IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Frederick E. Shelton, IV, et al.	
U.S. Patent No.:	9,113,874	
Issue Date:	August 25, 2015	Attorney Docket No.: 11030-0049IP6
Appl. Serial No.:	14/312,808	
Filing Date:	June 24, 2014	
Title:	SURGICAL INSTRUMENT SYSTEM	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 9,113,874 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Patent No. 9,113,874 to Shelton IV, et al. ("the '874 patent")
IS1002	Excerpts from the Prosecution History of the '874 patent ("the Prosecution History")
IS1003	Declaration of Dr. Bryan Knodel
IS1004	U.S. Patent No. 5,383,880 to Hooven ("Hooven")
IS1005	U.S. Patent No. 5,662,667 to Knodel et al. ("Knodel")
IS1006	U.S. Patent No. 5,796,188 to Bays ("Bays")
IS1007	U.S. Patent No. 5,702,408 to Wales et al. ("Wales")
IS1008	U.S. Patent No. 7,845,537 ("the '537 patent")
IS1009	U.S. Patent No. 8,161,977 ("the '977 patent")
IS1010	U.S. Patent No. 8,820,603 ("the '603 patent")
IS1011	U.S. Pat. App. Pub. No. 2002/0165541 ("Whitman")
IS1012	Excerpts from the Prosecution History of the '537 patent ("the '537 Prosecution History")
IS1013	Excerpts from the Prosecution History of the '977 patent ("the '977 Prosecution History")
IS1014	Excerpts from the Prosecution History of the '603 patent ("the '603 Prosecution History")

Intuitive Surgical, Inc., ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 1-21 ("the Challenged Claims") of U.S. Patent No. 9,113,874 ("the '874 patent").

The '874 patent relates to "a surgical instrument system … including a surgical instrument [such as a surgical stapler] and a remote user-controlled actuation console for controlling the surgical instrument." IS1001, Abstract. According to the Examiner's Reasons for Allowance, claim 1 of the '874 patent was allowed because it allegedly recited subject matter already found allowable in a parent application. IS1002 at 373 (Dec. 24, 2014, Notice of Allowability) ("[Claim 1] contain[s] allowable subject matter found in the parent application 13037515, now US Patent No 8,820,603."); IS1002 at 38 (Apr. 7, 2015, Notice of Allowability) (same). That statement, however, was incorrect as the parent claim to which the Examiner was referring in fact had been rejected on prior art grounds. IS1014 at 392-93 (Jan. 31, 2013, Non-Final Rejection) (rejecting claim 1 as being anticipated by Whitman). The parent claim was then thrice amended to avoid such prior art. IS1014 at 314 (Apr. 9, 2013, Response to Office Action) ("Applicants have now amended the claim to recite the limitation that the end effector includes a knife and a channel in the frame to receive the knife. Whitman does not disclose such a feature."); IS1014 at 250-51 (Aug. 20, 2013, Response to Office Action) (amending claim 1 to require a "rigid" shaft because "Whitman discloses only a

flexible shaft"); IS1014 at 223 (Nov. 25, 2013, Response to Office Action) (amending claim 1 to require that the motor be "located substantially" in the shaft). As such, the allowance of the '874 patent was the result of a factual mistake. Accordingly, as the USPTO correctly recognized in the parent application, the claimed systems were not new at the time of the alleged priority date of the '874 patent. As explained below, Hooven, either alone or in combination with Knodel and/or Bays, disclose all the elements of claims 1-21 of the '874 patent. Petitioner therefore requests IPR of the challenged claims on Grounds 1-4 below.

I. MANDATORY NOTICES UNDER 37 C.F.R § 42.8(a)(1)

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 *inter partes* review of the '874 patent. The '874 patent is the subject of Civil Action No. 1:17-cv-00871-LPS, filed on June 30, 2017, in the United States District Court for the District of Delaware.

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

Intuitive Surgical 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 IPR11030-0049IP6@fr.com (referencing No. 11030-0049IP6) and cc'ing PTABInbound@fr.com, katz@fr.com, phillips@fr.com, and oconnor@fr.com.

II. PAYMENT OF FEES UNDER 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.

III. 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 '874 patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR.

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

Petitioner requests IPR of claims 1-21 of the '874 patent on the grounds listed below. A declaration from Dr. Bryan Knodel (IS1003) is included in support.

Grounds	'874 Patent Claims	Basis for Rejection
Ground 1	**1-7, 9-14, 16-17, 19-21**	Anticipated by **Hooven** (IS1004) under 35 U.S.C. § 102(b)
Ground 2	**2-4, 9-18, 21**	Obvious over **Hooven** (IS1004) in view of **Knodel** (IS1005) under 35 U.S.C. § 103
Ground 3	**8**	Obvious over **Hooven** (IS1004) in view of **Bays** (IS1006) under 35 U.S.C. § 103
Ground 4	**1-8, 19**	Obvious over **Hooven** (IS1004) in view of **Knodel** (IS1005) and/or **Bays** (IS1006) and further in view of **Wales** (IS1007) under 35 U.S.C. § 103

The '874 patent issued from U.S. App. No. 14/312,808, filed on June 24, 2012, which is a continuation of U.S. App. No. 13/037,515, filed on March 1, 2011, now U.S. Pat. No. 8,820,603, which is a continuation-in-part of U.S. App. No. 12/236,277, filed on September 23, 2008, now U.S. Pat. No. 8,161,977, which is a continuation-in-part of U.S. App. No. 11/343,803, filed on January 31, 2006, now U.S. Pat. No. 7,845,537. Accordingly, the earliest possible date to which the '874 patent could claim priority (hereinafter the "earliest effective filing date") is January 31, 2006.

Petitioner does not concede that the '874 patent is entitled to this priority date, but has elected not to argue the issue in the present Petition because all prior art references identified in the Grounds presented below pre-date the earliest possible priority date for the '874 patent. However, Petitioner reserves the right to

present such an argument in this proceeding or other proceedings involving the '874 patent.

Hooven published on January 24, 1995, which is more than one year before the earliest effective filing date. Therefore, Hooven qualifies as prior art under 35 U.S.C. § 102(b). Hooven was made of record during prosecution of the '874 patent, but was never discussed by the examiner or the applicant.

Knodel published on Sepember 2, 1997, which is more than one year before the earliest effective filing date. Therefore, Knodel qualifies as prior art under 35 U.S.C. § 102(b). Knodel was not made of record during prosecution of the '874 patent.

Bays issued on August 18, 1998, which is more than one year before the earliest effective filing date. Therefore, Bays qualifies as prior art under 35 U.S.C. § 102(b). Bays was made of record during prosecution of the '874 patent, but was never discussed by the examiner or the applicant.

Wales issued on December 30, 1997, which is more than one year before the earliest effective filing date. Therefore, Wales qualifies as prior art under 35 U.S.C. § 102(b). Wales was made of record during prosecution of the '874 patent, but was never discussed by the examiner or the applicant.

IV. SUMMARY OF THE '874 PATENT

The '874 patent describes a "surgical instrument system…including a

surgical instrument [(*e.g.*, surgical stapler)] and a remote user-controlled actuation console for controlling the surgical instrument." IS1001, Abstract. Figure 1 of the '874 patent (below) shows the surgical instrument in a stand-alone configuration (without a "user-controlled actuation console").

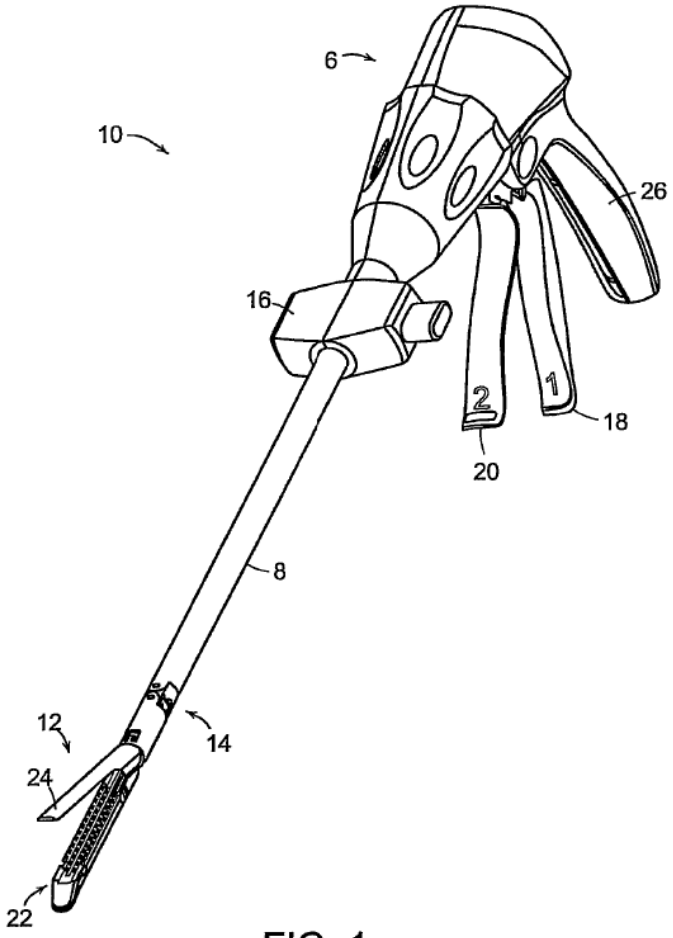


FIG. 1

There are no figures in the '874 patent that show a remote user-controlled

actuation console for controlling the surgical instrument.[1] IS1003, ¶28. Instead, the '874 patent points to consoles in "robotic surgical systems" that were "well known in the art," such as those disclosed in Petitioner's own prior art patents. IS1001, 30:48-61.[2] The claimed surgical instrument is old, and robotic surgical systems are old. The '874 patent fails to identify exactly what in the patent is allegedly novel. As discussed herein, the '874 patent merely describes prior art technology.

In the '874 patent, the surgical instrument includes: "an end effector [12] comprising an anvil [24] with staple forming features thereon, a housing frame [22] generally opposed to the anvil to hold a cartridge, a replaceable cartridge holding staples that can be urged out of the cartridge with a distal actuation of a deploying wedge, and at least one sensor." IS1001, 4:10-14, FIG. 3. The surgical

[1] Although the abstract and claims 1-8, 16-19, and 21 recite a "remote user-controlled actuation console," claims 9-15 of the '874 patent recite only a "remotely user-controlled console," and claim 20 recites only a "remote user-controlled console." The word "actuation" is absent in claims 9-15 and 20.

[2] Via the first CIP application, the patent also discloses a "remote computer device 2420" (FIGs. 54, 55), but this device only receives data from the instrument's control unit and does not actuate the instrument.

instrument includes "an elongated shaft [46] coupled to the housing frame [22]." IS1001, 4:15-16, FIG. 4. "The elongated shaft compris[es] a rotary drive shaft [48] operably interfacing with the deploying wedge [33] such that rotation of the rotary drive shaft…causes the deploying wedge to move longitudinally…." IS1001, 4:16-18. The drive shaft is powered by motor 65 and rotates drive screw 36, which is configured to apply firing motions to the wedge sled driver 33. IS1001, 20:22-29. The drive screw 36 is in threaded engagement with the knife 32 such that when drive screw 36 rotates, the wedge sled driver 33 moves linearly.

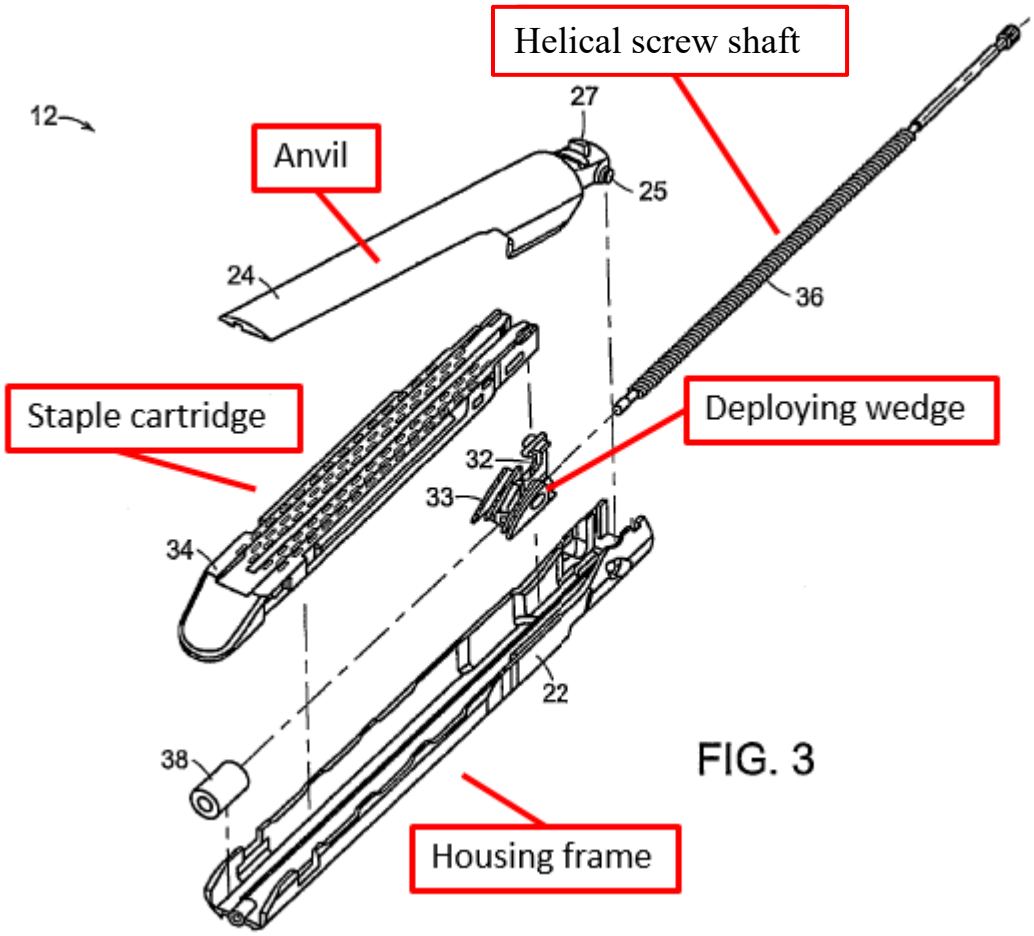


FIG. 3

IS1001, FIG. 3.

The instrument also includes "a closure member [42] configured to close the end effector [12]," which the patent discloses is a "closure tube" such as distal closure tube 42. IS1001, 4:58-59, FIG. 4:

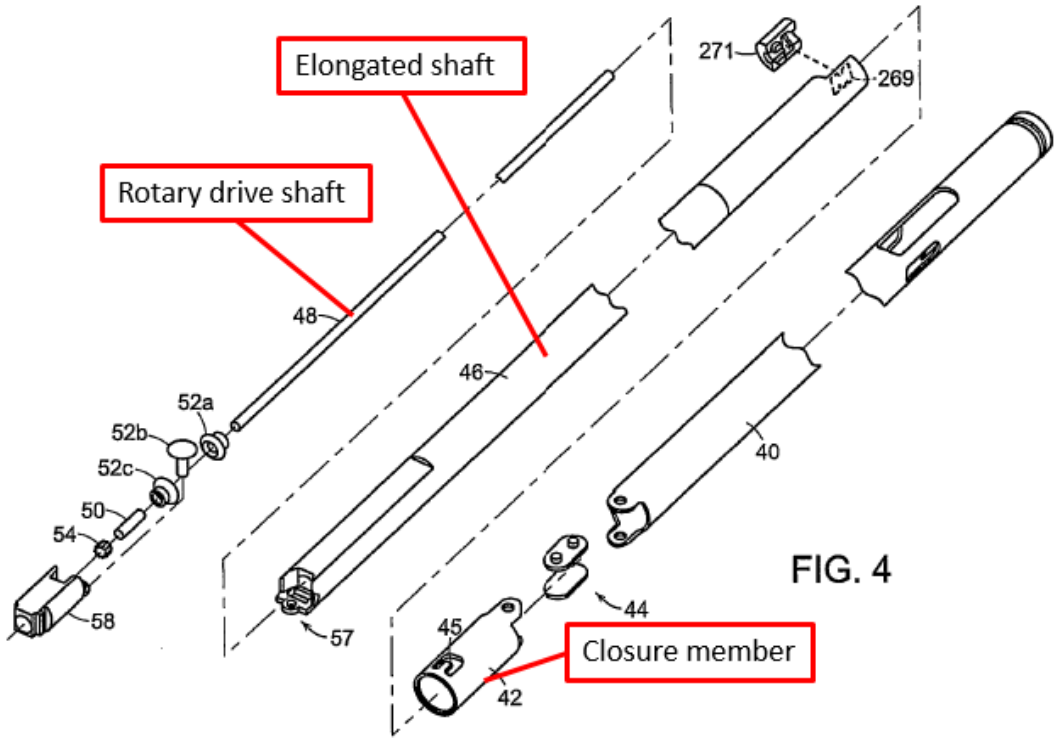


FIG. 4

V. SUMMARY OF THE PROSECUTION HISTORY

The chain of applications to which the '874 patent claims priority is provided above. *See* Section III.B, *supra*. Notably, as detailed here, claim 1 of the '874 patent is nearly identical to a claim rejected during prosecution of a parent application. In allowing claim 1 of the '874 patent, the examiner erroneously stated that it contains allowable subject matter from a parent application. But, to the contrary, the examiner had rejected the nearly identical claim during prosecution of the

parent application.[3]

In addition, the original great-grandparent application to which the '874 patent claims priority did not include disclosure that supports the challenged claims. Specifically, that application had no remote computer or console. The grandparent '277 continuation-in-part application added new matter relating to a control unit 2400 in the handle 6 of the instrument and a remote computer device 2420 for receiving data from the surgical instrument. *Compare* IS1008 ('537 patent) *with* IS1009 ('977 patent), FIGs. 54-56, 27:27-29:37. The parent '515 continuation-in-part application added descriptions of robotic surgical systems. *Compare* IS1009 ('977 patent) *with* IS1010 ('603 patent), 29:37-30:15; IS1014 ('603 Prosecution History) at 637 (original claim).

The '515 application was filed with a single claim, which is shown below.

[3] In the parent application, to gain allowance, the applicant added limitations not found in the claims of the '874 patent.

1. A surgical cutting and fastening instrument comprising:
    a. An end effector comprising an anvil with staple forming feature thereon, a housing frame generally opposed to the anvil to hold a cartridge, a replaceable cartridge holding staples that can be urged out the cartridge with a distal actuation of a deploying wedge, and at least one sensor;
    b. an elongated shaft, said shaft having a motor therein that is operably coupled to an actuation mechanism, said shaft having at least one articulation joint for positioning the cartridge at an angle not parallel to a longitudinal axis of said shaft;
    c. an electrically coupled remote controlled actuation consol;
    d. linear drive motion converter to convert rotary motion from said motor to linear motion.

IS1014 ('603 Prosecution History) at 637 (original claim). The USPTO rejected this claim, which is nearly identical to claim 1 challenged in this Petition, as anticipated by Whitman. IS1014 at 392-93 (Jan. 31, 2013, Non-Final Rejection).

After a first failed attempt to amend the claims and distinguish Whitman, the applicant amended claim 1 of the '515 application to require an elongated shaft that is "rigid,"[4] and added three new dependent claims. IS1014 at 249 (Aug. 20,

[4] Whitman disclosed a "flexible" elongated shaft connecting the motor to the instrument. IS1014 at 251 (Aug. 20, 2013, Response to Office Action) ("Whitman discloses only a flexible shaft 105 connecting a motor and an actuation mechanism."); IS1011, [0049]-[0051].

2013, Response to Office Action); *see also* IS1014 at 309-14 (Apr. 9, 2013, Response to Office Action) (amending claim 1); IS1014 at 255-56 (May 20, 2013, Final Rejection) (rejecting claim 1). After further prosecution, the '603 patent issued with only one claim that included the "rigid" limitation. IS1014 at 230-31 (Aug. 28, 2013, Non-Final Rejection); IS1014 at 222-24 (Nov. 25, 2013, Response to Office Action); IS1014 at 212-19 (Dec. 16, 2013, Notice of Allowance); IS1010 at 30:50-31:3.

In the application that issued as the '874 patent, the applicant re-submitted a claim nearly identical to the rejected original claim 1 of the parent '515 application, which, as explained above, did not include the "rigid" limitation added during prosecution of the parent '515 application. IS1002 ('874 Prosecution History) at 476 (original claim). The applicants did not inform the examiner that they had essentially re-submitted a previously rejected claim. In a preliminary amendment, the applicants also submitted 18 new claims, including two new independent claims. IS1002 at 379-83 (Dec. 11, 2014, Preliminary Amendment). None included the "rigid" limitation that had been added to the parent application's claims to gain allowance. Nonetheless, less than two weeks later, the same examiner who reviewed the '515 application issued a notice of allowance for all of the pending claims, stating that the independent claims "each contain[s] allowable subject matter found in the parent application…." IS1002 at 373 (Dec. 24, 2014,

Notice of Allowance). The examiner did not explain the inconsistency between his original rejection in the parent application and subsequent allowance of claim 1.

The applicants then filed a request for continued examination. IS1002 at 180 (Mar. 24, 2015). In that request, the applicants added three new independent claims. IS1002 at 189-91 (claims). Again, none of the new claims included the "rigid" limitation. *See* IS1002 at 189-191. Nonetheless, less than two weeks later, the examiner issued a notice of allowance, stating that all the independent claims "contain allowable subject matter found in the parent application 13037515, now US Patent No 8,820,603." IS1002 at 38 (Apr. 7, 2015, Notice of Allowance).

VI. CLAIM CONSTRUCTION

For the purposes of this IPR only, Petitioner submits that the terms of the '874 patent are to be given their broadest reasonable interpretation as understood by a POSITA at the time in view of the specification ("BRI"). 37 C.F.R. § 42.100(b).

VII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '874 PATENT IS UNPATENTABLE

For the reasons explained below, claims 1-21 of the '874 patent are invalid.

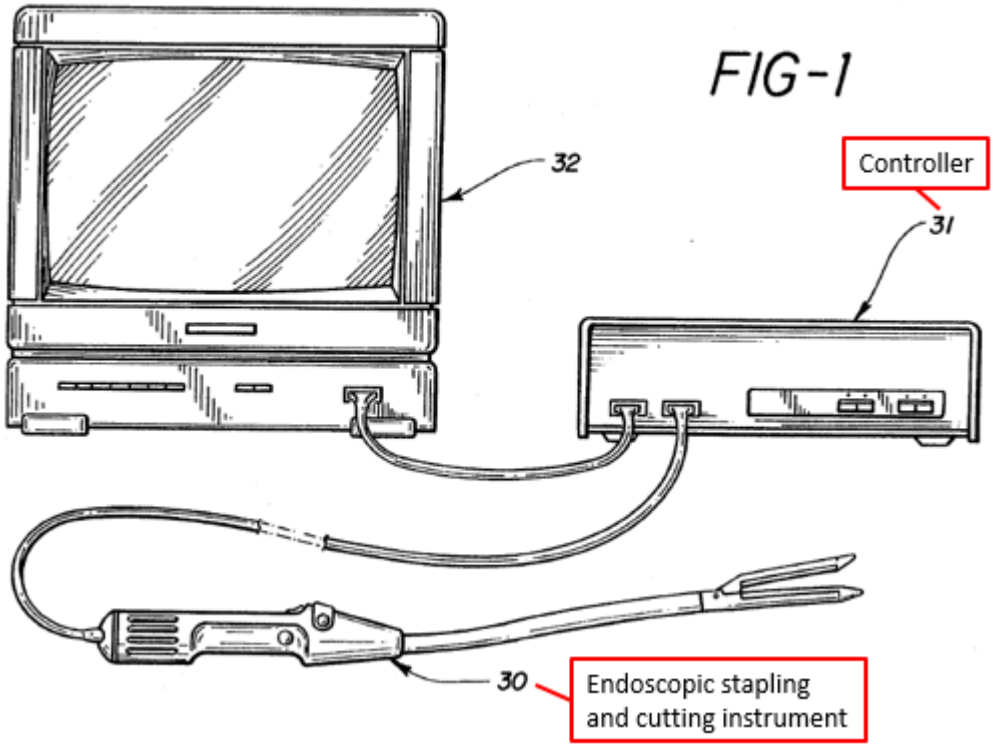
A. Ground 1: Hooven Anticipates Claims 1-7, 9-14, 16-17, and 19-21

Because claims 9 and 20 have been asserted in litigation, we begin with those claims, starting with claim 20.

Claims 20 and 9

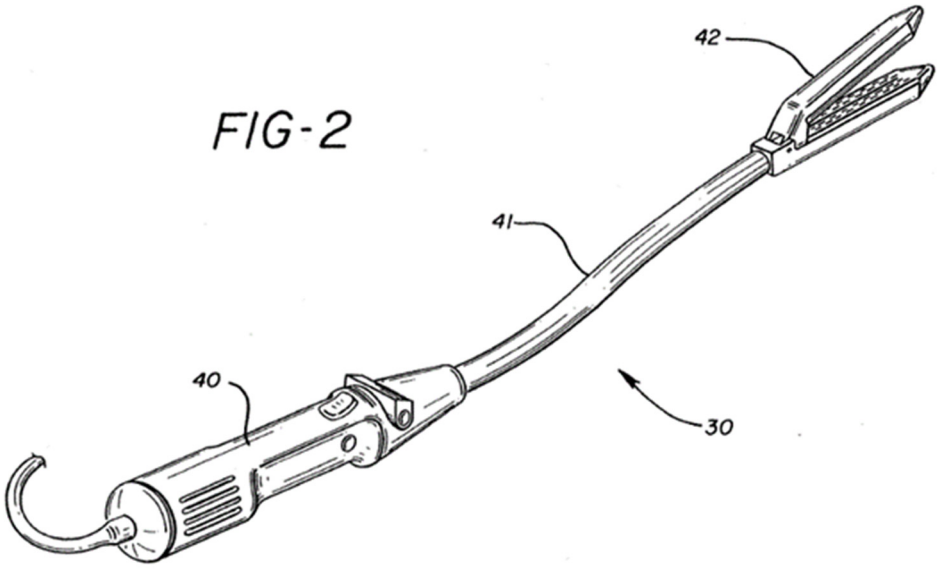
[20.1] A surgical instrument system, comprising:

If this preamble is deemed to be a limitation, Hooven discloses it. IS1003, ¶38. Hooven discloses a surgical instrument system including an instrument connected via a cable to a controller:



IS1004, FIG. 1; 3:21-23. Specifically, "an endoscopic instrument which has a head portion for carrying out a step in an endoscopic procedure. The step may be [] stapling, cutting, [] etc. or combinations of these steps." IS1004, 2:58-63; *see also* IS1004, FIGs. 1-9, 4:15-17 ("In [] Figure [1] an endoscopic stapling and cutting instrument 30 is interconnected with a controller 31 and a video display monitor 32."), 4:45-53 ("In the embodiment depicted in FIGS. 2 through 9, the

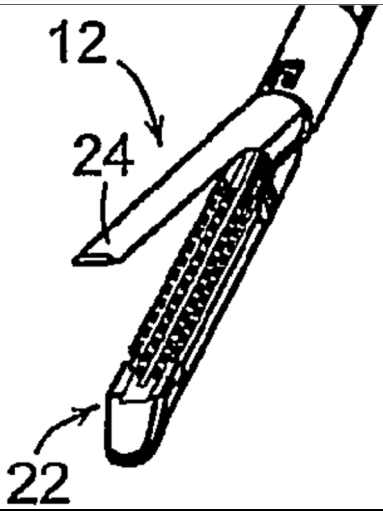
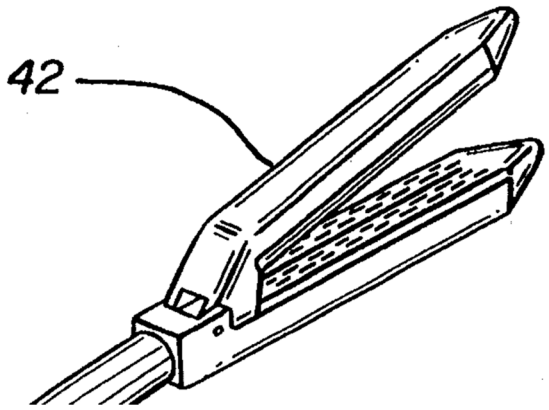
head portion is a linear stapler and cutter….").



IS1004, FIG. 2.

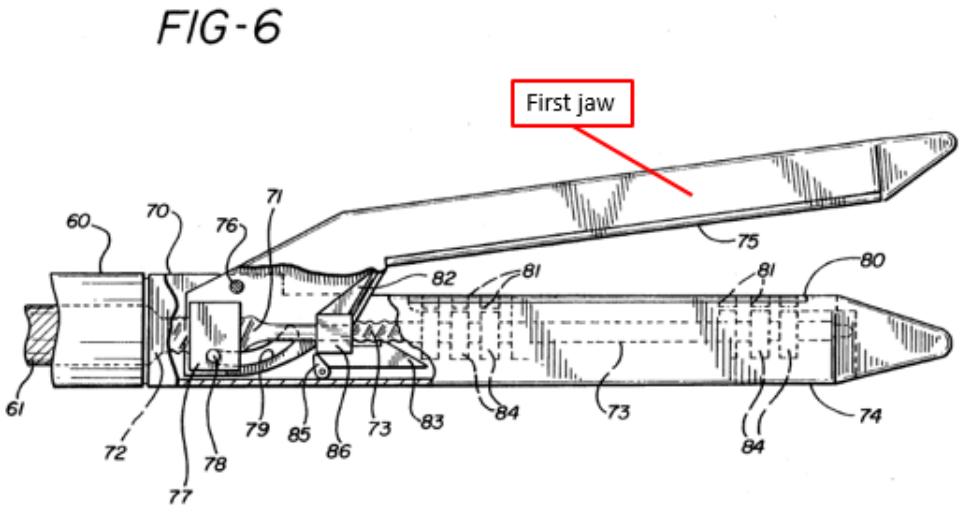
[20.2] an end effector comprising

Hooven discloses this limitation. IS1003, ¶39. Hooven's surgical instrument has an end effector called the "head or business portion 42 of the instrument." IS1004, 4:36-37. Hooven explains: "The head or business portion is that portion of the instrument which accomplishes a step in a surgical procedure, whether than be ligating, stapling, cutting, manipulating tissue, or combinations of such steps." IS1004, 4:38-42. The exemplary end effector of Hooven is the same type as the exemplary end effector in the '874 patent—namely a cutting and stapling end effector, *compare* IS1001, 4:9-13 *with* IS1004, 4:12-20:

'874 Patent (FIG. 55)	**Hooven (FIG. 1)**
	

[20.3] a first jaw`

Hooven discloses this limitation. IS1003, ¶40. Hooven's end effector 42 includes "an anvil portion 75," which is a first jaw. IS1004, 5:38-40, FIG. 6.



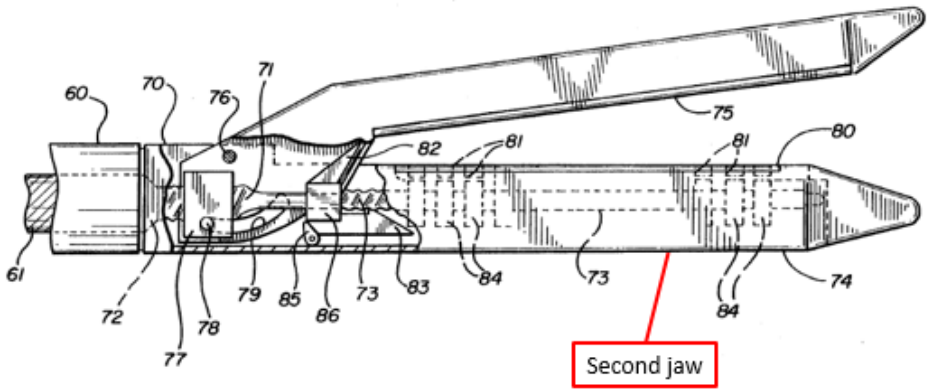
[20.4] a second jaw, wherein one of said first and second jaws is movable between an open position and a closed position relative to the other of said first and second jaws in response to a closing motion

Hooven discloses this limitation. IS1003, ¶¶41-42.

"A second jaw"

Hooven's end effector 42 includes "a staple or staple cartridge portion 74," which is a second jaw. IS1004, 5:38-40, FIG. 6; IS1003, ¶41.

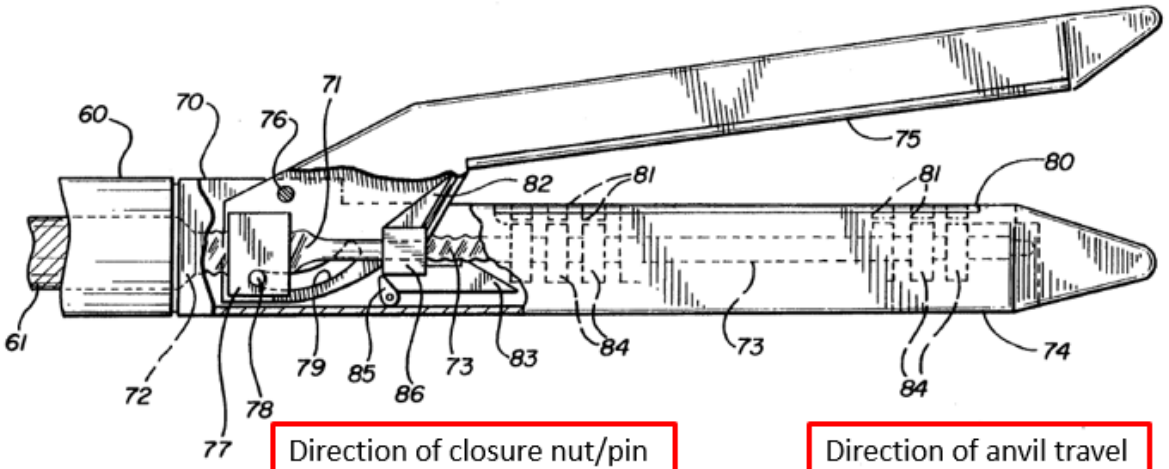
FIG-6



"Wherein one of said first and second jaws is movable between an open position and a closed position relative to the other of said first and second jaws in response to a closing motion"

Hooven's anvil 75 (*i.e.*, the first jaw) is movable between open and closed positions relative to the staple cartridge portion 74 (*i.e.*, the second jaw). IS1004, FIGs. 6 (open position), 7 (closed position); IS1003, ¶42.

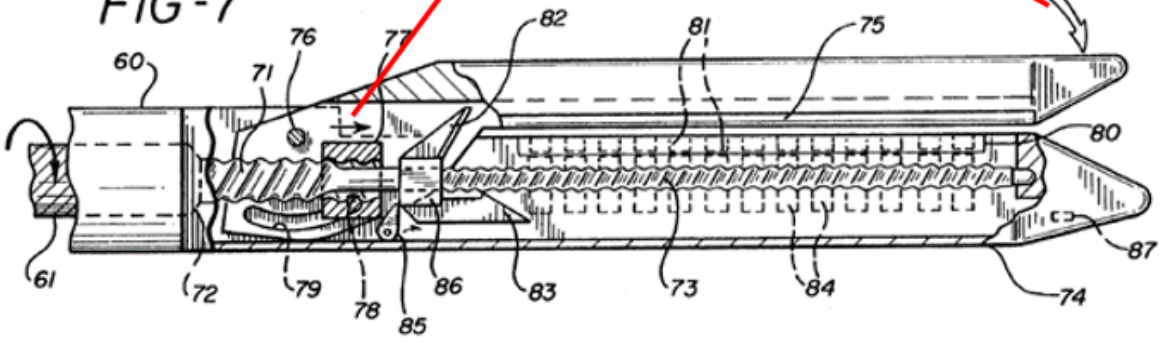
FIG-6



Direction of closure nut/pin travel during closing motion

Direction of anvil travel during closing motion

FIG-7



This movement is in response to distal motion of closure pin 78 (*i.e.*, a closing motion) applied to the slot 79 in anvil portion 74. IS1003, ¶42; *see also* IS1004, 5:40-55 (describing the closing motion of closure pin 78), FIGs. 6-7 (above). In the opening motion of closure pin 78, "the closure nut 77[, which includes closure pin 78,] retract[s] and open[s] the anvil portion 75 of the head of the instrument." IS1004, 5:40-55, 6:40-44; *see also* IS1004, FIGs. 6-10. The proximal and distal motions of closure pin 78 are opening and closing motions, respectively, to move

the jaws between open and closed positions. IS1003, ¶42.

[20.5] a driver element supported for axial travel through said end effector in response to a firing motion;

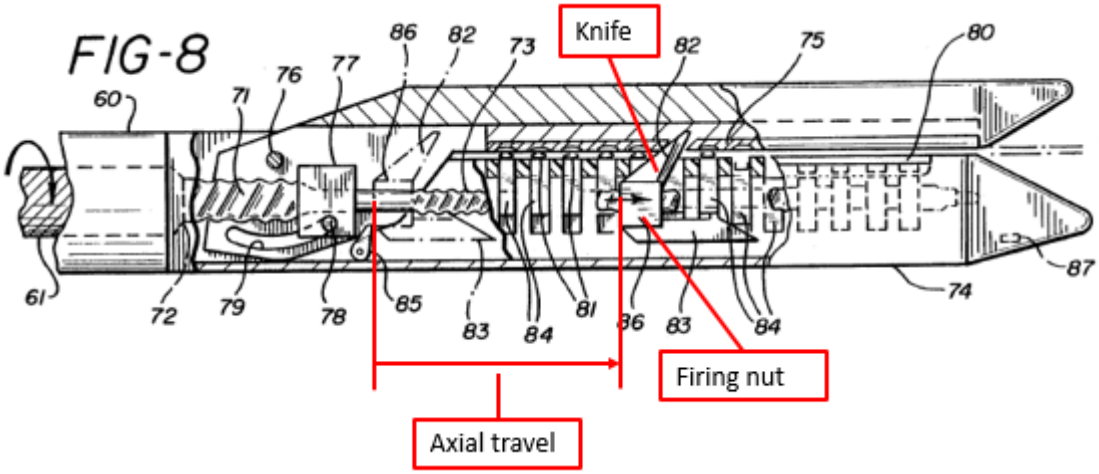
"Driver element"

Hooven discloses this limitation. IS1003, ¶¶43-44. Hooven discloses a "firing nut 86" that forcibly propels knife 82 via threads that interact with threaded rod 71, and it is thus a driver element. *Id.*; IS1004, 6:30-34 ("[F]iring nut 86 on which the knife 82 and wedges 83 are disposed … engages the threads of the smaller diameter portion 73 of the threaded rod to move forward along the rod and drive the staples 81 and cut tissue."). Hooven's firing nut is essentially the same as the driver element disclosed in the '874 patent, which is a threaded portion of "knife driving member 32," which is threadedly attached to the drive screw. IS1003, ¶43.

"Supported for axial travel through said end effector in response to a firing motion"

Hooven's firing nut 86 and knife 82 are supported on smaller diameter portion 73 of threaded rod 71 for axial travel through the surgical end effector after the anvil has been closed. IS1003, ¶44. "As depicted in [FIGs. 6-10], extending the length of the staple portion [74] of the instrument is the smaller diameter portion of the threaded rod [73]. Mounted on this rod, to move along the rod as the rod rotates, is a knife member 82 and a driving wedge member 83 which are inner

connected [and disposed on firing nut 86]. The wedge member precedes the knife member as they move along the threaded rod." IS1004, 6:9-16.

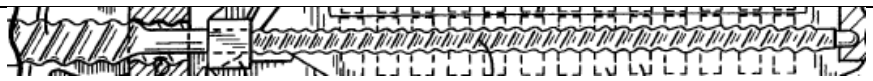


IS1004, FIG. 8; *see also* IS1004, 6:30-34 ("[T]he firing nut 86 on which the knife 82 and wedges 83 are disposed [] engages the threads of the smaller diameter portion 73 of the threaded rod to move forward along the rod [as it rotates] and drive the staples 81 and cut tissue."). The rotations of the threaded rod 71 are the firing motions. IS1004, 6:30-34; *compare* IS1004, FIG. 7 (depicting "the head of the instrument … in the closed position ready for firing") *with* IS1004, FIG. 8 (depicting "the head of the instrument … during the firing action" and showing the axial travel of firing nut 86 and knife 82); IS1003, ¶44.

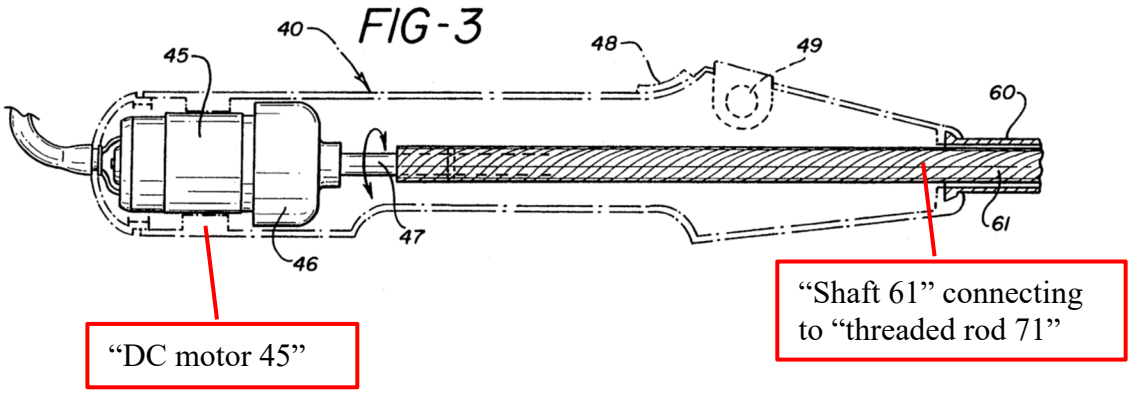
[20.6] a motor-powered firing element configured to apply the firing motion to said driver element

Hooven discloses this limitation. IS1003, ¶¶45-47. The smaller diameter portion 73 of Hooven's "threaded rod 71" is a motor powered firing element that is configured to apply firing motions to the knife via the drive nut. IS1003, ¶45. In

fact, Hooven's threaded rod is substantially similar to the '874 patent's drive screw 36. *Compare* IS1001, FIG. 3 *with* IS1004, FIG. 7.

'874 patent "drive screw 36"	
Hooven "threaded rod 71"	

Hooven's threaded rod 71 is also driven by a DC motor via a flexible drive shaft 61, so it is motor-powered. IS1004, 5:8-35.

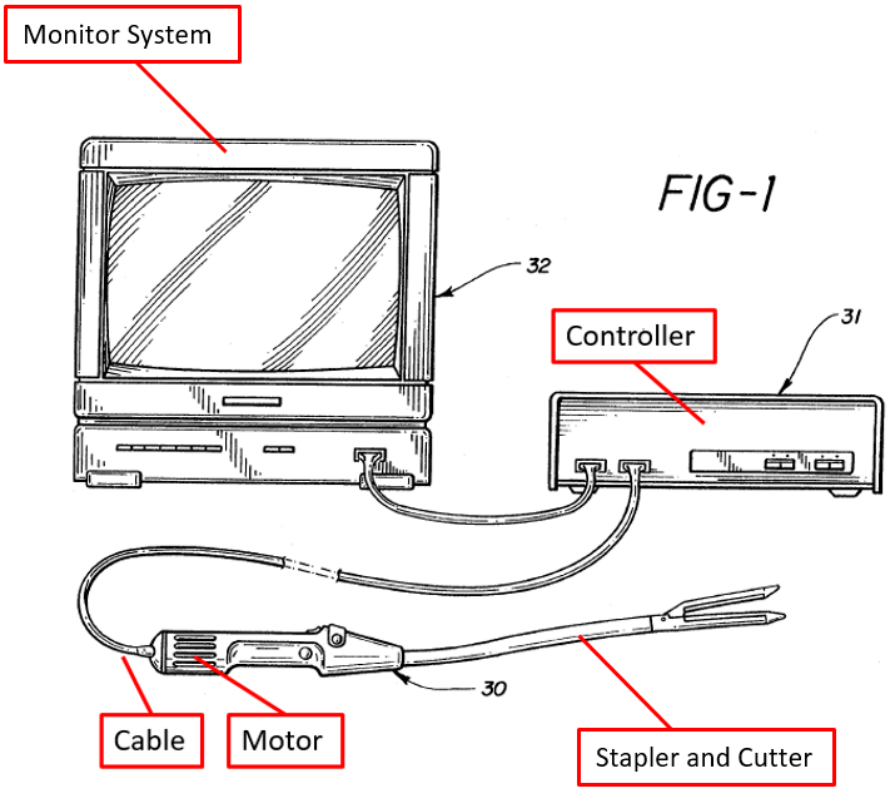


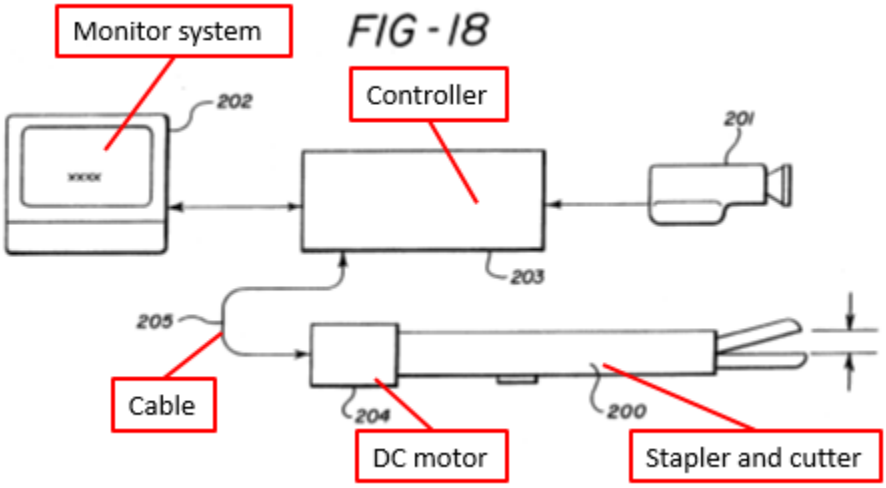
Hooven thus discloses a motor powered part used in the process of firing a stapler by applying firing motions (rotating a threaded rod), which, in turn, causes wedge member 83 and knife member 82 to travel axially and eject staples. IS1003, ¶47.

[20.7] a remote user-controlled console electrically coupled to said motor.

Hooven discloses this limitation. IS1003, ¶¶48-49. Hooven discloses a "controller 31" and a "video display monitor 32," which together form a "console." *Id.*; IS1004, FIGs. 1, 18; *see also* IS1004, 4:13-32 ("The controller may also include a display screen to present the data it has received from the instrument and

manipulate it in a desired way.").





Alternatively, the "controller 31" alone may be considered a "console." Hooven's controller is a "remote" console because it is separate from the instrument.

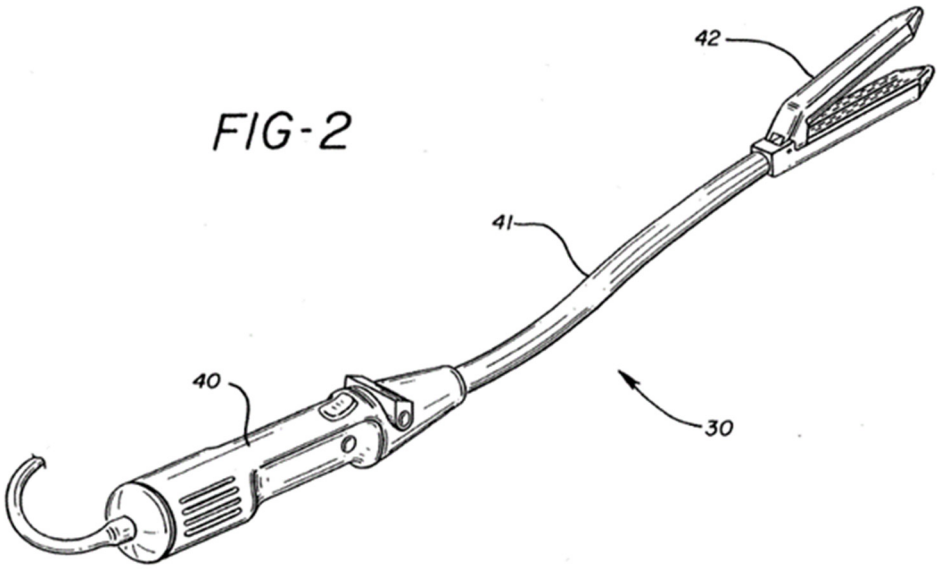
IS1003, ¶48; IS1004, FIGs. 1, 18. It is also user-controlled. IS1003, ¶48. For example, switches provided on the handle of the instrument allow the user to control the video display on the console or provide the console with signals to turn on and off the instrument. IS1003, ¶48; IS1004, 4:60-64; *see also* IS1004, FIG. 19 (showing "user interface"), 4:22-24 ("The controller may feed appropriate signals back to the instrument in order to operate the instrument."). The '874 Patent contemplates that "remote" devices need not be completely separated from the instrument: "That remote computer device 2420 may be external of the instrument 10 (i.e., not part of the instrument 10) . . . ." '874 Patent, 29:49-51. By stating that the "remote" device "may be" external of the instrument, the '874 Patent informs the reader that it need not be—"may be" means its optional, and not required. Accordingly, Hooven's "console" is "remote" even if the switches on the instrument are considered part of the console (in conjunction with remote controller 203).

Hooven's motor is also electrically coupled to the controller. IS1003, ¶49. "The endoscopic instrument [30] is powered by a DC motor 204 and is connected to the controller by a cable 205." IS1004, 8:57-59. Furthermore, the motor may receive control signals from the controller. IS1004, 4:17-20 ("The controller includes … motor drive circuits. The instrument is connected to the controller…."), 4:22-24 ("The controller may feed appropriate signals back to the

instrument in order to operate the instrument."). The controller may also "supply power to the instrument at the appropriate level, frequency, timing, etc." and "[w]ithin the controller may be several hardwired logic circuits controlling critical instrument functions." IS1004, 4:24-28.

[9.1] A surgical instrument comprising:

If this preamble is deemed to be a limitation, Hooven discloses it. IS1003, ¶50. Hooven discloses a surgical cutting and fastening instrument. IS1004, Abstract. Specifically, "an endoscopic instrument which has a head portion for carrying out a step in an endoscopic procedure. The step may be … stapling, cutting, [] etc. or combinations of these steps." IS1004, 2:58-63; *see also* IS1004, FIGs. 1-9, 4:15-17 ("Figure [1 shows] an endoscopic stapling and cutting instrument 30 is interconnected with a controller 31 and a video display monitor 32."), 4:45-53 ("In the embodiment depicted in FIGS. 2 through 9, the head portion is a linear stapler and cutter….").



IS1004, FIG. 2.

[9.2] a surgical end effector comprising:

See Ground 1, element [20.2].

[9.3] a first jaw

See Ground 1, element [20.3].

[9.4] a second jaw

See Ground 1, elements [20.4].

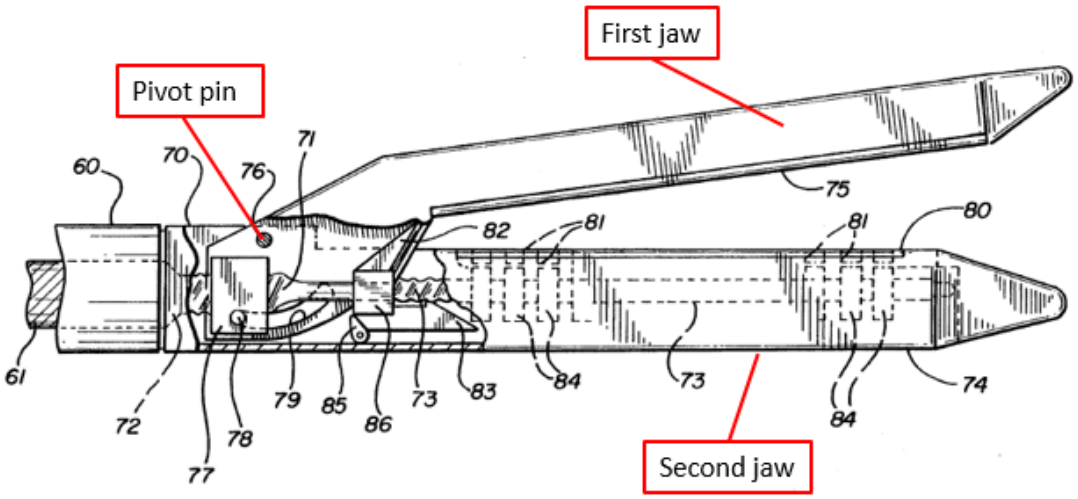
[9.5] said first and second jaws are supported relative to each other such that one of said first and second jaws is movable between open and closed positions relative to the other of said first and second jaws in response to opening and closing motions applied thereto

"Said first and second jaw are supported relative to each other"

Hooven discloses this limitation. IS1003, ¶54. "The staple portion [74 (said second jaw)] and the anvil portion [75 (said first jaw)] are pivotally connected to each other [(and thus supported relative to each other)] by the anvil pivot pin

76." IS1004, 5:40-41.

FIG-6



"Such that one of said first and second jaws is movable between open and closed positions relative to the other of said first and second jaws in response to opening and closing motions applied thereto"

See Ground 1, element [20.4]. The proximal and distal motions of closure pin 78 are opening and closing motions, respectively, to move the jaws between open and closed positions. IS1003, ¶55.

[9.6] a driver element supported for axial travel through the surgical end effector in response to firing motions applied thereto and wherein said surgical instrument further comprises:

See Ground 1, element [20.5].

[9.7] a motor powered firing element configured to apply said firing motions to said driver element

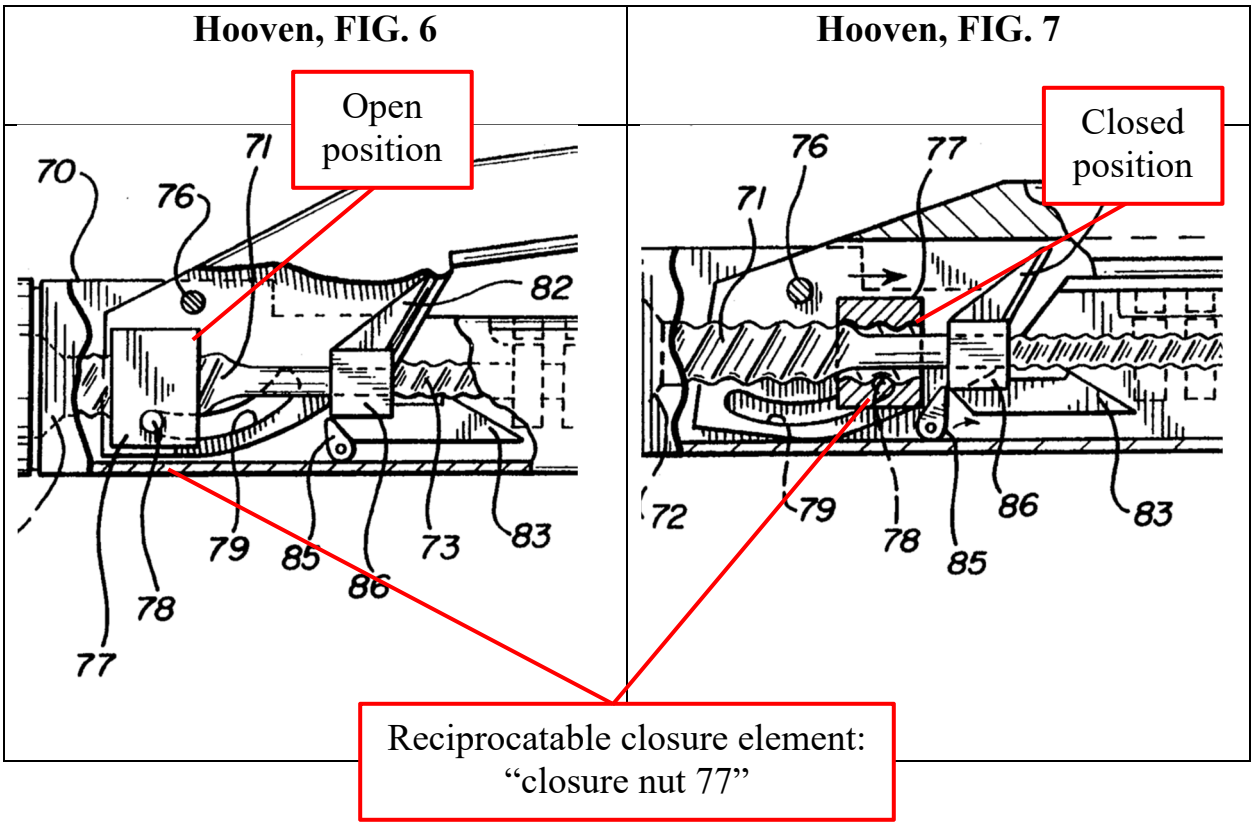
See Ground 1, element [20.6].

[9.8] a remotely user-controlled console electrically coupled to said surgical instrument

See Ground 1, element [20.7]. Element [20.7] recites a "remote user-controlled console electrically coupled to said motor." As discussed with regard to element [20.7] the console is "remote" because it is separate from the instrument. To the extent that the term "remotely" is taken literally to modify "user-controlled" rather than interpreted to mean "remote" to modify console, the console is also "remotely user controlled" because the user controls are remote from the console (they are located on the instrument itself). IS1003, ¶58; IS1004, FIGs. 1-2.

[9.9] a reciprocatable closure element configured to apply said opening and closing motions to said one of said first and second jaws.

Hooven discloses this limitation. IS1003, ¶59. Hooven discloses "closure nut 77," which reciprocates proximally and distally along the threaded rod 79. IS1004, 5:42-50. As the "closure nut 77" moves distally, it causes a closure pin 78 to close the anvil: "When the flexible shaft is rotated, the threaded rod is also rotated and on rotating the closure nut will move down the threaded rod and move the closure pin in the closure slot to close the anvil portion against the staple portion of the head of the instrument." IS1004, 5:46-50.



Claims 1-7, 10-14, 16-17, 19, and 21

[1.1] A surgical cutting and fastening instrument, comprising:

See Ground 1, element [9.1].

[1.2] an end effector comprising

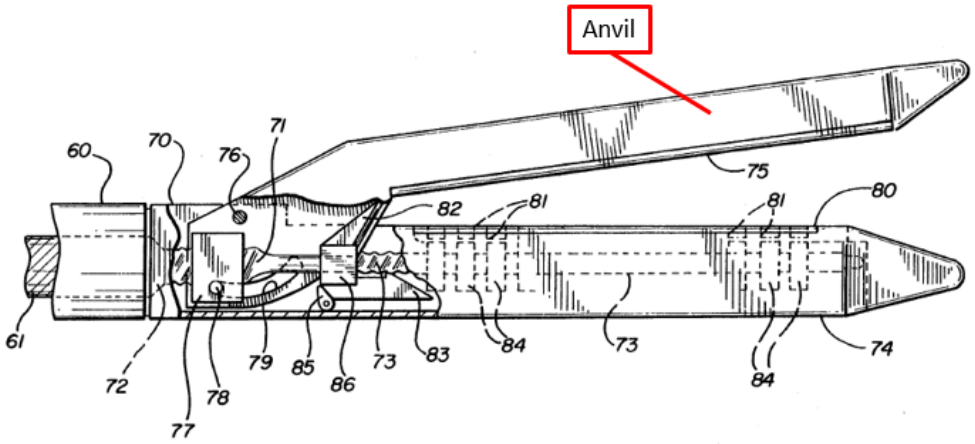
See Ground 1, element [20.2].

[1.3] an anvil with staple forming features thereon,

Hooven discloses this limitation. IS1003, ¶62. Hooven's end effector 42 includes "an anvil portion 75." IS1004, 5:38-40; *see also* IS1004, 6:20-23. Moreover, "[t]he staples pass through the tissue and against the anvil to form the staples in the tissue." IS1004, 5:38-40, FIG. 6. A POSITA would have understood

that an "anvil" against which staples are pressed "to form the staples in the tissue" has "staple forming features thereon." IS1003, ¶62.

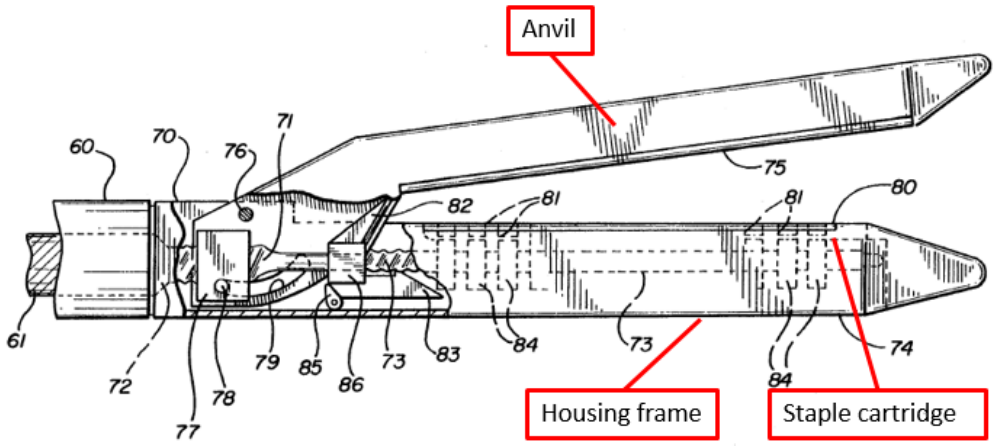
FIG-6



[1.4] a housing frame generally opposed to the anvil to hold a cartridge

Hooven discloses this limitation. IS1003, ¶63. Hooven's end effector 42 includes "a staple or staple cartridge portion 74." IS1004, 5:38-40, FIG. 6.

FIG-6



Staple cartridge portion 74 is a housing frame (it houses a removable staple cartridge 80) that is opposite anvil 75. IS1003, ¶63; IS1004, 6:3-9 ("Mounted in

the staple holding portion of the instrument is a removable staple cartridge 80. The cartridge holds four rows of staples 81…. The cartridge is placed so that it is opposite the anvil portion of the instrument and snaps into the staple holding portion of the instrument as shown."), 8:20-23 ("The head comprises a staple or staple cartridge holding member….").

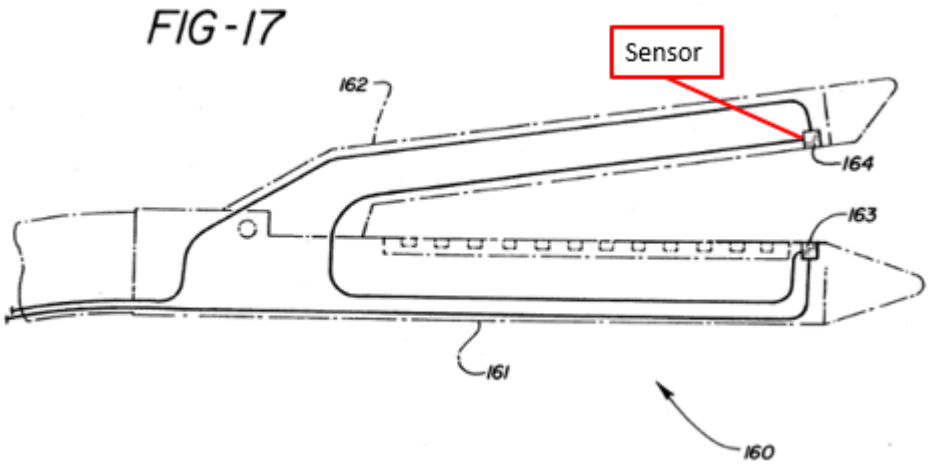
[1.5] a replaceable cartridge holding staples that can be urged out of the cartridge with a distal actuation of a deploying wedge

Hooven discloses this limitation. IS1003, ¶64. "Mounted in the staple holding portion of the [Hooven] instrument is a removable staple cartridge 80. The cartridge … snaps into the staple holding portion of the instrument as shown." IS1004, 6:3-9. A POSITA would have understood that a "removable staple cartridge" is a replaceable staple cartridge. IS1003, ¶64. Hooven also discloses distal actuation of "a wedge member 83" that urges staples out of the cartridge. *Id.* "As the wedge member [83] moves down the threaded rod [*i.e.*, is actuated distally], it drives the staples out of the cartridge, via the individual staple drivers." IS1004, 6:12-20.

[1.6] and at least one sensor

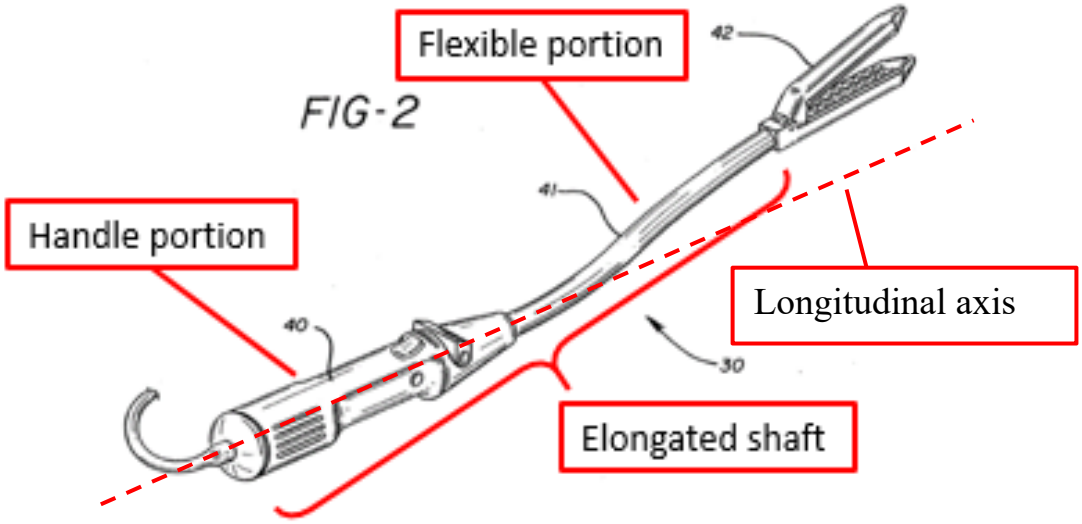
Hooven discloses this limitation. IS1003, ¶65. Hooven's "instrument includes miniature sensors to detect the power and/or force being used and limit switches and contacts to turn the motor on and off at predetermined positions…. The instrument may also include sensors to determine the position of the anvil to

the cartridge and whether or not staples are present in the cartridge." IS1004, 8:62-9:1; *see also* IS1004, 8:14-16 ("In FIG. 17, there is depicted the head of an instrument which includes a sensing member used to sense the blood oxygen content of adjacent tissue."), 8:24-25 ("A light emitting diode (LED) 163 and phototransistor receiver 164 [(a sensor)] are disposed in the staple holding member."), FIG. 17; see also FIG. 19.



[1.7] an elongated shaft

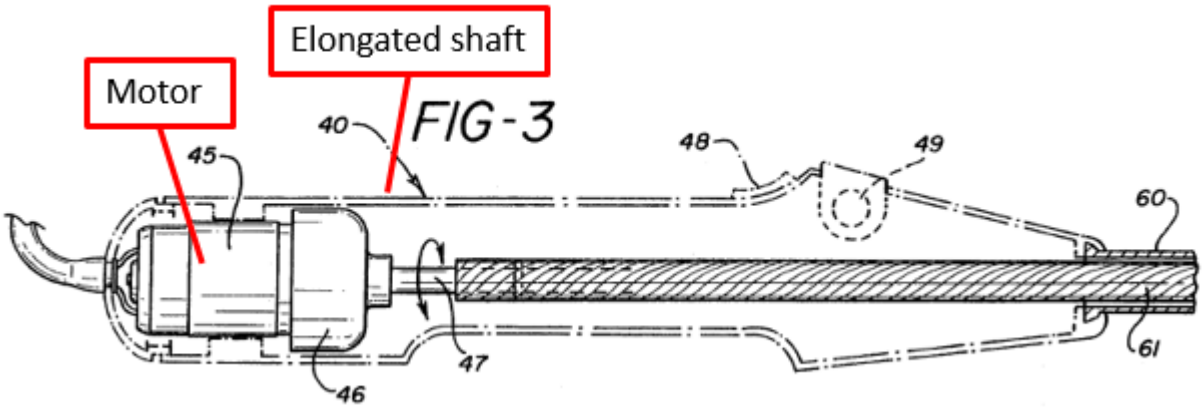
Hooven discloses this limitation. IS1003, ¶66. Hooven discloses an elongated shaft comprising a handle portion 40 and a flexible shaft portion 41. *Id.*; IS1004, FIGs. 2-3.



[1.8] said shaft having a motor therein that is operably coupled to an actuation mechanism

"Shaft having a motor therein"

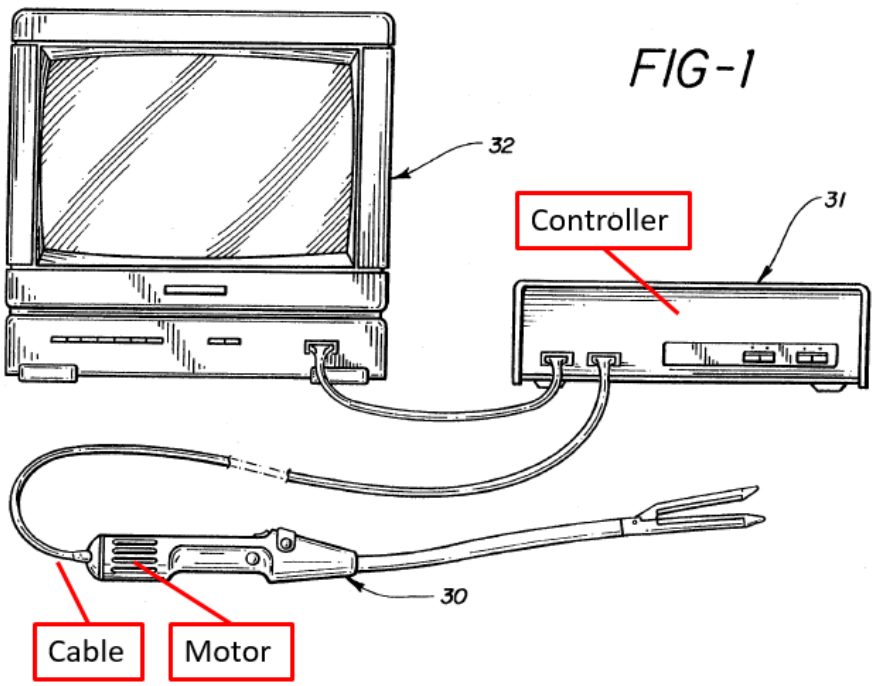
Hooven discloses this limitation. IS1003, ¶67. Hooven discloses motor 45 within handle 40, which is part of Hooven's elongated shaft. *Id.*; IS1004, FIGs. 3, 5; *see also* Ground 1, element [1.7].



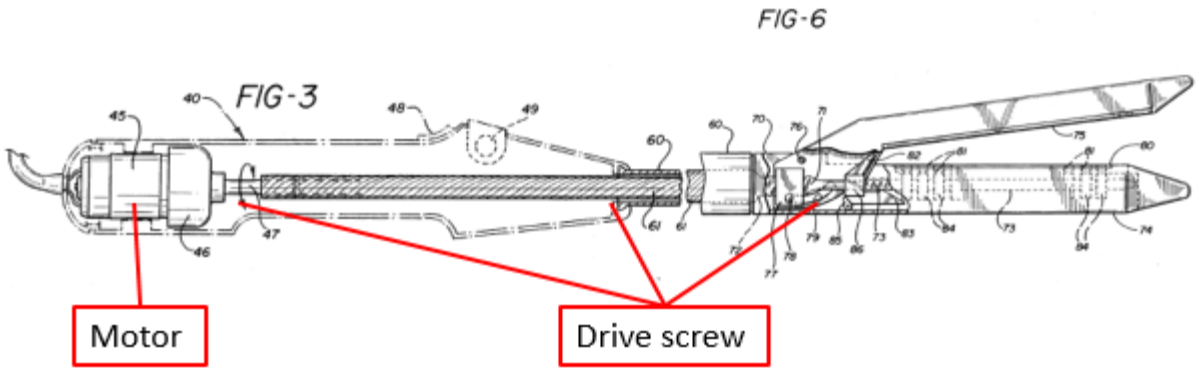
"Operably coupled to an actuation mechanism"

Hooven discloses this limitation. IS1003, ¶¶68-70. Hooven's motor 45 is operably coupled to the microprocessor, hardwired logic, and motor drive circuits

in controller 31 via cable 205. IS1004, 4:17-20 ("The controller includes a microprocessor, [] hardwired logic, [] and motor drive circuits."), 8:40-42 ("The operations that might be controlled would be the opening and closing of the anvil member [75] and/or the firing of the staples."), 9:1-30, FIGs. 1, 2, 18. The combination of one or more of these components, which actuate the motor (*i.e.*, microprocessor, hardwired logic, and motor drive circuits), is an actuation mechanism. IS1003, ¶68.



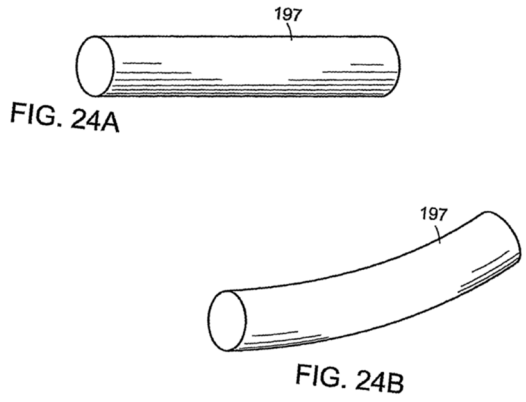
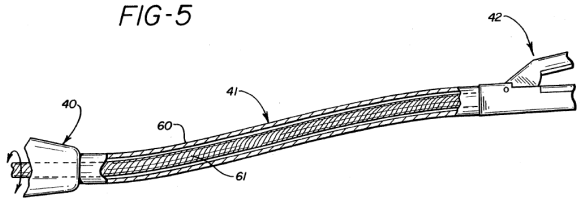
Hooven's motor 45 is also operably coupled to a drive shaft (*i.e.*, shaft 47, shaft 61, and threaded rod 71), which is another actuation mechanism. IS1004, FIGs. 3, 6; IS1003, ¶69. That is, to the extent that the actuation mechanism need not actuate the motor, but instead merely be coupled to the motor to actuate something else, Hooven discloses such an actuation mechanism as well.



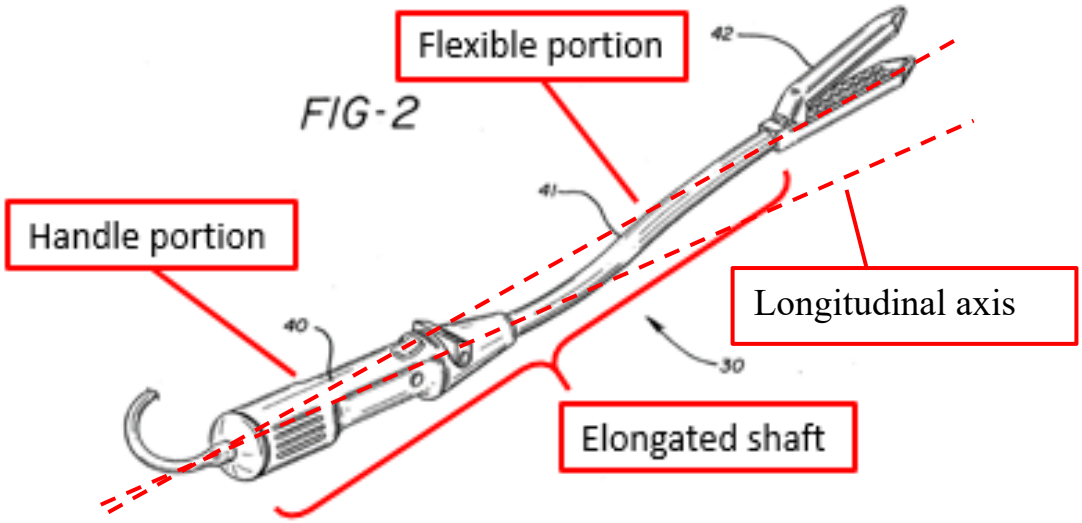
Hooven's motor 45 is further operably coupled to "on/off switch 48 and switch 49," as well as "limit switches and contacts to turn the motor on and off at predetermined positions," which are actuation mechanisms that "control the power supply being provided to the motor." IS1004, 4:60-63, 8:62-65; IS1003, ¶70.

[1.9] at least one articulation joint for positioning the cartridge at an angle not parallel to a longitudinal axis of said shaft

Hooven discloses this limitation. IS1003, ¶71. Specifically, Hooven discloses one of the three articulation joints of the '874 patent—namely, the "torsion cable that may be employed at the articulation point of the instrument according to various embodiments of the present invention." IS1001, 5:29-31. Hooven describes its torsion cable in the following way: "the shaft housing 60 is flexible. Through the center of the housing there extends the rotating, axially flexible, torsionally stiff shaft 61." IS1004, 5:17-19. The following side-by-side figures depicts the '874 patent's "torsion cable" and Hooven's flexible shaft:

'874 Patent **Figure 24** **"Torsion Cable"**	**Hooven** **Figure 5** **"Flexible Shaft"**
	

As shown in Figure 2 of Hooven, this articulation joint positions the cartridge at an angle not parallel to a longitudinal axis of the shaft:



[1.10] an electrically coupled remote user-controllable actuation console

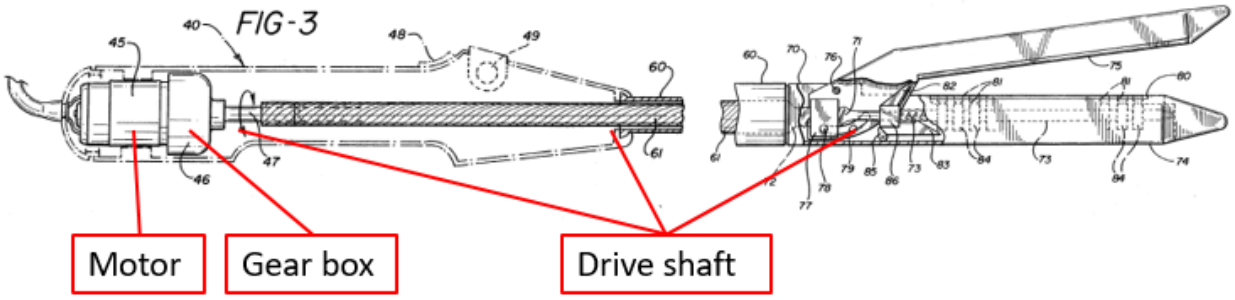
Hooven discloses this limitation. IS1003, ¶72; *see also* Ground 1, element [20.7]. Whereas claim 20 recites a "user controlled console," this claim requires a "user-controllable actuation console." Hooven's console meets this additional limitation. *See* Ground 1, claim [20.7]. Hooven's console is an actuation console

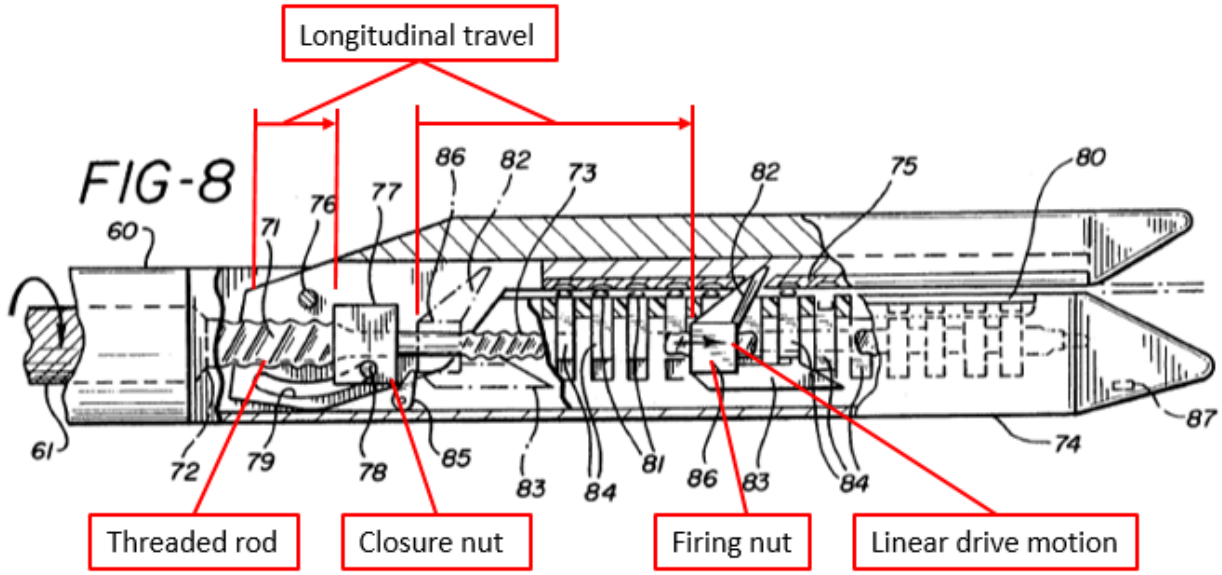
because it actuates the instrument by sending control signals to the instrument to control its operation. IS1004, 4:17-20 ("The controller includes a microprocessor, [] hardwired logic, [] and motor drive circuits."), 8:40-42 ("The operations that might be controlled would be the opening and closing of the anvil member [75] and/or the firing of the staples."), 9:1-30, FIGs. 1, 2, 18. Finally, Hooven's remote actuation console is electrically coupled to its display monitor, surgical instrument, and/or video camera. IS1003, ¶72; IS1004, FIGs. 1, 18.

[1.11] a linear drive motion converter to convert rotary motion from said motor to linear motion

Hooven discloses this limitation. IS1003, ¶73. Specifically, Hooven discloses threaded rod 71 providing rotary motion from DC motor 45 and closure nut 77 and firing nut 86, which each convert the rotary motion from the threaded rod 71 to linear motion. IS1004, FIG. 6. Specifically, "the threaded rod [71] is [] rotated [by motor 45] and on rotating the closure nut [77] will move [linearly] down the threaded rod…." IS1004, 5:46-50. "When the anvil portion 75 is closed … the firing nut 86 … engages the threads of the smaller diameter portion 73 of the threaded rod [71] to move forward [linearly] along the rod…." IS1004, 6:28-34; *see also* IS1004, 3:1-4 ("Means are disposed in the head of the instrument, to translate the motion of the shaft into a suitable force and/or [linear] motion in the head to carry out a desired step in the procedure; *i.e.*, to set and form staples…."), FIGs. 3, 6, 8.

FIG-6





[2] The surgical cutting and fastening instrument of claim 1 wherein said elongated shaft further comprises a closure element configured to reciprocate relative to said end effector in response to closing and opening motions applied thereto.

See discussion at Ground 1, element [9.9]. As explained above, Hooven's closure element (*i.e.*, closure nut 77) is configured to reciprocate (*i.e.*, move back and forth) relative to Hooven's end effector in response to closing and opening motions applied thereto. IS1003, ¶74.

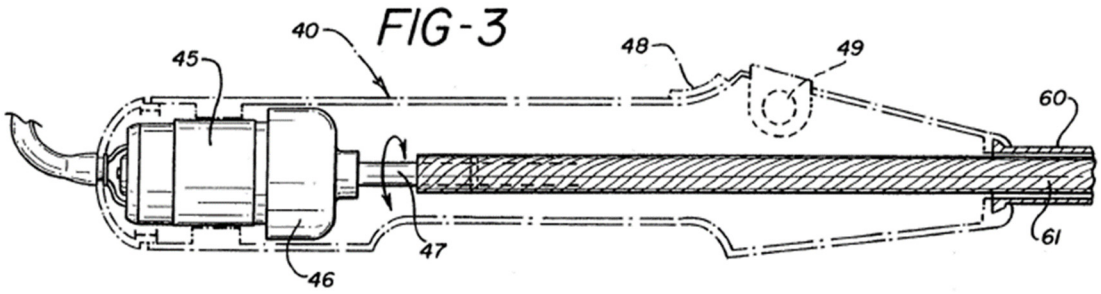
[3] The surgical cutting and fastening instrument of claim 2 wherein said closure element is configured to move said anvil to a closed position when said

closure element is driven in a distal direction and to move said anvil to an open position when said closure element is driven in a proximal direction.

Hooven discloses this limitation. IS1003, ¶75. *See* discussion at Ground 1, element [9.9]. As depicted in FIG. 7, Hooven's jaws close when Hooven's closure element ("closure nut 77") is driven in the distal direction. IS1004, 5:42-50. As depicted in FIG. 6, the Hooven's jaws move into an open position when closure nut 77 is driven in a proximal direction. IS1004, 5:42-50.

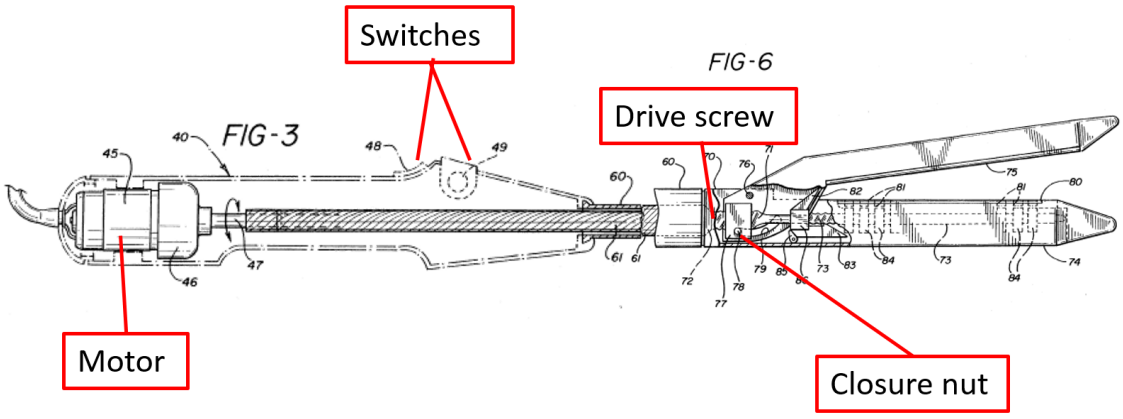
[4] The surgical cutting and fastening instrument of claim 2 wherein said closing and opening motions are applied to said closure element by manual manipulation of a closure actuator interfacing with said closure element.

Hooven discloses this limitation. IS1003, ¶¶76-77. Hooven discloses "a suitable on-off switch 48 and a switch 49 [(*i.e.*, closure actuators)] to control the power supply being provided by the motor" to close the anvil 75. IS1004, 4:60-63, FIG. 3.



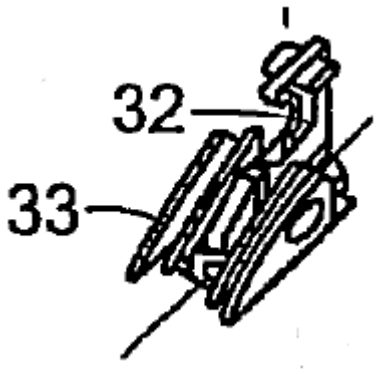
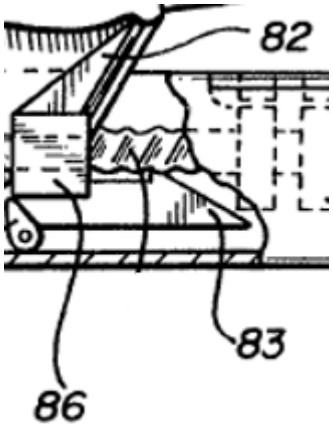
A POSITA would have understood that on-off switch 48 and switch 49 can be manipulated manually. IS1003, ¶77. A POSITA would also have understood that these switches turn on the motor 45, which drives the drive screw ("threaded rod 71"), which drives the closure element ("closure nut 77"). *Id.*; IS1004, FIGs.

3, 6.

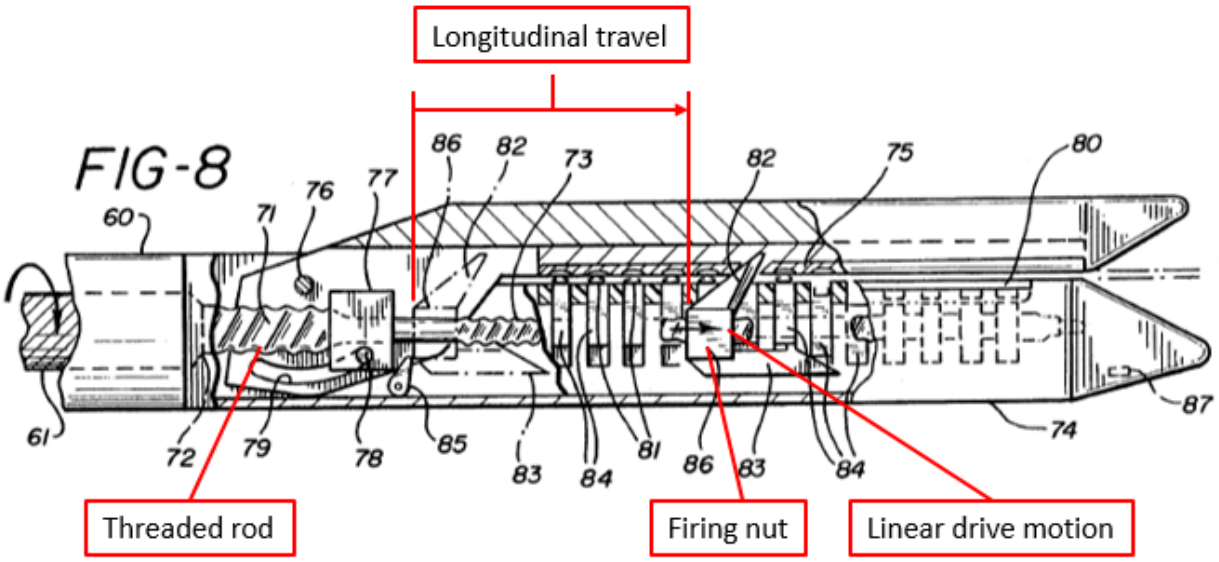


[5] The surgical cutting and fastening instrument of claim 1 further comprising a firing element configured for longitudinal travel through said end effector in response to an application of linear drive motions from said linear drive motion converter

Hooven discloses this limitation. IS1003, ¶¶78-80. Hooven discloses a firing element. For example, knife 82, which is coupled to, and propelled linearly and longitudinally by, firing nut 86. IS1003, ¶78; IS1004, FIG. 6. In both the '874 patent and in Hooven, the knife is connected to a drive screw by a threaded attachment to convert rotary motion to linear motion so that the knife moves linearly and distally when the drive screw is rotated. IS1003, ¶78; *compare* IS1001, FIG. 3 *with* IS1004, FIG. 6.

’874 patent, FIG. 3 “knife 32”	Hooven, FIG. 6 “firing nut 86 and knife 82”
	

The combination of these components is configured for longitudinal travel through the end effector (*i.e.*, head portion 42) in response to an application of linear drive motions (*i.e.*, distal and proximal motions) from the linear drive motion converter (*i.e.*, firing nut 86) to fire the stapler (*i.e.*, staple and cut tissue). IS1003, ¶80. “As depicted in [FIGs. 6-10], extending the length of the staple portion [74] of the instrument is the smaller diameter portion of the threaded rod [73]. Mounted on this rod, to move along the rod as the rod rotates, is a knife member 82 and a driving wedge member 83 which [is disposed on firing nut 86].” IS1004, 6:9-16; *see also* IS1004, 6:30-31. The distal and proximal motions of firing nut 86 are the linear drive motions. IS1004, 6:30-31; *compare* IS1004, FIG. 7 (depicting “the head of the instrument … in the closed position ready for firing”) *with* IS1004, FIG. 8 (depicting “the head of the instrument … during the firing action” and showing the axial travel of firing nut 86 and knife 82); IS1003, ¶80.



[6] The surgical cutting and fastening instrument of claim 5 wherein said firing element comprises a tissue cutting surface.

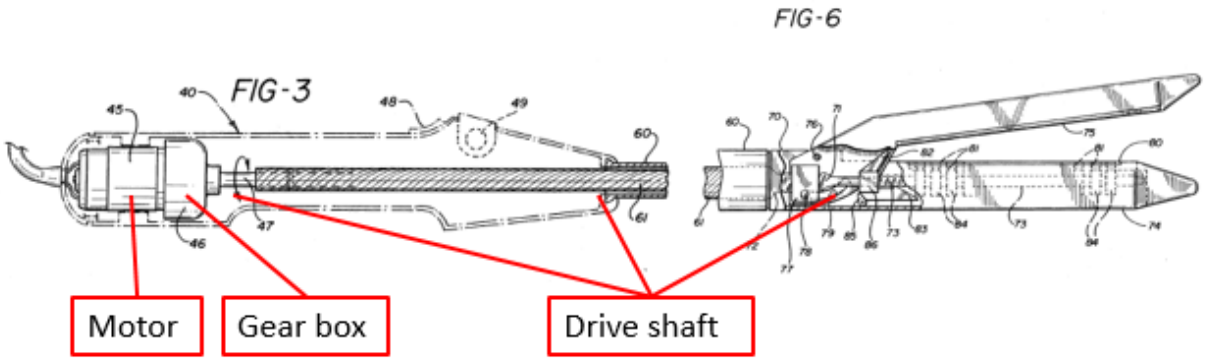
Hooven discloses this element. IS1003, ¶81. Hooven discloses "a knife member 82 [(*i.e.*, tissue cutting surface)] and a driving wedge member 83 [(*i.e.*, firing element)] which are inner-connected." IS1004, 6:13-15, FIG. 6.

[7.1] The surgical cutting and fastening instrument of claim 1 wherein said linear drive motion converter comprises:

See Ground 1, elements [1.1], [1.11].

[7.2] a rotary drive shaft operably interfacing with said motor

Hooven discloses this element. IS1003, ¶83. Hooven discloses "a rotatable drive shaft" comprising threaded rod 71, shaft 61, and shaft 47. IS1004, FIGs. 3, 6. This drive shaft operably interfaces with motor 45 via gear box 46. IS1004, FIGs. 3, 6.; IS1003, ¶83.



[7.3] a driver element in threaded engagement with said rotary drive shaft, said driver element supported for reciprocatable travel through said cartridge in response to rotation of said rotary drive shaft.

"Driver element"

See Ground 1, element [20.5].

"In threaded engagement with said rotary drive shaft"

See Ground 1, element [1.11] (showing threaded engagement of firing nut 86 with threaded rod 71).

[10] The surgical instrument of claim 9 wherein said closure element is configured to move said one of said first and second jaws to a closed position when said closure element is driven in a distal direction and to move said one of said first and second jaws to an open position when said closure element is driven in a proximal direction

See discussion at Ground 1, claim [3].

[11] The surgical instrument of claim 10 wherein said closure element is controlled through manual manipulation of a closure actuator interfacing with said closure element.

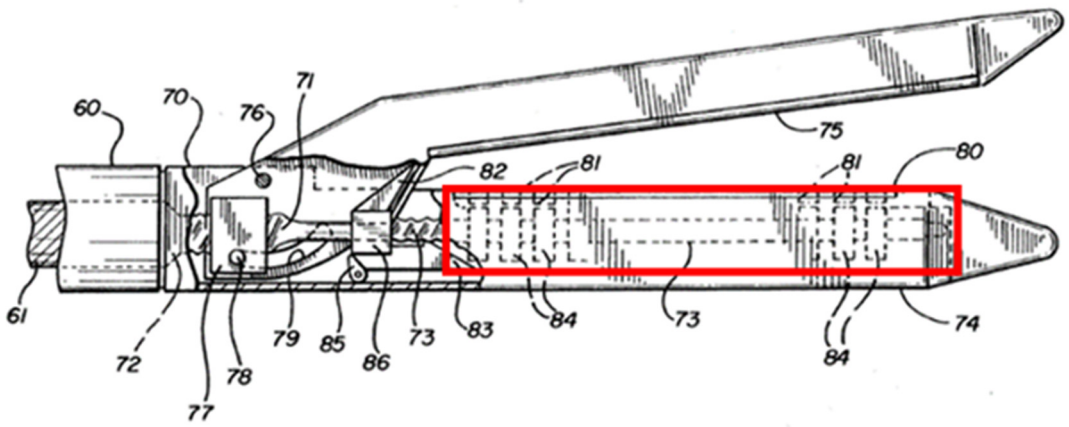
See discussion at Ground 1, claim [4].

[12] The surgical instrument of claim 10 wherein said other of said first and second jaws is configured to support a surgical staple cartridge.

Hooven discloses this limitation. IS1003, ¶88. "Mounted in the staple

holding portion [74] of the instrument is a removable staple cartridge 80." IS1004, 6:3-4, FIG. 6.

FIG-6



[13] The surgical instrument of claim 12 wherein said driver element comprises a tissue cutting surface.

Hooven discloses this limitation. IS1003, ¶89. *See* Ground 1, claim [6], element [20.5]. The knife 82 portion of Hooven's driver element (*i.e.*, firing nut 86 and knife 82) includes a tissue-cutting surface. IS1004, FIG. 6.

[14] The surgical instrument of claim 13 wherein said firing element comprises a rotary drive shaft in threaded engagement with said driver element.

Hooven discloses this limitation. IS1003, ¶90. *See* Ground 1, elements [7.1], [7.2], [20.6] (the smaller diameter portion 73 of threaded rod 71 is a rotary drive shaft in threaded engagement with firing nut 86 and knife 82, which are a driver element).

[16.1] A surgical cutting and fastening instrument comprising:

See discussion at Ground 1, element [1.1].

[16.2] an end effector comprising

See discussion at Ground 1, element [20.2].

[16.3] an anvil with staple forming features thereon

See discussion at Ground 1, element [1.3].

[16.4] a housing frame generally opposed to the anvil to hold a cartridge

See discussion at Ground 1, element [1.4].

[16.5] a replaceable cartridge holding staples that can be urged out the cartridge with a distal actuation of a deploying wedge

See discussion at Ground 1, element [1.5].

[16.6] at least one sensor

See discussion at Ground 1, element [1.6].

[16.7] an elongated shaft coupled to said housing frame, said elongated shaft comprising:

See discussion at Ground 1, element [1.7].

[16.8] a rotary drive shaft operably interfacing with said deploying wedge such that rotation of said rotary drive shaft in a first rotary direction causes said deploying wedge to move longitudinally in a distal direction and rotation of said rotary drive shaft in a second rotary direction causes said deploying wedge to move longitudinally in a proximal direction

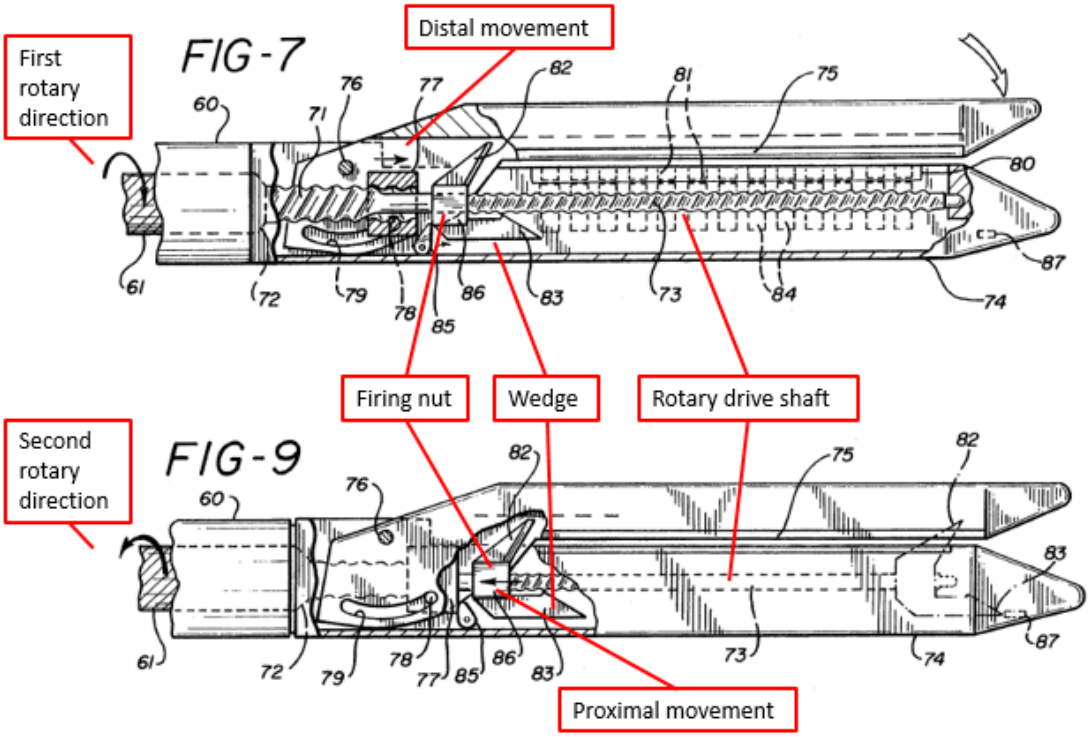
Hooven discloses this limitation. IS1003, ¶¶98-100.

"Rotary drive shaft"

See discussion at Ground 1, element [20.6] (the smaller diameter portion 73 of threaded rod 71 is a rotary drive shaft); IS1003, ¶99.

"Operably interfacing with said deploying wedge such that rotation of said rotary drive shaft in a first rotary direction causes said deploying wedge to move longitudinally in a distal direction and rotation of said rotary drive shaft in a second rotary direction causes said deploying wedge to move longitudinally in a proximal direction"

Hooven's rotary drive shaft (*i.e.*, shaft 47, shaft 61, and threaded rod 71) operably interfaces with Hooven's deploying wedge (*i.e.*, driving wedge member 83) via firing nut 86. IS1003, ¶100. The wedge moves distally and proximally based on the direction of rotation of the rotary drive shaft: "[F]iring nut 86 on which the [] wedges 83 are disposed [] engages the threads of the smaller diameter portion 73 of the threaded rod [71] to move forward along the rod and drive the staples 81…." IS1004, 6:28-34, FIG. 7. "Once the firing nut has moved to its most forward position to drive and form all of the staples and cut the tissue, it engages a suitable contact 87 which immediately reverses the motor to retract the firing nut." IS1004, 6:36-40, FIG. 9.



[16.9] a reciprocatable closure element, and wherein said surgical cutting and fastening instrument further comprises:

See discussion at Ground 1, element [9.9].

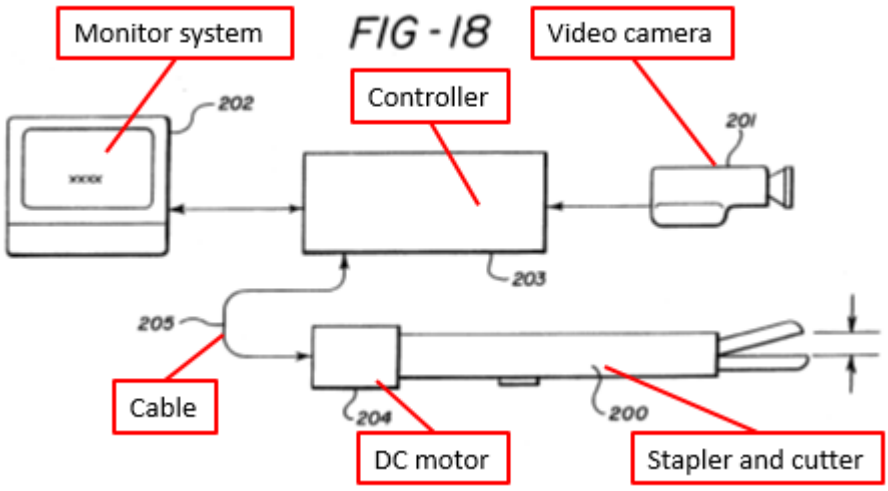
[16.10] a motor operably coupled to said rotary drive shaft

See discussion at Ground 1, element [1.8].

[16.11] a remote user-controllable actuation console electrically coupled to said motor.

Hooven discloses this limitation. IS1003, ¶¶103-04. *See* discussion at Ground 1, element [1.10]. In Hooven, the actuation console ("controller 203" alone or the combination of "controller 203" and "video display monitor 202") is electrically coupled to the motor so that the motor can send information to the controller and so the controller can send drive signals to the motor via the cable

connecting the controller to the instrument. In FIG. 18, the controller is shown as item 203 and the cable as item 205.



For example, the controller contains "motor drive circuits." IS1004, 4:13-20. In addition, "[a]ll sensors, switches, and motors are connected to the controller via the interface cable 205…. [Processed] information may also be fed back to the instrument controller to control some or all of the instrument functions." IS1004, 9:1-17; *see also* IS1004, 5:1-7.

[17] The surgical instrument of claim 16 wherein said deploying wedge comprises a tissue cutting surface.

Hooven discloses this limitation. IS1003, ¶105. The combination of Hooven's "knife member 82" and "driving wedge member 83" together form a "deploying wedge comprising a tissue cutting surface." *Id.*; IS1004, FIG. 6. *See* Ground 1, claim [6], element [20.5] (the knife 82 portion of Hooven's driver element (*i.e.*, firing nut 86 and knife 82) includes a tissue cutting surface).

[19.1] A surgical instrument system, comprising:

See Ground 1, element [20.1].

[19.2] an end effector, comprising:

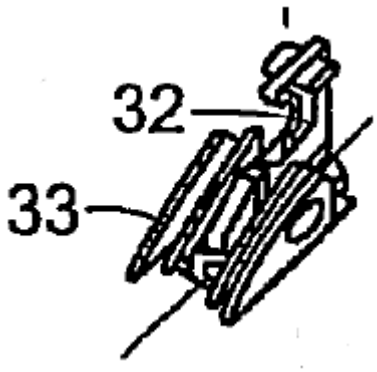
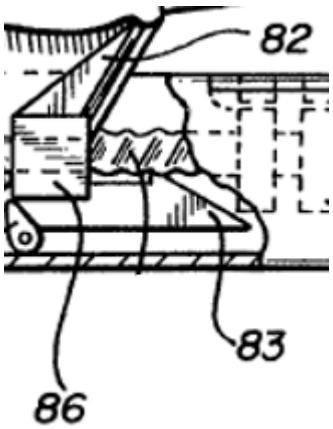
See Ground 1, element [20.2].

[19.3] an anvil

See Ground 1, element [1.3].

[19.4] a cartridge including staples that can be ejected out of said cartridge with a distal actuation of a firing member

Hooven discloses this limitation. IS1003, ¶¶109-10. Hooven discloses a "firing member" that moves distally and ejects staples from a cartridge, namely, the combination of firing nut 86 and knife 82, which propels wedge member 83. IS1004, 6:12-20, FIG. 6. This combination of components is substantially similar to the '874 patent's knife and wedge combination. IS1003, ¶109; *compare* IS1001, FIG. 3 *with* IS1004, FIG. 6.

'874 patent, FIG. 3 "knife 32"	Hooven, FIG. 6 "wedge member 83"
	

[19.5] at least one sensor

See Ground 1, element [1.6].

[19.6] an assembly comprising an elongate shaft including a longitudinal axis

See Ground 1, element [1.7].

[19.7] a motor

See Ground 1, element [1.8].

[19.8] an articulation joint for positioning said cartridge at an angle to said longitudinal axis of said elongate shaft

See Ground 1, element [1.9].

[19.9] a remote user-controllable actuation console electrically coupled to said motor

See Ground 1, element [1.10].

[19.10] a motion converter configured to convert a rotary drive motion produced by said motor to a linear drive motion

See Ground 1, element [1.11]. The linear motion discussed for element [1.11] is a linear drive motion. The knife and wedge are each driven through the end effector during staple firing as a result of the motion converter. IS1003, ¶116.

[21.1] A surgical instrument system, comprising:

See Ground 1, element [20.1].

[21.2] a firing member

See Ground 1, element [19.4].

[21.3] an end effector, comprising:

See Ground 1, element [20.2].

[21.4] an anvil

See Ground 1, element [1.3].

[21.5] a cartridge comprising staples that can be urged out of said staple cartridge by said firing member

See Ground 1, elements [1.5], [19.4], and [21.2]. Hooven's staples can be urged out of the staple cartridge by the combination of Hooven's drive nut 86, knife 82, and wedges 83 (*i.e.*, said firing member). IS1003, ¶121.

[21.6] at least one sensor

See Ground 1, element [1.6].

[21.7] an elongate shaft, comprising:

See Ground 1, element [1.7].

[21.8] a drive shaft operably interfacing with said firing member such that rotation of said drive shaft in a first rotary direction causes said firing member to move longitudinally in a distal direction and rotation of said drive shaft in a second rotary direction causes said firing member to move longitudinally in a proximal direction

See Ground 1, element [16.8].

[21.9] a closure member configured to close said end effector

See Ground 1, element [9.9].

[21.10] a motor operably coupled to said drive shaft

See Ground 1, element [1.8].

[21.11] a remote user-controlled actuation console electrically coupled to said motor.

See Ground 1, element [1.10].

B. Ground 2: Claims 15 and 18, and, If Necessary, Claims 2-4, 9-14, 16-17, and 21, Would Have Been Obvious Under § 103 over Hooven in View of Knodel

Claims 15 and 18

[15] The surgical instrument of claim 10 wherein said closure element comprises a hollow tubular shaft configured to interface with said one of said first and second jaws.

It would have been obvious in view of Knodel to modify Hooven's closure nut 77 and closure pin 78 with a hollow tubular shaft (*i.e.*, a closure tube) configured to interface with one of the first and second jaws. IS1003, ¶128. Knodel discloses a reciprocatable closure tube. *Id.* Specifically, Knodel discloses a "surgical clamping mechanism." IS1005, Title. The mechanism is for use in a surgical instrument, such as that disclosed by Hooven, which has an "elongated shaft" and "an end effector with first and second jaws." IS1005, Abstract.

When discussing prior art, Knodel states:

> A key feature of the clamping and grasping mechanisms of endoscopic surgical instruments is the mechanism which causes the upper or lower jaw to move from an open position for placing tissue between the jaws to a closed position for clamping that tissue. ***A common mechanism, particularly for endoscopic linear cutters, involves the use of a "camming" closure tube. This tube reciprocates back and forth***. In its rearward position, the jaws are in the open position. In its forward most position, the upper jaw has pivoted to its closed position so that the anvil and cartridge are adjacent each other.

IS1005, 2:13-23 (emphasis added).

Knodel also identifies deficiencies with prior art "camming" closure tube and discloses an improved reciprocating closure tube. IS1005, 2:13-2, FIGs. 4, 5. Figures 4 and 5 of Knodel, for example, depict the improved closure tube in both the open state (FIG. 4) and closed state (FIG. 5).

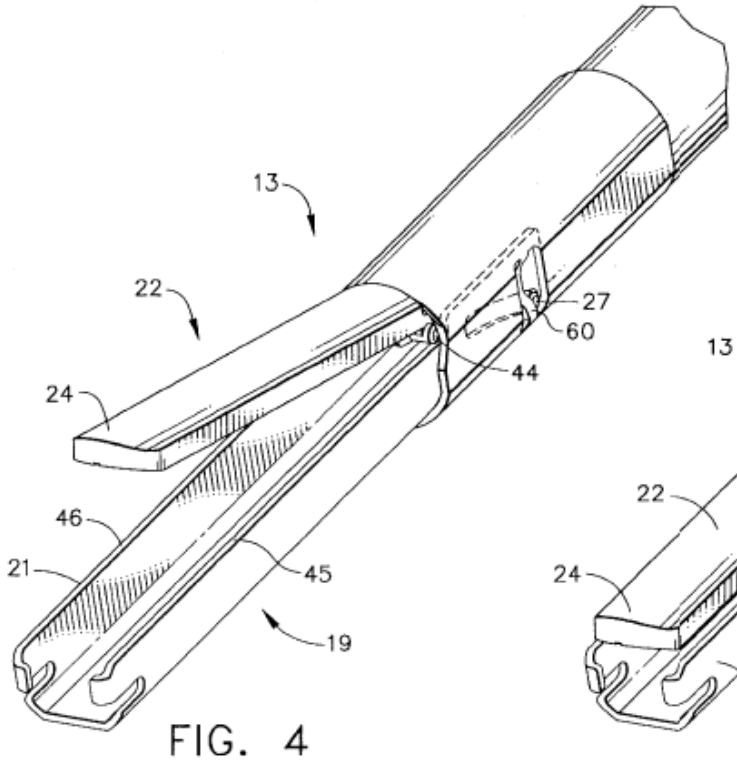


FIG. 4

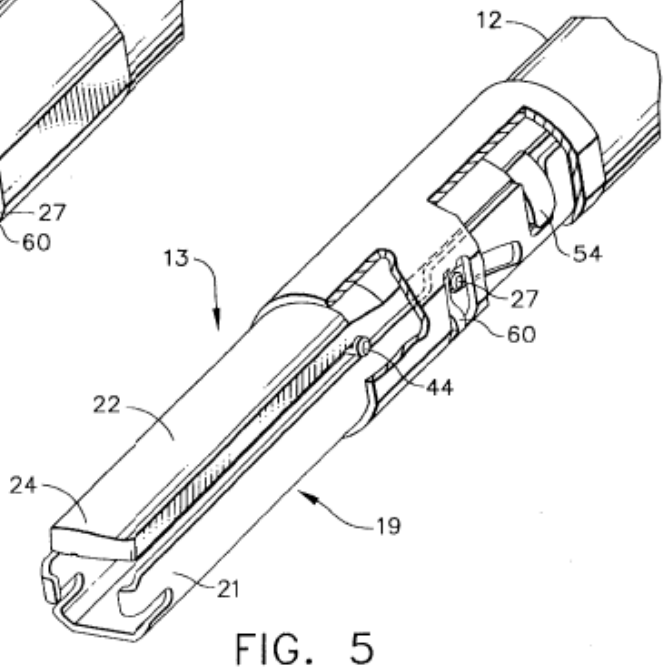


FIG. 5

In FIG. 2, "the cylindrical tube [] in this particularly preferred embodiment acts as the pusher member for moving the anvil relative to the channel from its open to closed positions." IS1005, 7:11-14, FIG. 2 (exploded view). The closure tube "has an anvil thrust surface 49 in contact with the closure tube bearing surface 47 of the anvil." IS1005, 7:54-56.

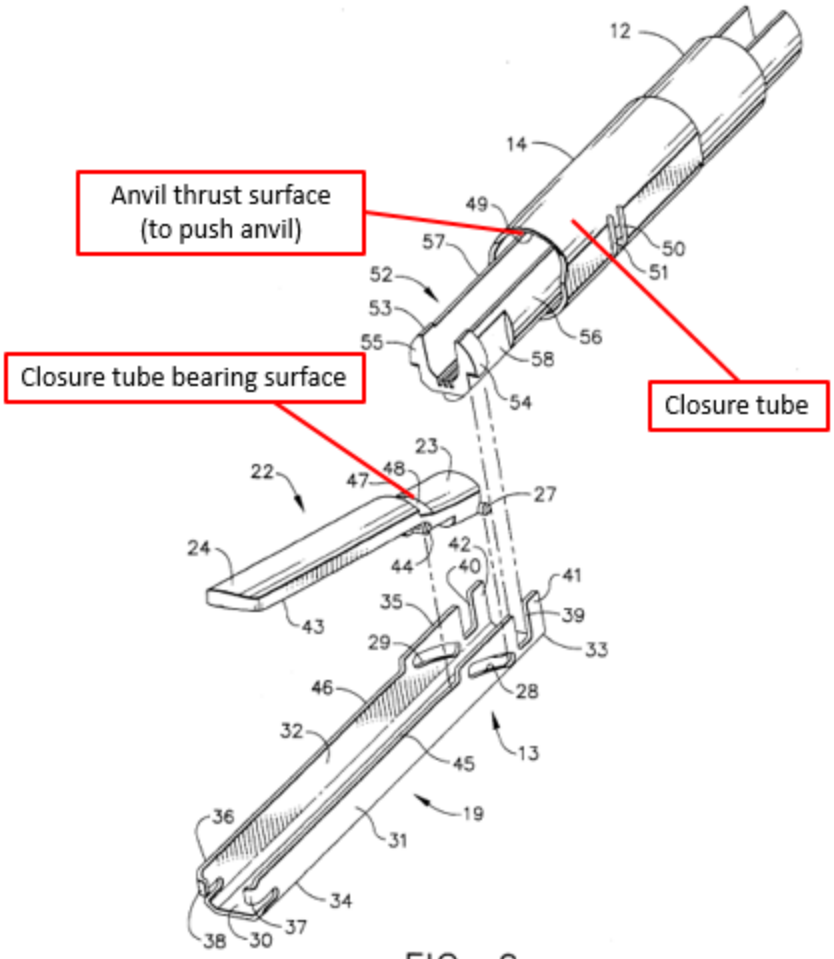


FIG. 2

A POSITA would have had reason to modify the closure nut 88 and closure pin 78 of Hooven to add the closure tube of Knodel. IS1003, ¶131. ***First***, as taught by Knodel, the closure tube offers an advantage of both closing and clamping, by pushing down on the outside of the anvil. *Id.* Based on the treachings of Knodel, a POSITA would have understood that it may be desirable to use such a tube in the Hooven device to enhance closing and clamping. *Id.* ***Second***, Knodel teaches numerous benefits of the disclosed closure tube, which would have given a POSITA reason to use such a tube when designing a surgical

instrument (the benefits including greater ease in clamping tissue and ability to use the entire surface of anvil for clamping). IS1005, Abstract.

Moreover, "[w]hen[, as here,] there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). As explained above, Hooven describes one predictable solution for closing the anvil of a surgical stapler (*i.e.*, a camming pin with a drive nut). Ground 1, element [9.9], *supra*. Like Hooven, Knodel describes a "surgical instrument [that] provides an attractive alternative to the conventional prior art mechanisms." IS1005, Abstract. Knodel also teaches both conventional closure tubes and an improved closure tube. IS1005, Abstract, 1:4-6:5. Thus, using a closure tube would have been an obvious design choice, well-known to a POSITA. IS1003, ¶132.

Finally, such a modification of Hooven's surgical instrument would have been well within a POSITA's abilities for several reasons. IS1003, ¶133. ***First***, it would have been merely the application of a known technique (*e.g.*, adding a closure tube) to a known system (*e.g.*, Hooven's surgical stapler) in the same field of endeavor (*i.e.*, surgical staplers). *Id.*; *KSR*, 550 U.S. at 417. ***Second***, in combination, each element (*i.e.*, Knodel's closure tube and Hooven's stapler) merely performs the same function as it does separately. IS1003, ¶133. And ***third***,

the combination of Hooven and Knodel proposed here would yield predictable results without significantly altering or hindering the functions performed by Hooven's device. *Id.*

Knodel's reciprocating closure tube, when combined with Hooven's surgical instrument as described above, meets this limitation. IS1003, ¶135. The closure tube is a hollow tubular shaft that pushes against the anvil, which is one of the first and second jaws. *Id.*

[16.1] A surgical cutting and fastening instrument comprising:

For claim 18, which depends from claim 16, we use Knodel as the primary reference and modify Knodel with the teachings of Hooven concerning the inner workings of the stapler and the use of a remote user-controllable actuation console. Accordingly, an analysis of claim 16 compared to the device resulting from this combination of Knodel and Hooven is provided.

With respect to the preamble, Knodel discloses a surgical cutting and fastening instrument. *See* IS1005, 6:10-43 (disclosing "endoscopic linear cutter 10"), 6:62-65, FIG. 1; IS1003, ¶137.

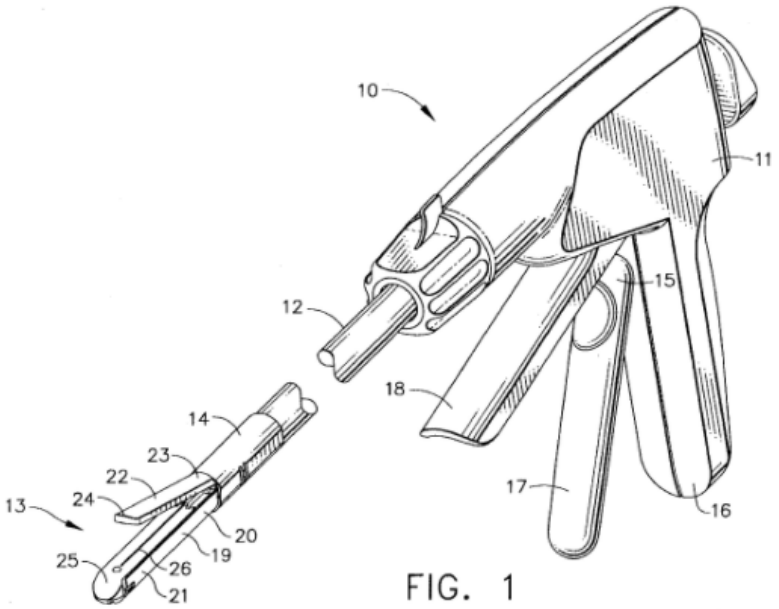


FIG. 1

[16.2] an end effector comprising

Knodel discloses this limitation. Knodel's surgical instrument includes "end effector 13." IS1005, 6:42-46, FIG. 1; IS1003, ¶138.

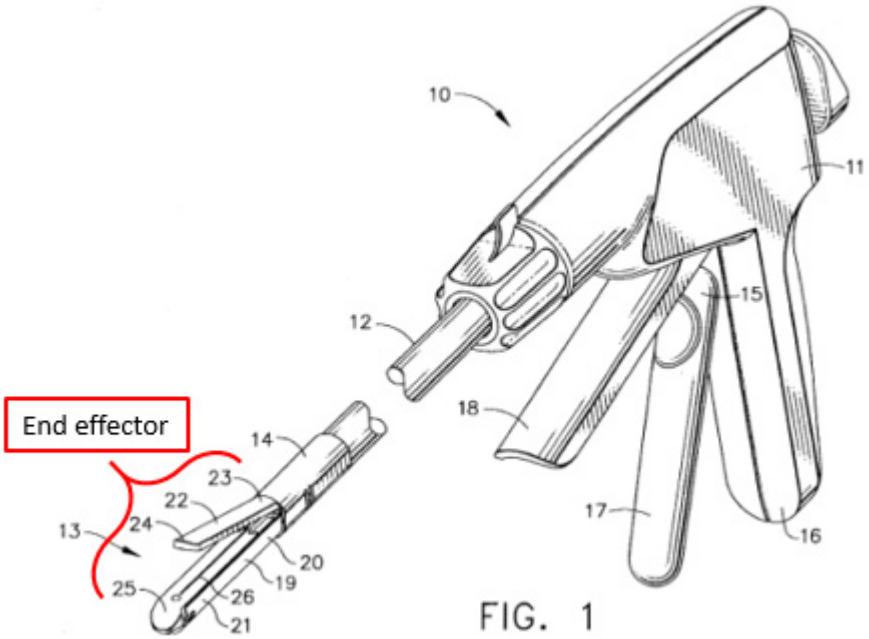


FIG. 1

[16.3] an anvil with staple forming features thereon

Knodel discloses this limitation. Knodel discloses "an anvil [22] against which the staples are formed." IS1005, 6:50-59, FIG. 1; IS1003, ¶139.

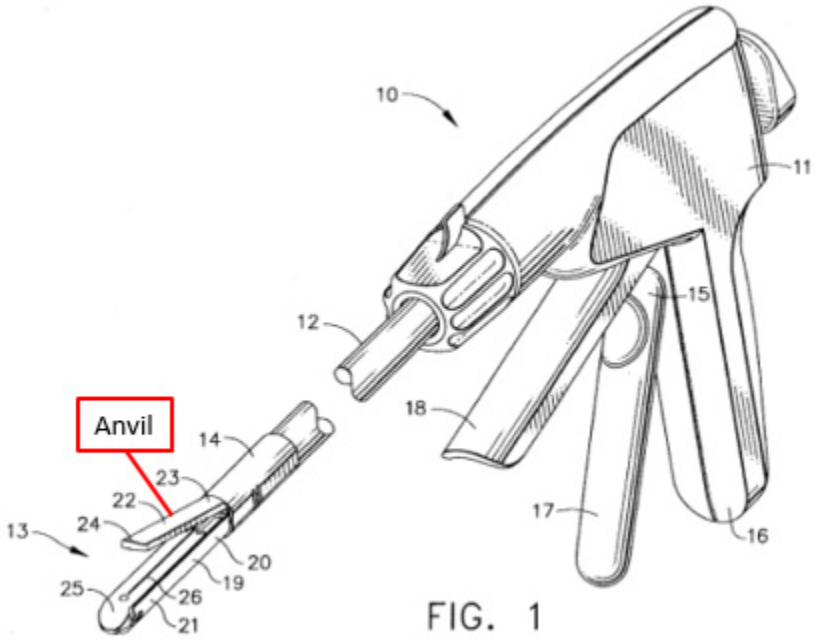


FIG. 1

[16.4] a housing frame generally opposed to the anvil to hold a cartridge

Knodel discloses this limitation. Knodel's "end effector [13] includes a first jaw … [that] is shaped in the form of an elongated channel [19] for receiving [(*i.e.*, holding)] a staple cartridge 25." IS1005, 6:50-55, FIG. 1. A POSITA would have understood that elongated channel 19 is a housing that houses staple cartridge 25. IS1003, ¶140. As shown in Figure 1 of Knodel, the first jaw 13 (*i.e.*, a housing) is generally opposed to the second jaw 22 (*i.e.*, the anvil). IS1005, FIG. 1.

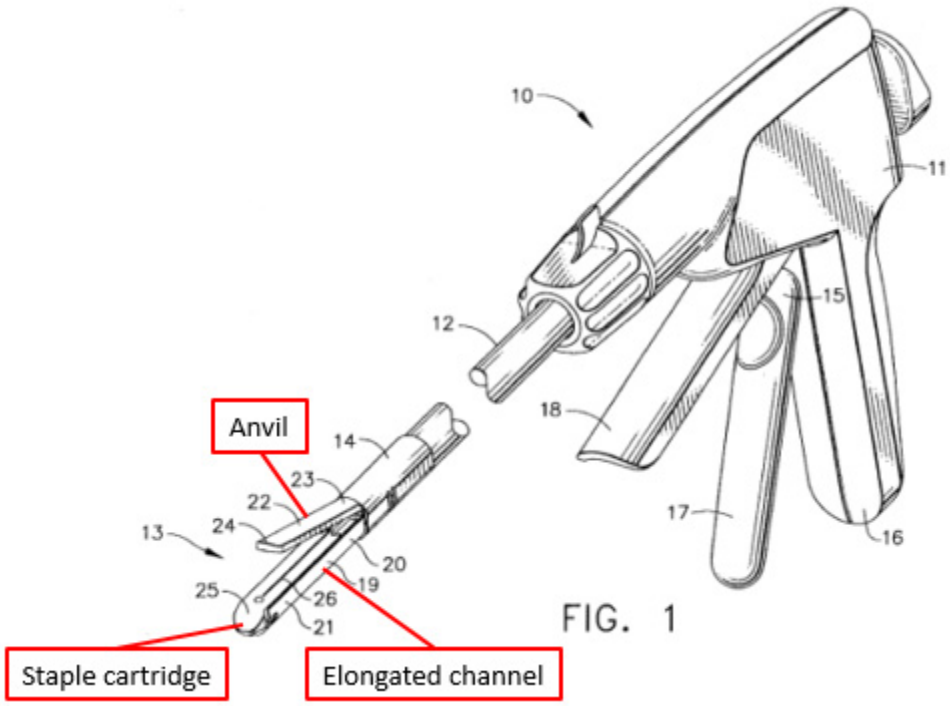


FIG. 1

[16.5] a replaceable cartridge holding staples that can be urged out the cartridge with a distal actuation of a deploying wedge

Knodel does not disclose the detail of the deploying wedge, but where Knodel is the primary reference, it would have been obvious to use Hooven's deploying wedge to fire the stapler of Knodel. IS1003, ¶141. As shown above in Ground 2, element [16.4], Knodel discloses a replaceable staple cartridge 25 with staples that may be fired "from the cartridge and through the tissue for formation of the staples against the anvil." IS1005, 6:62-65; *see also* IS1005, 5:47-50 (referring to "the user's ability to remove a spent cartridge from the channel and reload it with a new one"). Rather than describe the details of the firing mechanism, including the wedge, Knodel states that "[e]ndoscopic linear cutters [were] well known, and [that] the details of particular … firing mechanisms are

described in numerous patents." IS1005, 7:1-3. Hooven is such a patent. IS1003, ¶141. Accordingly, a POSITA would have turned to Hooven, based on Knodel's express suggestion to identify such references and to use their teachings concerning the details on the firing mechanism of a surgical stapler. *Id.*

[16.6] at least one sensor

Knodel does not disclose a sensor, but where Knodel is the primary reference, it would have been obvious in view of Hooven to modify Knodel's end effector to include at least one sensor. IS1003, ¶142. One reason to add Hooven's sensors to Knodel's surgical stapler is to capture of data for use by a remote user-controllable actuation console electrically coupled to a motor, as disclosed in Hooven. *Id.* Specifically, "the amount of torque required to pivot the anvil portion about the pivot pin can be sensed and the thickness of tissue between the anvil and the staple portion determined. [Then,] [i]t is a simple matter for a controller to manipulate this information and inform the surgeon as to whether or not he has the appropriate amount of tissue between the anvil portion and the staple portion of the head of the instrument upon closure or whether he has too much or too little tissue and should re-manipulate the instrument." IS1004, 5:55-65.

Another reason to add at least one sensor and a remote user-controllable actuation console electrically coupled to a motor is to provide a mechanism for maintaining the motor a constant speed. IS1003, ¶143. As explained in Hooven,

"[f]or a constant voltage drive, the force required to close the instrument may be measured by monitoring the motor current. The power delivered to the instrument may be controlled by varying motor voltage and/or current to achieve a constant motor speed with varying load." IS1004, 5:65-6:2.

Furthermore, when equipped with at least one sensor and a remote user-controllable actuation console electrically coupled to a motor, "the surgeon may be informed as to the position of the instrument in the procedure, the operation of the instrument; *i.e.*, whether it is in a position to be activated and activated correctly[,] and the like." IS1004, 2:40-48; IS1003, ¶144. The sensor(s) and a remote user-controllable actuation console electrically coupled to a motor also "provides sensing feedback to the surgeon to compensate for the loss of tactile feedback [and to] provide [the surgeon] with considerable knowledge regarding the instrument." IS1004, 2:40-48; *see also* IS1004, 8:14-49 ("the head of the instrument [] includes a sensing member used to sense the blood oxygen content of adjacent tissue…."), FIG. 17.

[16.7] an elongated shaft coupled to said housing frame, said elongated shaft comprising:

Knodel discloses this limitation. IS1003, ¶145. Knodel discloses "elongated shaft 12 … and an end effector 13 attached [(*i.e.*, coupled)] to the distal end of the shaft." IS1005, 6:42-46, FIG. 1. As explained above, end effector 13 includes an elongated channel 19 (*i.e.*, said housing frame). *See* Ground 2, element

[16.4].

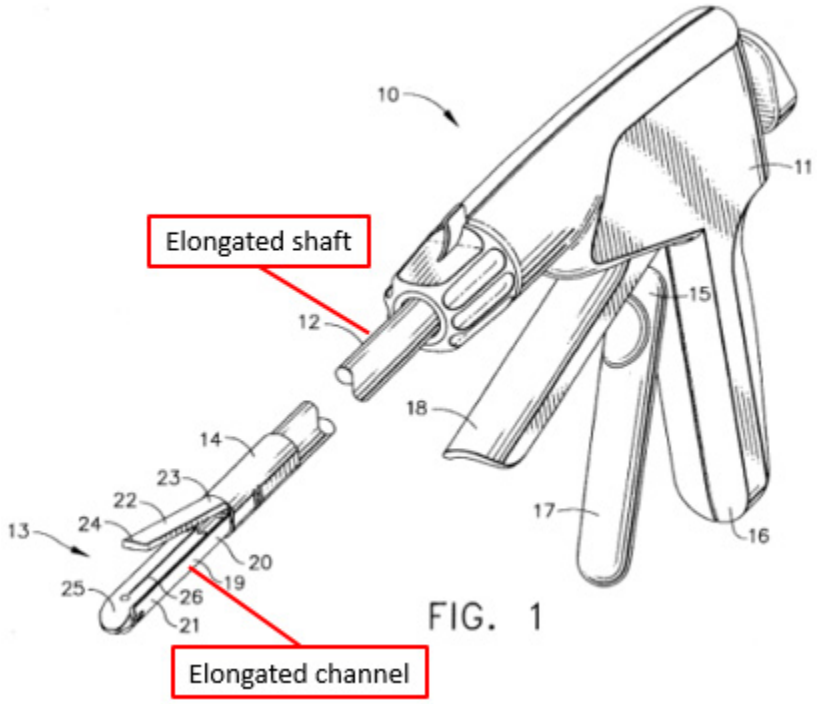


FIG. 1

[16.8] a rotary drive shaft operably interfacing with said deploying wedge such that rotation of said rotary drive shaft in a first rotary direction causes said deploying wedge to move longitudinally in a distal direction and rotation of said rotary drive shaft in a second rotary direction causes said deploying wedge to move longitudinally in a proximal direction

Knodel does not disclose this limitation, but where Knodel is the primary reference, it would have been obvious in view of Hooven to use a rotary drive shaft and deploying wedge in Knodel's stapler. IS1003, ¶146. Knodel points to other stapler patents, such as Hooven, for details of the firing mechanism: "[e]ndoscopic linear cutters [were] well known, and [that] the details of particular … firing mechanisms are described in numerous patents." IS1005, 7:1-3. Accordingly, a POSITA would have turned to a patent such as Hooven, based on the teachings of

Knodel, for details on the firing mechanism of a surgical stapler. IS1003, ¶146. *See* Ground 1, elements [1.5], [7.2], and [7.3].

[16.9] a reciprocatable closure element, and wherein said surgical cutting and fastening instrument further comprises:

Knodel discloses this limitation. IS1003, ¶147. Knodel's closure tube moves distally to close the anvil and proximally to open the anvil. *Id.*; *see* Ground 2, claim [15].

[16.10] a motor operably coupled to said rotary drive shaft

Knodel does not disclose this limitation, but where Knodel is the primary reference, it would have been obvious in view of Hooven to use Hooven's motor and its coupled rotary drive shaft and deploying wedge in the Knodel stapler. IS1003, ¶148. Knodel points to other stapler patents, such as Hooven, for details of the firing mechanism: "[e]ndoscopic linear cutters [were] well known, and [that] the details of particular … firing mechanisms are described in numerous patents." IS1005, 7:1-3. Hooven's motor, rotary drive shaft, and deploying wedge is one such drive mechanism that a POSITA would have used when implementing the stapler in Knodel. IS1003, ¶148. *See* Ground 1, element [1.8].

[16.11] a remote user-controllable actuation console electrically coupled to said motor.

Knodel does not disclose this limitation, but where Knodel is the primary reference, it would have been obvious in view of Hooven to add a remote user-controllable actuation console electrically coupled to the motor in the surgical

stapler resulting from a combination of Hooven and Knodel for the reasons explained above. *See* Ground 2, element [16.6]. For example, Hooven teaches that the remote user-controllable actuation console would be electrically coupled to the motor to gather data on the motor's operation and to control the motor. IS1003, ¶149.

[18] The surgical instrument of claim 16 wherein said reciprocatable closure member comprises a tubular structure that is substantially coextensive with said rotary drive shaft and longitudinally movable relative thereto.

Where Knodel is the primary reference, the combination of Knodel and Hooven disclose this limitation. IS1003, ¶150. *See* Ground 2, element [16.9]. In Knodel, the closure tube 12 runs the length of the shaft. IS1005, FIG. 1; *see also* IS1005, 6:42-46 ("The cutter [10] has … an elongated shaft [(i.e., closure tube)] 12 in the form of a cylindrical tube extending from the frame [for gripping the instrument 11], and an end effector 13 attached to the distal end 14 of the shaft [12]."). Thus, when the rotary drive shaft of Hooven is added to the surgical stapler of Knodel as described in claim 16, Knodel's closure tube would run the length of the drive shaft and therefore be substantially coextensive with the drive shaft. IS1003, ¶150.

Claims 2-4, 9-14, 16-17, and 21

Claims 2-4, 9-14, 16-17, and 21 recite a "closure element" or "closure member." As stated above, Hooven discloses these elements. Alternatively, if

these terms are construed to be limited to a closure tube, such as distal closure tube 42, then it would have been obvious to modify Hooven's closure nut 77 and closure pin 78 with the closure tube of Knodel for the reasons explained above. *See* Ground 2, claim [15]. And, as explained below, the "closure element/member" limitations of these claims would be met by Knodel's closure tube.

[2] The surgical cutting and fastening instrument of claim 1 wherein said elongated shaft further comprises a closure element configured to reciprocate relative to said end effector in response to closing and opening motions applied thereto.

Knodel's closure tube (closure element), when added to Hooven's surgical instrument as described above, is configured to reciprocate (*i.e.*, move back and forth) relative to Hooven's end effector in response to closing and opening motions applied thereto. IS1003, ¶152; Ground 2, claim [15].

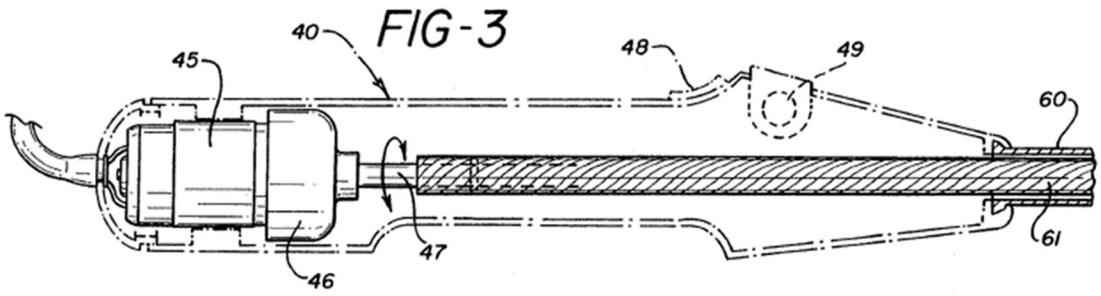
[3] The surgical cutting and fastening instrument of claim 2 wherein said closure element is configured to move said anvil to a closed position when said closure element is driven in a distal direction and to move said anvil to an open position when said closure element is driven in a proximal direction.

Knodel's reciprocating closure tube (*i.e.*, said closure element), when combined with Hooven's surgical instrument as described above, meets this limitation. IS1003, ¶153. In the Hooven/Knodel combination, Hooven's closure nut would move the reciprocating closure tube of Knodel back and forth to open and close the anvil. *Id.* Thus, Knodel's closure tube would be configured to move

Hooven's anvil (*i.e.*, said one of said first and second jaws) to a closed position when it is driven in a distal direction. *Id.* It would also be configured to move Hooven's anvil to an open position when it is driven in a proximal direction. *Id.*

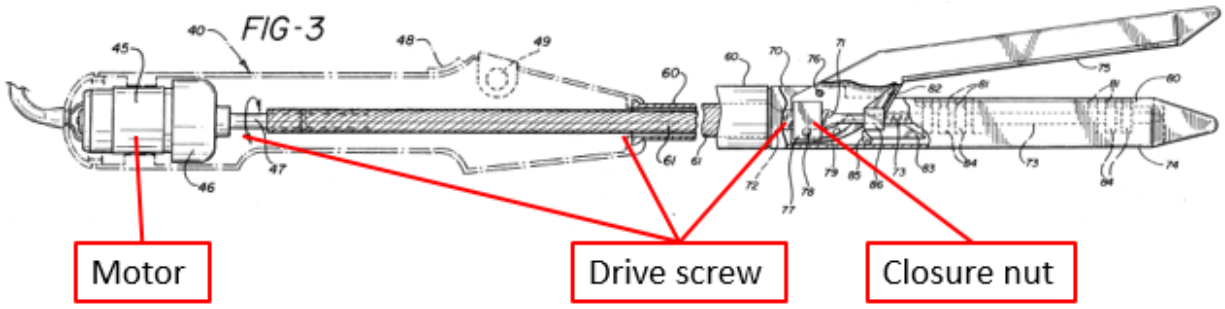
[4] The surgical cutting and fastening instrument of claim 2 wherein said closing and opening motions are applied to said closure element by manual manipulation of a closure actuator interfacing with said closure element.

The combination of Hooven and Knodel discloses this limitation. IS1003, ¶154. Hooven discloses "a suitable on-off switch 48 and a switch 49 [(*i.e.*, closure actuators)] to control the power supply being provided by the motor" to close the anvil 75. IS1004, 4:60-63, FIG. 3.



A POSITA would have understood that on-off switch 48 and switch 49 can be manipulated manually. IS1003, ¶155. A POSITA would also have understood that these switches turn on and control the motor that drives the drive screw ("threaded rod 71"), which drives the closure element ("closure nut 77"). *Id.*; IS1004, FIGs. 3, 6.

FIG-6



As explained above, in the Hooven/Knodel combination, the drive nut of Hooven would move the reciprocating closure tube of Knodel back and forth to open and close the anvil. IS1003, ¶156.

[9] … a reciprocatable closure element configured to apply said opening and closing motions to said one of said first and second jaws.

Knodel's closure tube (*i.e.*, closure element), when added to Hooven's surgical instrument as described above, is reciprocatable (*i.e.*, it can move back and forth) and is configured to apply the opening and closing motions to one of the first and second jaws. IS1003, ¶157; *see* Ground 2, claim [15].

[10] The surgical instrument of claim 9 wherein said closure element is configured to move said one of said first and second jaws to a closed position when said closure element is driven in a distal direction and to move said one of said first and second jaws to an open position when said closure element is driven in a proximal direction

See Ground 1, claim [3].

[11] The surgical instrument of claim 10 wherein said closure element is controlled through manual manipulation of a closure actuator interfacing with said closure element.

See Ground 1, claim [4].

[16] … a reciprocatable closure element …

See Ground 2, element [9.9], claim [15].

[21] … a closure member configured to close said end effector …

See Ground 2, claims [3], [15].

C. Ground 3: Claim 8 Would Have Been Obvious Under § 103 over Hooven in View of Bays

[8] The surgical cutting and fastening instrument of claim 1 wherein said motor is battery powered.

As discussed above, Hooven anticipates claim 1 (from which claim 8 depends). *See* Ground 1, claim [1]. Claim 8 adds a requirement that the motor be battery powered. Hooven does not disclose batteries, but it would have been obvious to a POSITA in view of Bays to make the Hooven's motor battery powered. IS1003, ¶162.

For example, Bays teaches a battery-powered surgical instrument that may be supplemented by DC power from a remote power booster:

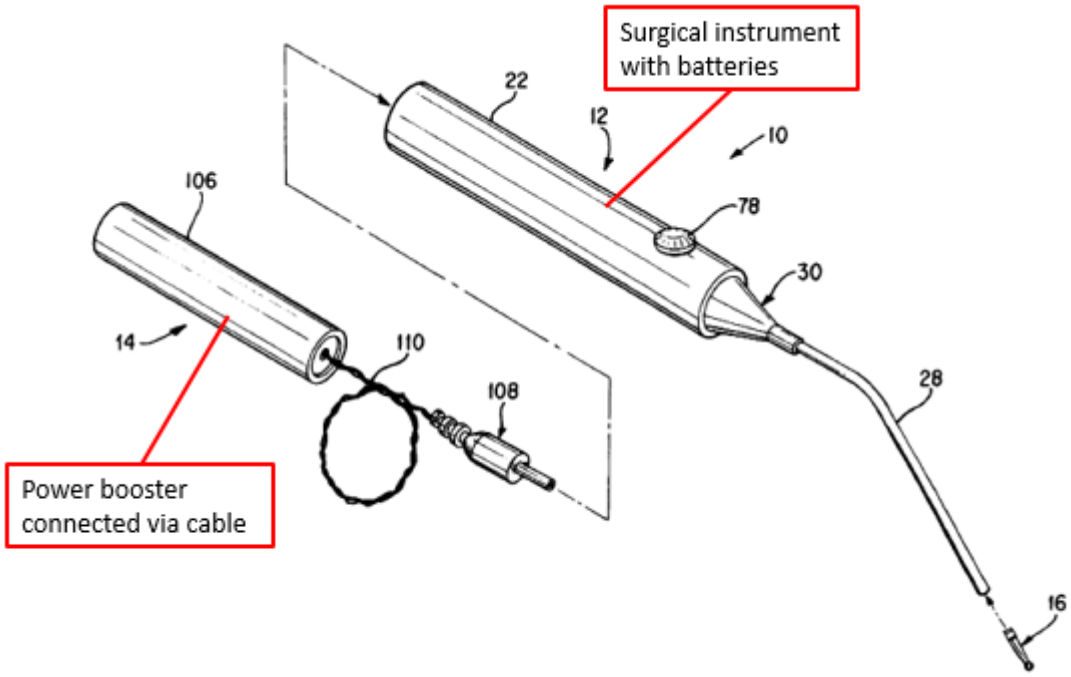


FIG. 1

IS1006, FIG. 1.

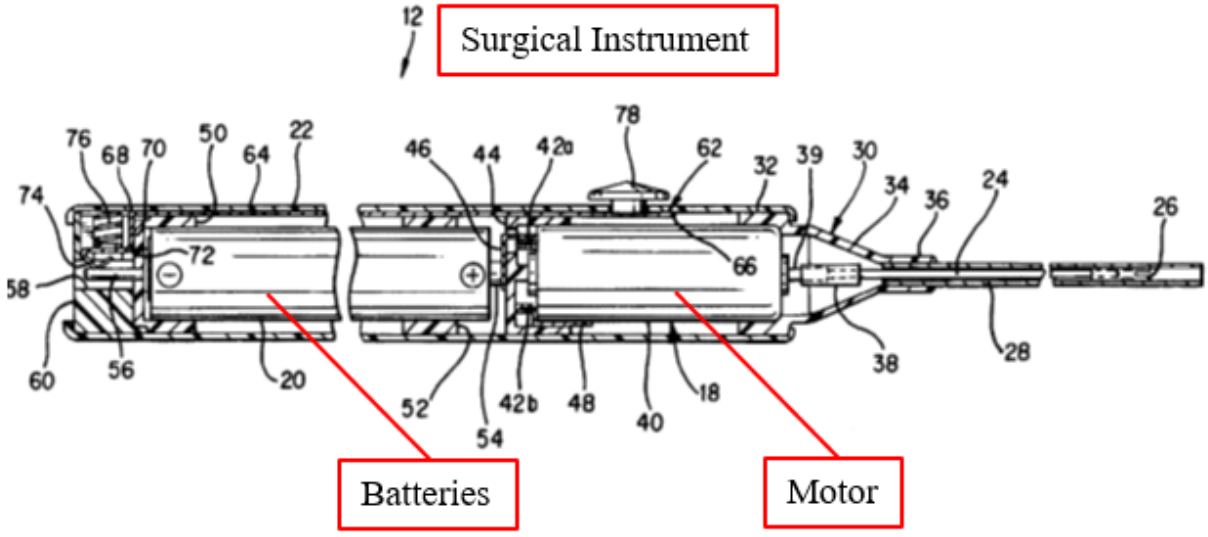


FIG. 2

IS1006, FIG. 2; *see also* IS1006, 7:57-60 (booster may be "remote from the surgical site.").

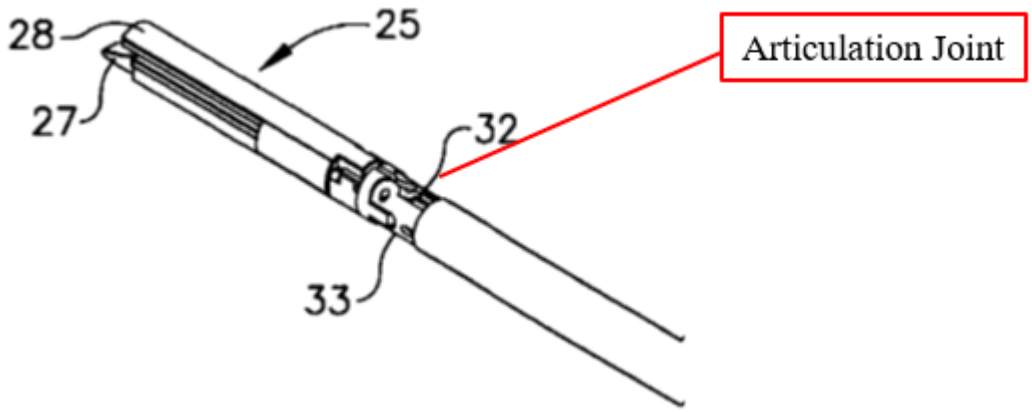
A POSITA would have been motivated to apply the teachings of Bays to Hooven and add to Hooven's surgical instrument batteries supplemented by booster power from Hooven's controller 31 (part of the "remote user-controllable actuation console"). Bays specifically teaches that "[w]hen using electrically operated medical instruments … there is frequently a need to modify the operating characteristic of the instrument such as speed, torque or power and/or to operate the instrument when a primary power source fails." IS1006, 1:12-17. Bays teaches a POSITA to "connect[] an external power source with a battery disposed in the handpiece to increase the voltage applied to the electrical device." IS1006, 1:42-46. Bays teaches that the battery provides advantages, such as allowing "the handpiece of the medical instrument [to] be powered by an internal battery and used alone … or with a booster attached" and that such a system "is useful for back-up power in the event the battery in the handpiece becomes partially or fully discharged." IS1006, 1:55-62.

Such a modification of Hooven's surgical instrument would have been well within a POSITA's abilities for several reasons. IS1003, ¶165; *see also* IS1006, 2:67-3:3 ("It will be appreciated [] that the medical instrument of the present invention can be embodied in any type of hand-held apparatus powered by a battery…."). ***First***, it would have been merely the application of a known technique (*e.g.*, using batteries to power a motor) to a known system (*e.g.*,

Hooven's surgical stapler) in the same field of endeavor (*i.e.*, powered surgical instruments). IS1003, ¶165; *KSR*, 550 U.S. at 417. ***Second***, in combination, each element (*i.e.*, Bays' batteries and Hooven's motor) merely performs the same function as it does separately, namely, supplying power to the instrument. IS1003, ¶165. And ***third***, the combination of Hooven and Bays proposed here would have yielded predictable results without significantly altering or hindering the functions performed by Hooven's device. IS1003, ¶165.

D. Ground 4: Claims 1-8 and 19 Would Have Been Obvious Under § 103 over Hooven in View of Knodel or Bays and Further in View of Wales

As discussed above, each of claims 1-8 and 19 of the '874 patent were either anticipated by Hooven or obvious over Hooven in view of Knodel and/or Bays. If Hooven is deemed not to disclose the "articulation joint for positioning the cartridge at an angle not parallel to [the] longitudinal axis of [the] shaft" recited in claims 1 and 19, it would have been obvious in view of Wales to modify Hooven's shaft 41 to replace Hooven's flexible articulation shaft with Wales's particular "articulation joint." IS1003, ¶166; IS1007, FIG. 1:



See also IS1007, FIG. 4:

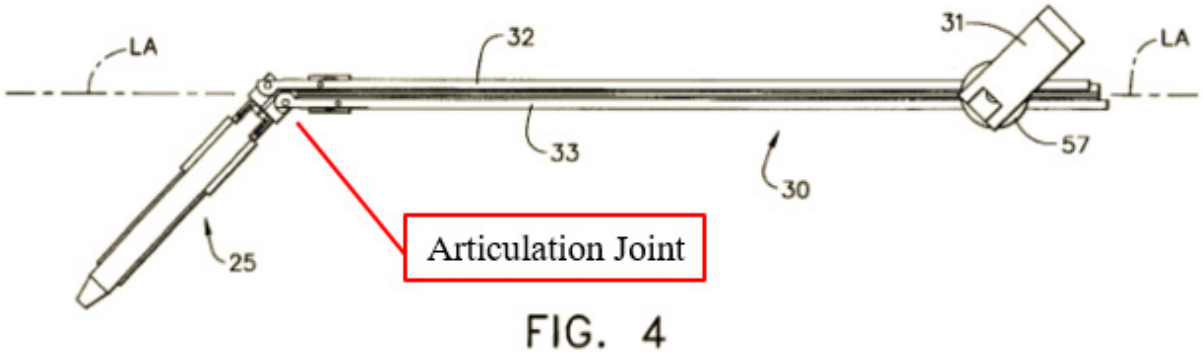


FIG. 4

A POSITA would have been motivated to modify Hooven's elongated shaft 41 to use Wale's pivoting linkage for several reasons. ***First***, as recognized in Wales, "[o]ften, it is necessary to adjust the positioning of the end effector of a surgical instrument to properly carry out the desired procedure. This often means that it is necessary to orient the end effector at an axis transverse to the long axis of the shaft of the instrument." IS1007, 1:16-21. ***Second***, Wales's pivoting linkage "exhibits little or no deflection on the end effector when it is in an articulated position and it is subjected to a high load." IS1007, 2:11-20. ***Third***, Wales's

pivoting linkage "allow[s] for the critical room needed in the center of the shaft adjacent the end effector for the incorporation of additional linkages and members which are needed to actuate the end effector…." IS1007, 2:16-19. And ***finally***, Wale's pivoting linkage allows the user to control articulation from a location proximal of the articulation point (*e.g.*, outside the body of an endoscopic instrument), whereas Hooven's flexible shaft allows only for bending the shaft at the point of articulation. IS1003, ¶167.

Furthermore, "[w]hen[, as here,] there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421. As explained above, Hooven describes one predictable solution for positioning a cartridge—*i.e.*, a flexible shaft. *See* Ground 1, element [1.10], *supra*. Wales describes another predictable solution—*i.e.*, a pivoting linkage in the elongated shaft. IS1007, FIG. 4; IS1003, ¶168.

Using a pivoting linkage was also an obvious design choice. IS1003, ¶169. As recognized in Wales, "[d]escriptions of articulating surgical instruments are plentiful" in the prior art. IS1007, 1:23-31 (citing 14 patents and 3 patent applications disclosing articulation joints); *see also* IS1001, 20:34-60 (incorporating by reference various prior art articulation joints). And, as shown by Wales, using a pivoting linkage was a known technique to improve similar devices

(*i.e.*, hand-held surgical staplers). IS1003, ¶169. Accordingly, a POSITA would have recognized that Wales' pivoting linkage is an effective and efficient mechanism for manipulating Hooven's end effector 42. *Id.*

Finally, such a modification of Hooven's elongated shaft 41 would have been well within a POSITA's abilities for several reasons. ***First***, it would have been merely the application of a known technique (*e.g.*, using a pivoting linkage in an elongated shaft) to a known system (*e.g.*, Hooven's surgical instrument 30) in the same field of endeavor (*i.e.*, surgical staplers). IS1003, ¶170; *KSR*, 550 U.S. at 417. ***Second***, in combination, each element (*i.e.*, Wale's pivoting linkage, Hooven's surgical instrument, Knodel's closure tube, and Bays's battery), merely performs the same function as it does separately. IS1003, ¶170. And ***third***, the combination of Hooven and Wales proposed here would have yielded predictable results without significantly altering or hindering the functions performed by Hooven's device or the devices resulting from the combination of Hooven with Knodel and/or Bays. *Id.*

VIII. CONCLUSION

Claims 1-21 of the '874 patent are invalid pursuant to Grounds 1-4 set forth above. Accordingly, Petitioner requests *Inter Partes* Review of these challenged claims.

Respectfully submitted,

Dated May 16, 2018

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CERTIFICATION UNDER 37 C.F.R. § 42.24

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 11,969 words, which is less than the 14,000 allowed under 37 C.F.R. § 42.24.

Dated May 16, 2018

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on May 16, 2018, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via FedEx, to the Patent Owner by serving the correspondence address of record as follows:

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