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.: 11030-0057IP1
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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Patent Trial and Appeal Board
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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	U.S. Pat. App. Pub. No. 2005/0263562 to Shelton, et al. ("Shelton '562")
IS1005	U.S. Pat. App. No. 14/175,148
IS1006	U.S. Pat. App. No. 11/141,753
IS1007	U.S. Pat. App. No. 13/369,601
IS1008	Redline comparison of the '379 patent and Shelton '562
IS1009	Declaration attesting to authenticity and accuracy of IS1008
IS1010	U.S. Patent No. 3,819,100 to Noiles ("Noiles")

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 ***actual*** priority date of the '379 patent.[1] Consequently, the Challenged Claims are anticipated by U.S. Pub. No. 2005/0263562 ("Shelton '562"), the relevant, substantive disclosure of which is word-for-word identical to the '379 patent. Petitioner therefore requests IPR of the Challenged Claims.

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

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

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

[1] As explained below, 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.

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 with 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 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

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

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.

LEAD COUNSEL	BACK-UP 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 IPR11030-0057IP1@fr.com (referencing No. 11030-0057IP1 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 ground 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 '562** (IS1004) under 35 U.S.C. § 102.

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

[3] The '379 Patent incorrectly identifies the '148 Application as a "continuation" of each of the '601 and the '753 Applications. As will be explained in more detail in Section VIII, this priority claim is wrong because the '148 Application combines the two applications and thus adds new matter to each. Consequently, the '148 Application is not entitled to the priority date of either the '601 Application or the '753 Application or their respective parent applications.

on Oct. 3, 2006.

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

For the reasons explained below in Section VIII, the ’379 patent cannot properly claim priority to a date earlier than the filing date of the ’148 application, namely February 7, 2014 (the “earliest effective filing date”).

Shelton ’562 published on December 1, 2005, which is more than one year before the earliest effective filing date, and thus qualifies as prior art under 35 U.S.C. § 102(a)(1). Shelton ’562 issued as U.S. Pat. No. 7,380,696, which was made of record during prosecution of the ’379 patent, but was never discussed by the examiner or the applicant.[4]

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.

[4] Applicants cited more than 4000 references during prosecution of the ’379 patent.

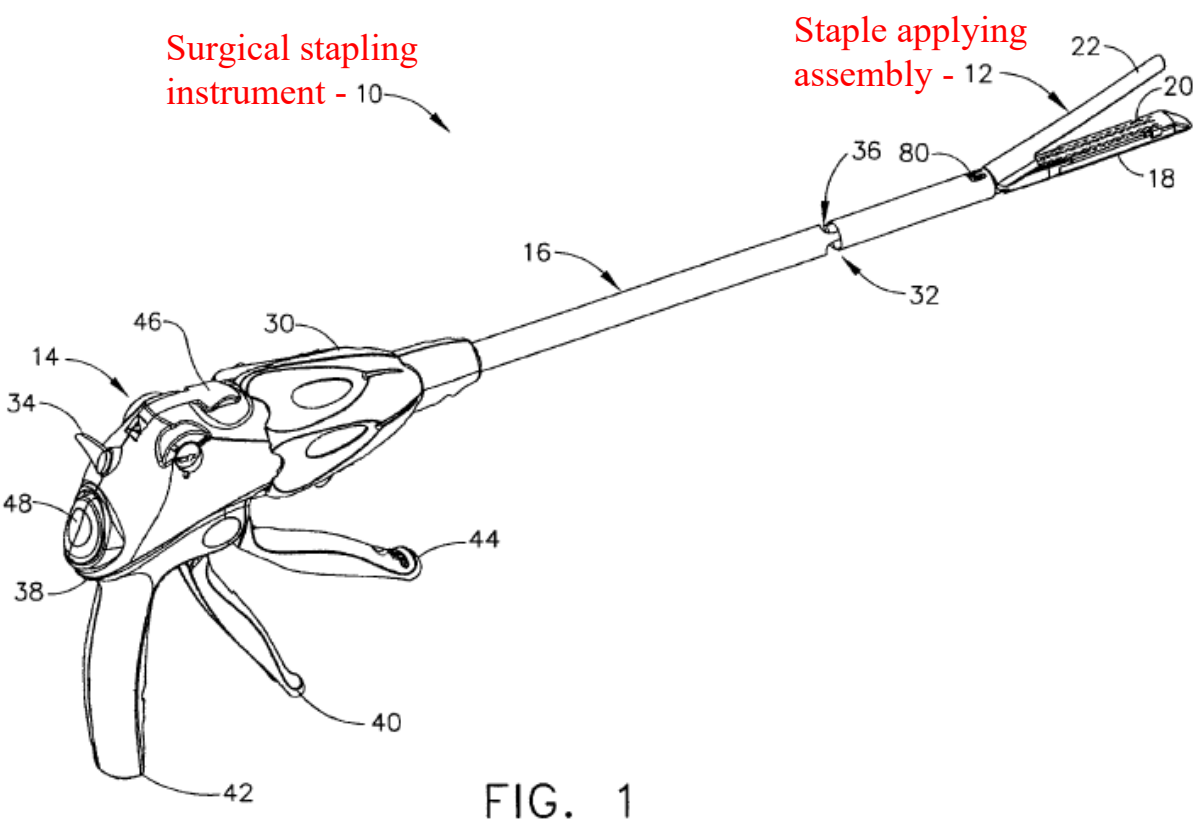
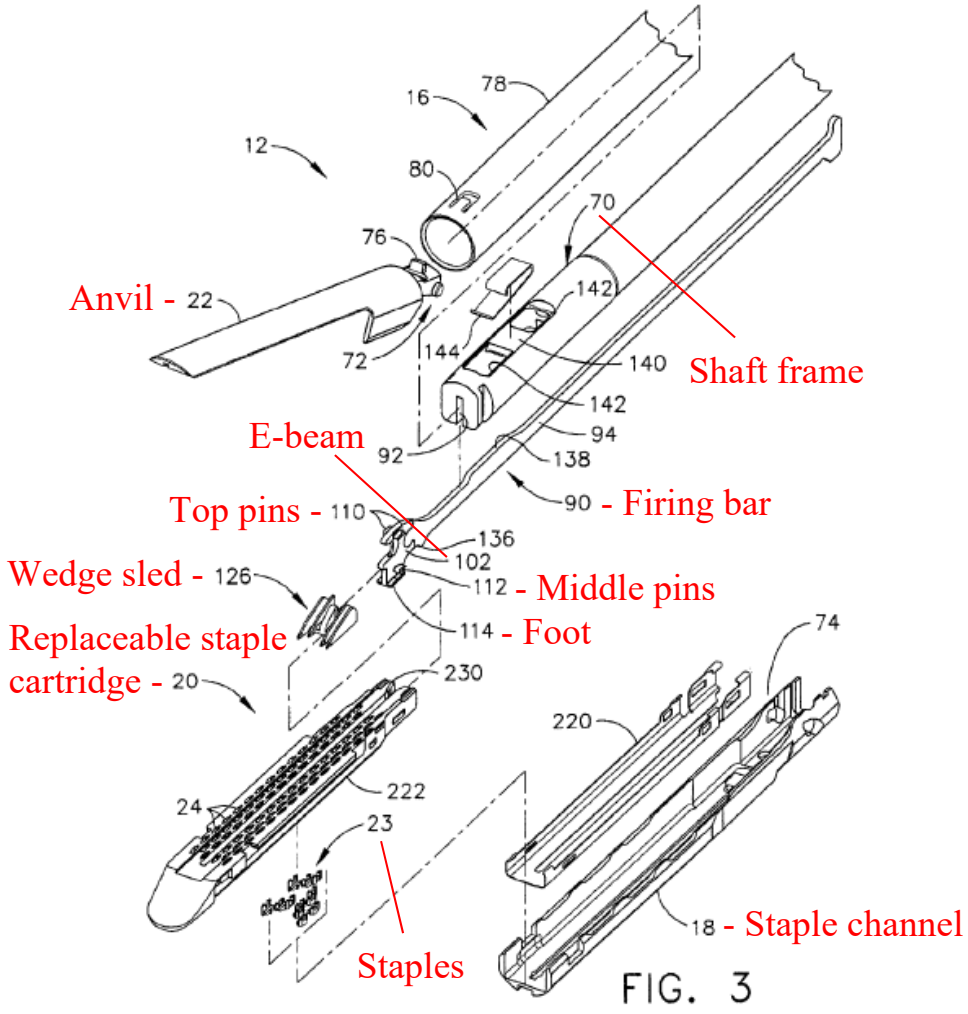


FIG. 1

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.

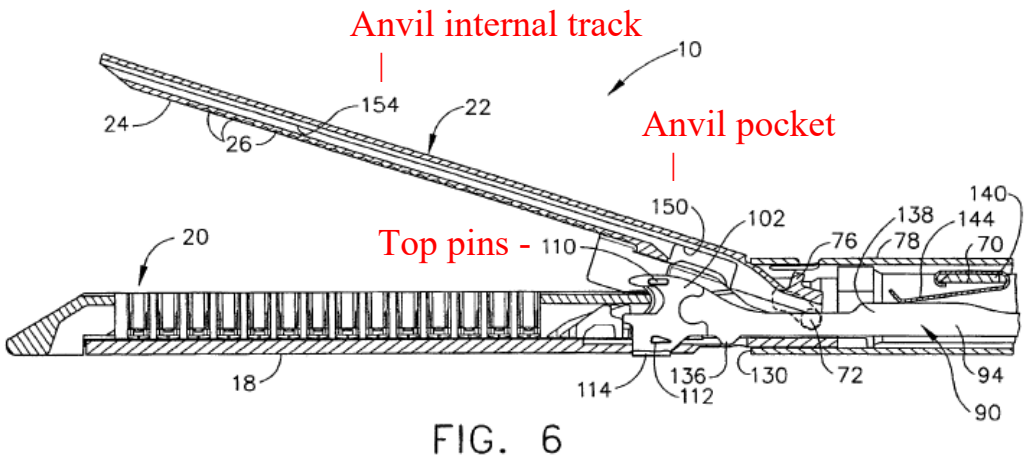


FIG. 6

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.

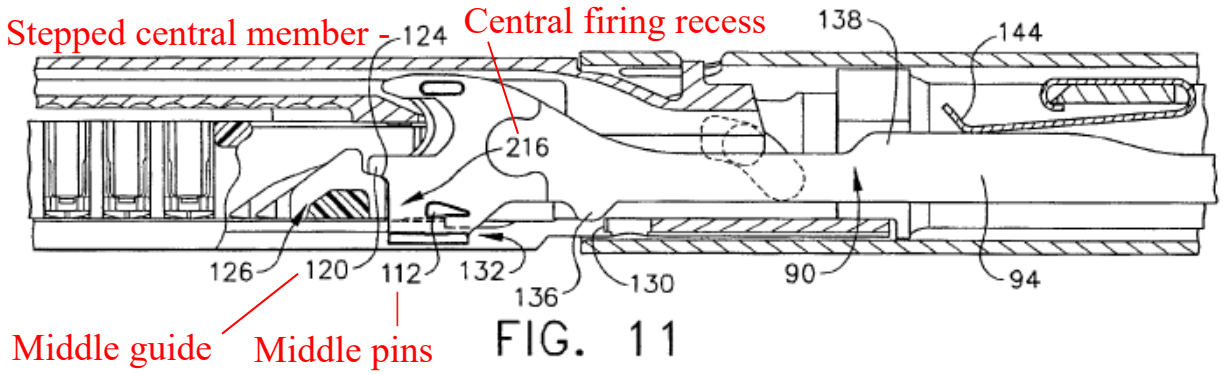


FIG. 11

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.

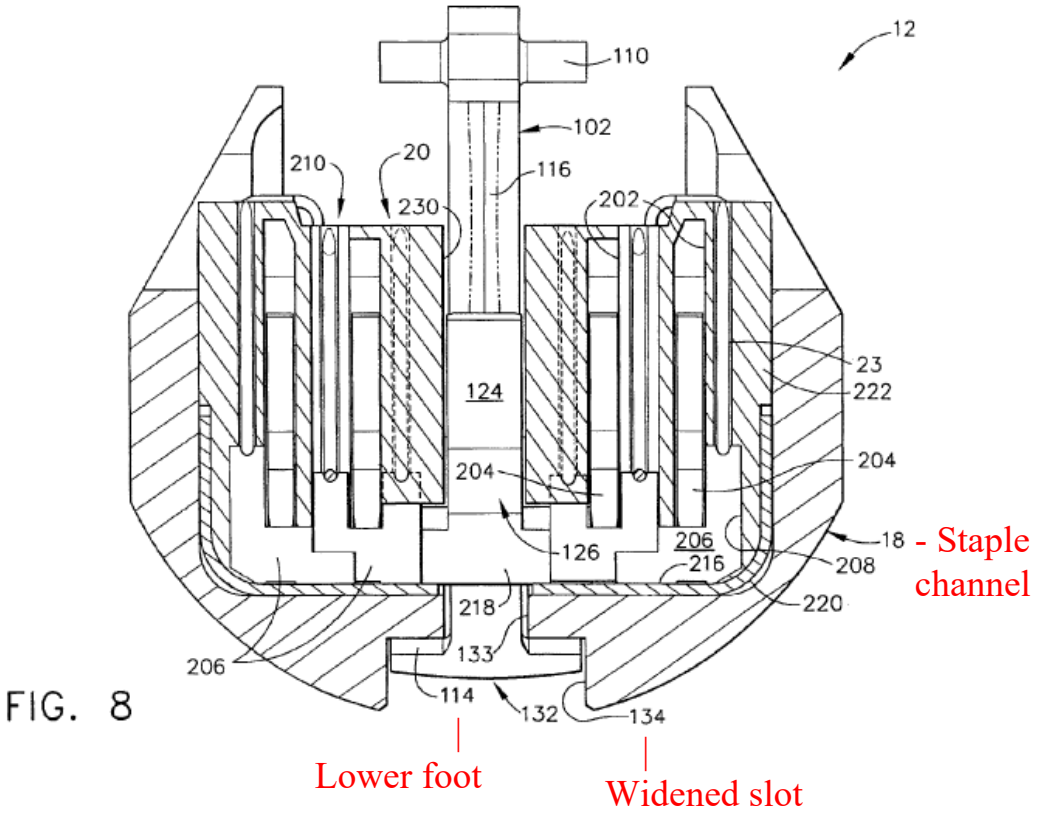
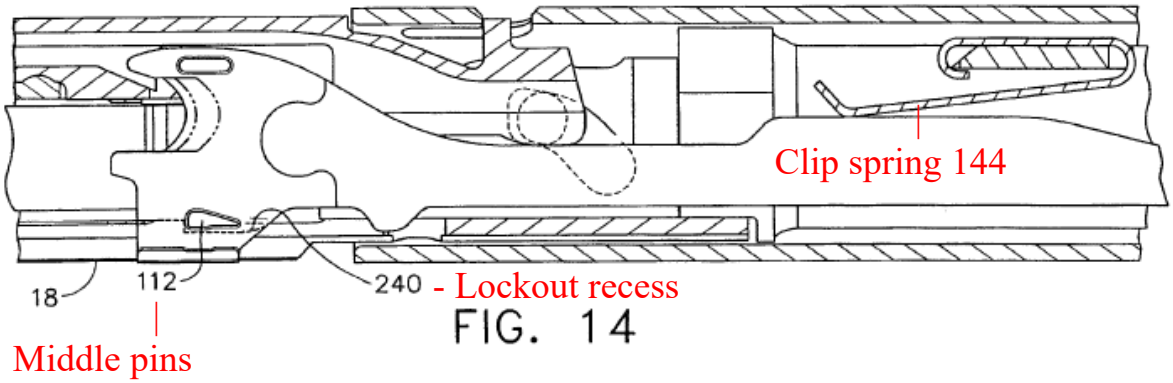


FIG. 8

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.[5] IS1003, ¶38.



IS1001, Fig. 14 (annotated).

[5] 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 and discussed in more detail below in Section VIII. 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. IS1002, 67-68 (Feb. 23, 2017 Rejection). In response, however, 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 earliest effective priority date of July 28, 2004, and Shelton '199 has a publication date of Nov. 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 later issued as claims 1-3 of the '379 patent. *Id.*, 10, 14; IS1001, 8:60-10:26.

VII. CLAIM CONSTRUCTION

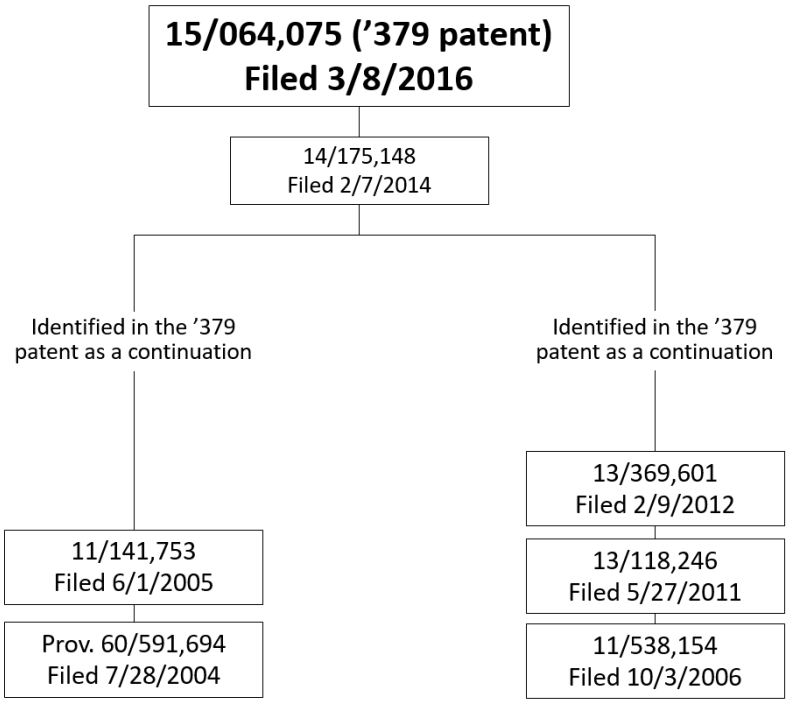
For purpose of this proceeding only, Petitioner submits that all claim terms should be given their plain and ordinary meaning.

VIII. PRIORITY DATE

A chart illustrating the priority claims on the face of the '379 patent is repro-

duced below, along with the Related U.S. Application Data section of the '379 patent:

Chart Illustrating '379 Patent Related U.S. Application Data



'379 Patent Related U.S. Application Data

Related U.S. Application Data

(63) Continuation of application No. 14/175,148, filed on Feb. 7, 2014, now Pat. No. 9,282,966, which is a continuation of application No. 13/369,601, filed on Feb. 9, 2012, now Pat. No. 8,783,541, which is a continuation of application No. 13/118,246, filed on May 27, 2011, now Pat. No. 9,060,770, which is a continuation-in-part of application No. 11/538,154, filed on Oct. 3, 2006, now abandoned, application No. 15/064,075, which is a continuation of application No. 14/175,148, filed on Feb. 7, 2014, now Pat. No. 9,282,966, which is a continuation of application No. 11/141,753, filed on Jun. 1, 2005, now Pat. No. 8,905,977.

(60) Provisional application No. 60/591,694, filed on Jul. 28, 2004.

IS1001 at pp. 1-2 (emphasis added); *see also* 1:7-47 (providing a similar "cross-

reference to related applications").

As can be seen in the chart above, the '379 patent first claims to be a continuation of the '148 application. IS1005. The '379 patent then claims that the '148 application is a continuation of two separate applications. First, continuation priority is claimed to the '753 application. IS1006. Second, continuation priority is claimed to the '601 application. IS1007. Thus, the applicants created two separate and distinct branches of the priority tree.[6] IS1001 at pp. 1-2, 1:7-14, 1:30-37.

For the reasons explained below, the '379 patent improperly claims priority to the '753 application and the '601 application. Thus, the '379 patent's earliest effective priority date is February 7, 2014—the filing date of the '148 application.

A. The Priority Claim Must Be Stated Correctly

The priority date of a patent is its filing date until Patentee "***proves*** entitlement" to an earlier date. *Natural Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018) (emphasis in original). Thus, before the '379 patent may benefit from the filing date of an alleged priority application, the Patent Owner

[6] As shown in the above chart, the '379 patent claims priority to additional earlier applications, but only through either the '601 or '753 applications. Those additional applications are not further addressed in this Petition because they are not relevant to the priority issues discussed herein.

must establish that several criteria are met. *See* 35 U.S.C. § 120 and 35 C.F.R. 1.78. If any of the criteria are not met, the '379 patent is not entitled to benefit from the filing date of the earlier application.

Critically, to claim the benefit of the filing date of an earlier-filed application, a patent application must "contain a specific reference to the earlier filed application." 35 U.S.C. § 120. To satisfy this "specific reference" requirement, the application claiming the benefit of the earlier application must correctly reference two details about the earlier application to which priority is claimed: (1) the earlier application's application number, and (2) the familial relationship of the earlier application. *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1315 (Fed. Cir. 2018) (denying a priority claim because applicant failed to comply with Section 120, as currently implemented in 37 C.F.R. 1.78(d)(2)); *see also Natural Alternatives*, 904 F.3d at 1381 (holding that the Board "did not err in determining that the [] patent was not entitled to claim the benefit of the filing date of the first application under § 120, as the priority claim in the [] patent was defective from the start").

A patent fails to meet the "specific reference" requirement of 35 U.S.C. § 120 if it "contains a misstatement of the relationship claimed [by the patentee]." *Simmons, Inc. v. Bombardier, Inc.*, 328 F.Supp.2d 1188, 1200 (D. Utah 2004); *see also Droplets*, 887 F.3d at 1315 (confirming that "the application claiming the benefit of one or more prior-filed copending nonprovisional applications must include

'a reference to each such prior-filed application …' indicating 'the relationship of the applications (*i.e.*, whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application …)' ") (quoting 37 C.F.R. § 1.78(d)(3) (2009)).

In *Simmons*, the patent-at-issue contained a reference to the application to which it sought to claim priority, but the familial relationship to that application was misstated. 328 F.Supp.2d at 1201. Because of the misstatement of the proper familial relationship, the court found that the patent-in-suit did not "contain a specific reference as required by 35 U.S.C. § 120" and declined to give the patent the benefit of the earlier-filed application. *Id.* The court reasoned that "it seems clear that not only is it appropriate to require a statement of some relationship in an application, but a statement of the *correct* relationship. Parties viewing a patent and taking legal risks based upon it are entitled to know the correct relationship of the applications." *Id.* (emphasis in original).

Similarly, in *Rowe Int'l Corp. v. Ecast, Inc.*, 586 F.Supp.2d 924, 969 (N.D. Ill. 2008), the court noted that a mistaken priority claim should not be ignored, stating: "Plaintiffs also argue that the 'minor mistake' of designating the '400 application a continuation of the '612 application, rather than a continuation-in-part, should not stand in the way of their claiming priority back to the earlier date. But this position lacks legal support (plaintiffs point only to the absence of authority to

the contrary)." *See also id*. at n. 11 ("It does appear that the '400 application departed from the substance of the '612 application and therefore should have been designated a continuation-in-part, with the corresponding implications for the '834 patent's effective date.").

Courts have left no doubt that a mistaken claim of priority is inexcusable. "'Although § 120 might appear to be a technical provision,' courts have long-recognized that 'it embodies an important public policy,' and thus have required strict adherence to its requirements." *Droplets*, 887 F.3d at 1316 (quoting *Sampson v. Ampex Corp*., 463 F.2d 1042, 1045 (2d Cir. 1972)). "[T]he information that must be disclosed is information that would 'enable a person searching the records of the Patent Office to determine with a minimum of effort the exact filing date upon which a patent applicant is relying to support the validity of his application or the validity of a patent issued on the basis of one of a series of applications.'" *Id.*, 1316-17. "Because the 'inventor is the person best suited to understand the relation of [the] applications,' it is 'no hardship to require [the inventor] to disclose this information.'" *Droplets,* 887 F.3d at 1317 (quoting *Sticker Indus. Supply Corp. v. Blaw-Know Co.,* 405 F.2d 90, 93 (7th Cir. 1968)). Thus, the Federal Circuit has squarely rejected the "so-called 'reasonable person' test on grounds that it 'runs afoul' of both § 120 and Rule 1.78, which require a correct, specific reference to each prior-filed application in precise detail." *Droplets,* 887 F.3d at 1317

(citing *Medtronic CoreValve, LLC v. Edwards Lifesciences Corp.,* 741 F.3d 1359, 1365-66 (Fed. Cir. 2014)).[7]

B. The '379 Patent Fails to Satisfy the "Specific Reference" Requirement for both the '601 Application and the '753 Application

Here, Patent Owner cannot prove that the '379 patent is entitled to a priority date earlier than February 7, 2014 (the filing date of the '148 application) because the '379 patent fails to provide a "specific reference" to either the '601 application or the '753 application. 35 U.S.C. § 120; *Droplets*, 887 F.3d at 1315. More specifically, the '379 patent states ***a*** familial relationship for the '601 and '753 applications, but does not state the ***correct*** familial relationship for those applications. For the reasons explained below, these incorrect statements of familial relationship do not satisfy Section 120.

[7] As explained in *Droplets,* Medtronic unsuccessfully argued that "the test for determining whether a priority claim contains the specific reference required by § 120 is whether a reasonable person reading the language of the claim would be able to determine the relationship between the priority applications." *Droplets,* 887 F.3d at 1317.

1. The '379 patent claims that the '148 application is a continuation of both the '601 application and the '753 application

The '379 patent states that the '148 application is a ***continuation*** of both the '601 application and the '753 application. A highlighted version of the Related U.S. Application Data of the '379 patent is reproduced below, along with the same chart that has already been shown above.

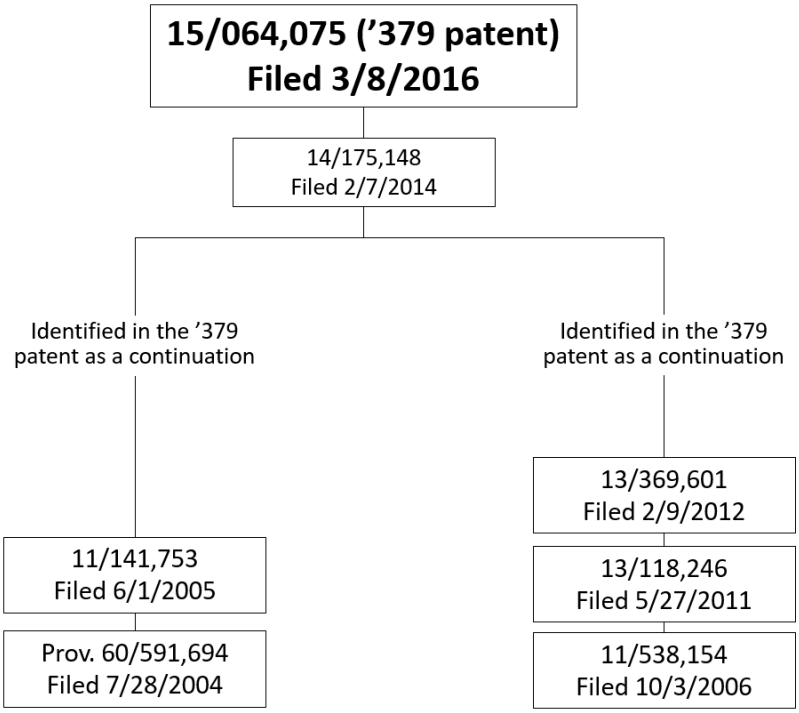
'379 Patent Related U.S. Application Data

Related U.S. Application Data

Continuation of application No. 14/175,148, filed on Feb. 7, 2014, now Pat. No. 9,282,966, which is a continuation of application No. 13/369,601, filed on Feb. 9, 2012, now Pat. No. 8,783,541, which is a continuation of application No. 13/118,246, filed on May 27, 2011, now Pat. No. 9,060,770, which is a continuation-in-part of application No. 11/538,154, filed on Oct. 3, 2006, now abandoned, application No. 15/064,075, which is a continuation of application No. 14/175,148, filed on Feb. 7, 2014, now Pat. No. 9,282,966, which is a continuation of application No. 11/141,753, filed on Jun. 1, 2005, now Pat. No. 8,905,977.

IS1001 at pp. 1-2.

Annotated Chart Illustrating '379 Patent Related U.S. Application Data



2. The '148 application is not a continuation of the '601 application or the '753 application

The '379 patent's statement that the '148 application is a continuation of both the '601 application and the '753 application is incorrect. By definition, a "continuation" of a parent application means that the child application does not contain new subject matter—*i.e.,* subject matter absent from the parent application. MPEP § 201.07. As explained below, the '148 application is not a "continuation" of either the '601 application or the '753 application because it contains subject matter absent from each of the earlier applications.

The '148 application is a combination of these respective applications, with additional new matter. Therefore, applicants might have claimed—***but did not***—

that the '148 application is therefore a continuation-in-part—not a continuation—of both. *See, e.g.*, *X2Y Attenuators, LLC v. Int'l Trade Comm'n*, 757 F.3d 1358, 1366 (Fed. Cir. 2014) ("A continuation-in-part application is just what its name implies. It partly continues subject matter disclosed in a prior application, but adds new subject matter not disclosed in the prior application. Thus, some subject matter of a CIP application is necessarily different from the original subject matter.") (quoting *Univ. of W. Va., Bd. of Trs. v. VanVoorhies*, 278 F.3d 1288, 1297 (Fed. Cir. 2002)) (defining a continuation-in-part).

The Manual of Patent Examining Procedure defines what constitutes a continuation application:

> A continuation application is an application for the invention(s) disclosed in a prior-filed copending nonprovisional application, international application designating the United States, or international design application designating the United States. ***The disclosure presented in the continuation must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application.***

MPEP § 201.07 (emphasis added). Thus, for the '148 application to truly be a continuation of the '601 application, the '148 application's disclosure cannot contain any new material that is not present in the '601 application; and, to truly be a continuation of the '753 application, the '148 application's disclosure cannot contain any new material that is not present in the '753 application. That is not so here.

The ’148 application cannot be a continuation of either the ’601 application or the ’753 application because its disclosure includes (i) subject matter absent from the ’601 application and (ii) subject matter absent from the ’753 application. *See* IS1003, ¶¶45-46. Unless the disclosures of the ’601 application and ’753 application were substantially identical (they were not), the ’148 application necessarily could not have been a continuation of *both* the ’601 application and ’753 application.

In fact, a simple comparison of the ’601 application with the ’753 application readily demonstrates that their disclosures are vastly different. *Compare* IS1007 and IS1006; *see also* IS1003, ¶¶45-46. The primary subject matter of the ’753 application is a surgical stapler having an electroactive polymer dispenser; the application has 17 figures and 20 pages of text. IS1006, 2-30. In contrast, the primary subject matter of the ’601 application is a robotically controlled surgical stapler; the application has 136 figures and 134 pages of text. IS1007, 1-235. The great majority of these figures and text are not overlapping in either of these two applications. IS1003, ¶45. Moreover, the ’753 application does not incorporate by reference the ’601 application, and the ’601 application does not incorporate by reference the ’753 application. *Id*.

In addition, in view of the foregoing comparison, the ’148 application cannot be a continuation of either the ’601 application or the ’753 application because the

'148 application incorporates by reference the entirety of both the '601 application and the '753 application. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (stating that incorporation by reference "makes clear that the material is effectively part of the host document as if it were explicitly contained therein").

Thus, there are a myriad of differences between the'148 application and both the '601 and the '753 applications. For example, the '148 application includes, via incorporation by reference, Figure 11 of the '753 application, which is not present in the '601 application:

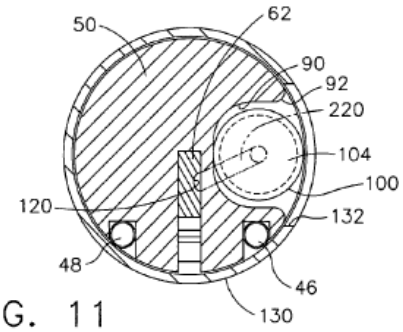


FIG. 11

Similarly, the '148 application includes, via incorporation by reference, Figure 8 of the '601 application, which is not present in the '753 application:

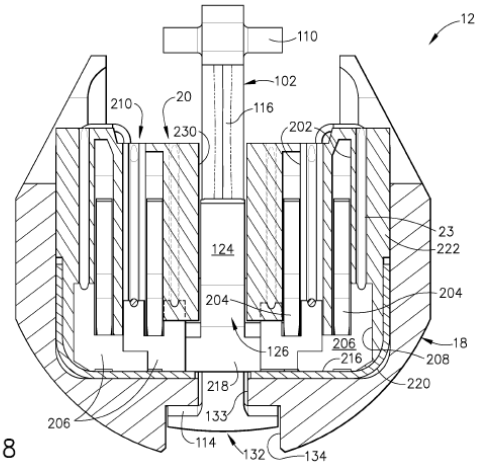


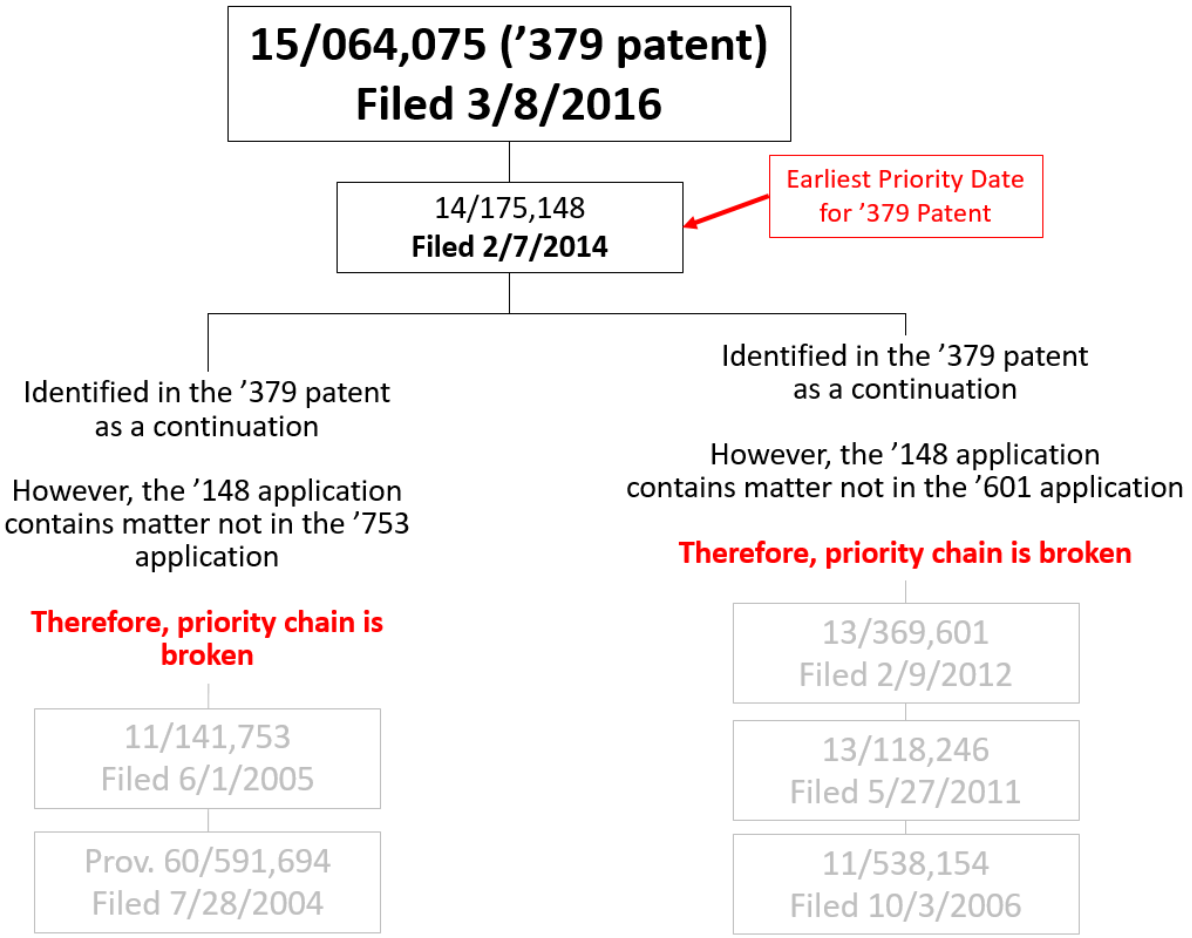
FIG. 8

Each of the ’601 and ’753 application’s disclosure is thus an incomplete subset of the ’148 application’s disclosure. Because the ’148 application includes disclosures that are not present in the ’601 application, it cannot be a continuation of that application. Similarly, because the ’148 application includes disclosures that are not present in the ’753 application, it cannot be a continuation of that application either. Therefore, the ’148 application is not a continuation of either the ’601 application or the ’753 application, and applicants failed to make a correct reference to the earlier-filed applications.

3. Because the ’379 patent fails to state its *correct* familial relationship to the ’601 application and the ’753 application, it does not satisfy the “specific reference” requirement

Because the ’379 patent does not ***correctly*** “identify the relationship of the applications”—namely, whether the later-filed application from which the ’379 patent issued is a “continuation, divisional, or continuation-in-part of the prior-filed” ’601 and ’753 applications—the Patent Owner cannot claim priority to the ’601

and '753 applications, nor can it claim the benefit of any other applications within their respective chains. 35 C.F.R. 1.78(d)(2); *see infra* Section VIII.A.

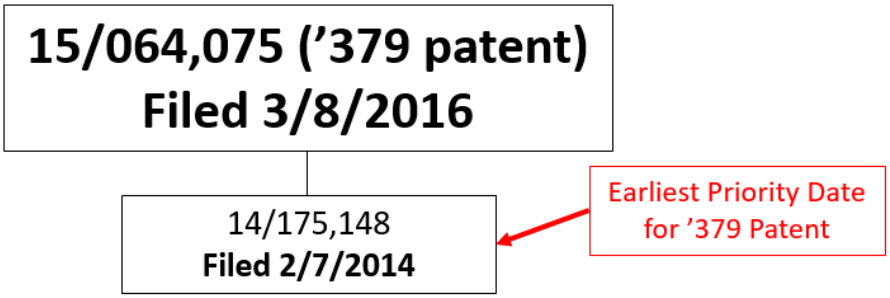


A ruling otherwise would fly in the face of 35 U.S.C. § 120, which has been interpreted to require that the specific reference requirement is "to provide clear notice to the public of the patentee's claimed priority date." *Droplets*, 887 F.3d at 1320. This clear notice is not provided where, as here, the familial relationship of a prior application is incorrectly stated. *See Simmons*, 328 F.Supp.2d at 1201. Instead, the misstated familial relationship "improper[ly] … place[s] the burden on the public to unearth and decipher a priority claim when the 'patentee is the person

best suited to understand the genealogy and relationship of her applications.'"" *Droplets*, 887 F.3d at 1317 (quoting *Medtronic*, 741 F.3d at 1366).

C. The Earliest Priority Date for the '379 Patent Is February 7, 2014

Because the '379 patent can claim priority to neither the '601 application nor the '753 application, the earliest priority date to which it is entitled is February 7, 2014—the filing date of the '148 application.



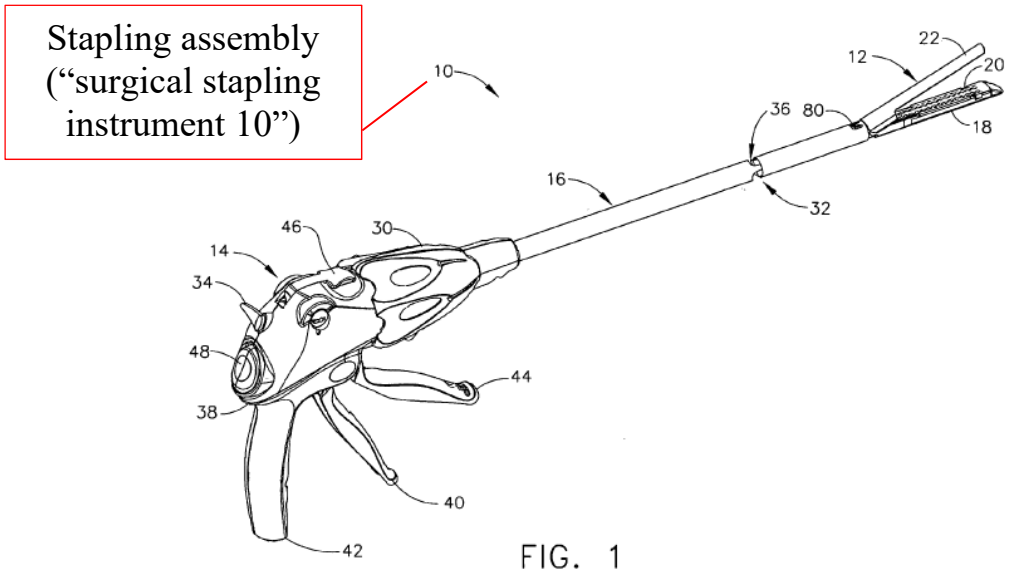
IX. SHELTON '562 ANTICIPATES CLAIMS 1–3

Shelton '562 was filed September 30, 2004, as U.S. App. No. 10/955,042 and issued June 3, 2008, as U.S. Pat. No. 7,380,696. Importantly, the written description of Shelton '562 is word-for-word identical to the written description of the '379 patent (with the exception of non-substantive descriptions such as referencing co-pending applications by their application numbers rather than their patent numbers, and different titles, abstracts, and priority claims). *See* IS1008 (redline comparison of Shelton '562 and the '379 patent); IS1003, ¶¶49-50. Thus, Patent Owner cannot dispute that Shelton '562 anticipates the challenged claims.

Nonetheless, Petitioner identifies the following exemplary disclosures of each limitation of each challenged claim in Shelton '562.

[1.1] A stapling assembly, comprising:

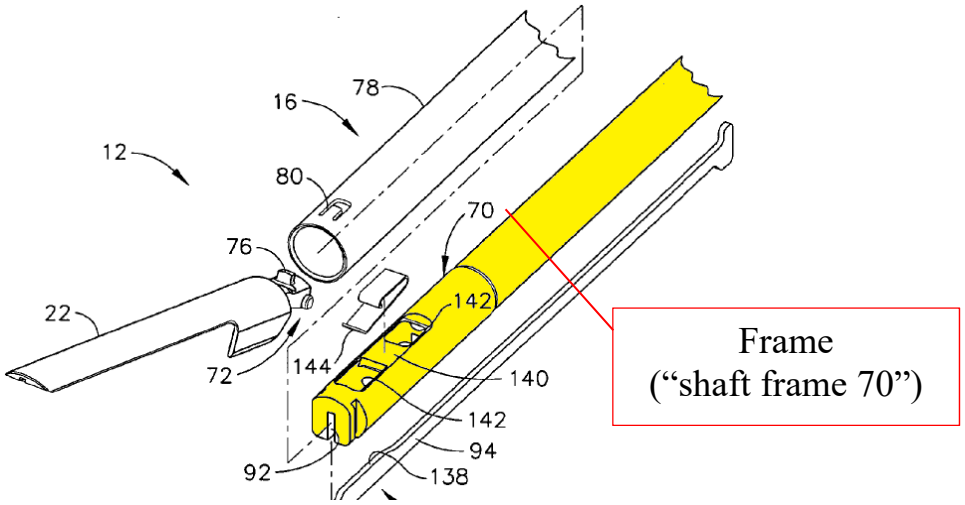
If the preamble is deemed to be a limitation, then Shelton '562 discloses a stapling assembly (surgical stapling instrument 10). IS1003, ¶52; IS1004, ¶¶34, 39, Figs. 1-2.



IS1004, Fig. 1 (annotated).

[1.2] a frame;

Shelton '562 discloses a frame (shaft frame 70). IS1003, ¶53; IS1004, ¶¶40-42, 47, Figs. 1-3, 10.



IS1004, Fig. 3 (excerpted, annotated).

[1.3] a distal end;

Shelton '562 discloses a distal end (shown below). IS1003, ¶54; IS1004, ¶¶34-37, 40, 43-44, 46, 48-50, Figs. 1-14. Shelton '562 states that the "surgical stapling instrument 10 has at its distal end an end effector, depicted as staple applying assembly 12." *Id.* at ¶ 34. Thus, the distal end is where the staple applying assembly 12 is located, as indicated below in FIG. 1. *Id.*; IS1003, ¶54.

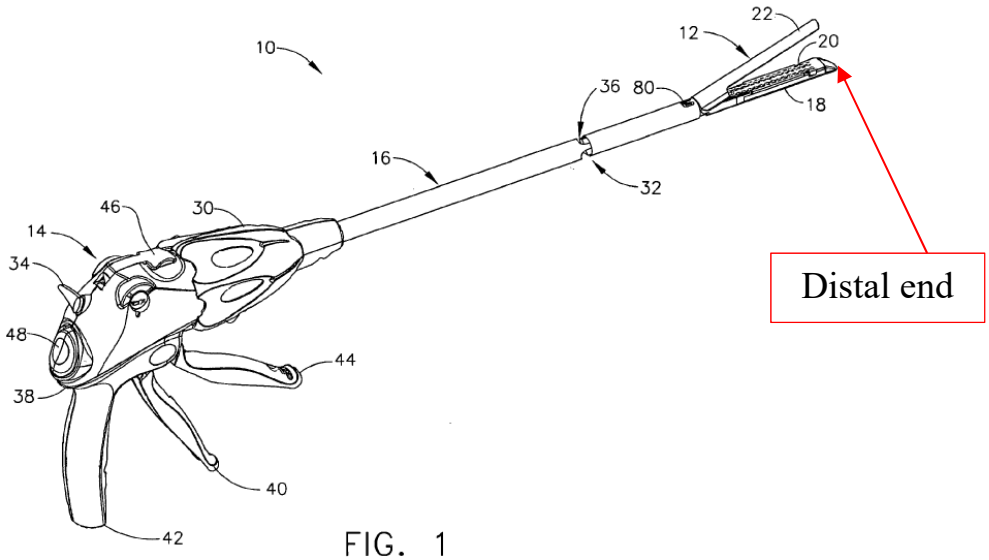
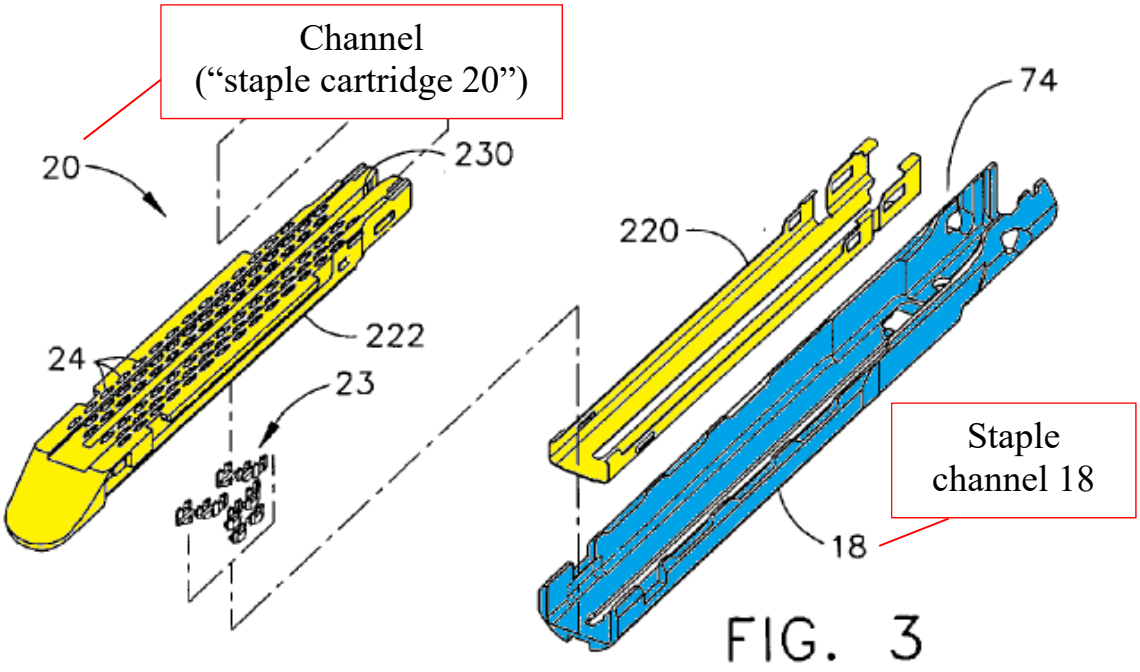


FIG. 1

IS1004, Fig. 1 (annotated).

[1.4] a first jaw comprising a channel;

Shelton '562 discloses a first jaw (combination of staple channel 18 and staple cartridge 20) comprising a channel (staple cartridge 20). IS1003, ¶55; IS1004, ¶¶34, 41-53, Figs. 1-3, 6-14.

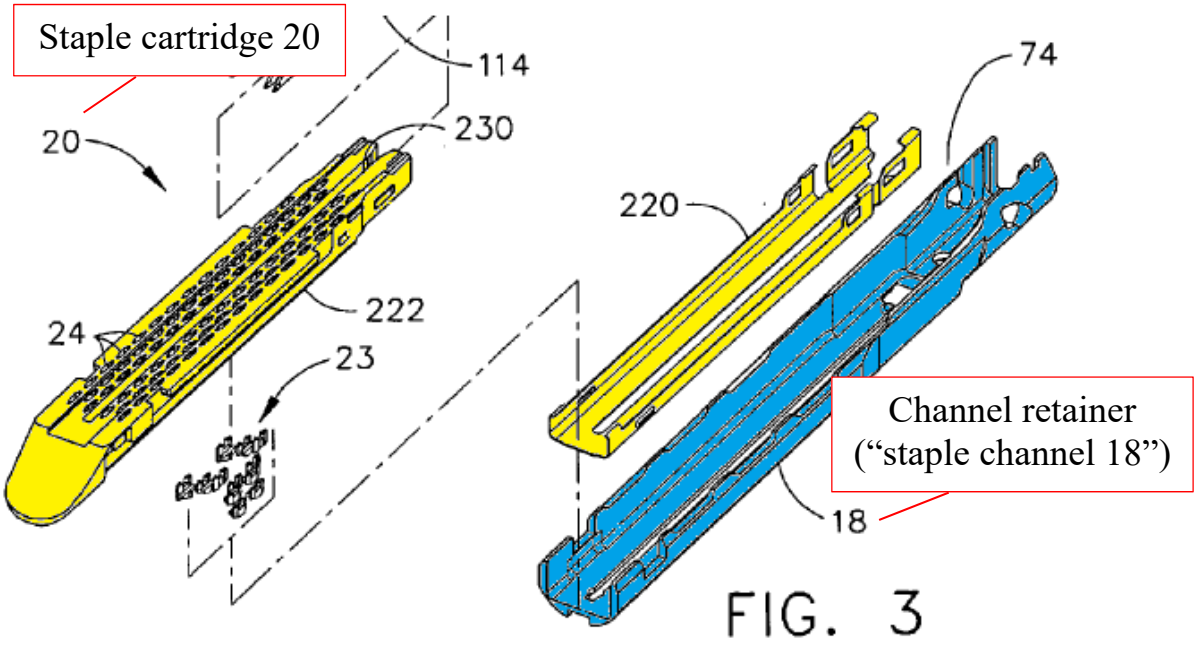


IS1004, Fig. 3 (excerpted, annotated).

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

Shelton '562 discloses a channel retainer (staple channel 18), wherein the channel (staple cartridge 20) is slidably attachable to the channel retainer. IS1003 ¶56; IS1004, ¶¶34, 41, 43, 45-50, 53, Figs. 1-3, 6-10, 12, 14. As explained in Shelton '562, "staple applying assembly 12 includes a staple channel 18 for receiving a

replaceable staple cartridge 20." IS1004, ¶34. And, after firing, "a new staple cartridge 20" can be "inserted into the staple channel 18." *Id.*, ¶50. As shown below in Figures 3 and 8, staple cartridge 20 can be attached to staple channel 18 by sliding staple cartridge 20 into staple channel 18. IS1003, ¶56; *Id.*, Figs. 3, 8.



IS1004, Fig. 3 (excerpted, annotated).

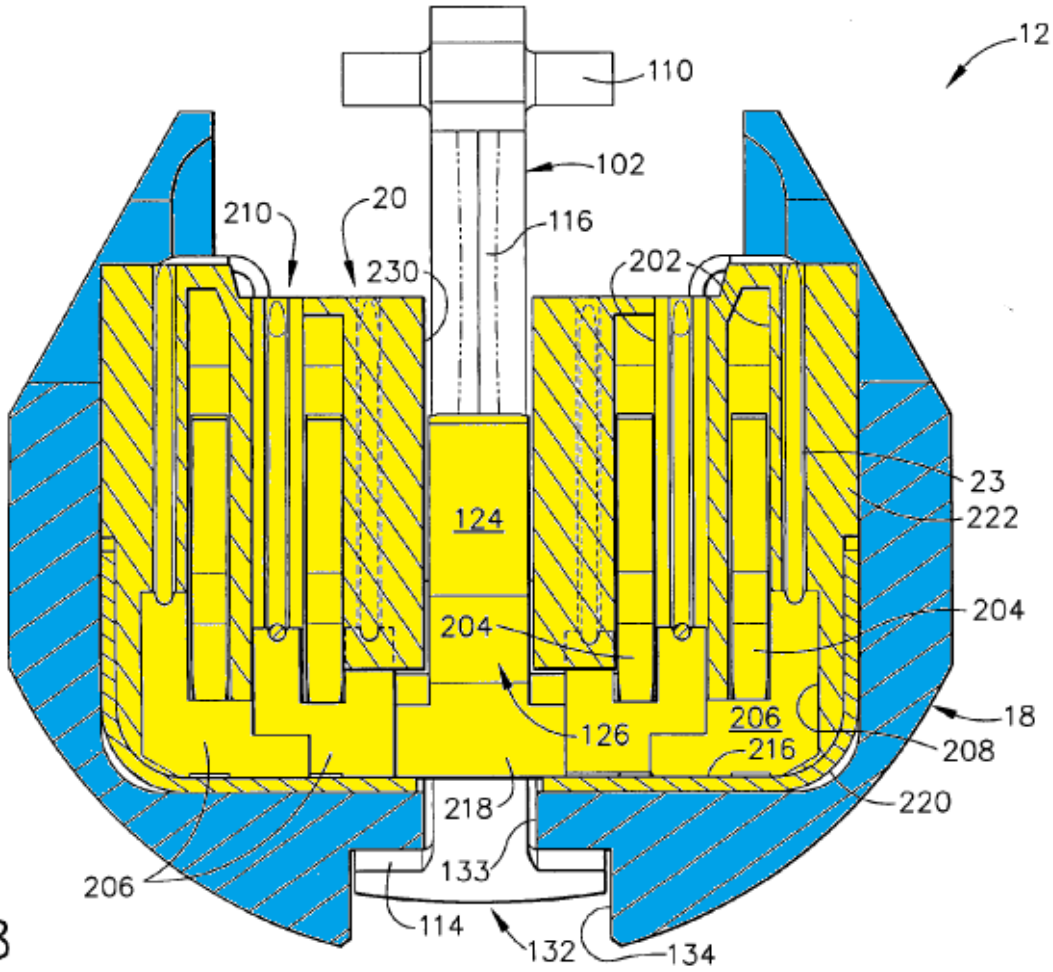


FIG. 8

Id., Fig. 8 (annotated).

[1.6] a second jaw extending from said frame;

Shelton '562 discloses a second jaw (anvil 22) extending from said frame (shaft frame 70). IS1003, ¶57; IS1004, ¶¶34, 36, 41, 43, 48-50, 52, Figs. 1-3, 6, 7, 9-14.

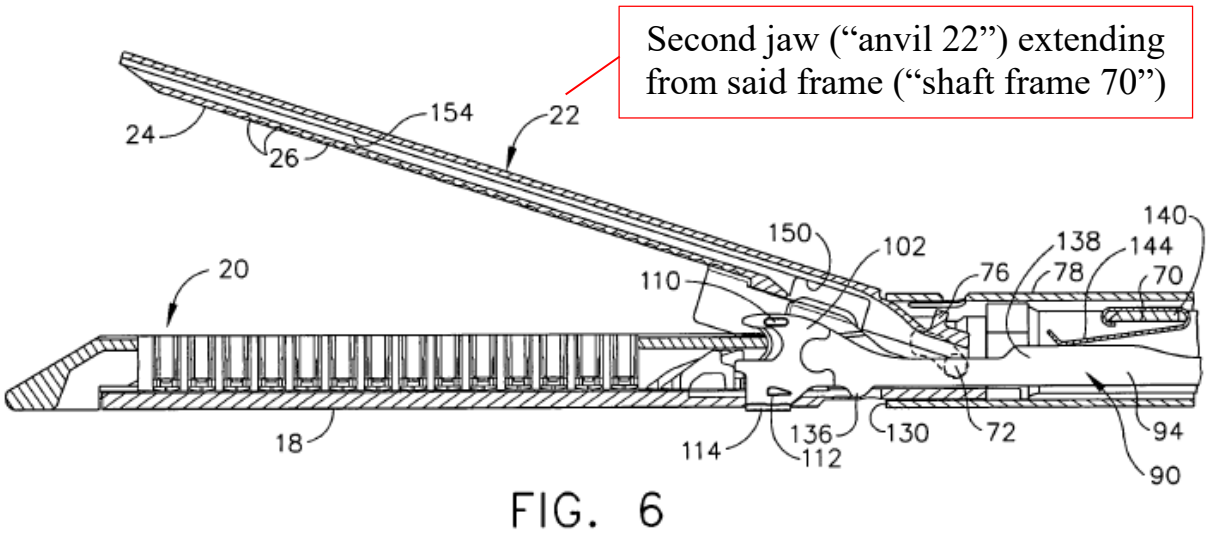


FIG. 6

IS1004, Fig. 6 (annotated).

[1.7] a plurality of staples;

Shelton '562 discloses a plurality of staples (staples 23, highlighted yellow). IS1003, ¶58; IS1004, ¶¶34, 49, 52, Figs. 3, 8.

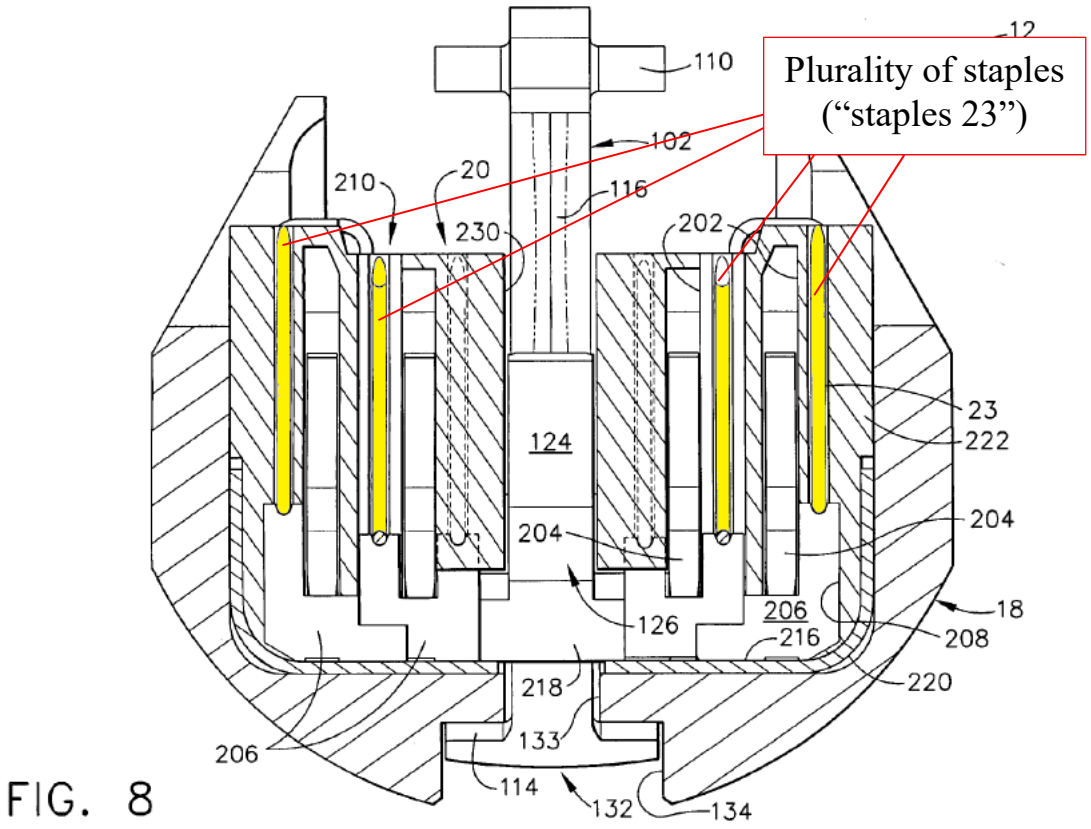


FIG. 8

IS1004, Fig. 8 (annotated).

[1.8] a staple firing member comprising

Shelton '562 discloses a stapling firing member (firing bar 90, including its distal portion E-beam 102). IS1003, ¶59; IS1004, ¶¶42-54, Figs. 2-14.

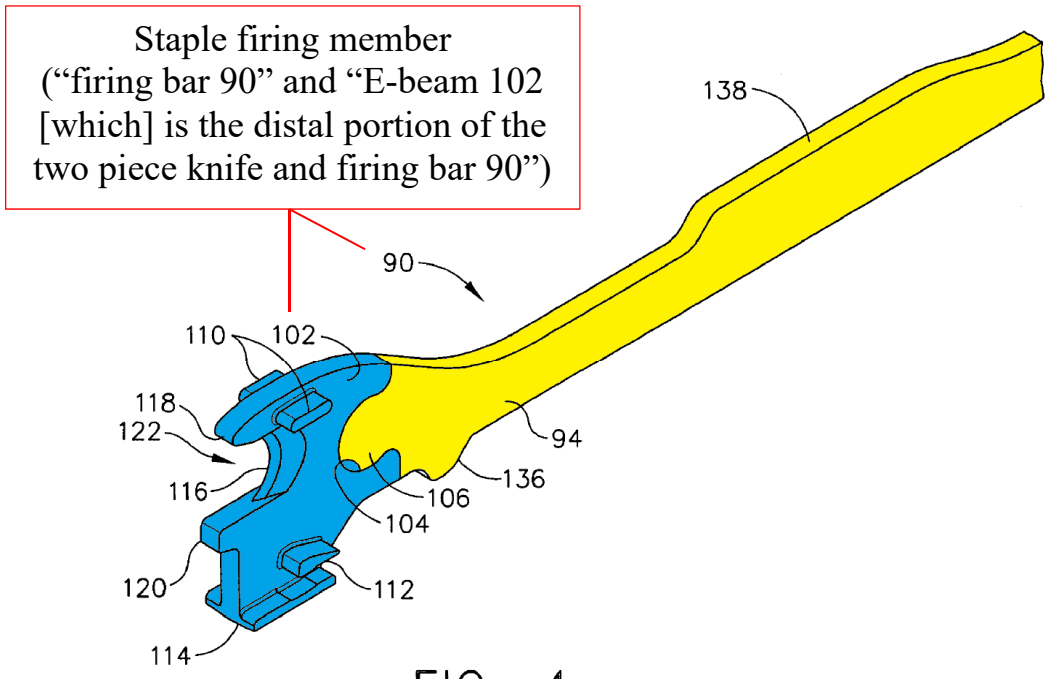


FIG. 4

IS1004, Fig. 4 (annotated).

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

Shelton '562 discloses a first cam (foot 114, highlighted in yellow) configured to engage said first jaw (combination of staple channel 18 and staple cartridge 20) via widened slot 134 on an undersurface of the staple channel 18 (highlighted in blue). IS1003, ¶¶60-61; IS1004, ¶¶10, 22, 43-45, 49, 51, 53, Figs. 2-4, 6-14. As explained in Shelton '562, "lower foot 114 of the E-beam 102 is dropped through a widened hole 130 in the staple channel 18 and the E-beam 102 is then advanced such that the E-beam 102 slides distally along a lower track 132 formed in the staple channel 18." IS1004, ¶45.

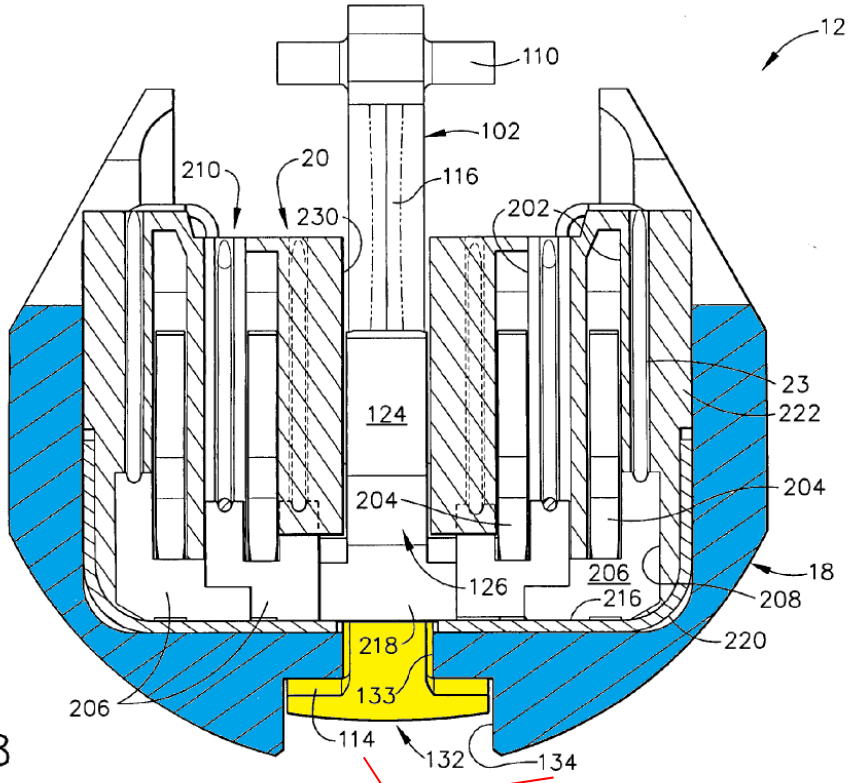


FIG. 8

Id., Fig. 8 (annotated).

Alternatively, Shelton '562 discloses a first cam (middle pin 112) configured to engage the first jaw (combination of staple channel 18 and staple cartridge 20) via firing recess 216 on the top surface of staple channel 18. IS1003, ¶61; IS1004, ¶¶10, 22, 43-45, 49, 51, 53, Figs. 2-4, 6-14.

[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 '562 discloses a second cam (top pins 110) configured to engage

said second jaw (anvil 22) via anvil track 154 when said staple firing member (firing bar 90/E-beam 102) is advanced from an unadvanced (*e.g.*, ready to fire) position toward said distal end. IS1003, ¶¶62-63; IS1004, ¶¶43-44, 48, Figs. 2-4, 6-14.

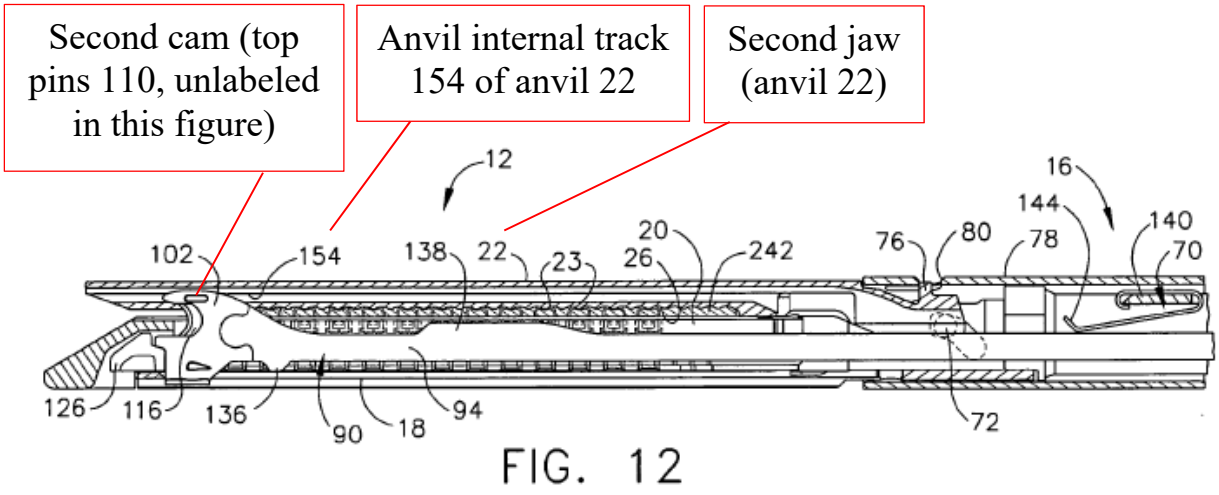


FIG. 12

IS1004, Fig. 12 (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 '562 discloses that one of the first jaw and second jaw (the second jaw; anvil 22) comprises a clearanced opening (anvil pocket 150) configured to permit the firing member (firing bar 90/E-beam 102), which includes top pins 110, to be unengaged with one of the first jaw and the second jaw (the second jaw; anvil 22) when the firing member (firing bar 90/E-beam 102) is in the unadvanced (proximal-most) position. IS1003, ¶¶64-66; IS1004, ¶¶43, 48, Figs. 6, 13. "In FIGS. 6-7, the 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." IS1004,

¶48.

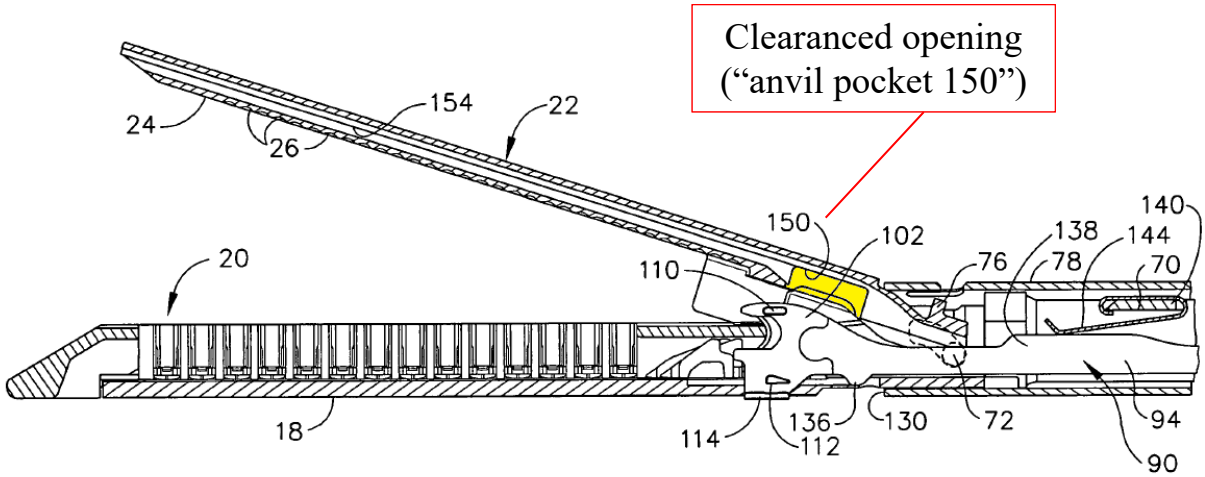


FIG. 6

Id., Fig. 6 (annotated).

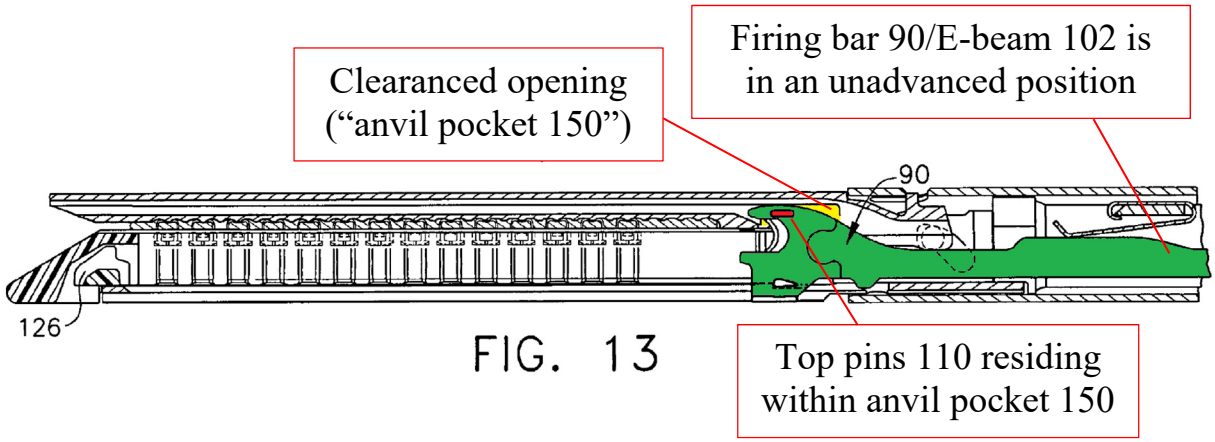


FIG. 13

Id., Fig. 13 (annotated)

The unengaged state of the top pins 110 with the anvil 22 when the firing bar 90/E-beam 102 is retracted is clearly contrasted with the engaged state of the top pins 22 with the anvil 22 when the firing bar 90/E-beam 102 is advanced, as explained in the discussion of limitation [1.8.2], *supra*. IS1003, ¶66.

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

Shelton '562 discloses a lockout (the combination of middle pin 112, middle guide 120, lockout recess 240, and wedge sled 126 with stepped central member 124) configured to block the advancement of said staple firing member (firing bar 90, including its distal portion E-beam 102) when said channel (staple cartridge 20) is not attached to said channel retainer (staple channel 18). IS1003, ¶¶67-69; IS1004, ¶¶43, 44, 49, 51-53, Figs. 2-14; Figs. 7, 10, 11, 13, 14.

As explained in Shelton '562, "E-beam 102 may be advantageously formed of a material having suitable material properties for forming a pair of top pins 110, a pair of middle pins 112 and a bottom pin or foot 114, as well as being able to acquire a sharp cutting edge 116." IS1004, ¶43. "The middle guide 120 also serves to engage and fire the staple applying apparatus 12 by abutting a stepped central member 124 of a wedge sled 126 (FIG. 5) that effects staple formation by the staple applying assembly 12…." *Id.* "In FIG. 14, the middle pin 112 is allowed to translate down into a lockout recess 240 formed in the staple channel 18 (also see FIGS. 7, 10)." *Id.*, ¶53.

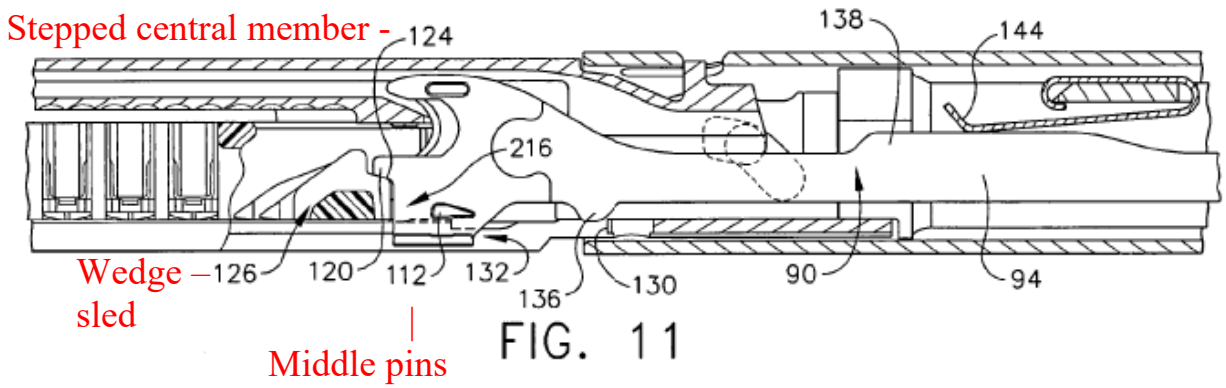


FIG. 11

Id., Fig. 11 (annotated)

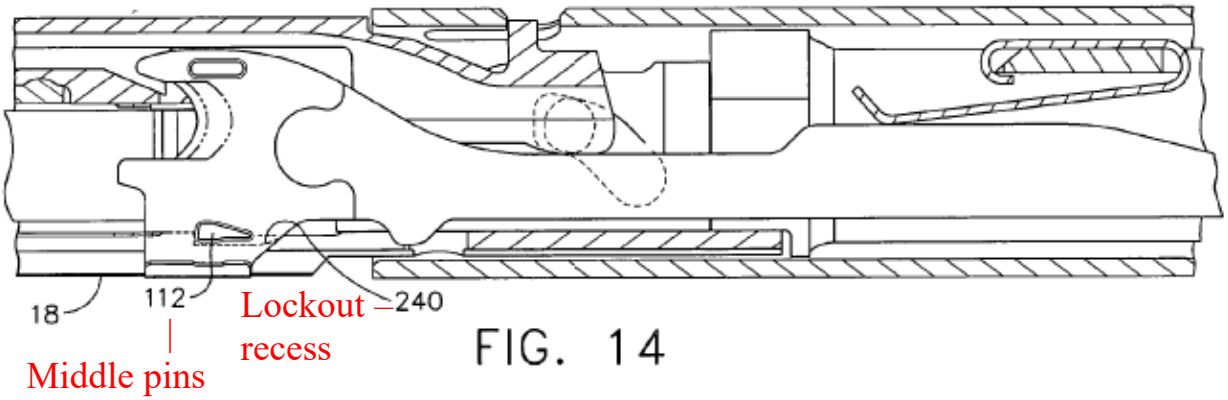


FIG. 14

Id., Fig. 14 (annotated).

Thus, "the middle pin 112 is allowed to translate down into a lockout recess 240 formed in the staple channel 18 (also see FIGS. 7, 10) [and] 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.*, ¶53.

[2.1] A stapling assembly, comprising:

See element [1.1]; IS1003, ¶70; IS1004, ¶¶34, 39, Figs. 1-2.

[2.2] a frame;

See element [1.2]; IS1003, ¶71; IS1004, ¶¶40-42, Figs. 1-3, 10.

[2.3] a distal end;

See element [1.3]; IS1003, ¶72; IS1004, ¶¶34-37, 40, 43-44, 46, 48-50, Figs. 1-14.

[2.4] a first jaw comprising a channel;

See element [1.4]; IS1003, ¶73; IS1004, ¶¶34, 41-53, Figs. 1-3, 6-14.

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

See element [1.5]; IS1003, ¶74; IS1004, ¶¶34, 41, 43, 45-50, 53, Figs. 1-3, 6-10, 12, 14.

[2.6] a second jaw extending from said frame;

See element [1.6]; IS1003, ¶75; IS1004, ¶¶34, 36, 41, 43, 48-50, 52, Figs. 1-3, 6, 7, 9-14.

[2.7] a plurality of staples;

See element [1.7]; IS1003, ¶76; IS1004, ¶¶34, 49, 52, Figs. 3, 8.

[2.8] a staple firing member comprising

See element [1.8]; IS1003, ¶77; IS1004, ¶¶42-54, Figs. 2-14.

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

See element [1.8.1]; IS1003, ¶78; IS1004, ¶¶10, 22, 43-45, 49, 51, 53, Figs. 2-4, 6-14.

[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 element [1.8.2]; IS1003, ¶79; IS1004, ¶¶43-44, 48, Figs. 2-4, 6-14.

[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

Shelton '562 discloses this limitation. IS1003, ¶¶80-82. Shelton '562's first cam (foot 114) and second cam (top pins 110) are configured to cooperatively hold the first jaw (staple channel 18) and the second jaw (anvil 22) relative to one another when the firing member (firing bar 90/E-beam 102) is advanced toward the distal end (*i.e.*, toward the staple applying assembly 12). *Id.*; IS1004, Abstract, ¶¶12, 13, 34, 43, 48, Figs. 9-14.

Specifically, Fig. 9 of Shelton '562 (reproduced below) shows the staple firing bar in a retracted position. IS1003, ¶81; IS1004, Fig. 9. In contrast, Fig. 12 of Shelton '562 (reproduced below) shows the staple firing bar in an advanced position. IS1003, ¶82; IS1004, Fig. 9. By moving the staple firing bar to an advanced position toward the distal end of the device, the first cam moves along a path along the first jaw, and the second cam moves along a path along the second jaw. IS1003, ¶82; IS1004, Figs. 9, 12. Thus, collectively and cooperatively, the first and second cams hold the first jaw and the second jaw relative to one another when the staple firing member is advanced. *Id.*

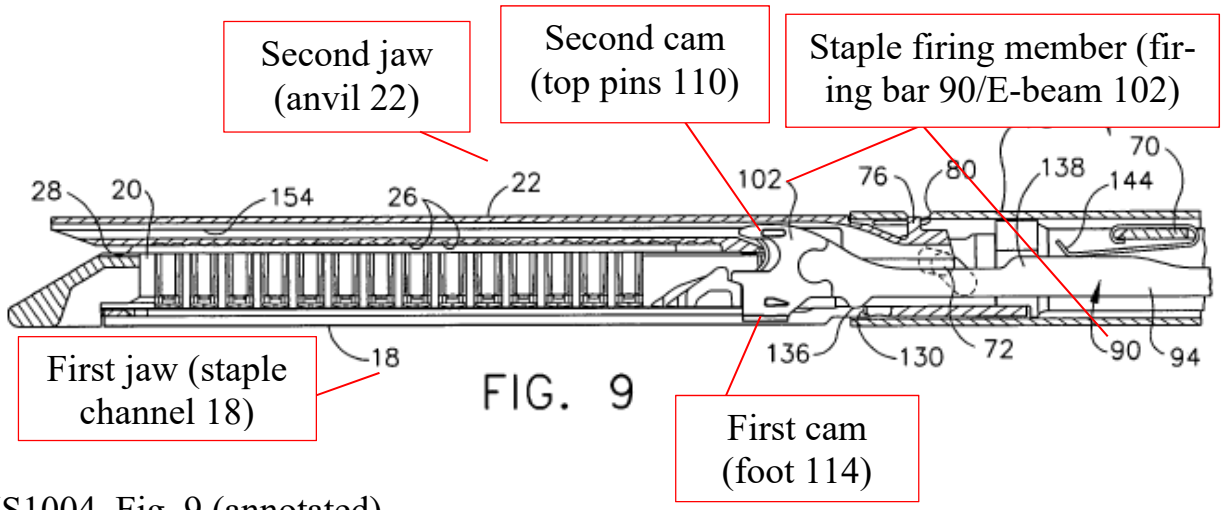


FIG. 9

IS1004, Fig. 9 (annotated).

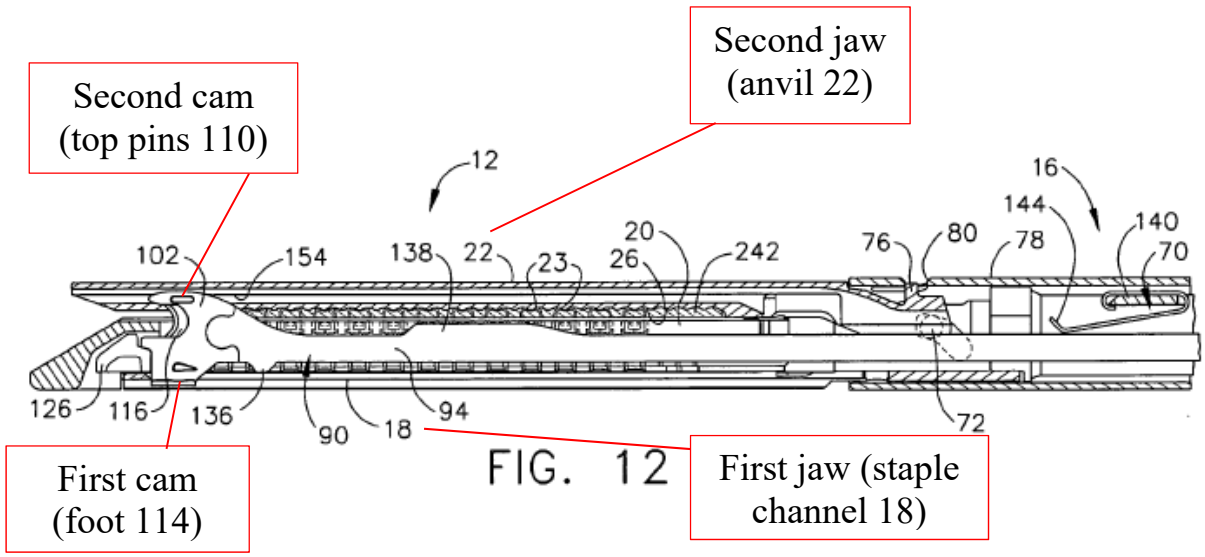


FIG. 12

Id., Fig. 12 (annotated).

[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 '562 discloses this limitation. IS1003, ¶¶83-86. For example, Shelton '562's second jaw (anvil 22) comprises a clearanced opening (anvil pocket

150) configured to receive the second cam (top pins 110) such that the first jaw (staple channel 18) is not held to the second jaw (anvil 22) when the staple firing member (firing bar 90/E-beam 102) is in the unadvanced position. *Id.*, IS1004, ¶¶43, 48, Figs. 6, 13.

Shelton '562 states that, as shown in Figs. 6-7, (Fig. 6 is reproduced below) "the 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." IS1004, ¶48. In Fig. 6, the anvil 22 is raised and can be freely lowered. IS1003, ¶¶84-86; IS1004, Fig. 6.

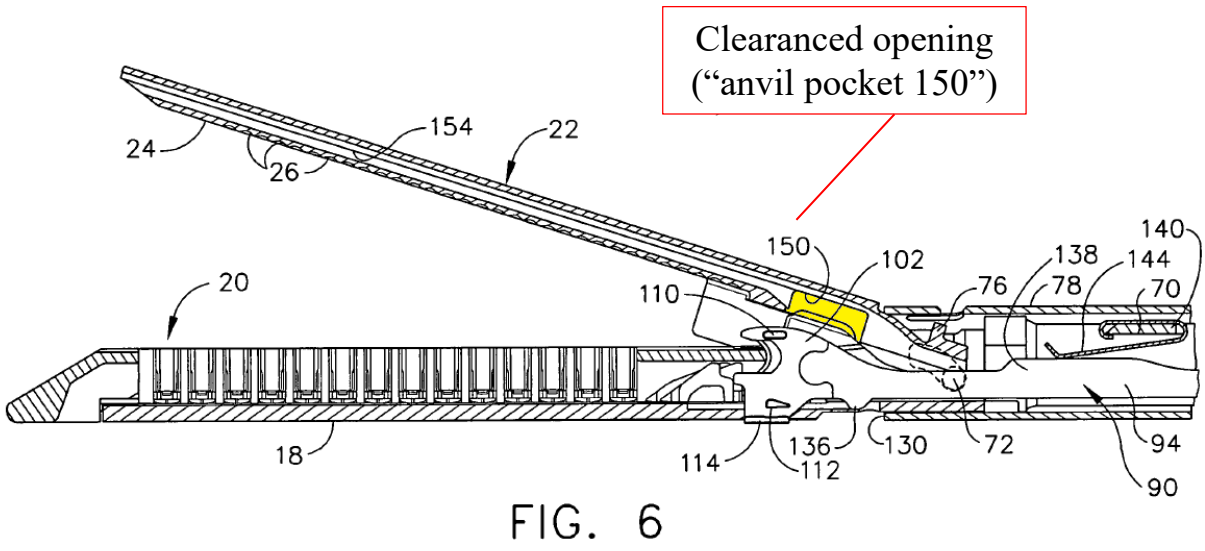
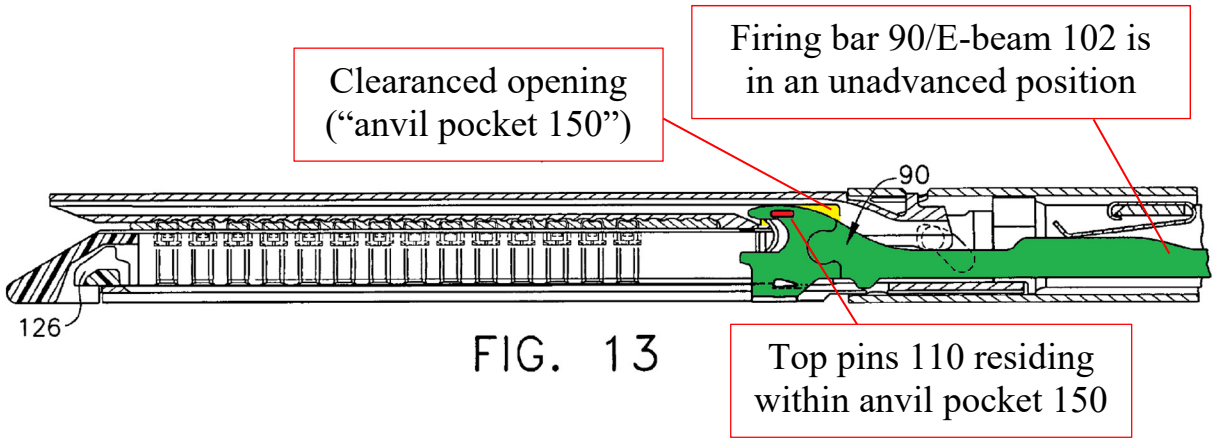


FIG. 6

Id., Fig. 6 (annotated).

The anvil pocket 150 can also be seen in Fig. 13 of Shelton, reproduced below, where the anvil 22 is not raised and the firing bar 90 is not advanced. IS1003, ¶¶85-86, IS1004, Fig. 13.



IS1004, Fig. 13 (annotated).

Shelton '562 states that a "downwardly open vertical anvil slot 152 (FIG. 2) laterally widens in the anvil 22 into an anvil internal track 154 that captures the top pins 110 of the E-beam 102 as they distally advance during firing." *Id.*, ¶48. However, prior to firing, the top pins 110 are received in the clearanced open of the anvil pocket 150, and thus, when the firing bar 90 is not advanced, the top pins 110 do not cause the first jaw (staple channel 18/staple cartridge 20) to be held to the second jaw (anvil 22). IS1003, ¶86; *see also* element [1.8.3]

[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 element [1.9]; IS1003, ¶87; IS1004, ¶¶43, 44, 49, 51-53, Figs. 2-14; Figs. 7, 10, 11, 13, 14.

[3.1] A stapling assembly, comprising:

See element [1.1]; IS1003, ¶88; IS1004, ¶¶34, 39, Figs. 1-2.

[3.2] a first jaw;

See element [1.6]. Anvil 22 discloses the "second jaw" in claim 1; the same

anvil 22 discloses the "first jaw" in claim [3]. IS1003, ¶89; IS1004, ¶¶34, 36, 41, 43, 48-50, 52, Figs. 1-3, 6, 7, 9-14.

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

Shelton '562 discloses a second jaw (combination of staple channel 18 and removable staple cartridge 20). IS1003, ¶¶90-91; IS1004, ¶¶34, 41-53, Figs. 1-3, 6-14; *see* element [1.4]. The combination of staple channel 18 and replaceable staple cartridge 20 disclose the "first jaw" in claim 1; the same staple channel 18 and replaceable staple cartridge 20 disclose the "second jaw" in claim 3. IS1003, ¶90.

Furthermore, Shelton '562's first jaw (anvil 22) is "pivotally attached" to the second jaw (combination of staple channel 18 and removable staple cartridge 20) and therefore rotatable relative to the second jaw. IS1003, ¶91; IS1004, ¶¶34, 41, 48. This can be clearly seen by contrasting the open jaws in Fig. 6 with the closed jaws in Fig. 9. IS1003, ¶91.

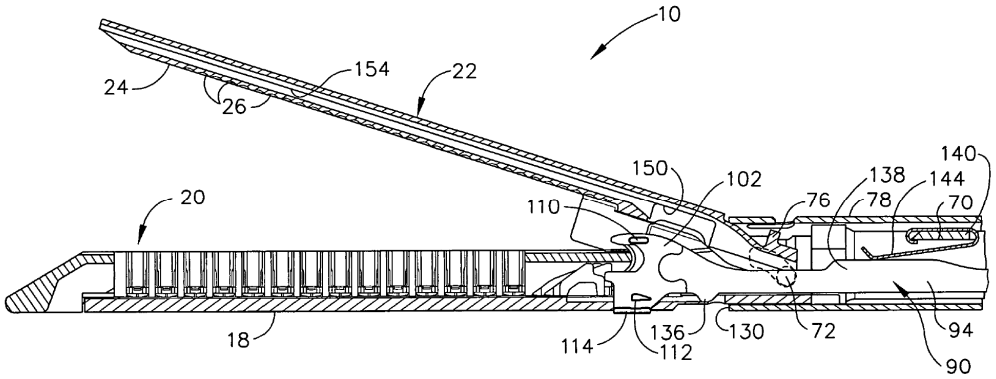


FIG. 6

IS1004, Fig. 6.

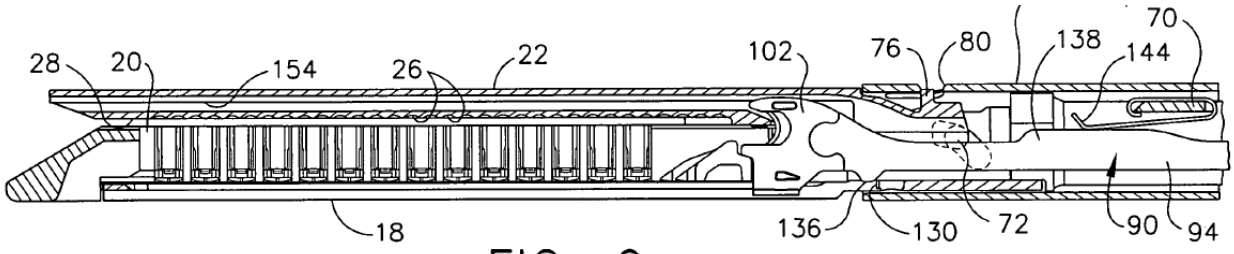


FIG. 9

Id., Fig. 9.

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

Shelton '562 discloses a detachable cartridge portion (detachable staple cartridge 20) comprising a plurality of staples (staples 23). IS1003, ¶¶92-93; IS1004, ¶34, 49, 50, 52, 53, Figs. 2-3, 5-6, 8-14; *see also* element [1.7].

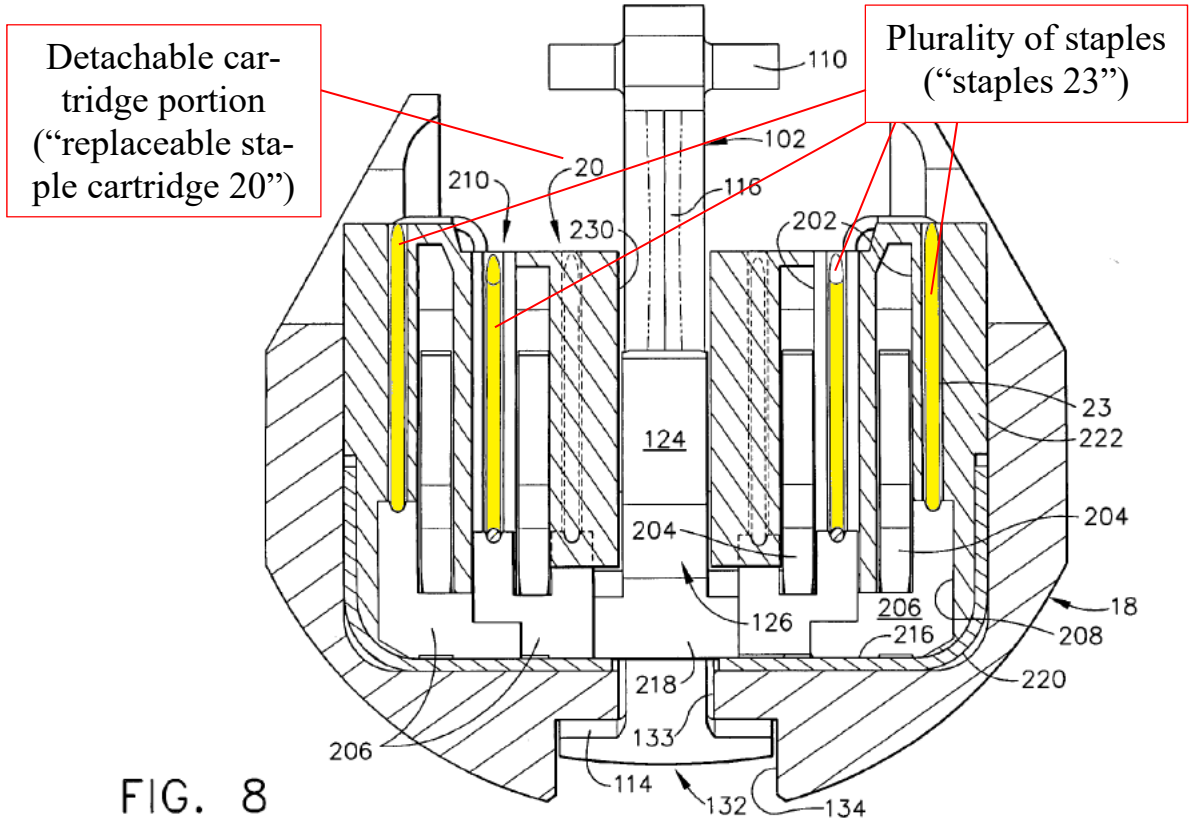


FIG. 8

IS1004, Fig. 8 (annotated).

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

Shelton '562 discloses an anvil (anvil undersurface 28, which is one of several components that make up the first jaw (anvil 22) and includes staple forming recesses 26) configured to deform the staples (23). IS1003, ¶94; IS1004, ¶34, Figs. 6,[8] 9, 12; *see also* limitation [1.6]; *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011) (holding that a claim separately reciting a "cutting box" and a "dust collection structure" did not require separate components, and was met by a single structure: a cutting box with integrated dust collection). As explained in Shelton '562, "anvil 22 … serves to deform staples 23 (FIG. 3) driven … against staple forming recesses 26 (FIG. 6) in an anvil undersurface 28 into a closed shape." IS1004, ¶34.

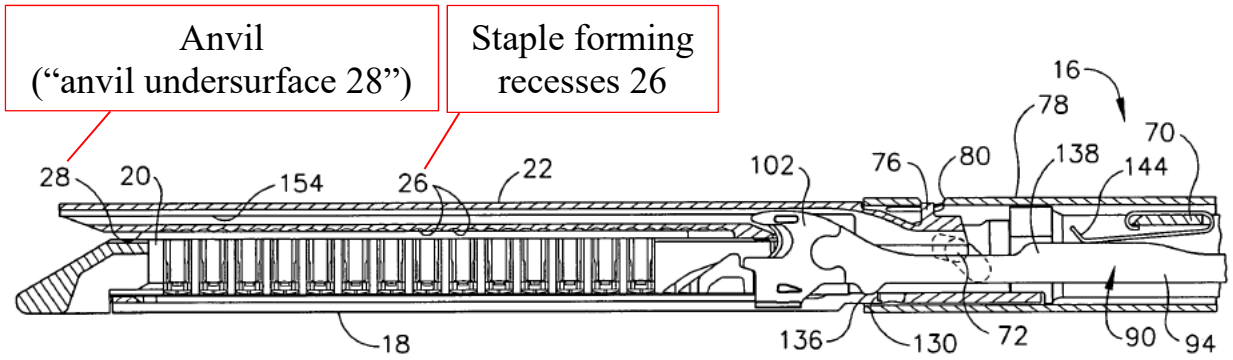


FIG. 9

[8] Note that Fig. 6 includes an error with regard to reference numerals: the undersurface is incorrectly labeled as 24, when it should be 28.

Id., Fig. 9 (annotated).

[3.6] a staple firing member comprising

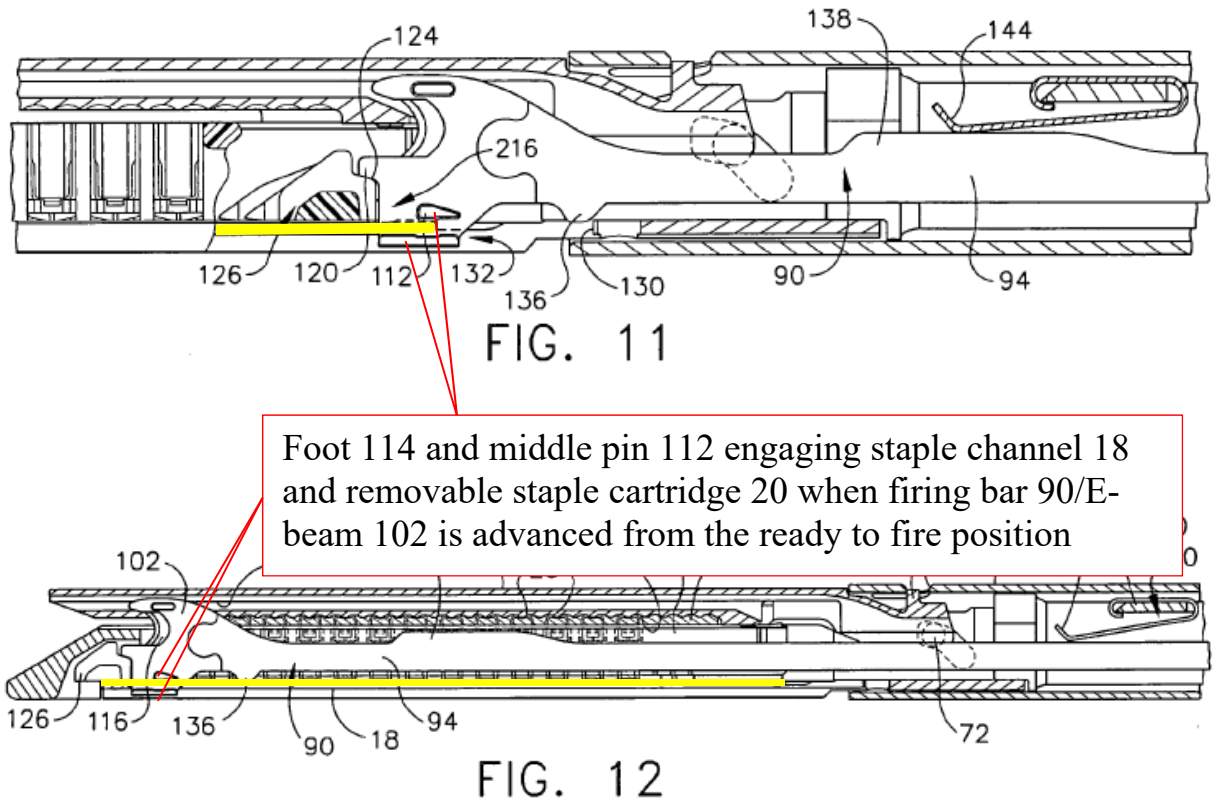
See element [1.8]; IS1003, ¶95; IS1004, ¶¶42-54, Figs. 2-14.

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

See element [1.8.2] (confirming that Shelton '562 discloses a first cam (upper pins 110) configured to engage the first jaw (anvil 22)); IS1003, ¶96; IS1004, ¶¶43-44, 48, Figs. 2-4, 6-14.

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

See element [1.8.1] (confirming that Shelton '562 discloses a second cam (foot 114 or middle pin 112) configured to engage the second jaw (combination of staple channel 18 (highlighted in yellow below) and removable staple cartridge 20) via widened slot 134 or firing recess 216, respectively); IS1003, ¶97; IS1004, ¶¶10, 22, 43-45, 49, 51, 53, Figs. 2-4, 6-14. Furthermore, the second cam (lower foot 114 or middle pin 112) is configured to engage the second jaw (combination of staple channel 18 and removable staple cartridge 20) when the staple firing member (firing bar 90/E-beam 102) is advanced from an initial (*e.g.*, ready to fire) position because foot 114 and middle pin 112 engage widened slot 134 and firing recess 216, respectively, after the firing member (firing bar 90/E-beam 102) is advanced distally from the ready to fire position. IS1003, ¶97; IS1004, ¶¶10, 22, 43-45, 49, 51, 53, Figs. 11-12.



IS1004, Figs. 11-12 (annotated).

[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 '562 discloses this limitation. IS1003, ¶¶99-101. For example, Shelton '562's first jaw (anvil 22) comprises a clearanced opening (anvil pocket 150) configured to receive the first cam (top pins 110) when the staple firing member (firing bar 90/E-beam 102) is an the initial (unadvanced) position such that the first cam (top pins 110) is not engaged with the first jaw (anvil 22) when the stapling firing member (firing bar 90/E-beam 102) is in the initial (unadvanced position). *Id.*, IS1004, ¶¶43, 48, Figs. 6, 13.

As shown in Figs. 6-7 (Fig. 6 is reproduced below), Shelton '562 states that "the 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." IS1004, ¶48. In Fig. 6, the anvil 22 is raised and can be freely lowered. IS1003, ¶100; IS1004, Fig. 6.

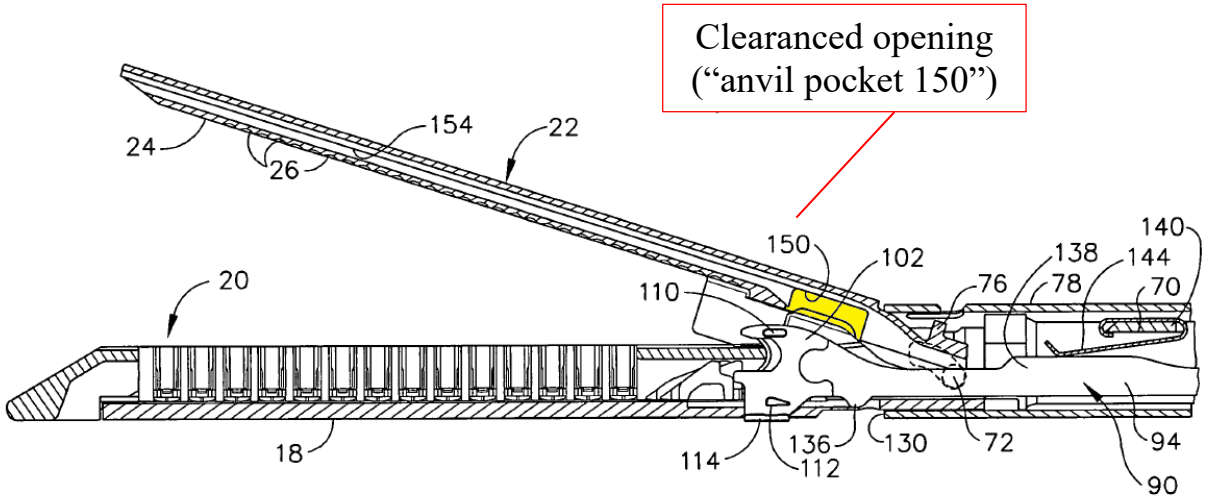


FIG. 6

Id., Fig. 6 (annotated).

The anvil pocket 150 can also be seen in Fig. 13 of Shelton, reproduced below, where the anvil 22 is not raised and the firing bar 90 is not advanced. IS1003, ¶101, IS1004, Fig. 13.

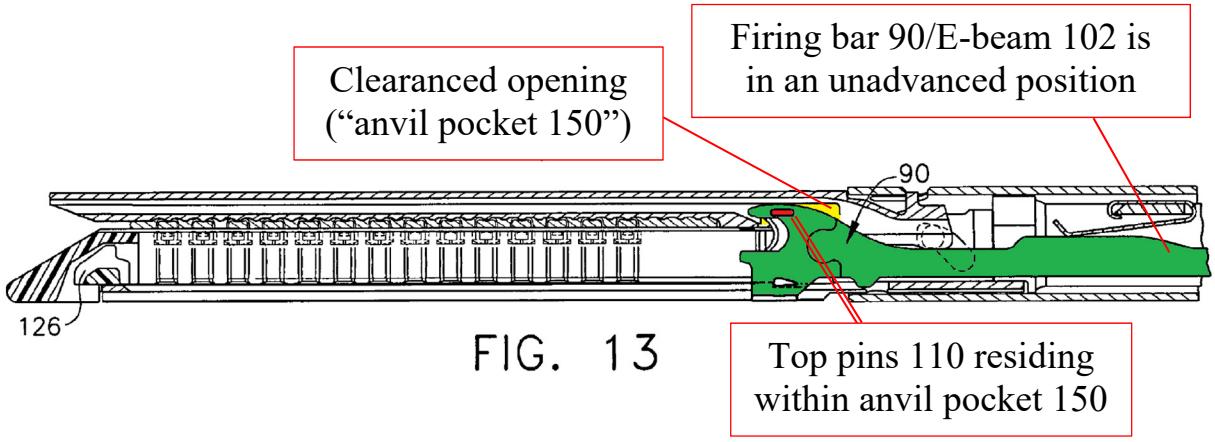


FIG. 13

IS1004, Fig. 13 (annotated).

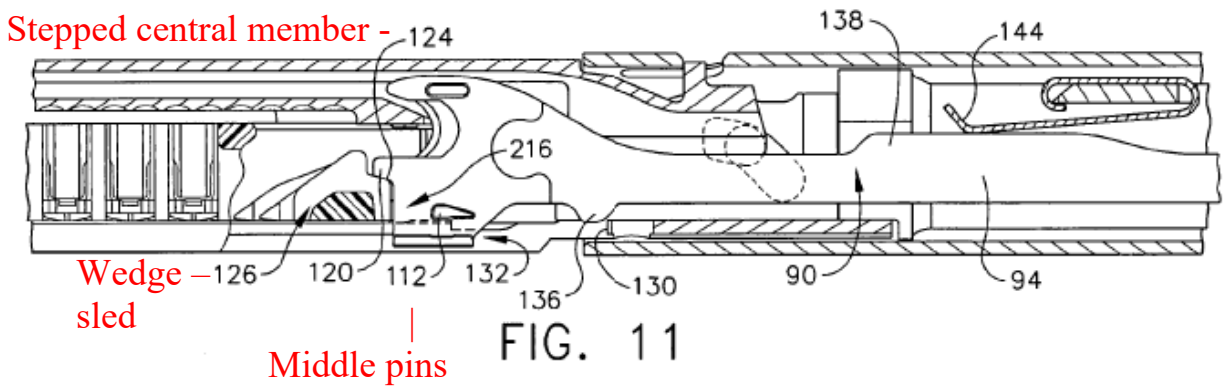
Shelton '562 states that a "downwardly open vertical anvil slot 152 (FIG. 2) laterally widens in the anvil 22 into an anvil internal track 154 that captures the top pins 110 of the E-beam 102 as they distally advance during firing." *Id.*, ¶48. However, prior to firing, the top pins 110 are received in the clearanced open of the anvil pocket 150, and thus, when the firing bar 90 is not advanced, the top pins 110 are not engaged with the first jaw (anvil 22). IS1003, ¶103; *see also* elements [1.8.3] and [2.8.4]. Rather, the top pins 110 (first cam) is not engaged with the anvil 22 (first jaw), nor is it engaged with any component because it resides within the anvil pocket 150. IS1003, ¶103.

[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.

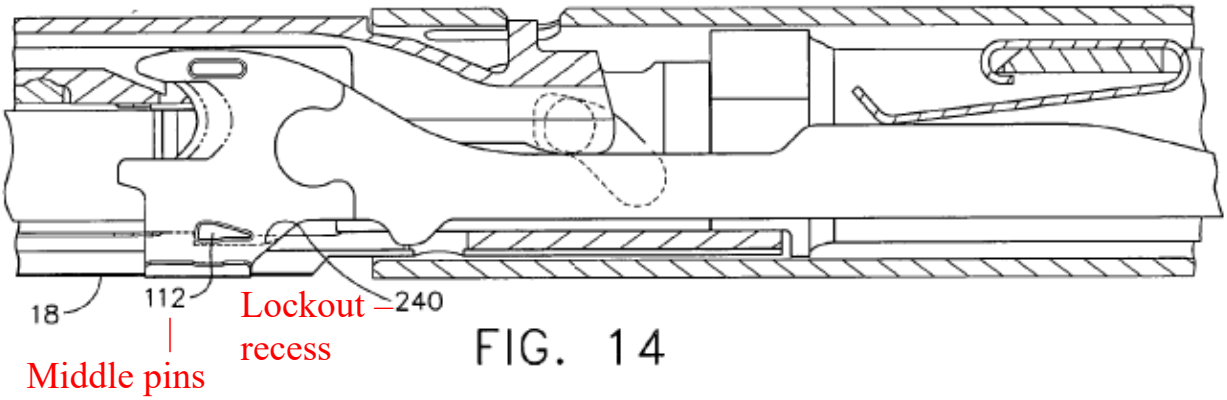
Shelton '562 discloses a lockout (the combination of middle pin 112, middle guide 120, lockout recess 240, and wedge sled 126 with stepped central member 124) configured to block the advancement of said staple firing member (firing bar 90, including its distal portion E-beam 102) when said detachable cartridge portion (staple cartridge 20) is not attached to said stapling assembly (surgical stapling instrument 10). IS1003, ¶¶104-107; IS1004, ¶¶43, 44, 49, 51-53, Figs. 2-14; Figs. 7, 10, 11, 13, 14.

As explained in Shelton '562, "E-beam 102 may be advantageously formed of a material having suitable material properties for forming a pair of top pins 110,

a pair of middle pins 112 and a bottom pin or foot 114, as well as being able to acquire a sharp cutting edge 116." IS1004, ¶43. "The middle guide 120 also serves to engage and fire the staple applying apparatus 12 by abutting a stepped central member 124 of a wedge sled 126 (FIG. 5) that effects staple formation by the staple applying assembly 12…." *Id.* "In FIG. 14, the middle pin 112 is allowed to translate down into a lockout recess 240 formed in the staple channel 18 (also see FIGS. 7, 10)." *Id.*, ¶53.



Id., Fig. 11 (annotated)



Id., Fig. 14 (annotated).

Thus, "the middle pin 112 is allowed to translate down into a lockout recess

240 formed in the staple channel 18 (also see FIGS. 7, 10) [and] 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.*, ¶53. In particular, the lockout is configured to block the advancement of the firing bar 90 when the staple cartridge 20 is not attached to the surgical stapling instrument (*e.g.*, if the cartridge 20 has been removed or has been fully spent). IS1003, ¶107; *see also* element [1.9].

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*[9] 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

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

Aug. 27, 2018).[10] Apparently concerned that the second district court action also 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.[11] 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,[12] the ITC's

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

[11] *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).

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

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 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).[13] 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

[13] An institution decision for Case No. 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 (Case IPR2018-00938) was denied on the merits—*i.e.,* not on discretionary grounds.

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.

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.[14]

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 ground presented in this petition is an anticipation

[14] 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.

ground that clearly renders the challenged claims unpatentable. Indeed, the asserted reference (Shelton '562) is ***identical*** to the '379 patent's disclosure in relevant part. A stronger case of anticipation is difficult to imagine. 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 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 Ground 1 set forth above. Accordingly, Petitioner requests *Inter Partes* Review of the challenged claims.

Respectfully submitted,

Dated October 16, 2019

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Ryan P. O'Connor, Reg. No. 60,254
Fish & Richardson P.C.

(Control No. IPR2020-00050)

Attorneys for Petitioner

CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 9,679 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated October 16, 2019

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CERTIFICATE OF SERVICE

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