IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Frederick E. Shelton IV, et al.	
U.S. Patent No.:	8,602,288	Attorney Docket No.: 11030-0054IP1
Issue Date:	December 10, 2013	
Appl. Serial No.:	13/369,588	
Filing Date:	February 9, 2012	
Title:	ROBOTICALLY-CONTROLLED MOTORIZED SURGICAL END EFFECTOR SYSTEM WITH ROATARY ACTUATED CLOSURE SYSTEMS HAVING VARIABLE ACTUATION SPEEDS	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 8,602,288 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Pat. No. 8,602,288 to Shelton IV, et al. ("the '288 patent")
IS1002	Prosecution History of the '288 Patent ("File History")
IS1003	Declaration of Dr. Gregory Fischer ("Fischer Decl.")
IS1004	U.S. Pat. App. Pub. No. 2005/0131390 ("Heinrich")
IS1005	U.S. Pat. No. 5,915,616 ("Viola")
IS1006	U.S. Pat. No. 7,510,107 ("Timm")
IS1007	U.S. Pat. No. 5,632,432 ("Schulze")
IS1008	U.S. Pat. No. 6,783,524 ("Anderson")
IS1009	U.S. Pat. No. 6,331,181 ("Tierney '181 patent")
IS1010	U.S. Pat. No. 7,524,320 ("Tierney '320 patent")
IS1011	U.S. Pat. No. 5,667,517 ("Hooven")
IS1012	U.S. Pat. App. Pub. No. 2007/0262116 ("the '116 app.")
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I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 10 and 11 of U.S. Pat. No. 8,602,288 ("the '288 patent"). The '288 patent relates to a "robotically-controlled motorized surgical end effector system with rotary actuated closure systems having variable actuation speeds." '288 patent, Title. The closure system first closes at a relatively fast rate, and then the closure system closes at a slower rate. Notably, the claimed instrument includes an "elongated shaft assembly comprising: . . . a rotatably movable portion in operable engagement with [an] axially movable portion wherein [(1)] an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, [(2)] a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and [(3)] said first rate is greater than said second rate." *E.g., id*., Claim 10.

As explained below, however, such instruments were not new or non-obvious at the time of the alleged priority date of the '288 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 present Petition.

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

Petitioner is not aware of any disclaimers, reexamination certificates, or petitions for IPR of the '288 patent. The '288 patent is the subject of Civil Action No. 1:18-cv-1325-LPS, filed on August 27, 2018 in the United States District Court for the District of Delaware. The following IPRs involve patents that belong to Patent Owner and have been asserted against Petitioner in the United States District Court for the District of Delaware: *Intuitive Surgical, Inc. v. Ethicon LLC*, Case Nos. IPR2018-00933, -934, -935, -936, -938, -1247, -1248, -1254, -1703, IPR2019-00880, -00991, and -01066.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel.

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D. Service Information

Please address all correspondence and service to the address listed above. Petitioner consents to electronic service by email at IPR11030-0054IP1@fr.com (referencing No. 11030-0054IP1 and cc'ing PTABInbound@fr.com, katz@fr.com, phillips@fr.com, and oconnor@fr.com).

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

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

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

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '288 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 10-11 of the '288 patent on the grounds listed below. A declaration from Dr. Fischer (IS1003) is included in support.

Ground	Claims	Basis for Rejection
Ground 1	**10-11**	Anticipated by **Heinrich** (IS1004) under pre-AIA 35 U.S.C. § 102.
Ground 2	**10-11**	Anticipated by **Timm** (IS1006) under pre-AIA 35 U.S.C. § 102.
Ground 3	**10-11**	Obvious over **Timm** (IS1006) in view of **Viola** (IS1005) under pre-AIA 35 U.S.C. § 103.

Ground	Claims	Basis for Rejection
Ground 4	**10-11**	Obvious over **Timm** (IS1006) in view of **Schulze** (IS1007) under pre-AIA 35 U.S.C. § 103.
Ground 5	**10-11**	Obvious over **Timm** (IS1006) in view of **Anderson** (IS1008) and, if necessary, **Viola** (IS1005) and **Schulze** (IS1007) under pre-AIA 35 U.S.C. § 103.
Ground 6	**10-11**	Obvious over **Heinrich** (IS1004) in view of **Anderson** (IS1008) under pre-AIA 35 U.S.C. § 103.
Ground 7	**10-11**	Obvious over **Heinrich** (IS1004) in view of **Viola** (IS1005) and, if necessary, **Anderson** (IS1008) under pre-AIA 35 U.S.C. § 103.

The '288 patent issued from U.S. App. No. 13/369,588, filed on Feb. 9, 2012, which is a continuation of U.S. App. No. 13/118,253, filed on May 27, 2011, which is a continuation-in-part of U.S. App. No. 12/235,972, filed on Sep. 23, 2008. The earliest date to which the '288 patent could claim priority is May 27, 2011 because the '972 application does not disclose the claimed subject matter. Fischer Decl., ¶¶2, 73-76.

If the priority date of the '288 patent is deemed to be May 27, 2011, then Heinrich, Viola, Timm, Schulze, and Anderson each qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(b). Each of these references was made of record during prosecution, but none were discussed by the examiner or the applicant.[1]

[1] Applicants cited more than 2000 references after the examiner issued a notice of allowance.

If the priority date of the '288 patent is deemed to be Sep. 23, 2008, then Heinrich, Viola, Schulze, and Anderson each still qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(b), and Timm qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

V. SUMMARY OF THE '288 PATENT

The abstract of the '288 patent describes a "surgical tool for use with a robotic system [that] includes an end effector comprising at least one component portion [that is] selectively movable between first and second positions and a shaft including an axially movable portion in operable communication with the at least one selectively movable component portion and a rotatably movable portion in operable engagement with the axially movable portion." '288 patent, Abstract. "An initial rotation of the rotatably movable portion causes the axially movable portion to move the selectively movable component portion from the first position into an intermediate position at a first rate." *Id.* And a "subsequent rotation of the rotatably movable portion in a same direction causes the axially movable portion to move the selectively movable component portion from the intermediate position to the second position at a second rate different from the first rate." *Id.*

"An exemplary non-limiting surgical tool 1200 that is well-adapted for use with a robotic system 1000 that has a tool drive assembly 1010 (FIG. 30) that is operatively coupled to a master controller 1001 that is operable by inputs from an

operator (*i.e.*, a surgeon) is depicted in FIG. 29." *Id.*, 27:20-24, Figs. 29-30.

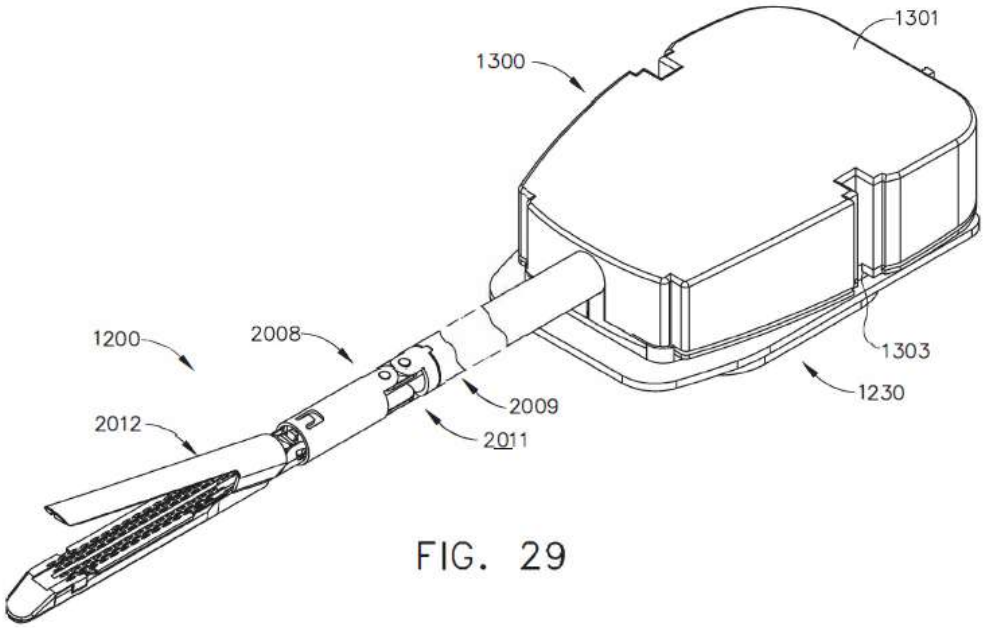


FIG. 29

In one embodiment, the surgical tool includes a shaft 3208 and surgical end effector 3212" that includes: an elongated channel 3222; a surgical staple cartridge 3234; and an anvil 3224 pivotally coupled to the elongated channel 3222. '288 patent, 50:10-18 (describing common components in Figure 66), Fig. 69.

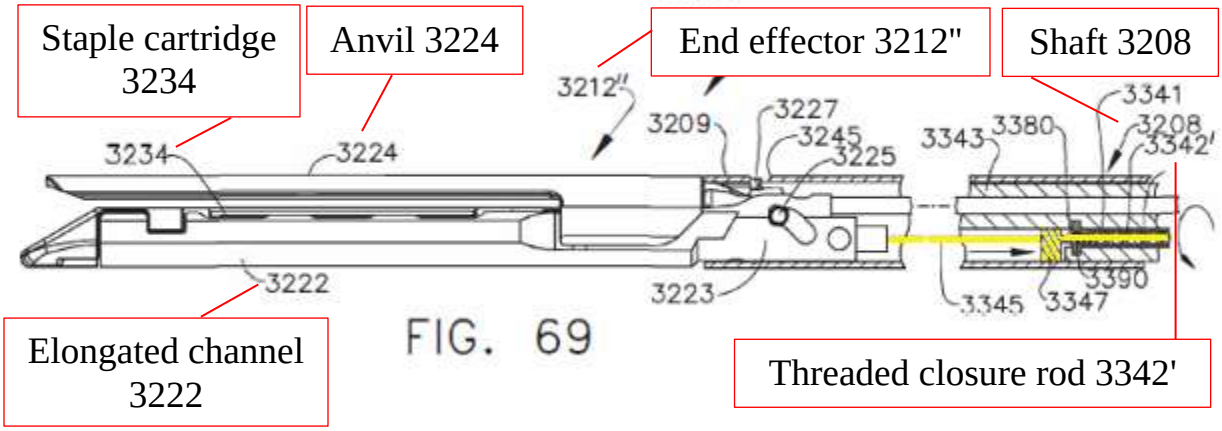


FIG. 69

When anvil 3224 is drawn in the proximal direction, it contacts the shaft 3208 and pivots to the closed position. *Id.*, 52:11-16, Fig. 69. This closing motion

is controlled by a "closure control system" that includes a threaded closure rod 3342' with "variable pitched grooves." *Id*., 51:39-46 (describing the same components in Figure 66), 53:39-43, Figs. 69, 70 (shown below). "[A]s can be seen in FIG. 70, the closure rod 3342' has a distal groove section 3380 and a proximal groove section 3382 [that] are configured for engagement with a lug 3390 [and] the distal groove section 3380 has a finer pitch than the groove section 3382." *Id*., 53:43-49.

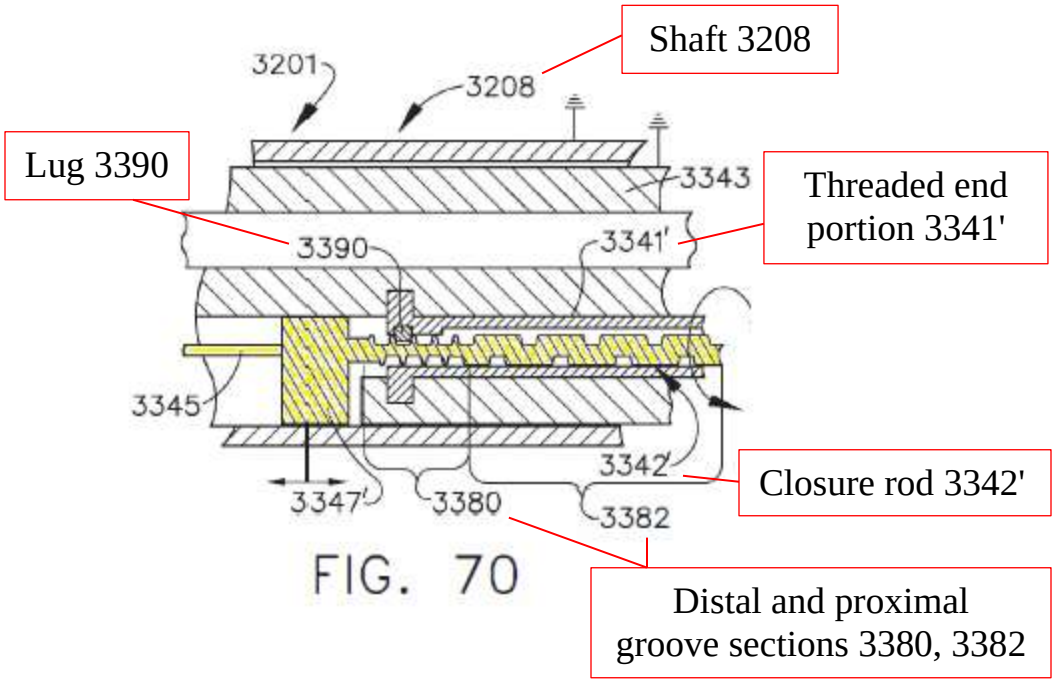


FIG. 70

In another embodiment, the surgical tool includes: (1) an elongated shaft assembly 3408 with a rotatable proximal closure tube segment 3410 and a distal closure tube segment 3430; and (2) a surgical end effector 3412 including an elongated channel 3522 and a pivotably coupled anvil 3524. '288 patent, 54:41-55:33, Figs. 72-75. The "anvil [3524] is open[ed] and closed by rotating the proximal

closure tube segment 3410." *Id.* And, as shown below in Figure 72, "distal closure tube segment 3430 includes a lug 3442 [in] threaded engagement with a variable pitch groove/thread 3414 formed in the . . . proximal closure tube segment 3410." *Id.*

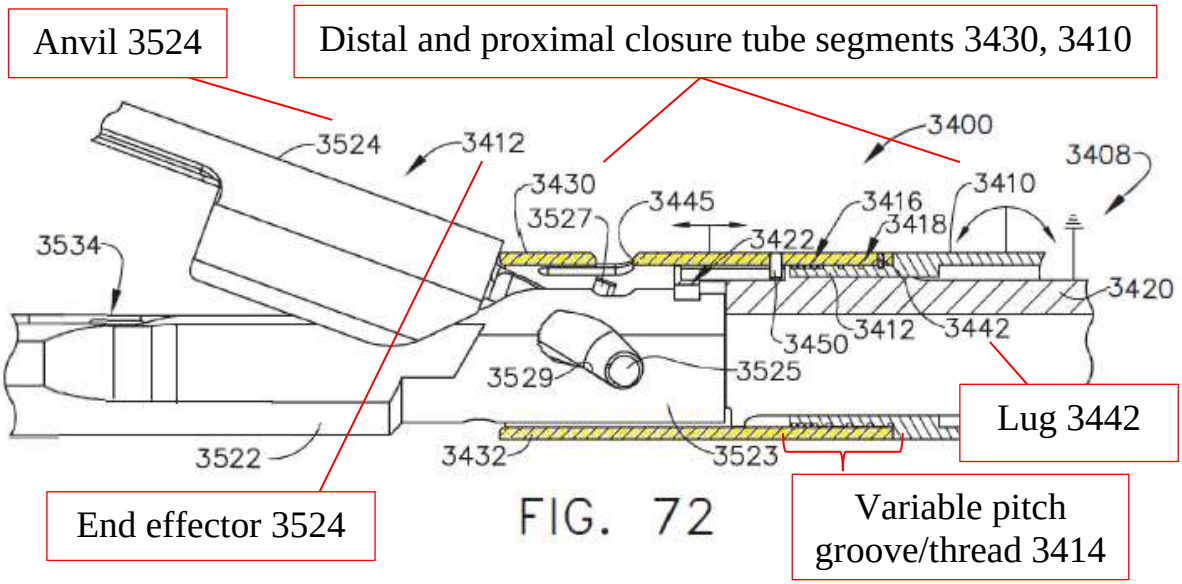
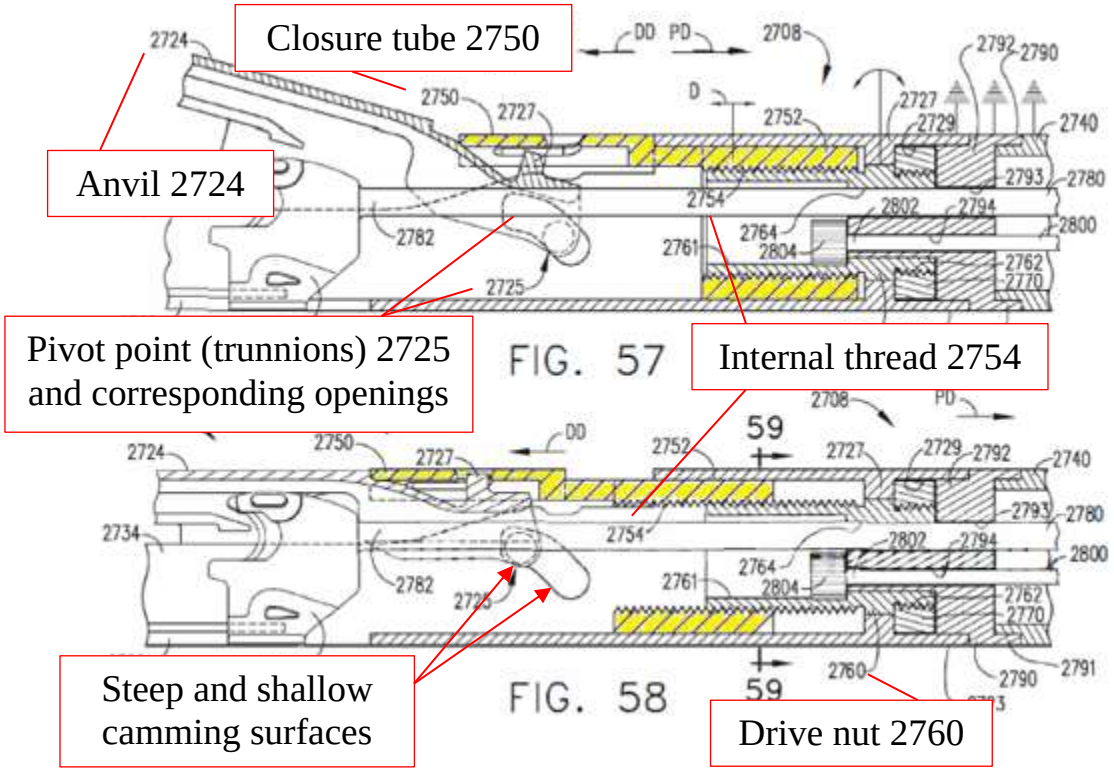


FIG. 72

The variable pitch groove/thread arrangement in each of these embodiments permits closure of the anvil at first and second rates when the lug engages the proximal and distal grooves, respectively. *Id.*, 53:50-64. Because the proximal groove is coarser than the distal groove, the first rate is greater. *Id.* This "arrangement serves to speed up the initial closing of the end effector for tissue manipulation and then[,] after the tissue has been properly positioned therein, generate the amount of closure forces to properly clamp the tissue for cutting and sealing." *Id.*

In yet another embodiment, the surgical tool includes: (1) an elongated shaft assembly with an "axially movable actuation member" in the form of a closure

tube 2750 and a "rotatably movable portion" in the form of a closure drive nut 2760; and (2) a surgical end effector including an anvil 2724 pivotally coupled to an elongated channel 2722. '288 patent, 44:35-47:48, Figs. 57-58. Movement of anvil 2724 "is accomplished by axially moving the closure tube 2750 in the distal direction 'DD'." *Id.*, 47:1-6, Figs. 57-58. And "[a]xial movement of the closure tube 2750 in the distal direction 'DD' is accomplished by applying a rotary control motion to the closure drive nut 2760." *Id.*



As shown above, pivot point (*i.e.*, trunnion) 2725 interacts with an opening that has multiple camming angles—a steeper proximal portion and a shallower distal portion—that permits closure of the anvil at first and second rates when pivot point 2725 engages the proximal and distal portions of the opening, respectively,

as anvil 2724 is driven distally by closure tube 2750. '288 patent, Figs. 57-58; *see also*, 50:15-18, 54:60-63, Figs. 66-69, 72-75. Because the proximal portion of the opening is steeper than the distal portion, the first rate is greater than the second rate. Fischer Decl., ¶39.

VI. SUMMARY OF THE PROSECUTION HISTORY

The chain of applications to which the '288 patent claims priority is provided above. *See* Section IV.B, *supra*. Notably, original claim 1 of U.S. Pat. App. No. 13/369,588 was rejected as being anticipated by U.S. Pat. No. 6,994,708 (Manzo). File History, 377-78 (Nov. 9, 2012 rejection). Original claims 2 and 9, which depended from original claim 1, were rejected as obvious over Manzo in view of U.S. Pat. No. 5,667,517 (Hooven). *Id*., 378-79. Original claims 3-4 were deemed allowable if rewritten in independent form, and original claims 5-8 were deemed allowable if rewritten to overcome certain objections under pre-AIA 35 U.S.C. § 112, ¶ 2. *Id*., 379.

Manzo discloses Petitioner's robotic surgical system, which is also disclosed in the '288 patent, and Hooven discloses a surgical stapler wherein the anvil is closed by a closure nut in threaded engagement with a portion of a threaded rod. Fischer Decl., ¶41.

In response, Applicants amended original claim 1 to require movement of the selectively movable portion of the surgical end effector from the intermediate

position to the second position at a second rate different from the first rate and added two new claims (original claims 19 and 20, which issued as claims 10 and 11) that are similar to, but broader than, original claim 1. File History, 346, 350-51 (Feb. 11, 2013 response); Fischer Decl., ¶42.

Two months later, the examiner issued a notice of allowance, which provided the following reasons for allowance:

> It is the subsequent rotation of said rotatably movable portion in the same direction causing the axially movable portion to move the selectively movable component portion of said surgical end effector from said intermediate position to a second position at a "second rate different from said first rate" in combination with the other claimed components that is allowable over the prior art.
>
> Regarding claim[] . . . 19 [(issued claim 10)], it is the first rate greater than the second rate in combination with the other claimed components of the tool that is allowable over the prior art of record.
>
> Regarding claim[] . . . 20 [(issued claim 11)], it is the rotatably movable portion comprising a closure member in threaded engagement with the axially movable portion in combination with the other claimed components of the tool that is allowable over the prior art of record.

File History, 334-35 (Apr. 22, 2013 NOA). Applicant subsequently submitted an IDS disclosing more than 2000 references. *Id*., 151-240 (July 15, 2013 RCE/IDS). Less than three weeks later, the examiner filed another notice of allowance reciting the same reasons for allowance. *Id*., 25 (Aug. 6, 2013 NOA).

VII. CLAIM CONSTRUCTION

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

A. "Component portion" (claims 10 and 11)

This term invokes pre-AIA 35 U.S.C. §112, ¶6 because it claims a function without disclosing sufficient structure for performing the function. Fischer Decl., ¶¶45-46. The terms "component" and "portion" are nonce words. *Id*. And the specification does not provide a structural definition for the claimed "component portion." *Id*.

The language of claims 10 and 11 explicitly recites the function performed by the "component portion": "selectively mov[ing] between first and second positions relative to at least one other component portion thereof." The corresponding structure is an anvil. *See, e.g*., '288 patent, Claim 2; Fischer Decl., ¶48. In some embodiments, the corresponding structure is the anvil of a linear stapler, which moves between open and closed position relative to a staple cartridge. *See, e.g*.,

'288 patent, 50:15-18, Figs. 1-3, 34-40, 46-48, 51-53, 56-58, 66-75. An example is linear stapler anvil 24 of Figure 3:

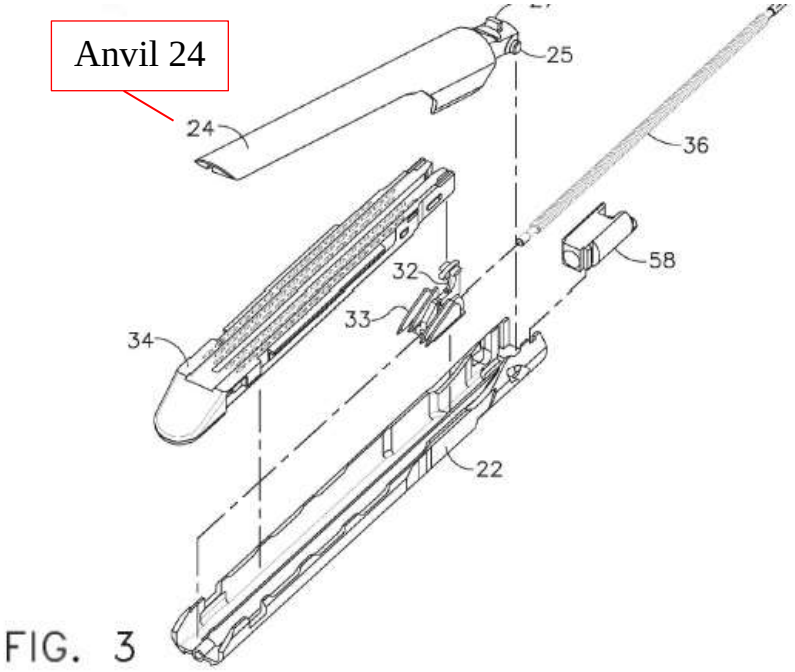
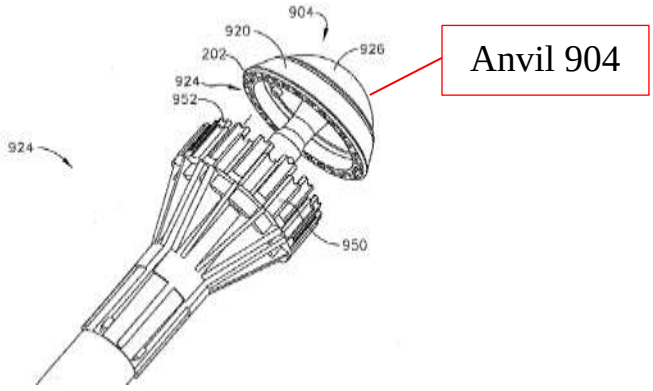


FIG. 3

In other embodiments, the corresponding structure is the anvil of a circular cutter, which also moves between open and closed position relative to a staple cartridge. *See, e.g.*, *id*., 1:63-65, 20:10-13; '116 app., ¶¶152-57, Figs. 85-86; *see also* '288 patent, 90:10-17; Fischer Decl., ¶49. The '116 app., which is incorporated by reference into the '288 patent, provides an example of a circular cutter anvil 904:



'116 app., Fig. 85; *see also* ¶¶152-57.

B. "Axially movable portion" (claims 10 and 11)

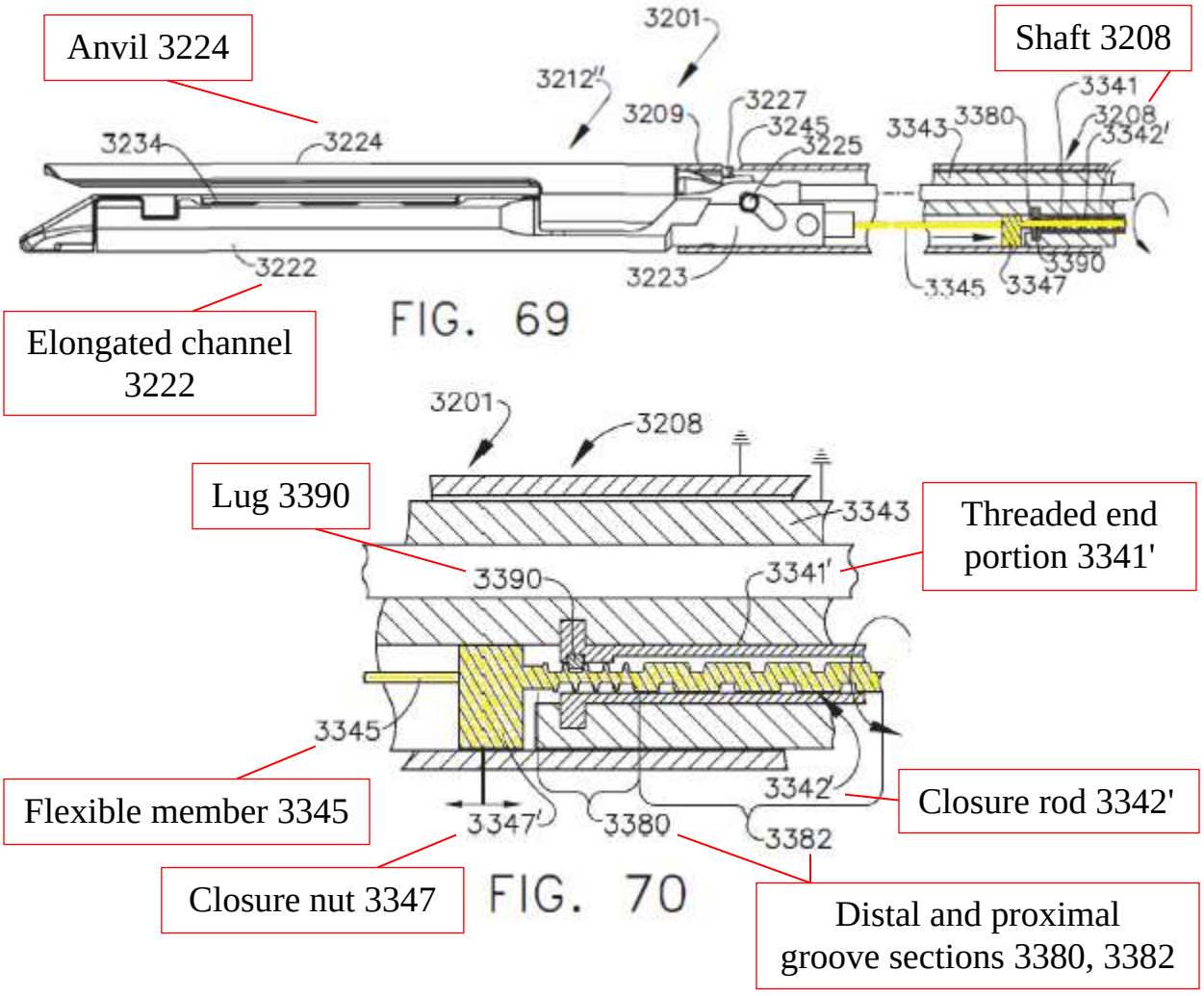
This term invokes pre-AIA 35 U.S.C. §112, ¶6 because it claims functions without disclosing sufficient structure for performing those functions. Fischer Decl., ¶¶51-52. The term "portion" is a nonce word. *Id*. The prefix "axially movable" does not impart any structure; it merely confirms that the structure can be moved along an axis. *Id*. And the specification does not provide a structural definition for the claimed "axially movable portion." *Id*.

The language of claims 10 and 11 explicitly recites the functions performed by the "axially movable portion": (1) moving said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate; and (2) moving said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate that is less than the first rate.

In one embodiment, the corresponding structure is the combination of threaded closure rod 3342', closure nut 3347, and flexible member 3345. '288 patent, 53:39-64, 53:13-18 (describing common components in Figure 68), Figs. 69-71[2]. Movement of the selectively movable component portion (anvil 3224) "is controlled by axially moving the elongated channel 3222 relative to the elongated

[2] Closure nut 3347 is mislabeled as 3347' in Figures 70-71.

shaft assembly 3208." *Id.*, 51:40-41. And the "axial movement of the elongated channel 3222 is controlled by" axially moving the combination of threaded closure rod 3342', closure nut 3347, and flexible member 3345. *Id.*, 51:39-65.



As shown above, closure rod 3342' is connected to closure nut 3347, which is connected to flexible member 3345, which is connected to elongated channel 3222 of the end effector. '288 patent, 50:15-18, 51:39-46, 53:39-64, Figs. 69-71. And the selectively movable portion of the end effector (anvil 3224) is "pivotally

coupled to elongated channel 3222." *Id*. Furthermore, "closure rod 3342' has a [fine pitched] distal groove section 3380 and a [coarse pitched] proximal groove section 3382 . . . configured for engagement with a lug 3390 supported within the hollow threaded end portion 3341'" of closure shaft 3340. *Id*.

This configuration "permits the elongated channel 3222 to be drawn into the shaft 3208 at a first speed or rate [when] lug 3390 [engages] proximal groove segment 3382" and "at a second speed or rate" "[w]hen the lug 3390 engages the distal groove segment [3380] . . . . Because the proximal groove segment 3382 is coarser than the distal groove segment 3380, the first speed will be greater than the second speed. . . . Thus, the anvil [3224] initially closes fast [and then] closes more slowly." *Id*.

In embodiments where the end effector is a circular cutter, a POSITA would have understood that the axially movable portion described above would be used to move the anvil initially between the first and intermediate positions, and subsequently between the intermediate and second positions. Fischer Decl., ¶58.

In another embodiment, the corresponding structure is the combination of distal closure tube segment 3430 and lug 3442. *Id*., 54:41-55:33, Figs. 72-75. As explained in the '288 patent, "distal closure tube segment 3430 includes a lug 3442 [in] threaded engagement with a variable pitch groove/thread 3414 formed in the distal end 3412 of the rotatable proximal closure tube segment 3410." *Id*. And

"the distal closure tube segment 3430 is [rotationally] constrained for axial movement." *Id.*

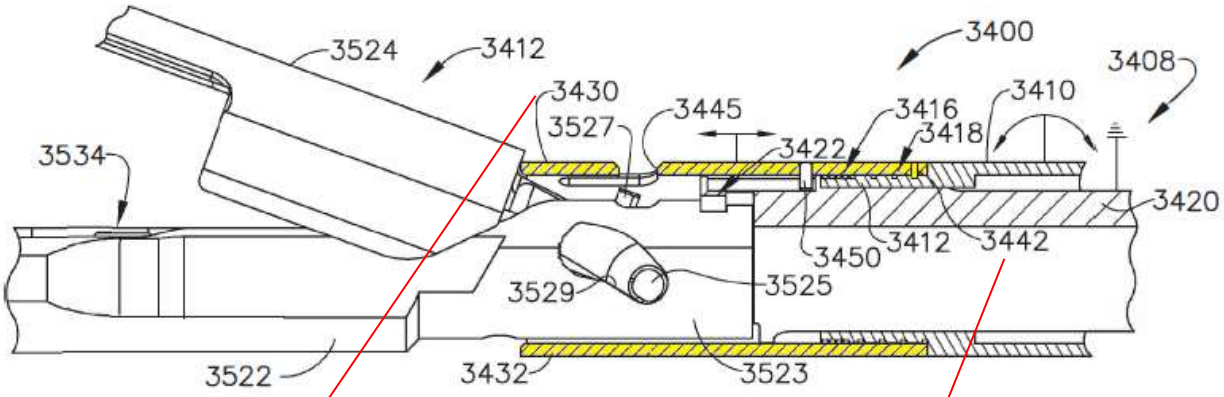


FIG. 72

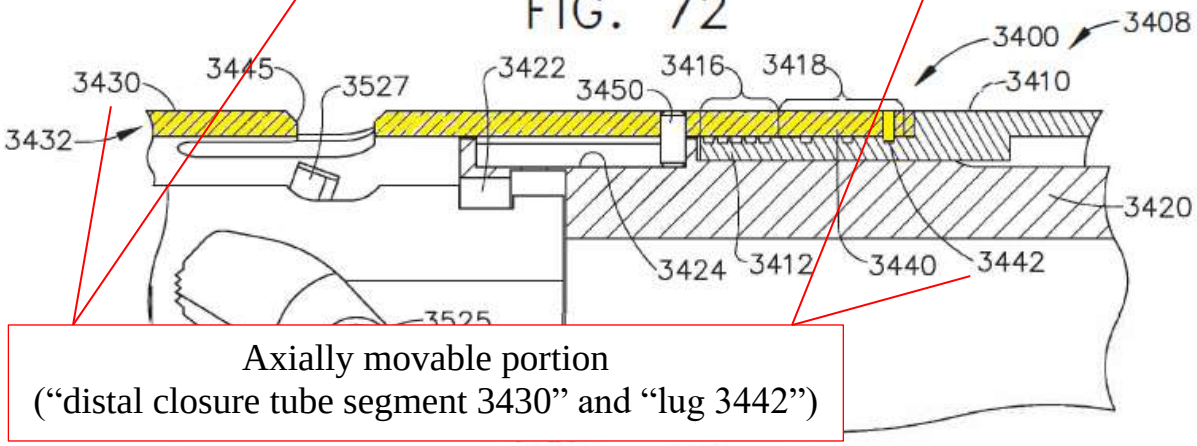
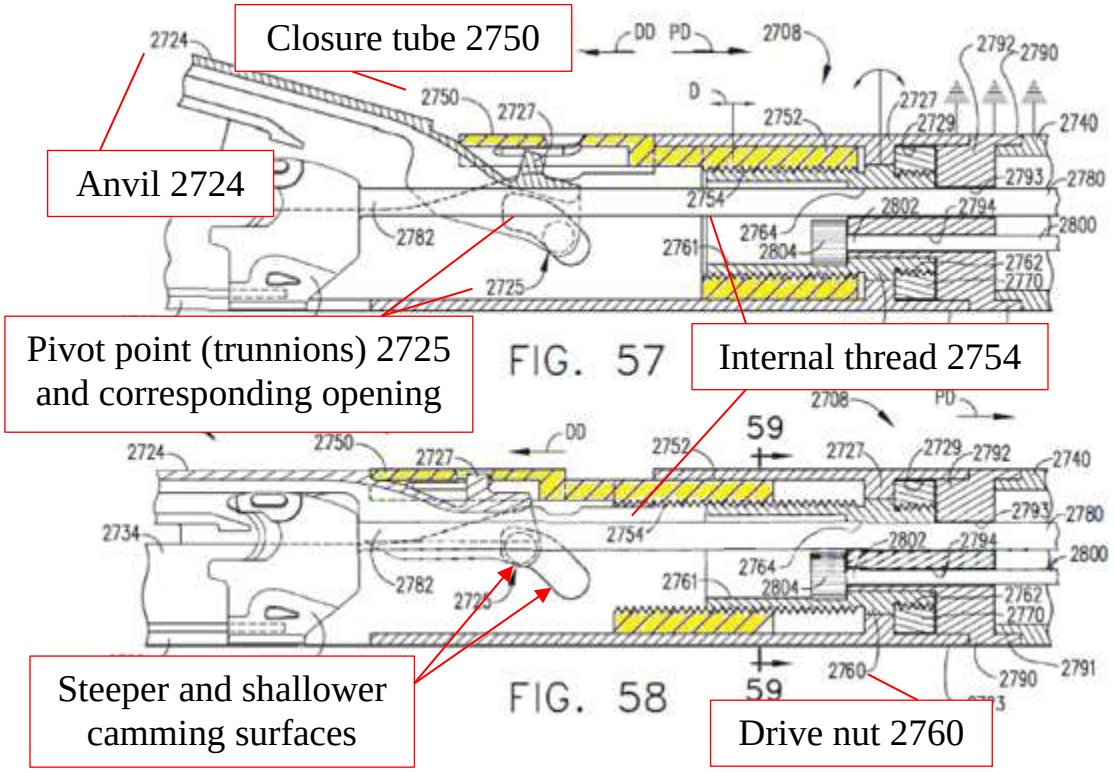


FIG. 73

"[T]he anvil [3524] is open[ed] and closed by rotating the proximal closure tube segment 3410. The variable pitch thread arrangement permits the distal closure tube segment 3430 to be driven in the distal direction 'DD' at a first speed or rate [and] at a second speed or rate. Because the proximal groove/thread section 3418 is coarser than the distal groove/thread segment 3416, the first speed will be greater than the second speed." *Id.*

In another embodiment, the corresponding structure is closure tube 2750, which includes internal thread 2754. '288 patent, 45:53-47:48, Figs. 57-58. Movement of the selectively movable component position (anvil 2724) "is accomplished by axially moving the closure tube 2750 in the distal direction 'DD'." *Id.*, 47:1-6, Fig. 57-58. And "[a]xial movement of the closure tube 2750 in the distal direction 'DD' is accomplished by applying a rotary control motion to the closure drive nut 2760." *Id.*



Furthermore, as shown above, pivot point 2725 interacts with a corresponding opening that has multiple camming angles—a steeper proximal portion and a shallower distal portion. '288 patent, Figs. 57-58; *see also*, 50:15-18, 54:60-63, Figs. 66-69, 72-75 (showing the same structures in related embodiments). Thus,

distal movement of closure tube 2750 moves anvil 2724 from a first position (*e.g.*, open; shown above in Figure 57) to an intermediate position (*e.g.*, the position of anvil 2724 when pivot point 2725 transitions from the steeper camming surface to the shallower camming surface in the corresponding opening) at a first rate. Fischer, Decl. ¶62; *see also* '288 patent, 50:15-18, 54:60-63, Figs. 66-69, 72-75. Anvil 2724 is moved from the intermediate position to a second position (*e.g.*, closed; shown above in Figure 58) at a second rate. *Id*. And the first rate is higher than the second rate because the steeper proximal portion of the opening that interacts with pivot point 2725 causes anvil 2724 to move faster than the shallower distal portion of the opening. *Id*.

C. "Rotatably movable portion" (claims 10 and 11)

This term invokes pre-AIA 35 U.S.C. §112, ¶6 because it claims functions without disclosing sufficient structure for performing those functions. Fischer Decl., ¶¶63-64. The term "portion" is a nonce word. *Id*. The prefix "rotatably movable" does not impart any structure; it merely indicates that the structure can be rotated. *Id*. And the specification does not provide a structural definition for the claimed "rotatably movable portion." *Id*.

The language of claims 10 and 11 explicitly recites the functions performed by the "rotatably movable portion": (1) causing said axially movable portion to move said selectively movable component portion of said surgical end effector

from said first position into an intermediate position at a first rate; and (2) causing said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate that is less than the first rate.

In one embodiment, the corresponding structure is the combination of hollow threaded end portion 3341' and lug 3390. *Id.*, ¶66; '288 patent, Fig. 70.

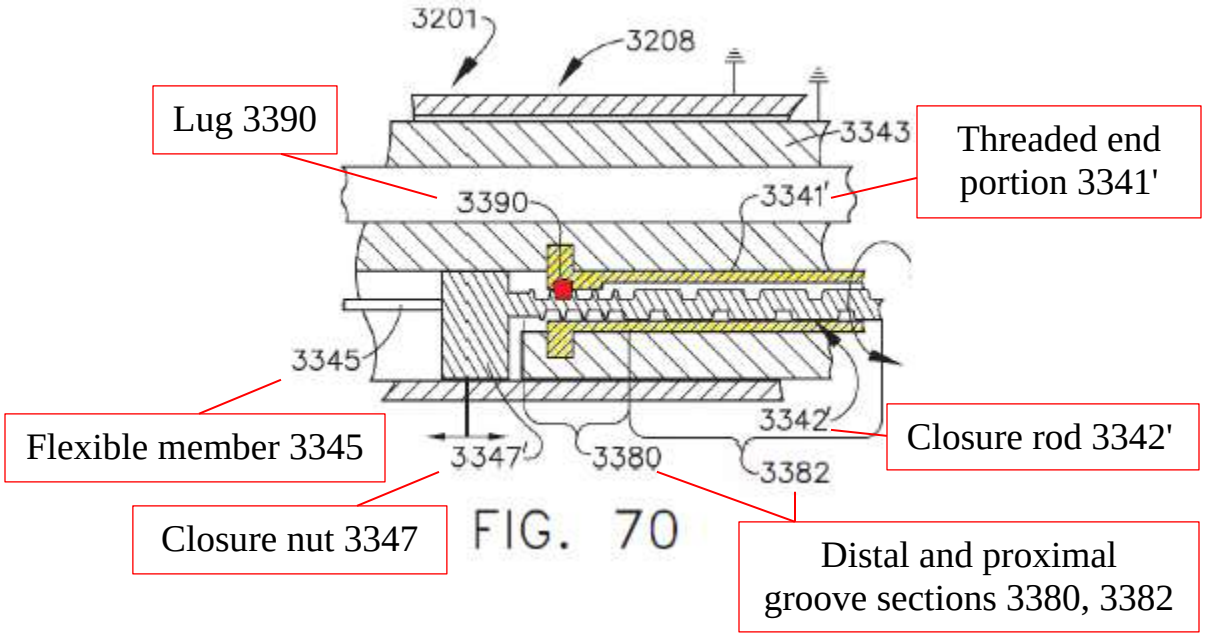


FIG. 70

As shown above, "distal and proximal groove sections 3380, 3382" of closure rod 3342' "are configured for engagement with a lug 3390 supported within the hollow threaded end portion 3341'," which rotates within the surrounding structure, but does not translate axially. '288 patent, 53:39-64. Thus, rotating threaded end portion 3341' causes the combination of threaded closure rod 3342', closure nut 3347, and flexible member 3345 (the claimed "axially movable portion"), which is free

to translate axially relative to the surrounding structures but does not rotate, to perform its claimed functions as explained in Section VII.B above. *Id.*

In embodiments where the end effector is a circular cutter, a POSITA would have understood that the rotatably movable portion described above would be used to cause said axially movable portion to perform its claimed functions. Fischer Decl., ¶68.

In another embodiment, the corresponding structure is rotatable proximal closure tube segment 3410, which includes variable pitch groove/thread 3414.

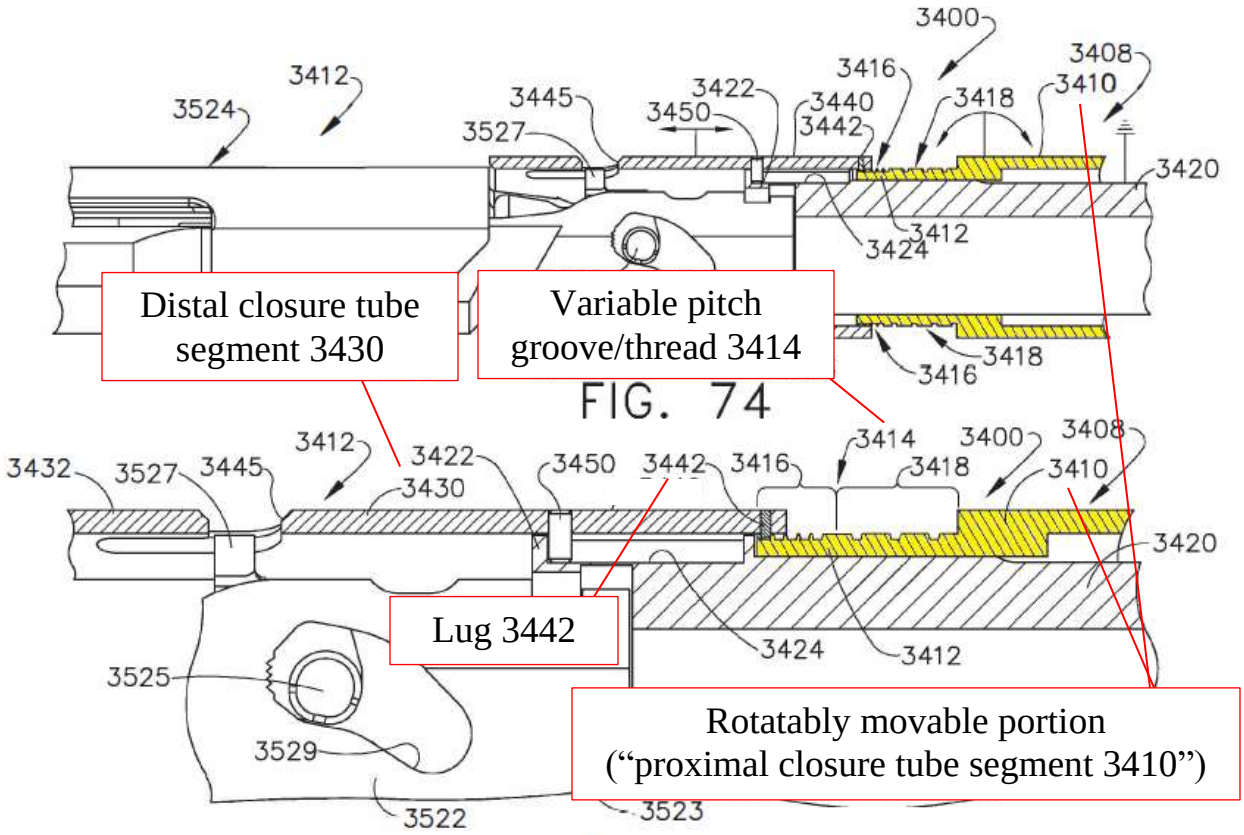


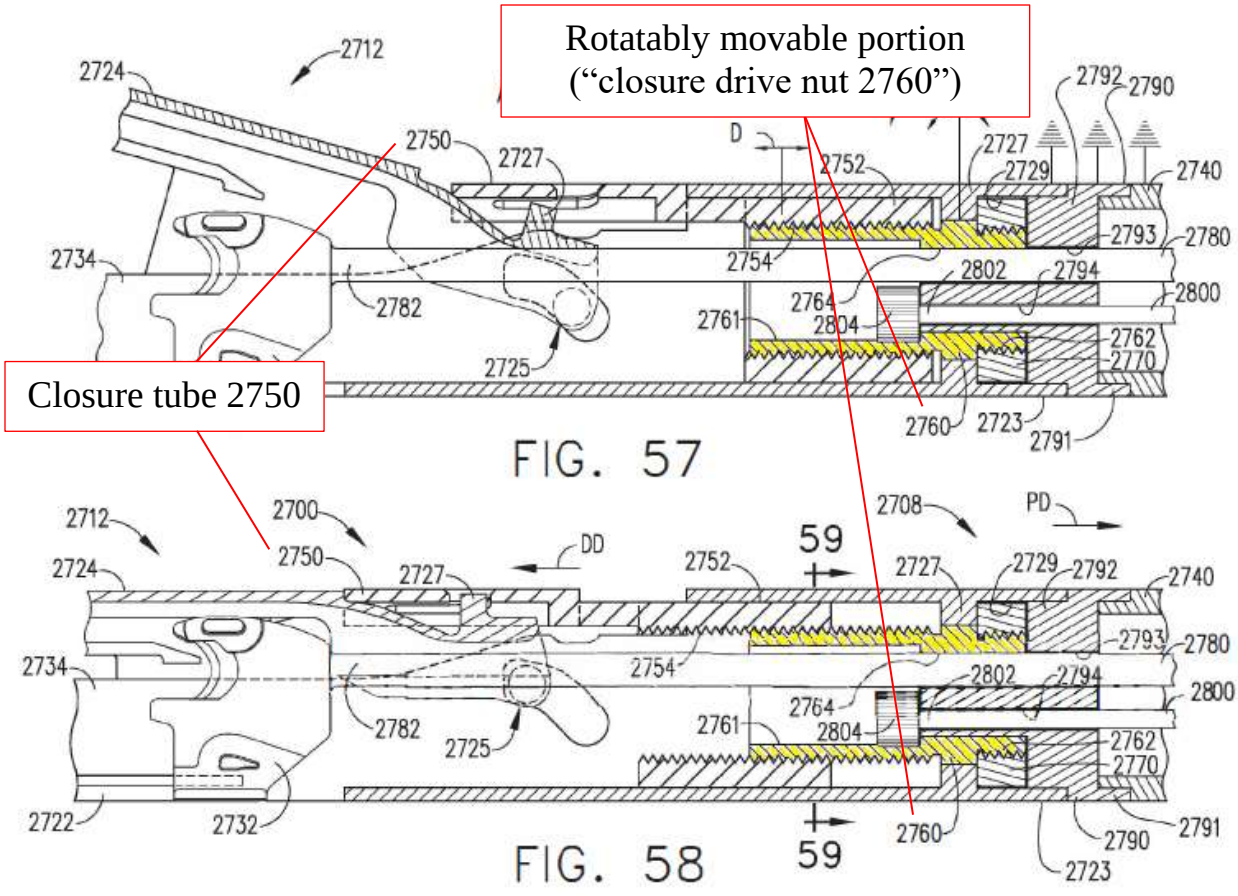
FIG. 74

FIG. 75

As shown above, variable pitch groove/thread 3414 located at the distal end of

proximal closure tube segment 3410 is configured for engagement with lug 3442 on distal closure tube segment 3430. '288 patent, Figs. 74-75. Thus, rotating proximal closure tube segment 3410 causes the combination of closure tube segment 3430 and lug 3442 (the axially movable portion) to perform its claimed functions as explained in Section VII.B above. *Id.*

In another embodiment, the corresponding structure is closure drive nut 2760, which the '288 patent identifies as "a rotatably movable portion." *Id.*, 45:53-46:4, 47:1-48, Figs. 57-58; *see also* 41:12-31, Figs. 52-53.



As shown above, closure tube 2750 is in threaded engagement with closure drive

nut 2760. *Id*. Thus, "[r]otation of the closure drive nut 2760 will cause the closure tube 2750 to move axially as represented by arrow 'D' in FIG. 57" to perform its claimed functions as explained above in Section VII.B. *Id*., 46:2-4.

VIII. SUMMARY OF THE PRIOR ART

A. Heinrich and Viola

Heinrich discloses a robotic surgical system 600 that includes an actuation assembly 612, a robotic arm 616, and a disposable loading unit 618. *See, e.g.*, Heinrich, ¶¶132, 140, Figs. 7, 9. "Disposable loading unit 618 . . . includes a head portion 640 for housing an electro-mechanical assembly 619 (*see* FIG. 8) therein for operating [a] surgical instrument 620." *Id*., ¶134.

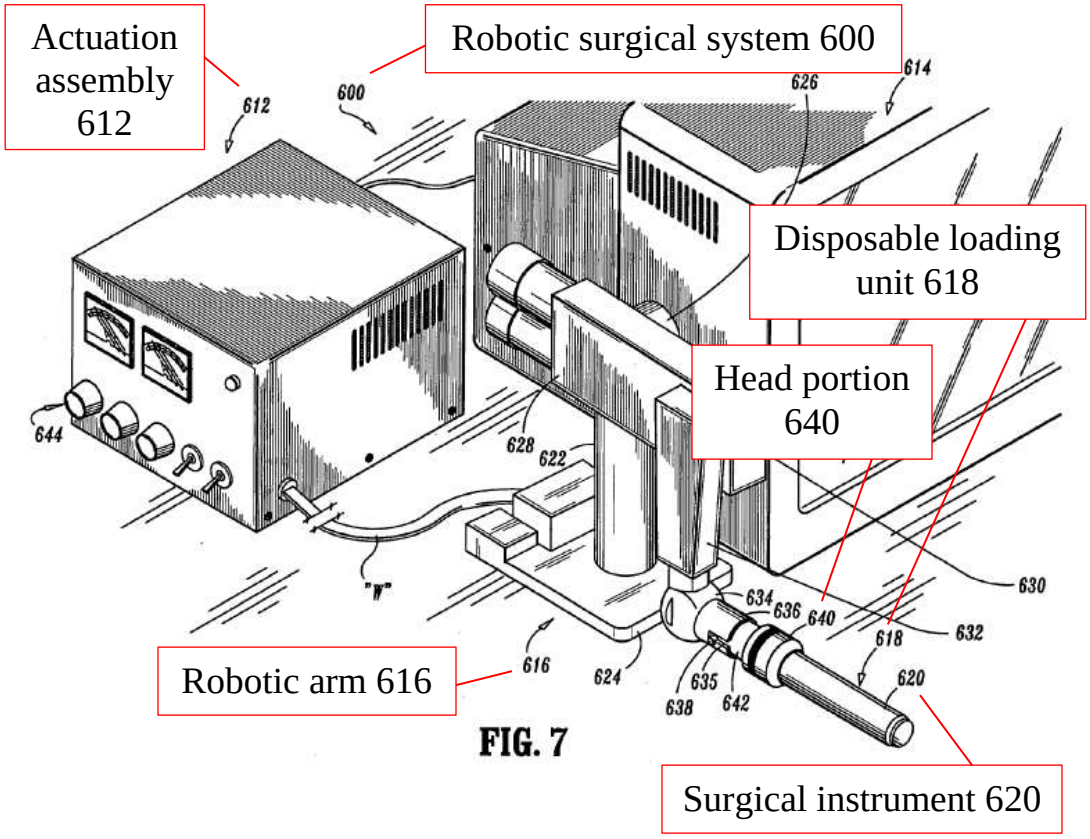


FIG. 7

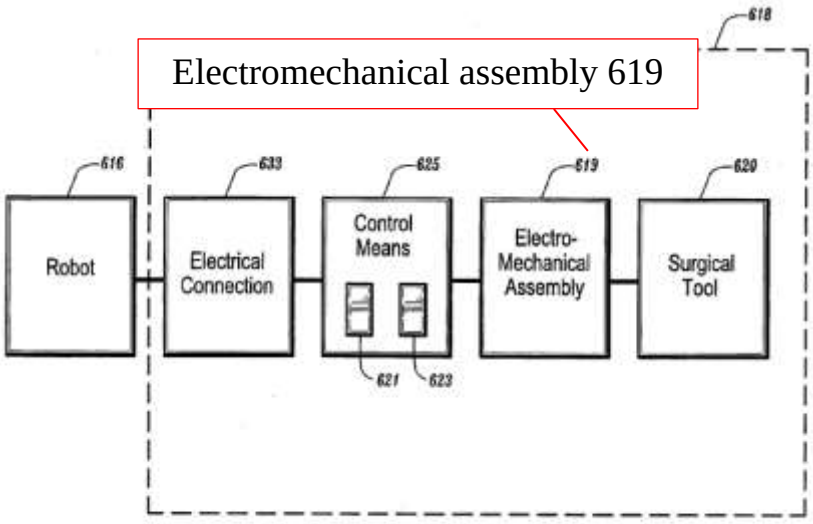
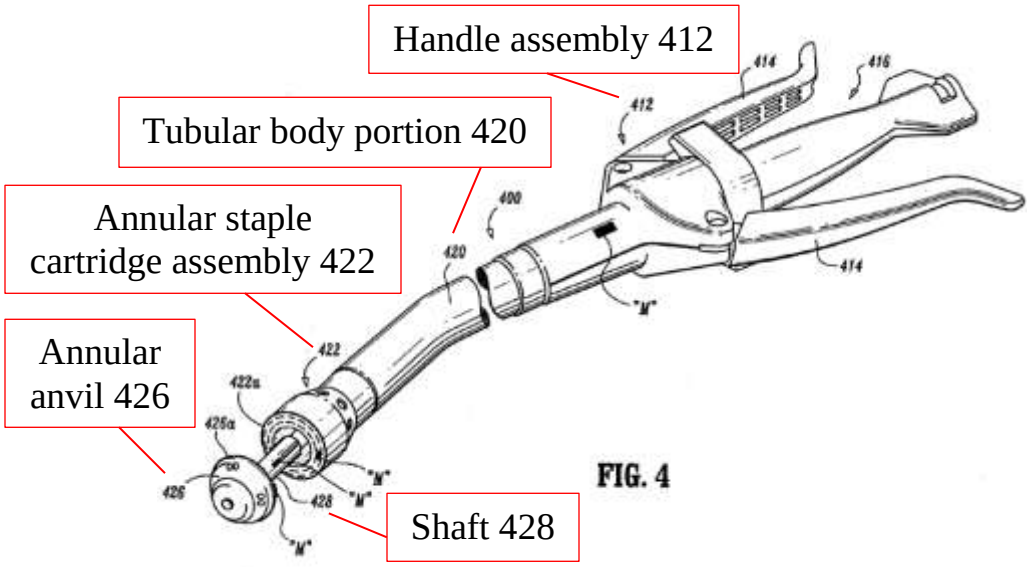


FIG. 8

Heinrich discloses that the generic surgical instrument 620 shown above in Figures 7-8 may be based on various handheld surgical instruments including surgical stapler 400. Heinrich, ¶¶100-103, 130, 133. And Heinrich broadly and unequivocally states that "the entire content of [Viola] is incorporated herein by reference, for a more detailed explanation of the operation of surgical stapler 400." *Id.*, ¶103. This statement incorporates all of Viola into Heinrich as if it was set out expressly rather than through incorporation. *See, e.g., Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000); *Biscotti Inc. v. Microsoft Corp.*, No. 2:13-CV-01015-JRG-RSP, 2017 U.S. Dist. LEXIS 144164, at *12 (E.D. Tex. May 11, 2017); Fischer Decl., ¶78.

Heinrich discloses that surgical stapler 400 includes a handle assembly 412 to open and close the end effector. Heinrich, ¶¶100, 103, Fig. 4. Surgical stapler

400 further includes a tubular body portion 420 extending from handle assembly 412, and annular staple cartridge assembly 422 operatively connected to a distal end of the tubular body portion 420, and an annular anvil 426 positioned opposite staple cartridge assembly 422 and connected to surgical stapler 400 by a shaft 428. *Id.*



Heinrich's incorporation of Viola discloses the internal structure of surgical stapler 400, including its "adjustable closure mechanism." Viola, Abstract. In one embodiment, the closure mechanism includes cam member 80 "with a helical groove 82 having a dual pitch." *Id.*, 9:21-43, Figs. 10-11. The first pitch 84 is greater than the second pitch 86. *Id.*

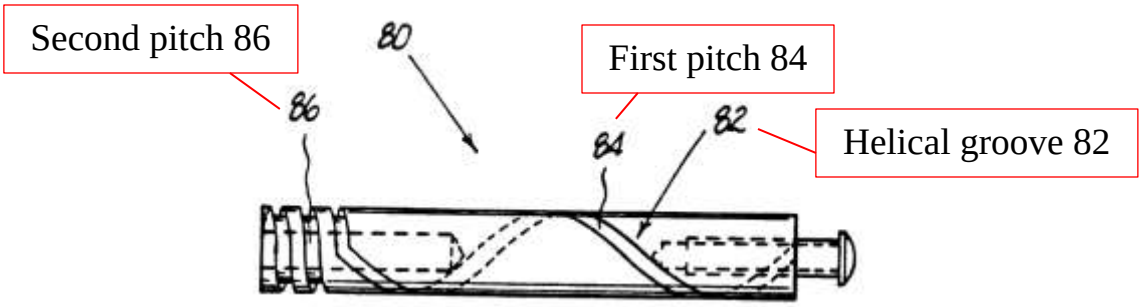


FIG. 10

In one embodiment, "cam member 80 is positioned within rotatable bushing 90 and rotatable sleeve member 92 [and] secured to inner rod 36." Viola, 9:34-37, Fig. 11. "Inner rod member 36 . . . is secured to flexible member 34." *Id.*, 8:64-66, Figs. 1, 11-12. And flexible member 34 is coupled to anvil member 26.[3] *Id.*, 7:34-39, Figs. 1, 11. Rotatable sleeve member 92 rotates upon rotation of grip member 18, but is prevented from moving longitudinally. *See id.*, 8:66-9:2 (describing a similar embodiment). In contrast, cam member 80 moves longitudinally, but is restricted from rotating.

[3] Viola's anvil member 26 corresponds to Heinrich's anvil 426. Fischer Decl., ¶81 n.2.

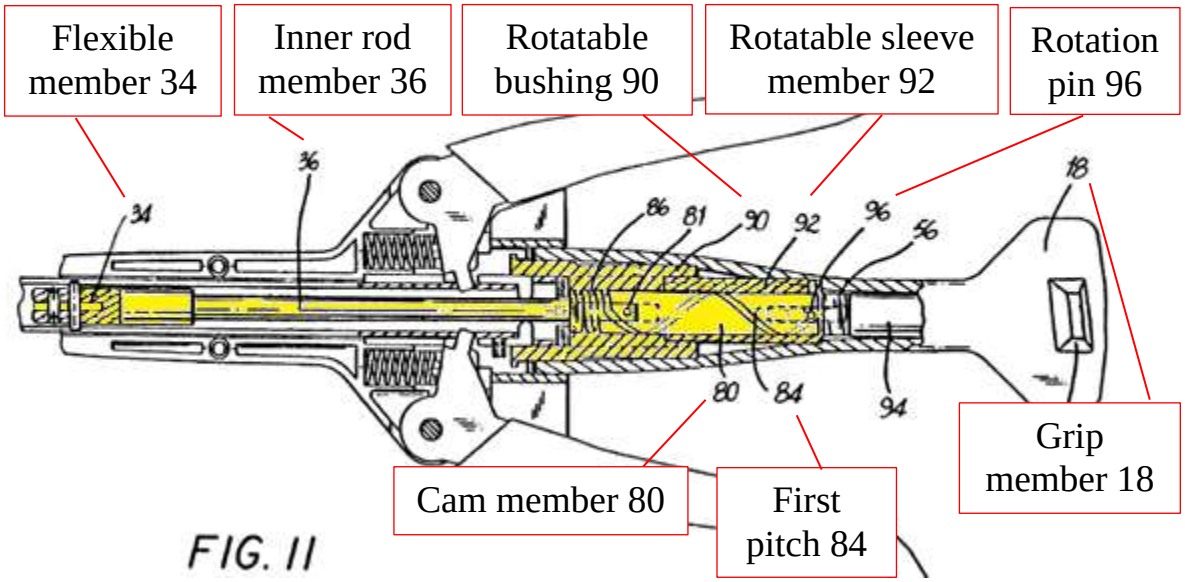


FIG. 11

As shown above, a "rotation pin 96 . . . is operably secured to rotatable sleeve 92, so that upon rotation of grip member 18, helical groove 82 begins to ride over pin member 96 at first pitch 84 [as seen in FIG. 11]. Cam member 80 begins to slide rearwardly in bore 94, thus [rapidly] drawing inner rod member 36 and flexible member 34 in a proximal direction." *Id.*, 9:37-43, Figs. 11-12.

"As cam member 80 reaches a point where rotation pin 96 is at the end of first pitch 84, anvil [426] is positioned adjacent [staple cartridge assembly 422]. Further rotation of grip member 18, as seen in FIG. 12, causes second pitch 86 to ride over pin 96 to provide for fine adjustment of the distance between anvil [426] and [staple cartridge assembly 422]." *Id.*, 9:43-51, Figs. 11-12; *see also* 3:26-38, 9:25-33.

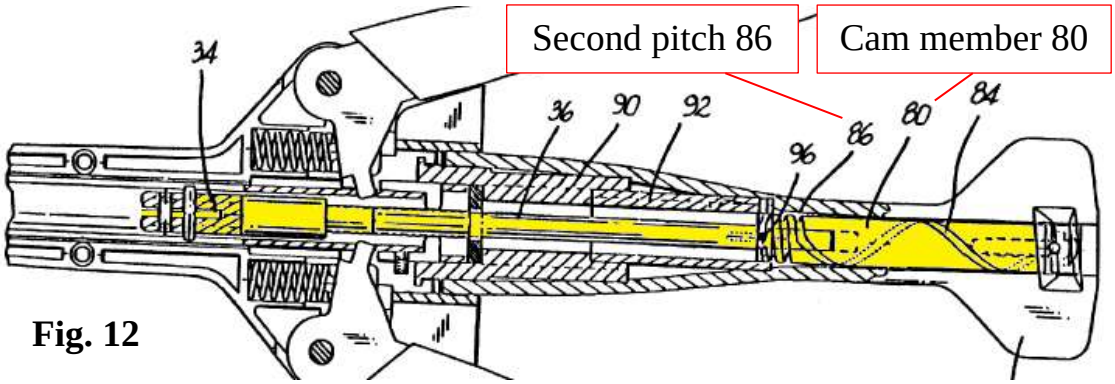


Fig. 12

"As used [in Heinrich], 'loading unit' is understood to include disposable loading units (e.g., DLU's) and single use loading units (e.g., SULU's). SULU's include removable cartridge units, *e.g.*, for open gastrointestinal anastomosis and transverse anastomosis staplers . . . ." Heinrich, ¶133. Furthermore, Heinrich states that "the above described surgical instruments [(*e.g.*, surgical stapler 400)] … can be employed with or interface directly with a robotic surgical system 600." Heinrich, ¶130. And, as shown below, Heinrich provides several examples of similar surgical tools modified to interface directly with robotic surgical system 600.

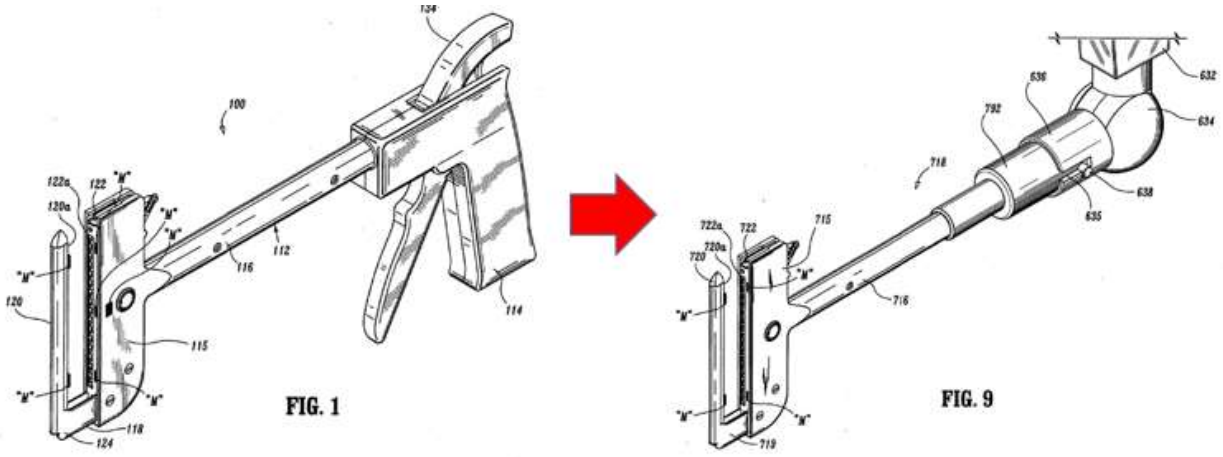
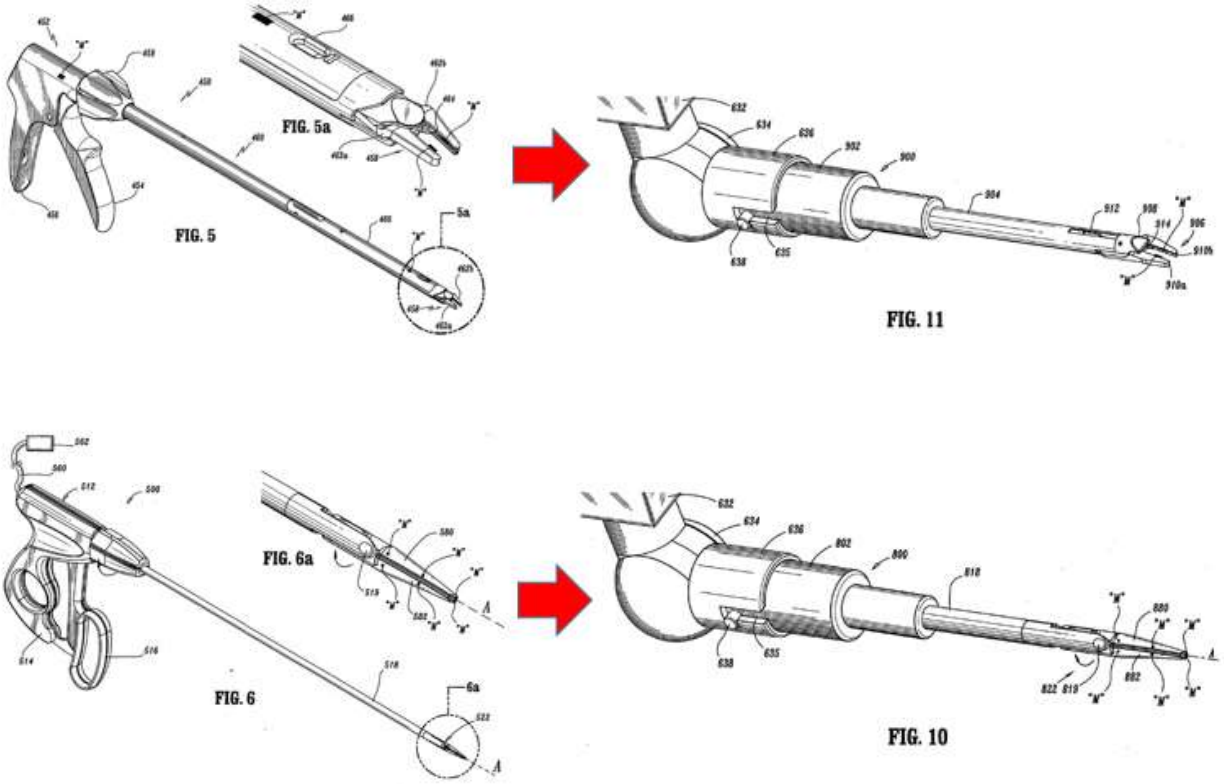


FIG. 1

FIG. 9



Compare Heinrich, Figs. 1, 5, 6 *with* Heinrich, Figs. 9, 11, 10, respectively.

Thus, a POSITA would have understood that Heinrich discloses the loading unit based on surgical stapler 400 operatively connected to robot 616 shown below in the composite image of Figures 4 and 9 from Heinrich, and a POSITA would have been able to implement such a configuration:

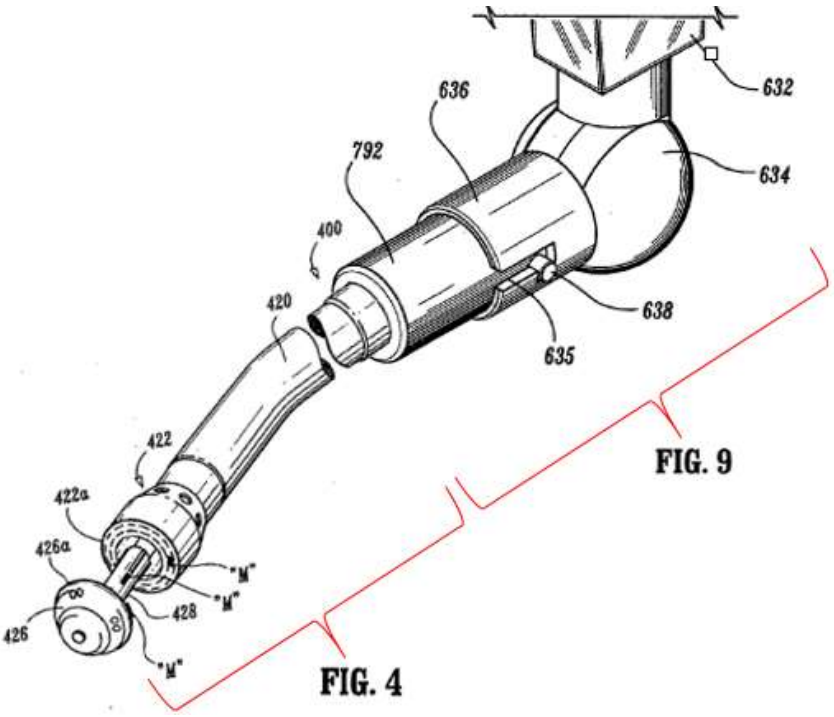


FIG. 9

FIG. 4

Fischer Decl., ¶85; *Blue Calypso, LLC v. Groupon, Inc*., 815 F.3d 1331, 1344 (Fed. Cir. 2016) ("[A] reference need not always include an express discussion of the actual combination to anticipate. Instead, a reference may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination.").

B. Timm

Timm discloses "a surgical instrument 4000 that is constructed for use in connection [with] a surgical tool assembly 100"," which is a surgical stapler. Timm, 35:44-41:18, Figs. 73-83.

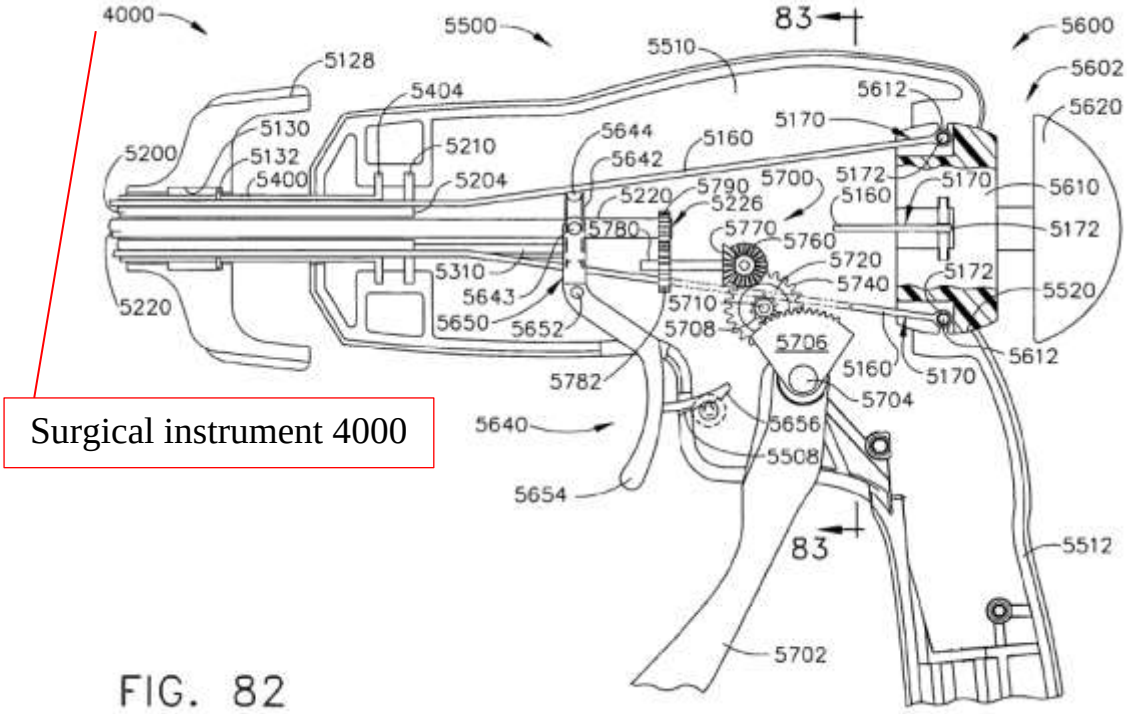


FIG. 82

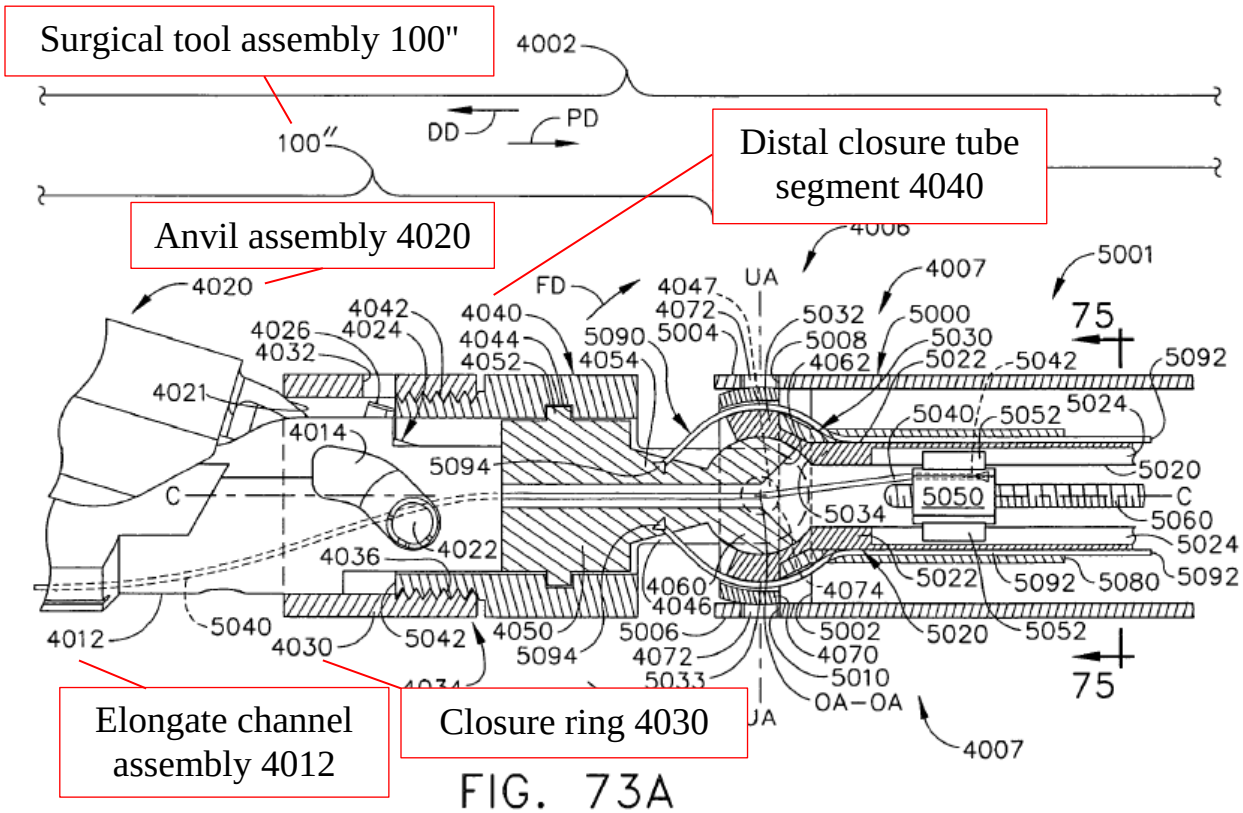


FIG. 73A

As shown above, surgical tool assembly 100" includes a distal closure tube segment 4040 and a closure ring 4030 as well as an elongate channel assembly 4012 and an anvil assembly 4020. *Id*., 35:64-36:24, Fig. 73A.

As shown in more detail below, anvil assembly 4020 is "pivotally coupled" to elongate channel assembly 4012 by "a pair of trunnions 4022 that are adapted to be received in corresponding slots 4014 in the walls of the elongate channel assembly 4012." *Id*., 35:64-36:24, Figs. 73A, 74A; *see also* Figs. 104-105. "The non-rotating closure ring 4030 is keyed to the elongate channel assembly 4012 and/or anvil assembly 4020 such that the closure ring 4030 cannot rotate relative to the elongate channel 4012." *Id*. And a "series of internal threads 4036 [are] provided in the proximal end 4034 of the non-rotating closure ring 4030 for threadably receiving a threaded distal end 4042 of a distal closure tube segment 4040." *Id*. Thus, "as the distal closure tube segment 4040 is rotated, the closure ring 4030 is driven axially in the distal direction DD [and] rides up a ramp 4021 on the proximal end of anvil assembly 4020 [into a proximal facing ledge] to cause the anvil assembly 4020 to [move distally and] pivot to a closed position." *Id*.; *see also* 45:45-55, Figs. 90-92, 104-105; Fischer Decl., ¶89. And the steeper camming surfaces of ramp 4021 and the proximal portions of slots 4014 cause anvil 4020 to move faster than the shallower distal camming surfaces of slots 4014. *Id*.

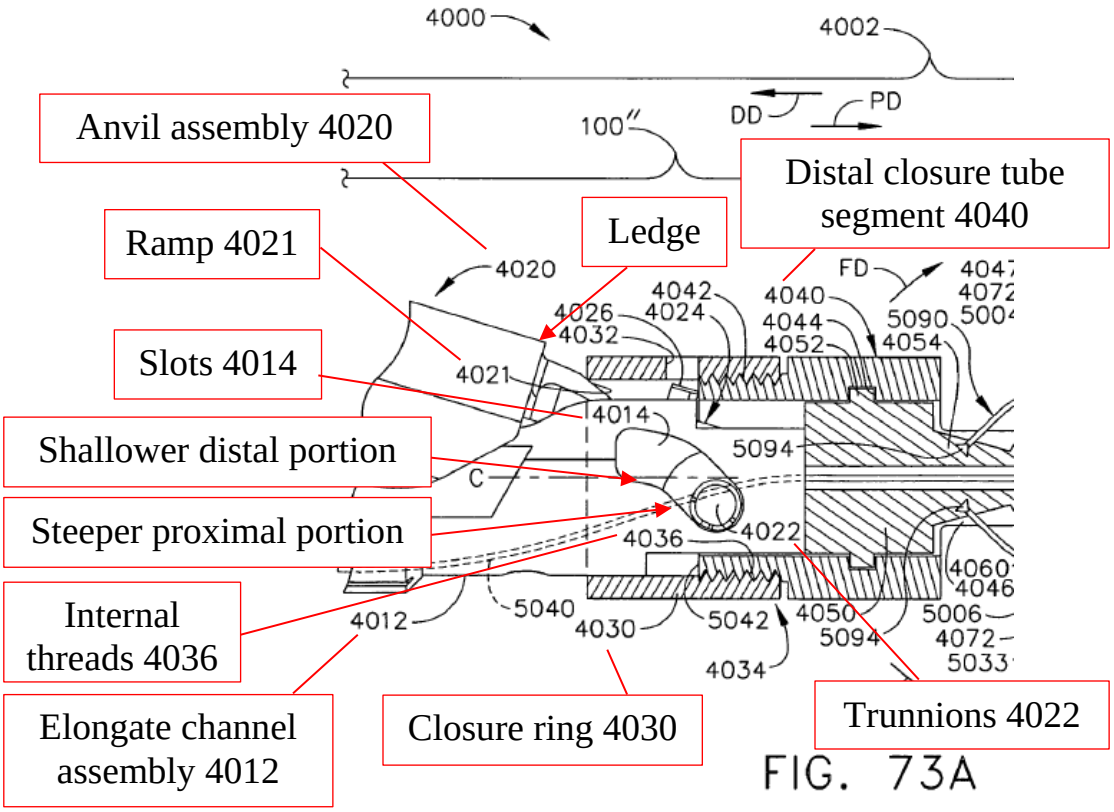
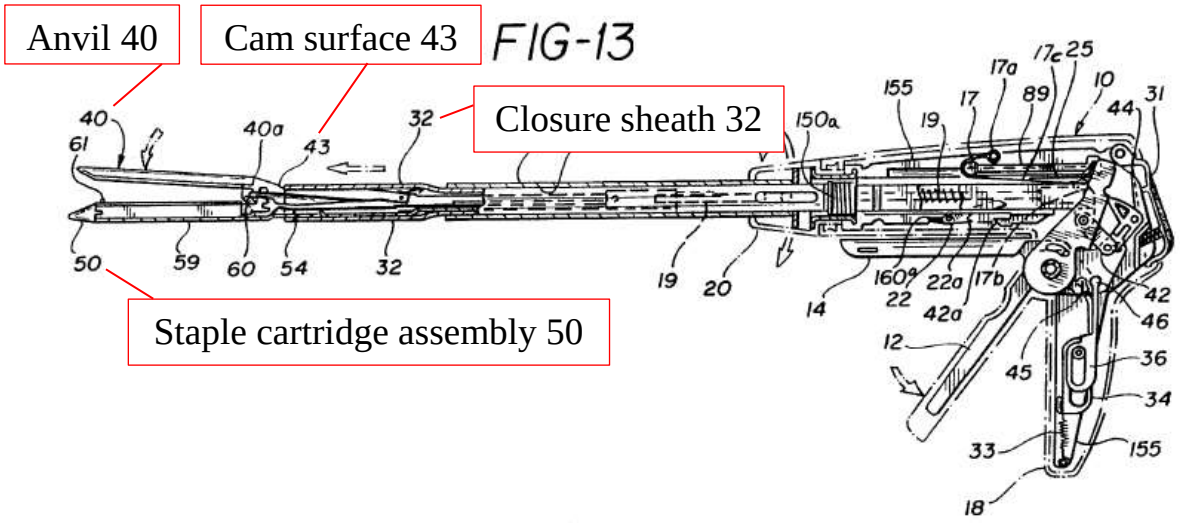


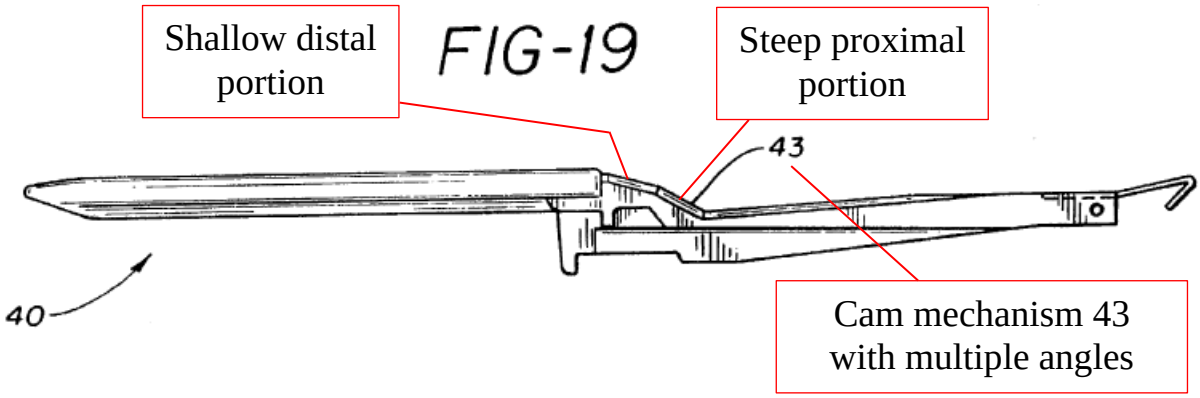
FIG. 73A

C. Schulze

Schulze discloses a linear surgical stapler with an end effector that includes an anvil 40 having a rear cam surface (or mechanism) 43 and a stapler cartridge assembly 50. Schulze, 13:4-6, 14:38-56, Figs. 18-25. The surgical stapler also include "a closure sheath 32 which is capable of camming the rear cam surface 43 of the anvil 40." *Id.*, 13:4-6, Fig. 13.



Schulze, Fig. 13. Notably, "[t]he cam mechanism 43 on the rear of the anvil 40 is designed with a multiple angle" that includes a "steeper proximal portion of the angle [that] allows faster closing of the anvil 40 against the cartridge assembly 50" and a "distal or more shallow angle." *Id.*, 14:38-56, Fig. 19. "These compound angles are specifically designed to give higher mechanical advantage when needed and faster closure and wider opening when needed." *Id.*, 14:53-56.



D. Anderson

Anderson describes a surgical instrument 28 for use with Petitioner's robotic surgical system 10. Fischer Decl., ¶92; Anderson, Abstract, 10:40-11:42, Figs. 1-

2. As shown below, robotic surgical system 10 includes a control station 12 operated by a surgeon or other user and a surgical work station, or "cart," 20. *Id.*

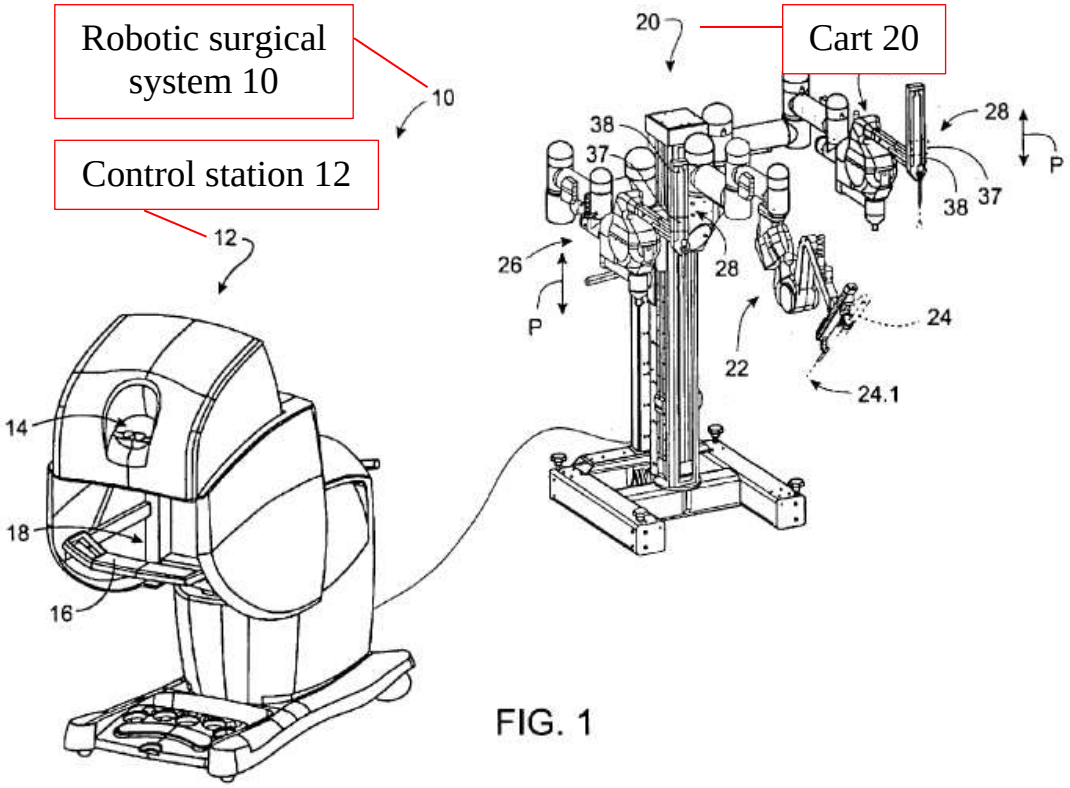


FIG. 1

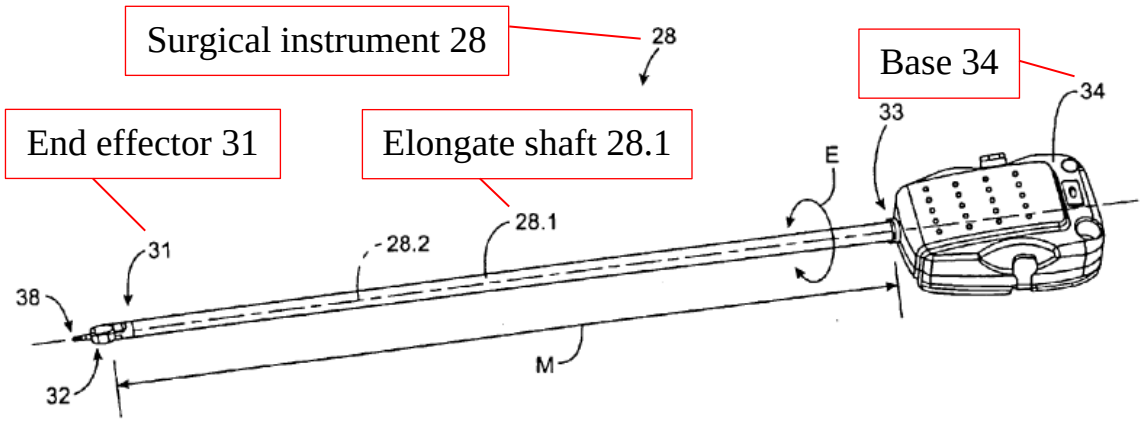


FIG. 2

The surgical instrument 28 "includes an elongate shaft [28.1] with an end effector [31] at one end and a base [34] at the opposite end." *Id.*, 10:25-30, 11:32-42. "The

tool base [34] is generally configured to engage the robotic surgical system [10] and to transmit forces from the robotic surgical system [10] to the [end effector]." *Id*., 10:32-35; *see also* 16:14-23 (incorporating U.S. Pat. App. No. 09/418,726, which issued as the Tierney '181 patent); 24:35-40 (same); Fischer Decl., ¶93.

Although the robotic system disclosed in Anderson is similar to the robotic system disclosed in Manzo, which was considered by the examiner during prosecution of the '288 patent, there is no basis for a determination under 35 U.S.C. § 325(d) that this petition relies on substantially similar prior art and/or arguments that have already been presented to the Office. For example, this Petition's reliance on Anderson is substantially different from the Examiner's reliance on Manzo. Thus, unlike this Petition, the Examiner did not consider whether the claimed subject matter would have been obvious over the robotic system of Anderson and Manzo in view of Timm and Viola. *Edwards Lifesciences Corp. v. Boston Scientific SciMed, Inc*., IPR2017-01295, Paper 9 (PTAB October 25, 2017). Moreover, Timm and Viola were cited but were never discussed by the examiner. *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00486, Paper 10 (PTAB July 15, 2015). Thus, not one of the six factors identified in *Becton, Dickinson and Company v. B. Braun Melsungen AG* weighs heavily in favor of denying institution. IPR2017-01586, Paper 8 at 17-28 (PTAB Dec. 15, 2017 (informative)).

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '288 PATENT IS UNPATENTABLE

For the reasons explained below, claims 10-11 of the '288 patent are unpatentable.

A. Ground 1: Heinrich anticipates claims 10-11

[10.1] A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator, said surgical tool comprising:

If the preamble is deemed to be a limitation, then Heinrich discloses it. Fischer Decl., ¶¶95-97. Heinrich discloses a surgical tool (surgical instrument 620[4]) for use with a robotic system (robotic surgical system 600) that has a tool drive assembly (electromechanical assembly 619) that is operatively coupled (via robot 616 and transmission wires ("W")) to a control unit (actuation assembly 612) of the robotic system that is operable by inputs (*e.g.*, by rotation of knobs 644) from an operator ("surgeon, nurse, technician, etc."). *Id*.; Heinrich, ¶¶100-103, 130, 132-34, 136, 137, 140, Figs. 7, 8.

[4] Surgical instrument 620 is also identified by Heinrich as surgical tool instrument 620 and surgical tool 620.

Control unit ("actuation assembly 612")

Robotic system ("robotic surgical system 600")

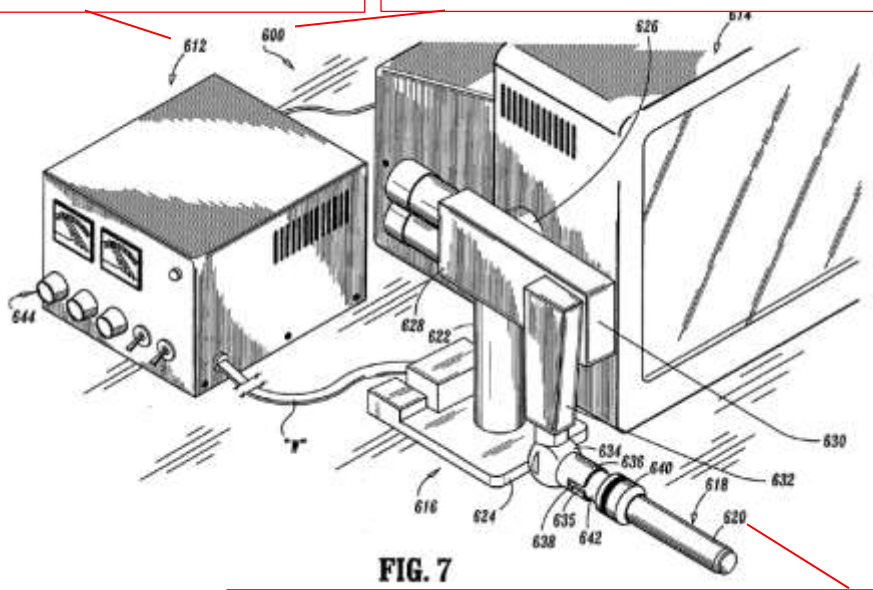


FIG. 7

Surgical tool ("surgical instrument 620")

Tool drive assembly ("electromechanical assembly 619")

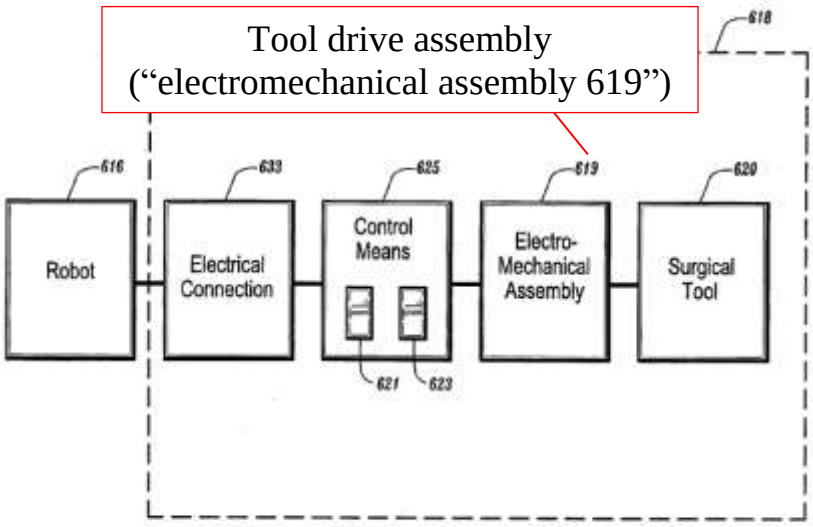


FIG. 8

Heinrich's Viola embodiment discloses that surgical instrument 620 can be based on surgical stapler 400. Fischer Decl., ¶96; Heinrich, ¶¶100-103, Figs. 4, 7, 8.

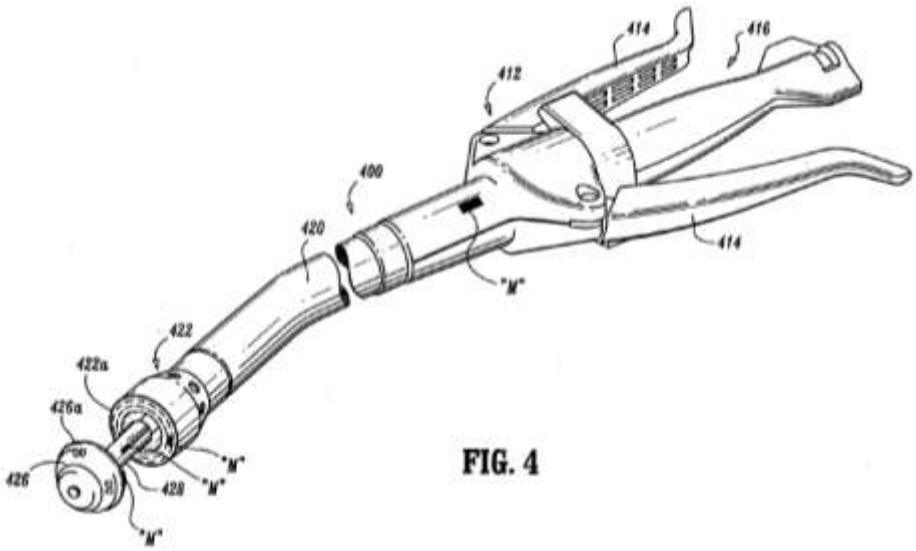


FIG. 4

And, as explained above in Section VIII.A, it would have been clear to a POSITA that Heinrich discloses a loading unit that includes this tool as shown below in the composite image of Figures 4 and 9 from Heinrich. Fischer Decl., ¶97.

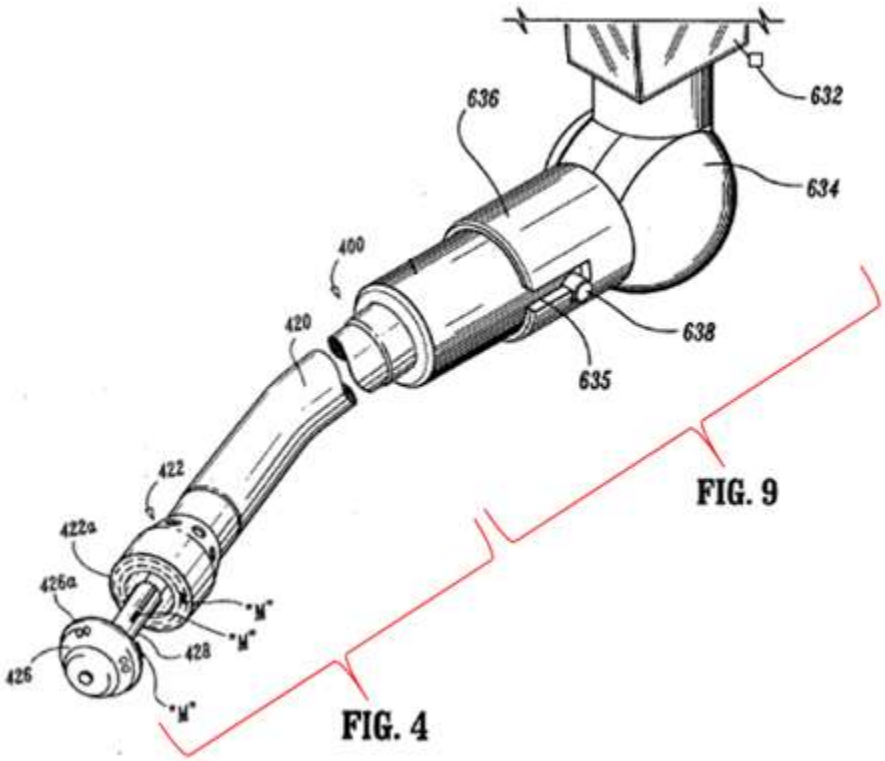


FIG. 9

FIG. 4

[10.2] a surgical end effector comprising at least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof

Heinrich discloses this limitation. Fischer Decl., ¶¶98-104.

"A surgical end effector comprising"

Heinrich discloses a surgical end effector that includes a staple cartridge assembly 422 and anvil 426. *Id*.; Heinrich, ¶100, Fig. 4; *see also* ¶103 (incorporating Viola by reference).

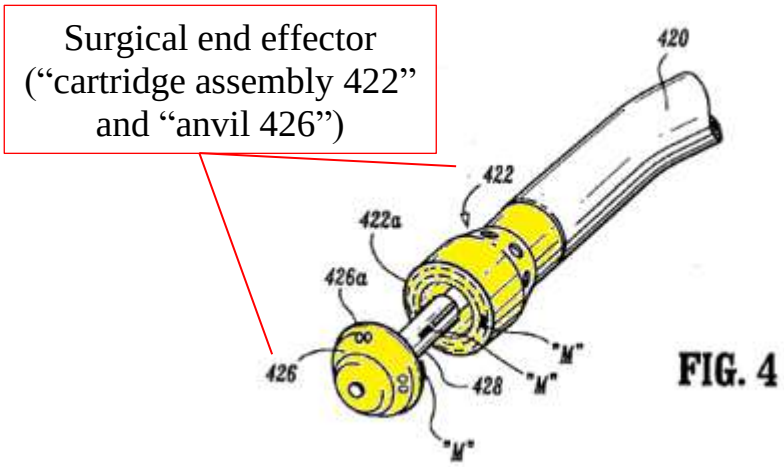
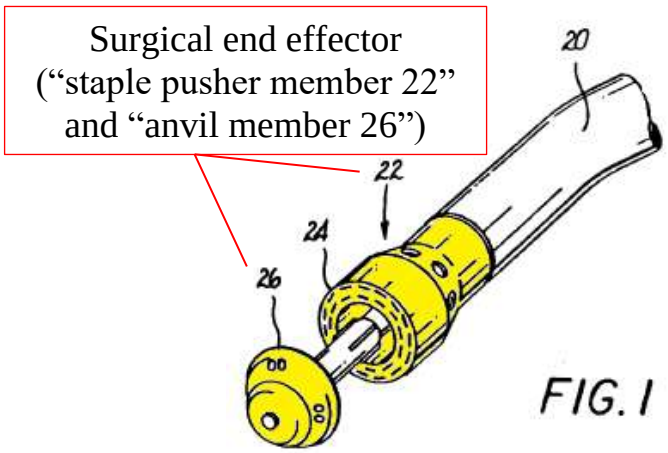


FIG. 4

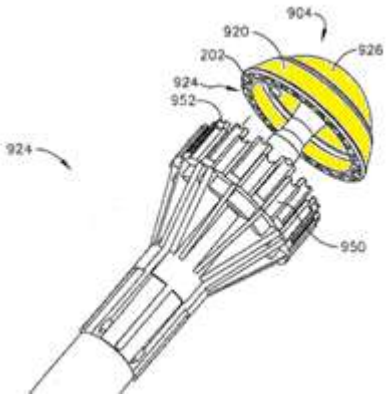
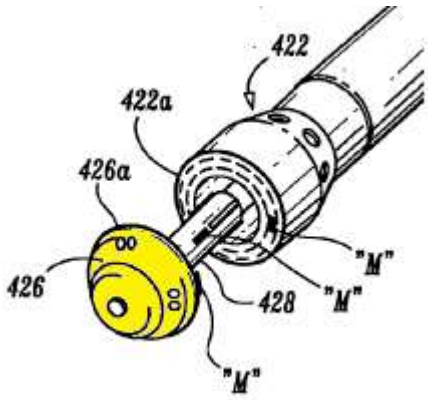
Heinrich's incorporation of Viola also discloses this element. Heinrich, ¶103. In Viola, these components of the end effector are identified as staple pusher member 22 and anvil member 26, respectively.[5] Fischer Decl., ¶100; Viola, 7:1-9, Fig. 1.

[5] Hereinafter we refer to them as anvil 426 and staple cartridge assembly 422.



"At least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof"

As explained above, the term "component portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is the anvil of a circular stapler. *See* Section VII.A. Heinrich discloses the same structure—anvil 426. Fischer Decl., ¶101; Heinrich, ¶¶100, 130, Fig. 4; Viola, 7:1-9, Fig. 1.

'116 app. (incorporated by reference into the '288 Patent)	Heinrich
	

To the extent there are any dissimilarities between anvil 426 and the circular

stapler anvils disclosed in the ’288 patent, anvil 426 is an equivalent structure because there are no substantial differences. Fischer Decl., ¶102. Like the circular stapler anvils disclosed in the ’288 patent, Heinrich’s anvil 426 performs the claimed function of selectively moving between first (open) and second (closed) positions relative to at least one other component portion thereof (the staple cartridge) in substantially the same way as the circular stapler anvils in the ’288 patent (moving toward the staple cartridge) to produce substantially the same result (closing the end effector). *Id.*

Furthermore, a POSITA would have recognized that: (1) Heinrich’s anvil 426 and the ’288 patent’s circular stapler anvils are interchangeable; and (2) the ’288 patent’s circular stapler anvils add nothing of significance to the prior art anvil disclosed in Heinrich. *Id.*, ¶103. Indeed, the ’288 patent explicitly recognizes that “different types of end effectors may be employed,” and that the “claims are intended to cover all such modifications and variations.” ’288 patent, 90:10-17; *see also* 1:62-63, 20:10-13.

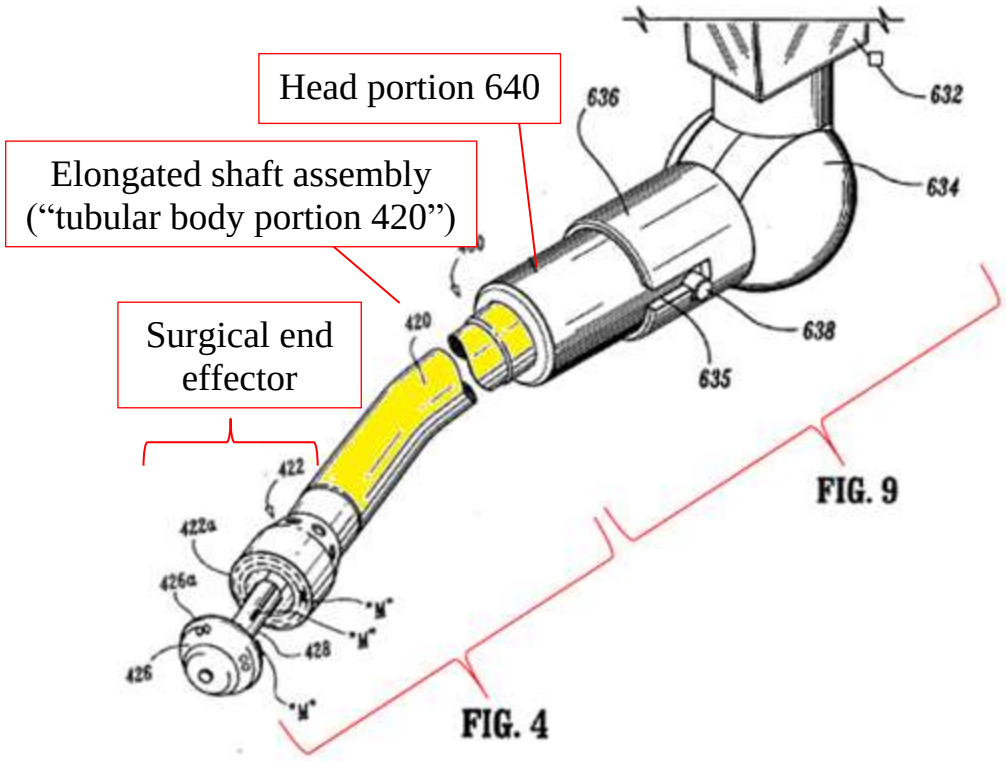
If the Board does not agree that the term “component portion” invokes 35 U.S.C. §112, ¶6, then anvil 426 is nonetheless at least one component portion of the end effector that is selectively movable between first (“open”; “extended position”) and second (“close[d]”; “retracted position”) positions relative to at least one other component portion thereof (staple cartridge assembly 422). Fischer Decl.,

¶104; Heinrich, ¶¶100, 103; Viola, 3:26-38. A POSITA would have understood that Heinrich's disclosure of opening and closing surgical stapler 400 refers to selective movement of anvil 426 relative to staple cartridge assembly 422. Fischer Decl., ¶104. And Viola explicitly describes "advancing the anvil [426] between the extended position away from the [staple cartridge assembly 422] and a retracted position adjacent the [staple cartridge assembly 422]." Heinrich, ¶103; Viola, 3:26-38.

[10.3] an elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising:

Heinrich discloses this limitation. Fischer Decl., ¶¶105-110. Heinrich discloses an elongated shaft assembly (*e.g.*, the combination of tubular body portion 420, rotatable bushing 90, rotation pin 96, rotatable sleeve member 92, cam member 80, inner rod 36, pin 81, and flexible member 34) operably coupled to the surgical end effector. *Id*.; Heinrich, ¶103, Fig. 4; Viola, 9:21-52, Figs. 1, 11-12.

As shown below in the composite image of Figures 4 and 9 of Heinrich, tubular body portion 420 is operably coupled to the surgical end effector:



Heinrich, Figs. 4, 9. Heinrich also discloses that electromechanical assembly 619 in head portion 640 operates the surgical instrument, which confirms the operable connection between the elongated shaft assembly and the end effector. *Id*., ¶¶134, 137; Fischer Decl., ¶107.

Heinrich's incorporation of Viola discloses that the elongated shaft assembly also includes the combination of rotatable bushing 90, rotation pin 96, rotatable sleeve member 92, cam member 80, inner rod 36, pin 81, and flexible member 34. Fischer Decl., ¶108; Heinrich, ¶¶100, 103, Fig. 4; Viola, 9:21-52, Figs. 1, 11-12.

Elongated shaft assembly
("rotatable bushing 90", "rotation pin 96", "rotatable sleeve member 92", "cam member 80", "inner rod 36", "pin 81", and "flexible member 34")

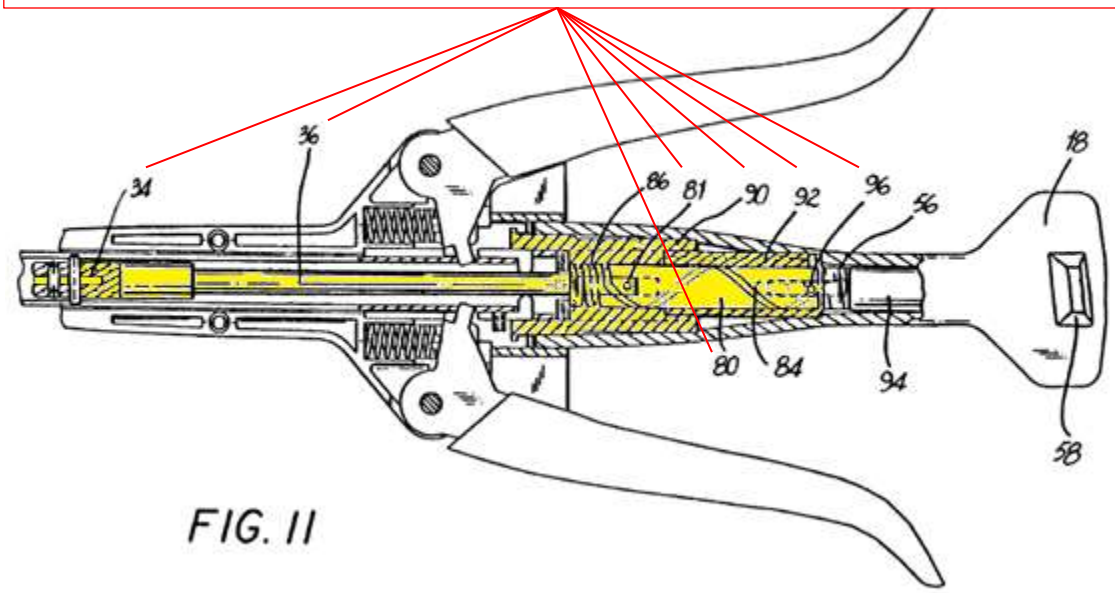


FIG. 11

"[C]am member 80 is positioned within rotatable bushing 90 and rotatable sleeve member 92." *Id.*, 9:35-52, Fig. 11. "A rotation pin 96 . . . is operably secured to rotatable sleeve 92." *Id.* "Cam member 80 is secured to inner rod 36 . . . by pin 81." *Id.*, 9:35-37, Figs. 11-12; *see also* 9:30-33. "Inner rod member 36 . . . is secured to flexible member 34." *Id.*, 8:64-66, Figs. 1, 11-12. And "[f]lexible member 34 . . . is coupled to the connection means 30 within [staple cartridge assembly 422] for connection to anvil [426]." *Id.*, 7:34-39, Figs. 1, 11; *see also* 7:3-6.

Although Viola's rotatable bushing 90 and rotatable sleeve member 92 are manually actuated with grip member 18, a POSITA would have understood that

Heinrich's loading unit 618 based on Viola's surgical stapler 400 is created by removing the grip member 18, and instead using electro-mechanical assembly 619 to rotate rotatable bushing 90 and rotatable sleeve member 92. Fischer Decl., ¶110.

[10.3.1] an axially movable portion in operable communication with said at least one selectively movable component portion of said surgical end effector

Heinrich discloses this limitation. Fischer Decl., ¶¶111-18.

"Axially movable portion"

As explained above, the term "axially movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is the combination of threaded closure rod 3342', closure nut 3347, and flexible member 3345.[6] *See* Section VII.B.

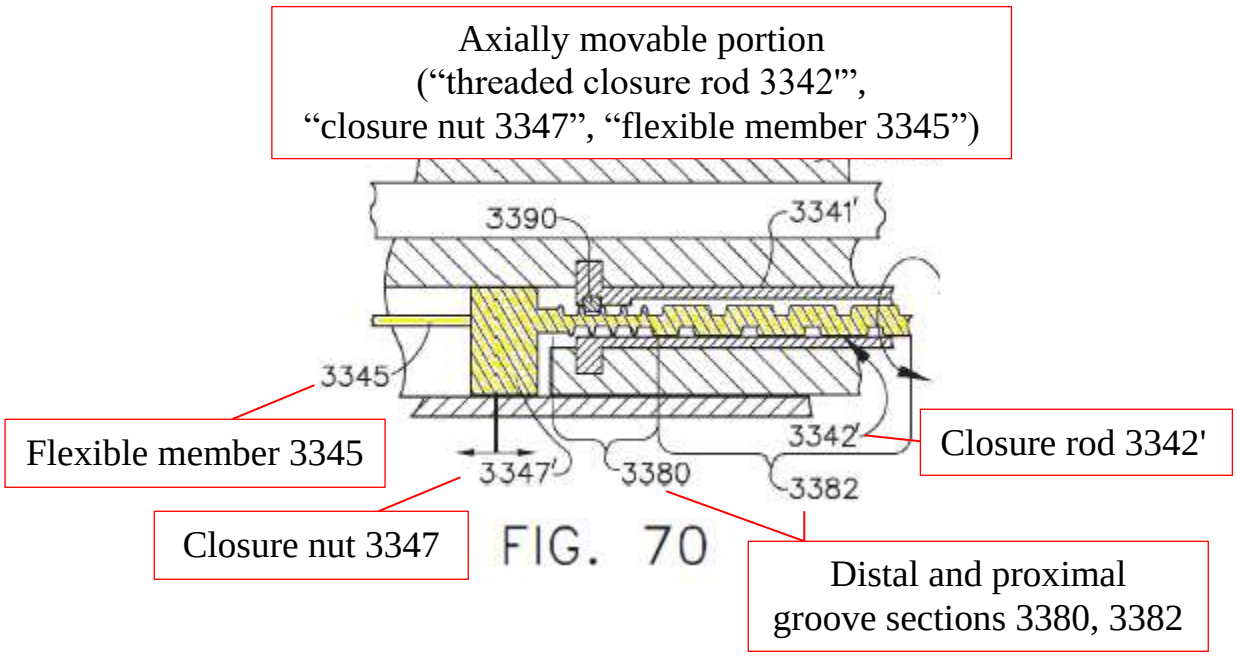
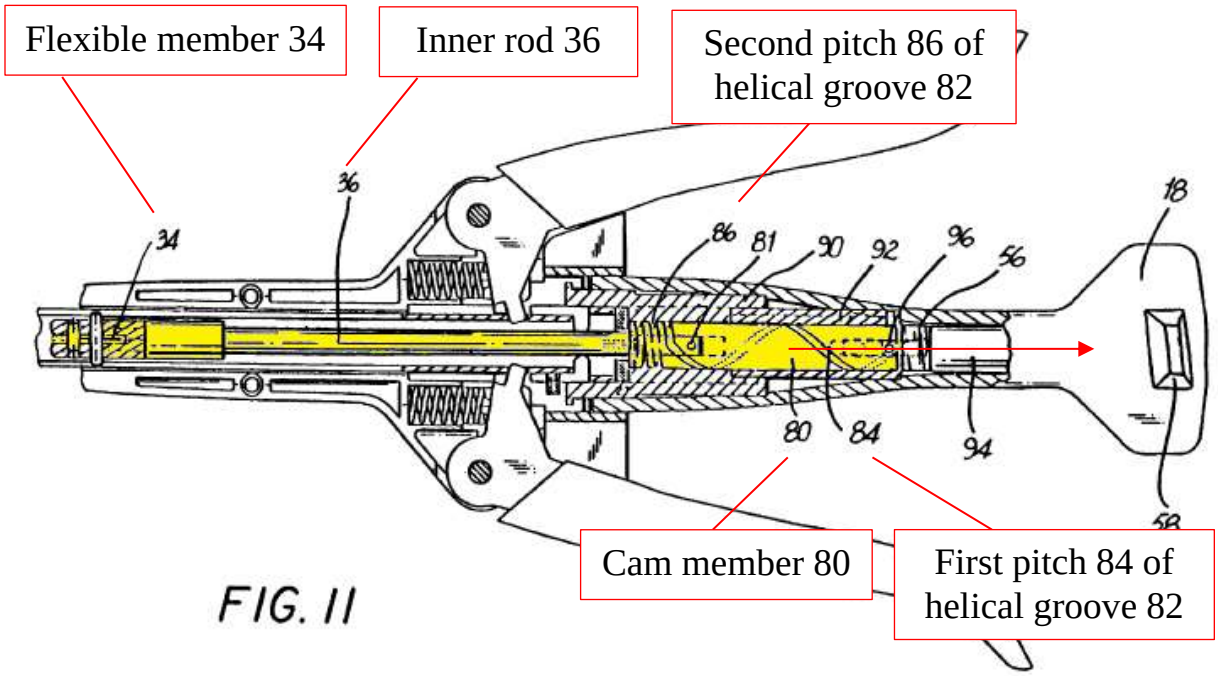


FIG. 70

Heinrich's incorporation of Viola discloses a nearly identical and equivalent

[6] As noted above, closure nut 3347 is mislabeled as 3347' in Figures 70-71.

structure (the combination of threaded cam member 80, inner rod 36, and flexible member 34). Fischer Decl., ¶113; Heinrich, ¶103; Viola, 3:27-35, 9:21-52, Figs. 10-12.



Indeed, there are no substantial differences between these two structures for several reasons. Fischer Decl., ¶114. Heinrich's axially movable portion performs the first claimed function of moving the selectively movable component portion of the surgical end effector (anvil 426) from the first position (open) into an intermediate position (the position of anvil 426 when "rotation pin 96 is at the end of first pitch 84") at a first rate ("rapid[ly]") in substantially the same way as the '288 patent to produce substantially the same result (quickly gripping the tissue). *Id*. And Heinrich's axially movable portion performs the second claimed function of mov-

ing said selectively movable component portion (anvil 426) of the surgical end effector from the intermediate position (the position of anvil 426 when "rotation pin 96 is at the end of first pitch 84") to the second position (closed) at a second rate (slowly; "incremental[ly]") that is less than the first rate (rapidly) in substantially the same way as the '288 patent to produce substantially the same result (slowly clamping the tissue). *Id*.

Similar to the interaction between closure rod 3342' and lug 3390 in the '288 patent, cam member 80 of Viola's axially movable portion "is provided with a helical groove 82 having a dual pitch . . . [that] ride[s] over pin member 96." Viola, 9:21-52, Figs. 10-12. "The first pitch 84 is greater than the second pitch 86, so that first pitch 84 provides for coarse adjustment or a large approximation of the anvil [426] towards [staple cartridge assembly 422], while second pitch 86 provides for fine adjustment or incremental movement of the anvil [426] towards [staple cartridge assembly 422]." *Id*.; *see also* Abstract.

Finally, a POSITA would have recognized that: (1) Heinrich's axially movable portion and the '288 patent's axially movable portion are interchangeable; and (2) the '288 patent's axially movable portion adds nothing of significance to the prior art structure disclosed in Heinrich. Fischer Decl., ¶116.

If the Board does not agree that the term "axially movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6, then the combination of cam member 80, inner rod

36, and flexible member 34 is nonetheless an axially movable portion of the elongated shaft assembly. Fischer Decl., ¶117. Like closure rod 3342' in the '288 patent's axially movable portion, cam member 80 of Viola's axially movable portion "slide[s] rearwardly in bore 94" (*i.e.*, moves axially), "thus drawing inner rod member 36 and flexible member 34 in a proximal direction." Viola, 9:40-42. The axial movement of cam member 80 (highlighted in red) relative to rotatable sleeve member 92 (highlighted in yellow) is shown below in Figures 11-12 of Viola.

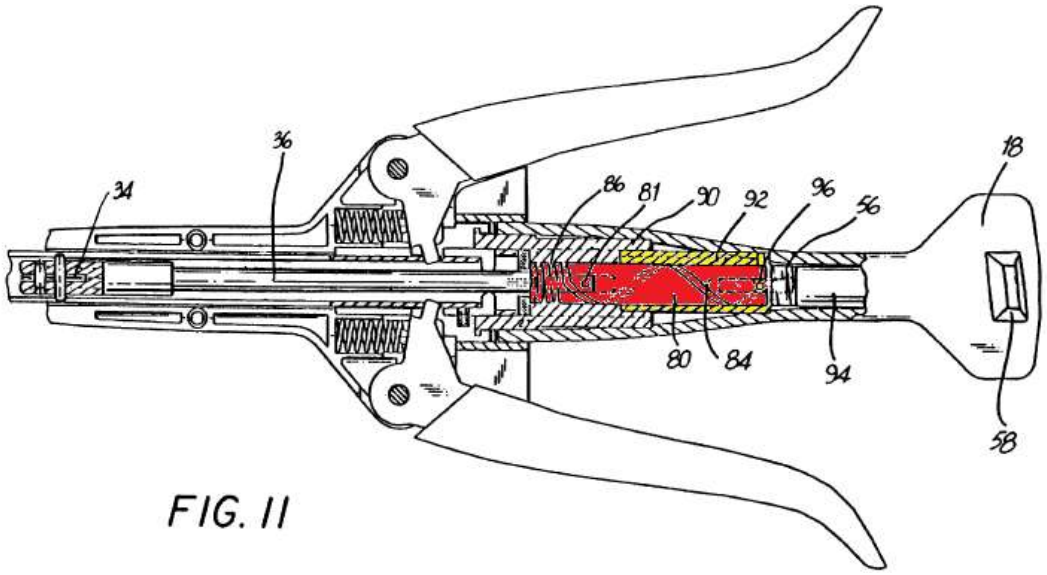


FIG. 11

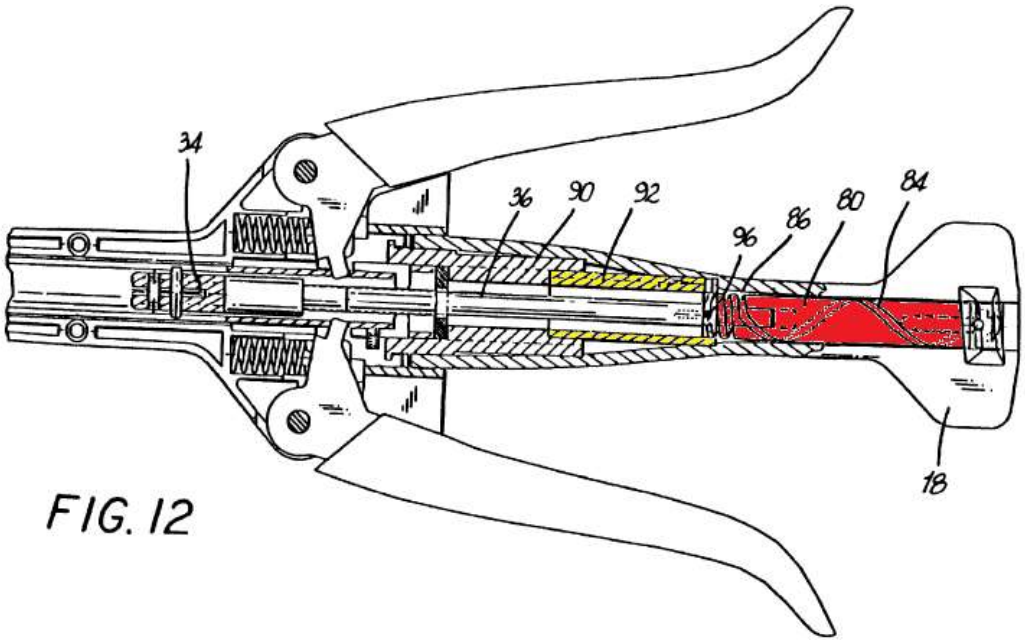


FIG. 12

"In operable communication with said at least one selectively movable component portion of said surgical end effector"

Heinrich's axially movable portion (the combination of cam member 80, inner rod 36, and flexible member 34) is in operable communication with the at least one selectively movable component portion (anvil 426) of the surgical end effector. Fischer Decl., ¶118; Heinrich, ¶103; Viola, 9:21-52, Figs. 11-12. As explained in Viola, flexible member 34 of the axially movable portion "is coupled to the connection means 30 within [staple cartridge assembly 422] for connection to anvil [426]." Viola, 7:34-39, Figs. 1, 11; *see also* 7:3-6. Thus, selective "[m]ovement of inner rod 36 and flexible member 34 [by the surgeon] controls the advancing and retracting of anvil [426]." *Id.*, 7:37-39.

[10.3.2] a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion

causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.

Heinrich discloses this limitation. Fischer Decl., ¶¶119-26.

"Rotatably movable portion"

As explained above, the term "rotatably movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is the combination of hollow threaded end portion 3341' and lug 3390. *See* Section VII.C.

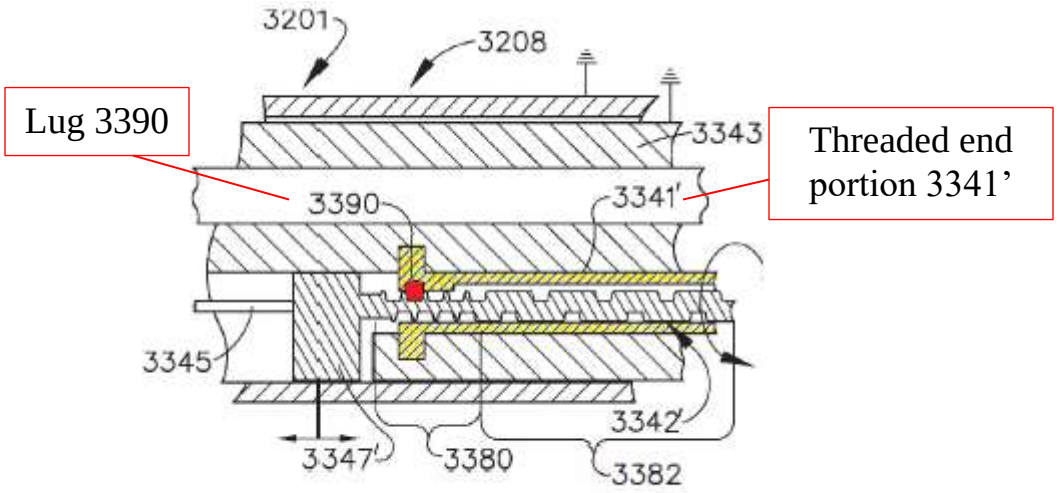


FIG. 70

Heinrich's incorporation of Viola discloses a nearly identical and equivalent structure (the combination of rotation pin 96 and rotatable sleeve member 92). Fischer Decl., ¶121.

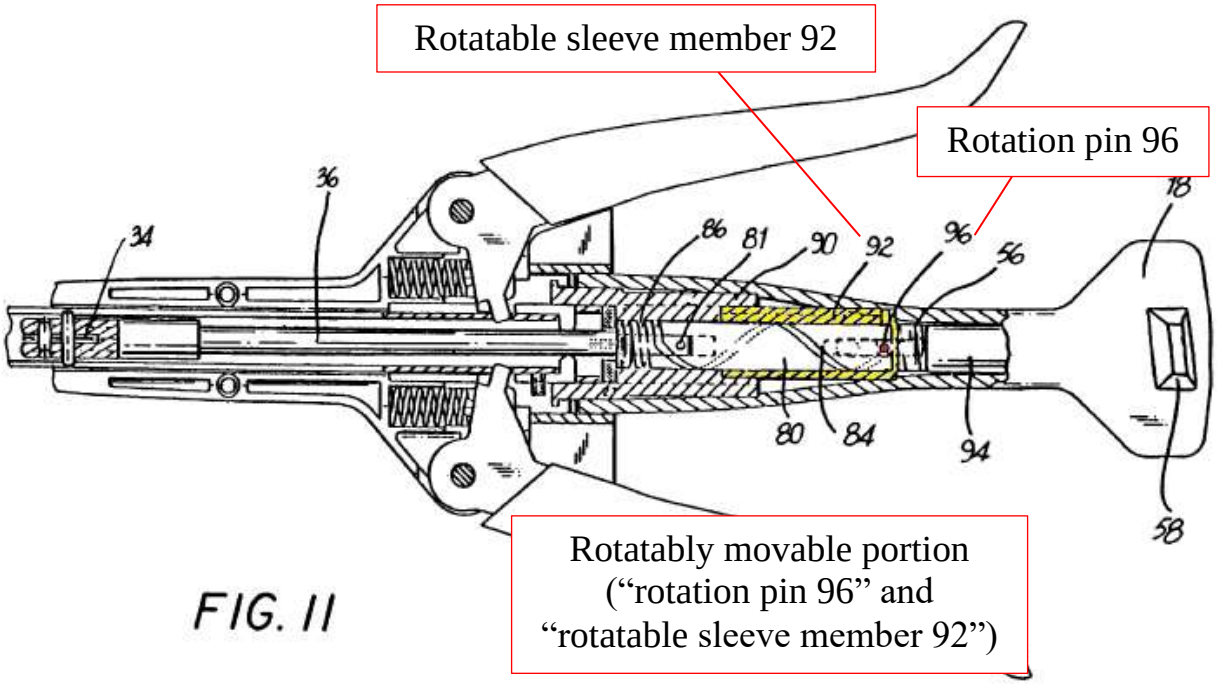


FIG. 11

Indeed, there are no substantial differences between these two structures for several reasons. *Id.*, ¶122. For example, the initial and subsequent rotations of Heinrich's rotatably movable portion cause the axially movable portion to perform its claimed functions (*see* Ground 1, element [10.3.1]) in substantially the same way (using a dual pitched slot/groove that interacts with a pin in the axially movable portion) to produce substantially the same result (initially closing the end effector at a first rate and then at a second rate, wherein the first rate is greater than the second rate) as the '288 patent. *Id.*

Like the '288 patent's lug 3390, Heinrich's pin 96 is "operably secured to rotatable sleeve 92, so that upon rotation [of rotatable sleeve 92] . . . helical groove 82 [of cam member 80] begins to ride over pin member 96 at [a] first pitch 84." Viola, 9:21-52, Figs. 10-12. "Further rotation . . . causes second pitch 86 to ride

over pin 96." *Id*. And "first pitch 84 provides for coarse adjustment or a large approximation of the anvil [426] towards [staple cartridge assembly 422], while second pitch 86 provides for fine adjustment or incremental movement of the anvil [426] towards [staple cartridge assembly 422]." *Id*.; *see also* Abstract. Thus, rotating the combination of rotation pin 96 and rotatable sleeve member 92 causes the axially movable portion (the combination of threaded cam member 80, inner rod 36, and flexible member 34) to perform its claimed functions as explained above in Ground 1, element [10.3.1]. *Id*.; Fischer Decl., ¶123.

A POSITA would have also recognized that: (1) Heinrich's rotatably movable portion and the '288 patent's rotatably movable portion are interchangeable; and (2) the structure corresponding to the '288 patent's rotatably movable portion adds nothing of significance to the prior art structure disclosed in Heinrich. *Id*., ¶124.

If the Board does not agree that the term "rotatably movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6, then the combination of rotation pin 96 and rotatable sleeve member 92 is nonetheless a rotatably movable portion of the elongated shaft assembly. Fischer Decl., ¶125. Like the combination of threaded end portion 3341' and lug 3390 in the '288 patent, the combination of rotation pin 96 and rotatable sleeve member 92 is a portion of the elongated shaft assembly that

can be rotated to cause the axially movable portion to perform its claimed functions. *Id.*; Viola, 9:35-52, Figs. 10-12.

"Rotatably movable portion in operable engagement with said axially movable portion"

Heinrich's rotatably moveable portion (the combination of rotation pin 96 and rotatable sleeve member 92) is in operable engagement with cam member 80 of the axially movable portion. *Id.*; Heinrich, ¶103; Viola, 9:21-52, Figs. 11-12. "As seen in FIG. 11, cam member 80 is positioned within rotatable bushing 90 and rotatable sleeve member 92. [And] rotation pin 96 . . . is operably secured to rotatable sleeve 92, so that . . . helical groove 82 [of cam member 80] . . . ride[s] over pin member 96." *Id.*

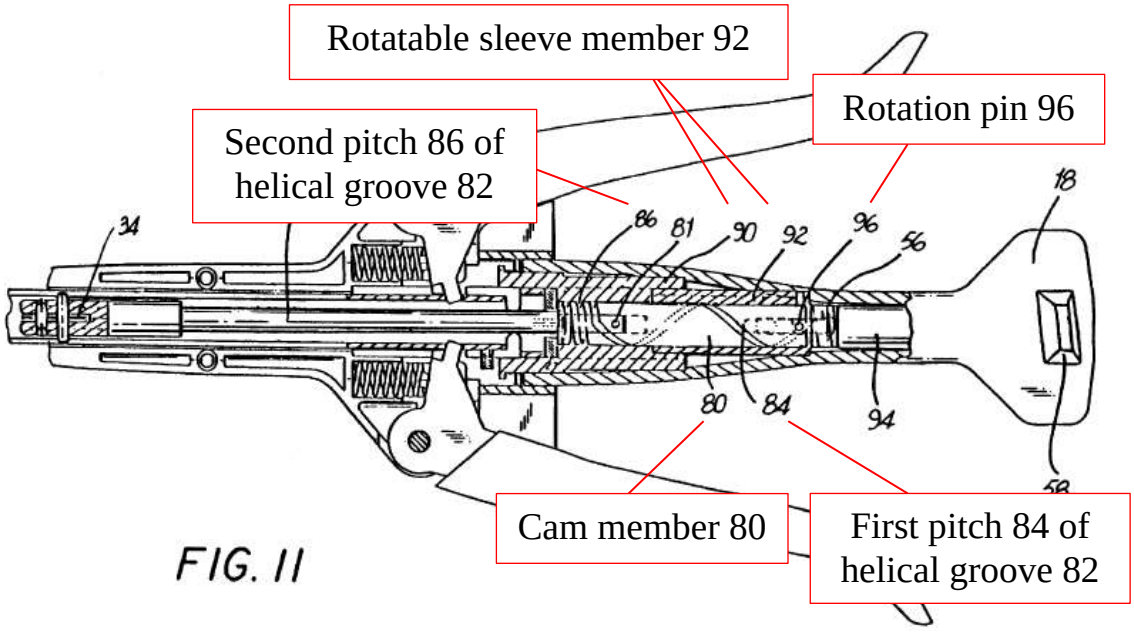


FIG. 11

[11] A surgical tool . . . wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion

Claim 11 repeats elements [10.1]-[10.3.2] of claim 10, but removes the limitation in element [10.3.2] that the first rate be greater than the second rate. Fischer Decl., ¶127; *compare* '288 patent, claim 10 *with id*., claim 11. Thus, Heinrich discloses the corresponding elements of claim 11. *See* Fischer Decl., ¶127; Ground 1, elements [10.1]-[10.3.2].

Claim 11 also adds a clause reciting: "wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion." Heinrich discloses this limitation as well. Fischer Decl., ¶128. The rotatably moveable portion of Heinrich's Viola embodiment (the combination of rotatable bushing 90, rotation pin 96, and rotatable sleeve member 92) comprises a closure member (the combination of rotation pin 96 and rotatable sleeve 92) in threaded engagement with threaded cam member 80 of the axially movable portion (the combination of threaded cam member 80, inner rod 36, and flexible member 34). *Id*.; Ground 1, element [10.3.2].

B. Ground 2: Timm anticipates claims 10-11

[10.1] A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator, said surgical tool comprising:

Timm discloses a surgical tool (surgical tool assembly 100"). Fischer Decl., ¶129; Timm, 35:44-41:18, Figs. 73-83.

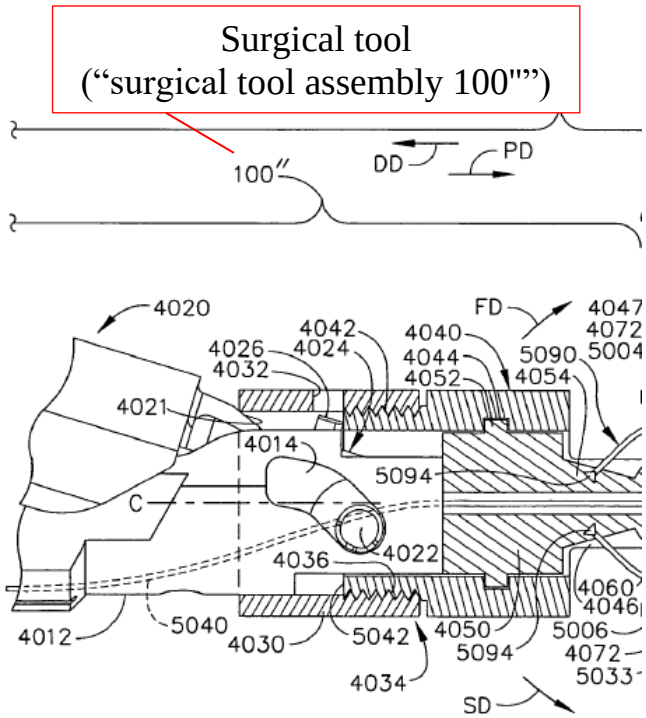


FIG. 73A

For Ground 2, the remainder of claim 10's preamble is not limiting. *See, e.g.*, *Georgetown Rail Equipment Co. v. Holland L.P.*, 867 F.3d 1229, 1236–38 (Fed. Cir. 2017). It does not recite any essential structure, provide antecedent basis for any elements in the body of the claim, recite any structure that is underscored as important by the specification, or distinguish the claimed invention from the prior art relied on by the examiner during prosecution. *Id*. It merely recites a purpose or intended use of the structurally complete surgical tool defined by the body of the claim. *Id*.

[10.2] a surgical end effector comprising at least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof

Timm discloses this limitation. Fischer Decl., ¶¶131-36.

"A surgical end effector comprising"

Timm discloses a surgical end effector (*e.g.*, the combination of anvil assembly 4020 and elongate channel assembly 4012). *Id.*; Timm, 35:64-67, Fig. 73A; *see also* Figs. 104-105.

Surgical end effector
("anvil assembly 4020" and "elongate channel assembly 4012")

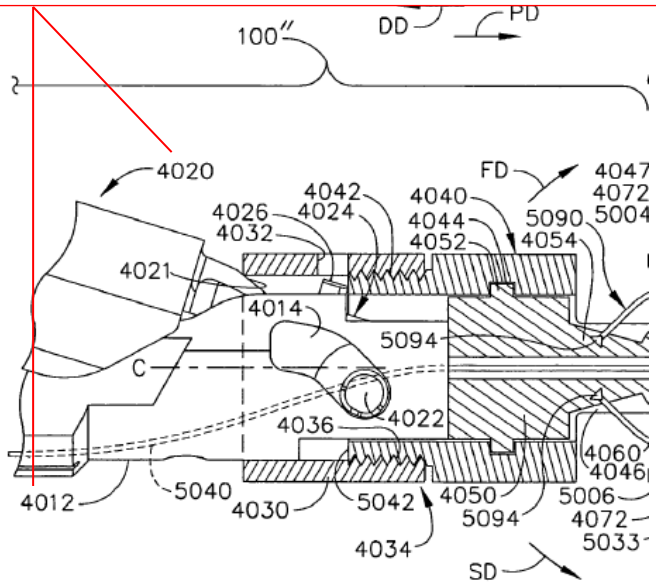
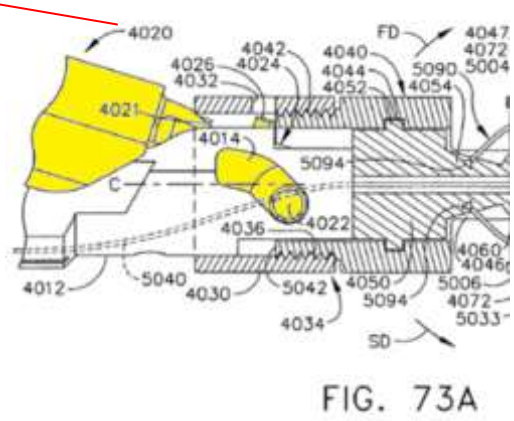
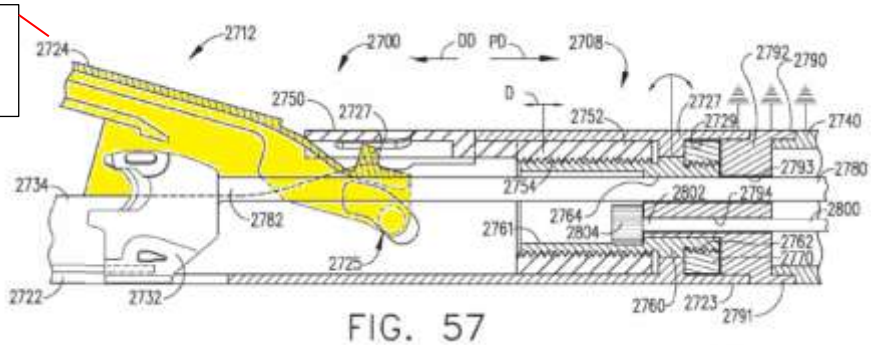


FIG. 73A

"At least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof"

As explained above, the term "component portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is the anvil of a linear stapler (*e.g.*, anvil 2724). *See* Section VII.A. Timm discloses substantially the same structure—anvil 4020. Fischer Decl., ¶133; Timm, 35:64-36:24, Fig. 73A; *compare*

Timm, Fig. 73A *with*'288 patent, Fig. 57; *compare also* Timm, Fig. 45 *with* '288 patent, Fig. 3.

Timm
Component portion ("anvil 4020"')    FIG. 73A
'288 patent
Component portion ("anvil 2724")    FIG. 57

To the extent there are any dissimilarities between Timm's anvil 4020 and the '288 patent's anvil 2724, Timm's anvil 4020 is an equivalent structure because there are no substantial differences between the two structures. Fischer Decl., ¶134. Like the '288 patent's anvil 2724, Timm's anvil 4020 performs the claimed function of selectively moving between first (open; shown above in Figure 73A) and second ("closed (clamped)") positions relative to at least one other component

portion thereof (elongate channel assembly 4012) in substantially the same way (pivoting toward elongate channel 4012) to produce substantially the same result (closing the end effector) as the ’288 patent’s anvil 2724. *Id*.

Furthermore, a POSITA would have recognized that: (1) Timm’s anvil 4020 and the ’288 patent’s anvil 2024 are interchangeable; and (2) the ’288 patent’s anvil 2724 adds nothing of significance to Timm’s anvil 4020. *Id*., ¶135. Indeed, the ’288 patent explicitly recognizes that “different types of end effectors may be employed,” and that the “claims are intended to cover all such modifications and variations.” ’288 patent, 90:10-17; *see also* 1:62-63, 20:7-13.

If the Board does not agree that the term “component portion” invokes pre-AIA 35 U.S.C. §112, ¶6, then anvil 4020 is nonetheless at least one component portion of the end effector that is selectively movable between first (open) and second (closed) positions relative to at least one other component portion thereof (elongate channel assembly 4012). Fischer Decl., ¶136; Timm, 35:64-36:24, Fig. 73A; *see also* Timm, Figs. 90-92.

[10.3] an elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising:

Timm discloses this limitation. Fischer Decl., ¶¶137-38. Timm discloses an elongated shaft assembly (*e.g*., closure ring 4030 and distal closure tube segment 4040) operably coupled to the surgical end effector. *Id*.; Timm, 36:3-21, Fig. 73A; *see also* 25:51-28:40, 46:22-39, Figs. 47-51, 90-91, 104-105.

Elongated shaft assembly
("closure ring 4030" and "distal closure tube segment 4040")

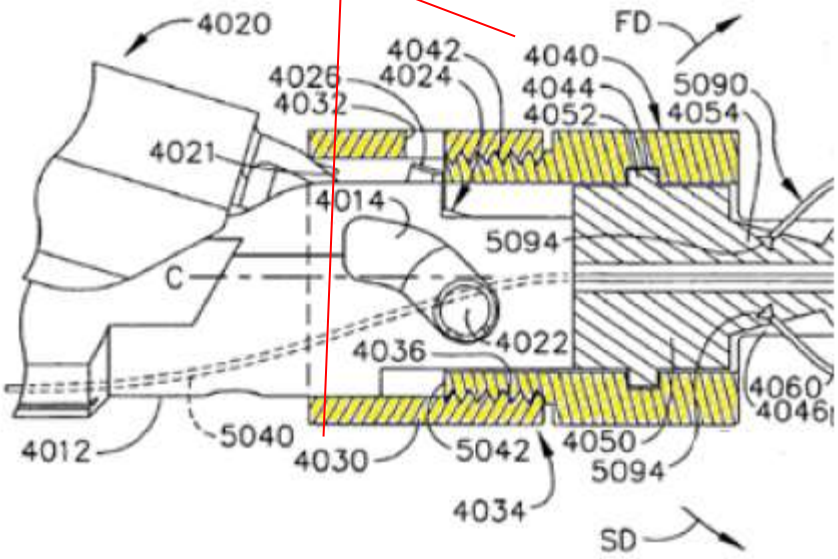


FIG. 73A

As explained in Timm, "non-rotating closure ring 4030 is keyed to the elongate channel assembly 4012 and/or anvil assembly 4020 such that the closure ring 4030 cannot rotate relative to the elongate channel 4012." *Id.*, 35:64-36:24, Figs. 73A, 74A; *see also* Figs. 104-105. Thus, "as the distal closure tube segment 4040 is rotated, the closure ring 4030 is driven axially in the distal direction DD [and] rides up a ramp 4021 on the proximal end of anvil assembly 4020 to cause the anvil assembly 4020 to [move distally and] pivot to a closed position." *Id.*, *see also* 45:45-55, Figs. 90-92, 104-105; Fischer Decl., ¶138.

[10.3.1] an axially movable portion in operable communication with said at least one selectively movable component portion of said surgical end effector

Timm discloses this limitation. Fischer Decl., ¶¶139-46.

"Axially movable portion"

As explained above, the term "axially movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is closure tube 2750. *See* Section VII. B.

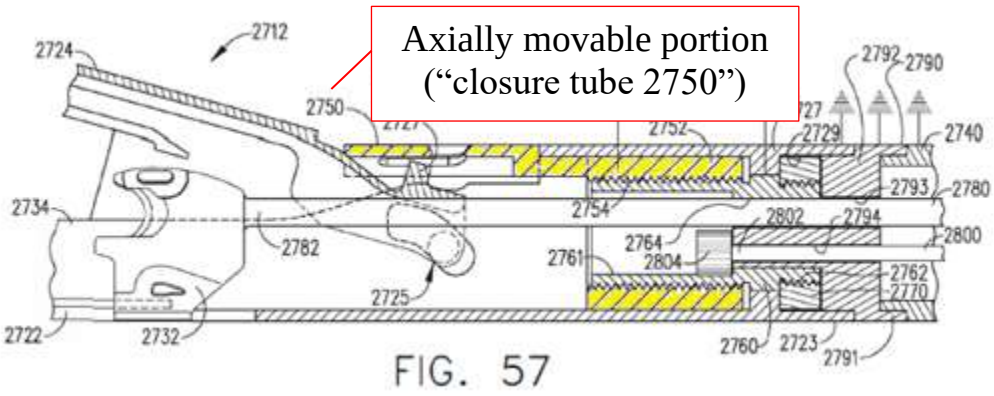


FIG. 57

Timm discloses a nearly identical and equivalent structure (closure ring 4030). Fischer Decl., ¶141; Timm, 36:3-21, 46:22-39, Figs. 73A, 74A, 104-105; *see also* Timm, 25:51-28:40, 46:22-39, Figs. 47-51, 90-91.

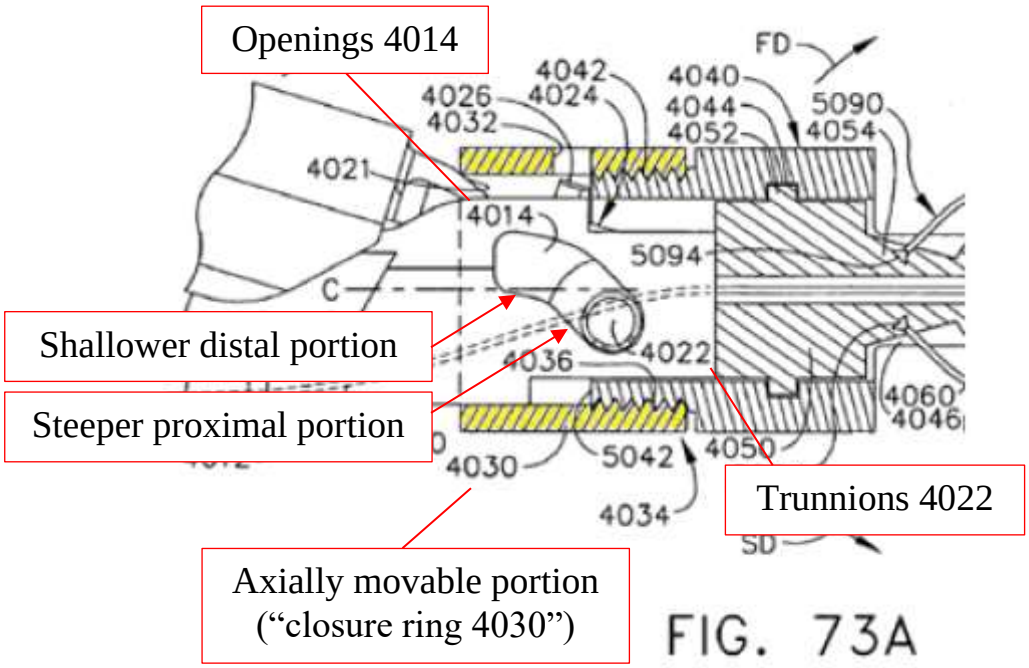


FIG. 73A

There are no substantial differences between these structures. Fischer Decl., ¶142. Like the '288 patent's openings that interact with pivot point (trunnions) 2725, Timm's corresponding slots 4014 have multiple camming angles—a steeper proximal portion and a shallower distal portion—that interact with trunnions 4022. *Id*. Thus, closure ring 4030 performs the first claimed function of moving the selectively movable component portion (anvil 4020) of the surgical end effector from the first position (open; shown above in Figure 73A) into an intermediate position (the position of anvil 4020 when trunnions 4022 transition from the steeper proximal camming surfaces to the shallower distal camming surfaces in corresponding slots 4014) at a first rate in substantially the same way (moving distally into contact with a portion of anvil 4020 to drive anvil 4020 distally and pivot anvil 4020 towards elongated channel 4012) to produce substantially the same result (quickly

gripping the tissue) as the ’288 patent. *Id.* Closure ring 4030 performs the second claimed function of moving said selectively movable component portion of the surgical end effector from the intermediate position to the second position (closed) at a second rate in substantially the same way (moving distally into contact with a portion of anvil 4020 to drive anvil 4020 distally and pivot anvil 4020 toward elongate channel 4012) to produce substantially the same result (slowly clamping the tissue) as the ’288 patent. *Id*., ¶143. And the first rate is higher than the second rate because the steeper proximal camming surfaces of slots 4014 cause anvil 4020 to move faster than the shallower distal camming surfaces of slots 4014. *Id*.

Furthermore, a POSITA would have recognized that: (1) Timm’s closure ring 4030 and the ’288 patent’s closure tube 2750 are interchangeable; and (2) the ’288 patent’s closure tube 2750 adds nothing of significance to Timm’s closure ring 4030. *Id*., ¶144.

If the Board does not agree that the term “axially movable portion” invokes pre-AIA 35 U.S.C. §112, ¶6, then closure ring 4030 is nonetheless an axially movable portion of the elongated shaft assembly. Fischer Decl., ¶145. Like the ’288 patent’s closure tube 2750, Timm’s “closure ring 4030 is driven axially in the distal direction.” *Id*.; Timm, 36:16-18, Fig. 73A; *see also* Figs. 104-105.

“<u>In operable communication with said at least one selectively movable component portion of said surgical end effector</u>”

Closure ring 4030 is also in operable communication with the at least one selectively movable component portion (anvil 4020) of the surgical end effector. Fischer Decl., ¶146; Timm, 35:64-36:24, Figs. 73A; *see also* 45:45-55, Figs. 90-92, 104-105. As explained in Timm, "closure ring 4030 is driven axially in the distal direction DD [and] rides up a ramp 4021 on the proximal end of anvil assembly 4020 to cause the anvil assembly 4020 to pivot to a closed position." *Id*., 36:16-21.

[10.3.2] a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.

Timm discloses this limitation. Fischer Decl., ¶¶147-51. As explained above, the term "rotatably movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is closure drive nut 2760. *See* Section VII.C.

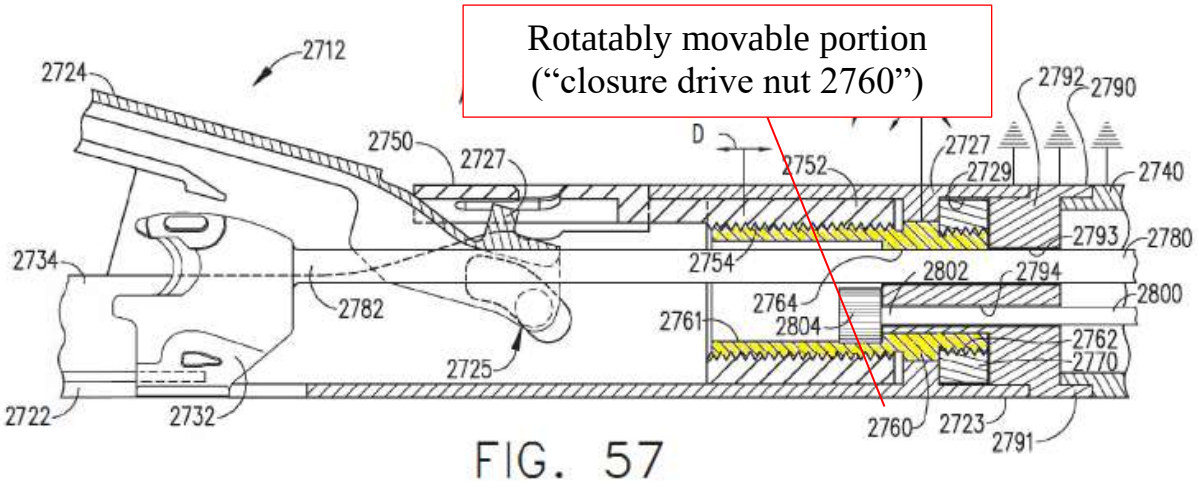


FIG. 57

Timm discloses a nearly identical and equivalent structure (distal closure tube segment 4040). Fischer Decl., ¶148; Timm, 36:12-21, Figs. 73A, 74A, 104-105; *see also* Timm, 25:51-28:40, 46:22-39, Figs. 47-51, 90-91.

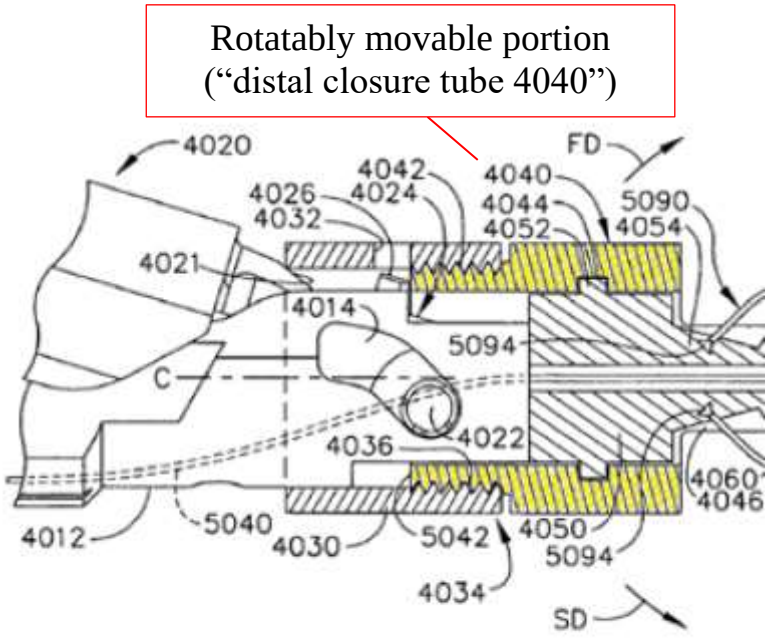


FIG. 73A

There are no substantial differences between Timm's distal closure tube segment 4040 and the '288 patent's closure drive nut 2760, which is also a rotatable

tube, for several reasons. Fischer Decl., ¶149. For example, the initial and subsequent rotations of Timm's distal closure tube segment 4040 cause the axially movable portion to perform its claimed functions (*see* Ground 2, element [10.3.1]) in substantially the same way (using a threaded engagement with the axially movable portion) to produce substantially the same result (initially closing the end effector at a first rate and then at a second rate, wherein the first rate is greater than the second rate) as the '288 patent's closure drive nut 2760. *Id*. The threaded portions of distal closure tube segment 4040 and closure drive nut 2760 that interact with their respective axially movable portions are essentially identical. And a POSITA would have recognized that the location of the '288 patent's closure drive nut 2760 inside the device and the means by which it is rotatably supported, add nothing of significance to Timm's distal closure tube segment 4040 because both structures perform the claimed function in substantially the same way. *Id*.

If the Board does not agree that the term "rotatably movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6, then Timm's distal closure tube segment 4040 is nonetheless a rotatably movable portion of the elongated shaft assembly. Fischer Decl., ¶150; Timm, 36:12-21, Figs. 73A, 74A, 104-105. Like the '288 patent's closure drive nut 2760, Timm's distal closure tube segment 4040 is a portion of the elongated shaft assembly that can be rotated to cause the axially movable portion to perform its claimed functions. Fischer Decl., ¶150.

"Rotatably movable portion in operable engagement with said axially movable portion"

The rotatably moveable portion (distal closure tube segment 4040) is in operable (threaded) engagement with the axially movable portion (closure ring 4030). Fischer Decl., ¶151. As explained in Timm, a "series of internal threads 4036 may be provided in the proximal end 4034 of the non-rotating closure ring 4030 for threadably receiving a threaded distal end 4042 of a distal closure tube segment 4040." Timm, 36:12-21. Thus, "as the distal closure tube segment 4040 is rotated, the closure ring 4030 is driven axially in the distal direction DD [and] rides up a ramp 4021 on the proximal end of anvil assembly 4020 to cause the anvil assembly 4020 to [be driven distally and] pivot to a closed position." *Id*.; *see also* 45:45-55, Figs. 90-92, 104-105.

[11] A surgical tool . . . wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion

Claim 11 repeats elements [10.1]-[10.3.2] of claim 10, but removes the limitation in element [10.3.2] that the first rate be greater than the second rate. Fischer Decl., ¶152; *compare* '288 patent, claim 10 *with id*., claim 11. Thus, Timm discloses the corresponding elements of claim 11. *See* Fischer Decl., ¶152; Ground 2, elements [10.1]-[10.3.2].

Timm also discloses the limitation reciting: "wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially

movable portion." Fischer Decl., ¶153. Timm's rotatably moveable portion (distal closure tube segment 4040) is a closure member in threaded engagement with the axially movable portion (closure ring 4030). *Id*.; Ground 2, element [10.3.2].

C. Ground 3: Claims 10-11 are obvious over Timm in view of Viola

[10.1]-[10.3]

See Ground 2, elements [10.1]-[10.3].

[10.3.1] an axially movable portion in operable communication with said at least one selectively movable component portion of said surgical end effector

Timm in view of Viola discloses this limitation. Fischer Decl., ¶¶155-66.

"Axially movable portion"

As explained above, the term "axially movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is distal closure tube segment 3430, which includes lug 3442. *See* Section VII.B.

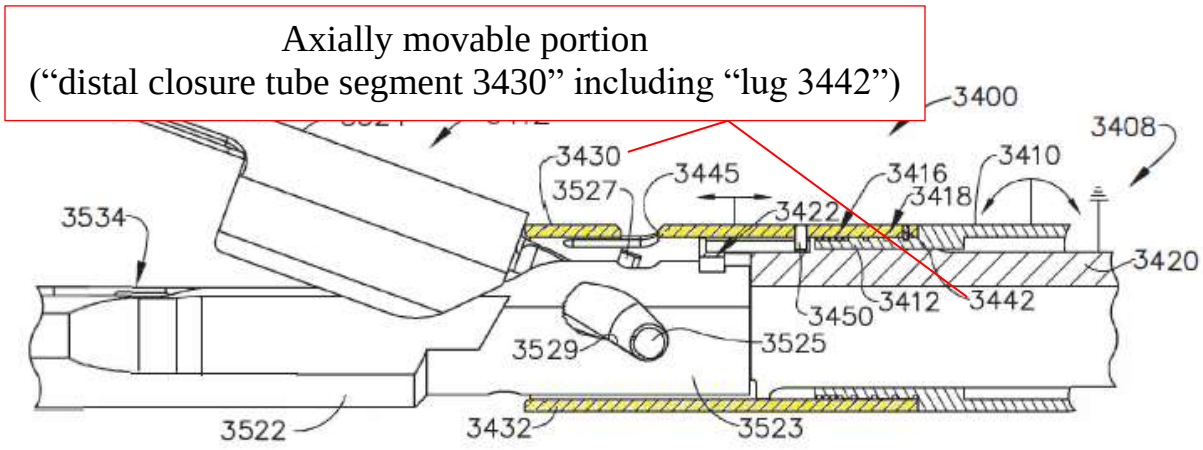


FIG. 72

As explained above, Timm discloses a similar structure (closure ring 4030, which includes single pitched threads). *See* Ground 2, element [10.3.1].

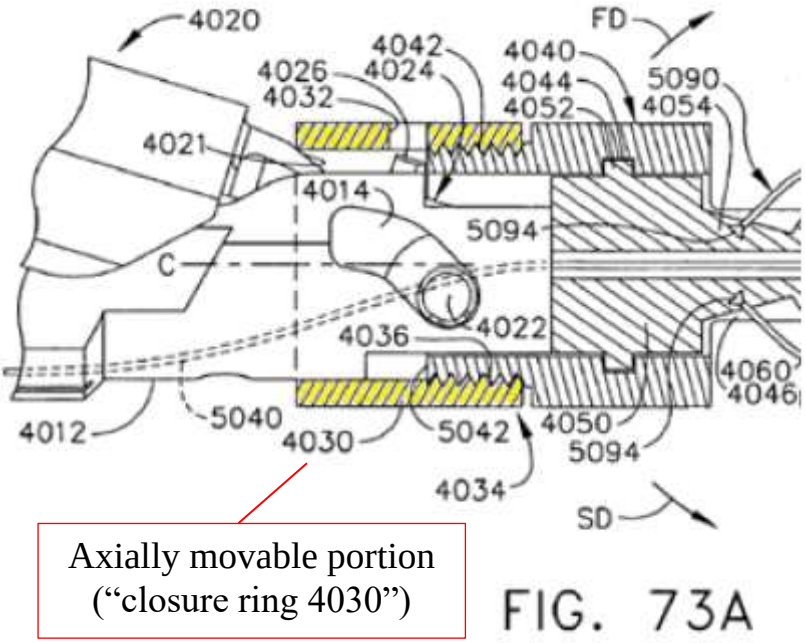


FIG. 73A

If the interactions of closure ring 4030, anvil 4020, trunnions 4022, and openings 4014 are deemed not to disclose moving anvil 4020 at two different rates, then it would have been obvious in view of Viola to replace the threaded engagement between Timm's closure ring 4030 and closure tube segment 4040 with a single pin that protrudes inward from the wall of the closure ring 4030 and a corresponding dual pitched slot/groove formed in closure tube segment 4040. Fischer Decl., ¶¶158-65.

The resulting closure ring 4030 would have been essentially identical and equivalent to the corresponding structure shown in Figures 72-75 of the '288 patent. *Id.*, ¶159. There are no substantial differences between these structures for several reasons. *Id.* First, modified closure ring 4030 performs the first claimed function of moving the selectively movable component portion of the surgical end

effector (anvil 4020) from the first position (open) into an intermediate position (the position of anvil 4020 when the pin is at the end of first pitch) at a first rate (rapidly) in substantially the same way as the ’288 patent (using a pin that interacts with the coarser pitched portion of the dual pitched slot/groove to rapidly move closure ring 4030 distally into contact with a portion of anvil 4020 to pivot anvil 4020 toward elongate channel 4012) to produce substantially the same result (quickly gripping the tissue). *Id.* And modified closure ring 4030 performs the second claimed function of moving anvil 4020 from the intermediate position to the second position (closed) at a second rate (slowly; incrementally) that is less than the first rate (rapidly) in substantially the same way as the ’288 patent (using a pin that interacts with the finer pitched portion of the dual pitched slot/groove to slowly move closure ring 4030 distally into contact with a portion of anvil 4020 to pivot anvil 4020 toward elongate channel 4012) to produce substantially the same result (slowly clamping the tissue). *Id*., ¶160.

A POSITA would have also recognized that: (1) modified closure ring 4030 and the ’288 patent’s distal closure tube segment 3430 are interchangeable; and (2) the ’288 patent’s distal closure tube segment 3430 adds nothing of significance to modified closure ring 4030. *Id*., ¶161.

If the Board does not agree that the term “axially movable portion” invokes

pre-AIA 35 U.S.C. §112, ¶6, then modified closure ring 4030 is nonetheless an axially movable portion of the elongated shaft assembly. *Id*., ¶162. Like the '288 patent's distal closure tube segment 3430, modified closure ring 4030 axially moves in the distal direction to pivot anvil 4020 to the closed position. *Id*.

A POSITA would have been motivated to modify the threaded engagement between Timm's closure ring 4030 and closure tube segment 4040 for the reasons provided in Viola—*e.g*., "expedit[ing] the surgical procedure"; "provid[ing] a quick and efficient means for approximating the anvil and fastener assembly while including means for accurately positioning the anvil in relation to the fastener assembly"; and "allow[ing] the surgeon to rapidly move the anvil towards the fastener assembly in a minimal amount of turns" of the closure knob. *Id*., ¶163; Viola, 2:28-45, 3:10-15. A POSITA would have further recognized that the finer pitched slot/groove section may provide more closure power when needed and seen the clear benefit from such a modification. Fischer Decl., ¶163; *see also* Schulze, 14:38-56 (explaining that "compound angles [like dual pitched threads] are specifically designed to give higher mechanical advantage when needed and faster closure and wider opening when needed"); *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 424 (2007).

Furthermore, a POSITA would have had "good reason to pursue the known options within his or her technical grasp" when, as here, "there are a finite number

of identified, predictable solutions." *KSR*, 550 U.S. at 421. In this case, Timm describes at least two predictable solutions for translating the rotational motion of the rotatably movable portion into axial movement of the axially movable portion—(1) slots interacting with pins; and (2) single pitched threads. Timm, 25:51-28:40, 36:12-21, Figs. 47-51, 73A, 74A, 104-105. And Viola discloses another—a dual pitched helical groove interacting with a pin. *See* Ground 1; element [10.3.1].

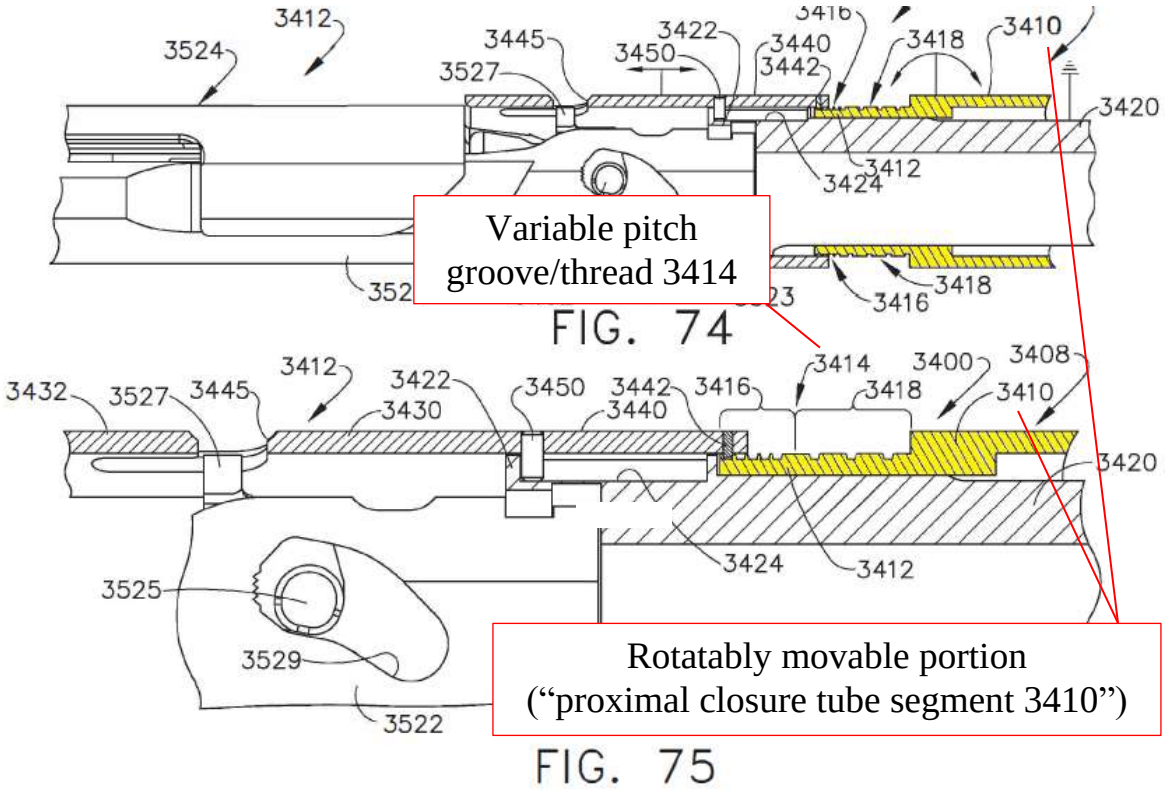
A POSITA would have had a reasonable expectation of success when combining Timm and Viola because the combination would have been well within a POSITA's abilities. Fischer Decl., ¶165. Indeed, it would have been merely the application of a known technique (using a dual pitched slot/groove interacting with a pin to translate rotational motion into linear motion at two different rates) with a known system (Timm's surgical stapler) in the same field of endeavor (surgical staplers). *Id.*; *KSR*, 550 U.S. at 417. And, in the combination, each element merely performs the same predictable function as it does separately, without significantly altering or hindering the functions performed by Timm's surgical stapler. Fischer Decl., ¶165. In fact, Timm's surgical stapler would continue to perform all of the functions it performed before the proposed modification and Viola's dual pitched slot/groove would simply provide faster closure when needed and higher mechanical advantage when needed. *Id.*

"In operable communication with said at least one selectively movable component portion of said surgical end effector"

Modified closure ring 4030 is also in operable communication with the at least one selectively movable component portion (anvil 4020) of the surgical end effector. Fischer Decl., ¶166. As explained in Timm, "closure ring 4030 is driven axially in the distal direction DD [and] rides up a ramp 4021 on the proximal end of anvil assembly 4020 to cause the anvil assembly 4020 to pivot to a closed position." Timm, 35:64-36:24, Figs. 73A, 74A, 104-105; *see also* 28:18-22, 45:45-55, Figs. 90-92, 104-105."

[10.3.2] a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.

Timm in view of Viola discloses this limitation. Fischer Decl., ¶¶167-72. As explained above, the term "rotatably movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6 and a corresponding structure is rotatable proximal closure tube segment 3410, which includes variable pitch groove/thread 3414. *See* Section VII.C.



As explained above, Timm discloses a similar structure (closure tube segment 4040, which includes single pitched threads). *See* Ground 2, element [10.3.2].

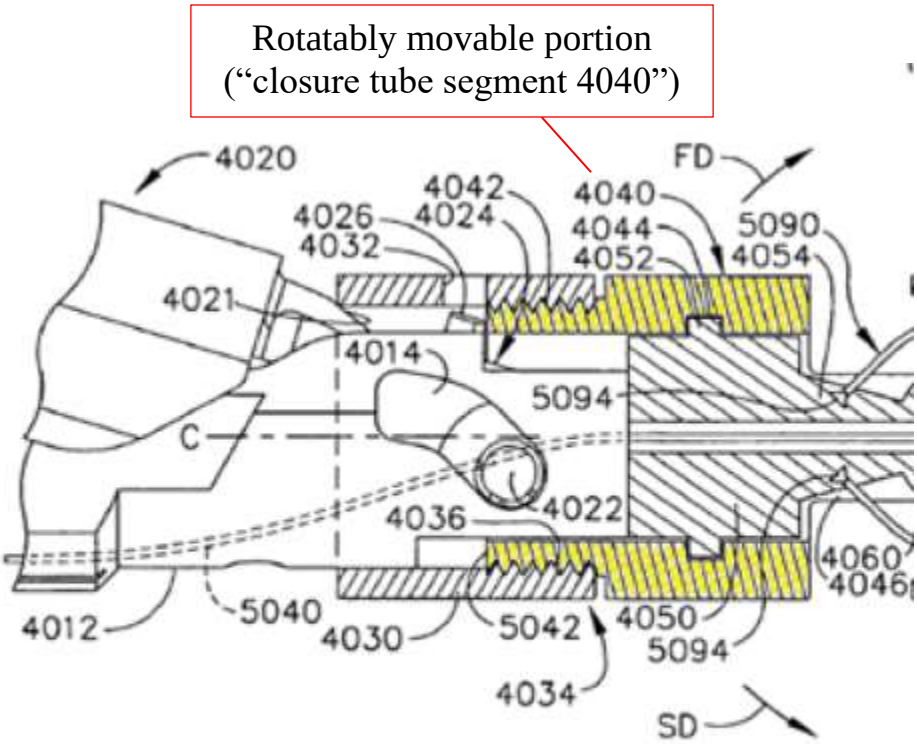


FIG. 73A

However, for the reasons explained above in Ground 3, element [10.3.1], it would have been obvious to replace the threaded engagement between Timm's closure ring 4030 and closure tube segment 4040 with a single pin that protrudes inward from the wall of the closure ring 4030 and a corresponding variable pitched slot/groove formed in closure tube segment 4040.

The resulting closure tube segment 4040 would have been essentially identical and equivalent to the corresponding structure shown in Figures 72-75 of the '288 patent. Fischer Decl., ¶170. There are no substantial differences between

Timm's modified closure tube segment 4040 and the '288 patent's proximal closure tube segment 3410 for several reasons. *Id*. For example, the initial and subsequent rotations of Timm's modified closure tube segment 4040 cause the axially movable portion to perform its claimed functions (*see* Ground 3, element [10.3.1]) in substantially the same way (using a dual pitched slot/groove that interacts with a pin in the axially movable portion) to produce substantially the same result (initially closing the end effector at a first rate and then at a second rate, wherein the first rate is greater than the second rate) as the '288 patent. *Id*. A POSITA would have also recognized that Timm's modified closure tube segment 4040 and the '288 patent's proximal closure tube segment 3410 are interchangeable. *Id*. And a POSITA would have recognized that the '288 patent's proximal closure tube segment 3410 adds nothing of significance to Timm's modified closure tube segment 4040. *Id*.

If the Board does not agree that the term "rotatably movable portion" invokes pre-AIA 35 U.S.C. §112, ¶6, then Timm's modified closure tube segment 4040 is nonetheless a rotatably movable portion of the elongated shaft assembly. *Id*., ¶171. Like the '288 patent's proximal closure tube segment 3410, Timm's modified closure tube segment 4040 is a portion of the elongated shaft assembly that can be rotated to cause the axially movable portion to perform its claimed functions. *Id*.

"Rotatably movable portion in operable engagement with said axially movable portion"

The rotatably moveable portion (Timm's modified closure tube segment 4040) is in operable engagement with the axially movable portion (Timm's modified closure ring 4030). *Id*., ¶172. In the proposed combination, a dual pitched slot/groove formed in closure tube segment 4040 interacts with (*i.e*., operably engages) a pin that protrudes inward from the wall of the closure ring 4030 to axially move closure ring 4030 distally when modified closure tube segment 4040 is rotated. *Id*.

[11] A surgical tool . . . wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion

Claim 11 repeats elements [10.1]-[10.3.2] of claim 10, but removes the limitation in element [10.3.2] that the first rate be greater than the second rate. Fischer Decl., ¶173; *compare* '288 patent, claim 10 *with id*., claim 11. Thus, Timm in view of Viola discloses the corresponding elements of claim 11. *See* Fischer Decl., ¶173; Ground 3, elements [10.1]-[10.3.2].

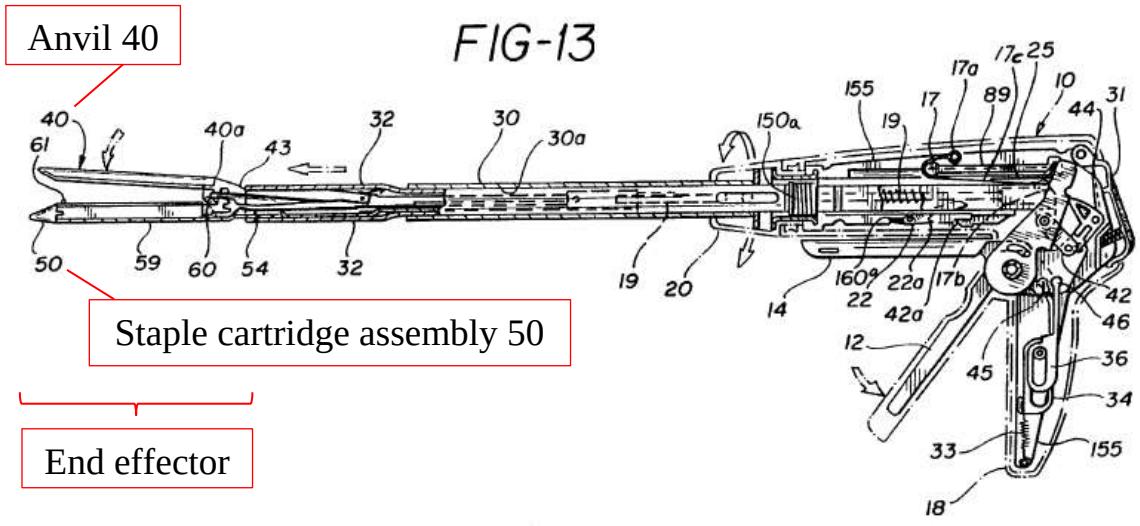
Timm in view of Viola also discloses the limitation reciting: "wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion." Fischer Decl., ¶174. The rotatably moveable portion (Timm's modified closure tube segment 4040) is a closure member in threaded engagement with the axially movable portion (modified closure ring

4030). *Id.*; Ground 3, element [10.3.2].

D. Ground 4: Claims 10-11 are obvious over Timm in view of Schulze

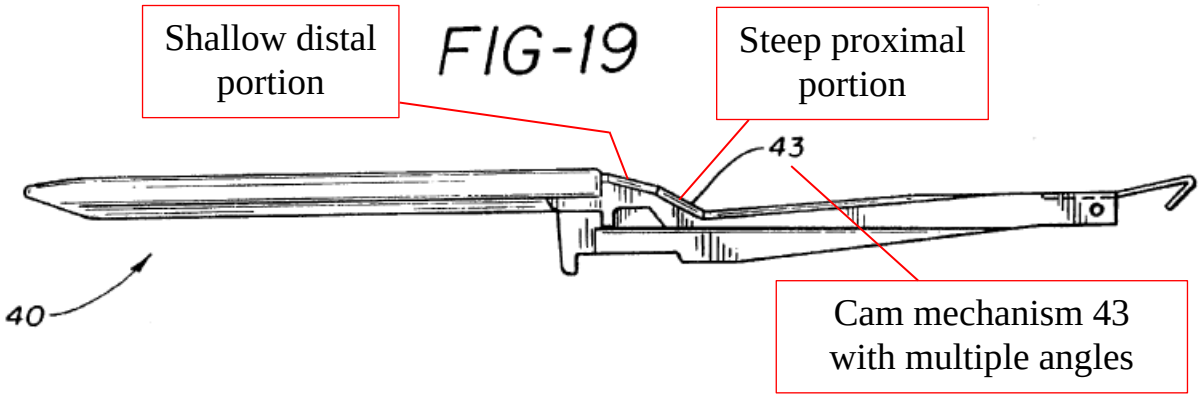
As explained above, Timm anticipates claims 10-11. *See* Ground 2. If Timm is deemed to not disclose that closure ring 4030 moves anvil 4020 from the first position into the intermediate position at a first rate, and from the intermediate position to the second position at a second rate, wherein the first rate is greater than the second rate, then it would have been obvious in view of Schulze to modify Timm's anvil 4020 to include a camming surface with multiple angles that performs these claimed functions. Fischer Decl., ¶¶175-79.

Like Timm, Schulze discloses a surgical stapler:



Schulze, Fig. 13. As shown above, the surgical stapler includes an end effector with an anvil 40 and a staple cartridge assembly 50. *Id.*; *see also* 14:38-56, Figs. 18-25. Notably, "[t]he cam mechanism 43 on the rear of the anvil 40 is designed

with a multiple angle" that includes a "steeper proximal portion of the angle [that] allows faster closing of the anvil 40 against the cartridge assembly 50" and a "distal or more shallow angle." *Id.*, 14:38-56, Fig. 19.



A POSITA would have been motivated to modify Timm's anvil 4020 to include a camming surface with multiple angles for the reasons provided in Schulze—*i.e.*, the "compound angles are specifically designed to give higher mechanical advantage when needed and faster closure and wider opening when needed." Schulze, 14:38-56; Fischer Decl., ¶178. And a POSITA would have seen the clear benefit from such a routine and common-sense modification. *Id.*; *KSR*, 550 U.S. at 424; *see also In re Magna Elecs., Inc.*, 611 F. App'x 969, 974 (Fed. Cir. 2015); *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009).

A POSITA would have had a reasonable expectation of success when combining Timm and Schulze. Fischer Decl., ¶179. Indeed, it would have been merely the application of a known technique (using a cam mechanism that has

multiple angles) with a known system (Timm's surgical tool) in the same field of endeavor (linear surgical staplers). *Id.*; *KSR*, 550 U.S. at 417. And, in combination, each element merely performs the same predictable function as it does separately without significantly altering or hindering the functions performed by Timm's surgical tool. Fischer Decl., ¶179. In fact, Timm's surgical tool would continue to perform all of the functions it performed before the proposed modification and Schulze's camming mechanism 43 would simply give higher mechanical advantage when needed and faster closure and wider opening when needed. *Id.* Thus, the proposed combination would have been well within a POSITA's abilities. *Id.*

E. Ground 5: Claims 10-11 are obvious over Timm in view of Anderson and, if necessary, Viola and Schulze

As explained above, if the statement of intended use in the preamble of claims 10 and 11 is not a limitation, then Timm anticipates claims 10-11 and, if necessary, Timm in view of Viola and Timm in view of Schulze render claims 10-11 obvious. *See* Grounds 2-4. If the statement of intended use in the preamble of claims 10 and 11 is deemed to be limiting, then it would have been obvious in view of Anderson to modify Timm's surgical tool and Timm's modified surgical tools "for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator." Fischer Decl., ¶¶180-88. Indeed, the PTO has already found that it

would have been obvious to combine a hand-held surgical stapler with Intuitive's robotic system. *See* File History, 378-79 (Nov. 9, 2012 rejection) (rejecting original claims 2 and 9 as obvious over the combination of Hooven's motor-powered hand-held stapler with Petitioner's robotic system, which is also disclosed in Anderson).

Anderson discloses a surgical tool (*e.g.*, surgical instruments 28, 80, and 300) for use with a surgical robotic system (robotic surgical system 10) that has a tool drive assembly ("actuators . . . such as electric motors or the like" alone or in combination with an engaging member rotatably mounted on the cartridge 37 of a robotic arm assembly 26) that is operatively coupled to a control unit (control station 12) of the robotic system that is operable by inputs from an operator ("a surgeon or other user"). Fischer Decl., ¶181; Anderson, 10:40-12:22, 15:3-8, 21:66-22:19, 23:31-45, Figs. 1-2, 12A-D, 20; *see also* Anderson, 16:14-23, 22:59-67, 24:35-40; Tierney '181 patent, Figs. 1-4, 6-7M, 8A-B, 14A-C and corresponding disclosures. As shown below, Anderson's robotic system appears to be the same surgical robotic system disclosed in the '288 patent. *Id*.

’288 patent

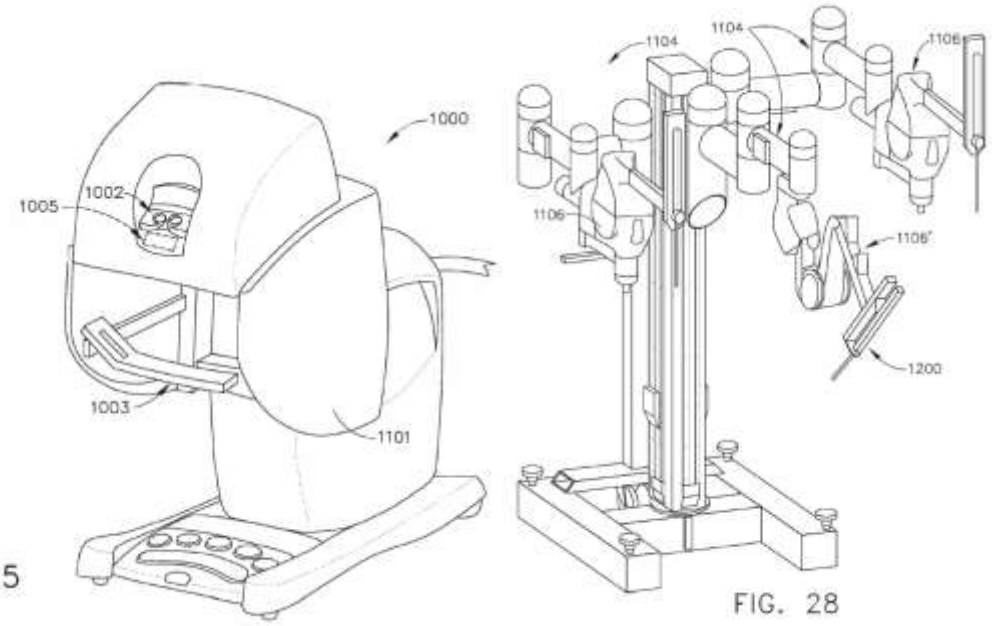


FIG. 25

FIG. 28

Anderson Prior Art

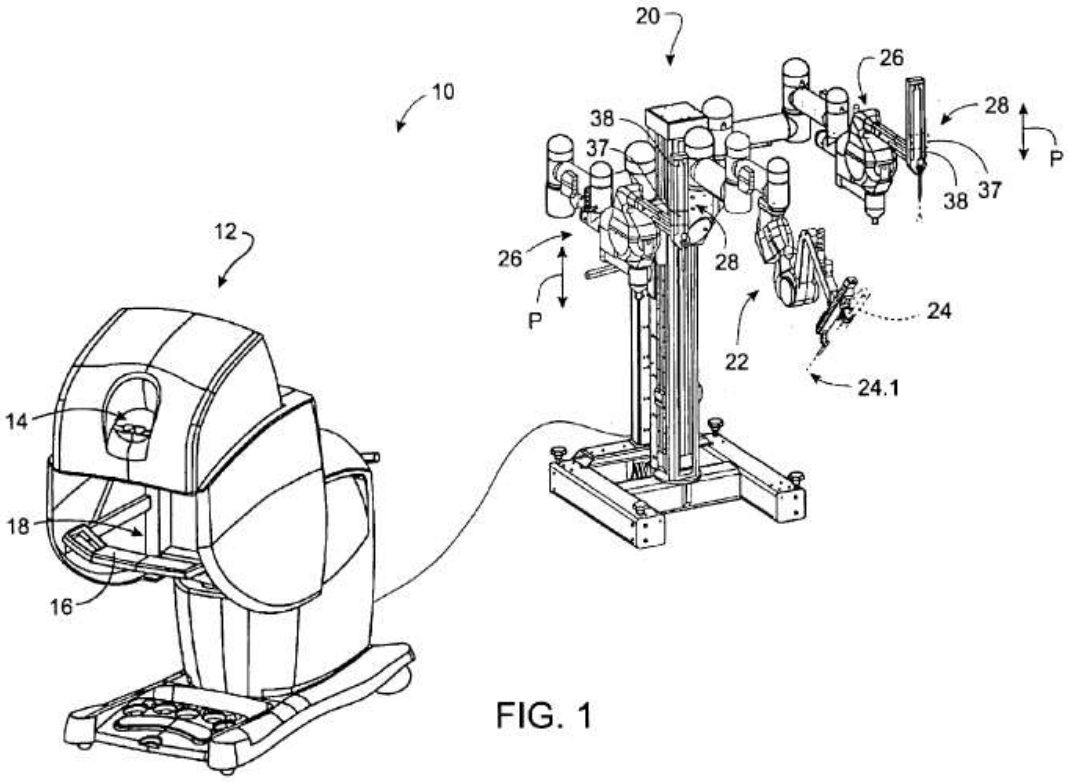
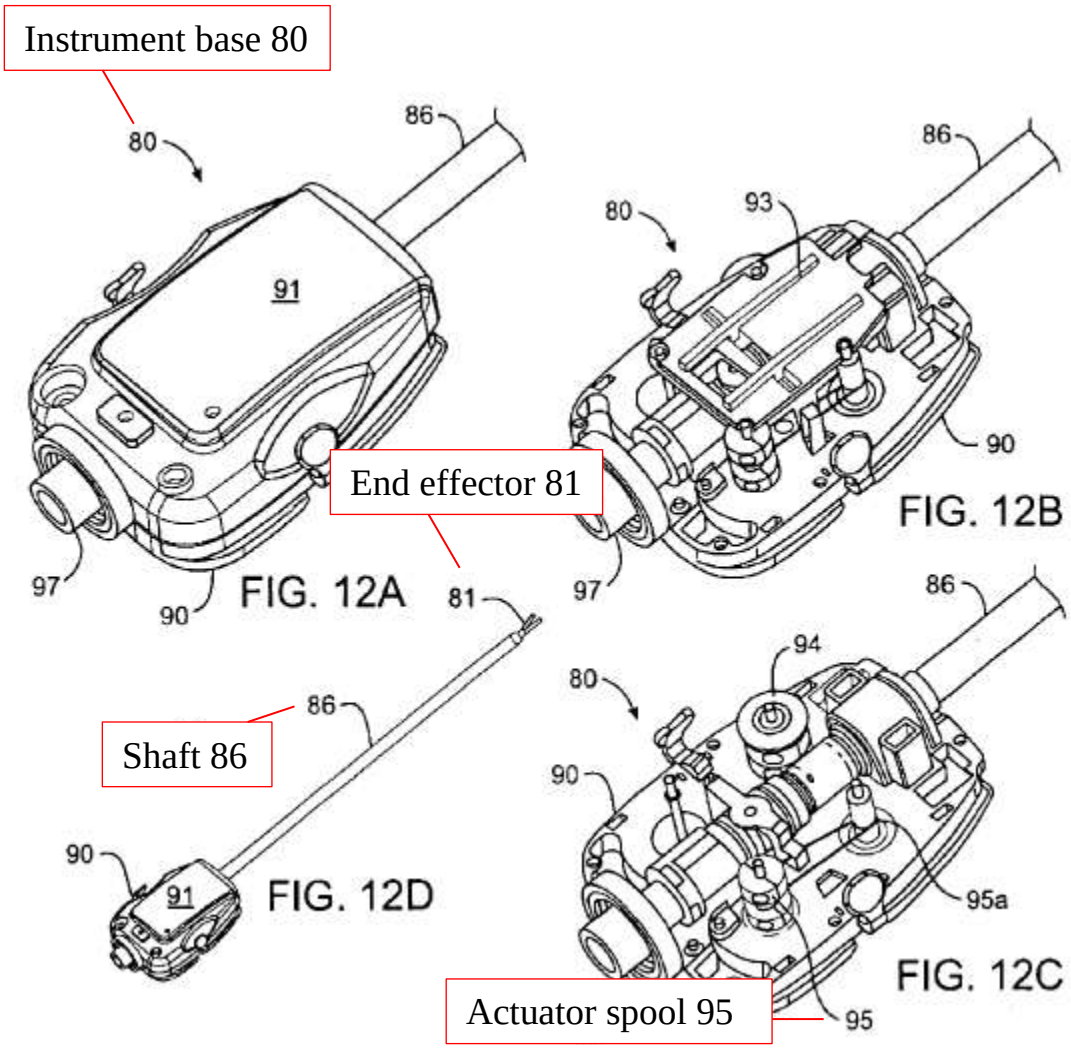


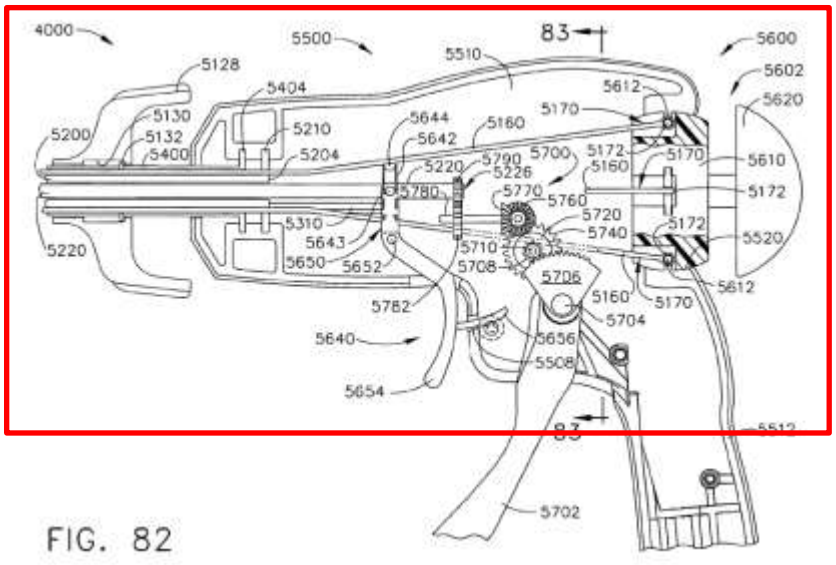
FIG. 1

Anderson's surgical instruments have an "instrument base . . . generally configured to releasably engage . . . robotic surgical system 10." Anderson, 11:31-42, Figs. 1-2; *see also* Figs. 11A-17, 20. Instrument base 80, for example, includes an end effector 81 that is "movable by one or more actuator rods housed within shaft 86. The motive force for actuating the rod is supplied by actuator spool 95, which engages an interface member (not shown) on [the] robotic surgical system." *Id.*, 16:62-66, Figs. 12A-D.



In other embodiments, "a gear train or other mechanical transmission means . . . may be used to rotationally couple the interface member" with the actuated component(s) of the instrument. *Id.*, 23:26-30.

A POSITA would have readily understood that Timm's surgical tool and modified surgical tools could be modified for use with Anderson's robotic system by removing the handle, trigger, and rotation knobs and connecting them to Anderson's actuators. Fischer Decl., ¶184; *see also Intuitive Surgical, Inc. v. Ethicon LLC*, Case Nos. IPR2018-01247, Paper No. 7 at pp. 20-23 (determining that "the Petition shows a reasonable likelihood that Petitioner would prevail with respect to [the challenged claim] being unpatentable over Anderson and Timm"). As shown below, many of the components in the red outline would be moved from Timm's handle to Anderson's instrument base for coupling to Anderson's robotic system:



Timm, Fig. 82; Fischer Decl., ¶184.

A POSITA would have been motivated to modify Timm's surgical tool and modified surgical tools for use with Anderson's robotic system for several reasons. Fischer Decl., ¶185. First, a POSITA would have recognized that Anderson contemplates use of its robotic surgical system with surgical "staplers." *Id*.; Anderson, 7:19-25. In essence, Anderson discloses a robotic surgical system that can accommodate virtually any surgical instrument that can be controlled by Anderson's rotary actuators, and contemplates that third party "OEM" instruments (such as Timm's surgical stapler) would be adapted for use with the Anderson robot:

> [T]he instrument probe assembly of the surgical instruments of the invention may include … suitable OEM components of … stapler probes, tissue grasping and cutting probes, and the like.

Id.; *see also* 15:3-28, 18:25-53. A POSITA therefore would have turned to Timm for details on how to implement a tool with a surgical stapler end effector to increase the number of uses for Anderson's system. Fischer Decl., ¶185.

Second, Timm contemplates modification of its handheld instruments for use with a surgical robot. *Id*., ¶186 Timm, for example, discloses that "[s]haft connector portion 20c [of the surgical stapler] . . . can be permanently or removably associated with a handle or other actuating assemblies of a manually (or other, e.g., ***robotic*** or computer) operated open or endoscopic surgical stapler 1." Timm,

8:3-8 (emphasis added), Fig. 1. Timm also discloses that the "use of the above described tool assembly 100 as part of a robotic system is also envisioned." *Id*., 12:1-3. And, as recognized in the '288 patent and Anderson, "minimally invasive robotic (or 'telesurgical') systems," like Anderson's, "increase surgical dexterity as well as to permit a surgeon to operate on a patient in an intuitive manner." '288 patent, 25:31-34; Anderson, 2:37-40. A POSITA therefore would have turned to Anderson for details on how to implement Timm's surgical tool and modified surgical tools using a robotic system. Fischer Decl., ¶186.

Third, Timm's end effector and modified end effectors are controlled by rotary motion, and Anderson provides rotary motion. *Id*., ¶187.

A POSITA would have had a reasonable expectation of success when combining Timm with Anderson. *Id*., ¶188. Indeed, it would have been merely the application of a known technique (use of Timm's surgical tool and modified surgical tools) with a known system (Anderson's surgical robot) in the same field of endeavor (surgical instruments). *Id*.; *KSR*, 550 U.S. at 417. And, in combination, each element merely performs the same predictable function as it does separately without significantly altering or hindering the functions performed by Timm's surgical tool and modified surgical tools and Anderson's robotic system. Fischer Decl., ¶188. Thus, the proposed combination would have been well within a POSITA's abilities. *Id*.

F. Ground 6: Claims 10-11 are obvious over Heinrich in view of Anderson

As discussed above, claims 10-11 are anticipated by Heinrich. *See* Ground 1. If the preamble of claims 10 and 11 is deemed to be a limitation, and Heinrich is deemed to not disclose "a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator," then it would have been obvious in view of Anderson to modify Heinrich's Viola loading unit embodiment for use with Anderson's robotic system for the same reasons that it would have been obvious to combine the Timm's surgical tool with Anderson's robotic system. Fischer Decl., ¶¶189-90; Ground 5 (summarizing Anderson's disclosure).

A POSITA would have readily understood that Heinrich's loading units could be modified for use with Anderson's robotic system by replacing the mounting platform 642 and head portion 640 of Heinrich's loading units 618 with Anderson's instrument base and controlling Heinrich's loading units 618 with Anderson's control station 12. Fischer Decl., ¶190.

G. Ground 7: Claim 10-11 are obvious over Heinrich in view of Viola and, if necessary, Anderson

As discussed above, Heinrich's Viola embodiment anticipates claims 10-11 and, if necessary, claims 10-11 are obvious over Heinrich in view of Anderson. *See* Grounds 1, 6. If Heinrich is deemed not to disclose the Viola subject matter

incorporated by reference, it would have been obvious to combine Heinrich with Viola to arrive at the same subject matter. Fischer Decl., ¶¶191-94.

A POSITA implementing the embodiment of Heinrich wherein surgical stapler 400 interfaces directly with robotic surgical system 600 would have been motivated to combine Heinrich with Viola for at least two reasons. *Id*., ¶192. First, if Heinrich's incorporation of Viola by reference is insufficient, then Heinrich does not disclose the internal structure of surgical instrument 400 and a POSITA would have needed to find references describing it or something similar to implement Heinrich's invention. *Id*. Accordingly, that POSITA would naturally have turned to a reference such as Viola, which teaches how to design and construct the surgical instrument's internal structure. *Id*. Second, Heinrich conveniently and explicitly directs a POSITA to Viola for the "detailed explanation of the operation of surgical stapler" 400. Heinrich, ¶103. It is difficult to imagine a stronger suggestion to combine the teachings of these references.

Furthermore, if Heinrich is deemed not to disclose the loading unit shown below in the composite images of Figures 4 and 9 of Heinrich, then such a device would have been obvious over Heinrich in view of Viola. Fischer Decl., ¶193.

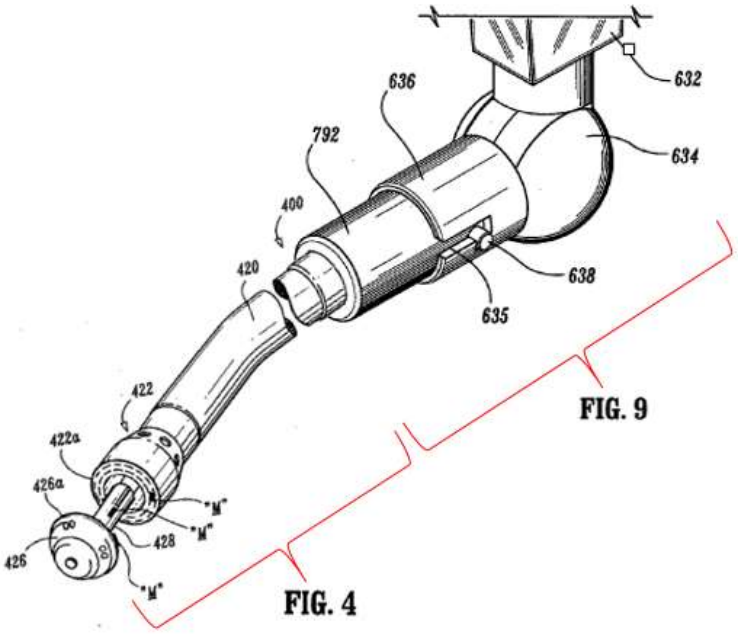


FIG. 9

FIG. 4

As noted above, Heinrich explicitly states that "the above described surgical instruments [(*e.g.*, surgical stapler 400)] . . . can be employed with or interface directly with a robotic surgical system 600." Heinrich, ¶130. Heinrich also explicitly states that the generic loading unit 618 shown in Fig. 7 above includes those having a shaft, a cartridge assembly, and an anvil, like surgical stapler 400. Heinrich, ¶133. And, as shown below, Heinrich provides several examples of modifying hand-held stapling sub-systems, like surgical stapler 400, to be removably attachable to Heinrich's robotic system 600. *Compare* Heinrich, Figs. 1, 5, 6 *with* Heinrich, Figs. 9, 11, 10, respectively.

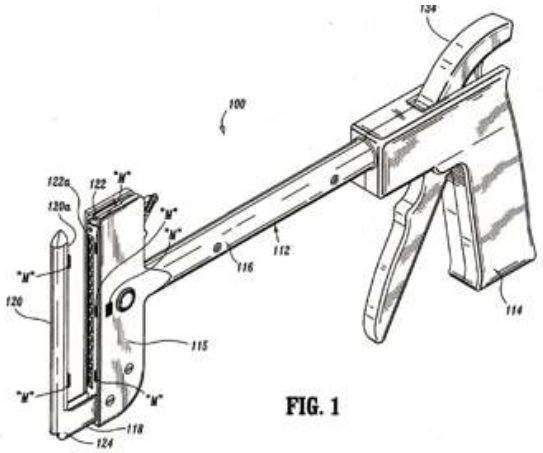


FIG. 1

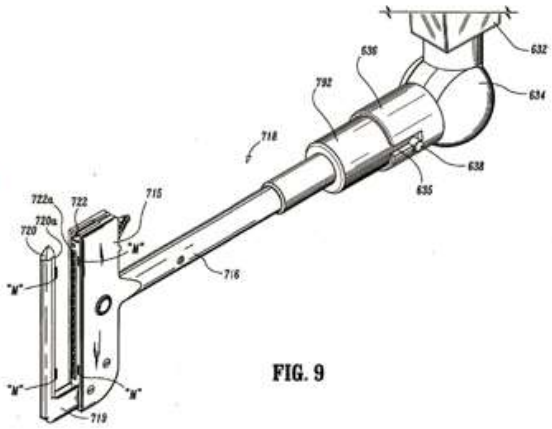


FIG. 9

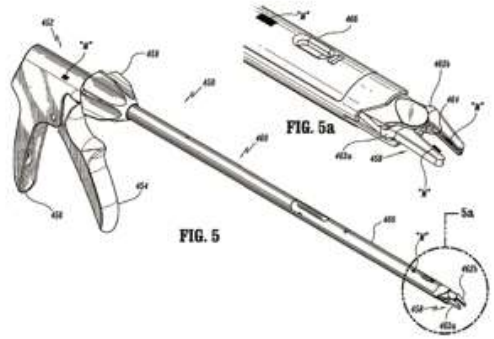


FIG. 5

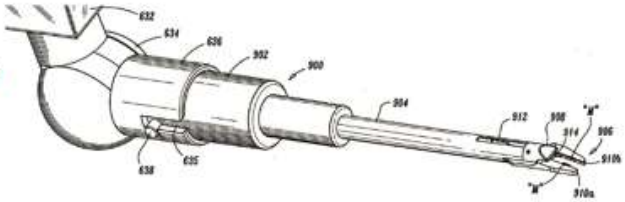


FIG. 11

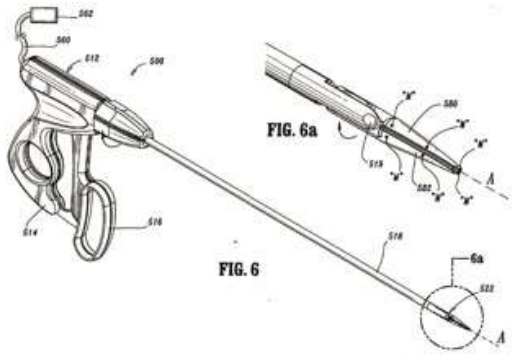


FIG. 6

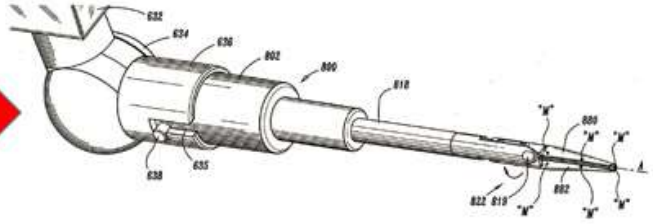


FIG. 10

X. CONCLUSION

Claims 10-11 of the ’288 patent are unpatentable pursuant to Grounds 1-7 set forth above. Accordingly, Petitioner requests *Inter Partes* Review of the challenged claims.

Respectfully submitted,

Dated May 23, 2019

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter partes* Review totals 13,983 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on May 23, 2019, a complete and entire copy of this Petition for *Inter partes* Review and all supporting exhibits were provided via Federal Express to the Patent Owner by serving the correspondence address of record as follows:

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