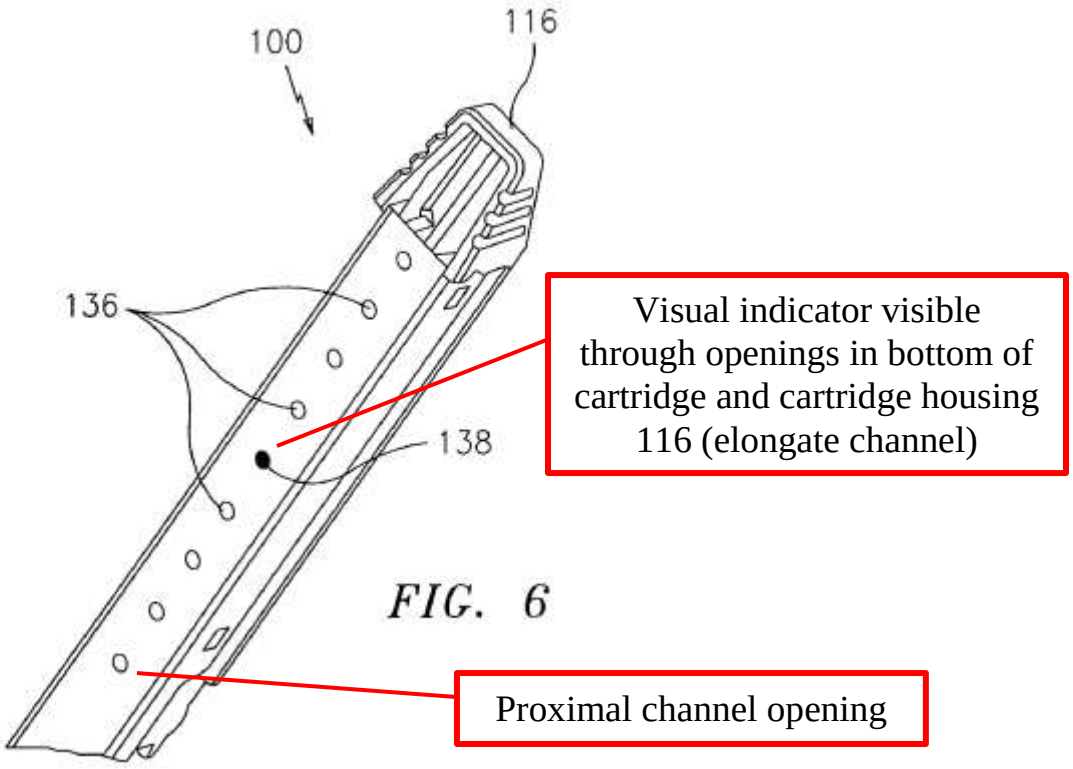


FIG. 6

Zemlok, FIG. 6.

The disclosure of Zemlok establishes that the visual indicator is visible through the bottom surface of cartridge housing (Zemlok, ¶27). This would be clear to a POSITA. FIG. 6 is described as "an enlarged perspective view of the ***fastener applying assembly*** having a series of openings on the cartridge for viewing the visual indicator through in the proximal position." Zemlok, ¶20 (emphasis added). Zemlok further states that the "surgical stapler 100" includes "a fastener applying assembly 114 that is operatively associated with a distal end portion of elongate body 112." Zemlok, ¶25. Thus, a POSITA would have understood that FIG. 6 to illustrate the distal end of the surgical stapler 100 with a cartridge installed. Knodel, ¶¶124-125. In fact, the structure in FIG. 6 is identified as part of item "100," which is the surgical stapler.

A POSITA would have also recognized that FIG. 6 appears to depict a cartridge, rather than a cartridge in cartridge holder 116. However, a POSITA would also have recognized that Zemlok clearly teaches that the openings in the cartridge 118 are visible through the cartridge holder 116, even if portions of the cartridge holder 118 are not completely visible. A POSITA would have understood that the cartridge holder would be structured with a longitudinal slot through which the openings in the cartridge would be visible or alternatively would be structured with its own set of openings that would align with the cartridge

openings. At bottom, the precise structure of the Zemlok cartridge holder is not material. Rather, what is material is that Zemlok clearly teaches that the openings in the bottom of the lower jaw are visible to the user when the Zemlok stapler is used. Knodel, ¶¶125-126.

Zemlok further specifically teaches a proximal channel opening visible through the bottom of the lower jaw of the surgical stapler 100. Zemlok specifically describes Figure 6 as providing "a series of openings" for viewing the visual indicator of the fastener blade "***in the proximal position***." Zemlok, ¶20 (emphasis added). Zemlok also states that the visual indicator may give an indication of the "proximal limit" of the staple driving mechanism. Zemlok, ¶29. Zemlok further states with reference to Figure 6 that "a series of position indicators or openings 136, on the outside of the cartridge 116 is shown. The position of a visual indicator 138 in relation to cartridge 116 is observable through these openings ***during the stapling and cutting operation***." Zemlok, ¶31 (emphasis added). Although this passage refers to the "cartridge" and not the "cartridge housing," the numeral 116 corresponds to the cartridge housing and a POSITA would have understood that for the "visual indicator" to be "observable through these openings during the stapling and cutting operation," the openings or a slot must be present in the cartridge housing 116 as well as in cartridge 118.

Otherwise, the openings would be covered by the cartridge housing and would not be "observable." Knodel, ¶¶65-76, 125-126.

Thus, even if the combination of Shelton and Green did not adequately teach or suggest inclusion of a proximal channel opening, Zemlok would clearly have motivated a POSITA to add such an opening for the purpose of viewing the firing element therethrough and would have further provided a motivation to a POSITA to add (in the combination with Shelton) an opening of sufficient size for the lockout mechanism of Shelton. Knodel, ¶¶126-127.

While Zemlok does not discuss including within its end effector a distinct passage below the cartridge channel and above the bottom surface of the elongate channel, Zemlok nevertheless discloses a channel through which its knife blade travels and discloses openings in the channel floor to allow visible observation of the location of the knife blade within the channel. Knodel, ¶¶128-129. A POSITA would therefore have been motivated by Zemlok's teachings of a visible indicator to modify Shelton in view of Green to preserve the internal lower passage of Green and the lower track (now covered) and proximal channel opening of Shelton. *Id.*[4]

[4] FIG. 8 of Zemlok discloses an alternative embodiment having a knife "retainer 242" with "indicator 238." The retainer sits outside the channel, and offers an

Because Zemlok does not disclose the lockout mechanism of Shelton, Zemlok does not disclose that its proximal channel opening is "sized to receive therein the at least one laterally extending lower foot." However, as stated with respect to Ground 1, it would have been obvious to a POSITA based on the sizing of Shelton's "widened slot 134" that if the Green cover stopped short of the area adjacent the proximal end of the channel, the proximal channel opening would be the width of the widened slot 134 and would also be long enough to receive Shelton's foot, and thus accommodate Shelton's lockout mechanism. This is because a POSITA combining Shelton, Green, and Zemlok would recognize the benefits of preserving Shelton's lockout mechanism and would thus be motivated to configure the proximal channel opening to receive Shelton's foot so that Shelton's lockout mechanism would work in the modified design. Knodel, ¶¶124-129.

In addition, although the openings in Zemlok appear small in FIG. 6, the drawing is not to scale, and nothing in Zemlok teaches away from sizing the proximal channel opening to accommodate a foot of an E-beam, should that feature be desirable. Knodel, ¶129.

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indicator that is "continuously observable." This embodiment is not the embodiment relied upon in this Petition.

22[e]: and means for guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element.

See Ground 1, element 22[e].

23. The surgical end effector of claim 22, wherein said means for guiding comprises at least one ramped surface provided on at least one of the at least one lower foot and a portion of the elongate channel defining the proximal channel opening.

See Ground 1, claim 23.

C. [GROUND 3]— Shelton in View of Green and Further in View of Zemlok Renders Obvious Claim 1 and 15

1[Pre]: A surgical end effector, comprising:

See Ground 1, element 22[pre].

1[a]: an elongate channel including a bottom including a proximal end and a distal end, the elongate channel being configured to operably support a staple cartridge therein;

See Ground 1, element 22[a].

1[b]: a firing element configured to translate between a starting position adjacent the proximal end of the bottom of the elongate channel and an ending position adjacent the distal end of the bottom of the elongate channel;

See Ground 1, element 22[b]. The "starting position" is the same as the "first position" in claim 22. Knodel, ¶134.

1[c]: a proximal channel opening through the proximal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the starting position;

Shelton in view of Green (and as further taught by the proximal and distal openings of Zemlok) discloses this limitation.

See Ground 1, element 22[d] as further supported by element 22[e]. Claim 22 refers to a "first position" whereas claim 1 refers to a "starting position." The '369 Patent does not treat these two positions differently. The "starting position" is the "first position adjacent the proximal end of the bottom of the elongate channel" as recited in claim 22. Knodel, ¶135.

In fact, Shelton alone discloses a slot and lower track 132 in the bottom of an elongate channel, and the slot and lower track 132 individually or combined discloses a proximal channel opening on the bottom of the elongate channel (as well as a channel opening along the length of the elongate channel). In Shelton, the slot and the lower track 132 individually or in combination allows the vertical portion of the firing element to descend through the bottom of the elongate channel, and thus allows the firing element to be visible from the outside of the elongate channel. Accordingly, the slot and lower track individually and in combination "facilitate[s] viewing of the firing element therethrough when the firing element is in the starting position."

This is apparent from FIG. 7 of Shelton, which discloses a view from the top of the elongate channel. As shown there, the bottom of the E-beam firing element is viewable from the top of the channel through the slot. A POSITA would have

understood that the same would be true from the bottom perspective. Viewing the elongate channel from the bottom, a portion of the firing element disposed within the elongate channel would be visible, in addition to the portion below the bottom of the elongate channel (i.e., the foot), and thus the exposed widened slot 134 and lower track 132 provides further capability to view the firing element "therethrough." I Knodel, ¶¶136-137.

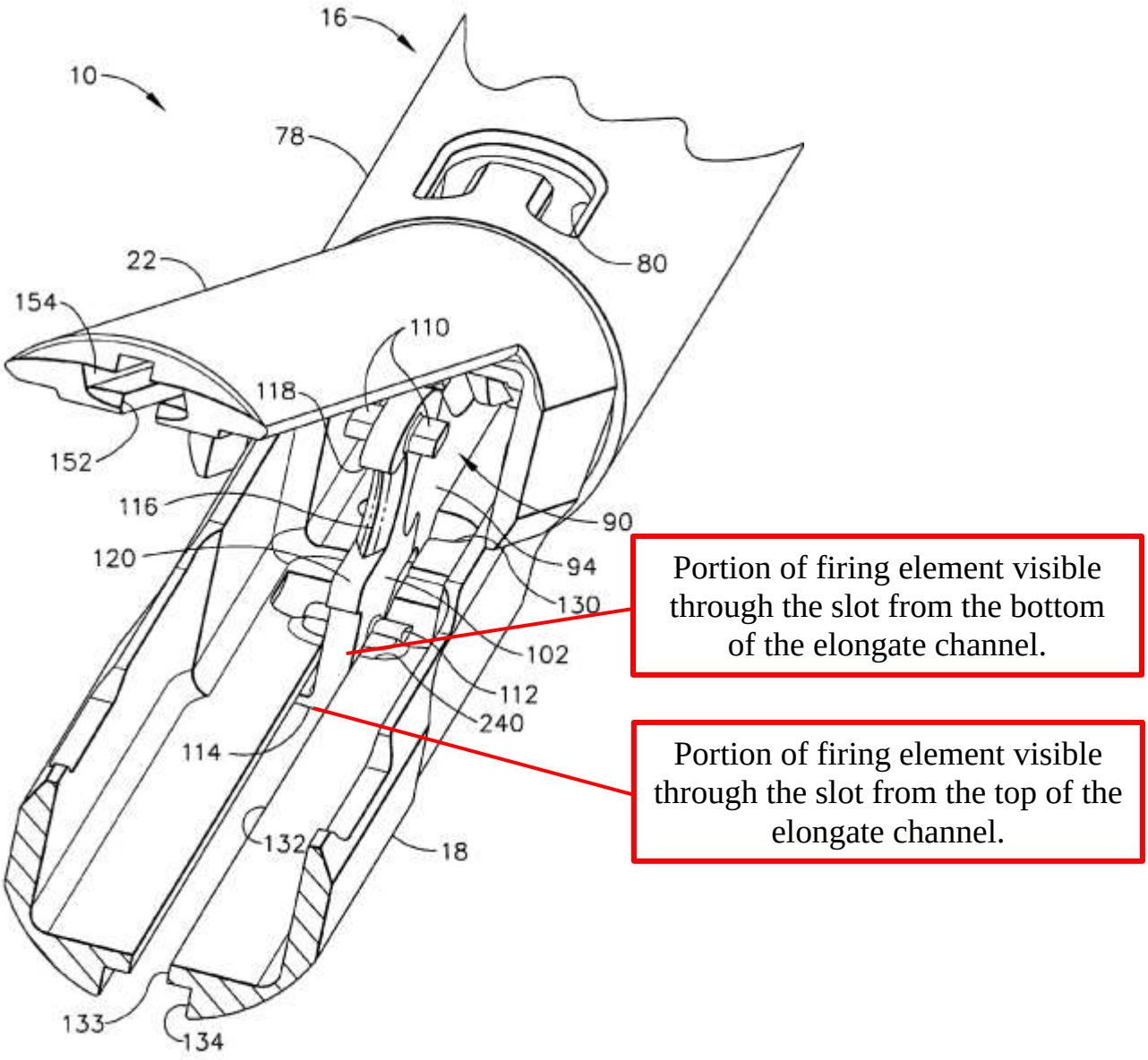

FIG. 7

1[d]: and a distal channel opening through the distal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the ending position, and wherein a portion of the bottom of the elongate channel extending between the proximal channel opening and the distal channel opening is closed and has no other openings therethrough.

Shelton in view of Green (and further in view of Zemlok's teaching of proximal and distal channel openings) discloses this limitation. Knodel, ¶¶138-143.

"*a distal channel opening through the distal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the ending position*"

For the same reasons as discussed with regard to the proximal channel opening of Ground 3, element 1[c], Shelton discloses a distal channel opening through the distal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough. Shelton discloses an exposed widened slot 134 and lower track 132 along the length of the bottom of the elongate channel, including along the distal end of the elongate channel. The slot and lower track facilitate viewing the firing element as previously discussed. When the firing element is in the ending position, it would be located at or adjacent to the distal end of the elongate channel, as shown in FIG. 12 of Shelton.

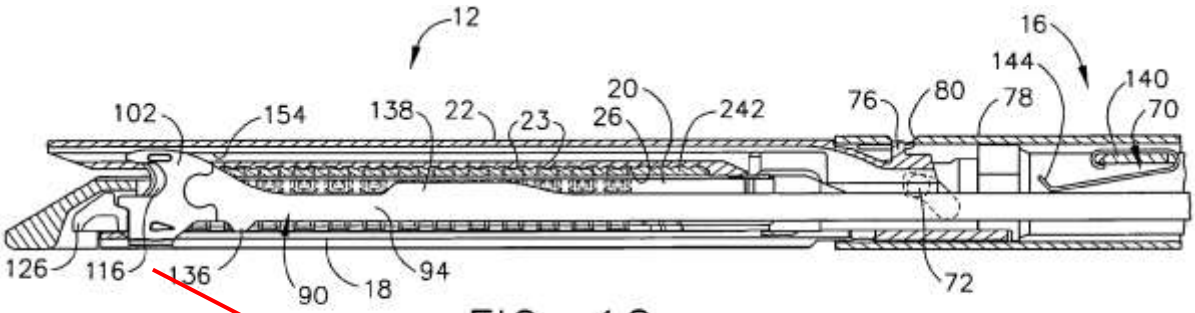

FIG. 12

"*wherein a portion of the bottom of the elongate channel extending between the proximal channel opening and the distal channel opening is closed and has no other openings therethrough*"

As discussed, in Shelton, a slot ("narrow slot 133" and "widened slot 134" of "lower track 132") runs along the length of the bottom of the elongate channel 18, and thus the "opening" runs from the proximal end to the distal end of the elongate channel. Shelton, 6:64-7:1. However, for the reasons discussed with regard to Ground 1, element 22[c] and Ground 2, element 22[d], it would have been obvious to enclose portions of the slot and lower track in view of the teachings of Green, while preserving the proximal and distal openings for viewing the progress of the firing element.

For example, a POSITA would have understood from Shelton that an important benefit of the Shelton slot and lower track is the ability to view the progress of the firing element. A POSITA would have understood from Green that enclosing at least a portion of the lower track provides the benefits of improved structural stability. Knodel, ¶¶138-140. Thus, a POSITA applying the teachings of Green to the instrument in Shelton would have been motivated to cover a large portion of the lower track 132 while leaving openings at least at the proximal end and possibly the distal end for viewing the firing element, and, of course, would

have had a reasonable expectation that the combination would succeed (given this is a simple mechanical modification). *Id.*

Moreover, as discussed with regard to Ground 2, element 22[d], it would have been obvious to a POSITA to provide at least proximal and distal openings for viewing the starting and ending progress of the firing element in view of the teachings of Zemlok (Knodel, ¶141):

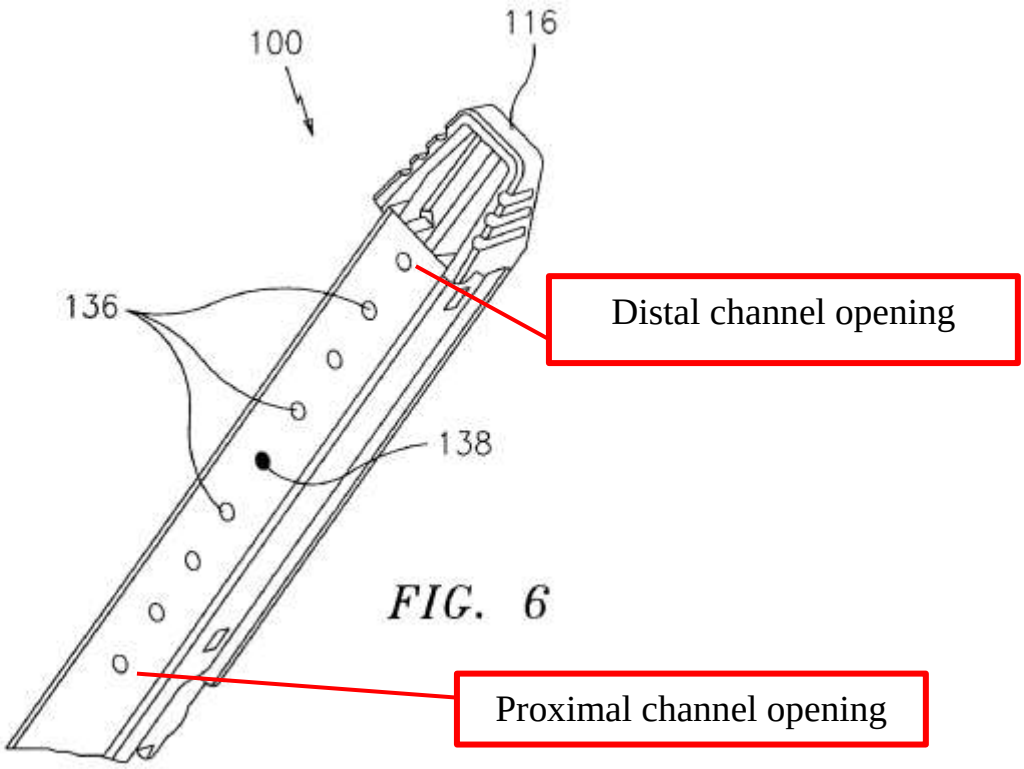

FIG. 6

Although Zemlok shows additional openings between the proximal and distal openings, there is no suggestion in Zemlok that such holes are mandatory or necessary. A POSITA had a limited number of predictable options in this regard: (1) no additional openings, or (2) some arrangement of one or more additional

openings. The selection of the number of openings is a simple matter of design choice and would be determined based on a balance of structural stability and ability to observe the firing element as it operates. Having openings at just the proximal and distal ends would suffice to identify when the firing element is at the proximal and distal ends of travel. If no further information is required, then no further openings need be provided, and the middle section of the lower track 132 may have a solid cover. Knodel, ¶¶142-143. *See In re Magna Elecs., Inc.*, 611 Fed. Appx. 969, 974 (Fed. Cir. 2015) (*citing In re Kuhle*, 526 F.2d 553, 555 (C.C.P.A. 1975) (finding a generic feature that "provides no novel or unexpected result" as "an obvious matter of design choice"); *Perfect Web Techs., Inc. v. InfoUSA, Inc*., 587 F.3d 1324, 1329 (Fed. Cir. 2009) (confirming that the obviousness analysis "may include recourse to logic, judgment, and common sense available to the person of ordinary skill"). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.,* 127 S. Ct. 1727, 1745-46 (2007). Moreover, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id*. at 1740.

In fact, Zemlok specifically discloses providing an indicator to allow observation of the "overall travel distance, proximal limit, and distal limit" of the firing element. Zemlok, ¶0029. Thus, a POSITA would have understood from this teaching that it would be sufficient to provide openings at the proximal and distal ends without the need for intermediate openings. Green would further suggest implementing the instrument in this way to improve the channel and firing element stability. Knodel, ¶143.

15: The surgical end effector of claim 1, wherein the firing element comprises a vertical portion including at least one laterally extending lower foot and wherein the elongate channel includes an internal passage for receiving the at least one laterally extending lower foot when the firing element moves between the starting position and ending position.

Shelton in view of Green and Zemlok discloses this claim. Knodel, ¶¶144-146.

"The surgical end effector of claim 1, wherein the firing element comprises a vertical portion including at least one laterally extending lower foot"

Shelton discloses this limitation. The "E-beam" of Shelton is a firing element that comprises a vertical portion and a laterally extending lower foot extending from the vertical portion. *See* Ground 1, element 22[b].

"and wherein the elongate channel includes an internal passage for receiving the at least one laterally extending lower foot when the firing element moves between the starting position and ending position."

Shelton in view of Green and Zemlok discloses this limitation. In the combination, the laterally extending lower foot travels in an internal passage and moves between the starting position (which is the same as the "first position" in claim 22) and the ending position. *See* Ground 1, element 22[c].

IX. CONCLUSION

Petitioner requests *Inter Partes* Review of the Challenged Claims pursuant to Grounds 1-3.

Respectfully submitted,

Dated May 9, 2019

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *inter partes* Review totals 9,829 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated May 9, 2019

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on May 9, 2019, a complete and entire copy of this Petition for I*nter Partes* Review 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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