IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Shelton, IV	
U.S. Pat. No.:	8,479,969	Attorney Docket No.: 11030-0049IP5
Issue Date:	July 9, 2013	
Appl. Serial No.:	13/369,609	
Filing Date:	Feb. 9, 2012	
Title:	DRIVE INTERFACE FOR OPERABLY COUPLING A MANIPULATABLE SURGICAL TOOL TO A ROBOT	

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,479,969 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

IS1001	U.S. Pat. No. 8,479,969 to Shelton, IV ("the '969 Patent")
IS1002	Prosecution History of the '969 Patent (Serial No. 13/369,609)
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IS1004	Declaration of Dr. Bryan Knodel (Anderson as Primary Reference)
IS1005	Reserved
IS1006	Reserved
IS1007	U.S. Patent No. 6,817,974 to Cooper *et al.* ("Cooper")
IS1008	U.S. Patent No. 6,699,235 to Wallace *et al.* ("Wallace")
IS1009	U.S. Patent No. 6,331,181 to Tierney *et al.* ("Tierney")
IS1010	U.S. Patent No. 6,783,524 to Anderson *et al.* ("Anderson")
IS1011	U.S. Patent No. 7,510,107 to Timm *et al.* ("Timm")
IS1012	U.S. Patent No. 5,465,895 to Knodel *et al.* ("Knodel")
IS1013	U.S. Patent No. 5,954,259 to Viola *et al.* ("Viola")
IS1014	U.S. Patent App. No. 2008/0167672 to Giordano *et al.* ("Giordano")

I. INTRODUCTION

Intuitive Surgical, Inc. ("Petitioner") petitions for *Inter Partes* Review ("IPR") of claims 19-26 of U.S. Patent 8,479,969 ("the '969 Patent"). The '969 Patent is entitled "Drive Interface for Operably Coupling a Manipulatable Surgical Tool to a Robot." Drive interfaces for surgical robots were well-known in the prior art. In fact, the '969 Patent incorporates by reference, and largely copies, the prior art drive interfaces of Petitioner:

> [T]he tool arrangement described above may be well-suited for use with those robotic systems manufactured by Intuitive Surgical, Inc. of Sunnyvale, Calif., U.S.A., many of which may be described in detail in various patents incorporated herein by reference. The unique and novel aspects of various embodiments of the present invention serve to ***utilize the rotary output motions supplied by the robotic system*** to generate specific control motions….

IS1001, 31:56-59.[1]

Indeed, the Anderson reference, which serves as the basis for all Grounds in this petition, is a prior art patent assigned to Petitioner that discloses a robotic surgical system of the type described in the '969 Patent. The prior art Anderson system is specifically designed to interface with a variety of surgical instruments, including those described in the '969 Patent, such as surgical staplers, tissue graspers, and tissue cutters. IS1010, 7:6-25; 11:32-65; 16:25-36; FIGs. 2-3; 12A-

[1] Emphasis in quotations added throughout unless otherwise stated.

D. The robotic surgical system described in the ’969 Patent is uncannily similar to Petitioner’s robotic surgical system described in the prior art Anderson patent:

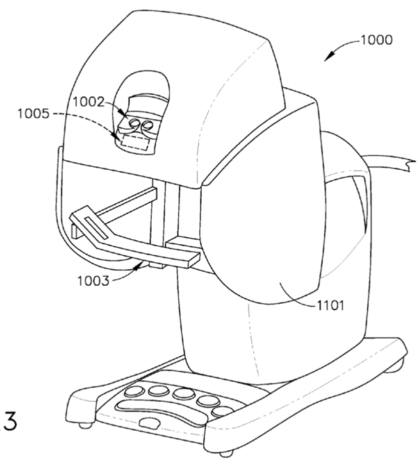
<table>
<tr><td colspan="2"><u>Robotic Controller</u></td></tr>
<tr><td><u>’969 Patent</u></td><td><u>Anderson</u></td></tr>
<tr><td>

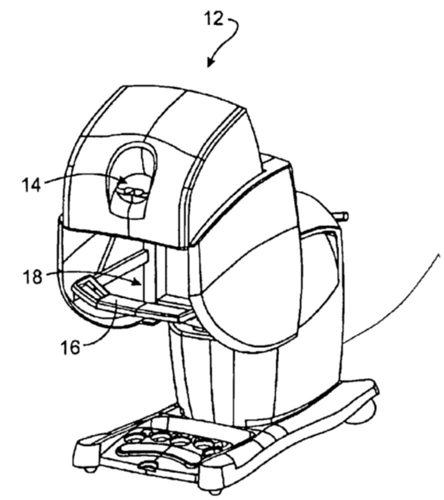
FIG. 23</td><td>

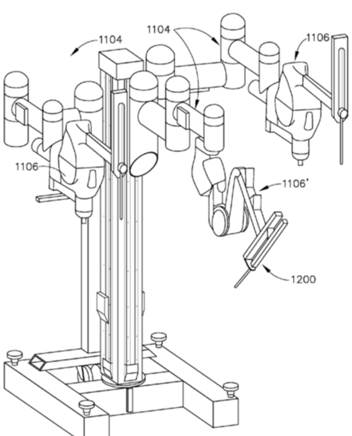
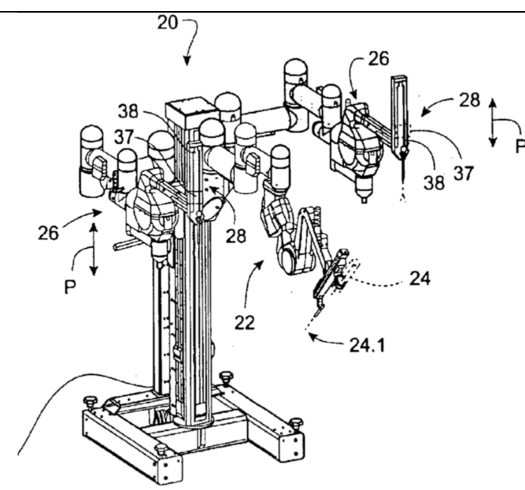
FIG. 1</td></tr>
<tr><td colspan="2"><u>Robotic Manipulator</u></td></tr>
<tr><td><u>’969 Patent</u></td><td><u>Anderson</u></td></tr>
<tr><td>

FIG. 25</td><td>
</td></tr>
</table>

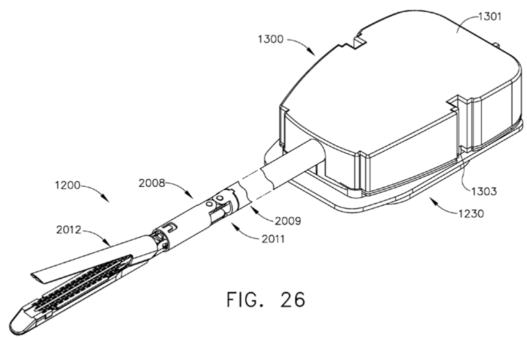
<table>
<tr><th colspan="2"><u>Surgical Tool With Proximal Tool Holder</u></th></tr>
<tr><th><u>’969 Patent</u></th><th><u>Anderson</u></th></tr>
<tr><td>

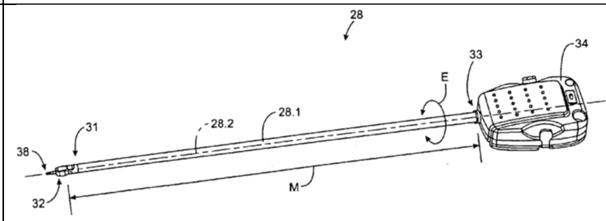
FIG. 26</td><td>

FIG. 2</td></tr>
</table>

Not only did the ’969 Patent incorporate Petitioner’s prior art disclosures into its patent, but the applicant originally drafted claims that read directly on Petitioner’s prior art patents. Specifically, the originally-filed independent claims were rejected as anticipated and obvious over Petitioner’s prior art “Tierney” reference (U.S. Patent No. 6,331,181). IS1002, 280-284; IS1009 (“Tierney”).

The applicant then amended the claims, adding details it contended were not disclosed in Tierney. However, the details supposedly absent from Tierney were well-known in Petitioner’s prior art surgical patents, as exemplified by Anderson and Cooper, and in the other references relied upon in this Petition. IS1004, ¶27. Anderson in combination with Cooper renders at least the challenged claims invalid as obvious. Petitioner requests IPR of the challenged claims on Grounds 1-5 below.

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

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

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

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

The ’969 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. Concurrently with this petition, Petitioner is filing two more IPR petitions related to the ’969 Patent directed to different sets of claims, different statutory bases, and/or different primary references.

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

Petitioner provides the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
Steven R. Katz, Reg. No. 43,706 3200 RBC Plaza, 60 South Sixth Street Minneapolis, MN 55402 Tel: 617-542-5070 / Fax: 877-769-7945	John C. Phillips, Reg. No. 35,322 Tel: 858-678-5070 Ryan P. O’Connor, Reg. No. 60,254 Tel: 858-678-5070

D. Service Information

Please address all correspondence to the address above. Petitioner consents to electronic service by email at IPR11030-0049IP5@fr.com (referencing No. 11030-0049IP5 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 '969 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 19-26 of the '969 Patent on the grounds listed below. A declaration from Dr. Bryan Knodel (IS1004) is provided in support.

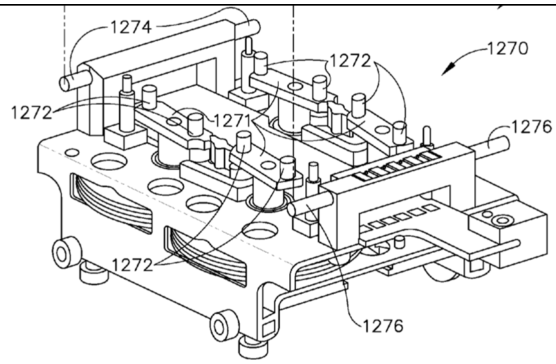
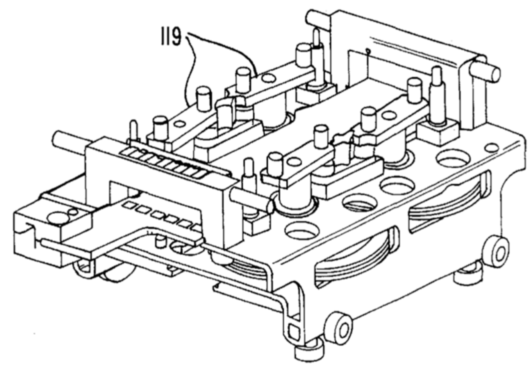
Grounds	Claims	Basis for Rejections under 35 U.S.C. § 103
Ground 1	23	Obvious over **Anderson** (U.S. 6,783,524) in view of **Cooper** (U.S. 6,817,974)
Ground 2	24	Obvious over **Anderson** in view of **Timm** (U.S. 7,510,107)
Ground 3	25-26	Obvious over **Anderson** in view of **Timm** and **Wallace** (U.S. 6,699,235)
Ground 4	19-20	Obvious over **Anderson** in view of **Knodel** (U.S. 5,465,895)
Ground 5	21-22	Obvious over **Anderson** in view of **Viola** (U.S. 5,954,259)

Anderson, Cooper, Timm, Wallace, Knodel, and Viola each qualify as prior art under at least 35 U.S.C. § 102(b) because they are all patents that issued more than one year before May 27, 2011, the earliest priority date for the challenged claims (as explained below).

The published application related to the Anderson patent was cited during prosecution but never discussed by the examiner or applicant. IS1002, 280-285. Cooper, Timm, Wallace, Knodel, and Viola were each made of record during prosecution as part of an 82-page IDS that listed over 2,000 references. IS1002, 357-438. None of these references were substantively addressed or cited in any office action during prosecution. IS1002, 280-285. Additionally, the combinations presented here were not considered by the examiner.

V. SUMMARY OF THE ’969 PATENT

The ’969 Patent contains subject matter related to both hand-held surgical instruments and robotic surgical instruments, but the claims all relate to the robotic embodiments. The title also makes this clear: “DRIVE INTERFACE FOR OPERABLY COUPLING A MANIPULATABLE SURGICAL TOOL TO A ROBOT.” IS1001, Title; 11:12-42; 23:50-24:39. The disclosed robotic surgical system includes the typical and expected components, such as a “master controller and robotic arm cart” with a “tool drive assembly” including multiple rotary drive members (referred to as “rotatable body portions” in the claims) that control surgical tools. IS1001, 23:50-62; 24:62-25:29; FIGs. 26-27. Each of these components was copied from Petitioner's prior art patents. For example, the tool drive assembly of the '969 Patent is found in the prior art Tierney patent (IS1009).

'969 Patent	**Prior Art Tierney Reference**
FIG. 27	FIG. 7J.

The tool drive assembly on the robotic arm drives driven disks on an adapter, which in turn, drives driven disks on the attached surgical tool itself. This robotic drive interface was copied from Petitioner as well:

<u>’969 Patent</u>

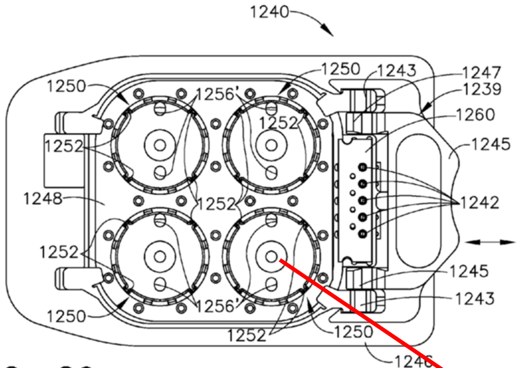
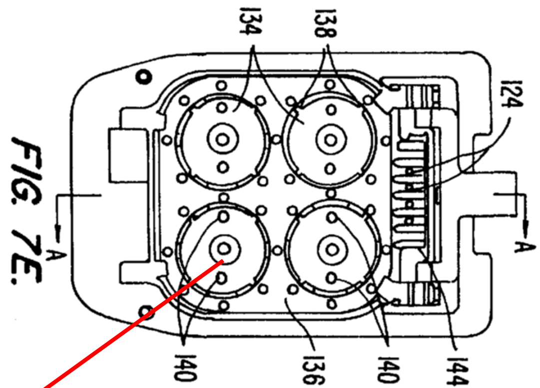


FIG. 29

<u>Prior Art Tierney Reference</u>



Driven disks

Each challenged claim adds to this prior art robotic interface details that, as shown in this petition, relate to well-known prior art surgical tool structures, such as tube gears for rotating end effectors, articulation joints for articulating end effectors, and gear-driven structures for driving a knife through a surgical stapler.

As demonstrated below, none of these features was novel as of the filing of the ’969 Patent or the parent application to which the ’969 Patent claims priority.

VI. PROSECUTION HISTORY

During prosecution, the USPTO issued a single office action rejecting the broad independent claims, but indicated that two independent picture claims and a variety of dependent claims contained allowable subject matter. IS1002, 280-284. The broad claims were rejected over Petitioner’s Tierney patent. IS1009 (Tierney); IS1002, 280-284. The applicant subsequently amended the independent claims to include subject matter deemed allowable and added new dependent claims containing the allowable subject matter of original dependent claim 7 (issued claim 19), claim 9 (issued claim 21), claim 12 (issued claim 23), and claim 14 (issued claim 24). IS1002, 304-311. The examiner then issued a notice of allowance. Rather than allow the patent to issue, applicant filed an RCE and submitted an IDS listing over 2,000 references. IS1002, 328-333; 357-483. A notice of allowance promptly followed, and the '969 Patent issued on July 9, 2013. IS1002, 547-552; IS1001, Face.

VII. PRIORITY DATE

The '969 Patent is directed to robotic embodiments. The robotic embodiments were added in the CIP application filed on May 27, 2011 (U.S. Application No. 13/118,259). The prior application, U.S. Application No. 11/651,807 does not provide support for any of the challenged claims. IS1014. For example, each of the challenged independent claims (19, 21, 23-24) recites a "tool mounting portion" "being configured to operably interface with ***the tool drive assembly***" that has at least one "rotatable body portion." The claims further state that the "tool drive assembly" is part of a robotic system: "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***." The parent '807 application provides no support for these recitations. IS1004, ¶¶28-29. Rather, the '807 parent application is directed toward handheld “endoscopic surgical instrument[s]” with only a passing reference to “robotic-assisted surgery.” IS1014, ¶¶15, 89, FIGs. 1-2.

VIII. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)

For the purposes of IPR only, Petitioner submits that the terms of the ’969 Patent are to be given their broadest reasonable interpretation as understood by one of ordinary skill in the art at the time in view of the specification (“BRI”). 37 C.F.R. § 42.100(b).[2]

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE ’969 PATENT IS UNPATENTABLE

As detailed below, claims 19-26 of the ’969 Patent are rendered invalid for obviousness by Anderson in view of one or more references.

A. Ground 1: Claim 23 Would Have Been Obvious Under § 103 over Anderson in View of Cooper

Claim 23 generally relates to a robotic instrument that rotates using a tube gear. Anderson discloses such a device, although it does not use the term “tube gear.” Cooper clearly teaches that the Anderson structure is a tube gear.

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[2] The Office has proposed a change to the claim construction standard. *See* 83 Fed. Reg. 21221 (proposed May 9, 2018). The prior art discussed herein invalidates the challenged claims under either standard. If the Office applies the new standard to this proceeding, then due process requires the Office afford Petitioner an opportunity to provide additional argument and evidence on that issue.

Specifically, Anderson describes a robotic surgical system with a surgical tool substantially similar to the surgical tool in the '969 Patent. The surgical tool includes an end effector connected via an elongate shaft to a base which mounts the tool to a robotic surgical system, as shown in FIG. 2:

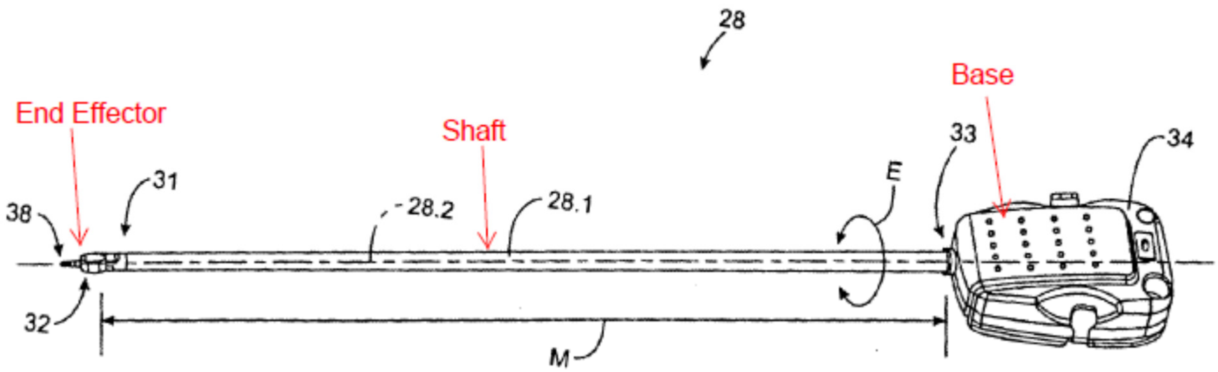


FIG. 2

IS1010, FIG. 2; 11:32-65. The shaft can rotate with respect to the base in the directions E about the longitudinal axis, as shown in FIG. 2 (above). The end effector can include, for example, a pivotable gripper for gripping tissue. IS1010, 15:30-60. The base contains multiple "transmission members" to transmit rotational motion from the robotic arm to the end effector. IS1010, 11:66-12:22; 16:7-23. Anderson discloses that the end effector may be rotated using a cable-driven system, but also discloses that "a gear train" may be used, and specifically "a right-angled helical gear pair." IS1010, 16:37-46; 23:25-36.

Cooper discloses a surgical tool similar to that disclosed in Anderson, but the focus of Cooper is on articulating wrists:

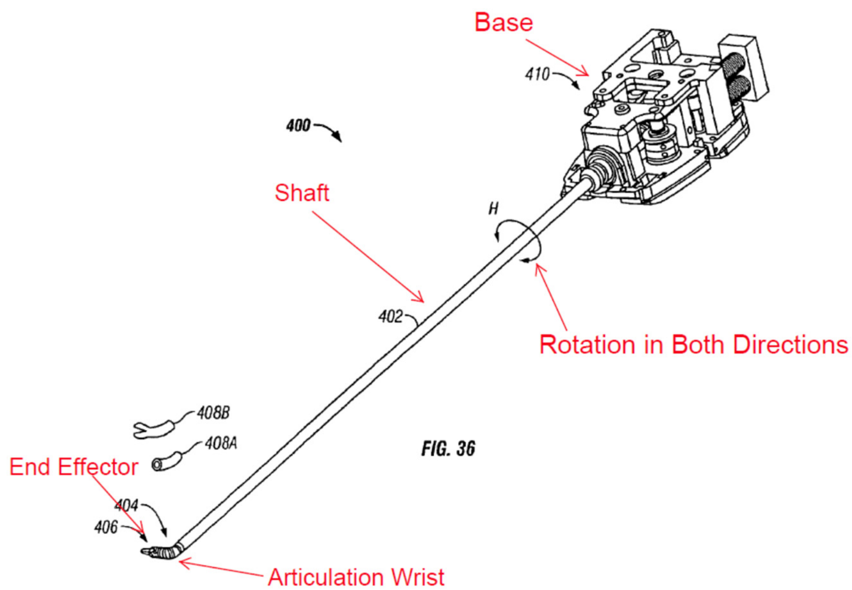


FIG. 36

IS1007, FIG. 36; 17:26-50. Whereas Anderson does not have a figure of its "right-angled helical gear pair," Cooper does have such a figure. Figure 64 of Cooper discloses a tube gear in a right-angled helical gear pair for rotating the end effector:

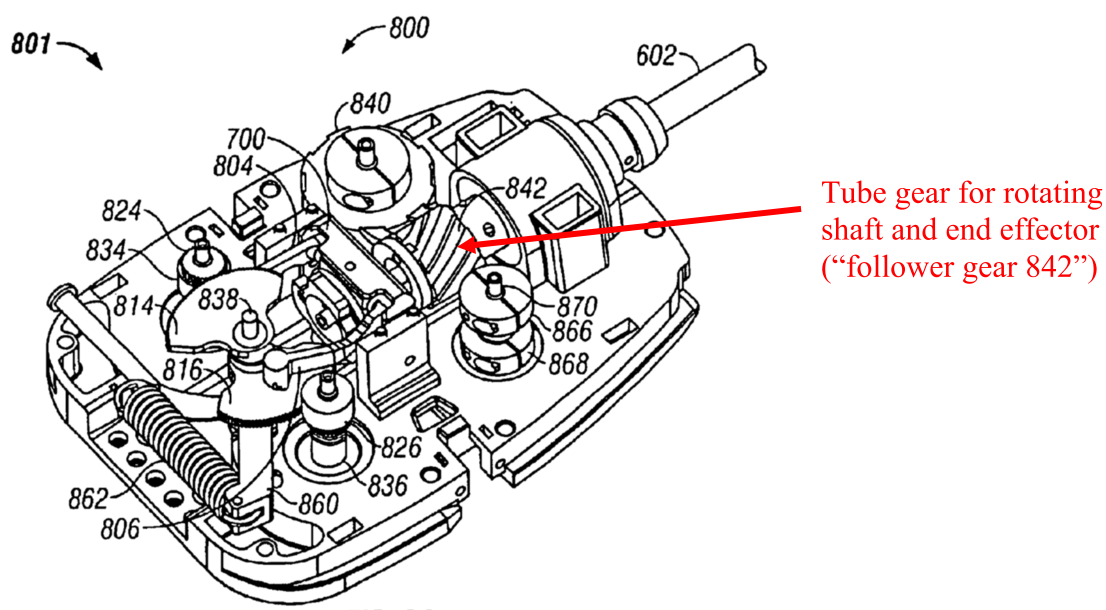


FIG. 64

IS1007, FIG. 64; 24:1-23; IS1004, ¶¶42-46. This is the same tube gear as disclosed in the ’969 Patent.

[23.P] 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 and is configured to provide at least one rotary output motion to at least one rotatable body portion supported on the tool drive assembly, said surgical tool comprising:

If the preamble is deemed limiting, Anderson discloses it, as explained below. IS1004, ¶¶47-51.

“A surgical tool for use with a robotic system”

FIG. 2 shows an example embodiment of a “surgical instrument 28” that is “configured to releasably engage a robotic surgical system:”

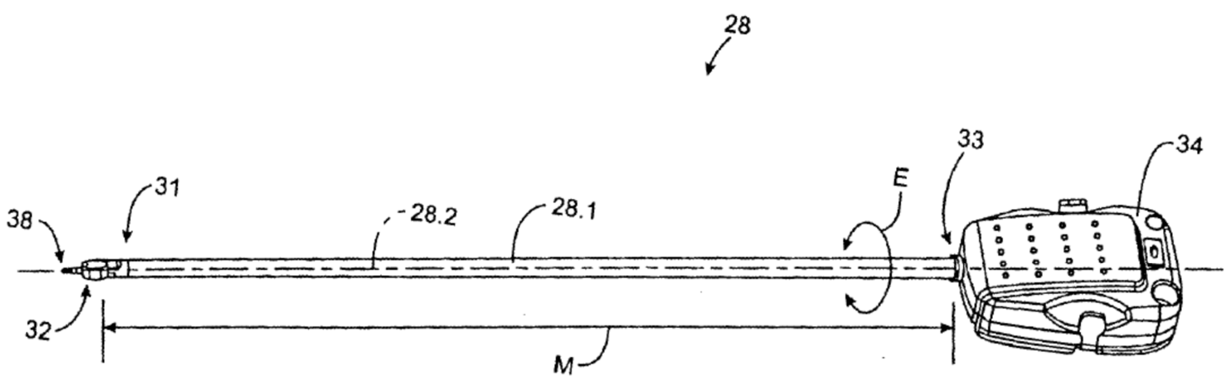


FIG. 2

IS1010, FIG. 2; 16:7-23; 11:32-42; 10:65-11:31; 4:7-11 (“a robotic surgical instrument for use with a robotic surgical system”); Abstract.

The robotic system “has a tool drive assembly that is operatively coupled to a control unit…”

FIG. 1 of Anderson shows the “robotic surgical system 10” having a "surgical work station" 20 (which includes the tool drive assembly) operatively coupled to "control station 12." A user at the "control station" controls operation of the surgical tool attached to the tool drive assembly of the surgical work station. The control station alone, or alternatively, in conjunction with portions of the "surgical work station" other than the tool drive assembly, form(s) the recited "control unit":

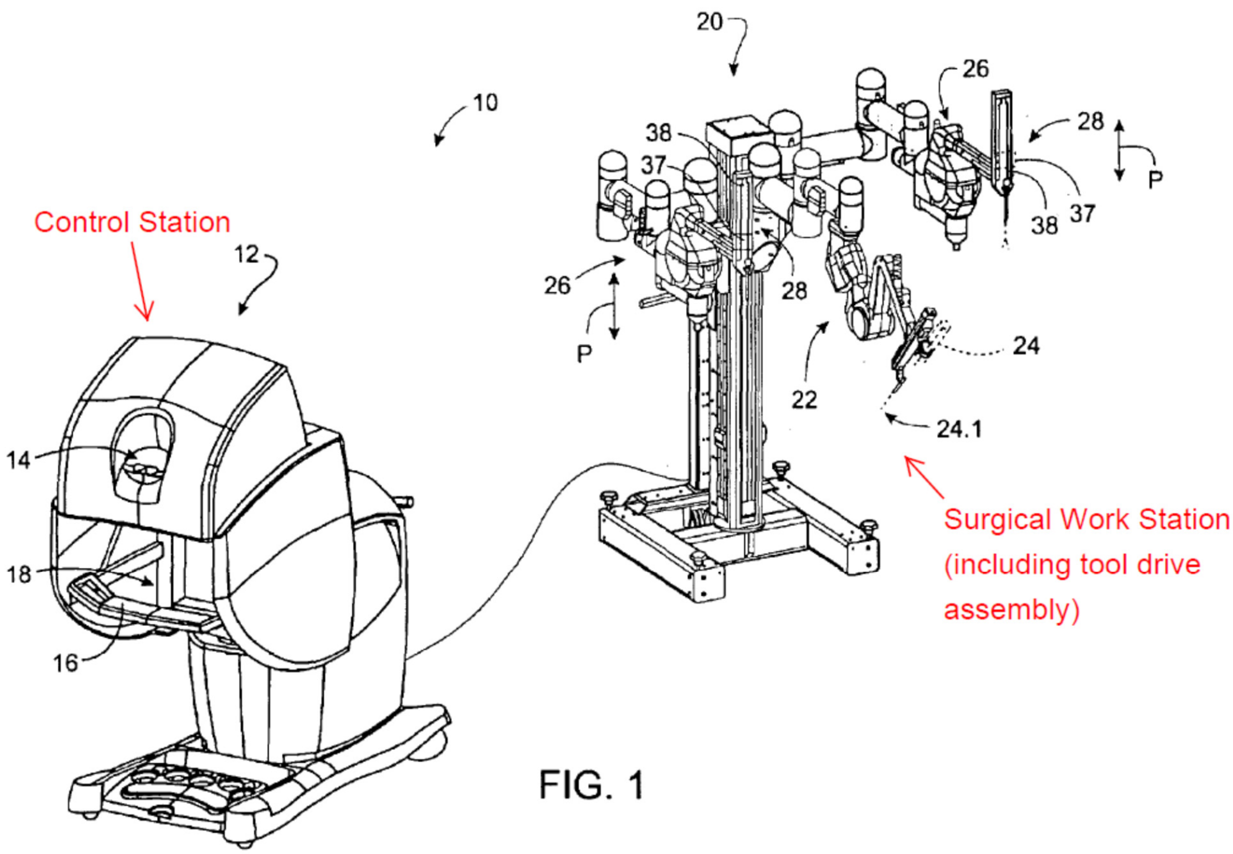


FIG. 1

IS1010, FIG. 1; 10:21-64.

<u>The control unit is "operable by inputs from an operator</u>"

The control station 12 portion of the control unit is operable by inputs from "a surgeon or other user." IS1010, 10:40-64; 11:59-65; 5:61-6:8 ("operator control input”).

<u>The tool drive assembly is “configured to provide at least one rotary output motion to at least one rotatable body portion supported on the tool drive assembly”</u>

The surgical work station 20 includes a plurality of robotic arm assemblies 26 that include motors and “engaging members” for coupling to, and providing rotary output motion to, shafts 70.1, 72.1, 74.1, and 76.1 (shown in red below) that extend from the base 34 of the surgical instrument 28:

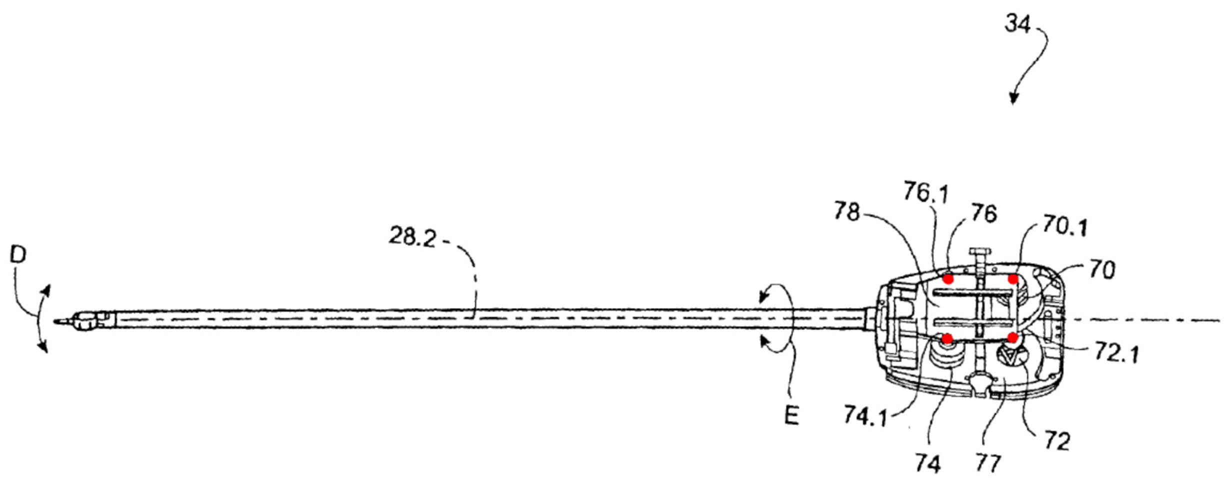


FIG. 3

IS1010, FIG. 3; 11:66-12:22; Abstract. The engaging members of the robotic arm assembly receive rotary motion from “actuators” such as “electric motors or the like, to cause selective angular displacement of each engaging member” to cause “angular displacement” (e.g., rotation) of the spools or gears mounted on the rotatable shafts within the base 34. *Id.* The engaging members are thus the recited “rotatable body portions supported on the tool drive assembly.” IS1004, ¶51.

[23.1] 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 in response to control motions applied to said selectively movable component portion;

Anderson discloses element [23.1], as explained below. IS1004, ¶¶52-54.

<u>"selectively movable" component portions</u>

Anderson discloses various end effector embodiments that have "selectively movable" components. For example, in FIG. 10, Anderson discloses an "end effector 81" that "includes a gripper 82 hingedly attached to shaft 84" that closes against an ultrasonic probe tip 85b:

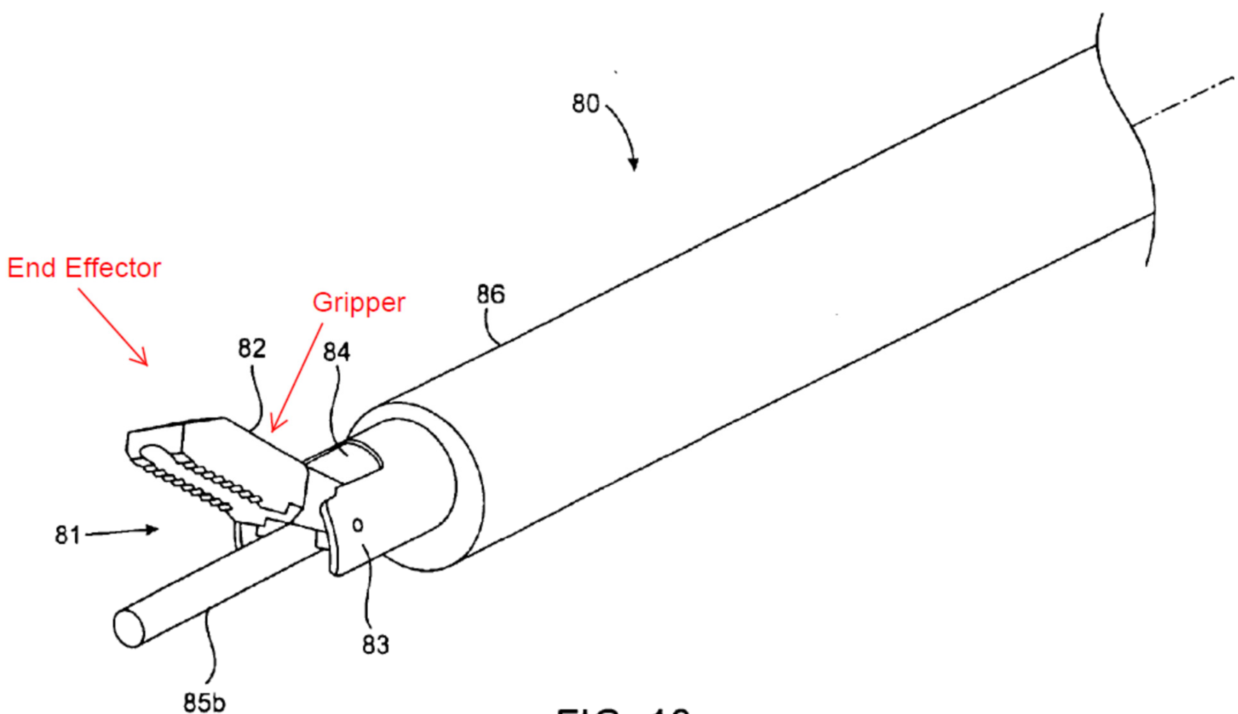


FIG. 10

IS1010, FIG. 10; 15:3-38; 15:48-60.

FIGs. 20-22 disclose other embodiments that have a "pivotally mounted gripper or clamp 303" which mates with an "ultrasonic blade 304":

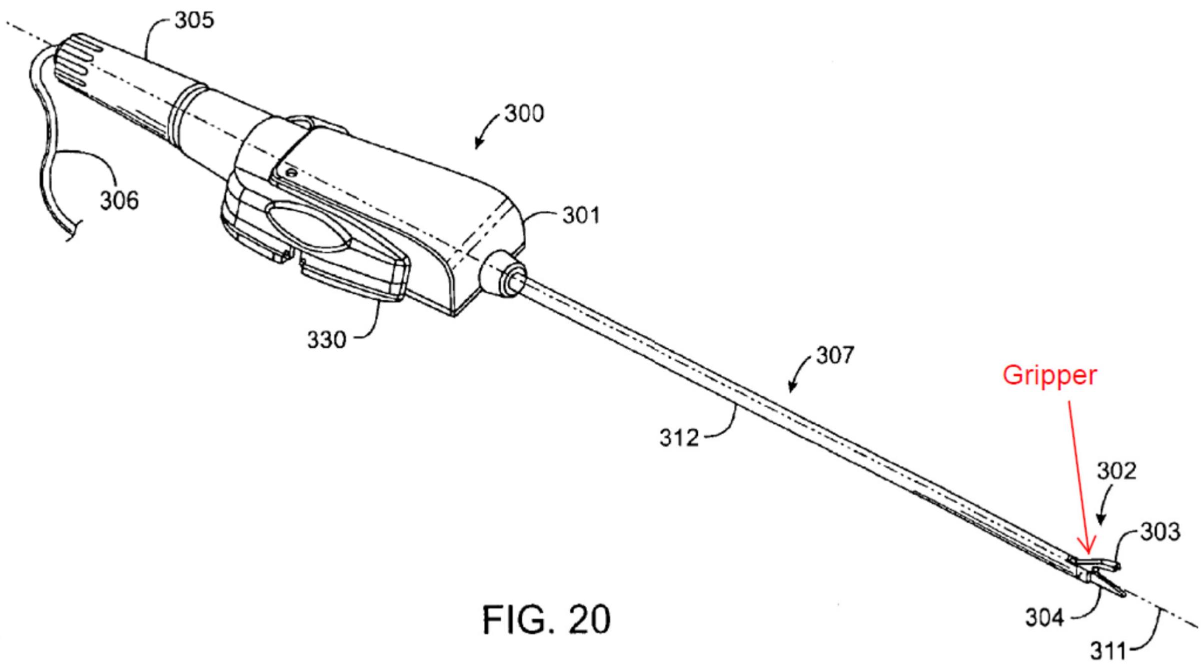


FIG. 20

IS1010, FIG. 20; 22:8-20; 24:54-65 ("reciprocating actuation of paddle shafts 351 causes the grip or [clamp] 303 to alternately open and close").

"in response to control motions"

Anderson explains that the gripper 82 moves in response to control motions, explaining that "components of base 90 enable forces originating at one or more master controllers of a robotic surgical system to be transmitted to end effector 81 to achieve an effect at a surgical site." IS1010, 16:7-23; *see also* 16:62-17:22 ("gripper 82 of end effector 81 is movable by one or more actuator rods housed within shaft 86"); 10:40-12:22 (generally describing actuation of the end effector in response to control motions); 24:54-65.

Likewise, "gripper 303" also moves in response to control motions. Although the control motions are not explicitly discussed with respect to gripper 303, a POSITA would understand that it would use the same control motions as the gripper on end effector 81 of FIG. 10. IS1004, ¶54.

[23.2] an elongated shaft assembly including a distal end operably coupled to said surgical end effector and defining a longitudinal tool axis, said elongated shaft assembly including a tube gear segment on a proximal end thereof; and

Anderson in view of Cooper discloses element [23.2], as explained below. IS1004, ¶¶55-62.

The "elongated shaft assembly …"

The "end effector 302" of Anderson's instrument 300 "is coupled to the distal end of the shaft 307," which is part of Anderson's elongated shaft assembly, which may include shaft 307, outer sheath 312, actuator rods, and spools or gears. IS1010, 22:8-19; 5:11-17; 23:25-30. As shown in FIG. 20 (*supra*), the shaft 307 defines a longitudinal "instrument axis 311." IS1010, 21:66-22:11.

The "tube gear"

Anderson discloses two shaft rotation mechanisms: a cable-driven mechanism and a gear-driven mechanism. Only the cable mechanism is depicted in the figures. In one embodiment of the cable mechanism, a "roll barrel 336" is rotated (see arrow B) via a cable connected to "roll interface member 344":

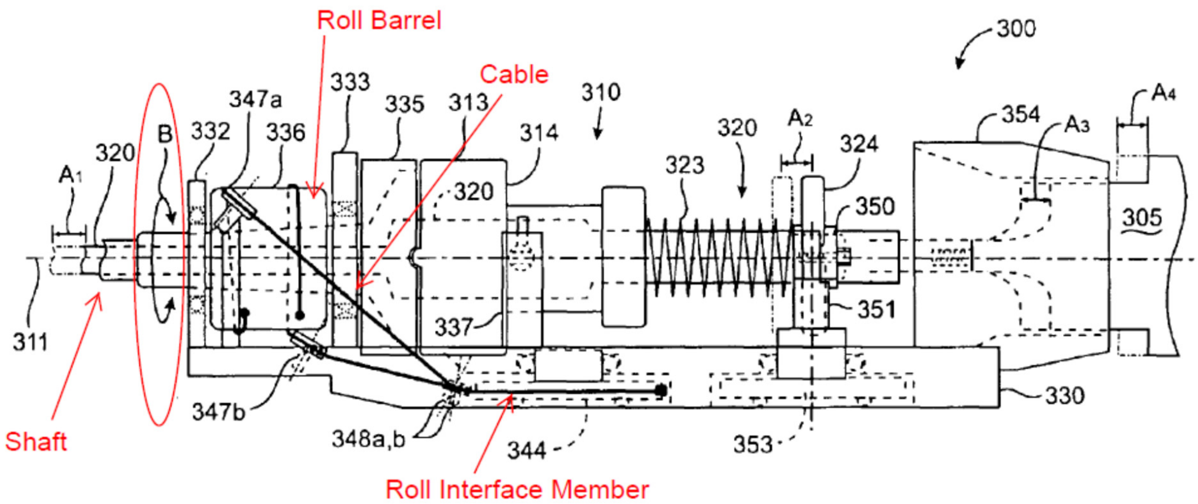


FIG. 22

IS1010, FIG. 22; 22:8-28; 22:59-23:14. Another cable-driven embodiment having a roll barrel ("roll barrel 96") to rotate the shaft of the instrument is shown in FIG. 13:

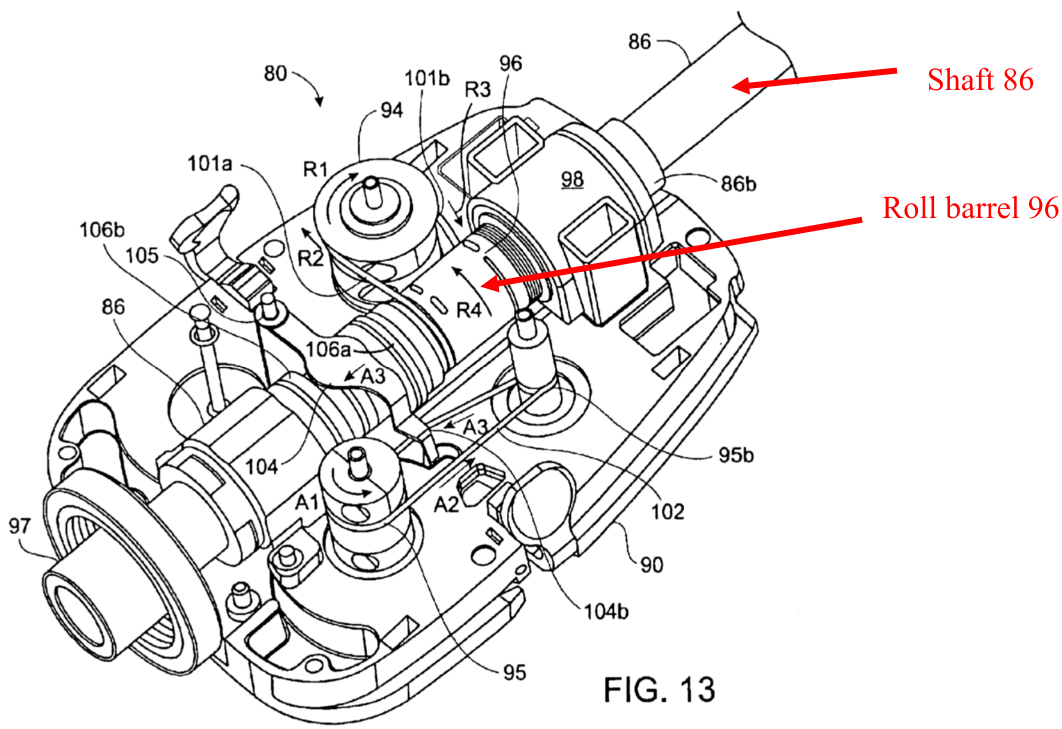


FIG. 13

The two roll barrels function "in generally the same manner," and both impart rotational motion to the shaft. IS1010, 22:59-61; 16:36-61.

Anderson further describes an alternative mechanism for rotating the shaft of the instrument: a tube gear embodiment in which "a gear train or other mechanical transmission means, *e.g.*, ***a right-angled helical gear pair***, may be used to rotationally couple the interface member 344 with the receiver 335." IS1010, 22:59-23:30. In the tube gear embodiment, the roll barrel 336 (shown in yellow, below) would be replaced by a helical tube gear, interface member 344 (shown in green, below) would also be replaced with a helical gear, and their positions would be adjusted so that they were in meshing engagement:

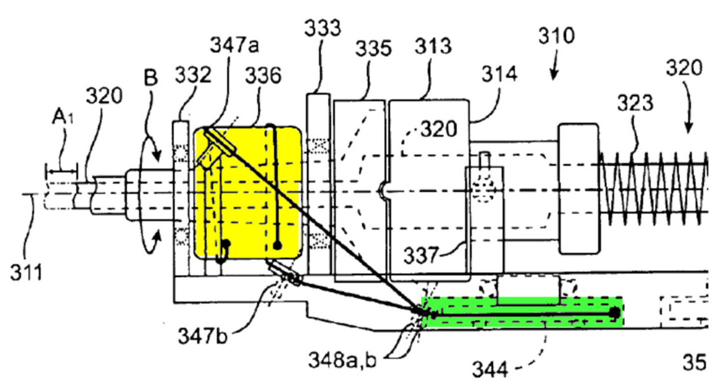
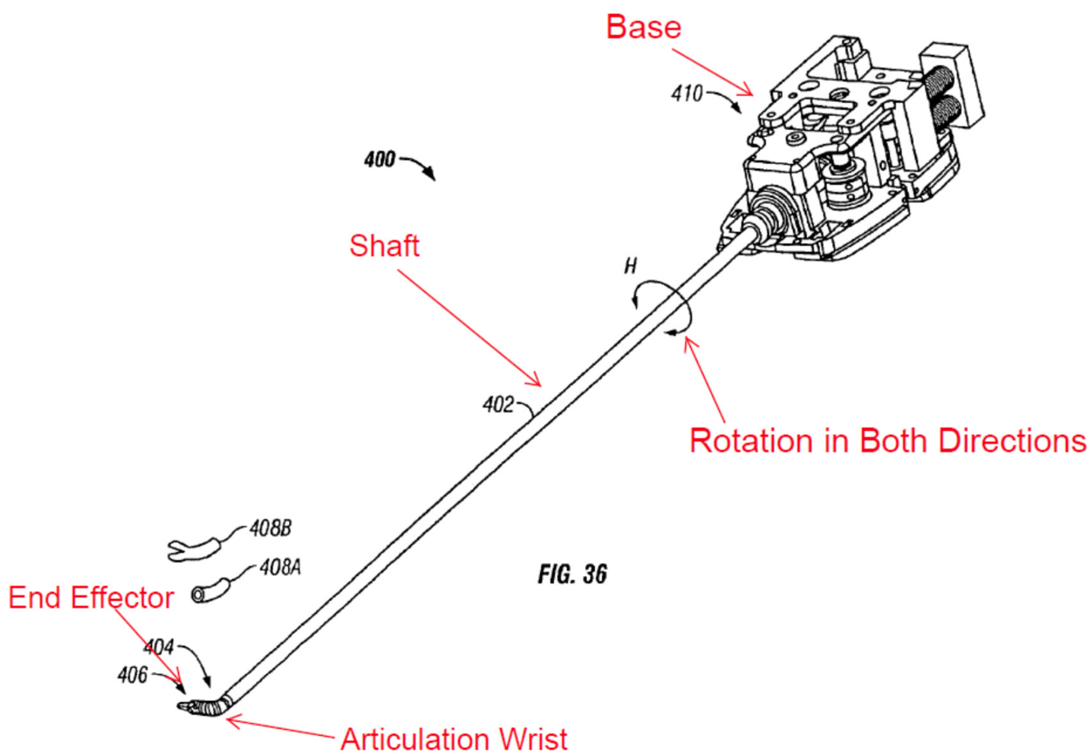


FIG. 22

IS1010; FIG. 22 (partial); IS1004, ¶59. Or to put it another way, in the alternate embodiment the roll barrel 336 would have helical gear teeth added to it so that it would become a tube gear, and interface member 344 would have helical gear teeth added to it so that it could meshingly interface with the tube gear. IS1004, ¶59.

Because Anderson has no figure depicting the "right-angled helical gear pair," this petition relies on the teachings of Cooper, which shows what the "right-angled helical gear pair" looks like. Cooper discloses "a surgical instrument 400" having a base ("back end mechanism 410") for coupling to a robotic surgical system and a shaft that rotates "as indicated by arrows H":



IS1007, FIG. 36; 17:26-50.

Furthermore, Cooper discloses that a "helical drive gear 840" is in meshing engagement with tube gear ("follower gear 842") to drive the shaft rotation, as shown in FIG. 64:

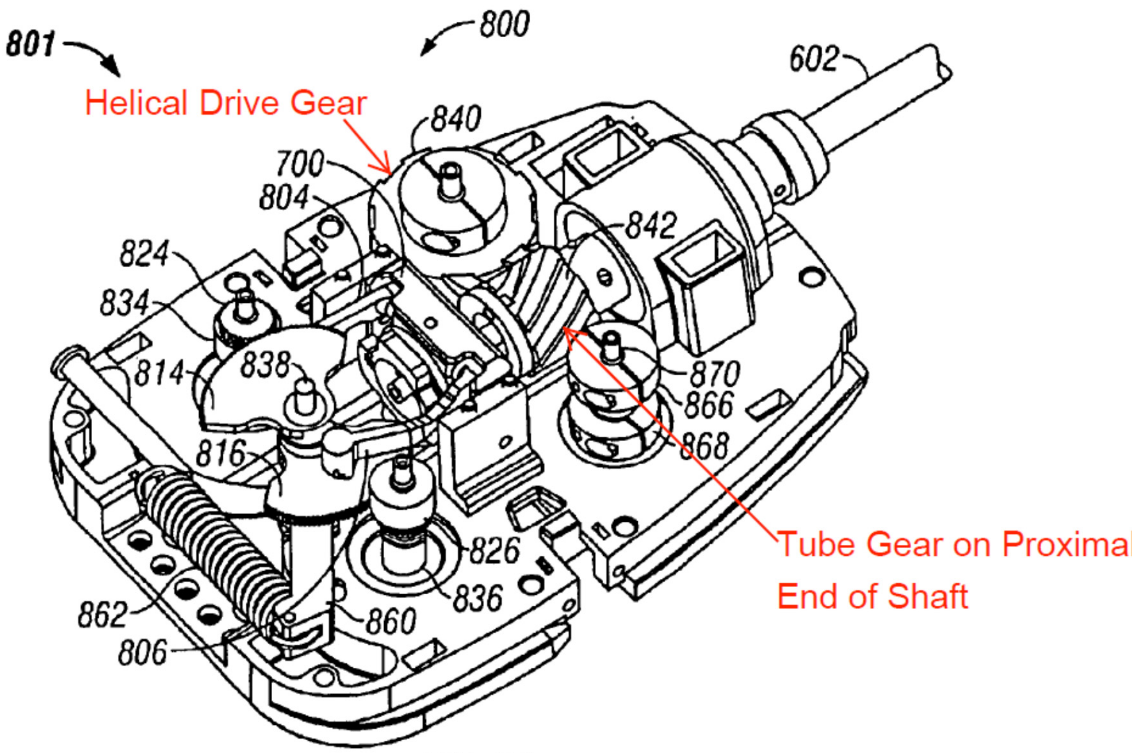
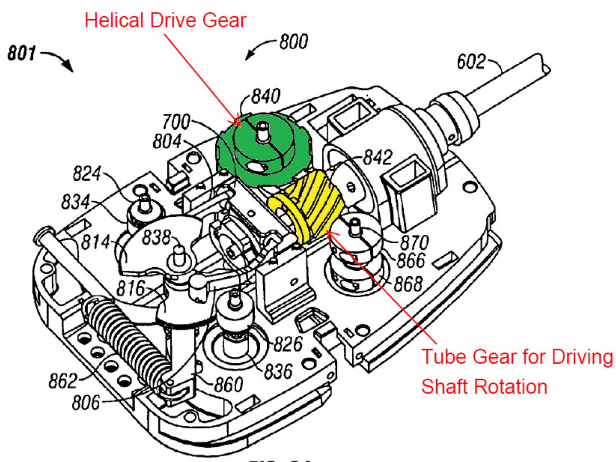
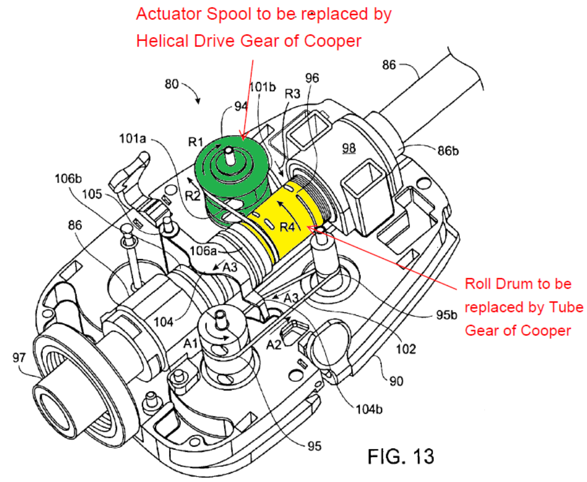


FIG. 64

IS1007, FIG. 64; 24:1-23; IS1004, ¶60.

As can be seen in FIG. 64, the "helical drive gear 840" is positioned at a right angle relative to the tube gear ("follower gear 842") that drives shaft rotation. A POSITA would have recognized that Cooper's helical drive gear 840 and tube gear ("follower gear 842") form the "right-angled helical gear pair" disclosed in Anderson. IS1004, ¶61.

A comparison of FIG. 64 of Cooper with FIG. 13 of Anderson shows that Anderson discloses a cable mechanism for rotating the shaft of the instrument in which (1) a drive spool ("spool 94") is in virtually the same location as Cooper's helical drive gear 840, and (2) a roll drum 96 is in virtually the same location as Cooper's tube gear ("follower gear 842").

Cooper	**Anderson**
 FIG. 64	 FIG. 13

IS1010, FIG. 13; 16:25-61; 22:59-23:30; IS1007, FIG. 64; 24:1-23. A POSITA would have been motivated to replace the spool 94 and roll drum 96 of FIG. 13 of Anderson with the helical drive gear 840 and tube gear ("follower gear 842") of Cooper's FIG. 64 based on the explicit disclosure in Anderson that a roll drum and spool may be replaced by a "right-angled helical gear pair." IS1010, 22:59-23:30; IS1004, ¶61.

Multiple reasons would have prompted a POSITA to modify Anderson's FIG. 13 and/or FIG. 22 to use the gear arrangement of Cooper. **First**, a POSITA would have recognized that the teaching of a "right-angled helical gear pair" in Anderson describes the tube gear structure of Cooper. IS1010, 22:59-23:30;

IS1004, ¶61.

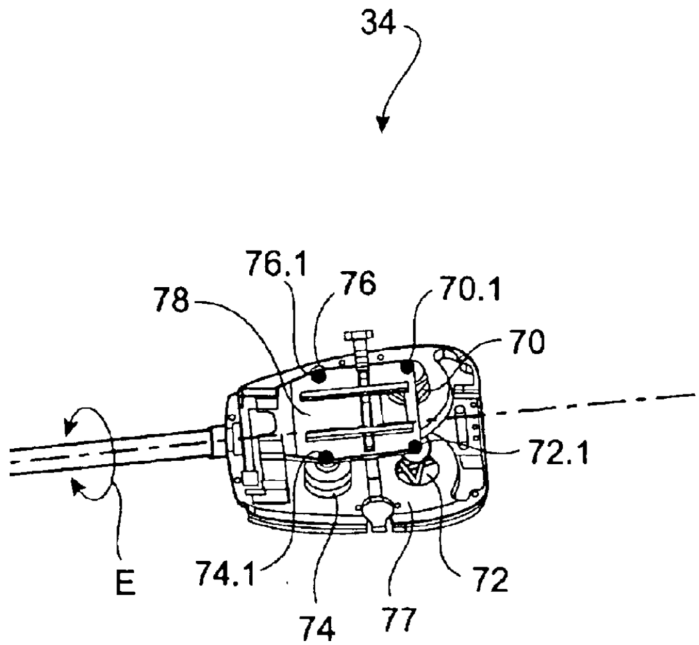
Second, a POSITA would have recognized that such a configuration would lead to "improved efficiency and cost-effectiveness" over other methods of conveying rotational motion. IS1007, 24:21-23. For example, a gear pair requires fewer parts and can provide greater torque than a comparable cable arrangement. IS1010, 22:59-23:30; IS1004, ¶61.

Third, a POSITA would have been prompted to modify Anderson's device to include Cooper's helical drive gear and tube gear because doing so would be merely the application of a known technique (use of tube gears to generate shaft rotation) to a known system (e.g., Anderson's surgical instrument) ready for improvement to yield predictable results. IS1004, ¶61; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Here, both Anderson and Cooper disclose surgical instruments configured to releasably couple to a robotic surgical system to receive rotational driving motion from the robotic surgical system and a POSITA would have recognized that applying Cooper's suggestions to Anderson's surgical instrument would have led to predictable results without significantly altering or hindering the functions performed by Anderson's surgical instrument, as contemplated by Anderson. IS1004, ¶61; IS1010, 25:10-11. Finally, both Anderson and Cooper are assigned to the same entity—Intuitive Surgical, Inc.—and both relate to similar surgical tools for robotic-assisted surgery and thus a POSITA would look to both references. IS1010, 1:14-18; IS1007, 1:44-47.

[23.3] a tool mounting portion operably coupled to said elongated shaft assembly, said tool mounting portion being configured to operably interface with the tool drive assembly when coupled thereto,

Anderson discloses element [23.3]. IS1004, ¶¶63-65. In Anderson, the "instrument base," which interfaces the surgical tool to the arm assembly of a robotic surgical system's "surgical work station 20," is the tool mounting portion. IS1010, 11:35-38 ("Base 34 is generally configured to releasably engage a robotic surgical system, such as robotic surgical system 10 in FIG. 1."), FIG. 3; 22:8-19 ("The surgical instrument 300 includes a base 330"), FIG. 20; 23:30-35 (noting that in the "examples of the invention shown in FIGS. 10-25, [] a mechanical robotic actuator interface is described"). In each embodiment, an elongate shaft assembly is coupled to the base. IS1010, 11:32-36; 22:10-14; FIGS. 11-22.

The base is configured to engage "[a] robotic surgical system interface." IS1010, 22:20-33; 22:59-67. Anderson describes that for instrument 28 "[a]t the outer surface, each shaft 70.1, 72.1, 74.1, 76.1 includes an engaging member (not shown) configured to releasably couple with a complementary engaging member (not shown) rotatably mounted on the carriage 37 of a robotic arm assembly 26 (see FIG. 1)." IS1010, 11:66-12:22. FIG. 3 shows the shafts configured to couple to engaging members of the robotic arm assembly:



IS1010, FIG. 3 (partial).

Anderson states that this description for instrument 28 applies to the similar features of instrument 300 as well. IS1010, 18:19-24.

[23.4] said tool mounting portion comprising a rotational transmission assembly comprising a rotational gear assembly in meshing engagement with the tube gear segment and operably coupled to one of the at least one rotatable body portions supported on the tool drive assembly

Anderson in view of Cooper discloses element [23.4], as explained below. IS1004, ¶¶66-68.

<u>"tube gear"</u>

Anderson's base 330 has two alternate rotational transmission assemblies: a cable-driven assembly, as depicted in the figures, such as FIG. 21, and a gear-driven assembly described in the text:

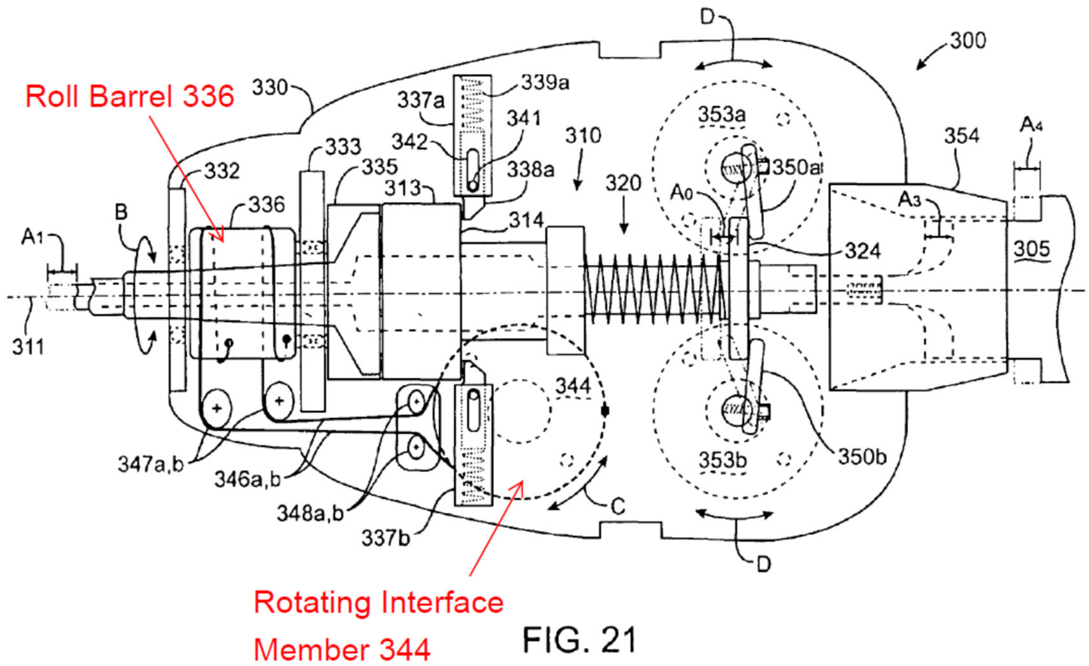


FIG. 21

IS1010, FIG. 21; 16:36-61; 22:8-19; 22:59-23:30 ("a right-angled helical gear pair"). A POSITA would have understood that the driven gear replacing the roll barrel would have been a tube gear. IS1004, ¶67. In addition, Cooper explicitly discloses a rotational transmission system in which the driven gear in the right-angled helical gear pair used to rotate the end effector is a tube gear. IS1004, ¶68. The rotational gear assembly includes the drive gear in the right-angled helical gear pair (helical drive gear 840 in Cooper). *See* discussion for element [23.2].

"operably coupled to one of the at least one rotatable body portions supported on the tool drive assembly"

Anderson's transmission assembly (which includes "transmission members 70, 72, 74, and 76") engages with rotatable "engaging members" on "carriage 37 of a robotic arm," which are the rotatable body portions on the tool drive assembly.

IS1010, 11:66-12:16. In the combination, Anderson's "transmission member" used to rotate the end effector would be a drive gear of a "right-angle helical gear pair" rather than a spool. IS1010, 23:26-31; IS1004, ¶68.

> ***[23.5] such that upon application of a rotary output motion in a first direction to said rotational gear assembly by said at least one rotatable body portion, said rotational gear assembly rotates said elongated shaft assembly and said surgical end effector in a first rotary direction about said longitudinal tool axis and upon application of said rotary output motion in a second direction to said rotational gear assembly, said rotational gear assembly rotates said elongated shaft assembly and said surgical end effector about said longitudinal tool axis in a second rotary direction relative to the tool mounting portion.***

Anderson in view of Cooper discloses element [23.5]. IS1004, ¶¶69-72. Specifically, Anderson discloses rotation in both directions when discussing FIG. 22, as shown by the dual arrow labeled "B."

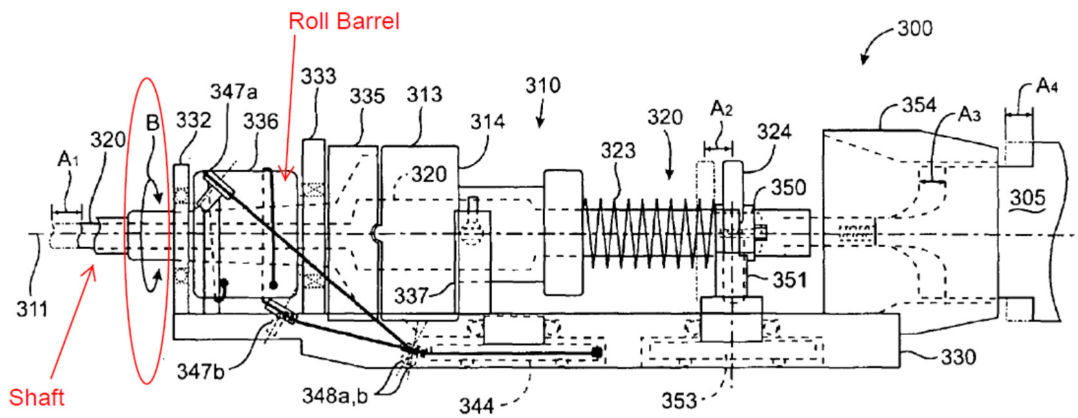


FIG. 22

This embodiment may alternatively have a "right-angled helical gear pair" for shaft rotation, and thus Anderson discloses bidirectional rotation with a helical gear pair. IS1010, 22:59-67; 23:26-30.

Anderson is also clear that rotation of the shaft "***is reversible and controllable by the robotic surgical system***." IS1010, 16:57-61; *see also* 22:59-23:14 ("A robotic surgical system interface member … is configured to engage[] the pivotally mounted instrument roll interface member 344 so as to controllably rotate interface member 344 ***in either direction*** through a selected range of motion.").

Likewise, Cooper discloses rotation of the elongated shaft assembly and end effector in both directions about a longitudinal axis, as shown by arrows H in FIG. 36. IS1007, 17:34-49. A POSITA would understand that the robotic controller controls such rotation: "[T]he robotic arm is used to manipulate the back end mechanism 410 to operate … the end effector." *Id.*; IS1004, ¶72. In the system resulting from the predictable combination of Anderson with Cooper, the rotation of the shaft in either direction is accomplished by rotation of helical drive gear 840 in either direction which drives a tube gear ("follower gear 842") to rotate the shaft (as discussed above). IS1007, FIG. 64; 24:1-23. IS1004, ¶72.

B. Ground 2: Claim 24 Would Have Been Obvious Under § 103 over Anderson in View of Timm

Claim 24 recites many of the standard robotic surgical system elements discussed above and adds "a proximal spine portion pivotally coupled to [a] distal spine portion at an articulation joint to facilitate articulation of said surgical end effector." Timm describes precisely such a configuration. Specifically, Timm discloses an articulating surgical stapler. IS1011, 2:25-55; 1:42-53; Abstract; FIG. 1.

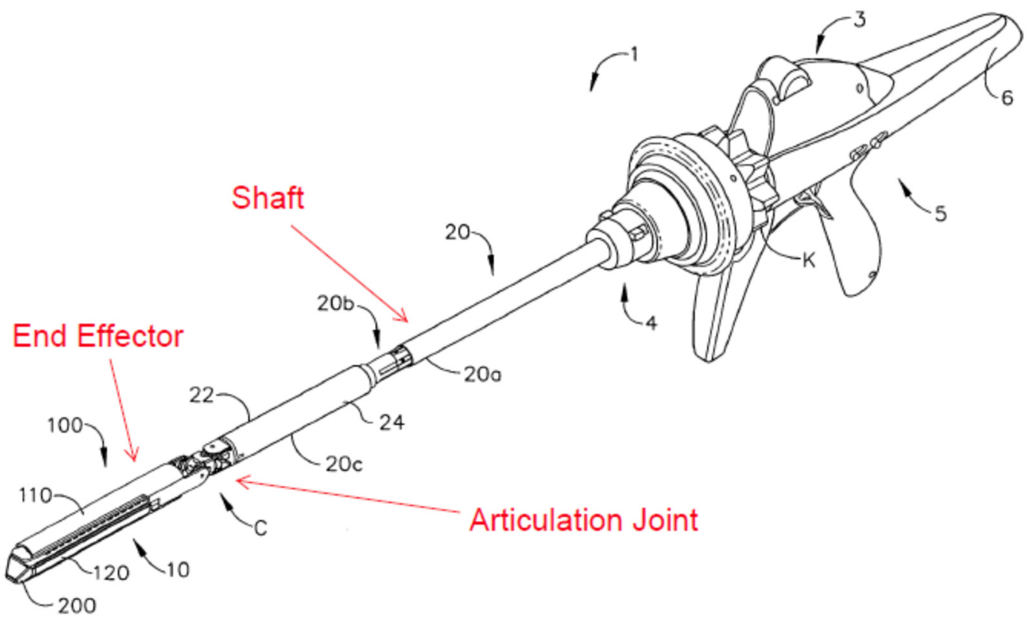


FIG. 1

The articulation is implemented by a proximal spine segment 2720 ("proximal spine portion") pivotally coupled to distal spine segment 2740 ("distal spine portion") at articulation ball joint 2760 ("articulation joint"), as shown in FIG. 52:

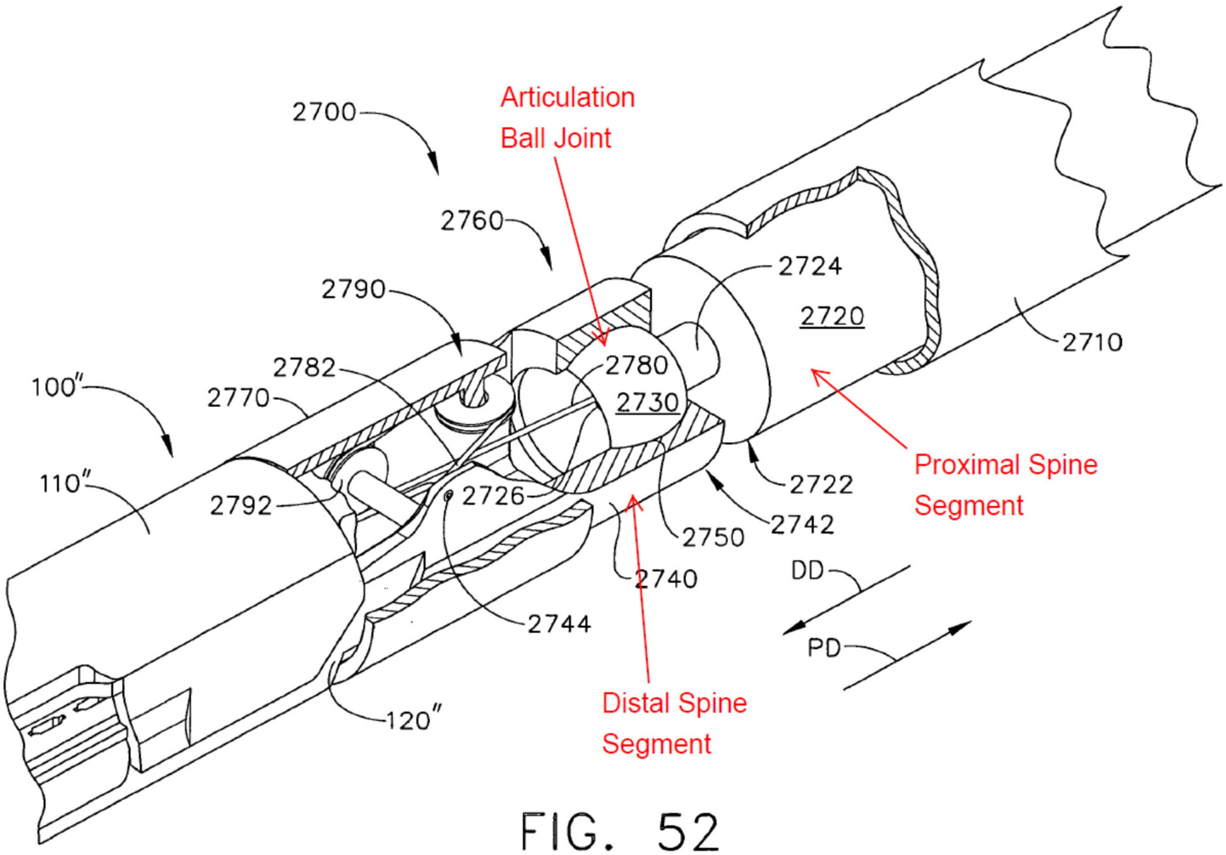


FIG. 52

IS1011, FIG. 52; 28:50-29:3; *see also* FIGs. 62-66; 31:62-32:31; 30:58-31:35.

A POSITA would have been motivated to use Timm's end effector with Anderson for several reasons. **First**, Timm's end effector provides surgical stapling, which is one of the stated possible uses of the Anderson robotic system. IS1010, 7:15-23. In essence, Anderson discloses a robotic surgical system that can accommodate virtually any surgical instrument that can be controlled by the rotary actuators of Anderson, 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.

Second, Timm's surgical stapler offers the benefits of articulation and dynamic clamping which would enhance Anderson's robotic surgical system for the reasons discussed in Timm itself. IS1011, 9:12-21. ***Third***, Timm has an end effector controlled by rotary motion, and Anderson provides rotary motion. **Fourth**, Timm teaches the benefits of gears in a "quick disconnect" system in a stapler. Thus, a POSITA would combine Timm's gears with Anderson's interface designed for use with staplers, among other instruments. IS1004, ¶75-83.

> ***[24.P] 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 and is configured to provide at least one rotary output motion to at least one rotatable body portion supported on the tool drive assembly, said surgical tool comprising:***

The preamble of claim 24 is identical to the preamble of claim 23 and is therefore disclosed by Anderson for the reasons discussed with respect to element [23.P]. *Supra*, analysis of element [23.P]; IS1010, FIGs. 1-3; 10:65-11:42; 4:7-11; Abstract; 10:21-64; 11:59-12:22; 5:61-6:8; IS1004, ¶84.

> ***[24.1] 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 in response to control motions applied to said selectively movable component portion;***

Element [24.1] is identical to element [23.1] and is therefore disclosed by Anderson for the reasons discussed above. *Supra*, analysis of element [23.1];

IS1010, FIGs. 10, 20; 11:32-36; 15:3-60; 16:7-23; 16:62-17:22; 10:40-12:22; 22:8-20; 24:54-65; 18:20-24; IS1004, ¶85.

Timm also discloses element [24.1] in at least two ways. IS1004, ¶86.

As a **first** example, Timm discloses a "dynamic clamping member 150" having a "knife 155" which can be "part of the replaceable staple cartridge assembly." IS1011, 10:1-10; 9:31-55.

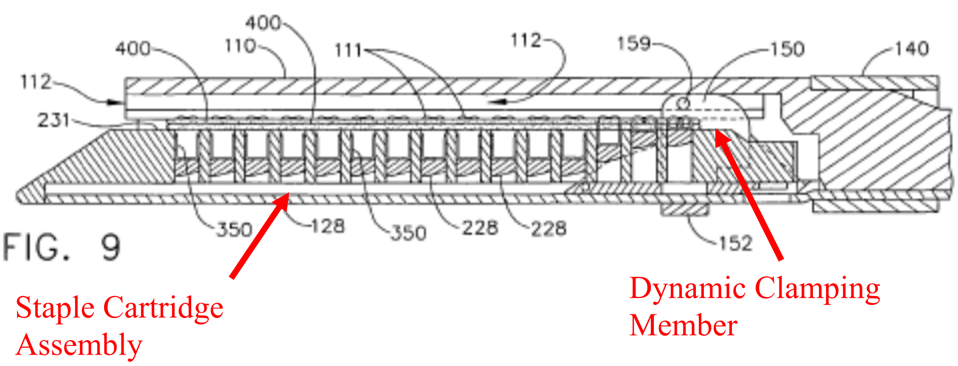


FIG. 9

The "dynamic clamping member" moves through the cartridge when the stapler is fired, and it is thus a selectively movable component that moves relative the rest of the cartridge. IS1011, 11:36-56. The dynamic clamping moves in response to control motions generated by a gear assembly. IS1011, 11:36-56; 14:39-15:12; FIGs. 18-21; IS1004, ¶86.

In a **second** example, Timm's stapling end effector includes a "closure ring" that pushes the anvil to pivot the anvil closed. The closure ring is thus another selectively movable component that moves relative to the rest of the end effector and relative to the anvil specifically.

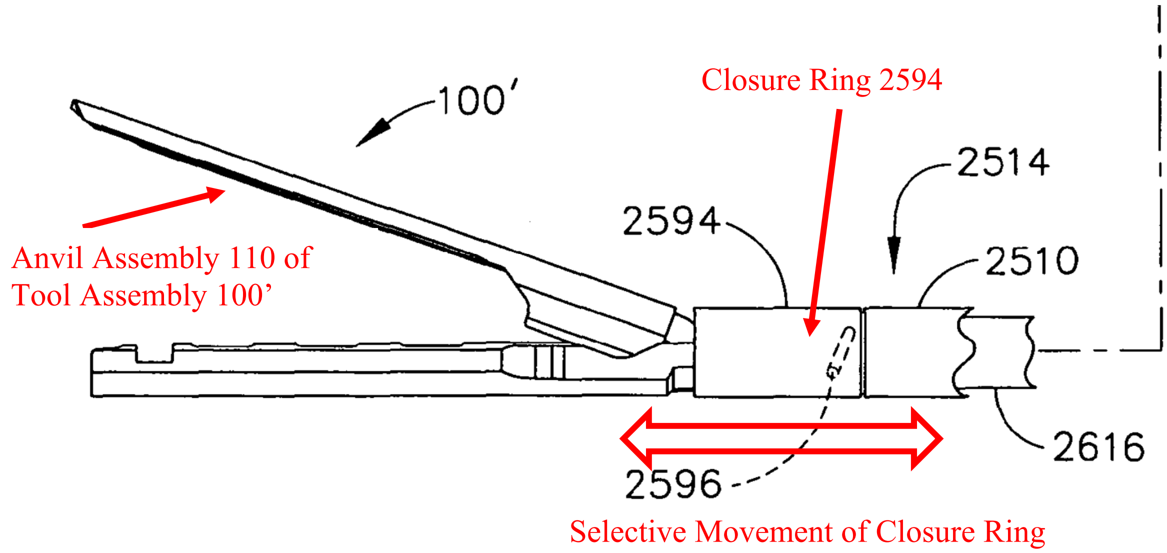


FIG. 49

IS1011, FIG. 49, 27:38-47.

The closure ring is actuated by a radial gear. IS1011, 27:6-24.

[24.2] an elongated shaft assembly defining a longitudinal tool axis and comprising: a distal spine portion operably coupled to said end effector; and a proximal spine portion pivotally coupled to said distal spine portion at an articulation joint to facilitate articulation of said surgical end effector about an articulation axis that is substantially transverse to said longitudinal tool axis; and

Anderson in view of Timm discloses element [24.2]. IS1004, ¶¶88-92.

"<u>an elongated shaft assembly defining a longitudinal tool axis,</u>"

Every example of Anderson's surgical instrument includes a shaft defining a longitudinal tool axis, such as shaft 307, which is part of an elongated shaft assembly that may include shaft 307, outer sheath 312, actuator rods, and spools or gears. IS1010, 22:8-19; 5:11-17; 23:25-30. The shaft assembly defines longitudinal "instrument axis 311" as shown in FIG. 20:

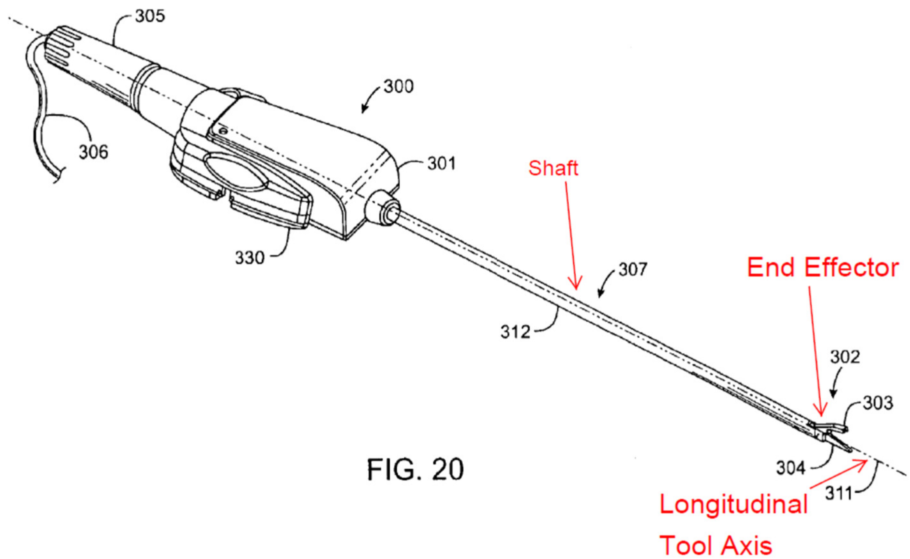


FIG. 20

IS1010, FIG. 20; 21:66-22:11.

Each embodiment in Timm also discloses a shaft assembly defining a longitudinal axis, including a shaft and various other components, such as gears, cables, articulation mechanisms, quick release mechanisms, etc. (*see generally,* IS1010, FIGS. 1, 41-44, 50-90. The shaft portion of the shaft assembly is labeled 20 in FIG. 1:

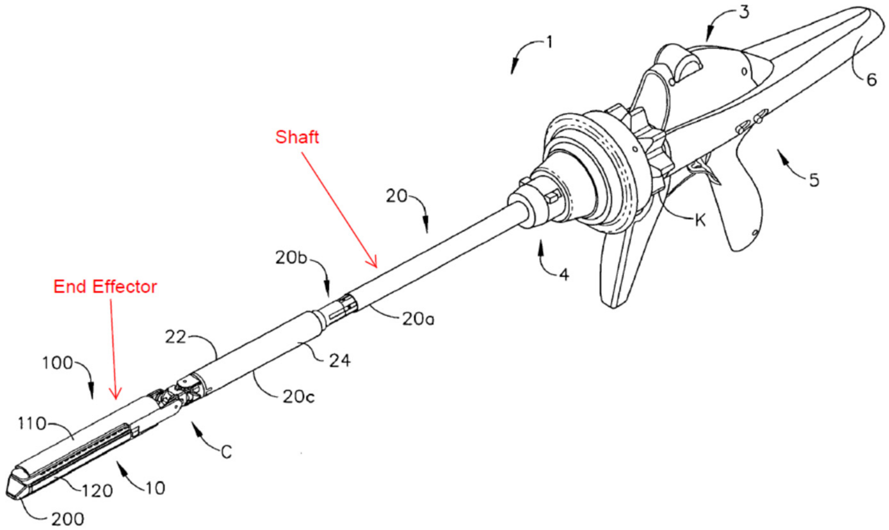


FIG. 1

IS1011, FIG. 1.

"a distal spine portion operably coupled to said end effector"

Timm discloses that "the ***distal spine segment*** 2740 is attached to the elongate channel assembly 120" to which the anvil 110" is pivotally attached." IS1011, 28:65-29:3. Timm's elongate channel assembly 120" and anvil 110" make up the end effector of Timm's surgical instrument. IS1011, 28:65-29:3; 8:3-16; 9:12-30; IS1004, ¶89.

"a proximal spine portion pivotally coupled to said distal spine portion at an articulation joint to facilitate articulation of said surgical end effector about an articulation axis that is substantially transverse to said longitudinal tool axis"

Timm's elongate shaft includes "proximal spine segment 2720" pivotally coupled to "distal spine segment 2740" by "articulation ball joint 2760" as shown in FIG. 52:

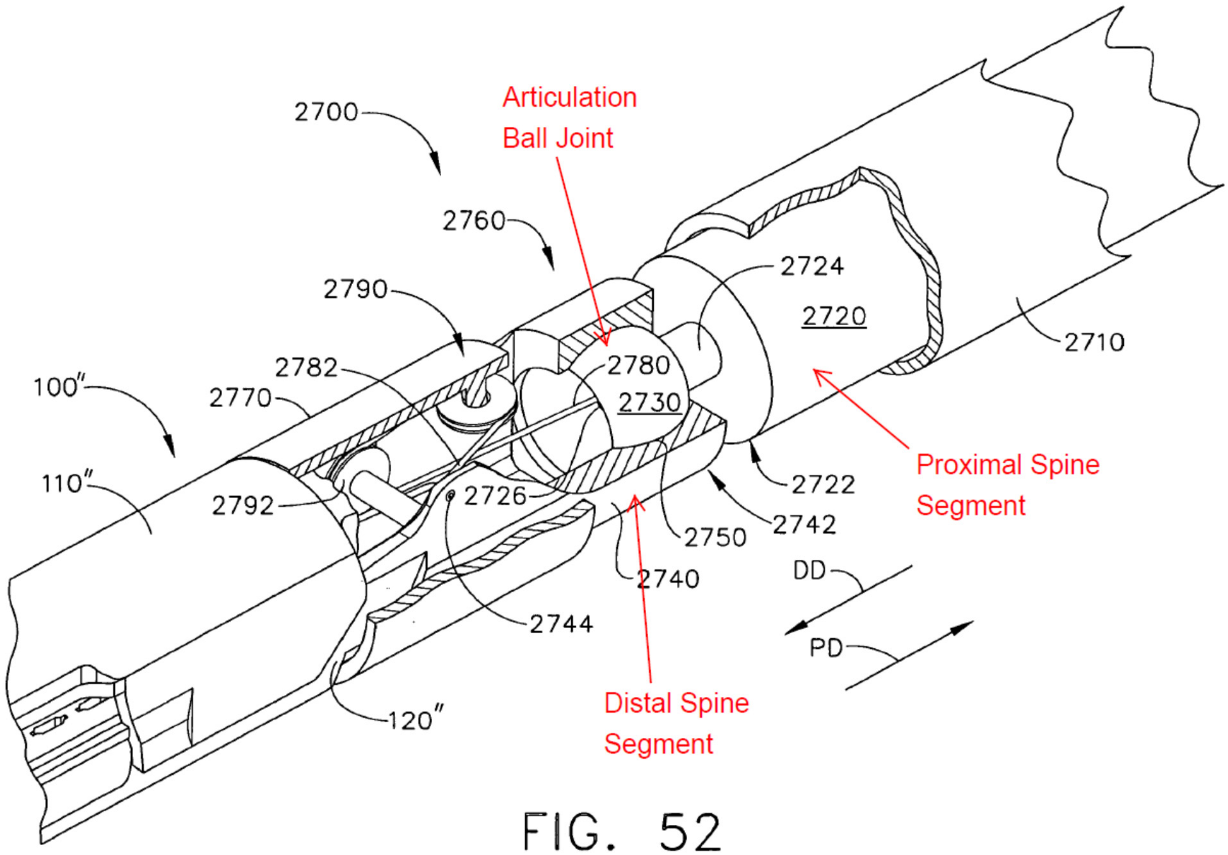


FIG. 52

IS1011, FIG. 52; 28:50-29:3; *see also* FIGs. 62-66; 31:62-32:31 (describing "lockable articulation joint" pivotally coupling proximal and distal spine segments); IS1004, ¶90. As shown in FIG. 52, the proximal spine segment defines a longitudinal tool axis. The articulation ball joint 2760 "affords the distal spine segment 2740 the ability to articulate in multiple directions relative to the proximal spine segment 2720," which, as a POSITA would have recognized, are all about articulation axes that are substantially transverse to the longitudinal tool axis defined by the shaft (Y and Z axes are transverse to the shaft axis). IS1011, FIG. 52; 9:2-4; 28:41-29:3; IS1004, ¶90.

Multiple reasons would have prompted a POSITA to modify Anderson to include pivotally coupled distal and proximal spine portions (as suggested by Timm). **First**, a POSITA would have recognized that such a configuration would provide "the ability to articulate in multiple directions relative to the proximal spine segment," thereby allowing a surgeon to better approach a surgical site from the correct angle, improve performance, and increase utility of the device. IS1011, 22:56-65; 9:2-4; IS1004, ¶¶90, 91.

Second, Anderson contemplates that its instruments will provide "wrist-like rotational or pivotal joint" movements, and Timm provides the necessary details for implementing such a joint. IS1010, 6:43-54; IS1004, ¶91.

Third, Timm provides details on how to construct a particular surgical stapler and provide the various drive mechanisms for use with such a surgical stapler. A POSITA would have recognized that the proximal and distal spine segments connected via an articulation joint of Timm's surgical stapler would provide the benefits of increased directional control within a patient. IS1010, 7:15-25; IS1011, 8:3-16; 28:41-29:3; 35:36-63; IS1004, ¶91.

Fourth, Timm specifically teaches that its "proximal spine segment 2720 … may be supported [by] any one of a number of known arrangements," including being "removably associated with a … robotic or computer" actuator such as that which Anderson describes. IS1010 11:59-65 ("actuators, such as electric motors");

IS1011, 28:45-49; 8:3-7; *see also* 12:1-3 ("[U]se of the above described tool assembly 100 as part of a robotic system is also envisioned."); IS1004, ¶91.

Fifth, a POSITA would have been prompted to combine Anderson and Timm to use Timm's surgical stapler adapted for use with the Anderson robotic system because doing so would be merely the application of a known technique (surgical stapler design) to a known system (e.g., Anderson's surgical robot) ready for improvement to yield predictable results. IS1004, ¶91; *KSR*, 550 U.S. at 417. Here, both Anderson and Timm disclose surgical instruments having shafts and end effectors and configured to releasably couple to a robotic surgical system, and a POSITA would have recognized that applying Timm's suggestions to Anderson's surgical instrument would have led to predictable results without significantly altering or hindering the functions performed by Anderson's surgical instrument. IS1004, ¶91.

[24.3] at least one gear-driven portion that is in operable communication with said at least one selectively movable component portion of said surgical end effector and wherein said surgical tool further comprises:

Anderson in view of Timm discloses element [24.3]. IS1004, ¶¶93-103. Although Anderson is primarily directed toward embodiments that rely on spool-and-cable assemblies to drive motion of the end effector, Anderson also contemplates "other actuation interface devices" such as "a gear train or other mechanical transmission means." IS1010, 15:48-60; 16:62-17:9; 23:25-36.

Timm discloses at least two selectively movable components that are actuated by—and thus in operable communication with—gear-driven portions: (1) the dynamic clamping member and (2) the closure ring.

With respect to the **first** example, the "dynamic clamping member 150" having "knife 155" is selectively movable relative to the anvil and cartridge of the end effector, and is in operative communication with a gear-based winch assembly via advance and retraction cables that connect the winch assembly to the dynamic clamping member. IS1011, 13:4-26. "[T]he advance cable 1302 and the retract[ion] cable 1330 may be driven by, for example, a cable drive system 1000 which, for example, may comprise a manually actuatable winch assembly 1001," as shown in FIG. 17:

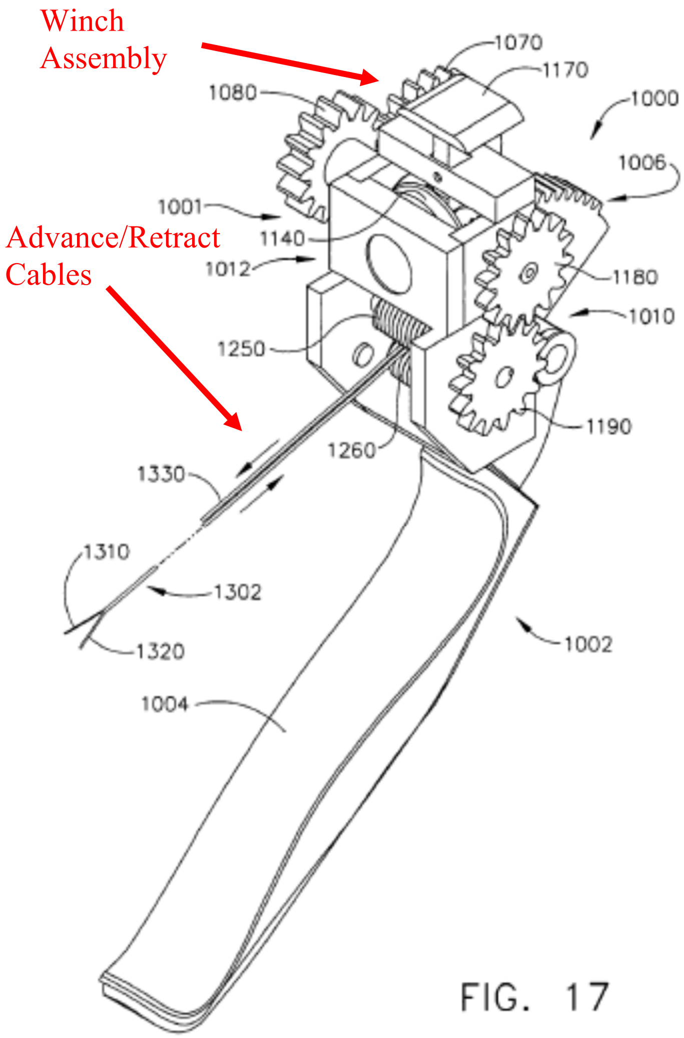


FIG. 17

IS1011, 13:27-31; FIG. 17. The winch assembly 1001 is comprised of many gears and gear-driven portions, including "gear segment 1006," "primary drive gear 1040," "second drive gear 1070," "third drive gear 1080," etc. as shown in FIG. 18:

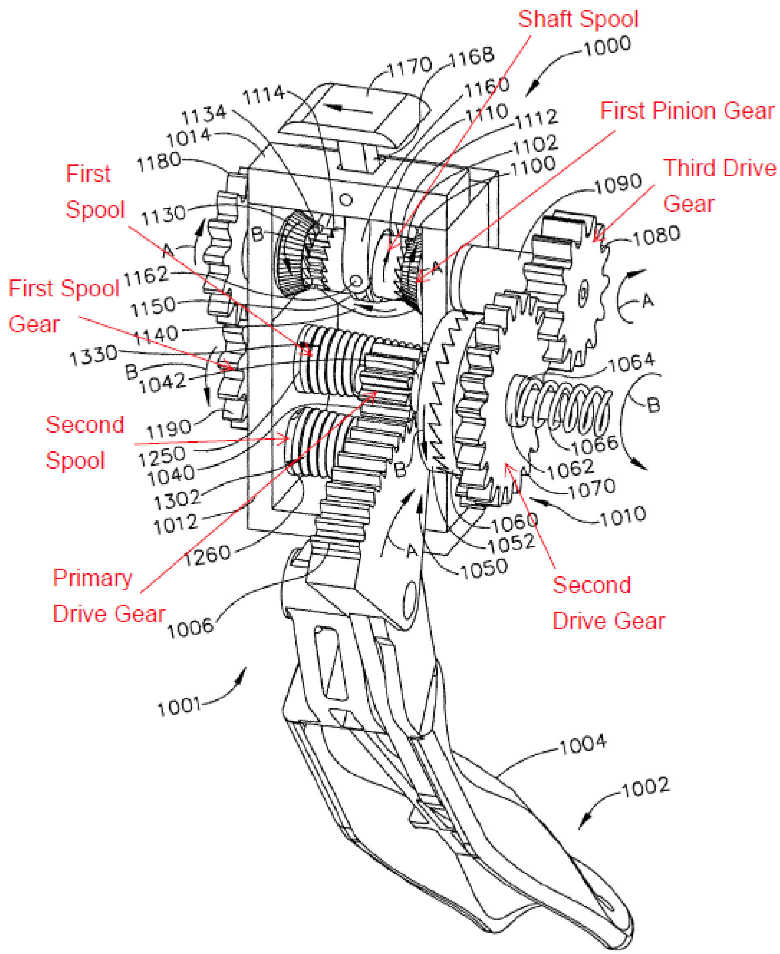


FIG. 18

IS1011, FIG. 18; 11:36-56; 14:39-15:12. IS1004, ¶95.

As shown in FIG. 15, the advance cable 1302 and the retraction cable 1330 are connected to dynamic clamping member 150, and are gear-driven:

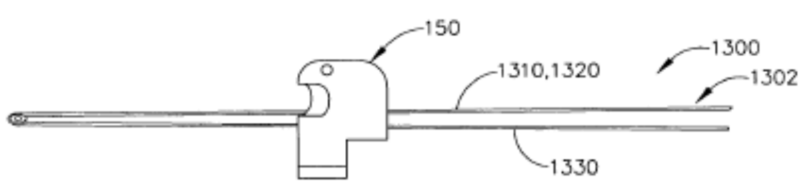


FIG. 15

IS1011, FIG. 15; 13:4-42, 14:25-15:12, 16:1-29. Pulling firing trigger 1004 moves one or more gears (e.g., primary drive gears), which applies a force to at least one "gear-driven portion[]" (e.g., second spool 1260), which applies tension to advance cable 1302 to move a "selectively movable component portion of [the] surgical end effector" (e.g., the dynamic clamping member).

As shown in FIG. 18 (above), "first teeth 1102 of the first pinion gear 1100 are ***in meshing engagement with*** the primary teeth 1112 of the shaft spool 1110," thereby making the shaft spool 1110 a "gear-driven portion." IS1011, FIG. 18; 14:39-15:12. Also, the first spool 1250 drives the second spool 1260 "to wind up the advance cable 1302" via "first spool transfer gear 1220, reversing gear 1230, and second spool drive gear 1240":

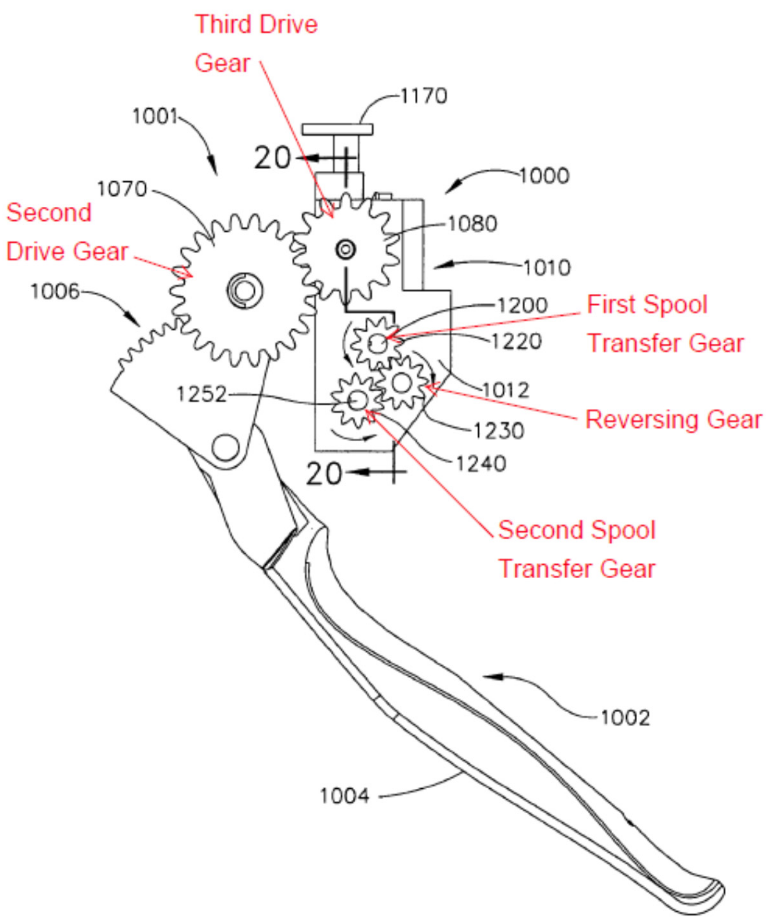


FIG. 19

IS1011, 14:39-15:12; FIGs. 18-19. The gears that cause rotation of the first and second spools are therefore also gear-driven portions which advances the dynamic clamping member 150. IS1004, ¶97; IS1011, 15:13-25; *see also* FIG. 21; 18:1-52 (describing an embodiment in which "a drive gear 1410 [] is in meshing engagement with a rack 1420" to "advance the dynamical clamping member 150, knife 155, and sled 160 in the distal direction").

Timm discloses another example of a gear-driven knife/dynamic clamping member with respect to FIGs. 83-84:

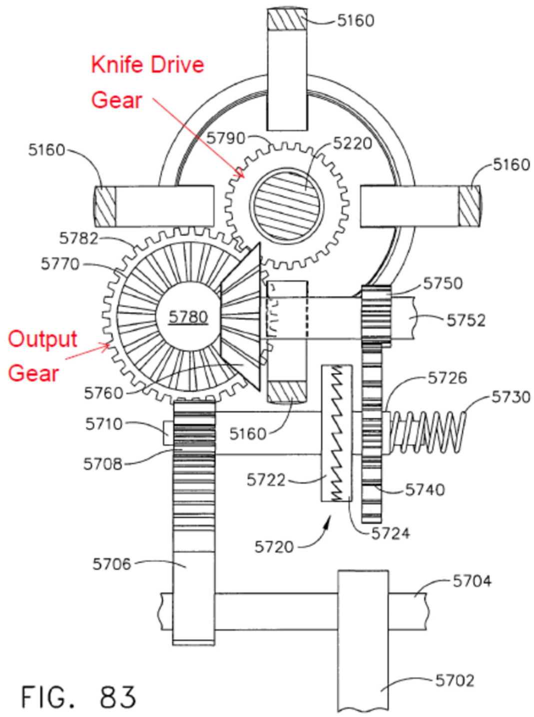


FIG. 83

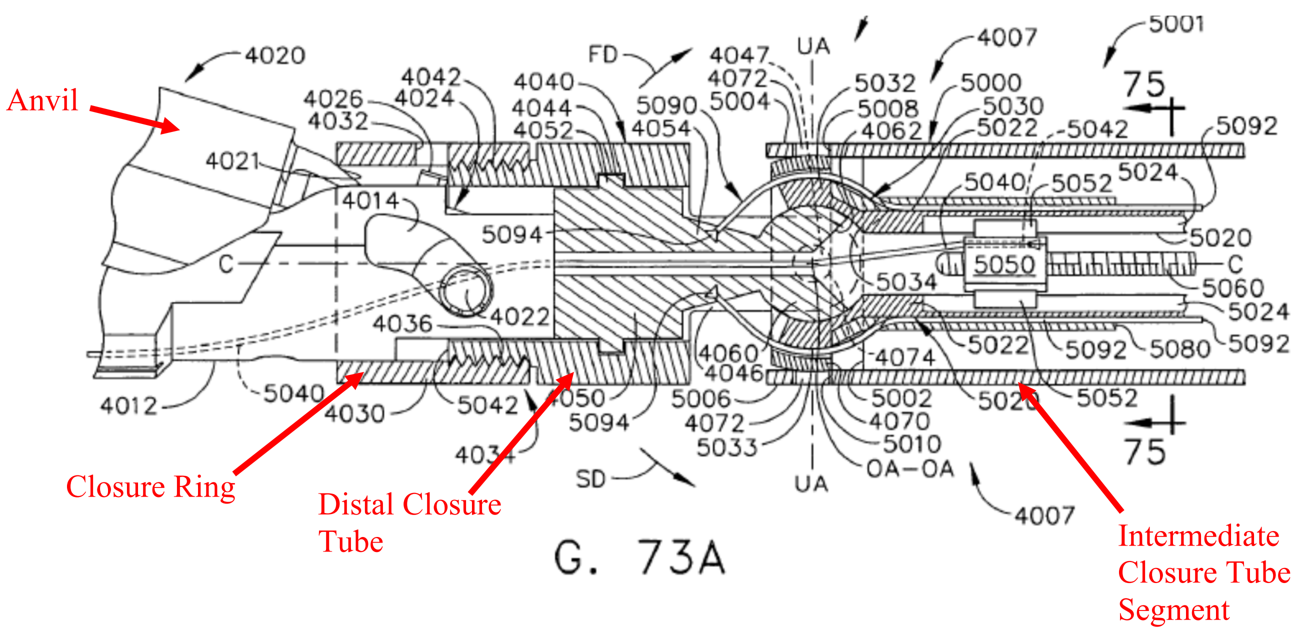
IS1011, FIG. 83; Fig. 82, 42:4-36. The "output gear 5782 [is] … in meshing engagement with a knife drive gear 5790 attached to the proximal end 5226 of the knife drive shaft 5220" (a gear-driven portion within the shaft assembly of Timm). *Id.*; IS1004, ¶98.

A POSITA would have understood that the combination of Anderson and Timm would include Timm's surgical stapler end effector and shaft (as described above), and would have included part or all of any of the specific gear-driven actuation assemblies described by Timm to drive the motions of Timm's surgical tool. IS1004, ¶99. This is especially true given that Anderson contemplates "other actuation interface devices," such as "a gear train or other mechanical transmission means," and Timm discloses that its surgical instrument "may be supported [by] any one of a number of known arrangements," including being "removably associated with" a "robotic or computer" actuator such as that which Anderson describes. IS1010, 23:25-36; IS1011, 28:45-49; 8:3-7; *see also* 12:1-3 ("[U]se of the above described tool assembly 100 as part of a robotic system is also envisioned."); IS1004, ¶99.

Furthermore, A POSITA would have recognized that use of Timm's gear mechanism for driving the knife/dynamic clamping member would have allowed for "changes in the gear ratios … to attain improved mechanical advantages for driving the knife assembly 170 (dynamic clamping assembly 150, knife 155, sled 160) within the elongate channel assembly." IS1011, 19:22-27; IS1004, ¶100. A POSITA would have therefore elected to use the known gear-driven actuation assemblies described by Timm to activate the end effectors in the system resulting from the predictable combination of Anderson with Timm to achieve predictable advantages. IS1004, ¶100.

A POSITA would have understood that in the combination of Anderson and Timm, the surgical stapler end effector, shaft, and actuation assemblies of Timm (as described above) would be driven by Anderson's rotary robotic interface in the tool mounting portion. In the combination, the trigger of Timm (which imparts a rotary actuation motion) would be replaced with the rotatable body portion of Anderson, with the driven gear positioned at the proximal end of the shaft in the combination. IS1004, ¶101.

Turning to the **second** exemplary selectively movable component disclosed by Timm, Timm discloses a "gear-driven portion" that is movable to drive the closure ring to pivot the anvil from an open to closed position relative to the staple cartridge. *See* IS1011, FIGs. 50, 48; 27:25-52; 10:54-11:7. Specifically, when "closure ring 4030 is driven axially in the distal direction DD [i.e., to the left of FIG. 73A] … it rides up a ramp 4021 … to cause the anvil assembly 4020 to pivot to a closed position." *Id.* Closure ring 4030 moves axially when the distal closure tube segment 4040, which is threadedly engaged with closure ring 4030, is rotated relative to closure ring 4030. *Id.*



G. 73A

The distal closure tube segment is driven by the intermediate closure tube segment in the shaft of the device. IS1011, 38:25-44, 36:45-37:8, 35:64-36:24;

FIG. 73A; IS1004, ¶102.

The intermediate closure tube segment 5001 is gear-driven. IS1011, 38:25-44. The intermediate closure tube segment 5001 is driven by the proximal closure tube segment 5020 at a "quick disconnect" interface between the disposable reload unit 4002 and the permanent portion of the instrument. *Id*. To facilitate the easy connection and disconnection of the intermediate closure tube segment from the proximal closure tube segment, the two segments are coupled via radial gears on the face of each closure tube segment. IS1004, ¶103. When a new disposable portion of the instrument is inserted into the quick disconnect feature, the radial gear teeth 5003 of the intermediate closure tube are pushed into meshing engagement with the radial gear teeth 5124 of the proximal closure tube, thus allowing the rotation of the proximal closure tube to drive the rotation of the intermediate closure tube. *Id.*; IS1011, 38:25-44. The intermediate closure tube is thus a "gear-driven portion."

The specification of Timm explains: "[The] intermediate closure tube segment 5001 has a series of ***radial gear teeth*** 5003 formed thereon for ***meshing engagement with gear teeth 5124*** … on a distal end 5122 of a proximal closure tube segment 5020" such that rotation of the proximal closure tube causes rotation of the intermediate closure tube. IS1011, 38:37-44.

The figures in Timm show where the radial gears are located. For example,

Figure 76 shows a front facing view of the intermediate closure tube with the radial gear teeth illustrated as boxes around the circumference of the intermediate closure tube face:

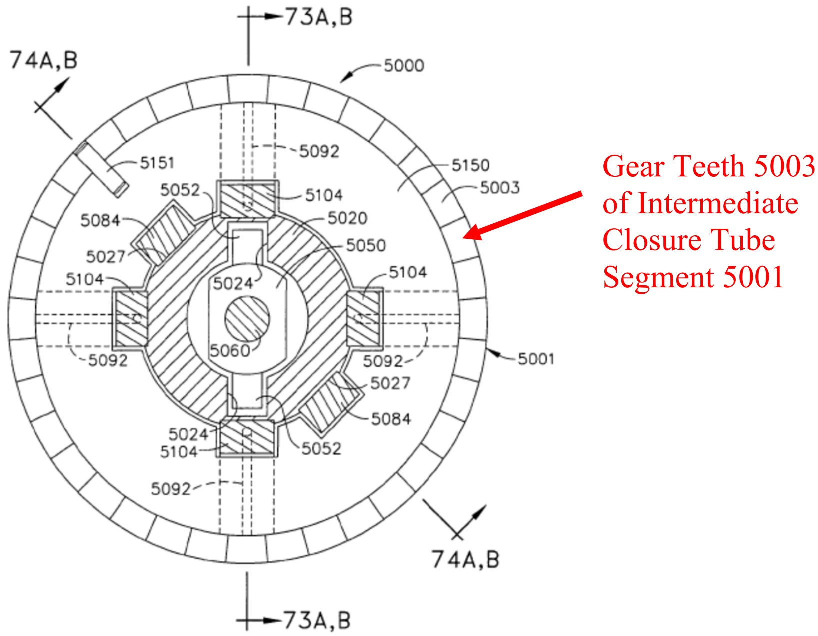
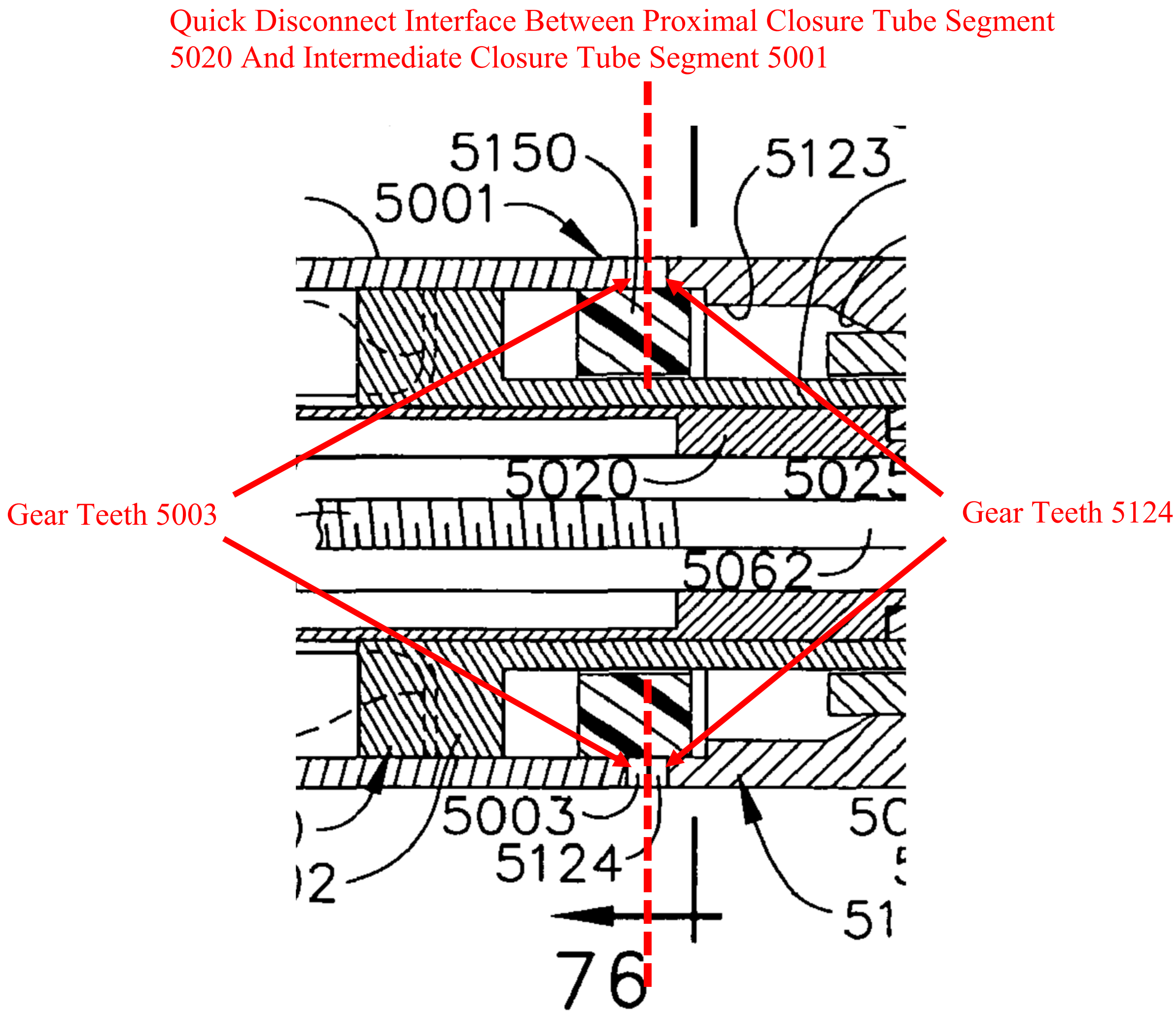


FIG. 76

IS1011, FIG. 76. A cross sectional view of the radial gears are shown in FIG. 73B, which illustrates the quick disconnect feature 4008. The following excerpt shows the location of the radial gears:



IS1011, FIG. 73B (excerpt).

A POSITA would have been motivated to use Timm's gear-driven closure mechanism with the Anderson system to gain the benefit of Timm's "quick disconnect" feature, which "facilitate[s] quick detachment of a reload unit 4002 and reattachment of a new reload unit 4002 without the use of tools." IS1011, 38:25-57. IS1004, ¶104. Furthermore, a POSITA would have understood that in the combination of Anderson and Timm, the surgical stapler end effector, closure tube, and actuation assemblies of Timm (as described above) would be driven by Anderson's rotary robotic interface in the tool mounting portion. IS1004, ¶104.

[24.4] a tool mounting portion operably coupled to a [proximal/distal]*[3] *end of said proximal spine portion, said tool mounting portion being configured to operably interface with the tool drive assembly when coupled thereto, said tool mounting portion comprising:

Anderson in view of Timm discloses element [24.4]. In Anderson, the "instrument base," which interfaces the surgical tool to the arm assembly of a robotic surgical system's "surgical work station 20," is the tool mounting portion. IS1010, 11:35-38. In the combination, Anderson's tool mounting portion would be operably coupled to the proximal end of the proximal spine portion of Timm's shaft assembly via a direct connection. IS1004, ¶105; IS1010, 22:8-33; 22:59-67; 18:20-24; 11:66-12:22; FIGs. 1, 3, 20. Anderson's tool mounting portion is also configured to engage "[a] robotic surgical system interface" which couples the tool mounting portion to the tool drive assembly. IS1010, 22:20-33; 22:59-67. *See* analysis for nearly identical element [23.3] above.

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[3] On January 23, 2018, the PTO entered a Certificate of Correction replacing the word "distal" with the word "proximal" in element [24.4]. IS1002, 686. Petitioner contends the Certificate was not effective, and applies the claim both with and without the Certificate.

If the January 23, 2018 Certificate of Correction is not effective, then Anderson in view of Timm still discloses this limitation. IS1004, ¶105. Specifically, in the combination, Anderson's tool mounting portion would be operably coupled to the distal end of the proximal spine portion of Timm's shaft assembly via the structure of the distal spine portion itself. *Id*.; IS1010, 22:8-33; 22:59-67; 18:20-24; 11:66-12:22; FIGs. 1, 3, 20.

[24.5] a driven element rotatably supported on said tool mounting portion and configured for driving engagement with a corresponding one of the at least one rotatable body portions of the tool drive assembly to receive corresponding rotary output motions therefrom; and

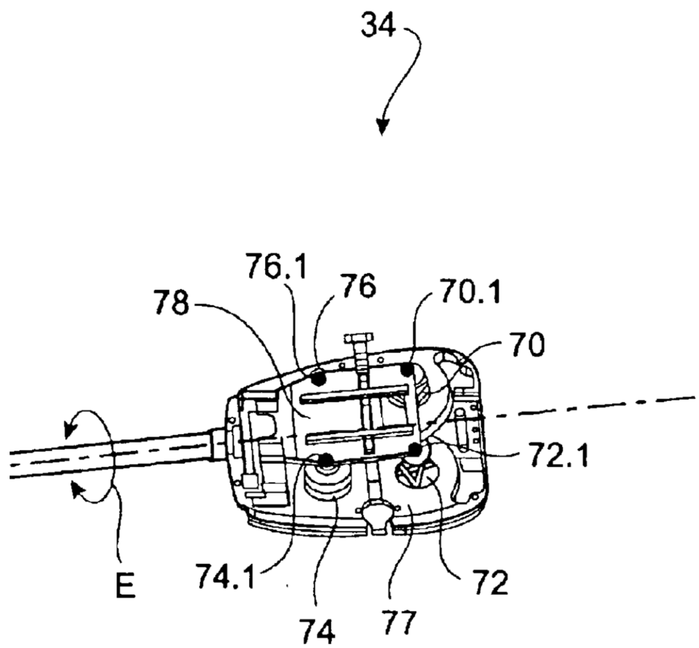
Anderson in view of Timm discloses element [24.5]. IS1004, ¶¶106-108.

"a driven element rotatably supported on said tool mounting portion"

Anderson discloses that the base of the surgical instrument includes several transmission members 70, 72, 74, and 76, which each include "spools secured on shafts 70.1, 72.1, 74.1, and 76.1" which are "configured to rotate." IS1010, 11:66-12:22. The shafts 70.1, 72.1, 74.1, and 76.1 constitute driven elements. IS1004, ¶107.

"configured for driving engagement with a corresponding one of the at least one rotatable body portions of the tool drive assembly to receive corresponding rotary output motions therefrom"

Anderson discloses that "[a]t the outer surface, each shaft 70.1, 72.1, 74.1, 76.1 includes an engaging member (not shown) configured to releasably couple with a ***complementary engaging member*** (not shown) rotatably mounted on the carriage 37 of a robotic arm assembly 26 (see FIG. 1)." IS1010, 11:66-12:22. FIG. 3 shows the shafts configured to couple to engaging members of the robotic arm assembly:



IS1010, FIG. 3 (partial). Anderson also discloses that the "instrument roll interface member 344" of FIGs. 21-22 is driven by rotational motion from the robotic tool drive assembly. IS1010, 22:59-23:30. As discussed above, this driven member can be "a gear train" such as "a right-angled helical gear pair." *Id.* The "engaging member," alone or in conjunction with one or more downstream elements is the recited "driven element." Anderson also explains that "instrument actuator interface member 353a and 353b" are driven by rotational motion from the robotic surgical system in a manner similar to the interface member 344. IS1010, 24:23-39. A POSITA implementing the system resulting from the combination of Anderson with Timm would have recognized that the shafts extending from the base of Anderson's surgical instrument would be used to drive the gear assemblies of the embodiments disclosed by Timm. IS1004, ¶108. *See also* discussion of the tool mounting portion and tool drive assembly in element [23.3] above.

> ***[24.6] a transmission assembly in operable engagement with said driven element and in meshing engagement with a corresponding one of said at least one gear-driven portions to apply actuation motions thereto to cause said corresponding one of said at least one gear-driven portions to apply at least one control motion to said selectively movable component.***

Anderson in view of Timm discloses element [24.6]. IS1004, ¶¶109-114. In the combination, Timm's end effector, shaft, and transmission assembly are modified to replace the Timm handle with the Anderson base (robotic surgical system interface with driven elements) so that the Anderson transmission members impart rotary motion to the transmission assembly. Anderson discloses that "[m]ovement of end effector 38" is caused by rotation of the transmission members 70, 72, 74, and 76 in response to rotation of "actuators, such as electric motors" of the robotic arm of the surgical system. IS1010, 11:59-12:22. Anderson further discloses that rotation of the actuation interface members 353a-b causes actuation of the end effector. IS1010, 24:31-65.

With respect to the **first** exemplary selectively movable component of Timm, the combination would have the transmission assembly of Timm driven by one of Anderson's transmission members to drive the knife and dynamic clamping member. For example, the embodiment of FIGs. 18-20 described above with respect to element [24.3] would be modified such that the primary drive gear receives rotational motion from one of Anderson's transmission members. IS1011, FIGs. 18-20; 14:39-15:12; IS1004, ¶110; IS1004, ¶110. In the alternative embodiment described with respect to FIG. 21, a POSITA would have recognized that "drive gear 1410 [] is in meshing engagement with a rack 1420" to "advance the dynamical clamping member 150, knife 155, and sled 160 in the distal direction." IS1011 FIG. 21; 18:1-52; IS1004, ¶111.

With respect to the embodiment of FIGs. 83-84, a POSITA would have understood that "drive gear 5750" would receive rotational motion from one of Anderson's transmission members, that the gears 5760 and 5782 form part of the transmission assembly, and that the knife drive gear, which drives advancement of the knife and dynamic clamping member, is in meshing engagement with output gear 5782. IS1011, FIG. 83; 42:4-36; IS1004, ¶112.

With respect to the **second** exemplary selectively movable component, the transmission assembly for the closure tube includes proximal closure tube segment 5020 in Timm's transmission assembly, which would be rotated by one of the Anderson transmission members in the resulting combination. The transmission assembly would thus be in meshing engagement with the gear-driven intermediate closure tube segment 5001. IS1011, 22:43-55; 38:34-44; 42:37-47; IS1004, ¶113; *see* discussion for element [24.3].

A POSITA would have understood that modifying Anderson to include the surgical stapler end effector, shaft, and transmission assemblies of Timm (as described above), would include part or all of the specific gear-driven transmission assemblies described by Timm to drive the closure ring, as Timm contemplates using "other actuation interface device," such as Anderson. IS1004, ¶114; IS1010, 23:25-36; IS1011, 28:45-49; 8:3-7; *see also* 12:1-3 ("[U]se of the above described tool assembly 100 as part of a robotic system is also envisioned."); IS1004, ¶115.

C. Ground 3: Claims 25-26 Would Have Been Obvious Under § 103 over Anderson in View of Timm and Wallace

[25] The surgical tool of claim 24 wherein said at least one gear-driven portion comprises an articulation system interfacing with said distal spine portion and said transmission assembly.

Anderson in view of Timm and Wallace discloses claim 25. IS1004, ¶¶116-124. Timm discloses a cable-driven articulation system. IS1010, 37:55-38:9. It would have been obvious in view of Wallace to replace Timm's cable-driven articulation system with the gear-driven articulation system of Wallace.

In fact, a POSITA would have recognized that, in the system resulting from the predictable combination of Anderson with Timm, Anderson contemplates "other actuation interface devices" such as "a gear train or other mechanical transmission means" and that this suggestion in Anderson for using a gear train would apply equally to all actuation motions, including actuation of articulation motion. IS1010, 23:25-36. Accordingly, Anderson itself suggests turning to a system such as Wallace's for teachings on gear-driven actuation. IS1004, ¶122; IS1008, 13:6-14:15; IS1010, 23:25-36.

Wallace discloses "a robotic surgical tool for use in a robotic surgical system" that, much like the surgical instruments of Anderson, includes a shaft for supporting a surgical end effector, the shaft supported by a "tool base 62 [that] includes an interface 64 which mechanically and electrically couples the tool 50 to a manipulator on the robotic arm cart" as shown in FIGs. 1 and 2A:

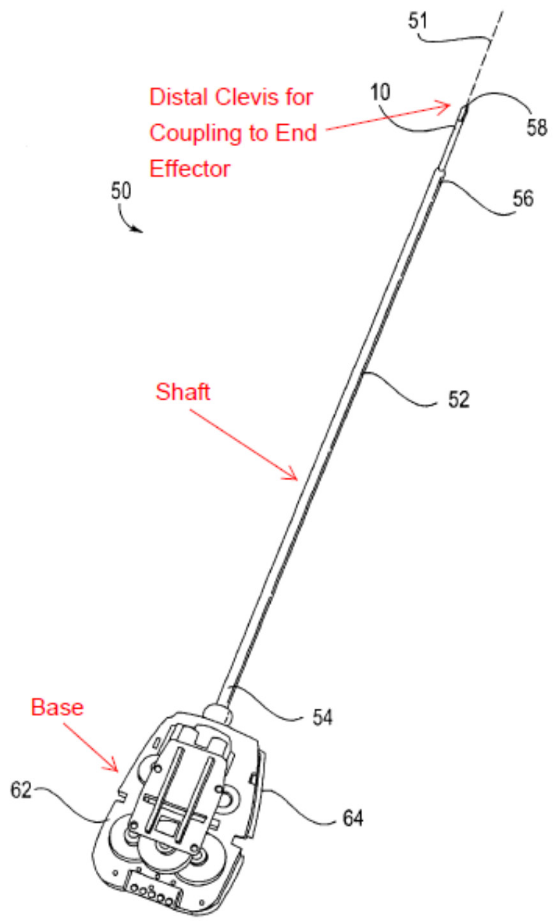


Fig. 1

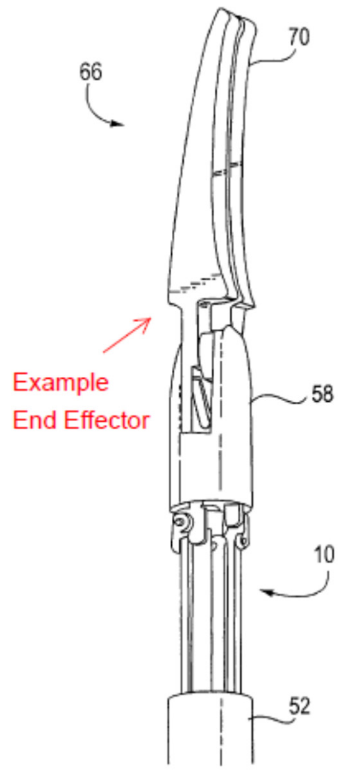
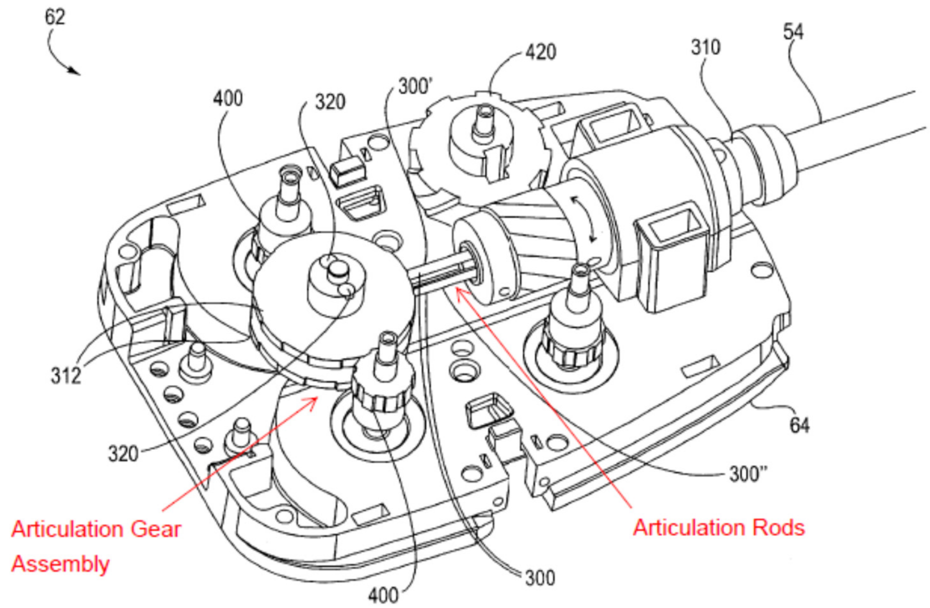
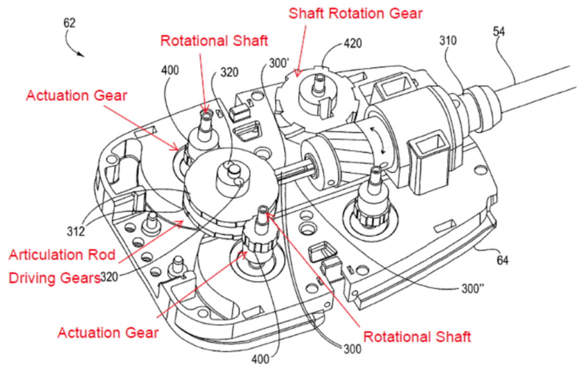
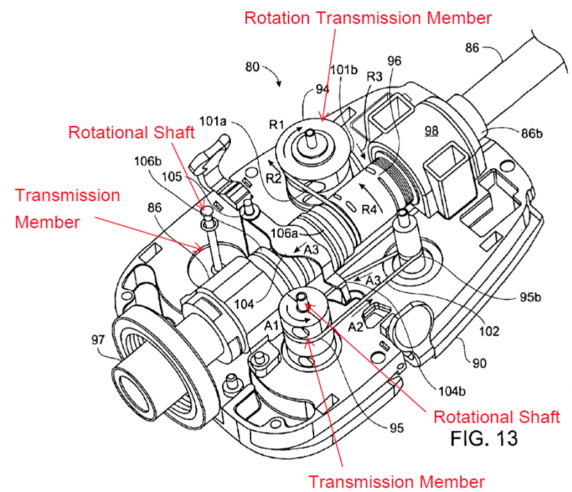


Fig. 2A

IS1008, FIGs. 1, 2A; Abstract; 7:33-56. Wallace further discloses an articulation assembly comprising a "wrist joint or mechanism" actuated by "a plurality of rods" that are driven by a gear assembly including "sector gears 312" and "gears 400" to advance and retract rods to cause articulation of the articulation wrist joint. IS1008, 7:57-65; 13:6-14:15; IS1004, ¶124.



IS1008, FIG. 30; 13:6-14:15. From this disclosure of Wallace, a POSITA would have understood that the articulation rods are "gear-driven" and that "[m]anipulation of the rods 300 actuates the wrist mechanism to position the ***distal*** clevis in a desired orientation." IS1008, 13:44-48; IS1004, ¶124. A POSITA would have understood that in the system resulting from the predictable combination of Anderson with Timm and Wallace, Timm's cable-driven articulation joint would be replaced with Wallace's gear-driven articulation rods, which would connect to the distal spine segment of Timm. IS1004, ¶124. As is apparent from FIG. 30 of Wallace, the gears 400 of Wallace would interface with the transmission members of Anderson:

Wallace	**Anderson**
Figure 30	FIG. 13

For example, Anderson has four transmission members, and one would be used for end effector rotation, one would be used for opening and closing the end effector jaws, and two would be used for articulation (one for each degree of freedom). Each articulation transmission member would control two reciprocating articulation rods. IS1004, ¶124; IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; 16:25-32; FIGs. 3, 13, 21-22; IS1008, 13:44-14:15; 13:6-25. Therefore, a POSITA would recognize that the gears 400 and sector gears 312 of Wallace, in combination with the rotational shafts of Anderson, form at least part of the transmission assembly that drives the articulation rods.

Multiple reasons would have prompted a POSITA to modify the system of Anderson and Timm to include a gear-driven articulation assembly (as suggested by Wallace). **First**, a POSITA would have recognized that Timm discloses an "active articulation system … for applying articulation motions to the distal spine segment" and further contemplates use with "a robotic system" but only provides details for the active articulation system that are relevant to a handheld (rather than robot-driven) surgical instrument, and that Wallace provides the details necessary for implementation of active articulation with a robotic surgical system. IS1011, 12:1-3; 8:3-7; 37:55-38:8; 40:34-63 (describing manual manipulation of Timm's articulation assembly); IS1008, Abstract; 7:33-56; 13:6-14:15; IS1004, ¶119.

Second, a POSITA would have been motivated to modify the system of Anderson and Timm to include a gear-driven articulation assembly (as suggested by Wallace) because Wallace's articulation wrist assembly "allows ease of assembly, reduction of parts and an increased range of motion." IS1008, 10:59-67; IS1004, ¶120. As Wallace states, the "simple" articulation design "reduce[s] possible points of failure." IS1008, 2:61-3:5.

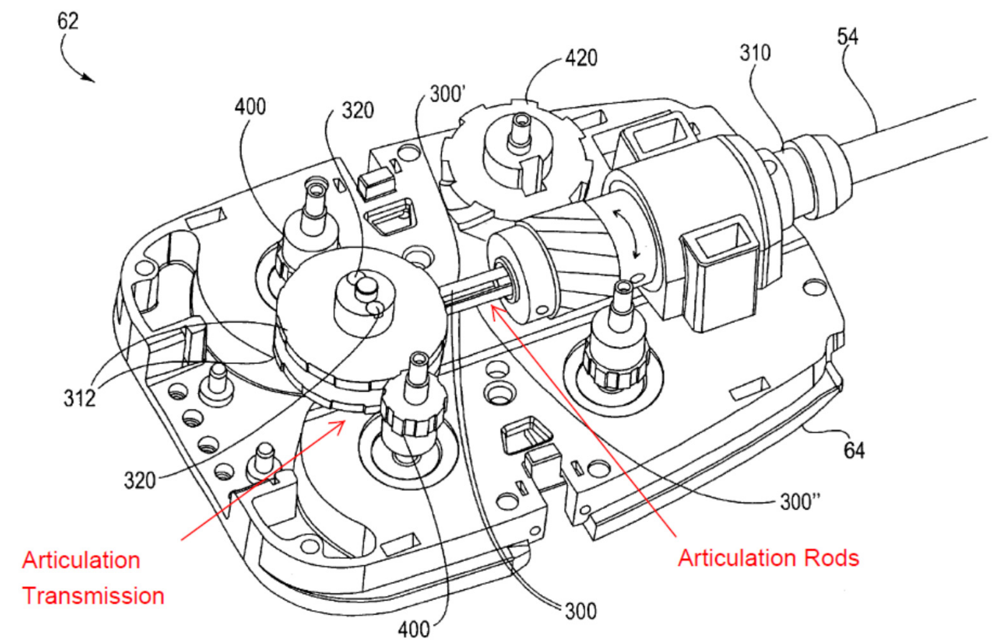
Third, a POSITA would have been prompted to modify the system of Anderson and Timm to include Wallace's gear-driven articulation assembly because doing so would be merely the application of a known technique (gear-driven articulation) to a known system (e.g., Anderson's surgical system as modified by Timm) ready for improvement to yield predictable results. IS1004, ¶121; *KSR*, 550 U.S. at 417. Indeed, Anderson contemplates that "various alternatives, modifications and equivalents may be used," and Wallace suggests just such an improvement. IS1010, 25:10-11.

[26] The surgical tool of claim 25 wherein said transmission assembly comprises an articulation transmission and wherein said articulation system comprises: a first articulation bar having a distal end coupled to a proximal portion of said elongated shaft assembly at a first lateral point that is laterally offset in a first lateral direction from said articulation axis, said first articulation bar having a proximal end that operably interfaces with said articulation transmission; and a second articulation bar having a distal end coupled to said proximal portion of said elongated shaft assembly at a second lateral point that is laterally offset in a second lateral direction from said articulation axis, said second articulation bar having a proximal end that operably interfaces with said articulation transmission.

Anderson in view of Timm and Wallace discloses claim 26. IS1004, ¶125.

"<u>articulation transmission</u>"

As discussed with respect to claim 25, *supra*, the articulation gear assembly of Wallace that includes "sector gears 312" and "gears 400" as shown in FIG. 30 is an articulation transmission:



IS1008, FIG. 30; 13:6-14:14.

first/second articulation bar…

As shown in FIG. 3, Wallace's articulation assembly includes four laterally offset articulation bars (rods 14) that "extend through a guide tube 20" of the proximal portion of Wallace's shaft and terminate at the "distal member 12":

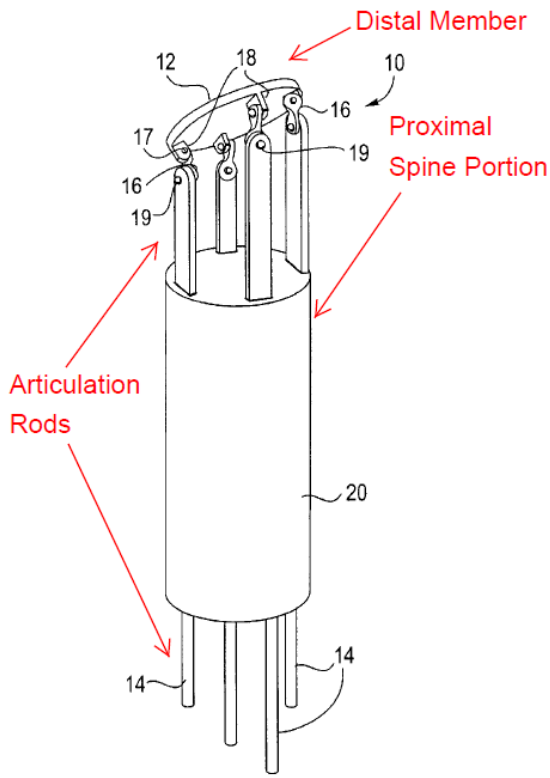


Fig. 3

IS1008, FIG. 3; 7:57-8:12; IS1004, ¶127. As seen in FIG. 3, the articulation rods are laterally offset in different lateral directions and they each have a distal end coupled to the proximal portion of the elongated shaft assembly via the rods sliding through the guide tube 20. Wallace describes that "[a]s the rods 14 are slid up and down the guide slots 30 of the guide tube 20, the orthogonal linkages 16 transfer the motion to the distal member 12." IS1008, 8:13-24.

"<u>[first/second] articulation bar having a proximal end that operably interfaces with said articulation transmission</u>"

The proximal ends of the rods (i.e., articulation bars) are coupled to the sector gears by pins 320 such that "by rotating the sector gear 312 clockwise, rod

300′ is advanced while rod 300″ is retracted," and "[m]anipulation of the rods 300 actuates the wrist mechanism to position the distal clevis in a desired orientation" as shown by FIG. 29:

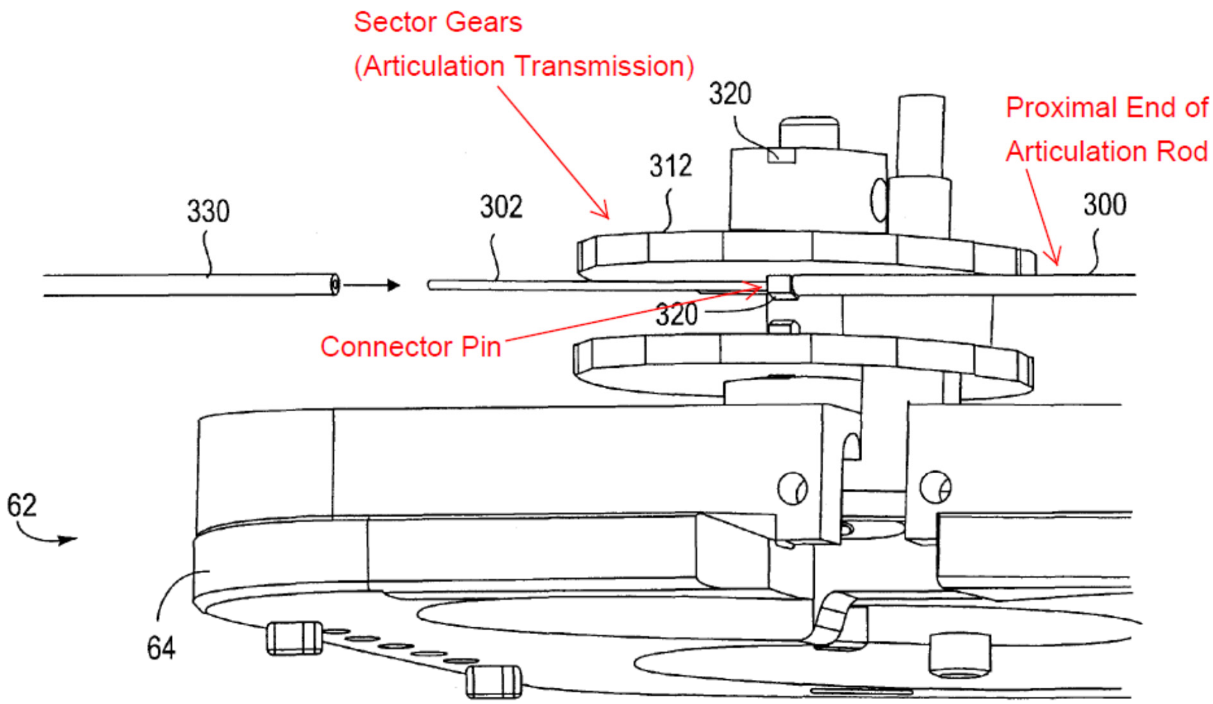


Figure 29

IS1008, FIG. 29, 13:44-14:14; *see also* FIGs. 24-30.

D. Ground 4: Claims 19-20 Would Have Been Obvious Under § 103 over Anderson in View of Knodel

Claim 19 recites the standard elements discussed above in addition to "a knife bar that is movably supported within said elongated shaft assembly for selective axial travel therein, said knife bar interfacing with said cutting instrument." Knodel describes precisely such a configuration. Specifically, Knodel describes "[a] surgical stapler instrument … for applying lateral lines of staples to tissue while cutting the tissue between those staple lines." IS1012, Abstract. Similar to the system of Anderson, Knodel's surgical instrument includes an end effector supported by a shaft, as shown in FIG. 1:

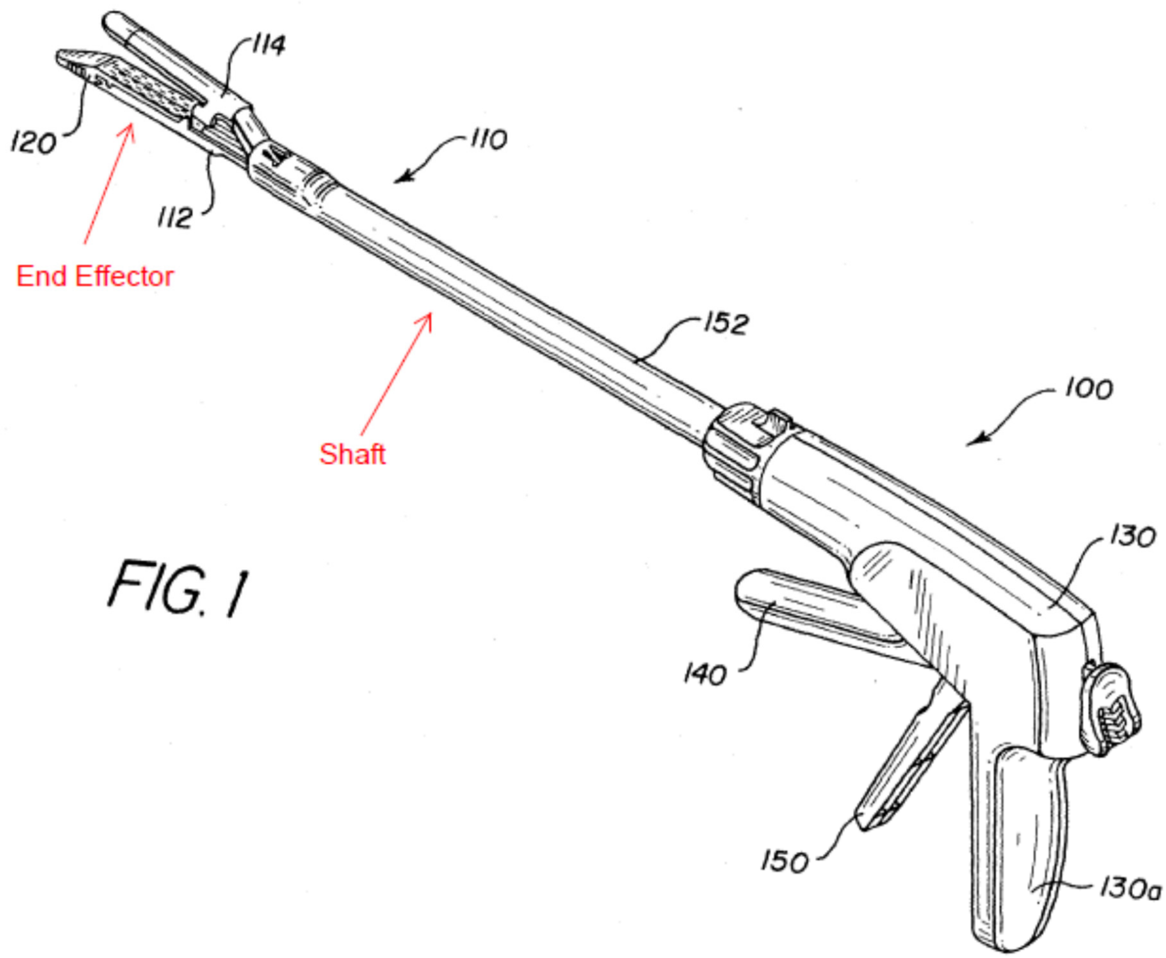
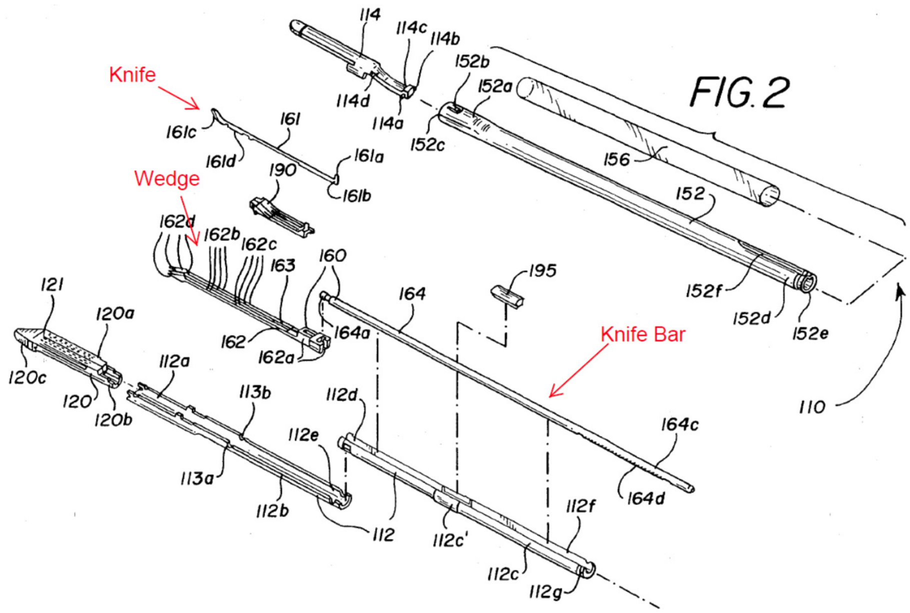
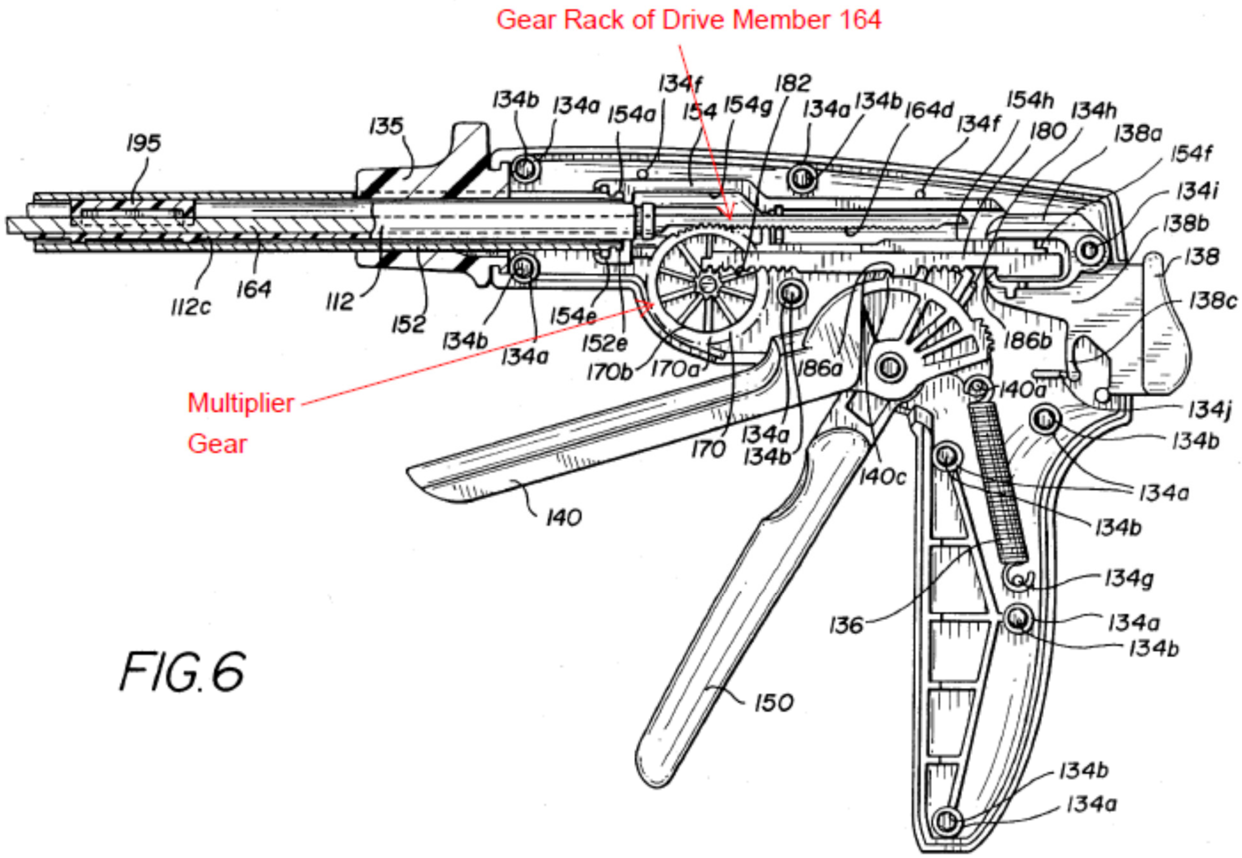


FIG. 1

IS1012, FIG. 1; 5:52-6:10. Knodel further discloses a knife bar supported within the shaft in the form of "drive member 164" that moves distally within the shaft to impart driving force on the wedge work member 162 and knife 161 of the stapler device as shown in FIG. 2:



IS1012, FIG. 2; 9:10-17; 10:65-11:12; 10:10-18 (describing that a "pusher block 162a" of the wedge "effects movement of the knife"). Furthermore, the drive member 164 is driven by a "gear rack 164d" in meshing engagement with a multiplier gear 170 as shown in FIG. 6:



IS1012, FIG. 6; 10:65-11:12; 9:10-35.

[19.P] 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 and is configured to provide at least one rotary output motion to at least one rotatable body portion supported on the tool drive assembly, said surgical tool comprising:

Anderson in view of Knodel discloses the preamble. The preamble of claim 19 is identical to the preamble of claim 23 and is therefore disclosed by Anderson for the reasons discussed with respect to element [23.P]. *Supra*, analysis of element [23.P]; IS1010, FIGs. 1-3; 10:65-11:42; 4:7-11; Abstract; 10:21-64; 11:59-12:22; 5:61-6:8; IS1004, ¶134.

[19.1] a surgical end effector comprising: a surgical staple cartridge; and a cutting instrument that is axially movable within said surgical staple cartridge between a starting position and an ending position in response to control motions applied thereto

Anderson in view of Knodel discloses element [19.1]. IS1004, ¶135.

"a surgical end effector comprising: a surgical staple cartridge"

The robotically operated surgical instruments described by Anderson are configured to actuate a wide variety of end effectors, including surgical staplers. IS1010, 7:6-25. Additionally, Knodel discloses "[a] surgical stapler instrument … for applying lateral lines of staples to tissue while cutting the tissue between those staple lines." IS1012, Abstract. Knodel discloses a "staple cartridge 120" in the end effector. IS1012, 5:52-65.

"a cutting instrument that is axially movable within said surgical staple cartridge…"

The end effector of Knodel's device "releasably receives a staple cartridge 120" and includes "a knife 161." IS1012, 5:52-65. The knife 161 engages a "pusher block 162a" of a wedge 162 that "effects movement of the knife." IS1012, 10:10-18; 12:1-6 ("Distal movement of the wedge work member 162 also effects distal movement of the knife 161 such that severing of the tissue 200 occurs."). Knodel discloses that the wedge 162 (which drives the knife 161) moves from a first position to a second position in response to "movement of the firing trigger." IS1012, 10:49-11:12; IS1004, ¶137.

Multiple reasons would have prompted a POSITA to modify Anderson to include the gear-driven knife bar and surgical stapler assembly of Knodel. **First**, a POSITA would have recognized that Anderson contemplates use of its robotic surgical system with "stapler probes" and Knodel provides details on a "surgical stapler" type end effector, the gear assembly for actuating the surgical stapler, and the knife bar configuration for transferring the activation motion from the gear assembly to the surgical stapler type end effector. IS1010, 7:19-25; IS1012, 5:52-6:10; 9:10-17; 10:65-11:12; 10:10-18; IS1004, ¶131. A POSITA therefore would have turned to Knodel for details on how to implement Anderson's surgical system with a surgical stapler end effector to increase the number of uses for Anderson's system.

Second, a POSITA would have been motivated to modify Anderson's system to include a surgical stapler end effector having a gear-driven knife bar assembly (as suggested by Knodel) because Knodel discloses an "improved motion transfer mechanism which is easily adaptable for use in various stapler instruments." IS1012, 1:53-67; IS1004, ¶132. A POSITA would have recognized that Anderson discloses just such a surgical system that could be readily improved by Knodel's "improved motion transfer mechanism." IS1012, 1:53-67; IS1004, ¶132.

Third, a POSITA would have been prompted to modify Anderson's system to include Knodel's gear-driven knife bar because doing so would be merely the application of a known technique to a known system (e.g., Anderson's surgical system) ready for improvement to yield predictable results. IS1004, ¶133; *KSR*, 550 U.S. at 417. Here, both Anderson and Knodel disclose surgical instruments having shafts and gear-driven end effectors, and a POSITA would have recognized that applying Knodel's suggestions to Anderson's surgical system would have led to predictable results without significantly altering or hindering the functions performed by Anderson's system. IS1004, ¶133.

[19.2] an elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising at least one gear-driven portion comprising a knife bar that is movably supported within said elongated shaft assembly for selective axial travel therein, said knife bar interfacing with said cutting instrument;

Anderson in view of Knodel discloses element [19.2]. IS1004, ¶139.

"an elongated shaft assembly operably coupled to said surgical end effector"

Anderson discloses an elongated shaft assembly supporting a surgical end effector:

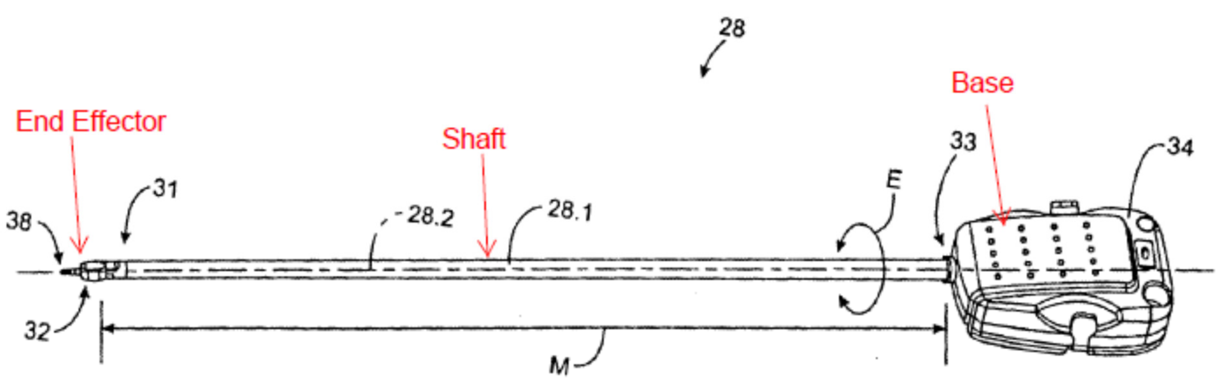


FIG. 2

IS1010, FIG. 2; 11:43-65.

Knodel's surgical device also includes a surgical end effector supported on an elongated shaft:

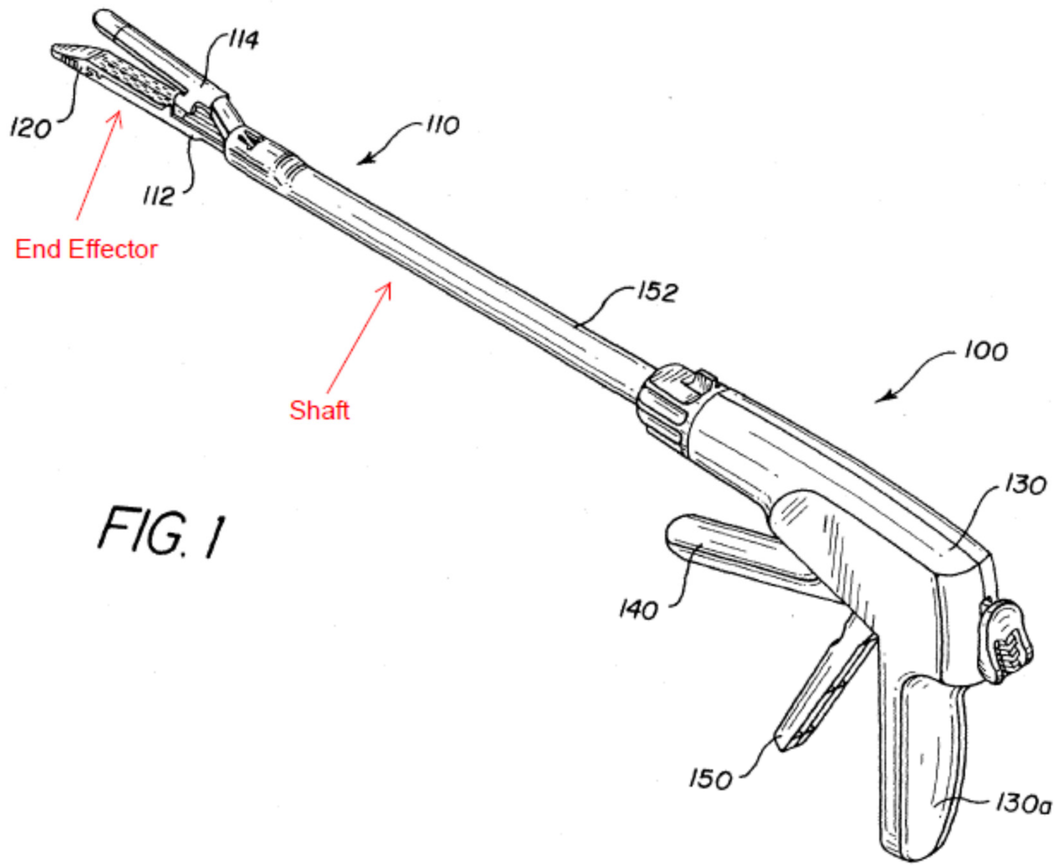
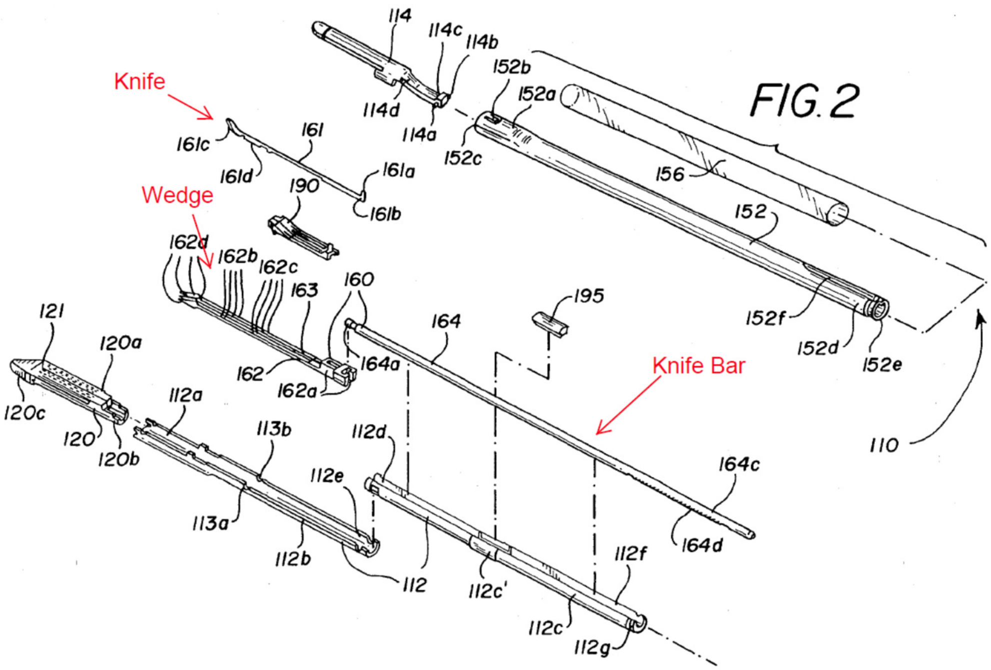


FIG. 1

IS1012, FIG. 1; 5:52-6:10.

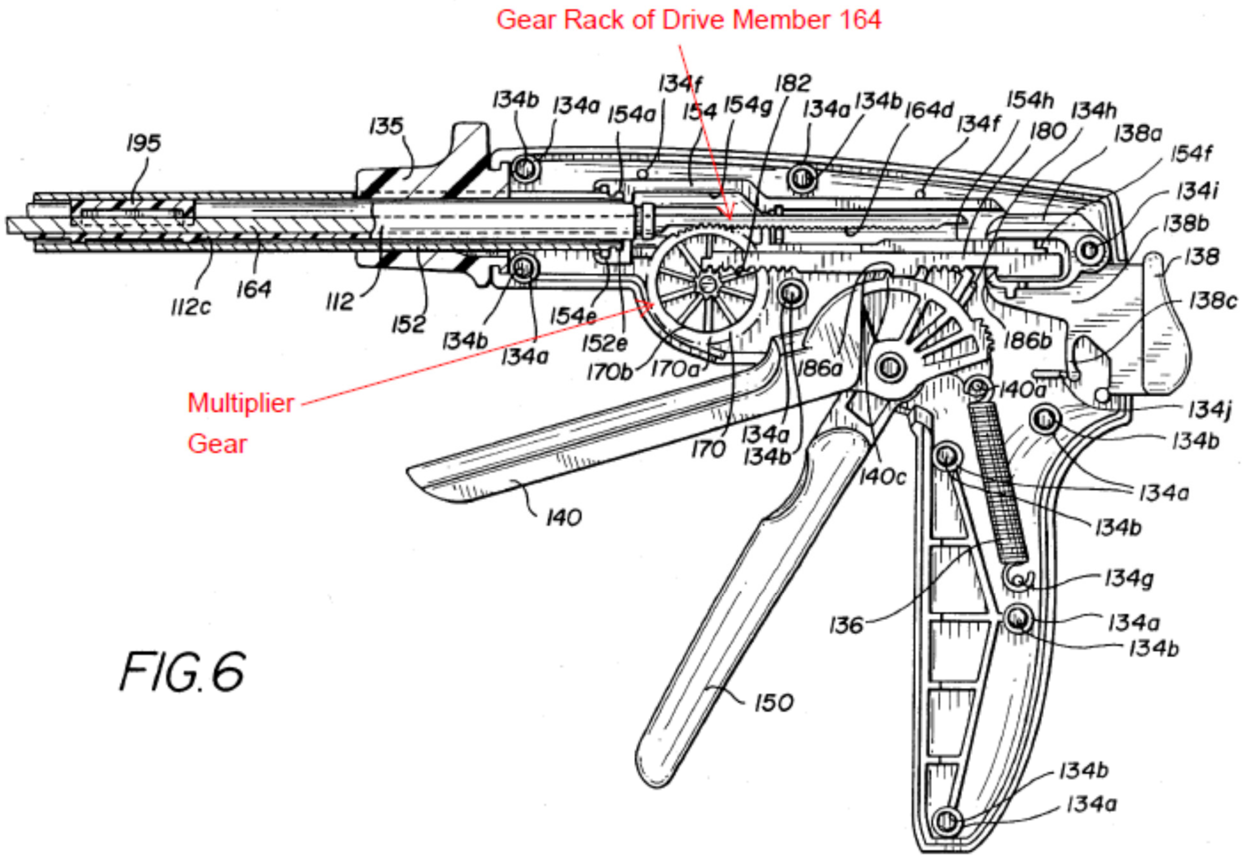
"said elongated shaft assembly comprising at least one gear-driven portion comprising a knife bar…"

Knodel further discloses a knife bar supported within the shaft in the form of "drive member 164" that moves distally within the shaft assembly to impart driving force on the wedge work member 162 and knife 161 of the stapler device as shown in FIG. 2:



IS1012, FIG. 2; 9:10-17; 10:65-11:12; 10:10-18. Knodel discloses that the "metal drive member 164" (i.e., the knife bar) is "snap-fitted" to the "wedge work member 162" and further that "[d]istal movement of the wedge work member 162 also effects distal movement of the knife 161." IS1012, 9:10-17; 12:1-6. Therefore, Knodel's knife bar 164 is movably supported within the shaft and interfaces with the knife 161. IS1004, ¶141.

Furthermore, the drive member 164 is driven by a "gear rack 164d" formed on the drive member 164 in meshing engagement with a multiplier gear 170 as shown in FIG. 6:



IS1012, FIG. 6; 10:65-11:12; 9:10-35.

[19.3] a tool mounting portion operably coupled to said elongated shaft assembly, said tool mounting portion being configured to operably interface with the tool drive assembly when coupled thereto, said tool mounting portion comprising:

Anderson in view of Knodel discloses element [19.3]. Element [19.3] is identical to element [23.3] and is therefore disclosed by Anderson for the reasons discussed above. *Supra*, analysis of element [23.3]; IS1010, 22:8-33; 22:59-67; 18:20-24; 11:66-12:22; FIGs. 1, 3, 20; IS1004, ¶143. Additionally, a POSITA would have understood that modifying Anderson to include the surgical stapler end effector and knife bar ("drive member 164") of Knodel would have included using one of Anderson's "transmission members 70, 72, 74, and 76" having "shafts 70.1, 72.1, 74.1, and 76.1" and/or "instrument actuator interface member 353a and 353b" to provide rotational motion to the gear assembly that drives Knodel's drive member 164. IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3, 21-22; IS1004, ¶143.

[19.4] a driven element rotatably supported on said tool mounting portion and configured for driving engagement with a corresponding one of the at least one rotatable body portions of the tool drive assembly to receive corresponding rotary output motions therefrom; and

Anderson in view of Knodel discloses element [19.4]. Element [19.4] is identical to element [24.5] and is therefore disclosed by Anderson for the reasons discussed above. *Supra*, analysis of element [24.5]; IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3; 21-22; IS1004, ¶144.

[19.5] a transmission assembly in operable engagement with said driven element and in meshing engagement with the knife bar to apply actuation motions thereto to cause said knife bar to apply at least one control motion thereto.

Anderson in view of Knodel discloses element [19.5]. IS1004, ¶145. For example, Anderson discloses that "[m]ovement of end effector 38" is caused by rotation of the transmission members 70, 72, 74, and 76 in response to rotation of "actuators, such as electric motors" of the robotic arm assembly. IS1010, 11:59-12:22. Anderson further discloses that rotation of the actuation interface members 353a-b causes actuation of the end effector. IS1010, 24:31-65. A POSITA would have understood that modifying Anderson to include the surgical stapler end effector and knife bar ("drive member 164") of Knodel would have included using one of Anderson's "transmission members 70, 72, 74, and 76" having "shafts 70.1, 72.1, 74.1, and 76.1" and/or "instrument actuator interface member 353a and 353b" to provide rotational motion to the gear assembly that drives Knodel's drive member 164. IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3, 21-22. Therefore, the transmission assembly of the resulting combination (e.g., the gear assembly of Knodel in communication with Anderson's transmission members) is in operable engagement with said driven element (one or more of Anderson's shafts) to receive actuation motions. IS1004, ¶146. Furthermore, the Anderson transmission members would drive Knodel's "gear rack 164d" in meshing engagement with a multiplier gear 170 of Knodel's gear assembly as shown in FIG. 6, which drives drive member 164 and thus the knife:

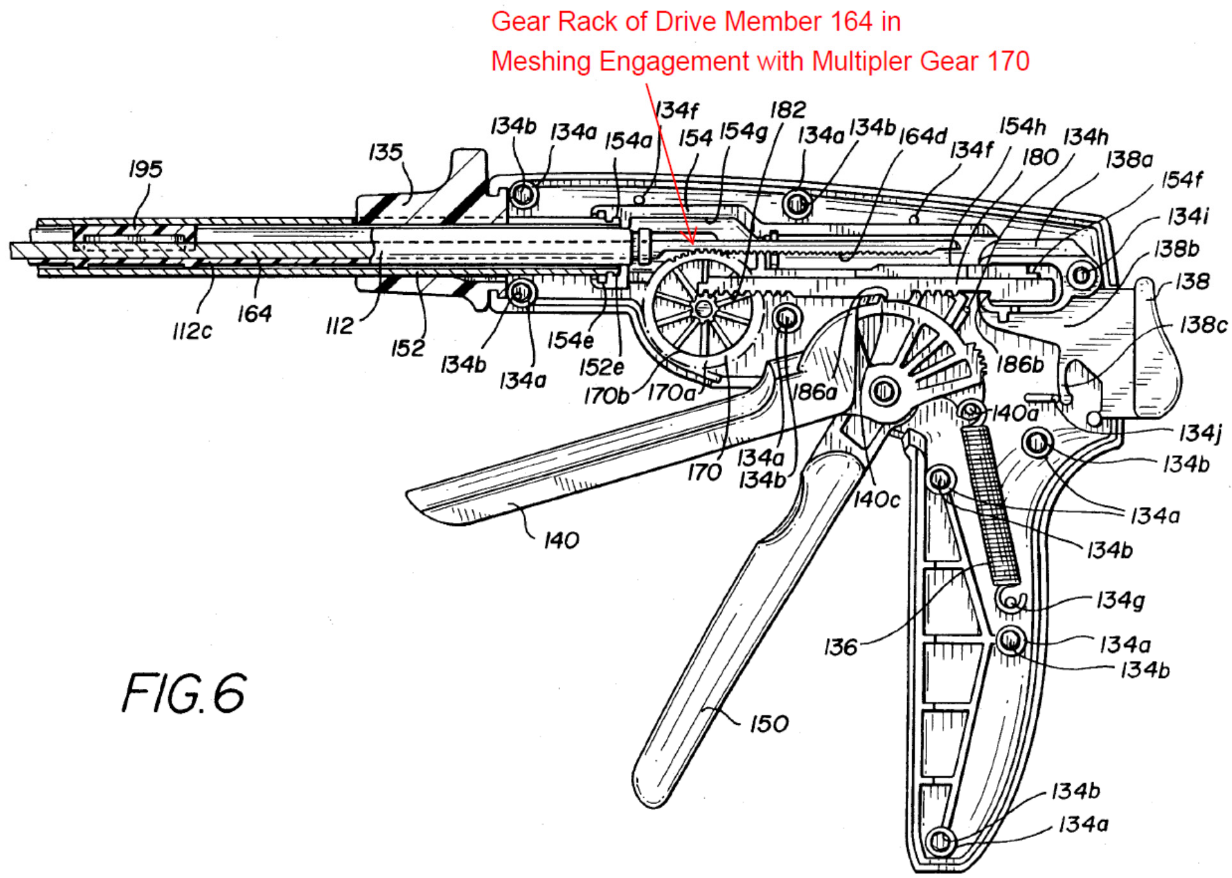


FIG. 6

IS1012, FIG. 6; 10:65-11:12; 9:10-35.

[20] The surgical tool of claim 19 wherein said knife bar has a knife gear rack formed on a proximal end thereof and wherein said transmission assembly comprises a knife transmission assembly comprising a knife gear assembly in meshing engagement with said knife gear rack, said knife gear assembly operably coupled to one of the at least one rotatable body portions supported on the tool drive assembly such that upon application of a rotary output motion in a first direction to said knife gear assembly by said at least one rotatable body portion, said knife bar drives said cutting instrument distally through said surgical staple cartridge and upon application of said rotary output motion in a second direction to said knife gear assembly, said knife bar moves said cutting instrument proximally through said surgical staple cartridge.

Anderson in view of Knodel discloses claim 20. IS1004, ¶147-150.

"said knife bar has a knife gear rack formed on a proximal end thereof"

As shown in FIG. 6 (above), Knodel describes that "proximal end 164c of the drive member 164 is provided with a gear rack 164d." IS1012, 9:10-35; FIGs. 6, 10, 12.

"said transmission assembly comprises a knife transmission assembly comprising a knife gear assembly in meshing engagement with said knife gear rack"

As Knodel describes, "[t]he first pinion gear 170a is engaged with the gear rack 164d provided on the metal drive member 164." IS1012, 9:10-35; FIGs. 6, 10, 12. As shown in FIG. 6 (above), the engagement between gear rack 164d and gear 170a is a meshing engagement. IS1004, ¶149.

"said knife gear assembly operably coupled to one of the at least one rotatable body portions…"

As explained above, a POSITA would have understood that modifying Anderson to include the surgical stapler end effector and knife bar ("drive member 164") of Knodel would have included using one of Anderson's "transmission members 70, 72, 74, and 76" having "shafts 70.1, 72.1, 74.1, and 76.1" and/or "instrument actuator interface member 353a and 353b" to provide rotational motion to the gear assembly that drives Knodel's drive member 164, which includes gear 170a. In the combination, the motions come from rotatable body portions on the robot arm. IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3, 21-22; IS1004, ¶150.

Moving knife bar "proximally" and "distally"

Knodel further describes that the "drive member 164" is part of the "reciprocating section 160" that is "adapted to move back and forth along an axis of the implement portion" and through the cartridge. IS1012, 9:10-17; 2:21-41; Abstract; 9, 2:21-41; 10:65-11:12 ("[M]ovement of the firing trigger 140 causes the metal ***drive member 164*** and ***the wedge work member*** 162 to ***reciprocate between a first reciprocating position***, shown in FIGS. 6, 7, 7A and 10, and ***a second reciprocating position***, shown in FIGS. 11 and 12."); 13:5-9; 11:13-25; IS1004, ¶151.

E. Ground 5: Claims 21-22 Would have Been Obvious Under § 103 over Anderson in View of Viola

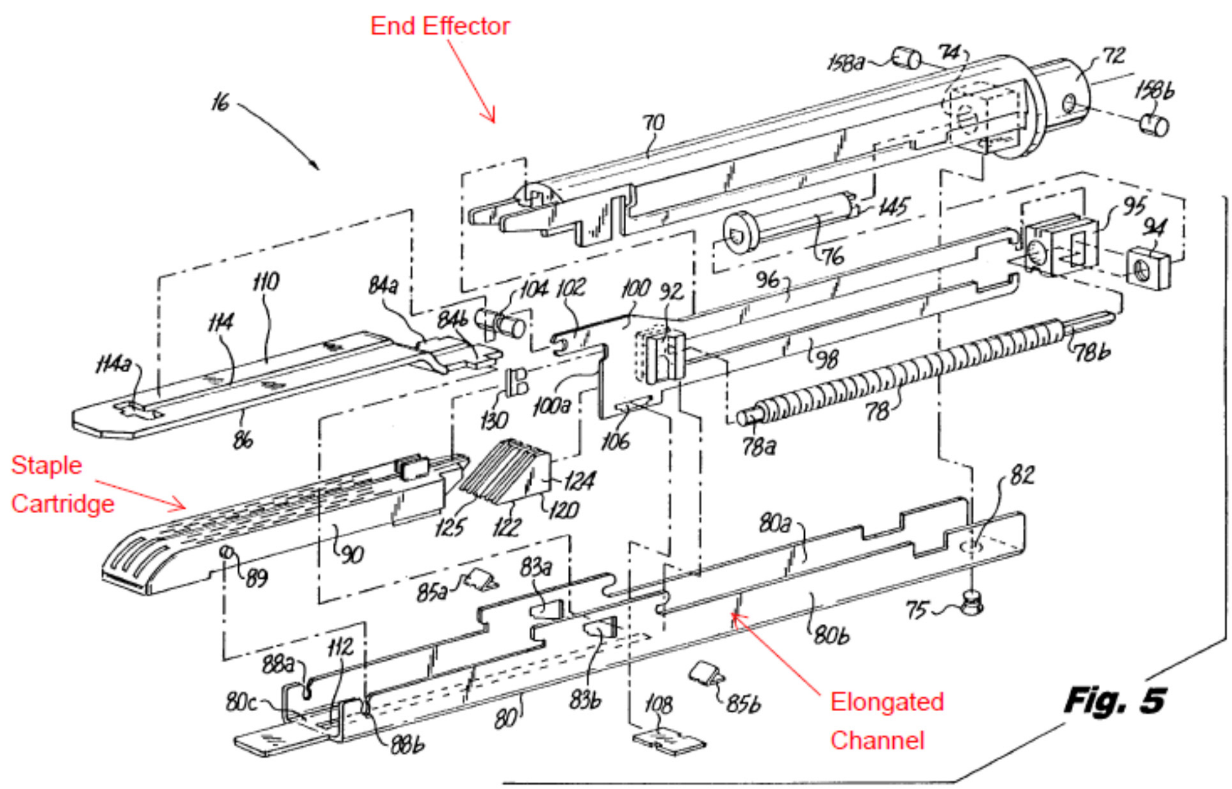
Claim 21 recites the standard elements discussed with regard to the previous independent claims and adds a "rotary end effector drive shaft" to drive the knife of a surgical stapler. Viola describes precisely such a configuration.

[21.P] 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 and is configured to provide at least one rotary output motion to at least one rotatable body portion supported on the tool drive assembly, said surgical tool comprising:

Anderson in view of Viola discloses the preamble. The preamble of claim 21 is identical to the preamble of claim 23 and is therefore disclosed by Anderson for the reasons discussed with respect to element [23.P]. *Supra*, analysis of element [23.P]; IS1010, FIGs. 1-3; 10:65-11:42; 4:7-11; Abstract; 10:21-64; 11:59-12:22; 5:61-6:8; IS1004, ¶157.

[21.1] a surgical end effector comprising: an elongated channel configured to support a surgical staple cartridge therein;

Anderson in view of Viola discloses element [21.1]. IS1004, ¶158. For example, Anderson's robotically operated surgical instruments are configured to actuate a wide variety of end effectors, including surgical staplers. IS1010, 7:6-25. Additionally, Viola discloses a "surgical stapler" having an end effector in the form of "cartridge assembly 16" having "an elongated housing channel 80" for supporting a "retainer cartridge 90" that retains "a plurality of surgical fasteners" as shown in FIG. 5



IS1013, FIG. 5; 4:5-17; 5:44-58; 6:3-32. A POSITA would have recognized that Viola's retainer cartridge 90 is a staple cartridge. IS1004, ¶158.

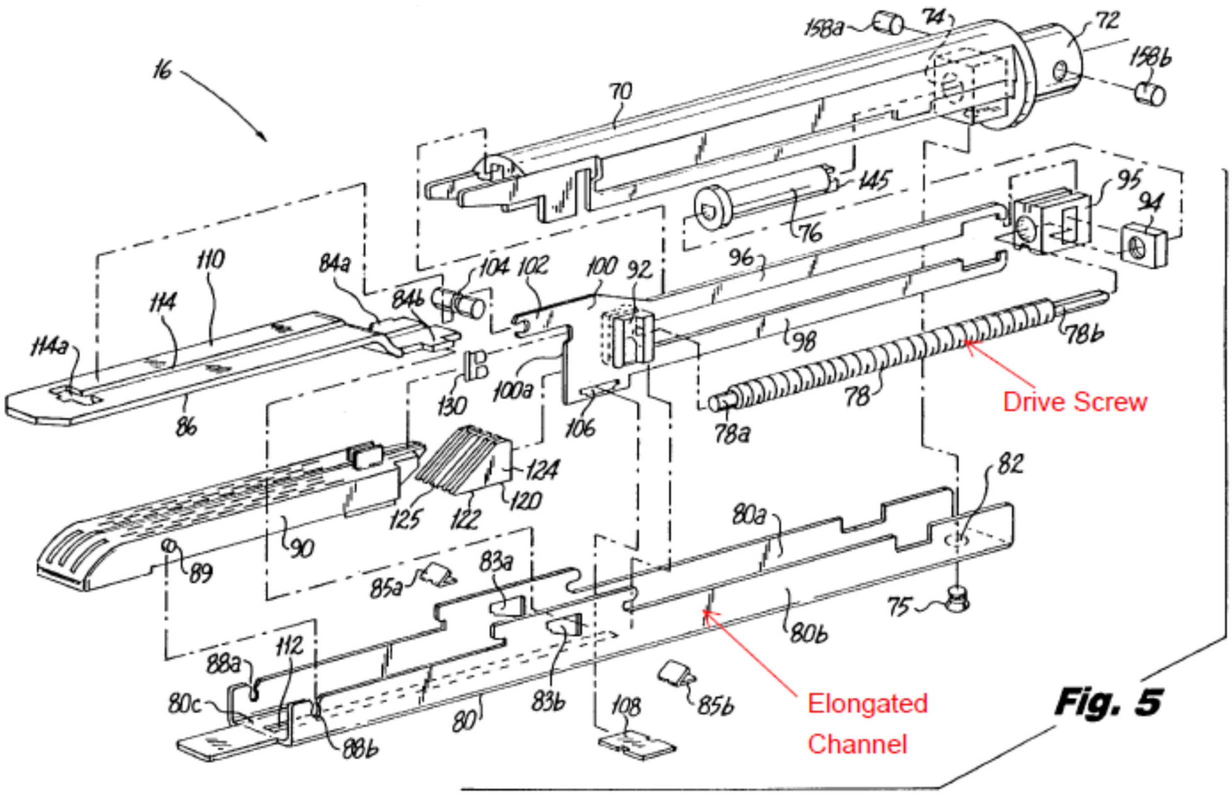
Multiple reasons would have prompted a POSITA to modify Anderson to include the drive screw driven surgical stapler assembly of Viola. **First**, a POSITA would have recognized that Anderson contemplates use of its robotic surgical system with "stapler probes," and Viola provides details on a "surgical stapler". IS1010, 7:19-25; IS1013, 4:5-17; 5:44-58; 6:3-59; IS1004, ¶154. A POSITA therefore would have turned to Viola for details on how to implement Anderson's surgical system with a surgical stapler end effector to increase the number of uses for Anderson's system.

Second, a POSITA would have been motivated to modify Anderson's system to include a surgical stapler end effector having a rotational drive screw (as suggested by Viola) because Viola's discloses a "beneficial" actuation mechanism that is "actuable with only a limited degree of physical force." IS1013, 2:1-20; IS1004, ¶155. Indeed, Viola's screw based drive mechanism "increas[es] the torque delivered by the motor assembly" thereby reducing the amount of force that must be imparted by the motor, IS1013, 4:18-25, and thus requiring smaller motors and reduce wear. IS1004, ¶155.

Third, a POSITA would have been prompted to modify Anderson's system to include Viola's screw driven surgical stapler because doing so would be merely the application of a known technique (drive screw for a surgical stapler) to a known system (e.g., Anderson's surgical system) ready for improvement to yield predictable results. IS1004, ¶156; *KSR*, 550 U.S. at 417. Here, both Anderson and Viola disclose motor driven surgical instruments having shafts and gear-driven end effectors, naturally leading a POSITA to apply the teachings of Viola to Anderson. IS1004, ¶156; IS1010, 25:10-11.

[21.2] a rotary end effector drive shaft operably supported within an elongated channel;

Anderson in view of Viola discloses element [21.2]. IS1004, ¶160. For example, Viola's drive screw 78 is a rotary end effector drive shaft that is supported within the elongated channel 80 of the end effector, as shown in FIG. 5:



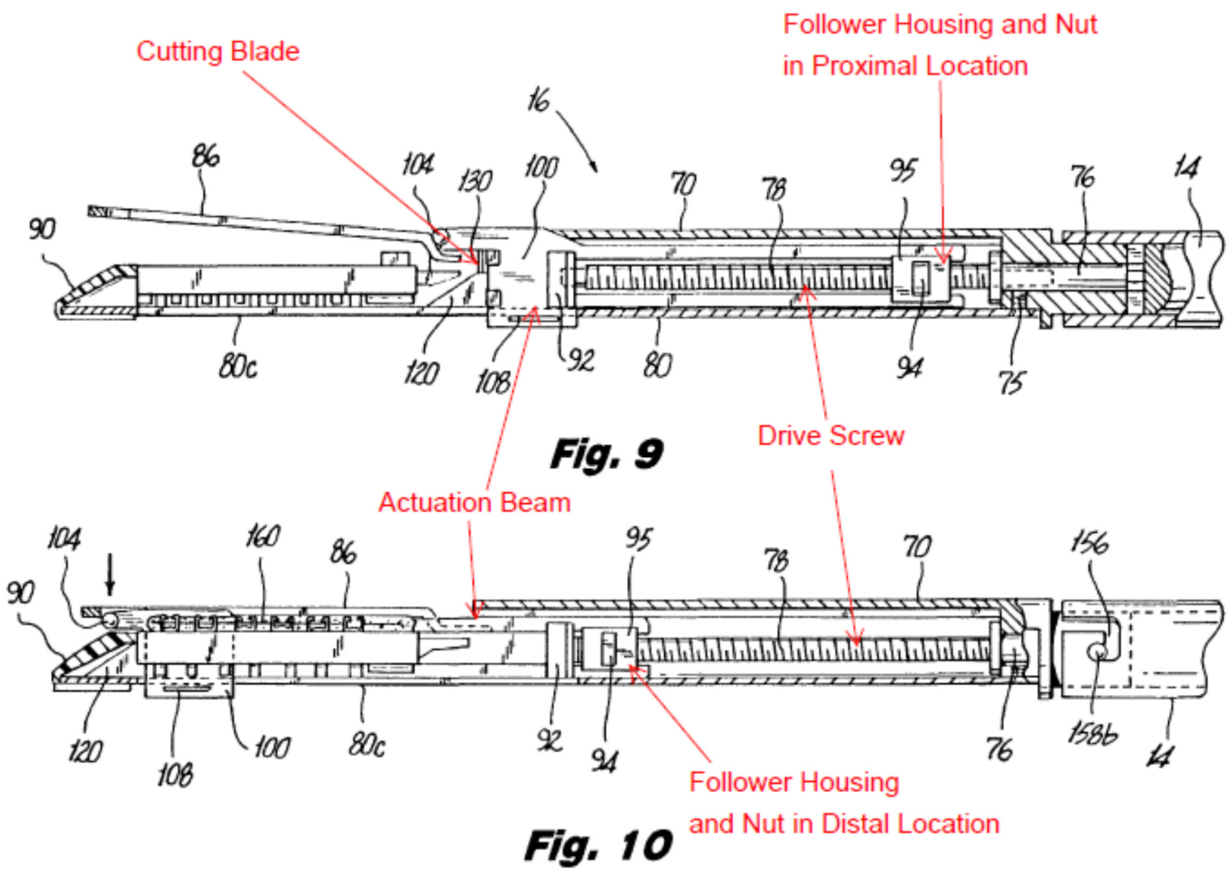
IS1013, FIG. 5; 5:55-6:50; *see also* FIG. 9; IS1004, ¶156.

[21.3] a knife member having a tissue-cutting portion thereon threadedly received on said rotary end effector drive shaft such that rotation of said rotary end effector drive shaft in a first direction causes said knife member to move in a distal direction through said surgical staple cartridge and when said rotary end effector drive shaft is rotated in a second direction, said knife member moves in a proximal direction through said surgical staple cartridge and wherein said surgical tool further comprises:

Anderson in view of Viola discloses element [21.3]. IS1004, ¶161.

"a knife member having a tissue-cutting portion thereon threadedly received on said rotary end effector drive shaft"

Viola discloses a knife member in the form of a cutting blade on an actuation beam 100 that is threadedly coupled to the drive screw 78 (e.g., the rotary end effector drive shaft) by a follower nut as shown in FIGs. 9-10:



IS1013, FIGs. 9-10; 6:37-59.

"such that rotation of said rotary end effector drive shaft [for distal and proximal movement of knife]…"

Viola discloses that when the drive screw 78 is rotated in a first direction, the follower housing mounted to the follower nut moves in a distal direction along the drive screw 78 to cause "actuation beam 100 [to] translate[] distally with the follower housing." IS1013, 6:55-59; *see also* 7:65-8:5 ("[A]ctuation sled 120 is driven from the proximal position illustrated in FIG. 9, through retention cartridge

90, to the distal-most position shown in FIG. 10.”).

A POSITA would have recognized, based on the disclosures of Viola, that the structure would likewise retract. IS1004, ¶164. Viola states, for example, that the drive motor can reverse direction (which would cause rotation in the opposite direction and retraction of the knife) and that the system includes a “trigger mechanism for selectively ***reversing the polarity of the motor assembly***.” IS1013, 7:56-65; 2:50-54; 5:9-12 (“***reversing*** the direction of the motor and ***drive shaft***”). Such a second (retraction) motion is necessary to open the anvil because the Viola actuation beam has an I-beam structure to clamp the anvil when in the distal direction. Thus, Viola discloses drive screw rotation in both directions such that the knife moves distally and proximally. IS1013, FIGs. 9-10; IS1004, ¶164.

Furthermore, a POSITA would have recognized that Anderson’s rotary drive members support rotation in either direction: “generally … actuator motion is ***reversible*** and controllable by the robotic system, producing a controllable forward or ***rearward actuator.***” IS1010, 17:51-54; IS1004, ¶165. As another example, Anderson discloses that rotation of actuation spools “is reversible and controllable by the robotic surgical system.” IS1010, 16:52-61; FIGs. 13, 21; IS1004, ¶165.

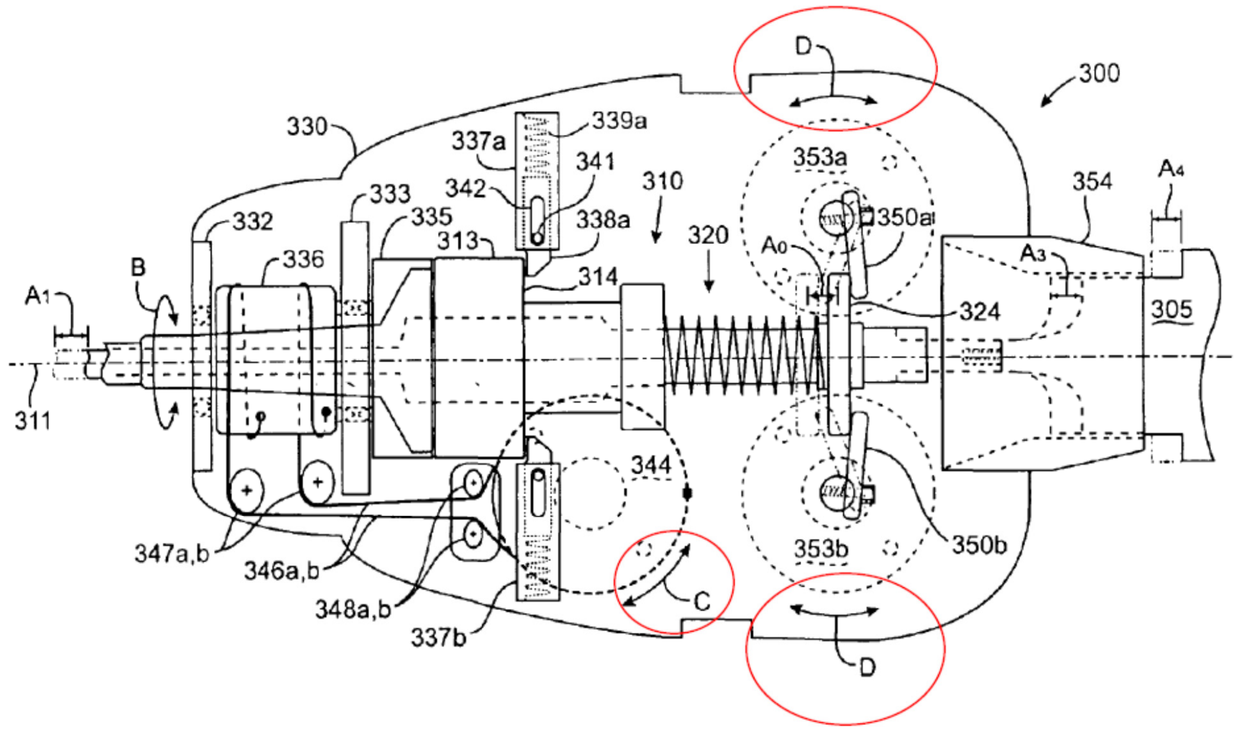


FIG. 21

IS1010, FIG. 21; 24:40-53; 22:59-23:14.

[21.4] an elongated shaft assembly operably coupled to said elongated channel, said elongated shaft assembly comprising at least one gear-driven portion that is in operable communication with said rotary end effector drive shaft:

Anderson in view of Viola discloses element [21.4]. IS1004, ¶166.

"an elongated shaft assembly operably coupled to said elongated channel"

FIG. 1 of Viola discloses "cartridge adapter 70" which is at the distal portion of the elongated shaft assembly that is coupled to the "elongated housing channel 80":

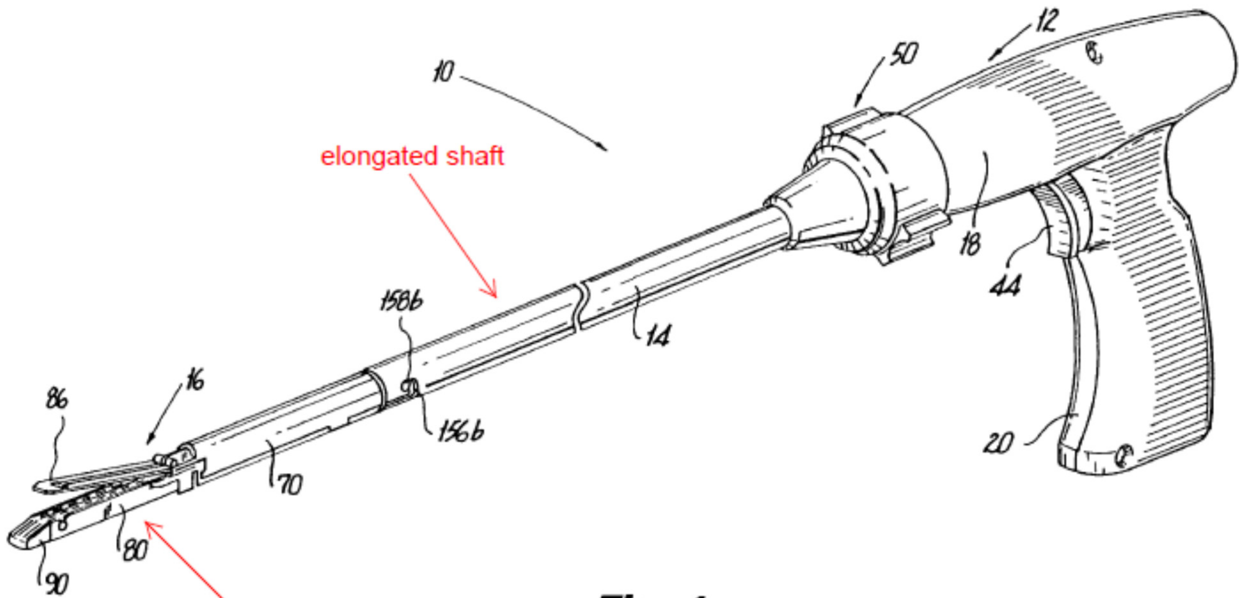
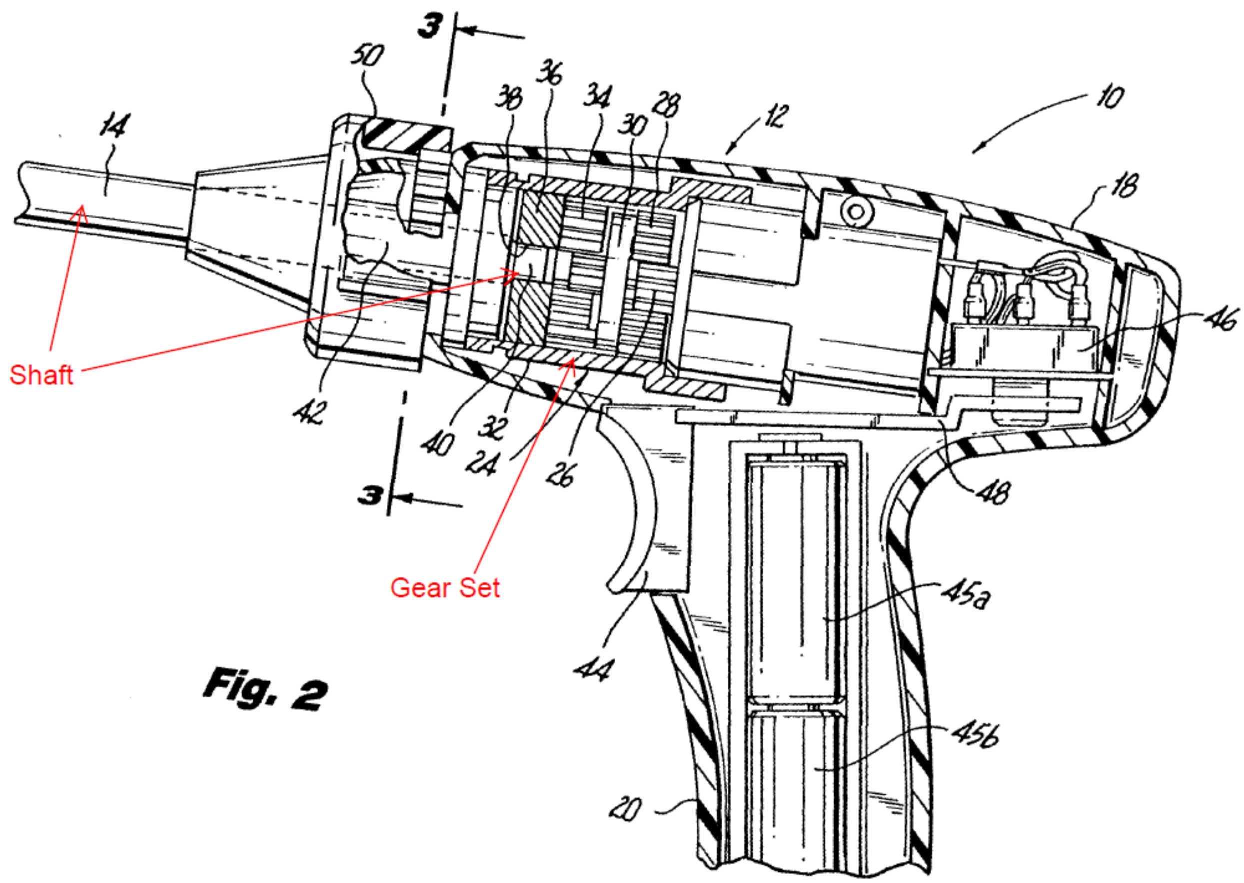


Fig. 1

IS1013, FIG. 1; 4:10-17; 5:44-58.

"said elongated shaft assembly comprising at least one gear-driven portion that is in operable communication with said rotary end effector drive shaft"

Viola's "***gear set 24*** … transfer[s] rotational motion to ***drive shaft 42***, which, in turn, transfers ***rotational motion to axial drive screw 78***." IS1013, 7:56-65; 4:18-39 (describing details of the gear set 24). FIG. 2 shows the gear set 24 at the proximal end of the elongated shaft assembly:



IS1013, FIG. 2.

[21.5] a tool mounting portion operably coupled to said elongated shaft assembly, said tool mounting portion being configured to operably interface with the tool drive assembly when coupled thereto, said tool mounting portion comprising:

Anderson in view of Viola discloses element [21.5]. Element [21.5] is identical to element [23.3] and is therefore disclosed by Anderson for the reasons discussed above. *Supra*, analysis of element [23.3]; IS1010, 22:8-33; 22:59-67; 18:20-24; 11:66-12:22; FIGs. 1, 3, 20; IS1004, ¶169.

[21.6] a driven element rotatably supported on said tool mounting portion and configured for driving engagement with a corresponding one of the at least one rotatable body portions of the tool drive assembly to receive corresponding rotary output motions therefrom; and

Anderson in view of Viola discloses element [21.6]. Element [21.6] is identical to element [24.5] and is therefore disclosed by Anderson for the reasons discussed above. *Supra*, analysis of element [24.5]; IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3, 21-22; IS1004, ¶170.

[21.7] a transmission assembly in operable engagement with said driven element and in meshing engagement with a corresponding one of said at least one gear-driven portions to apply actuation motions thereto to cause said corresponding one of said at least one gear-driven portions to apply at least one control motion to said rotary end effector drive shaft.

Anderson in view of Viola discloses element [21.7]. IS1004, ¶171. A POSITA would have understood that modifying Anderson to include the surgical stapler and drive screw of Viola would have included using one of Anderson's "transmission members 70, 72, 74, and 76" having "shafts 70.1, 72.1, 74.1, and 76.1" and/or "instrument actuator interface member 353a and 353b" to provide rotational motion to the gear set 24 that drives Viola's drive screw 78. IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3, 21-22; IS1013, 7:56-65; 4:18-39; IS1004, ¶172. Furthermore, Viola discloses that rotational motion is imparted on the drive screw 78 by drive shaft 42. IS1013, 5:65-6:2. The "proximal end 40" of drive shaft 42 is coupled to a "hub member 36" that is driven by "planetary gears

34" which are in meshing engagement with a "pinion portion of carrier 30" to receive driving motion therefrom as shown in FIG. 2:

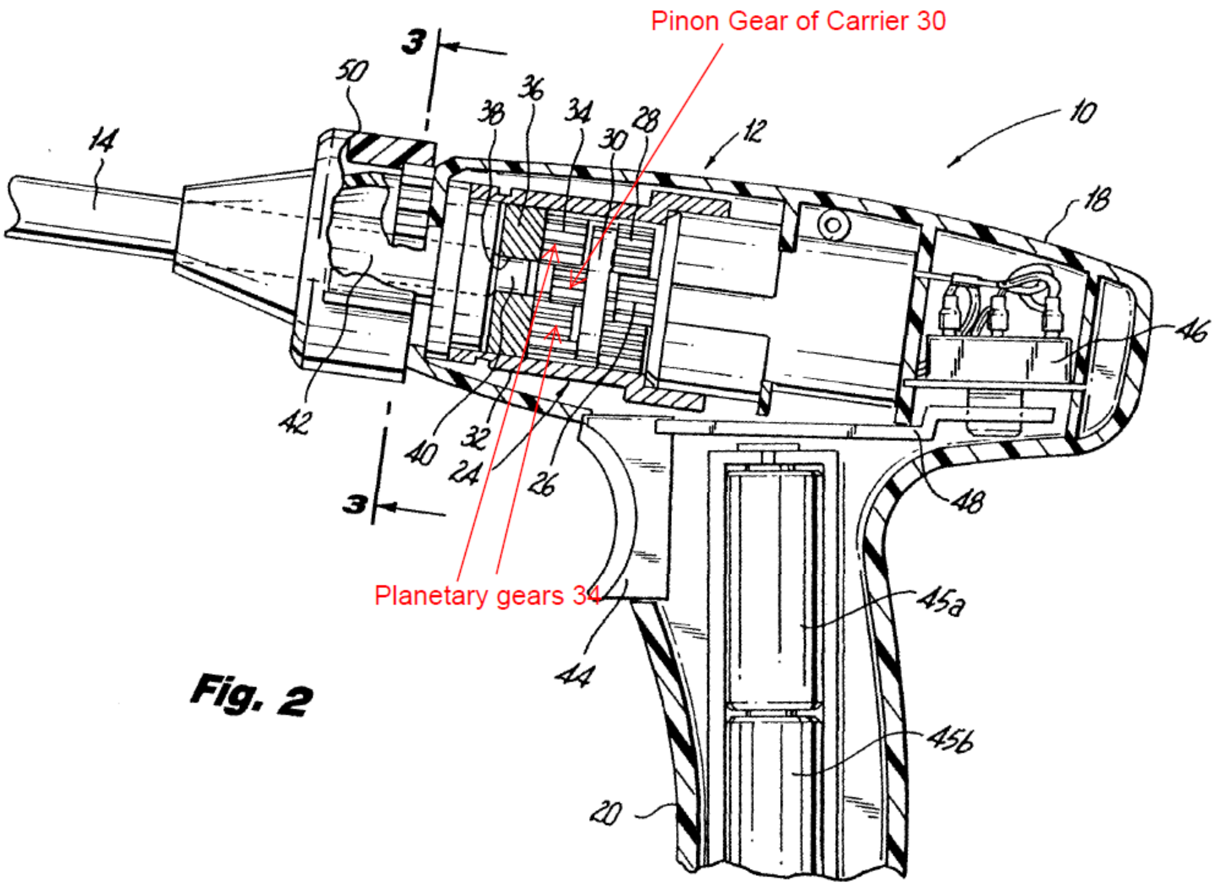


Fig. 2

IS1013, FIG. 2; 4:18-39; 7:56-65.

> ***[22] The surgical tool of claim 21 wherein one of said at least one gear-driven portions comprises an elongated proximal drive shaft operably supported in said elongated shaft assembly …***

Anderson in view of Viola discloses claim 22. IS1004, ¶169.

Viola discloses that "[d]rive shaft 42 extends from hub 36 ***through the elongate body portion [shaft assembly] 14*** of surgical apparatus 10 to the cartridge assembly 16." IS1013, 4:34-39; IS1004, ¶173.

[22.1] and having a distal end in driving engagement with said rotary end effector drive shaft,

Viola discloses a "[c]oupling 76 is detachably connected … to the distal end of drive shaft 42" which serves to "transmit[] rotational motion from the drive shaft 42 to the drive screw 78." IS1013, 5:65-6:2; 6:45-52; 7:14-20 ("axial drive screw 78 is detachably connected to drive shaft 42 through cartridge coupling 76").

[22.2] and wherein said transmission assembly comprises a rotary drive transmission operably supported on said tool mounting portion and in driving engagement with a proximal end of said proximal drive shaft and operably coupled to one of the at least one rotatable body portions supported on the tool drive assembly such that, upon application of a rotary output motion in one direction to said rotary drive transmission by said at least one rotatable body portion, said proximal drive shaft rotates said rotary end effector drive shaft in said first direction and upon application of said rotary output motion in a second direction to said rotary drive transmission, said proximal drive shaft causes said rotary end effector drive shaft to rotate in said second direction.

As explained in regard to claim 21, the combination would use a transmission assembly on Anderson's tool mounting portion that is coupled to the proximal end of drive shaft 42 and drives Viola's knife and receives rotary power from the rotatable body portions on Anderson's tool drive assembly. IS1004, ¶176. Rotating the rotary drive in one direction would drive the knife distally, and in the other direction would drive the knife proximally. IS1010, 11:66-12:22; 22:59-23:30; 24:23-39; FIGs. 3, 21-22; 5:65-6:2; 7:14-20; 7:56-65 ("gear set 24 to transfer rotational motion to drive shaft 42, which, in turn, transfers rotational motion to axial drive screw 78"). The gear set in the Viola handle would reside in the Anderson tool mounting portion in the combination. IS1010, 4:18-39.

X. CONCLUSION

Claims 19-26 of the ’969 Patent are invalid over the prior art pursuant to Grounds 1-5 set forth above. Accordingly, Petitioner request *Inter Partes* Review of the challenged claims.

Respectfully submitted,

Dated: June 14, 2018

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Attorney for Petitioner

(Trial No. IPR2018-01247)

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

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 13,750, which is less than the 14,000 allowed under 37 C.F.R. § 42.24(a)(i).

Respectfully submitted,

Dated: June 14, 2018

/Steven R. Katz/
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Attorney for Petitioner

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 June 14, 2018, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided by Federal Express, cost prepaid, to the Patent Owner by serving the correspondence address of record as follows:

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