IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Frederick E. Shelton, IV, et al.	
U.S. Patent No.:	9,844,379	Attorney Docket No.: 11030-0057IP2
Issue Date:	December 19, 2017	
Appl. Serial No.:	15/064,075	
Filing Date:	March 8, 2016	
Title:	SURGICAL STAPLING INSTRUMENT HAVING A CLEARANCED OPENING	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 9,844,379 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Pat. No. 9,844,379 to Shelton, et al. ("the '379 patent")
IS1002	Excerpts from the Prosecution History of the '379 Patent ("the Prosecution History")
IS1003	Declaration and CV of Dr. Bryan Knodel
IS1004	Reserved
IS1005	Reserved
IS1006	Reserved
IS1007	Reserved
IS1008	Reserved
IS1009	Reserved
IS1010	U.S. Patent No. 3,819,100 to Noiles ("Noiles")
IS1011	U.S. Pat. No. 5,413,267 to Solyntjes et al. ("Solyntjes")
IS1012	U.S. Pat. No. 5,031,814 to Tompkins et al. ("Tompkins")
IS1013	U.S. Pat. App. Pub. US 2004/0232195 ("Shelton '195")
IS1014	U.S. Pat. No. 7,000,818 to Shelton, et al. ("Shelton '818")
IS1015	U.S. Pat. No. 4,429,695 to Green ("Green")
IS1016	U.S. Patent No. 3,499,591 to Green ("Green II")

IS1017	U.S. International Trade Commission, Inv. No. 337-TA-1167, Order No. 5: Initial Determination Setting a 17-Month Target Date (Jul. 24, 2019)

I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1-3 ("the challenged claims") of U.S. Patent No. 9,844,379 ("the '379 patent"). The '379 patent relates generally to an endoscopic surgical instrument for stapling and severing tissue. The challenged claims are directed to a stapling assembly having a lockout configured to block advancement of a staple firing member when a detachable staple cartridge is not attached to the stapling assembly. But such instruments were not new at the time of the earliest claimed priority date of the '379 patent.[1] As explained in detail below, the challenged claims were anticipated by U.S. Patent No. 7,000,818 ("Shelton '818"), and would have been obvious over U.S. Patent No. 4,429,695 ("Green") in view of U.S. Patent No. 5,413,267 ("Solyntjes"). Petitioner therefore requests IPR of the challenged claims.

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

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

[1] As explained in a related, concurrently filed petition, the '379 patent is not entitled to either of the earliest two priority dates upon which Patent Owner relied to obtain allowance of the patent, and consequently, the effective filing date can be no earlier than February 7, 2014. This Petition, however, relies on references that are prior art even if the '379 patent were accorded its earliest claimed filing date.

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

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

Petitioner is not aware of any disclaimers or reexamination certificates of the '379 patent. Concurrently with this Petition, Petitioner is filing one other IPR petition related to the '379 patent directed to different statutory bases and different primary references, along with a statement ranking the petitions.

On March 12, 2019, Patent Owner moved to amend its complaint in Civil Action No. 1:18-cv-1325-LPS in the United States District Court for the District of Delaware to assert the '379 patent against Petitioner. On May 28, 2019, Patent Owner filed an amended complaint in the United States International Trade Commission (ITC), alleging infringement of the '379 patent by Petitioner. On June 28, 2019, the ITC instituted Investigation No. 337-TA-1167 based on Patent Owner's complaint.[2]

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

[2] In view of the ITC proceedings, the Delaware District Court stayed the proceedings before deciding the motion to amend.

of Delaware: *Intuitive Surgical, Inc. v. Ethicon LLC*, Case Nos. IPR2018-00933, -934, -935, -936, -938, -1247, -1248, -1254, and -1703, and IPR2019-00880, -991, -1066, and 1110. All of the IPRs were instituted except IPR2018-00938, and the decision on whether to institute has not issued in IPR2019-00991, -1066, and -1110.

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 IPR11030-0057IP2@fr.com (referencing No. 11030-0057IP2 and cc'ing PTABInbound@fr.com, phillips@fr.com, katz@fr.com, oconnor@fr.com, and jhuang@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 '379 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

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

Petitioner requests an IPR of claims 1-3 of the '379 patent on the grounds listed below. A declaration from Dr. Bryan Knodel (IS1003) is included in support.

Ground	Claims	Basis for Rejection
Ground 1	**1-3**	Anticipated by **Shelton '818** (IS1014) under pre-AIA 35 U.S.C. § 102(e).
Ground 2	**1-3**	Obvious over **Green** (IS1015) in view of **Solyntjes** (IS1011) under pre-AIA 35 U.S.C. § 103.

The '379 patent issued from U.S. App. No. 15/064,075, filed on Mar. 8, 2016, which is a continuation of U.S. App. No. 14/175,148, filed on Feb. 7, 2014 ("the '148 Application"), which patentee asserted is a continuation of U.S. App. No. 13/369,601, filed on Feb. 9, 2012 ("the '601 Application"), and which patentee asserted is a continuation of U.S. App. No. 11/141,753, filed on Jun. 1, 2005 ("the '753 Application").[3]

The '601 Application is a continuation of U.S. App. No. 13/118,246, filed

[3] As explained in the concurrently filed '379 IPR petition, the '379 Patent incorrectly identifies the '148 Application as a "continuation" of each of the '601 and the '753 Applications.

on May 27, 2011, which is a continuation-in-part of U.S. App. No. 11/538,154, filed on Oct. 3, 2006.

The ’753 Application claims priority to U.S. Provisional App. No. 60/591,694, filed on Jul. 28, 2004.

Thus, the earliest possible date to which the ’379 patent could claim priority is July 28, 2004 (hereinafter the “claimed priority date”). Petitioner does not concede that the ’379 patent is entitled to this priority date, but has elected not to argue the issue in the present Petition because all prior art references identified in the Grounds presented below pre-date the claimed priority date. However, Petitioner reserves the right to present such an argument in this proceeding and notes that it has presented such an argument in the IPR petition filed concurrently with this Petition, which also challenges each claim of the ’379 patent.

Shelton ’818 (IS1014) was filed on May 20, 2003, prior to the claimed filing date. Shelton ’818 is “by another” because it names Frederick E. Shelton, IV, Michael Earl Setser, and Brian J. Hemmelgarn as inventors.[4] Thus, Shelton ’818 qualifies as prior art under pre-AIA 35 U.S.C. § 102(e). Shelton ’818 was made of

[4] The ’379 patent names Frederick E. Shelton, IV, Michael Earl Setser, and William B. Weisenburgh, II as inventors.

record during prosecution of the '379 patent, but was never discussed by the examiner or the applicant.[5]

Green (IS1015) issued on February 7, 1984, more than one year before the claimed filing date, and thus qualifies as prior art under pre-AIA 35 U.S.C. § 102(b). Green was made of record during prosecution of the '379 patent, but was never discussed by the examiner or the applicant.

Solyntjes (IS1011) issued on May 9, 1995, more than one year before the claimed filing date, and thus qualifies as prior art under 35 U.S.C. pre-AIA § 102(b). Solyntjes was made of record during prosecution of the '379 patent, but was never discussed by the examiner or the applicant.

V. SUMMARY OF THE '379 PATENT

The '379 patent describes a surgical stapling instrument "suitable for endoscopically inserting an end effector that is actuated by a longitudinally drive firing member, and more particularly a surgical stapling and severing instrument that has an articulating shaft." IS1001, 1:52-55. In the illustrated embodiments, the "surgical stapling instrument 10 has at its distal end an end effector, depicted as a staple applying assembly 12." *Id*., 4:58-61, Fig. 1.

[5] Applicants cited more than 4000 references during prosecution of the '379 patent.

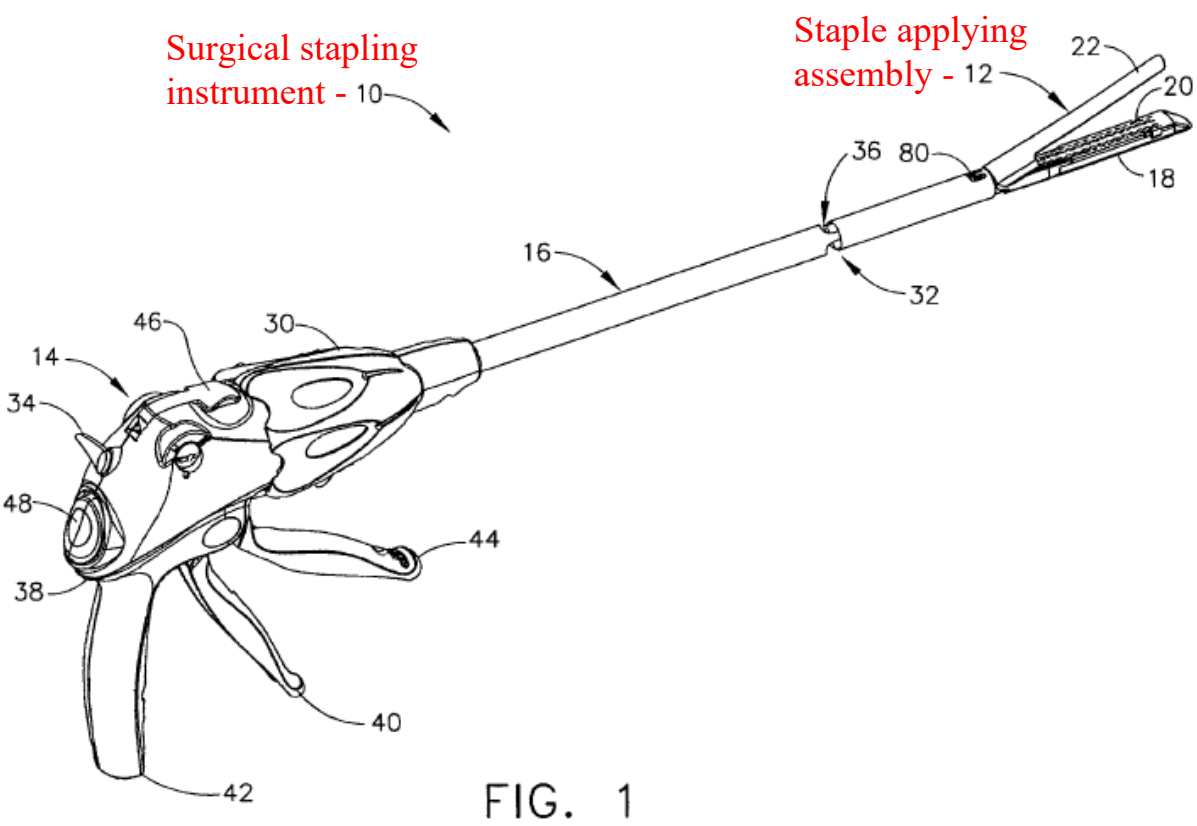
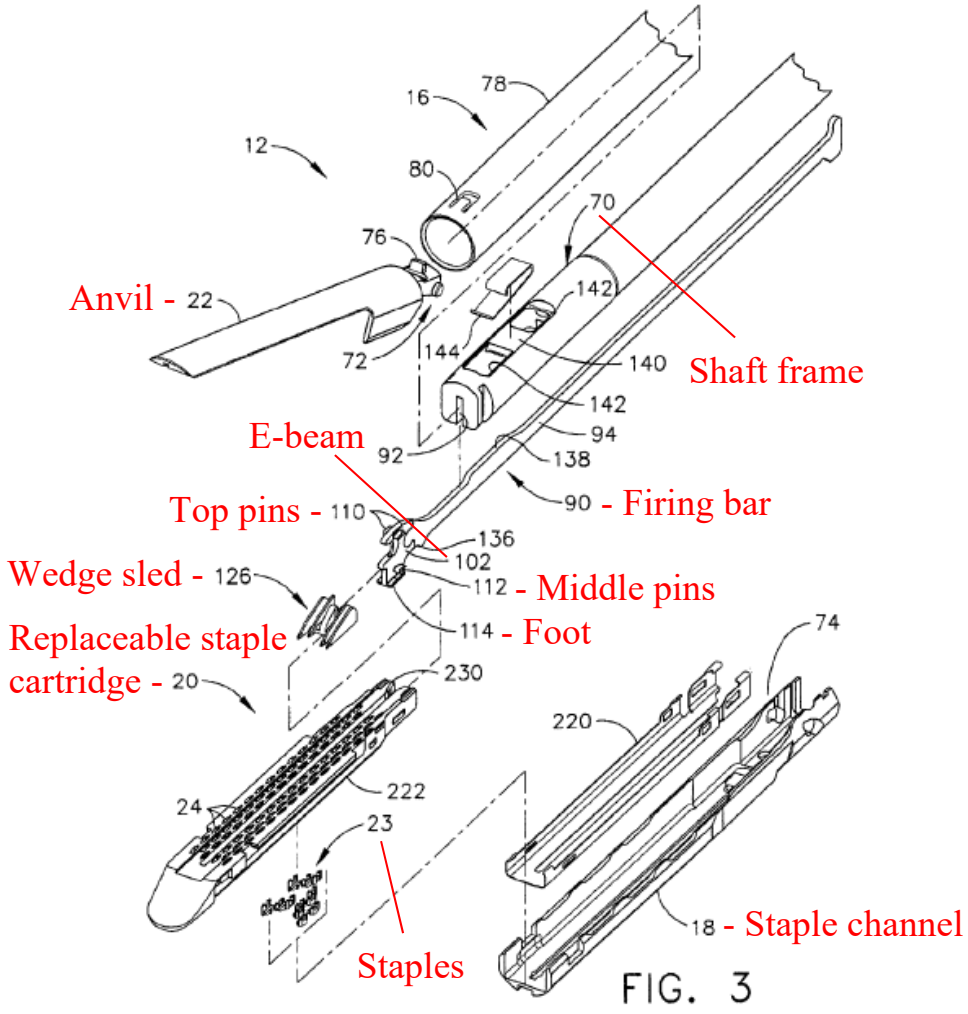


FIG. 1

Id., Fig. 1 (annotated).

"The staple applying assembly 12 includes a staple channel 18 for receiving a replaceable staple cartridge 20 [that includes a wedge sled 126]." *Id.*, 4:61-63, Fig. 2. "Pivotally attached to the staple channel 18 is an anvil 22 that clamps tissue to the staple cartridge 20 and serves to deform staples 23 (FIG. 3) . . . into a closed shape." '379 patent, 4:61-7:1, 7:42-44, Fig. 3. Collectively, the staple channel 18 and staple cartridge 20 form a first jaw, and the anvil 22 forms a second jaw. IS1003, ¶28. An exploded view of components comprising these "jaws" is shown in Fig. 3 of the '379 Patent, reproduced below:



Id., Fig. 3 (annotated).

"[S]taple applying assembly 12 accomplishes the functions of clamping onto tissue, driving staples and severing tissue by two distinct motions transferred longitudinally down the shaft 16 over a shaft frame 70." *Id.*, 5:47-50, Fig. 3. "The shaft frame 70 encompasses and guides . . . a longitudinally reciprocating, two-piece knife and firing bar 90 [that includes an] E-beam 102 . . . which facilitates separate

closure and firing as well as spacing of the anvil 22 from the elongate staple channel 18 during firing." *Id*., 6:18-31, Fig. 3. The "E-Beam . . . [includes] a pair of top pins 110, a pair of middle pins 112 and a bottom pin or foot 114." *Id*., 6:39-44, Figs. 3-5.

The '379 Patent explains that the firing bar 90 and E-beam 102 combination can be moved from a retracted position, *e.g.*, Figs. 6 and 13, to a partially advanced position, *e.g.*, Fig. 11, to an advanced position *e.g.,* Fig. 12. In Figure 6, "E-beam 102 is retracted with the top pins 110 thereof residing within an anvil pocket 150 near the pivoting proximal end of the anvil 22." *Id*., 7:29-36, Fig. 6. When the E-beam 102 is in this retracted position, "the surgeon is able to repeatably open and close the staple applying assembly 12" because no part of the firing bar 90 is locking the jaws (*e.g.*, the anvil 22 and staple channel 18) to one another. *Id*., 7:36-38; IS1003, ¶33. When a new staple cartridge is loaded into staple channel 18 and E-beam 102 is fired, "anvil internal track 154 . . . captures the top pins 110 of the E-beam 102 as they distally advance during firing . . . affirmatively spacing the anvil 22 from the staple channel 18." IS1001, 7:29-36. Advancement of the firing bar 90/E-beam can be seen in FIG. 11 where the "two-piece knife and firing bar 90 has been distally advanced a small distance" until it is full advanced in FIG. 12. *Id.*, 8:5-17, Figs. 11-12; IS1003, ¶¶36-37.

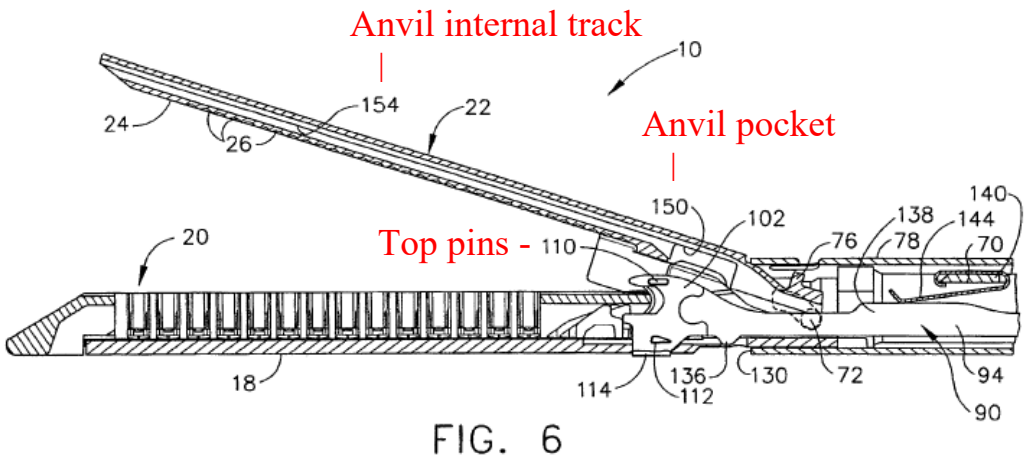


FIG. 6

Id., Fig. 6 (annotated).

Middle guide 120 of firing bar 90 "rests upon the stepped central member 124 of the wedge sled 126, thus maintaining the middle pin 112 of the E-beam within the central firing recess 216" of the staple cartridge. *Id.*, 7:53-58, 8:5-13, Figs. 8, 11.

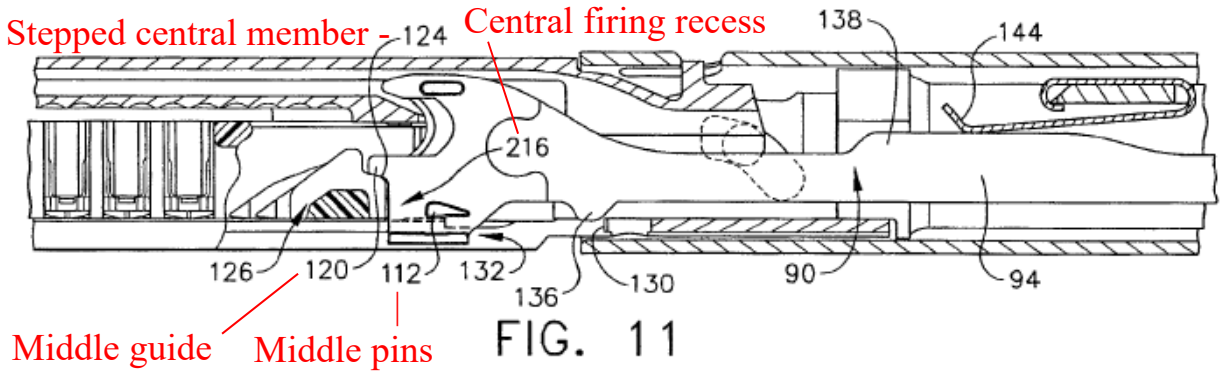


FIG. 11

Id., Fig. 11 (annotated).

Lower foot 114 rides within "widened slot 134 on an undersurface of the staple channel 18." *Id.*, 6:61-7:8, Figs. 6-7.

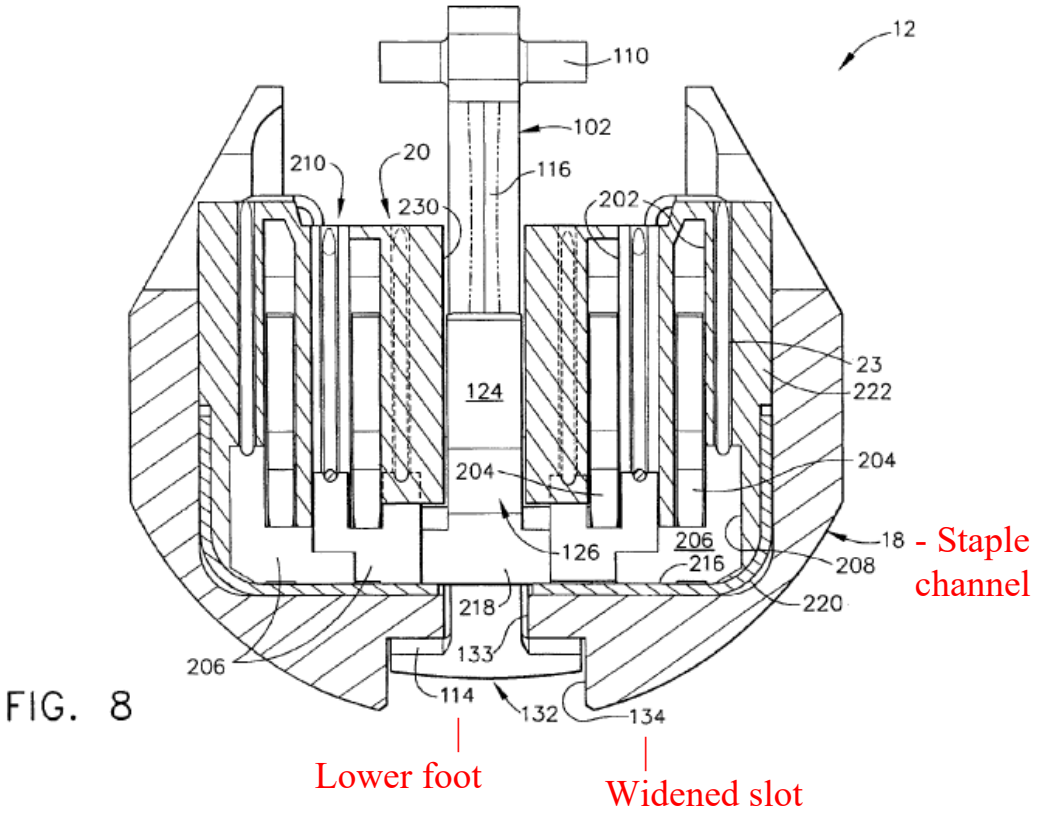
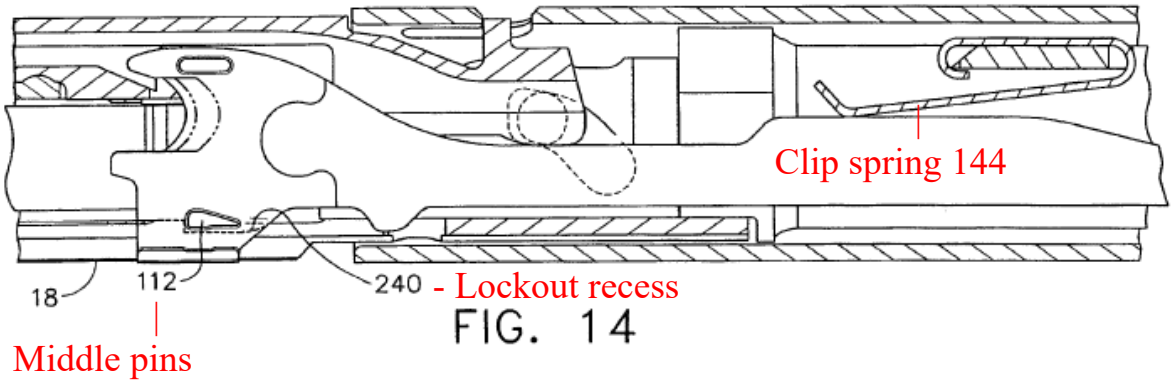


FIG. 8

Id., Fig. 8 (annotated).

After "firing bar 90 has been distally fired, [thereby] advancing wedge sled 126 to cause formation of staples 23 while severing tissue 242[,] firing bar 90 is retracted, leaving the wedge sled 126 distally positioned." *Id.*, 8:14-19, Fig. 12. If, subsequent to retracting the firing bar 90, the operator attempts to re-fire firing bar 90 distally when the wedge sled 126 is "distally positioned" (and/or when the staple cartridge is removed from the stapling assembly completely), clip spring 144 forces the firing bar 90 and, in particular, middle pin 112 "down into a lockout recess 240 formed in the staple channel 18"—a position referred to as "a lockout po-

sition." *Id*., 4:25-27, 8:20-26, Figs. 7, 10, 14; IS1003, ¶38. In this "lockout position," the operator would receive a tactile indication as the middle pin 112 encounters the distal edge of the lockout recess 240 when the wedge sled 126 (not shown in FIG. 14) is not proximally positioned (i.e., missing staple cartridge 20 or spent staple cartridge 20)." *Id*. Consequently, when the staple cartridge is missing or spent, the operator is unable to cause the firing bar 90 to move in the distal direction.[6] IS1003, ¶38.



IS1001, Fig. 14 (annotated).

[6] Surgical staplers having a lockout mechanism that prevented firing when the staple cartridge was missing were notoriously well-known by the time of the '379 patent. *See, e.g.,* U.S. Patent No. 3,819,100 ("Surgical Stapling Instrument"), which issued over 45 years ago, and discloses a "means … for preventing the forward movement of thrust bar until a staple-carrying cartridge has been mounted on the stapler." IS1010, 3:11-26.

VI. SUMMARY OF THE PROSECUTION HISTORY

The chain of applications to which the '379 patent claims priority is provided above in Section IV.B. Notably, issued claims 1-3 (original claims 6-8) were rejected under pre-AIA 35 U.S.C. § 102(a) as being anticipated by U.S. Patent Application Publication 2004/0232199 to Shelton et al ("Shelton '199"). IS1002, 67-68 (February 23, 2017 Rejection). In response, Applicant improperly argued that Shelton '199 was not prior art under Section 102(a) because the application that issued as the '379 patent purportedly had an effective priority date of July 28, 2004, and Shelton '199 has a publication date of November 25, 2004. *Id*., 24 (May 23, 2017 Response). Applicant also argued that Shelton '199 was not prior art under Section 102(e) because the application that issued as the '379 patent names the same inventive entity as Shelton '199. *Id*. Following Applicant's response filed on August 14, 2017, the Patent Office mailed a notice allowance, allowing claims 6-8, which issued as claims 1-3 of the '379 patent. *Id.*, 10, 14; IS1001, 8:60-10:26.

VII. CLAIM CONSTRUCTION

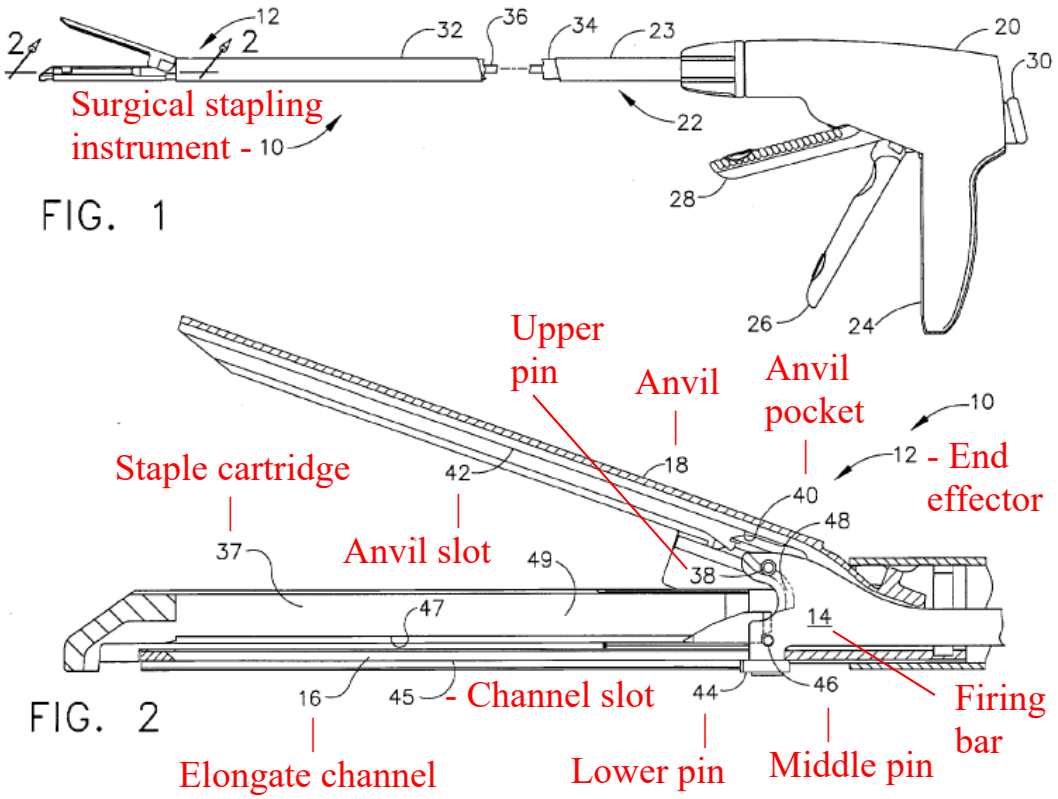
For purpose of this proceeding only, Petitioner submits that all claim terms should be given their plain and ordinary meaning.

VIII. SUMMARY OF THE PRIOR ART

A. Summary of Shelton '818

Like the '379 patent, Shelton '818 describes a "surgical stapling and severing instrument." IS1014, 4:21-25; IS1003, ¶49. As explained below, Shelton '818 discloses two lockout mechanisms that serve the same purpose as the claimed "lockout" in the '379 Patent—namely, to block advancement of a staple firing member when a detachable staple cartridge is not attached to the stapling assembly. IS1003, ¶49.

In the illustrated embodiments "surgical stapling and severing instrument 10 incorporates an end effector 12 having an E-beam firing mechanism ('firing bar') 14 that advantageously controls the spacing of the end effector 12. In particular, an elongate channel 16 and a pivotally translatable anvil 18 are maintained at a spacing that assures effective stapling and severing." IS1014, 4:25-32, Figs. 1-2.



Id., Figs. 1-2 (annotated).

The end effector 12 is positioned at the distal end of the surgical stapling instrument 10 and includes an anvil 18 positioned above the elongate channel 16 and staple cartridge. *Id.*, 4:43-50, Fig. 2; IS1003, ¶50. The anvil 18 works with the combined elongate channel 16 and staple cartridge 37 as jaws to clamp tissue. IS1003, ¶51; IS1014, 4:43-53, Fig. 2. "The elongate channel 16 receives a staple cartridge 37," which can be removed and replaced. IS1014, 5:2-3; *see also* 9:1-3, 9:11-16, 9:54-58, 10:4-8.

The end effector 12 has a "firing bar 14" that moves transversely along the surgical stapling instrument 10 "between opposing jaws to sever the tissue and

drive . . . the staples." IS1003, ¶¶52-53; IS1014, 1:67-2:3. As shown above, "firing bar 14 includes three vertically spaced pins that control the spacing of the end effector 12 during firing"—upper pin 38, lower pin (firing bar cap) 44, and middle pin 46. IS1014, 5:7-35, Figs. 2-4. "[U]pper pin 38 is staged to enter an anvil pocket 40 near the pivot between the anvil 18 and elongate channel 16." *Id.*, 5:10-12, 9:7-9 (explaining that upper pin 38 is aligned in a noninterfering fashion with anvil pocket 40 when firing bar 14 is at its proximal position), Figs. 2-4, 10. "When fired with the anvil 18 closed, the upper pin 38 advances distally within a longitudinal anvil slot 42 extending distally through anvil 18." *Id.* This is shown in Figure 19, where the firing bar is not advanced, and Figure 21, where the firing bar is partially advanced. *Id.*, Figs. 19, 21; IS1003, ¶53.

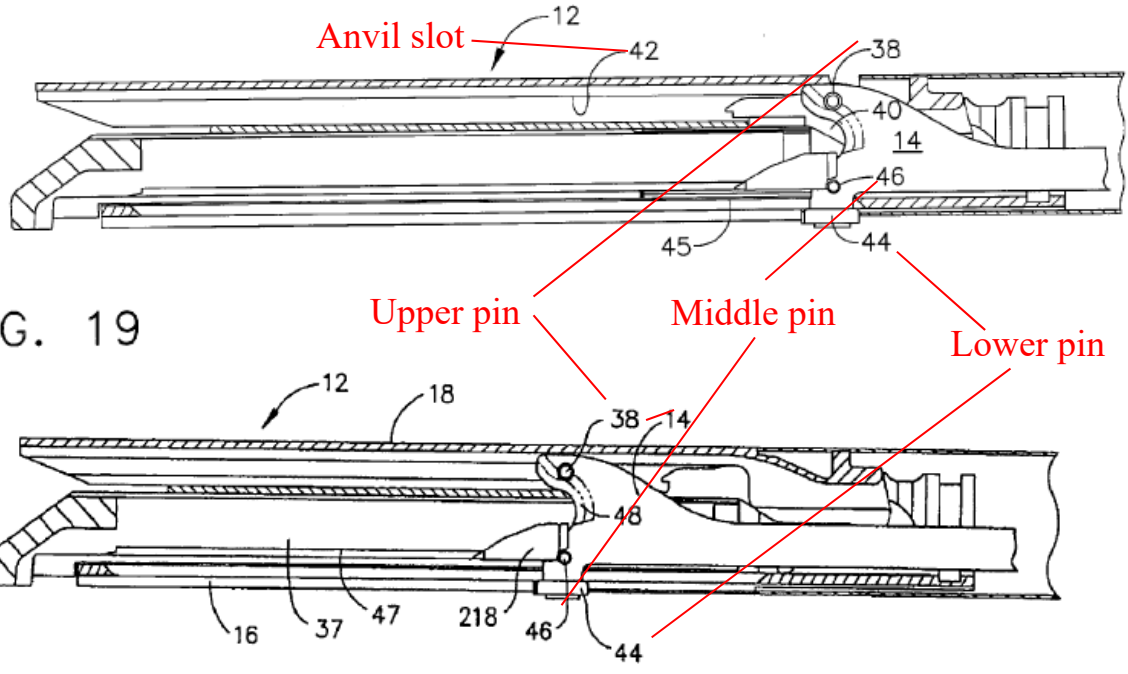


FIG. 19

FIG. 21

IS1014, Figs. 19, 21 (annotated).

Lower pin (firing bar cap) 44 "upwardly engages a channel slot 45 in the elongate channel 16." *Id.*, 5:18-23, Figs. 2-4, 16; IS1003, ¶54.

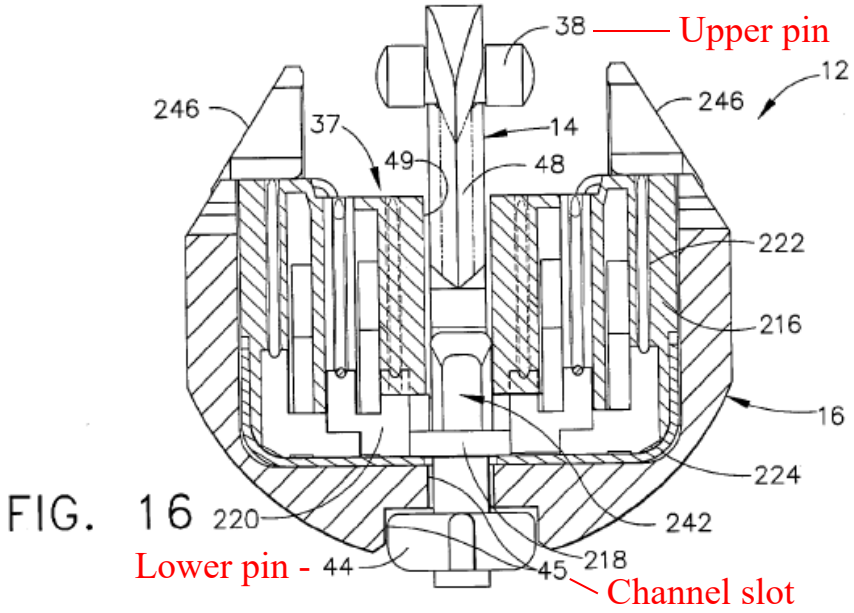


FIG. 16

IS1014, Fig. 16 (annotated).

Middle pin 46 "passes through a firing drive slot 47 formed in a lower surface of the cartridge 37 and an upward surface of the elongate channel 16, thereby driving the staples therein . . . ." *Id.*, 5:24-27, Figs. 2-4.

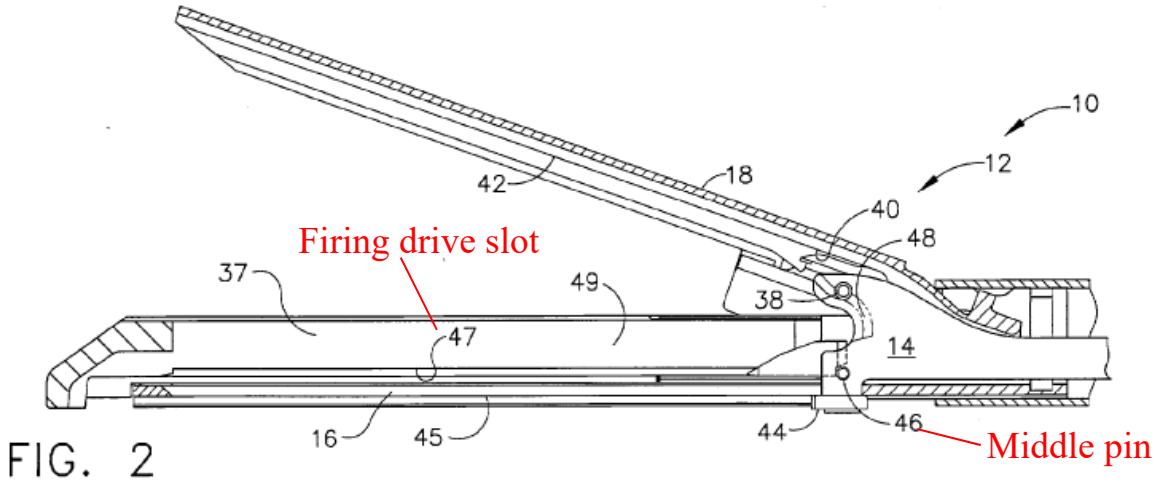
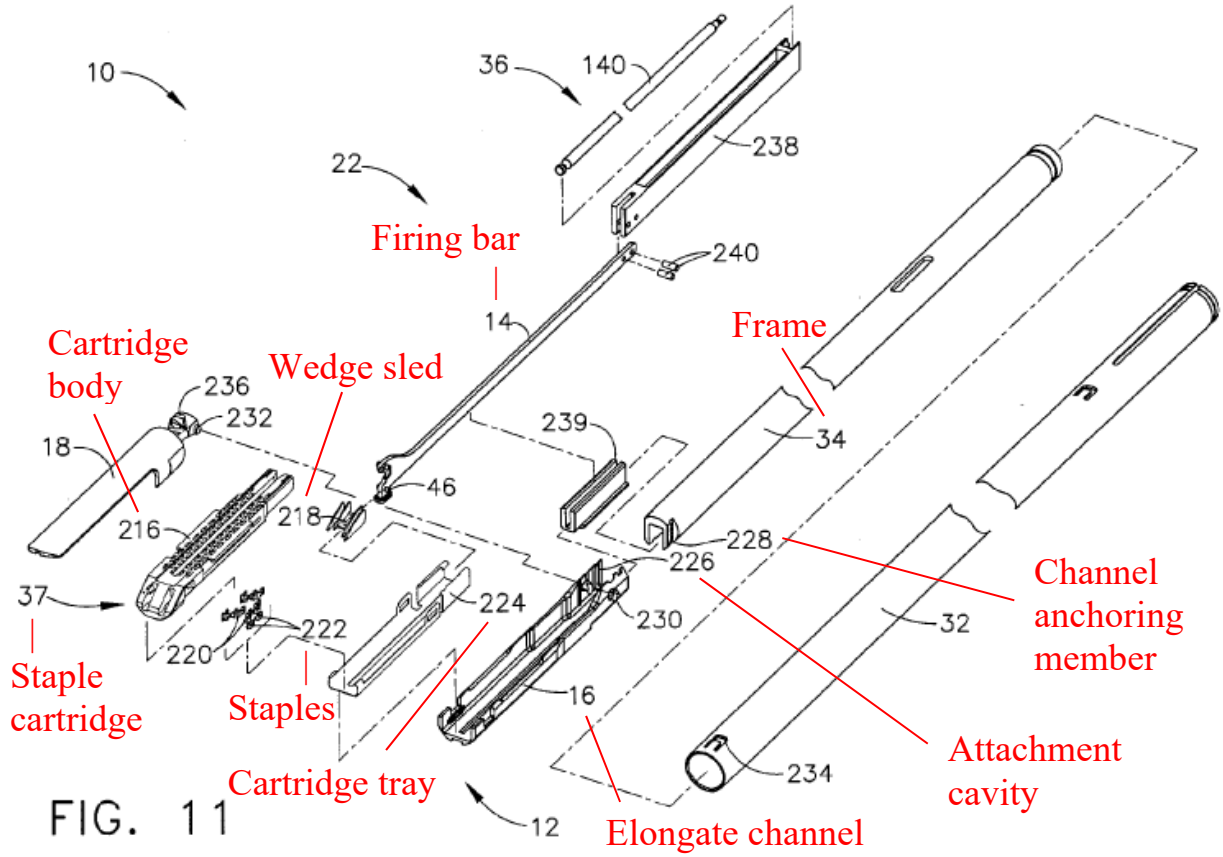


FIG. 2

Id., Fig. 2 (annotated).

The end effector also includes an elongate channel 16 that forms a bottom jaw of the device. IS1003, ¶¶51, 56. "The elongate channel 16 has a proximally placed attachment cavity 226 that receives a channel anchoring member 228 on the distal end of the frame 34" that guides firing bar 14. *Id.*, 9:39-53, Fig. 11. "[S]ta-ple cartridge 37 . . . comprise[s] a cartridge body 216, a wedge sled 218, single and double drivers 220, staples 222, and a cartridge tray 224. When assembled, the cartridge tray 224 holds the wedge sled 218, single and double drivers 220, and staples 222 inside the cartridge body 216." *Id.*, 9:21-26, Fig. 11.



Id., Fig. 11 (annotated).

The "integral wedge sled 218 [of staple cartridge 37] provides an opportunity for a number of lockout features, described in greater detail in [Shelton '818's] first and third . . . co-pending applications," which Shelton '818 "incorporate[s] by reference in their entirety." *Id.*, 1:8-26, 9:35-38. The first of these incorporated applications published as U.S. Patent Application Publication No. 2004/0232195 ("Shelton '195," IS1013). IS1003, ¶57, n.2. This statement incorporates all of Shelton '195 into Shelton '818 as if it were set out expressly rather than through incorporation. *See, e.g., id.; Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272,

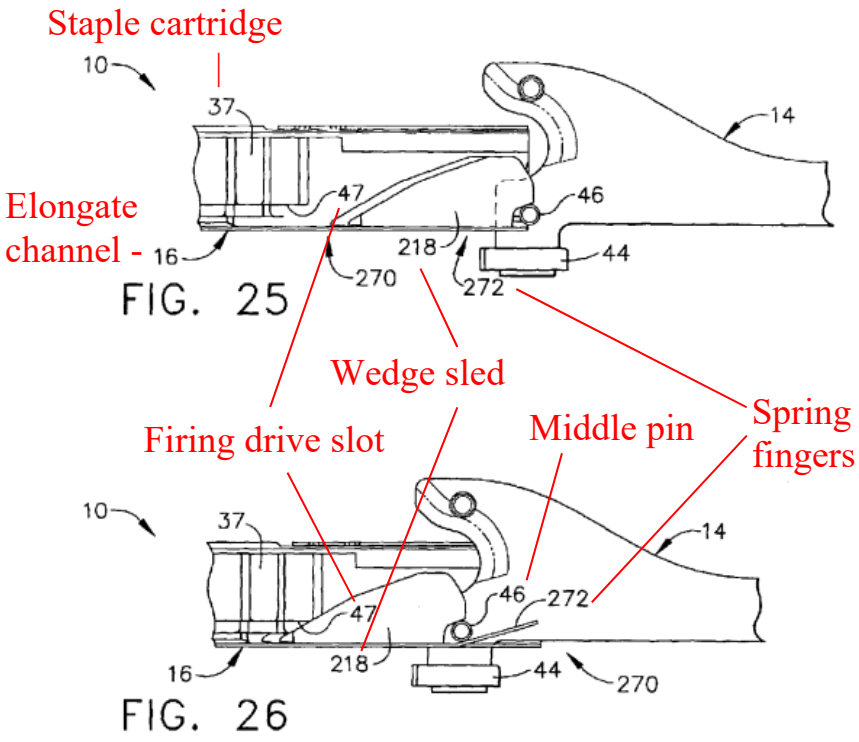
1282 (Fed. Cir. 2000); *Biscotti Inc. v. Microsoft Corp*., No. 2:13-CV-01015-JRG-RSP, 2017 U.S. Dist. LEXIS 144164, at *12 (E.D. Tex. May 11, 2017).

Like Shelton '818, Shelton '195 discloses "a surgical stapling and severing instrument." IS1013, ¶ 45. Shelton '195's instrument further includes a "single lockout mechanism 270 [that] advantageously responds to a missing staple cartridge 37 or a spent staple cartridge 37 . . . by blocking the middle pin 46 of the firing bar." *Id.*, 11:60-12:2, Fig. 24.[7] "In particular, the single lockout mechanism 270 is depicted as a pair of bent spring fingers 272 [that] raise up to block the middle pin 46 of the firing bar 14 when the wedge sled 218 (not shown in FIG. 24) is not present, such as when the cartridge 37 is removed or when the cartridge 37 has been fired." *Id*., 12:4-11.

Shelton '195 describes two different lockout mechanisms. IS1003, ¶¶58-59; *see, e.g.,* IS1013, ¶¶41, 43-44, Figs. 25-28, 30-34. Figures 25–28 "depict the single lockout mechanism 270, specifically the bent sprint[sic] fingers 272 sequentially as the surgical stapling and severing instrument 10 is fired." *Id*., ¶96. In Figure 25, "an unfired staple cartridge 37 has been inserted into the elongate channel 16 with the wedge sled 218 depressing the bent spring fingers 272 so that the firing

[7] *See* supra note 5 and accompanying text (citing to prior art (IS1010) demonstrating that lockout mechanisms were well-known by the time of the '379 patent).

drive slot 47 formed between the cartridge 37 and the elongate channel 16 is unimpeded." *Id.*, ¶96, Fig. 25.

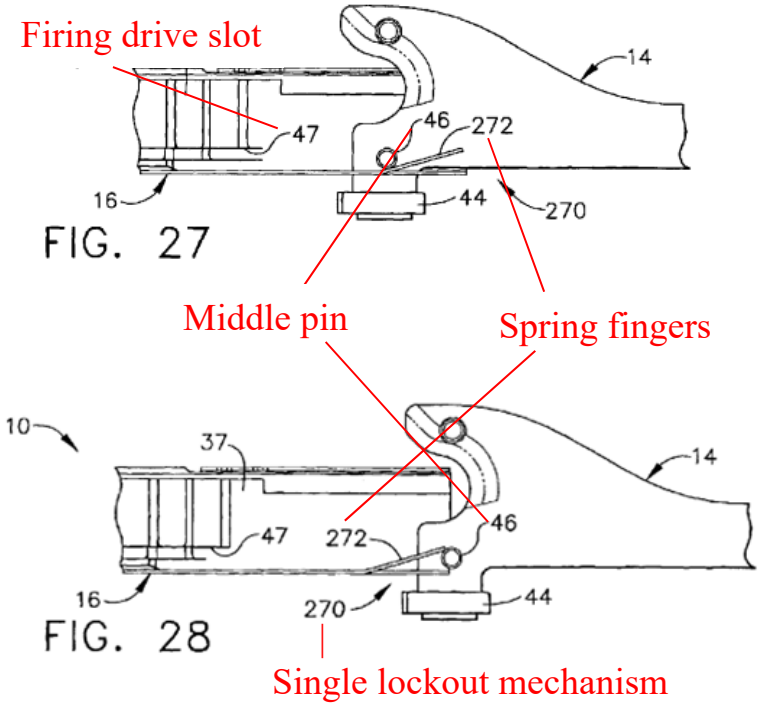


Id., Figs. 25-26 (annotated).

In Figure 26, "firing of the cartridge 37 has commenced, with the wedge sled 218 and the middle pin 46 of the firing bar 14 having distally traversed off of the bent spring fingers 272, which then spring up into the firing drive slot 47." *Id.*, ¶97, Fig. 26.

In Figure 27, "the staple cartridge 37 is now spent with the wedge sled 218 fully driven distally and no longer depicted. The firing bar 14 is being retracted proximally. Because the bent spring fingers 272 pivot from a more distal point, the

firing bar 14 is able to ride up onto the bent spring fingers 272 during retraction, causing them to be depressed out of the firing drive slot 47." *Id.*, ¶98, Fig. 27.



Id., Figs. 27-28 (annotated).

In Figure 28, "the firing bar 14 is fully retracted and [middle pin 46] now confronts a non-depressed pair of bent spring fingers 272 to prevent distal movement. The single lockout mechanism 270 thereby activated remains during the period in which the spent staple cartridge 37 is removed until an unfired staple cartridge 37 is installed." *Id.*, ¶99, Fig. 28.

Figure 29 "depicts a lockout trough 274 that may advantageously be included in the single lockout mechanism 270 in order to provide increased mechanical strength." *Id.*, ¶ 100, Fig. 29.

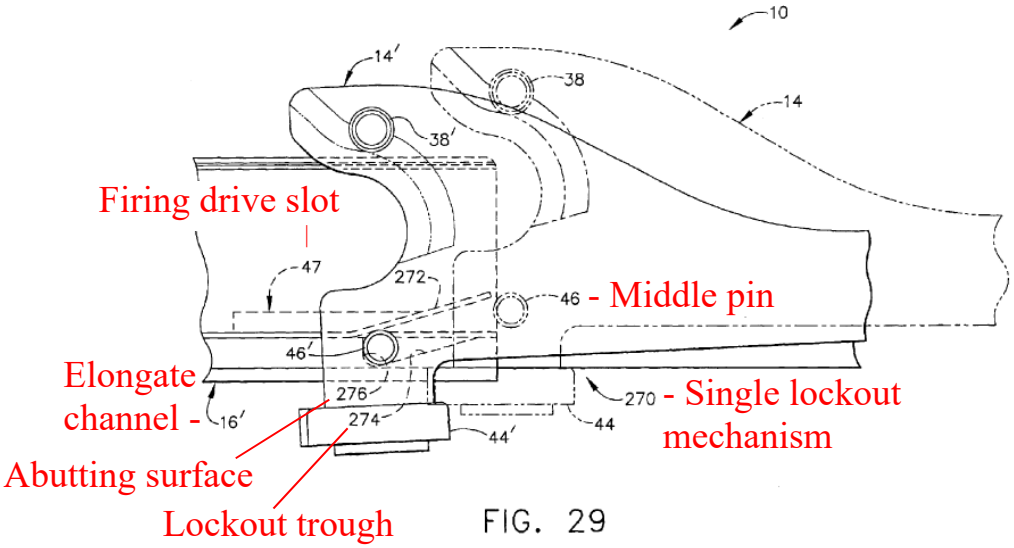


FIG. 29

Id., Fig. 29 (annotated).

As shown above, the "lockout trough 274 communicates with the firing drive slot 47 when the bent spring fingers 272 are not depressed. Moreover, the lockout trough 274 is downwardly ramped in a distal direction such that the middle pin 46 of the firing bar 14 is directed toward an abutting surface 276 at a distal end of the lockout trough 274, thereby reacting the distal movement of the firing bar 14 into an elongate channel 16'." *Id.*, ¶100, Fig. 29.

In addition to the first single lockout mechanism, Shelton '195 shows a second single lockout mechanism with reference to Figs. 30-34. *Id.*, ¶¶33-34. Figure 30 shows the second "single lockout mechanism 270, depicted as a pair of lockout hooks 280 having ramped ends 282 distally placed with regard to attachment devices 284 inserted through apertures 286 in the elongate channel 16. The ramped ends 282 lie above a hook recess 288 defined in the elongate channel 16." *Id.*,

¶102, Fig. 30. A "thin shaft 290 coupl[es] the attachment devices 284 to . . . the ramped end 282 of each lockout hook 280." *Id.*

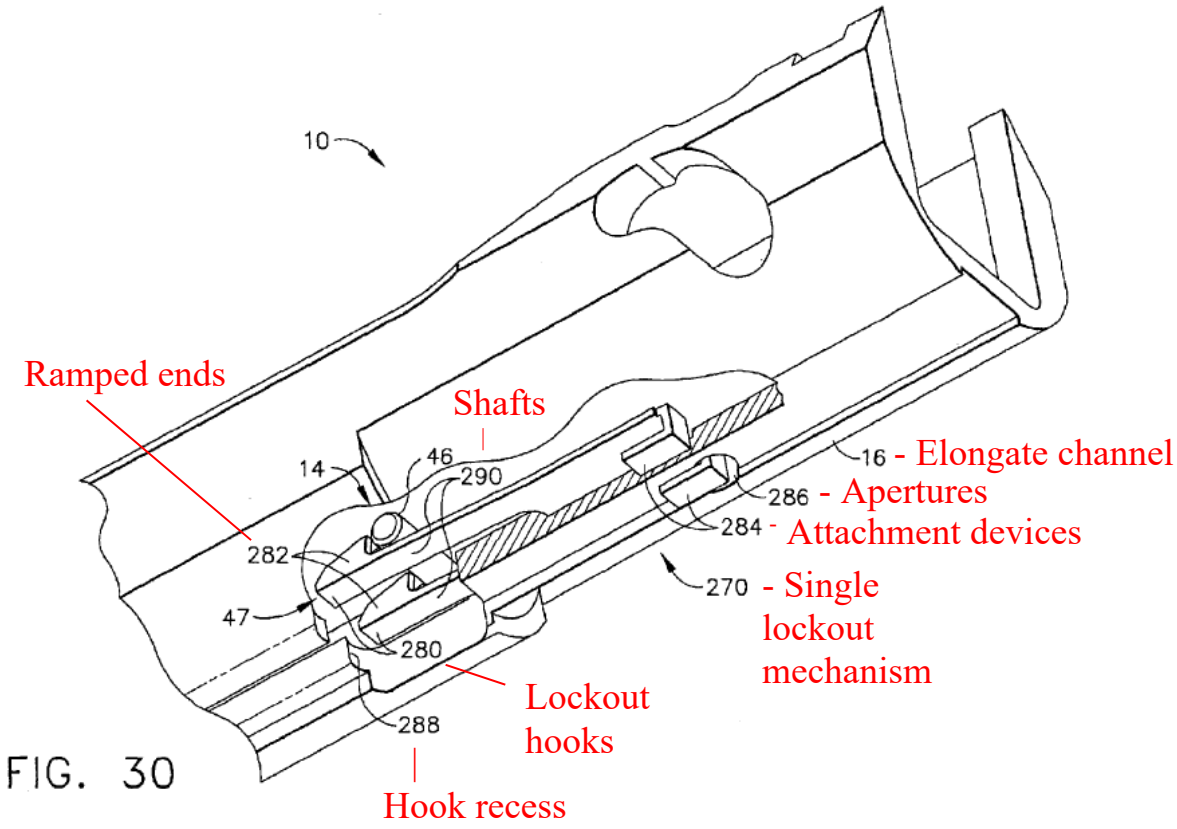
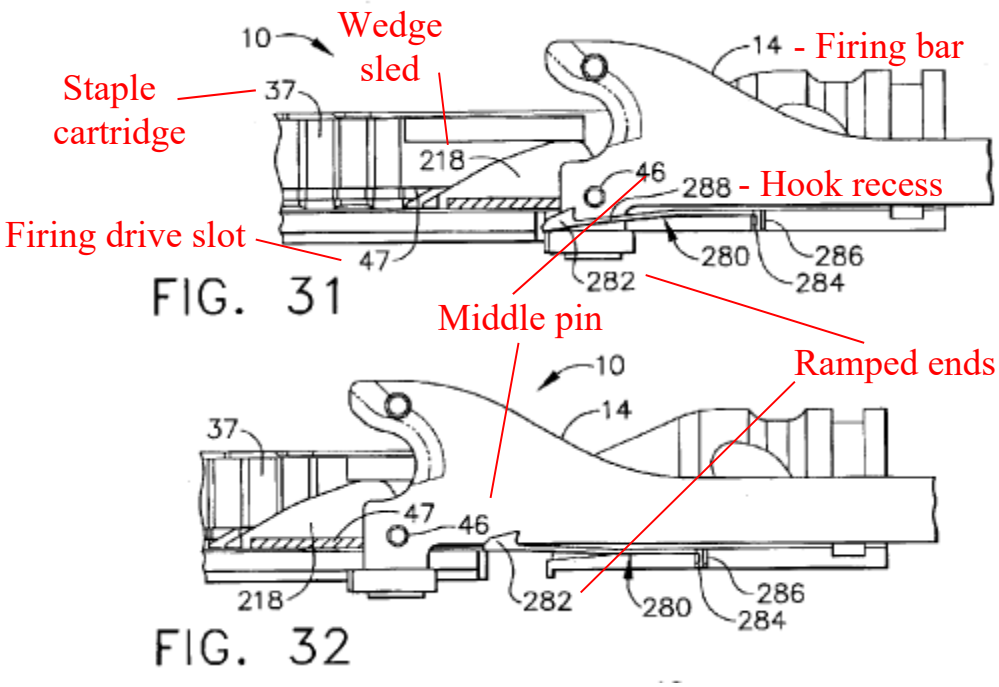


FIG. 30

Id., Fig. 30 (annotated).

Figures 31-34 "depict the sequence of operation of the lockout hooks 280. In FIG. 31, the staple cartridge 37 is unfired so that the distally positioned wedge sled 218 depresses the ramped ends 282 into the hook recess 288, allowing the middle pin 46 of the firing bar 14 to move distally during firing, as depicted in FIG. 32. With the wedge sled 218 and middle pin 46 distally removed with respect to the lockout mechanism 270, the ramped ends 282 resiliently raise out of the hook recess [288] to occupy the firing drive slot 47." *Id.*, ¶103, Figs. 31-32.



Id., Figs. 31-32 (annotated).

In Figure 33, "the firing bar 14 is being retracted to the point of contacting the ramped ends 282 of the lockout hook 280. Since the distal end of the ramped ends 282 is lower than the proximal part of the ramped ends 282, the middle pin 46 of the firing bar 14 rides over the ramped ends 282, forcing them down into the hook recess 288 until middle pin 46 is past the ramped ends 282, as depicted in FIG. 34, wherein the ramped ends 282 resiliently spring back up to block the middle pin 46. Thus, the firing bar 14 is prevented from distal movement while the spent staple cartridge 37 is replaced with an unfired staple cartridge 37." *Id.*, ¶104, Figs. 33-34.

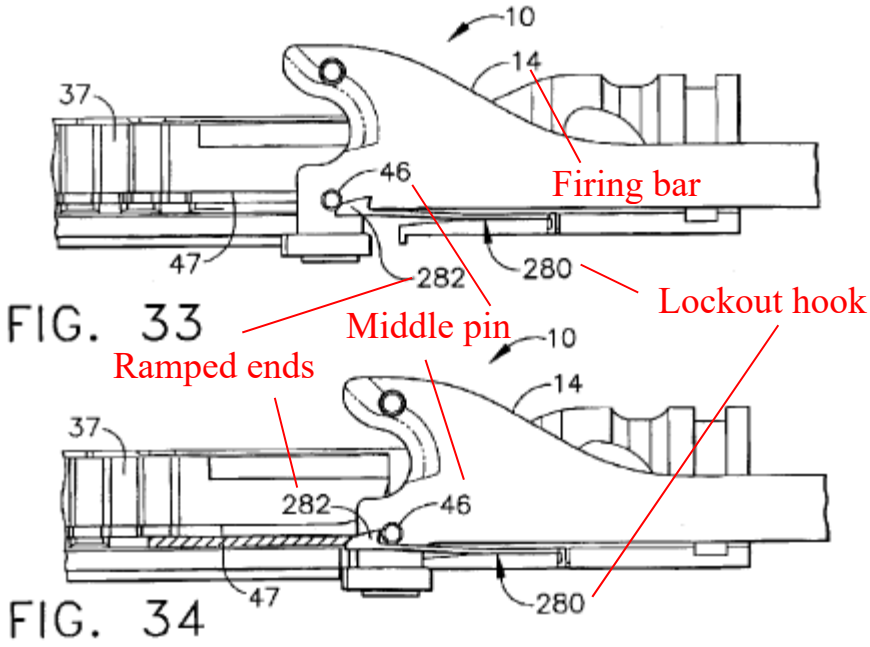


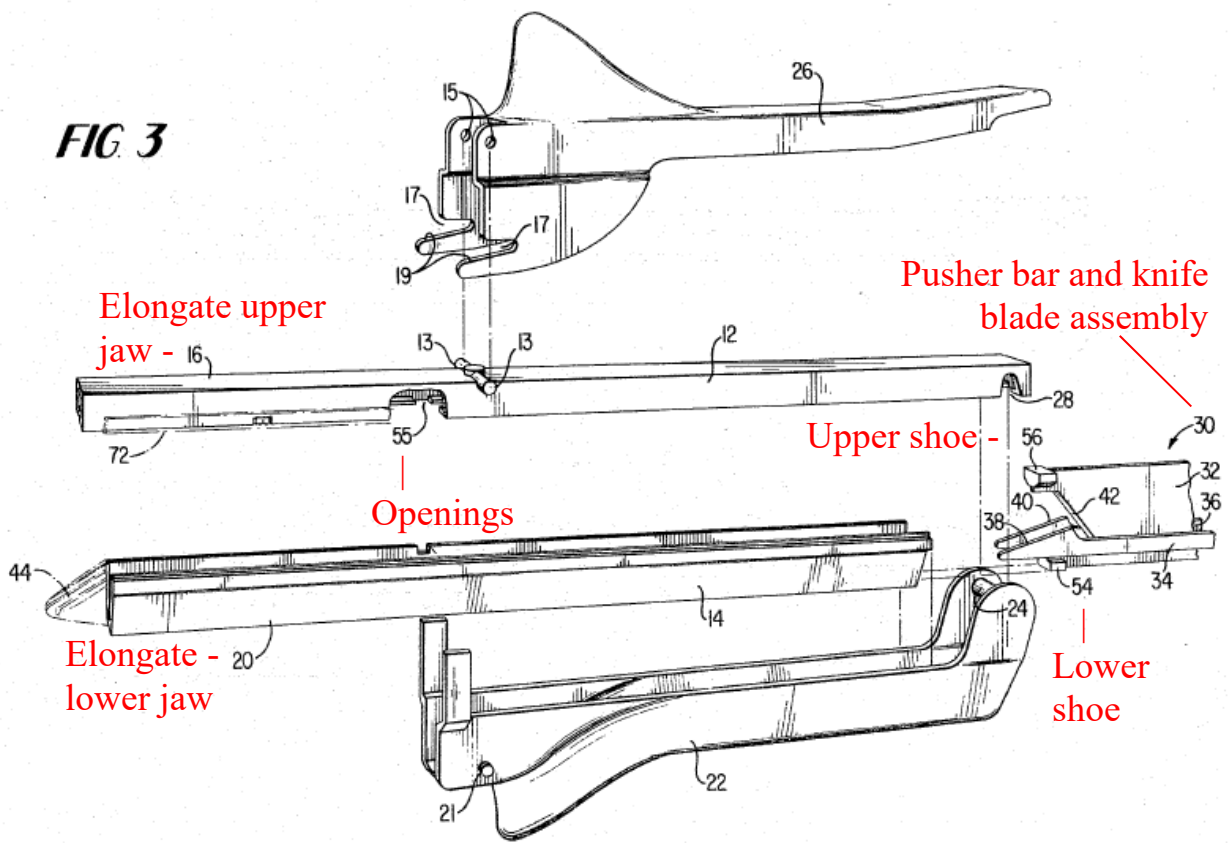
FIG. 33

FIG. 34

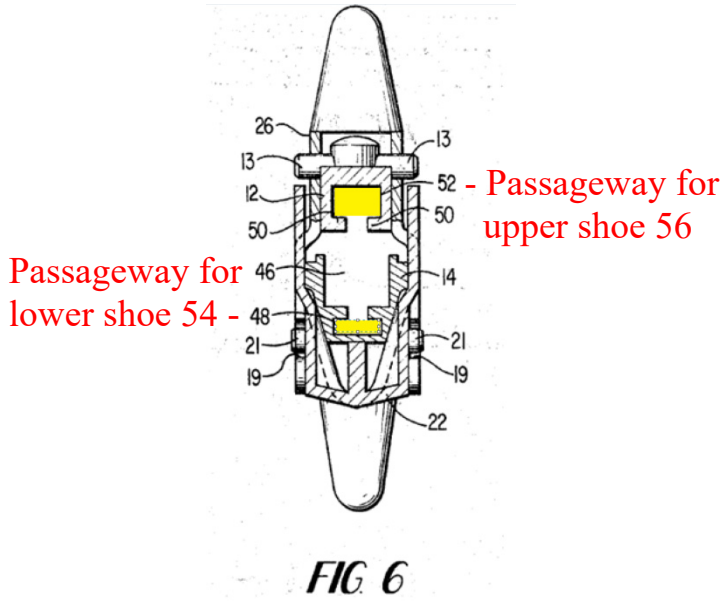
Id., Figs. 32-33 (annotated).

B. Summary of Green

Like the '379 patent, Green discloses a surgical stapling instrument 10 that maintains the distance and alignment between the jaws of the stapler using a beam (pusher bar and knife blade assembly 30) that engages the jaws 16, 20 of the stapler 10. IS1003, ¶69; IS1015, 4:37-60, 6:26-38, Figs. 1-12. As shown in Figure 3, pusher bar and knife blade assembly 30 includes "lower and upper shoes 54 and 56, respectively." *Id.*, 4:37-60, Figs. 3-6. As shown in Figure 6, "lower shoe 54 … fits in passageway 48 … and upper shoe 56 is likewise shaped to fit in passageway 52." *Id.* Openings 55 are provided in upper jaw 16 that "allow shoes 56 to enter channel 52 as the instrument is closed." *Id.*, 6:14-17, Figs. 3, 6.



Id., Fig. 3 (annotated).



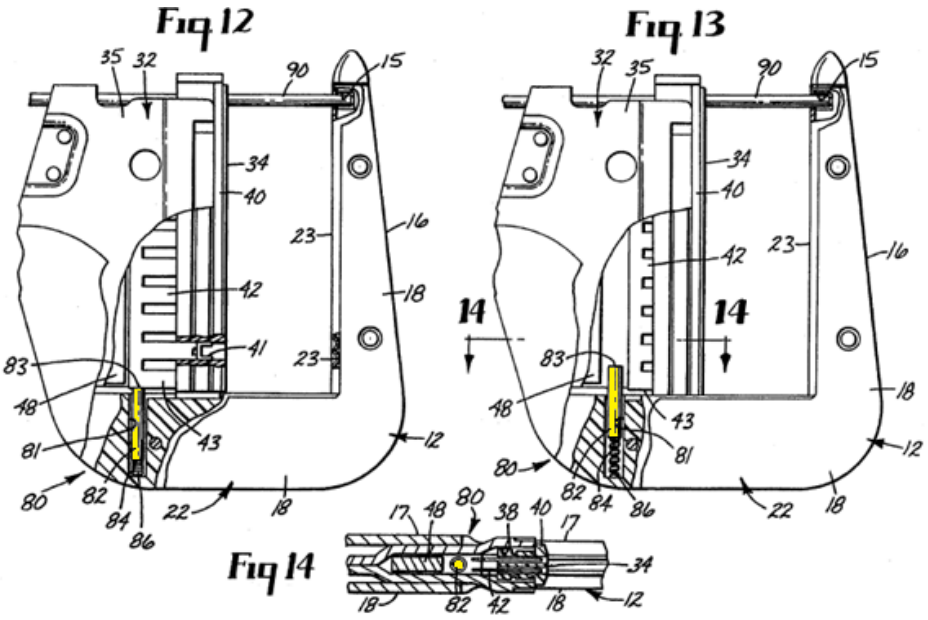
Id., Fig. 6 (annotated).

As shown in Figure 6, "the vertical spacing between the shoes correspond[s]

to the vertical spacing between the passageways 48 and 52 in the lower and upper frames when the frames are locked together." *Id*., 4:37-60.

C. Summary of Solyntjes

Like the '379 patent, Solyntjes discloses a surgical stapler 10 that blocks the advancement of a staple firing member when no staple cartridge is installed or a spent staple cartridge is installed. IS1011, 11:1-18, 12:51-13:8, Figs. 12-14; IS1003, ¶74. More specifically, Solyntjes discloses a locking pin or plate 82 (highlighted yellow below) that moves "between a free travel position (FIG. 12) with the first end 83 of the locking pin [or plate] 82 generally abutting an edge of the pusher 42 … and blocking position (FIG. 13) with the first end 83 of the locking pin [or plate] 82 projecting into the path of the ram 48." IS1011, 11:1-18, Figs. 12-13; *see also* 16:30-55. Thus, pin/plate 82 "will not only prevent the stapler from firing when loaded with a spent cartridge, but will prevent the firing of the stapler 10 when the stapler is not loaded with a cartridge housing 40 at all." *Id*., 12:51-13:8.



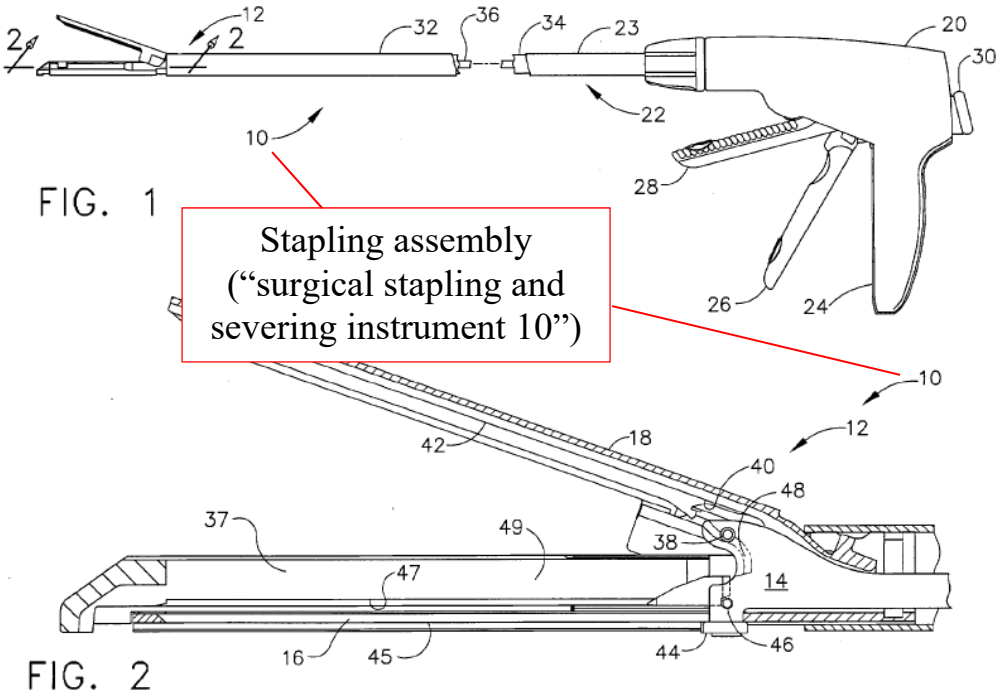
Id., Figs. 12-14 (annotated).

IX. CLAIMS 1-3 ARE INVALID

A. Ground 1: Claims 1-3 are anticipated by Shelton '818

[1.1] A stapling assembly, comprising:

If the preamble is limiting, Shelton '818 discloses a stapling assembly (surgical stapling and severing instrument 10). IS1003, ¶76; IS1014, Abstract, 2:62-4:17, 4:22-26, Figs. 1-2.



IS1014, Figs. 1-2 (annotated).

[1.2] a frame;

Shelton '818 discloses a frame (frame 34). IS1003, ¶77; IS1014, 4:62-65, 6:25-34, 9:39-53, Figs. 1, 6-9, 11. For example, Shelton '818 states that a "closure sleeve 32 encloses a frame 34, which in turn encloses a firing drive member 36." IS1014, 4:62-64.

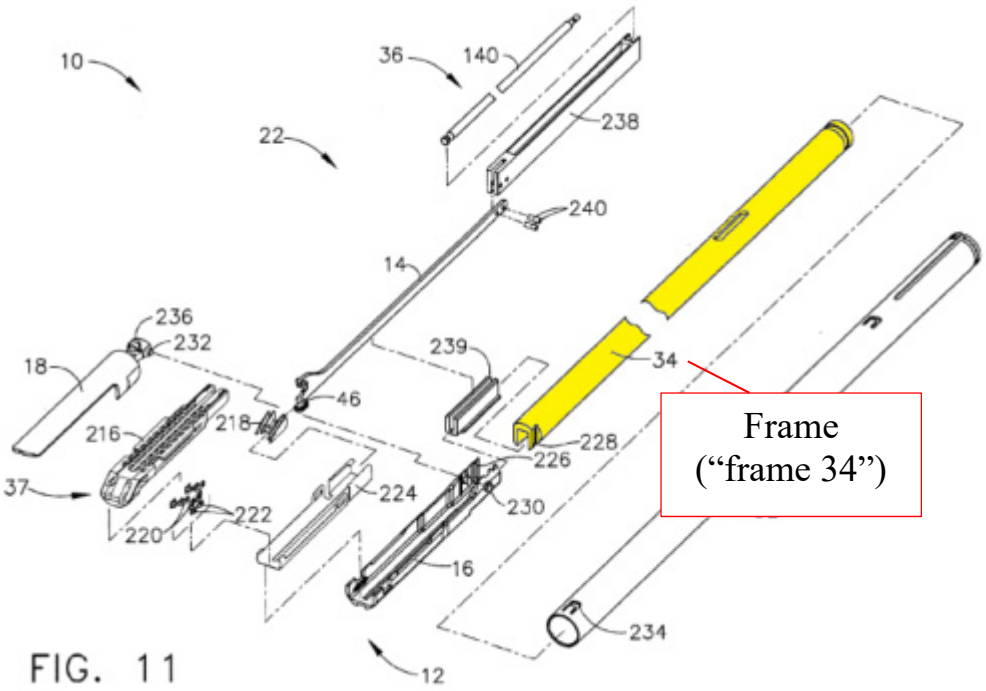


FIG. 11

Id., Fig. 11 (annotated).

[1.3] a distal end;

Shelton '818 discloses a distal end (the end of instrument 10 that includes end effector 12). IS1003, ¶78; IS1014, 3:27-30, 4:33-36, Figs. 1, 10-13, 19, 21, 23. For example, Shelton '818 states, "FIG. 10 depicts an isometric view of the end effector at the distal end of the surgical stapling and severing instrument of FIG. 1." IS1014, 3:27-30. Because the end effector 12 is located at the distal end of the instrument, a POSITA would have understood the distal end of the instrument is located as indicated in annotated Figure 1 below. IS1003, ¶78.

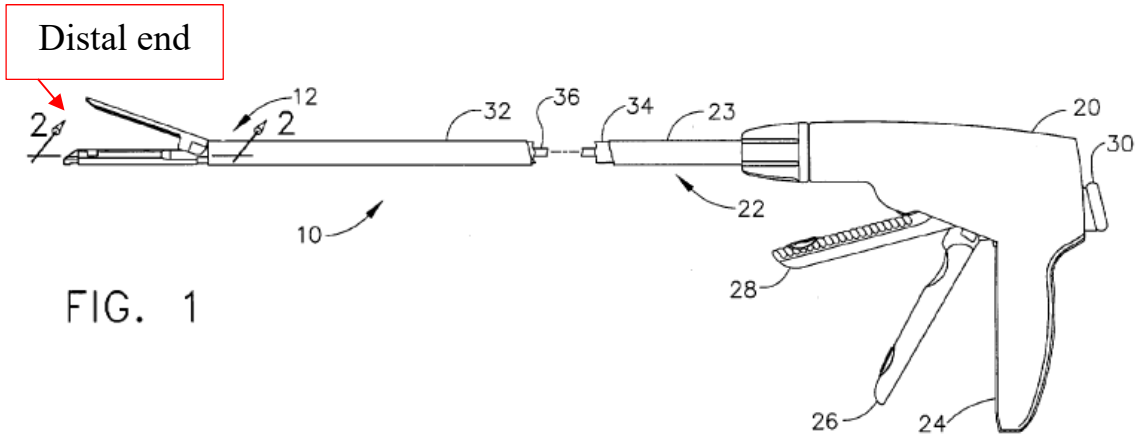


FIG. 1

IS1014, Fig. 1 (annotated).

[1.4] a first jaw comprising a channel;

Shelton '818 discloses a first jaw (combination of elongate channel 16 and staple cartridge 37) comprising a channel (staple cartridge 37). IS1003, ¶79; IS1014, 4:28-31, 5:2-3, Figs. 2, 11. For example, Shelton '818 states that the "elongate channel 16 receives a staple cartridge 37." IS1014, 5:2-3. As shown in Figure 11, the staple cartridge 37 defines a channel with a passage. *Id.*, FIG. 11; IS1003, ¶79.

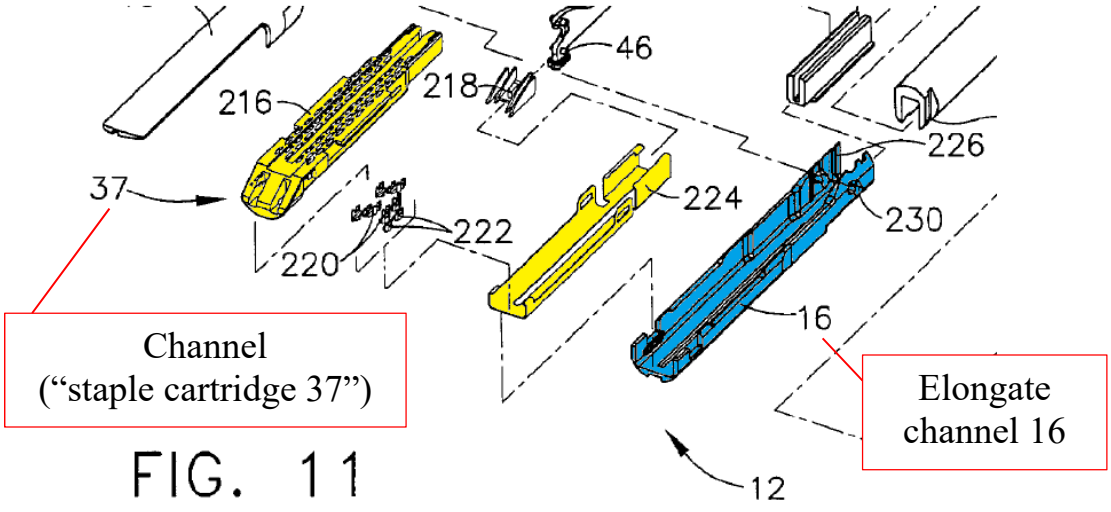
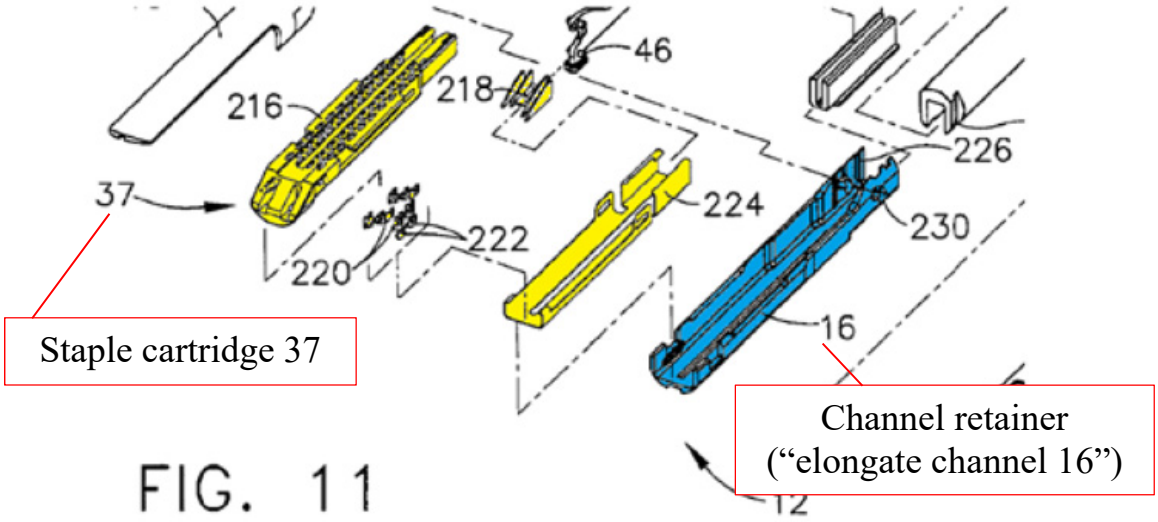


FIG. 11

IS1014, Fig. 11 (excerpted, annotated).

[1.5] a channel retainer, wherein said channel is slidably attachable to said channel retainer;

Shelton '818 discloses a channel retainer (elongate channel 16), wherein the channel (staple cartridge 37) is slidably attachable to the channel retainer. IS1003, ¶80; IS1014, 9:11-18, Figs. 10-13, 16. As Shelton '818 explains, "cartridge [37] … is snapfit into the elongate channel 16." IS1014, 9:15-16, Fig. 10-13, 16.



Id., Fig. 11 (excerpted, annotated).

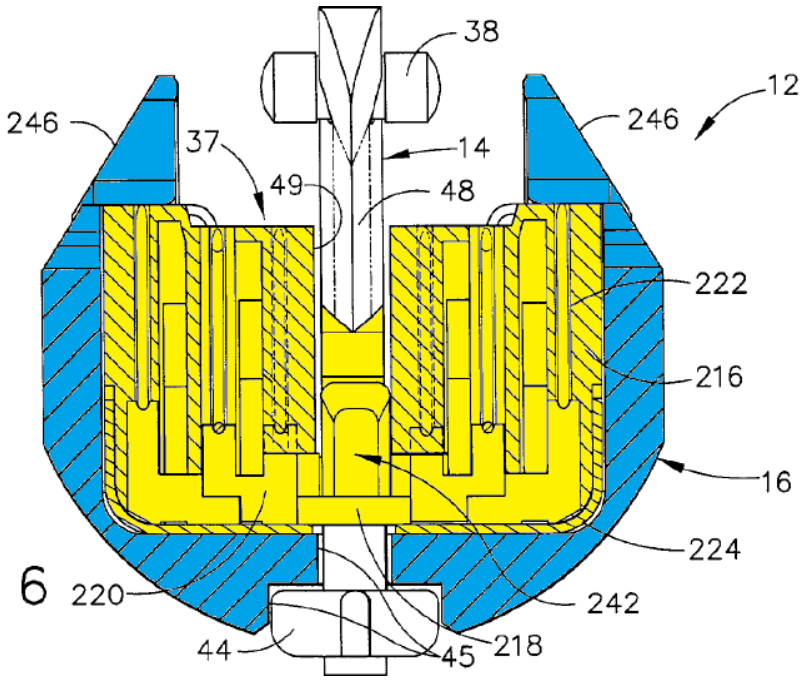
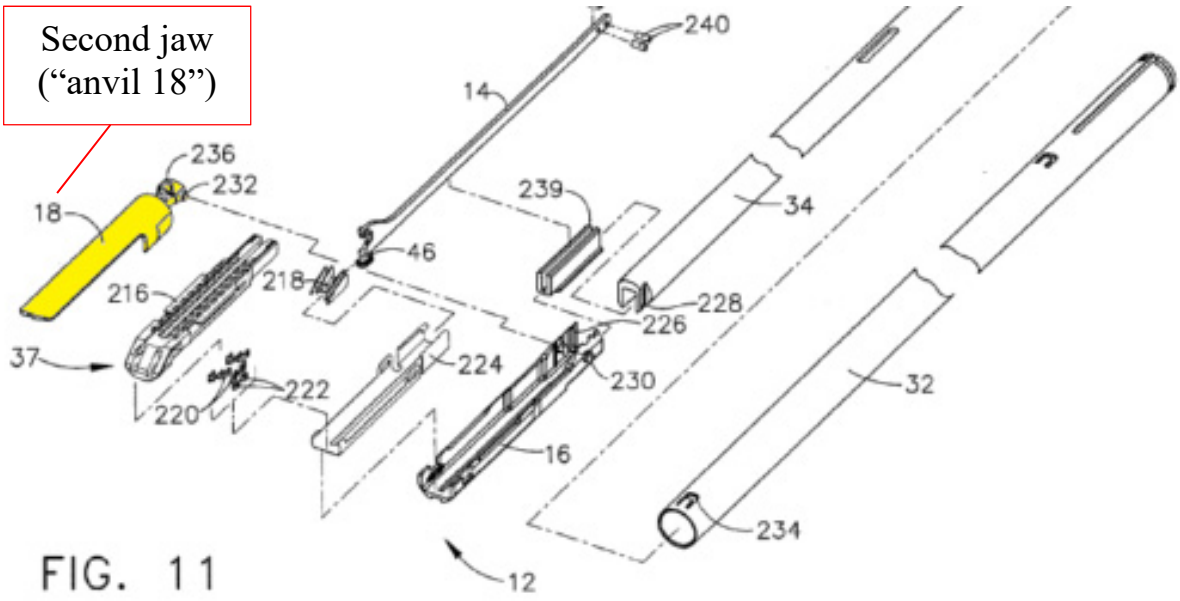


FIG. 16

Id., Fig. 16 (annotated).

[1.6] a second jaw extending from said frame;

Shelton '818 discloses a second jaw (anvil 18) extending from the frame (34). IS1003, ¶81; IS1014, 4:62-5:2, 9:39-44, Figs. 2, 11. For example, Shelton '818 states that the "frame connects the handle portion 20 to the end effector 12." IS1014, 4:64-65. As shown below in Figure 11, the anvil 18 is part of the end effector 12, which is connected to and extends from the frame 34, so the anvil 18 likewise extends from the frame 34. IS1014, Figs. 2, 11; IS1003, ¶81.



IS1014, Fig. 11 (excerpted, annotated).

[1.7] a plurality of staples;

Shelton '818 discloses a plurality of staples (staples 222). IS1003, ¶82; IS1014, 9:19-26, 9:65-10:1, 10:17-21, 11:5-9, Figs. 11-12, 16. "The staple cartridge 37 is shown as being comprised of … staples 222." IS1014, 9:19-23.

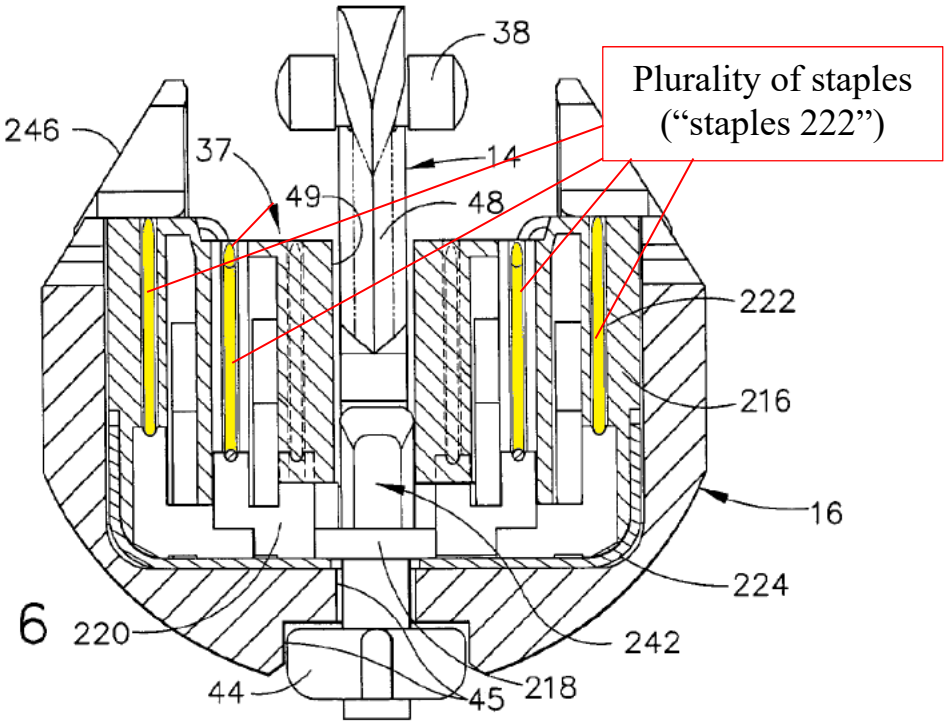
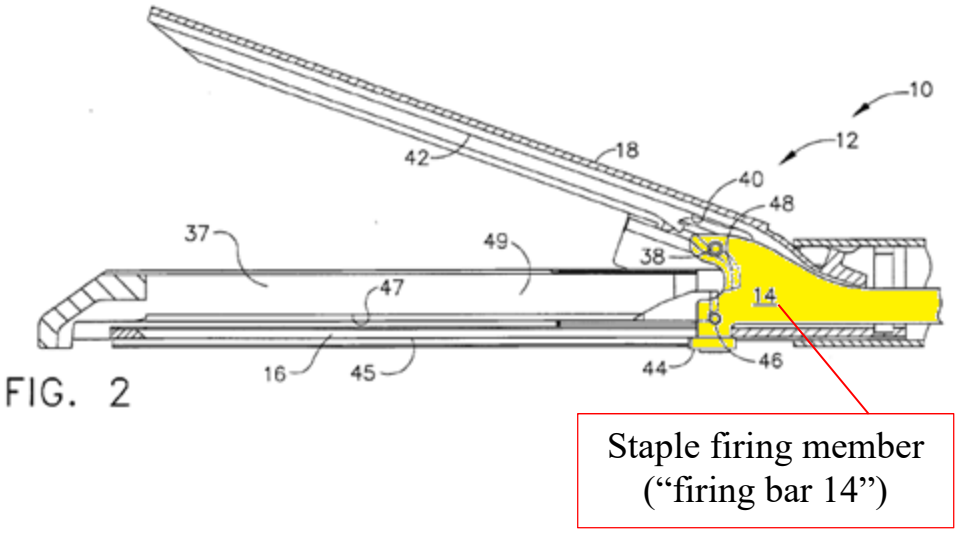


FIG. 16

Id., Fig. 16 (annotated).

[1.8] a staple firing member comprising

Shelton '818 discloses a staple firing member (firing bar 14). IS1003, ¶83; IS1014, 4:26-29, 5:7-67, Figs. 2, 11-13. In particular, Shelton '818 states that the "surgical stapling and severing instrument 10 incorporates an end effector 12 having an E-beam firing mechanism ('firing bar') 14 that advantageously controls the spacing of the end effector 12." IS1014, 4:26-29.



Id., Fig. 2 (annotated).

[1.8.1] a first cam configured to engage said first jaw and

Shelton '818's firing member includes a first cam (firing bar cap 44) that is configured to engage the first jaw (combination of elongate channel 16 and staple cartridge 37). IS1003, ¶¶84-85; IS1014, 5:18-23, 10:4-8, 10:52-57, Figs. 2-4, 12-16, 19, 21, 23. As Shelton '818 explains, "[f]iring bar 14 also includes a lower most pin, or firing bar cap 44, that upwardly engages a channel slot 45 in the elongate channel 16, thereby cooperating with the upper pin 38 to draw the anvil 18 and the elongate channel 16 slightly closer together in the event of excess tissue clamped therebetween." IS1014, 5:18-23, Figs. 2, 16, 19, 21, 23; *see also* IS1014, 9:1-18 (noting that "firing bar 14 is at its proximal position" when end effector is open); IS1003, ¶84.

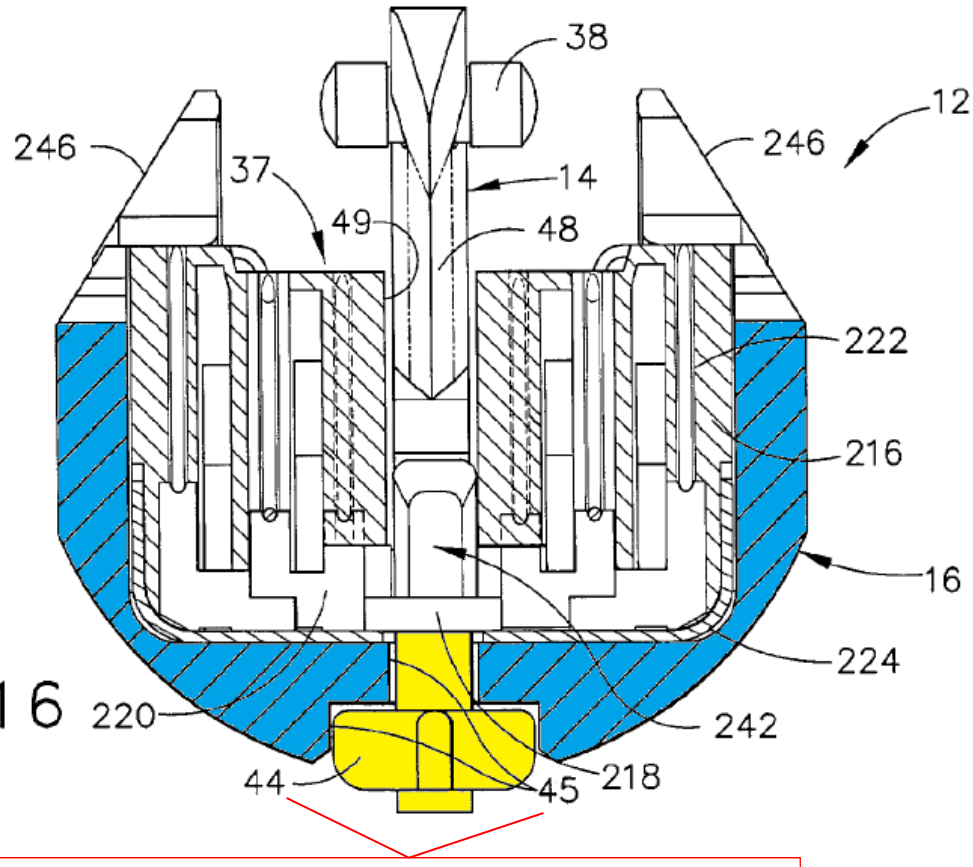


FIG. 16

First cam ("firing bar cap 44") engaged with channel slot 45 on underside of first jaw (elongate channel 16)

IS1014, Fig. 16 (annotated).

Alternatively, Shelton '818 discloses a first cam (middle pin 46) configured to engage the first jaw (combination of elongate channel 16 and staple cartridge 37) via "firing drive slot 47 formed in a lower surface of the cartridge 37 and an upward surface of the elongate channel 16." IS1003, ¶85; IS1014, 5:24-35, Figs. 2-4.

[1.8.2] a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position toward said distal end,

Shelton '818's staple firing member (firing bar 14) also includes a second

cam (upper pin 38) configured to engage the second jaw (anvil 18) when the staple firing member is advanced from an unadvanced position (shown below in Figure 19) toward the distal end. IS1003, ¶¶86-87; IS1014, 5:7-17, Figs. 2-4, 12-16, 19, 21, 23. As Shelton '818 explains, firing bar 14 includes "an upper pin 38 [that] is staged to enter an anvil pocket 40 near the pivot between the anvil 18 and elongate channel 16," and "[w]hen fired with the anvil 18 closed, the upper pin 38 advances distally within a longitudinal anvil slot 42 extending distally through anvil 18." IS1014, 5:10-15, Figs. 2, 19, 21, 23; IS1003, ¶86.

When the firing bar 14 is not advanced (*e.g.*, Figs. 2, 19), the firing bar 14 is not engaged with the anvil 18. IS1003, ¶87; IS1014, Figs. 2, 9. However, when the firing bar 14 is advanced (*e.g.*, Figs. 21, 23), the firing bar 14 is engaged with the anvil 18. IS1003, ¶87; IS1014, Figs. 21, 22.

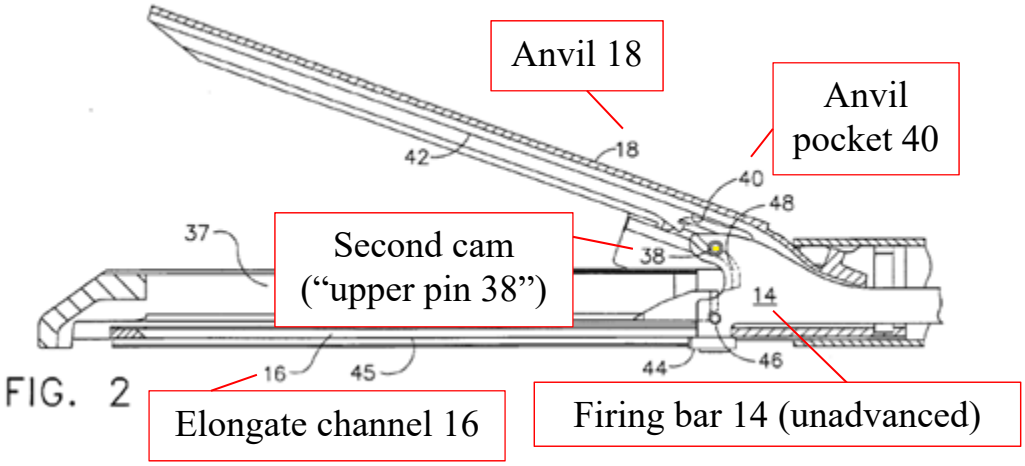


FIG. 2

Id., Fig. 2 (annotated).

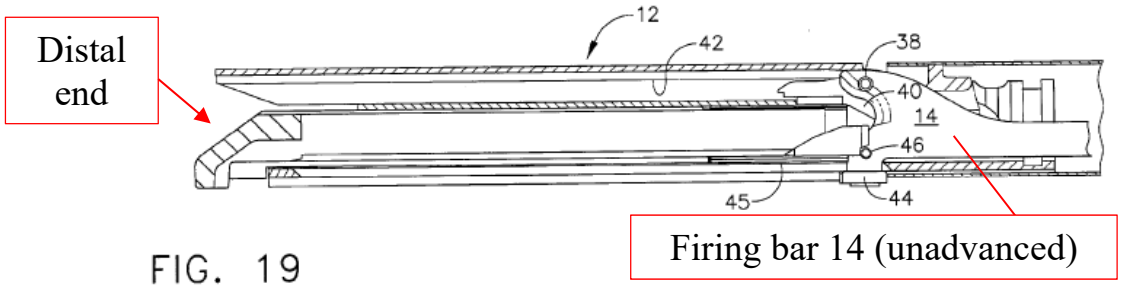


FIG. 19

Id., Fig. 19 (annotated).

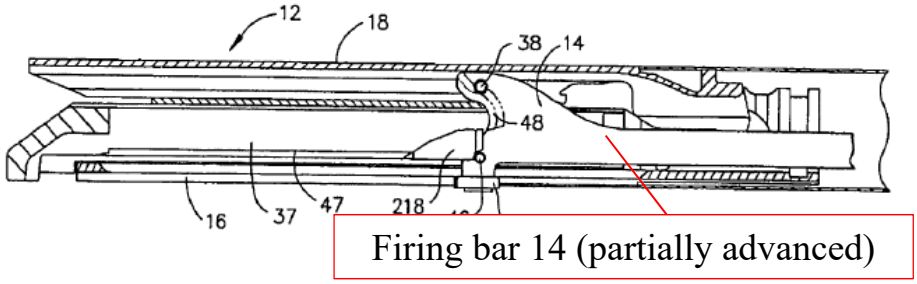


FIG. 21

Id., Fig. 21 (annotated).

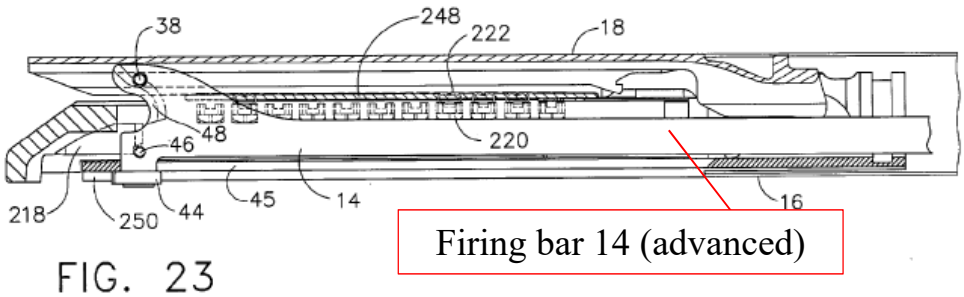


FIG. 23

Id., Fig. 23 (annotated).

[1.8.3] wherein one of said first jaw and said second jaw comprises a clearanced opening configured to permit said firing member to be unengaged with one of said first jaw and said second jaw when said firing member is in said unadvanced position; and

Shelton '818's second jaw includes a clearanced opening (anvil pocket 40) that is configured to permit the firing member to be unengaged (aligned in a noninterfering fashion) with one of said first jaw and said second jaw (anvil 18) when

the firing member is in the unadvanced position. IS1003, ¶¶88-91; IS1014, 5:7-11, 9:1-9, Figs. 2, 10, 14. For example, "upper pin 38 is staged to enter an anvil pocket 40 near the pivot between the anvil 18 and elongate channel 16." IS1014, 5:7-11, Figs. 2, 14, 23.

The anvil pocket 40, which is a clearanced opening, can be seen in Figs. 2 and 14, which show the firing bar 14 in an unadvanced position (*i.e.*, not advanced to the distal end of the device). IS1003, ¶¶88-91; IS1014, Figs. 2, 14.

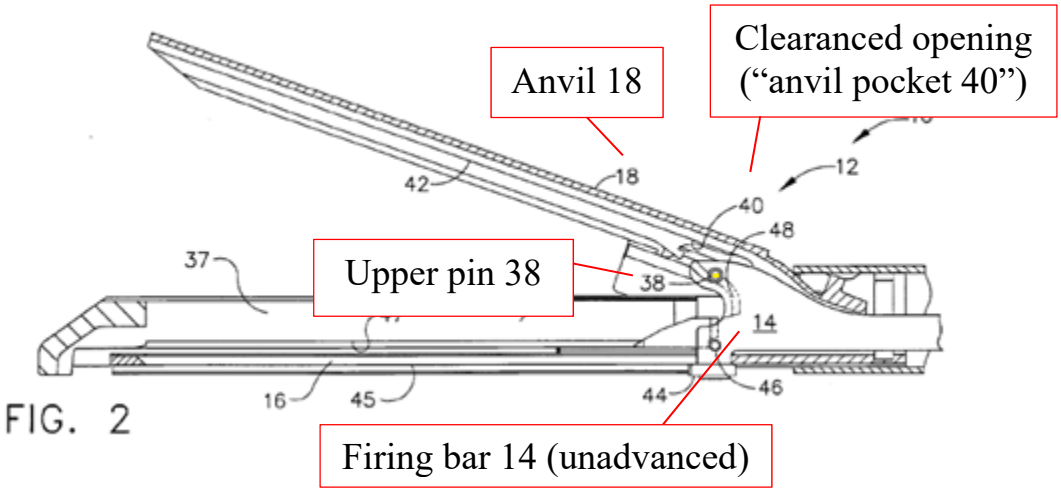


FIG. 2

Id., Fig. 2 (annotated).

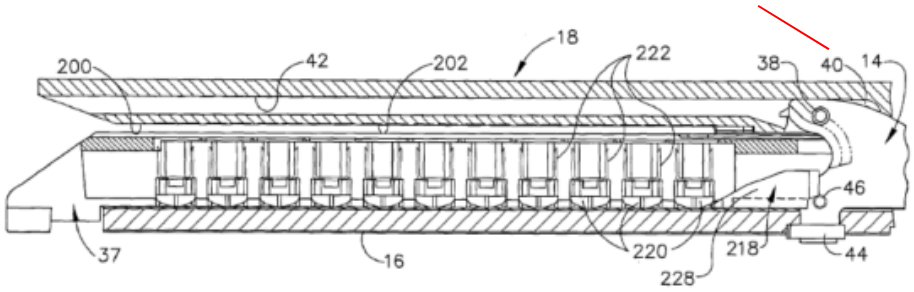


FIG. 14

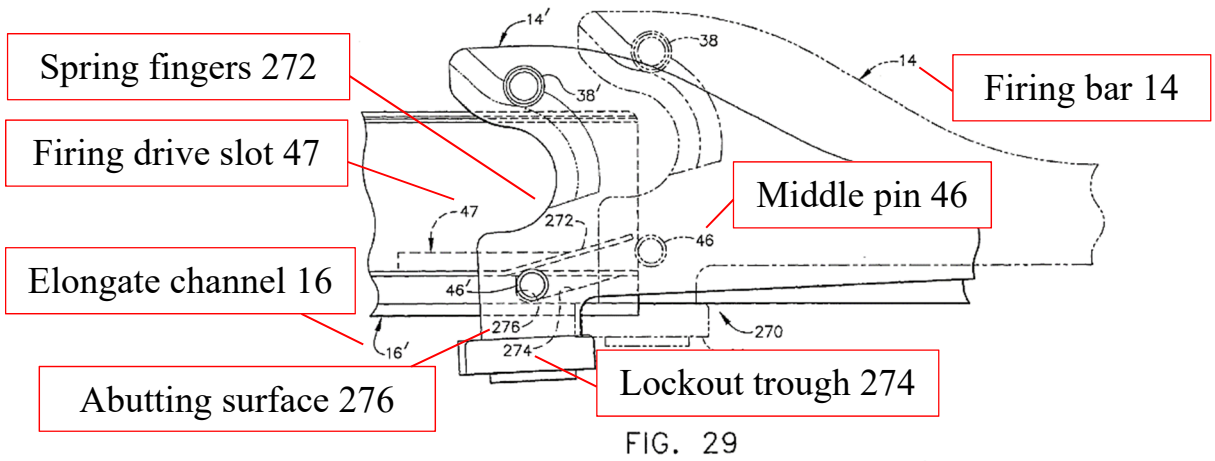
Id., Fig. 14 (annotated).

As shown above in Figures 2 and 14 (reproduced above), "firing bar 14 is at

its proximal position, with the upper pin 38 aligned in a noninterfering fashion with the anvil pocket 40." *Id*., 9:7-9; *see also* 10:13-15 (noting that "FIG. 14 depicts the end effector 12 closed in a tissue clamping position with the firing bar 14 unfired [and] upper pin 38 is in the anvil pocket 40"), Figs. 10, 14. Thus, the second jaw (anvil 18) comprises a clearanced opening (anvil pocket 40) configured to permit the firing member (firing bar 14) to be unengaged with the second jaw (anvil 18) when said firing member (firing bar 14) is in said unadvanced (or retracted) position. IS1003, ¶91.

[1.9] a lockout configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.

As provided above in Section VIII.A, Shelton '818 incorporates by reference the entirety of Shelton '195. Shelton '818's incorporation of Shelton '195 discloses a lockout (combination of Shelton '195's middle pin 46 and lockout trough 274) configured to block the advancement of the staple firing member (firing bar 14) when the channel (staple cartridge 37) is not attached to the channel retainer (elongate channel 16), or to the stapling assembly. IS1003, ¶¶92-96; IS1014, 1:8-26, 9:35-38; IS1013, ¶¶40-44, 94-104, Figs. 24-34.

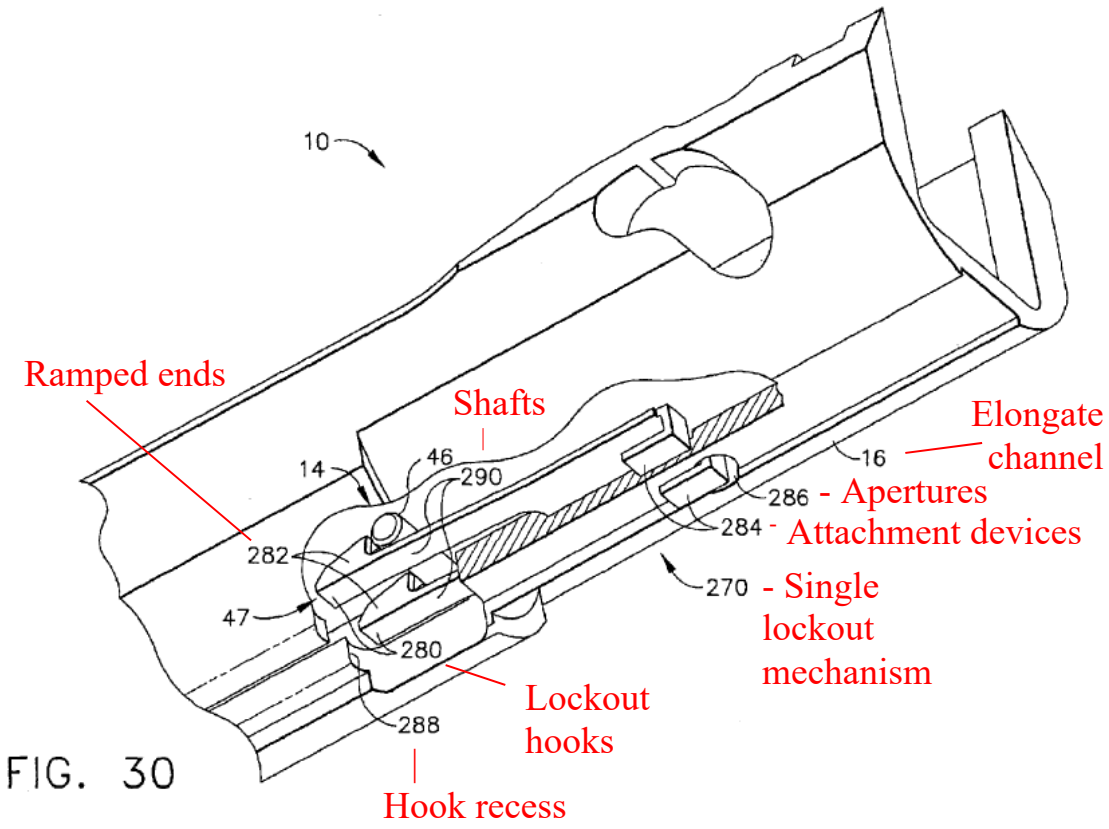


IS1013, Fig. 29 (annotated).

Like the '379 patent's lockout, Shelton '195's lockout "advantageously responds to a missing staple cartridge 37 or a spent staple cartridge 37 . . . by blocking the middle pin 46 of the firing bar." IS1013, ¶94, Fig. 24; IS1003, ¶¶92-93. Specifically, "a pair of bent spring fingers 272 raise up to block the middle pin 46 of the firing bar 14 when the wedge sled 218 (not shown in FIG. 24) is not present, such as when the cartridge 37 is removed or when the cartridge 37 has been fired." *Id.*, ¶95. A "lockout trough 274 communicates with the firing drive slot 47 when the bent spring fingers 272 are not depressed. Moreover, the lockout trough 274 is downwardly ramped in a distal direction such that the middle pin 46 of the firing bar 14 is directed toward an abutting surface 276 at a distal end of the lockout trough 274, thereby reacting [to] the distal movement of the firing bar 14 into an elongate channel 16'." *Id.*, ¶100, Fig. 29.

Similarly, the combination of middle pin 46 and lockout hooks 280, which are included in a second embodiment of Shelton '195, is another example of the

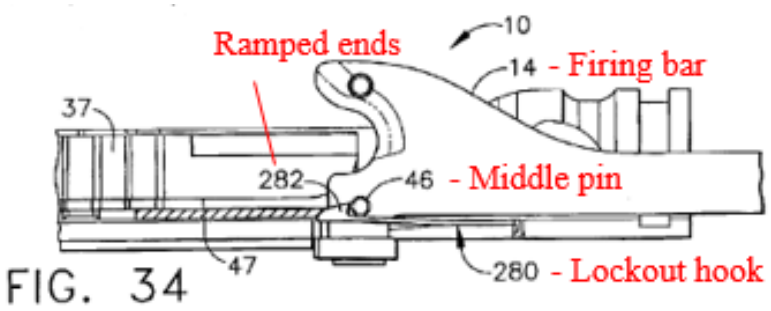
claimed lockout. IS1014, 1:8-26, 9:35-38; IS1013, ¶¶43-44, 102-104, Figs. 30-34; IS1003, ¶¶94-95. This second embodiment (shown below in Figure 30 of Shelton '195) includes "a pair of lockout hooks 280 having ramped ends 282 distally placed with regard to attachment devices 284 inserted through apertures 286 in the elongate channel 16. The ramped ends 282 lie above a hook recess 288 defined in the elongate channel 16." IS1013, ¶102, Fig. 30. A "thin shaft 290 coupl[es] the attachment devices 284 to . . . the ramped end 282 of each lockout hook 280." *Id.*



Id., Fig. 30 (annotated).

As shown below in Figure 34, when there is no wedge sled 218 to depress ramped ends 282 into hook recess 288, "ramped ends 282 [of lockout hook 280]

block the middle pin 46. Thus, the firing bar 14 is prevented from distal movement while the spent staple cartridge 37 is replaced with an unfired staple cartridge 37." *Id.*, ¶104, Figs. 30-34.



Id., Fig. 34 (annotated).

Thus, Shelton '818 discloses a lockout configured to block the advancement of the firing bar 14 when the staple cartridge 37 is not attached to the elongate retainer 16. IS1003, ¶96.

[2.1] A stapling assembly, comprising:

See Ground 1, element [1.1]; IS1003, ¶97; IS1014, Abstract, 2:62-4:17, 4:22-26, Figs. 1-2.

[2.2] a frame;

See Ground 1, element [1.2]; IS1003, ¶98; IS1014, 4:62-65, 6:25-34, 9:39-53, Figs. 1, 6-9, 11.

[2.3] a distal end;

See Ground 1, element [1.3]; IS1003, ¶99; IS1014, 4:33-36, Figs. 1, 10-13, 19, 21, 23.

[2.4] a first jaw comprising a channel;

See Ground 1, element [1.4]; IS1003, ¶100; IS1014, 4:28-31, 5:2-3, Figs. 2, 11.

[2.5] a channel retainer, wherein said channel is slidably attachable to said channel retainer;

See Ground 1, element [1.5]; IS1003, ¶101; IS1014, 9:11-18, Figs. 10-13, 16.

[2.6] a second jaw extending from said frame;

See Ground 1, element [1.6]; IS1003, ¶102; IS1014, 4:62-5:2, 9:39-44, Figs. 2, 11.

[2.7] a plurality of staples;

See Ground 1, element [1.7]; IS1003, ¶103; IS1014, 9:19-26, 9:65-10:1, 10:17-21, 11:5-9, Figs. 11-12, 16.

[2.8] a staple firing member comprising

See Ground 1, element [1.8]; IS1003, ¶104; IS1014, 4:26-29, 5:7-67, Figs. 2, 11-13.

[2.8.1] a first cam configured to engage said first jaw and

See Ground 1, element [1.8.1]; IS1003, ¶105; IS1014, 5:18-23, 10:4-8, 10:52-57, Figs. 2-4, 12-16, 19, 21, 23.

[2.8.2] a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position toward said distal end,

See Ground 1, element [1.8.2]; IS1003, ¶106; IS1014, 5:7-17, Figs. 2-4, 12-

16, 19, 21, 23.

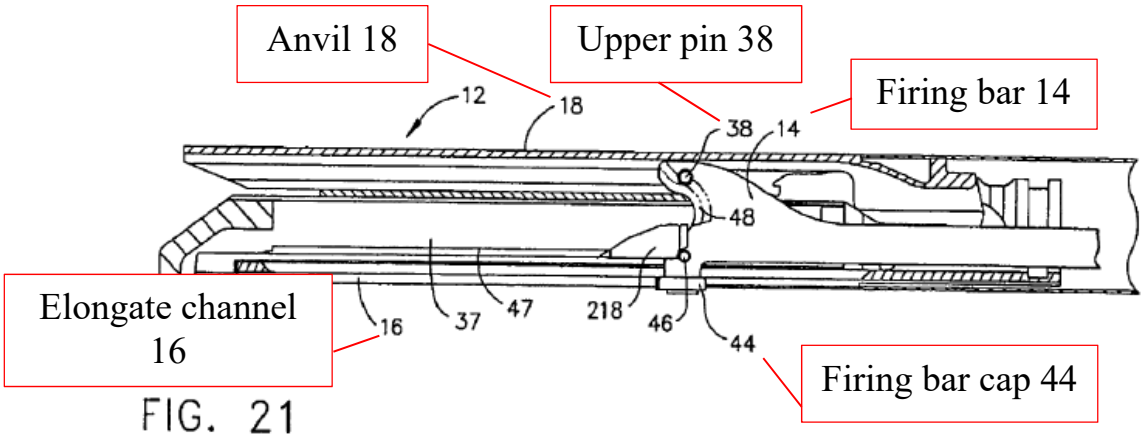
[2.8.3] wherein said first cam and said second cam are configured to co-operatively hold said first jaw and said second jaw relative to one another when said staple firing member is advanced toward said distal end, and

Shelton '818's first cam (firing bar cap 44) and second cam (upper pin 38) are configured to co-operatively hold the first jaw (elongate channel 16) and the second jaw (anvil 18) relative to one another when the firing member (firing bar 14) is advanced toward the distal end. IS1003, ¶¶107-109; IS1014, 5:18-24, Figs. 2, 16, 19, 21, 23; *see also* Ground 1, element [1.8.2].

As Shelton '818 explains, "[f]iring bar 14 also includes a lower most pin, or firing bar cap 44 [(first cam)], that upwardly engages a channel slot 45 in the elongate channel 16 [portion of the first jaw], thereby cooperating with the upper pin 38 [(second cam)] to draw the anvil 18 [(second jaw)] and the elongate channel 16 [portion of the first jaw] slightly closer together in the event of excess tissue clamped there-between." IS1014, 5:18-24.

For example, Figure 21 (reproduced below) shows the firing bar in a partially advanced position between the fully retracted position and the fully advanced position at the distal end of the device. IS1003, ¶109, IS1014, Fig. 21. As shown in Figure 21, the first and second cams (the firing bar cap 44 and upper pin 38, respectively) hold the first and second jaws (elongate channel 16 and anvil 18, re-

spectively) relative to one another when the firing member (firing bar 14) is advanced from the proximal end toward the distal end.



Id., Fig. 21.

[2.8.4] wherein one of said first jaw and said second jaw comprises a clearanced opening configured to receive one of said first cam and said second cam such that said first jaw is not held to said second jaw when said staple firing member is in said unadvanced position; and

Shelton '818's second jaw comprises a clearanced opening (anvil pocket 40) that is configured to receive the second cam (upper pin 38) such that the first jaw (elongate channel 16/staple cartridge 37) is not held to the second jaw (anvil 18) when the staple firing member (firing member 14) is in the unadvanced position. IS1003, ¶¶110-113; IS1014, 5:7-11, 9:1-9, Figs. 2, 10, 14. More specifically, "upper pin 38 is staged to enter an anvil pocket 40 near the pivot between the anvil 18 and elongate channel 16." IS1014, 5:7-11, Figs. 2, 14, 23.

The anvil pocket 40, which is a clearanced opening, can be seen in Figs. 2

and 14, which shows the firing bar 14 in an unadvanced position (*i.e.*, not advanced to the distal end of the device). IS1003, ¶¶110-112; IS1014, Figs. 2, 14.

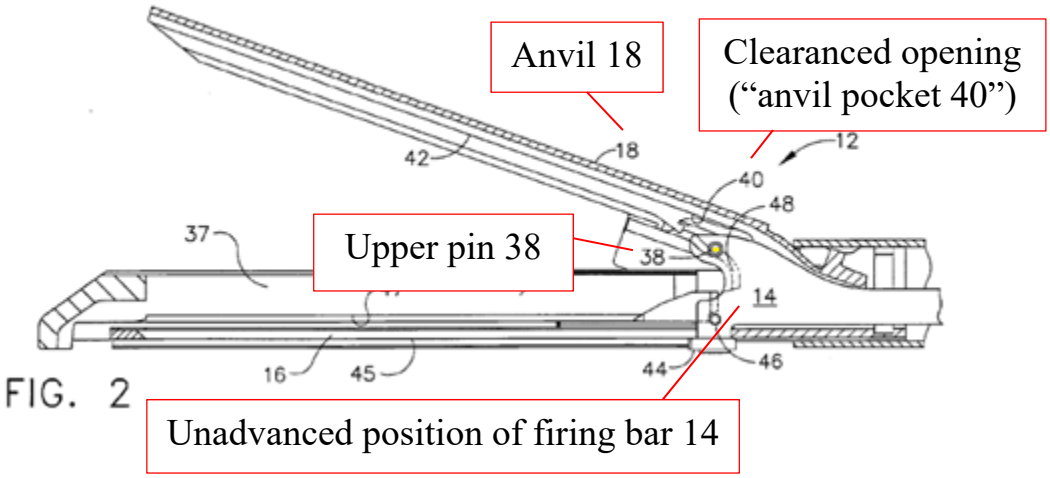


FIG. 2

Id., Fig. 2 (annotated)

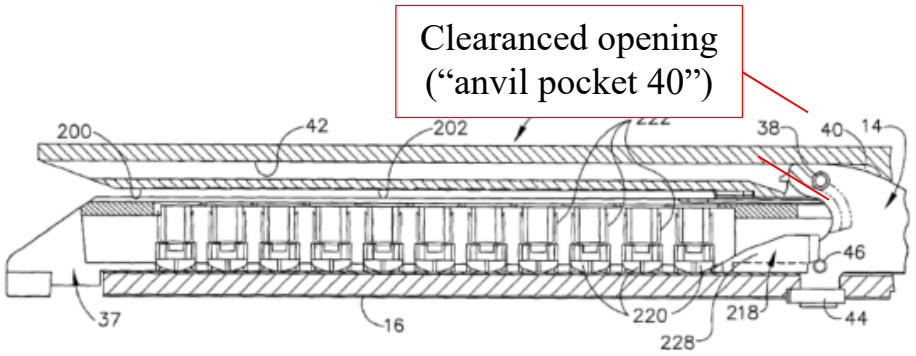


FIG. 14

Id., Fig. 14 (annotated).

As shown in Figures 2 and 14 (reproduced above), "firing bar 14 is at its proximal position, with the upper pin 38 aligned in a noninterfering fashion with the anvil pocket 40." *Id.*, 9:7-9; *see also* 10:13-15 (noting that "FIG. 14 depicts the end effector 12 closed in a tissue clamping position with the firing bar 14 unfired [and] upper pin 38 is in the anvil pocket 40"), Figs. 10, 14. Thus, the second jaw

(anvil 18) comprises a clearanced opening (anvil pocket 40) in which the second cam (upper pin 38) resides when the firing member (firing bar 14) is not advanced. IS1003, ¶¶111-113. With the second cam (upper pin 38) residing in the clearanced opening of the anvil pocket 40 instead of engaged with the anvil 18 to hold the anvil to the first jaw (elongate channel 16/staple cartridge 37), the first jaw is not held to the second jaw when the firing member is not advanced. IS1003, ¶113.

[2.9] a lockout configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.

See Ground 1, element [1.9]; IS1003, ¶114; IS1014, 1:8-26, 9:35-38; IS1013, ¶¶40-44, 94-104, Figs. 24-34.

[3.1] A stapling assembly, comprising:

See Ground 1, element [1.1]; IS1003, ¶115; IS1014, Abstract, 2:62-4:17, 4:22-26, Figs. 1-2.

[3.2] a first jaw;

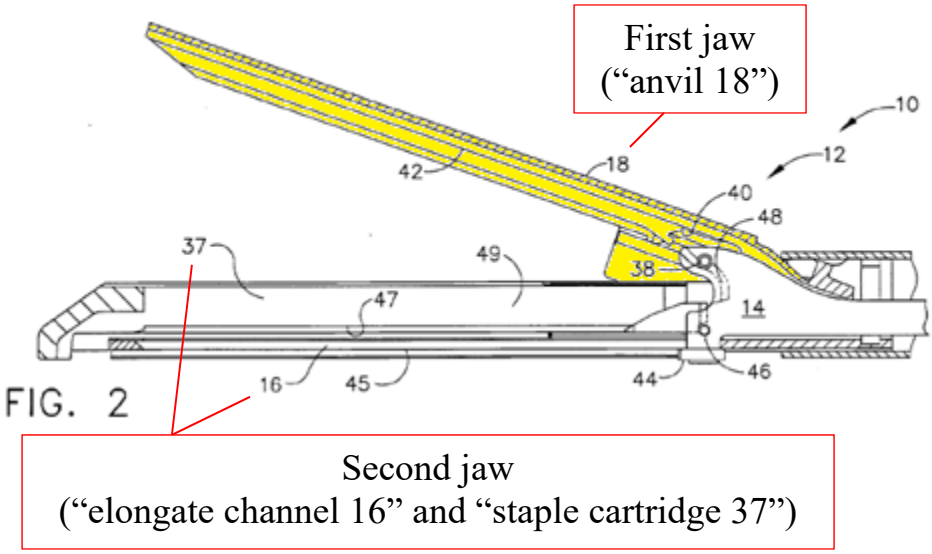
See Ground 1, element [1.6]; IS1003, ¶116; IS1014, 4:62-5:2, 9:39-44, Figs. 2, 11.

[3.3] a second jaw, wherein said first jaw is rotatable relative to said second jaw;

Shelton ’818 discloses a second jaw (combination of elongate channel 16 and staple cartridge 37). *See* Ground 1, element [1.4]; IS1003, ¶¶117-119; IS1014, 4:28-31, 5:2-3, Figs. 2, 11. Additionally, Shelton ’818’s first jaw (anvil 18) is rotatable relative to the second jaw (combination of elongate channel 16 and staple

cartridge 37). IS1003, ¶118; IS1014, 4:65-5:1, 6:63-67, Figs. 2, 14. As Shelton '818 explains, "[w]ith the closure sleeve 32 withdrawn proximally . . . the anvil 18 springedly opens, pivoting away from the elongate channel 16." IS1014, 4:65-5:1. "Distal movement of the closure sleeve 32 effects pivotal translation movement of the anvil 18 distally and toward the elongate channel 16 of the end effector 12." *Id*., 6:63-67.

The rotation of anvil 18 from the open position to the closed position relative to elongate channel 16 and staple cartridge 37 is shown below in Figures 2 and 14 of Shelton. IS1003, ¶119; IS1014, Figs. 2, 14.



IS1014, Fig. 2 (annotated).

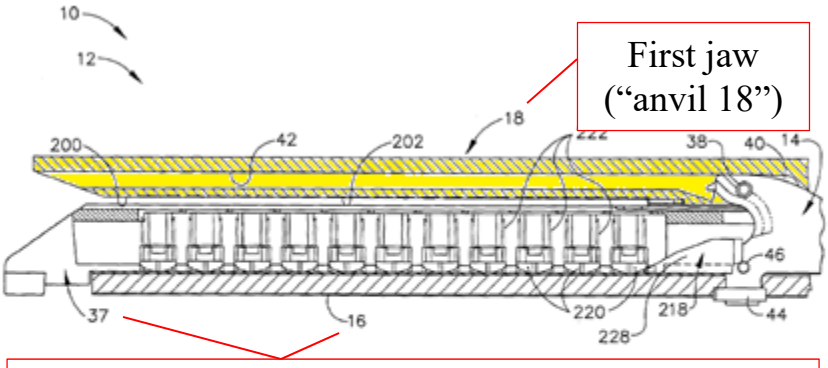


FIG. 14

Id., Fig. 14 (annotated).

[3.4] a detachable cartridge portion comprising a plurality of staples;

Shelton '818 discloses a detachable cartridge portion (replaceable staple cartridge 37) comprising a plurality of staples (staples 222). IS1003, ¶¶120-122; IS1014, 9:19-26, Figs. 11-12; *see* Ground 1, element [1.7]. For example, with reference to Figure 11, Shelton '818 discloses a "staple cartridge 37 . . . comprised of a cartridge body 216, a wedge sled 218, single and double drivers 220, staples 222, and a cartridge tray 224." IS1014, 9:19-23. "When assembled, the cartridge tray 224 holds the wedge sled 218, single and double drivers 220, and staples 222 inside the cartridge body 216." *Id.*, 9:23-26.

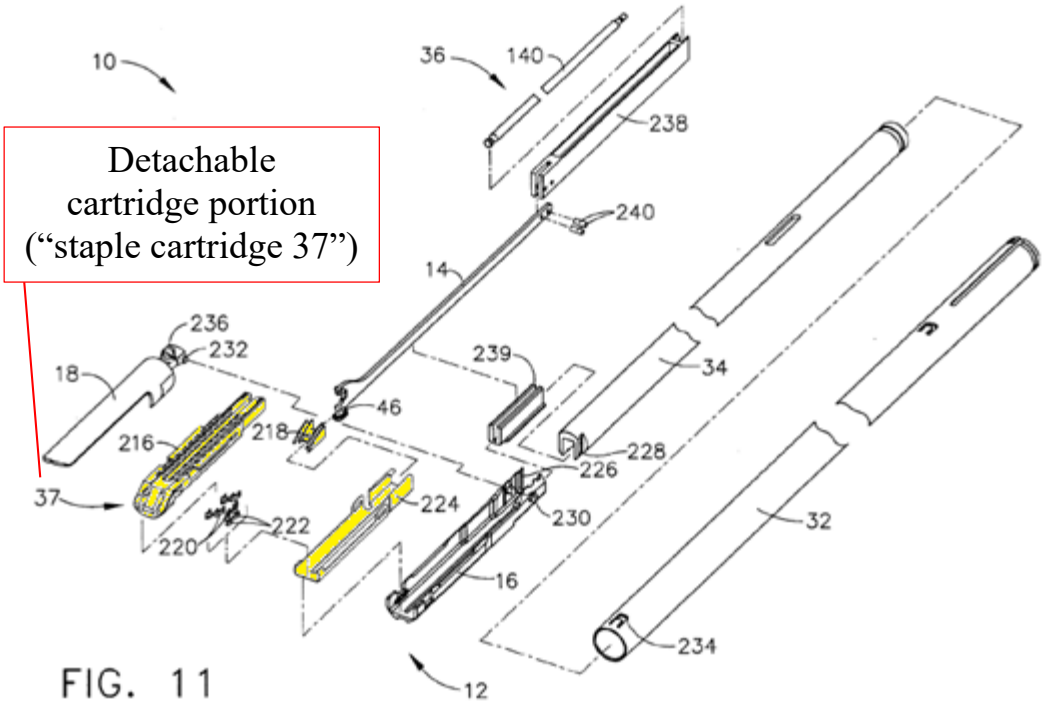


FIG. 11

Id., Fig. 11 (annotated).

Fig. 16 shows the staple cartridge 37 comprising a plurality of staples 222. *Id.*, Fig. 16; IS1003, ¶122.

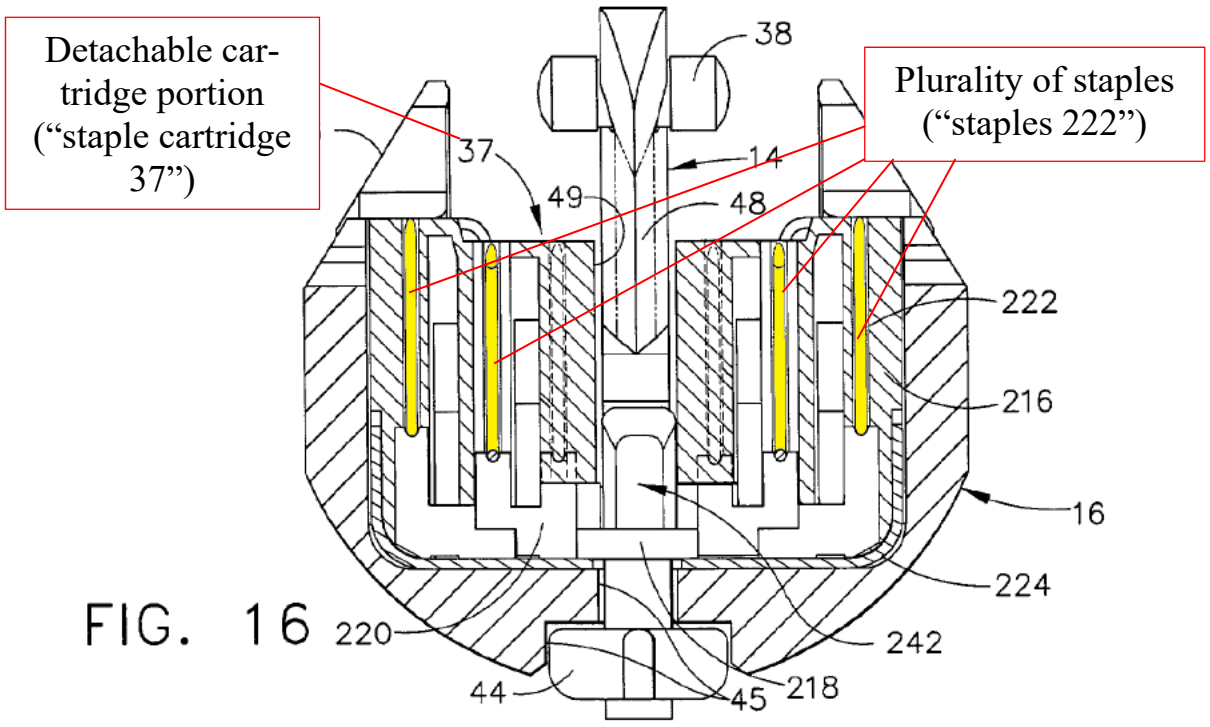


FIG. 16

IS1014, Fig. 16 (annotated).

[3.5] an anvil configured to deform said staples; and

Shelton '818 discloses an anvil (surface 200 of anvil 18, which includes anvil forming pockets 202) configured to deform staples 222. IS1003, ¶123; IS1014, 9:3-5, 9:65-10:1, Fig. 12. Shelton '818 explains, "lower surface 200 of the anvil 18 [includes] a plurality of stapling forming pockets 202." IS1014, 9:3-5. "Staples 222 (not shown in FIG. 12) resting upon the drivers 220 are . . . forced upward into contact with the anvil forming pockets 202 on the anvil 18 to form closed staples." *Id.*, 9:65-10:1.

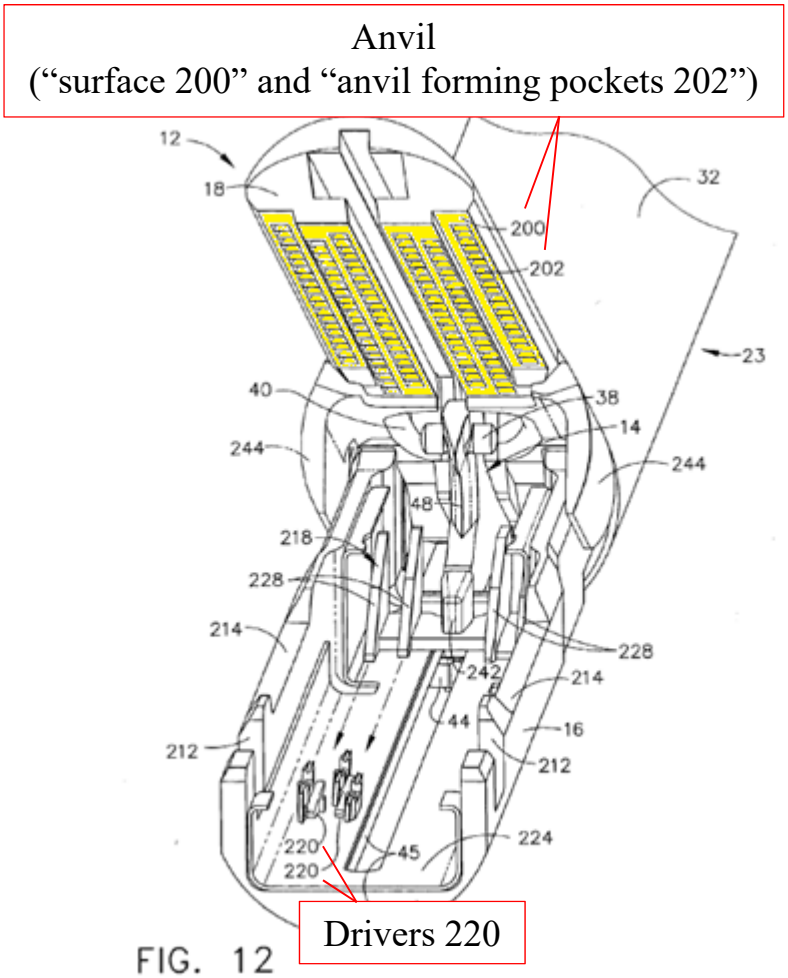


FIG. 12

Id., Fig. 12 (annotated).

[3.6] a staple firing member comprising

See Ground 1, element [1.8]; IS1003, ¶124; IS1014, 4:26-29, 5:7-67, Figs. 2, 11-13.

[3.6.1] a first cam configured to engage said first jaw and

See Ground 1, element [1.8.2] (upper pin 38); IS1003, ¶125; IS1014, 5:7-17, Figs. 2-4, 12-16, 19, 21, 23.

[3.6.2] a second cam configured to engage said second jaw when said staple firing member is advanced from an initial position, and

See Ground 1, element [1.8.1] (firing bar cap 44; alternatively, middle pin 46); IS1003, ¶¶126-127; IS1014, 5:18-23, 5:25-35, 10:4-8, 10:52-57, 10:67-11:4, Figs. 2-4, 12-16, 19, 21, 23. Additionally, both the firing bar cap 44 and the middle pin 46 are configured to engage the combination of elongate channel 16 and staple cartridge 37 when the firing bar 14 is advanced distally from an initial position. IS1003, ¶¶126-127.

For example, Figure 21 (reproduced below) shows the firing bar advancing from a retracted position. IS1003, ¶¶87, 126, IS1014, Fig. 21. As shown in Figure 21, the second cam (the firing bar cap 44, or alternatively, the middle pin 46) is configured to engage the second jaw (combination of elongate channel 16 and staple cartridge 37), causing the first jaw and the second jaw (anvil 18 and elongate channel 16, respectively) to be held relative to one another when the firing member (firing bar 14) is advanced toward the distal end. IS1003, ¶¶126-127; IS1014, Fig. 21.

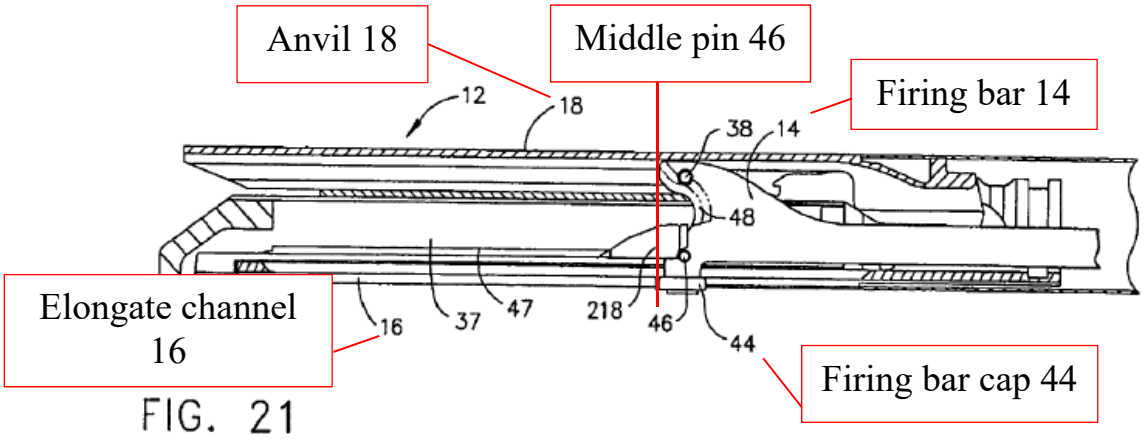


FIG. 21

IS1014, Fig. 21.

[3.6.3] wherein said first jaw comprises a clearanced opening configured to receive said first cam when said staple firing member is in said initial position such that said first cam is not engaged with said first jaw when said staple firing member is in said initial position; and

Shelton '818's first jaw (anvil 18) comprises a clearanced opening (anvil pocket 40) that is configured to receive the first cam (upper pin 38) when the staple firing member (firing bar 14) is in the initial (unadvanced) position such that the first cam (upper pin 38) is not engaged with the first jaw (anvil 18) when the staple firing member (firing bar 14) is in the initial (unadvanced) position. IS1003, ¶¶128-132; IS1014, 5:7-11, 9:1-9, Figs. 2, 10, 14. More specifically, "upper pin 38 is staged to enter an anvil pocket 40 near the pivot between the anvil 18 and elongate channel 16." IS1014, 5:7-11, Figs. 2, 14, 23.

The anvil pocket 40, which is a clearanced opening, can be seen in Figures 2 and 14, which shows the firing bar 14 in an unadvanced position (*i.e.*, not advanced to the distal end of the device). IS1003, ¶¶129-131; IS1014, Figs. 2, 14.

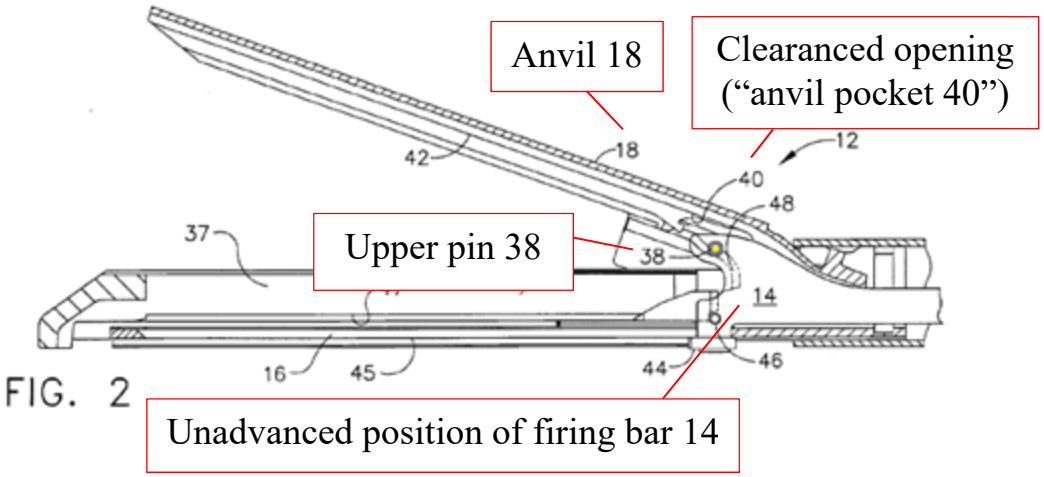


FIG. 2

Id., Fig. 2 (annotated)

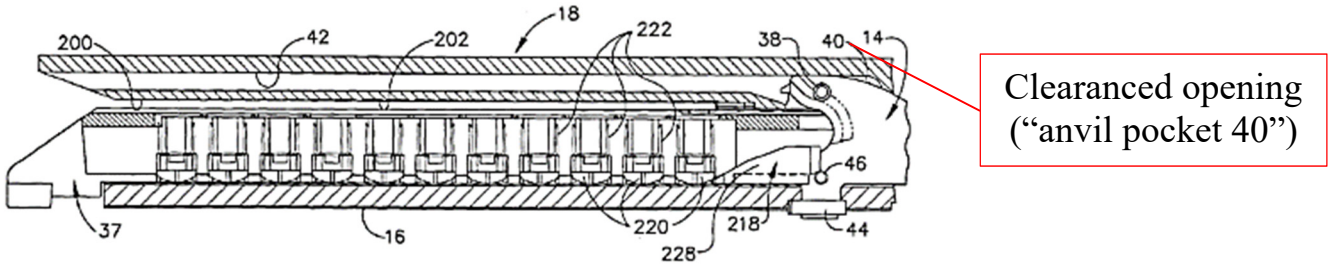


FIG. 14

Id., Fig. 14 (annotated).

As shown above in Figures 2 and 14 (reproduced above), "firing bar 14 is at its proximal position, with the upper pin 38 aligned in a noninterfering fashion with the anvil pocket 40." *Id.*, 9:7-9; *see also* 10:13-15 (noting that "FIG. 14 depicts the end effector 12 closed in a tissue clamping position with the firing bar 14 unfired [and] upper pin 38 is in the anvil pocket 40"), Figs. 10, 14. Thus, the first jaw (anvil 18) comprises a clearanced opening (anvil pocket 40) in which the first cam (upper pin 38) resides when the staple firing member (firing bar 14) is not advanced. IS1003, ¶132. With the first cam (upper pin 38) residing in the clearanced

opening of the anvil pocket 40, the first cam (upper pin 38) is not engaged with the first jaw (anvil 18) when the staple firing member (firing bar 14) is not advanced. IS1003, ¶132.

[3.7] a lockout configured to block the advancement of said staple firing member when said detachable cartridge portion is not attached to said stapling assembly.

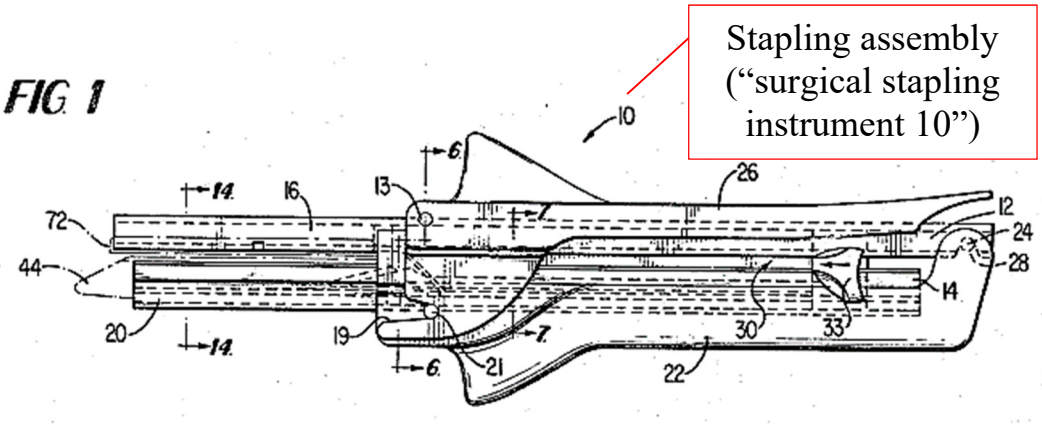
Shelton '818's incorporation of Shelton '195 discloses a lockout (combination of Shelton '195's middle pin 46 and lockout trough 274) configured to block the advancement of the staple firing member (firing bar 14) when the detachable cartridge portion (staple cartridge 37) is not attached to the stapling assembly (surgical stapling and severing instrument 10). IS1003, ¶¶133-137; IS1014, 1:8-26, 9:35-38; IS1013, ¶¶40-44, 94-104, Figs. 24-34.

In particular, the discussion of Ground 1, element [1.9] above shows how Shelton '818's incorporation of Shelton '195 teaches a lockout configured to block the advancement of the staple firing member when a channel, or a detachable cartridge portion (staple cartridge 37) is not attached to the channel retainer, or to the stapling assembly at all. IS1003, ¶¶133-137.

B. Ground 2: Claims 1-3 are obvious over Green in view of Solyntjes

[1.1] A stapling assembly, comprising:

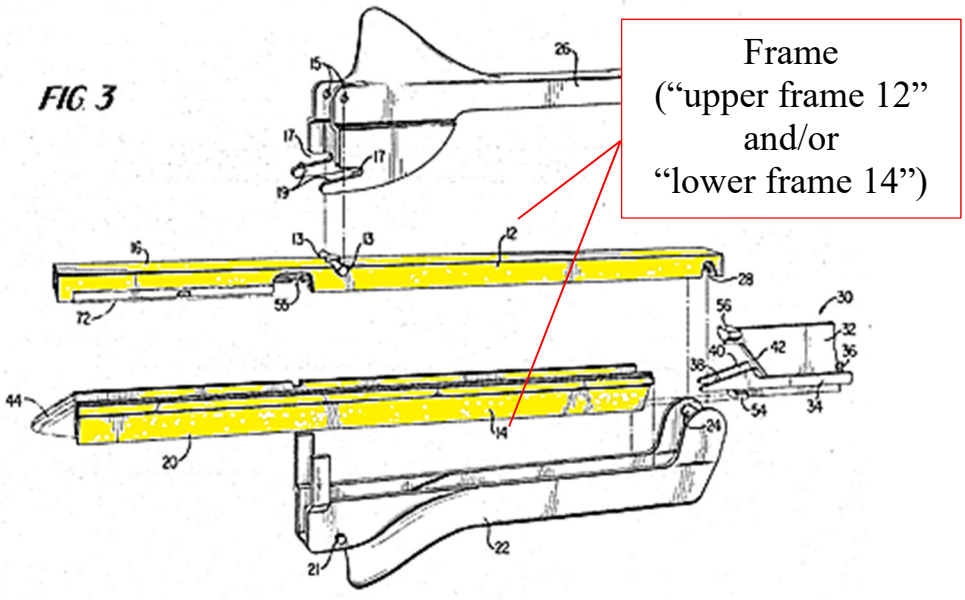
If the preamble is limiting, Green discloses a stapling assembly (surgical stapling instrument 10). IS1003, ¶138; IS1015, Abstract, 3:14-25, Fig. 1.



IS1015, Fig. 1 (annotated).

[1.2] a frame;

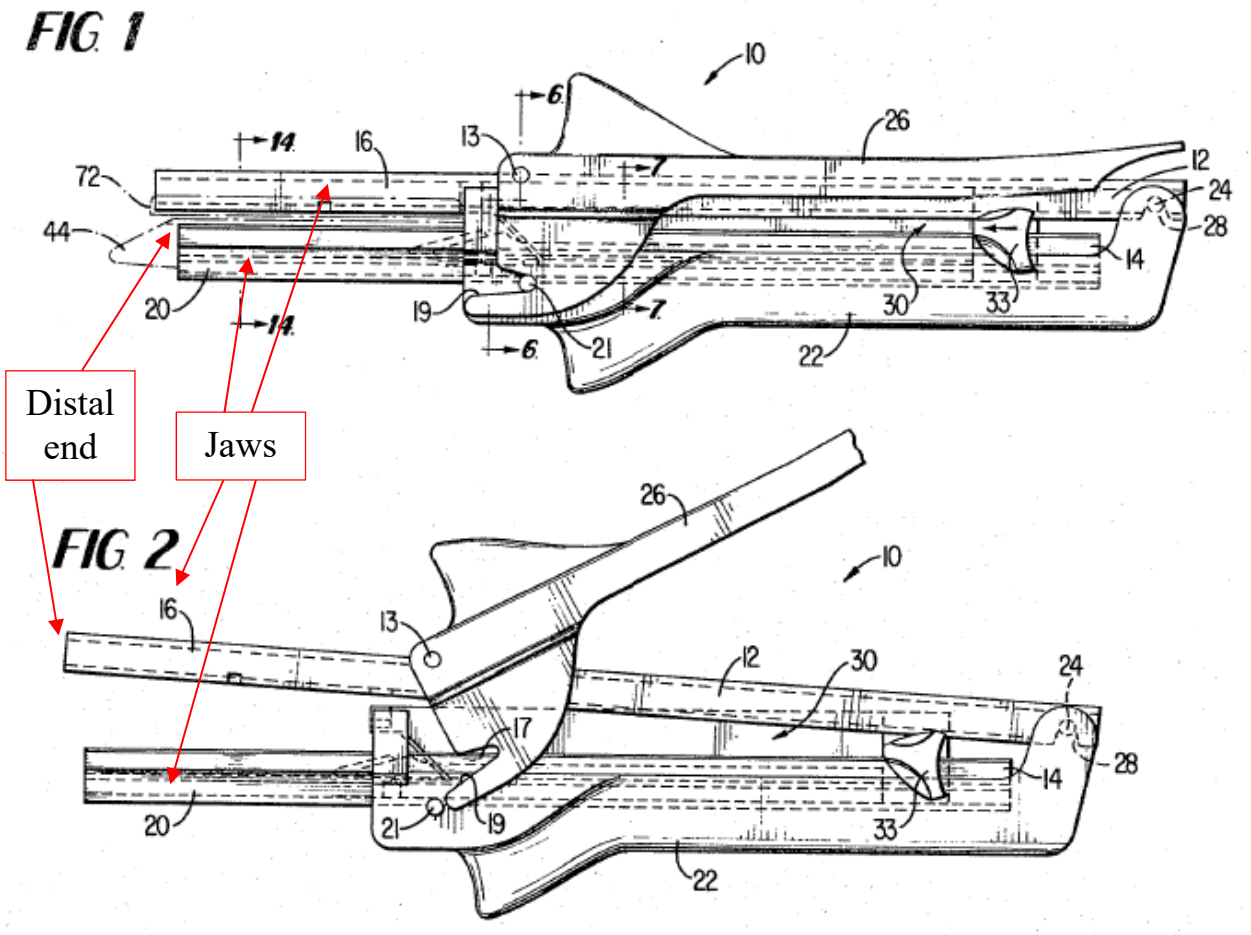
Green discloses a frame (upper frame 12 and/or lower frame 14). IS1003, ¶139; IS1015, 3:23-34, Figs. 1, 3. For example, Green states that the "present instrument, generally indicated by reference 10 includes an upper frame 12 and a lower frame 14." IS1015, 3:23-25; *see also* 3:25-34.



IS1015, Fig. 3 (annotated)

[1.3] a distal end;

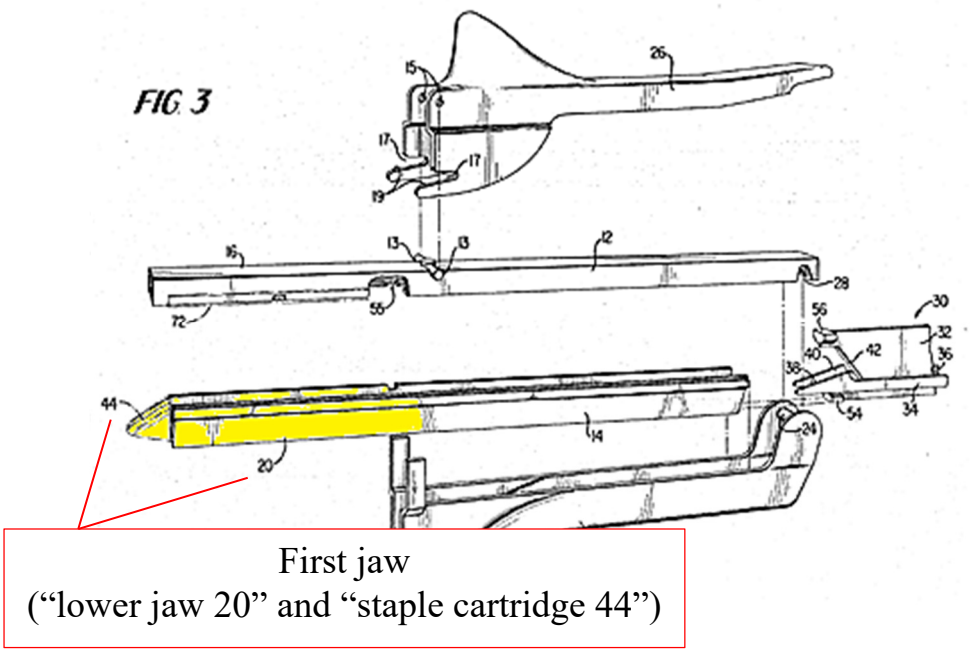
Green discloses a distal end (end of instrument 10 shown below). IS1003, ¶140; IS1015, 3:23-31, 6:9-14, Figs. 1-2. Green explains that "[i]n use, the instrument in the assembled open condition, substantially shown in FIG. 2 is inserted into a body cavity, so that tissue to be stapled is accepted between jaws 16 and 20." IS1015, 6:9-14. A POSITA would have understood that the distal end of the device would be located at the point of insertion of the device into a body cavity, so given the location of jaws 16 and 20, the distal end of the device is located as indicated in Figs. 1-2 below. IS1003, ¶140.



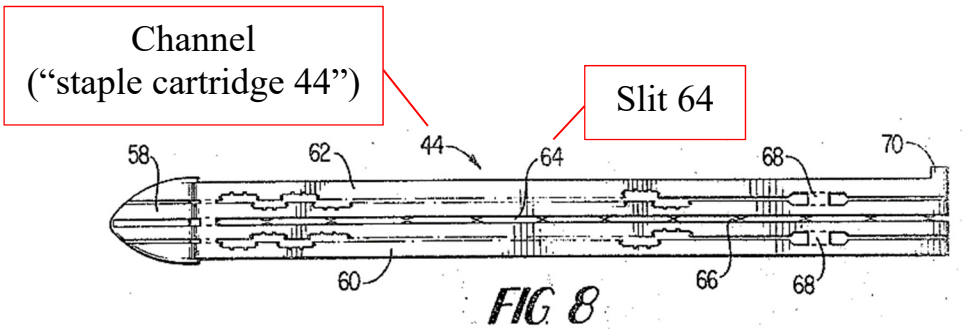
IS1015, Figs. 1-2 (annotated).

[1.4] a first jaw comprising a channel;

Green discloses a first jaw (combination of lower jaw 20 and disposable staple cartridge 44) comprising a channel (cartridge 44). IS1003, ¶141; IS1015, 3:25-27, 3:48-54, 5:5-14, Figs. 3, 8-10. Green discloses that the "forward end portion of the lower frame 14 defines an elongate lower jaw 20," and a "disposable staple cartridge 44" is "inserted into the lower jaw 20." IS1015, 3:25-27, 3:48-50. The "cartridge 44 has … a pair of longitudinal ribs 60 and 62 extending rearward from the nose portion and defining a slit 64 [*i.e.*, channel] therebetween … for passage of the knife carrier 32." IS1015, 5:5-10, Figs. 8, 10, 14.



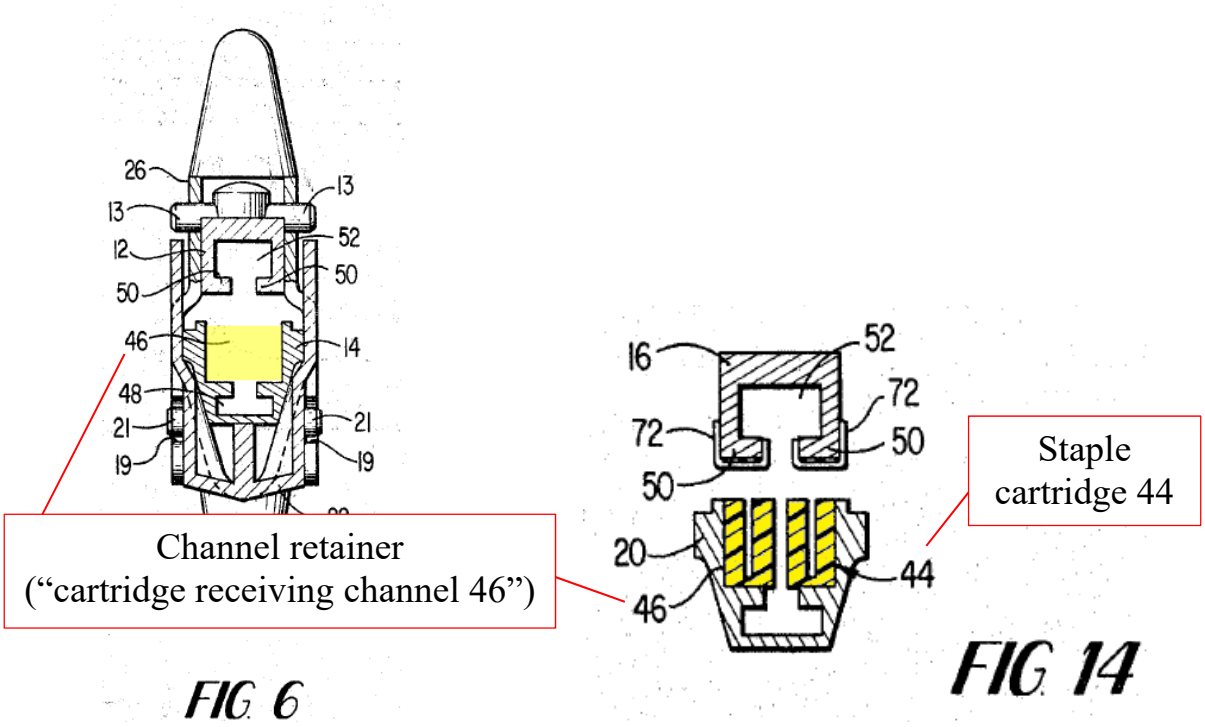
Id., Fig. 3 (annotated).



Id., Fig. 8 (annotated).

[1.5] a channel retainer, wherein said channel is slidably attachable to said channel retainer;

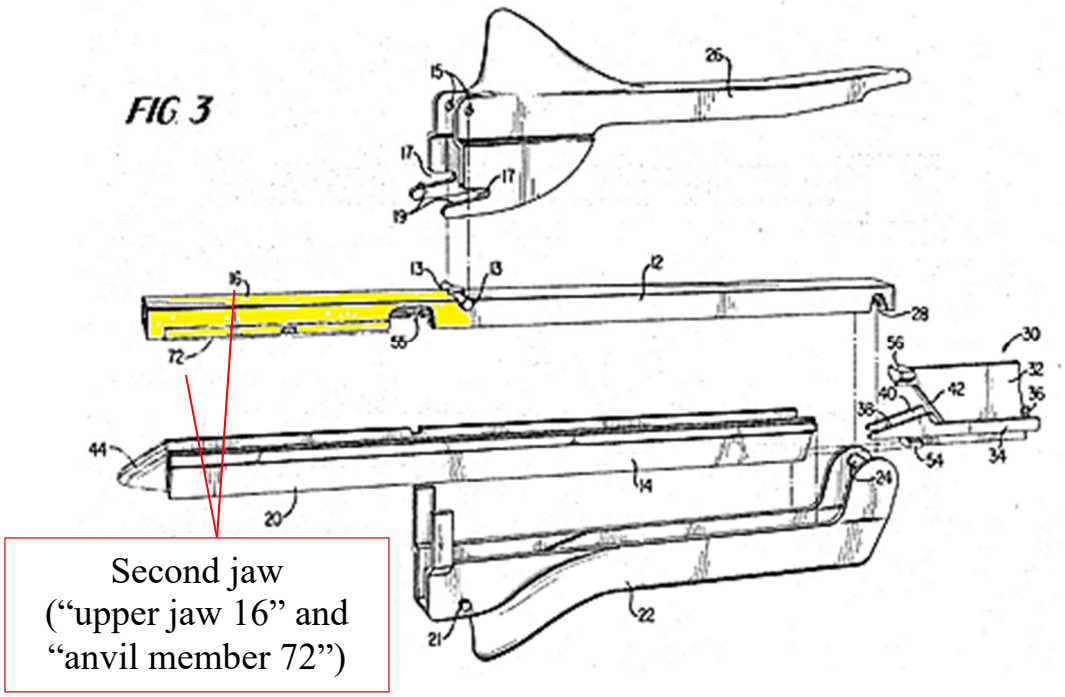
Green discloses a channel retainer (cartridge receiving channel 46), wherein the channel (staple cartridge 44) is slidably attachable to the channel retainer. IS1003, ¶142; IS1015, 3:48-50, 5:5-26, Figs. 3, 6, 8-9, 14. As Green explains, "cartridge 44 sits in the cartridge receiving channel 46 … positive longitudinal location of the cartridge being effected by means of a projecting cartridge lug 70 and a complementary cut out in one of the side walls of channel 46." IS1015, 5:21-26. A POSITA would have understood that cartridge 44 slides in and out of cartridge receiving channel 46 when installed or removed, respectively. IS1003, ¶142.



IS1015, Figs. 6, 14 (annotated).

[1.6] a second jaw extending from said frame;

Green discloses a second jaw (combination of upper jaw 16 and anvil member 72) extending from the frame (upper frame 12/lower frame 14). IS1003, ¶143; IS1015, 3:23-27, 3:48-54, 5:33-47, Figs. 3, 11. For example, Green states that "the forward end portion of upper frame 12 defines an elongate upper jaw 16." IS1015, 3:25-27. "[T]wo anvil members 72 having staple shaping depressions in their outer surface . . . are placed on the upper jaw 16." *Id.*, 3:48-54. These "individual elongate anvils 72 . . . sit with a friction fit on the shoulders 50 of the upper jaw." *Id.*, 5:33-36.



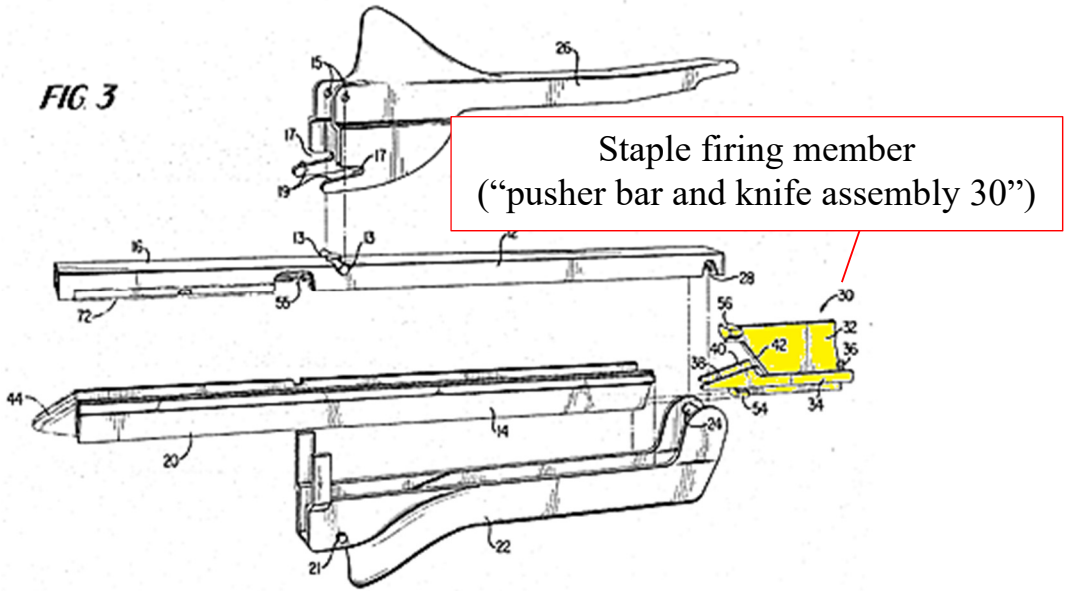
Id., Fig. 3 (annotated).

[1.7] a plurality of staples;

Green discloses a plurality of staples. IS1003, ¶144; IS1015, 3:48-49 ("four laterally spaced longitudinal rows of staples").

[1.8] a staple firing member comprising

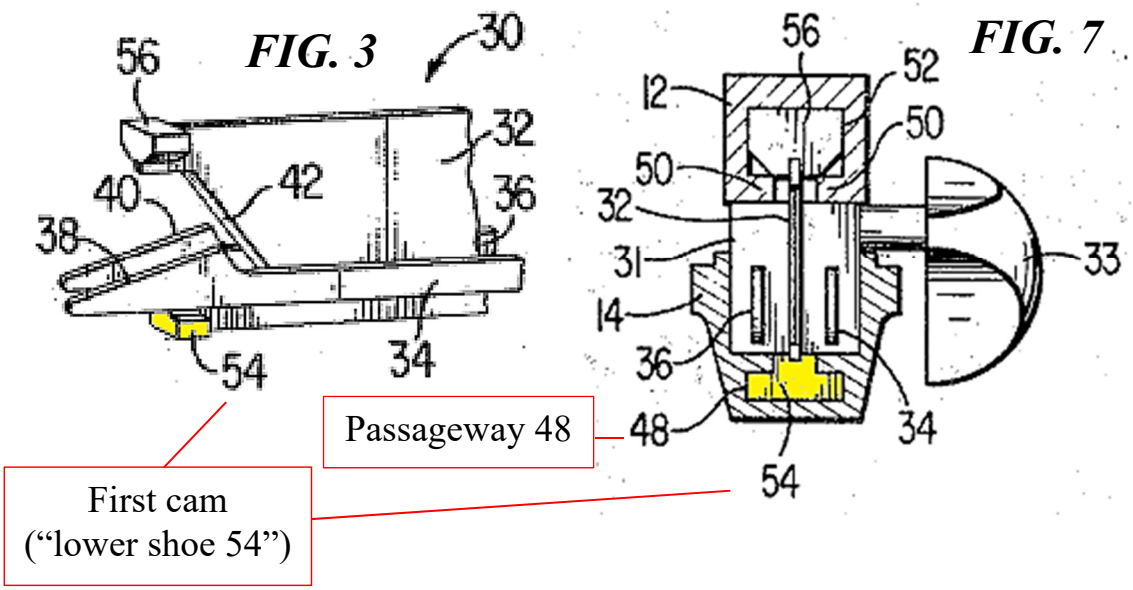
Green discloses a staple firing member (pusher bar and knife assembly 30). IS1003, ¶145; IS1015, 1:18-21, 3:40-47, 3:60-65, 4:30-60, Figs. 3-5. In use, "the pusher bar and knife assembly, which is initially in a rearward position relative to the jaws, is then pushed forward causing the pusher bar cams to enter longitudinal slits in the staple cartridge, in which slits are accommodated rows of individual staple pushers." IS1015, 3:60-65.



IS1015, Fig. 3 (annotated).

[1.8.1] a first cam configured to engage said first jaw and

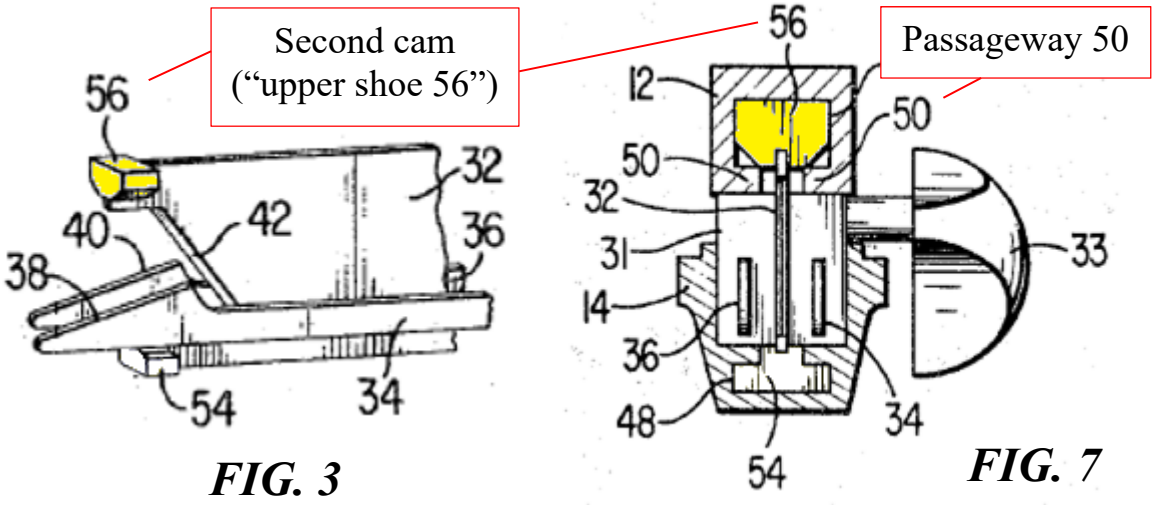
Green's staple firing member includes a first cam (lower shoe 54) that is configured to engage the first jaw via passageway 48 in lower jaw 20. IS1003, ¶¶146-148; IS1015, 3:40-45, 4:10-60, 6:9-41, Figs. 3-4, 6-7, 14.



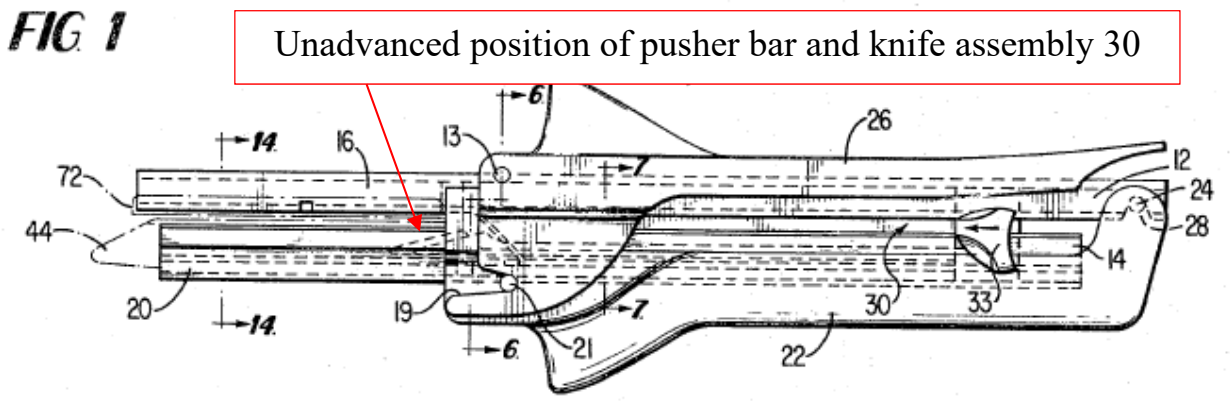
IS1015, Figs. 3, 7 (annotated).

[1.8.2] a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position toward said distal end,

Green's staple firing member includes a second cam (upper shoe 56) configured to engage the second jaw (via passageway 52 in upper jaw 16) when the staple firing member is advanced from an unadvanced position toward the distal end. IS1003, ¶¶149-150; IS1015, 3:40-45, 4:10-60, 5:55-65, 6:9-41, Figs. 1-4, 6-7, 14. The unadvanced position includes, for example, when the pusher bars are moved from the position where they enter the longitudinally slit ribs 60 and 62 of cartridge 44 and are held by the friction pieces, shown in Figures 1-2. IS1015, 5:63-67, 6:26-33, Figs. 1-2.



IS1015, Figs. 3, 7 (annotated).

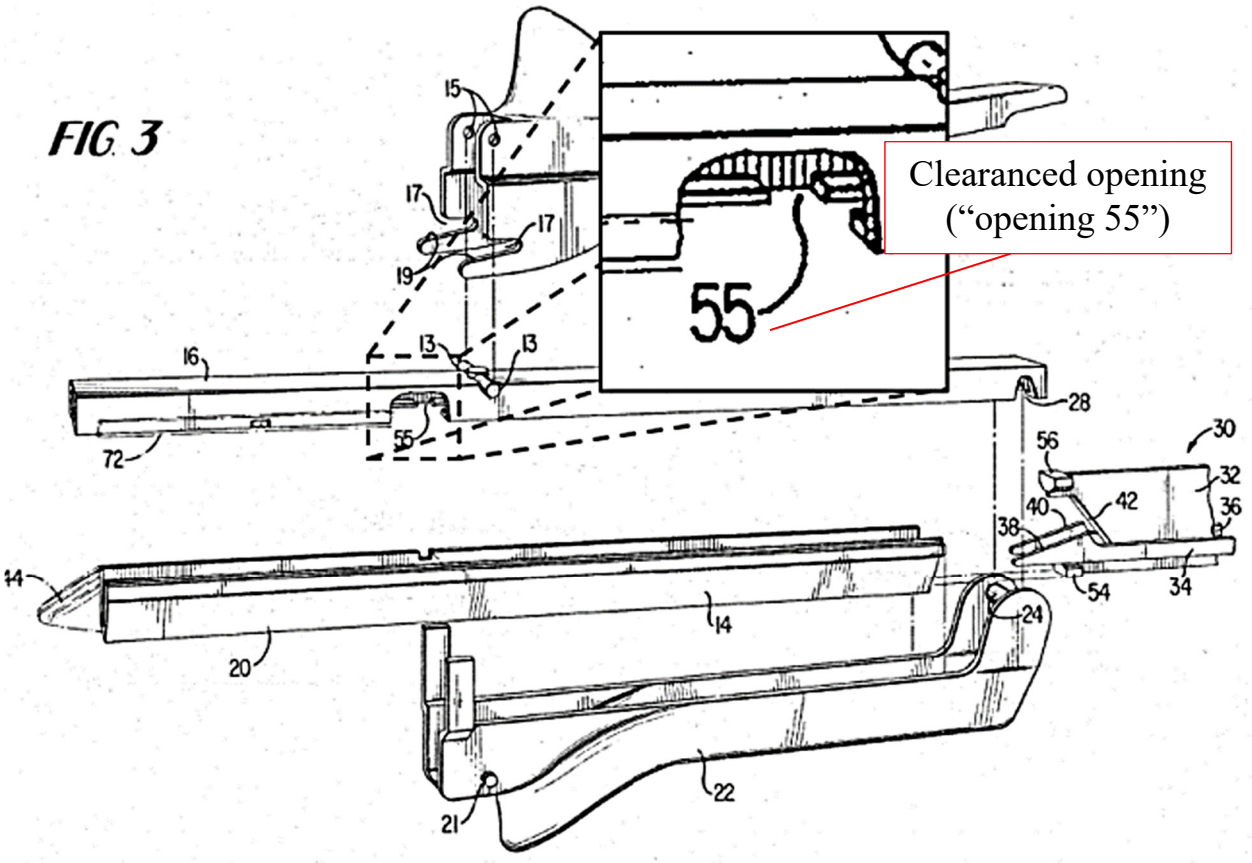


Id., Fig. 1 (annotated).

[1.8.3] wherein one of said first jaw and said second jaw comprises a clearanced opening configured to permit said firing member to be unengaged with one of said first jaw and said second jaw when said firing member is in said unadvanced position; and

Green's second jaw includes a clearanced opening (opening 55) that is configured to permit the firing member (pusher assembly 30) to be unengaged with one of said first jaw and said second jaw (combination of upper jaw 16 and anvil member 72) when the firing member is in the unadvanced position. IS1003, ¶¶151-153; IS1015, 6:9-25, Fig. 3. Like the '379 patent's anvil pocket 150, Green's "openings 55 (see FIG. 3) are provided in shoulders 50 of the upper frame 12 which allow shoes 56 to enter channel 52 as the instrument is closed." IS1015, 6:14-17; IS1003, ¶152. "When stapling is completed, the pusher assembly 30 is retracted to the initial position,"—*i.e.*, unadvanced position—"allowing shoes 56 to be removed from channel 52 through openings 55, so that the instrument can be opened." IS1015, 6:22-25. Modiified Figure 3 below shows the location of the

clearanced openings.



Id., Fig. 3 (modified, annotated).

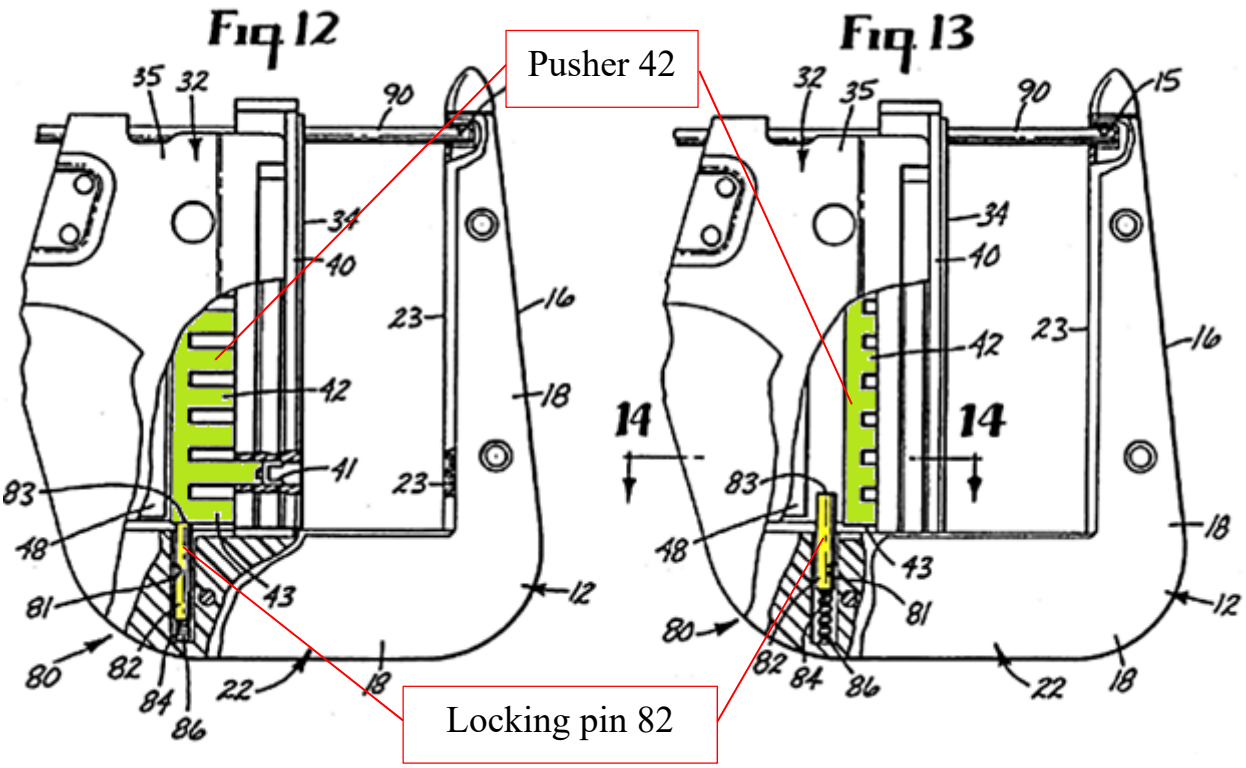
Thus, when the firing member (pusher assembly 30) is in an unadvanced position, the shoe 56 is also retracted into the clearanced opening (opening 55) such that the firing member (pusher assembly 30) is not engaged with the second jaw (upper frame 12). IS1003, ¶153.

[1.9] a lockout configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.

To the extent that Green does not explicitly disclose this limitation, it would

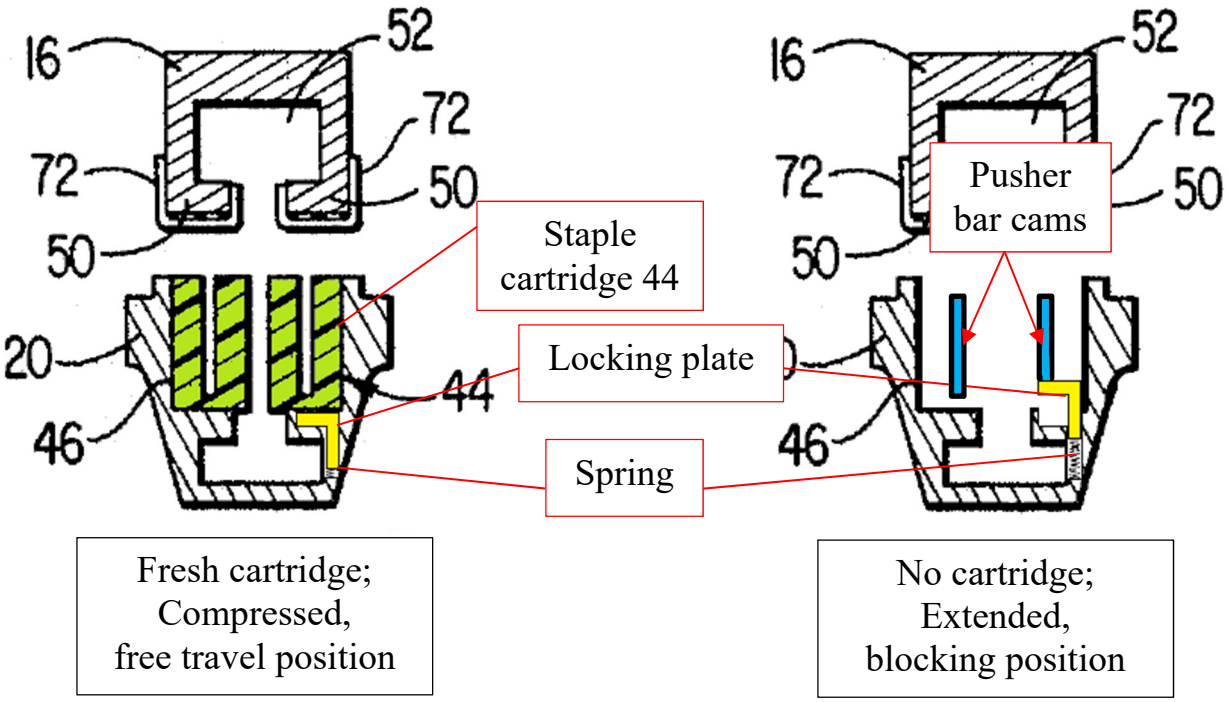
have been obvious in view of Solyntjes to modify Green's surgical stapling instrument to include a lockout configured to block the advancement of the staple firing member when the channel is not attached to the channel retainer, or to the stapling assembly. IS1003, ¶¶154-172.

Like the '379 patent, Solyntjes discloses a surgical stapler 10 that blocks the advancement of a staple firing member when no staple cartridge or a spent staple cartridge is installed. *Id*., ¶155; IS1011, Abstract, 10:64-11:18, 12:51-13:8, Figs. 12-14. More specifically, Solyntjes discloses a locking pin or plate 82 (highlighted yellow below) that moves "between a free travel position (FIG. 12) with the first end 83 of the locking pin [or plate] 82 generally abutting an edge of the pusher 42 [highlighted green below] … and blocking position (FIG. 13) with the first end 83 of the locking pin [or plate] 82 projecting into the path of the ram 48." IS1011, 11:1-18, Figs. 12-13; *see also* 16:30-55. Thus, pin or plate 82 "will not only prevent the stapler from firing when loaded with a spent cartridge, but will prevent the firing of the stapler 10 when the stapler is not loaded with a cartridge housing 40 at all." *Id*., 12:51-13:8.



Id., Figs. 12 (with pusher 42 in a pre-fired position, where pusher 42 is holding locking pin 82 in safety aperture 81) and 13 (with pusher 42 in a fired position, past locking pin 82 and no longer holding locking pin 82 in the safety aperture) (annotated).

It would have been obvious to a POSITA to modify the surgical stapling instrument of Green to include Solyntjes's safety locking mechanism, as shown below in two modified versions of Green's Figure 14, which show a cross-section of the stapling instrument at its distal end. IS1003, ¶157; IS1015, Figs. 1, 14.



IS1015, Fig. 14 (modified); IS1003, ¶157.

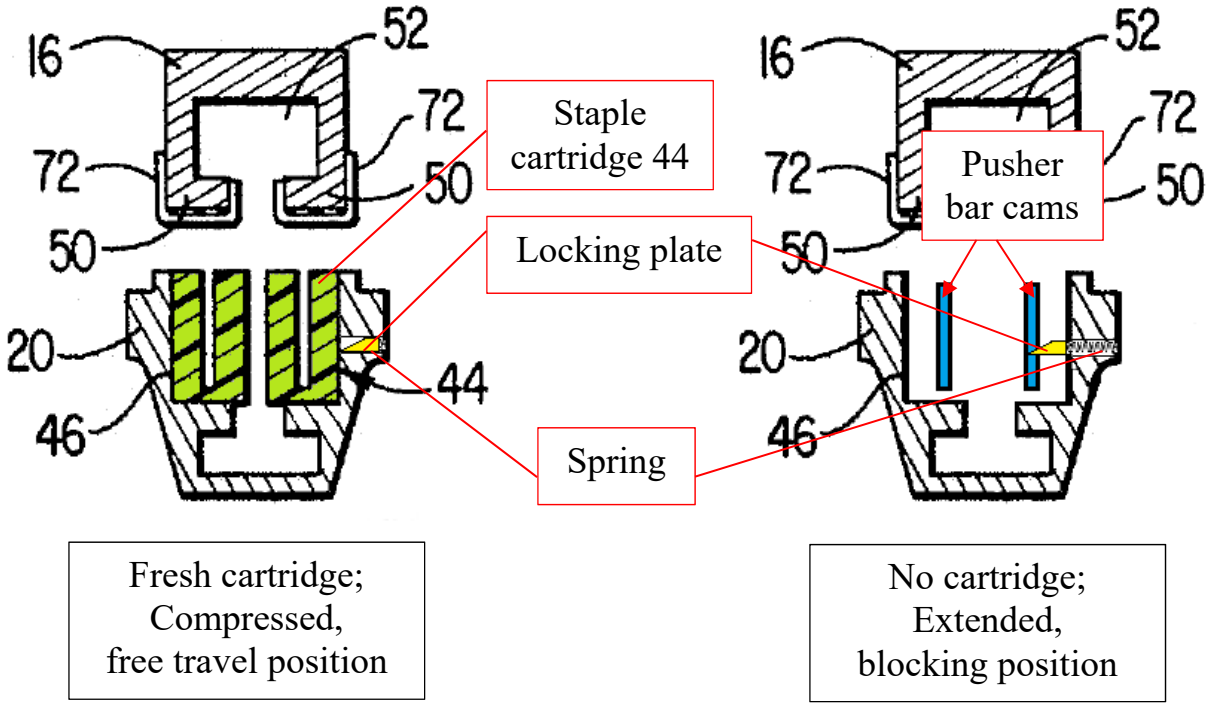
As shown above, Solyntjes' locking plate (highlighted yellow) block one of the laterally spaced pusher bar cams (highlighted blue) from advancing (*e.g.*, or moving out of the page toward the reader, as in the figures) when no staple cartridge is installed. IS1003, ¶157. Another plate could also be installed on the other side of the jaw to project into the path of the other pusher bar cam. *Id.*

Modified Figure 14 on the left shows the location and the compressed, free travel position of the locking plate when a fresh, unfired staple cartridge 44 (highlighted green) is installed, such that the locking plate would not block the pusher bar. *Id.*, ¶158. Modified Figure 14 on the right shows the extended, blocking position of the locking plate when no staple cartridge is installed, such that the locking

plate blocks the advancement of at least one pusher bar cam to block the advancement of Green's pusher bar and knife assembly 30. *Id*. A spring keeps the locking plate in the blocking position, as taught by Solyntjes. IS1011, 11:13-18; IS1003, ¶158.

Like Solyntjes's locking plate, the locking plate in the Green/Solyntjes stapler is compressed by a bottom surface of the proximal-most stapler pusher in Green's staple cartridge 44 when a fresh, unfired staple cartridge is installed. IS1003, ¶159.

An alternative Green/Solyntjes stapling instrument can include a locking plate configured to block the pusher bars from the side of the cartridge receiving channel 46, rather than from the bottom. *Id.*, ¶160. This is shown below in another modified version of Figure 14 of Green.



IS1015, Fig. 14 (modified, annotated).

As shown above, the locking plates in this alternative obvious combination of Green/Solyntjes, the horizontal locking plate would have a "ramped camming surface," as taught by Solyntjes, so that the staple cartridge 44 can be installed in the cartridge receiving channel 46 without obstruction. IS1003, ¶161; IS1011, 15:59-62. When the staple cartridge 44 is installed in the cartridge receiving channel 46 of the Green/Solyntjes stapler, the outer side walls of the staple cartridge push down on the ramped camming surface of the locking plate, causing the locking plate to compress (above at left). IS1003, ¶161. However, if no cartridge is present (above at right), the locking plate extends, blocking the advancement of the pusher bar and preventing the firing of staples. *Id*.

This orientation of the alternative Green/Solyntjes stapler provides the further benefit of providing lockout functionality both when a cartridge is not installed and when a spent cartridge is installed in the cartridge receiving channel 46 of the stapling assembly. IS1003, ¶¶162-167; IS1015,1:28-31, 4:65-5:1, 5:2-5; IS1016, 6:71-7:15, Fig. 23.

To the extent that a POSITA implemented this specific example of the proposed combination, that person would have known how to select the appropriate spring rate for Solyntjes's biasing spring 86 so that the plate would move into the

extended, blocking position when unobstructed, but would remain compressed if blocked by a staple pusher. IS1003, ¶168.

Multiple reasons would have prompted a POSITA to modify Green's surgical stapling device based on Solyntjes to include a locking mechanism. First, a POSITA would have been prompted to modify Green's device based on Solyntjes's suggestion to achieve the predictable benefit of "prevent[ing] the stapler 10 from firing when loaded with a spent cartridge" and also "when the stapler is not loaded with a [stapler cartridge] at all." IS1003, ¶169; IS1011, 12:62-66. Providing such a safety mechanism, as in Solyntjes, would advantageously prevent the inadvertent severing of tissue when the device is loaded with a spent cartridge or no cartridge. IS1003, ¶169. The modified device of Green also advantageously "prevents firing of the stapler 10 should [a fired stapler cartridge] be replaced with another fired cartridge." *Id.*; IS1011, 12:67-13:3. Rather, the stapling device "can be refired only by replacing [the fired cartridge] with an unfired or read-to-fire [stapler cartridge]" that has an edge surface "in the proper position to move the pin [or plate] 82 to the free-travel position." IS1003, ¶169; IS1011, 13:4-8.

Second, a POSITA would have been motivated to modify Green's instrument to include Solyntjes's locking mechanism because it would have made Green's instrument safer and more efficient. IS1003 at ¶170; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 424 (2007). As Solyntjes explains:

> [I]t is difficult to determine when [staplers] are loaded with a 'spent' cartridge or with a cartridge that does not contain staples. On occasion, a spent cartridge may be inadvertently left in a stapler after it has been fired during a surgical procedure where the stapler is used several times for the same patient, or a spent cartridge may be inadvertently loaded into a stapler that is about to be fired in the patient. If a stapler is loaded with a cartridge housing other than a ready-to-fire cartridge housing and the stapler is clamped on tissue to be stapled, the compressive forces created by the stapler subject the tissue to undesirable and unnecessary trauma. The sequence of (1) clamping the stapler with a spent cartridge on tissue, (2) firing the "dud" stapler, (3) subsequently rearming, (4) again approximating the stapler adjacent the tissue to be stapled and (5) reclamping the stapler wastes precious time during the surgical procedure.
>
> Additionally … staplers may be used in procedures in which the surgeon … create[s] an incision on a side of closed staples …. A spent stapler cartridge used in such procedures may result in unnecessary blood loss, inadequate hemostasis and tissue trauma for the patient undergoing the procedure.

IS1011, 1:53-2:17; *see also* Tompkins (IS1012), 1:50-2:6 (confirming that a POSITA would have known it was "beneficial to have a locking mechanism," like

Solyntjes's, in a GIA-type surgical stapler, like Green's). Furthermore, Solyntjes's locking mechanism provides the additional benefit of "not only prevent[ing] the stapler … from firing when loaded with a spent cartridge, but … also prevent[ing] the firing of the stapler … when the stapler is not loaded with a cartridge housing … at all." IS1011, 12:62-66; IS1003, ¶170.

Third, a POSITA would have been prompted to modify Green's instrument based on Solyntjes's suggestion (using locking plates/pins) because doing so would be merely be the application of a known technique (*e.g.*, using locking pins/plates to prevent firing of a stapler when staples are not present) to a known apparatus (Green's stapling instrument) ready for improvement to yield predictable results. IS1003, ¶171. Indeed, "when a patent 'simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR*, 550 U.S. at 417. Here, Green and Solyntjes describe highly similar systems for surgical stapling, and a POSITA would have been able to readily and predictably apply the suggestions of Solyntjes to Green's design. IS1003, ¶171. Indeed, Green expressly contemplated that its instrument "is not limited to its specific features and modifications are possible," and Solyntjes suggested such beneficial modifications that would not have hindered the basic function of Green's stapling instrument. IS1015, 6:42-46; IS1003, ¶171. Moreover, Solyntjes's locking

plate and Green's instrument merely perform the same predictable functions as they do separately without significantly altering or hindering the functions performed by Green's instrument (*i.e.*, clamping, cutting, stapling) or Solyntjes's locking plate (blocking the pusher when the staple cartridge is spent or not installed). IS1003, ¶171.

[2.1] A stapling assembly, comprising:

See Ground 2, element [1.1]; IS1003, ¶172; IS1015, Abstract, 3:14-25, Fig. 1.

[2.2] a frame;

See Ground 2, element [1.2]; IS1003, ¶173; IS1015, 3:23-34, Figs. 1, 3.

[2.3] a distal end;

See Ground 2, element [1.3]; IS1003, ¶174; IS1015, 3:23-31, 6:9-14, Figs. 1-2.

[2.4] a first jaw comprising a channel;

See Ground 2, element [1.4]; IS1003, ¶175; IS1015, 3:25-27, 3:48-54, 5:5-14, Figs. 3, 8-10.

[2.5] a channel retainer, wherein said channel is slidably attachable to said channel retainer;

See Ground 2, element [1.5]; IS1003, ¶176; IS1015, 3:48-50, 5:5-26, Figs. 3, 6, 8-9, 14.

[2.6] a second jaw extending from said frame;

See Ground 2, element [1.6]; IS1003, ¶177; IS1015, 3:23-27, 3:48-54, 5:33-47, Figs. 3, 11.

[2.7] a plurality of staples;

See Ground 2, element [1.7]; IS1003, ¶178; IS1015, 3:48-49.

[2.8] a staple firing member comprising

See Ground 2, element [1.8]; IS1003, ¶179; IS1015, 1:18-21, 3:40-47, 3:60-65, 4:30-60, Figs. 3-5.

[2.8.1] a first cam configured to engage said first jaw and

See Ground 2, element [1.8.1]; IS1003, ¶180; IS1015, 3:40-45, 4:10-60, 6:9-41, Figs. 3-4, 6-7, 14.

[2.8.2] a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position toward said distal end,

See Ground 2, element [1.8.2]; IS1003, ¶181; IS1015, 3:40-45, 4:10-60, 5:55-65, 6:9-41, FIGs. 1-4, 6-7, 14.

[2.8.3] wherein said first cam and said second cam are configured to co-operatively hold said first jaw and said second jaw relative to one another when said staple firing member is advanced toward said distal end, and

Green's first cam (lower shoe 54) and second cam (upper shoe 56) are configured to co-operatively hold (restrain) the first jaw (combination of lower jaw 20 and disposable staple cartridge 44) and the second jaw (combination of upper jaw 16 and anvil member 72) relative to one another when the firing member (pusher

bar and knife assembly 30) is advanced toward the distal end. IS1003, ¶¶182-184; IS1011, 2:7-56, 4:10-60, 6:26-41, Figs. 1, 3, 7; *see also* Ground 2, element [1.8.2]. As Green explains, "since the shoes 54 and 56 are accurately laterally aligned and carried by a relatively rigid member … they provide adequate localized support to the jaws … [that] resists forces tending both laterally to distort the jaws and to open the jaws vertically." IS1011, 6:26-38.

[2.8.4] wherein one of said first jaw and said second jaw comprises a clearanced opening configured to receive one of said first cam and said second cam such that said first jaw is not held to said second jaw when said staple firing member is in said unadvanced position; and

Green's second jaw includes a clearanced opening (opening 55) configured to receive the second cam (upper shoe 56) such that the first jaw (combination of lower jaw 20 and disposable staple cartridge 44) is not held to the second jaw (combination of upper jaw 16 and anvil member 72) when the staple firing member (pusher assembly 30) is in the unadvanced position. IS1003, ¶¶185-188; IS1015, 6:9-25, Fig. 3; *see also* Ground 2, element [1.8.3]. Like the '379 patent's anvil pocket 150, Green's "openings 55 (see FIG. 3) are provided in shoulders 50 of the upper frame 12 which allow shoes 56 to enter channel 52 as the instrument is closed." IS1015, 6:14-17; IS1003, ¶186. "When stapling is completed, the pusher assembly 30 is retracted to the initial [unadvanced] position, allowing shoes 56 to be removed from channel 52 through openings 55, so that the instrument can be opened." IS1015, 6:22-25. Notably, because the "instrument can be opened," the

first and second jaws are not held together when the pusher assembly 30 is in the unadvanced position. *Id.*; IS1003, ¶¶187-188.

[2.9] a lockout configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.

The combination of Green and Solyntjes teaches this element. *See* Ground 2, element [1.9]; IS1003, ¶189; IS1015, 1:28-31, 4:65-5:5, 6:42-46, Fig. 14; IS1011, Abstract, 1:53-2:17, 10:64-11:18, 12:51-13:8, 16:30-55, Figs. 12-14; IS1016, Fig. 23; *see also* IS1012, 1:50-2:6.

[3.1] A stapling assembly, comprising:

See Ground 2, element [1.1]; IS1003, ¶190; IS1015, Abstract, 3:14-25, Fig. 1.

[3.2] a first jaw;

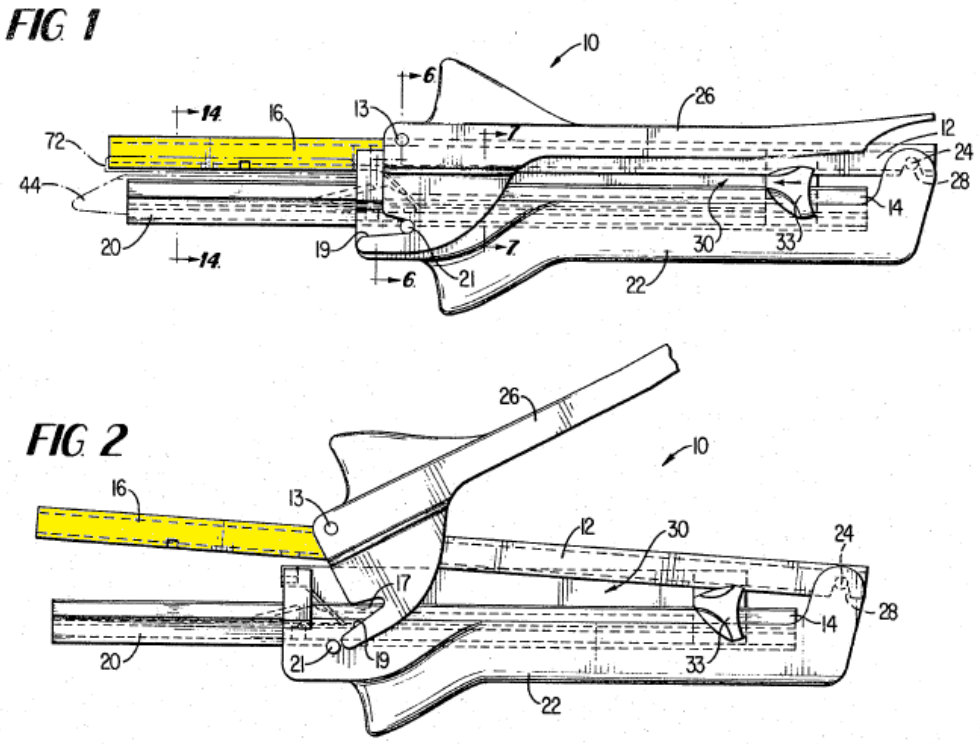
See Ground 2, element [1.6] (confirming that Green discloses a first jaw—the combination of upper jaw 16 and anvil member 72); IS1003, ¶191; IS1015, 3:23-27, 3:48-54, 5:33-47, Figs. 3, 11.

[3.3] a second jaw, wherein said first jaw is rotatable relative to said second jaw;

Green discloses a second jaw (combination of lower jaw 20 and disposable staple cartridge 44), wherein said first jaw (combination of upper jaw 16 and anvil members 72) is rotatable relative to said second jaw. IS1003, ¶¶192-193; IS1015 at 3:25-27, 3:48-54, 5:5-14, Figs. 3, 8-10; *see also* Ground 2, element [1.4] (confirming that Green discloses a second jaw—the combination of lower jaw 20 and

disposable staple cartridge 44).

Furthermore, Green's first jaw (combination of upper jaw 16 and anvil members 72) is rotatable relative to the second jaw (combination of lower jaw 20 and disposable staple cartridge 44). IS1003, ¶193; IS1011, 3:34-37. As Green explains, "handle 26 can be used to open and close the frames [and therefore the first and second jaws at the distal end of the frames] about the pivot means 24, 28 between the open condition shown in FIG. 2 and the locked condition shown in FIG. 1." IS1011, 3:34-37.



Id., Figs. 1-2 (annotated).

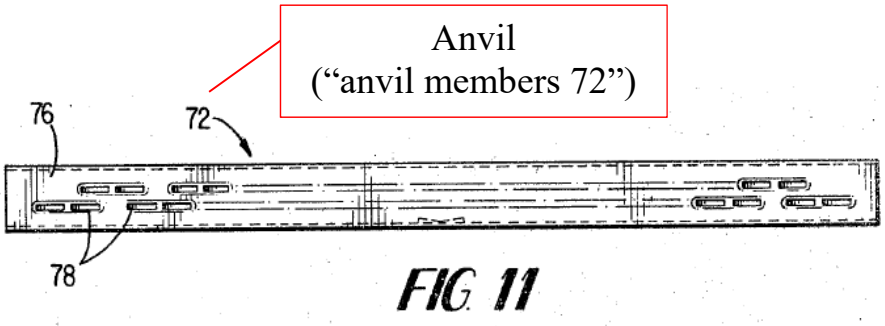
[3.4] a detachable cartridge portion comprising a plurality of staples;

Green discloses a detachable cartridge portion (disposable staple cartridge

44) comprising a plurality of staples (four laterally spaced longitudinal rows of staples). IS1003, ¶194; IS1011, 3:48-54, 4:65-5:26, Figs. 1-3, 8-10, 14; *see also* Ground 2, element [1.4] (discussing disposable staple cartridge 44).

[3.5] an anvil configured to deform said staples; and

Green discloses an anvil (anvil members 72) configured to deform staples. IS1003, ¶195; IS1011, 3:50-54, Fig. 11. As Green explains, "two anvil members 72 having staple shaping depressions in their outer surfaces, complimentary to the positioning of the individual staples in the staple cartridge, are placed on the upper jaw 16." IS1011, 3:50-54.



Id., Fig. 11 (annotated).

[3.6] a staple firing member comprising

See Ground 2, element [1.8]; IS1003, ¶196; IS1015, 1:18-21, 3:40-47, 3:60-65, 4:30-60, Figs. 3-5.

[3.6.1] a first cam configured to engage said first jaw and

See Ground 2, element [1.8.2] (confirming that Green discloses a first cam (upper shoe 56) configured to engage the first jaw (combination of upper jaw 16

and anvil member 72) via passageway 52); IS1003, ¶197; IS1015, 4:30-60, 5:55-65, 6:9-41, Figs. 1-4, 6-7, 14.

[3.6.2] a second cam configured to engage said second jaw when said staple firing member is advanced from an initial position, and

Green discloses a second cam configured to engage said second jaw when said staple firing member is advanced from an initial position. IS1003, ¶¶198-199; IS1015, 3:40-45, 4:10-60, 5:55-65, 6:9-41, FIGs. 1-4, 6-7, 14; *see* Ground 2, element [1.8.1] (confirming that Green discloses a second cam (lower shoe 54) configured to engage the second jaw (combination of lower jaw 20 and disposable staple cartridge 44) via passageway 48).

Furthermore, the second cam is configured to engage the second jaw when the staple firing member is advanced from an initial position (where the "pusher bars enter the longitudinally slit ribs 60 and 62 of cartridge 44 and are [held] by the friction pieces," shown in Figures 1-2) because lower shoe 54 engages passageway 48 "during stapling" (*i.e.*, when the firing member is advanced distally from the initial position). IS1003, ¶199; IS1015, 5:63-67, 6:26-33.

[3.6.3] wherein said first jaw comprises a clearanced opening configured to receive said first cam when said staple firing member is in said initial position such that said first cam is not engaged with said first jaw when said staple firing member is in said initial position; and

Green's first jaw (combination of upper jaw 16 and anvil member 72) in-

cludes a clearanced opening (opening 55) configured to receive the first cam (upper shoe 56) when the staple firing member (pusher assembly 30) is in the initial (retracted) position such that the first cam (upper shoe 56) is not engaged with the first jaw (upper jaw 16 and anvil member 72) when the staple firing member (pusher assembly 30) is in the initial position. IS1003, ¶¶200-204; IS1015, 6:9-25, Fig. 3; *see also* Ground 2, element [1.8.3].

Like the '379 patent's anvil pocket 150, Green's "openings 55 (see FIG. 3) are provided in shoulders 50 of the upper frame 12 which allow shoes 56 to enter channel 52 as the instrument is closed." IS1015, 6:14-17; IS1003, ¶202. "When stapling is completed, the pusher assembly 30 is retracted to the initial [unadvanced] position, allowing shoes 56 to be removed from channel 52 through openings 55, so that the instrument can be opened." IS1015, 6:22-25. With the first cam (upper shoe 56) received in the openings 55 when the firing member (pusher assembly 30) is not advanced, the first cam (upper shoe 56) does not engage the first jaw (upper jaw 16 and anvil member 72) so the first and second jaw are not held together. *Id.*; IS1003, ¶¶203-204.

[3.7] a lockout configured to block the advancement of said staple firing member when said detachable cartridge portion is not attached to said stapling assembly.

The combination of Green and Solyntjes teaches this element. *See* Ground 2, element [1.9]; IS1003, ¶¶205-206; IS1015, 1:28-31, 4:65-5:5, 6:42-46, Fig. 14; IS1011, Abstract, 1:53-2:17, 10:64-11:18, 12:51-13:8, 16:30-55, Figs. 12-14;

IS1016, Fig. 23; *see also* IS1012, 1:50-2:6. In particular, the discussion of Ground 2, element [1.9] above shows how the obvious combination of Green and Solyntjes teaches a lockout configured to block the advancement of the staple firing member when a channel, or a detachable cartridge portion (staple cartridge) is not attached to the channel retainer or to the stapling assembly at all. IS1003, ¶¶205-206.

X. THIS PETITION SHOULD NOT BE DISCRETIONARILY DENIED

Patent Owner may argue that this Petition should be discretionarily denied under 35 U.S.C. § 314(a) based on *NHK Spring*[8] and progeny. Any such argument by Patent Owner should be rejected for several reasons.

First, unlike the situation in *NHK Spring*, there is virtually no chance that the district court action concerning the '379 patent, which has been stayed, will go to trial before the PTAB issues a Final Written Decision ("FWD") in this proceeding. The '379 patent was first asserted against Petitioner on March 12, 2019, in a second civil action in the U.S. District Court of Delaware (case no. 18-cv-1325, filed Aug. 27, 2018).[9] Apparently concerned that the second district court action also

[8] Case IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential).

[9] Previously, Patent Owner had filed a first district court action asserting infringement of seven patents related to, but not including, the '379 patent. U.S. District Court for the District of Delaware, case no. 17-cv-871, filed June 30, 2017. That

would be stayed based on IPR petitions filed against the newly asserted patents, Patent Owner filed an ITC complaint in which it asserted the '379 patent against Petitioner a second time.[10] After the ITC action was instituted, the second district court action was stayed pending the final disposition of the ITC action.

In view of the postures of the proceedings concerning the '379 patent, the Board should not discretionarily deny this Petition. Even though the ITC action ***may*** involve a determination concerning the validity of the '379 patent,[11] the ITC's target completion date (December 7, 2020; IS1017) is roughly 14 months after filing of this Petition. Fourteen months is far more distant than the parallel district court trial in *NHK Spring*, which was scheduled for only six months away. And the district court action involving the '379 patent will not commence until the ITC

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first action was stayed pending the outcome of IPRs on the asserted patents. *See* Case Nos. IPR2018-00933, -934, -935, -936, -938, -1247, -1248.

[10] *Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof*, Inv. No. 337-TA-1167, May 28, 2019 Amended Complaint (Public Version Filed May 30, 2019).

[11] As explained below, the ITC investigation may conclude with no validity determination having been made.

action has reached a final conclusion and all appeals have been exhausted. As a result, the second district court action will not go to trial, much less be completed, before a final decision would issue in this proceeding.

Second, the ITC target completion date relates solely to the ITC's final determination in the first instance and does not take into account the additional time consumed by the inevitable appeal to the Federal Circuit, and a potential remand, which likely would add at least two years or more before the ITC action reached its final disposition. Consequently, even though the ITC's target completion date (December 2020) is roughly four months before a final decision would issue in this IPR proceeding (April 2021), final disposition of the ITC action would not occur until long after the final decision in this proceeding.

Third, if it is determined in the ITC action that the '379 patent is not infringed, then the ITC need not, and indeed may not, reach a determination on the patent's validity. *See, e.g., Beloit Corp. v. Valmet Oy,* 742 F.2d 1421, 1423 (Fed. Cir. 1984) ("The Commission … is at perfect liberty to reach a 'no violation' determination on a single dispositive issue [such as non-infringement.]"). In that case, the PTAB would be the first tribunal to consider the '379 patent's validity since the district court action involving the '379 patent is stayed.

Fourth, two of the five patents asserted in the ITC proceeding are already the subject of four instituted IPR proceedings (IPR2018-01247, -01248, -01254,

IPR2019-00880) and one other asserted patent is the subject of an IPR petition filed May 9, 2019 (IPR2019-01066).[12] Accordingly, instituting review of another patent involved in the same ITC proceeding will allow for the efficient review of related patents.

Fifth, as noted above, regardless of the outcome at the ITC, one or both parties are likely to appeal the ITC's determination to the Federal Circuit. Thus, there is a good chance that any appeal of a final decision in this proceeding would overlap with the appeal of the ITC case. The Federal Circuit may consolidate such appeals, thereby allowing the decision of this Board to impact the final outcome of the ITC case, and thereby promote judicial efficiency. Either way, any remand could delay the conclusion of the ITC proceeding potentially for years. Consequently, even if a final decision issued in this proceeding after the ITC target completion date, allowing this proceeding to go forward could bring finality much sooner.

[12] An institution decision for IPR2019-01066 is due by November 16, 2019. Of the other two patents asserted in the ITC proceeding, one is the '379 patent—the subject of this Petition—and the other is U.S. Patent 9,113,874, the IPR petition for which (IPR2018-00938) was denied on the merits—*i.e.,* not on discretionary grounds.

Sixth, as the Board has acknowledged in a related proceeding, "*NHK Spring* does not suggest, much less hold, that *inter partes* review should be denied under § 314(a) solely because [another tribunal] is scheduled to consider the same validity issues before the *inter partes* review would be complete." Case IPR2018-01703, Paper 7 (PTAB Feb. 19, 2019). This holding applies here with even greater force because "the same validity issues" as presented in this Petition will not necessarily be considered in the ITC proceeding. Rather, additional or different prior art references may be relied on in establishing invalidity.[13]

Seventh, the Board should not exercise its discretion under Section 314(a) here because "the merits of the case weigh heavily in favor of granting institution." *Apotex Inc. v. UCB Biopharma SPRL,* Case IPR2019-00400, paper 17 at 31-32 (PTAB Jul. 15, 2019). The grounds presented in this petition are dead-on and include an anticipation ground that clearly renders the challenged claims unpatentable. Moreover, judicial efficiency is not necessarily paramount. Rather, "[t]he [AIA] "does not guarantee increased judicial efficiency in resolving patent disputes in each case, and no litigant is required to adopt a strategy that increases judicial

[13] As of the filing date of this Petition, Petitioner is still considering which validity defenses will be asserted in the ITC proceeding. In that regard, additional or different prior art references beyond those asserted in the Petition may be asserted.

efficiency at a cost of reducing its likelihood of prevailing in the dispute." *Id.* at 32-33.

Finally, Congressional intent militates against discretionary denial. Through 35 U.S.C. § 315(b), Congress established a one-year bar to file a petition for *inter parties* review after service of a complaint. In so doing, Congress was intending to "afford defendants a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation." 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011). Indeed, as is the case here, "[h]igh-technology companies . . . are often sued by [patent owners] asserting multiple patents with large numbers of vague claims, making it difficult to determine in the first few months of the litigation which claims will be relevant and how those claims are alleged to read on the defendant's products." *Id.* Thus, it would be unfair—and in clear contravention of legislative intent—to refuse Petitioner access to the efficiencies intended through this forum by denying institution simply because completion of the co-pending ITC investigation happens to be (presently) scheduled before a final decision would issue in this proceeding. The timing requirements of the AIA clearly did not intend for something as arbitrary as an investigation completion date to be used as a measuring stick for determining the fate of an IPR. Not only would parties who otherwise satisfy Congressional eligibility standards be denied access to an IPR, the Board would effectively be turning over institution decisions to other fora and

encouraging forum shopping, such as Patent Owner has done here by filing the ITC action. Such a result would clearly be antithetical to Congressional intention to avail parties of an alternative and efficient means of addressing patentability.

XI. CONCLUSION

Claims 1-3 of the '379 patent are unpatentable pursuant to Grounds 1-2 set forth above. Accordingly, Petitioner requests *Inter Partes* Review of the challenged claims.

Respectfully submitted,

Dated October 16, 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 13,969 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

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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 October 16, 2019, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits and Power of Attorney were provided via Federal Express to the Patent Owner by serving the correspondence address of record as follows:

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