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 RESPONSE

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EXHIBIT LIST FOR IPR2018-01247

Ethicon Exhibit #	Description
Ex. 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)
Ex. 2002	Patent Statutory Disclaimer for U.S. Patent No. 8,479,969 filed on October 15, 2018
Ex. 2003	U.S. Patent No. 7,524,320
Ex. 2004	U.S. Patent No. 7,473,258
Ex. 2005	[Reserved]
Ex. 2006	Declaration of Dr. Shorya Awtar
Ex. 2007	Declaration of Dr. Elliott Fegelman
Ex. 2008	Additional excerpts from technology tutorial
Ex. 2009	Mucksavage et al., Differences in Grip Forces Among Various Robotic Instruments and da Vinci Surgical Platforms, Journal Of Endourology, Vol. 25, No. 3 (March 2011)
Ex. 2010	Deposition Transcript of Bryan Knodel, IPR2018-01247 (April 3, 2019)
Ex. 2011	Deposition Transcript of Bryan Knodel, IPR2018-01254 (April 4, 2019)
Ex. 2012	U.S. Patent No. 8,640,788
Ex. 2013	Order Invalidating the January 2018 Certificate of Correction Relating to U.S. Patent No. 8,479,969, *Ethicon v. Intuitive Surgical, Inc.*, C.A. No. 17-871 (D. Del. Feb. 11, 2019)
Ex. 2014	WIPO Publication No. 2015/153642 A1

Ethicon Exhibit #	Description
Ex. 2015	U.S. Patent No. 8,186,555
Ex. 2016	U.S. Patent No. 5,307,976
Ex. 2017	Hermann Mayer et al., *Haptic Feedback in a Telepresence System for Endoscopic Heart Surgery*, Presence, Vol. 16, No. 5, pp. 459-470 (October 2007)
Ex. 2018	Allison M. Okamura, *Haptic feedback in robot-assisted minimally invasive surgery*, Current Opinion in Urology, 19:102-107 (2009)
Ex. 2019	U.S. Patent Application Publication No. 2012/0209314
Ex. 2020	U.S. Patent No. 6,978,921

I. INTRODUCTION

The challenged claims of U.S. Patent No. 8,479,969 ("the 969 Patent") are directed to an endocutter surgical tool that includes a gear-driven portion and that operatively couples to a robotic surgical system. More specifically, claim 24 and its dependent claims 25-26 are directed to a surgical tool with an articulation joint operably coupled to a tool mounting portion that is designed to meet the demands of an endocutter coupled to a robotic system. Thus, the 969 Patent describes and claims novel assemblies that are capable of utilizing inputs from robotic surgical systems to drive robotic endocutter surgical tools. The assemblies improve upon the tool base designs of prior robotic surgical tools, which were designed to operate simpler instruments such as grasping jaws, scalpels, and electrocautery probes. As the 969 Patent explains, prior art robotic systems and the tools designed for use with them were "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.

Trial was instituted on Grounds 2-5 in the Petition. Each of Petitioner's grounds are obviousness challenges premised on U.S. Patent No. 6,783,524 ("Anderson") (Ex. 1010), which is focused on a robotic tool that is designed to operate an ultrasonic (also called harmonic) end effector. The tool base of the disclosed robotic tool has limited functionality and is incapable of driving an endocutter as designed. To meet the remaining limitations of the challenged claims,

Petitioner seeks to combine Anderson together with various handheld endocutter devices that operate in a fundamentally different way than the robotic tool of Anderson. As explained below, Intuitive has failed to demonstrate that the challenged claims are obvious.

First, with respect to claim 24, Intuitive proposes to arrive at a robotic endocutter with an articulation joint by combining Anderson with the handheld endocutter disclosed in U.S. Patent No. 7,510, 107 ("Timm") (Ex. 1011) (Ground 2, Claim 24). As a preliminary matter, Intuitive's Petition and associated expert declaration entirely fail to explain how the combination discloses the limitation in claim 24 requiring "a tool mounting portion operably coupled to a distal end of said proximal spine portion." The challenge should be rejected for this reason alone. Even setting aside this deficiency, Petitioner's combination of Timm and Anderson is premised on use of the "lockable articulation joint" in Timm. This joint employs "passive articulation," which requires pressing the end effector against another structure in order to articulate it. As the accompanying declarations of Dr. Elliott Fegelman (Ex. 2007) and Dr. Shorya Awtar (Ex. 2006) explain, a POSITA would never have utilized a passive articulation joint in a robotic endocutter because, unlike handheld tools, robotic surgical systems and tools lack the tactile feedback that is necessary in order to perform passive articulation safely and effectively.

Second, for all of the claims at issue in Grounds 2-3, Petitioner has not

established a reasonable expectation of success. The difference between the non-endocutter tools and associated drive systems in Anderson and the Timm handheld endocutter tool[1] are significant, and Intuitive does not account for them. The Timm handheld endocutter involves a high torque, low speed hand trigger to drive end effector controls requiring forces on the order of 70 to 120 pounds. The tool base in Anderson is designed to interface with a low torque, high speed motor in order to drive end effector controls requiring forces on the order of 10 pounds or less. Thus, the proposed combination would involve a fundamental change in the principle of operation of Timm and Anderson and require re-design of the tool base, which would be a complicated endeavor beyond the level of skill of a POSITA. On this point, Intuitive's own contemporary patent filings confirm that existing robotic systems, such as those in Anderson, could not generate sufficient clamping force for endocutters. *See* Ex. 2006, ¶¶ 86-89. Indeed, Intuitive's position in a published application in 2011 that there was a "need for surgical end effectors with high actuation force, for example, clamping force" (Ex. 2012 at 2:4-39) directly contradicts the conclusory assertion in this IPR that combining a handheld

[1] Although Timm makes a passing reference to robotic control and/or motor power without any detail or explanation, the only illustrated embodiment is a handheld embodiment that includes a manual trigger.

endocutter with a robotic system "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." Petition at 39.

Third, with respect to dependent claims 25 and 26, Petitioner proposes to add the robotic tool base of Wallace (U.S. Patent No. 6,699,235) (Ex. 1008) to the combination of Anderson and Timm in order to arrive at an articulating robotic endocutter that includes a gear-driven articulation system (claim 25) and that is driven by first and second articulation bars (claim 26) (Ground 3, claims 25-26). Because claims 25-26 depend from claim 24, Petitioner's combination fails for the same reasons above. Moreover, Petitioner's combination fails because it seeks to add active articulation mechanisms to an admittedly passive articulation joint that is relied on to satisfy claim 24. A passive articulation joint and active articulation joint are mutually exclusive and incompatible. Finally, Petitioner's proposed combination fails because, like Anderson, Wallace's tool base utilizes three rotary drive motions (those of the two gears 400 and one gear 420) to control two instrument motions (wrist articulation and shaft roll). The Wallace reference does not even explain how closing is accomplished, let alone how an additional control motion (firing) could be accomplished. Thus, the addition of Wallace does nothing to remedy the deficiencies of Anderson's tool base. Further, as noted above, Petitioner's own publications belie Petitioner's boilerplate assertion that "includ[ing] Wallace's gear-

driven articulation assembly … would be merely the application of a known technique … to a known system … ready for improvement to yield predictable results." Petition at 61-62.

Fourth, Petitioner proposes to combine Anderson with a handheld endocutter disclosed in Knodel (U.S. Patent No. 5,465,895) (Ex. 1012) (Ground 4, Claims 19-20) to arrive at a robotic endocutter with a gear-driven knife bar. However, a POSITA would have been deterred from combining this handheld endocutter with a robotic system because the resulting device would lack the tactile feedback that surgeons would have deemed critical for operating an endocutter in the 2011 timeframe. Moreover, for similar reasons discussed above, a POSITA would have lacked a reasonable expectation of success in modifying the Knodel handheld endocutter for use on a robotic system.

Fifth, Petitioner proposes to combine Anderson with a handheld endocutter disclosed in Viola (U.S. Patent No. 5,954,259) (Ex. 1013) (Ground 5, claims 21-22) to arrive at a robotic endocutter with a rotary shaft that is ultimately gear driven. Intuitive's proposed combination fails, however, because it does not disclose the limitations in claim 21 requiring "an end effector comprising…a rotary end effector drive shaft…[and] a knife member having a tissue-cutting portion thereon threadedly received on said rotary drive shaft."

For these reasons, and the additional reasons explained in detail below, Patent

Owner respectfully requests that the Board find all challenged claims patentable over the asserted grounds of invalidity.

II. THE 969 PATENT

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 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*. An endocutter embodiment of the 969 Patent is depicted in Figure 132:

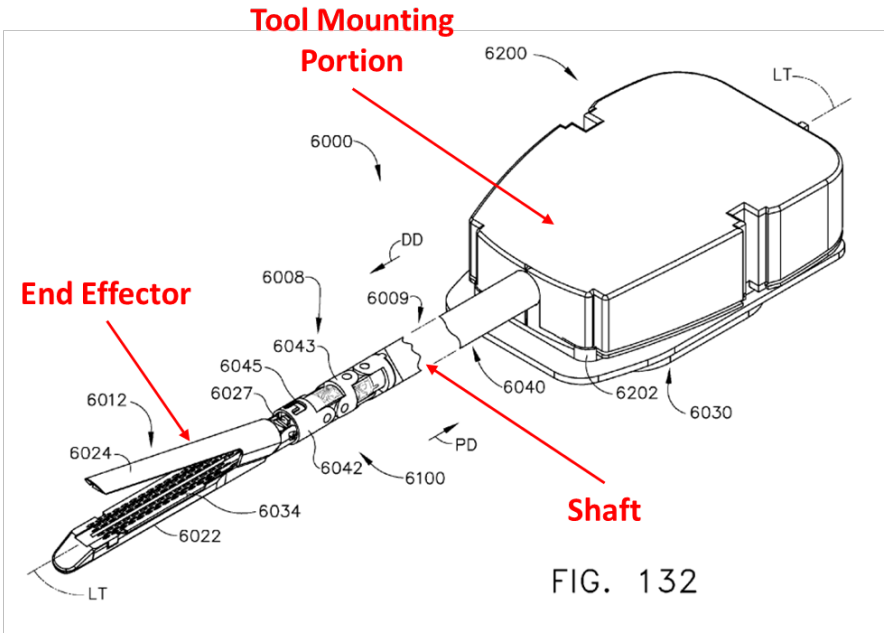


FIG. 132

Ex. 1001, Fig. 132 (annotated)

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). Ex. 1001, 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). Ex. 1001, 84:27-37. As shown in the figure below, the tool base includes transmission assemblies (closure transmission 6512 and knife drive transmission 6550) in meshing engagement with a gear-driven portion to provide the control motions of both clamping and firing. Ex. 1001, 83:24-31, 84:38-48. In this way, the 969 Patent provides a tool base that is driven by electric motors and is capable of generating sufficient force to clamp and fire an endocutter.

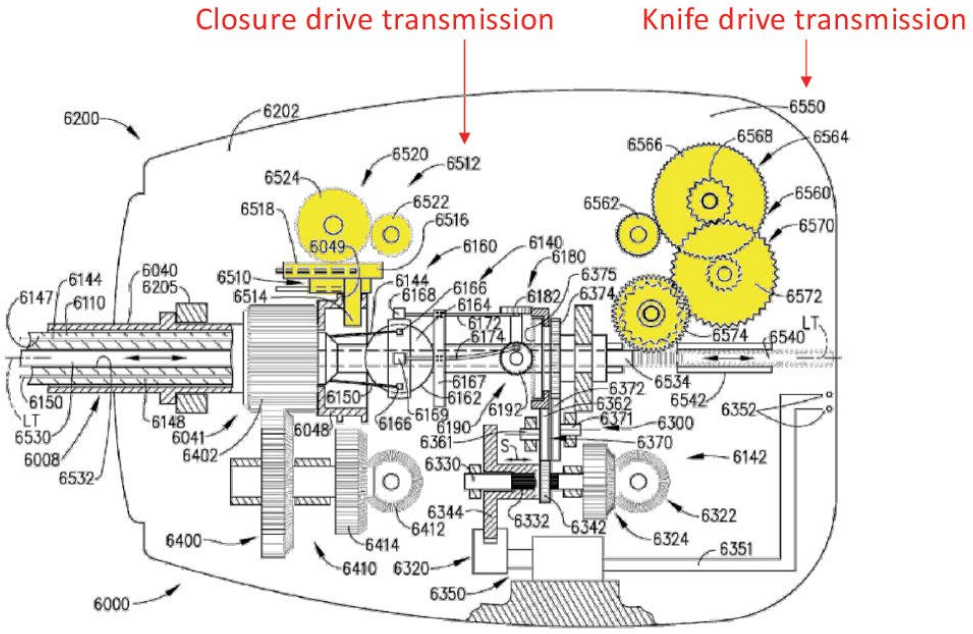


FIG. 136

Ex. 1001, Fig. 136 (annotated)

Claim 24 further requires an elongated shaft comprising proximal and distal spine portions coupled at an articulation joint to facilitate articulation of the end effector, and further that the tool mounting portion is operably coupled to the distal end of the proximal spine portion. The end effector 6012 is located on one end of the elongated shaft (6008), which has an articulation joint (6100). Ex. 1001, 76:62-67. The articulation joint (6100), shown in Fig. 132, 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). As can be in seen in Figure 133,

the articulation joint is controlled by two pairs of articulation cables, designated 6144, 6146, 6150, and 6152. *See also* Ex. 2006, ¶ 22.

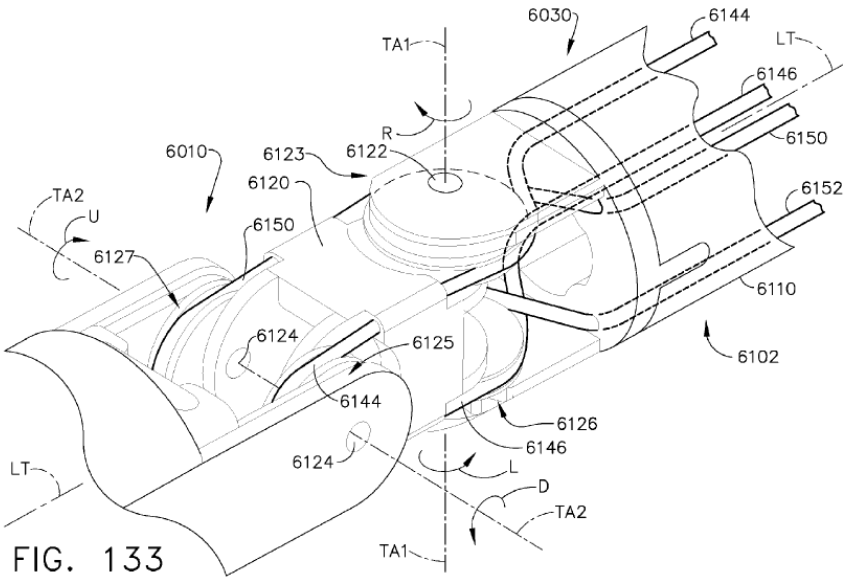


FIG. 133

Ex. 1001, Fig. 133

The articulation joint is operably coupled to the tool mounting portion by the articulation cables thereby allowing the joint to be operated by rotary motion received from the robotic system.[2] Ex. 2006, ¶ 22. As indicated by the red lines below in Figure 136, the articulation cables 6144 and 6150 enter the tool mounting portion through passages in the instrument shaft (the cables 6146 and 6152, which

[2] The endocutter embodiment in Figures 32-36 also includes an articulation joint operably coupled to the tool mounting portion. Ex. 1001, 30:65-31:43. The embodiment in Figures 32-36 can only articulate about one axis.

run parallel to 6144 and 6150 are not visible in this perspective). Ex. 2006, ¶ 22.

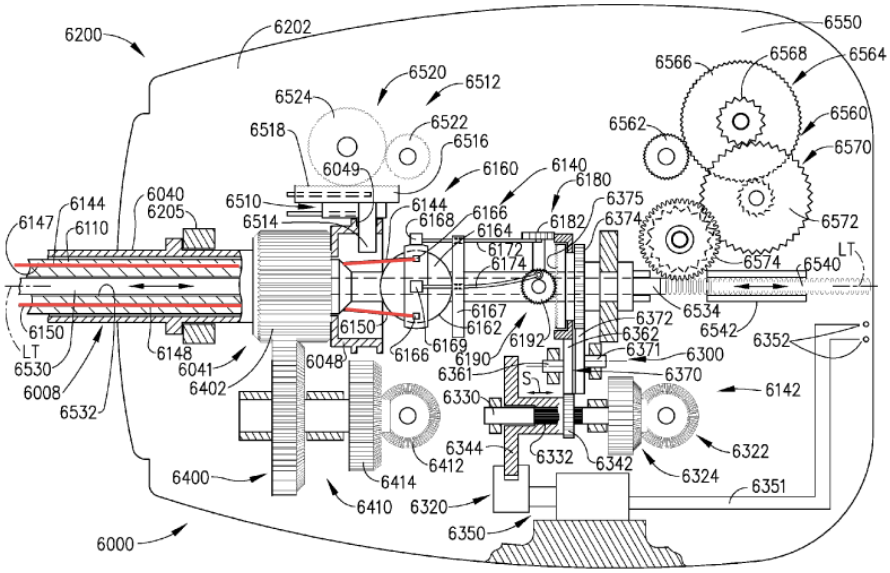


FIG. 136

Ex. 1001, Fig. 136 (annotated)

As shown in Figure 137 below, the articulation cables couple to an articulation control arrangement 6160 of the tool mounting portion. *Id.*, 79:28-53. As shown in great detail in Figure 137, the articulation control arrangement is, through a series of push cables and gears, coupled to the articulation drive gear 6322, which receives rotary motion from the robotic system through a rotary element on the adapter side of the tool mounting portion, thus allowing the robotic system to operate the articulation joint. *Id.*, 79:54-80:39.

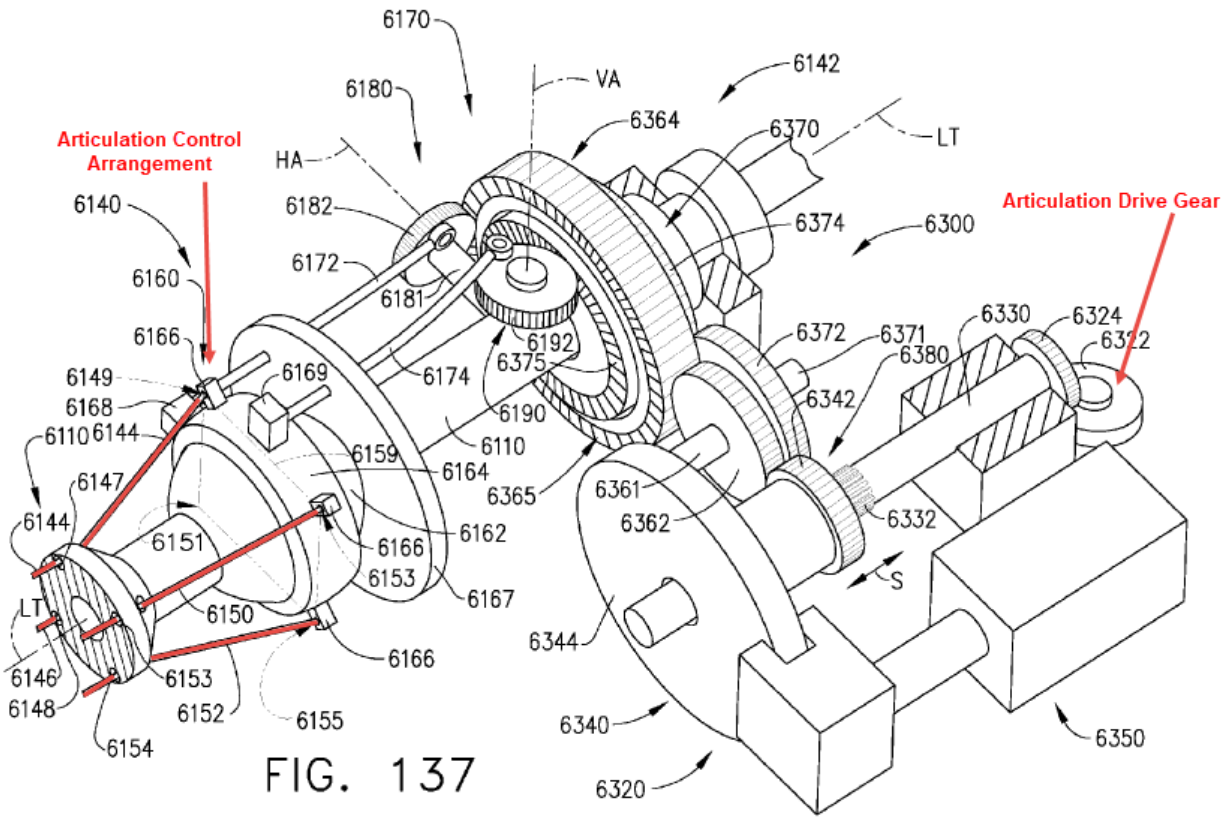


FIG. 137

Ex. 1001, Fig. 137 (annotated)

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. Ex. 1001, 85:17-32. Furthermore, unlike prior art robotic tool drive systems, which were "unable to generate the magnitude of forces required

to effectively cut and fasten tissue," the closure drive and firing transmissions in the 969 Patent are designed to generate the necessary force to close the anvil and cut and staple tissue. Ex. 1001, 23:6-29, 84:20-26, 85:4-10.

III. 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.[3]

IV. THE PRIOR ART

A. Anderson (U.S. Patent No. 6,783,524) (Ex. 1010)

Anderson discloses a robotic surgical tool with an end effector that includes an ultrasound probe tip for cutting and cauterizing tissue at the surgical site. Ex. 1010, Abstract. Anderson's robotic surgical system and surgical instrument are shown in Figures 1 and 2, respectively. The surgical instrument attaches to the robotic surgical system through the instrument base 34. Ex. 1010, 11:66-12:11.

[3] 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).

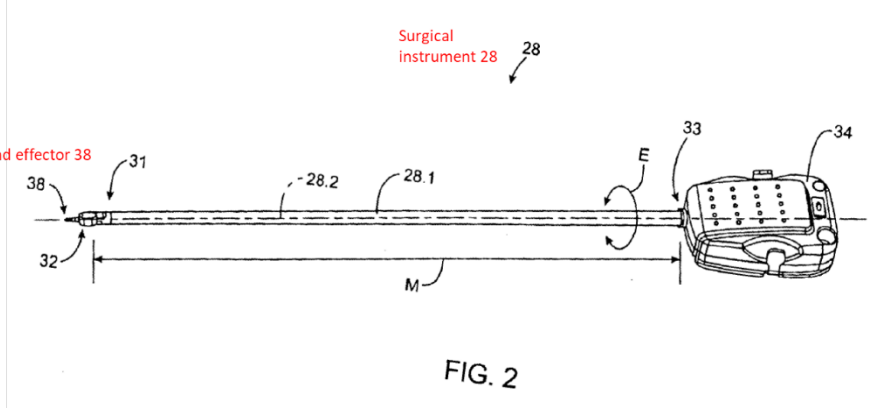


FIG. 2

Ex. 1010, Fig. 2 (annotated)

Figures 10-19 illustrate a "preferred embodiment of a robotic tool 80 having aspects of the present invention. The tool 80 includes an ultrasound treatment instrument assembly…." Ex. 1010, 15:3-5. The end effector 81 of the robotic tool includes gripper 82 and ultrasound probe tip 85b. Ex. 1010, 15:29-60.

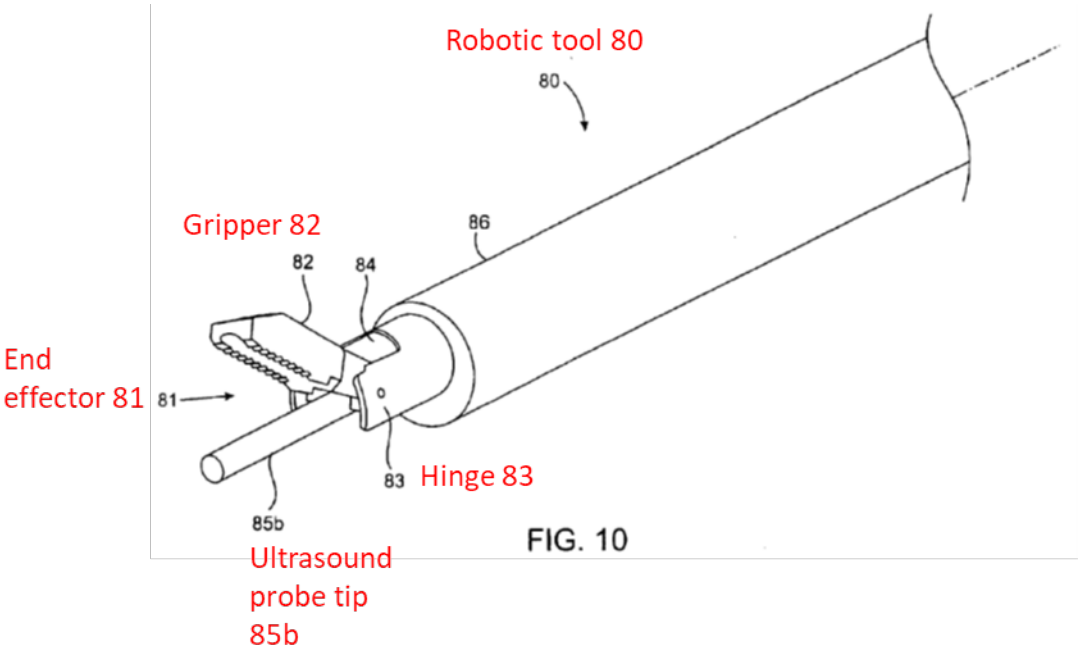
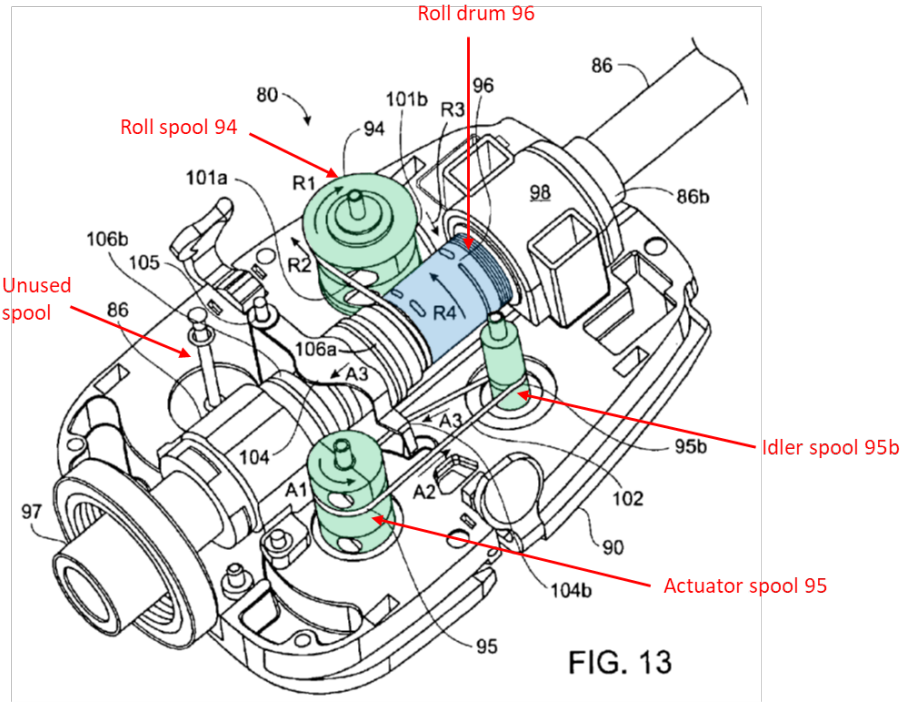


FIG. 10

Ex. 1010, Fig. 10 (annotated)

The instrument base associated with this tool is illustrated in greater detail in Figure 13. Relevant components are annotated below:



Ex. 1010, Fig. 13 (annotated)

As illustrated above, the instrument base includes roll spool 94, actuator spool 95, idler spool 95b, an unused spool, and roll drum 96. Roll cable 101a/b runs between roll spool 94 and roll drum 96 to roll the instrument shaft. Ex. 1010, 16:45-61. The actuator spool 95 and idler spool 95b are connected by cable loop 102. These components control the gripper 82 of end effector 81 (illustrated above in Figure 10). Ex. 1010, 16:62-17:9. To summarize, Anderson's instrument base includes three rotary spools (roll spool 94, actuator spool 95, and idler spool 95b) that control two instrument motions (shaft rotation and gripper open/close). Anderson also discloses one additional rotary output that is unused, but could be utilized for an additional control motion.

The 969 Patent cites Anderson as an example of a prior art robotic system and notes that systems such as those disclosed in Anderson were not capable of generating the forces required for a device that cuts and fastens tissue (i.e., an endocutter). Ex. 1001, 23:6-29 (disclosing that robotic systems including "U.S. Pat. No. 6,783,524, entitled 'Robotic Surgical Tool With Ultrasound Cauterizing and Cutting Instrument'…have in the past been unable to generate the magnitude of forces required to effectively cut and fasten tissue.").

Petitioner's apparent argument that the passing reference to "stapler probes" in Anderson means that Anderson is directed to, discloses, or suggests an endocutter is wholly without merit. Petition at 31. Petitioner's expert acknowledged at his deposition that the term "stapler" is a generic term that can refer to a device that merely staples and is fundamentally different from an endocutter. Ex. 2010, 24:19-22 ("Q. Yeah. Stapler does not necessarily refer to an endocutter; is that right? A. It doesn't -- it doesn't have to, no, that's true."); *id.*, 25:17-24 ("Q. Okay. So then like I said, so then it's fair to say that the word stapler -- A. Yes. Q. -- can mean a device that just applies a staple, and it can also sometimes mean a device that, you know, cuts and staples on both sides of the cut points? A. It can mean both of those things, yes."); *id.*, 28:21-29:6 ("Q. And [Exhibit 2004] is an example of a stapler that is an endoscopic stapler; right? A. It is. Mm-hmm. Q. And this stapler just applied staples; correct? A. That is correct. Q. It does not cut tissue like an endocutter? A. That is

correct. Q. Would you agree this is a vastly different device than an endocutter? A. It is a vastly different device."). Furthermore, as explained by Dr. Awtar, a POSITA reviewing the totality of Anderson would have understood that it is in no way directed to providing a tool base that is capable of driving an articulating endocutter. Ex. 2006, ¶¶ 30-37, 79-89, 94-98.

B. Timm (U.S. Patent No. 7,510,107) (Ex. 1011)

Timm discloses a handheld endocutter. *See, e.g.*, Ex. 1011, Abstract; Fig. 1. The handheld endocutter of Timm also includes an articulation joint. The description in Timm plainly divides the articulation joints into two categories: passive joints and active joints. Intuitive's expert declarant, Dr. Knodel, relies solely on the former in his proposed obviousness combination.

Figures 52-72 of Timm disclose a ball and socket "lockable articulation joint" that employs "passive articulation." Ex. 2006, ¶¶ 39-41; *see also* Ex. 1011, 28:41-60 ("FIGS. 52-54 illustrate another cable-actuated closure system…The ball-shaped member 2730 and socket 2750 collectively form a ball joint"), 29:55-56 ("FIGS. 55-57 illustrate a cable controlled lockable articulation joint"), 30:59-60 ("FIGS. 58-61 illustrate another cable controlled lockable articulation joint"), 31:52-53 ("FIGS. 62-64 illustrate another lockable articulation joint"), 32:47-48 ("FIGS. 65-67 depict another lockable articulation joint"), 33:20-21 ("FIGS. 68-70 illustrate another lockable articulation joint"), 34:9-10 ("FIG. 71 illustrates another passive

articulation joint"), 34:58-59 ("FIG. 72 illustrates another passive articulation joint."). Each of these embodiments includes the following description of passive articulation:

> **To use this embodiment, the clinician positions the tool assembly 100 in the patient and then applies an articulation force to the tool assembly with another surgical instrument or by bringing the tool assembly 100 into contact with a portion of the patient to articulate the tool assembly** to a desired position before drawing the actuation member 3050 in the proximal direction PD. After the tool assembly 100 has been articulated to the desired position, the clinician draws the actuation member 3050 in the proximal direction to cause the ball segments 3020 to expand radially outwardly and **lock the ball-shaped member 3016 in that orientation within the socket 3034 to thereby retain the distal spine segment 3030 (and the tool assembly 100 attached thereto) in that articulated position**. **Such system employs a "passive" articulation technique.**

Ex. 1011, 32:32-46[4]; *see also id.*, 30:44-57, 31:36-51, 33:5-19, 33:62-34:8, 34:46-57, 35:24-35. Despite relying on the "lockable articulation joint" recited in these embodiments, the Petition and Knodel declaration make no reference to these portions of the specification that clearly identify the joint as employing passive articulation.

[4] All emphasis is added unless otherwise noted.

Distinguishable from the passive articulation joints of Figs. 52-72, Timm also discloses "active articulation" joints in the embodiments of Figures 73-89. Ex. 1011, 37:55-58 ("the present invention may further include an active articulation system"), 42:37-39 ("FIGS. 85-89 illustrate another surgical instrument embodiment 6000 that employs an active or controllable articulation joint"). These embodiments employ a joystick assembly at the back of the handle assembly and pushing/pulling wires that couple the joystick assembly to the articulation joint.

> In various embodiments, the active articulation system 5090 may further comprise an articulation control system, generally designated as 5600, that is operably supported by the handle assembly 5500 and interfaces with the articulation wires 5092. As can be seen in FIG. 82, articulation control system 5600 may comprise a joy stick assembly ….Thus, to articulate the tool assembly 100″ relative to the connector segment 4004, the clinician can grasp the hand grip portion 5512 in one hand and the articulation knob 5620 in the other hand. By manipulating the articulation knob 5620, the clinician can apply articulation motions to the distal wire mount 5100 and ultimately to the four articulation wires 5092….

Ex. 1011, 40:34-63. These "active articulation" embodiments are ***never*** described by Timm as a "lockable articulation joint." Moreover, the Petition and associated expert declaration do not rely on these active articulation embodiments in the obviousness analysis of claim 24. Indeed, the only substantive discussion of the active articulation embodiments in Dr. Knodel's declaration is in the section of the

declaration regarding dependent claims 25-26, and for the purpose of explaining why the active articulation system in Timm ***is not relevant*** to a robotic system, and therefore would not be combined with Anderson:

> **[Timm]'s disclosure of an active articulation system only details the implementation of an active articulation system relevant to handheld (and manually-operated) surgical instruments** and that Wallace teaches active articulation with a robotic surgical system. Timm, 12:1-3; 8:3-7; 37:55-38:8; 40:34-63 (manual manipulation); Wallace, Abstract; 7:33-56; 13:6-14:15.

Ex. 1004, ¶ 118. *See also* Ex. 2006, ¶¶ 38-44.

C. Wallace (U.S. Patent No. 6,699,235) (Ex. 1008)

Wallace is directed to providing a robotic surgical instrument that addresses the "lack of dexterity" with existing endoscopic tools and "include[s] mechanisms to provide three degrees of rotational movement of an end effector around three perpendicular axes to mimic the natural action of surgeon's wrist." Ex. 1008, 2:39-41, 2:60-65. Wallace achieves this objective with a platform wrist mechanism shown in Fig. 3 (as well as in Fig. 2A with grasping jaws attached to the wrist mechanism).

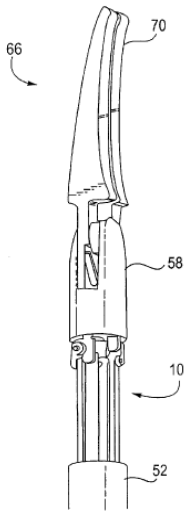


Fig. 2A

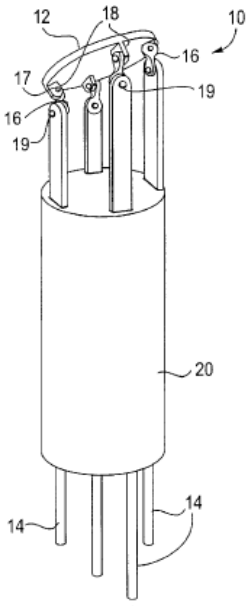
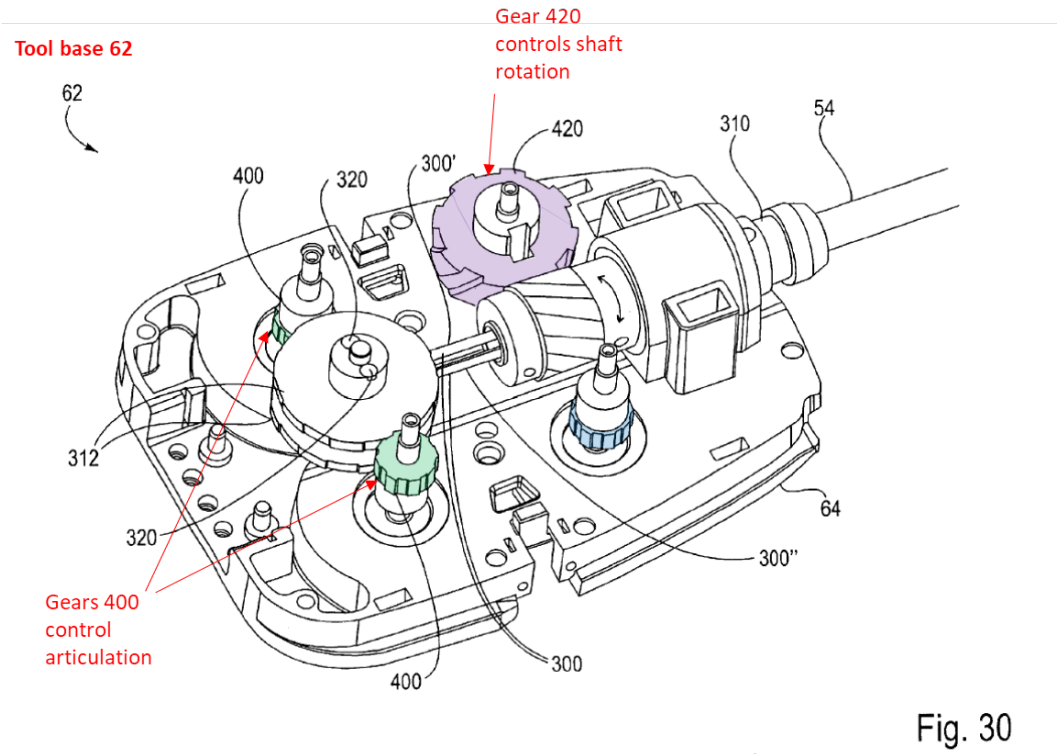


Fig. 3

Ex. 1008, Fig. 2A and Fig. 3

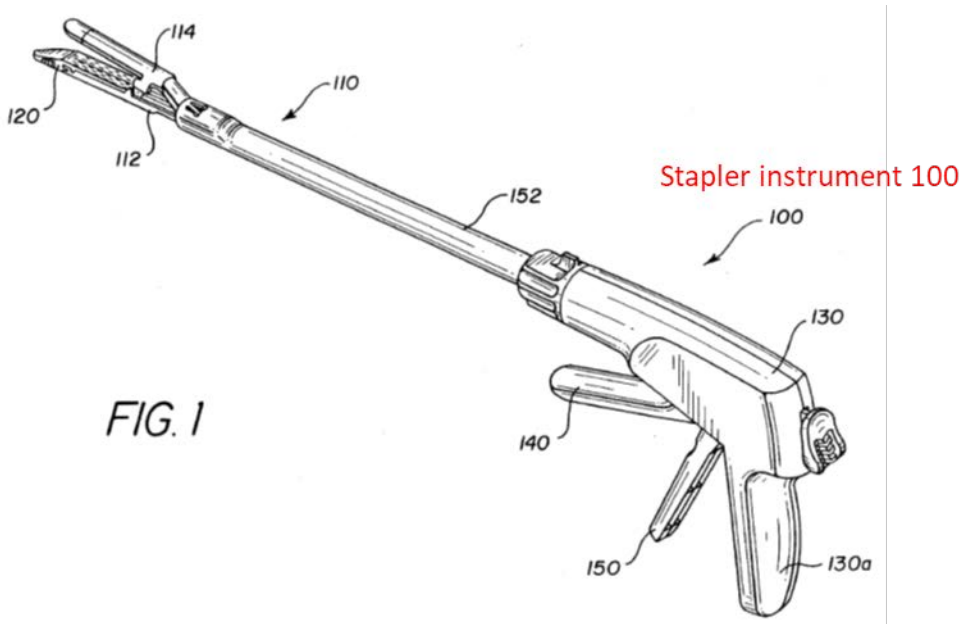
Wallace's instrument couples to a robotic system through a tool base 62, which is illustrated in Figures 26-30. Ex. 1008, 7:37-40. It is undisputed that the tool base disclosed in Wallace is not designed to drive an endocutter and Wallace also does not disclose a mechanism for opening and closing the jaws of an end effector attached to the wrist mechanism. Ex. 2006, ¶¶ 51-52; Ex. 2011, 24:20-23, 28:23-29:10, 37:25-38:11. Wallace's tool base utilizes three rotary drive motions (those of the two gears 400 and the one gear 420) to control two instrument motions (wrist articulation and shaft rotation). *See also* Ex. 2006, ¶¶ 45-53.



Ex. 1008, Fig. 30 (annotated)

D. Knodel (U.S. Patent No. 5,465,895) (Ex. 1012)

Knodel relates to a handheld surgical stapler illustrated in Figure 1 below. Ex. 1012, Abstract. The Petition relies on Knodel solely with respect to Ground 4, which is directed at independent claim 19 and dependent claim 20 of the 969 Patent.



Ex. 1012, Fig. 1 (annotated)

Knodel further discloses a closure trigger 150, firing trigger 140, multiplier 170, drive member 164, wedge work member 162, and knife member 161. These components of Knodel's stapler instrument are illustrated in Figures 2 and 6. Knodel discloses that the surgeon pulls the closure trigger 150 to close the instrument on tissue. Ex. 1012, 11:40-45 ("A summary of the operation of the instrument 100 now follows....**Next, the surgeon moves the closure trigger 150 proximally** until positioned directly adjacent to the base section 130a. This movement causes the yoke 154 and the closure tube 152 to move distally."). After closing the stapler with trigger 150, the firing mechanism is actuated by pulling the firing trigger 140. Ex. 1012, 11:56-12:6 ("After tissue clamping has occurred, **the surgeon moves the firing trigger 140 proximally** until positioned directly adjacent to the closure trigger 150, see FIG. 12.").

Knodel is cited in the 969 Patent specification and described as an endocutter with "distinct closing and firing motions." Ex 1001, 2:13-24. Knodel does not disclose any mechanisms for articulation, nor does it disclose tools designed for robotic surgical systems. *See also* Ex. 2006, ¶¶ 54-58.

E. Viola (U.S. Patent No. 5,954,259) (Ex. 1013)

Viola is directed to a non-articulating powered handheld endocutter illustrated in Figure 1 below. Ex. 1013, Abstract. The Petition relies on Viola solely with respect to Ground 5, which addresses independent claim 21 and dependent claim 22.

Viola discloses an arrangement in which a rotary drive screw is located proximal to the end effector as shown in Figures 9 and 10 below. Ex. 2006, ¶ 60.

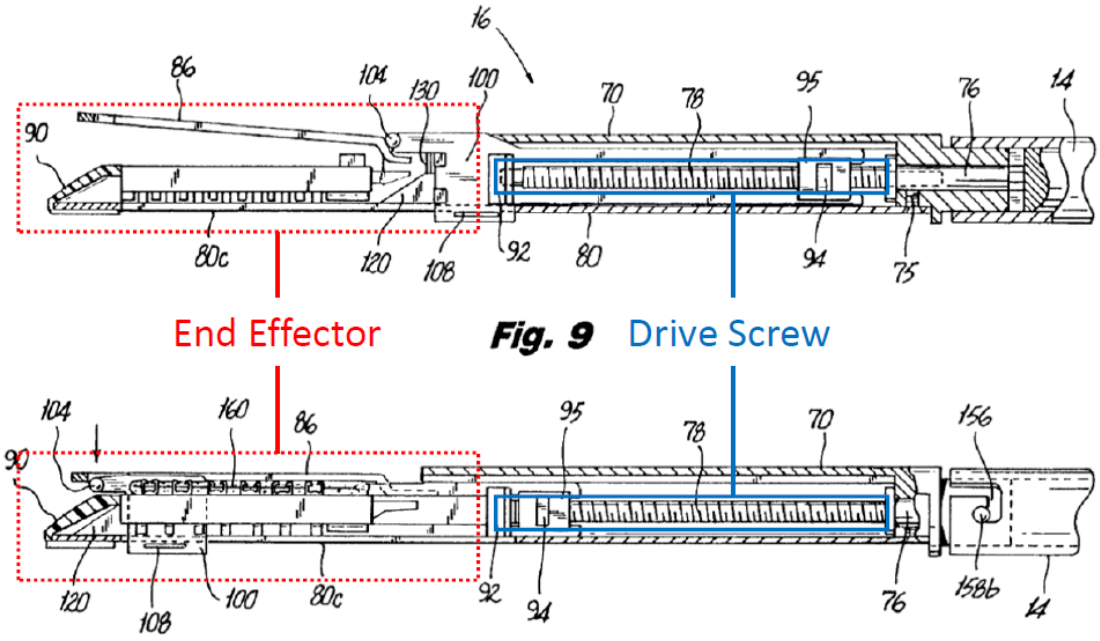
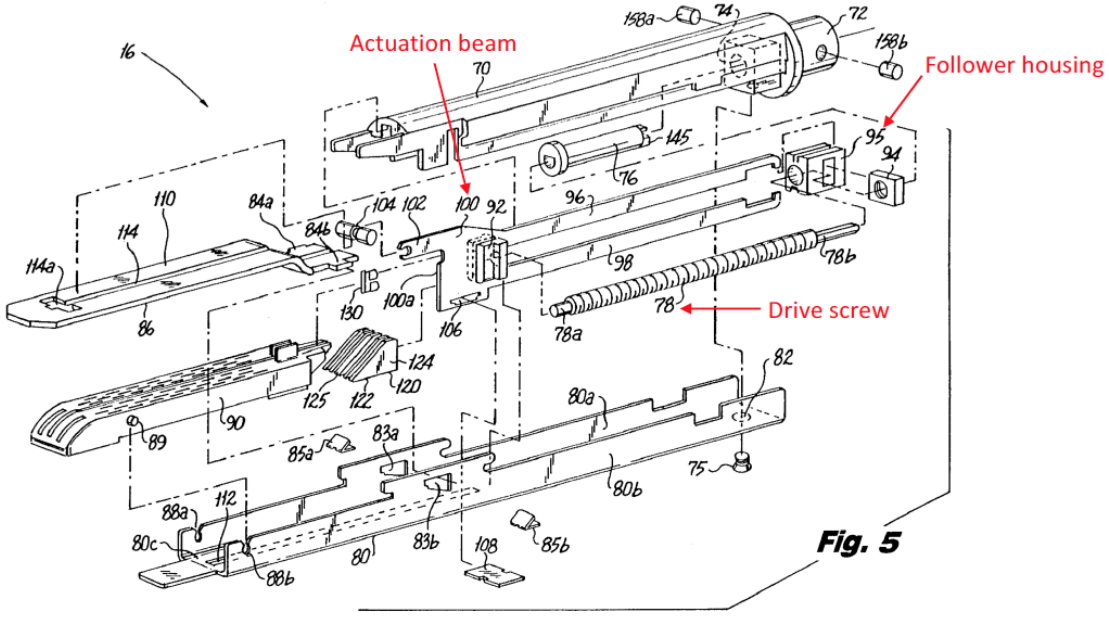


Fig. 9

Fig. 10

Ex. 1013, Figs. 9 and 10 (annotated)

In addition, Viola discloses that the rotary drive screw is threadedly engaged with a follower nut mounted in follower housing 95. Ex. 1013, 6:50-55 ("A follower nut 94 is threadably associated with drive screw 78 and is mounted within a follower housing 95. Follower housing 95 is mounted in such a manner so as to translate in a longitudinal direction in response to axial rotation of drive screw 78."). This is illustrated in Figure 5 below. The follower housing 95 is operatively connected to actuation beam 100, which includes a cutting blade, via beam extensions 96 and 98. Ex. 1013, 6:55-59 ("Proximal elongate beam extensions 96 and 98 of actuation beam 100 operatively connect actuation beam 100 to follower housing 95 so that the actuation beam 100 translates distally with the follower housing.")



Ex. 1013, Fig. 5 (annotated)

Viola does not disclose any mechanisms for articulation, nor does it disclose

tools designed for robotic surgical systems. *See also* Ex. 2006, ¶¶ 59-62.

V. THE CHALLENGED CLAIMS ARE PATENTABLE

The table below sets forth the Grounds and references relied upon:

Ground	Claims	Argument
2	24	Obvious over Anderson in view of Timm
3	25-26	Obvious over Anderson in view of Timm and Wallace
4	19-20	Obvious over Anderson in view of Knodel
5	21-22	Obvious over Anderson in view of Viola

As explained below, Petitioner has failed to meet its burden of demonstrating that any of the combinations of prior art render obvious the challenged claims of the 969 Patent.

A. Ground 2: Petitioner Has Not Demonstrated That the Anderson/Timm Combination Renders Claim 24 Obvious

1. The Petition Fails to Demonstrate That the Anderson/Timm Combination Discloses or Renders Obvious Claim Limitation 24.4 ("a tool mounting portion operably coupled to a distal end of said proximal spine portion …")

Claim 24 requires a "proximal spine portion" and a "tool mounting portion operably coupled to a distal end of said proximal spine portion." Ex. 1001, Claim 24. A certificate of correction issued in January 2018 correcting this language to read a "tool mounting portion operably coupled to a proximal end of said proximal spine portion." However, a District Court has held the certificate of correction invalid. *See* Order Invalidating the January 2018 Certificate of Correction Relating to U.S. Patent No. 8,479,969, *Ethicon LLC et al. v. Intuitive Surgical, Inc. et al.*, C.A. 17-871, D.I.

292 (D. Del. Feb. 11, 2019) (Ex. 2013). Petitioner's analysis in the Petition of the uncorrected claim language is reproduced below:

> 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**.

Petition at 52. This conclusory sentence fails entirely to explain how the proposed combination discloses "a tool mounting portion operably coupled to a distal end of said proximal spine portion" as required by the limitation 24.4. Furthermore, the citation to Dr. Knodel's declaration at ¶ 105 provides no support or explanation for why the combination discloses "a tool mounting portion operably coupled to a distal end of said proximal spine portion." Petitioner may contend that the citation above is incorrect, and should have referred to ¶ 104 of Dr. Knodel's declaration instead. However, even allowing for that correction, the Petition lacks a reasoned and supported explanation because ¶ 104 of Dr. Knodel's declaration only adds ambiguity—repeating word-for-word the same statement in the Petition, except substituting "proximal spine portion itself" for "distal spine portion itself." Ex. 1004, ¶ 104 ("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 via the proximal spine portion itself.").

Petitioner's failure to provide an explanation as to how claim limitation 24.4 is disclosed by the combination is fatal to Ground 2. *See, e.g., Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363-64 (Fed. Cir. 2016) ("In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.… Simply stating that Haskell discloses 'predetermined system timing' does not satisfy Harmonic's burden. Harmonic fails to explain how Haskell's predetermined system timing discloses or suggests the specific timing required by claim 11. Indeed, Harmonic's expert offered no testimony on Haskell's 'predetermined system timing.' And Harmonic mentioned the feature to the Board only once in a single sentence without any elaboration.… On appeal, Harmonic still has not sufficiently explained how Haskell's predetermined system timing corresponds to the 'predefined period of time' limitation in claim 11.").

Indeed, as further detailed in Section V.A.2 below, Petitioner's combination of Anderson and Timm relies on Timm's passive articulation joint to disclose this limitation. However, a passive articulation joint does not involve a distal end of a proximal spine that is "operably coupled" to the tool mounting portion. In this regard, it is clear in the context of the 969 Patent that operable coupling between the tool mounting portion and the spine portion refers to an active articulation joint that

is operated via the tool mounting portion. Ex. 1001, 30:26-31:43, 78:19-79:53. In contrast, a passive articulation joint is manipulated by external forces, not the tool mounting portion. Thus, a passive articulation joint would not involve operable coupling of the spine to a tool mounting portion. *See* Ex. 2006, ¶¶ 66-69.

2. A POSITA Would Not Have Utilized Timm's Passive Articulation Joint In Anderson's Robotic System

Claim 24 requires "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." Ex. 1001, Claim 24. Petitioner relies on the passive articulation joint disclosed in Timm to meet this limitation of claim 24. Specifically, the analysis of this limitation in the Petition is found at pages 36-37, which specifically identify Figures 52 and Figures 62-66 (which are described as a "lockable articulation joint"). Similarly, Dr. Knodel's declaration at ¶¶ 88-89 identifies the "lockable articulation joint" of Figures 52 and 62-66. Moreover, Dr. Knodel concedes at ¶ 118 of his declaration that the active articulation system in Timm, which employs a joystick assembly at the back of the handle, is only relevant to a handheld device, and therefore, would not be combined with a robotic system. Ex. 1004, ¶ 118 ("while Timm contemplates use with a 'robotic system', it's disclosure of an active articulation system only details the implementation of an active articulation system relevant to handheld (and manually-operated) surgical instruments"). Accordingly,

the pertinent analysis for the Board is whether a POSITA would have been motivated to combine the passive articulation disclosed in Timm with the robotic tool and system in Anderson. As explained in detail by Dr. Fegelman and Dr. Awtar, a POSITA ***would not*** have combined Anderson with Timm's passive articulation joint.

Petitioner's declarant Dr. Elliott Fegelman was a practicing general surgeon in the 2011 timeframe and had experience with both laparoscopic and robotic surgical tools. Ex. 2007, ¶¶ 6-7. Consistent with Timm's description, Dr. Fegelman explains that passive articulation requires pressing the exterior of the end effector of a surgical tool against another structure. Ex. 2007, ¶ 17. As a result, performing passive articulation safely and requires real-time, tactile feedback to ensure that excessive forces are not applied to the instrument or another structure, such as an internal body part. Ex. 2007, ¶ 19. Further, video feedback alone would have been unacceptable because it does not indicate the forces being applied. Ex. 2007, ¶¶ 19, 24. Real-time, tactile feedback was and is available through the surgeon's grip on the hand-held portion of a laparoscopic instrument; however, it would not have been available in a robotic system in the 2011 timeframe. Ex. 2007, ¶ 23.

Indeed, it was well-known that robotic systems were incapable of providing haptic feedback concerning the forces that applied to the exterior of the end effector when performing passive articulation. *See, e.g.*, Ex. 2009 at 523 ("Due to the lack of

haptic feedback, visual cues are necessary to estimate grip forces and tissue tensions during surgery."); *id.* at 526 ("The current robotic platforms do not employ the use of haptic feedback."); *id.* at 527 ("Although the current technology may be limited by the lack of direct haptic feedback, this study is the first to establish direct forces exerted by the robotic instruments."). Furthermore, Dr. Fegelman explains that a key perceived benefit of robotic tools in the 2011 timeframe was the surgeon's ability to have complete control over the tool. A passive articulation mechanism in a robotic tool would relinquish this complete control and thus negate a key perceived benefit of robotics. Ex. 2007, ¶ 25.

As a result, a surgeon would have found a robotic tool with passive articulation to be clinically unacceptable, and a POSITA would have been aware of these facts in the 2011 timeframe. Accordingly, a POSITA would not have combined a passive articulation joint with a robotic tool given the lack of feedback available in a robotic system and the need for feedback in order to use a passive articulation joint safely and effectively. Ex. 2006, ¶¶ 73-76. Indeed, to this date, Patent Owner is unaware of a single instance in which a passive articulation joint has been used with a robotic tool. Ex. 2007, ¶ 21. The failure of Petitioner and Dr. Knodel to address the realities of utilizing passive articulation demonstrates the superficial nature of the motivation to combine analysis provided in the Petition. A POSITA, however, would be aware of these realities and would not have proceeded with the

proposed combination. Ex. 2006, ¶¶ 73-76.

3. A POSITA Would Not Have Had A Reasonable Expectation of Success in Combining Anderson's Tool Base With Timm's Handheld Endocutter

Petitioner's analysis of claim 24 proposes the following combination of elements: (1) the endocutter end effector and shaft from Timm; (2) the tool base from Anderson designed to drive a harmonic tool; and (3) then re-designing the tool base from Anderson to drive components in Timm. As explained below, Petitioner has failed to explain why a POSITA would have had a reasonable expectation of success in making the proposed combination. Furthermore, as Dr. Awtar explains, neither reference discloses a tool base designed for a robotic system that is capable of driving an endocutter end effector, which requires high forces for clamping and firing, and a POSITA would have lacked a reasonable expectation of success because the manually actuated endocutter in Timm and the robotic harmonic tool in Anderson have fundamentally different principles of operation.

a. Petitioner Fails to Show a Reasonable Expectation of Success

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" (internal citation and quotations omitted). *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed.

Cir. 2012).

Petitioner's only argument concerning reasonable expectation of success is a boilerplate recitation regarding application of a known technique to a known system to yield a predictable result.

> 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.

Petition at 39. The only support for this boilerplate is additional boilerplate language in Dr. Knodel's declaration at ¶ 90.[5] This unsupported, conclusory testimony should

[5] Many of Petitioner's citations to Dr. Knodel's declaration appear to be off by at least one paragraph number. Patent Owner has attempted to identify the applicable paragraph numbers where possible.

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.").

Moreover, for the reasons discussed below, the evidence of record shows that, contrary to Petitioner's unsupported assertions, a POSITA would not have reasonably expected to be successful in combining a handheld, manually-actuated endocutter with a robotic harmonic tool in the way proposed by Petitioner. Indeed, Petitioner's own contemporaneous statements in 2011 demonstrate that such a re-design to arrive at a robotic endocutter was outside the level of ordinary skill.

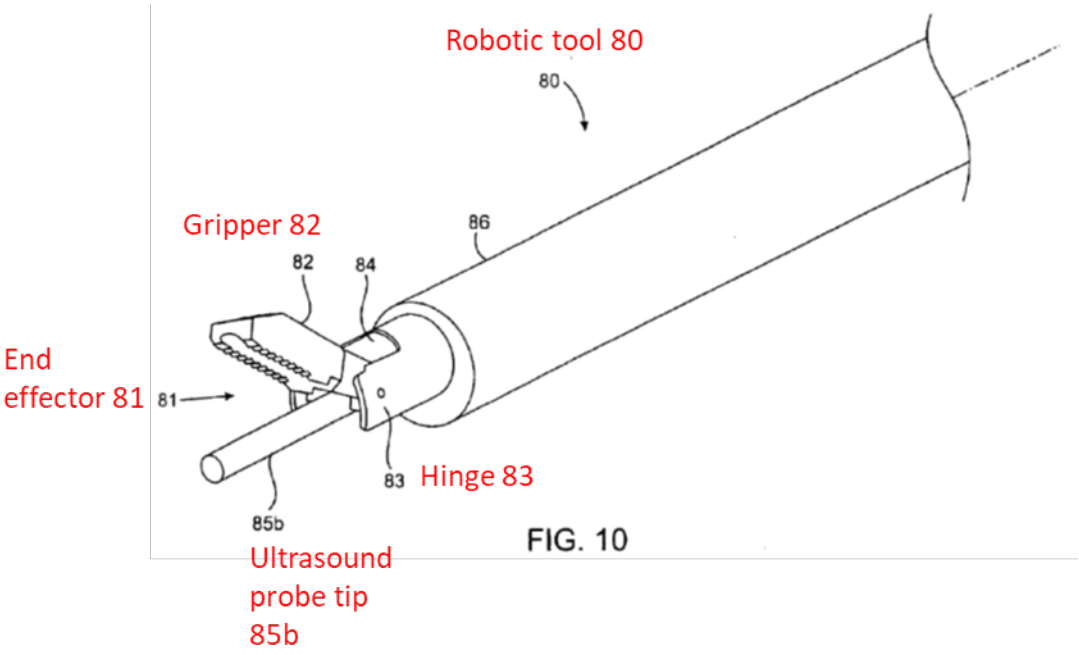
b. A POSITA Would Have Recognized That Combining Anderson With Timm's Endocutter Would Have Required a New Design to Provide Sufficient Forces for the Endocutter

As Dr. Awtar explains, and as further explained below, a POSITA would not have had a reasonable expectation of success in combining Anderson's tool base with Timm's handheld endocutter. Ex. 2006, ¶¶ 77-89.

(1) Anderson's Tool Base Is Designed for a Harmonic Tool, Which Is Fundamentally Different From an Endocutter

As an initial matter, Anderson's tool base is designed to control a harmonic end effector, which is fundamentally different from an endocutter. Ex. 2006, ¶¶ 79-

81. For example, harmonic devices are incapable of articulation because the ultrasound probe tip must be vibrated at a high frequency in order to impart sufficient energy onto tissue in order cut and/or coagulate it. It is only physically possible to vibrate the probe tip at sufficiently high frequencies along the longitudinal axis of the device. *See* Ex. 2006, ¶ 79. A non-articulating ultrasound probe tip is illustrated in Figure 10 of Anderson, below.



Ex. 1010, Fig. 10 (annotated)

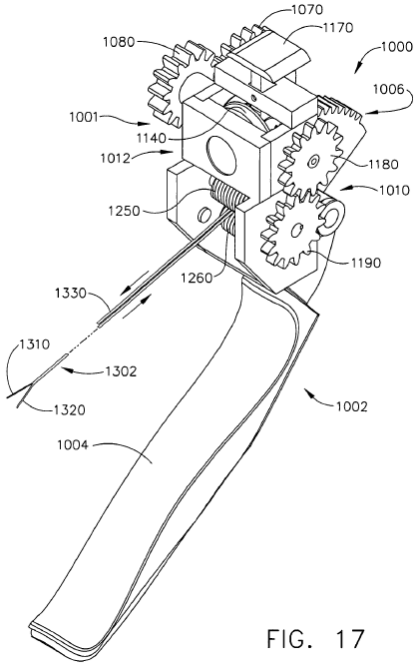
The gripping force required for a non-endocutter tool, such as the gripper 82 shown above, is also far less than for an endocutter device. The 969 Patent, for example, discloses that in embodiments where its drive system was used to power an endocutter, the gears in the closure gear assembly were sized to generate "approximately 70-120 pounds of closure forces." Ex. 1001, 84:20-26. In contrast,

a 2011 paper measured the grip forces generated by Intuitive's da Vinci robotic surgery systems when they were used with various non-endocutter robotic instruments such as graspers, retractors, forceps, scissors, needle drivers, and clip appliers. The forces reported in that study were at least one order of magnitude smaller than the endocutter closure forces described in the 969 Patent, ranging from 2.26 Newtons (approximately 0.5 pounds) for a double fenestrated grasper to 37.57 Newtons (approximately 8.5 pounds) for a clip applier. Ex. 2009 at 526. *See also* Ex. 2006, ¶¶ 79-81.

(2) Manually-Actuated, Handheld Endocutters and Robotic Surgical Tools Operate on Fundamentally Different Principles

As Dr. Awtar explains, a person of ordinary skill in the art would have encountered substantial challenges in attempting to adapt Timm's endocutter for use with Anderson's robotic system. Ex. 2006, ¶¶ 82-85. Timm's handheld endocutter used a fundamentally different system for transferring force to the end effector when compared to Anderson's robotic system. The primary embodiment that Petitioner relies on is actuated by a manual trigger 1004, which a person of ordinary skill in the art would have understood is a relatively low-speed, high-torque mechanism because the mechanism requires the surgeon to exert a relatively large amount of force (which is proportional to torque) to move the handle over a relatively short distance (*i.e.*, moving at a low speed).

Figure 17 of Timm shows that the firing trigger only pivots a short distance at a low speed when actuated by a surgeon to fire the device.



Ex. 1011 Fig. 17

Given the differences in how force is generated and transferred in robotic systems relative to handheld systems, a POSITA would not have had a reasonable expectation of success in adapting Timm for use with Anderson's robotic system. It would be necessary to address various factors in modifying the trigger-driven endocutter design of Timm to be motor-driven via a robotic system. Ex. 2006, ¶¶ 82-85. This includes how to achieve the mechanical advantage needed to produce the relatively high forces required of an endocutter while maintaining the compact size needed for a minimally invasive instrument. *Id.* Although a gear drive could achieve such a mechanical advantage, a single gear stage is limited due to practical

limitations. *Id.* Accordingly, a gear drive system would likely require multiple stages, complicating the design for the compact size required of a minimally invasive instrument. *Id.* Neither Petitioner nor Dr. Knodel have provided any evidence that a POSITA could have addressed these and other design issues associated with the proposed combinations of Anderson and Timm.

(3) Both Patent Owner's and Petitioner's Publications Confirm that a POSITA Would Have Lacked a Reasonable Expectation of Success

Additional publications from both Ethicon and Intuitive demonstrate that drive systems for other robotic instruments known in or before 2011 (including the robotic system disclosed in Anderson) were insufficient to power an endocutter end effector, such as the one disclosed in Timm. For example, the 969 Patent specifically identifies Anderson's robotic system as one of several prior art robotic systems that were unable to generate the forces required to cut and fasten tissue:

> Over the years a variety of minimally invasive robotic (or "telesurgical") systems have been developed to increase surgical dexterity as well as to permit a surgeon to operate on a patient in an intuitive manner. Many of such systems are disclosed in the following U.S. patents which are each herein incorporated by reference in their respective entirety: … **U.S. Pat. No. 6,783,524, entitled "Robotic Surgical Tool With Ultrasound Cauterizing and Cutting Instrument"** … **Many of such systems, however, have in the past**

> **been unable to generate the magnitude of forces required to effectively cut and fasten tissue.**

Ex. 1001, 23:6-29.

Intuitive's patents and published applications similarly describe that robotic instrument drive systems that were known as of 2011 were insufficient to cut and staple tissue. For example, U.S. Patent No. 8,640,788, which was filed by Intuitive in 2010 and initially published on May 19, 2011 as Application Publication No. 2011/0118754, describes that known drive systems for robotic instruments such as graspers and needle drivers (i.e., instruments with opposing jaws) were incapable of providing the high forces necessary for clamping, stapling, and cutting tissue, as required of Timm's endocutter:

> During the surgical procedure, the telesurgical system can provide mechanical actuation and control of a variety of surgical instruments or tools having end effectors that perform various functions for the surgeon, for example, holding or driving a needle, grasping a blood vessel, dissecting tissue, or the like, in response to manipulation of the master input devices.
>
> * * *
>
> Non robotic linear clamping, cutting and stapling devices have been employed in many different surgical procedures. For example, such a device can be used to resect a cancerous or anomalous tissue from a gastro-intestinal tract. Unfortunately, many known surgical devices,

> including known linear clamping, cutting and stapling devices, often have opposing jaws that may be difficult to maneuver within a patient. For known devices having opposing jaws that are maneuverable within a patient, such devices may not generate sufficient clamping force for some surgical applications (e.g., tissue clamping, tissue stapling, tissue cutting, etc.), which may reduce the effectiveness of the surgical device. **Thus, there is believed to be a need for an improvement in the maneuverability of surgical end effectors, particularly with regard to minimally invasive surgery. In addition, there is believed to be a need for surgical end effectors with high actuation force, for example, high clamping force**.

Ex. 2012 at 2:4-39.

In 2011, Intuitive also filed an application that published in 2012 as U.S. Patent Application Publication No. 2012/0209314. This publication similarly acknowledged that adapting handheld endocutter technology for use with robotic systems (such as Anderson) continued to pose a challenge for the industry:

> A huge variety of tools have been developed for open surgery, many (though not necessarily all) of which have been successfully modified for minimally invasive surgical procedures. For example, manual clamps, linear cutters, and stapling devices can apply significant therapeutic clamping forces on tissues, which can enhance a variety of surgical procedures. Unfortunately, work in connection with the present invention indicates that adapting open surgical clamping devices (and developing methods for safely and effectively using them) within minimally invasive settings may be more challenging than expected. **In**

> **particular, developing and using surgical clamping jaws capable of generating desired clamping force while also providing the desired maneuverability for use within size-restricted minimally invasive surgical access and treatment sites has proven to be quite difficult. Transferring the advantages available from surgical staplers, linear cutters, and surgical clamping tools to robotic surgical settings may involve even more challenges, particularly given the different paradigms in surgeon-directed tool movement, tool activation, and physician feedback presented by the new telesurgical treatment systems**.

Ex. 2019, [0008].

B. Ground 3: Petitioner Has Not Demonstrated That the Anderson/Timm/Wallace Combination Renders Claims 25-26 Obvious

Claims 25 and 26 depend from claim 24 and require a gear-driven articulation system (claim 25) and that the articulation is driven by first and second articulation bars (claim 26). Petitioner has not demonstrated that these claims are obvious for the reasons explained below.

1. Because Petitioner Has Not Demonstrated That Independent Claim 24 is Obvious, It Cannot Demonstrate That Dependent Claims 25-26 Are Obvious

Ground 3 of the Petition is predicated on claim 24 being rendered obvious by the combination of Anderson and Timm. Petition at 57-65 (addressing only the limitations of claims 25 and 26 for the combination of Anderson, Wallace and Timm). For the reasons discussed in Section V.A, Petitioner has not demonstrated

that the combination of Anderson and Timm renders obvious claim 24. Thus, for the same reasons, Petitioner has not demonstrated that its dependent claims 25 and 26 are obvious.

2. The Passive Articulation Joint of the Anderson/Timm Combination Is Not Compatible With the Active Articulation System of Wallace

Intuitive proposes to add Wallace's active articulation system to the combination of Anderson and Timm in order to disclose the gear-driven articulation system (claim 25) and that the articulation is driven by first and second articulation bars (claim 26). However, as discussed in Sections V.A.1 and V.A.2, Intuitive proposes to combine Anderson and the passive articulation joint of Timm to meet the limitations of claim 24. This is confirmed by Dr. Knodel's statement regarding the motivation to add Wallace to the combination:

> First, one of skill in the art would have seen that while **Timm contemplates use with "a robotic system", it's disclosure of an active articulation system only details the implementation of an active articulation system relevant to handheld (and manually-operated) surgical instruments and that Wallace teaches active articulation with a robotic surgical system**. Timm, 12:1-3; 8:3-7; 37:55-38:8; 40:34-63 (manual manipulation); Wallace, Abstract; 7:33-56; 13:6-14:15.

Ex. 1004, ¶ 118.

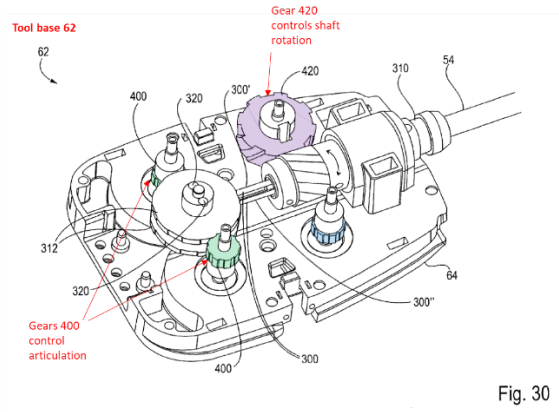
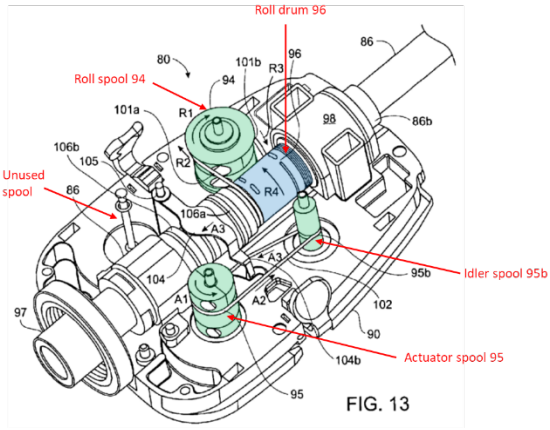
As a result, this combination of a passive articulation joint for purposes of

claim 24 with an active articulation joint for purposes of claims 25-26 is illogical. The two types of articulation joints are mutually exclusive and are incompatible with each other. *See also* Ex. 2006 (Awtar Decl.), ¶¶ 92-93.

3. Combining Timm's Endocutter with Wallace's Platform Wrist Requires More Control Inputs Than Are Available in Wallace/Anderson

The Petition proposes the combination of Timm's endocutter with Wallace's platform wrist and the Wallace/Anderson tool base. This proposed combination requires a robotic system with more control inputs than are available in the Wallace/Anderson robotic systems.

The Wallace/Anderson robotic systems plainly disclose four available control inputs. Ex. 2006, ¶¶ 94-95. The Wallace articulation wrist requires two control inputs (gears 400) for articulation, and both Wallace and Anderson disclose the use of one control input for shaft roll (gear 420 / roll spool 94). Wallace does not disclose how to use its rotary inputs to control end effector actuation in conjunction with its articulating wrist joint, while Anderson discloses the use of two control inputs (spool 95 and 95b) to perform a gripping motion. These tool bases are illustrated below:

Wallace	Anderson
	
Ex. 1008 (annotated)	**Ex. 1010 (annotated)**

The tool bases in Wallace and Anderson have at most one available rotary input. However, the addition of Timm's endocutter requires the motions of clamping and firing. A POSITA would be deterred from making this combination for several reasons.

First, none of the references disclose utilizing a single input motion to perform both clamping and firing. Rather, Timm specifically discloses that firing is a separate motion from closing. *See, e.g.*, Ex. 1011, 14:39-15:25 (disclosing a firing trigger 1004 that drives a component containing a knife ("dynamic clamping member") through the elongate channel assembly, which is a separate motion from closing the anvil). This is consistent with the disclosure in the prior art that there is an advantage to have separate closing and firing motions. Ex. 2020, 2:36-50.

Second, Intuitive itself explained in a 2015 patent publication that modifying the robotic system itself to add new motor outputs is cost prohibitive, and as such,

not an option a POSITA would pursue when developing a new robotic tool:

> In general, improved minimally invasive robotic surgery systems are desirable. **Often, new surgical instruments are developed for use on existing telesurgical system platforms. Thus, the instrument is required to adapt to the telesurgical system, since development of a new telesurgical system for a particular surgical application is cost prohibitive**. **However**, **issues arise when existing telesurgical platforms do not have the required amount of motor outputs for all of the mechanisms of a particular surgical instrument. Thus, there is a need to adapt new surgical devices to existing telesurgical systems without limiting the surgical capabilities and without requiring modification to the existing telesurgical systems**.

Ex. 2014, [0007]. This application further concedes that a need existed for mechanisms that would allow a new surgical tool (e.g., an endocutter) to be adapted for use with a robotic system without resorting to modification of the robotic system. The 969 Patent discloses a device that fulfills that need.

At his deposition, Dr. Knodel—recognizing the problem posed by combining Timm's endocutter, Wallace's platform wrist and the Wallace/Anderson tool base—attempted to change his opinion, and in doing so, provided inconsistent testimony that the combination for dependent claims 25 and 26 does not actually involve Timm's endocutter:

> Q: Right. So to clarify, your combination here in ground three involves

> Timm's endocutter end effector; Wallace's articulating wrist --
>
> A: Right.
>
> Q: -- and a back end tool mount that will drive all of that?
>
> A: Yes.
>
> ***
>
> Q: So for this combination, I guess what you're saying to me is the end effector, it could be the harmonic, it could be the endocutter. It could be -- let me finish before you answer -- the cautery isolation tool. Your picking any one of those is fine?
>
> A: I'm saying -- yes, what I'm saying is that I wasn't trying to map this completely to an endocutter.

Ex. 2010, 80:13-19, 82:23-83:6; *see also id.* at 81:3-25 (questions regarding the number of rotary inputs available in Wallace/Anderson). Such an argument, however, would be illogical and impermissible given that Petitioner's analysis for these dependent claims is predicated on the combination of Timm's endocutter and the Anderson tool base for independent claim 24. *See In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.").

C. Ground 4: Petitioner Has Not Demonstrated That the Anderson/Knodel Combination Renders Claims 19-20 Obvious

Claim 19 requires a surgical tool for use with a robotic system that includes, *inter alia*, a "knife bar that is movably supported within [an] elongated shaft assembly for selective axial travel therein, said knife bar interfacing with [a] cutting instrument." Ex. 1001, Claim 19. Claim 20 is dependent on claim 19. Petitioner proposes to combine Anderson with Knodel. As discussed above, Knodel relates to a handheld, non-articulating endocutter with a gear-driven knife bar (knife member 161). Intuitive's combination fails for the reasons discussed below.

1. A POSITA Would Have Been Deterred From Combining Anderson With Knodel's Handheld Endocutter

Knodel's endocutter is a handheld device with no suggestion that it could be utilized in a robotic system. A POSITA would have known that tactile feedback is critical to the operation of an endocutter such as Knodel during the clamping and firing process. Ex. 2006, ¶¶ 103-107. Indeed, U.S. Patent No. 8,186,555 (the 555 Patent) (Ex. 2015), which published as an application on August 2, 2007, explains that motor-driven endocutters had not been adopted by physicians as of that date due to the loss of tactile feedback:

> **Surgeons typically prefer to experience proportionate force distribution to that being experienced by the end-effector in the forming the staple to assure them that the cutting/stapling cycle is complete**, with the upper limit within the capabilities of most surgeons

> (usually around 15-30 lbs). **They also typically want to maintain control of deploying the staple and being able to stop at anytime if the forces felt in the handle of the device feel too great** or for some other clinical reason. **These user-feedback effects are not suitably realizable in present motor-driven endocutters**. As a result, there is a general **lack of acceptance by physicians of motor-drive endocutters** where the cutting/stapling operation is actuated by merely pressing a button.

Ex. 2015 at 3:1-3:14; *see also* Ex. 2016 at 7:1-3 ("This has the advantage of providing the user with high tactile feedback. That is, the user is readily able to tell whether the system is overloaded with tissue."). In the combination proposed by Petitioner, however, the handheld instrument disclosed in Knodel would be removed from the surgeon's hand. This would result in a loss of tactile feedback for clamping, which as described above, could result in an instrument that would be undesirable for physicians. Ex. 2006, ¶ 105.

Indeed, it was well-known before 2011 that the lack of tactile or haptic feedback was a significant drawback to the use of robotic surgical systems such as Anderson:

> Despite the obvious potential advantages of **robot-assisted, endoscopic surgery**, most researchers and surgeons in this area agree that the **lack of haptic feedback is the most important drawback of currently available systems** (Mitsuishi, Tomisaki, Yoshidome, Hashizume, & Fujiwara, 2000). The inability of the operator to sense

> the applied forces causes increased tissue trauma and frequent suture material damage.

Ex. 2017 at 460.

> **Haptics generally describes touch feedback, which may include kinesthetic (force) and cutaneous (tactile) feedback.** In manual minimally invasive surgery (MIS), surgeons feel the interaction of the instrument with the patient via a long shaft, which eliminates tactile cues and masks force cues. Some studies have linked the lack of significant haptic feedback in MIS to increased intraoperative injury [1]. **In teleoperated robot-assisted minimally invasive surgery (RMIS), all natural haptic feedback is eliminated because the surgeon no longer manipulates the instrument directly. The lack of effective haptic feedback is often reported by surgeons and robotics researchers alike to be a major limitation of current RMIS systems**.

Ex. 2018 at 102.

Given that the advantages associated with tactile feedback were known to be critical to the user of an endocutter such as Knodel, and robotic systems such as Anderson lacked tactile feedback on clamping, a POSITA would not have been motivated to combine Anderson with Knodel as proposed by Petitioner. Ex. 2006, ¶ 107.

2. A POSITA Would Not Have Had a Reasonable Expectation of Success

Petitioner's analysis proposes the following combination of elements: (1) the

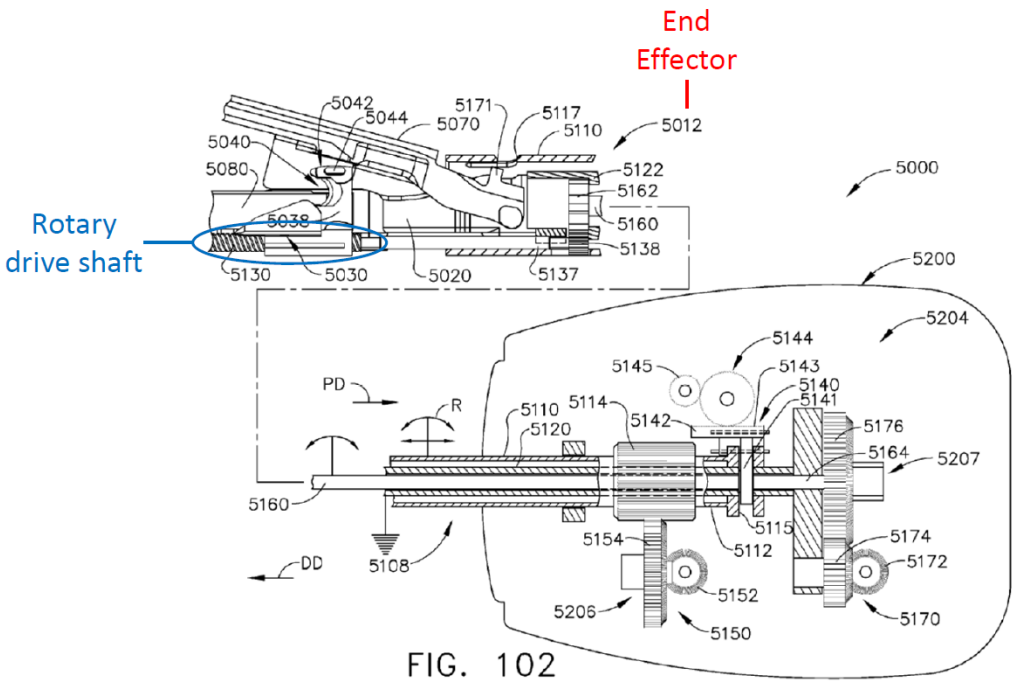
endocutter end effector and shaft from Knodel; (2) the tool base from Anderson designed to drive a harmonic tool; and (3) then re-designing the tool base from Anderson to drive components in Knodel. Like Ground 2, Petitioner's reasonable expectation of success argument in the Petition is nothing more than boilerplate language. Petition at 70-71; *see also* Ex. 1004, ¶ 132. Furthermore, the evidence presented in Section V.A.3.b applies here to the combination of Knodel's manually actuated handheld endocutter and Anderson's harmonic tool base. Accordingly, a POSITA would have lacked a reasonable expectation of success in combining Anderson with Knodel.

D. Ground 5: Petitioner Has Not Demonstrated That the Anderson/Viola Combination Renders Claims 21-22 Obvious

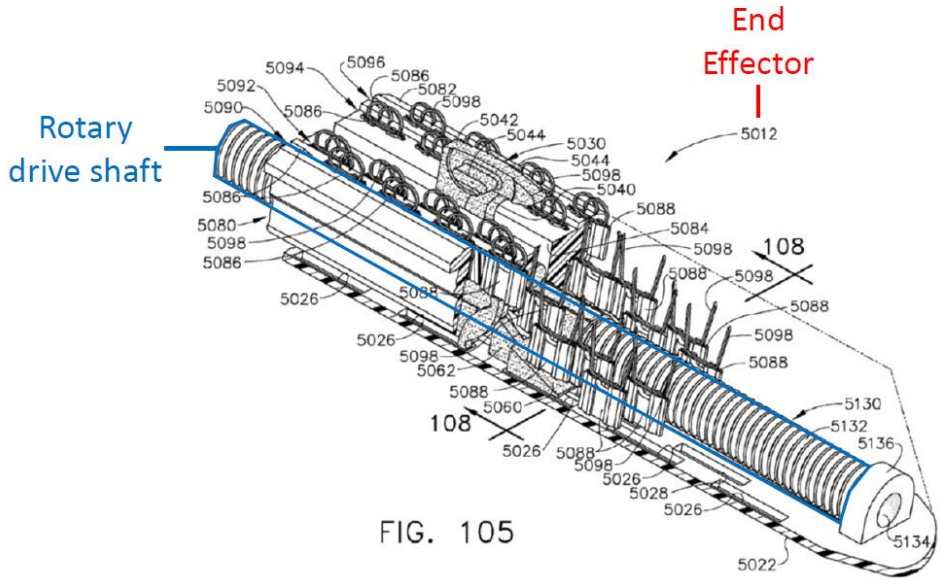
Claim 21 (as well as claim 22 which depends from claim 21) requires a surgical tool for use with a robotic system that includes, *inter alia*, "an end effector comprising…a rotary end effector drive shaft…[and] a knife member having a tissue-cutting portion thereon threadedly received on said rotary drive shaft." Ex. 1001, Claim 21. Petitioner relies exclusively on Viola as disclosing the limitations of a rotary end effector drive shaft and a knife member threadedly engaged on that rotary end effector drive shaft. Petition at 82-84. As explained below, Viola discloses neither.

First, the claims require that end effector comprises the "rotary end effector drive shaft." Unlike the rotary end effector drive shaft disclosed and claimed in the

969 Patent, Viola's rotary drive shaft is not part of the end effector. As shown below, in the 969 Patent, the rotary drive shaft is plainly contained within the end effector:



Ex. 1001, Fig. 102 (annotated)



Ex. 1001, Fig. 105 (annotated)

In contrast, the rotary drive screw in Viola is located entirely proximal to the end effector. Ex. 2006, ¶¶ 111-12. Figure 9 of Viola, which shows the device before clamping and firing, and Figure 10 of Viola, which shows the device after clamping and firing, both illustrate the location of the rotary drive screw as terminating proximal to the end effector. *See also* Ex. 1013, Fig. 3:45-50, 7:56-8:15.

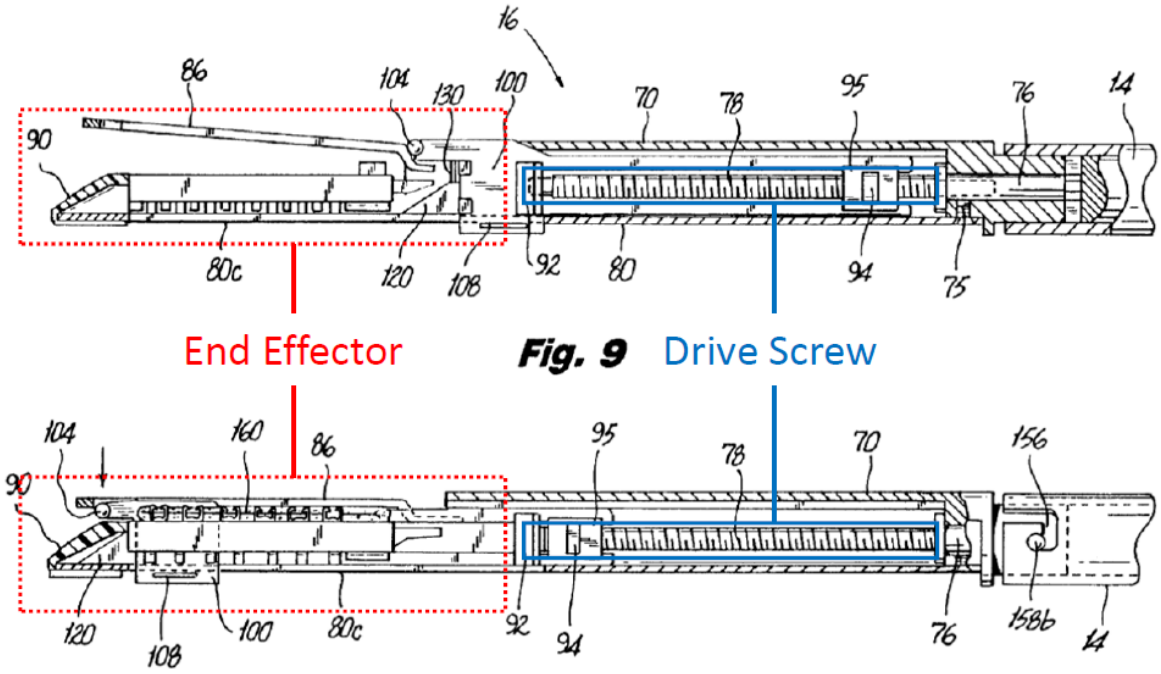


Fig. 9

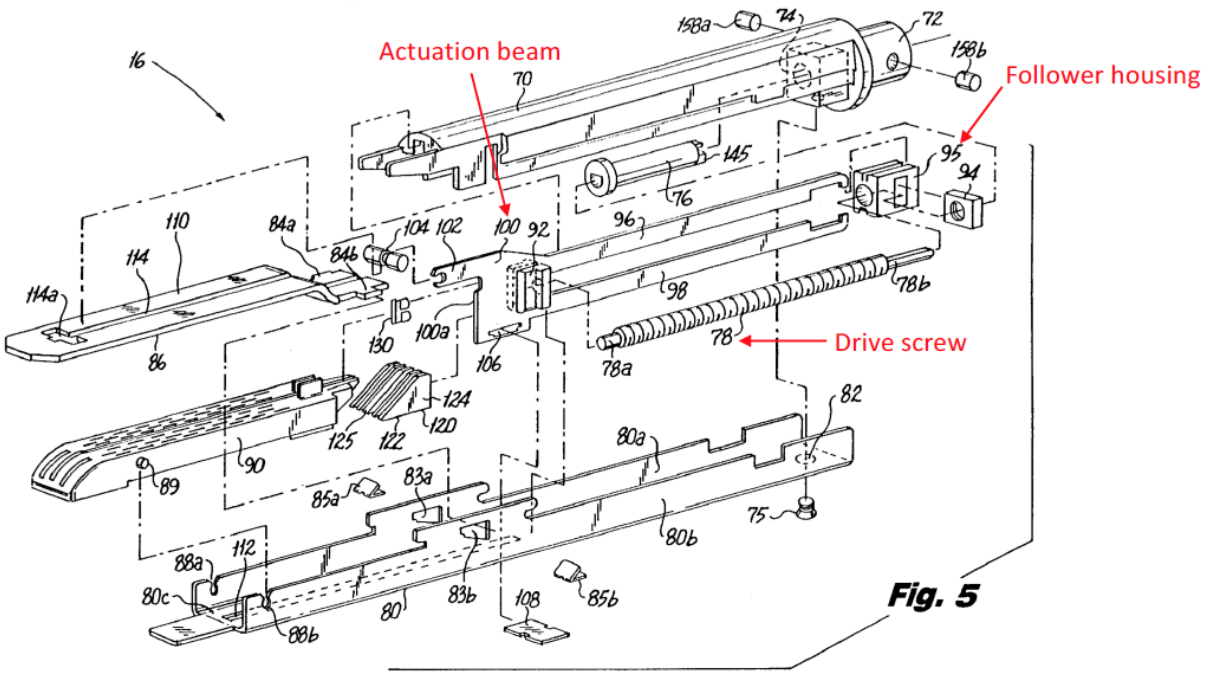
Fig. 10

Ex. 1013, Figs. 9 and 10 (annotated)

Accordingly, Viola fails to disclose an end effector comprising a "rotary end effector drive shaft." Ex. 2006, ¶¶ 111-14.

Second, Viola fails to disclose a knife member threadedly engaged on the

drive shaft as required by claim 21. Ex. 2006, ¶ 115. Viola discloses that the rotary drive screw is threadedly engaged with a follower nut mounted in follower housing 95. Ex. 1013, 6:50-55 ("A follower nut 94 is threadably associated with drive screw 78 and is mounted within a follower housing 95. Follower housing 95 is mounted in such a manner so as to translate in a longitudinal direction in response to axial rotation of drive screw 78."). This is illustrated in Figure 5 below.



Ex. 1013, Fig. 5 (annotated)

This configuration in Viola is distinct from the claimed and disclosed embodiment in the 969 Patent of a knife member threadedly engaged on the rotary drive shaft. This claimed embodiment is illustrated in Figures 107 and 108 below, which show the knife member threadedly engaged with the rotary end effector drive

shaft. *See also* Ex. 2005, ¶¶ 115-17.

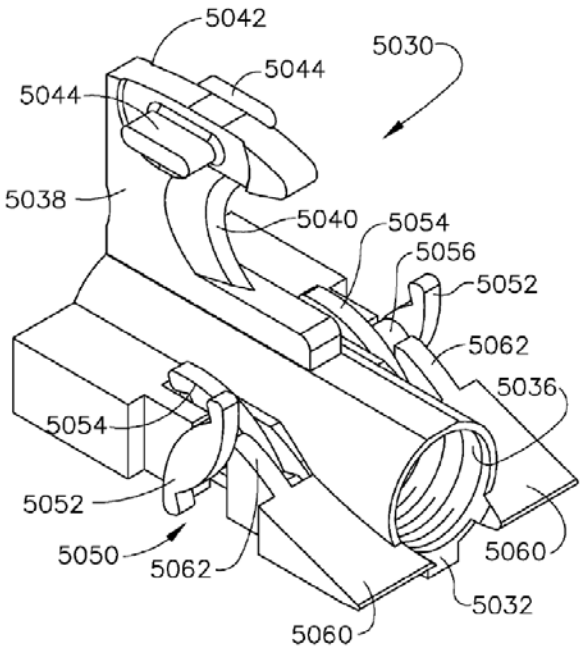


FIG. 107

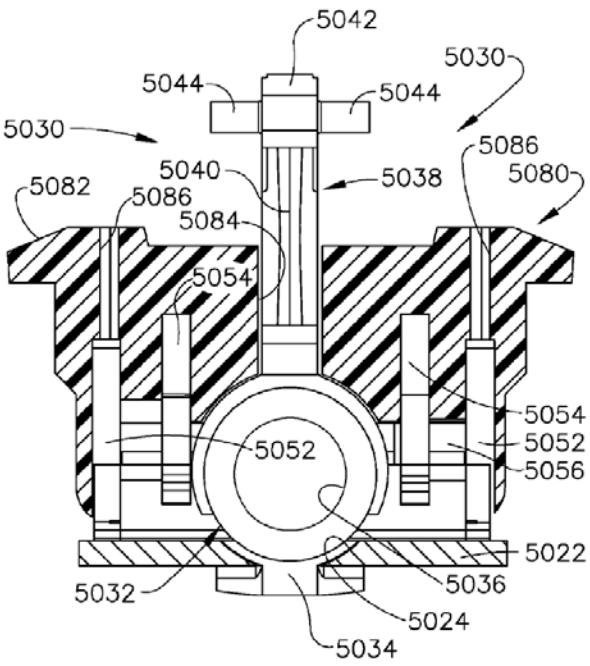


FIG. 108

Ex. 1001, Figs. 107 and 108

VI. CONCLUSION

For the reasons stated, Intuitive has failed to carry its burden to establish that claims 19-26 of the 969 Patent are invalid over the prior art. The claims should be upheld as patentable.

Dated: April 19, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Patent Owner Response, exclusive of the exempted portions as provided in 37 C.F.R. § 42.24(a), contains no more than 9,829 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(a). In preparing this certificate, counsel has relied on the word count of the word-processing system used to prepare the paper (Microsoft Word).

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CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2019, a copy of **PATENT OWNER ETHICON LLC'S RESPONSE** and any accompanying exhibits were served by filing the documents through the PTAB's E2E Filing System as well as delivering a copy via electronic mail upon the following:

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