IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	David C. Yates et al.		
U.S. Patent No.:	8,602,287	Attorney Docket No.:	11030-0053IP1
Issue Date:	December 10, 2013		
Appl. Serial No.:	13/486,175		
Filing Date:	June 1, 2012		
Title:	MOTOR DRIVEN SURGICAL CUTTING INSTRUMENT		

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,602,287 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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IS1005	U.S. Pat. App. Pub. No. 2007/0175956 to Swayze et al. (“Swayze”)
IS1006	U.S. Pat. No. 4,346,335 to McInnis (“McInnis”)
IS1007	U.S. Pat. App. Pub. No. 2009/0090763 to Zemlok et al. (“Zemlok”)
IS1008	U.S. Pat. No. 6,953,139 to Milliman (“Milliman”)
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IS1012	U.S. Pat. No. 7,422,136 to Marczyk (“Marczyk”)

IS1013	Excerpts from D.P. Kothari, I.J. Nagrath, *Electric Machines*, Third Edition (2005) ("Kothari")
IS1014	U.S. Pat. App. Pub. No. 2008/0298784 to Kastner ("Kastner")
IS1015	U.S. Pat. No. 6,978,921 to Shelton et al. ("Shelton")
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IS1018	U.S. Pat. App. Pub. No. 2008/0078801 to Shelton et al. ("Shelton III")
IS1019	Excerpt from Webster's Ninth New Collegiate Dictionary (Merriam-Wester Inc. 1999) ("Webster's")

I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 13-15 and 17-18 of U.S. Pat. No. 8,602,287 ("the '287 patent"). The '287 patent relates to a "motor-driven surgical cutting and fastening instrument that comprises an end effector, an electric motor, and a motor control circuit." '287 patent, Abstract.

"The motor control circuit … adjustably control[s] movement of [a] moveable member of the end effector during forward rotation of the electric motor" by (1) switching between first and second operational modes during rotation of the motor in a first rotational direction; and (2) supplying more current to the motor in the second mode than in the first mode. *Id.*; *see also* Claims 13, 17. The motor control circuit operates in the first operational mode when a firing element of the instrument is positioned within a first range of positions, which is between an initial position and a second range of positions along the firing path. *Id*. And the motor control circuit operates in the second operational mode when the firing element is positioned within the second range of positions, which is between the first range of positions and an end-of-stroke position. *Id*.

As explained below, such instruments were obvious at the time of the earliest possible effective filing date of the '287 patent. Petitioner therefore requests IPR of claims 13-15 and 17-18.

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

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

Intuitive Surgical, Inc. is the real party-in-interest. No other party had access to the Petition, and no other party had any control over, or contributed to any funding of, the preparation of, or filing of the present Petition.

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

Petitioner is not aware of any disclaimers, reexamination certificates, or petitions for IPR of the '287 patent. The '287 patent is the subject of Civil Action No. 1:18-cv-1325-LPS, filed on August 27, 2018 in the United States District Court for the District of Delaware. Pending U.S. Pat. App. Nos. 14/847,831, 14/850,106, 14/850,130, 15/372,984, 15/805,898, and 16/146,065 claim priority to U.S. Pat. App. No. 13/486,175—the application from which the '287 patent issued. And the following IPRs involve patents that belong to Patent Owner and have been asserted against Petitioner in the United States District Court for the District of Delaware: *Intuitive Surgical, Inc. v. Ethicon LLC*, Case Nos. IPR2018-00933, -934, -935, -936, -938, -1247, -1248, -1254, -1703 and IPR2019-00880, -1066.

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 IPR11030-0053IP1@fr.com (referencing No. 11030-0053IP1 and cc'ing PTABInbound@fr.com, katz@fr.com, phillips@fr.com, and oconnor@fr.com).

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

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

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

A. Grounds for standing under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '287 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

B. Challenge under 37 C.F.R. § 42.104(b) and relief requested

Petitioner requests an IPR of claims 13-15 and 17-18 of the '287 patent on the grounds listed below. A declaration from Dr. Fischer is included in support.

Ground	Claims	Basis for Rejection
Ground 1	**13-15, 17-18**	Obvious over **Swayze** (IS1005) in view of **Smith** (IS1004) and also **Smith** in view of **Swayze** under pre-AIA 35 U.S.C. § 103.

Ground	Claims	Basis for Rejection
Ground 2	**13-15, 17-18**	Obvious over **Swayze** (IS1005) in view of **McInnis** (IS1006) under pre-AIA 35 U.S.C. § 103.
Ground 3	**13-15, 17-18**	Obvious over **Zemlok** (IS1007) in view of **Whitman** (IS1009) under pre-AIA 35 U.S.C. § 103.
Ground 4	**13-15, 17-18**	Obvious over **Zemlok** (IS1007) in view of **Milliman** (IS1008) and further in view of **Whitman** (IS1009) under pre-AIA 35 U.S.C. § 103.

The ’287 patent issued from U.S. App. No. 13/486,175, filed on June 1, 2012, which is a continuation of U.S. App. No. 12/235,782, filed on September 23, 2008, now U.S. Pat. No. 8,210,411. Thus, the earliest possible date to which the ’287 patent could claim priority is September 23, 2008.

Swayze, McInnis, Milliman, and Whitman each qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(b) because they are all patents that issued, or patent applications that published, more than one year before September 23, 2008. Except for McInnis, each of these references was made of record during prosecution of the ’287 patent, but none were discussed by the examiner or the applicant.[1]

Smith qualifies as prior art under at least pre-AIA 35 U.S.C § 102(a). The patent that issued from Smith’s priority applications (U.S. Pat. No. 8,038,046) was made of record during prosecution of the ’287 patent, but was never discussed by the examiner or the applicant.

[1] Applicants cited more than 2000 references during prosecution of the ’287 patent.

Zemlok qualifies as prior art under at least pre-AIA 35 U.S.C § 102(e). Zemlok was made of record during prosecution of the ’287 patent, but was never discussed by the examiner or the applicant. However, Zemlok II, which is a continuation-in-part of Zemlok, was cited and discussed by the examiner during prosecution of the ’287 patent.

V. SUMMARY OF THE ’287 PATENT

The ’287 patent describes a “motor-driven surgical cutting and fastening instrument that comprises an end effector, an electric motor, and a motor control circuit.” ’287 patent, Abstract. “[T]he end effector 12 is configured to act as an endocutter for clamping, severing and stapling tissue….” *Id.*, 3:21-27, Figs. 1-2. And the “electric motor 65 [is] disposed in an upper portion of the pistol grip portion 26 of the handle 6.” *Id.*, 6:12-14, Figs. 7-10.

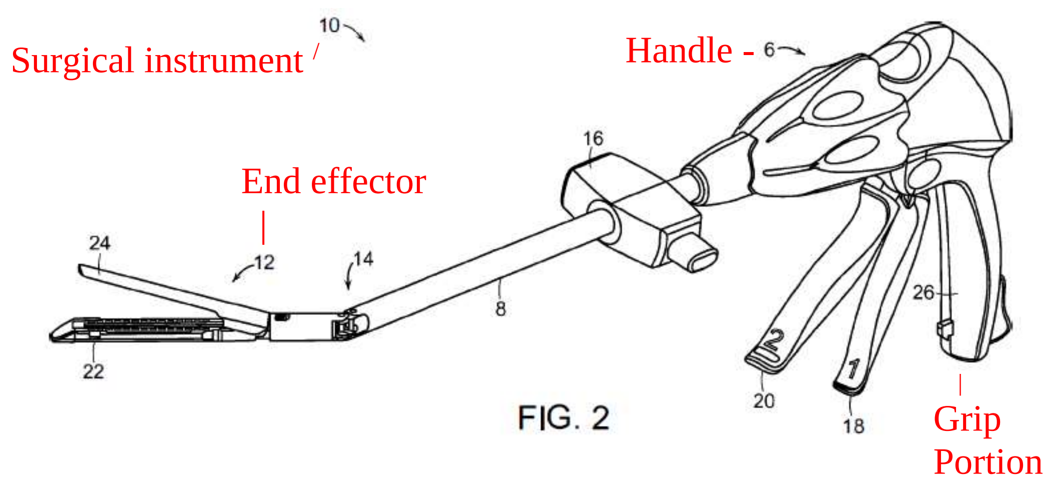
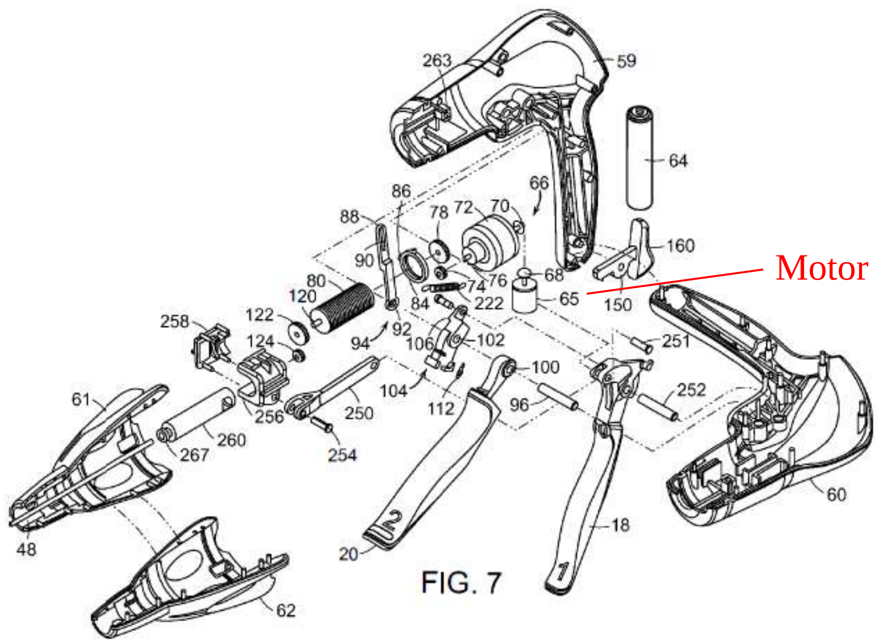
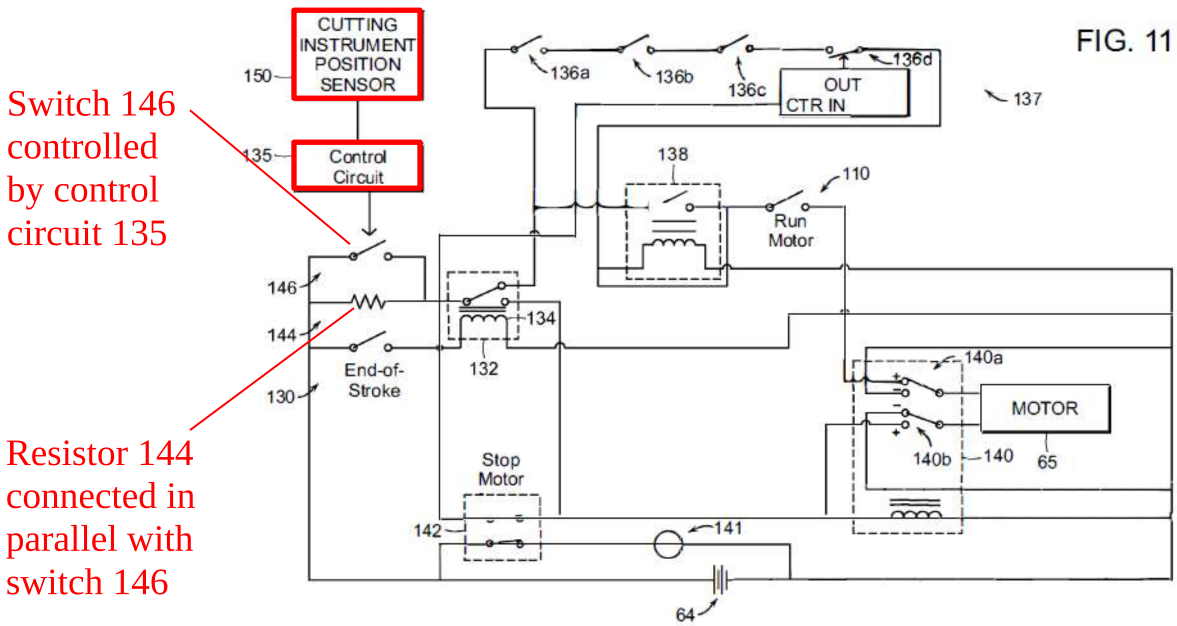


FIG. 2



In general, the "motor control circuit may comprise … a current control circuit … for varying the current supplied to the motor from the power source … and consequently, the output torque supplied by the motor, such that the motor has at least (i) a first, low power operational mode for a first portion of a cutting stroke cycle of the cutting instrument, and (ii) a second, high power operational mode for a second portion [of] the cutting stroke cycle of the cutting instrument." *Id.*, 1:65-2:9. "That way … the motor can start out at a low power mode at the beginning of the cutting stroke to provide a soft start quality." *Id.*, 2:10-12. This soft start functionality can "limit the sudden jerking start" of the cutting instrument and/or reduce "the likelihood of the motor overpowering the cartridge lockout mechanism." *Id.*, 12:33-39.

"FIG. 11 is a schematic diagram of the motor control circuit." *Id.*, 9:6-7.



As shown above, the circuit includes "a resistive element 144 and a switch 146 connected in parallel…. The switch 146 may be controlled by a control circuit [135[2]] that is responsive to the cutting instrument position sensor 150 [and] … may open the switch 146 when the cutting instrument 32 is … very near to the beginning of its stroke…." *Id.*, 9:24-34, Fig. 11. "[C]ontrol circuit 135 may comprise a processor and memory" or "analog timer circuits (*e.g.*, RC-based timer circuits) for controlling the switch timing of the switch[] 146." *Id.*, 14:12-15, 14:34-65.

When "switch 146 [is] open, current flows through the resistive element 144 … to the motor 65. Current flowing through the resistive element 144 reduces the magnitude of the current delivered to the motor 65, thereby reducing the power de-

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[2] Column 9, line 29 incorrectly refers to control circuit 135 as 148.

livered by the motor 65…. Conversely, once the cutting instrument 32 moves sufficiently far from its beginning point …, the control circuit [135] may close the switch 146, thereby shorting the resistive element 144, thereby increasing the current to the motor 65, thereby increasing the power delivered by the motor [65]." *Id*., 9:38-51, Fig. 11.

VI. SUMMARY OF THE PROSECUTION HISTORY

The chain of applications to which the '287 patent claims priority is provided above. *See* Section IV.B, *supra*. Original claims 1-3 were rejected as anticipated by Zemlok II. File History, 417-19. However, original dependent claim 4 (issued claim 1), was deemed allowable if rewritten in independent form. *Id*. at 420; *see also id.* at 514-18. In the statement of reasons for allowance, the examiner noted that switching between operational modes based on a determination of the cutting instrument's position was the perceived point of novelty for original claim 4. *Id*. at 420-21.

Applicant subsequently amended the pending claims as requested, added eight new claims (22-29), and, for the first time, disclosed more than 2000 prior art references. *Id*. at 249-332. Less than two weeks later, during an April 19, 2013 interview, the examiner indicated that original "claim 4 was in form for allowance," but that new original claim 22 (issued claim 13) "could be interpreted to read on by

[sic] the prior art" (*e.g.*, Zemlok II).[3] *Id.*, 86. The examiner suggested incorporating the subject matter of new original claim 23, which more specifically defined the first and second ranges of positions, and Applicant agreed. *Id*. The examiner then issued a new notice of allowance reciting the same reasons for allowance as the first notice of allowance. *Id.*, 15-17.

VII. CLAIM CONSTRUCTION

For purposes of this proceeding only, Petitioner submits constructions for the following terms. All remaining terms should be given their plain and ordinary meaning.

A. "Firing element" (claims 13 and 17)

This term invokes pre-AIA 35 U.S.C. § 112, ¶ 6 because it claims a function without disclosing sufficient structure for performing that function. Fischer Decl., ¶35. The term "element" is a nonce word. The prefix "firing" does not impart suf-

[3] Unlike original claim 4, new original claim 22 did not define the locations of the cutting instrument associated with the first and second operational modes or require controlling the motor according to a switching architecture as a result of a sensor's determination of the position of a cutting instrument.

ficient structure. *Id*. And the specification does not provide any structural definition for the claimed "firing element." *Id*. In fact, the term "firing element" appears only in the claims of the '287 patent. *Id*.

The functions recited in the claims are firing and moving along a firing path. *Id*. The corresponding structure is cutting instrument/knife 32. *Id*., ¶37; '287 patent, 4:23-28, 4:38-53, 5:35-54, Figs. 3, 5.

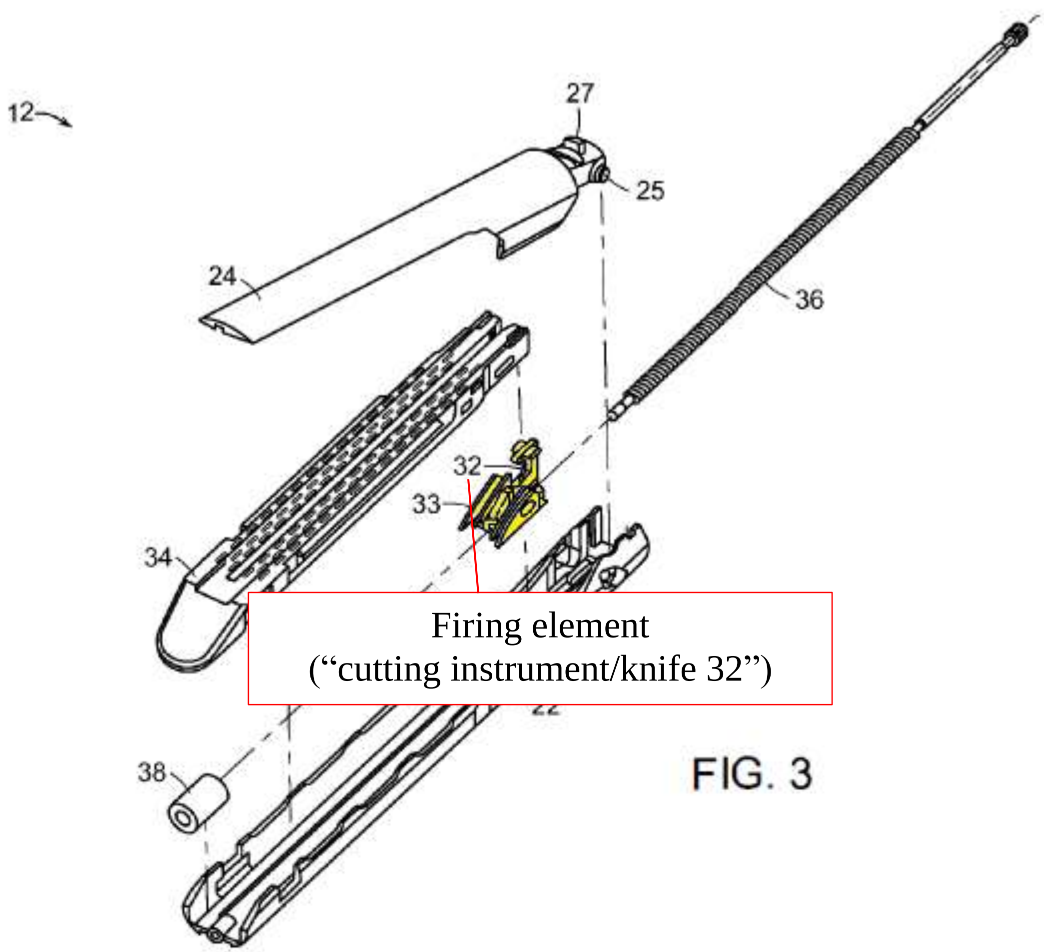


FIG. 3

B. "Initial position" (claims 13 and 17)

In the co-pending litigation, Patent Owner alleges infringement of the '287 patent by surgical staplers that, unlike the embodiments disclosed in the '287 patent, use an "I-beam" to perform both a clamping operation and a firing operation. IS1017, ¶¶61-72. More importantly, Patent Owner alleges that the I-beam is the claimed "firing element" and that the starting point of the I-beam for the clamping operation is the claimed "initial position." *Id*. However, it is clear from the plain language of the claims and the specification that the claimed "initial position" is the starting point of the firing element for the firing operation.

For example, claims 13 and 17 each recite "a firing element … configured to move along a firing path, and wherein the firing path comprises: an initial position." This context confirms that the "initial position" is the starting point of the firing element on the firing path. And the plain meaning of "firing path" is the path (track) for the firing operation. Webster's, 862 (defining "path" to mean "a track specially constructed for a particular use"); '287 patent, 10:5 ("firing operations").

The specification of the '287 is consistent with the plain language of the claims. Indeed, the firing operation is the only operation disclosed in the specification of the '287 patent wherein the firing element (knife 32) moves along a firing path. Fischer Decl., ¶40. Thus, in every disclosed embodiment, the "initial position" of the firing element is necessarily the starting point of the firing element for the firing operation.

C. "Operational mode" (claims 13 and 17)

In the co-pending litigation, Patent Owner alleges infringement of the '287 patent by surgical staplers that, unlike the embodiments disclosed in the '287 patent, use a motor to perform both a clamping operation and a firing operation. IS1017, ¶¶61-72. More specifically, Patent Owner alleges that the clamping operation is the claimed "first operational mode" and that the firing operation is the claimed "second operational mode." *Id.* However, it is clear from the plain language of the claims and the specification that each claimed "operational mode" is a phase of the firing operation.

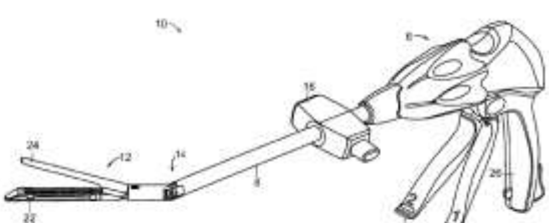
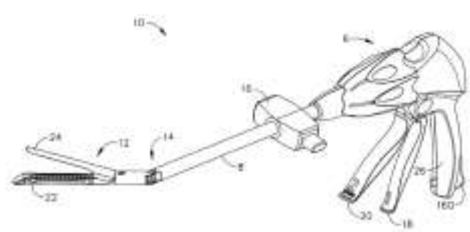
For example, claims 13 and 17 each recites that "the control circuit operates in the [first | second] operational mode when the firing element is positioned within a [first | second] range of positions *along the firing path*." And, as explained above, the plain meaning of "firing path" is a path (track) for the firing operation. Section VII.B.

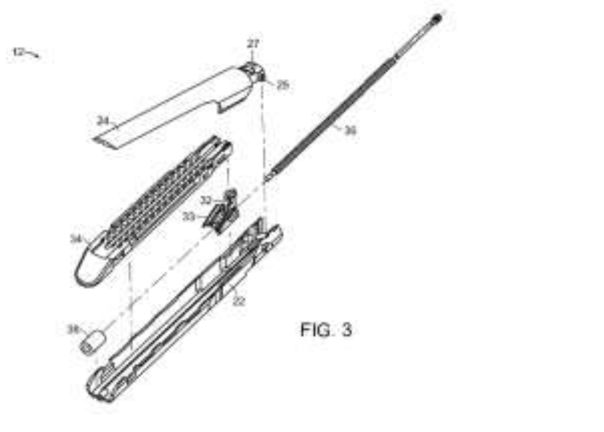
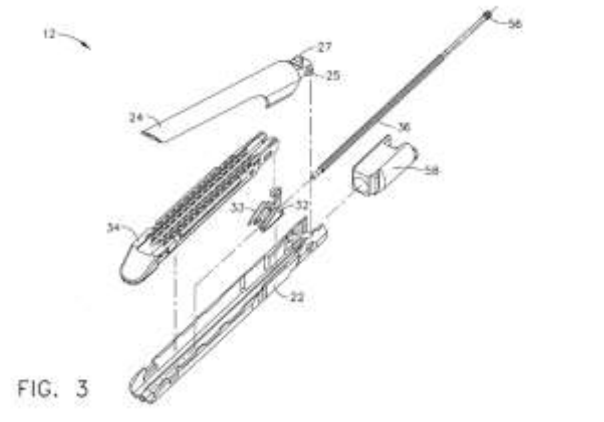
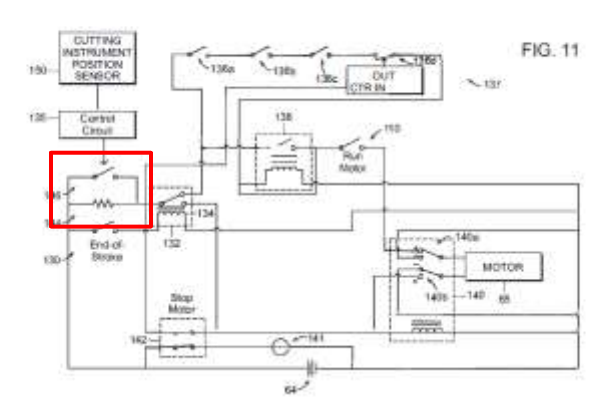
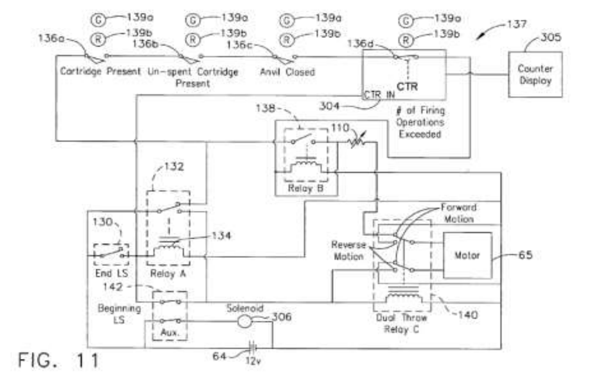
The specification is consistent with the plain language of the claims. For example, the specification exclusively discloses embodiments in which the clamping operation is a purely manual (*i.e.*, not motor-driven) operation, and current is supplied to a motor in a given "operational mode" only when a firing trigger activates sensor/switch 110 and only "***after*** locking the closure trigger." Fischer Decl., ¶¶43, 47; '287 patent, 1:22-29, 1:37-43, 1:65-2:20, 4:38-45, 6:33-55, 6:61-64, 8:21-67, 9:15-21, 9:24-51, 12:4-41, 13:36-44. Not surprisingly, the specification equates running the motor with the firing operation. '287 patent, 15:26 ("run motor (or fire) switch 110"). And, in every disclosed embodiment, the motor current is varied between operational modes only during the firing operation. Fischer Decl., ¶¶43-48.

VIII. SUMMARY OF THE PRIOR ART

A. Swayze

Swayze discloses a surgical instrument that is essentially identical to the surgical instrument disclosed in the '287 patent, except that it does not disclose a conventional soft start circuit (identified by the red box below) in the motor control circuit. Fischer Decl., ¶49; *compare* '287 patent, Figs. 2, 3, 11 *with* Swayze, Figs. 2, 3, 11.

'287 Patent	**Swayze**
 FIG. 2	 FIG. 2

’287 Patent	**Swayze**
 FIG. 3	 FIG. 3
 FIG. 11	 FIG. 11

Like the ’287 patent, Swayze broadly and unequivocally states that Shelton is “incorporated by reference” because it “provides more details about such two stroke cutting and fastening instruments.” Swayze, ¶49. This statement incorporates all of Shelton into Swayze as if it were set out expressly rather than through incorporation. *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000);

Fischer Decl., ¶53.[4] Notably, Shelton discloses that an integral wedge sled, like Swayze's sled 32, "provides an opportunity for a number of lockout features" (*e.g.*, a "spent cartridge lockout") and incorporates Shelton II by reference because it describes those lockout features "in greater detail." Swayze, ¶49; Shelton, 1:8-28, 10:27-38.

B. Smith

Smith discloses a motor control circuit for a linear surgical stapler that is configured to switch between a low force mode and a high force mode—based on the position of a knife blade 1060—to ensure that a "lock-out feature," which prevents inadvertent movement of blade 1060, is not overpowered by the motor. Smith, ¶199.

Figure 32 of Smith is "an exemplary embodiment of an end effector" of a linear stapler comprising: a sled 102; a knife blade 1060 with lower guide wings 1065; a cartridge holder 1030 with a floor 1034; an edge 1035; and a depression 1037. *Id.*, ¶¶73, 199, Fig. 32.

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[4] *See also Biscotti Inc. v. Microsoft Corp.*, No. 2:13-CV-01015-JRG-RSP, 2017 U.S. Dist. LEXIS 144164, at *12 (E.D. Tex. May 11, 2017).

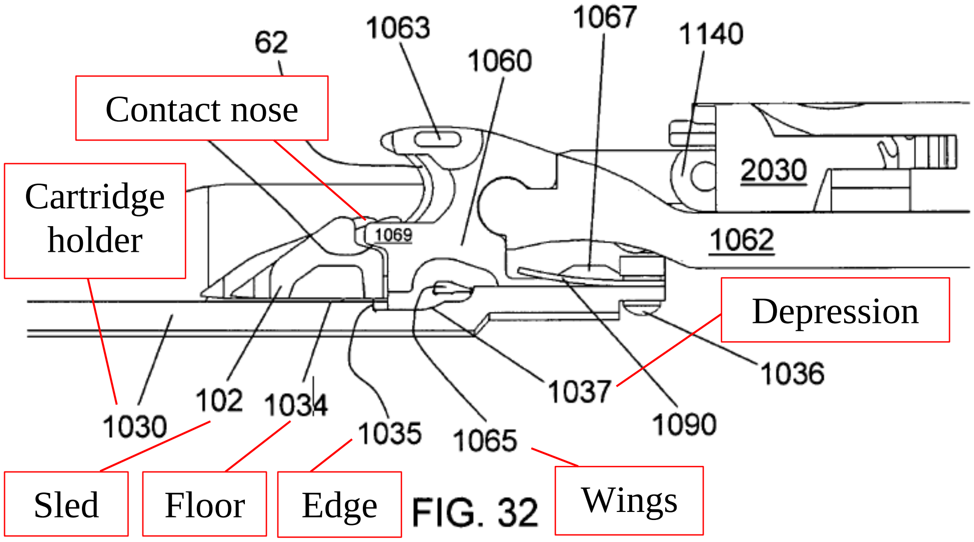


FIG. 32

As explained in Smith, "knife blade 1060 should be allowed to move distally only when … sled 102 is in the position illustrated in FIG. 32." *Id.*, ¶199. If sled 102 is not present in this position to prop up contact nose 1069 of blade 1060 because, for example, no staple cartridge is installed or the staple cartridge has been fired, "blade 1060 should not be allowed to move, or should be restricted in its movement." *Id.*, ¶199, Fig. 32. Thus, Smith's "lock-out feature" allows lower guide wings 1065 of blade 1060 to follow depression 1037 and hit edge 1035 if sled 102 is not present to prevent further forward movement of blade 1060. *Id.*

However, "[w]ith the forces able to be generated by the power supply, motor and drive train of [Smith], the blade 1060 can be pushed distally so strongly that the wings 1065 are torn away." *Id.*, ¶200; *see also* ¶199. Thus, Smith's control circuit operates in a low force mode to move blade 1060 from its initial position to a position after wings 1065 clear edge 1035, and then operates in a high force mode for the remainder of the cutting stroke. *Id*. Smith's control circuit provides this functionality using a "two-part force generation limiter" circuit wherein "only one or a few of the cells in the power supply are connected to the motor during the first part of the stapling/cutting stroke" and "most or all of the cells in the power supply are connected to the motor" in the "second part of the stapling/cutting stroke." *Id*.; *see also* Figs. 33, 35.

In one embodiment, the two-part force generation limiter circuit includes four power cells 602 and a switch 1100 that can be in position A or B.

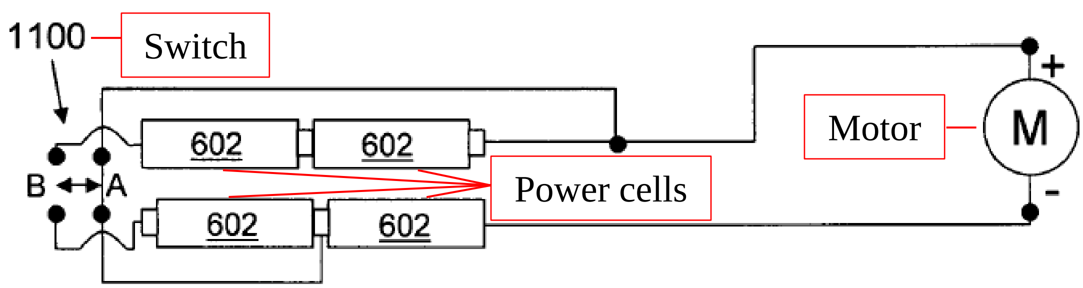


FIG. 33

In a similar embodiment, the two-part force generation limiter circuit includes six power cells 602, 602' and a switch 1100 that can be in position A or B as well as additional functionality.

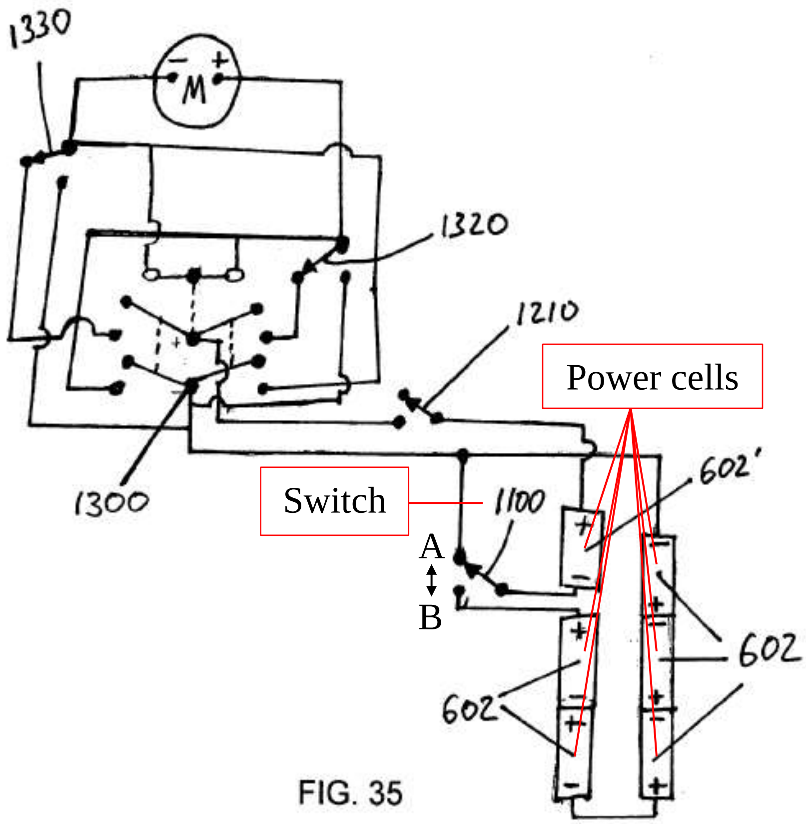


FIG. 35

As shown below, in both embodiments, "when the switch 1100 is in the 'A' position, the motor (*e.g.*, stapling motor 210 [("M")]) is only powered with one power cell 602 [or 602']." *Id.*, ¶¶200, 205.

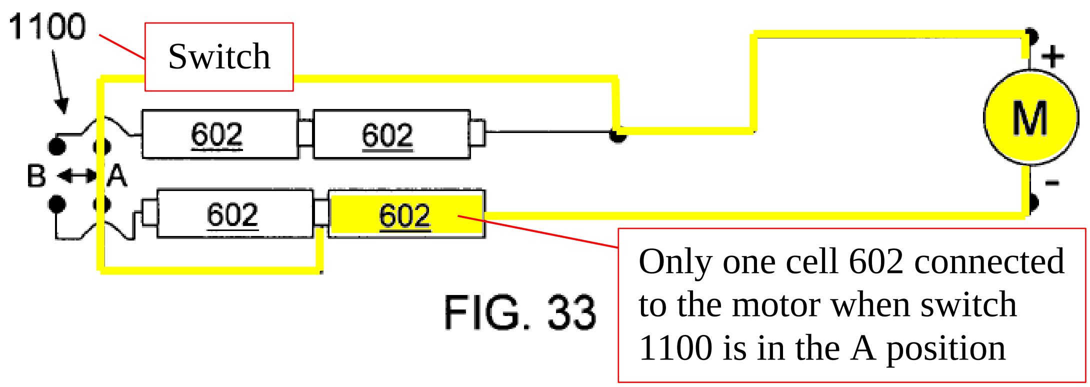


FIG. 33

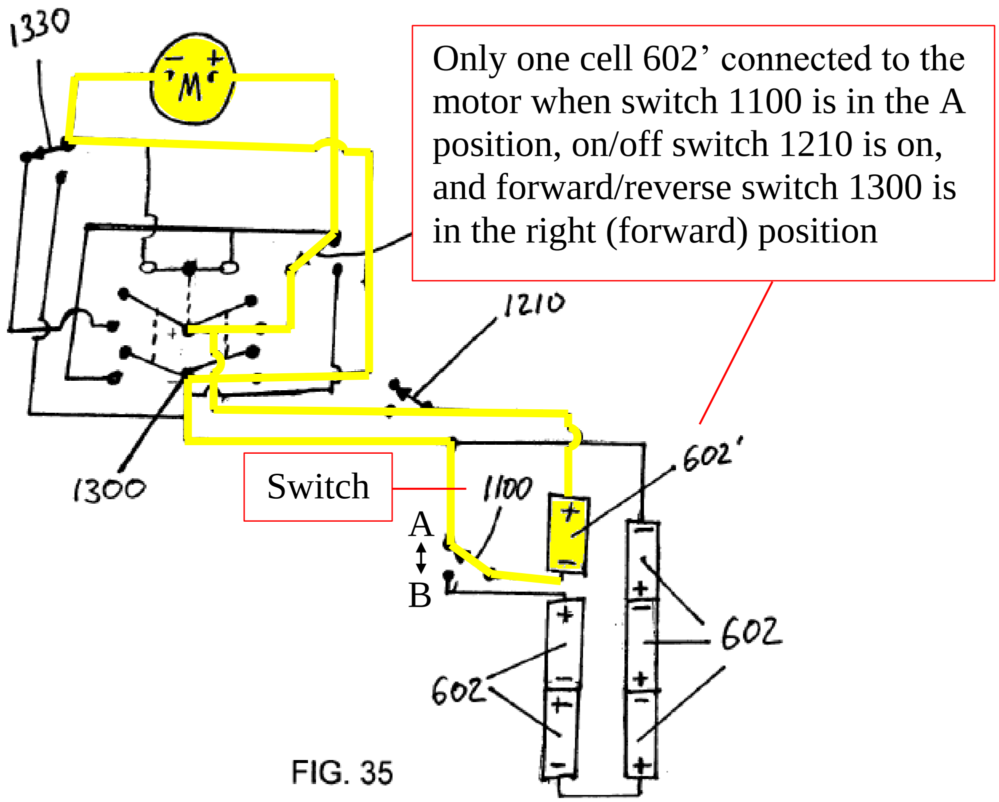


FIG. 35

"However, when the switch 1100 is in the 'B' position, the motor is powered with all … of the cells 602 of the power supply 600, thereby increasing the amount of force that can be supplied to the blade 1060." *Id.*

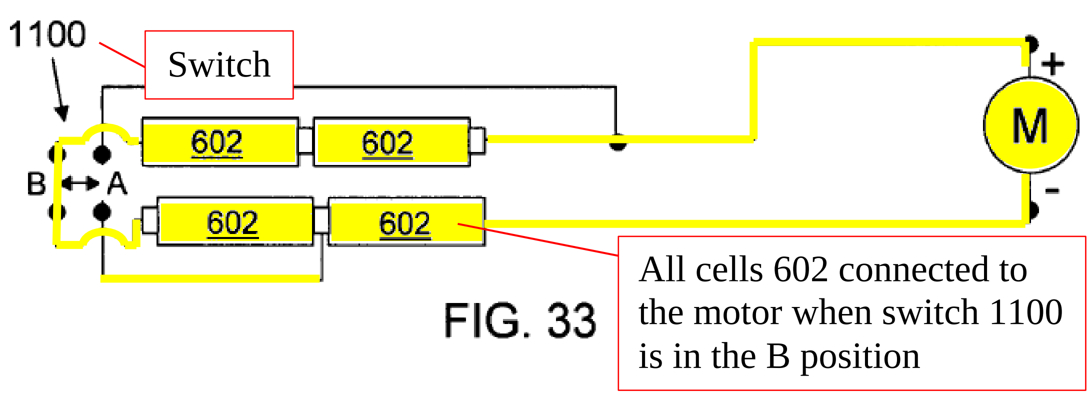


FIG. 33

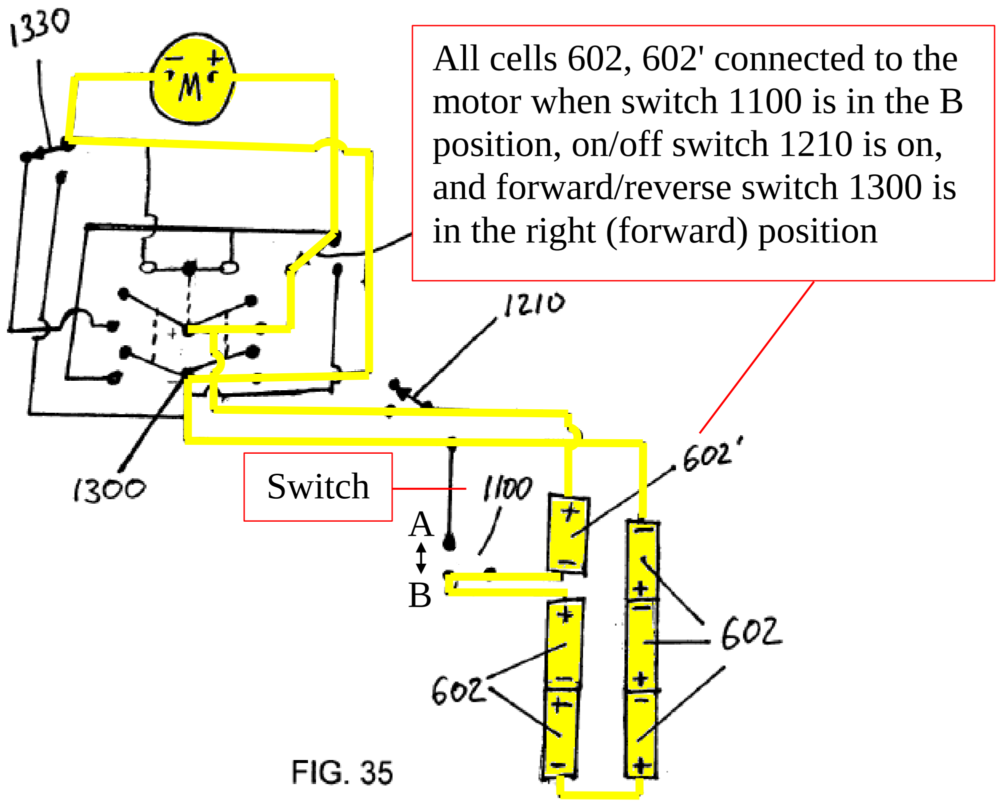


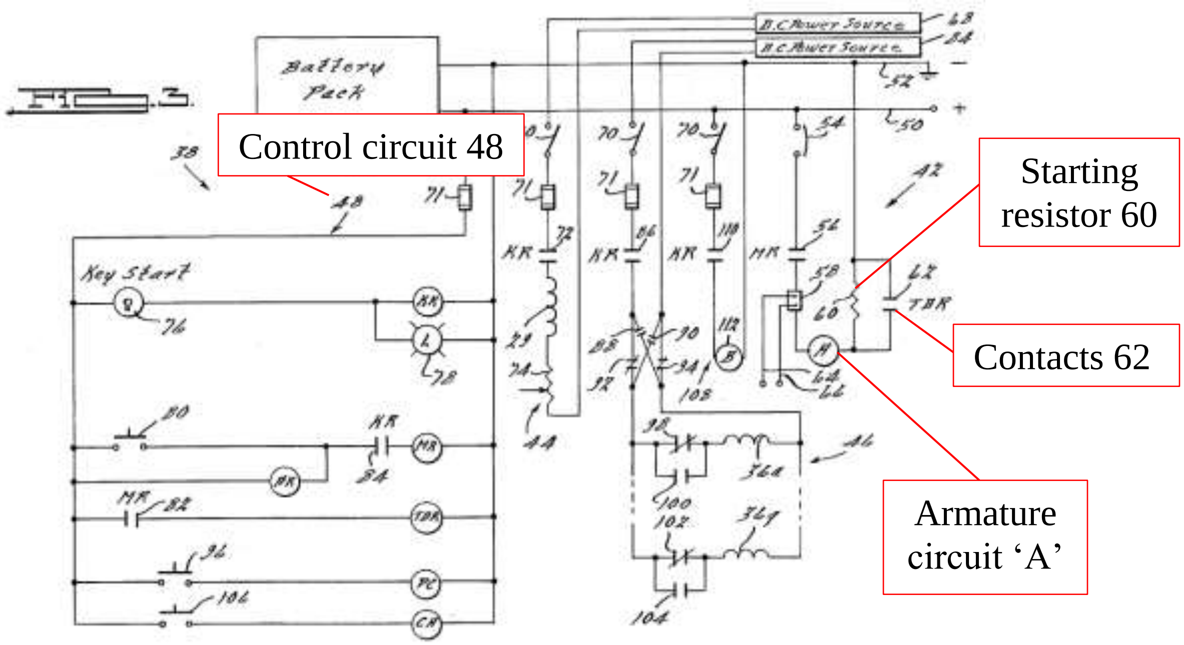
FIG. 35

"Control of the switch 1100 between the A and B positions can occur by positioning a second switch somewhere along the blade control assembly or along the sled 102, the second switch sending a signal to a controller after the wings 1065 have passed the edge 1035." *Id.*; *see also* ¶¶116-17. "Alternatively, encoders [or pulse generators] can be used instead of limit switches…." *Id.*, ¶121.

Thus, when blade 1060 is in the first part of the stapling/cutting stroke, switch 1100 is in position A and the motor is powered with only one cell 602. This reduces the amount of current that can be supplied to the motor if wings 1065 of blade 1060 are held in place by edge 1035 because, for example, there is no staple cartridge. When a fresh, unfired staple cartridge is installed, wings 1065 can clear edge 1035. At that point, switch 1100 is moved to position B and the motor is powered with all of the cells 602 of the power supply 600, which increases the current that can be supplied to the motor. *Id.*, ¶¶199-200, Figs. 33, 35.

C. McInnis

McInnis discloses a soft start assembly for an electric motor comprising a "starting resistor 60 … connected in series with the armature circuit 'A' [of the motor] to prevent a high in rush of current when the motor is started, as is conventional in the art." McInnis, 5:56-59, Fig. 3. McInnis also discloses "contacts 62 [that] are connected across starting resistor 60 to provide a short circuit across this resistor [60] shortly after the motor is started." *Id.*, 5:59-62.



In one embodiment, "[c]ontacts 62 are controlled by a time delay relay 'TDR' in relay control circuit 48." *Id.*, 5:62-63. However, McInnis confirms that "other switching means may also be utilized. Accordingly, the relays may be replaced by conventional electronic components…. Additionally, the D.C. electric motor … may utilize a micro-computer or programmable controller as the basis of a motor controller in the appropriate application." *Id*., 9:1-11.

McInnis is analogous art as it is either in the same field of endeavor as the claimed invention or is reasonably pertinent to the problem faced by the inventors. Fischer Decl., ¶71; *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004); *see also Medtronic, Inc. v. Cardiac Pacemakers*, 721 F.2d 1563, 1573–74 (Fed. Cir. 1983) (holding that a POSITA of pacemaker design "faced with a rate-limiting problem … would look to the solutions of others faced with rate limiting problems" not in the context of pacemakers). Indeed, faced with the problem of "limiting the motor's ability to exert full load immediately," a POSITA would have considered the solutions of others faced with the same problem—such as McInnis, which describes the solution as "conventional in the art" of controlling D.C. electric motors. Fischer Decl., ¶71; '287 patent, 12:33-39; McInnis, 5:56-59; *see also* McInnis, 5:33-37 (confirming that its motor controller for an electric vehicle "may be suitably modified for other appropriate motor control applications"); Kothari, pp. 370-371 (confirming that McInnis's solution is conventional and broadly applicable). Moreover, the functional and structural similarities between the motor control circuits of McInnis and the '287 patent would have led a POSITA working in the specific field of motor control circuits for surgical instruments to consider similar motor control circuits, including McInnis's motor control circuit. *See, e.g., In re Bigio*, 381 F.3d at 1325-26 (the Board correctly consulted "the structure and function of the claimed invention" in concluding that "one of ordinary skill in the art working in the specific field of hairbrushes [would have been led] to consider all similar brushes including toothbrushes").

D. Zemlok

Zemlok discloses the same features of Zemlok II that were cited by the examiner during prosecution of the '287 patent. Fischer Decl., ¶73. Zemlok's motor-powered surgical instrument 10, which includes linear surgical stapler end effector 160, is shown below in Figure 1 of Zemlok:

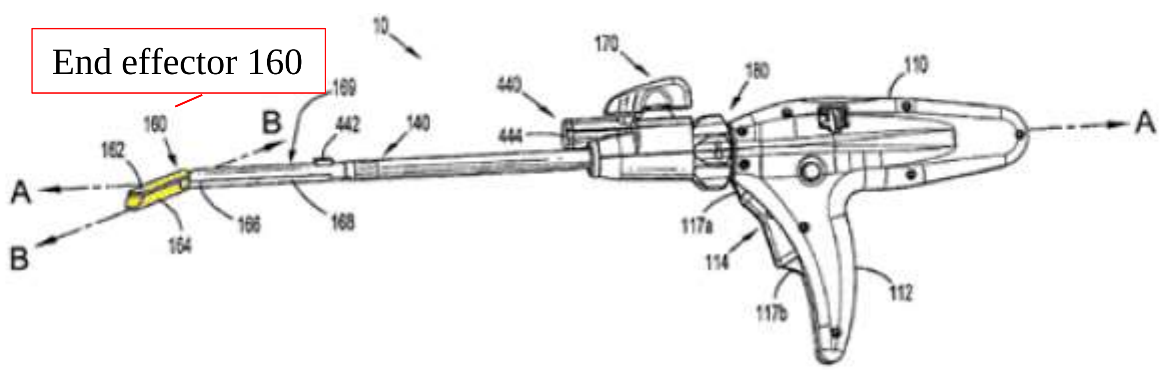


FIG. 1

Zemlok, Fig. 1. Zemlok broadly and unequivocally states that "the disclosure of [Milliman] is hereby incorporated by reference herein" for "[f]urther details of firing and otherwise actuating end effector 160." Zemlok, ¶81; *see also* ¶88. This statement incorporates all of Milliman into Zemlok as if it were set out expressly rather than through incorporation. *Harari*, 656 F.3d at 1335; *Advanced Display*, 212 F.3d at 1282; *Biscotti*, 2017 U.S. Dist. LEXIS 144164, at *12; Fischer Decl., ¶75.

Zemlok II is a continuation-in-part of Zemlok and the PTO has already found that the portions of Zemlok included in Zemlok II disclose everything in challenged claims 13-14 except operating the control circuit in the first (low current) operational mode ***when the firing element is positioned between the initial position and the second range of positions*** (the first range of positions) and operating the control circuit in the second (high current) operational mode ***when the firing element is positioned between the first range of positions and the end-of-stroke position*** (the second range of positions). File History, 217-22, 417-19; *see also* 86-94.

E. Whitman

Figure 13 of Whitman discloses a control system for controlling a motor-powered surgical stapler.

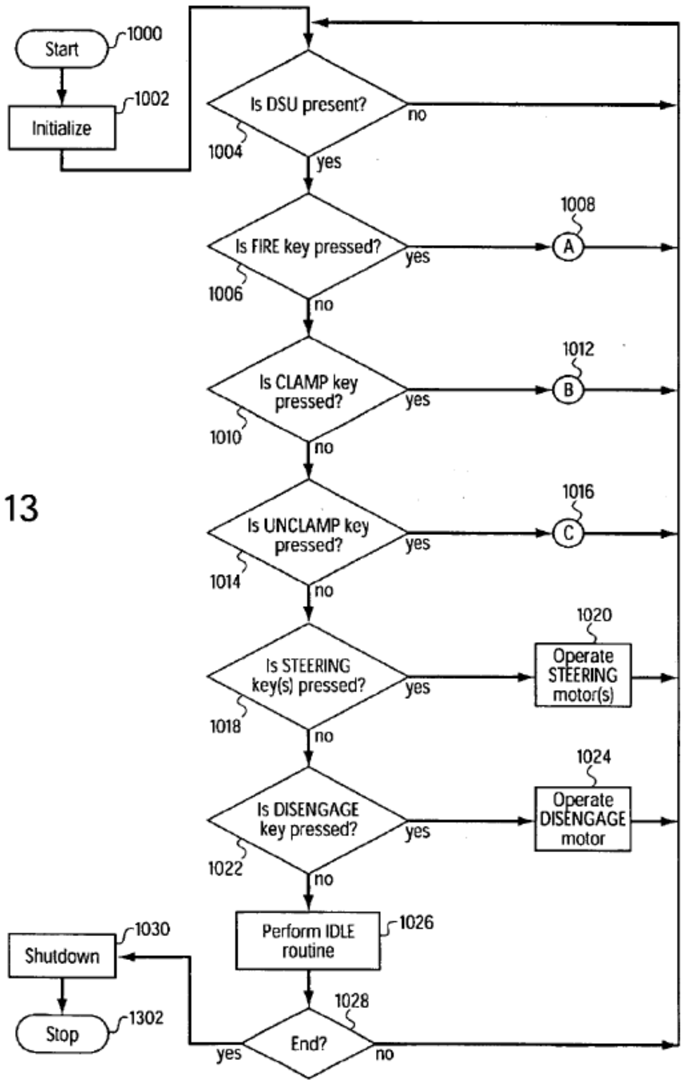
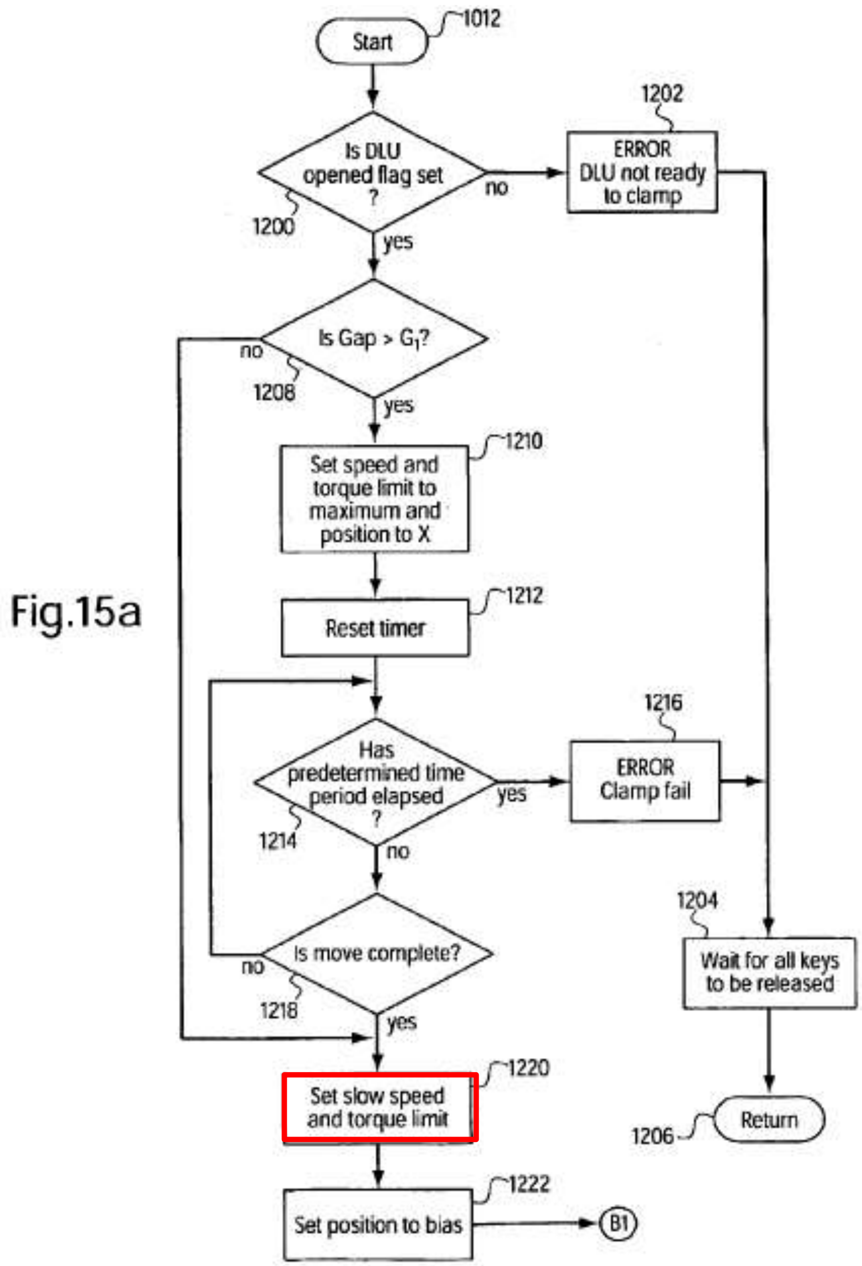


Fig. 13

Whitman, Abstract, 4:1-3, 4:22-65, Figs. 1, 13. And Figures 15a-b of Whitman illustrate the clamping routine. *Id.*, 4:7-9, Figs. 15a-b. As shown below, the torque/current limit is reduced in step 1220:



Id.; *see also* 17:33-18:13.

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '287 PATENT IS UNPATENTABLE

For the reasons explained below, claims 13-15 and 17-18 of the '287 patent are unpatentable.

A. Ground 1: Claims 13-15 and 17-18 are obvious over Swayze in view of Smith and Smith in view of Swayze

[13.1] A surgical instrument, comprising:

If the preamble is deemed to be a limitation, Swayze discloses it. Fischer Decl., ¶80. Specifically, Swayze discloses a surgical instrument ("surgical cutting and fastening instrument 10"). *Id*.; Swayze, ¶43, Fig. 2.

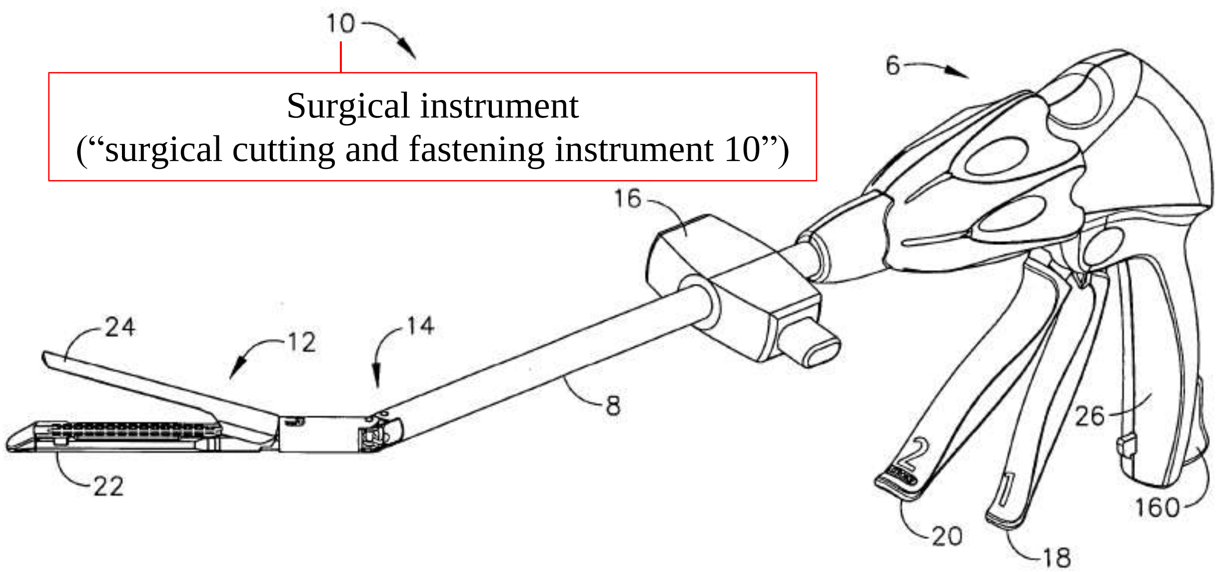


FIG. 2

[13.2] an end effector comprising a firing element, wherein the firing element is configured to move along a firing path, and wherein the firing path comprises: an initial position; and an end-of-stroke position;

Swayze discloses this element. Fischer Decl., ¶81.

"<u>An end effector comprising</u>"

Swayze's "surgical cutting and stapling instrument [10] includes an end effector [12]." *Id*., ¶82; Swayze, Abstract, ¶¶25, 38, 44, Figs. 2-5.

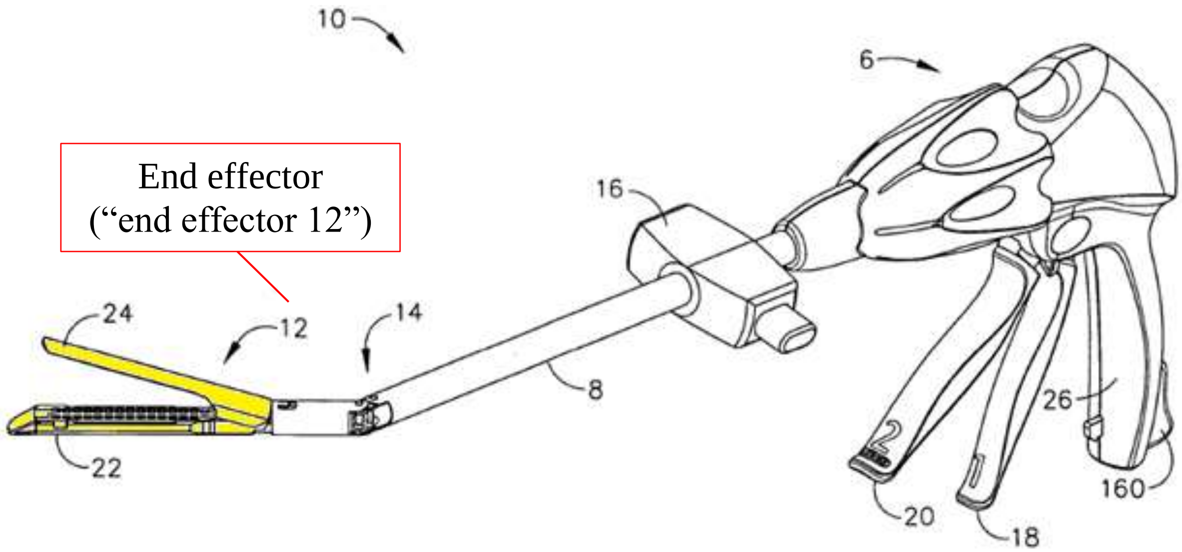
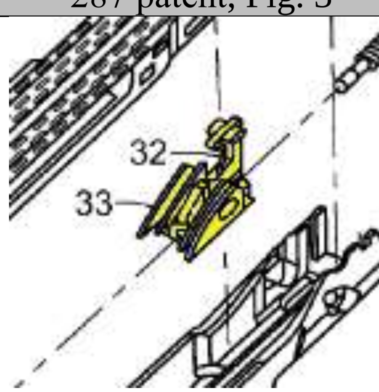
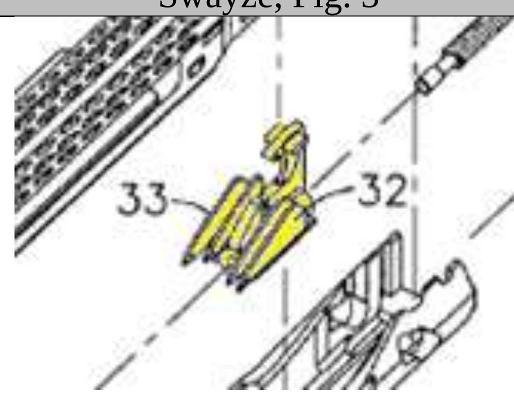


FIG. 2

"<u>A firing element, wherein the firing element is configured to move along a firing path, and wherein the firing path comprises: an initial position; and an end-of-stroke position</u>"

As explained above in Section VII.A, "firing element" invokes 35 U.S.C. § 112, ¶ 6 and the corresponding structure is knife 32. Swayze discloses the same structure. Swayze, ¶¶49, 52, Figs. 3, 5-6.

'287 patent, Fig. 3	Swayze, Fig. 3
	

Like the ’287 patent’s firing element, the function of Swayze’s firing element is firing and moving along a firing path comprising an initial position (proximal, “un-fired position,” which is the starting point of the firing element for the firing operation) and an end-of-stroke position (distal, “fully deployed,” “end-of-stroke” position). Fischer Decl., ¶84; *compare* ’287 patent, Figs. 3, 6 *with* Swayze, ¶¶69, 74, 78, 81, 109, Figs. 3, 6.

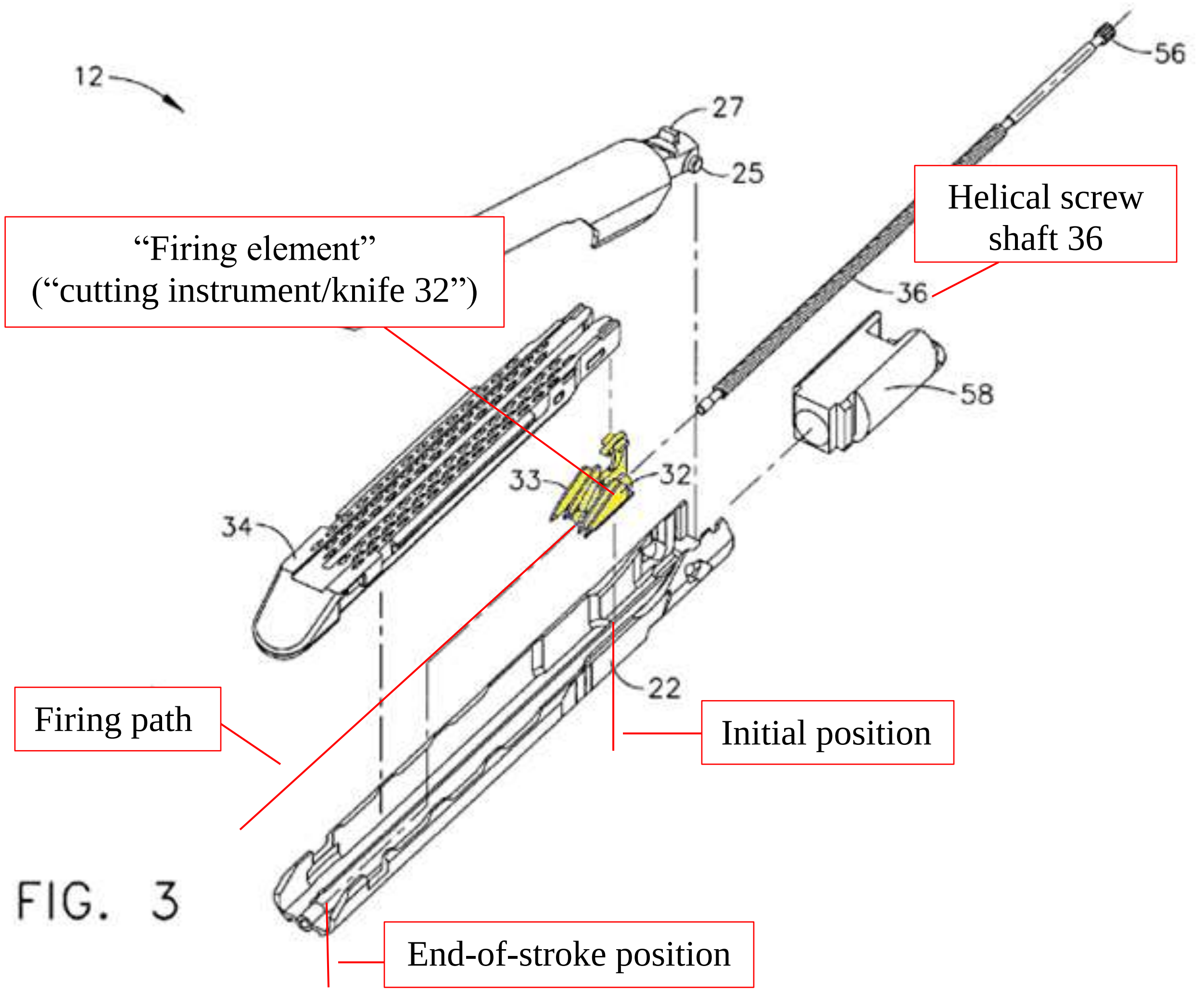


FIG. 3

[13.3] an electric motor, wherein the electric motor drives the firing element in a first direction along the firing path when the electric motor is rotated in a first rotational direction; and

Swayze discloses this element. Fischer Decl., ¶85. Swayze discloses an electric motor (motor 65) that drives the firing element (knife 32) in a first direction (distally) along the firing path when motor 65 rotates in a first rotational direction (forward), which rotates helical screw shaft 36. *Id.*; Swayze, ¶¶52, 54, 59, 61, 79-81, 103, Fig. 7.

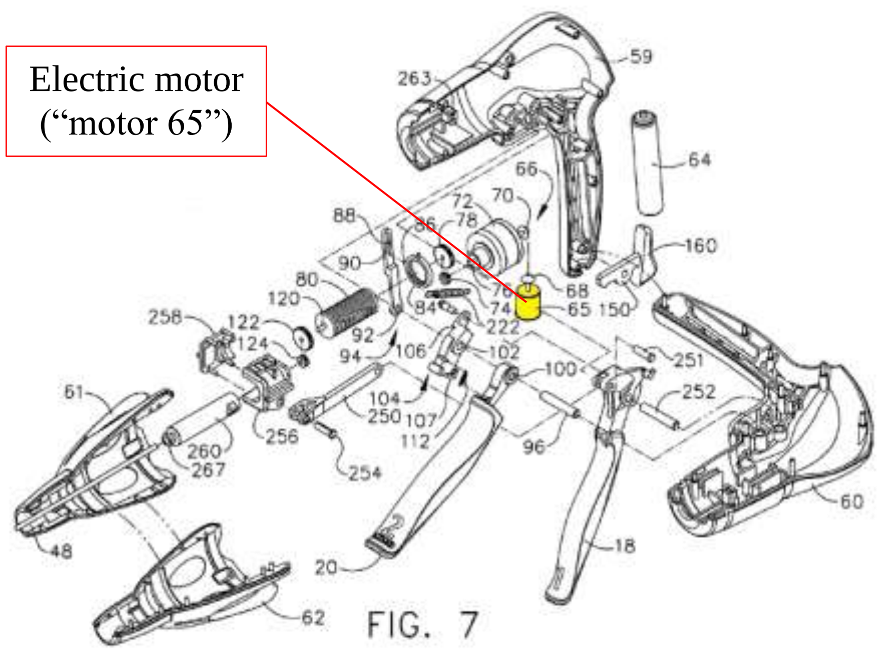


FIG. 7

As explained in Swayze, "forward rotation of the motor 65 … causes deployment of the knife 32 in the end effector 12. That is, the knife 32 and sled 33 are caused to traverse the channel 22 longitudinally [in the distal direction], thereby cutting tissue clamped in the end effector 12." *Id.*, ¶61.

[13.4] a control circuit for controlling the electric motor, wherein the control circuit is configured to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction, and wherein the plurality of operational modes comprises:

Swayze in view of Smith and Smith in view of Swayze both disclose this element. Fischer Decl., ¶87.

"<u>A control circuit for controlling the electric motor</u>"

Swayze discloses a control circuit (combination of Swayze's "electrical circuit" and "control circuit") for controlling electric motor 65. *Id.*, ¶88; Swayze, ¶¶59-60, 62, 67, 109, 112, Fig. 11. Figure 11 of Swayze "is a schematic diagram of an electrical circuit of the instrument 10." Swayze, ¶67, Fig. 11. As shown below, the electrical circuit includes "interlock circuit 137 through which current … must pass in order for electrical operation of the motor 65 to be initiated," a "reverse motor sensor 130," which is activated "[w]hen the end effector 12 reaches the end of its stroke" and "causes the motor 65 to reverse its rotational direction," and a "stop motor (or beginning-of-stroke) sensor 142," which removes power from motor 65 when "knife 32 is fully retracted." *Id.*, ¶¶59-60, 81-82, Fig. 11.

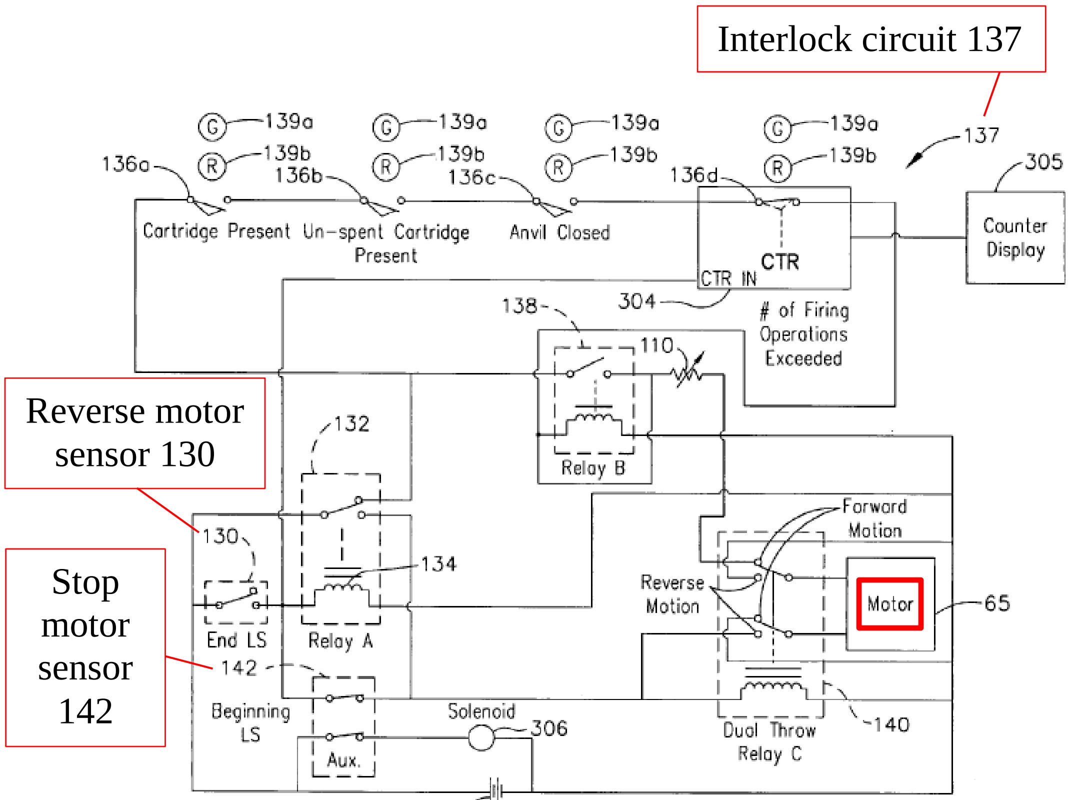


FIG. 11

In the embodiment shown above, reverse and stop motor sensors 130, 142 are limit switches. *Id.*, ¶¶59-60. In other embodiments, "instrument 10 also includes a control circuit (not shown), which may be implemented using a microcontroller … that receives the digital signals from [an] encoder 268." *Id.*, ¶109. "Based on the signals from the encoder 268, the control circuit … can calculate if the knife 32 is fully deployed, fully retracted, or at an intermittent [sic] stage" and, for example, "send a signal to the motor 65 to reverse direction to cause retraction of the knife 32." *Id.*, ¶¶109, 112; *see also* ¶108, Fig. 38.

The embodiments that include the control circuit and encoder 268 are not illustrated in Swayze. Thus, we show them below in Figure 11A, which is a copy of

Figure 11 that has been: (1) supplemented to show Swayze's control circuit and encoder 268; and (2) modified by replacing limit switches 130, 142 with corresponding switches that are controlled by the control circuit.

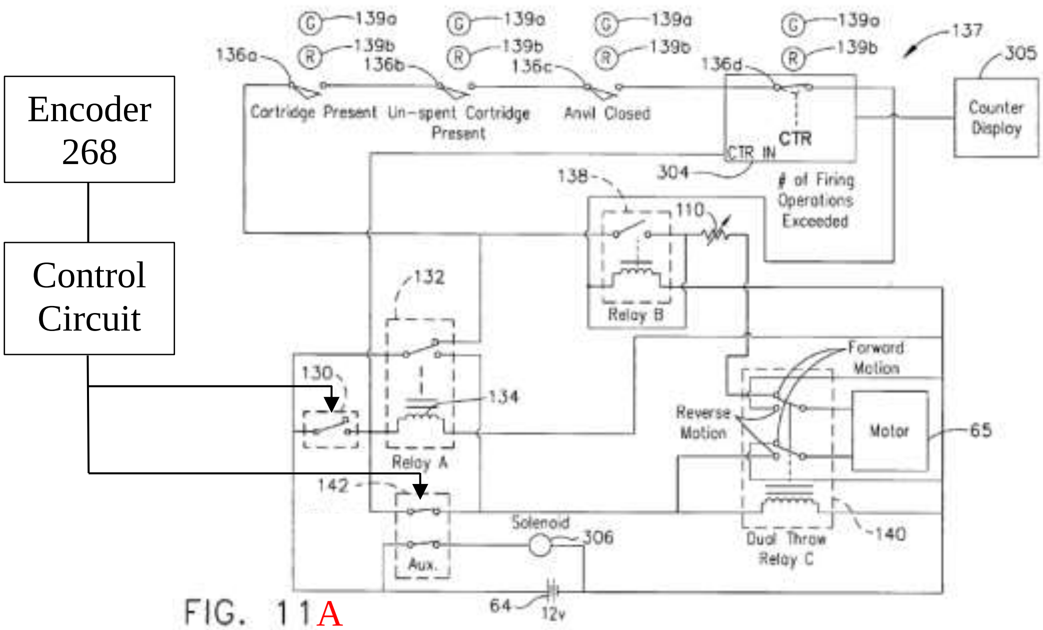


FIG. 11A

"Wherein the control circuit is configured to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction"

It would have been obvious in view of Smith to modify Swayze's control circuit to switch between operational modes during rotation of the electric motor in the first rotational direction. Fischer Decl., ¶91. It also would have been obvious in view of Swayze to modify Smith's control circuit for use with Swayze's instrument to create essentially the same device. We discuss both options below.

Like Swayze, Smith discloses a motor-powered "linear stapling device" that includes "an end effector" with a firing element (knife blade 1060) and a "lock-out feature." *Id.*, ¶92; Smith, ¶¶73, 80, 97, 119, 150, 158, 199, Fig. 32.

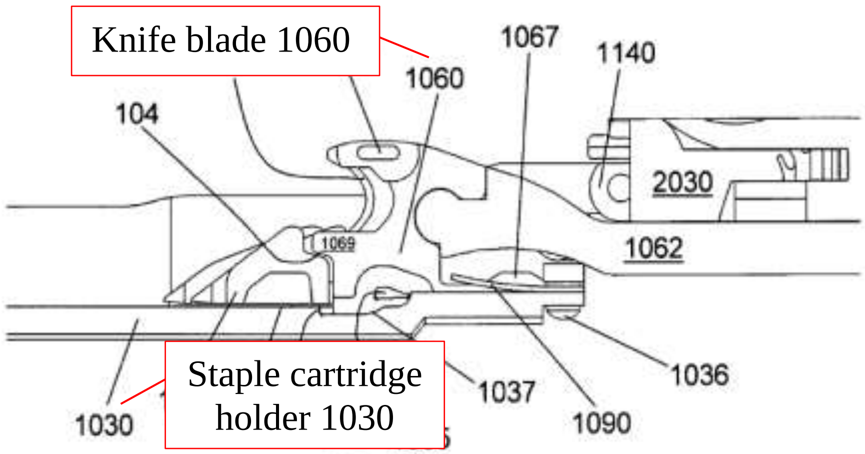


FIG. 32

Smith also discloses a control circuit 500 for controlling an electric motor 210 of the linear stapling device. Fischer Decl., ¶93; Smith, ¶¶74, 105, 112, 115, 116, 200, Figs. 33, 35. Smith's control circuit includes a "two-part force generation limiter" circuit that is configured to switch between a low force mode and a high force mode during rotation of the electric motor in the first rotational direction. *Id.*

In one embodiment, the two-part force generation limiter circuit includes four power cells 602 (batteries) and a switch 1100 that can be in position A or B.

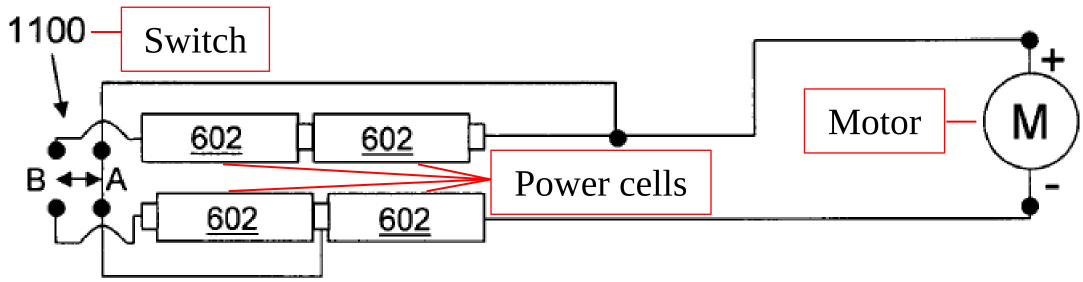


FIG. 33

In a similar embodiment, the circuit includes six power cells 602, 602' and a switch 1100 that can be in position A or B.

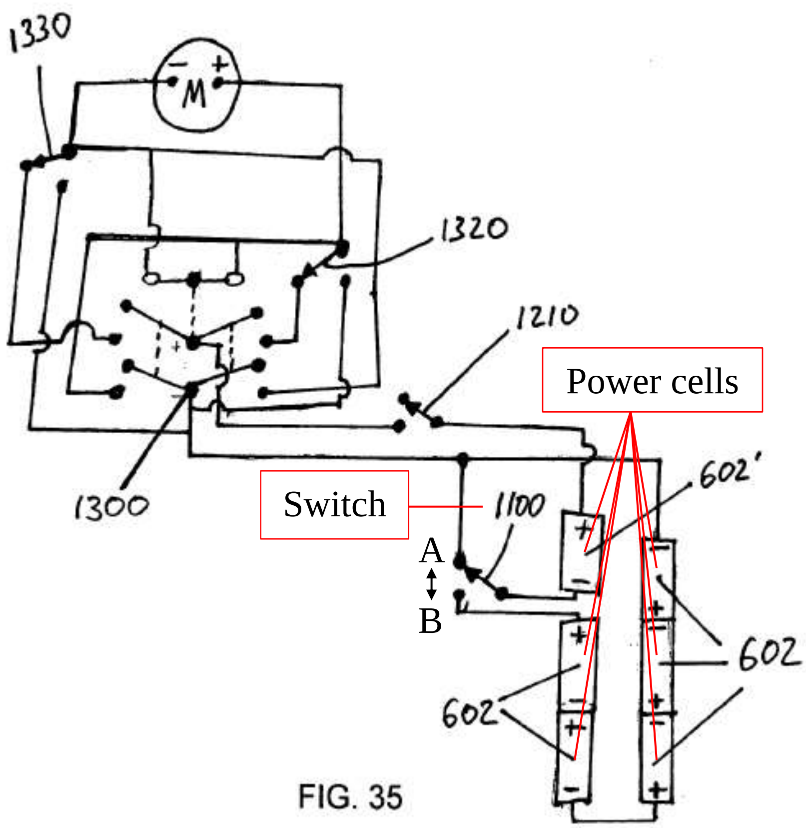


FIG. 35

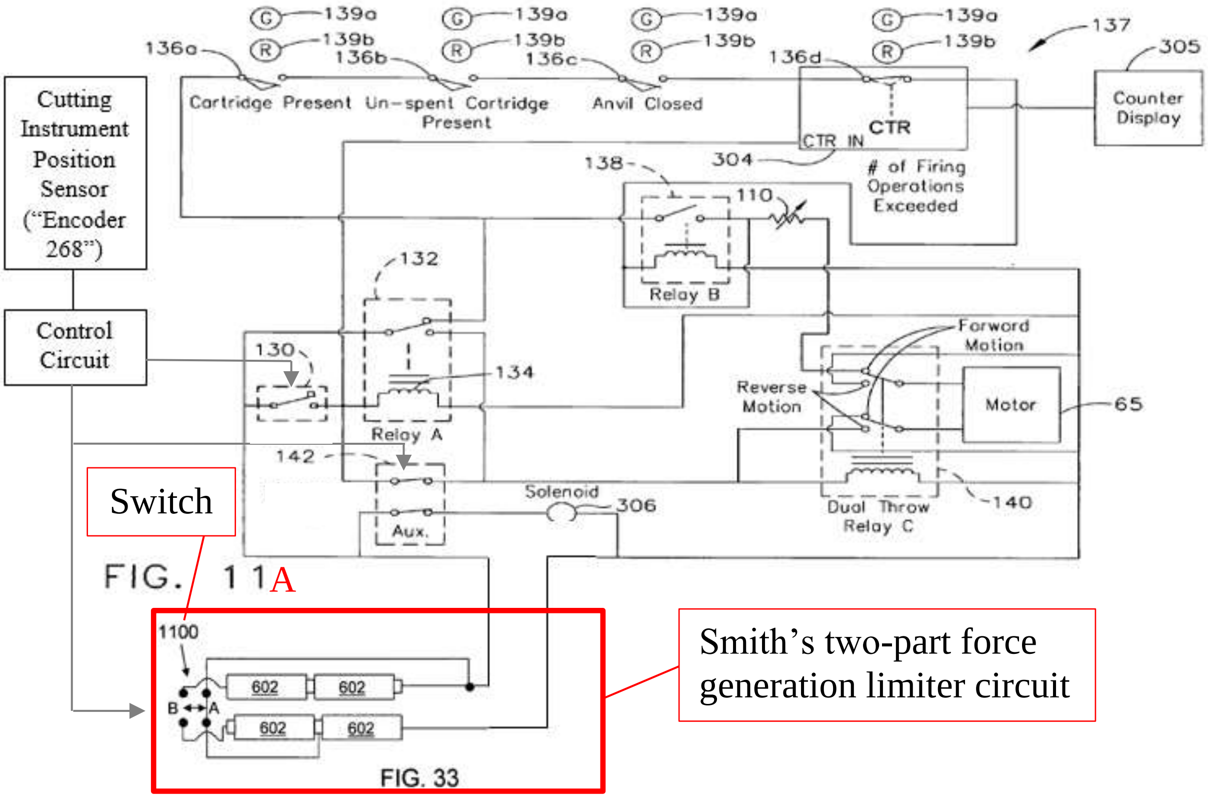
As shown above in Section VIII.B, "when the switch 1100 is in the 'A' position, the motor [(M)] is only powered with one power cell 602 [or 602']." *Id.*, ¶¶200, 205. "However, when the switch 1100 is in the 'B' position, the motor is powered with all … of the cells 602 of the power supply 600, thereby increasing the amount of force that can be supplied to the blade 1060." *Id*.

The "switch 1100 between the A and B positions" occurs during rotation of the motor because it is controlled "by positioning a second switch somewhere along the blade control assembly or along the sled 102, the second switch sending a signal to a controller after the wings 1065 have passed the edge 1035." *Id*.; *see also* Fischer Decl., ¶99.

Swayze in view of Smith

In the device resulting from the modification of Swayze in view of Smith, Smith's two-part force generation limiter circuit and associated power cells 602 (batteries) would replace Swayze's battery 64, and Swayze's modified control circuit would: (1) determine, based on signals from encoder 268, when knife 32 passes the spent cartridge lockout, and (2) control the position of Smith's switch 1100, and consequently the number of power cells powering the motor.

The resulting circuits are shown below in the composite images of Swayze's Figure 11A and Smith's Figures 33 and 35.


Cutting Instrument Position Sensor ("Encoder 268")
Control Circuit
Cartridge Present
Un-spent Cartridge Present
Anvil Closed
CTR
CTR IN
# of Firing Operations Exceeded
Counter Display
Relay B
Relay A
Forward Motion
Reverse Motion
Motor
Dual Throw Relay C
Solenoid
Aux.
136a
136b
136c
136d
139a
139b
137
305
304
138
110
132
130
134
142
306
140
65
Switch
FIG. 11A
1100
602
B
A
FIG. 33
Smith's two-part force generation limiter circuit

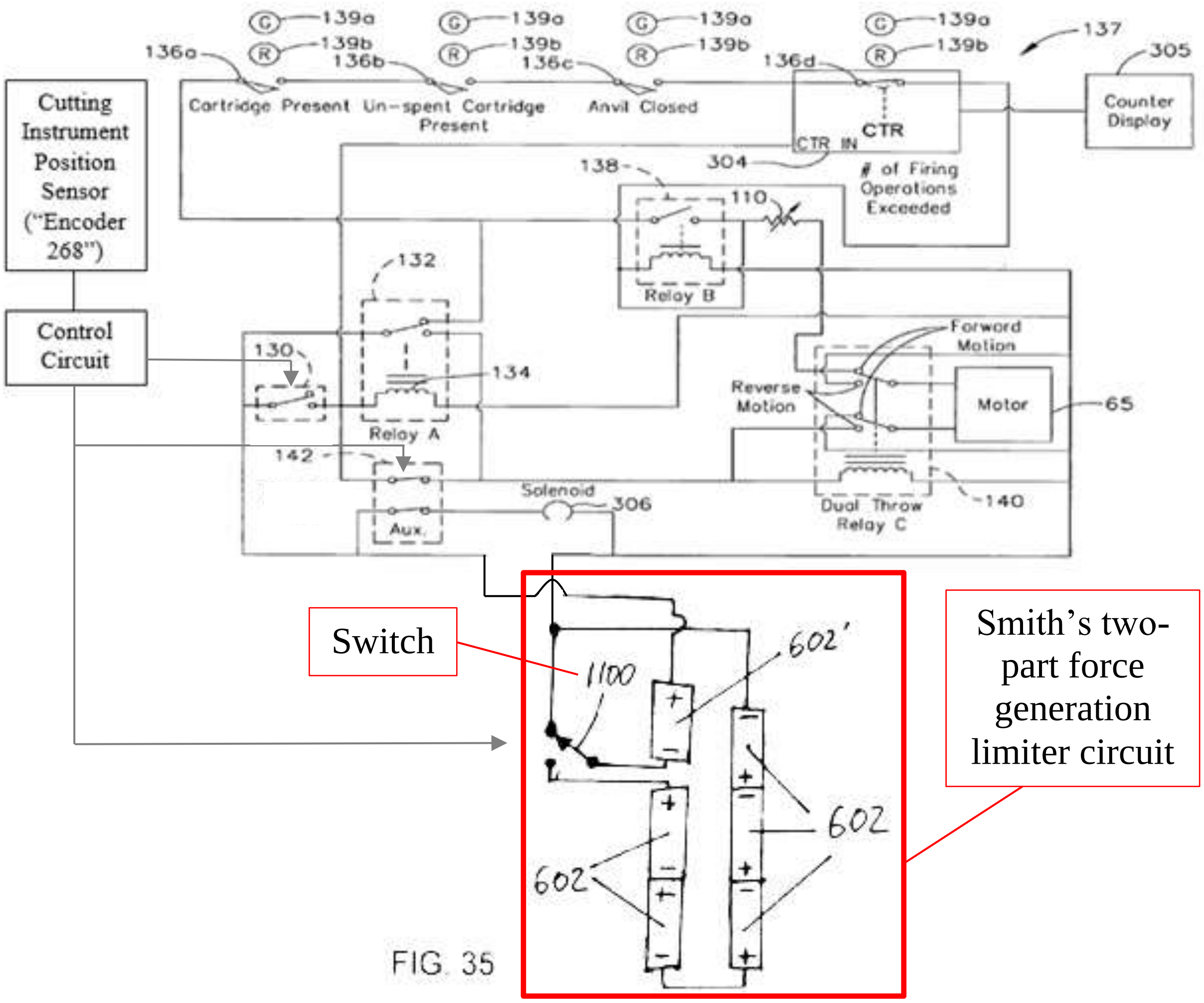


FIG. 35

As illustrated above, Swayze's control circuit controls switch 1100 based on the calculated position of knife 32 determined using data from encoder 268.

A POSITA would have been motivated to make this modification for several reasons. Fischer Decl., ¶103. For example, use of Smith's two-part force generation limiter circuit, employing a plurality of operational modes, makes Swayze's instrument safer. *Id.*; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 424 (2007).

As explained in Swayze, "firing the instrument without having a staple cartridge installed, or firing the instrument having an installed but spent staple cartridge, may result in cutting of tissue without simultaneous stapling to minimize bleeding." Swayze, ¶23. In Swayze, this risk is reduced by using interlock circuit 137—the safety feature that attempts to "prevent cutting of the tissue when the staple cartridge is not installed, is improperly installed, or is spent" by selectively supplying current to motor 65 only when various conditions are met (*e.g.*, when there is an unspent staple cartridge installed). *Id.*, ¶16. Swayze's incorporation of Shelton also discloses a "spent cartridge lockout"—an independent safety feature that acts to prevent cutting of tissue when the staple cartridge is spent by physically impeding distal movement of the knife. Shelton, 1:8-28, 10:27-38; Fischer Decl., ¶103.

Because Swayze's incorporation of Shelton does not provide figures illustrating a spent cartridge lockout, Figure 28 from Shelton II, which Shelton incorporates by reference, is shown below as an example of the various spent cartridge lockouts that a POSITA would have understood are disclosed by Swayze's incorporation of Shelton. Shelton II, Fig. 28; Fischer Decl., ¶104.

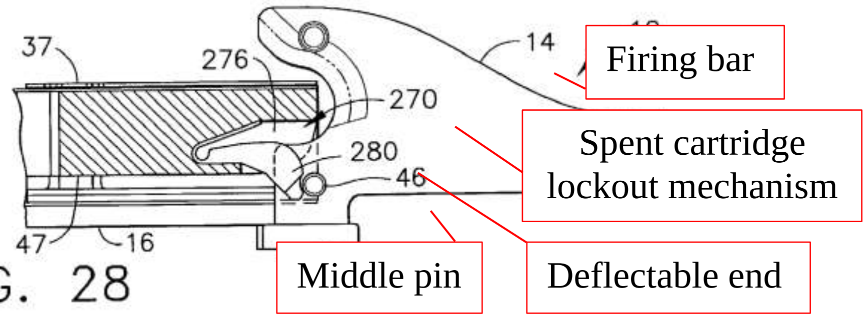


FIG. 28

As shown above, Shelton II's spent cartridge lockout mechanism 270 uses a deflectable end 280 to block middle pin 46 (in roughly the same location as Swayze's wings) of firing bar 14 when sled 218 is not present. Fischer Decl., ¶104; Smith, ¶¶199-200, Fig. 32; Shelton II, 4:22-32, 12:15-13:34, Figs. 24-28.

A POSITA would have understood the benefit of using the spent cartridge lockout with Swayze's device as a backup to interlock circuit 137. Fischer Decl., ¶105. For example, a POSITA would have understood that *electrical* interlock circuit 137 may not be as robust as the *mechanical* spent cartridge lockout, particularly in the fluid-filled environment where Swayze's device would operate. *Id*. Notably, fluid may affect signal conduction between electrical contacts and lead to a false positive condition where the user fires the knife with a spent cartridge. *Id*. But this result can be prevented by using a mechanical spent cartridge lockout as a backup. *Id*.

Yet Smith notes a potential problem with using spent cartridge lockout mechanisms in motor-powered surgical staplers. Specifically, Smith notes that the high forces applied by an electric motor can overpower the features of a mechanical lockout mechanism that functions to physically impede the knife's distal movement. Smith, ¶¶199-200; Fischer Decl., ¶106. Thus, a POSITA would have been motivated to incorporate Smith's two-part force generation limiter circuit to mitigate the high forces applied by the motor from overpowering the spent cartridge lockout mechanism (*e.g.*, by tearing off or damaging Shelton II's deflectable end 280 or the wings of Swayze's knife 32). *Id.*; *see also* Swayze, ¶67 (noting that "[i]t will be appreciated that … additional lockout sensor switches for responding to other conditions detrimental to operation of the instrument 10 may be provided").

Finally, Smith discloses a way to "optimize the power supply (*i.e.*, battery)" of the two-part force generation limiter circuit so that "a limited power supply can produce … forces sufficient to move a substantial amount of weight, for example, over 82 kg." Smith, ¶¶196, 208. This would have allowed a POSITA to use a power supply sufficient to generate the forces necessary to perform the cutting and stapling operations, while addressing the concern that using these forces could damage the cartridge lockout. Fischer Decl., ¶107. Thus, by using the two-part force generation limiter circuit, the optimal battery size and/or cost of Swayze's self-powered surgical stapler is achieved. *Id.*

Smith in view of Swayze

Smith's disclosure of a motor-powered linear stapler is primarily directed to a control circuit for increasing the power supplied to the motor from the batteries and protecting the physical features of a lockout mechanism that physically impedes distal movement of the knife when there is no staple cartridge installed or a previously fired staple cartridge installed. Smith, however, assumes a POSITA is familiar with motor-powered linear staplers. Thus, it also would have been obvious to modify Smith's control circuit for use with a motor-powered linear stapler like Swayze's.

In the device resulting from the modification of Smith in view of Swayze, Smith's control circuit (described above) would be modified to power and control Swayze's instrument and Smith's "second switch" would be positioned "somewhere along [Swayze's knife 32] control assembly or along the sled [33], the second switch sending a signal to [Smith's] controller after the wings [of Swayze's knife 32] have passed the edge" of the spent cartridge lockout. Smith, ¶200; Fischer Decl., ¶109. "Alternatively, encoders [or pulse generators could] be used" instead of the second switch. *Id*.; Smith, ¶121.

Furthermore, to the extent Swayze's incorporation of Shelton is deemed not to disclose use of the spent cartridge lockout with Swayze's instrument, a POSITA modifying Smith's control circuit for use with Swayze's instrument would nonetheless have used the spent cartridge lockout with the resulting device because the primary purpose of Smith's two-part force generation limiter circuit is to protect the physical features of a spent cartridge lockout mechanism that physically impedes distal movement of the knife. Smith, ¶¶199-200; Fischer Decl., ¶110. Thus, a POSITA would have been taught by Smith to include a spent cartridge lockout mechanism and would have looked for a spent cartridge lockout mechanism that is compatible with Swayze's instrument. *Id*. And, in fact, Swayze conveniently and explicitly incorporates Shelton, which notes that Swayze's integral sled "provides an opportunity for a number of lockout features," such as a "spent cartridge lockout." Swayze, ¶49; Shelton, 1:8-28, 10:27-38.

A POSITA would have been motivated to modify Smith's control circuit for use with Swayze's instrument for several reasons. Fischer Decl., ¶¶111-14. First, Smith contemplates use of its control circuit with motor-powered linear staplers like Swayze's. *Id*. A POSITA therefore would have turned to Swayze for details on how to implement Smith's control circuit with Swayze's instrument, to increase the number of uses for Smith's control circuit. *Id*.

Second, Smith does not disclose the full structure of a motor-powered linear stapler. *Id*., ¶112. Thus, a POSITA would have needed to find a reference describing such devices to implement Smith's invention. *Id*. Accordingly, that POSITA would naturally have turned to a reference such a Swayze, which teaches how to design and construct a motor-powered linear stapler. *Id*.

Third, unlike Smith, Swayze discloses a motor-powered linear stapler that includes: (1) "distinct closing and firing actions;" and (2) "articulation control." Swayze, ¶¶20, 45, Figs. 1-2. According to Swayze, "[o]ne specific advantage of being able to close upon tissue before firing is that the clinician is able to verify via an endoscope that the desired location for the cut has been achieved, including a sufficient amount of tissue has been captured between opposing jaws." Swayze, ¶21. And a POSITA would have recognized that Swayze's articulation control would provide the benefits of increased control over the positioning of the end effector. Fischer Decl., ¶113.

Finally, a POSITA would have had a reasonable expectation of success when combining Swayze and Smith. *Id.*, ¶114. Indeed, both of the proposed combinations described above would have been well within a POSITA's abilities for several reasons. *Id*. For example, each would have been merely the application of a known technique (using Smith's two-part force generation limiter circuit) with a known system (Swayze's instrument) in the same field of endeavor (motor-powered surgical staplers). *Id.*; *KSR*, 550 U.S. at 417. And Smith's two-part force generation limiter circuit and Swayze's instrument merely perform the same predictable functions as they do separately without significantly altering or hindering the functions performed by Swayze's instrument (*i.e.*, clamping, cutting, and stapling) or Smith's circuit (*i.e.*, reducing the amount of force applied in the initial part of the firing stroke). Fischer Decl., ¶114.

[13.4.1] a first operational mode, wherein the control circuit operates in the first operational mode when the firing element is positioned within a first range of positions along the firing path, wherein the first range of positions is positioned between the initial position and a second range of positions, and wherein a first amount of current is supplied to the electric motor during the first operational mode; and

Smith in view of Swayze and Swayze in view of Smith both disclose this limitation. Fischer Decl., ¶¶115-22.

"<u>A first operational mode</u>"

Smith's two-part force generation limiter circuit operates in a first operational mode (low force mode, which is a phase of the firing operation). *See* Ground 1, element [13.4].

"<u>Wherein the control circuit operates in the first operational mode when the firing element is positioned within a first range of positions along the firing path, wherein the first range of positions is positioned between the initial position and a second range of positions</u>"

Smith's two-part force generation limiter circuit operates in the low force mode when the firing element (Swayze's knife 32) is positioned within a first range of positions along the firing path ("the first part of the stapling/cutting stroke"; "the first part of blade travel"; "the beginning of the stroke"), wherein the first range of positions is positioned between the initial position ("proximal/start position" of knife 32) and a second range of positions ("the second part of the stapling/cutting stroke"). Fischer Decl., ¶¶117-21; Smith, ¶¶200, 205, Figs. 32, 33, 35.

As explained above in Ground 1, element [13.4], Smith's two-part force generation limiter circuit operates in the first (low force) operational mode when "switch 1100 is in the 'A' position." *Id.* And switch 1100 is in the "A" position when firing element is in "the first part of the stapling/cutting stroke." *Id.*

In Smith's end effector, as shown below, "the first part of the stapling/cutting stroke" is between the initial position ("proximal/start position" of knife 1060's wings 1065) and a second range of positions ("the second part of the stapling/cutting stroke") that begins at a point along the firing path "after the wings 1065 have passed the edge 1035." *Id.*

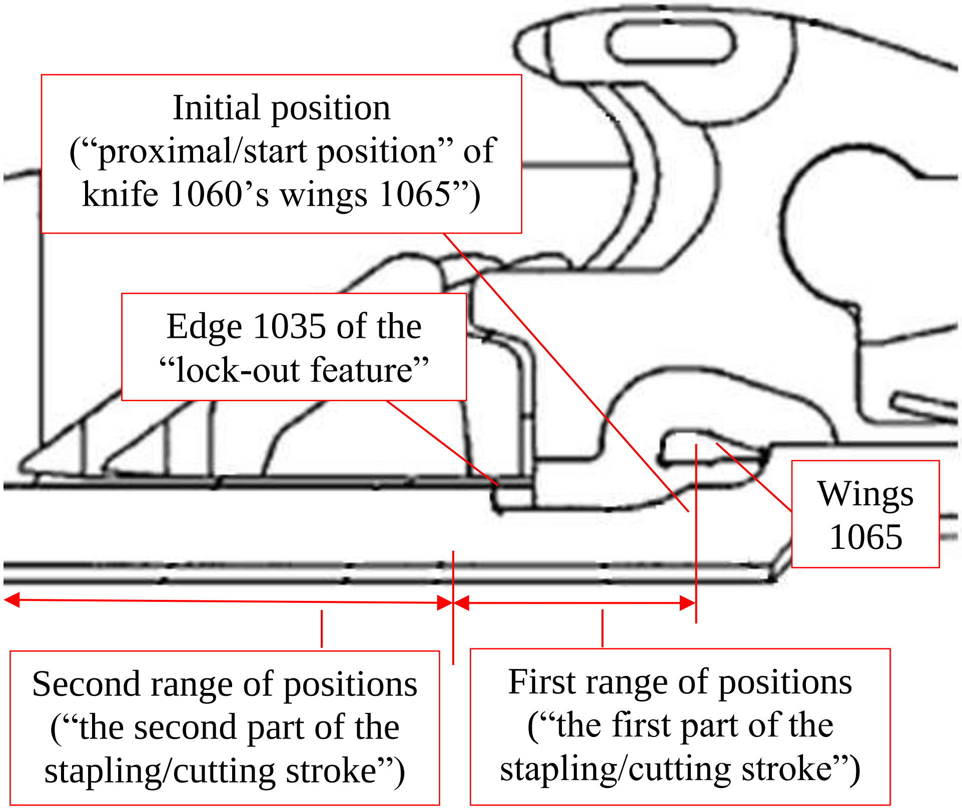


FIG. 32[5]

The corresponding elements and positions in Swayze's end effector with a spent cartridge lockout mechanism are shown below in the composite image of Figure 6 of Swayze and Figure 25 of Shelton II, the latter of which is an example of the spent cartridge lockout disclosed by Swayze's incorporation of Shelton:

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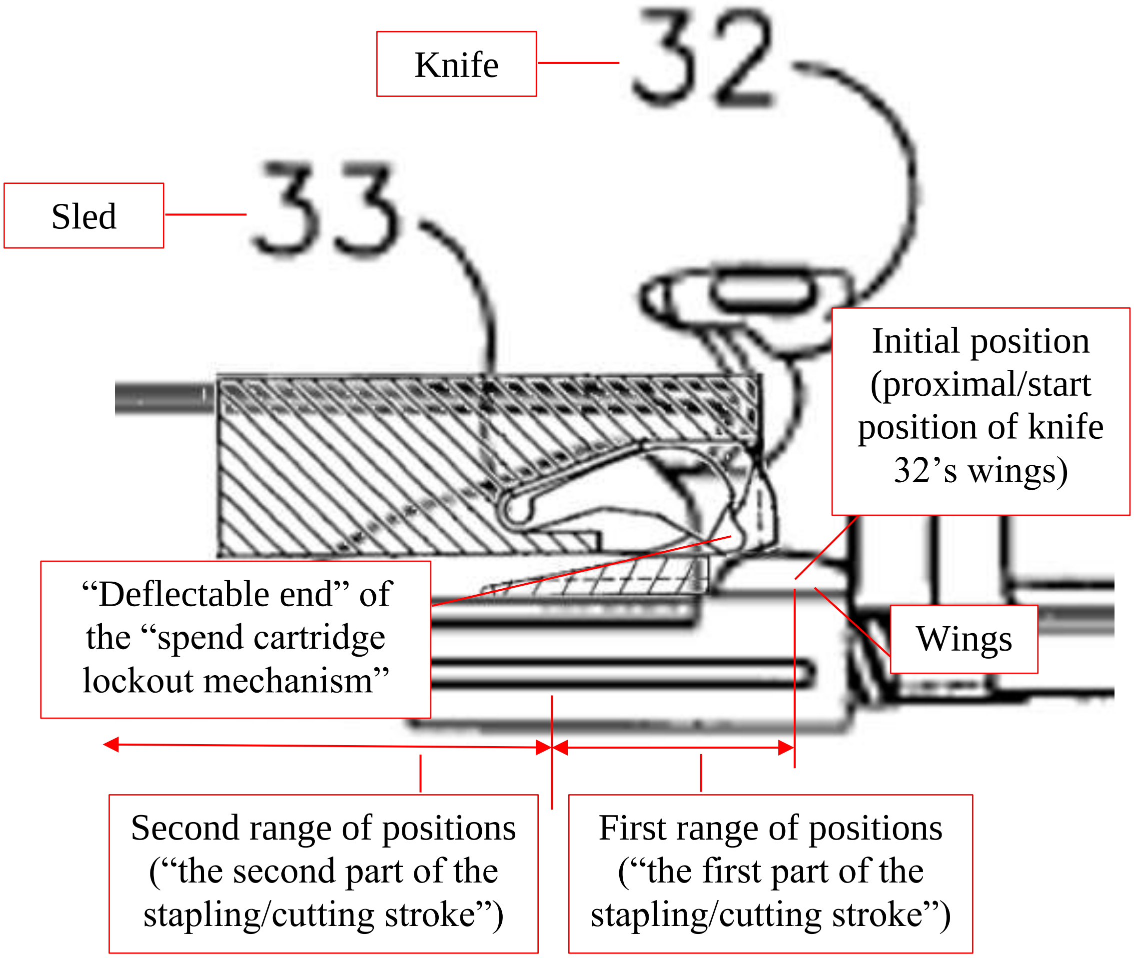
[5] The first range of positions shown in Figure 32 is exemplary. Claim 13 does not require the first range of positions to necessarily extend all the way from the initial position to the beginning of the second range of positions.



Fischer Decl., ¶120; Swayze, ¶51, Fig. 6; Shelton II, Fig. 25. As shown above, "the first part of the stapling/cutting stroke" is between the initial position ("proximal/start position" of knife 32's wings) and a second range of positions ("the second part of the stapling/cutting stroke") that begins at a point along the firing path after the wings have passed the edge of the spent cartridge lockout. *Id.*

"Wherein a first amount of current is supplied to the electric motor during the first operational mode"

In the four power cell embodiment, Smith's two-part force generation limiter circuit supplies a first amount of current (*e.g.*, the peak current that can be supplied by one power cell 602) to the corresponding electric motor (Swayze's motor 65, which would be optimized for the four power cell embodiment) during the first (low force) operational mode. Fischer Decl., ¶122; Smith, ¶¶172, 180, 198, 200, Figs. 33, 35. Similarly, in the six power cell embodiment, Smith's two-part force generation limiter circuit supplies a first amount of current (*e.g.*, the peak current that can be supplied by one power cell 602') to the corresponding electric motor (Swayze's motor 65, which would be optimized for the six power cell embodiment) during the first (low force) operational mode. *Id*.

[13.4.2] a second operational mode, wherein the control circuit operates in the second operational mode when the firing element is positioned within the second range of positions along the firing path, wherein the second range of positions is positioned between the first range of positions and the end-of-stroke position, wherein a second amount of current is supplied to the electric motor during the second operational mode, and wherein the second amount of current is greater than the first amount of current.

Swayze in view of Smith and Smith in view of Swayze both disclose this limitation. Fischer Decl., ¶¶123-31.

"<u>A second operational mode</u>"

Smith's two-part force generation limiter circuit operates in a second operational mode (high force mode, which is a phase of the firing operation). *See* Ground 1, element [13.4].

"Wherein the control circuit operates in the second operational mode when the firing element is positioned within the second range of positions along the firing path, wherein the second range of positions is positioned between the first range of positions and the end-of-stroke position"

Smith's two-part force generation limiter circuit operates in the second operational mode when the firing element is positioned within the second range of positions along the firing path, wherein the second range of positions is located between the first range of positions and the "end-of-stroke" position. Fischer Decl., ¶¶125-27; Swayze, ¶¶51, 59, Fig. 6; Smith, ¶200, Figs. 32, 33, 35; Ground 1, elements [13.1], [13.4.1]. As explained above in Ground 1, element [13.4], Smith's two-part force generation limiter circuit operates in the second (high force) operational mode when "switch 1100 is in the 'B' position." *Id*. And switch 1100 is in the "B" position when the firing element is in "the second part of the stapling/cutting stroke." *Id*.

In Smith's end effector, as shown below, "the second part of the stapling/cutting stroke" is between the first range of positions ("the first part of the stapling/cutting stroke") and the end-of-stroke ("distal most") position. *Id*.

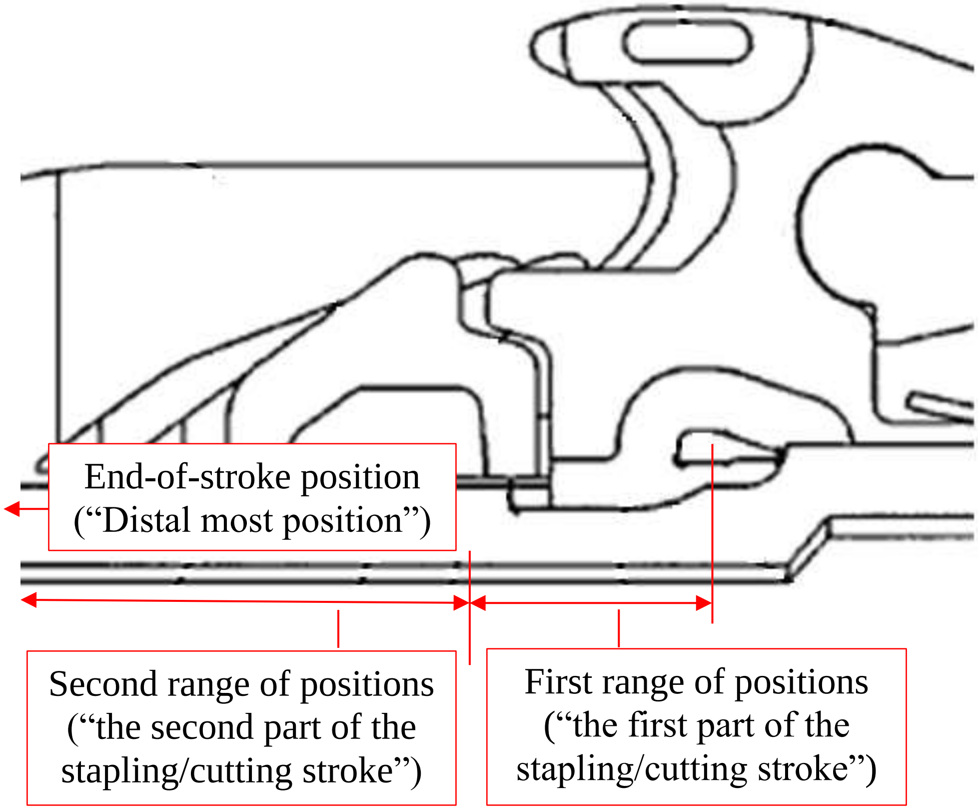


FIG. 32[6]

The corresponding positions in Swayze's end effector with a spent cartridge lockout mechanism are shown below in the composite images of Figure 6 of Swayze and Figure 25 of Shelton II:

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[6] The second range of positions shown in Figure 32 is exemplary. Claim 13 does not require the second range of positions to necessarily extend all the way from the end of the first range of positions to the end-of-stroke position.

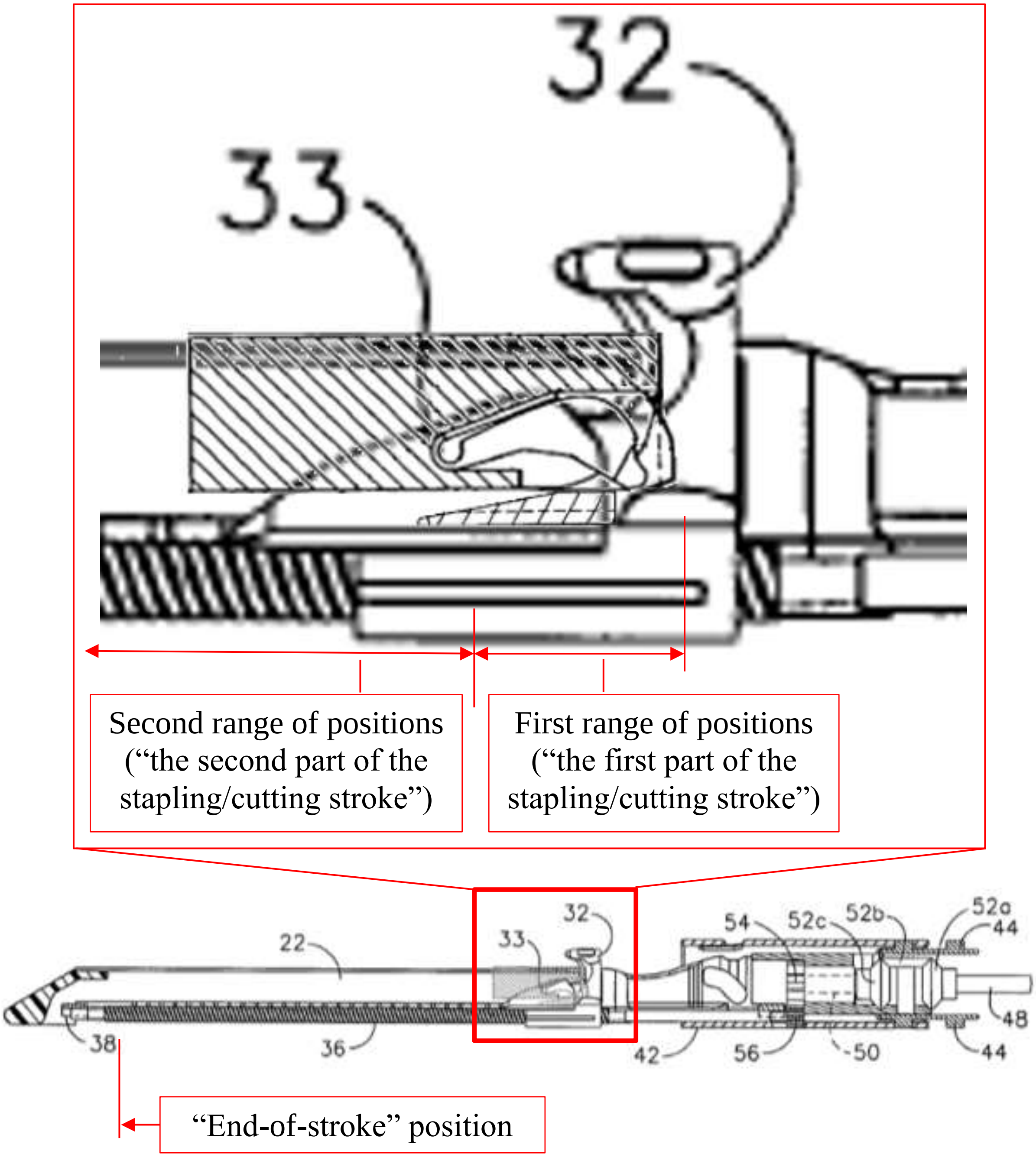


FIG. 6

Fischer Decl., ¶127; Swayze, ¶59, Fig. 6; Shelton II, Fig. 25.

"Wherein a second amount of current is supplied to the electric motor during the second operational mode"

In the four power cell embodiment, Smith's two-part force generation limiter circuit supplies a second amount of current (*e.g.*, the peak current that can be supplied by all four power cells 602) to its corresponding electric motor during the second (high force) operational mode. Fischer Decl., ¶128; Smith, ¶¶171-72, 180, 198, 200. Similarly, in the six power cell embodiment, Smith's two-part force generation limiter circuit supplies a second amount of current (*e.g.*, the peak current that can be supplied by all six power cells 602, 602') to its corresponding electric motor 65 during the second operational mode. *Id*.

"Wherein the second amount of current is greater than the first amount of current"

The second amount of current is greater than the first amount of current. Fischer Decl., ¶¶129-31; Smith, ¶¶171-72, 200, 205, Figs. 32, 33, 35. In the four power cell embodiment, the second amount of current (*e.g.*, the peak current that can be supplied by all four power cells) is approximately four times greater than the first amount of current (*e.g.*, the peak current that can be supplied by one power cell 602). Fischer Decl., ¶129. Similarly, in the six power cell embodiment, the second amount of current (*e.g.*, the peak current that can be supplied by all six power cells 602) is approximately six times greater than the first amount of current (*e.g.*, the peak current that can be supplied by one power cell 602'). *Id*.

As explained in Smith, "a desirable [motor] configuration will have the lowest winding resistance to draw the most current from the power supply (*i.e.*, battery pack)." Smith, ¶180. However, "the motor windings should be balanced to the particular battery pack so that, in a stall condition, the motor does not draw current from the cells sufficient to activate the PTC." *Id*.; *see also* ¶¶167-68 (explaining that a PTC is "a device that is constructed to limit conduction of the battery as the battery increases in temperature" and therefore, when triggered, "decrease the current passing through the circuit to a minimal level"). Thus, a POSITA would have understood that the winding resistance of each motor (*i.e.*, the motor in the four power cell embodiment and the motor in the six power cell embodiment) is selected to maximize the current that can be drawn in a stall condition from all the power cells in its corresponding power supply (*i.e.*, the peak current) without triggering the PTC because that "would impermissibly delay use of [the] surgical stapler during an operation." Fischer Decl., ¶130; Smith, ¶180.

Furthermore, a POSITA would have understood that, in a stall condition, the peak current is determined by Ohm's law—*i.e.*, Voltage = Current x Resistance (V=IR), wherein the resistance is the resistance of the circuit path comprising primarily the winding resistance of the motor, which is constant, and the voltage is the voltage of the power supply. Fischer Decl., ¶131. Thus, by reducing the number of power cells connected in series from four to one in the four power cell embodiment and from six to one in the six power cell embodiment, which reduces the voltage of each power supply, Smith's two-part force generation limiter circuits necessarily reduce by a proportional amount the peak current that can be supplied by each power supply to its corresponding motor. *Id*.

[14] The surgical instrument of claim 13, further comprising a sensor configured to detect a condition of the firing element indicative of the position of the firing element along the firing path, wherein the sensor is in signal communication with the control circuit.

Swayze in view of Smith and Smith in view of Swayze both disclose this element. Fischer Decl., ¶132. The device from Swayze in view of Smith includes a control circuit and encoder 268, which is a sensor configured to detect a condition of the firing element indicative of the position of the firing element along the firing path (*e.g.*, whether knife 32 is "fully deployed, fully retracted, or at an intermittent [sic] stage"). *Id*.; Swayze, ¶¶59-60, 109, 111-12. Similarly, the device from Smith in view of Swayze includes either: (1) a "switch somewhere along the blade control assembly or along the sled [33]," (2) "encoders," or (3) pulse generators/counters, each of which is a sensor configured to detect a condition of the firing element indicative of the position of the firing element along the firing path (*e.g.*, "position information," including whether the firing element has passed the lockout feature). Smith, ¶¶121, 200; Fischer Decl., ¶132. Each of these sensors is in communication with its respective control circuit. *Id*.; Ground 1, element [13.4].

[15] The surgical instrument of claim 13, wherein the control circuit controls the electric motor to rotate in a second rotational direction to move the firing element in a second direction along the firing path, wherein the second direction is different than the first direction, and wherein the second rotational direction is different than the first rotational direction.

Swayze in view of Smith and Smith in view of Swayze both disclose this element. Fischer Decl., ¶133. In both devices, the corresponding control circuit (*see* Ground 1, element [13.4]) controls the electric motor to rotate in a second rotational direction (reverse) to move the firing element in a second direction (proximally) along the firing path, wherein the second direction (proximally) is different than the first direction (distally) and the second rotational direction (reverse) is different than the first rotational direction (forward). *Id*.; Swayze, ¶¶59, 62, 67, 81, 112; Smith, ¶¶202, 204. In the device from Swayze in view of Smith, the "reverse motor sensor 130, when activated, sends a signal to the motor 65 to reverse its rotation direction, thereby withdrawing the knife 32 of the end effector 12 following the cutting operation." Swayze, ¶59. In the device resulting from the modification of Smith in view of Swayze, "switch [1300] is placed in the left position … in which power is supplied to the motor to run the motor in a second direction, defined as the reverse direction," to "power the blade 1060 in a proximal direction." Smith, ¶¶202, 204.

[17.1] A surgical instrument, comprising:

See Ground 1, element [13.1].

[17.2] an end effector comprising a firing element, wherein the firing element is con-figured to move along a firing path, and wherein the firing path comprises: an initial position; and an end-of-stroke position;

See Ground 1, element [13.2].

[17.3] a sensor that detects a condition of the firing element indicative of the position of the firing element along the firing path;

See Ground 1, claim [14].

[17.4] an electric motor, wherein the electric motor drives the firing element in a first direction along the firing path when the electric motor is rotated in a first rotational direction; and

See Ground 1, element [13.3].

[17.5] a control circuit for controlling the electric motor, wherein the control circuit is configured to operate in a plurality of operational modes during rotation of the electric motor in the first rotational direction, and wherein the plurality of operational modes comprises:

See Ground 1, element [13.4].

[17.6.1] a first operational mode, wherein the control circuit operates in the first operational mode when the detected condition is indicative of the firing element positioned within a first range of positions along the firing path, wherein the first range of positions is positioned between the initial position and a second range of positions, and wherein a first amount of current is supplied to the electric motor during the first operational mode; and

See Ground 1, element [13.4.1].

[17.6.2] a second operational mode, wherein the control circuit operates in the second operational mode when the detected condition is indicative of the firing element positioned within the second range of positions along the firing path, wherein the second range of positions is positioned between the first range of positions and the end-of-stroke position, wherein a second amount of current is

supplied to the electric motor during the second operational mode, and wherein the second amount of current is greater than the first amount of current.

See Ground 1, element [13.4.2].

[18] The surgical instrument of claim 17, wherein the control circuit controls the electric motor to rotate in a second rotational direction to move the firing element in a second direction along the firing path, wherein the second direction is different than the first direction, and wherein the second rotational direction is different than the first rotational direction.

See Ground 1, claim [15].

B. Ground 2: Claims 13-15 and 17-18 are obvious over Swayze in view of McInnis

[13.1] – [13.3]

See Ground 1, elements [13.1] - [13.3].

[13.4] a control circuit for controlling the electric motor, wherein the control circuit is configured to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction, and wherein the plurality of operational modes comprises:

Swayze in view of McInnis discloses this element. Fischer Decl., ¶¶143-53.

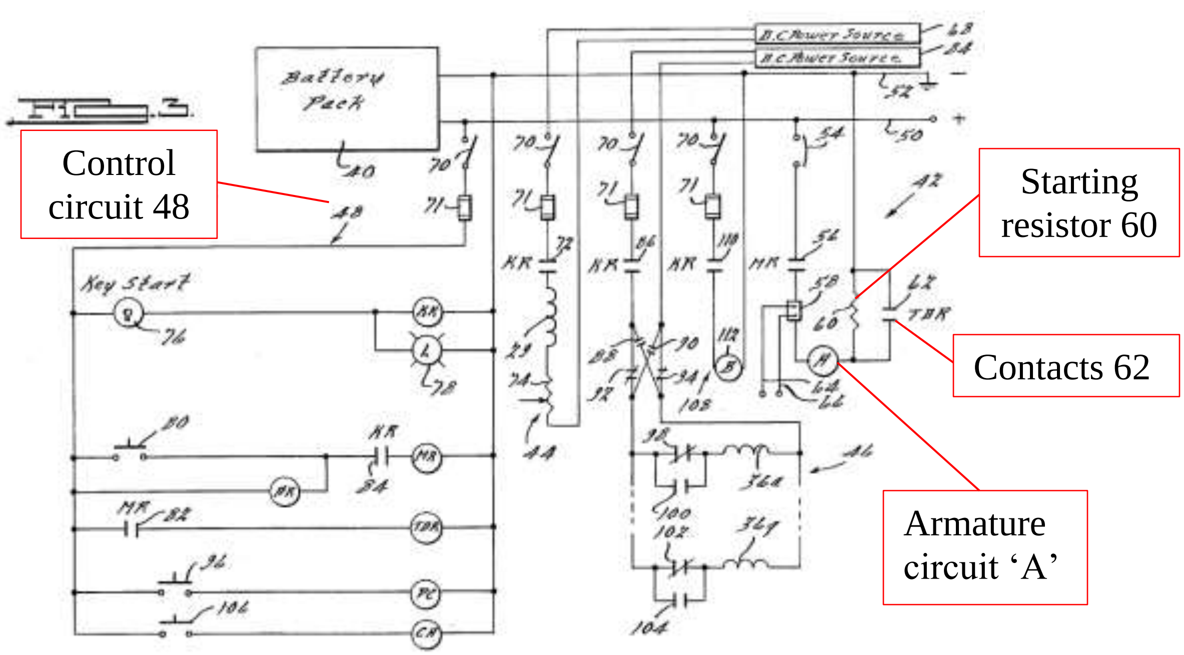
"A control circuit for controlling the electric motor"

See Ground 1, element [13.4].

"Wherein the control circuit is configured to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction"

It would have been obvious in view of McInnis to modify Swayze's control circuit to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction. Fischer Decl., ¶¶145-53.

Like Swayze, McInnis discloses a control circuit 48 for an electric motor, wherein control circuit 48 includes a soft start assembly comprising: (1) a "starting resistor 60 … connected in series with the armature circuit 'A' [of the motor] to prevent a high in rush of current when the motor is started, ***as is conventional in the art***;" and (2) "contacts 62 … connected across starting resistor 60 to provide a short circuit across this resistor shortly after the motor is started." McInnis, 5:56-62 (emphasis added), Fig. 3. Like at least one embodiment of the '287 patent, "[c]ontacts 62 are controlled by a time delay relay 'TDR' in relay control circuit 48." *Id.*, 5:62-63.



As shown below, the control circuit resulting from the combination of Swayze's control circuit with McInnis's soft start circuit ("the Swayze/McInnis control circuit") would be essentially identical to the control circuit disclosed in Figure 11 of the '287 patent. *Compare* '287 patent, Fig. 11 *with* Swayze, Fig. 11 (modified to include McInnis's soft start assembly, which is identified by the red box, as well as Swayze's control circuit and position sensor).

'287 Patent

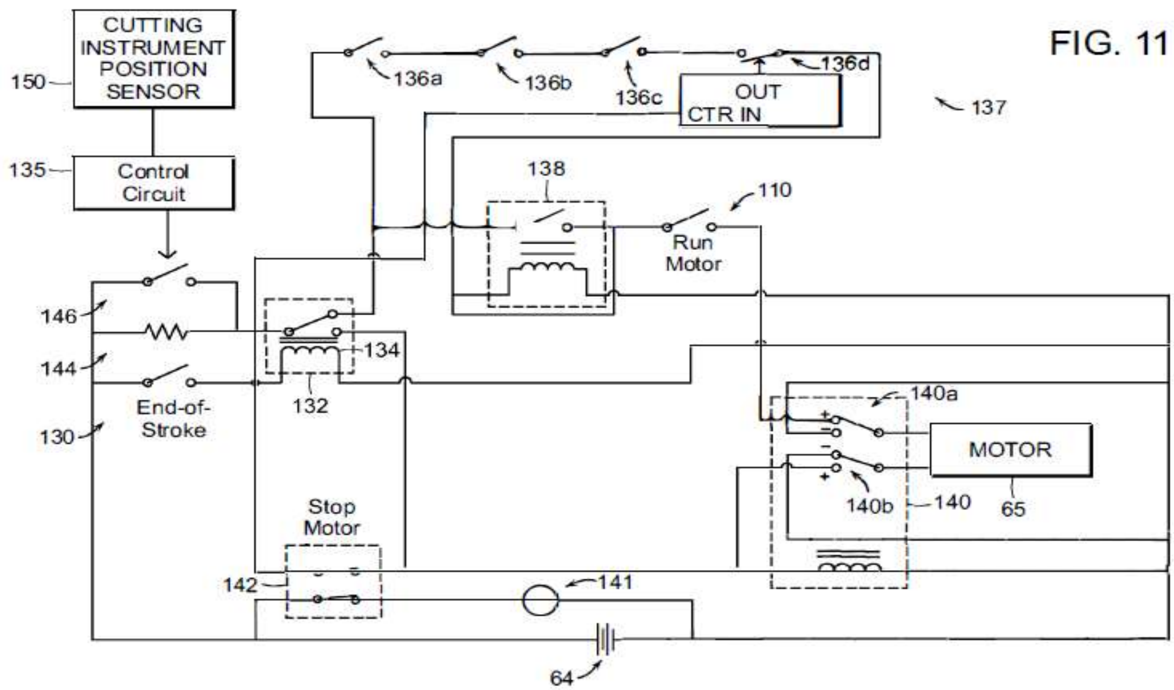


FIG. 11

Combination of Swayze and McInnis

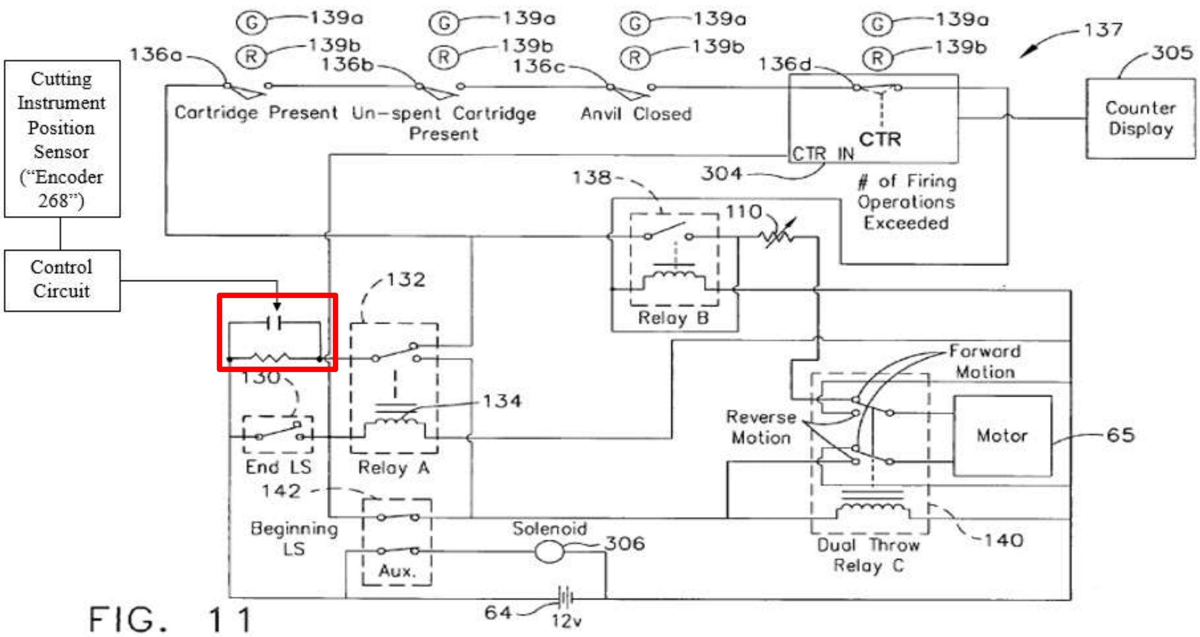


FIG. 11

Thus, like the control circuit disclosed in the '287 patent, the Swayze/McInnis control circuit is configured to switch between a plurality of operational modes (low current mode and high current mode) during rotation of the electric motor, wherein each operational mode is a phase of the firing operation. Fischer Decl., ¶148. As explained in McInnis, contacts 62 "provide a short circuit across … resistor [60] shortly after the motor is started." McInnis, 5:59-62; *see also* 6:55-57. Thus, the modified control circuit switches between the low and high current modes during rotation of the motor and after it has been rotating for a preselected period of time. *Id.*; Fischer Decl., ¶148.

A POSITA would have been motivated to modify Swayze's control circuit to included McInnis's soft start circuit for the reason provided in McInnis—*i.e.*, "to prevent a high in rush of current when the motor is started, as is conventional in the art." McInnis, 5:56-62; Fischer Decl., ¶149. Indeed, a POSITA would have understood that this high in rush of current can: (1) cause the motor to apply abnormally large amounts of torque that can cause mechanical shock to the motor shaft and/or the driven equipment, reducing their life; (2) cause intolerably heavy sparking at the brushes of the motor that can destroy the commutator and brush-gear, (3) make the device more difficult to control; and/or (4) draw more than the permissible amount of current from the power supply. *Id*.; Kothari, pp. 370-371; *see also* McInnis, 5:56-59 (disclosing a soft start circuit "to prevent a high in rush of current when the motor is started, as is conventional in the art"); Zemlok, ¶159 (disclosing "soft start" functionality in a motor powered surgical stapler to "prevent damaging current and torque spike[s] when transitioning between static to dynamic mode"); Kastner, ¶30 (disclosing that "[s]oft-starting can also be useful in hand-held power tools" to "minimize fatigue and potential injury, while allowing greater control of the tool"); Smith, p. 11 (adding "PWM ramping," a type of soft start functionality, to a motor powered surgical stapler); Ground 1.

Furthermore, McInnis confirms it would have been "appreciated by those skilled in the art that [McInnis's] motor controller may be suitably modified for other appropriate motor control applications." McInnis, 5:35-38. And McInnis confirms that its time delay relay "may be replaced by conventional electronic components" like Swayze's control circuit. *Id*., 9:1-11.

Finally, a POSITA would have had good reason to pursue the known options within his or her technical grasp when, as here, "there are a finite number of identified, predictable solutions" for soft starting an electric motor and McInnis discloses a conventional solution. *KSR*, 550 U.S. at 421; Fischer Decl., ¶152.

A POSITA would have had a reasonable expectation of success when combining Swayze and McInnis because the combination would have been well within their abilities. Fischer Decl., ¶153. Indeed, it would have been merely the application of a conventional technique (using a starting resistor connected in parallel with a controlled switch) with a known system (Swayze's control circuit) in the same field of endeavor (electric motor control). *Id*.; *KSR*, 550 U.S. at 417. And, in combination, McInnis's soft start circuit merely performs the same predictable function as it does separately (*i.e*., reducing the amount of current that can be supplied to the motor when it starts and allowing full current after a predetermined amount of time) without significantly altering or hindering the functions performed by Swayze's surgical stapler (*i.e*., clamping, cutting, and stapling). Fischer Decl., ¶153.

[13.4.1] a first operational mode, wherein the control circuit operates in the first operational mode when the firing element is positioned within a first range of positions along the firing path, wherein the first range of positions is positioned between the initial position and a second range of positions, and wherein a first amount of current is supplied to the electric motor during the first operational mode; and

Swayze in view of McInnis discloses this element. Fischer Decl., ¶154. The Swayze/McInnis control circuit operates in a first operational mode (low current mode, which is a phase of the firing operation) when the firing element is positioned within a first range of positions along the firing path (the first part of the stapling/cutting stroke). *Id*. Prior to firing, Swayze's firing element is at the initial position and the motor is stopped. *Id*.; Swayze, ¶¶67, 111, Fig. 6. When firing is initiated, the motor starts rotating in the forward direction and the control circuit operates in the low current mode because McInnis's time delay circuit is on. Fischer Decl., ¶154. The motor rotates helical screw shaft 36 causing knife 32 to advance a distance along the firing path (the first part of the stapling/cutting stroke) during the time that McInnis's time delay circuit is on. *Id*. Thus, the control circuit operates in low current mode when the firing element is in the first part of the stapling/cutting stroke, which is positioned between the initial position and a second range of positions (the second part of the stapling/cutting stroke). *Id*. And a first amount of current (*e.g.*, the peak current that can be supplied through starting resistor 60) is supplied to the electric motor. *Id*.

[13.4.2] a second operational mode, wherein the control circuit operates in the second operational mode when the firing element is positioned within the second range of positions along the firing path, wherein the second range of positions is positioned between the first range of positions and the end-of-stroke position, wherein a second amount of current is supplied to the electric motor during the second operational mode, and wherein the second amount of current is greater than the first amount of current.

Swayze in view of McInnis discloses this element. Fischer Decl., ¶155. The Swayze/McInnis control circuit operates in the second operational mode (high current mode, which is also a phase of the firing operation) when the firing element is positioned within the second range of positions along the firing path (the second part of the stapling/cutting stroke). *Id*.

The control circuit begins operating in the high current mode when the time delay relay turns off. At that time, a second (higher) current can be supplied to the motor to rotate helical screw shaft 36 to advance knife 32 from its position when the time delay relay switches off to its end-of-stroke position (the second part of the stapling/cutting stroke). *Id*., ¶156. Thus, the second range of positions is located between the first range of positions and the end-of-stroke position. *Id*. The second current (*e.g.*, the peak current that can be supplied through contacts 62) is supplied to the electric motor. *Id*. And the second amount of current, which bypasses starting resistor 60, is greater than the first amount of current. *Id*.

[14] The surgical instrument of claim 13, further comprising a sensor configured to detect a condition of the firing element indicative of the position of the firing element along the firing path, wherein the sensor is in signal communication with the control circuit.

See Ground 1, claim [14].

[15] The surgical instrument of claim 13, wherein the control circuit controls the electric motor to rotate in a second rotational direction to move the firing element in a second direction along the firing path, wherein the second direction is different than the first direction, and wherein the second rotational direction is different than the first rotational direction.

See Ground 1, claim [15].

[17] - [18]

See Ground 2, claims [13]-[15]; *see also* Ground 1, claims [17]-[18] (identifying the elements of claims [13]-[15] that correspond to the elements of claims [17] and [18]).

C. Ground 3: Claims 13-15 and 17-18 are obvious over Zemlok in view of Whitman under Patent Owner's apparent construction

Although relevant disclosures of Zemlok were considered during prosecution, there is no basis for a determination under 35 U.S.C. § 325(d) that Ground 3 relies on substantially similar prior art and/or arguments that have already been presented to the PTO. First, the examiner did not consider whether the challenged claims would have been obvious in view of Whitman. *Compare* Ground 3 *with* Section VI; *Edwards Lifesciences Corp. v. Boston Scientific SciMed, Inc*., IPR2017-01295, Paper 9 (PTAB October 25, 2017). Second, Whitman was cited but was never discussed by the examiner. *Microsoft Corp. v. Parallel Networks Licensing*, LLC, PR2015-00486, Paper 10 (PTAB July 15, 2015). Third, the examiner lacked the benefit of Patent Owner's broad infringement allegations.[7] *See*

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[7] To be clear, Petitioner's unpatentability arguments concerning the combination of Zemlok and Whitman are based solely on Patent Owner's infringement allegations, with which Petitioner does not agree.

IS1017, ¶¶66-67. Thus, not one of the six factors identified in *Becton, Dickinson and Company v. B. Braun Melsungen AG* weighs in favor of such a finding. IPR2017-01586, Paper 8 at 17-28 (PTAB Dec. 15, 2017 (informative)).

[13.1] A surgical instrument, comprising:

If the preamble is deemed to be a limitation, then Zemlok discloses it. File History, 417-19; Fischer Decl., ¶163. Specifically, Zemlok discloses a "powered surgical stapler" 10. *Id*.; Zemlok, Abstract, Fig. 1.

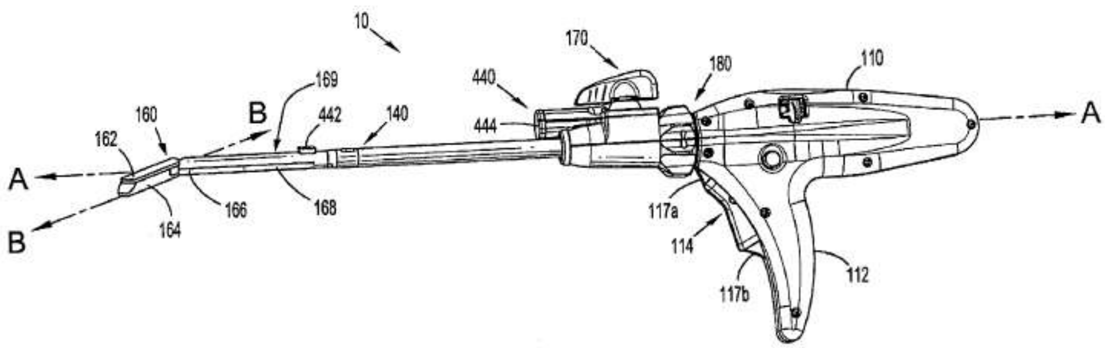


FIG. 1

[13.2] an end effector comprising a firing element, wherein the firing element is configured to move along a firing path, and wherein the firing path comprises: an initial position; and an end-of-stroke position;

Zemlok discloses this element under Patent Owner's apparent construction. File History, 417-19; Fischer Decl., ¶¶164-69.

"<u>An end effector comprising a firing element</u>"

Zemlok discloses an end effector 160 comprising an I-beam structure on the distal end of the drive beam 213 and therefore meets the broad interpretation of "firing element" applied by Patent Owner in the litigation. *See, e.g., id*.; Zemlok, Abstract, ¶¶8-13, 48-49, 52, 81-83, 88, 113, Figs. 1, 8-9, 17-18, 21.

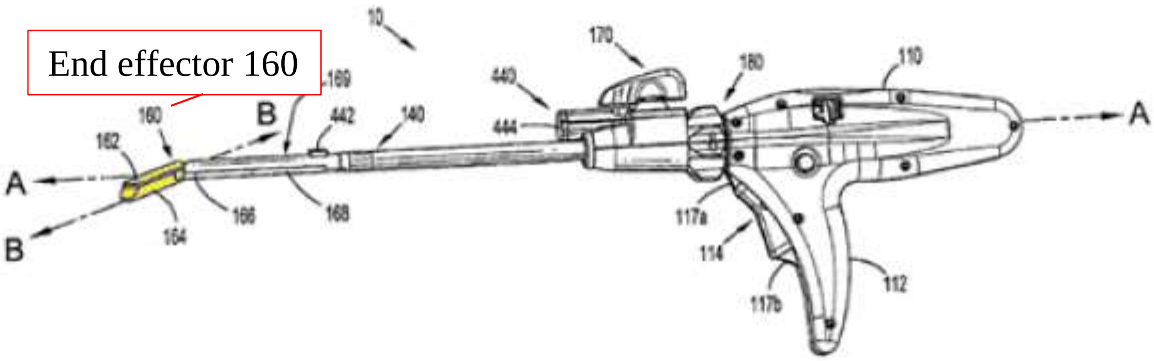


FIG. 1

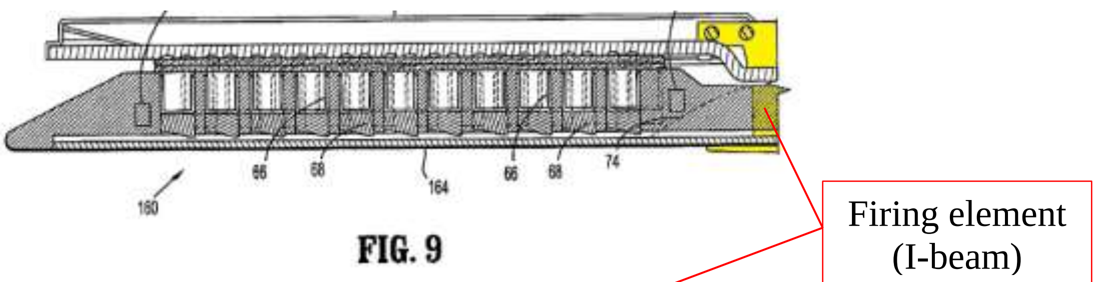


FIG. 9

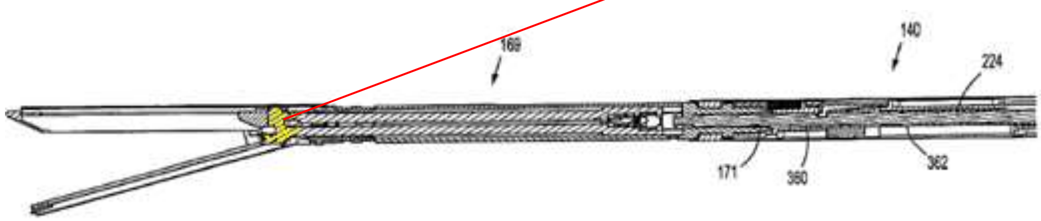


FIG. 18

The I-beam structure includes a knife blade and a retention flange 40 having a pair of cam members 40a. *Id.*, Fig. 8.

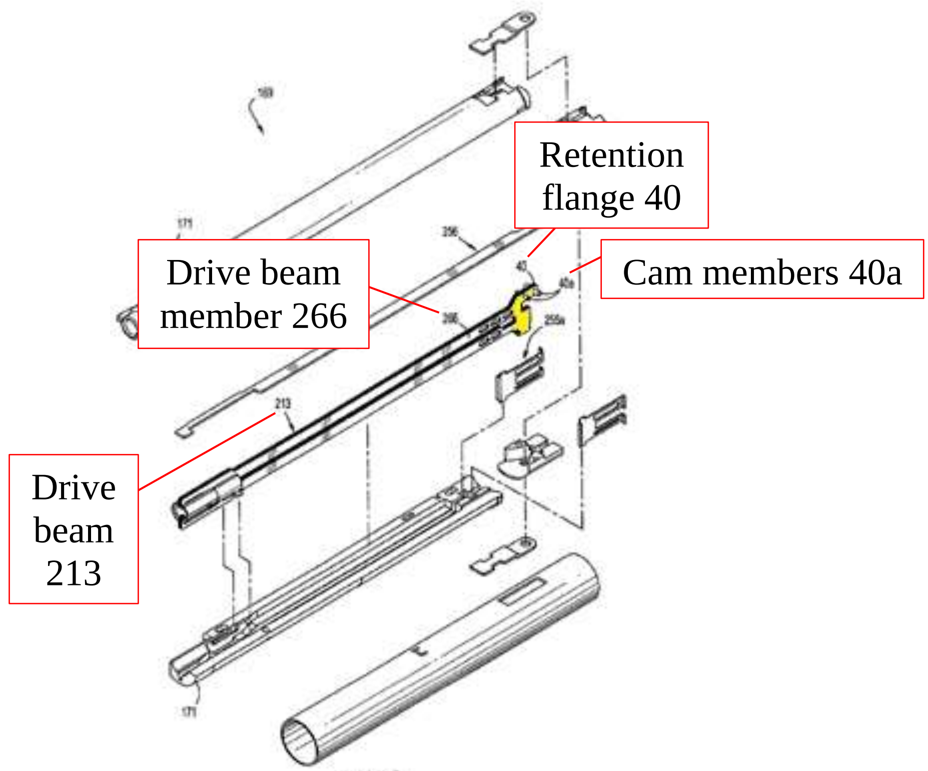


FIG. 8

The I-beam structure is also disclosed by Zemlok's incorporation of Milliman. Zemlok, ¶¶81-83; Milliman, Figs. 21, 24, 45. As shown below, the I-beam includes a knife blade 280 and a support member 287:

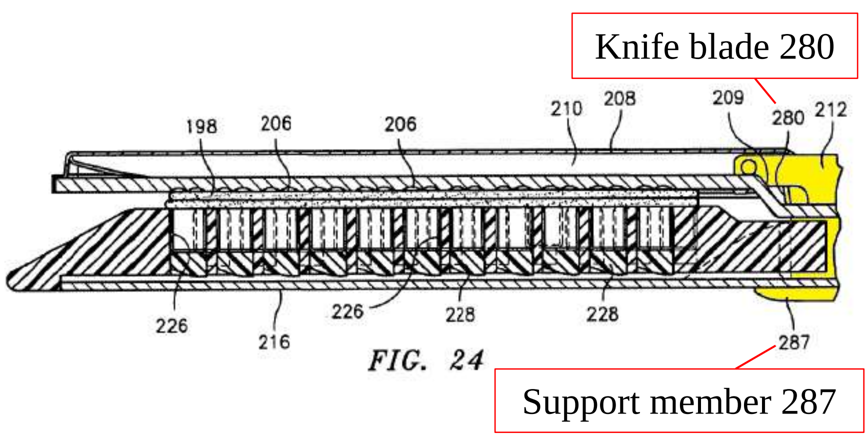


FIG. 24

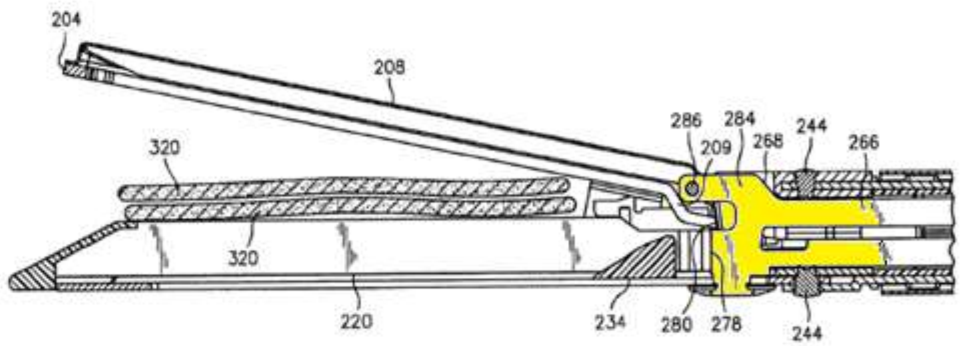


FIG. 45

"Wherein the firing element is configured to move along a firing path"

Zemlok's firing element (I-beam) is configured to move along a firing path (a cutting travel path) from the proximal end of the staple cartridge to the distal end of the staple cartridge. File History, 417-19; Fischer Decl., ¶167; Zemlok, ¶¶54, 56, 79-83, 88, 103, 111-13, 125-26, 157, Figs. 9, 17-18; Milliman, Figs. 21, 24, 38, 45, 49, 51-52.

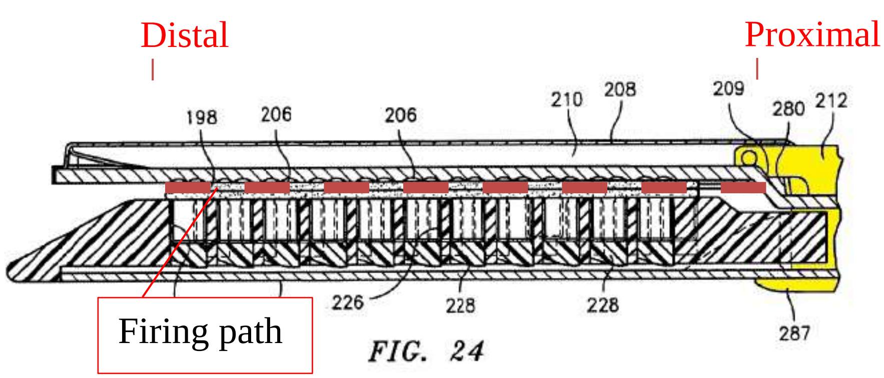


FIG. 24

"Wherein the firing path comprises: an initial position; and an end-of-stroke position"

Zemlok's firing path comprises "an initial position at a beginning of the cutting travel path" (*i.e.*, starting point of the I-beam for the firing operation) "and an end-of-stroke position at an end of the cutting travel path." File History, 417-19; Fischer Decl., ¶168; Zemlok, ¶¶81-83, 88, 113, Figs. 9, 17-18; *see also* Zemlok, ¶¶54, 56, 79-80, 103, 111-12, 125-26, 157; Milliman, Figs. 21, 24, 49, 51-52.

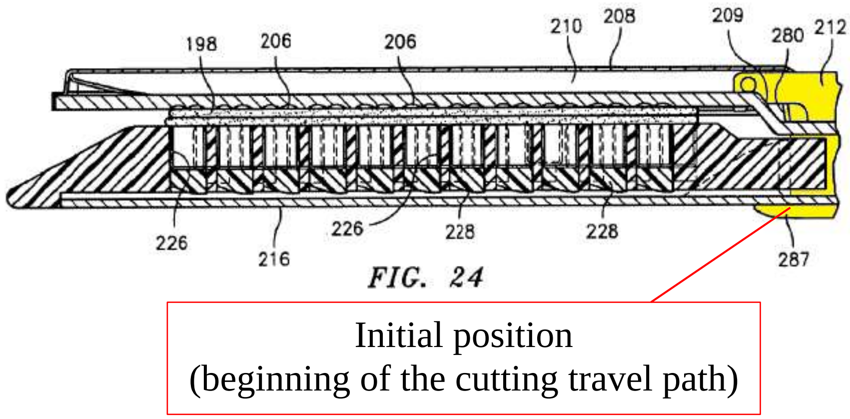


FIG. 24

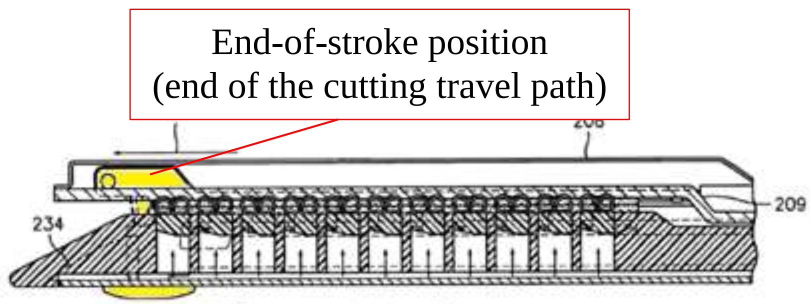


FIG. 52

Zemlok also discloses the I-beam's starting point for the clamping operation and therefore meets the broad interpretation of "initial position" applied by Patent Owner in the litigation. Fischer Decl., ¶169; Zemlok, Fig. 18; Milliman, Fig. 45.

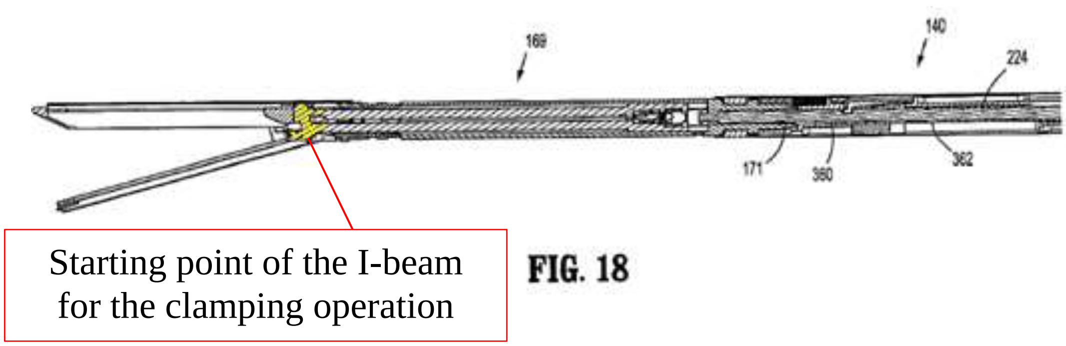


FIG. 18

[13.3] an electric motor, wherein the electric motor drives the firing element in a first direction along the firing path when the electric motor is rotated in a first rotational direction; and

Zemlok discloses this element. File History, 417-19; Fischer Decl., ¶170. Zemlok discloses an electric motor (electrical drive motor 200), wherein the electric motor drives the firing element in a first direction (distally) along the firing path when the electric motor is rotated in a first rotational direction ("*e.g.*, counter-clockwise"). *Id*.; Zemlok, ¶¶54, 56, 74, 79-83, 88, 103, 111-13, 125-26, 157.

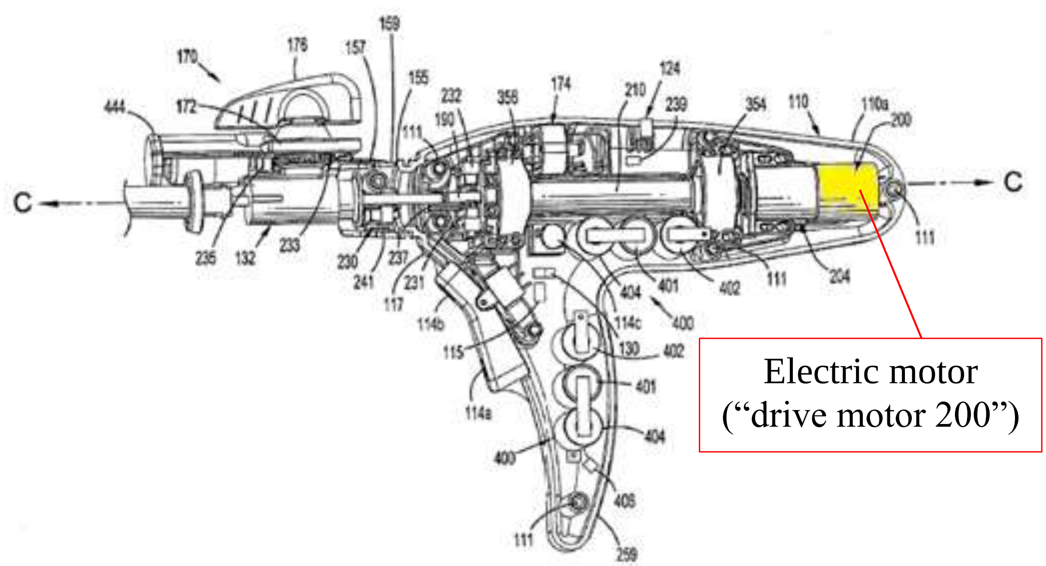


FIG. 4

[13.4] a control circuit for controlling the electric motor, wherein the control circuit is configured to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction, and wherein the plurality of operational modes comprises:

Zemlok discloses this element under Patent Owner's apparent construction. Fischer Decl., ¶¶171-75.

"A control circuit for controlling the electric motor"

Zemlok discloses a control circuit (microcontroller 500 and/or microcontroller 600) for controlling the electric motor. *Id.*; File History, 417-19; Zemlok, ¶¶103, 111-12, 147, 150, 158-59, 167-70, Figs. 13, 20.

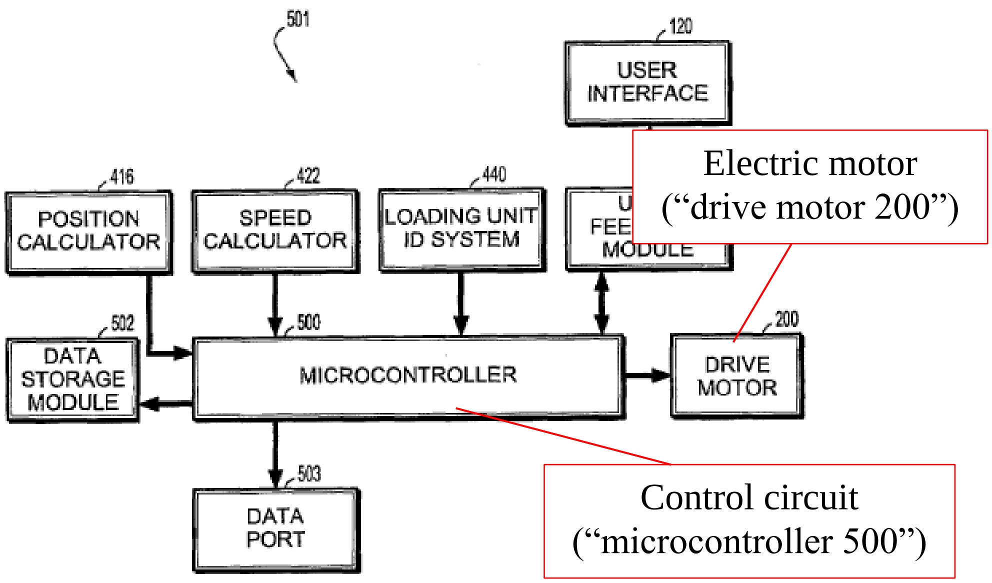


FIG. 20

"Wherein the control circuit is configured to switch between a plurality of operational modes during rotation of the electric motor in the first rotational direction"

Zemlok's control circuit is configured to switch between a plurality of operational modes (*e.g.*, "clamping, grasping, firing, sealing, [and] cutting"), which all require rotation of the electric motor in the first rotational direction to move the I-beam distally, and therefore meets the broad interpretation of this limitation applied by Patent Owner in the litigation. Fischer Decl., ¶¶173-75; Zemlok, ¶¶111-

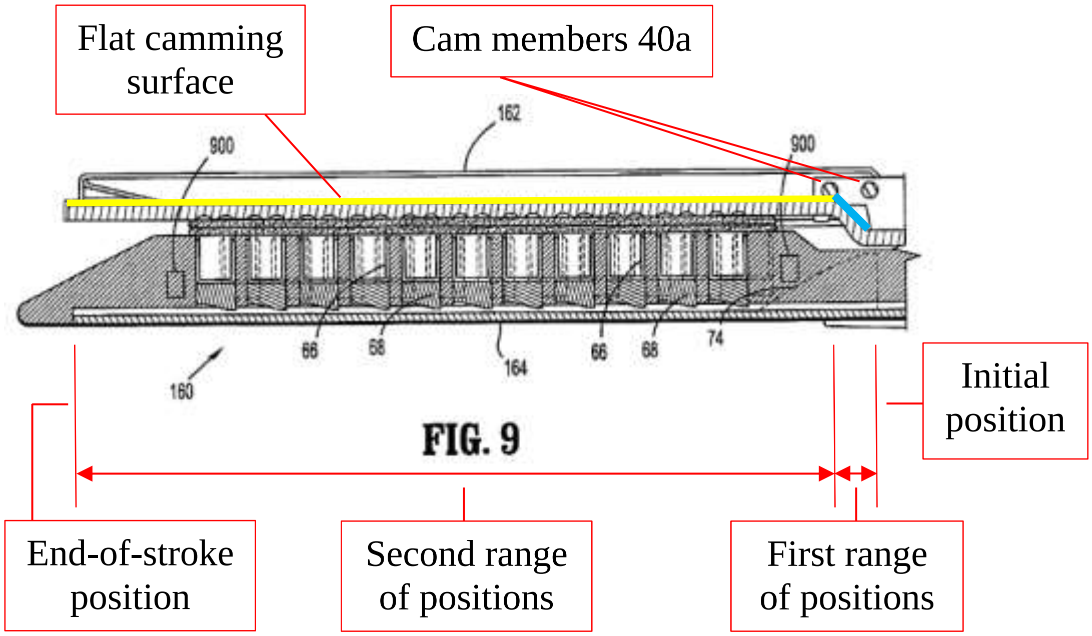
13, 130, 147, 150, 158-59. As explained in Zemlok, a "limit switch may be activated … to determine … [the] mode of the instrument 10 (*e.g.*, clamping, grasping, firing, sealing, cutting, retracting)." Zemlok, ¶112; *see also* ¶81.

"[A]s the firing rod 220," and therefore the firing element, "is moved in the distal direction from its resting (*e.g.*, initial) position" by the initial rotation of drive motor 200 in the first direction, "the firing rod 220" and firing element are "moved further distally to initiate clamping." *Id*., ¶113. "Further advancement of the firing rod 220" and firing element by further rotation of drive motor 200 in the first direction initiates firing. *Id*.

Handle portion 112 of Zemlok's instrument includes switches 114a, 114b, and 114c. *Id*., ¶¶54-58. "[S]witch 114a is configured to activate the drive motor 200 in a first direction to … clamp[] the anvil." *Id*. "[S]witch 114b may be configured to retract the firing rod." *Id*. And switch 114c "change[s] the mode of operation from clamping to firing." *Id*., ¶¶58-59; *see also* ¶¶64-66. For the purpose of this ground and Petition only, and to avoid any dispute on this point, Petitioner shall assume that Zemlok's control circuit switches from clamping mode to firing mode when the motor is <u>not</u> rotating. Fischer Decl., ¶175.

[13.4.1] a first operational mode, wherein the control circuit operates in the first operational mode when the firing element is positioned within a first range of positions along the firing path, wherein the first range of positions is positioned between the initial position and a second range of positions, and wherein a first amount of current is supplied to the electric motor during the first operational mode; and

Zemlok in view of Whitman discloses this element under Patent Owner's apparent construction. Fischer Decl., ¶¶176-84. Zemlok's control circuit operates in a first operational mode ("clamping" mode) when the firing element is positioned within a first range of positions (the positions where cam members 40a of the I-beam engage the anvil's inclined camming surface; the clamping mode range of positions), wherein the first range of positions is positioned between the initial position (starting point of the I-beam for the clamping operation) and a second range of positions (the positions where cam members 40a of the I-beam engage the anvil's flat camming surface; the firing mode range of positions), and wherein a first amount of current (*e.g.*, the amount of current required to clamp the tissue) is supplied to the electric motor during the first operational mode. *Id*.; Zemlok, ¶¶112-13, Fig. 9; *see also* Milliman, Fig. 45.



Zemlok discloses a clutch 300 and a pulse width modulation controller to prevent high load damage to tissue and/or the end effector. Fischer Decl., ¶177; Zemlok, ¶¶86, 130, 151, 153, 155, 169-70. Zemlok also discloses determining the operational mode and adjusting the spring loading of the clutch or the pulse width modulation signal. *Id*. However, Zemlok does not disclose setting a torque/current limit in the clamping mode that is lower than the torque limit in the firing mode.

It would have been obvious in view of Whitman to limit the amount of current that can be supplied to Zemlok's motor during Zemlok's clamping operational mode. Fischer Decl., ¶¶178-84. Like Zemlok, Whitman discloses an electric motor-powered surgical stapler comprising a memory unit that stores a plurality of operating programs or algorithms. Whitman, Abstract. And the algorithm is configured to switch the control circuit between various operational modes (*e.g.*, clamping and firing):

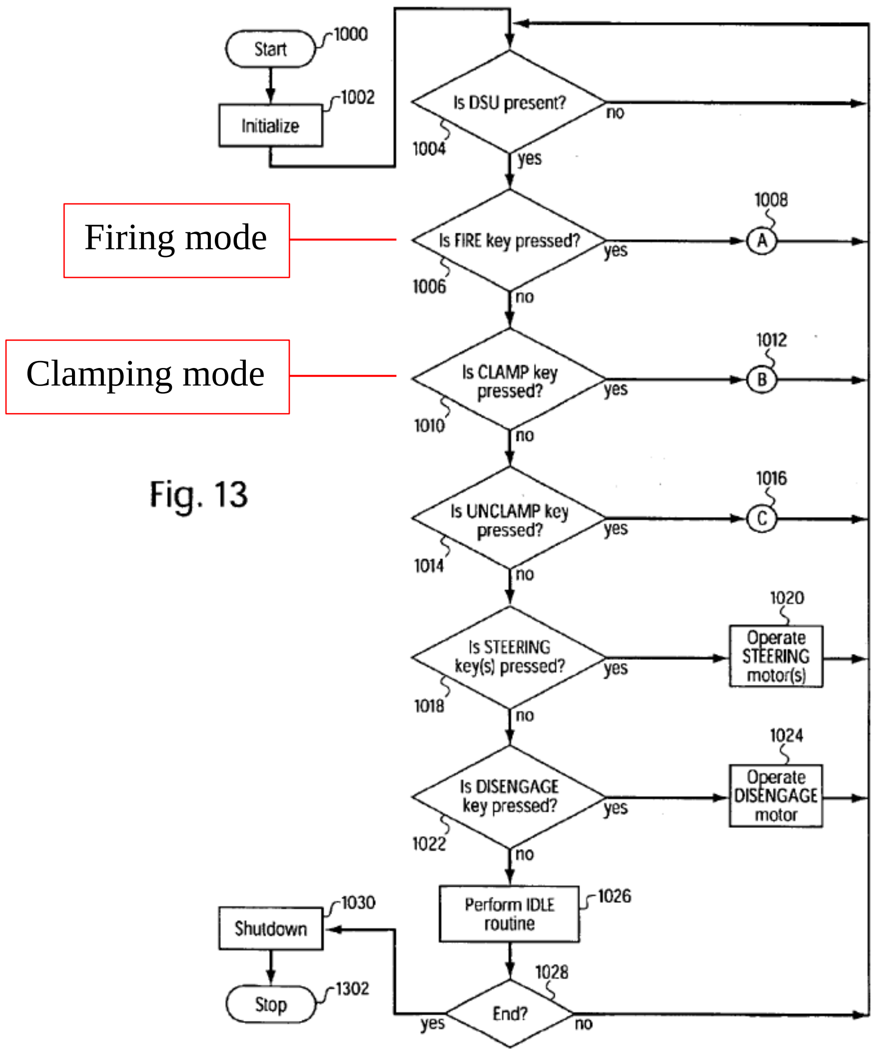
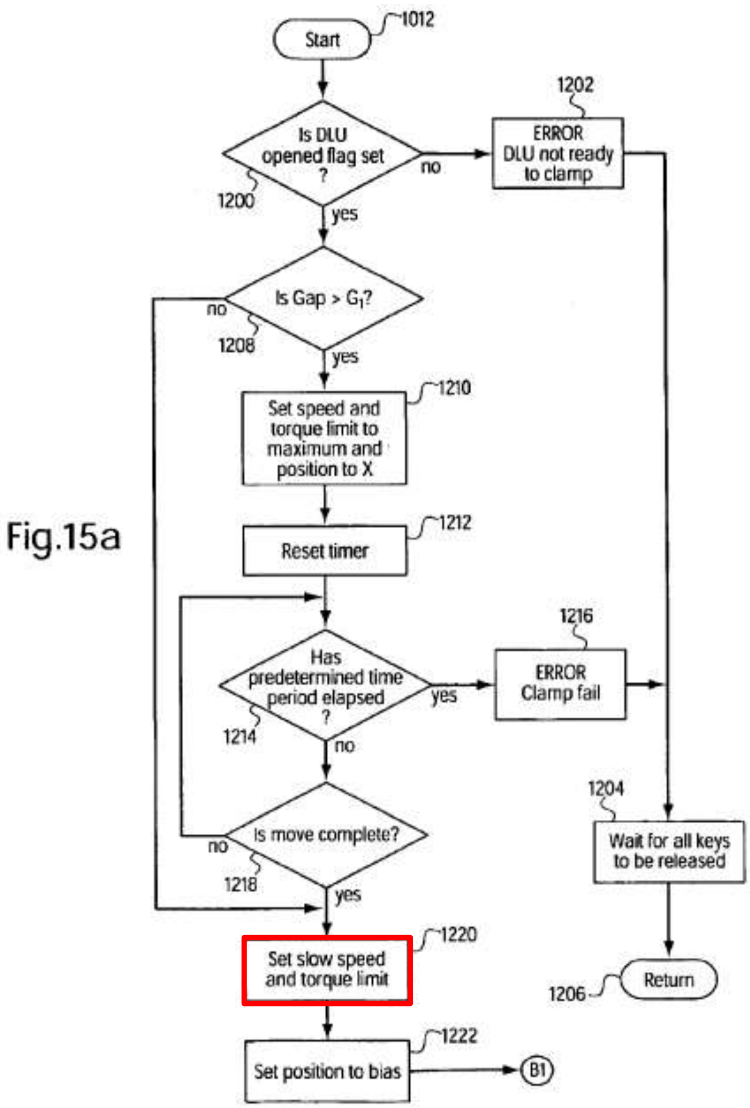


Fig. 13

In Whitman's clamping operational mode, the motor's torque limit is reduced when the gap between the anvil and the staple cartridge is less than "a predetermined threshold G_1, such as, for example, 5.0 mm." Whitman, 17:33-18:13; Fischer Decl., ¶179. A POSITA would have understood that torque of a motor is proportional to the current through it, and therefore that Whitman discloses setting a current limit during the clamping operational mode that is less than the maximum current that can be provided to the motor. *Id*. As shown below, this reduced current limit is set in step 1220:



Whitman, Fig. 15a.

A POSITA would have been motivated to modify Zemlok's device to make this modification because they would have understood that the amount of torque/current required to simultaneously perform the stapling and cutting operations in the firing mode is higher than the amount of torque/current required to clamp and not damage the tissue in the clamping mode. Fischer Decl., ¶180; Zemlok, ¶¶86, 151, 153, 155; Baker, p. 1293; Smith, ¶¶4, 6; Shelton III, ¶¶19, 24, 29; Swayze, ¶¶21-22 (confirming the clamping force can be generated manually but the firing force may be too high for some users to generate manually); Marczyk, 3:58-63 (confirming that the "firing stroke" is "the high-force portion of the activation sequence"). Thus, it would have been desirable to supply more current to the motor in the firing mode than in the clamping mode. *Id*. Indeed, a POSITA would have understood that: (1) the higher torque limit in Whitman's firing mode yields the predictable advantage of generating sufficient forces to cut and staple tissue and therefore improves the effectiveness of the device; and (2) the lower torque limit in Whitman's clamping mode yields the predictable advantage of protecting the clamped tissue from excess trauma and therefore produces a safer device. *Id*.

Furthermore, a POSITA would have had "good reason to pursue the known options within his or her technical grasp" when, as here, "there are a finite number of identified, predictable solutions." *KSR*, 550 U.S. at 421. In this case, Whitman describes one predictable solution for limiting the motor torque—*i.e.*, setting a torque limit in motor-control software. Fischer Decl., ¶182. And Zemlok discloses another—a clutch and/or a PWM controller. *Id*.

A POSITA would have had a reasonable expectation of success when combining Zemlok and Whitman, both of which concern motor-powered surgical staplers. *Id*., ¶183. As explained above, Zemlok's control circuit "includes internal memory which stores one or more software applications (*e.g.*, firmware) for controlling the operation and functionality of the instrument 10." Zemlok, ¶147. "The microcontroller 500 processes input data from the user interface 120 and adjusts the operation of the instrument 10 in response to the inputs." *Id*. "Additional parameters which may be used by the microcontroller 500 to control the instrument 10 include … tissue thickness." *Id*., ¶150; *see also* ¶¶153-55. And the "adjustments to the instrument 10 may includ[e] … torque limitation by reducing duty cycle or pulsing the voltage on and off to limit average current delivery during a predetermined period of time" and/or "in the event that limits are reached or approached." *Id*., ¶147, 170; *see also* ¶¶130, 169.

Thus, combining Zemlok with Whitman would have been well within a POSITA's abilities because it would have been merely the application of a known technique (setting torque limits in firmware) with a known system (Zemlok's surgical stapler) in the same field of endeavor (motor-powered surgical staplers). Fischer Decl., ¶184; *KSR*, 550 U.S. at 417. Indeed, it would have been a simple matter of updating Zemlok's firmware to include Whitman's clamping control algorithm and adjusting the duty cycle of Zemlok's pulse modulation control signal.

Fischer Decl., ¶184. Furthermore, in combination, Whitman's firmware merely performs the same predictable function (*i.e.*, limiting torque for the clamping mode) as it does separately without significantly altering or hindering the functions performed by Zemlok's instrument (*i.e.*, clamping, cutting, and stapling tissue). *Id*.

[13.4.2] a second operational mode, wherein the control circuit operates in the second operational mode when the firing element is positioned within the second range of positions along the firing path, wherein the second range of positions is positioned between the first range of positions and the end-of-stroke position, wherein a second amount of current is supplied to the electric motor during the second operational mode, and wherein the second amount of current is greater than the first amount of current.

Zemlok in view of Whitman discloses this element under Patent Owner's apparent construction. Fischer Decl., ¶¶185-89.

"A second operational mode"

The Zemlok/Whitman control circuit operates in a second operational mode (*e.g*., "firing" mode). *See* Ground 3, element [13.4].

"Wherein the control circuit operates in the second operational mode when the firing element is positioned within the second range of positions along the firing path, wherein the second range of positions is positioned between the first range of positions and the end-of-stroke position"

See Ground 3, elements [13.4], [13.4.1].

"Wherein a second amount of current is supplied to the electric motor during the second operational mode"

A second amount of current (the amount of current required to staple and cut tissue) is supplied to the electric motor during the second operational mode. Fischer Decl., ¶188. For example, during the firing mode, Zemlok discloses running the motor in constant speed mode and shutting down the motor when a stall condition is detected. *E.g.*, Zemlok, ¶¶124, 168; *see also* ¶¶85, 90, 124. Thus, a POSITA would have understood that, as the load on the motor increases during the firing mode, microcontroller 500 increases the supply of current to the motor as needed up until a stall condition is detected and the microcontroller 500 is supplying the maximum allowable amount of current to the motor. Fischer Decl., ¶188.

"Wherein the second amount of current is greater than the first amount of current"

The second amount of current (the maximum amount of current that may be supplied in the firing mode) is greater than the first amount of current (the maximum amount of current that may be supplied in the clamping mode). Fischer Decl., ¶189; Ground 3, element [13.4.1].

[14] The surgical instrument of claim 13, further comprising a sensor configured to detect a condition of the firing element indicative of the position of the firing element along the firing path, wherein the sensor is in signal communication with the control circuit.

Zemlok discloses this element. File History, 417-19; Fischer Decl., ¶190. Zemlok discloses a sensor (position calculator 416, linear displacement sensor 237, clamp position sensor 232, and/or encoder 420) configured to detect a condition of the firing element indicative of the position of the firing element along the firing path, wherein the sensor is in signal communication with Zemlok's control circuit. *Id*.; Zemlok, ¶¶111, 114-17, 146, Fig. 6.

[15] The surgical instrument of claim 13, wherein the control circuit controls the electric motor to rotate in a second rotational direction to move the firing element in a second direction along the firing path, wherein the second direction is different than the first direction, and wherein the second rotational direction is different than the first rotational direction.

Zemlok discloses this element. Fischer Decl., ¶191. Zemlok's control circuit controls the electric motor to rotate in a second rotational direction (reverse) to move the firing element in a second direction (proximally) along the firing path, wherein the second direction (proximally) is different than the first direction (distally) and the second rotational direction (reverse) is different than the first rotational direction (forward). *Id*.; Zemlok, ¶¶54, 59, 62, 67, 81, 112, 124-25, 131, Claim 7.

[17] - [18]

See Ground 3, claims [13]-[15]; *see also* Ground 1, claims [17]-[18] (identifying the elements of claims [13]-[15] that correspond to the elements of claims [17] and [18]).

D. Ground 4: Claims 13-15 and 17-18 are obvious over Zemlok in view of Milliman and further in view of Whitman under Patent Owner's apparent construction

As discussed above, claims 13-15 and 17-18 would have been obvious over Zemlok in view of Whitman. *See* Ground 3. If Zemlok is deemed not to disclose the Milliman subject matter incorporated by reference, it would have been obvious to combine Zemlok and Milliman to arrive at the same subject matter. Fischer Decl., ¶¶193-94.

A POSITA implementing Zemlok's invention would have been motivated to combine Zemlok with Milliman for at least two reasons. *Id*. First, if Zemlok's incorporation of Milliman by reference is insufficient, then Zemlok does not disclose certain details regarding the internal structure of Zemlok's end effector and a POSITA would have needed to find a reference describing it or something similar to implement Zemlok's invention. *Id*. Accordingly, that POSITA would naturally have turned to a reference such as Milliman, which teaches how to design and construct the end effector's internal structure. *Id*. Second, Zemlok conveniently and explicitly directs a POSITA to Milliman for "[f]urther details of firing and otherwise actuating [the] end effector." Zemlok, ¶¶81, 88.

X. CONCLUSION

Claims 13-15 and 17-18 of the '287 patent are unpatentable pursuant to the grounds presented in this Petition. Accordingly, Petitioner respectfully requests *Inter Partes* Review of these claims.

Respectfully submitted,

Dated May 17, 2019

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,732 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated May 17, 2019

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on May 17, 2019, a complete and entire copy of this Petition for *Inter 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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