UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

ETHICON LLC,
Patent Owner

IPR2018-01247
U.S. Patent No. 8,479,969

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit #	Description
2001	Excerpts of a technology tutorial filed in *Ethicon v. Intuitive Surgical*, C.A. No. 1-17:cv-871 (LPS) (CJB) (D. Del. June 28, 2018)
2002	Patent Statutory Disclaimer for U.S. Patent No. 8,479,969 filed on October 15, 2018
2003	U.S. Patent No. 7,524,320

I. INTRODUCTION

Ethicon is a market leader in developing endocutter[1] technology and commercially released its first endocutter in 1996. Since then, Ethicon has developed numerous endocutters to address changing surgical needs. In 2011, Ethicon introduced its first motor-powered endocutter – the ECHELON FLEX™ Powered ENDOPATH® Stapler. Ethicon's motor-powered endocutters offer numerous benefits including dramatically reducing the force required to operate an endocutter and providing reliability across a broad range of tissue thicknesses.

The challenged claims of U.S. Patent No. 8,479,969 ("the 969 Patent") are directed to an articulating endocutter surgical tool that operatively couples to a robot surgical system. More specifically, the 969 Patent improves upon prior robotic surgical tools, such as an ultrasound probe, that were known to be "unable to generate the magnitude of forces required to effectively cut and fasten tissue" as is required of an endocutter. Ex. 1001, 23:6-29. The 969 Patent's innovative tool base for an endocutter overcame these limitations of the prior art systems.

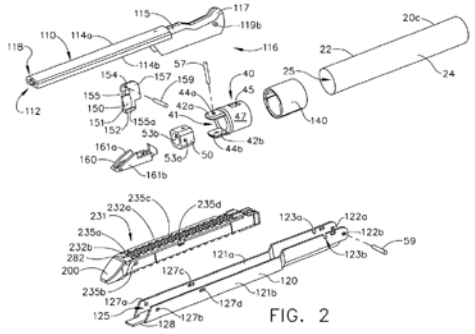
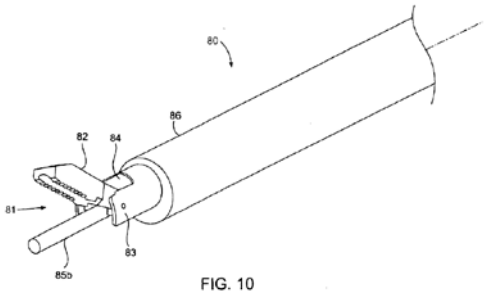
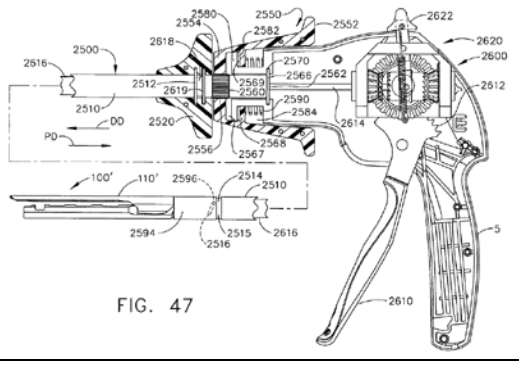
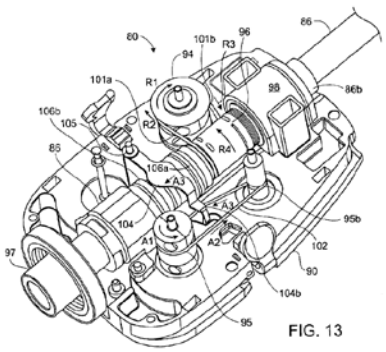
[1] An endocutter is a surgical instrument that both staples and cuts tissue. The term "stapler" can also be used to refer to this type of device, but can also refer to a device that only staples. Exhibit 2001 includes excerpts of a technology tutorial on endocutters that was filed in the District of Delaware on June 28, 2018.

Petitioner's obviousness challenge is based on U.S. Patent No. 6,783,524 ("Anderson"), a patent issued in 2004 that is assigned to Petitioner. Anderson discloses an ultrasound probe with an end effector and a rotating shaft. While Anderson's ultrasound probe can cut and cauterize tissue using ultrasound energy, it cannot cut and fasten through mechanical means such as a cutting blade or surgical staples. Indeed, consistent with this lack of mechanical cutting capability, the 969 Patent specification discloses Anderson as an example of a prior art robotic surgery system, and notes that many of such systems "have in the past been unable to generate the magnitude of forces required to effectively cut and fasten tissue." Ex. 1001, 23:6-29.

Anderson's instrument couples to a robotic system through a comparatively rudimentary tool base that controls the shaft rotation and end effector. In order to arrive at the more sophisticated instruments claimed by the 969 Patent, Petitioner proposes to combine Anderson with aspects of various handheld surgical instruments disclosed in U.S. Patent Nos. 7,510,107 ("Timm"), 6,699,235 ("Wallace"), 5,465,895 ("Knodel"), and 5,954,259 ("Viola"). As Petitioner admits, all of these secondary references were made of record during prosecution.

Petitioner's obviousness grounds, however, fail to satisfy the basic standard for establishing obviousness. Petitioner does not explain how Anderson's tool base could be adapted to preserve the functionality of Anderson's probe while also

supporting the additional functionalities that Petitioner proposes to incorporate from Timm, Wallace, Knodel, and Viola. Indeed, as shown in the figures below, it is apparent that combining the handheld endocutter systems of Timm, Knodel, and Viola and the non-endocutter robotic tool of Anderson is not a simple matter of taking the endocutter end effector from Timm and attaching it to the robotic tool base of Anderson. Petitioner's combination is pure hindsight because it wholly neglects the more complex drive system required for an endocutter as compared to the non-endocutter tool of Anderson, as well as the significant difference in a drive system for a handheld tool versus a robotic tool.

	Timm (Handheld Endocutter)	**Anderson (Robotic Ultrasound Probe)**
End effector	 FIG. 2	 FIG. 10
Drive System	 FIG. 47	 FIG. 13

Additionally, Petitioner fails to offer any evidence of reasonable expectation of success in the combination of any of the references. This failure alone is grounds to deny institution. *See Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1360-61 (Fed. Cir. 2017) ("where a party argues a skilled artisan would have been motivated to combine references, ***it must show*** the artisan would have had a reasonable expectation of success from doing so") (internal citation and quotation omitted).[2]

For these reasons, and the additional reasons explained in detail below, Patent Owner respectfully requests that the Board deny institution as to all grounds asserted in the petition.

II. STATUTORY DISCLAIMER

On October 15, 2018, Ethicon filed with the U.S. Patent and Trademark Office a statutory disclaimer of claim 23 of the 969 Patent under 35 U.S.C. § 253(a) and 37 C.F.R. § 1.321(a). A copy of the statutory disclaimer is submitted as Exhibit 2002 in this proceeding. Based on this disclaimer, the 969 Patent is to be treated as though claim 23 never existed. *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) ("This court has interpreted the term 'considered as part of the original patent' in section 253 to mean that the patent is treated as though the

[2] All emphasis added unless otherwise noted.

disclaimed claims never existed."). As a result of the statutory disclaimer of claim 23, and pursuant to 37 C.F.R. § 42.107(e), it is respectfully submitted that the institution decision in this proceeding should be based only on the remaining challenged claims—19-22 and 24-26—of the 969 Patent.

III. THE 969 PATENT

A. Overview

The challenged claims of the 969 Patent are directed to novel implementations of a "surgical tool for use with a robotic system." The surgical tool of independent claim 24 includes, *inter alia*, a transmission assembly in meshing engagement with a gear-driven portion to apply control motions to a selectively moveable component of the end effector, as well as an elongated shaft comprising proximal and distal spine portions coupled at an articulation joint to facilitate articulation of the end effector. Ex. 1001, claim 24. The surgical cutting and stapling tool of independent claims 19 and 21 includes, *inter alia*, a transmission assembly in meshing engagement with a gear-driven portion to apply control motions to a cutting instrument axially movable within the end effector. *Id.*, claims 19, 21.

The claimed surgical tools each include "a tool mounting portion operably coupled to" the instrument shaft that is "configured to operably interface with the tool drive assembly" of the robotic system in order to apply control motions to various components of the instrument, such as the cutting blade or the selectively

movable end effector. *Id*., claim 21. An endocutter embodiment of the 969 Patent is depicted in Figure 132:

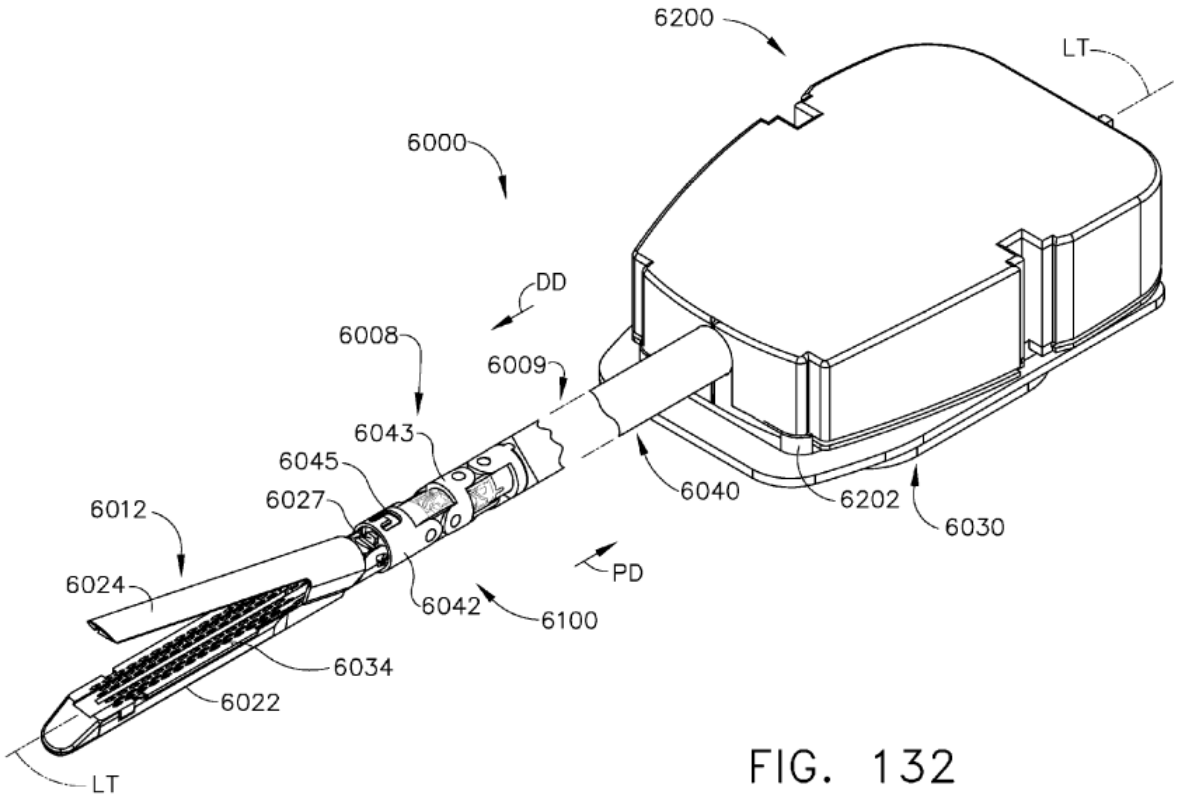


FIG. 132

Ex. 1001, Fig. 132

The instrument includes an endocutter end effector (6012) that has a movable upper jaw/anvil (6024) that moves between first and second positions relative to the lower jaw (6022). *Id*., 77:7-13. The endocutter end effector also includes a cutting instrument that moves between first and second positions relative to the lower jaw (6022). *Id*., 84:27-37. The end effector 6012 is located on one end of the elongated shaft (6008), which has an articulation joint (6100). *Id*., 76:62-67. The articulation joint 6100 allows the shaft to selectively articulate on two axes, one that is transverse

to the longitudinal tool axis (designated "LT"), and one that is transverse to both the first articulation axis and LT. *Id*., 77:38-46. These axes are designated "TA1" and "TA2" in Figure 133, which provides a more detailed view of the articulation joint 6100:

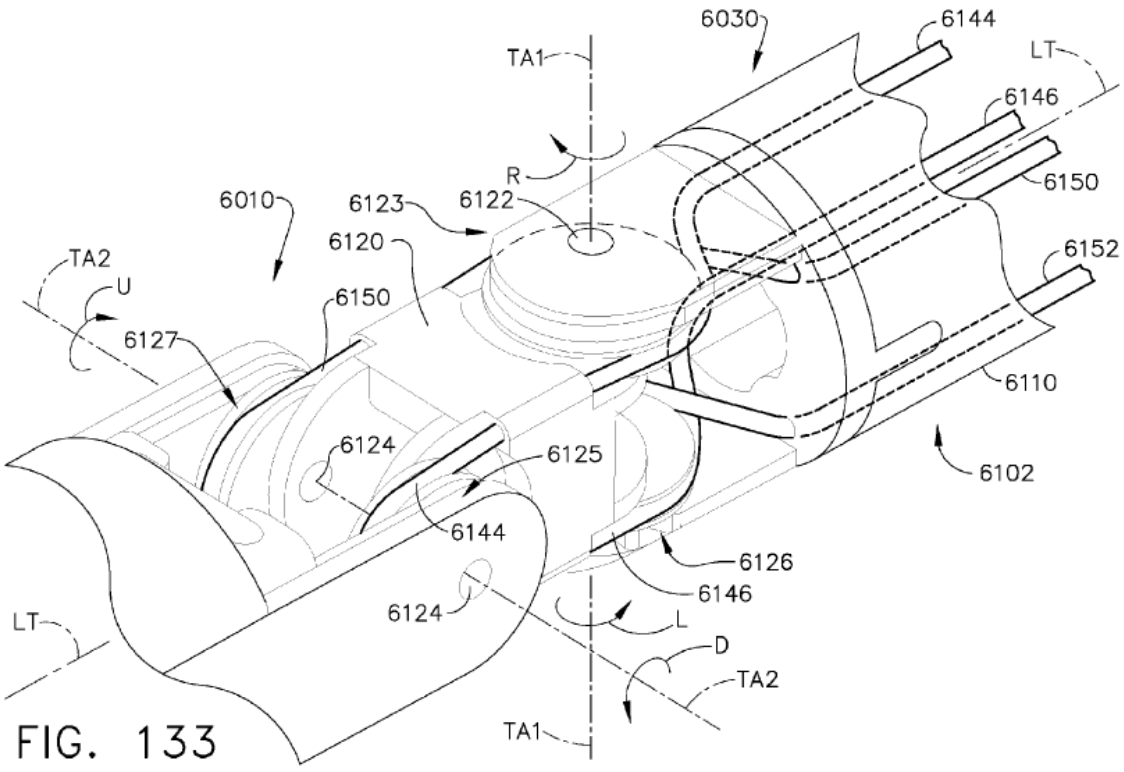


FIG. 133

Ex. 1001, Fig. 133

The instrument couples to the surgical system via the tool mounting portion (6200). *Id*., 77:1-2. Figure 136 below shows the tool mounting portion 6200 in detail. The tool mounting portion includes an articulation transmission system (6142) that controls articulation about the articulation joint 6100. *Id*., 78:23-34. The

robotic system controls the articulation transmission system by applying a first rotary output motion to the articulation drive gear (6322). *Id*., 81:28-82:19.

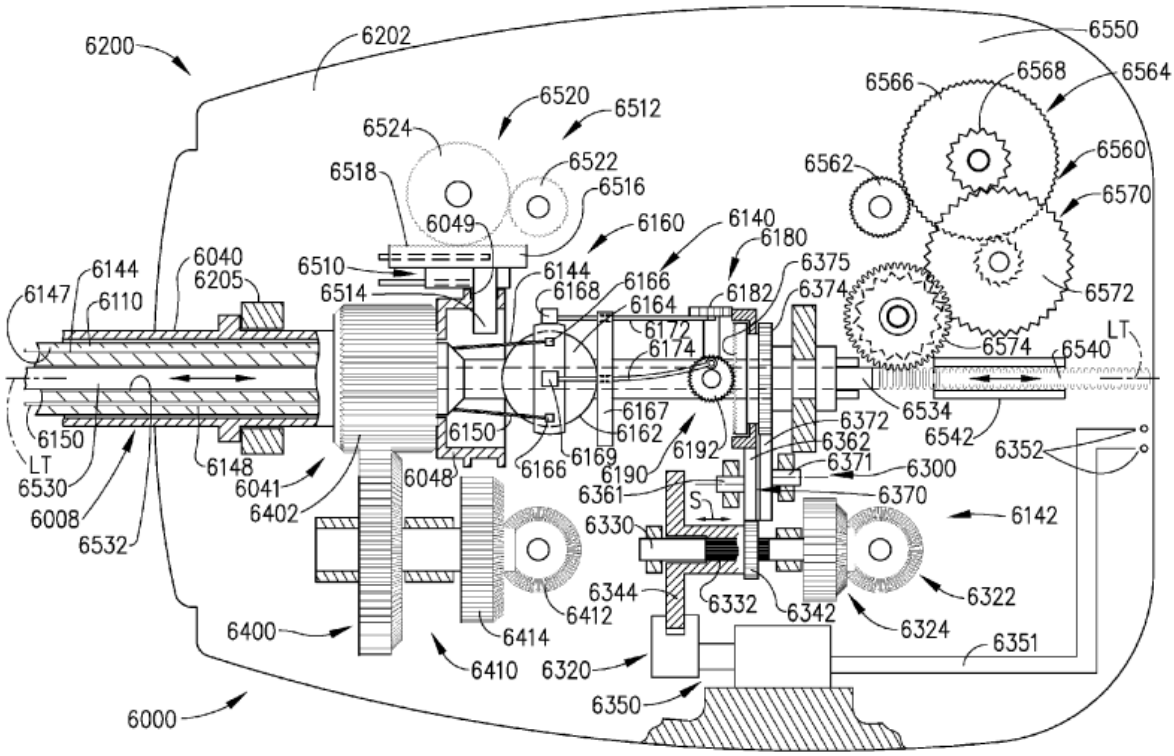


FIG. 136

Ex. 1001, Fig. 136

The tool mounting portion includes closure transmission (6512) including a closure gear assembly (6520) to close the anvil 6420 of the endocutter in response to a third rotary output motion from the robotic system to the closure spur gear (6522). *Id*., 83:44-84:26.

The tool mounting portion additionally includes a knife drive transmission portion (6550) including a knife gear assembly (6560) to fire the cutting instrument

to cut tissue in response to a fourth rotary output motion from the robotic system to the knife spur gear (6562). *Id*., 84:38-85:16.

The tool mounting portion also includes a rotational transmission assembly (6400) that imparts rotary control motion for rotating the instrument shaft about the longitudinal axis LT-LT. *Id*., 82:42-51. The robotic system controls the rotational transmission assembly by applying a second rotary output motion to the rotation drive gear (6412). *Id*., 83:8-15.

Thus, as discussed above and described in detail by the 969 Patent, the "unique and novel transmission arrangement" of the 969 Patent allows a robotic system with four output motions to control (i) articulation about two different articulation axes that are substantially transverse to each other and the longitudinal tool axis: (ii) end effector rotation about the longitudinal tool axis; (iii) opening/closing of the end effector anvil to clamp tissue; and (iv) firing the cutting instrument to cut tissue. *Id*., 85:19-32. As noted in the 969 Patent, "[t]he unique and novel shifter arrangements . . . enable two different articulation actions to be powered from a single rotatable body portion of the robotic system." *Id*., 85:32-36. Unlike prior art robotic tool mounts, such as those of Anderson's system, which were "unable to generate the magnitude of forces required to effectively cut and fasten tissue," the gears of the 969 Patent's embodiments were further sized to generate the

necessary force to close the anvil and cut and staple tissue. *Id*., 23:6-29, 84:20-26, 85:4-10.

Petitioner devotes several pages of the Petition to alleging that the 969 Patent copied Petitioner's Anderson patent, which, as discussed below, is also the primary reference in all of Petitioner's proposed grounds of invalidity. Petition at 1-3. Petitioner's insinuations, however, misrepresent the contributions of the 969 Patent. As an initial matter, the 969 Patent does not purport to have invented robotic surgical systems; indeed, the 969 Patent specification expressly discloses examples of known prior art robotic systems and robotic tools, ***including Anderson***. Ex. 1001, 23:6-29. Thus, the inclusion of figures 23 and 25 depicting known robotic systems is of no moment, and provides the appropriate context for the invention.

Importantly, the 969 Patent further discloses that these systems were known to be "unable to generate the magnitude of forces required to effectively cut and fasten tissue." *Id*. As discussed above, the 969 Patent's innovative tool base overcame these limitations of the prior art systems. Moreover, as discussed in greater detail below, Anderson discloses a tool base for an ultrasound probe, not an endocutter. Ex. 1010, Abstract. Unlike an endocutter, an ultrasound probe does not use a mechanical cutting component to cut tissue or staples to close tissue. Rather, it severs and cauterizes tissue by applying ultrasound energy. Because of this difference, Anderson's instrument need control only two functions—opening and

closing the end effector jaws and rotating the shaft—which it does using three of four rotary outputs from the robotic system. *Id.*, 16:45-17:9. The 969 Patent, by contrast, discloses a novel instrument base that allows a robotic system, using only four rotary outputs, to control an endocutter that grasps tissue in the end effector, cuts and staples tissue, articulates about an articulation joint, and rotates about a longitudinal axis. Ex. 1001, 85:17-36. The Petition's allegations of copying wholly ignore the significant advancements described and claimed in the 969 Patent as compared to the surgical tool disclosed in Anderson.

B. Priority Date

Petitioner contends that the challenged claims of the 969 Patent are not entitled to a priority date earlier than May 27, 2011. Petition at 9-10. The 969 Patent claims priority to application No. 11/651,807, which was filed on Jan. 10, 2007. Ex. 1001, (63). Because the Petition should be denied, for the reasons set forth herein, regardless of the effective filing date of the challenged claims, Patent Owner does not address Petitioner's priority date arguments herein, but reserves all rights to subsequently contend in any instituted IPR or in any other proceeding that the challenged claims are entitled to their earliest claimed effective filing date.

IV. CLAIM CONSTRUCTION

For purposes of IPR only, the claims of the 969 Patent should be construed using the broadest reasonable construction in light of the specification of the patent.

See Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); 37 C.F.R. § 42.100(b)[3].

V. THE PRIOR ART

A. Anderson

Anderson is directed to a robotic surgical tool with an ultrasound cutting and cauterizing end effector. Ex. 1010, Abstract. Anderson states that robotic surgery systems allegedly addressed some of the disadvantages of traditional endoscopic surgical instruments, such as the "lack of intuitiveness, dexterity and sensitivity of endoscopic tools." *Id*., 2:16-40. Anderson also describes advantages of ultrasound surgical tools, such as "reduced collateral tissue damages, reduced risk of unwanted burns, and the like." *Id*., 3:45-53. According to Anderson, however, ultrasound instruments for use with robotic surgical systems were not readily available. *Id*., 3:53-55. Thus, Anderson is directed to "providing ultrasound energy via a robotic surgical instrument for use with a robotic surgical system," in order to "enable the

[3] Patent Owner recognizes that the USPTO has issued a final rule revising the claim construction standard for IPR proceedings filed on or after November 13, 2018. *See* 83 Fed. Reg. 51,340 (Oct. 11, 2018). Because Petitioner filed its Petition on June 14, 2018, the broadest reasonable interpretation standard should apply to this IPR pursuant to pre-October 11, 2018 37 C.F.R. § 42.100(b).

advantages associated with ultrasound to be combined with the advantages of minimally invasive robotic surgery." *Id*., 4:7-11.

Anderson's ultrasound instrument is shown in Figure 2.

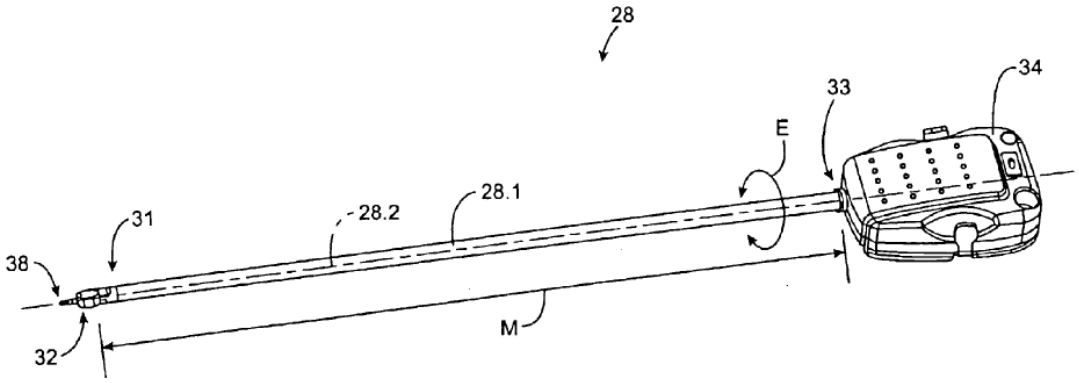


FIG. 2

Ex. 1010, Fig. 2

The instrument includes a shaft 28.1 that can rotate as indicated by the arrows labeled E. Ex. 1010, 11:43-46. In some embodiments, the end effector 38 also includes a gripping jaw, labeled 82 in Figure 10:

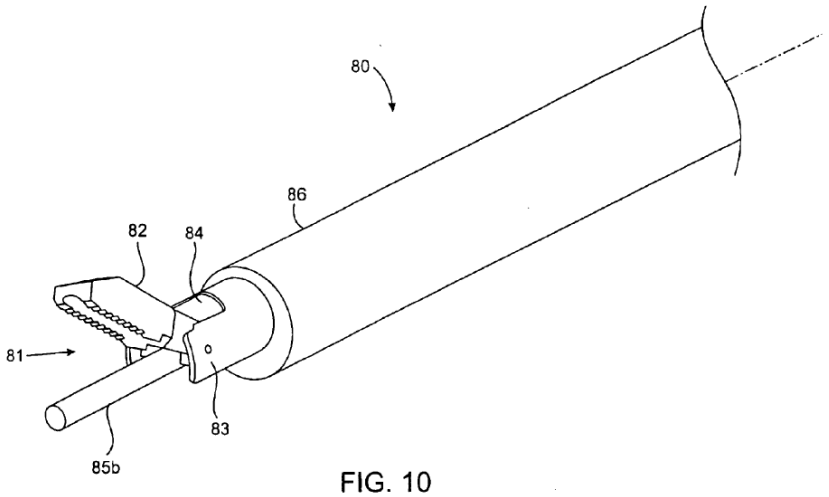


FIG. 10

Ex. 1010, Fig. 10

The instrument attaches to the robotic system through the instrument base 34. *Id*., 11:66-12:11.

Figure 13, reproduced below, illustrates Anderson's instrument base in greater detail. The instrument base includes a roll spool 94, an actuator spool 95, an idler spool 95b, and an unlabeled spool position (located opposite the actuator spool 95). Roll cable 101 spans between roll spool 94 and a roll drum 96, and these three components work together to control the rotation of the instrument shaft. Ex. 1010, 16:45-61. Actuator spool 95 and idler spool 95b are connected by cable loop 102, and together these components control the gripper 82 of the end effector. *Id*., 16:62-17:9. The unlabeled spool opposite actuator spool 95 is unused.

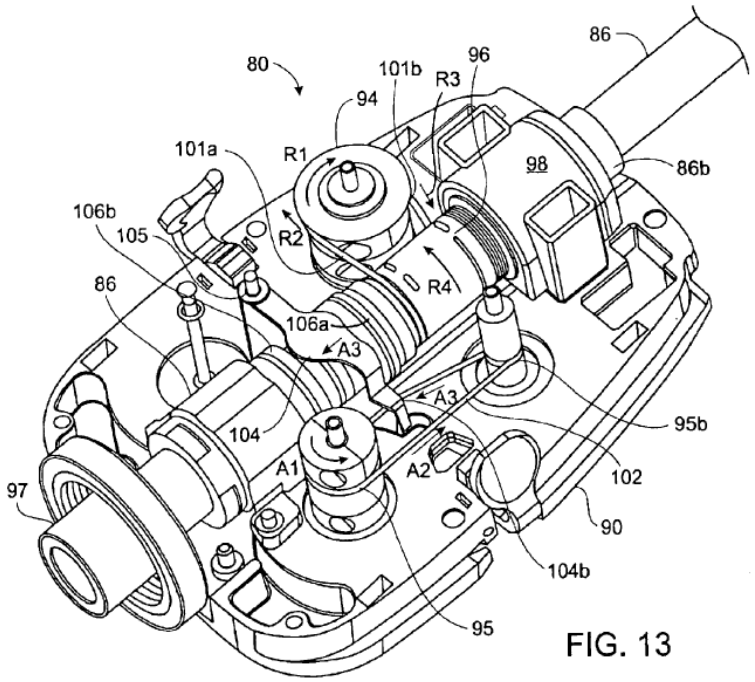


FIG. 13

Ex. 1010, Fig. 13

Thus, the Anderson instrument base utilizes three rotary output motions (roll spool 94, actuator spool 95, and idler spool 95b) to control two instrument motions (shaft rotation and gripper open/close), with one additional rotary output available for additional control.

Anderson was cited in the specification of the 969 Patent, as an example of prior art robotic systems that "have in the past been unable to generate the magnitude of forces required to effectively cut and fasten tissue." Ex. 1001, 23:6-29.

B. Timm

Timm is a patent assigned to Patent Owner that discloses a handheld endocutter with a cable drive system. Ex. 1011, Abstract; Fig. 1. According to Timm, prior art cable-driven surgical instruments "suffer[ed] from a low mechanical advantage and tend[ed] to require relatively high forces to pull the knife through its stroke." *Id*., 2:7-9. Additionally, such instruments purportedly "may suffer from the inadvertent disengagement of the cable from the pulley system which may disable the device." *Id*., 2:12-14. The improvement disclosed by Timm is an instrument with a "cable transition support" and a "cable retention arrangement for retaining the drive cable around at least a portion of the cable transition support." *Id*., 2:25-55. Timm's instrument is depicted in Figure 1:

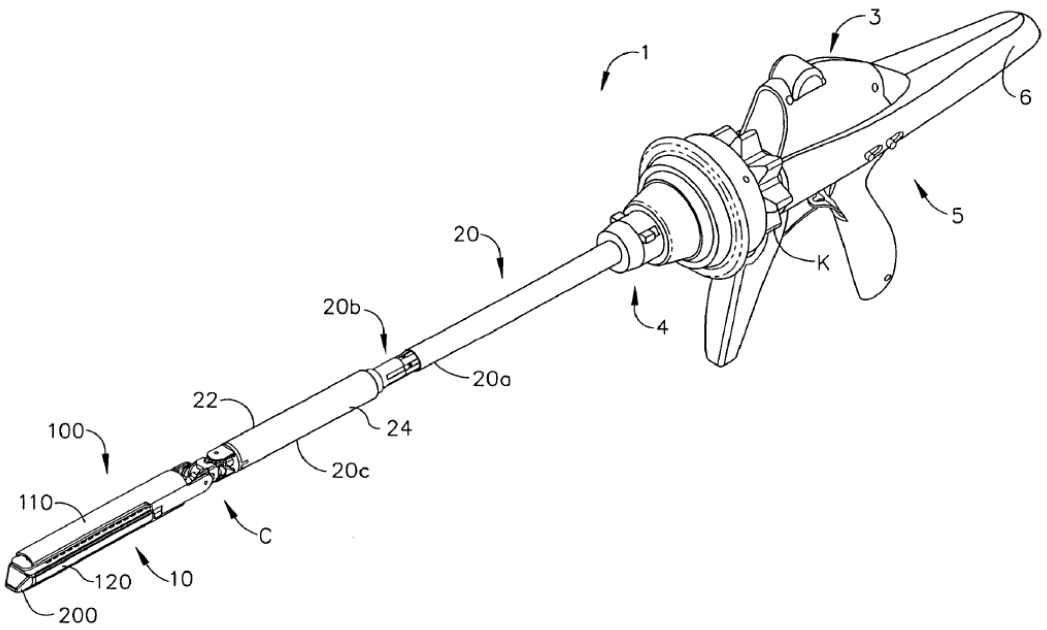


FIG. 1

Ex. 1011, Fig. 1

As shown above, the instrument includes a shaft 20 that comprises a distal end 20a, attachment mechanism 20b, and shaft connector portion 20c. Ex. 1011, 7:49-58. The surgeon can rotate the shaft by manually turning the knob K. *Id*., 9:4-5. Shaft connector portion 20c connects to a disposable loading unit (DLU) 10 through the connector mechanism C. *Id*., 7:55-58. DLU 10 comprises a tool assembly 100 that includes an elongated channel assembly 120, an anvil assembly 110, and a staple cartridge assembly 200 placed inside the elongated channel. *Id*., 8:3-16. The tool assembly further includes a "dynamic clamping member" 150 that moves along the length of the elongated channel to actuate the cutting mechanism. *Id*., 8:12-16, 10:1-13. The surgeon operates the clamping and cutting mechanism by pulling the firing trigger on the device handle. *Id*., 14:39-15:67.

A close-up of an exemplary embodiment of the connector mechanism C is shown in Figure 52:

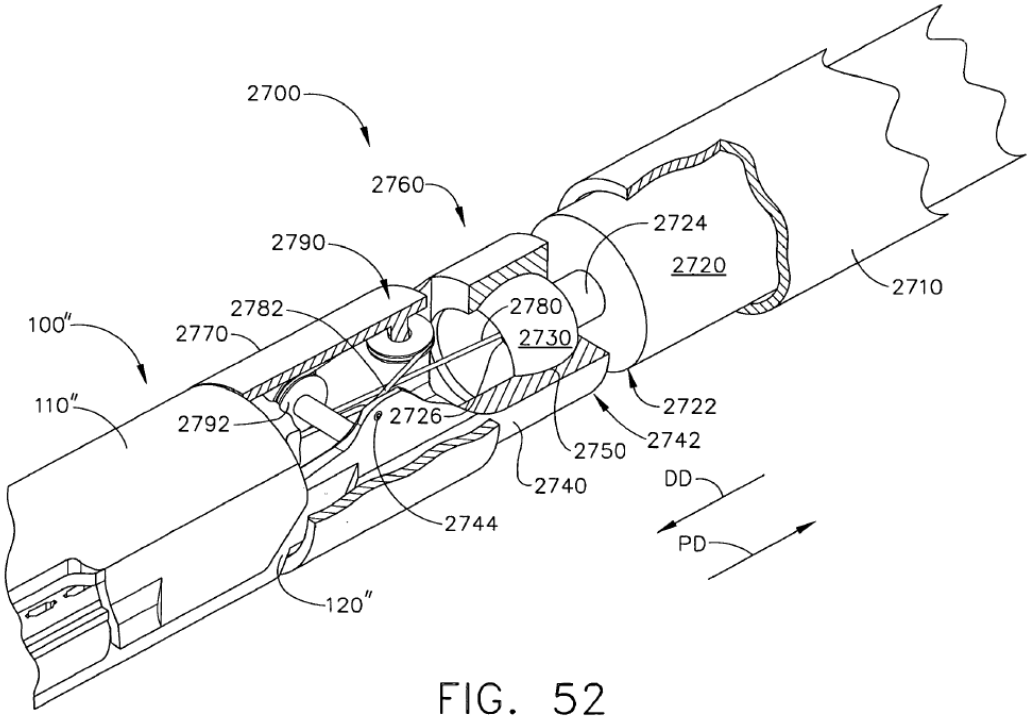
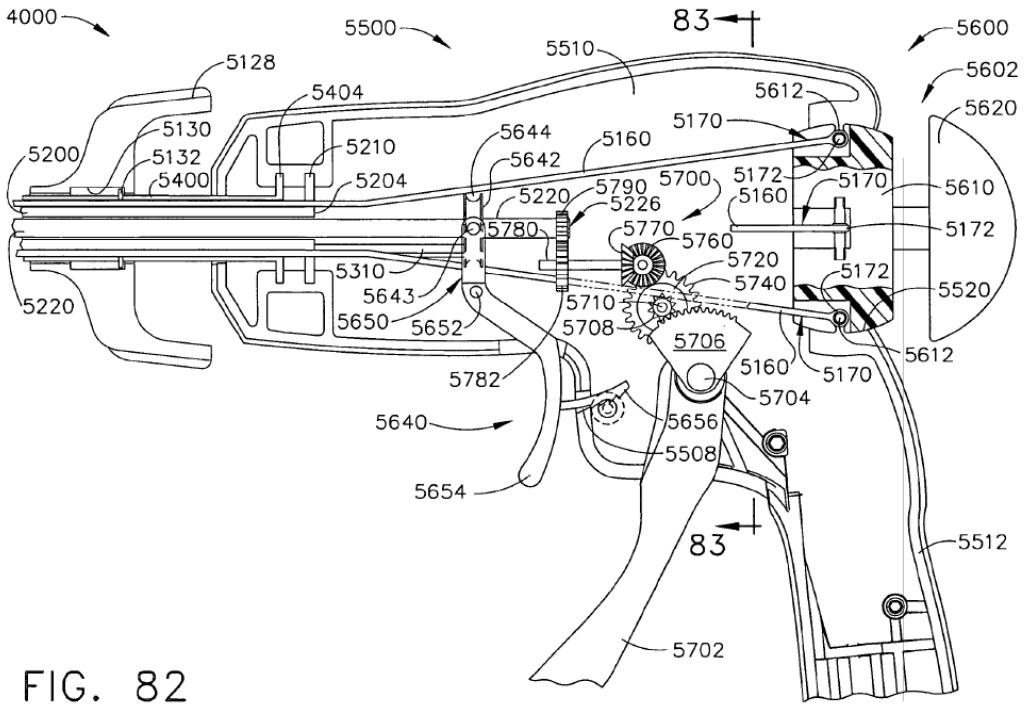


FIG. 52

Ex. 1011, Fig. 52

As shown above, this implementation includes a ball-shaped member 2730 that fits into socket 2750 to form a ball joint, allowing articulation of the distal portion of the shaft. Ex. 1011, 28:50-65. Timm describes that in some embodiments, the articulation system further includes four articulating wires that the surgeon can push or pull to articulate the distal portion of the shaft accordingly. *Id*., 37:55-38:8.

An embodiment of the device handle for such an implementation is shown in Figure 82:



Ex. 1011, Fig. 82

The handle includes an articulation knob 5620, which is part of a "joy stick assembly" 5602. *Id*., 40:34-51. By grasping the hand grip portion 5512 in one hand and manipulating the articulation knob 5620 with the other, the surgeon can apply articulation motions to the articulation wires 5092 in order to articulate the distal portion of the spine while operating the device. *Id*., 40:52-63.

C. Wallace

Wallace is directed to a robotic surgical instrument with a "wrist mechanism" that allows the end effector to articulate under the control of a series of rods. Ex. 1008, Abstract. Examples of the wrist mechanism are shown in Figures 2A and 3.

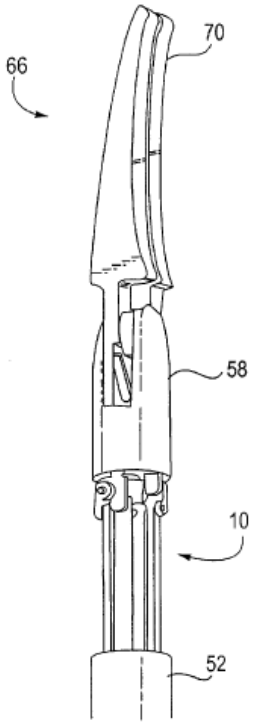


Fig. 2A

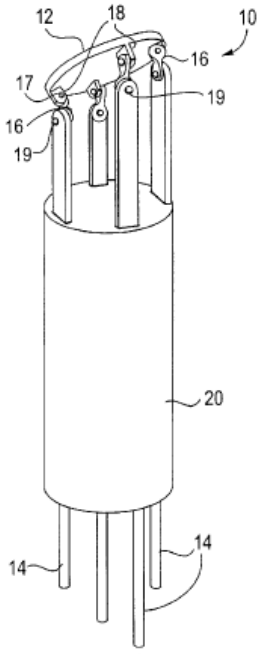


Fig. 3

Ex. 1008, Figs. 2A and 3

Wallace's instrument couples to a robotic system through a tool base 62, shown in Figure 30. *Id*., 7:37-40. The articulation rods shown in Figures 2A and 3 emerge into the tool base as rods 300. *Id*., 13:44-45. Gears 400 rotate the sector gears 312, which advances or retracts individual ones of the rods 300 to actuate the

wrist mechanism. *Id*., 13:47-54. Gear 420 rotates the roll pulley 310, which causes the rods and the instrument shaft to rotate around the central axis of the shaft. *Id*., 13:66-14:10. Thus, Wallace's tool base utilizes three rotary output motions (those of the two gears 400 and the one gear 420) to control two instrument motions (wrist articulation and shaft rotation).

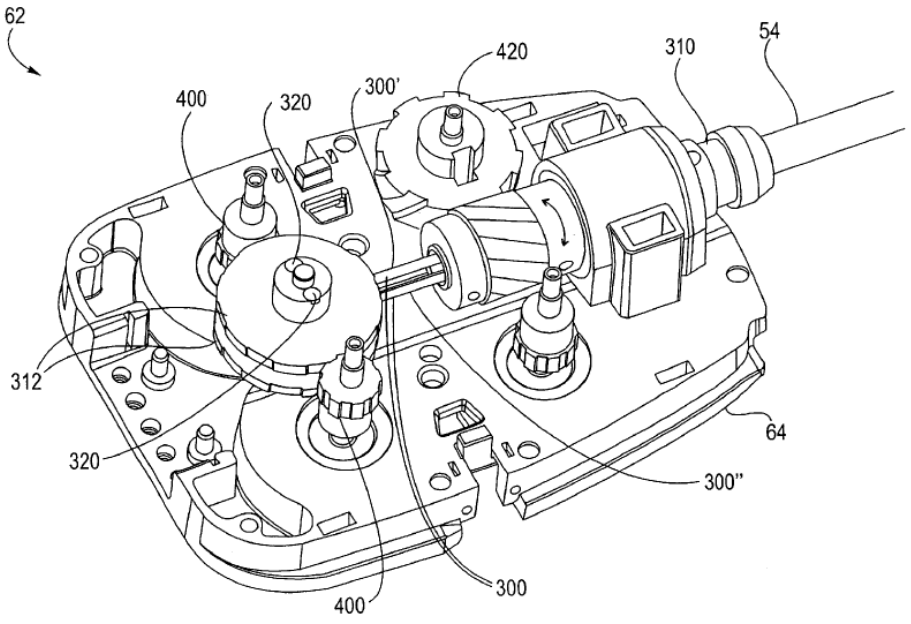


Fig. 30

Ex. 1008, Fig. 30

D. Knodel

Knodel is an expired patent directed to a handheld surgical stapler. Ex. 1012, Abstract. As shown below in Figure 1, Knodel's instrument comprises an endocutter end effector on an elongated shaft coupled to a handle.

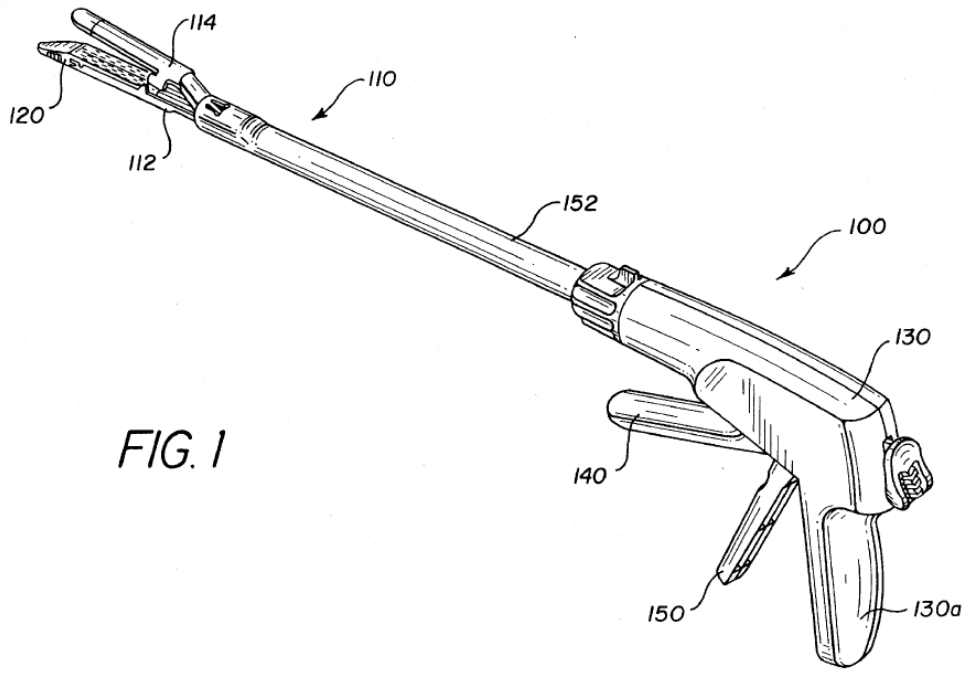
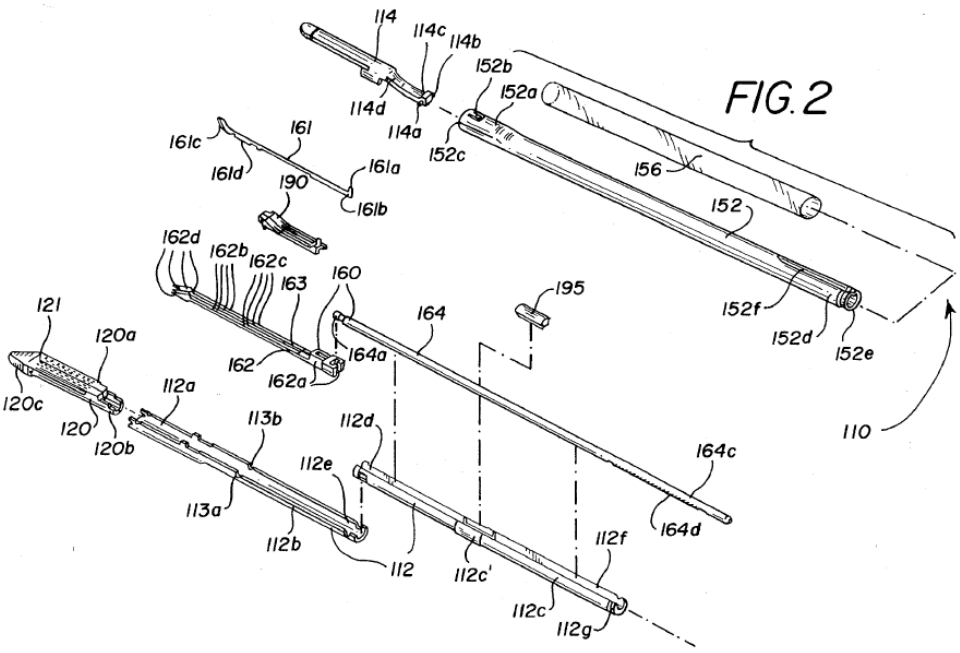


FIG. 1

Ex. 1012, Fig. 1

As is relevant to Petitioner's challenge, Knodel's instrument includes a "drive member" 164, shown in the exploded view of the distal end of the instrument in Figure 2.



Ex. 1012, Fig. 2

When the firing mechanism of the device is actuated by pulling the firing trigger 140, the drive member 164 and wedge work member 162 move distally along the end effector, which causes staples to fire from the staple cartridge. Ex. 1012, 11:56-12:1. The distal movement of the wedge work member also causes the knife member 161 to move distally, which severs the stapled tissue. *Id*., 12:1-6.

Knodel contains no disclosure regarding tools designed for robotic surgery systems.

E. Viola

Viola is an expired patent directed to a powered handheld endocutter. Ex. 1013, Abstract.

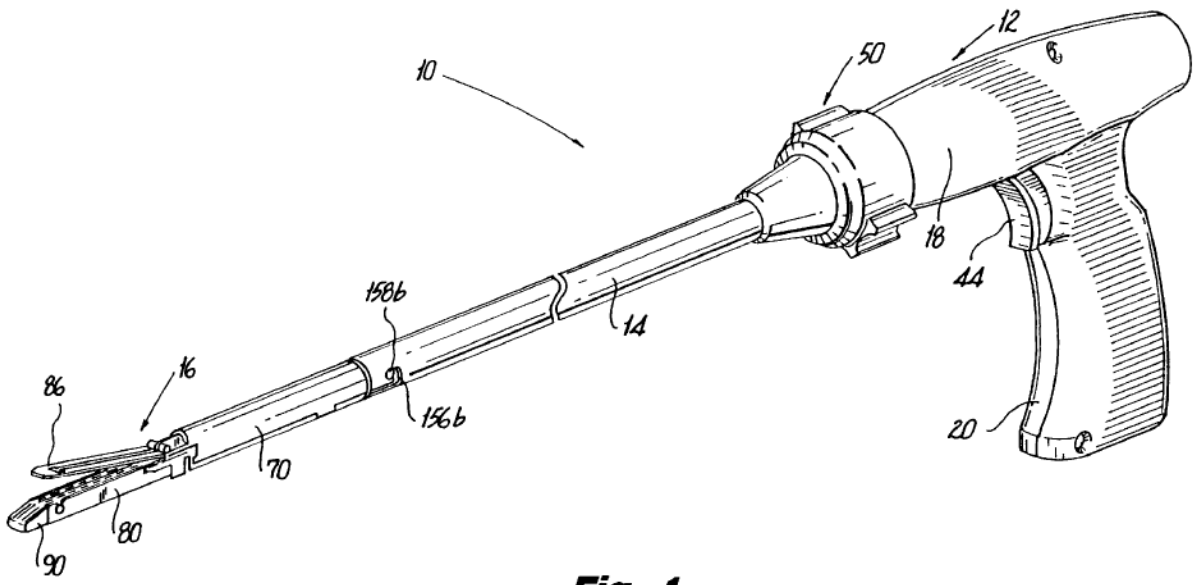


Fig. 1

Ex. 1013, Fig. 1

As is relevant to Petitioner's challenges, Viola purportedly discloses an end effector that is controlled via a rotary drive shaft (in the form of drive screw 78) that is shown in Figure 5, an exploded view of Viola's end effector:

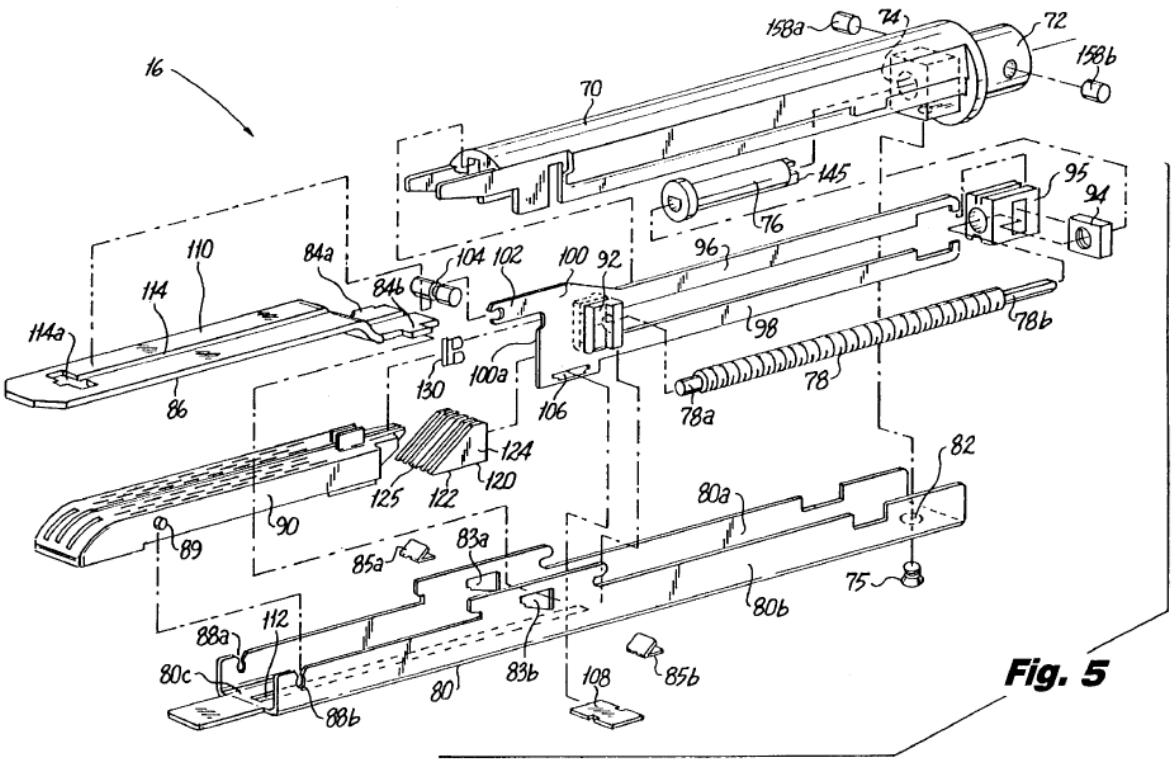


Fig. 5

Ex. 1013, Fig. 5

When the surgeon depresses trigger 44 on the handle of Viola's device, a motor assembly contained within the handle transfers rotational motion to the drive screw 76 through a drive shaft 42, which drives an actuation beam 100 forward into the channel of the endocutter, causing the anvil 86 to close and staples to fire from the cartridge 90. Ex. 1013, 7:45-8:5.

Viola includes no disclosures regarding shaft articulation or tools designed for robotic surgical systems.

VI. REASONS WHY THE PETITION SHOULD BE DENIED

A. Ground 1 Should Be Denied Pursuant To 37 C.F.R. § 42.107(e)

Ground 1 of the Petition is directed solely to claim 23, which Patent Owner has disclaimed. As such, Ground 1 should be denied institution.

B. Grounds 2-5 Should be Denied Because Petitioner Does Not Establish A Motivation To Combine Or Reasonable Expectation of Success

All of the remaining asserted grounds are obviousness combinations. In an obviousness ground, it is the Petitioner's burden to show "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Kinetic Concepts Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (citation omitted). Petitioner falls far short of meeting this burden for each of the remaining grounds.

First, Petitioner provides no explanation for how the robotic ultrasound tool of Anderson and the handheld endocutter of Timm would be combined with each other as proposed in Ground 2, much less with Wallace as proposed in Ground 3.

Second, Petitioner does not provide any evidence of a reasonable expectation of success. The Federal Circuit has "held that where a party argues a skilled artisan would have been motivated to combine references, it ***must show*** the artisan would have had a reasonable expectation of success from doing so." *Arctic Cat Inc.*, 876 F.3d at 1360-61 (internal citation and quotations omitted). "[K]knowledge of the goal does not render its achievement obvious, and obviousness generally requires

that a skilled artisan have reasonably expected success in achieving that goal." *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013) (internal quotes and cites omitted).

Petitioner mentions a reasonable expectation of success only in passing quotations of obviousness rationales, providing no factual evidence or analysis to support a reasonable expectation of success in any of the grounds. For this reason, the Petition fails as a matter of law.

1. Ground 2: Petitioner provides no explanation for how to combine the incompatible systems of Anderson and Timm

First, Petitioner has provided no cognizable combination of Anderson and Timm to disclose the subject matter of claim 24.

With respect to limitation 24.2, which requires "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 tranverse to said longitudinal tool axis," (Ex. 1001, 95:48-54) Petitioner broadly contends that a POSITA would have modified Anderson "to use Timm's end effector with Anderson" and "to include pivotally coupled distal and proximal spine portions (as suggested by Timm)." Petition at 31, 38.

Petitioner's cursory description does not logically follow from the disclosures of Anderson and Timm. As discussed above in Section V.A., Anderson was directed

toward an ultrasound probe for use with a robotic surgical system. Ex. 1010, Abstract. To that end, Anderson's instrument attaches to a robotic system through an instrument base 34. *Id*., 11:66-12:11.

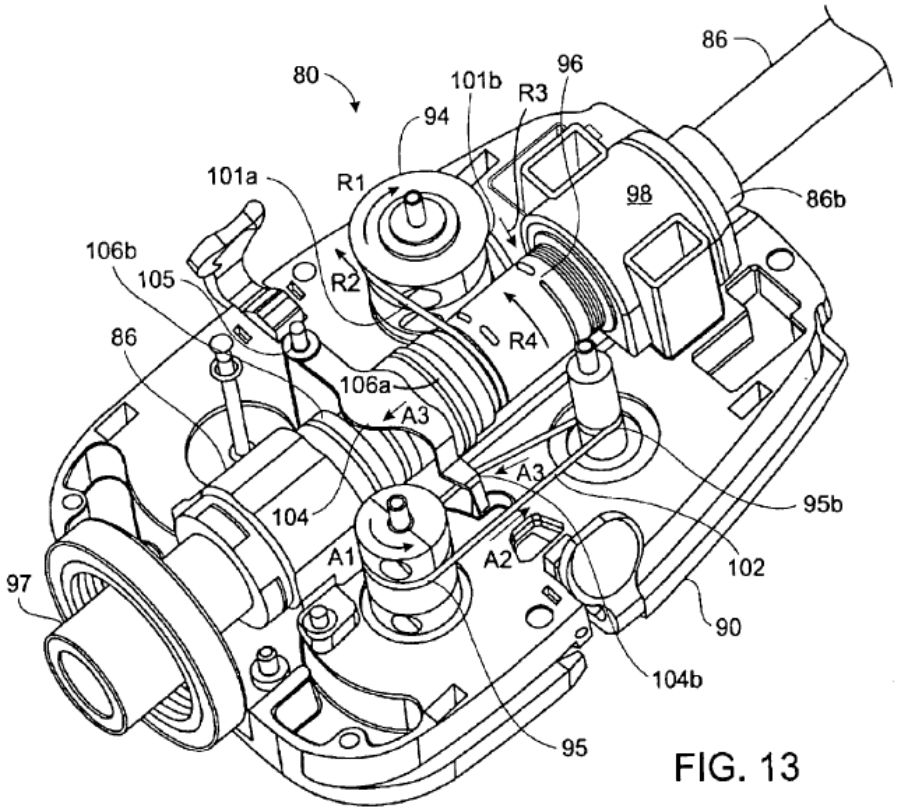


FIG. 13

Ex. 1010, Fig. 13

As discussed in Section V.A., the instrument base provides four spools for accepting rotary outputs from the robotic system: roll spool 94, actuator spool 95, idler spool 95b, and an unlabeled spool position (located opposite the actuator spool 95). Roll cable 101 spans between roll spool 94 and a roll drum 96, and these three components work together to control the rotation of the instrument shaft. Ex. 1010, 16:45-61. Actuator spool 95 and idler spool 95b are connected by cable loop 102,

and together these components control the gripper 82 of the end effector. *Id*., 16:62-17:9. The unlabeled spool opposite actuator spool 95 is unused. Thus, the Anderson instrument base utilizes three rotary output motions (roll spool 94, actuator spool 95, and idler spool 95b) to control two instrument motions (shaft rotation and gripper open/close), with one additional rotary output available for additional control. Because Anderson's instrument utilizes ultrasound energy to cut and cauterize tissue, it does not disclose a control motion for firing a staple cartridge or actuating a knife to cut tissue.

In contrast, the handheld surgical device of Timm is an endocutter, and therefore requires a control motion to initiate the mechanical cutting and stapling of tissue. The surgeon provides this control motion by pulling the firing trigger on the device handle. Ex. 1011, 14:39-15:67. A control motion for articulating the shaft at the articulation joint is provided by manually operating a "joystick assembly" 5602 on the end of the handle, *id*., 40:52-63, and shaft rotation is controlled by manually turning the knob K on the handle. *Id*., 9:4-5. Unlike in Anderson, where the surgeon performs all controls from the robotic system, Timm's instrument requires the surgeon to directly manipulate the controls on the tool itself.

Petitioner offers no explanation for how a POSITA would have combined these references, beyond the cursory allegation that a POSITA would have modified Anderson to use Timm's end effector and articulation joint. Petition at 31, 38.

Petitioner does not clarify whether the combined surgical instrument would have retained any physical controls on a handle, as in Timm, or whether all control motions would be provided through the robotic system, as in Anderson. Critically, to the extent that the Petition is understood to suggest the latter, Petitioner does not explain how Anderson's instrument base would be modified to provide additional rotary outputs to provide the necessary control motions for firing Timm's endocutter or articulating the shaft about the articulation joint. As discussed above, Anderson's instrument base has four spools for receiving four rotary outputs. Three of these spools—roll spool 94, actuator spool 95, and idler spool 95b—are already used in Anderson to provide shaft rotation and control the end gripper of Anderson's probe. That leaves a single spool to accommodate both firing the endocutter *and* articulating the shaft. Petitioner provides no explanation whatsoever of how a single rotary could be used to control two disparate functions in the proposed hybrid system.

Petitioner's failure becomes even more evident with respect to limitation 24.3, which requires "at least one gear-driven portion that is in operable communication with said at least one selectively movable component portion of surgical end effector." Petitioner points to two different disclosures in Timm as allegedly providing this element. First, Petitioner points to a system of gears located in the handle of Timm's instrument that operate cables to move the knife 155 of Timm's endocutter, as shown in the following figures from the Petition:

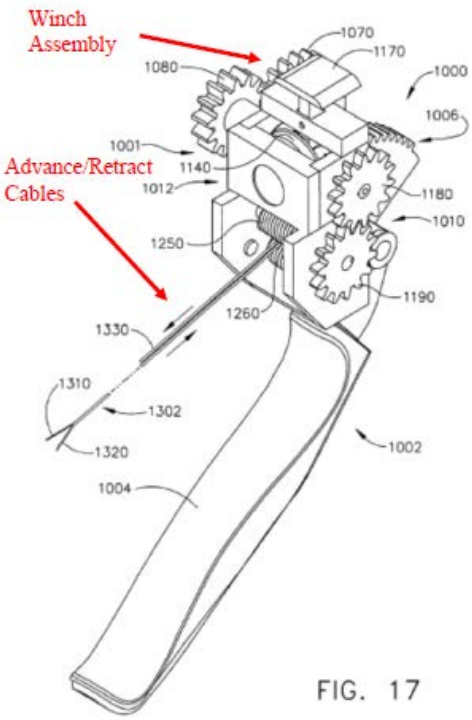


FIG. 17

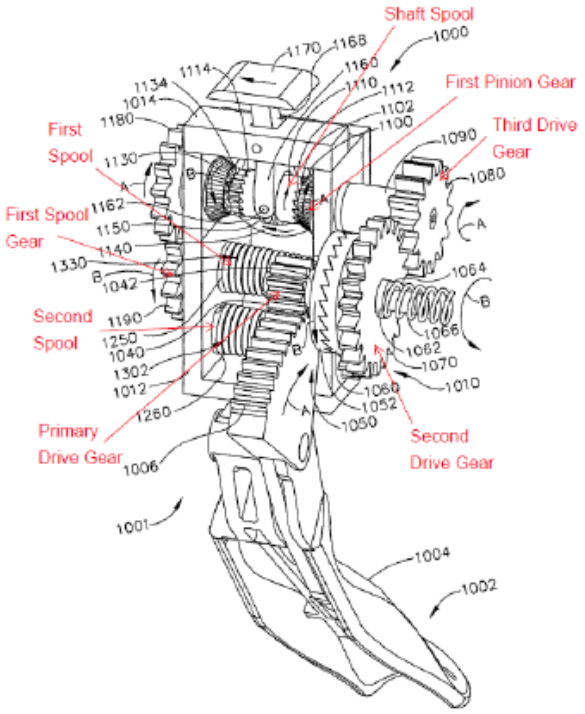


FIG. 18

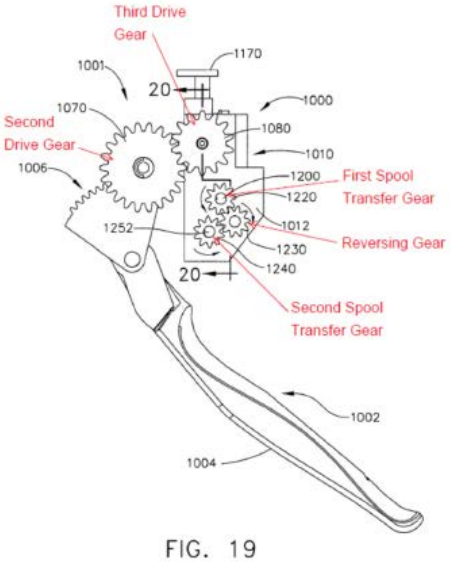


FIG. 19

Ex. 1011, Figs. 17, 18, and 19

Petition at 41-42, 44. Second, Petitioner points to a toothed intermediate closure tube segment 5001, which indirectly facilitates movement of a closure ring 4030 to close the anvil of Timm's endocutter. Petition at 47-49.

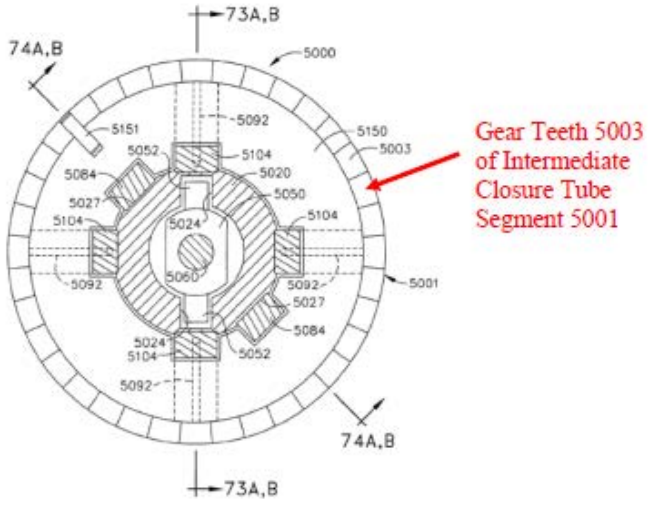


FIG. 76

Ex. 1011, Fig. 76

With respect to both theories, Petitioner cursorily asserts that a POSITA would have incorporated these gear-driven mechanisms into Anderson's instrument. Petition at 45, 50. Once again, however, Petitioner offers no explanation for how a POSITA would have actually combined the references. Petitioner does not clarify, for example, how the gears from the handle and/or intermediate closure tube segment of Timm's instrument would have been incorporated into Anderson's device. Petitioner does not describe where on Anderson's instrument base the additional gears from Timm would be incorporated, what existing components of Anderson's instrument base they would replace, or how they would interact with the

remaining components of Anderson's instrument base to provide an operative device.

Petitioner offers nothing to reconcile any of these incompatibilities between Anderson and Timm, beyond conclusory assertions that the combination "would have led to predictable results without significantly altering or hindering the functions performed by Anderson's surgical instrument." *See, e.g.*, Petition at 39. Petitioner's only purported evidence in support of this proposed combination is the testimony of its expert, which merely parrots word-for-word the argument in the Petition, without further explanation or elaboration. *Compare* Petition at 39 *with* Ex. 1004, ¶ 90. This unsupported testimony should be given no weight. 37 C.F.R. § 42.65(a); *Compass Bank v. Intellectual Ventures II*, IPR2014-00786, Paper 46 at 31 (P.T.A.B. Sept. 23, 2015); *see also Corning Inc. v. DSM IP Assets*, IPR2013-00050, Paper 77 at 22-23, 25 (P.T.A.B. May 1, 2014) (giving expert opinion little weight where it "repeats [Patent Owner's] attorney argument word-for-word.").

In short, the proposed combination of Anderson with Timm is incompatible and inoperable, and Petitioner has offered no evidence to the contrary.

2. Ground 3: Petitioner provides no explanation for how to combine the incompatible systems of Anderson, Timm, and Wallace

Ground 3 challenges claims 25 and 26, which depend on claim 24, by purporting to further combing Petitioner's proposed combination of Anderson and

Timm with Wallace. Thus, as an initial matter, this combination fails because Petitioner has not explained how a POSITA would have combined the incompatible systems of Anderson and Timm, as set forth in the preceding section.

Additionally, Wallace is also incompatible with both Anderson and Timm. As explained in Section V.C., Wallace discloses a robotic surgical instrument with an articulating wrist that is controlled by articulation rods. Gears 400 on Wallace's tool base 62 rotate the sector gears 312, which advance or retract individual ones of the rods 300 to actuate the wrist mechanism. Ex. 1008, 13:47-54.

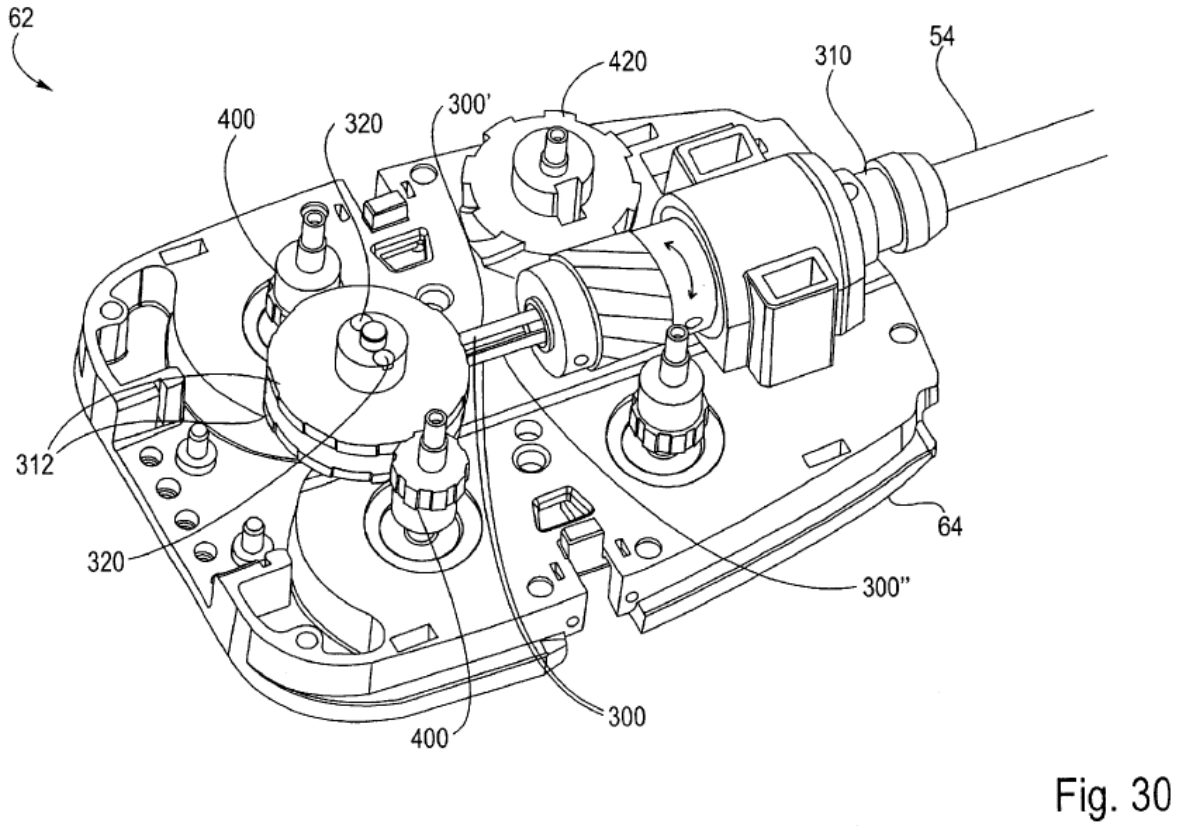


Fig. 30

Ex. 1008, Fig. 30

Gear 420 on the tool base rotates the roll pulley 310, which causes the rods and the instrument shaft to rotate around the central axis of the shaft. *Id*., 13:66-14:10. Thus, Wallace's tool base utilizes three rotary output motions (those of the two gears 400 and the one gear 420) to control two instrument motions (wrist articulation and shaft rotation).

Petitioner contends that a POSITA would have modified the combination of Anderson and Timm to further "include a gear-driven articulation assembly (as suggested by Wallace)." Petition at 60. But Petitioner fails to explain how Wallace's articulation could be further incorporated into the combination of Anderson and Timm, which, as already discussed above, is itself incompatible and inoperable. While the Petition states that in the proposed combination, "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," (*id*.) this attempted explanation fails because Petitioner neglects that its proposed combination includes Timm's end effector. *See* Petition at 31 (asserting that a POSITA would have modified Anderson "to use Timm's end effector with Anderson"). As discussed above, Timm's end effector is an endocutter, which requires an additional control motion to operate the firing mechanism. Thus, the proposed combination requires

at least *five* transmission members: one for end effector rotation, one for opening and closing the end effector jaws, one for firing the stapler, and two for articulation (one for each degree of freedom, as taught in Wallace). As Petitioner admits, Anderson's tool base has only four transmission members. Petition at 60. Thus, like the proposed combination of Anderson and Timm, the proposed combination of Anderson, Timm, and Wallace is incompatible.

3. Grounds 4 and 5: Petitioner provides no explanation for how to combine the incompatible systems of Anderson, Knodel and Viola

Ground 4 challenges claims 19 and 20 based on Anderson in view of Knodel, and Ground 5 challenges claims 21 and 22 based on Anderson in view of Viola. As discussed in Section V, Knodel and Viola both disclose handheld endocutters.

With respect to Ground 4, Petitioner proposes to combine Anderson's ultrasound probe with Knodel's endocutter end effector and gear-driven knife bar. Petition at 70. With respect to Ground 5, Petitioner proposes to combine Anderson's ultrasound probe with Viola's endocutter end effector and rotary drive shaft. Petition at 81. Both of these combinations fail because Petitioner does not explain how a POSITA would have combined Anderson's ultrasound probe with the mechanical cutting and stapling elements from Knodel and Viola.

Anderson states that the purpose of its invention was "providing ultrasound energy via a robotic surgical instrument for use with a robotic surgical system," thus

"enabl[ing] the advantages associated with ultrasound to be combined with the advantages of minimally invasive robotic surgery." Ex. 1010, 4:7-11; *see also id*. at 3:56-60. These advantages included "reduced collateral tissue damages, reduced risk of unwanted burns, and the like." *Id*., 3:45-53. To the extent that Petitioner now urges the Board to replace Anderson's ultrasound end effector with a mechanical endocutter end effector, Petitioner fails to explain how a POSITA would have made this modification to Anderson while still meeting Anderson's stated goal of enabling the advantages of ultrasound surgery. To the extent that Petitioner argues that a POSITA would have used ultrasound energy with a mechanical endocutter, Petitioner fails to explain how a POSITA would have configured the proposed combination such that this was even possible, and also does not cite any evidence that a POSITA would have understood such an arrangement to preserve the stated advantages of ultrasound energy.

Additionally, while Petitioner asserts that the various drive elements of Knodel and Viola could be combined with Anderson's tool base, *see* Petition at 76, 85, Petitioner provides no explanation regarding *how* a POSITA purportedly would have adapted these drive elements – which were designed for a manually-operated handle with a trigger, as shown in Knodel and Viola – to interact with the four rotary elements of Anderson's robotic instrument base. For example, Petitioner provides no explanation of how a POSITA could have adapted Anderson's cable-driven

mechanism for actuating the end effector with Knodel's gear-driven mechanism *or* Viola's drive shaft mechanism.

In sum, Petitioner's proposed obviousness combinations for Grounds 4 and 5 fail because Petitioner argues that a POSITA would have combined fundamentally different and incompatible devices, with no explanation of how such a combination could have been made.

4. Petitioner's proposed combinations fundamentally change the principle of operation of Anderson

In addition to resulting in an incompatible and/or inoperable device, Petitioner's proposed combinations for all of the grounds fundamentally alter Anderson's basic principle of operation, and therefore would not have been obvious for this additional reason. *See In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959); *Plas-Pak Indus. v. Sulzer MixPac AG*, 600 F. App'x 755, 759 (Fed. Cir. 2015).

Anderson expressly sets forth that the purpose of its invention was "providing ultrasound energy via a robotic surgical instrument for use with a robotic surgical system," thus "enabl[ing] the advantages associated with ultrasound to be combined with the advantages of minimally invasive robotic surgery." Ex. 1010, 4:7-11; *see also id*. at 3:56-60. As discussed in Sections V.B., V.D., and V.E., Timm, Knodel, and Viola all pertain to mechanical endocutters, which cut using a physical cutting instrument and close tissue using physical staplers, rather than by ultrasound energy. Because each of the obviousness combinations proposed in Grounds 2-5 relies upon

at least one of Timm, Knodel, or Viola, they would require fundamentally altering one of Anderson's basic principles of operation—using ultrasound energy in order to gain the advantages that ultrasound surgery has over other cutting and cauterizing systems, "such as reduced collateral tissue damage, reduced risk of unwanted burns, and the like." *Id*., 3:51-53, 3:56-60, 4:7-11. Because the proposed combinations alter Anderson's fundamental principle of operation, they would not have been obvious to a POSITA.

5. Petitioner fails to show a reasonable expectation of success

Finally, the Petition does not demonstrate a reasonable expectation of success in any of the proposed combinations.

First, as discussed above, all of Petitioner's proposed combinations are incompatible and inoperable. Thus, for the same reasons discussed in Sections VI.B.1 through VI.B.4, a POSITA would not have had a reasonable expectation of success from attempting the proposed combinations.

Second with respect to all of the grounds, Petitioner's only arguments on reasonable expectation to success are conclusory assertions that the proposed combinations would have yielded "predictable results," "without significantly altering or hindering the functions performed by Anderson's surgical instrument." Petition at 39, 61, 71, 82. The only evidence Petitioner offers to support these assertions is the testimony of its expert, which merely parrots back the words of the

Petition. *See* Ex. 1004, ¶¶ 82, 90, 117, 123, 129, 132, 145, 155. This unsupported testimony should be given no weight. 37 C.F.R. § 42.65(a); *Compass Bank v. Intellectual Ventures II*, IPR2014-00786, Paper 46 at 31; *see also Corning Inc. v. DSM IP Assets*, IPR2013-00050, Paper 77 at 22-23, 25 (giving expert opinion little weight where it "repeats [Patent Owner's] attorney argument word-for-word.").

Petitioner's inability to show reasonable expectation of success is unsurprising. As discussed extensively in the preceding sections, one of the core innovations of the 969 Patent was the development of a novel and inventive instrument base that allowed a surgical instrument that grasps tissue in the end effector, cuts and staples tissue, articulates about an articulation joint, and rotates about a longitudinal axis to be controlled by a robotic system using only four rotary output motions. Ex. 1001, 85:17-36. Anderson's tool base accepts four rotary output motions, but because of the significant differences between an ultrasound probe and an endocutter, is designed to operate less efficiently, requiring three of the four rotary output motions just to grasp tissue and rotate the shaft. Petitioner's proposed combinations fail to account for these critical differences between the prior art and the claims of the 969 Patent, thus resulting in inoperable hybrid devices for which a POSITA would not have had a reasonable expectation of success. For this reason, all of the grounds in the Petition fail as a matter of law.

C. The Board Should Exercise Its Discretion To Deny Institution Pursuant To § 325(d)

Under § 325(d), the Board has discretion to deny institution because "the same or substantially the same prior art or arguments previously were presented to the Office." *Praxair Distrib., Inc. v. INO Therapeutic LLC*, IPR2015-00893, Paper 14 at 8 (P.T.A.B. Sept. 22, 2015). In determining whether to exercise this discretion, the Board considers, *inter alia*, the similarities and material differences between the asserted art and the prior art involved during examination, as well as the cumulative nature of the asserted art and the prior art evaluated during examination. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17 (P.T.A.B. Dec. 15, 2017).

These considerations counsel against institution because *all* of Petitioner's prior art references were evaluated during examination. As discussed in Sections III.A. and V.A., the 969 Patent specification expressly disclosed and incorporated by reference Anderson, as an example of prior art robotic systems that "have in the past been unable to generate the magnitude of forces required to effectively cut and fasten tissue." Ex. 1001, 23:6-29. Moreover, the specification discussed not just how it improves over Anderson, but also over other substantially similar, non-endocutter, prior art robotic systems. *Id.* Indeed, Petitioner concedes that "[t]he published application related to the Anderson patent was cited during prosecution," contending only that Anderson "was never discussed by the examiner or applicant."

Petition at 6; Ex. 1002 at 285. Petitioner does not dispute, however, that the Examiner cited and considered Anderson as part of prosecution. Moreover, the Examiner issued an office action rejecting several of the originally filed claims of the 969 Patent based on Tierney, resulting in Patent Owner amending its claims to include subject matter that was allowable over Tierney. Petition at 3; Ex. 1002 at 280-284, 295-311. As Petitioner itself sets forth in its petition filed in a related IPR proceeding, IPR2018-01254, which also challenges the claims of the 969 Patent, Tierney discloses a prior art robotic surgical system that is substantially the same as the system disclosed in Anderson. *Compare* Petition at 2-3 with IPR2018-01254, Paper 2 at 2-4. A grandchild application of Tierney that has the same figures and specification – U.S. Patent No. 7,524,320 – is also among the several robotic surgery system references explicitly discussed at col. 23, lines 6-29 of the 969 Patent specification. Exhibit 2003. Thus, Anderson's teachings and other substantially similar disclosures were squarely before the Patent Office during examination. *See Agrinomix, LLC v. Mitchell Ellis Prods., Inc.*, IPR2017-00525, Paper No. 6 at 11 (P.T.A.B. June 14, 2017) ("As noted by Patent Owner, however, Nöthen was discussed in the Specification of the '583 patent, was cited by the applicant in an information disclosure statement, and was relied upon by the Examiner in an office action to reject certain limitations of the dependent claims. Thus, although the Examiner may only have relied upon Nöthen to address the limitation of a dependent

claim, that fact does not obviate that Nöthen was before the Examiner and that the Examiner relied upon it in rejecting certain claims during prosecution.") (internal citations omitted).

It is also without dispute that Petitioner's remaining prior art references – Timm, Wallace, Knodel, and Viola – were all disclosed during prosecution. Ex. 1002 at pp. 357 (Knodel), 395 (Viola), 401 (Wallace), 410 (Timm). Moreover, Petitioner does not dispute that each reference appears, without strikethrough, on the Examiner's list of references cited by applicant and considered by examiner, which was signed and initialed by the examiner, with the notation "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH," to indicate that the examiner had considered all of the references. *Id*. at 568 (Knodel), 606 (Viola), 612 (Wallace), 621 (Timm). Thus, there is no dispute that the examiner considered Timm, Wallace, Knodel, and Viola during prosecution. *See, e.g.*, *Cultec, Inc. v. Stormtech Inc.*, IPR2017-00777, Paper No. 7 at 10 (P.T.A.B. Aug. 22, 2017) ("Moreover, the Examiner considered the Third Party Submission. The Submission was signed by the Examiner on December 11, 2015. As stated on the signed form, the Examiner's signature 'indicates all documents listed above have been considered.' Additionally, typed on the bottom of the form is the statement 'ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.F.F./'

No references were lined through. 'B.F.F.' appears to be the initials of the Examiner.") (internal citations omitted).

Every prior art reference relied upon by Petitioner in Grounds 2-5 was indisputably considered by the Examiner during prosecution. The complete identity and resultant lack of any material differences between the asserted prior art and the prior art evaluated during examination therefore strongly counsels against institution, especially in view of the fact that the claims were amended expressly to overcome a rejection based on Tierney, which discloses substantially the same robotic surgery system as Anderson. *See Unified Patents Inc. v. Berman*, IPR2016-01571, Paper No. 10 at 12 (P.T.A.B. Dec. 14, 2016) ("Petitioner fails to present any argument distinguishing the Examiner's prior consideration of Russell or to provide a compelling reason why we should readjudicate substantially the same prior art and arguments as those presented during prosecution and considered by the Examiner. This would not be an efficient use of Board resources in this matter.") (internal citations omitted). For this reason, the Board should exercise its discretion under § 325(d) to deny institution.

VII. CONCLUSION

Petitioner has failed to demonstrate a reasonable likelihood of success that it will prevail on any of the challenged claims of the 969 Patent. Accordingly, Patent

Owner respectfully requests that institution of *inter partes* review should be denied.

Respectfully submitted

Dated: October 17, 2018

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CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 7,247 words (excluding the table of contents, the table of authorities, mandatory notices under 37 CFR § 42.8, the certificate of service, certificate of compliance, and appendix of exhibits), as calculated by the "Word Count" feature of Microsoft Word 2016, the word processing program used to create it.

2. The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Respectfully submitted,

WEIL, GOTSHAL AND MANGES LLP

Dated: October 17, 2018

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 17, 2018, the foregoing **PATENT OWNER'S PRELIMINARY RESPONSE** was served via electronic mail, upon the following:

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