IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Shelton, IV	
U.S. Pat. No.:	9,585,658	Attorney Docket No.: 11030-0049IP4
Issue Date:	Mar. 7, 2017	
Appl. Serial No.:	15/093,020	
Filing Date:	April 7, 2016	
Title:	STAPLING SYSTEMS	

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,585,658 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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IS1004	U.S. Patent No. 6,981,628 to Wales ("Wales")
IS1005	U.S. Patent No. 5,465,895 to Knodel et al. ("Knodel")
IS1006	U.S. Patent App. Pub. No. US 2003/0083673 A1 to Tierney et al. ("Tierney")
IS1007	Merriam-Webster's Collegiate Dictionary, Eleventh Edition (2004) ("Dictionary")

I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1-14 of U.S. Patent 9,585,658 ("the '658 patent"). The '658 patent relates to surgical staplers, which "are often used to deploy staples into soft tissue to reduce or eliminate bleeding from the soft tissue, especially as the tissue is being transected." IS1001 ('658 patent) at 1:55-58. Surgical staplers typically include an end effector with two jaws—a lower jaw that holds a cartridge with staples and an upper jaw that forms an anvil against which staples are deformed. *Id.* at 1:58-2:7.

The patented surgical stapler closes and opens the anvil by applying pushing and pulling forces to different locations on the anvil. For closing, a "closure cam is configured to move longitudinally to engage [a] cam surface and transmit a closing motion to the anvil." For opening, "an opening member [is] configured to move longitudinally to apply an opening force to the anvil at a location other than the cam surface to move the anvil into the open position." IS1001 at Abstract.

Such an instrument was not new as of the alleged priority date of the '658 patent. In fact, both Wales and Knodel disclose the open-and-close-at-different-locations feature. Wales, either alone or in combination with Tierney, or in combination with Tierney and Knodel, discloses all the elements of claims 1-14. Petitioner therefore requests IPR of the challenged claims on Grounds 1-4 below.

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

A. Real Parties-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 present Petition.

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

Petitioner is not aware of any disclaimers, reexamination certificates, or petitions for *inter partes* review of the '658 patent. The '658 patent is the subject of Civil Action No. 1:17-cv-00871-LPS, filed on June 30, 2017, in the United States District Court for the District of Delaware.

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
Steven R. Katz, Reg. No. 43,706 3200 RBC Plaza, 60 South Sixth Street Minneapolis, MN 55402 Tel: 617-542-5070 / Fax: 877-769-7945	John C. Phillips, Reg. No. 35,322 Tel: 858-678-5070

D. Service Information

Please address all correspondence to the address above. Petitioner consents to electronic service by email at IPR11030-0049IP4@fr.com (referencing No. 11030-0049IP4 and cc'ing PTABInbound@fr.com, katz@fr.com and

phillips@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 '658 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 IPR of claims 1-14 of the '658 patent on the grounds below. A declaration from Dr. Bryan Knodel (IS1003) is provided in support.

Grounds	Claims	Basis for Rejections
Ground 1	1-14	Anticipated under § 102 by **Wales** (6,981,628)
Ground 2	3, 8	Obvious under § 103 over **Wales** in view of **Knodel** (5,465,895)
Ground 3	1-14	Obvious under § 103 over **Wales** in view of **Tierney** (US 2003/0083673)
Ground 4	3, 8	Obvious under § 103 over **Wales** in view of **Tierney** and further in view of **Knodel**

The '658 patent issued from U.S. App. No. 15/093,020, filed on April 7,

2016, which is a continuation of U.S. App. No. 14/867,418, filed on September 28, 2015, now U.S. Pat. No. 9,750,498, which is a continuation of U.S. App. No. 14/314,788, filed on June 25, 2014, now Pat. No. 9,186,143, which is a continuation of U.S. App. No. 13/118,223, filed on May 27, 2011, now Pat. No. 8,931,682, which is a continuation-in-part of U.S. App. No. 13/020,053, filed on Feb. 3, 2011, now Pat. No. 8,196,796, which is a continuation of U.S. App. No. 11/810,015, filed on June 4, 2007, now Pat. No. 7,905,380. Accordingly, the earliest possible date to which the '658 patent could claim priority is June 4, 2007.

Petitioner does not concede that the '658 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 herein predate the earliest possible priority date for the '658 patent. However, Petitioner explicitly reserves the right to present such an argument in this proceeding or other proceedings involving the '658 patent.

Wales, Knodel, and Tierney each qualify as prior art under 35 U.S.C. § 102(b) as patents or publications published more than one year before the earliest possible priority date of the '658 patent (June 4, 2007). Wales issued on January 3, 2006 (and was published as US Pub. App. 2005/0006430 on January 13, 2005). Knodel issued on November 14, 1995. Tierney was published on May 1, 2003.

During prosecution, the applicant filed a 161-page IDS listing over 4,500

references. IS1002 at 324-484 and 698-858. Among the over 4,500 references, Wales and Knodel were listed, and thus officially made "of record." Specifically, Knodel was identified at page 49 of the 161-page IDS and Wales was identified at page 72 of the 161-page IDS. IS1002 at 372 and 395 (pages 49 and 72 of the IDS, respectively). Neither Wales nor Knodel were discussed by the Examiner during prosecution.

The patent that issued from Tierney (U.S. Patent No. 7,524,320), was incorporated by reference into the '658 patent specification. IS1001 at 26:43-50. It was also identified at page 81 of the IDS. IS1002 at 404. However, Tierney was not discussed by the Examiner.

V. SUMMARY OF THE '658 PATENT

The '658 patent concerns a "stapling system" having an "end effector" with two jaws that move relative to each other (*e.g.*, their distal ends move toward and away from each other using a rotating motion in combination with an axial motion) so that they may open and close. The first jaw holds a staple cartridge and the second jaw forms an anvil. The end effector is connected to an elongate shaft, which is connected to a housing. The opening and closing motion of the jaws is driven by a rotary drive member in the housing that drives a "closure tube" back and forth along the shaft. IS1001 at 20:26-61 and 92:1-93:4 (claim 1).

A hand-held embodiment is depicted in FIG. 23.

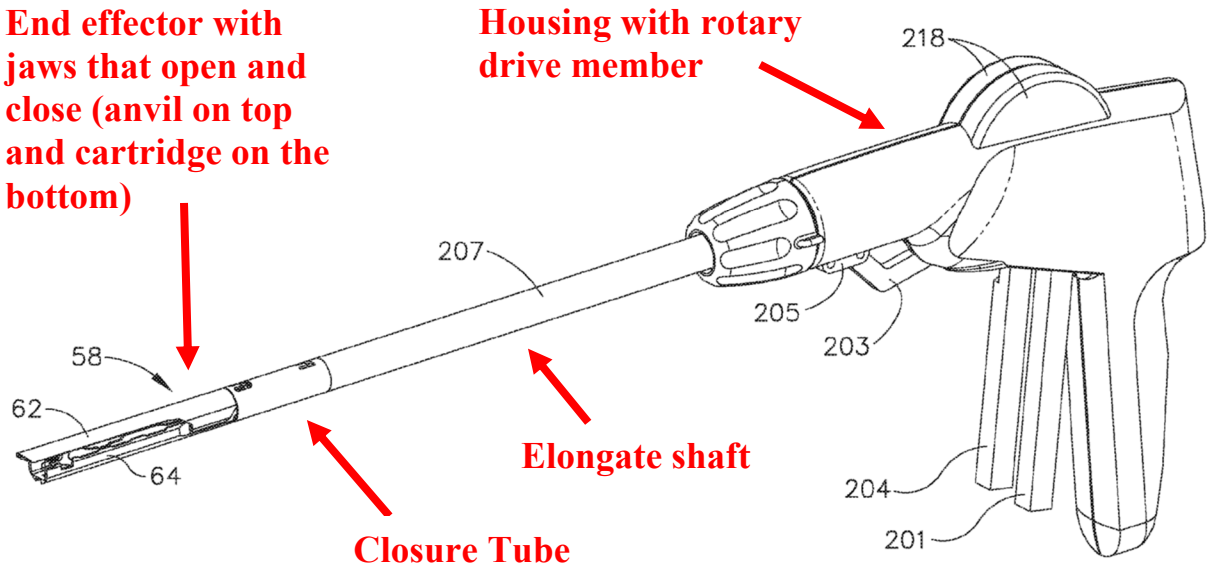


FIG. 23

IS1001 at FIG 23; *See also* FIG. 1. The closure tube is effectively an outer sheath over at least a portion of the elongate shaft. In response to movement of a rotary drive member (*e.g.*, trigger 201), the closure tube pushes the anvil closed and pulls the anvil open. IS1001 at FIGS. 26-28. The device also has additional rotary drive members (*e.g.*, ratchet assemblies 210 and 212) to drive additional motions of the end effector, such as to advance or retract the cutting member. IS1001 at 21:4-24; FIG. 25.

The '658 patent also discloses a robotic embodiment, depicted, for example, in FIG. 55:

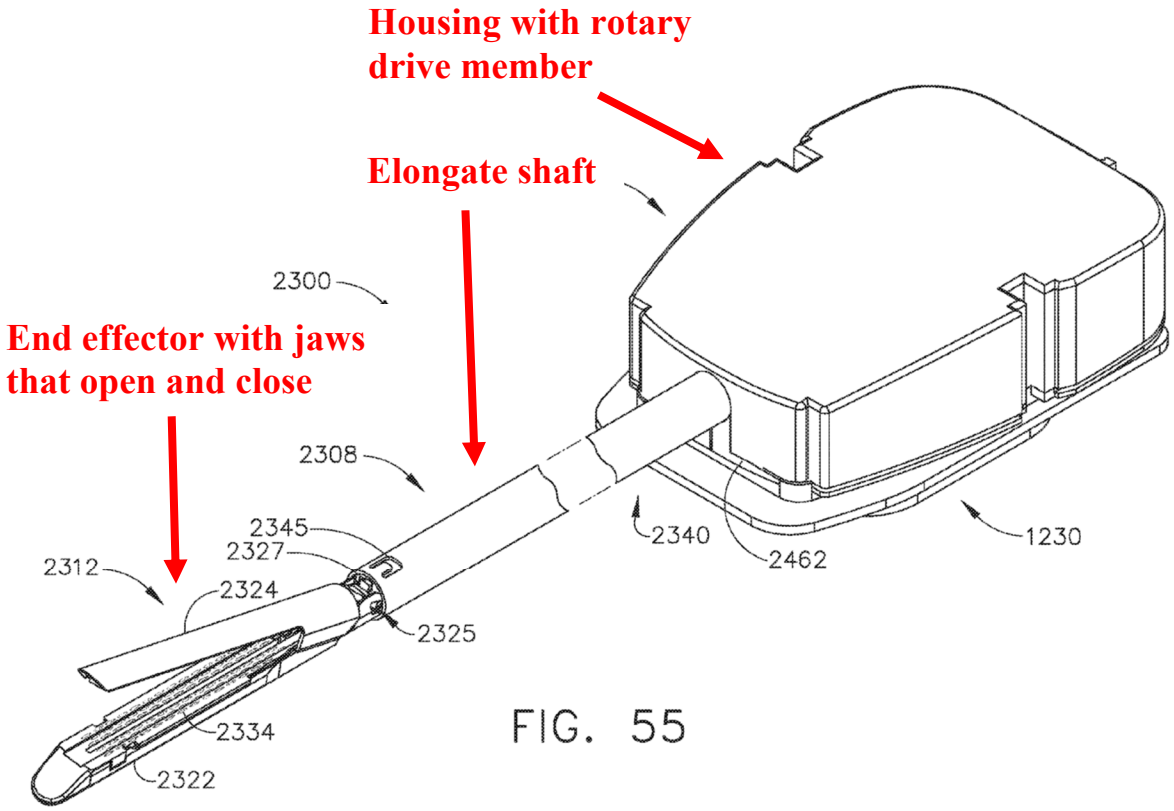


FIG. 55

IS1001 at FIG. 65. In the robotic embodiment, the housing includes a "rotary drive gear 2491" which drives "rotary drive gear 2492" which "ultimately results in the rotation of [a] rotary drive nut 2382 in the first direction which results in the axial travel of the closure tube 2370 in the distal direction 'DD'." IS1001, 40:14-18. Rotary drive gear 2491 and rotary drive gear 2492 are each "rotary drive members."

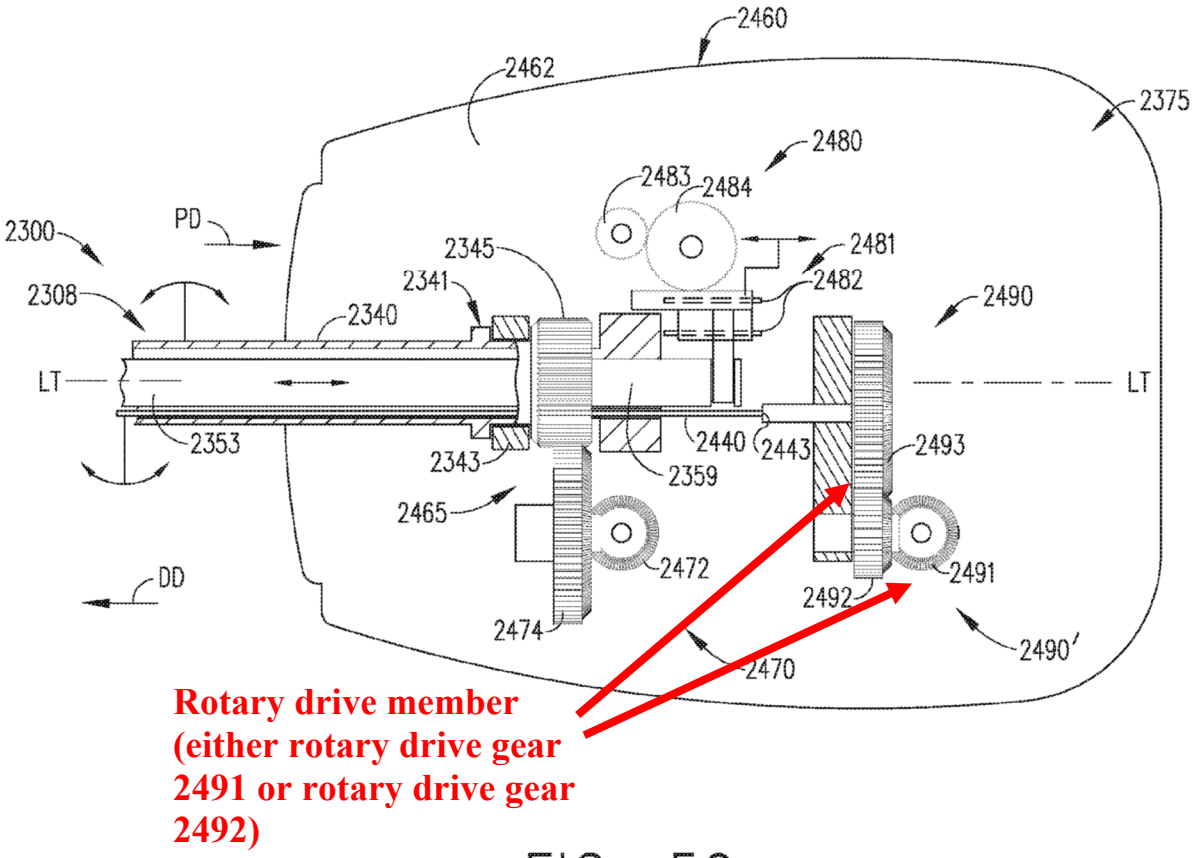
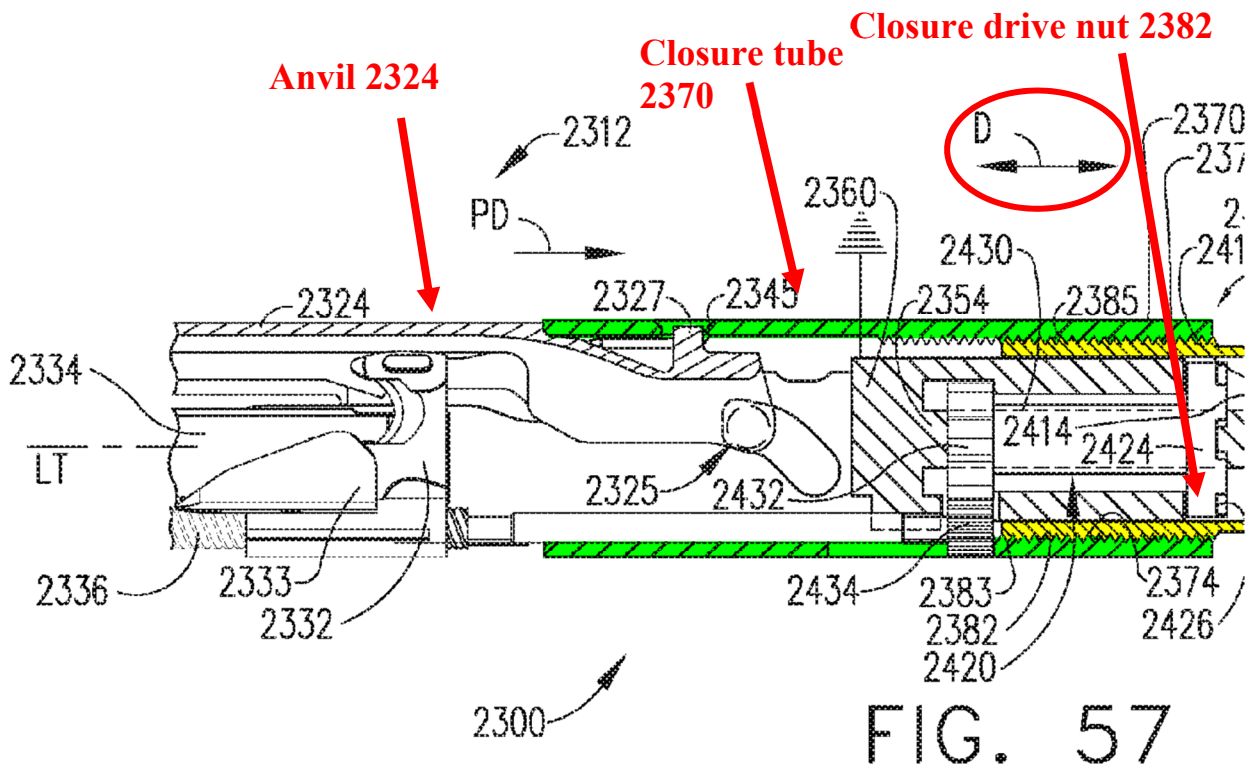


FIG. 59

IS1001 at FIG. 59.

As shown in FIG. 57 (reproduced below), the rotary drive gears are coupled to the "closure drive nut 2382" in the elongate shaft by a "closure clutch assembly." IS1001 at 39:65-40:41. "The closure drive nut 2382 [highlighted in yellow below] has a distal end 2383 that has a threaded portion 2385 that threadably engages the internal thread 2374 of the closure tube 2370 [highlighted in green below]. Thus, rotation of the closure drive nut 2382 will cause the closure tube 2370 to move axially as represented by arrow 'D' in FIG. 57." IS1001 at 37:17-22.



IS1001, FIG. 57 (Excerpt).

Like the hand-held embodiment, the robotic embodiment of the '658 patent uses the closure tube to open and close the anvil. To close the anvil, the end of the closure tube pushes against a surface of the anvil. To open the anvil, an opening in the closure tube pulls a tab on the anvil. IS1001 at 32:36-46.

To close the jaws, the front end of the closure tube pushes against the top surface of the anvil causing it to move distally and to rotate downward onto the lower jaw. "As the distal closure tube 2042 is driven distally, the end of the closure tube segment 2042 will engage a portion of the anvil 2024 and cause the anvil 2024 to pivot to a closed position." IS1001 at 32:36-39.

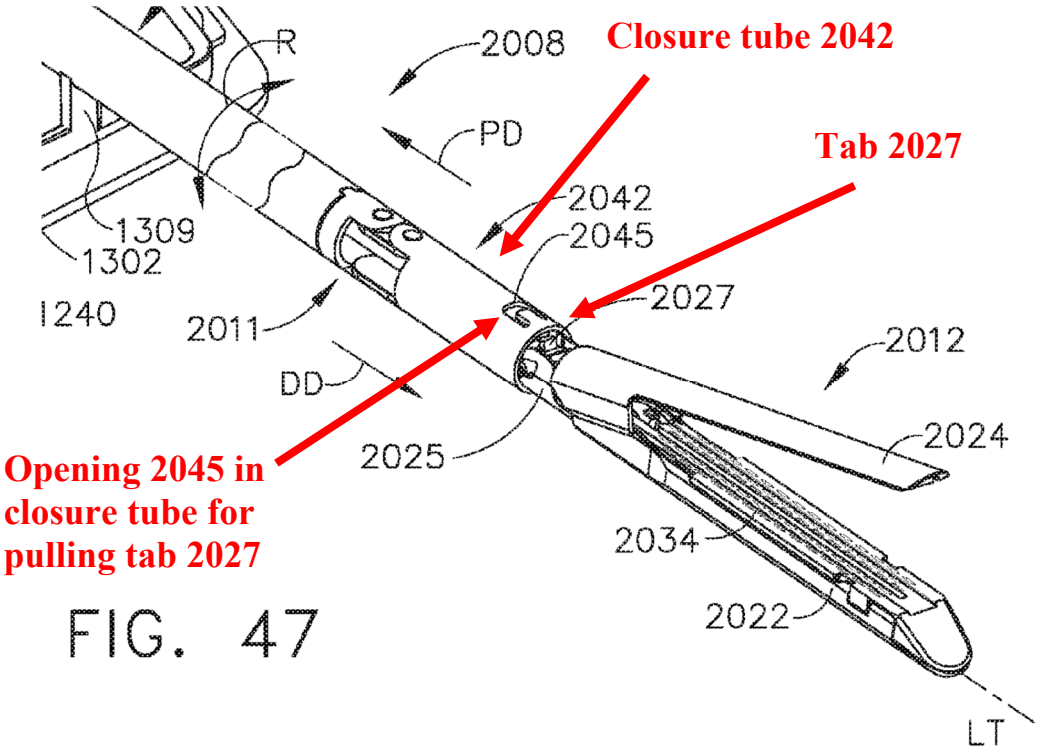


FIG. 47

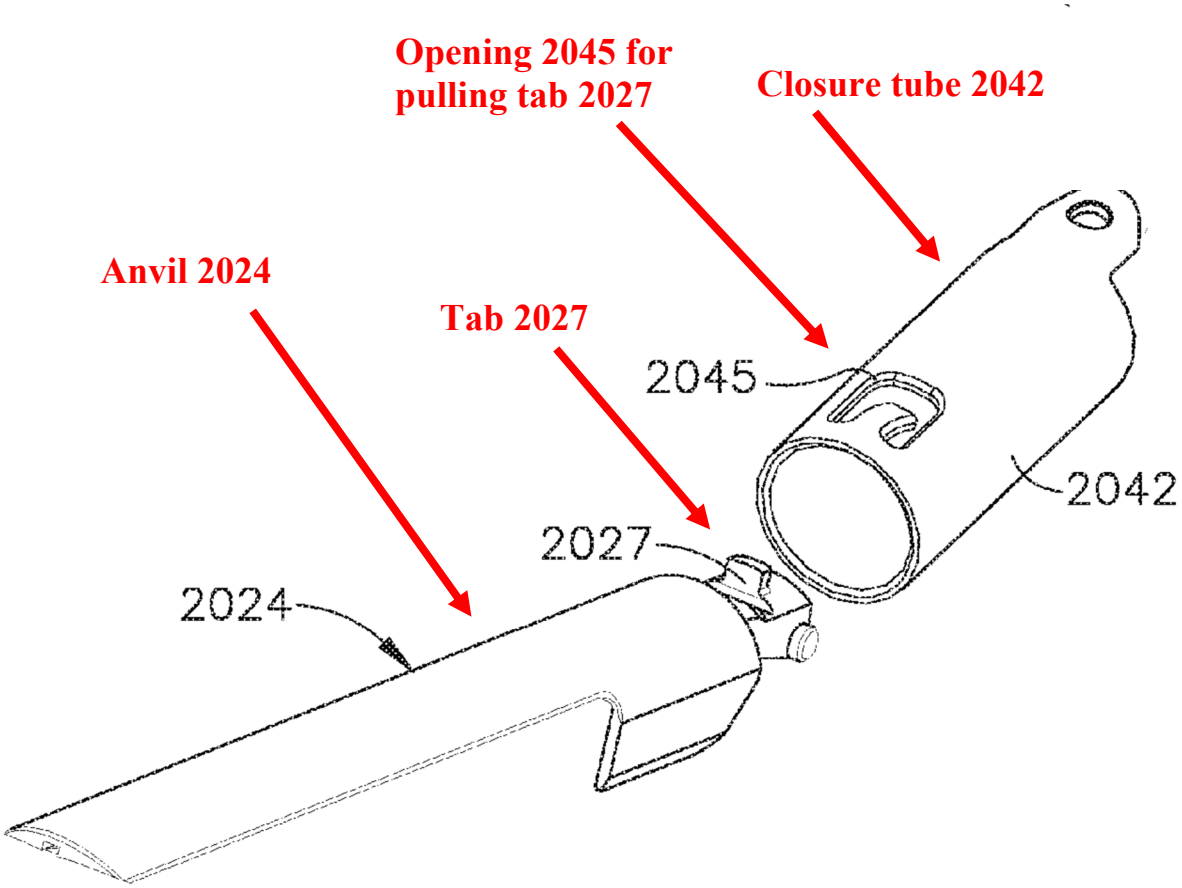
IS1001, FIG. 47.

To open the jaws, the closure tube pulls on tab 2027 on the anvil (which is a location other than the top surface of the anvil). Specifically, closure tube 2042 has "opening 2045 therein that interacts with the tab 2027 of the anvil 2024 to facilitate the opening thereof." IS1001 at 32:43-46.

Claim 1, for example, recites that the "anvil comprises a cam surface" and a "closure cam" imparts a "closing motion" by engaging the "cam surface." In addition, an "opening member" opens the anvil by applying an opening force to the anvil "at a location other than said cam surface." IS1001 at 92:62-93:3.

A blow up of the closure tube is also shown in the following excerpt from

FIG. 44:



IS1001 at FIG. 44 (Excerpt).

Surgical staplers using closure tubes were well-known in the prior art, and more specifically, were placed in the prior art by the assignee of the ’658 patent years before the earliest possible priority date of the patent. Both Wales and Knodel, discussed *infra*, disclose surgical staplers that use a closure tube to open and close the anvil in the same manner as claimed in the ’658 patent. Essentially, the assignee, Ethicon Endo-Surgery, is attempting to patent technology it had years earlier placed in the public domain.

VI. PROSECUTION HISTORY

The application from which the '658 patent issued received a first-action Notice of Allowance on July 12, 2016 (IS1002 at 248-250), less than one month after the Applicant filed its preliminary amendment containing the examined claims (the amendment was filed on June 17, 2016; IS1002 at 235-239), and just over three months after the application was filed (the application was filed on April 7, 2016; IS1002 at 1-220). There had been no intervening rejection, interview, nor other action.

The Examiner indicated that the claims were allowed because of the final limitation of claim 1 (and similarly in the other independent claims): an opening member that pulls the anvil at a different location from where the closing member pushes:

> It is the opening member, which is independent from the clamping clam [sic cam] and the clam [sic cam] surface, configured to move longitudinally to apply a pulling force to the anvil at a location other than said cam surface to move said anvil into said fully-open position in combination with the other claimed elements of the device that are novel over the prior art of record.

IS1002 at 254.

On October 5, 2016, the applicant filed a request for continued examination, amended the inventorship to remove the primary inventor, rewrote the Title, Abstract, and introductory portion of the Specification, and added a claim. IS1002

at 268-314. The applicant also filed a 161-page Information Disclosure Statement containing over 4,500 references. IS1002 at 324-484. Approximately six weeks later (on November 21, 2016), the application was again allowed with no intervening objection or interview, and without further comment. IS1002 at 686-692.

The '658 patent issued on March 7, 2017.

VII. CLAIM CONSTRUCTION UNDER 37 C.F.R. §§ 42.104(B)(3)

For the purposes of IPR only, Petitioner submits that the terms of the '658 patent are to be given their broadest reasonable interpretation as understood by one of ordinary skill in the art at the time in view of the specification ("BRI").[1] 37 CFR §§ 42.100(b). Also, for purposes of this IPR only, Petitioner submits that the following specific construction should be used.

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[1] Petitioner acknowledges that the Office has proposed to change from the BRI standard to the standard applied in District Courts. See 83 Fed. Reg. 21221 (proposed May 9, 2018). Petitioner submits that the prior art discussed herein invalidates the challenged claims under either standard. If the Office changes the rule after the filing of the Petition and applies the new standard to this proceeding, then due process requires the Office afford Petitioner an opportunity to provide additional argument and evidence on that issue.

"rotary drive member" (claims 1, 4, and 5) / **"rotary member"** (claims 6, 9, and 10) / **"rotatable drive member"** (claim 11-14) – a gear, trigger, or other component that rotates to cause movement of another component. IS1003, ¶31. These terms are found only in the summary of the invention and in the claims. However, the detailed description in the specification describes various components that rotate to drive other components. For example, in FIG. 28, "closure trigger 201" rotates about a pivot pin to drive "closure link 203" causing anvil 62 to close. IS1001 at 20:34-47; FIG. 28.

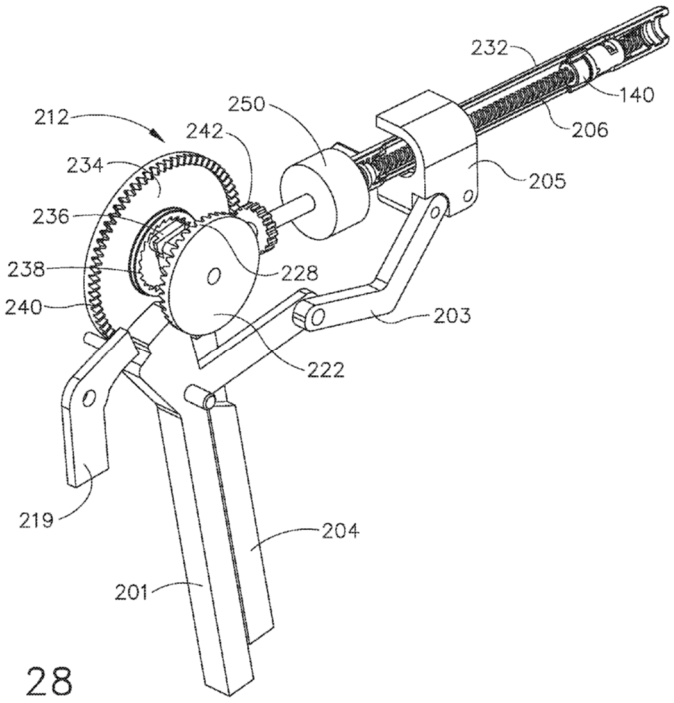


FIG. 28

The proposed construction also is consistent with the plain meaning of the terms "rotary," "rotatable," "drive," and "member." IS1007 at 1084 (defining "rotary" as "characterized by rotation" and "turning on an axis . . ." and identifying

"rotatable" as a form of "rotate"); IS1007 at 381-382 (defining "drive" as "to set or keep in motion or operation."); IS1007 at 774 (defining "member" as "a part of a whole.").

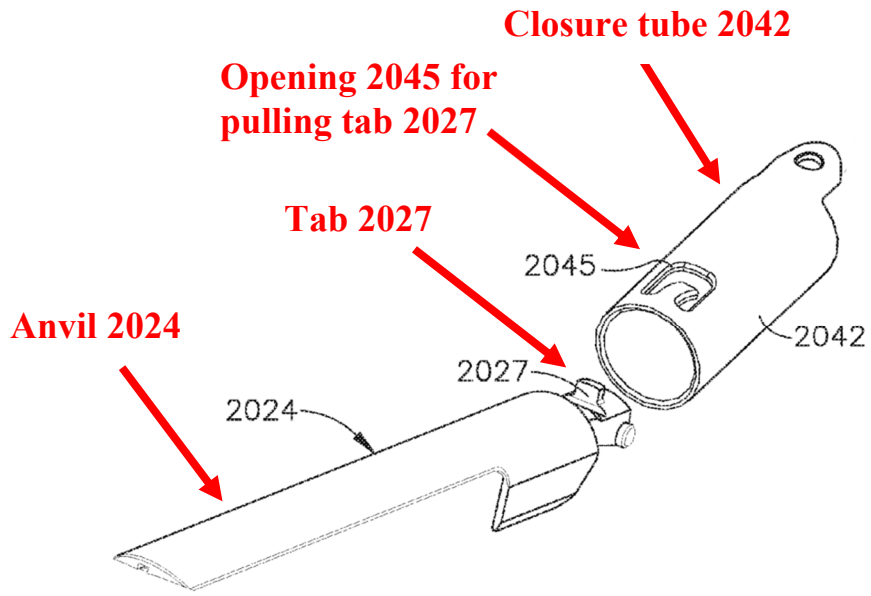
VIII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '658 PATENT IS UNPATENTABLE

As detailed below, claims 1-14 of the '658 patent are anticipated by Wales,[2] or, at the very least, would have been rendered obvious by Wales in view of additional references.

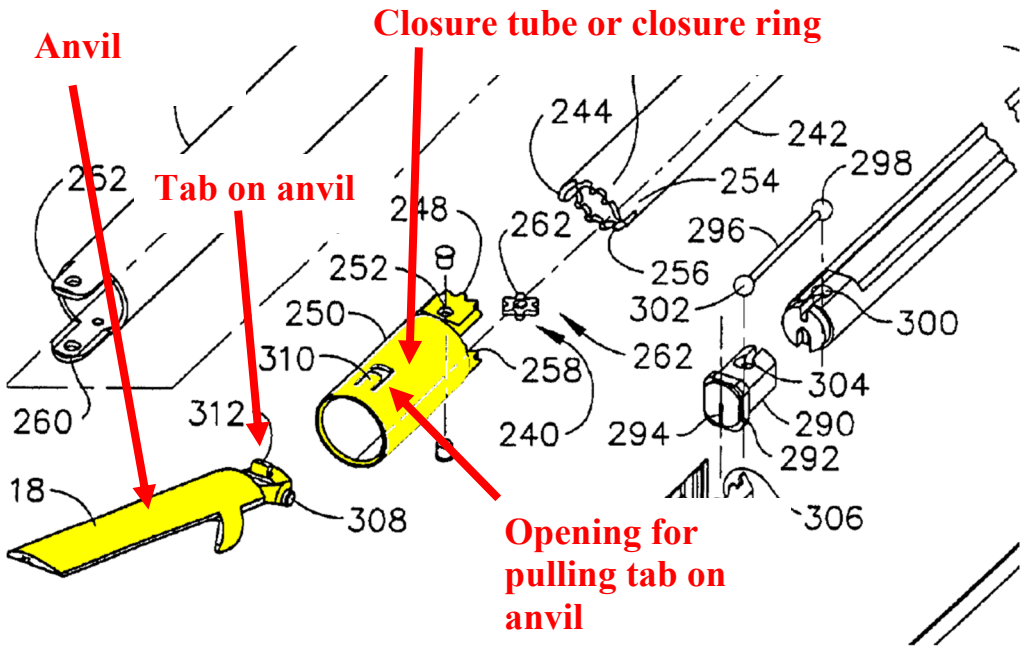
A. Ground 1: Claims 1-14 are Anticipated under § 102 By Wales

Wales discloses a surgical stapler with the same structure for opening and closing the jaws as that described and claimed in the '658 patent. IS1003, ¶¶40-43, 52. Specifically, Wales discloses a "closure ring 250" (also called "closure tube 250" at 9:44-45) that is virtually identical to the '658 patent's "closure tube 2042." Compare the '658 patent, FIG. 2 to Wales, FIG. 11:

[2] Petitioner notes that both the '658 patent and Wales are assigned to Ethicon.



'658 Patent: IS1001 at FIG. 44 (excerpt)

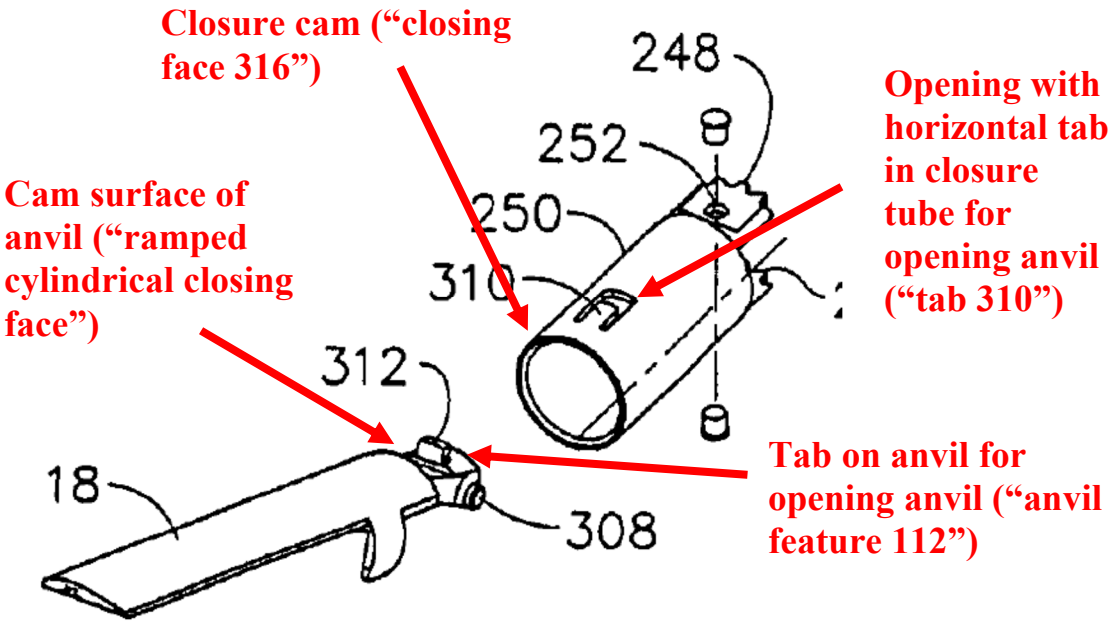


Prior Art Wales Reference: IS1004 FIG. 11 (excerpt)

In addition, the "closure tube 250" (also called a "closure ring 250") in Wales operates in the same manner as claimed in the '658 patent. The end of the closure tube acts as a cam to push down the surface of the anvil to close the anvil, and the closure tube has an opening that pulls the tab ("anvil feature 312") on the anvil to open it:

> The closure ring 250 that encompasses the articulating frame member 290 includes a distally presented tab 310 that engages an anvil feature 312 proximate but distal to the anvil pivot 308 on the anvil 18 to thereby effect opening. When the closure ring 250 is moved forward, its distally presented closing face 314 contacts a ramped cylindrical closing face 316, which is distal to tab 312 of the anvil 18. This camming action closes the anvil 18 downward until the closing face 314 of the closure ring 250 contacts a flat cylindrical face 318 of the anvil 18.

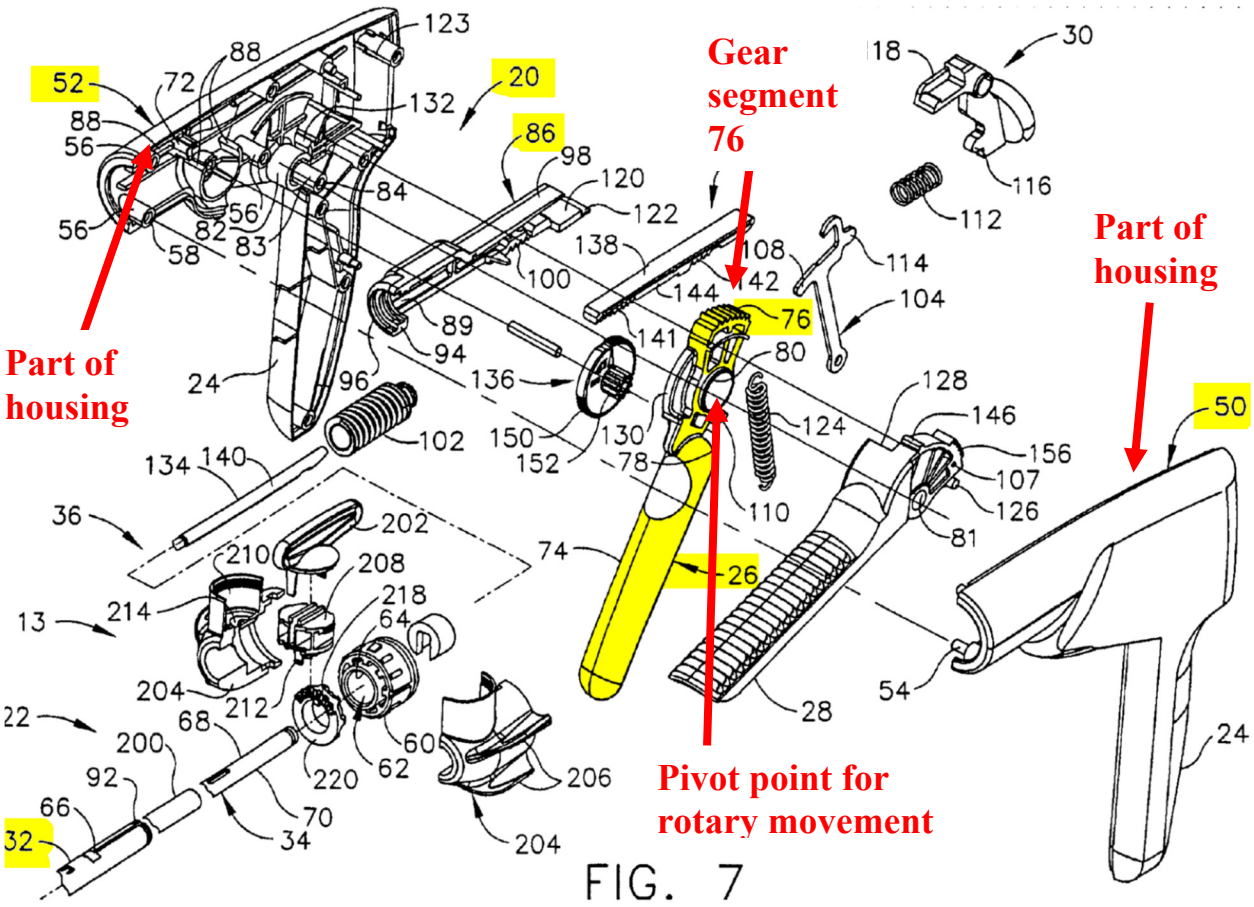
IS1004, 10:20-30, FIG. 11; IS1003, ¶¶60-63.



IS1004, FIG. 11 (excerpted)

[1.1] A stapling system, comprising: a housing comprising a rotary drive member;

Wales discloses a stapling system comprising a housing comprising a rotary drive member. IS1003, ¶53-54. Wales discloses a stapling system. In particular, it discloses "surgical instruments that are suitable for endoscopically inserting an end effector . . . e.g. . . . staplers . . . to a surgical site . . . ." IS1004, 1:34-40; FIGs. 3-5 (showing stapler end effector). Wales also discloses housing "base sections 50, 52" that form a handle portion, which includes a rotary drive member: "gear segment section 76" of "closure trigger 26." IS1004, 6:23-33.



IS1004, FIG. 7, 5:66-67 ("the handle portion 20 is comprised of first and second base sections 50 and 52") and 6:34-44 ("A cylindrical support member 83 extending from the second base section 52 passes through the bore 80 for ***pivotally mounting the closure trigger 26 on the handle*** portion 20).");[3] IS1003 ¶53; *see also* IS1004, 4:57-64, FIG. 1.

The trigger causes rotary drive member ("gear segment section 76") to rotate about the pivot point, which causes "yoke 86 and, hence, the closure sleeve 32 [to]

[3] Emphasis added to quotations throughout unless otherwise indicated.

move distally." IS1004, 6:52-64. The closure sleeve 32, in turn, causes "closure ring 250" to move distally. IS1004, 8:15-9:42; *see also* IS1004, FIGs. 1, 6, 7, 6:32-37, 6:45-64.

[1.2] an elongate shaft extending from said housing, wherein said elongate shaft defines a longitudinal axis;

Wales discloses an elongate shaft extending from the housing, wherein said elongate shaft defines a longitudinal axis. IS1003, ¶55. As Wales explains:

> The surgical and stapling and severing instrument 10 includes a handle portion 20 connected to an implement portion 22, ***the latter further comprising a shaft 23*** distally terminating in the articulating mechanism 11 and the end effector 12.

IS1004, 4:57-64. The shaft is strikingly similar to the shaft in the '658 patent and is clearly "elongate"—that is it is longer than it is wide. This is shown in Figure 1:

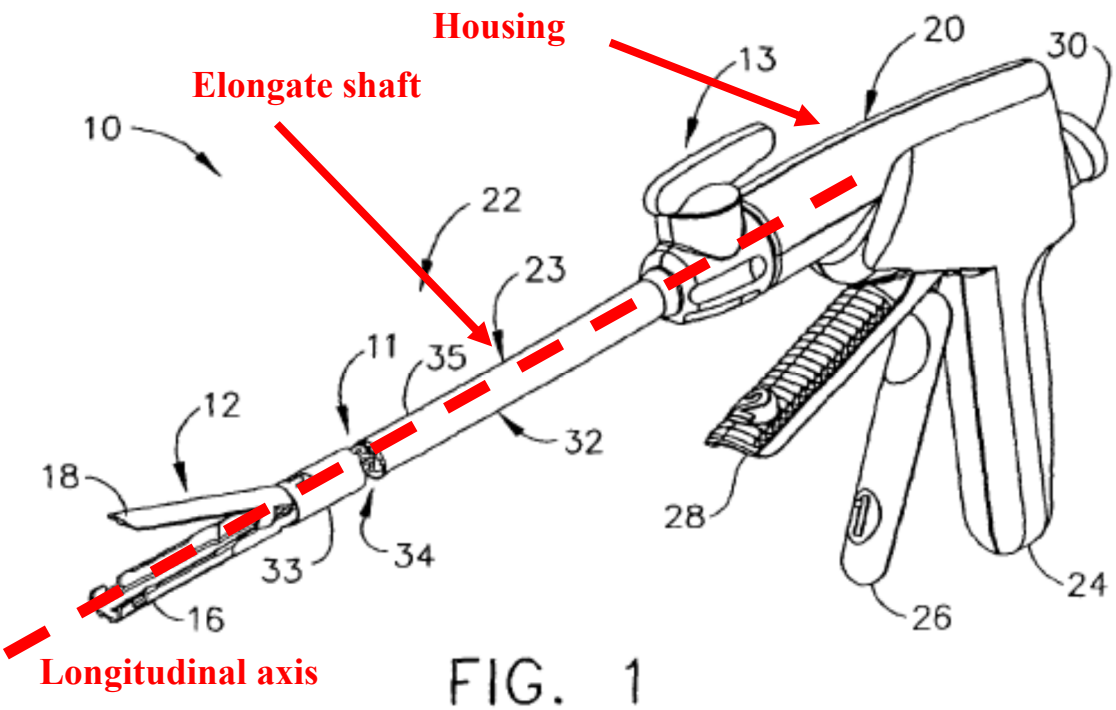

Housing
Elongate shaft
Longitudinal axis
10
13
20
30
22
23
11
35
12
32
18
28
33
34
16
24
26

FIG. 1

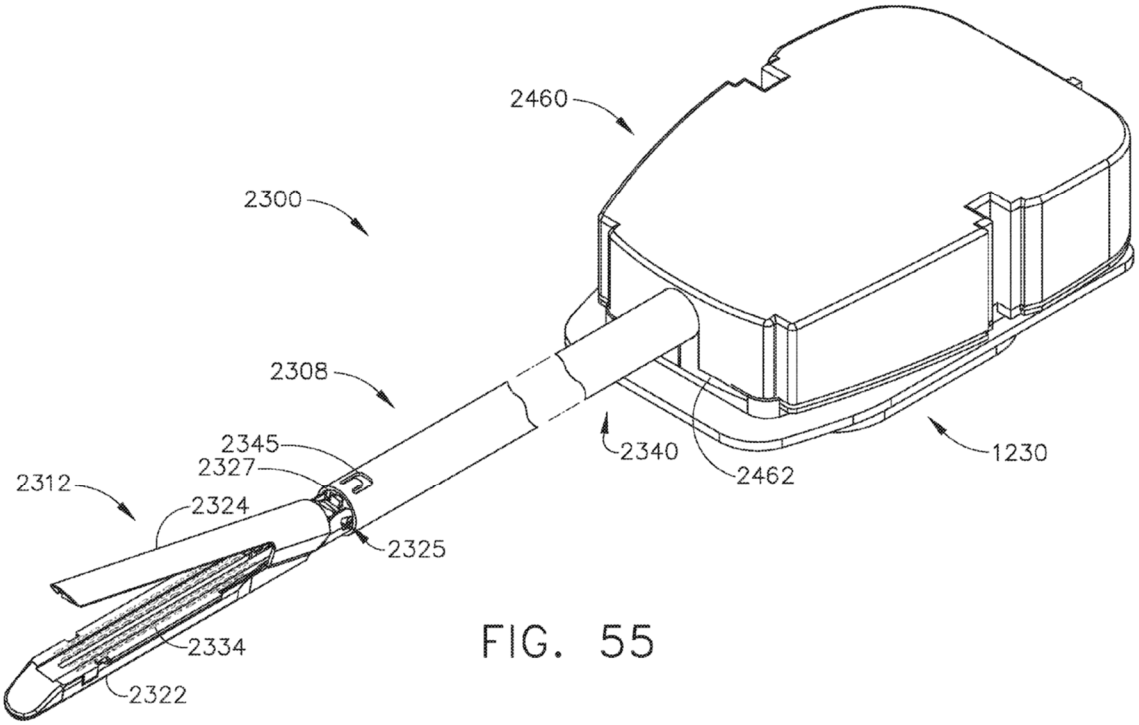

2460
2300
2308
2345
2327
2312
2324
2325
2340
2462
1230
2334
2322

FIG. 55

IS1004 at FIG. 1; *compare to, e.g.*, IS1001 at FIGS. 23, 38, and 45-48.

[1.3] an end effector, comprising: a jaw configured to support a staple cartridge;

Wales discloses an end effector comprising a jaw configured to support a staple cartridge. IS1003, ¶56. Figure 3 of Wales clearly shows the lower jaw of the end effector 12 containing staple cartridge 37:

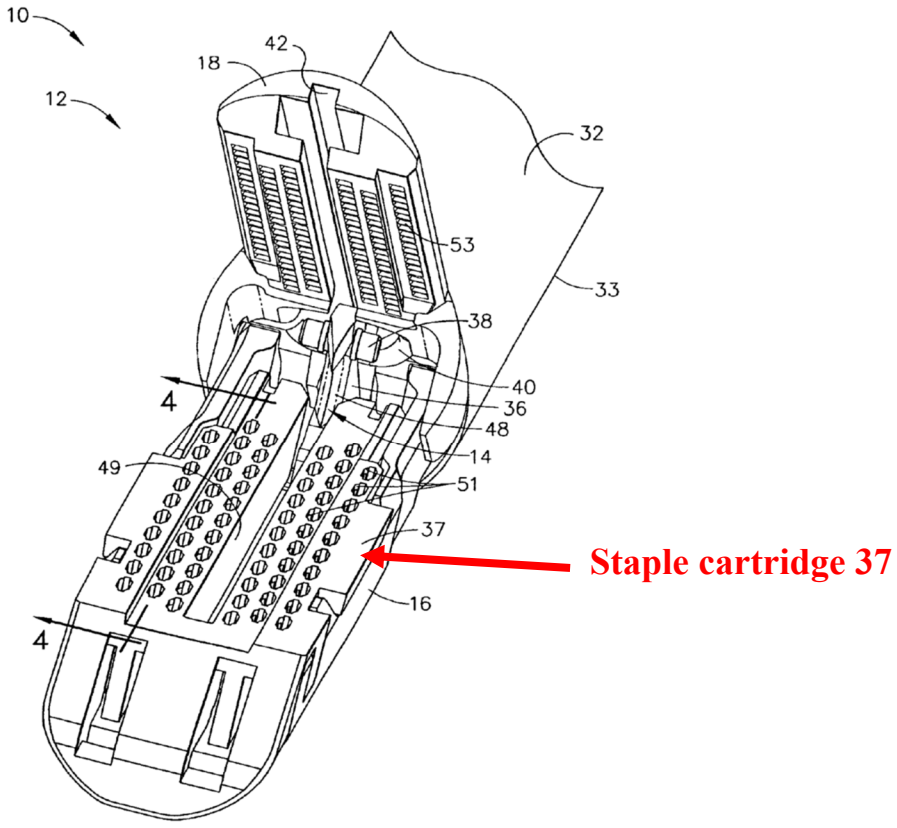
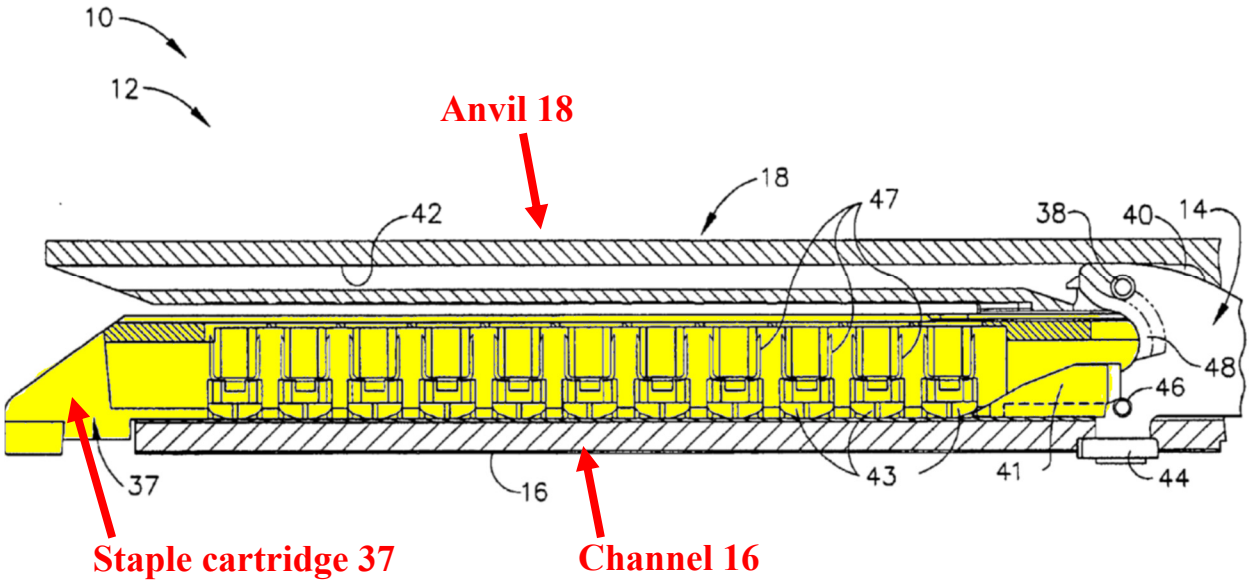


FIG. 3

IS1004, FIG. 3; *accord* IS1004, 3:47-55, 5:34-37. Figure 4 of Wales shows a side view section of the end effector of Figure 3 in the closed position, the section generally taken along lines 4-4 of Figure 3 to expose portions of cartridge 37:



IS1004, FIG. 4 (both showing anvil 18 and elongate channel 16).

[1.4] and an anvil rotatable relative to said jaw between an open position and a fully-closed position, wherein said anvil comprises a cam surface;

Figures 3 and 4 of Wales disclose an anvil that is rotatable relative to the lower jaw (which contains a cartridge), between an open position and a fully-closed position, wherein the anvil comprises a cam surface. The cam surface is the surface where the closure tube contacts the anvil to rotate it from an open position to a closed position. That is, it is the surface that works with the closure tube to translate the linear closure tube movement into rotary movement of the anvil. IS1003, ¶57-58.

Figure 3 of Wales depicts the anvil in an open position (rotated upward) and Figure 4 of Wales depicts the anvil in a closed position (rotated downward).

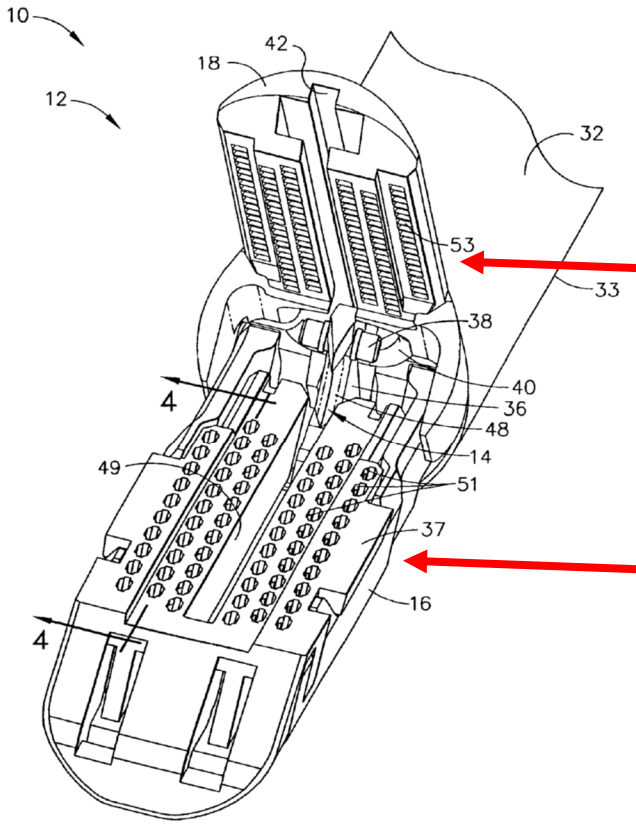
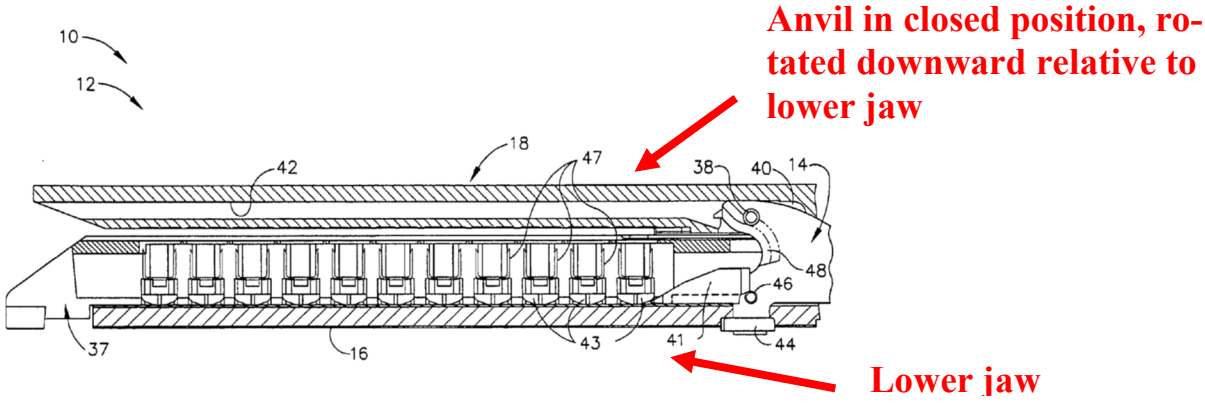
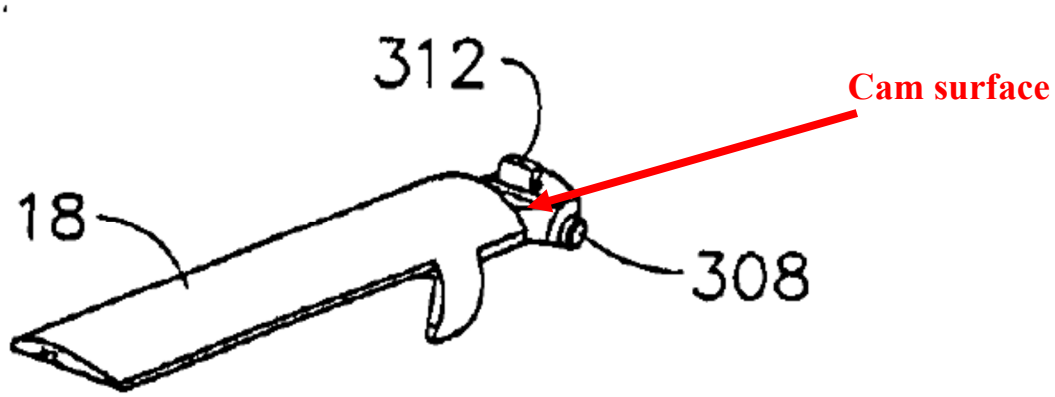


FIG. 3



The anvil in Wales comprises a cam surface, which is the "ramped cylindrical closing face."



IS1004, FIG. 11 (Excerpt). Wales explains: "When the closure ring 250 is moved forward, its distally presented closing face 314 contacts a ramped cylindrical closing face 316, which is distal to tab 312 of the anvil 18. This camming action closes the anvil 18 downward until the closing face 314 of the closure ring 250 contacts a flat cylindrical face 318 of the anvil 18." IS1004, 10:20-30; IS1003, ¶60; *see also* IS1004, 4:54-56, 5:3-14, 5:36-39, 6:60-64, 8:54-56, 10:14-30.

[1.5] a closure cam operably coupled with said rotary drive member, wherein said closure cam is configured to move longitudinally to engage said cam surface and transmit a closing motion to said anvil to move said anvil into said fully-closed position;

Wales discloses a closure cam operably coupled with the rotary drive member, wherein said closure cam is configured to move longitudinally to engage the cam surface and transmit a closing motion to said anvil to move said anvil into said fully-closed position. IS1003, ¶¶57-62. In particular, the closure cam is the

"distally presented closing face 314" on the closure ring 250, and the cam surface, as discussed above, is the "ramped cylindrical closing face 316" on the anvil. The "distally presented closing face 314" is moved distally, or longitudinally, to push the ramped cylindrical closing face 316 of the anvil downward:

> The elongate channel 16 also has an anvil cam slot 306 that pivotally receives an anvil pivot 308 of the anvil 18. . . . When the closure ring 250 is moved forward, its [*sic*] distally presented closing face 314 contacts a ramped cylindrical closing face 316, which is distal to tab 312 of the anvil 18. This camming action closes the anvil 18 downward until the closing face 314 of the closure ring 250 contacts a flat cylindrical face 318 of the anvil 18.

IS1004, 10:19-30.

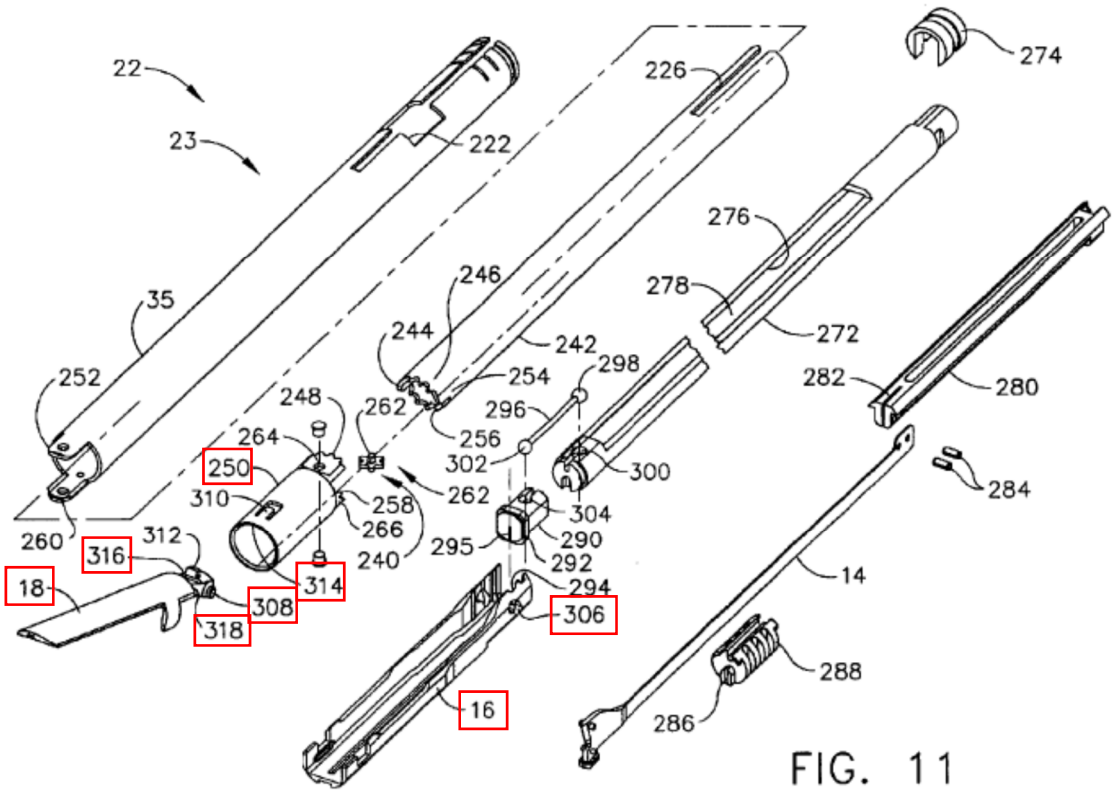
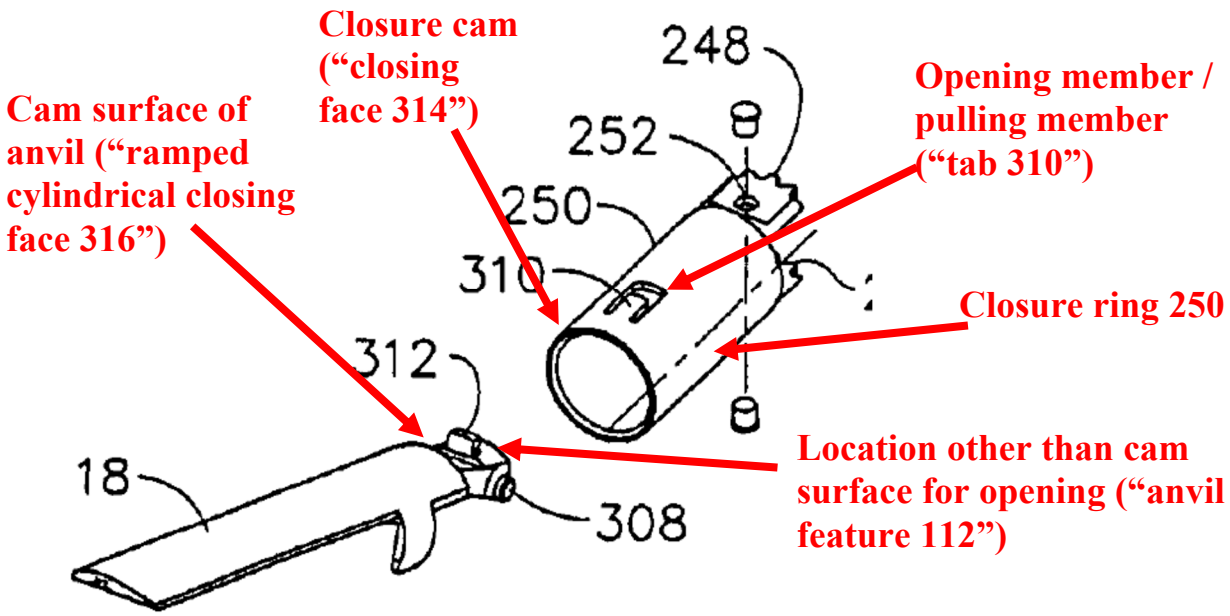


FIG. 11

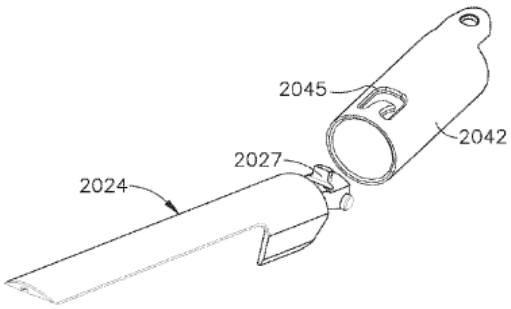
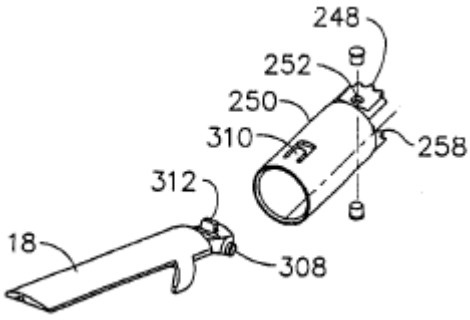


IS1004, FIG. 11 (full and excerpted). The closure cam 314 of Wales is coupled to the rotary drive member. When the rotary drive member is rotated, linear motion is imparted to the closure ring, and thus to closure cam 314. In particular, the trigger causes rotary drive member ("gear segment section 76") to rotate about the pivot point, which causes "yoke 86, and hence, the closure sleeve 32 [to] move distally." IS1004, 6:52-64. The closure sleeve 32, in turn, causes "closure ring 250" to move distally. IS1004, 8:15-9:53. *See also* IS1004, 4:57-64; 6:32-51.

[1.6] and an opening member configured to move longitudinally to apply an opening force to said anvil at a location other than said cam surface to move said anvil into said open position.

Wales discloses an opening member configured to move longitudinally to apply an opening force to said anvil at a location other than said cam surface to

move said anvil into said open position. IS1003, ¶62. The opening member in Wales is the "distally presented tab 310" within the opening of the closure ring 250. Wales discloses: "The closure ring 250 . . . includes a distally presented tab 310 that engages an anvil feature 312 proximate but distal to the anvil pivot 308 on the anvil 18 to thereby effect opening." IS1004, 10:20-30, 8:54-56. The opening member of Wales is identical to the opening member in the '658 patent.

	
IS1001 ('658 Patent), FIG. 44 (excerpted)	IS1004 (Wales) FIG. 11 (excerpted)

[2] The stapling system of claim 1, further comprising said staple cartridge.

Wales discloses the stapling system of claim 1, further comprising said staple cartridge. IS1003, ¶64. In particular, Wales discloses that "FIGS. 3-5 depict the end effector 12" that includes "staple cartridge 37." FIG. 3 is reproduced below:

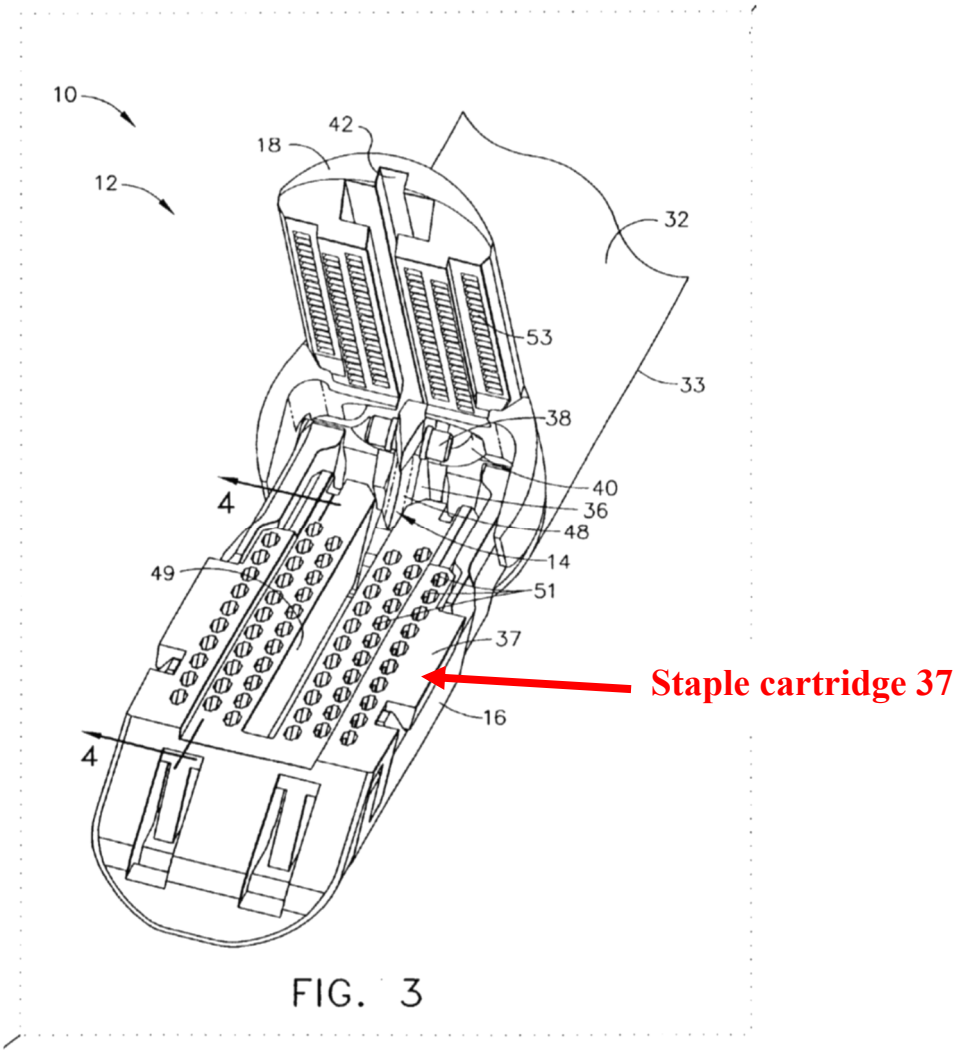


FIG. 3

IS1004, 5:34-64, FIG. 3.

[3] The stapling system of claim 2, wherein said staple cartridge is removably replaceable within said jaw.

Wales discloses the stapling system of claim 2, wherein said staple cartridge is removably replaceable within said jaw. IS1003, ¶65. In particular, it discloses: "In FIG. 3, the firing bar 14 is proximally positioned, allowing an unspent staple cartridge 37 to be installed into the elongate channel 16." IS1004, 5:34-43; *see also id.*, FIG. 1, 3, 11. A POSITA would have understood that the phrase

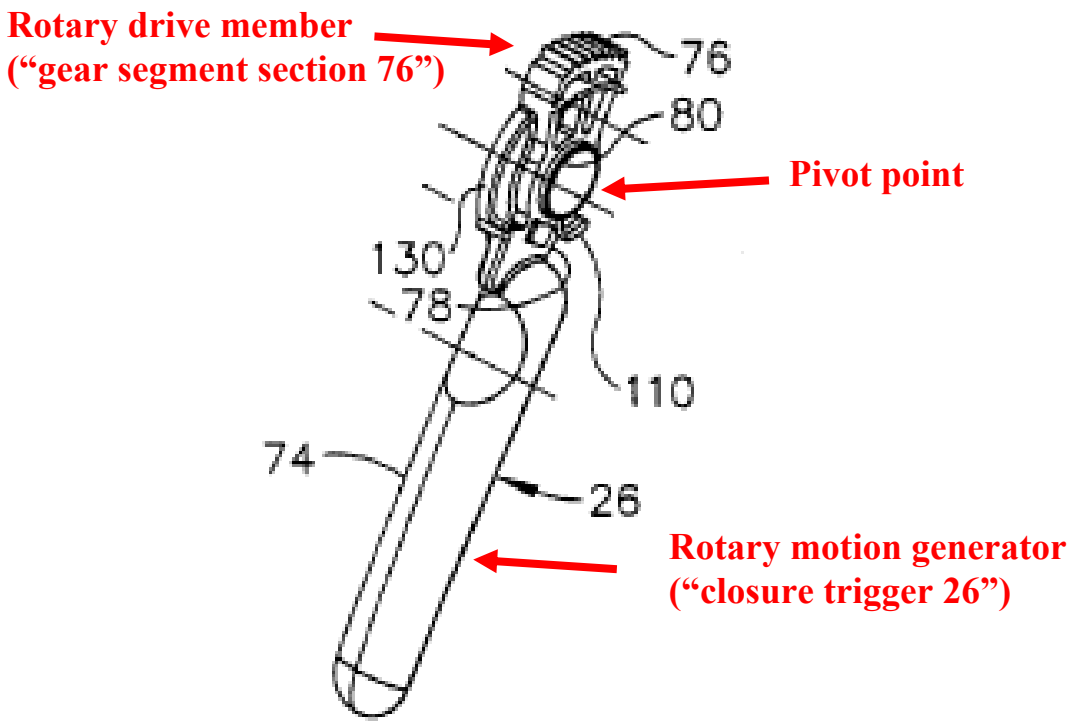
"allowing an unspent staple cartridge [] to be installed into the elongate channel" in the context of Wales, and specifically figures 2, 3, and 4, means that the spent cartridge may be removed and replaced with an unspent staple cartridge. Figures 1 and 2, for example, depict the instrument before first use or after a spent cartridge has been removed. The reason that there would be a "spent cartridge" outside the device is precisely because it has been removed from the device after stapling. IS1003, ¶65. A POSITA would have understood that staple cartridges are ordinarily replaceable in surgical staplers so that the stapler does not have to be thrown out after a single use. A POSITA would have understood that a cartridge to be inserted in the stapler would be replaceable. IS1003, ¶65-66.

[4] The stapling system of claim 1, further comprising a rotary motion generator configured to rotate said rotary drive member.

Wales discloses a rotary motion generator configured to rotate said rotary drive member. IS1003, ¶67. In particular, Wales discloses that "closure trigger 26" with a "handle section 74," which generates a rotary motion that rotates the rotary drive member ("gear segment section 76"). IS1004, 6:33-44. Wales also states:

> A proximal end 98 of the yoke 86 has a gear rack 100 that is engaged by the gear segment section 76 of the closure trigger 26. When the closure trigger 26 is moved toward the pistol grip 24 of the handle portion 20, the yoke 86 and, hence, the closure sleeve 32 move distally . . . .

IS1004, 6:53-64.



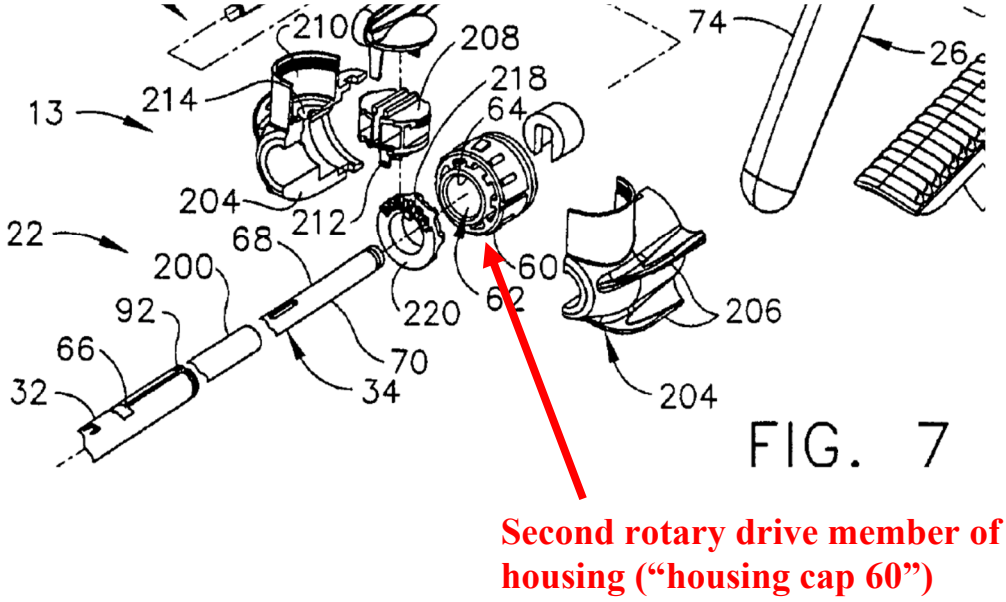
IS1004, FIG. 7 (excerpted).

[5] The stapling system of claim 1, wherein said housing further comprises a second rotary drive member configured to transmit a second operative motion to said end effector.

Wales discloses, within the housing, a second rotary drive member configured to transmit a second operative motion to said end effector. IS1003, ¶68. A second operative motion in Wales is rotation of the end effector about the longitudinal axis. In particular, Wales discloses a "housing cap 60 [that] has a bore 62 extending completely through it for engaging and ***rotating the implement portion 22*** about its longitudinal axis. . . . Thus, the end effector 12 (not shown in

FIGS. 3-4) rotates [around the longitudinal axis] with the housing cap 60."

IS1004, 6:10-21.



[6.1] A stapling system, comprising: a housing comprising a rotary member;

Wales discloses element [6.1]. *See* analysis of element [1.1], *supra*. For the purposes of this petition, the term "rotary drive member" and "rotary member" have the same meaning. Regardless, if the terms were construed differently, "rotary member" would be broader than "rotary drive member," and thus because a "rotary drive member" is found in the prior art, the "rotary member" of this claim is necessarily likewise found in the same prior art disclosure. IS1003, ¶¶69.

[6.2] an elongate shaft extending from said housing, wherein said elongate shaft defines a longitudinal axis;

Wales discloses element [6.2]. *See* analysis of element [1.2], *supra*; IS1003, ¶70.

[6.3] an end effector, comprising: a first jaw;

Wales discloses element [6.3]. *See* analysis of element [1.3], *supra*; IS1003, ¶71. Whereas element [1.3] required a "jaw configured to support a staple cartridge," this element is broader, requiring a "first jaw." Because the prior art has the jaw recited in claim 1, it necessarily has the jaw recited here, which can be the same jaw. IS1003, ¶126.

[6.4] and a second jaw rotatable relative to said first jaw between an open position and a fully-closed position, wherein said second jaw comprises a cam surface;

Wales discloses element [6.4]. *See* analysis of element [1.4], *supra.* IS1003, ¶72. In particular, the "second jaw" of element [6.4] corresponds to the "anvil" of element [1.4].

[6.5] a closure cam operably coupled with said rotary member, wherein said closure cam is configured to move longitudinally to engage said cam surface and transmit a closing motion to said second jaw to move said second jaw into said fully-closed position;

Wales discloses element [6.5]. *See* analysis of element [1.5], *supra.* IS1003, ¶73.

[6.6] and an opening system configured to move longitudinally to apply an opening force to said second jaw at a location other than said cam surface to move said second jaw into said open position.

Wales discloses element [6.6]. *See* analysis of element [1.6], *supra.* IS1003, ¶74. The opening system includes closure ring 250 which moves longitudinally to pull (thus applying an opening force to) the tab on the anvil to open the anvil. The tab is at a location other than the cam surface.

[7] The stapling system of claim 6, further comprising a staple cartridge.

Wales discloses the stapling system of claim 6, further comprising a staple cartridge. *See* analysis of claim 2, *supra.* IS1003, ¶75.

[8] The stapling system of claim 7, wherein said staple cartridge is removably replaceable within said first jaw.

Wales discloses a removably replaceable staple cartridge. *See* analysis of claim 3, *supra.* IS1003, ¶76.

[9] The stapling system of claim 6, further comprising a rotary motion generator configured to rotate said rotary member.

Wales discloses claim 9. *See* analysis of claim 4, *supra.* IS1003, ¶77.

[10] The stapling system of claim 6, wherein said housing further comprises a second rotary member configured to transmit a second operative motion to said end effector.

Wales discloses claim 10. *See* analysis of claim 5, *supra.* IS1003, ¶78.

[11.1] A stapling system, comprising: a housing comprising a rotatable drive member;

Wales discloses element [11.1]. *See* analysis of element [1.1], *supra.* IS1003, ¶¶79. For the purposes of this petition, the term "rotary drive member" and "rotatable drive member" have the same meaning. Regardless, even if the terms were construed differently, the element in the prior art identified as a "rotary drive member" equally meets the term "rotatable drive member." The disclosed "rotary drive member" is certainly "rotatable" and, indeed, does rotate. IS1003, ¶91.

[11.2] an elongate shaft extending from said housing, wherein said elongate shaft comprises a longitudinally-extending tube;

Wales discloses an elongate shaft extending from said housing, wherein said elongate shaft comprises a longitudinally-extending tube. IS1003, ¶80. As Wales explains:

> The surgical and stapling and severing instrument 10 includes a handle portion 20 connected to an implement portion 22, the latter further comprising a shaft 23 distally terminating in the articulating mechanism 11 and the end effector 12.

IS1004, 4:57-64. This may be seen in Figure 1, which depicts shaft 23, which includes a longitudinally-extending tube:

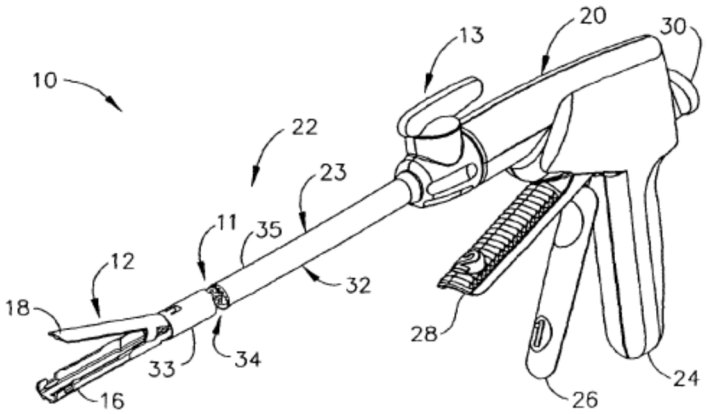
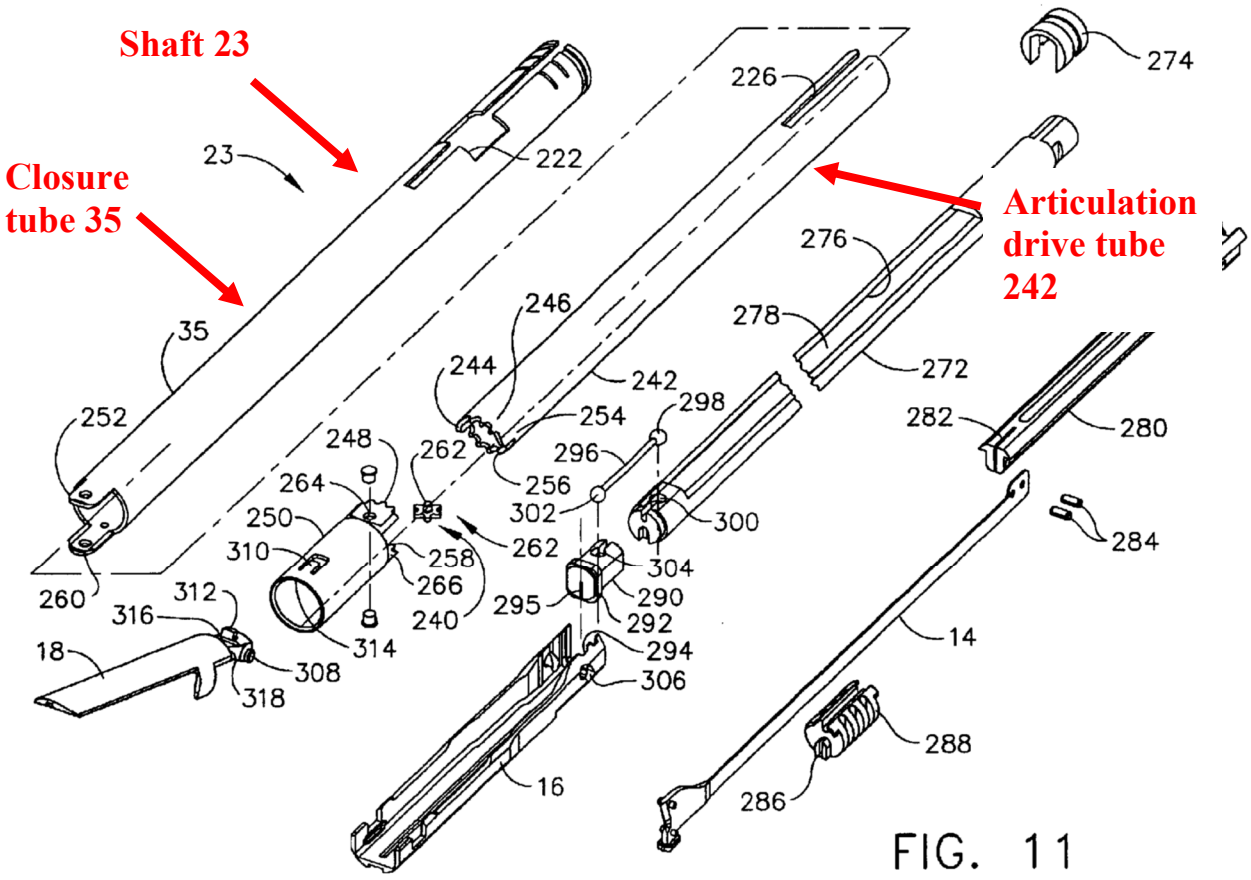


FIG. 1

IS1004, FIG. 1. In fact, the shaft comprises multiple tubes, including closure tube 35 shown above (closure tube 35 and closure ring 250 together form "closure sleeve 32") and articulation drive tube 242:

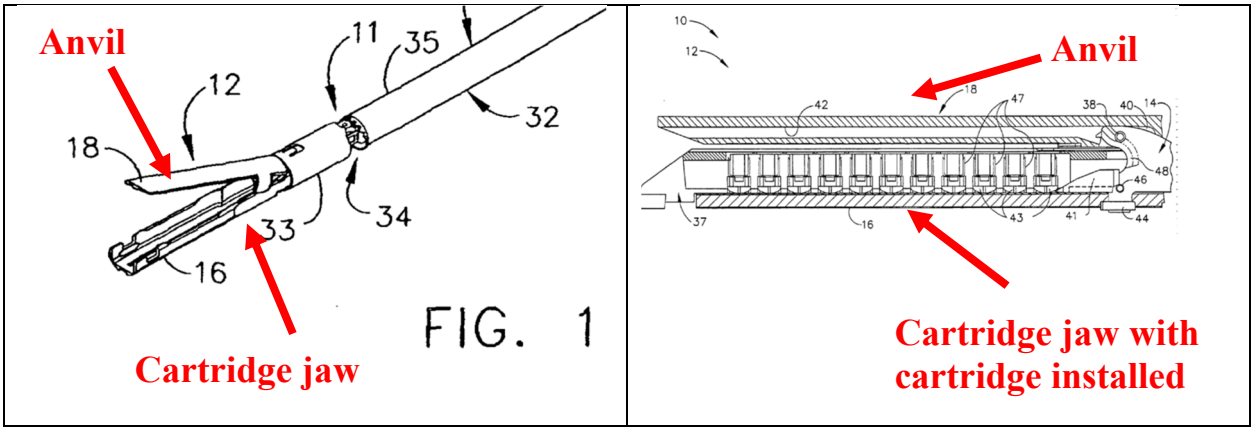


IS1004 at FIG. 11; 4:57-61; 5:4-12; 9:17-20.

[11.3] an end effector, comprising: a staple cartridge jaw comprising staples removably stored therein;

Wales discloses an end effector, comprising: a staple cartridge jaw comprising staples removably stored therein. IS1003, ¶81. In particular, Wales discloses that "[t]he surgical and stapling and severing instrument 10 includes . . . the end effector 12." IS1004, 4:57-64. The end effector 12 contains two jaws, an upper jaw forming an anvil and a lower jaw that receives a removable staple cartridge. The jaw portions 16 and 18 of the effector are shown in both open and

closed positions in FIGS. 1 and 4 of Wales. FIG. 1 discloses the lower jaw without the staple cartridge and FIG. 4 discloses the lower jaw with the cartridge installed:



IS1004, Figs 1 and 4.

Wales discloses staples removably stored in the cartridge jaw. The staple cartridge of Wales houses staples, and the staples are removably stored therein. Specifically, the staples are fired from the cartridge through tissue and formed against the anvil. IS1003, ¶83. A firing trigger causes "the stapling and severing of clamped tissue in the end effector." IS1004 at 4:66-67. Wales further states:

> [M]iddle pin 46 actuates the staple cartridge 37 by entering into a firing slot within the staple cartridge 37, driving a wedge sled 41 into upward camming contact with staple drivers 43 that in turn ***drive a plurality of staples 47 out of staple apertures 51 in the staple cartridge 37 into forming contact with staple pockets 53 on an inner surface of the anvil 18***.

IS1004 at 5:56-64.

[11.4] and an anvil rotatable relative to said staple cartridge jaw between a fully-open position and a fully-clamped position, wherein said anvil comprises a cam surface;

Wales discloses element [11.4]. *See* analysis of elements [1.4], *supra*. Whereas element [1.4] recited an "open position," this element recites a "fully-open position." The analysis for element [1.4] nonetheless applies because Wales discloses a "fully-open position" of the anvil. *See, for example*, IS1004, FIGS. 1 & 3. *See also* IS1003, ¶¶84-85. Indeed, the term "fully-open position" is used only in the claims and the summary of the invention. Throughout the detailed description, the term used is "an open position" or "the open position." *Compare* IS1001, 3:13-14 and 3:24 to *e.g.*, 6:5-8; 6:20-23; 19:24; 51:51-58. There is thus no basis in the '658 patent to distinguish "the open position" from "a fully-open position." Moreover, any differences between the "open position" and "fully-open position" are not material to this petition because Wales discloses a fully-open position. That is, when Wales discloses an open anvil, it is fully open. IS1003, ¶¶84-86.

Element [11.4] also differs from element [1.4] in that this element requires the anvil to rotate to a "fully-clamped position" whereas element [1.4] recites that the anvil rotate into a "fully-closed position." The patent only uses the term "fully-clamped" in the claims and the summary of the invention. Throughout the detailed description, the term used is "clamped," and not "fully-clamped." *Compare*

IS1001, 3:14, 3:21 with 30:6, 33:40, 56:14-16 ("When in the closed position, the tissue to be cut and stapled is properly clamped between the anvil and the surgical staple cartridge.")

Moreover, the precise differences between a "fully-closed position" and "fully clamped position," if any, are not material to this petition because Wales discloses both "fully-closed" and "fully-clamped" positions. That is, when Wales is fully-closed, it is also fully-clamped. IS1003, ¶87. In particular, Wales teaches that its mechanism can cause anvil 18 to either close ***or clamp***. IS1004, 4:57-64 ("The handle portion 20 includes a pistol grip 24 toward which a ***closure trigger 26 is pivotally drawn by the clinician to cause clamping***, or closing, of the anvil 18 toward the elongate channel 16 of the end effector 12."); IS1004, 4:52-56 ("For instance, a firing mechanism, advantageously depicted as an E-beam firing bar 14 (depicted in FIG. 3), that severs ***clamped tissue***, engages an elongate channel 16 and a pivotally attached anvil 18."); IS1004, 4:61-5:2 ("A firing trigger 28 is farther outboard of the closure trigger 26 and is pivotally drawn by the clinician to cause the stapling and severing ***of clamped tissue*** in the end effector 12. Thereafter, a release button 30 is depressed to release ***the clamped tissue***."); IS1004, 7:19-26 (closure trigger set "in a tissue ***clamping*** position.")

Indeed, Wales states: "This camming action closes the anvil 18 downward until the closing face 314 of the closure ring 250 contacts a flat cylindrical face 318

of the anvil 18." When the two faces meet, the anvil has been fully clamped by the force of the closing face against the flat face of the anvil. IS1004, 10:19-30; IS1003, ¶88.

[11.5] a clamping cam operably coupled with said rotatable drive member, wherein said clamping cam is configured to move longitudinally to engage said cam surface and transmit a clamping force to said anvil to move said anvil into said fully-clamped position;

Wales discloses element [11.5]. *See* analysis of elements [1.5], *supra.* IS1003, ¶89. For the purposes of this petition, the term "rotary drive member" and "rotatable drive member" have the same meaning. Regardless, even if the terms were construed differently, the element in the prior art identified as a "rotary drive member" equally meets the term "rotatable drive member." The disclosed "rotary drive member" is certainly "rotatable" and, indeed, does rotate. IS1003, ¶91.

In addition, as discussed with respect to element [11.4], the closing mechanism of Wales also provides clamping. Thus, the element corresponding to the closure cam also serves as a clamping cam, and accordingly the analysis for element [11.4] is fully applicable here. The "closing face" of the closure tube or closure ring provides both a closing and clamping force to the anvil. Indeed, Wales states that "[t]his camming action closes the anvil 18 downward until the closing face 314 of the closure ring 250 contacts a flat cylindrical face 318 of the anvil 18." When the two faces meet, the anvil has been clamped by the force of the closing face against the flat face of the anvil. IS1004 at 10:19-30; IS1003, ¶90.

[11.6] and an opening member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil into said fully-open position.

Wales discloses element [11.6]. *See* analysis of element [1.6], *supra*.

IS1003, ¶92. *See also* analysis of element [11.4] regarding the applicability of the analysis re "open position" to the "fully-open position." Wales discloses a closure ring that pulls the tab on the anvil to move the anvil into a "fully-open position."

[12] The stapling system of claim 11, further comprising a rotary motion generator configured to rotate said rotatable drive member.

Wales discloses claim 12. *See* analysis of claim 4, *supra.* IS1003, ¶93.

[13] The stapling system of claim 11, wherein said housing further comprises a second rotatable drive member configured to transmit a second operative motion to said end effector.

Wales discloses claim 13. *See* analysis of claim 5, *supra*; IS1003, ¶94.

[14.1] A stapling system, comprising: a housing comprising a rotatable drive member;

Wales discloses element [14.1]. *See* analysis of element [11.1], *supra.*

IS1003, ¶95.

[14.2] an elongate shaft extending from said housing, wherein said elongate shaft comprises a longitudinally-extending tube;

Wales discloses element [14.2]. *See* analysis of element [11.2], *supra.*

IS1003, ¶96.

[14.3] an end effector, comprising: a staple cartridge jaw comprising staples removably stored therein;

Wales discloses element [14.3]. *See* analysis of element [11.3], *supra.*

IS1003, ¶97.

[14.4] and an anvil rotatable relative to said staple cartridge jaw between a fully-open position and a fully-clamped position, wherein said anvil comprises a cam surface;

Wales discloses element [14.4]. *See* analysis of element [11.4], *supra.*

IS1003, ¶98.

[14.5] a clamping cam operably coupled with said rotatable drive member, wherein said clamping cam is configured to move longitudinally to engage said cam surface and transmit a clamping force to said anvil to move said anvil into said fully-clamped position;

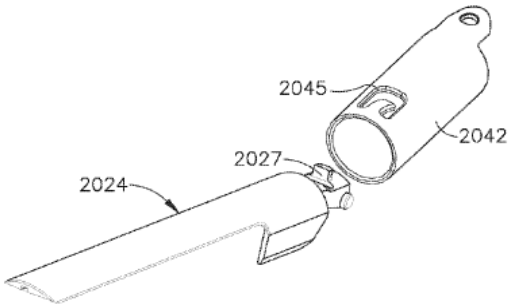
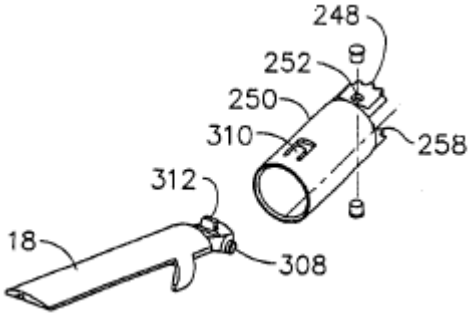
Wales discloses element [14.5]. *See* analysis of element [11.5], *supra.*

IS1003, ¶99.

[14.6] and a pulling member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil.

Wales discloses a pulling member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil. IS1003, ¶100. *See* analysis of element [1.6]. The "opening force" of element [1.6] in Wales is accomplished by a pulling force applied by the tab in the opening of the closure ring, which is a pulling member. That is, the anvil is pulled from the top rather than pushed up from the bottom. Wales discloses: "The closure ring 250 . . . includes a distally presented tab 310 that engages an anvil feature 312 proximate but distal to the anvil pivot 308 on the anvil 18 to thereby effect opening." IS1004, 10:20-30. Indeed, this is the identical structure disclosed by the

'658 patent. *Compare id. with* IS1001, 30:26-29, 30:57-61, 32:43-46; *see also* IS1003, ¶100.

	
'658 Patent FIG. 44 (excerpted)	Wales FIG. 11 (excerpted)

B. Ground 2: Claims 3 and 8 would have been Obvious under § 103 over Wales in view of Knodel

[3] The stapling system of claim 2, wherein said staple cartridge is removably replaceable within said jaw.

[8] The stapling system of claim 7, wherein said staple cartridge is removably replaceable within said first jaw.

As explained above, a POSITA would have understood that Wales discloses a removably replaceable cartridge as recited in claims 3 and 8, and thus Wales anticipates these claims.

Alternatively, it would at least have been obvious to a POSITA at the time of the filing of the '658 patent to use replaceable cartridges, as was common practice at the time. IS1003, ¶¶102-108. There are multiple reasons that a POSITA would have used a replaceable cartridge with the Wales stapler. **First**, a POSITA would have known that if the cartridge could not be replaced, then the entire instrument

would have to be thrown out after one use, and a POSITA would have known that such a design would be wasteful and unnecessary. Although single use products existed, a POSITA would understand that Wales' design, with its insertable cartridge, is not such a product. IS1003, ¶107.

Second, a POSITA would have recognized that the cartridge in Wales is inserted after the instrument is assembled, and that it is not part of the base assembly. IS1003, ¶¶66-67. A POSITA would have further recognized that there is no mechanism disclosed to permanently affix the cartridge in place after it is inserted into the channel. IS1003, ¶102.

Third, the prior art teaches advantages of replaceable cartridges, and a POSITA would have applied such teachings to the Wales instrument. For example, Knodel teaches a replaceable cartridge for use in surgical staplers, and a POSITA would have applied that teaching to the cartridge in Wales:

> Reference is now made to FIG. 1, which illustrates a surgical stapler and severing instrument 100 formed in accordance with the present invention. The stapler instrument 100 includes an implement portion 110 having an elongated channel 112 and an anvil 114, see also FIGS. 2 and 3. ***A distal end 112a of the elongated channel 112 releasably receives a staple cartridge 120.***

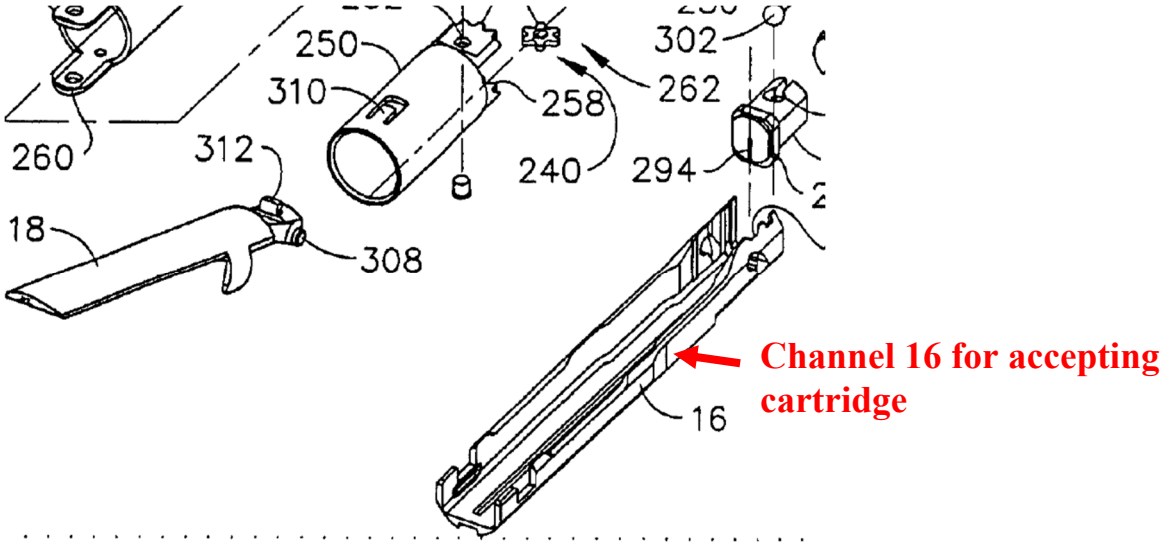
IS1005, 5:52-58, 12:18 ("The spent cartridge is then discarded."); IS1003, ¶104; *see also* IS1005, 6:61-7:9, 11:40-42 ("A fully loaded cartridge 120 is snap-fitted

into the distal end 112a of the channel 112."), Fig. 2..

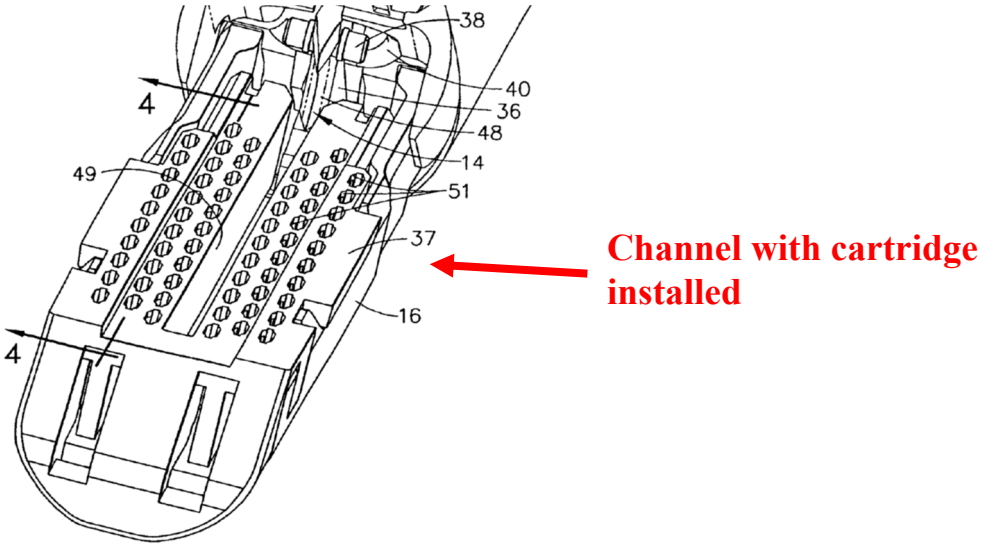
A POSITA would have recognized that both Knodel and Wales concern endoscopic surgical staplers with cartridges and thus a POSITA would have looked to both references when designing a surgical stapler with a cartridge. IS1003, ¶¶106-107. A POSITA would have seen that Knodel describes replaceable stapler cartridges for surgical staplers as desirable, and that Wales discloses just such a device. A POSITA applying the teachings of Wales in designing a stapler would have also been motivated to investigate and advantageously apply the teachings of other patents of the same company, Patent Owner Ethicon, such as Knodel. *Id*. Accordingly, a POSITA would have applied the teachings of a replaceable surgical stapler cartridge to Wales, to the extent the POSITA did not recognize Wales already had such a disclosure. *Id*.

Fourth, Wales discloses that an "unspent staple cartridge 37" is "installed into the elongate channel 16." IS1004, 5:34-43; *see also id.* FIG. 3. Even if a POSITA hypothetically would have failed to understand that a spent cartridge must be removable in order for an unspent cartridge to be inserted in the stapler described in Wales, a POSITA would have used replaceable cartridges based upon the teachings of Wales in view of Knodel. A POSITA would have further recognized that there would be little, if any, reason to add structure to prevent removal of an inserted cartridge after installation, which would be contrary to

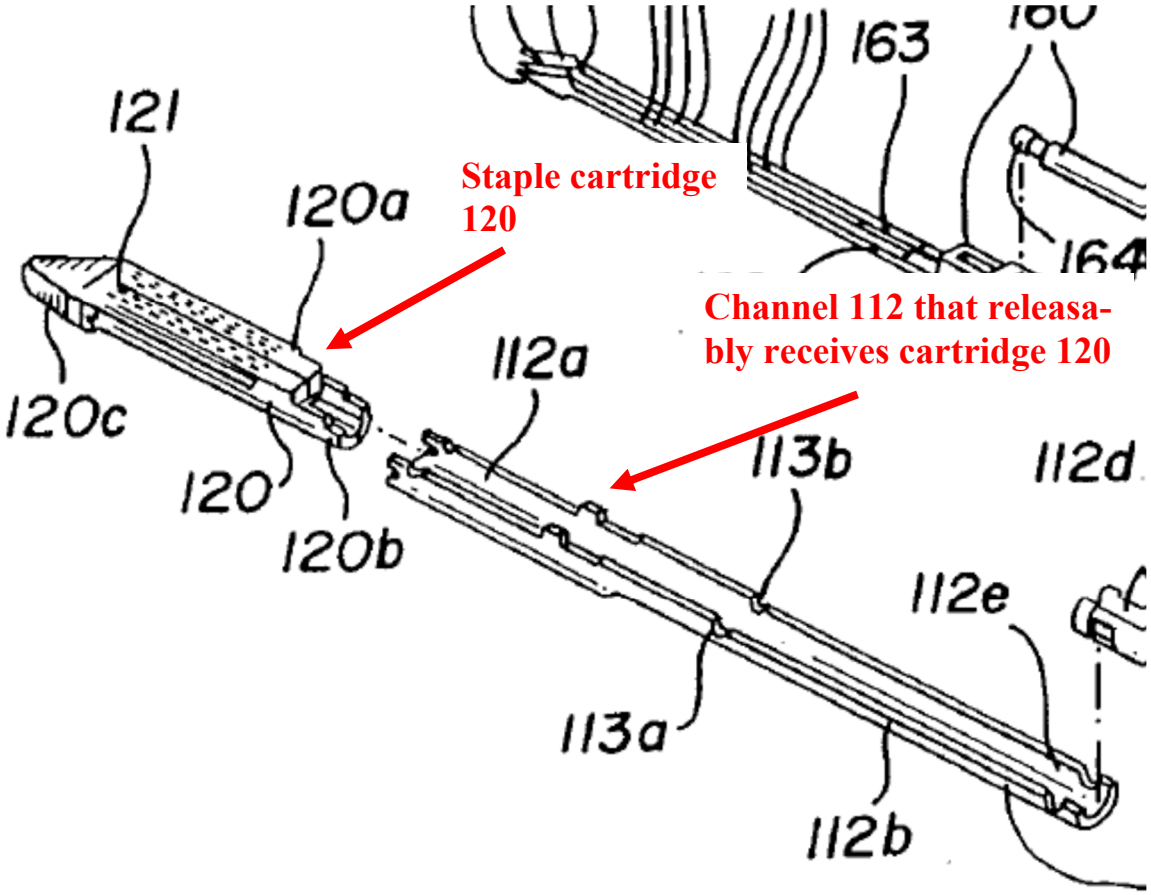
conventional practice. IS1003, ¶107. Moreover, the channel 16 of Wales is substantially similar to the channel of Knodel, and a POSITA would have recognized that both are able to accommodate replaceable cartridges. *Id.*; *compare* Wales, FIGS. 3 and 11 *with* Knodel, FIG. 1:



IS1004 at FIG. 11 (excerpt)



IS1004 at FIG. 3 (excerpt)



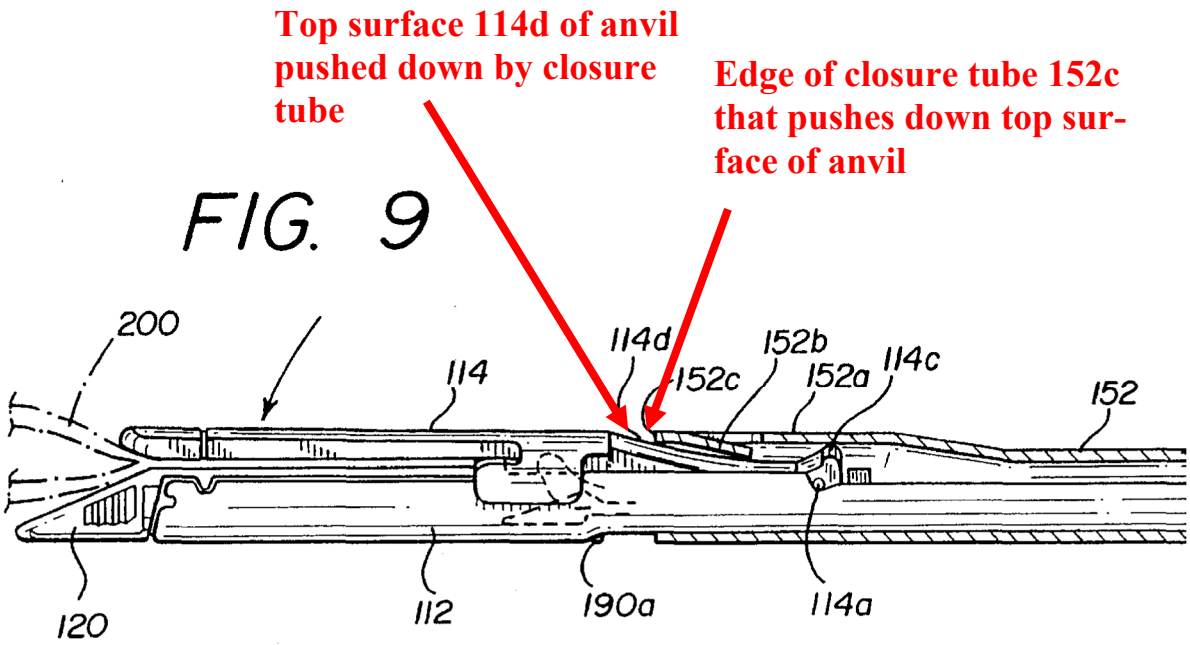
IS1005, FIG. 1 (excerpt)

Finally, a POSITA would have been motivated to combine Wales and Knodel because both disclose surgical staplers with similar end effectors. IS1003, ¶108. In fact, Knodel not only discloses a surgical stapler endoscopic end effector with a staple cartridge and anvil, but Knodel also discloses a closure tube that pushes the anvil down at one location and pulls the anvil up at another location, just like Wales (and the '658 patent). For example, Knodel discloses a closure tube with a distal edge that pushes down the top surface of the anvil:

> The outer distal edge 152c of the closure tube 152 defines a camming surface. When the closure tube 152 moves distally, the distal edge 152c

engages an upper portion 114d of the anvil 114 causing the anvil 114 to pivot toward the distal end 112a of the channel 112 to its tissue-clamping position, see FIGS. 4 and 9.

IS1005 at 7:43-49.

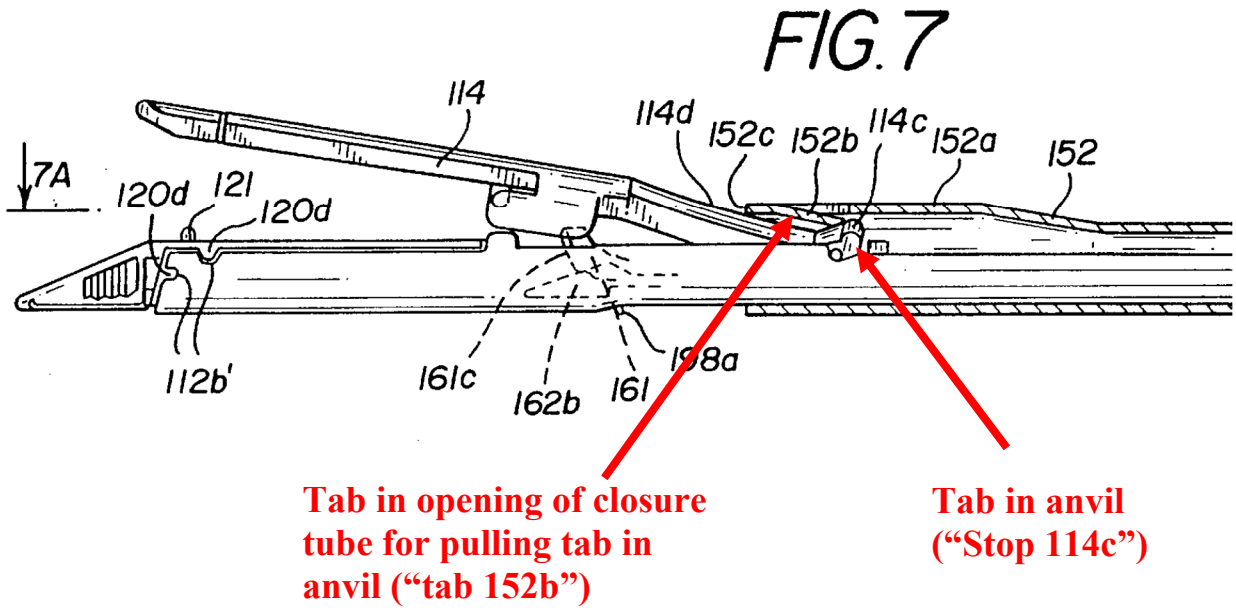


IS1005 at FIG. 9.

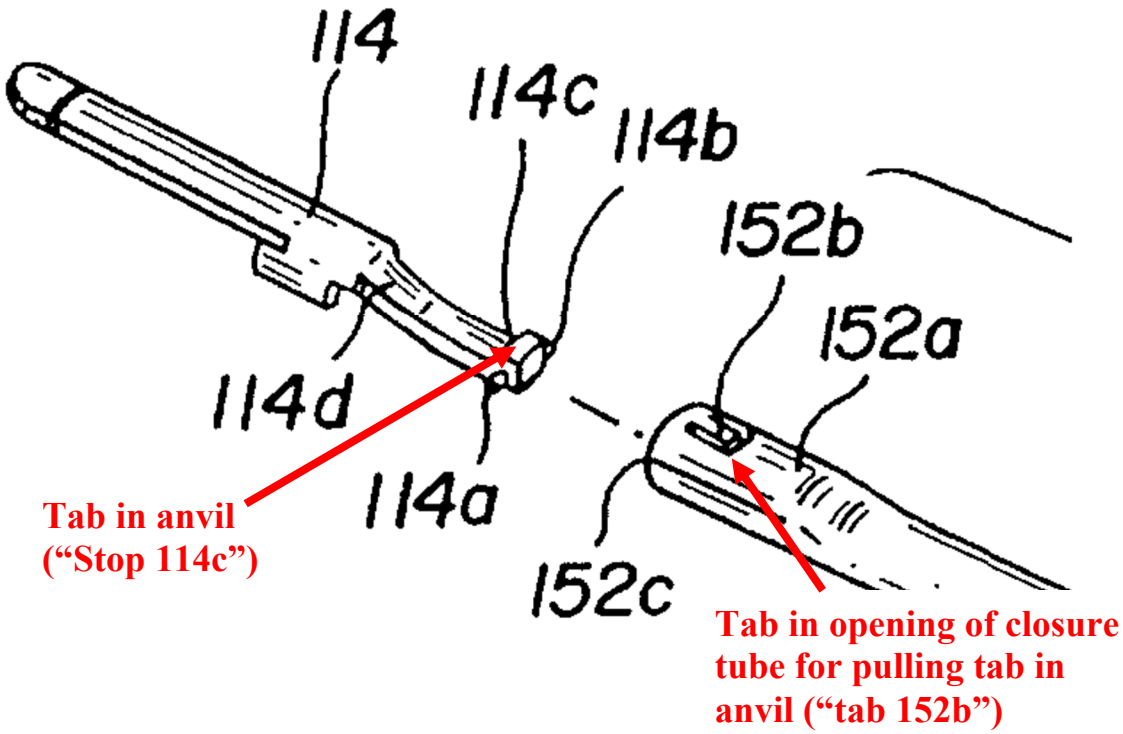
Knodel also discloses an opening and tab in the closure tube that pulls a tab on the anvil to move the anvil into the open position:

A stop 114c is provided at the proximal end of the anvil 114, see FIG. 8A. Upon proximal movement of the closure tube 152, the tab 152b engages the stop 114c to pivot the anvil 114 away from the distal end 112a of the channel 112, see FIG. 7.

IS1005 at 7:39-43.



IS1005 at FIG. 7. A perspective view of these structures is shown in FIG. 2:



IS1005 at FIG. 2 (excerpt). Accordingly, a POSITA would have recognized the

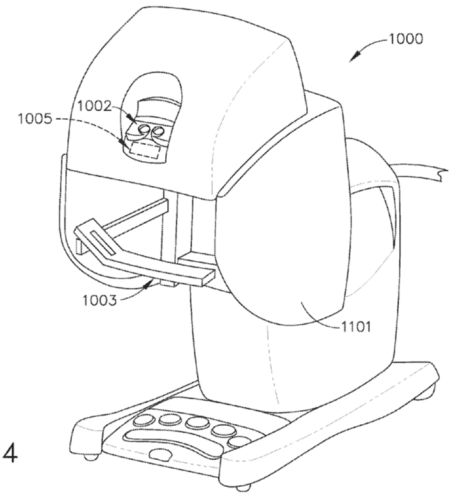
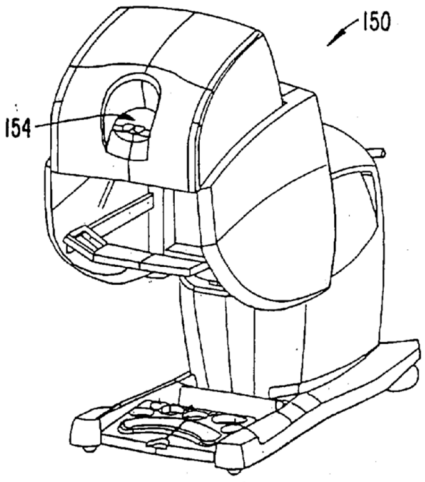
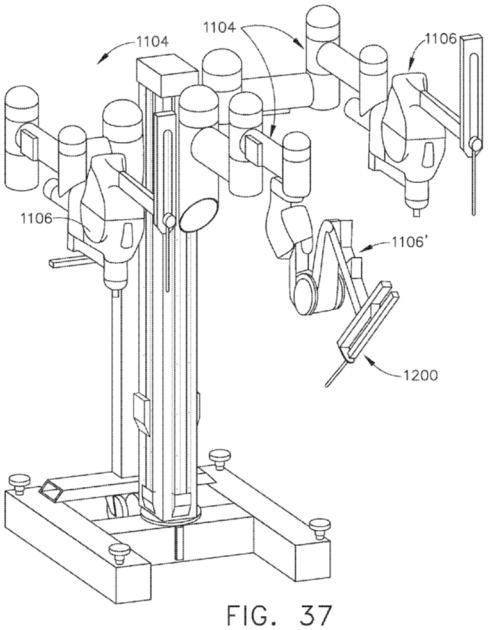
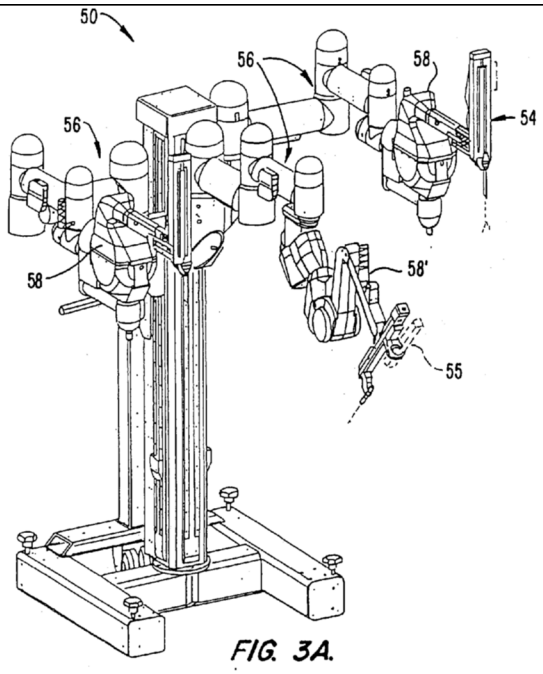
extensive similarities between Wales and Knodel and combine features of both devices accordingly, including the feature of the replaceable staple cartridge. IS1003, ¶¶102-108.

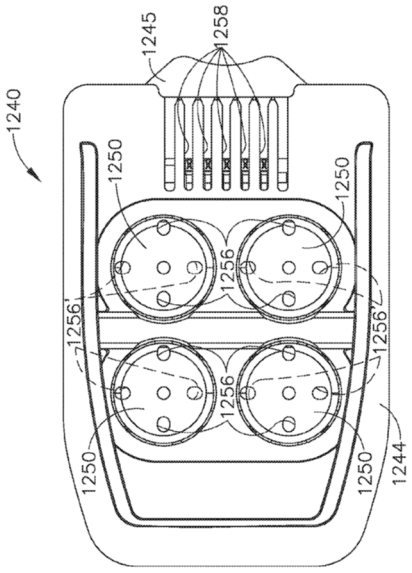
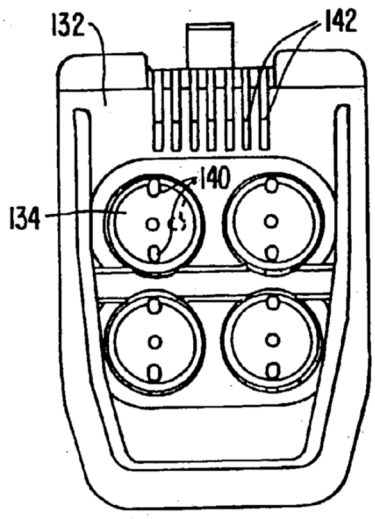
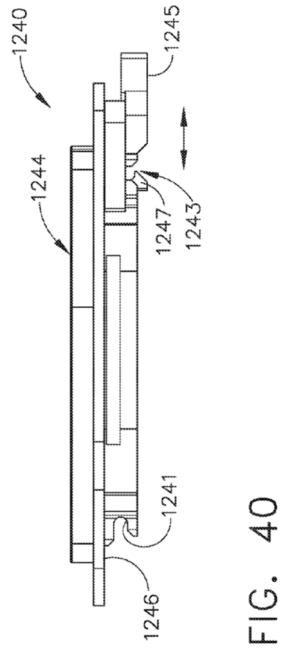
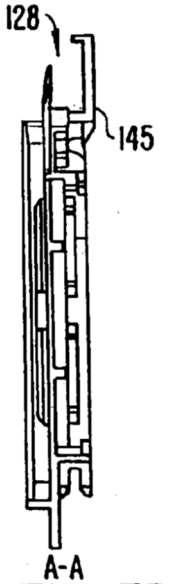
C. Ground 3: Claims 1-14 would have been Obvious under § 103 Over Wales in View of Tierney

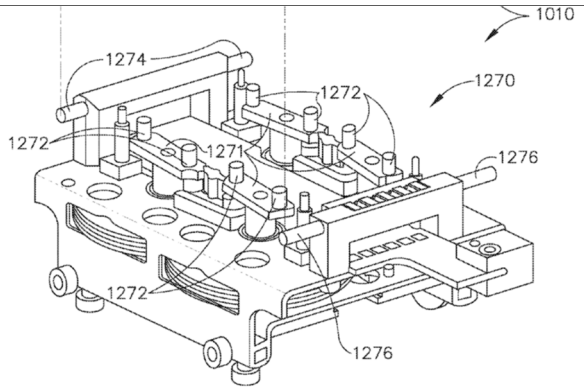
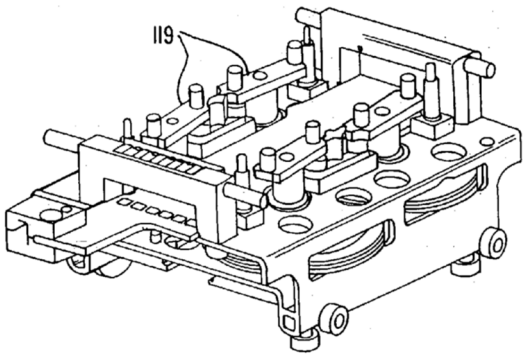
As discussed above, Wales alone or in combination with Knodel discloses and/or would have rendered obvious all elements of claims 1-14.

If Wales is deemed not to disclose the "rotary drive member," "rotatory member," "rotatable drive member," and/or "rotary motion generator," then each and every claim would have been obvious over Wales (or Wales and Knodel as described above) in view of Tierney.

Tierney discloses the same robotic interface as disclosed in the '658 patent and, indeed, the '658 patent incorporates the patent issuing to Tierney by reference and includes figures that were either copied from Tierney or substantially based on figures from Tierney:

The ’658 Patent	**Tierney Prior Art**
 FIG. 34	 FIG. 8B.
Robotic Controller	
 FIG. 37	 FIG. 3A.
Robotic Cart Structure with Linkages	

The '658 Patent	**Tierney Prior Art**
 FIG. 42	 FIG. 7C.
Adapter for Coupling Instrument to Robot	
 FIG. 40	 FIG. 7D.
Side View of Adapter	

The '658 Patent	**Tierney Prior Art**
 FIG. 39	 FIG. 7J.
Robotic Tool Holder with Driving Elements	

Tierney teaches a robotic surgical system that can accommodate various surgical tools. The tools are controlled, in part, by rotatable driven disks that receive rotary motion from driving elements on the robot arms and use that rotary motions to control the movement of surgical end effectors. IS1006, FIGs. 7C, 7J (above). "This invention relates to robotically assisted surgery, and more particularly provides surgical tools having improved mechanical and/or data interface capabilities to enhance the safety, accuracy, and speed of minimally invasive and other robotically enhanced surgical procedures." IS1006 at ¶3. Tierney notes that "a surgeon will typically employ a significant number of different surgical instruments during each surgical procedure" and that "a number of surgical instruments will often be attached and detached from a single instrument holder of a manipulator during an operation." IS1006 at ¶5.

There are multiple reasons why a POSITA would have been motivated to modify the Wales instrument based on the teachings of Tierney so that the Wales instrument could be connected to the Tierney robot. IS1003, ¶113. **First**, Wales specifically states that its instrument would be useful in remote control (that is, robotic) applications: "For yet another example, although an illustrative handle portion 20 described herein is manually operated by a clinician, it is consistent with aspects of the invention for some or all of the functions of a handle portion to be powered (e.g., pneumatic, hydraulic, electromechanical, ultrasonic, etc.). Furthermore, controls of each of these functions may be manually presented on a handle portion or be remotely controlled (e.g., wireless remote, ***automated remote console,*** etc.)." IS1004 at 13:15-22; IS1003, ¶150.

Second, Tierney specifically contemplates that its surgical robot would be used with a variety of surgical instruments, including surgical staplers: "The present invention provides robotic surgery systems, devices, and methods. Robotic surgery will generally involve the use of multiple robotic arms. One or more of ***the robotic arms will often support a surgical tool*** which may be articulated (***such as*** jaws, scissors, graspers, needle holders, microdissectors, ***staple appliers***, tackers, suction/irrigation tools, clip appliers, or the like)." IS1006 at ¶¶42, 59; IS1003, ¶151.

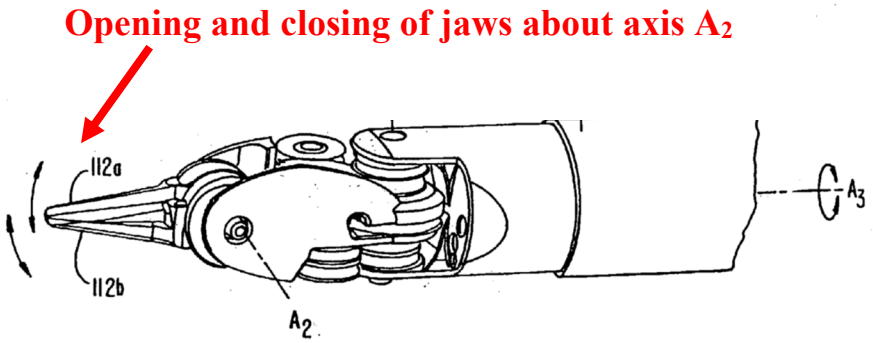
Third, Tierney teaches the benefits of the use of surgical robots. "The

invention will also have applications for surgical procedures which are difficult to perform using existing minimally invasive techniques, such as Nissen Fundoplications. Additionally, it is anticipated that these surgical systems will find uses in entirely new surgeries that would be difficult and/or impossible to perform using traditionally open or known minimally invasive techniques." IS1006 at ¶43. Tierney also teaches that its surgical robot provides for more rapid tool changes, leading to enhanced safety and reliability, and thus further suggests that multiple tools will be adapted for coupling to the Tierney robot. IS1006 at ¶8; IS1003, ¶156.

Tierney discloses that four or more motions of an end effector may be controlled by the four driven elements on the robotic interface. Tierney specifically states that those motions may include the opening and closing of jaws. For example:

> As illustrated in FIG. 4A, a drive system 116 mechanically couples first and second end effector elements 112a, 112b to driven elements 118 of interface 110. Drive system 116 is more fully described in U.S. Pat. No. 5,792,135, the full disclosure of which is incorporated herein by reference. Stated simply, the drive system translates mechanical inputs from driven elements 118 into articulation of the wrist about first and second axes Al, A2, as well as into actuation of the two element end effector by relative movement of the end effector elements about axis A2.

IS1006, ¶56.



A POSITA would have applied the teachings of Tierney to Wales to use one of the rotatable driven elements to open and close the anvil of Wales. IS1003, ¶113. Thus, the combination of Wales and Tierney would have resulted in a surgical stapler for a robotic system where one of the rotatable driven discs is used to drive a closure tube back and forth to open and close an anvil. A POSITA would have readily understood how to implement the combination after reviewing the teachings of Wales and Tierney. IS1003, ¶156.

[1.1] A stapling system, comprising: a housing comprising a rotary drive member;

Wales in view of Tierney discloses this element. IS1003, ¶¶111-114. In Ground 1, Petitioner has shown that Wales discloses this element, and identified "Gear Segment Section 76" as the "rotary drive member." Alternatively, a POSITA would have modified Wales pursuant to the teachings of Tierney to replace the handle in Wales with a robotic tool mounting structure which has the same rotary drive member as that disclosed in the '658 patent. The resulting instrument would combine the tool of Wales with the interface of Tierney. In the

combination, the interface would provide a rotary drive member that is essentially the same as the structure disclosed in the robotic embodiment of the '658 patent. The interface would include a "housing comprising a rotary drive member." In Tierney, "[i]nterface 110 of a proximal housing 108 is illustrated in FIG. 6. As seen schematically in FIG. 4A, driven elements 118 each include a pair of pins 122 extending from a surface of the driven element." IS1006 at ¶60. The "driven elements 118" are the rotary drive members in Tierney.

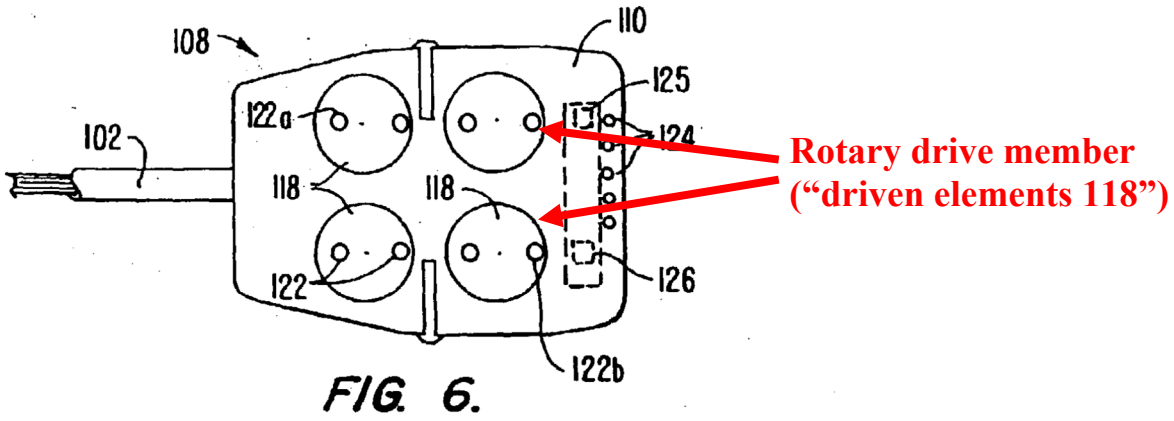


FIG. 6.

IS1006, FIG. 6. Like the '658 patent, the driven elements of Tierney receive rotary power from the robot manipulator arm and provide mechanical power to the connected tools. For example, "[s]tated simply, the drive system translates mechanical inputs from driven elements 118 into articulation of the wrist about first and second axes A1, A2, as well as into actuation of the two element end effector by relative movement of the end effector elements about axis A2." IS1006 at ¶56.

Tierney discloses that its robotic interface is readily adaptable to any tool drive system. "A wide variety of alternative drive systems might be employed, including alternative cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like. In some of these drive systems, motion of end effector 112 about the axes may be coupled to multiple driven elements 118. In other embodiments, there may be a one to one correspondence between driven elements 118 and motion of an end effector element about an axis." IS1006 at ¶57. Thus, a POSITA would have readily understood that the robotic interface of Tierney could be coupled to the tool assembly of Wales to produce the claimed structure of the '658 patent. Compare the driven element 118 of Tierney, above, to the closure gear 2110 of the '658 patent, shown in FIG. 47, which is coupled to one of the "driven discs 1304," shown in FIG. 43. IS1001 at 32:4-8; IS1003, ¶114:

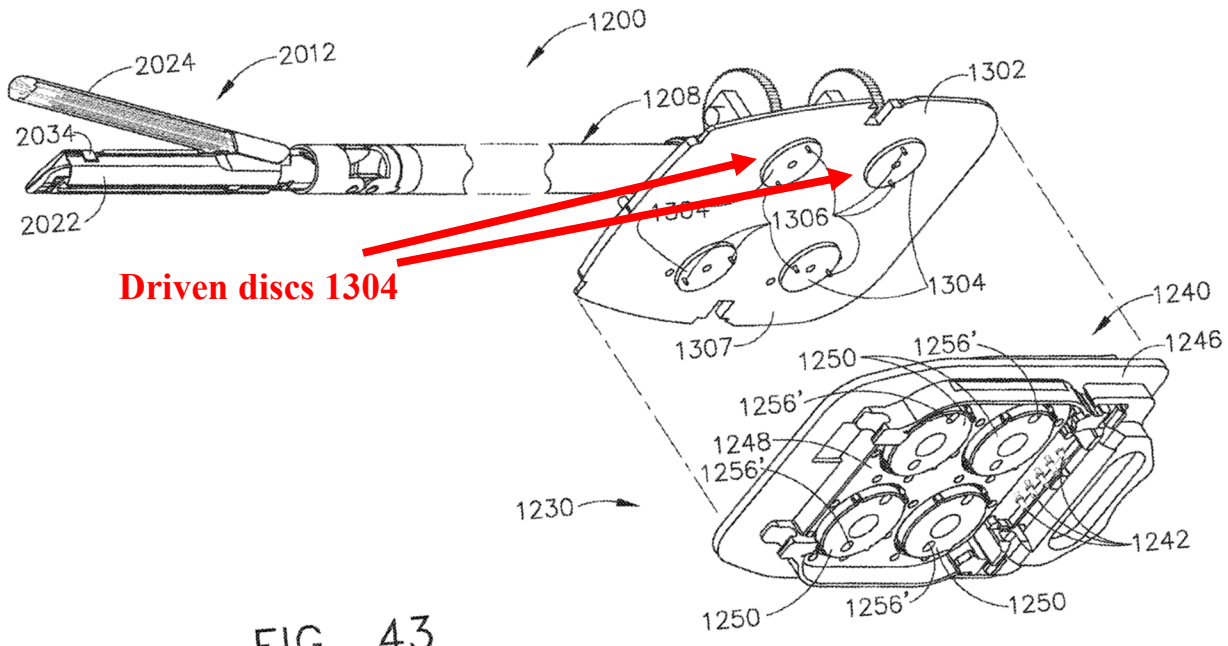


FIG. 43

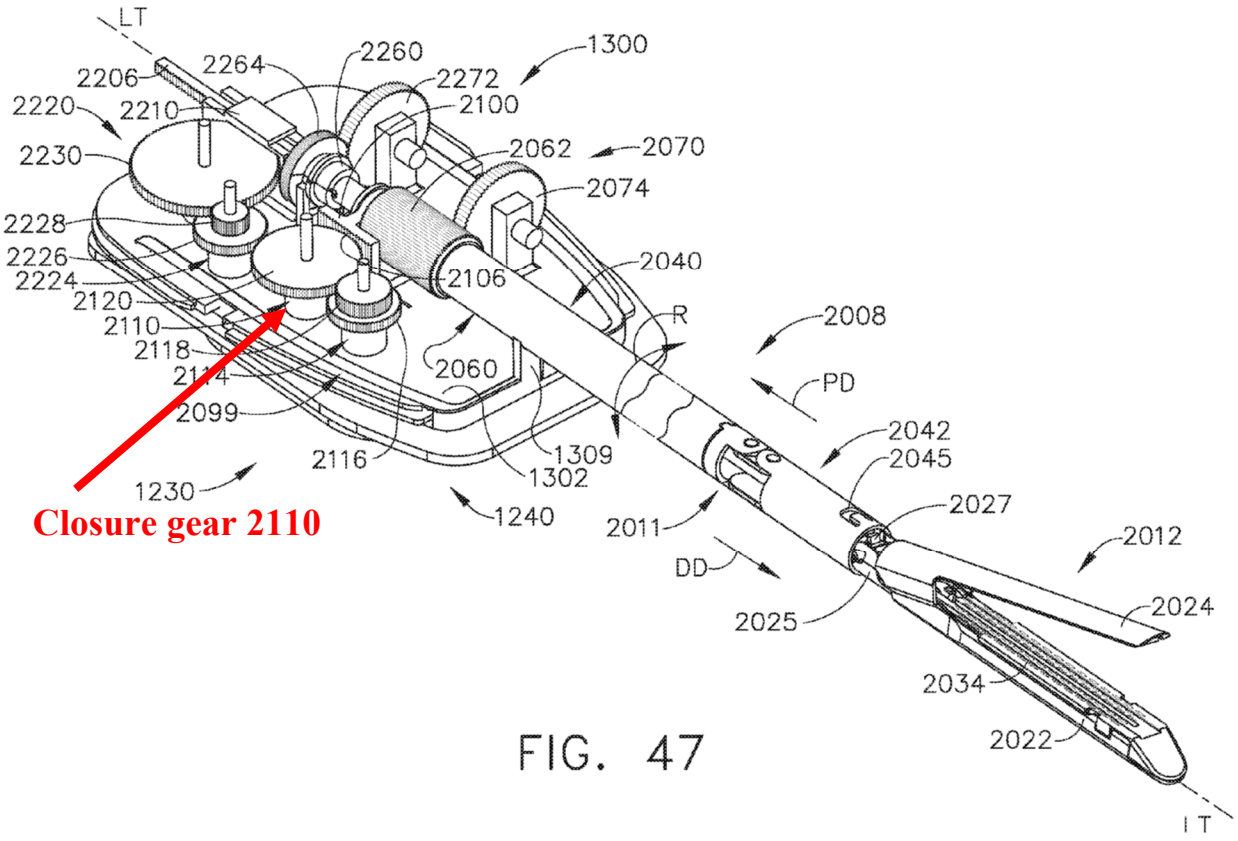
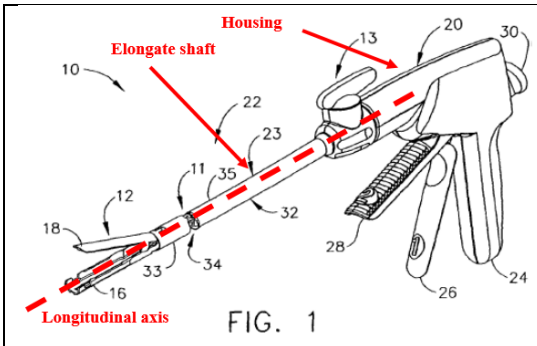
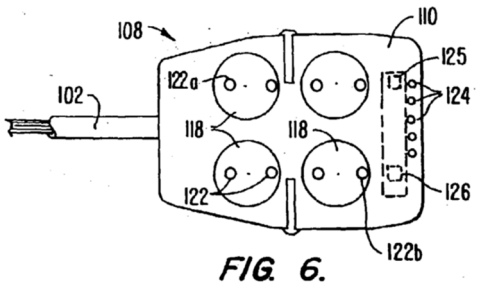


FIG. 47

[1.2] an elongate shaft extending from said housing, wherein said elongate shaft defines a longitudinal axis;

Wales in view of Tierney discloses this element. In the combination, the handle of the Wales instrument is replaced by the interface of Tierney such that the combination has an elongate shaft extending from the robotic interface housing instead of the handle housing, wherein said elongate shaft defines a longitudinal axis. IS1003, ¶115. *See* IS1004, FIG. 1 and IS1006, FIG. 6; *see* analysis in Ground 1, element [1.2].

 FIG. 1	 FIG. 6.
Wales, FIG. 1	**Tierney, FIG. 6**

[1.3] an end effector, comprising: a jaw configured to support a staple cartridge;

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales connected via the elongated shaft of Wales to the robotic interface housing of Tierney. Wales discloses an end effector comprising a jaw configured to support a staple cartridge. IS1003, ¶116. *See* analysis in Ground 1 for element [1.3].

[1.4] and an anvil rotatable relative to said jaw between an open position and a fully-closed position, wherein said anvil comprises a cam surface;

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales. Wales discloses an anvil rotatable relative to the lower jaw that contains the cartridge between an open position and a fully-closed position, wherein the anvil comprises a cam surface. IS1003, ¶117. *See* analysis in Ground 1 for element [1.4].

[1.5] a closure cam operably coupled with said rotary drive member, wherein said closure cam is configured to move longitudinally to engage said cam surface and transmit a closing motion to said anvil to move said anvil into said fully-closed position;

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales. Wales discloses a closure cam operably coupled with the rotary drive member, wherein said closure cam is configured to move longitudinally to engage the cam surface and transmit a closing motion to said anvil to move said anvil into said fully-closed position. In the combination, the driven element 118 of Tierney replaces the rotary drive member of Wales. IS1003, ¶118. *See* analysis in Ground 1 for element [1.5].

[1.6] and an opening member configured to move longitudinally to apply an opening force to said anvil at a location other than said cam surface to move said anvil into said open position.

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales. Wales discloses an opening member configured to move longitudinally to apply an opening force to said anvil at a location other than said cam surface to move said anvil into said open position. IS1003, ¶119. *See* analysis in Ground 1 for element [1.6].

[2] The stapling system of claim 1, further comprising said staple cartridge.

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales. Wales discloses the stapling system of claim 1, further comprising said staple cartridge. IS1003, ¶120. *See* analysis in Ground 1

for claim 2.

[3] The stapling system of claim 2, wherein said staple cartridge is removably replaceable within said jaw.

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales. Wales discloses the stapling system of claim 2, wherein said staple cartridge is removably replaceable within said jaw. IS1003, ¶121. *See* analysis for Ground 1, claim 3.

[4] The stapling system of claim 1, further comprising a rotary motion generator configured to rotate said rotary drive member.

Wales in view of Tierney discloses this element. The "drive elements 119" on the robot arm drive the "rotatable bodies 134" on the adapter, which in turn drive the "driven elements 118." "As seen schematically in FIG. 4A, driven elements 118 provide mechanical coupling of the end effector to drive motors mounted to the manipulator." IS1006 at ¶60. The rotational motion is provided from the drive elements to the driven elements via the adaptor. "The adapter comprises a plurality of movable bodies. Each movable body has a first surface driven by the drive elements of the holder, and a second surface driving the driven elements of the tool." IS1006 at ¶19; IS1003 at ¶122.

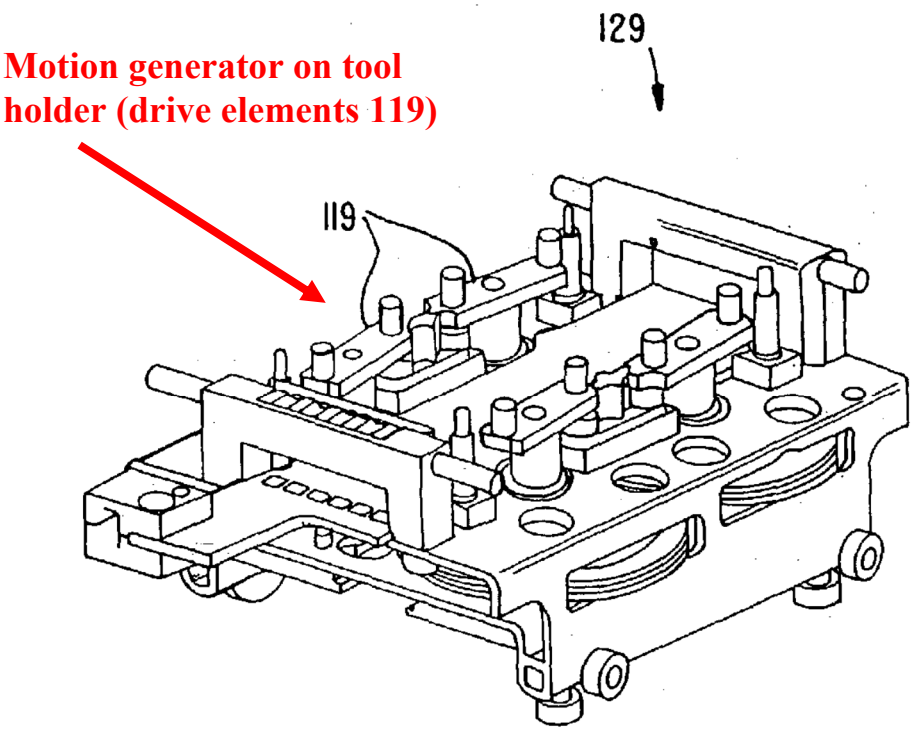


FIG. 7J.

In the combination, the rotary drive member corresponds to the "driven elements 118" on the tool. The rotary motion generator is either the "rotatable bodies 134" or the "drive elements 119," both of which are configured to rotate the "driven elements 118." "Openings 140 on the tool side 130 and holder side 132 of rotatable bodies 134 are configured to accurately align the driven elements 118 of the tool with the drive elements of the holder." IS1006 at ¶67; IS1003, ¶122. As shown in FIG. 7E of Tierney, the "rotatable bodies 134" on "adaptor 128" drive the driven elements 118 on the tool such that the driven elements 118 rotate.

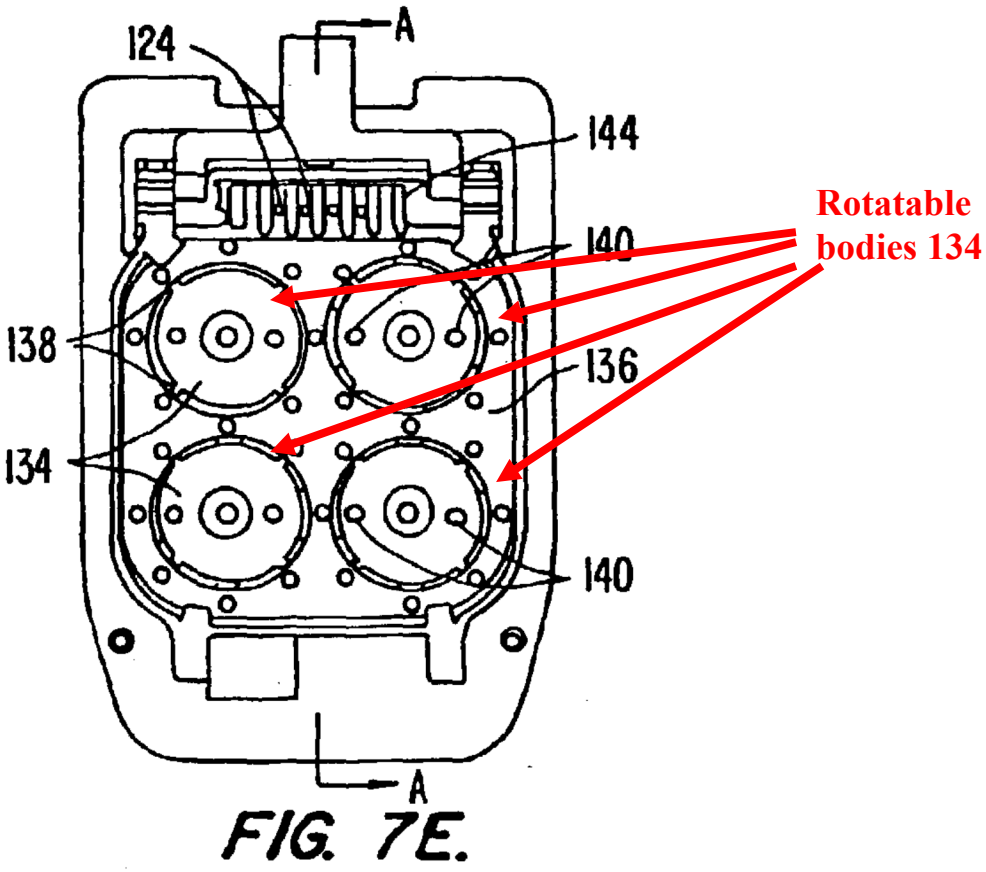


FIG. 7E.

IS1006 at FIG. 7; *see also Id.* at ¶67, 7F-7L. IS1003, ¶122.

[5] The stapling system of claim 1, wherein said housing further comprises a second rotary drive member configured to transmit a second operative motion to said end effector.

Wales in view of Tierney discloses this element. The combination has a housing including a second rotary drive member configured to transmit a second operative motion to said end effector. IS1003, ¶123. For example, FIG. 7, above, discloses four rotatable bodies, and each drives a respective driven element 118. Tierney discloses that each driven elements 118 can transmit operative motions to the end effector, such as wrist articulation and rotation. For example, "the drive

system translates mechanical inputs from driven elements 118 into articulation of the wrist about first and second axes Al, A2, as well as into actuation of the two element end effector by relative movement of the end effector elements about axis A2. In addition, driven elements 118 can effect rotation of the end effector about the axis of shaft 102 (A3) by rotating the shaft relative to proximal housing 108." IS1006 at ¶56.

[6.1] A stapling system, comprising: a housing comprising a rotary member;

Wales in view of Tierney discloses element [6.1]. *See* analysis in this Ground of element [1.1]. For the purposes of this petition, the term "rotary drive member" and "rotary member" have the same meaning. Regardless, if the terms were construed differently, "rotary member" would be broader than "rotary drive member," and thus because a "rotary drive member" is found in the prior art, the "rotary member" of this claim is necessarily likewise found in the prior art. IS1003, ¶124.

[6.2] an elongate shaft extending from said housing, wherein said elongate shaft defines a longitudinal axis;

Wales in view of Tierney discloses element [6.2]. *See* analysis in this Ground of element [1.2], *supra*; IS1003, ¶125.

[6.3] an end effector, comprising: a first jaw;

Wales in view of Tierney discloses element [6.3]. *See* analysis in this Ground of element [1.3], *supra*; whereas element [1.3] required a "jaw configured

to support a staple cartridge," this element is broader, requiring a "first jaw." Because the prior art has the jaw recited in claim 1, it necessarily has the jaw recited here, which can be the same jaw. IS1003, ¶126.

[6.4] and a second jaw rotatable relative to said first jaw between an open position and a fully-closed position, wherein said second jaw comprises a cam surface;

Wales in view of Tierney discloses element [6.4]. *See* analysis in this Ground of element [1.4], *supra.* IS1003, ¶127. In particular, the "second jaw" of element [6.4] corresponds to the "anvil" of element [1.4].

[6.5] a closure cam operably coupled with said rotary member, wherein said closure cam is configured to move longitudinally to engage said cam surface and transmit a closing motion to said second jaw to move said second jaw into said fully-closed position;

Wales in view of Tierney discloses element [6.5]. *See* analysis in this Ground of element [1.5], *supra.* IS1003, ¶128.

[6.6] and an opening system configured to move longitudinally to apply an opening force to said second jaw at a location other than said cam surface to move said second jaw into said open position.

Wales in view of Tierney discloses element [6.6]. *See* analysis in this Ground of element [1.6], *supra.* IS1003, ¶129.

[7] The stapling system of claim 6, further comprising a staple cartridge.

Wales in view of Tierney discloses the stapling system of claim 6, further comprising a staple cartridge. *See* analysis in this Ground of claim 2, *supra*; IS1003, ¶130.

[8] The stapling system of claim 7, wherein said staple cartridge is removably replaceable within said first jaw.

Wales in view of Tierney discloses a removably replaceable staple cartridge. *See* analysis in this Ground of claim 3, *supra.* IS1003, ¶131

[9] The stapling system of claim 6, further comprising a rotary motion generator configured to rotate said rotary member.

Wales in view of Tierney discloses claim 9. *See* analysis in this Ground of claim 4, *supra*; IS1003, ¶132.

[10] The stapling system of claim 6, wherein said housing further comprises a second rotary member configured to transmit a second operative motion to said end effector.

Wales in view of Tierney discloses claim 10. *See* analysis in this Ground of claim 5, *supra*; IS1003, ¶133.

[11.1] A stapling system, comprising: a housing comprising a rotatable drive member;

Wales in view of Tierney discloses element [11.1]. *See* analysis in this Ground of element [1.1], *supra*; IS1003, ¶134. For the purposes of this petition, the term "rotary drive member" and "rotatable drive member" have the same meaning. Regardless, even if the terms were construed differently, the element in the prior art identified as a "rotary drive member" equally meets the term "rotatable drive member." The disclosed "rotary drive member" is certainly "rotatable" and, indeed, does rotate. IS1003, ¶134.

[11.2] an elongate shaft extending from said housing, wherein said elongate shaft comprises a longitudinally-extending tube;

Wales in view of Tierney discloses an elongate shaft extending from said housing, wherein said elongate shaft comprises a longitudinally-extending tube. IS1003, ¶135. Figure 1 of Wales which depicts shaft 23, which includes a longitudinally-extending tube (*see* analysis in Ground 1 for this element):

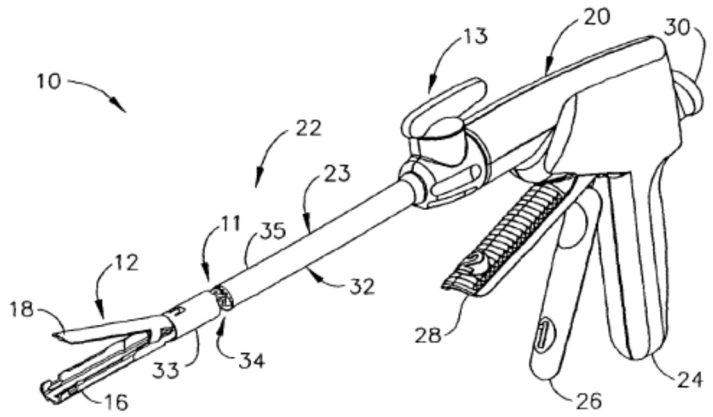


FIG. 1

IS1004, FIG. 1. In the combination of Wales and Tierney, the handle 20 of Wales is replaced with the robotic interface housing of Tierney so that the instrument may be mounted on Tierney's robot:

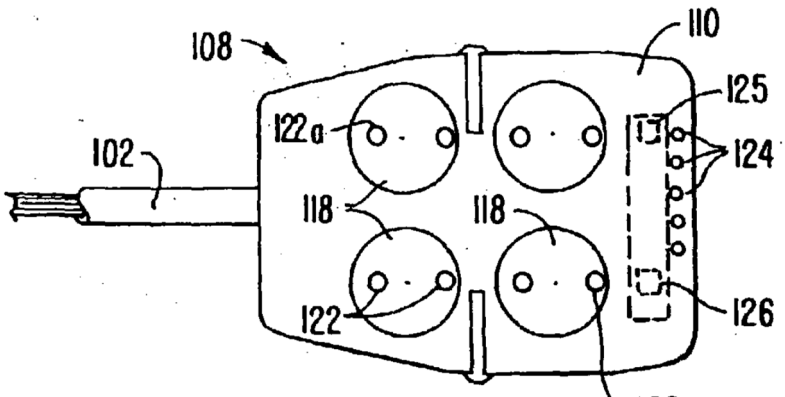


FIG. 6.

IS1006, FIG. 6. Shaft 102 of Tierney, FIG. 6 would correspond to shaft 23 of Wales.

[11.3] an end effector, comprising: a staple cartridge jaw comprising staples removably stored therein;

Wales in view of Tierney discloses this element. The combination would use the end effector of Wales, and Wales discloses an end effector, comprising: a staple cartridge jaw comprising staples removably stored therein. IS1003, ¶136; *see* analysis in Ground 1 for element [11.3].

[11.4] and an anvil rotatable relative to said staple cartridge jaw between a fully-open position and a fully-clamped position, wherein said anvil comprises a cam surface;

Wales in view of Tierney discloses element [11.4]. The combination would use the end effector of Wales, and Wales discloses an anvil rotatable relative to said staple cartridge jaw between a fully-open position and a fully-clamped position, wherein said anvil comprises a cam surface. IS1003, ¶137; *see* analysis in Ground 1for element [11.4].

[11.5] a clamping cam operably coupled with said rotatable drive member, wherein said clamping cam is configured to move longitudinally to engage said cam surface and transmit a clamping force to said anvil to move said anvil into said fully-clamped position;

Wales in view of Tierney discloses element [11.5]. The combination would use the end effector of Wales, and Wales discloses a clamping cam operably coupled with said rotatable drive member, wherein said clamping cam is configured to move longitudinally to engage said cam surface and transmit a

clamping force to said anvil to move said anvil into said fully-clamped position. IS1003, ¶¶138-139; *see* analysis in Ground 1 for element [11.5]. The clamping cam would be operatively coupled to one of the driven elements 118 of Tierney and thus to the rotatable bodies 134 and drive elements 119. *See* analysis in this Ground for claim 4.

[11.6] and an opening member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil into said fully-open position.

Wales in view of Tierney discloses element [11.6]. The combination would use the end effector of Wales, and Wales discloses an opening member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil into said fully-open position. IS1003, ¶140; *see* analysis in Ground 1 for element [11.6].

[12] The stapling system of claim 11, further comprising a rotary motion generator configured to rotate said rotatable drive member.

Wales in view of Tierney discloses claim 12. *See* analysis in this Ground of claim 4, *supra*; IS1003, ¶141.

[13] The stapling system of claim 11, wherein said housing further comprises a second rotatable drive member configured to transmit a second operative motion to said end effector.

Wales in view of Tierney discloses claim 13. *See* analysis in this Ground of claim 5, *supra*; IS1003, ¶142.

[14.1] A stapling system, comprising: a housing comprising a rotatable drive member;

Wales in view of Tierney discloses element [14.1]. *See* analysis in this Ground of element [11.1], *supra*; IS1003, ¶143.

[14.2] an elongate shaft extending from said housing, wherein said elongate shaft comprises a longitudinally-extending tube;

Wales in view of Tierney discloses element [14.2]. *See* analysis in this Ground of element [11.2], *supra*; IS1003, ¶144.

[14.3] an end effector, comprising: a staple cartridge jaw comprising staples removably stored therein;

Wales in view of Tierney discloses element [14.3]. *See* analysis in this Ground of element [11.3], *supra*; IS1003, ¶145.

[14.4] and an anvil rotatable relative to said staple cartridge jaw between a fully-open position and a fully-clamped position, wherein said anvil comprises a cam surface;

Wales in view of Tierney discloses element [14.4]. *See* analysis in this Ground of element [11.4], *supra*; IS1003, ¶146.

[14.5] a clamping cam operably coupled with said rotatable drive member, wherein said clamping cam is configured to move longitudinally to engage said cam surface and transmit a clamping force to said anvil to move said anvil into said fully-clamped position;

Wales in view of Tierney discloses element [14.5]. *See* analysis in this Ground of element [11.5], *supra*; IS1003, ¶147.

[14.6] and a pulling member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil.

Wales in view of Tierney discloses a pulling member configured to move longitudinally to apply a pulling force to said anvil at a location other than said cam surface to move said anvil. IS1003, ¶148. *See* analysis in this Ground of element [1.6]. The "opening force" of element [1.6] in Wales is accomplished by a "pulling force" which pulls the anvil up by having "distally presented tab 310 engage anvil feature 312." The anvil is pulled from the top rather than pushed up from the bottom. Wales discloses: "The closure ring 250 . . . includes a distally presented tab 310 that engages an anvil feature 312 proximate but distal to the anvil pivot 308 on the anvil 18 to thereby effect opening." IS1004, 10:20-30.

D. Ground 4: Claims 3 and 8 would have been Obvious under § 103 over Wales in view Tierney, and further in view of Knodel

[3] The stapling system of claim 2, wherein said staple cartridge is removably replaceable within said jaw.

[8] The stapling system of claim 7, wherein said staple cartridge is removably replaceable within said first jaw.

As explained above with regard to Ground 3, claim 3, a POSITA would have understood that the combination Wales and Tierney would result in a surgical stapler instrument that uses the Wales end effector (and Wales staple cartridge) with the handle of Wales replaced by the robotic interface of Tierney. Tierney notes that "more and more different surgical tools are provided for use with a

robotic system." IS1006, ¶¶7-8. Tierney teaches that the tools have a robotic manipulator interface for connecting the tool to the robot (instead of a traditional tool handle), as depicted in FIG. 4:

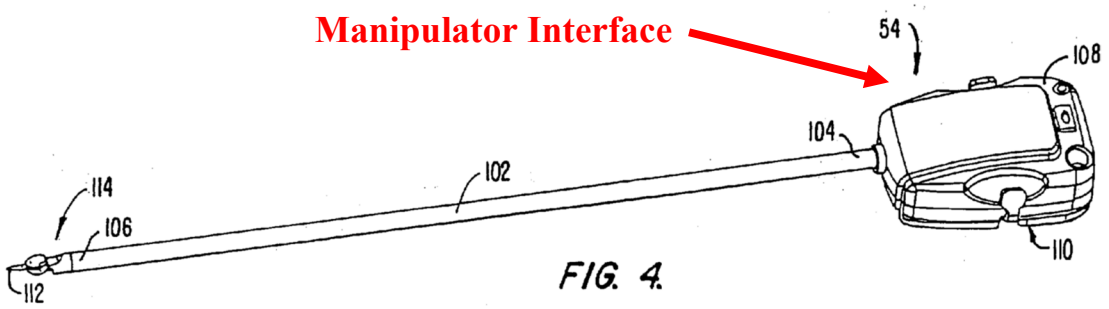


FIG. 4.

In Tierney, the handle is removed from the instrument and, instead, "the robotic surgery system allows the surgeon to manipulate the surgical tools as if the handle in the surgeon's hand [at the remote console] and the end effector in the surgeon's field of view define a single contiguous surgical instrument." IS1006, ¶71.

It would have been obvious to a POSITA at the time of the filing of the '658 patent to use replaceable cartridges, as was common practice at the time, and as disclosed by Knodel. IS1003, ¶¶157-158. All the reasons to combine Wales with Knodel apply with equal force to the Wales/Tierney combination. Knodel teaches a replaceable staple cartridge in an end effector. The Wales/Tierney combination uses the Wales end effector and therefore the teachings of Knodel would naturally extend to the Wales end effector in the Wales/Tierney combination. The motivation to ensure that the Wales cartridge is replaceable is no less strong in a robotic system than in a manual system. In both situations, it is desirable to

replace the staple cartridge so that the tool does not have to be thrown out after a single use. IS1003, ¶¶157-158. *See also* analysis in Ground 2, which provides additional reasons and motivations to combine Knodel with Wales.

IX. CONCLUSION

Claims 1-14 of the '658 patent are invalid over the prior art pursuant to Grounds 1-4 set forth above. Accordingly, Petitioner request *inter partes* review of these challenged claims.

Respectfully submitted,

Dated: May 23, 2018

/Steven R. Katz/
Steven R. Katz, Reg. No. 43,706
Fish & Richardson P.C.

(Trial No. IPR2018-00936)

Attorney for Petitioner

CERTIFICATION UNDER 37 CFR § 42.24(d)

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 11,996, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(i).

Respectfully submitted,

Dated: May 23, 2018

/Steven R. Katz/
Steven R. Katz, Reg. No. 43,706
Fish & Richardson P.C.

Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on May 23, 2018, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided by Federal Express, cost prepaid, to the Patent Owner by serving the correspondence address of record as follows:

JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK NJ 08933-7003

/Diana Bradley/

Diana Bradley
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(858) 678-5667