IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Christopher J. Schall, et al.	
U.S. Patent No.:	7,490,749	Attorney Docket No.: 11030-0052IP1
Issue Date:	February 17, 2009	
Appl. Serial No.:	11/729,355	
Filing Date:	March 28, 2007	
Title:	SURGICAL STAPLING AND CUTTING INSTRUMENT WITH MANUALLY RETRACTABLE FIRING MEMBER	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 7,490,749 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Patent No. 7,490,749 to Schall, et al. ("'749 Patent")
IS1002	Excerpts from the Prosecution History of the '749 Patent ("the Prosecution History")[1]
IS1003	Declaration of Dr. Knodel, including Curriculum Vitae
IS1004	US Patent Publication No. 2006/0175375 ("Shelton II")
IS1005	US Patent Publication No. 2005/0178813 ("Swayze")
IS1006	US Patent No. 8,322,455 ("Shelton I")
IS1007	Complaint for Patent Infringement, *Ethicon LLC, et al. v. Intuitive Surgical, Inc., et al.*, Case No. 1:18-cv-01325 (D. Del. Aug. 27, 2018)
IS1008	How Design Teams Use DFM/A to Lower Costs and Speed Products to Market (1996) (retrieved from http://www.ame.org/sites/default/files/target_articles/96q1a2.pdf)
IS1009	Electronic Comparison of Written Description of Swayze (US 2005/0178813; Original) to Shelton II (US 2006/0175375; Underline/Strikethrough)
IS1010	U.S. Patent No. 5,941,442
IS1011	U.S. Patent No. 5,865,361
IS1012	Excerpts from McGraw-Hill Dictionary of Scientific and Technical Terms (6th Edition, 2003)

[1] Copies of foreign patent references removed.

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1 and 3 ("the Challenged Claims") of U.S. Patent No. 7,490,749 ("the '749 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.

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 '749 Patent. The '749 Patent is the subject of Civil Action No. 1:18-cv-01325, filed on August 27, 2018 in the District Court for the District of Delaware. And the following IPRs involve patents that belong to Patent Owner and have been asserted against Petitioner in the District of Delaware: *Intuitive Surgical, Inc. v. Ethicon LLC*, Case Nos. IPR2018-00933, -934, -935, -936, -938, -1247, -1703, -1248, and -1254.

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 IPR11030-0052IP1@fr.com (referencing No. 11030-0052IP1 and cc'ing PTABInbound@fr.com, katz@fr.com, griswold@fr.com, kdarby@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 '749 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 and 3 of the '749 Patent on the grounds listed below. A declaration from Dr. Knodel (IS1003) is included in support.

Ground	Claims	Basis
Ground 1	1, 3	Anticipated and/or Obvious by Shelton II (IS1004)
Ground 2	1, 3	Anticipated and/or Obvious by Swayze (IS1005)
Ground 3	1, 3	Anticipated by Shelton I (IS1006)

Shelton II (US 2006/0175375) was published August 10, 2006. Shelton II lists entirely different inventors than the '749 Patent, and was published before the '749 Patent's earliest effective filing date (March 28, 2007). Shelton II, therefore, is prior art under pre-AIA 35 U.S.C. §§ 102(a) and 102(e).

Swayze (US 2005/0178813) was published August 18, 2005, more than a year before the '749 Patent's earliest effective filing date. Swayze, therefore, is prior art under pre-AIA 35 U.S.C. § 102(b).

Shelton I (US 8,322,455) was filed June 27, 2006 and issued December 4, 2012. Shelton I lists entirely different inventors than the '749 Patent, and Shelton I's filing date antedates the '749 Patent's earliest effective filing date. Shelton I,

therefore, is prior art under pre-AIA 35 U.S.C. § 102(e).

IV. OVERVIEW OF THE '749 PATENT

The '749 Patent describes endoscopic surgical instruments—surgical staplers "capable of applying lines of staples to tissue while cutting the tissue between those staple lines," in particular. '749 Patent, 18-25. And the '749 Patent focused on such an instrument "with a manually actuatable retraction mechanism" and "[without] an additional retraction means." '749 Patent, 2:66-3:4. The '749 Patent removed the commonly used retraction springs that tend to "increase[] the amount of firing forces that must be generated to overcome the spring force and fire the end effector components." '749 Patent, 2:34-65. As shown below, however, a manual retraction mechanism lacking a retraction spring was already known.

V. PROSECUTION OF THE '749 PATENT

Prosecution leading to the '749 Patent was short. A first Office Action raising a restriction requirement was mailed on June 16, 2008 (IS1002, 105-110), and a Notice of Allowance issued less than four months later on October 1, 2008 (IS1002, 13-18). While the '749 Patent lists hundreds of applicant-submitted prior art references, the examiner made no prior art rejections. *See* IS1002, 52-56, 105-110.

The examiner's articulated rationale for allowing the '749 Patent does not support the allowed claims. For example, the examiner's statement emphasizes elements that are not the independent claims (*e.g.*, "retraction member," "firing mechanism," "driving mechanism"). IS1002, 55. The examiner's statement also refers to unidentified "closest prior art" that describes "retraction mechanisms which manually move the firing mechanisms in both directions proximally and distally." *Id.* But the examiner did not explain how such a teaching is distinguishable from the '749 Patent's claims. And, more importantly, the examiner's finding that this teaching is "the closest prior art" suggests other more pertinent references—such as Shelton II, Swayze, and Shelton I that have a different retraction mechansim—were overlooked.

VI. RELATION TO *EX PARTE* PROSECUTION

While Shelton II, Swayze, and Shelton I were among hundreds of references

before the examiner, the prosecution record reflects the examiner did not fully appreciate the teachings of these references. For example, in the thousands of pages of applicant-submitted prior art[2], the examiner missed Shelton II's express statement that its manual retraction assembly "could be utilized without the assistance of a retraction spring," which would yield the '749 Patent's "sole retraction motion" feature identified in the examiner's reasons for allowance. *See* Shelton II, ¶0154; IS1002, 55; analysis *infra* at Ground 1, Element 1[d]. The examiner also lacked the benefit of Patent Owner's broad infringement allegations against Petitioner, in which Patent Owner contends the "sole retraction motion" feature is met when a primary retraction mechanism malfunctions, leaving only a backup manual retraction mechanism. *See* IS1007, 14 (alleging infringement against a "Manual Release Knob" used when there is "[a] lack of power or a non-recoverable fault"). Under these allegations, the "sole retraction motion" is likewise met by the disclosures in Shelton II and Swayze of manual retraction assemblies that serve as a redundancy to an automatic retraction spring that "may become disconnected." Shelton II, ¶0144, Swayze, ¶0155; *see also* analysis *infra*

[2] IS1002, 35-40, 82-90, 115-116, 121-123, 134-135.

at Ground 1, Element 1[d][3].

It is not surprising that the full teachings of Shelton I, Swayze, and Shelton II were overlooked. Not only was the examiner burdened by hundreds of references submitted by the applicant, but each of the invalidating references used here are voluminous. For example, Shelton II is 61-pages within which the examiner could have easily overlooked the critical teaching that the manual retraction assembly "could be utilized without assistance of a retraction spring" (¶0154).

The examiner also could not have known how Patent Owner would later characterize its claims in fashioning an overly broad infringement theory that requires a malfunctioning primary mechanism to be ignored when assessing whether the backup manual mechanism causes the "sole" retraction motion. IS1007, 14-15. Critically, this teaching is disclosed by both Shelton II and Swayze (also a 61-page reference), which state that the automatic retraction spring "may become disconnected," thus requiring use of the manual backup retraction mechanism. Shelton II, ¶0144, Swayze, ¶0155. For at least these reasons, despite

[3] These arguments are based solely on Patent Owner's infringement allegations and their implicit claim constructions, with which Petitioner does not concede subjective agreement.

the wealth of references listed on the face of the patent, the issued claims of the '749 Patent have yet to be fully tested against the prior art.

Accordingly, there is no basis for a determination under 35 U.S.C. § 325(d) that substantially similar prior art and/or arguments have already been presented to the Office. *Cf. Becton, Dickinson and Company v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-28 (PTAB Dec. 15, 2017 (informative)).

VII. THE '749 PATENT'S SURGICAL INSTRUMENT

The '749 Patent's Figure 1 (annotated below) illustrates a surgical stapling and severing instrument 10 featuring a handle assembly 20 having a pistol grip 36 and supporting an end effector 12 controlled through user actuation of a closure trigger 26 and a firing trigger 34. *See generally* '749 Patent, 5:34-6:35.

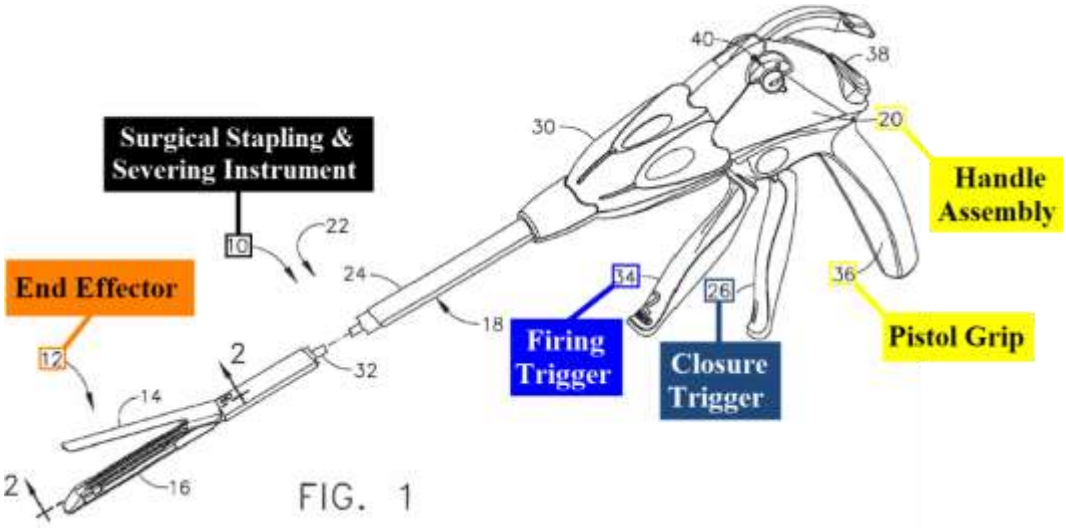


FIG. 1

End effector 12 features a pivoting anvil 14 and an elongate channel 16 housing a staple cartridge 82. '749 Patent, 7:42-8:18, Figure 2 (annotated below), 3-6. Staples 92 are "fired" from cartridge 82 by pushing an E-beam 80 through elongate channel 16 in the distal direction from a retracted position (Figure 5, below) to a fired position (Figure 6, below). *Id.*

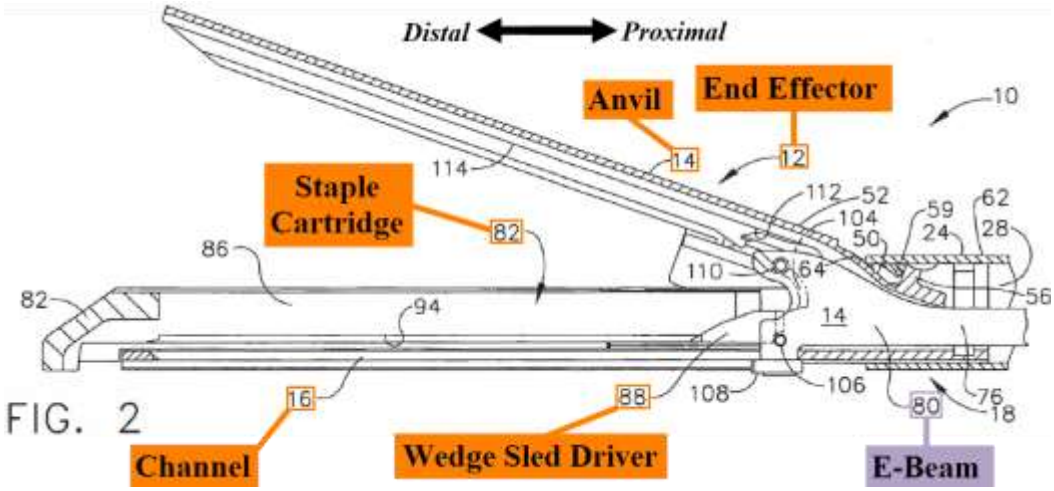


FIG. 2

This firing motion causes E-beam 80 to push a wedge sled driver 88 through staple cartridge 82, which sequentially actuates drivers 90 that forcibly eject (or "fire") staples 92 upward into the closed anvil 14. *Id.*

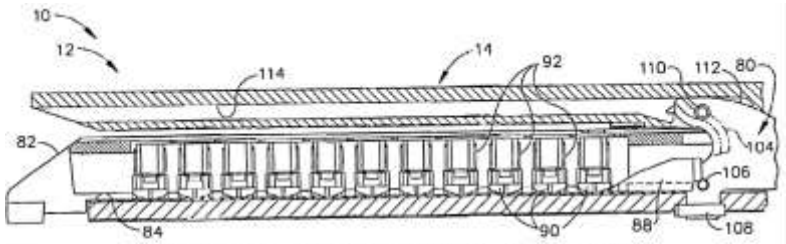
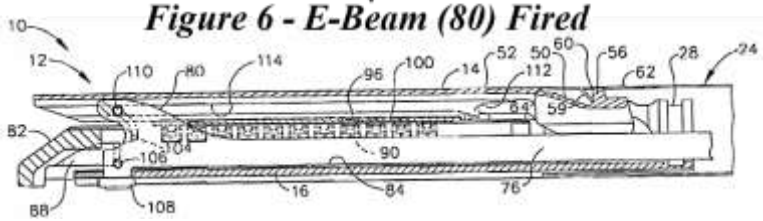


Figure 5 - E-Beam (80) Retracted

Figure 6 - E-Beam (80) Fired



To move anvil 14 from an open position (Figure 2) to a closed position (Figure 5), the user pulls closure trigger 26 inward toward pistol grip 36 to operate a "longitudinally reciprocating" closure tube 24. '749 Patent, 9:10-14; *see also id.*, 5:60-62, Figures 1, 4, 8.

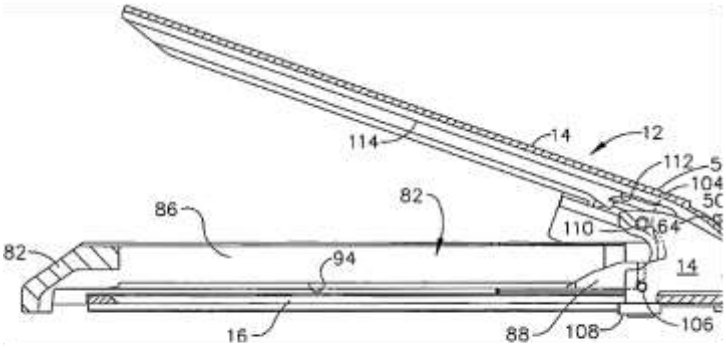
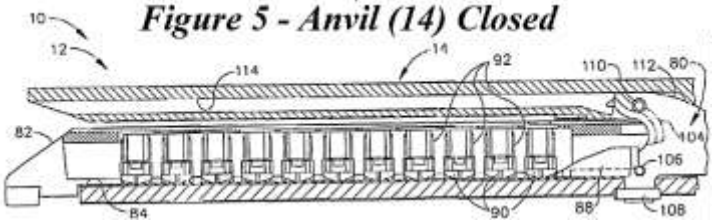


Figure 2 - Anvil (14) Open

Figure 5 - Anvil (14) Closed



As the user pulls closure trigger 26, the trigger's upper portion 160 pushes a closure yoke 162 in the distal direction (*i.e.*, away from pistol grip 36). '749 Patent, 9:28-40, Figures 7-8. A closure link 164 is pivotally attached to upper portion 160 and closure yoke 162, such that rotational movement of upper portion 160 is converted to longitudinal movement of closure yoke 162. *Id.*

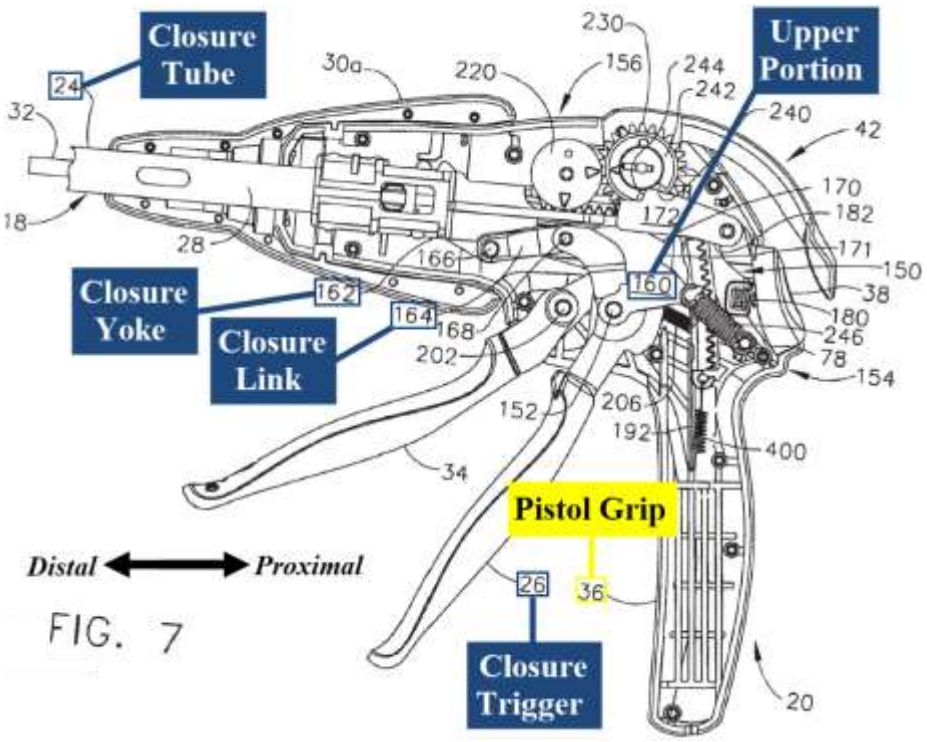


FIG. 7

Closure yoke 162 then forces closure tube 24 to move longitudinally in the distal direction (*see id*.), moving pivot pins 54 of anvil 14 distally through kidney shaped openings 58 of elongate channel 16, which causes anvil 14 to rotate downward from the open position to the closed position. '749 Patent, 7:2-23, Figure 4.

Once released (by pressing a closure release button 38), a tension spring 246 draws closure trigger 26 through a recovery stroke to its starting position. '749 Patent, 9:35-10:4, Figures 7-8. This causes the trigger's upper portion 160 to pull closure yoke 162, and therefore closure tube 24, in the proximal direction (*i.e*., towards pistol grip 36), moving pivot pins 54 proximally through kidney shaped openings 58 and rotates anvil 14 upward to the open position. '749 Patent, 7:2-23, 9:28-35, Figures 4, 7-8.

With anvil 14 closed to clamp the patient's tissue, staples 92 are fired from staple cartridge 82 into anvil 14 by manual actuation of firing trigger 34. *See generally* '749 Patent, 7:42-8:18, 10:4-12:7, Figures 1-6, 8, 10, 11. The user actuates firing trigger 34 by pulling it towards pistol grip 36. '749 Patent, 6:8-35. Rotation of firing trigger 34 towards pistol grip 36 causes the upper portion 204 of firing trigger 34 to engage the links 196a-d of a linked rack 200 through a side pawl mechanism 210. '749 Patent, 10:19-28; *see also id*., 11:4-8, 11:25-12:7, Figures 8, 10-11.

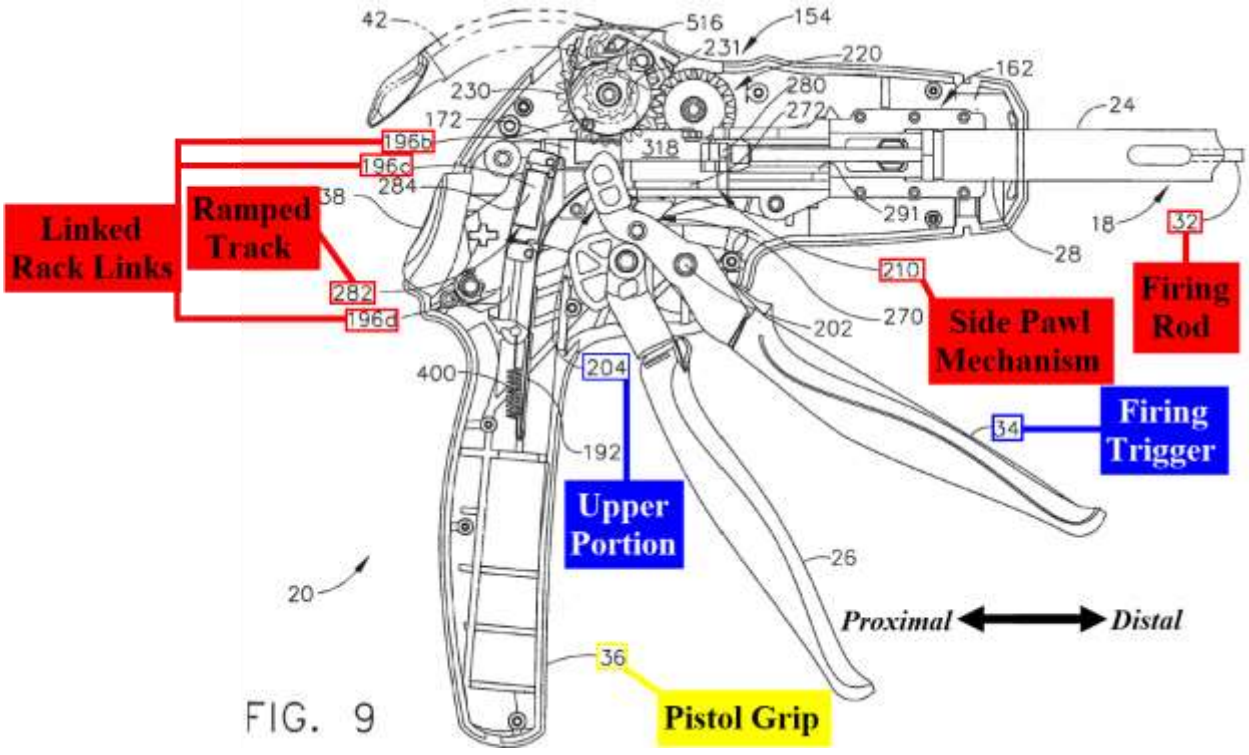


FIG. 9

More specifically, as the user pulls firing trigger 34, side pawl mechanism 210 engages the ramped track 282 of an adjacent link 196a-d to longitudinally advance linked rack 200 in the firing (distal) direction. *Id*. When firing trigger 34 is pulled

by the user through a full firing stroke, side pawl mechanism 210 disengages (or "kicks out") from linked rack 200 during the spring-biased return stroke of firing trigger 34. *Id*.

The distal end of linked rack 200's front link 196a is connected to the proximal end of a firing rod 32 that communicates longitudinal movement from linked rack 200 to E-beam 80 through a series of components housed by a frame 28 mounted within closure tube 24. '749 Patent, 11:8-10. As the '749 Patent explains, firing rod 32 engages a firing trough member 66, and firing trough member 66 is attached to a firing bar 76 having an E-beam 80 extending from its distal end. '749 Patent, 7:24-42, Figure 4.

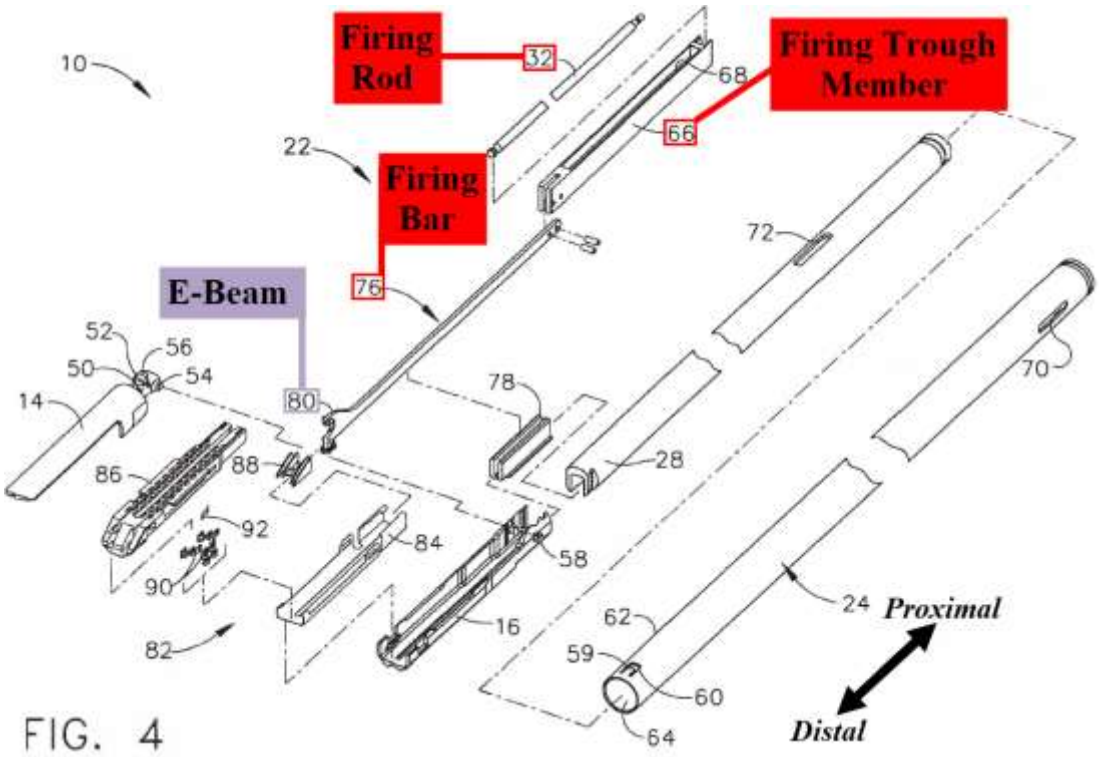


FIG. 4

The claimed "sole retraction motion" (Element 1[d]) that retracts E-beam 80 (via firing bar 32) from a fired position within end effector 12 to a retracted position is generated by the user manually depressing a retraction lever 42. IS1003, ¶37. Depressing retraction lever 42 causes a locking pawl 516, which is biased by an L-shaped spring tab 522, to drivingly engage the teeth of a small ratchet gear 231 projecting into a hub 506 of lever 42. '749 Patent, 12:55-13:6, Figures 7-17; *see also id.*, 12:9-56.

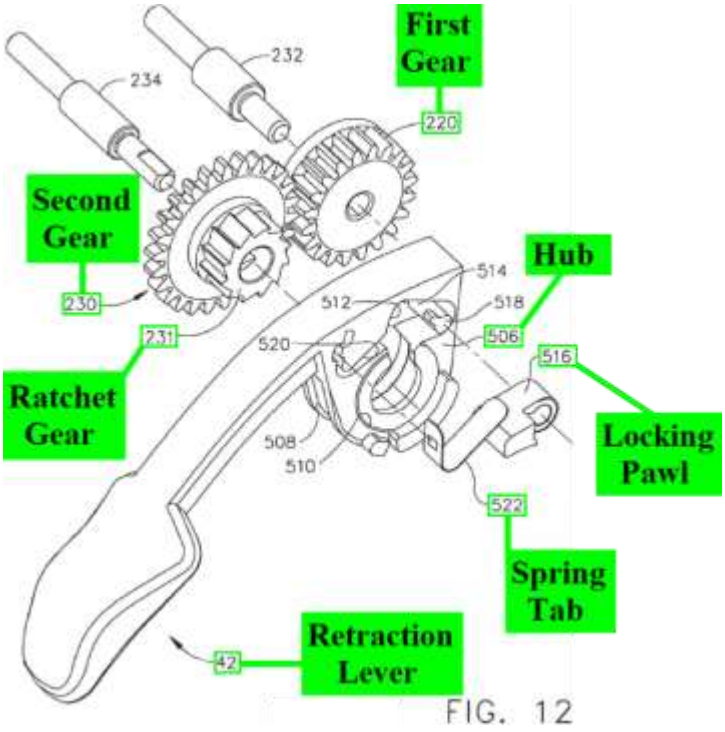


FIG. 12

This drives (counterclockwise[4]) a larger second gear 230 connected to ratchet gear 231, which, in turn, drives (clockwise) a first gear 220 meshed to a toothed surface

[4] Clockwise/counterclockwise directionality is with specific reference to Figure 12.

222 of linked rack 200. *Id* (Figures 16-17 are illustrative). The meshing engagement between first gear 220 and toothed surface 222, causes linked rack 200, and therefore firing bar 32, to be drawn in the longitudinal (proximal) retraction direction. *Id*.

Retracting E-Beam 80 from a fired position to a retracted position may require multiple actuations of retraction lever 42. *Id*. Accordingly, a recovery spring 525 is provided to urge the depressed retraction lever 42 back upwards towards its starting position, with pawl 516 disengaging from the teeth of ratchet gear 231 during this motion, permitting the retraction lever 42 to be actuated again. *Id*.

VIII. CLAIM CONSTRUCTION

Terms of the Challenged Claims should generally be given their plain and ordinary meaning consistent with the '749 Patent's specification, which we have done here, unless otherwise noted. For example, as discussed below, four terms at issue in this proceeding require a 112(6) construction.

A. Firing Member

The term "member" is a nonce term and the purely functional nature of the modifier "firing" would not have connoted structure to a POSITA. IS1003, ¶40 (explaining that the term "member" and its generic dictionary definition[5] has no clear meaning to a POSITA for a specific type of structure). The surrounding claim language also fails to suggest structure. *Id*. As such, the negative presumption against 112(6) treatment under *Williamson v. Citrix Online*, LLC, 792 F.3d 1339 (Fed. Cir. 2015) is overcome.

The claimed functions performed by the "member" are "firing" and "mov[ing] from a retracted position to a fired position in response to a longitudinal firing motion applied thereto," which require no further construction. As to these functions, the '749 Patent explains (*see* Section VII, *supra*) that E-beam 80 is moved longitudinally from a retracted position to a fired position by a firing rod 32 coupled to a linked rack 200 driven by manual actuation of a firing trigger 34. *See generally* '749 Patent, 7:42-8:18, 10:4-12:7, Figures 1-6, 8, 10, 11. As E-beam 80 performs the claimed "mov[ing]" function, it also performs the "firing" function by pushing a wedge sled driver 88 that causes drivers 90 in a staple cartridge 82 to

[5] The term "member" is defined as "[a] structural unit" or "an individual object that belongs to a set." IS1012, 7.

eject staples 92 and form them against clamped anvil 14. '749 Patent, 7:42-8:18. The corresponding "firing member" structure therefore includes E-beam 80. IS1003, ¶¶41-42.

Notably, the '749 Patent's E-beam 80 is a three-pin design featuring an upper pin 110, a middle pin 106, and a lower pin 108. '749 Patent, 7:59-8:18, Figures 2 (below), 5-6. Middle pin 106 drives the staple cartridge 82's wedge sled driver 88 to effectuate firing of staples 92. *Id*. Bottom pin 108 engages and slides along a bottom surface of end effector channel 16. *Id*. And top pin translates through a slot 114 of anvil 14, so as to maintain spacing between anvil 14 from end effector channel 16 during the stapling/severing process. *Id*.

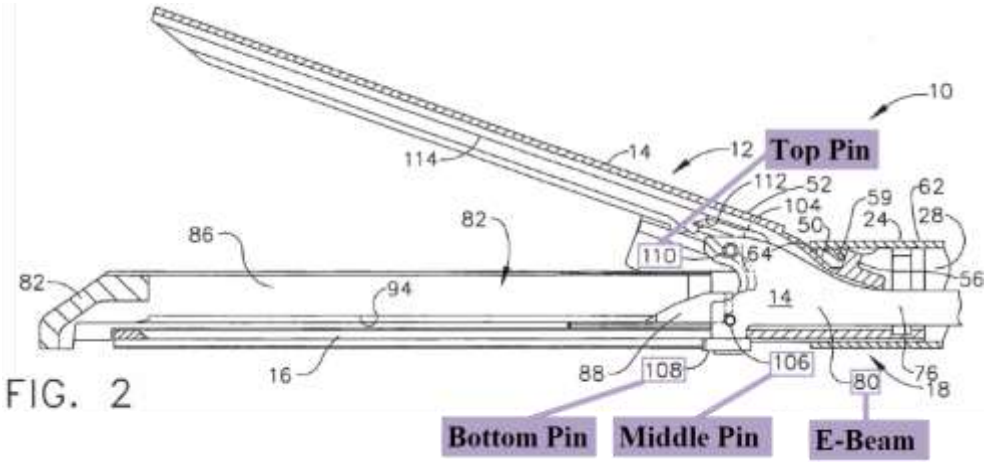


FIG. 2

B. Retraction Assembly

The term "assembly" is a nonce term and the purely functional nature of the modifier "retraction" would not have connoted structure to a POSITA. IS1003, ¶43 (explaining that the term "assembly" and its generic dictionary definition[6] has no clear meaning to a POSITA for a specific type of structure). The surrounding claim language also fails to suggest structure. *Id*. As such, the negative presumption against 112(6) treatment under *Williamson* is overcome.

The claimed functions performed by the "assembly" are "retract[ing]" and "interfacing with said firing drive such that manual actuation of said retraction assembly causes said firing drive to generate a sole retraction motion which is communicated to said firing member to cause said firing member to move from said fired position to said retracted position," which require no further construction. As to these retraction functions, the '749 Patent explains (*see* Section VII, *supra*) that manually actuating retraction lever 42 drives a gear train via a locking pawl 516 biased by a spring tab 522 residing in a hub 506 of retraction lever 42. *See generally* '749 Patent, 12:9-13:6, Figures 7-17. The gear train includes ratchet gear 231, second gear 230, and first gear 220. *Id*. First gear

[6] The term "assembly" is defined as "[a] unit containing the component parts of a mechanism, machine, or similar device." IS1012, 3.

220 meshes with a toothed surface 222 of linked rack 200 to progressively urge linked rack 200—and therefore firing rod 32 and E-beam 80, which are both drivingly coupled to linked rack 200—in the longitudinal (proximal) retraction direction. *Id.*

The corresponding "retraction assembly" structure (identified above) therefore includes a first gear 220 meshed to a toothed surface 222 of linked rack 200, a second gear 230 meshed to first gear 220 that includes a ratchet gear 231, a spring-biased, multi-stroke retraction lever 42 including a hub 506 into which ratchet gear 231 extends, and a locking pawl 516 mounted within hub 516 and biased by an L-shaped spring tab 522 against ratchet gear 231. IS1003, ¶¶44-45.

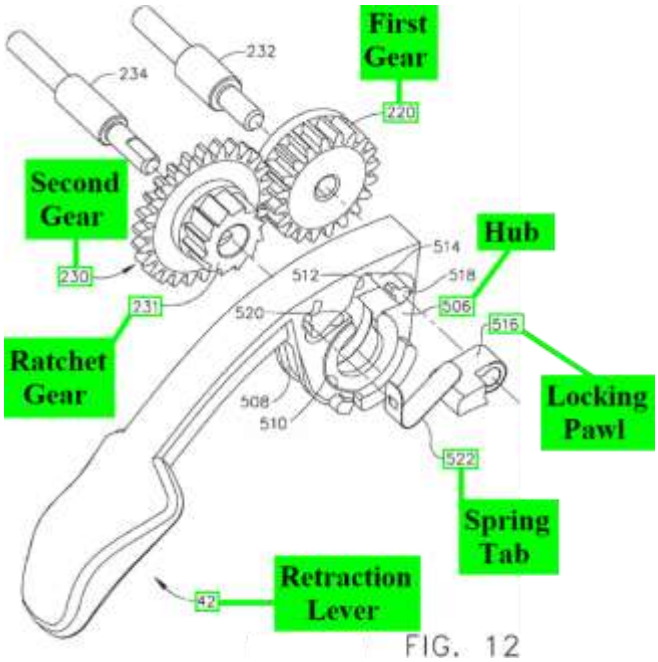


FIG. 12

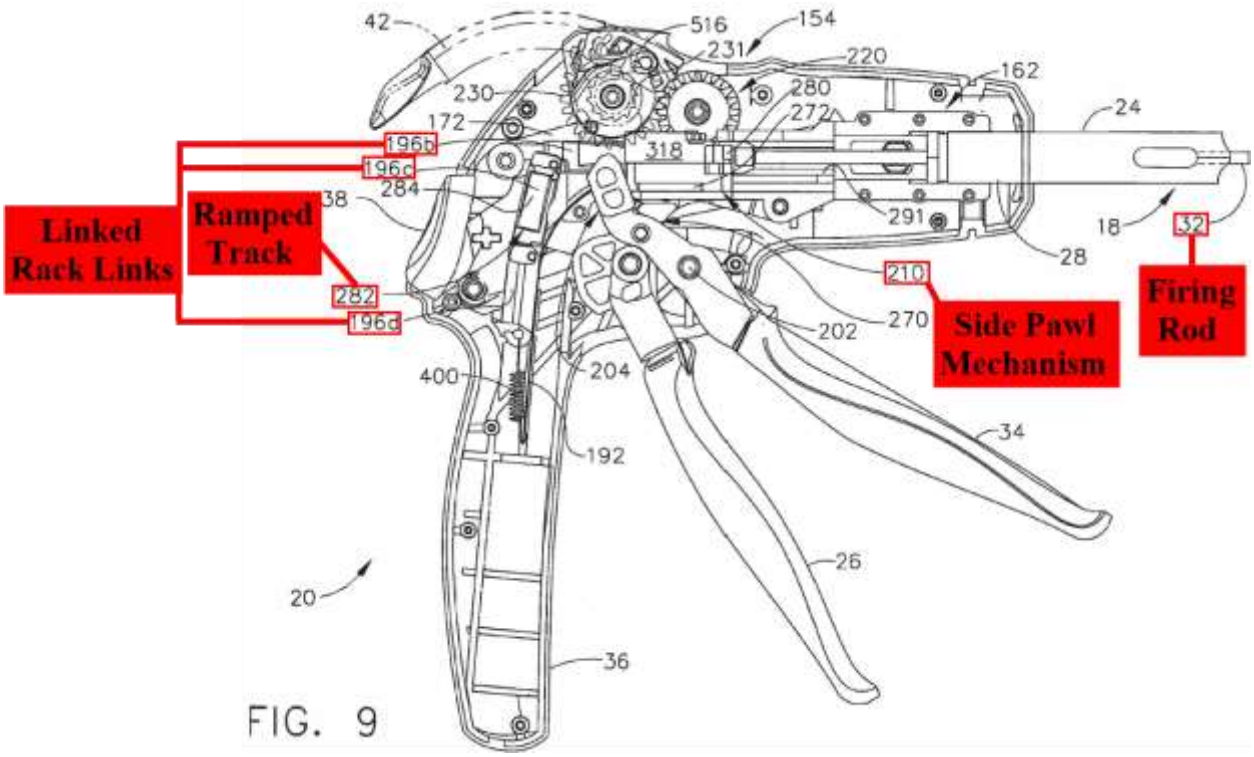
C. Firing Drive

The term "drive" is a nonce term and the purely functional nature of the modifier "firing" would not have connoted structure to a POSITA. IS1003, ¶46 (explaining that the term "drive" and its generic dictionary definition[7] has no clear meaning to a POSITA for a specific type of structure). The surrounding claim language also fails to suggest structure. *Id*. As such, the negative presumption against 112(6) treatment under *Williamson* is overcome.

The claimed functions performed by the "drive" are "firing" and "selectively generat[ing] said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly," which require no further construction. As to these functions, the '749 Patent explains (*see* Section VII, *supra*) that manually actuating firing trigger 34 causes an upper portion 204 of firing trigger 34 to engage the links 196a-d of a linked rack 200 through a kick-out side pawl mechanism 210 that interfaces with a ramped track 282 presented on one side of each link 196a-d. '749 Patent, 6:8-35, 10:19-28; *see also id*., 11:4-10, 11:25-12:7, Figures 8, 10-11. The distal end of the front link 196a is connected to the proximal

[7] The term "drive" in noun form is defined as "[t]he means by which a machine is given motion or power . . ., or by which power is transferred from one part of a machine to another." IS1012, p. 5.

end of a firing rod 32 that communicates longitudinal movement from linked rack 200 to E-beam 80 through a series of components housed by a frame 28 mounted within closure tube 24. '749 Patent, 11:8-10; *see also* 7:24-42, Figure 4.



The corresponding "firing drive" structure (identified above) therefore includes a linked rack 200 including links 196a-d having a ramped track 282, a firing rod 32 attached to linked rack 200, and a side pawl mechanism 210 coupled to a firing trigger 34. IS1003, ¶¶47-48.

D. Closure Drive

The term "drive" is a nonce term and the purely functional nature of the modifier "closure" would not have connoted structure to a POSITA. IS1003, ¶49 (explaining that the term "drive" and its generic dictionary definition has no clear meaning to a POSITA for a specific type of structure). The surrounding claim language also fails to suggest structure. *Id*. As such, the negative presumption against 112(6) treatment under *Williamson* is overcome.

The claimed functions performed by the "drive" are "clos[ing]" and "generat[ing] a closing motion and an opening motion," which require no further construction. As to these functions, the '749 Patent explains (*see* Section VII, *supra*) that manually actuating closure trigger 26 causes its upper portion 160 to push or pull a closure yoke 162 via a pivotally mounted closure link 164. '749 Patent, 9:10-14, 9:28-40, Figures 7-8. Movement of closure yoke 162 causes a closure tube 24 to move longitudinally in the distal or proximal direction, which closes or opens anvil 14. '749 Patent, 5:60-62, 7:2-23, 9:10-14, 9:28-40, Figures 1, 4, 7-8.

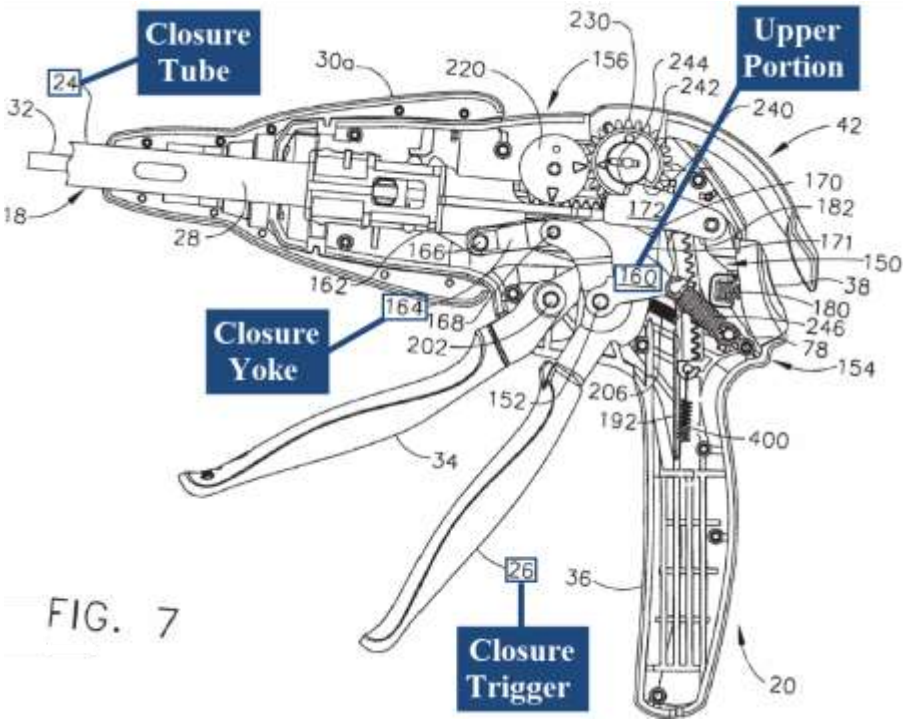


FIG. 7

The corresponding "closure drive" structure (identified above) therefore includes a closure trigger 26 having an upper portion 160 coupled to a closure yoke 162 through a closure link 164 (referred to collectively as closure drive 23). IS1003, ¶¶50-51.

IX. 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. IS1003, ¶25.

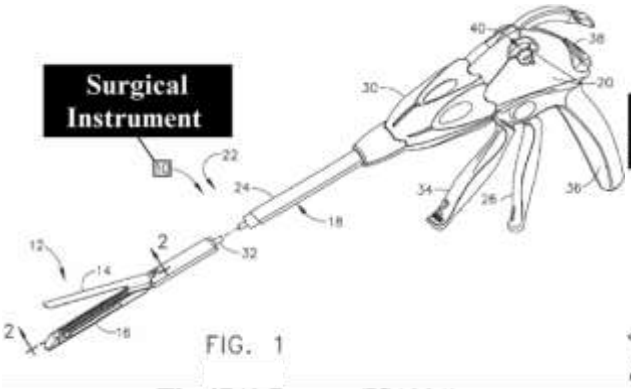
X. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. [GROUND 1]—Shelton II Anticipates and/or Renders Obvious the Challenged Claims Under Both 112(6) and Non-112(6) Interpretations

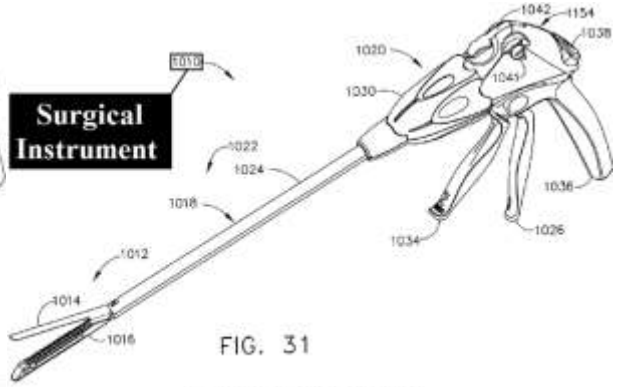
Overview of Shelton II

The disclosures of Shelton II and the ’749 Patent are very similar. See generally IS1003, ¶¶53-54. The similarities will be discussed in detail in the element-by-element analysis of the claims that follows this overview. Starting with the ’749 Patent, as discussed (*see* Section VII, *supra*), its surgical stapling and severing instrument features a pistol-grip handle assembly supporting an end effector at a distal end of an elongate shaft assembly, in addition to respective closure and firing drives for operating the end effector by manually actuating corresponding closure and firing triggers. *See generally* ’749 Patent, 5:34-6:35, 9:27-13:25. Shelton II describes the same arrangement, as demonstrated by the following side-by-side comparison of figures. *See generally* Shelton II, ¶¶0125-0132, 0135-0141.

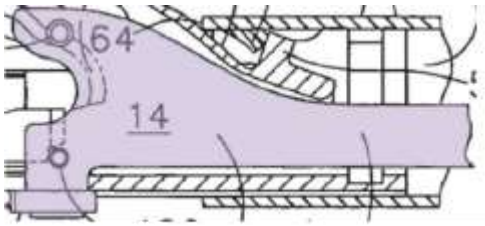
* * *



The '749 Patent (IS1001)

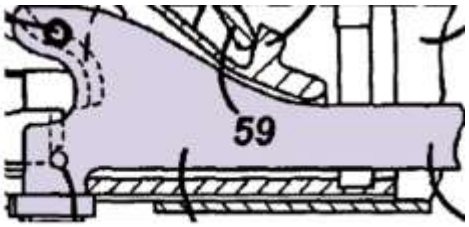


Shelton II (IS1005)

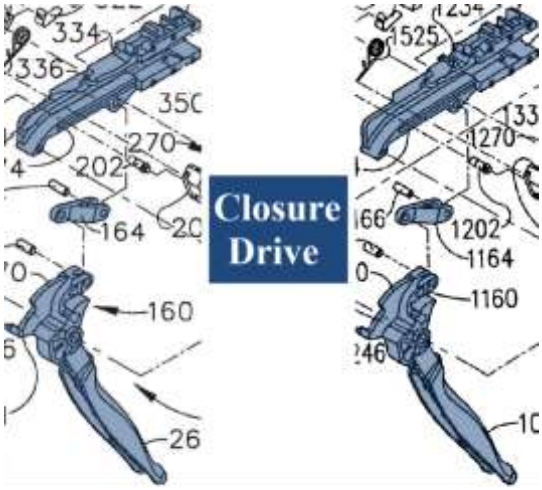


'749 Patent (IS1001)

Firing Member

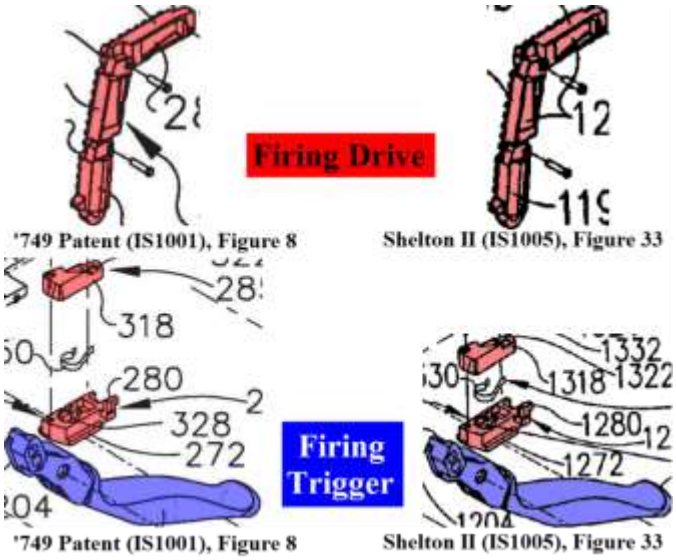


Shelton II (IS1005)



'749 Patent (IS1001) Figure 8

Shelton II (IS1005) Figure 33



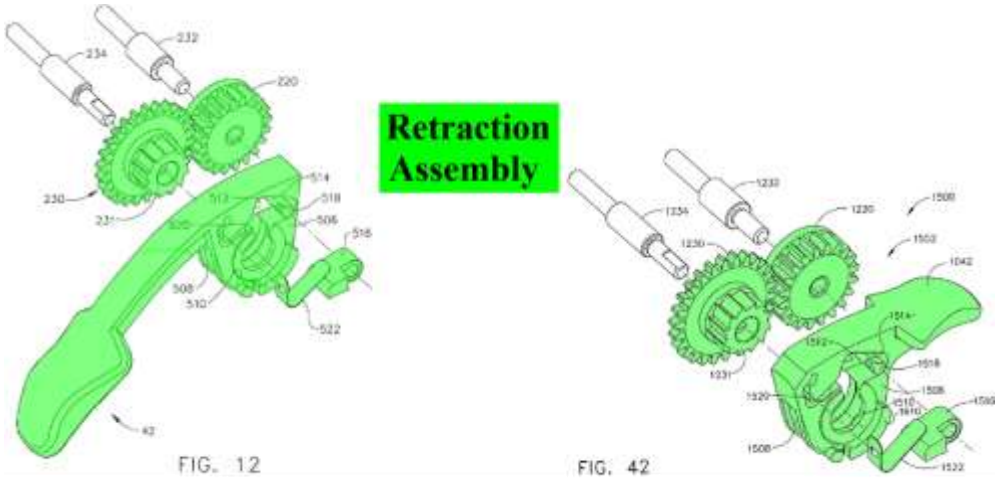
'749 Patent (IS1001), Figure 8

Shelton II (IS1005), Figure 33

* * *

As discussed (*see* Section VII, *supra*), the ’749 Patent further describes a manually-actuated retraction assembly that interfaces with the firing drive to retract a firing member from its fired position within the end effector to a retracted

position. ’749 Patent, 12:9-13:6. Shelton II describes such a retraction assembly as well, as demonstrated by the following comparison. Shelton II, ¶¶0141-0144.



'749 Patent (IS1001) **Shelton II (IS1005)**

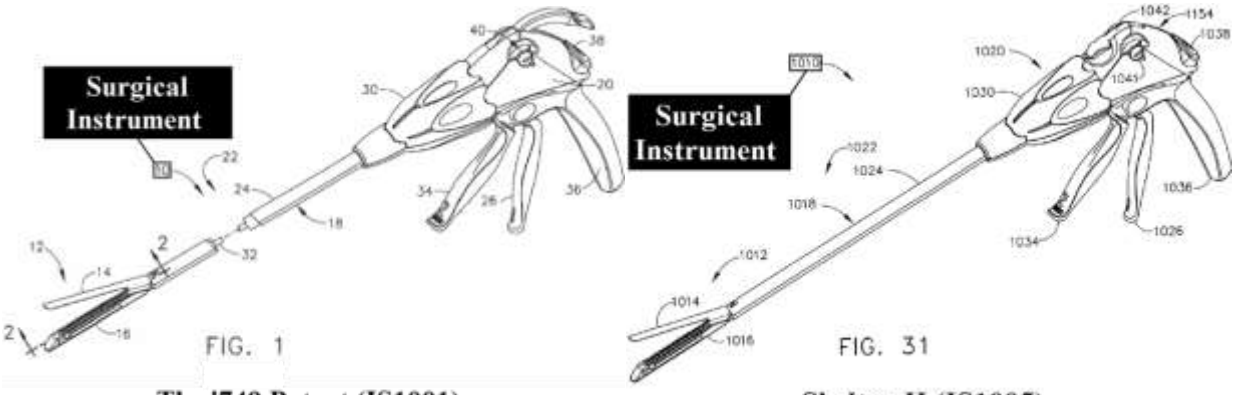
Shelton II also describes an automatic retraction spring and an anti-backup mechanism that prevents premature activation of the retraction spring. Shelton II, ¶¶0131-0134; IS1003, ¶55. In the preferred embodiments of Shelton II’s surgical instrument, the automatic retraction spring serves as the primary manner of retracting the firing member, with the manually-actuated retraction assembly serving as a redundancy for when the retraction spring malfunctions. Shelton II, ¶0144.

Thus, the preferred embodiment of Shelton II differs from the ’749 Patent’s claimed embodiment in that the ’749 Patent’s claimed embodiment eliminates the retraction spring, and recites that the retraction assembly “causes said firing drive to generate a sole retraction motion” (thus, without any springs or force generators). ’749 Patent, 16:14-28; IS1003, ¶56. However, manual retraction

without the need for a spring was not new, and was, in fact, already disclosed by Shelton II. Shelton II's manual retraction assembly causes its firing drive to generate a retraction motion "without the assistance of a retraction spring." Shelton II, ¶0154; *see also id*., ¶¶0014, 0051, 0144; IS1003, ¶¶57-62. And, in any event, a version of Shelton II's surgical instrument that eliminated the retraction spring and relied solely upon the manual retraction assembly—as disclosed and claimed by the '749 Patent—would have been obvious to a POSITA. IS1003, ¶¶64-69.

1[pre]: "A surgical instrument, comprising:"

Whether the preamble is a limitation, Shelton II discloses it. IS1003, ¶90. Shelton II discloses a surgical instrument (surgical stapling and severing instrument 1010) (below, left). *Id*.; Shelton II, ¶0125, Figure 31.



The '749 Patent (IS1001) **Shelton II (IS1005)**

1[a]: "a handle assembly;"

Shelton II discloses Element 1[a]. IS1003, ¶91. Shelton II discloses a handle assembly (handle assembly 1020) (below). *Id*.; Shelton II, ¶¶0125-0126,

Figures 31-37. Shelton II's disclosure corresponds to the '749 Patent's handle assembly 20. *Id*.; '749 Patent, 5:34-6:11, Figures 1, 7-9, 11.

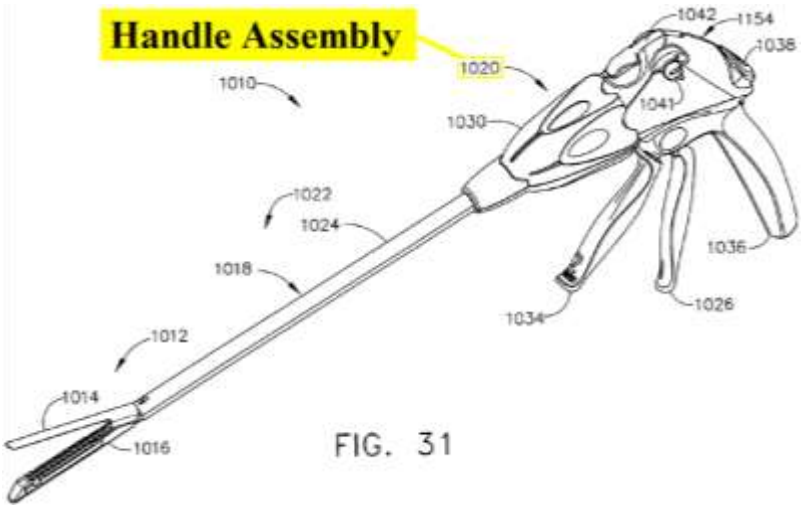
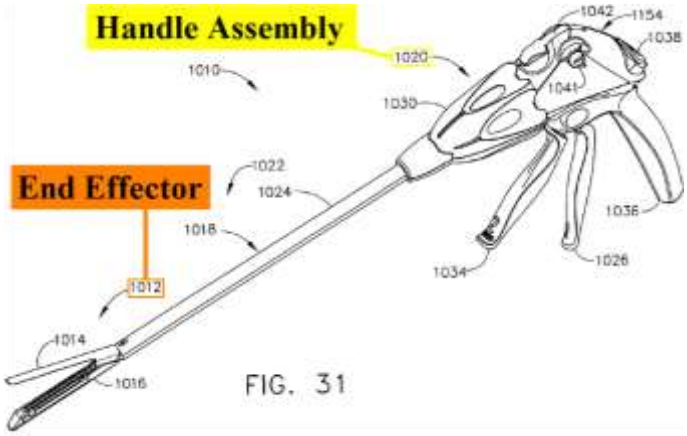


FIG. 31

1[b]: "an end effector for performing a surgical operation, said end effector operably coupled to said handle assembly and"

Shelton II discloses Element [1.b]. IS1003, ¶¶92-94. Shelton II discloses an end effector (end effector 1012, referred to interchangeably as a "staple applying apparatus") (below). *Id*.; Shelton II, ¶¶0002, 0125 (explaining that "advantageous features described above are maintained for an end effector," *e.g.*, at ¶¶0076-0082), Figures 2-6, 31. Shelton II explains that its end effector 1012 is manipulated and operated (through closure and firing triggers 1026/1034) by the handle assembly 1020. Shelton II, ¶¶0125-0126, Figures 31-33.



Shelton II's end effector 1012 is "operably coupled" (as claimed) to handle 1020. *Id.*, IS1003, ¶94.

1[b.i]: "[the end effector] operably supporting a firing member that is movable from a retracted position to a fired position in response to a longitudinal firing motion applied thereto;"

Shelton II discloses Element 1[b.i] under both 112(6) and non-112(6) interpretations. IS1003, ¶¶95-98. For example, Shelton II describes an E-beam 80, which is structurally the same as, or at least equivalent to, the '749 Patent's E-beam 80, the corresponding structure mapped to the claimed "firing member" under 112(6) *supra* at Section VIII. *Id.*

Just like the '749 Patent, Shelton II describes that E-beam 80 moves through the staple cartridge 82 during firing in response to a firing motion applied through

a firing bar 76. *Compare* Shelton II, ¶¶077-0078, Figure 2 (below)[8] *with* '749 Patent, 7:24-58, Figure 2 (below). As E-beam 80 is moved through staple cartridge 82 and along end effector channel 16, it pushes a wedge sled driver 88 against drivers 90 that fire staples 92 against a closed anvil 14. *Id.* Also like the '749 Patent, Shelton II's E-beam 80 is a three-pin design including a bottom pin 10 sliding along the surface of end effector channel 16, a middle pin engaging a wedge sled driver 88, and a top pin 110 translating through an anvil slot 114. *Compare* Shelton II¶¶79-80, Figures 2, 5, 6 *with* '749 Patent, 7:59-8:18, Figures 2, 5, 6.

'749 Patent (IS1001) Shelton II (IS1005)

The structure of Shelton II's E-beam 80 is the same as, or at least equivalent to that of the '749 Patent's E-beam 80, and it serves the same function. IS1003, ¶97. Indeed, comparison of Shelton II at ¶¶0076-0080 and the '749 Patent at 6:65-

[8] As noted (Element 1[b], *supra*), Shelton II incorporates the prior discussion of end effector 12 from its first embodiment (Figures 1-30) into the subsequent discussion of its second embodiment (Figures 31-54). Shelton II, ¶¶0067, 0125.

8:18 reveals a virtually identical written description, even employing the same reference numerals to describe the same parts illustrated identically in Figures 2-4 of each document. There are no substantial differences between Shelton's II's E-beam 80 and the '749 Patent's E-beam 80—these structures are not only interchangeable, they are the same.

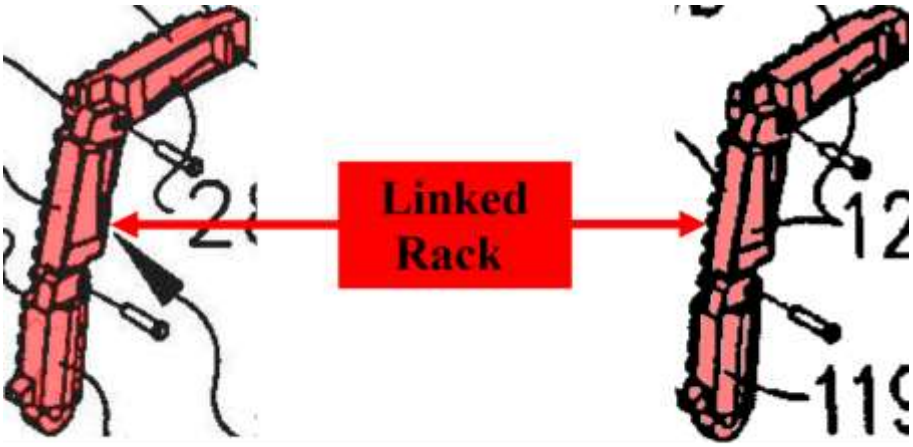
1[c]: "a firing drive supported by said handle assembly and configured to selectively generate said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly; and"

Shelton II discloses Element 1[c] under both 112(6) and non-112(6) interpretations. IS1003, ¶¶99-104. As discussed (*see* Section VIII, *supra*), the corresponding structure to the claimed "firing drive" disclosed in the '749 Patent is a linked rack 200 including links 196a-d having a ramped track 282, a firing rod 32 attached to linked rack 200, and a side pawl mechanism 210 coupled to a firing trigger 34.[9] As was also discussed (*see* Section VII, *supra*), as the user pulls firing trigger 34, side pawl mechanism 210 engages the ramped track 282 of an adjacent link 196a-d to advance linked rack 200 in the longitudinal firing (distal) direction.

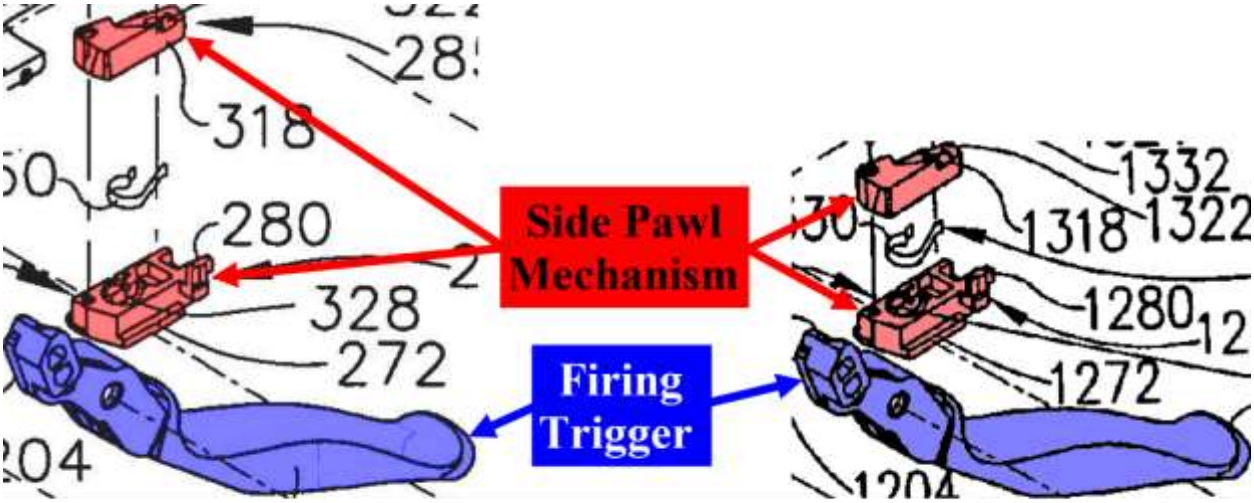
[9] If the term "firing drive" is narrowly construed to require a "firing trigger" (dependent claim 7), Shelton II discloses a firing trigger 1034 that is structurally equivalent to that of the '749 Patent. IS1003, ¶99, n6 (citing Shelton II, ¶¶0130, 138-141).

'749 Patent, 6:8-35, 10:19-28; *see also id*., 11:4-10, 11:25-12:7, Figures 8, 10-11. When firing trigger 34 is pulled by the user through a full firing stroke, side pawl mechanism 210 disengages (or "kicks out") from linked rack 200 during the return stroke of firing trigger 34. *Id*.

Shelton II discloses a nearly-identical "firing drive" combination by way of its linked rack 1200 including links 1196a-d having a ramped track 1282, a firing rod 1032 attached to linked rack 1200, and a side pawl mechanism 1210 coupled to a firing trigger 1034. Shelton II, ¶¶0130-0132, 0138-0141, Figures 31-37. The function and operation of Shelton II's firing drive components are essentially the same, and consistent with, that of the '749 Patent's. IS1003, ¶¶100-101. The user pulls Shelton II's firing trigger 1034 to advance linked rack 1200 (and therefore firing rod 1032, which is drivingly coupled thereto) in the firing direction through engagement with side pawl mechanism 1210, which "kicks out" to disengage from linked rack 1200 when firing trigger 1034 is released. Shelton II, ¶¶0130-0132, 0138-0141, Figures 31-37. The comparison of annotated excerpts below demonstrates the identity, or at least structural equivalency, of their firing drives. IS1003, ¶100.



'749 Patent (IS1001) Shelton II (IS1005)



'749 Patent (IS1001) Shelton II (IS1005)

As would have been understood by a POSITA, the firing drive components of Shelton II and the '749 Patent are not materially different, and are therefore the same or at least structural equivalents under 112(6). IS1003, ¶102. The firing drive of Shelton II and that of the '749 Patent perform the identical function of "selectively generat[ing] said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly" (as claimed) in the same way (*i.e.*, using a kick-out side pawl mechanism to drive the linked rack attached to a firing rod) to achieve the same result (*i.e.*, firing an E-beam "firing member" through an end effector). IS1003, ¶102.

In addition to the above-discussed identical functionality and identical or at least equivalent structure, Shelton II further discloses that "[the] firing drive [is] supported by said handle assembly" (as claimed). IS1003, ¶103. Like the '749 Patent, all of the components of Shelton II's surgical instrument 1010 are coupled (directly or indirectly) to the handle housing 1154, the pistol grip portion 1036 of which is grasped and manipulated by a user. Shelton II, ¶¶0126, 0128, 0131, 0138, 0142, Figures 31-37, 39-40. Because housing 1154 is supported by the user's grasp and the other components are coupled to housing 1154, the other components—including the firing drive components—are "supported by" housing 1154 of handle 1020 (as claimed). IS1003, ¶103. And Shelton II's firing trigger 1034 is "operably coupled" to handle 1020 (as claimed) because it is connected to

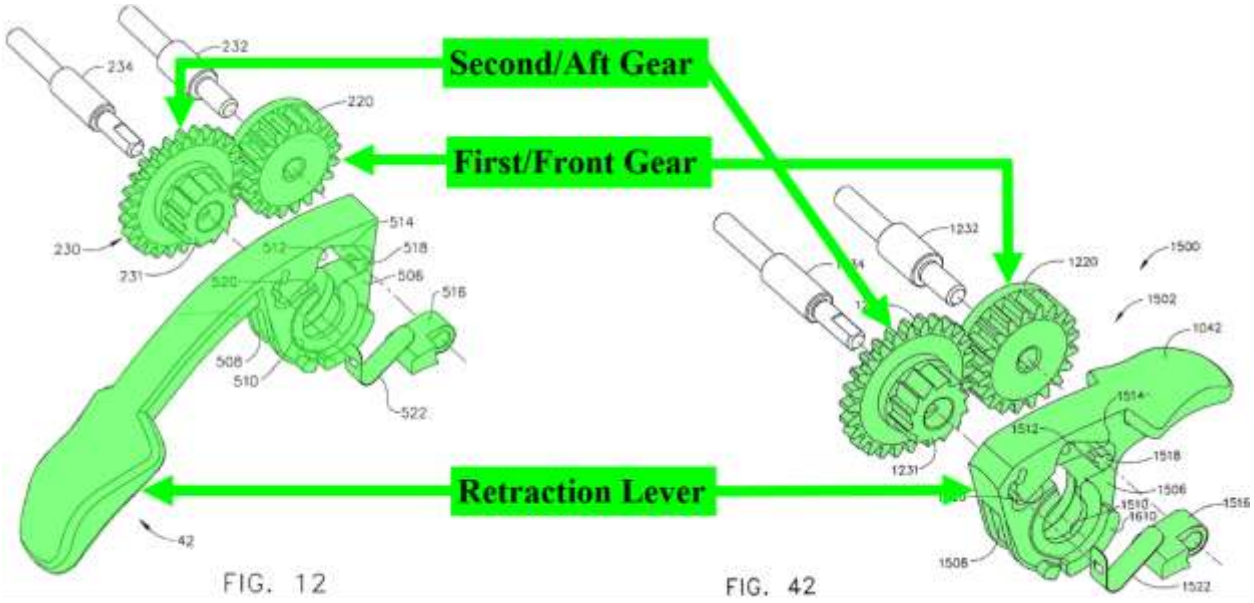
handle 1020 while manually actuated by a user. Shelton II, ¶¶0126, 0130, 0138; IS1003, ¶104.

1[d]: "a retraction assembly supported by said handle assembly and interfacing with said firing drive such that manual actuation of said retraction assembly causes said firing drive to generate a sole retraction motion which is communicated to said firing member to cause said firing member to move from said fired position to said retracted position."

Shelton II discloses and/or demonstrates obviousness of Element 1[d] under both 112(6) and non-112(6) interpretations. IS1003, ¶¶105-112; *see also id*., ¶¶55-69. As discussed (*see* Section VIII, *supra*), the corresponding structure to the claimed "retraction assembly" in the '749 Patent is a first gear 220 meshed to a toothed surface 222 of linked rack 200, a second gear 230 meshed to first gear 220 that includes a ratchet gear 231, a spring-biased, multi-stroke retraction lever 42 including a hub 506 into which ratchet gear 231 extends, and a locking pawl 516 mounted within hub 516 and biased by an L-shaped spring tab 522 against ratchet gear 231. As was also discussed (*see* Section VII, *supra*), manual actuation of retraction lever 42 drives second gear 230 (via its ratchet gear 231), which drives first gear 220, and causes first gear 220 to draw linked rack 200 (part of the firing drive, *see* Element 1[c], *supra*) in the longitudinal (proximal) retraction direction. '749 Patent, 12:55-13:6.

Shelton II discloses the same or at least a structurally-equivalent "retraction assembly" combination including its front idler gear 1220 meshed to a toothed

surface 1222 of linked rack 1200, an aft idler gear 1230 meshed to front idler gear 1220 that includes a ratchet gear 1231, a spring-biased, multi-stroke manual retraction lever 1042 including a hub 1506 into which ratchet gear 1231 extends, and a locking pawl 1516 mounted within hub 1506 and biased by an L-shaped spring tab 1522 against ratchet gear 1231. Shelton II, ¶¶0142-0144, Figures 33, 35, 40, 42-45. Shelton II's retraction assembly components are not materially different from those of the '749 Patent's. IS1003, ¶¶106, 108-111. Like the '749 Patent, Shelton II's retraction lever 1042 is operated to drive meshing front aft and idler gears 1220/1230, that engage and cause linked rack 1200 (part of the firing drive, *see* Element 1[c], *supra*) to move in the longitudinal (proximal) retraction direction. Shelton II, ¶¶0142-0144, Figures 33, 35, 40, 42-45. The comparison of annotated excerpts below demonstrates the identity or at least structural equivalency between their retraction assemblies. IS1003, ¶¶106, 108-111.



'749 Patent (IS1001) **Shelton II (IS1005)**

Shelton II's "retraction assembly . . . causes said firing drive to generate a sole retraction motion"[10]

As the '749 Patent's specification makes clear, this "sole retraction motion" feature means the firing member is retracted "without the assistance of springs or other force generating members that may be employed to apply a retraction force to the firing drive." '749 Patent, 16:14-19. On this point, Shelton II teaches that "a manual retraction mechanism consistent with aspects of the invention may be utilized without the assistance of a retraction spring." Shelton II, ¶0154 (emphasis added). In other words, Shelton II discloses that its inventions, including surgical instrument 1010, could be provided without tension/compression spring 1184, and its manual retraction assembly would function to retract the firing member

[10] *See generally* IS1003, ¶¶55-63.

"without the assistance of springs or other force generating members that may be employed to apply a retraction force to the firing drive," just as the '749 Patent describes (16:14-19). IS1003, ¶¶57-62. Such an arrangement is consistent with the '749 Patent's explanation of the "sole retraction motion" feature. IS1003, ¶61.

Moreover, based on this disclosure, a POSITA would have immediately envisioned a configuration of Shelton's surgical instrument 1010 lacking tension/compression spring 1184 (and all of its associated components) and relying solely upon the above-discussed manual retraction assembly components to retract E-beam 80. IS1003, ¶62; *see Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068-70 (Fed. Cir. 2017) (citing *Kennametal, Inc. v. Ingersoll Cutting Tool Co*., 780 F.3d 1376, 1381 (Fed. Cir. 2015) and *Blue Calypso, LLC v. Groupon, Inc*., 815 F.3d 1331, 1344 (Fed. Cir. 2016) for the proposition that a prior art reference still anticipates if a POSITA would have "at once envisage[d] the claimed arrangement").

Additionally, in the co-pending litigation, Patent Owner asserts this claim to cover a surgical stapling and severing instrument that has both a primary robotically-driven mechanism and a manual back-up mechanism. IS1007, 14-15. If the claim is read consistent with Patent Owner's allegations, the '749 Patent's "sole retraction motion" feature would then be met by Shelton II's retraction assembly when the tension/compression spring 1184 that facilitates automatic

retraction of E-beam 80 is ineffective to facilitate automatic retraction. IS1003, ¶63. Shelton II explains its manual retraction assembly is provided because the "tension/compression spring 1184 may become disconnected with the linked rack [1200] distally positioned." Shelton II, ¶0144; *see also id*., ¶¶0124, 0131-0133; IS1003, ¶63.

It would have been obvious to modify Shelton II's surgical instrument such that the "retraction assembly . . . causes said firing drive to generate a sole retraction motion"[11]

Modification of Shelton II's surgical instrument 1010 to eliminate tension/compression spring 1184 would result in the claimed arrangement, and such a modification would have been obvious, not inventive. Indeed, multiple reasons (taken together or independently) would have motivated a POSITA to make this modification.

First, and as discussed above, Shelton II teaches that one predictable modification of its embodiments features:

> "a manual retraction mechanism . . . utilized without the assistance of a retraction spring."

Shelton II, ¶0154 (emphasis added). This alone would have prompted a POSITA to pursue predictable variations of surgical instrument 1010 without tension/compression spring 1184 to assist with retraction. IS1003, ¶64; *see also*

[11] *See generally* IS1003, ¶¶64-69.

MPEP 2141(III) (the teaching-suggestion-motivation test remains a valid rationale in support of an obviousness conclusion) (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007)). The retraction mechanism of the as-modified Shelton II embodiment would function in a manner identical to the functioning of the Shelton II embodiment when the tension/compression spring 1184 is "disconnected" (*i.e.*, not functioning to apply a retraction force). IS1003, ¶64 (citing Shelton II, ¶¶0051, 0144).

Second, a POSITA would have understood and appreciated that removing tension/compression spring 1184 would yield the predictable advantage of a reduction in the amount of force required to manually actuate Shelton II's firing drive. IS1003, ¶¶65-67; *see also* MPEP §2144(II) (citing *In re Sernaker*, 702 F.2d 989, 994-95 (Fed. Cir. 1983) and *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick*, 464 F.3d 1356, 1368 (Fed. Cir. 2006) in support of the proposition that an expected advantage is the strongest rationale in support of a reference combination). Again, Shelton II's own disclosure informs. Specifically, Shelton II recognizes a conflict of competing interests when incorporating a retraction spring (like tension/compression spring 1184)—*i.e.*, the added spring provides assistance during the retraction process, but increases the amount of force a user must apply to sever and staple during the firing stroke (because the user needs to overcome the force applied by the retraction spring). IS1003, ¶¶65-66

(citing Shelton II, ¶¶0007, 0009-0011, 0066). While Shelton II's disclosure incorporates features to mitigate the increased firing force requirement stemming from a retraction spring, a POSITA would still have recognized that this adverse effect would be completely resolved by eliminating the retraction spring. IS1003, ¶67 (citing Shelton II, ¶¶0007-0008, 0066, 0072, 0133). Thus, particularly in the context of design scenarios focused on reducing the firing force requirement, a POSITA would have viewed the removal of Shelton II's tension/compression spring 1184 as an opportunity to achieve a predictable advantage. *Id*.

Third, in addition to the advantage of a significant reduction in the firing force requirement, a POSITA would have understood that eliminating tension/compression spring 1184 would simplify Shelton II's surgical instrument 1010, and therefore yield the predictable advantage of lower manufacturing costs. IS1003, ¶68 (citing IS1008, 1-2, 4-6). For example, a POSITA would have understood that elimination of tension/compression spring 1184—along with the anti-backup mechanism 1250 that "prevents the combination tension/compression spring 1184 from retracting the linked rack 1200 between firing strokes" and the automatic retraction mechanism 1289 that releases the anti-backup mechanism at the end of a full firing stroke—would significantly reduce the number of parts and streamline assembly of surgical instrument 1010. IS1003, ¶68 (citing Shelton II, ¶¶0133-0137).

Fourth, it would have been a matter of routine design choice and/or common sense for a POSITA to select one of two fully redundant mechanisms that are recognized solutions to the same problem of retracting E-beam 80 via linked rack 1200. IS1003, ¶69; *see also In re Magna Elecs., Inc.*, 611 Fed. Appx. 969, 974 (Fed. Cir. 2015) (citing *In re Kuhle*, 526 F.2d 553, 555 (CCPA 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) (Obviousness analysis "may include recourse to logic, judgment, and common sense available to the person of ordinary skill[.]"). As the Federal Circuit recently held in affirming an IPR final written decision, a finding that "two designs were known in the art, recognized as solutions to [a] particular problem, and functionally equivalent" is sufficient to support the legal conclusion of obviousness. *Philips Lighting N. Am. Corp. v. Wangs All. Corp.*, No. 2017-1526, 2018 U.S. App. LEXIS 10015, at *8 (Fed. Cir. Apr. 18, 2018) (nonprecedential).

Fifth, it has long been recognized that "making automatic" is generally not considered inventive; and the opposite proposition implicated here—making manual—is even more obvious. MPEP 2144.04(III) (citing *In re Venner,* 262 F.2d 91, 95 (CCPA 1958)).

* * *

Turning now to the issue of equivalency, a POSITA would have understood that the similar retraction assemblies of Shelton II (under one or both of the above-discussed anticipation or obviousness theories) and the '749 Patent are not materially different, and are therefore equivalents under 112(6). *Chiuminatta*, 145 F.3d at 1309-10. Each combination of retraction assembly components performs the identical function of "interfacing with said firing drive such that manual actuation of said retraction assembly causes said firing drive to generate a sole retraction motion which is communicated to said firing member to cause said firing member to move from said fired position to said retracted position" (as claimed) in the same way (*i.e.*, using a gear set driven by a manually operated lever) to achieve the same result (*i.e.*, retraction of an E-beam "firing member" through an end effector). IS1003, ¶¶108-109; *Odetics*, 185 F.3d at 1267.

While at a granular level of detail there are slight differences between the '749 Patent's disclosure and that of Shelton II, those difference are insubstantial with respect to the claimed function. IS1003, ¶¶110-111. For example, the '749 Patent's retraction lever 42 extends proximally and is pressed downward while Shelton II's retraction lever 1042 extends distally and is pulled it upward. *Compare* '749 Patent, 12:55-59 *with* Shelton II, ¶0144. But this minor difference is insignificant because it is unrelated to the claimed functionality of causing the firing drive to generate a sole retraction motion of the firing member. IS1003,

¶¶110-111; *Odetics*, 185 F.3d at 1268 (citing *Chiuminatta*, 145 F.3d at 1308-09, for the proposition that structure "unrelated to the recited function" disclosed in the patent is irrelevant to 112(6)). In other words, the difference in orientation between retraction levers 42/1042 does not impact the way (*i.e.*, using a gear set driven by a manually operated lever) the claimed function is performed or the result (*i.e.*, retraction of an E-beam "firing member" through an end effector) of the function. IS1003, ¶¶110-111. In the case of either the '749 Patent's retraction lever 42 or Shelton II's retraction lever 1042, manual actuation produces a rotation of the retraction lever, and this rotating motion subsequently drives the rest of their corresponding retraction assemblies in an identical manner. *Id*.

In addition to the above-discussed functionality and identical and equivalent structure, Shelton II further discloses that "[the] retraction assembly [is] supported by said handle assembly" (as claimed). As discussed (*see* Element 1[c], *supra*), all of the components of Shelton II's surgical instrument—including the retraction assembly components—are coupled to (directly or indirectly) and "supported by" housing 1154 of handle 1020. IS1003, ¶107.

3[pre]: "The surgical instrument of claim 1 further comprising:"

See Elements 1[pre]-1[d], *supra*.

3[a]: "a closure drive supported by said handle assembly and configured to generate a closing motion and an opening motion; and"

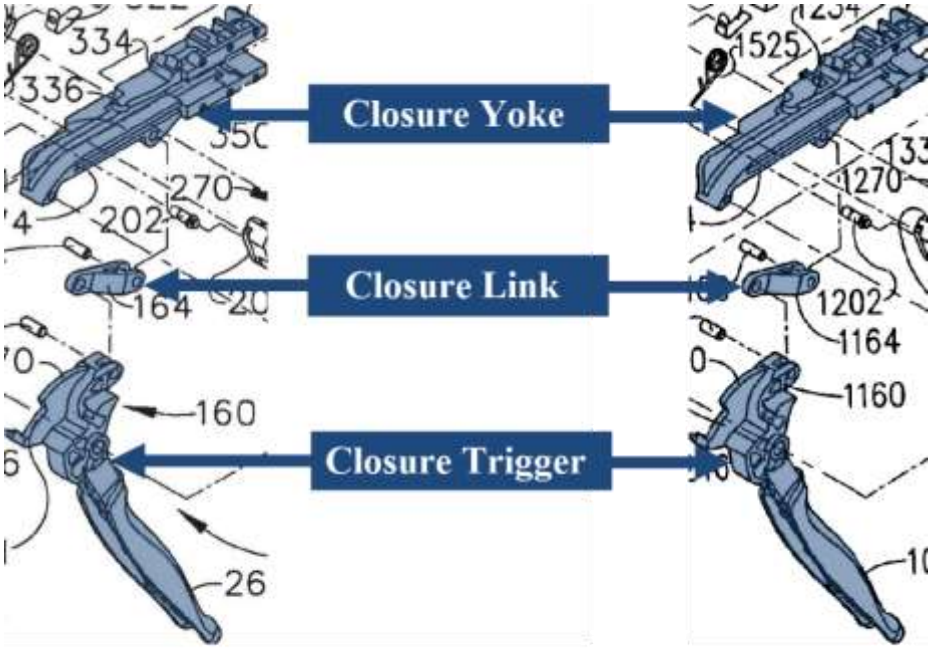
Shelton II discloses Element 3[a] under both 112(6) and non-112(6) interpretations. IS1003, ¶¶113-117. As discussed (*see* Section VIII, *supra*), the corresponding structure to the claimed "closure drive" of '749 Patent features the combination of a closure trigger 26 including an upper portion 160 coupled to a closure yoke 162 through a closure link 164 (referred to collectively as closure drive 23). As was also discussed (*see* Section VII, *supra*), as the user rotates closure trigger 26 towards handle 36, an upper portion 160 of closure trigger 26 moves (via closure link 164) closure yoke 162 in a distal direction, and closure yoke 162 moves a closure tube 24 in the distal direction to close anvil 40 of end effector 12. IS1001, 7:2-23, 9:10-10:4, Figures 2, 4, 6-8. And as closure trigger 26 traverses its recovery stroke (once released by user actuation of a closure release button 38), the upper portion 160 of closure trigger 26 moves (via closure link 164) closure yoke 162 in a proximal direction, and closure yoke moves closure tube 24 in the proximal direction to open anvil 40. *Id*.

Shelton II discloses a nearly-identical "closure drive" combination by way of its closure trigger 1026 including an upper portion 1160 coupled to a closure yoke 1162 through a closure link 1164. Shelton II, ¶¶0125-0129, Figures 31-35;

see also id., ¶¶0076, 0084, Figures 2, 4, 6-8[12]; IS1003, ¶¶114-16. Like the '749 Patent, when Shelton II's closure trigger 1026 is rotated towards handle 1036 by a user, an upper portion 1160 of closure trigger 1026 moves closure yoke 1162 (via closure link 164) in a distal direction, which in turn moves a closure tube 1024 in the distal direction to close the anvil 1014 of end effector 1012. *Id.*

And, when Shelton II's closure trigger 1026 is released (by pressing a closure release button 1038), its upper portion 1160 moves closure yoke 1162 (via closure link 1064) in a proximal direction, which in turn moves closure tube 1024 in the proximal direction to open anvil 1014. *Id.* The comparison of annotated excerpts below between the '749 Patent's Figure 8 (left) and Shelton II's Figure 33 (right) demonstrates the structural equivalency of their "closure drives." IS1003, ¶¶114-116.

[12] A POSTA would have understood that these additional citations (¶¶0076, 0084, Figures 2, 4, 6-8) apply equally to the Figure 31 embodiment. IS1003, ¶114, n7.



As would have been understood by a POSITA, the closure drives of Shelton II and the '749 Patent are not materially different, and are therefore identical or at least equivalents under 112(6). IS1003, ¶116; *Chiuminatta*, 145 F.3d at 1309-10. Each closure drive performs the identical function of "generat[ing] a closing motion and an opening motion" (as claimed) in the same way (*i.e.*, using a closure trigger that activates a closure yoke through a closure link) to achieve the same result (*i.e.*, closing an anvil when the closure trigger is rotated towards the handle and opening the anvil when the closure trigger is restored to its pre-closure position). IS1003, ¶116; *Odetics*, 185 F.3d at 1267.

In addition to the above-discussed functionality and identical or equivalent structure, Shelton II further discloses that "[the] closure drive [is] supported by

said handle assembly" (as claimed). As discussed (*see* Element 1[c], *supra*), all of the components of Shelton II's surgical instrument—including the closure drive components—are coupled to (directly or indirectly) and "supported by" housing 1154 of handle 1020. IS1003, ¶117.

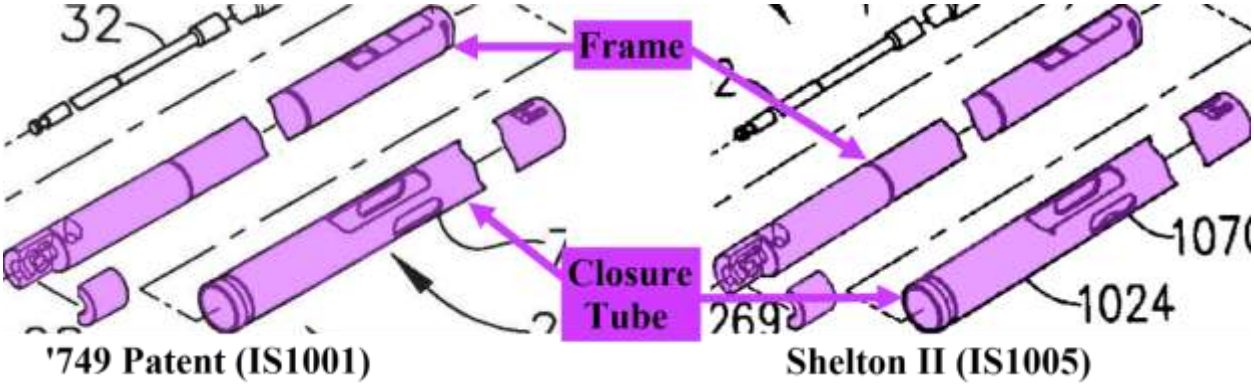
3[b]: "an elongate shaft assembly coupling said end effector to said handle assembly and configured to transfer said opening and closing motions and said firing and retraction motions thereto."

Shelton II discloses Element 3[b]. IS1003, ¶¶118-122. To start, the '749 Patent describes an "elongate shaft assembly" featuring the combination of a closure tube 24 and a frame 28 (referred to collectively as elongate shaft assembly 18). '749 Patent, 5:34-6:11, 9:10-26. Closure tube 24 is a "longitudinally reciprocating" structure moved by closure drive 23 in the distal direction to close anvil 14 and moved by closure drive 23 in the proximal direction to open anvil 14. '749 Patent, 5:60-6:11, 7:2-23, 9:10-40, Figures 2, 4, 6-8. Frame 28 is mounted in the bore of closure tube 24 and supports (among other things) firing rod 32, which, as part of the firing drive (*see* Element 1[c], *supra*), transfers firing and retraction motion to E-beam 80. '749 Patent, 5:60-6:11, 7:-58, 9:10-26, Figures 4, 8.

Shelton II discloses a very similar "elongate shaft assembly" including a closure tube 1024 and a frame 1028. IS1003, ¶¶119-121. Like the '749 Patent, Shelton II's closure tube 1024 is a "longitudinally reciprocating" structure driven by a closure drive (*see* Element 3[a], *supra*) to open and close an anvil 1014 of end

effector 1012. Shelton II, ¶¶0125-0128, Figures 31-35; *see also id.*, ¶¶0076, 0084, Figures 2, 4, 6-8[13]. And, the '749 Patent, Shelton II's frame 1028 supports a firing rod 1032, which transfers firing and retraction motion to E-beam 80. Shelton II, ¶¶0127, 0125 (explaining that "advantageous features described above are maintained for an end effector," *e.g.*, at ¶¶0077-0078), 0133, Figures 4, 33.

The comparison of annotated excerpts below between the '749 Patent's Figure 8 (left) and Shelton II's Figure 33 (right) demonstrates the likeness between their "elongate shaft assemblies." IS1003, ¶¶119-121.



As would have been understood by a POSITA, the shaft assembly components of Shelton II and the '749 Patent are not materially different. IS1003, ¶¶119-121. Each of Shelton II's and the '749 Patent's shaft assemblies "transfer[s] said opening and closing motions and said firing and retraction motions [to the end effector]" (as claimed) by using a longitudinally reciprocating closure tube and a

[13] *See supra* n15.

frame within the closure tube that supports a firing rod to achieve opening/closing of an anvil and firing/retraction of an E-beam. *Id*.

Shelton II further discloses that "[the] elongate shaft assembly coupl[es] said end effector to said handle assembly" (as claimed). IS1003, ¶121. For example, Shelton II explains that closure tube 1024 supports frame 1028, and frame 1028 couples end effector 1012 to handle 1020. Shelton II, ¶¶0125-0127 ("The elongate channel 101[6] [of end effector 1012] is connected to the handle 1020 by a frame 1028 (FIG. 33) that is internal to the closure tube 1024."), Figures 31-33.

B. [GROUND 2]—Swayze Anticipates and/or Renders the Challenged Claims Obvious Under Both 112(6) and Non-112(6) Interpretations

Overview of Swayze

Swayze's disclosure is nearly identical to that of the Shelton II. IS1003, ¶70 (citing IS1009). These two references share the exact same figures, a similar written description that is word-for-word identical in large sections, and employs the same reference numerals to identify the same components. *Id*. Despite these similarities, there are two differences of note. **First**, Swayze is prior art under 102(b), while Shelton II is not. Thus, Patent Owner cannot attempt to swear behind Swayze. **Second**, unlike Swayze, Shelton II expressly states that its the manual retraction assembly "could be utilized without the assistance of a retraction spring," which would yield the "sole retraction motion" feature of the '749 Patent's

claims. Shelton II, ¶0154. So, while Shelton II and Swayze both anticipate the Challenged Claims, Shelton II supports an additional argument that is not applicable to Swayze. IS1003, ¶71.

1[pre]: "A surgical instrument, comprising:"

Whether the preamble is a limitation, Swayze discloses Element 1[pre] for the same reasons as Shelton II discussed *supra* at Ground 1, Element 1[pre]. *See* Swayze, ¶0132, Figure 31; IS1003, ¶123.

1[a]: "a handle assembly;"

Swayze discloses Element 1[a] for the same reasons as Shelton II discussed *supra* at Ground 1, Element 1[a]. *See* Swayze, ¶¶0132-0133, Figures 31-37; IS1003, ¶124.

1[b]: "an end effector for performing a surgical operation, said end effector operably coupled to said handle assembly and"

Swayze discloses Element 1[b] for the same reasons as Shelton II discussed *supra* at Ground 1, Element 1[b]. *See* Swayze, ¶¶0075-0082, 0132-0133, Figures 2-6, 31; IS1003, ¶125.

1[b.i]: "[the end effector] operably supporting a firing member that is movable from a retracted position to a fired position in response to a longitudinal firing motion applied thereto;"

Swayze discloses Element 1[b.i] under both 112(6) and non-112(6) interpretations for the same reasons as Shelton II discussed *supra* at Ground 1, Element 1[b.i]. *See* Swayze, ¶¶0077-0078, Figures 2-4; IS1003, ¶126.

1[c]: "a firing drive supported by said handle assembly and configured to selectively generate said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly; and"

Swayze discloses Element 1[c] under both 112(6) and non-112(6) interpretations for the same reasons as Shelton II discussed *supra* at Ground 1, Element 1[c]. *See* Swayze, ¶¶0133, 0135, 0137-0139, 0147-0151, Figures 31-37, 39-40; IS1003, ¶127.

1[d]: "a retraction assembly supported by said handle assembly and interfacing with said firing drive such that manual actuation of said retraction assembly causes said firing drive to generate a sole retraction motion which is communicated to said firing member to cause said firing member to move from said fired position to said retracted position."

As explained below, Swayze discloses and/or demonstrates obviousness of Element 1[d] under both 112(6) and non-112(6) interpretations for generally the same reasons as Shelton II discussed *supra* at Ground 1, Element 1[d]. *See* Swayze, ¶¶0152-0155, Figures 33, 35, 40, 42-45; IS1003, ¶128. Swayze discloses a backup mechanism for when the retraction spring becomes inoperable, which would meet the broad interpretation applied by Patent Owner in the litigation. Under this broad interpretation, Swayze discloses Element 1[d] in describing that its back-up retraction mechanism is operated when tension/compression spring 1184 has become disconnected from linked rack 1200, and therefore does not exert

a retraction force.[14] Swayze, ¶0155; *see also* analysis at Ground 1, Element 1[d] (the discussion addressing anticipation in view of Shelton II's identical teaching is relevant for Swayze here).

The obviousness analysis based on Swayze differs, slightly, from that of Shelton II, coming from the knowledge of a POSITA, for example, as corroborated by Shelton II. Despite this difference, the obviousness analysis presented *supra* at Ground 1, Element 1[d] is largely the same.

Modification of Swayze's surgical instrument 1010 to eliminate tension/compression spring 1184 would result in the claimed arrangement, and such a modification would have been obvious, not inventive. IS1003, ¶¶72-79. Indeed, multiple reasons (taken together or independently) would have motivated a POSITA to this modification. *Id*.

First, a POSITA would have known that: (**A**) Swayze's manual retraction assembly is redundant to its automatic retraction spring (*i.e.*, tension/compression spring 1184); and (**B**) both of these retraction mechanisms need not be provided for the tool to operate. IS1003, ¶73. Therefore, a POSITA pursuing a simpler, less featured design of Swayze's surgical instrument would have been motivated to

[14] This anticipation argument is based solely on Patent Owner's infringement allegations, with which Petitioner does not concede subjective agreement.

eliminate the automatic retraction spring, leaving only the manual retraction assembly. IS1003, ¶74. In seeking such a simpler surgical instrument, the POSITA would have eliminated the automatic retraction spring knowing that the automatic retraction spring is prone to failure—for example, when the automatic retraction spring "become[s] disconnected." Swayze, ¶0155; IS1003, ¶74. Thus, in pursuing a design with a sole retraction mechanism, a POSITA would have been motivated to eliminate the automatic version to maintain the reliability of Swayze's surgical instrument. IS1003, ¶¶74-75. A POSITA would have had a reasonable expectation of success in implementing this design, at least because surgical instruments with fully manual retraction mechanisms were well known long before the '749 Patent. IS1003, ¶75 (citing US 5,941,442 (1010), US 5,865,361 (IS1011)).

In addition, the POSITA would have known, as evidenced by Shelton II—a document published (August 10, 2006) more than seven months before the earliest effective filing date of the '749 Patent (March 28, 2007)—that one predictable modification of a surgical instrument like Swayze's would include "a manual retraction mechanism . . . utilized without the assistance of a retraction spring." Shelton II, ¶0154; IS1003, ¶76. This corroborates that a POSITA would have known to pursue predictable variations of Swayze's surgical instrument 1010 without tension/compression spring 1184 to assist with retraction. IS1003, ¶76;

see also KSR, 550 U.S. at 418-19 (endorsing the TSM test as not inconsistent with the *Graham* analysis). Recall that Swazye's and Shelton II's respective disclosures of embodiments are virtually identical. IS1003, ¶70 (citing IS1009). Thus, a POSITA would have known that Shelton II's teaching of eliminating the retraction spring would apply equally to Swayze. IS1003, ¶76; *see also KSR*, 550 U.S. at 418 ("Often, it will be necessary for a court to look to . . . the background knowledge possessed by a person having ordinary skill in the art[.]" (emphasis added)).

Second, a POSITA would have understood and appreciated that removing tension/compression spring 1184 would yield the predictable advantage of a reduction in the amount of force required to manually actuate Swayze's firing drive. IS1003, ¶¶77-78; *see also* MPEP §2144(II) (citing *In re Sernaker*, 702 F.2d 989, 994-95 (Fed. Cir. 1983) and *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick*, 464 F.3d 1356, 1368 (Fed.Cir. 2006)). Specifically, a POSITA having read Swayze's disclosure would have recognized a conflict of competing interests when incorporating a retraction spring (like tension/compression spring 1184)—*i.e.*, the added spring provides assistance during the retraction process, but increases the amount of force required to sever and staple during the firing stroke. IS1003, ¶77 (citing Swayze, Abstract, ¶¶0008-0009, 0013, 0066, 0071). While Swayze's disclosure incorporates features to mitigate the increased firing force requirement stemming from a retraction spring,

a POSITA would have recognized that this adverse effect would be completely resolved by eliminating the retraction spring. IS1003, ¶78 (citing Swayze, ¶¶0008-0009, 0066, 0071). Thus, particularly in the context of design scenarios focused on reducing the firing force requirement, a POSITA would have viewed the removal of Swayze's tension/compression spring 1184 is an opportunity to achieve a predictable advantage. IS1003, ¶78.

Third, in addition to the advantage of a significant reduction in the firing force requirement, a POSITA would have understood that eliminating tension/compression spring 1184 would simplify Swayze's surgical instrument 1010, and therefore yield the predictable advantage of lower manufacturing costs. IS1003, ¶79 (citing IS1008, 1-2, 4-6). For example, as would have been understood by a POSITA, elimination of tension/compression spring 1184—along with the anti-backup mechanism 1250 that "prevents the combination tension/compression spring 1184 from retracting the linked rack 1200 between firing strokes" and the automatic retraction mechanism 1289 that releases the anti-backup mechanism at the end of a full firing stroke—would significantly reduce the number of parts and streamline assembly of surgical instrument 1010. IS1003, ¶79 (citing Swayze, ¶¶0140-0146).

Fourth, it would have been a matter of routine design choice and/or common sense for a POSITA to select one of two fully redundant mechanisms that

are recognized solutions to the same problem of retracting E-beam 80 via linked rack 1200. IS1003, ¶74, n4; *see also In re Magna Elecs., Inc.*, 611 Fed. Appx. 969, 974 (Fed. Cir. 2015).

Fifth, it has long been recognized that "making automatic" is generally not considered inventive; and the opposite proposition implicated here—making manual—is even more obvious. MPEP 2144.04(III) (citing *In re Venner,* 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

3[pre]: "The surgical instrument of claim 1 further comprising:"

See Elements 1[pre]-1[d], *supra*.

3[a]: "a closure drive supported by said handle assembly and configured to generate a closing motion and an opening motion; and"

Swayze discloses Element 3[a] under both 112(6) and non-112(6) interpretations for the same reasons as Shelton II discussed *supra* at Ground 1, Element 3[a]. *See* Swayze, ¶¶0076, 0085, 0132-0136, Figures 2, 4, 6-8, 31-35; IS1003, ¶129.

3[b]: "an elongate shaft assembly coupling said end effector to said handle assembly and configured to transfer said opening and closing motions and said firing and retraction motions thereto."

Swayze discloses Element 3[b] for the same reasons as Shelton II discussed *supra* at Ground 1, Element 3[b]. *See* Swayze, ¶¶0076, 0085, 0132-0135, Figures 2, 4, 6-8, 31-35; IS1003, ¶130.

C. [GROUND 3]—Shelton I Anticipates the Challenged Claims Under a Non-112(6) Construction

Overview of Shelton I[15]

Like the ’749 Patent, Shelton I is directed to surgical instruments for performing stapling and severing operations. *Compare* Shelton I, Abstract, 1:6-33, 3:43-46 *with* ’749 Patent, Abstract, 1:17-54, 2:66-3:4, 5:34-38. More specifically, Shelton I’s disclosure relates to stapling and severing instruments that are entirely “manually actuated” with a sole retraction mechanism providing a sole retraction motion. *Compare* Shelton I, 3:47-50 *with* ’749 Patent, 5:53-59.

Similar to the ’749 Patent, Shelton I’s Figure 1 (annotated below) illustrates a surgical stapling and severing instrument 10 featuring a pistol-grip handle assembly 200 supporting an end effector 12 controlled through user actuation of a closure trigger 320 and a firing trigger 610. *Compare* Shelton I, 3:43-51, 7:44-8:61, 10:52-11:24, 12:14-13:45 *with* ’749 Patent, 5:34-6:35.

[15] *See generally* IS1003, ¶¶80-89.

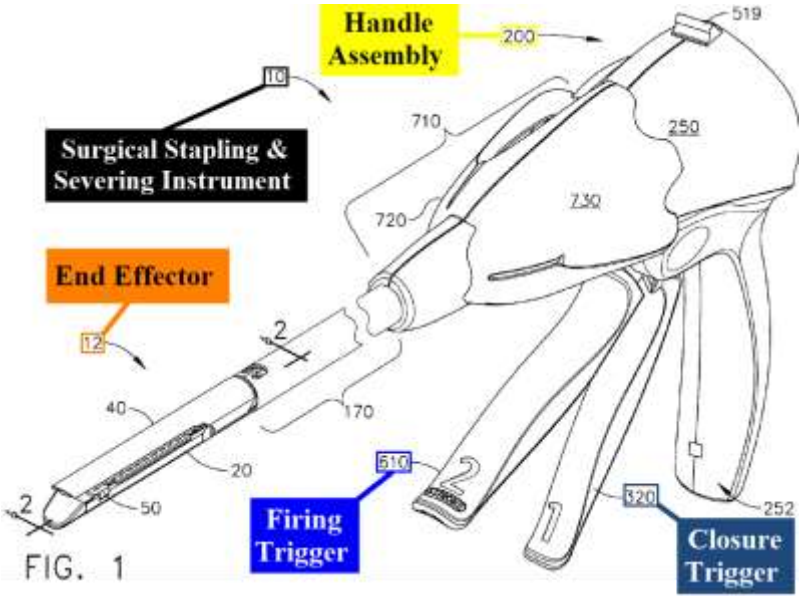


FIG. 1

End effector 12 features a pivoting anvil 40 and an elongate channel 20 housing a staple cartridge 50. Shelton I, 4:8-24, Figure 2 (annotated below), 5-9. Staples 70 are "fired" from cartridge 50 by pushing a knife bar 30 through elongate channel 20 in the distal direction to actuate drivers 66 that eject staples 70 upward and form them against the closed anvil 40. Shelton I, 4:8-49, 4:65-5:63. Here again Shelton I parallels the '749 Patent's written description. '749 Patent, 7:42-8:18, Figures 2-6.

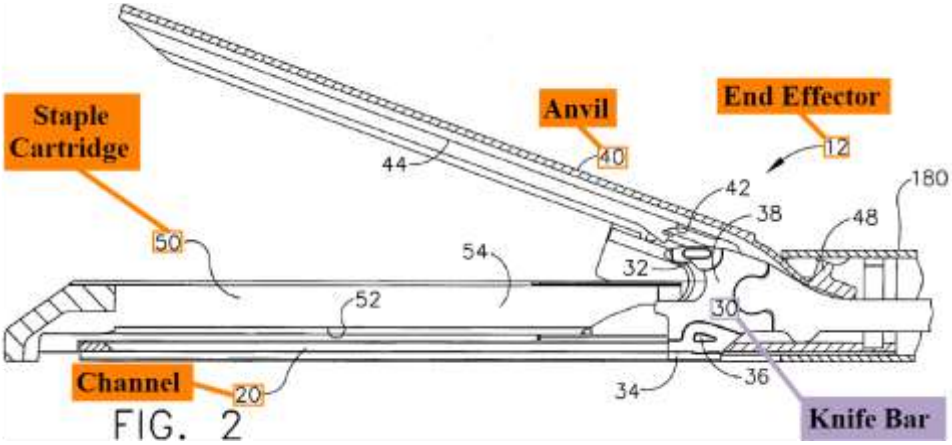


FIG. 2

To move anvil 40 from an open position (Figure 11) to a closed position (Figure 12), the user rotates closure trigger 320 inward toward the pistol grip portion 252 of handle assembly 200. Shelton I, 7:44-8:61, Figures 10-12.

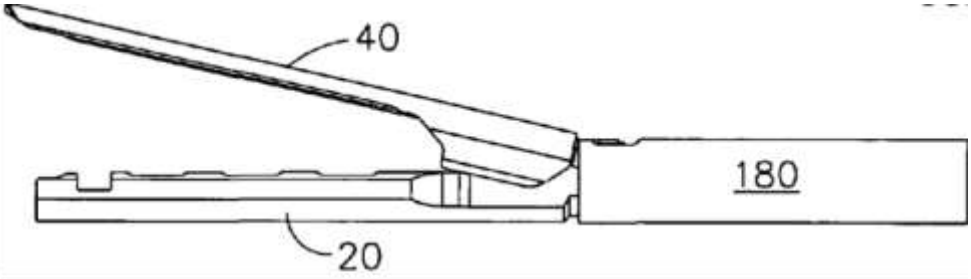
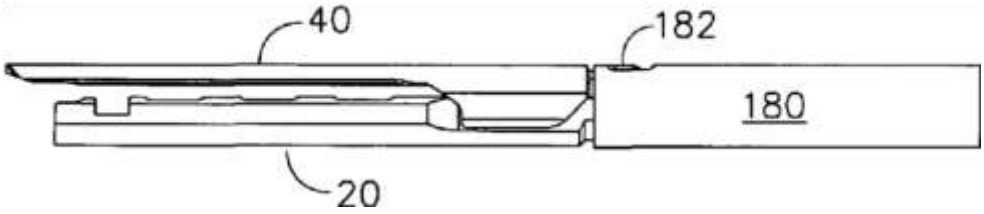


Figure 11 - Anvil (40) Open

Figure 12 - Anvil (40) Closed



User actuation of closure trigger 320 drives an attached linkage assembly 330 to move a closure shuttle 300 longitudinally in the distal direction (arrow "B" in Figure 12). Shelton I, 7:57-9:19. When closure trigger 320 is rotated away from the handle's pistol grip portion 252, linkage assembly 330 moves closure shuttle 300 longitudinally in the proximal direction (arrow "C" in Figure 11). *Id*.

Closure shuttle 300 is coupled to a spine assembly 100 (Figure 6) that is mounted to move telescopically within a closure tube assembly 170 and carries end effector 12 at its distal end. Shelton I, 4:65-5:39, 6:24-30, 8:36-61, Figures 2, 5-6,

11-12. Distal telescopic movement of spine assembly 100 relative to the closure tube assembly 170 via closure shuttle 300 (when closure trigger 320 is released) opens anvil 40 by causing an anvil closure tab 48 to engage with a corresponding tab 182 of a distal closure tube segment 180 at the end of closure tube assembly 170. Shelton I, 5:15-39, 8:36-61, Figures 2, 6, 10-12. Proximal telescopic movement of spine assembly 100 relative to the closure tube assembly 170 (when closure trigger 320 is actuated) closes anvil 40 by disengaging the anvil closure tab 48 from tab 182 of the distal closure tube segment at the end of the closure tube assembly 170. *Id*.

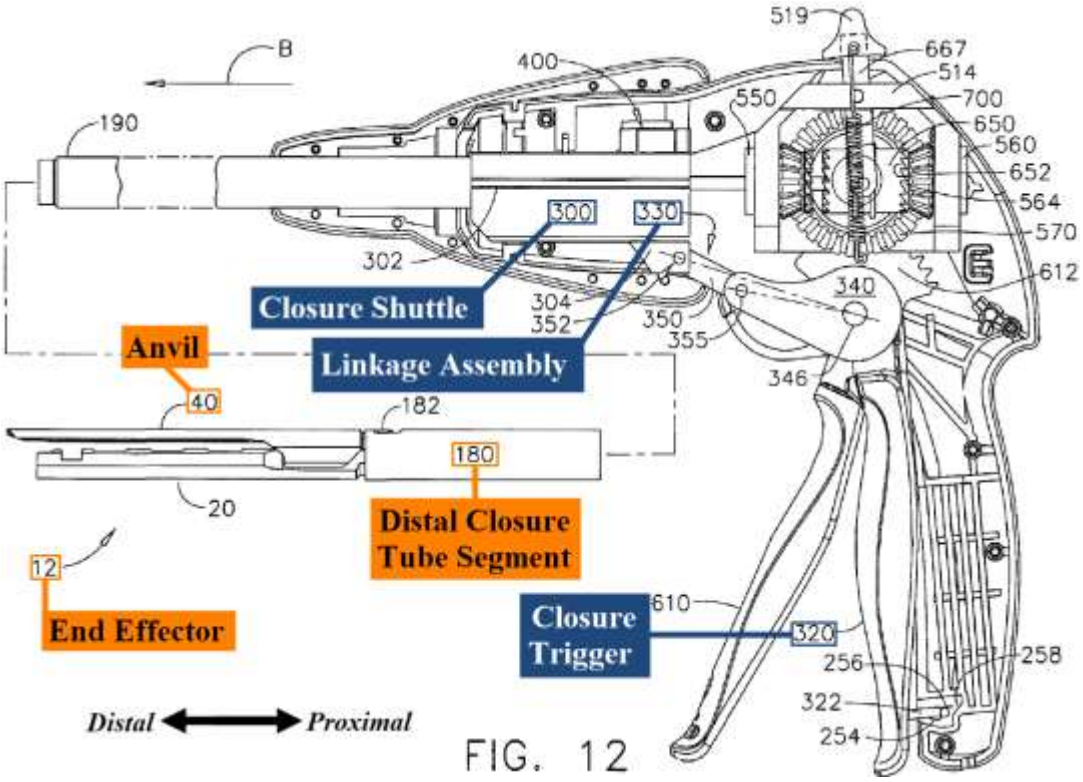


FIG. 12

With anvil 40 closed to clamp the patient's tissue, staples 70 are fired from staple cartridge 50 into anvil 40 by manual actuation of firing trigger 610. *See*

generally Shelton I, 10:52-11:24, 12:14-13:45, Figures 18-19. Actuation of firing trigger 610 (by pulling it towards pistol grip portion 252 of handle assembly 200) causes the trigger's gear segment 620 to engage a firing drive gear 600. Shelton I, 10:48-11:24, Figures 10, 15-19.

Drive gear 600 is keyed to a drive disc 590 mounted for one-way engagement with a ratchet disc 580 keyed to a bevel gear 570. Shelton I, 10:25-51, Figure 15. The one-way engagement between drive disc 590 and ratchet disc 580 means that ratchet disc 580 is only rotated by drive disc 590 when firing trigger 610 is pulled by the user towards pistol grip portion 252, and not as firing trigger 610 is pulled back into its starting position by a recovery spring 630. *Id.* This arrangement enables progressive advancement of the staple-firing knife bar 30 through multiple strokes of firing trigger 610, which requires less force on the part of the user than would a single stroke. Shelton I, 13:33-40; IS1003, ¶86.

Bevel gear 570, which is driven by ratchet disc 580 on each manual pull of firing trigger 610, simultaneously drives a right hand pinion gear 560 and a left hand pinion gear 550 in opposite rotational firing ("D" arrow) and rotational retracting ("E") directions, respectively. Shelton I, 10:9-24, Figure 15. An adjustable shifter gear 650 is spring-biased to engage right hand pinion gear 560, which drives a shifter shaft 680 in the rotational firing direction. Shelton I, 10:9-24, 11:25-38, Figure 15.

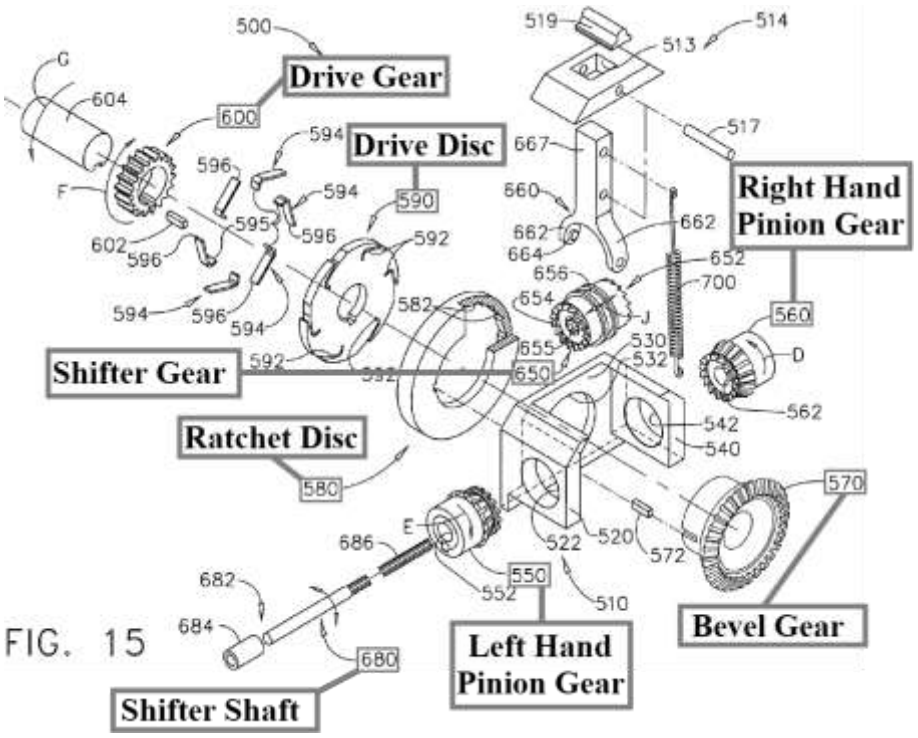


FIG. 15

Shifter shaft 680 is coupled to an input shaft 414 of a planetary gear set 400 that drives a firing screw 240 in the rotational firing direction, which advances a firing bar 210 in a longitudinal firing (distal) direction. Shelton I, 7:7-24, 9:20-64, 11:36-41, Figures 6, 10, 13-15. Knife bar 30 is coupled to firing bar 210, and thus distal movement of firing bar 210 advances knife bar 30 through elongate channel 20 of end effector 12 to fire staples 70 from staple cartridge 50. Shelton I, 4:8-49, 4:65-5:63, 9:65-10:8, 12:14-13:14, Figures 2, 5-6.

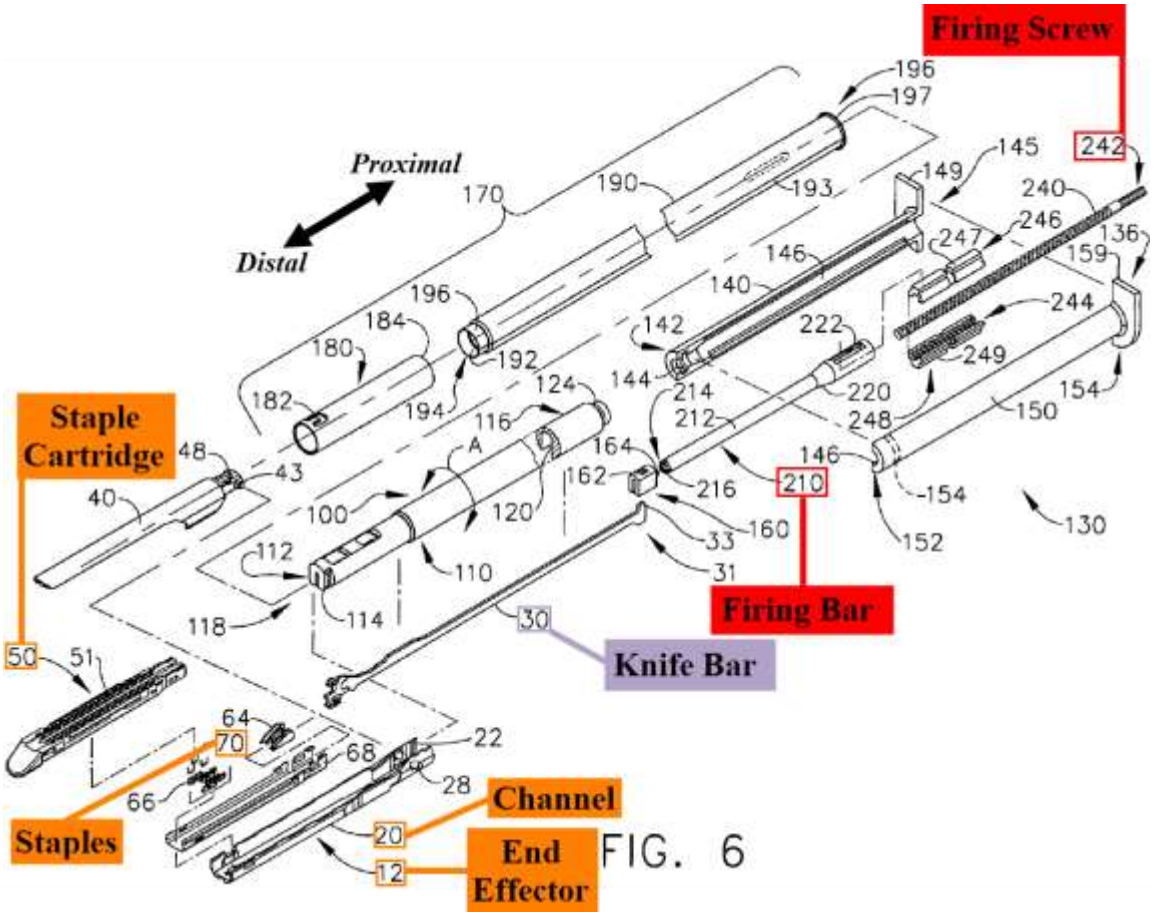


FIG. 6

To retract knife bar 30 from the fired position within end effector 12, the user manually actuates shifter button 519, which pushes a shift arm yoke 660 attached to shifter gear 650 against the bias of a spring 700. Shelton I, 11:55-12:12, 13:17-32, Figure 15. This causes shifter gear 650 to disengage from right hand pinion gear 560 and engage left hand pinion gear 550. *Id*. Thus, when the user actuates firing trigger 610, shifter shaft 680 and firing screw 240 are driven in the rotational retraction direction to withdraw firing bar 210 and knife bar 30 in the longitudinal retraction (proximal) direction. *Id*.

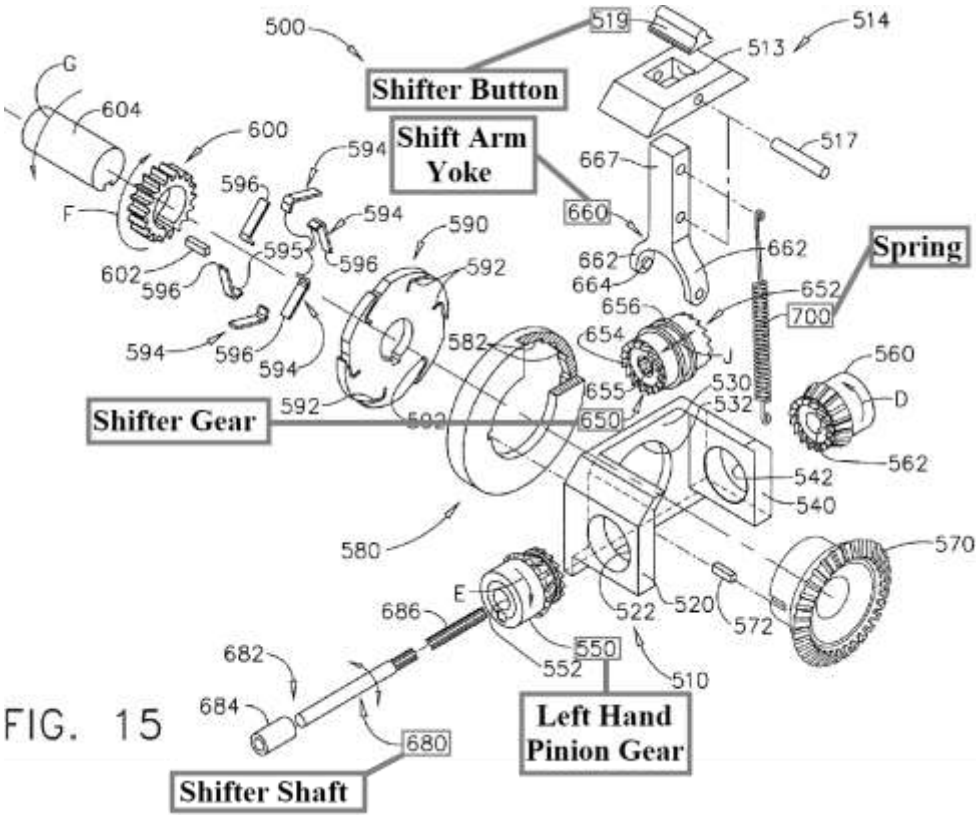


FIG. 15

1[pre]: "A surgical instrument, comprising:"

Whether the preamble is a limitation, Shelton II discloses it. IS1003, ¶132. Like the '798 Patent, Shelton I discloses a surgical instrument (surgical stapling and severing instrument 10) (visual comparison below). *Id.*; Shelton I, 3:47-50, 12:13-24, Figure 1.

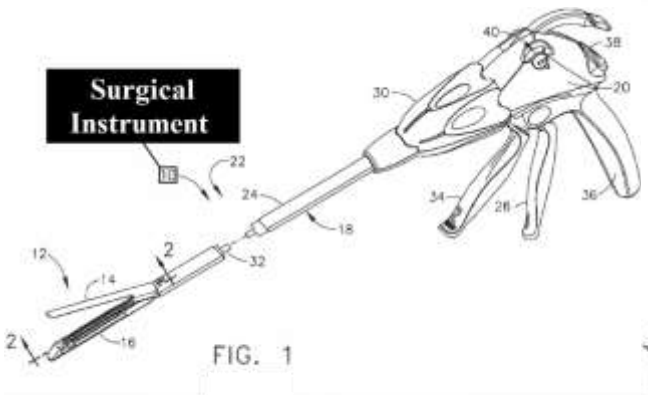


FIG. 1

The '749 Patent (IS1001)

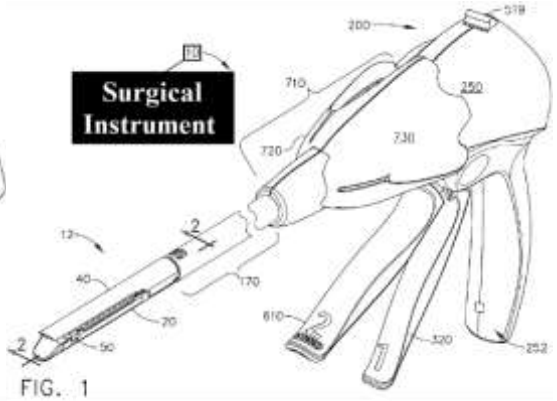


FIG. 1

Shelton I (IS1007)

1[a]: "a handle assembly;"

Shelton I discloses Element 1[a]. IS1003, ¶133. Consistent with the '798 Patent, Shelton I discloses a handle assembly (handle assembly 200) (below). *Id.*; Shelton I, 3:47-50, 7:44-56, Figures 1, 10-12, 16-19.

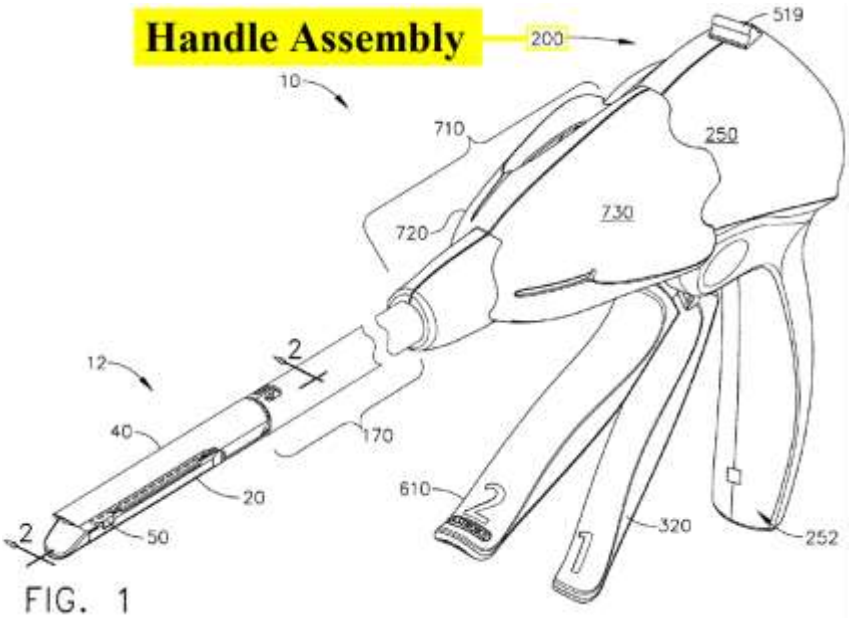
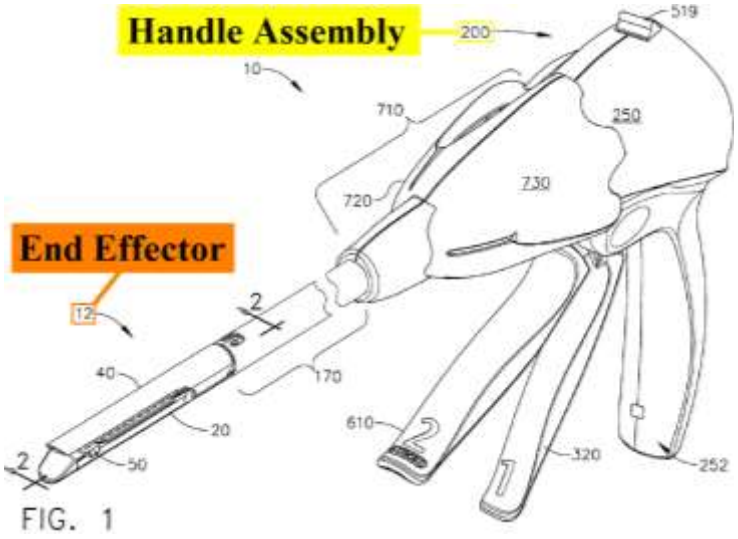


FIG. 1

1[b]: "an end effector for performing a surgical operation, said end effector operably coupled to said handle assembly and"

Shelton I discloses Element [1.b]. IS1003, ¶¶134-136. Shelton I discloses an end effector (end effector 12) (below). *Id.*; Shelton I, 3:47-50, 4:8-20, 4:57-6:23, Figures 1-2, 5-10. Consistent with the '798 Patent, Shelton I's end effector 12 is specifically designed for performing a stapling and severing surgical operation. *Id.* Shelton I explains that its end effector 12 is "manually actuated by manipulation of control members on [the] handle assembly 200 to which it is attached." Shelton I, 3:47-50. Shelton I's end effector 12 is "operably coupled"

(as claimed) to handle assembly 200 because it is operated using handle assembly 200 while attached to handle assembly 200. IS1003, ¶135.



1[b.i]: "[the end effector] operably supporting a firing member that is movable from a retracted position to a fired position in response to a longitudinal firing motion applied thereto;"

Shelton I discloses Element 1[b.i]. IS1003, ¶¶137-139. Shelton I discloses an E-beam firing mechanism ("knife bar 30"), which corresponds to the claimed "firing member." *Id*; Shelton I, 3:51-56, 4:8-20, 5:15-55, 6:15-23, 7:7-12, 9:20-22, 9:65-10:3, Figures 2-9. Consistent with '798 Patent (visual comparison below), Shelton I's knife bar 30 moves through an elongate channel 20 of end effector 12 in response to a longitudinal firing motion applied via firing bar 210. *Id*. Elongate channel 20 receives and supports a staple cartridge 50 including (among other things) a wedge sled 64, a set of drivers 66, and a set of staples 70. *Id*. As knife bar 30 moves longitudinally through end-effector channel 20 from a retracted position to a fired position (in the distal direction away from the user and handle

assembly 200), it pushes wedge sled 64 into contact with drivers 66, which fire staples 70 upward into contact with an anvil 40 of end effector 12. *Id*. A lower pin 34 and a middle pin 36 of knife bar 30 engage elongate channel 20 as knife bar 30 progresses through channel 20. Shelton I, 4:35-49. Thus, knife bar 30 (the claimed "firing member") is "operably support[ed]" by end effector 12—*i.e*., the end-effector's channel 20 engages knife bar 30 throughout operation of knife bar 30. IS1003, ¶138.

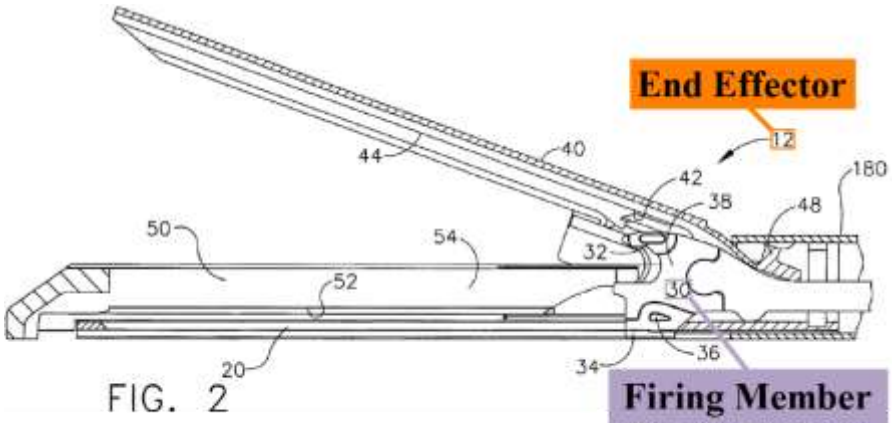


FIG. 2

Shelton I (IS1007)

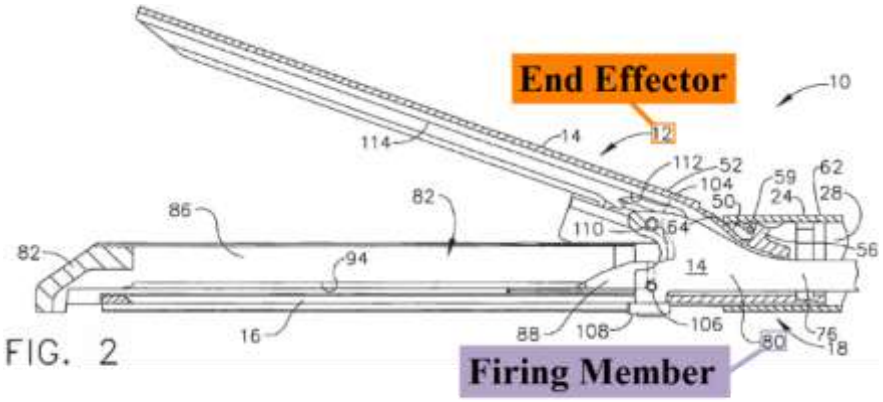


FIG. 2

The '749 Patent (IS1001)

1[c]: "a firing drive supported by said handle assembly and configured to selectively generate said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly; and"

Shelton I discloses Element 1[c]. IS1003, ¶¶140-151. As discussed *infra*, Shelton I's torque transmission/conversion components correspond to the claimed "firing drive . . . configured to selectively generate said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly" under at least two alternative mappings.[16] IS1003, ¶¶140-141 (explaining torque transmission/conversion through Shelton I's surgical instrument).

Firing Drive Mapping #1

As a first example, Shelton I discloses a "firing drive" that includes the following components (marked in red below[17]): drive gear 600, drive disc 590, ratchet disc 580, bevel gear 570, right hand pinion gear 560, left hand pinion gear 550, shifter gear 650, shifter shaft 680, planetary gear 400, firing screw 240, and firing bar 210. IS1003, ¶¶142-144. These components "generate said longitudinal firing motion upon actuation of a firing trigger" (as claimed) because:

[16] If "firing drive" is narrowly construed to require a "firing trigger" (dependent claim 7), Shelton I would still anticipate. IS1003, ¶141, n10 (citing Shelton I, 10:52-11:24, 12:42-13:32, Figures 10, 16-19).

[17] Subcomponents also in red.

1) torque applied when the user pulls firing trigger 610 is transmitted through drive gear 600, drive disc 590, ratchet disc 580, bevel gear 570, right hand pinion gear 560, shifter gear 650, and shifter shaft 680; and
2) the transmitted torque is converted into longitudinal firing motion of knife bar 30 by planetary gear 400, firing screw 240, and firing bar 210.

Id. While the '749 Patent describes a different collection of structural parts in its firing drive, the functionality is the same. IS1003, ¶145 (discussing '749 Patent, 10:4-12:7).

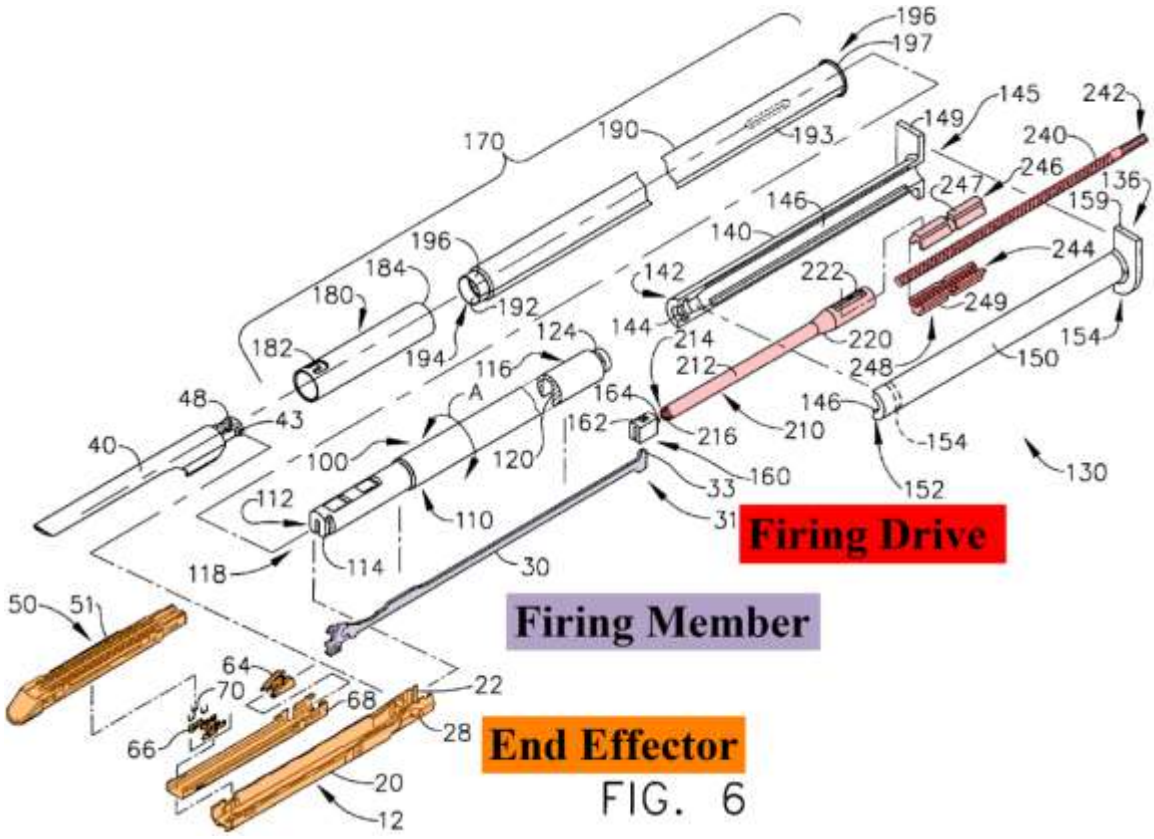


FIG. 6

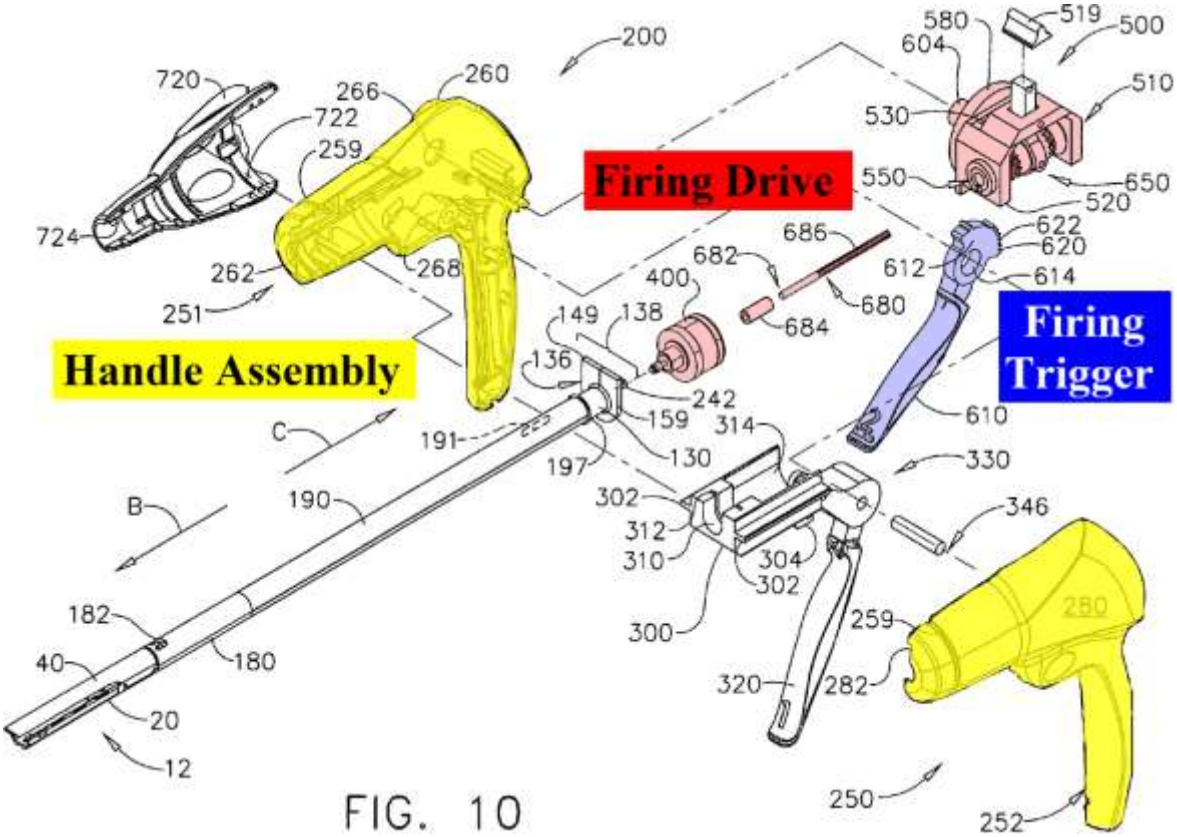

Firing Drive
Handle Assembly
Firing Trigger
200
720
266
260
722
259
724
262
268
251
580
604
519
500
510
530
550
650
520
622
620
614
612
686
682
400
680
684
149
138
136
242
159
314
610
C
191
197
130
330
B
190
302
312
310
346
304
302
182
300
259
280
40
180
320
282
20
12
250
252

FIG. 10

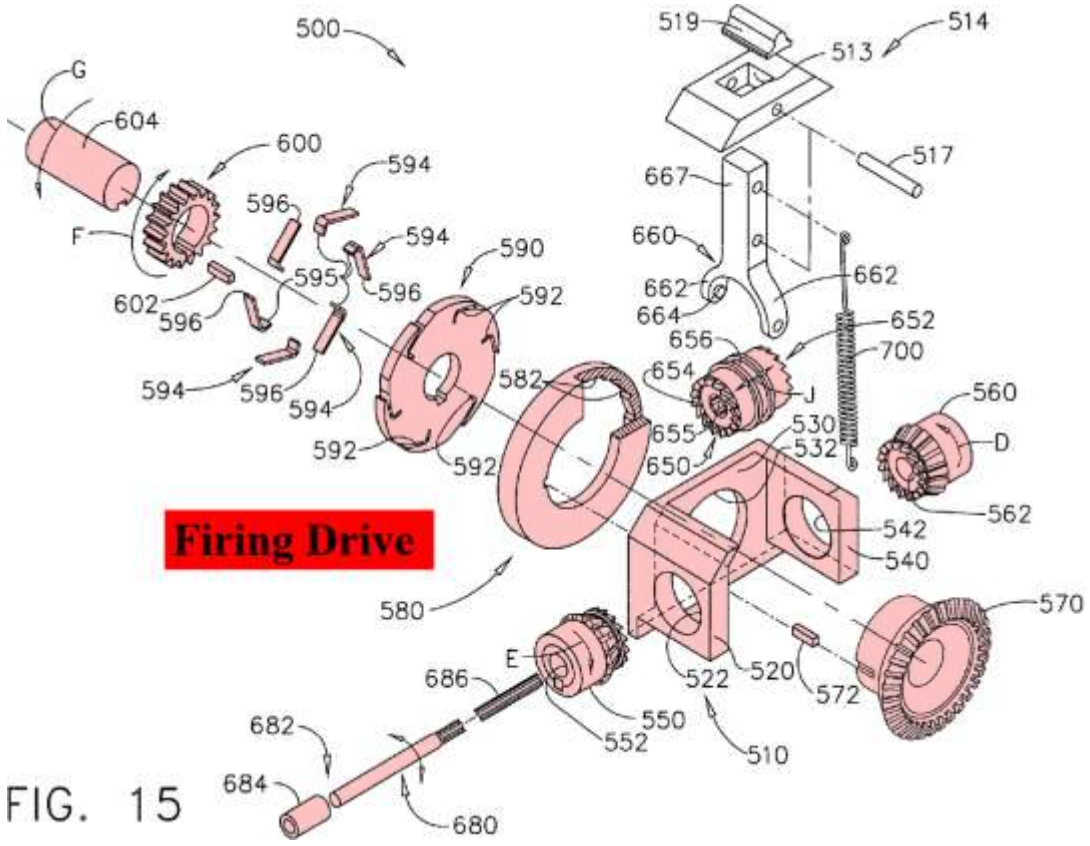

Firing Drive
500
519
514
513
G
604
600
517
667
594
596
F
660
590
662
595
602
596
592
664
652
656
700
654
582
J
560
655
530
D
650
532
592
562
542
540
580
570
E
686
522
520
572
682
550
552
510
684
680

FIG. 15

Firing Drive Mapping #2

As a second example, Shelton I discloses a "firing drive" that includes the following components (marked in red below): planetary gear 400, firing screw 240, and firing bar 210. These components "generate said longitudinal firing motion upon actuation of a firing trigger" (as claimed) because torque applied when the user pulls firing trigger 610 is converted into longitudinal firing motion of knife bar 30 by planetary gear 400, firing screw 240, and firing bar 210. IS1003, ¶146. While the '749 Patent describes a different collection of structural parts in its firing drive, the functionality of converting torque applied to the firing trigger into longitudinal motion of the firing member is the same. IS1003, ¶146 (discussing '749 Patent, 10:4-12:7).

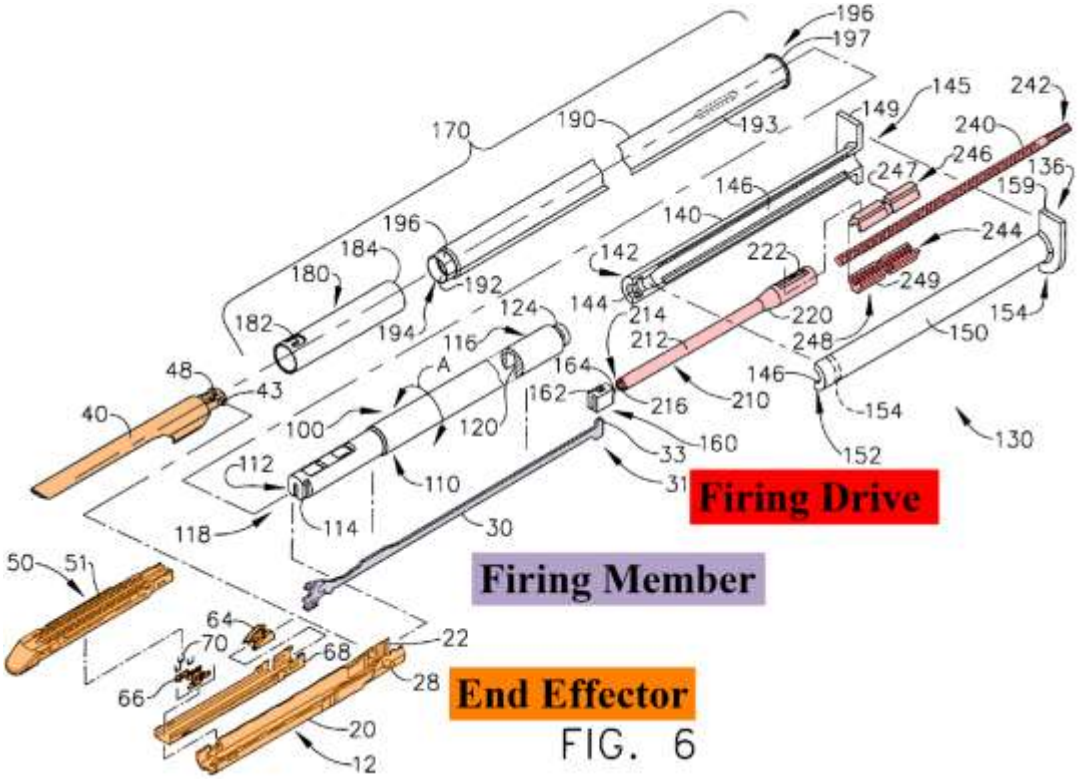


FIG. 6

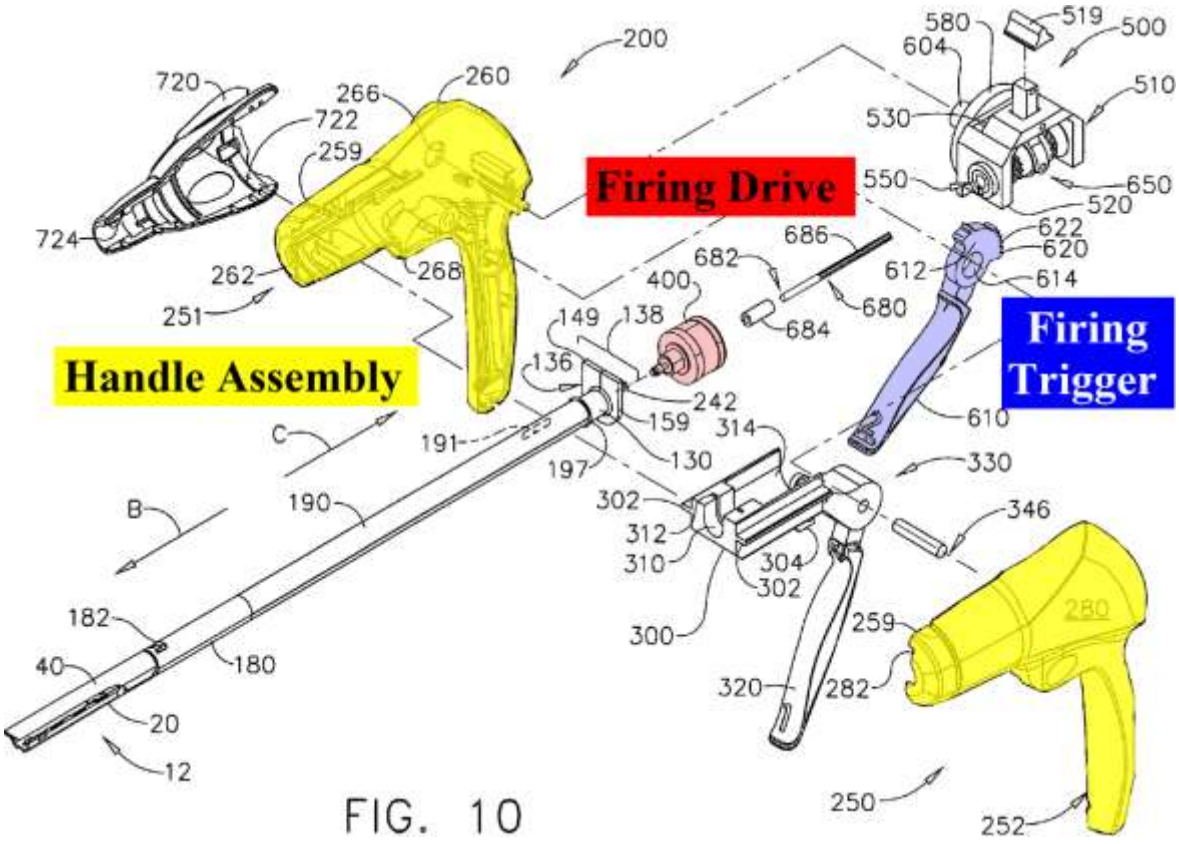


FIG. 10

Shelton I's "firing drive" generates longitudinal motion "selectively"

Torque applied through Shelton I's firing trigger 610 is transmitted to and through the firing drive components (under both mappings) when it is pulled in a firing stroke by the user—*i.e.*, proximally toward pistol grip portion 252—but not when it is driven by spring force away from pistol grip portion 252 on a recovery stroke. IS1003, ¶147 (explaining the functionality of ratchet disc 580 with reference to Shelton I, 10:25-48). The firing drive components, therefore, generate the firing motion "selectively"—only during the firing stroke of firing trigger 610. IS1003, ¶147. The '749 Patent similarly describes a firing drive that only transmits

and converts torque from the trigger to the firing member during a firing stroke. IS1003, ¶147 (referencing '749 Patent, 10:19-28, 11:25-12:7).

Additionally, the components of Shelton I's firing drive (under both mappings) "selectively generate" the longitudinal firing motion because they only move the firing member (knife bar 30) in the distal (firing) direction when the shifter gear 650 is engaged with right hand pinion gear 560, and not when the user operates shifter button 519 to engage shifter gear 650 with left hand pinion gear 550. IS1003, ¶148 (referencing Shelton I, 11:25-12:12, 12:41-13:32).

Shelton I's "firing drive" is "supported by said handle assembly"

Shelton I's handle assembly 200 includes "a pistol grip-type housing 250 that is fabricated in two pieces"—*i.e.*, right hand case member 260 and left hand case member 280. Shelton I, 7:44-56. All of the components of Shelton I's surgical instrument 10 are coupled (directly or indirectly) to housing 250, the pistol grip portion 252 of which is grasped and manipulated by a clinician during use. Shelton I, 7:44-56, 8:3-16, 10:9-10, Figures 1, 10-12, 16-19. Because housing 250 is supported by the user's grasp and the other components are coupled to housing 250, a POSITA would have understood that the other components—including the firing drive components (under both mappings)—are "supported by" housing 250 of handle assembly 200. IS1003, ¶150.

Shelton I's "firing trigger" is "operably coupled to said handle assembly"

Shelton I's firing trigger 610 is "operably coupled" to handle assembly 200 because it is connected to handle assembly 200 while manually actuated by a user. Shelton I, 10:52-11:24, Figures 10, 16-19; IS1003, ¶151. More specifically, firing trigger 610 is rotatably supported on a firing post mounted between the right hand case member 260 and left hand case member 280 of handle assembly 200. Shelton I, 10:55-60. To actuate firing trigger 610, the user draws firing trigger 610 towards pistol grip 252 of handle assembly 200. Shelton I, 11:14-24; *see also id*., 7:47-56. The '749 Patent describes a similar arrangement, confirming that Shelton I's disclosure meets the claim feature. IS1003, ¶151 (referencing '749 Patent, 10:4-28).

1[d]: "a retraction assembly supported by said handle assembly and interfacing with said firing drive such that manual actuation of said retraction assembly causes said firing drive to generate a sole retraction motion which is communicated to said firing member to cause said firing member to move from said fired position to said retracted position."

Shelton I discloses Element 1[d]. IS1003, ¶¶152-157. As discussed (*see* Overview of Shelton I; Elements 1[b.i], 1[c], *supra*), Shelton I provides a "firing member" in the form of knife bar 30 that is manually fired and retracted through end effector 12 in response to user-actuation of firing trigger 610. As was also discussed, components that transmit and/or convert torque from firing trigger 610 into longitudinal motion of knife bar 30 can be mapped to the claimed "firing

drive." *See* Element 1[c], *supra* (Firing Drive Mappings #1 and #2). Similarly, components that cause the firing drive to move knife bar 30 in the retraction direction (proximal to the user, towards handle assembly 200) can be mapped to the claimed "retraction assembly." IS1003, ¶152. The following alternative retraction assembly mappings correspond to the alternative firing drive mappings set forth at Element 1[c] (*i.e.*, firing drive mapping #1 corresponds to retraction assembly mapping #1, etc.).

Retraction Assembly Mapping #1

As a first example, Shelton I discloses a "retraction assembly" that includes the following components (marked in green below[18]): shifter button 519, shift arm pin 517, top member 514, yoke 660, and spring 700. IS1003, ¶154. These retraction assembly components "interfac[e] with said firing drive" (as claimed) because yoke 660 engages shifter gear 650 (*see* Element 1[c], Firing Drive Mapping #1, *supra*). The position of yoke 660 dictates whether shifter gear 650 is engaged with right hand pinion gear 560 for firing knife bar 30 (mapped to claimed "firing member" at Element 1[b.i], *supra*) or left hand pinion gear 550 for retracting knife bar 30. IS1003, ¶154 (citing Shelton I, 11:25-12:12, 12:56-13:32, Figures 10, 15). Yoke 660 is moved to a position that engages shifter gear 650

[18] Subcomponents also in green.

with left hand pinion gear 550 for retraction when the user manually operates shifter button 519. *Id*. Thus, Shelton I's retraction assembly is "manually actuated," as claimed. IS1003, ¶154.

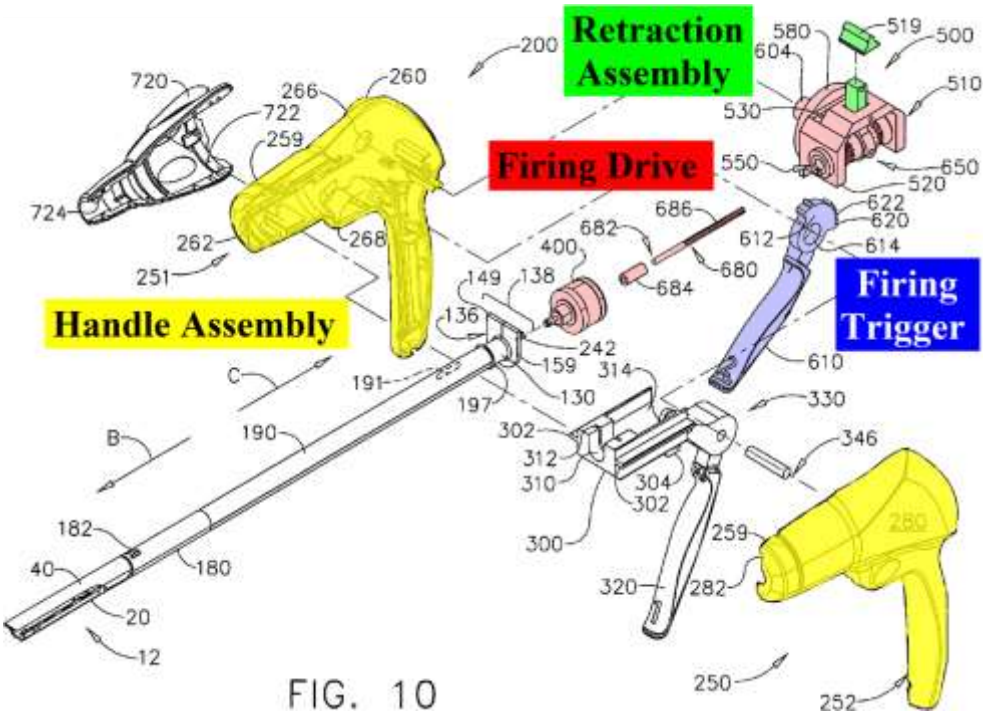


FIG. 10

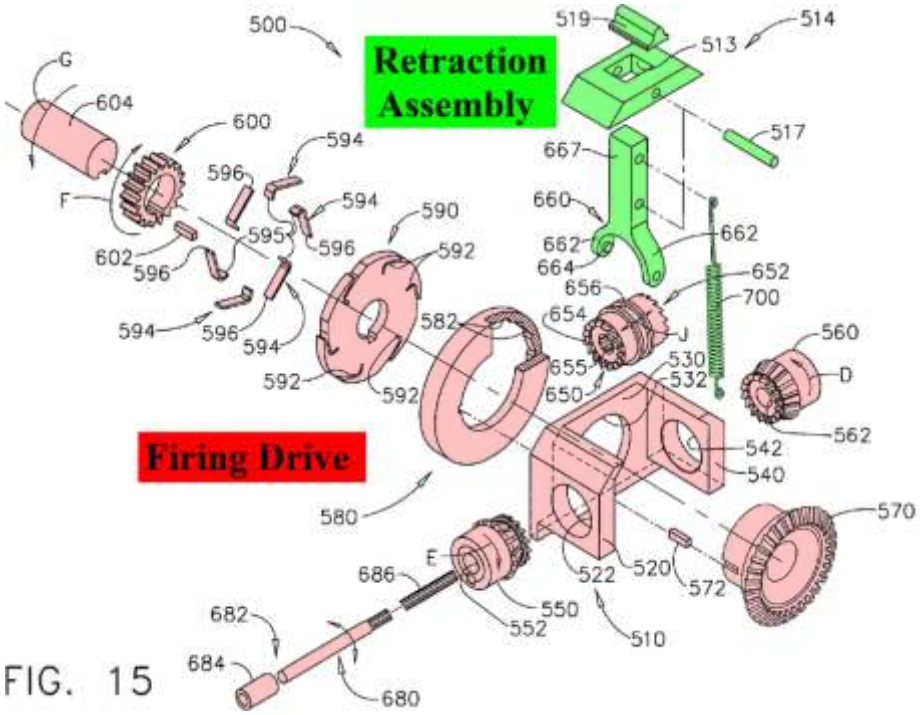


FIG. 15

When shifter button 519 is manually actuated to engage shifter gear 650 with left hand pinion gear 550 and when the user pulls firing trigger 610, torque transmitted and converted (or "generated") by the firing drive is communicated to knife bar 30 by firing bar 210 as longitudinal motion that causes knife bar 30 to move from a fired position to a retracted position, just as claimed. IS1003, ¶155 (citing Shelton I, 11:25-12:12, 12:56-13:32, Figures 10, 15). The longitudinal retraction motion generated by Shelton I's firing drive when Shelton I's retraction assembly is manually actuated is the "sole" retraction motion. *Id*. This means the firing member is retracted "without the assistance of springs or other force generating members that may be employed to apply a retraction force to the firing drive." '749 Patent, 16:14-19. As the '749 Patent requires, Shelton I's surgical instrument does not include any springs or force generating members that apply a retraction force to the firing drive. IS1003, ¶154. Shelton I's firing drive is entirely manually driven. *Id*.

Retraction Assembly Mapping #2

As a second example, Shelton I discloses a "retraction assembly" that includes the following components (marked in green below): drive gear 600, drive disc 590, ratchet disc 580, bevel gear 570, left hand pinion gear 550, shifter gear 650, shifter shaft 680. IS1003, ¶156. These retraction assembly components "interface[e] with said firing drive" (as claimed) because shifter shaft 680 engages

planetary gear 400 (*see* Element 1[c], Firing Drive Mapping #2, *supra*). The rotation direction of shifter shaft 680 dictates whether planetary gear 400 drives firing screw 240 and firing bar 210 to push knife bar 30 (mapped to claimed "firing member" at Element 1[b.i], *supra*) in the firing direction or pulls knife bar 30 in the retracting direction. IS1003, ¶156 (citing Shelton I, 7:7-24, 9:20-64, 11:36-12:12, 13:17-32, Figures 6, 10, 13-15).

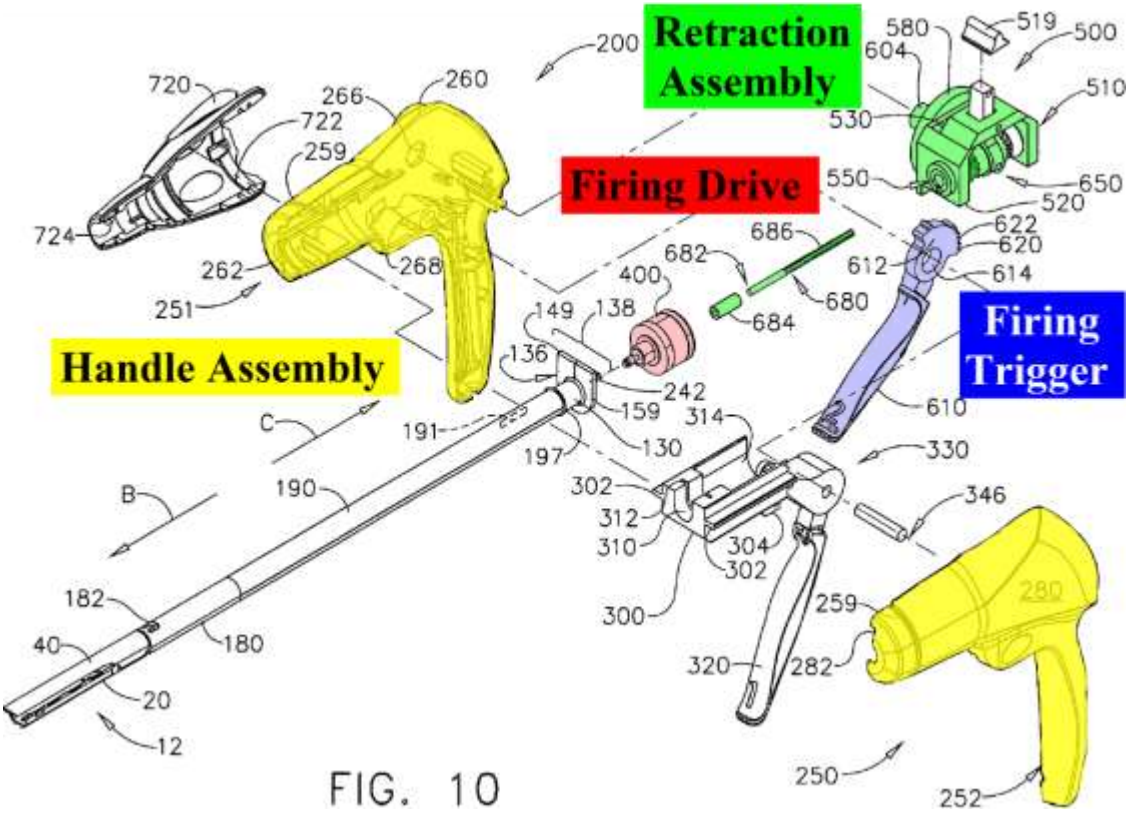


FIG. 10

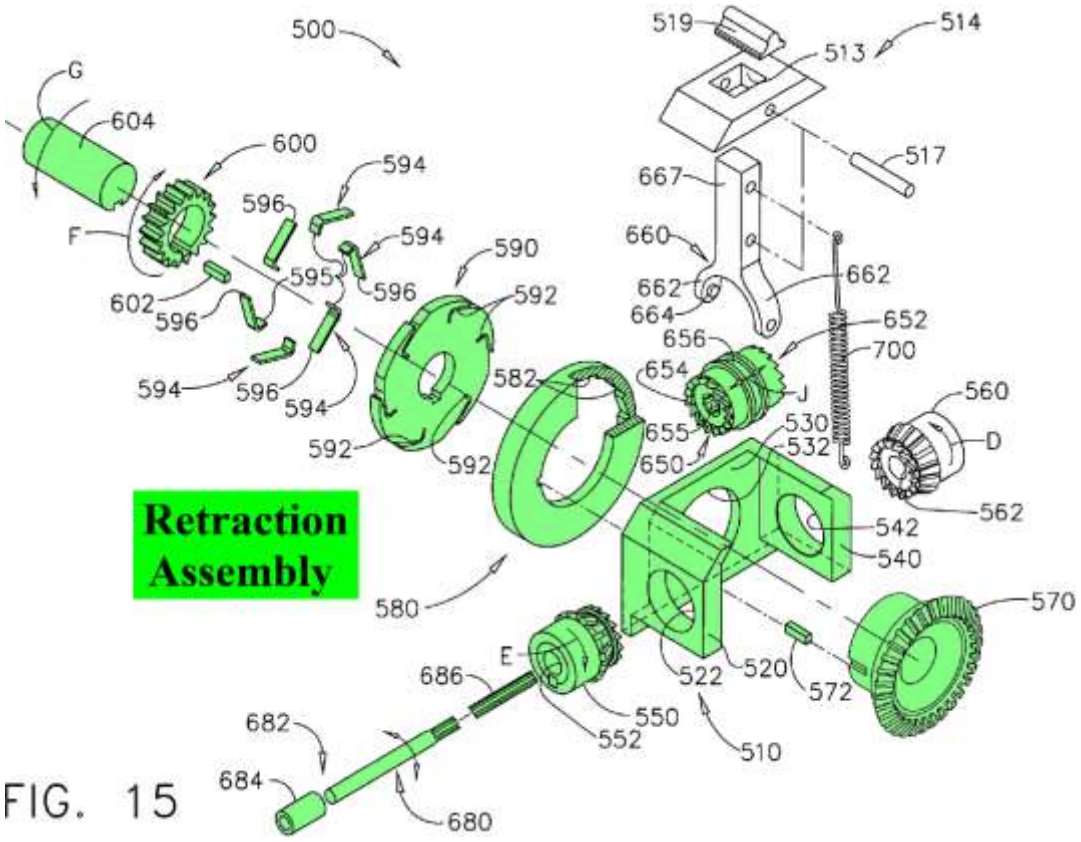


FIG. 15

When the user moves shifter gear 650 into engagement with left hand pinion gear 550 (via shifter button 519) and pulls trigger 610, shifter shaft 680 is driven in a direction that causes the firing drive components (planetary gear 400, firing screw, 240, and firing bar 210) to generate and communicate a longitudinal retraction motion to knife bar 30, moving knife bar 30 from a fired position to a retracted position. IS1003, ¶157 (citing Shelton I, 9:20-10:8, 11:25-12:12, 12:56-13:32, Figures 10, 15). Shelton I's retraction assembly is "manually actuated" (as claimed) because manual operation of shifter button 519 and firing trigger 610 by the user sets the components of the retraction assembly into motion. *Id*. As in Retraction Assembly Mapping #1, Shelton I's firing drive is completely manual,

meaning that no springs or force generating members apply a retraction force to it. *Id*. Thus, the longitudinal retraction motion generated by Shelton I's firing drive when Shelton I's retraction assembly is manually actuated is the "sole" retraction motion. *Id*.

Shelton I's "retraction assembly" is "supported by said handle assembly"

As discussed (*see* Element 1[c], *supra*), all of the components of Shelton I's surgical instrument—including the retraction assembly components (under both mappings)—are coupled to (directly or indirectly) and "supported by" housing 250 of handle assembly 200. IS1003, ¶153.

3[pre]: "The surgical instrument of claim 1 further comprising:"

See Elements 1[pre]-1[d], *supra*.

3[a]: "a closure drive supported by said handle assembly and configured to generate a closing motion and an opening motion; and"

Shelton I discloses Element 3[a]. IS1003, ¶¶158-159. As discussed (*see* Overview of Shelton I, *supra*), Shelton I's surgical instrument 10 includes a manually-actuated closure trigger 320 for opening and closing an anvil 40 of end effector 12. Shelton I, 7:44-8:61, Figures 10-12. When the user rotates closure trigger 320 inward (*i.e*., toward pistol grip 252), the applied torque is transmitted and converted by a linkage assembly 330 and a closure shuttle 300 into longitudinal motion that pushes a spine assembly 100 coupled to anvil 40 in the distal direction to close anvil 40. Shelton I, 4:65-5:39, 6:24-30, 7:57-9:19, 8:36-

61, Figures 2, 5-6, 11-12. When the user rotates closure trigger 320 outward (*i.e.*, away from pistol grip 252), linkage assembly 330 and closure shuttle 300 pull spine assembly 100 in the proximal direction to open anvil 40. *Id*. Thus, linkage assembly 330 and closure shuttle 300, are "configured to generate a closing motion"—*i.e.*, when closure trigger 320 is pulled inward—"and [further configured to generate] an opening motion"—*i.e.*, when closure trigger 320 is released outward. IS1003, ¶158. These components, therefore, correspond to the claimed "closure drive" (marked in navy blue below[19]). *Id*.

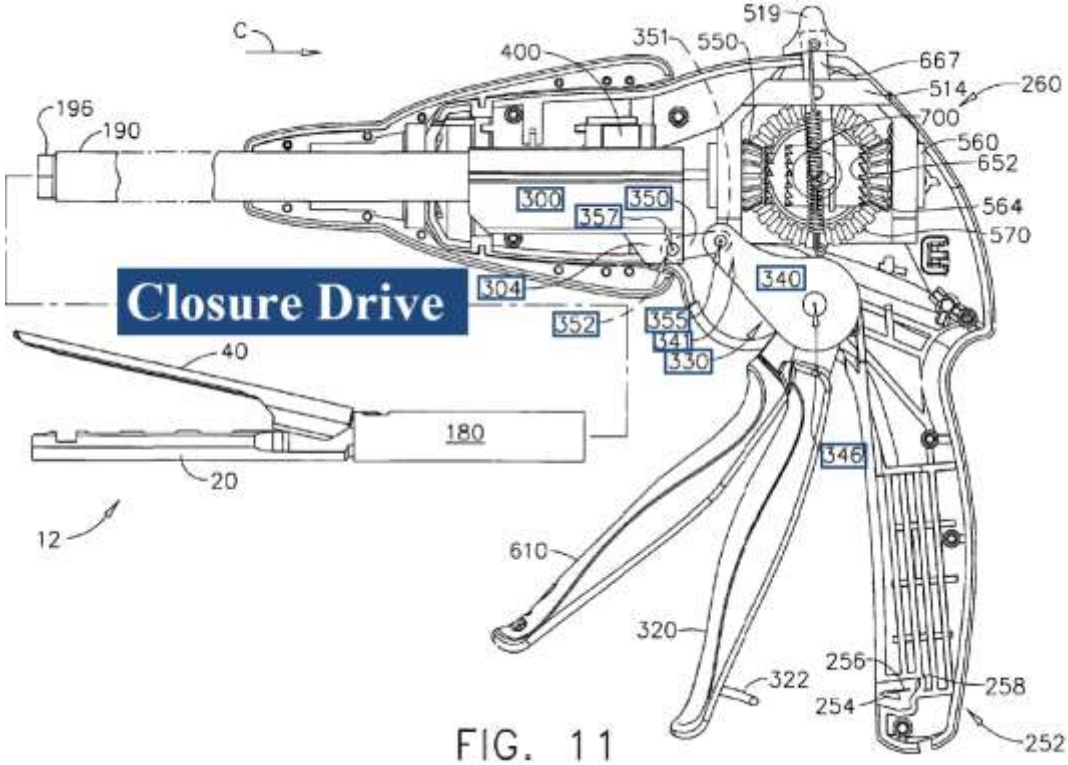


FIG. 11

[19] Subcomponents also in navy blue.

As discussed (*see* Element 1[c], *supra*), a POSITA would have understood that all of the components of Shelton I's surgical instrument—including the above-discussed closure drive components—are coupled to (directly or indirectly) and "supported by" housing 250 of handle assembly 200. IS1003, ¶159.

3[b]: "an elongate shaft assembly coupling said end effector to said handle assembly and configured to transfer said opening and closing motions and said firing and retraction motions thereto."

Shelton I discloses Element 3[b]. IS1003, ¶¶160-162. As discussed (*see* Overview of Shelton I; Elements 1[b.i], 3[a], *supra*), Shelton I's surgical instrument 10 includes an end effector 12 having an anvil 40 that:

1) closes when spine assembly 100 (to which it is attached) is pushed in the distal direction by a closure drive (*i.e.*, linkage assembly 330, closure shuttle 300; *see* Element 3[a], *supra*) in response to pulling closure trigger 320; and
2) opens when spine assembly 100 is pulled in the proximal direction by the closure drive in response to releasing closure trigger 320.

Shelton I, 4:8-24, 4:65-5:39, 6:24-30, 7:57-9:19, 8:36-61, Figures 2, 5-6, 11-12. As was also discussed (*see* Overview of Shelton I, *supra*), spine assembly 100 is telescopically mounted within a closure tube assembly 170 that engages with and actuates the end effector's anvil 40 based on relative movement between spine assembly 100 and closure tube assembly 170. *Id*. Thus, spine assembly 100 and closure tube assembly 170—together corresponding to the claimed "elongate shaft

assembly" (marked in magenta below[20])—are "configured to transfer said opening and closing motions" to end effector 12 (specifically anvil 40), just as claimed. IS1003, ¶160.

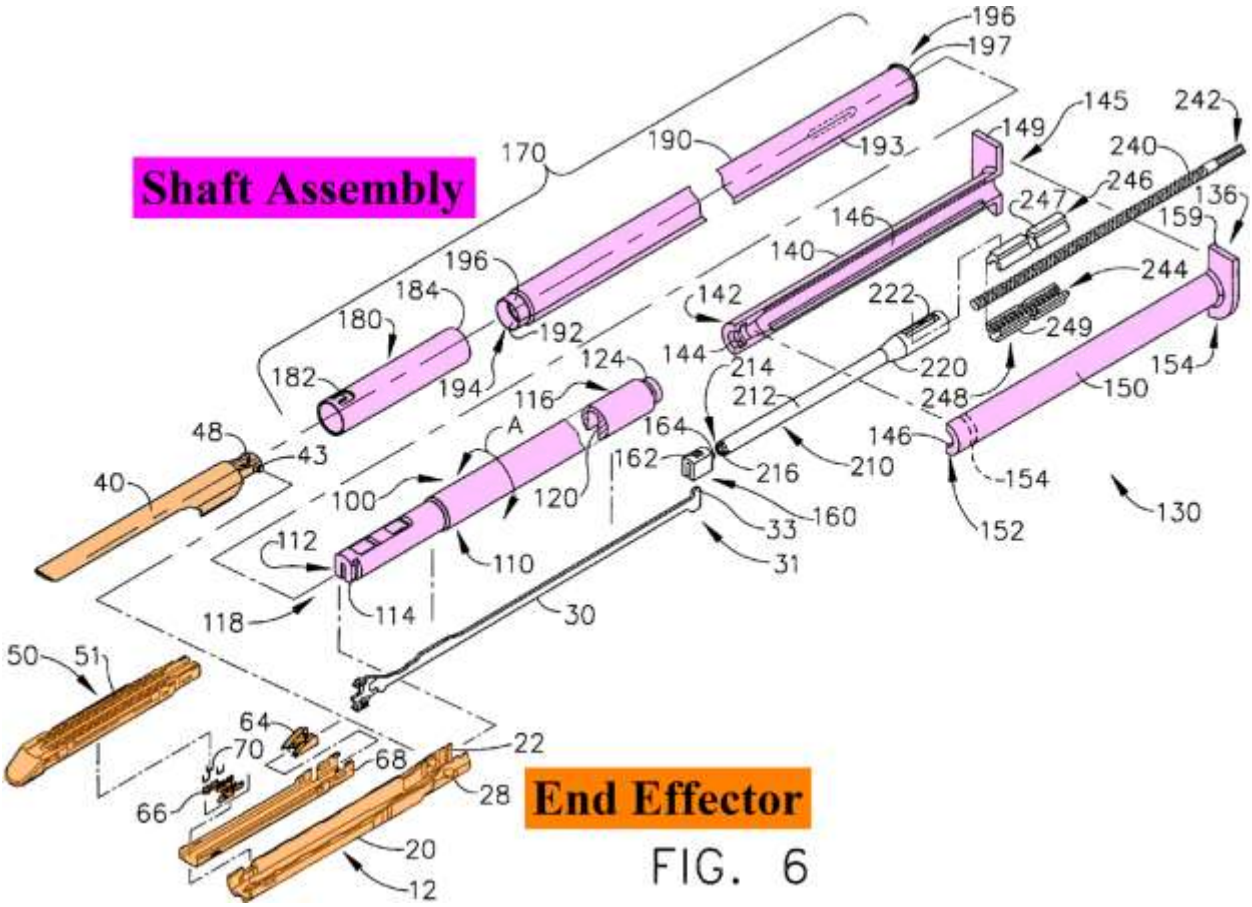


FIG. 6

Shelton I's "shaft assembly"—*i.e.*, spine assembly 100 and closure tube assembly 170—is also "configured to transfer . . . said firing and retraction motions" to end effector 12. IS1003, ¶161. As discussed (*see* Overview of Shelton I; Elements 1[c], 1[d], *supra*), Shelton I's firing drive (under both

[20] Subcomponents also in magenta.

mappings) includes a firing screw 240 and a firing bar 210 that communicate firing/retracting motions to knife bar 30 (mapped to the claimed "firing member" at Element 1[b.i], *supra*). Shelton I, 6:24-7:24, 9:20-64, 11:36-41, Figures 6, 10, 13-15. Firing screw 240 and firing bar 210 are supported to move telescopically within spine assembly 100. *Id*. Spine assembly 100—part of Shelton I's "shaft assembly"—transfers firing/retraction motions to end effector 12 (as claimed) because it supports the firing drive components that communicate the firing/retracting motions to the firing member (knife bar 30) that moves through end effector 12. IS1003, ¶161. The '749 Patent describes a similar paradigm, where elements of the firing drive are housed within a frame 28 mounted within a closure tube 24 of the shaft assembly 18. *Id* (discussing '749 Patent, 5:60-6:11, 7:-58, 9:10-26, Figures 4, 8).

In addition to transferring opening/closing and firing/retracting motions to end effector 12, Shelton I's shaft assembly "coupl[es] said end effector to said handle assembly," as claimed. IS1003, ¶162. To wit, end effector 12 is attached to spine assembly 100, and Shelton I specifically states that "[t]he elongate channel 20 [of end effector 12] is coupled to the handle assembly 200 by means of a spine assembly 100." Shelton I, 5:23-24 (emphasis added); *see also id*., 4:65-67, Figure 6.

XII. CONCLUSION

Petitioner requests *inter partes* review of the Challenged Claims pursuant to Grounds 1-3.

Respectfully submitted,

Dated March 27, 2019

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(Control No. IPR2019-00880)

Attorneys for Petitioner

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 13,973 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated March 27, 2019

/Joshua A. Griswold/
Joshua A. Griswold, Reg. No. 46,310
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Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on March 27, 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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