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

DECLARATION OF DR. SHORYA AWTAR

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I. INTRODUCTION

1. My name is Dr. Shorya Awtar. I have been retained by counsel for Patent Owner Ethicon LLC ("Ethicon") in the above captioned *inter partes* review to consult with counsel, review documents, form opinions, prepare expert declarations, and be available to testify as to my opinions.

2. I understand that Petitioner Intuitive Surgical, Inc. ("Intuitive") has asserted that claims 19-22 and 24-26 of U.S. Patent No. 8,479,969 (the "969 Patent") are invalid as obvious. I have been asked to give expert opinions and testimony related to the issue of the validity of claims 19-22 and 24-26 of the 969 Patent,[1] including the background of the technology at issue, and the scope and content of the prior art.

3. My opinions are based on reviewing the Petition, Dr. Knodel's declaration (Ex. 1004), the Patent Owner Response, the transcripts of Dr. Knodel's depositions, and the relevant portions of all exhibits cited in any of the foregoing documents and this declaration.

4. The opinions I have formed as explained herein are informed by and based on my consideration of the documents listed above, as well as my own

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[1] I understand that challenged claim 23, which relates to Petitioner's Ground 1, has been disclaimed. *See* Ex. 2002.

knowledge and experience based upon my work in the relevant field of technology, as discussed below. All statements made herein of my own knowledge are true, and all statements made herein based on information and belief are believed to be true. Although I am being compensated for my time in preparing this declaration, the opinions articulated herein are my own, and I have no stake in the outcome of this proceeding or any related litigation or administrative proceedings. My study is ongoing, and I may supplement or amend these opinions based on the production of additional evidence, as a result of further analysis, or in rebuttal to positions subsequently taken by Intuitive and/or Dr. Knodel.

II. PRIORITY DATE AND LEVEL OF ORDINARY SKILL IN THE ART

5. I have been asked to assume that the priority date of the claims of the 969 Patent is May 27, 2011. I understand that Intuitive's expert, Dr. Knodel, has also utilized a priority date of May 27, 2011 in his analysis. *See* Ex. 1004 at ¶¶ 28-30. I reserve the right to address the priority date of the claims of the 969 Patent should Intuitive subsequently contest this issue.

6. I understand that Dr. Knodel has opined that a person of ordinary skill in the art for the 969 Patent would include someone who had the equivalent of a Bachelor's degree or higher in mechanical engineering with at least 3 years working experience in the design of comparable surgical devices. Ex. 1004 at ¶¶ 24-26. While I generally agree with the level of education and type of work

experience proposed by Dr. Knodel, I note that a person of ordinary skill in the art would additionally have had an understanding as to how the instrument design can affect the clinical outcomes associated with instrument use (*e.g.*, how effective a particular design is at forming staples). The opinions I express in this declaration are given from the perspective of a person of ordinary skill in the art as of the effective filing date of the 969 Patent, based on the level of education and work experienced proposed by Dr. Knodel in conjunction with the understanding of instrument design discussed above. I meet the criteria set forth by Dr. Knodel as well as the additional criteria set forth above, and consider myself a person with at least ordinary skill in the art pertaining to the 969 Patent.

III. QUALIFICATIONS

7. I am currently an Associate Professor of Mechanical Engineering at the University of Michigan, a position I have held since 2013. Prior to being promoted to Associate Professor, I was an Assistant Professor at the University of Michigan from 2007-2013. I am also the Director of the Precision Systems Design Laboratory at the University of Michigan ("PSDL"). My research in the PSDL covers machine and mechanism design, flexure mechanisms, parallel kinematics, mechatronic systems, flexible system dynamics and controls, and precision engineering. Specific research projects that I have worked on include medical devices for minimally

invasive surgery, motion stages for metrology and manufacturing, electromagnetic and electrostatic actuators, and micro-electromechanical systems.

8. In addition to my employment at the University of Michigan, I am also the cofounder and current Chief Technology Officer of FlexDex Surgical. FlexDex is an early stage technology startup created based on research performed in the PSDL. FlexDex develops surgical tools for use in minimally invasive (i.e., laparoscopic) surgical procedures.

9. I received my Sc.D. in Mechanical Engineering from the Massachusetts Institute of Technology ("MIT") in 2004. Prior to receiving my Sc.D. at MIT, I earned a Bachelor's degree in Mechanical Engineering from the Indian Institute of Technology, Kanpur in 1998, and a Master's degree in Mechanical Engineering from Rensselaer Polytechnic Institute in 2000.

10. Further details regarding my education and work experience are contained in my CV as Appendix A. I am being compensated at an hourly rate of $750, which is my standard rate for consulting engagements. My compensation is not dependent on the substance of my statements in this Declaration or the outcome of this case.

IV. RELEVANT LEGAL STANDARDS

11. I am not a lawyer, and I offer no legal opinions in this declaration. I have, however, been advised by counsel as to various legal standards that apply to

the technical issues I address in this declaration, and I have applied those standards in arriving at my conclusions.

12. I understand that the claims of a patent are presumed valid, and a Petitioner in an *inter partes* review proceeding must prove invalidity of the challenged claims by a preponderance of the evidence.

13. I have been informed that, when analyzing whether the challenged claims of the 969 Patent are invalid as obvious, one must determine whether the invention in each claim of the 969 Patent would have been obvious to a person of ordinary skill in the art, taking into account 1) the scope and content of the prior art; 2) the differences between the prior art and the claimed invention; 3) the level of ordinary skill in the art; and 4) any secondary considerations of non-obviousness.

14. I have been informed that a determination of obviousness requires that a person of ordinary skill in the art would have had a reason to modify or combine prior art references to achieve the claimed invention. I have also been informed that a determination of obviousness requires that a person of ordinary skill have a reasonable expectation of success in combining the prior art references to achieve the claimed invention.

15. I have been informed that secondary considerations may show that the claimed subject matter is not obvious. These secondary considerations can include, for example, commercial success (evidence of commercial success that can be

attributed to the merits of the invention), failure of others (evidence that others have tried and failed to solve the problem or satisfy the need resolved by the claimed invention), and skepticism (evidence that those of skill in the art were skeptical as to the merits of the invention, or even taught away from the invention).

V. OVERVIEW OF THE TECHNOLOGY DISCLOSED IN THE 969 PATENT

16. The 969 Patent was filed on February 9, 2012 as Application No. 13/369,609 (which was based on a series of continuation and continuation-in-part applications stemming from Application No. 11/651,807, filed on January 10, 2007, now U.S. Patent No. 8,456,520) and issued on July 9, 2013. The named inventor is Frederick E. Shelton, IV.

17. The 969 Patent generally relates to surgical instruments for use in minimally invasive surgical procedures. *See e.g.*, Ex. 1001 at 85:37-50 ("In addition, the present invention may be in laparoscopic instruments, for example."). An exemplary surgical instrument described in the 969 Patent is a surgical stapler, which can also be referred to as an endocutter or a linear cutter. *See, e.g., id.* at 1:66-2:24. Surgical staplers include an end effector, which comprises a pair of jaws that are configured to grasp and clamp on tissue within the body of a patient. *Id*. One of the jaws can include a staple cartridge that holds a plurality of staples, while the other jaw is generally referred to as an anvil. *See id*. Once the tissue is secured between the jaws, a driver can traverse a channel in the staple cartridge, which drives the

staples and causes them to be deformed against the anvil to form several rows of staples that secure the tissue. *See id*. The end effector can also include a cutting instrument, such as a knife, which advances between the rows of staples to cut the tissue after it has been secured with the staples. *See id*. The figure below provides an exploded view of an exemplary end effector described in the 969 Patent, including the jaw, staple cartridge, lower jaw, and driver for driving the staples:

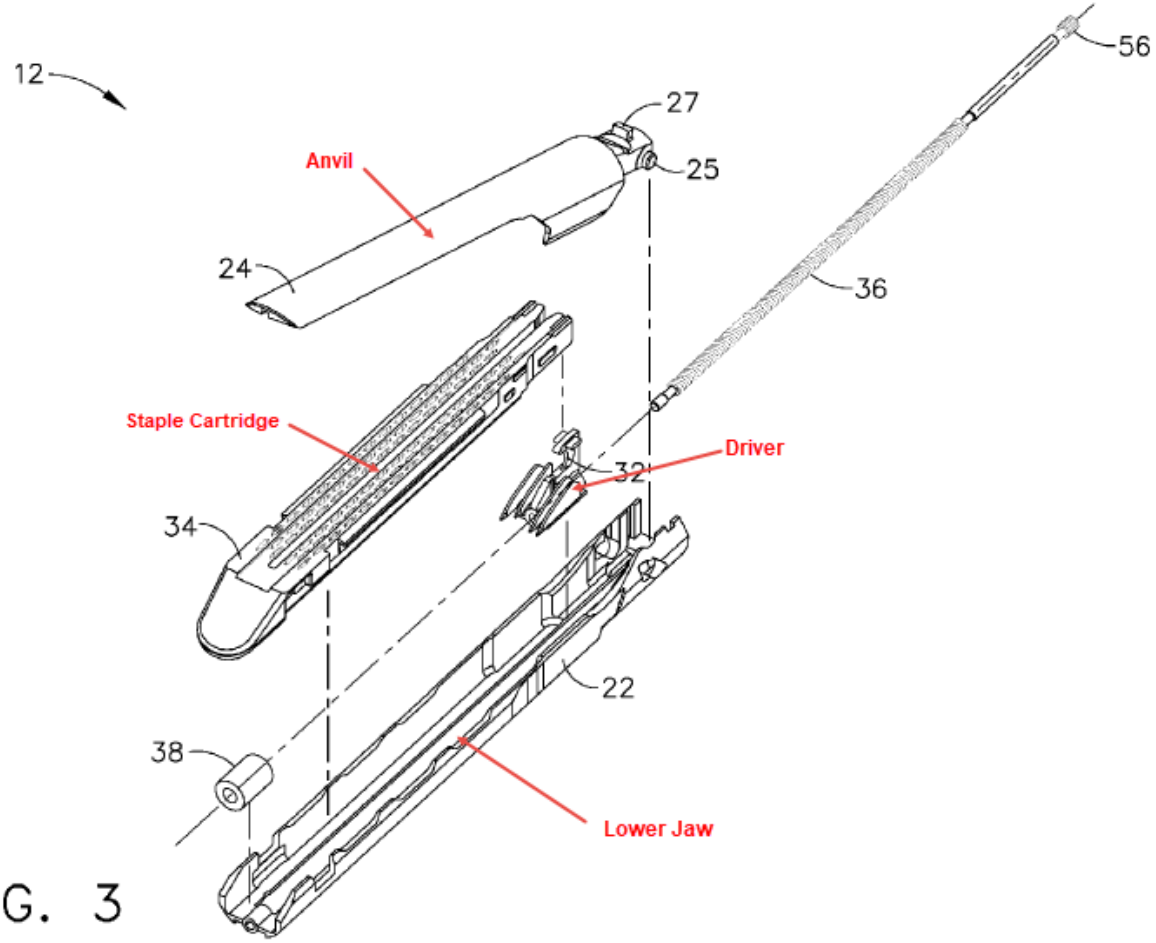


FIG. 3

Ex. 1001 at Fig. 3

18. The 969 Patent discloses handheld instrument embodiments, as well as those intended for use with robotic surgical systems. *See e.g.*, Ex. 1001 at 3:6-4:36. The figure on the left illustrates a handheld instrument embodiment, which can be actuated via a trigger, while the figure on the right illustrates a robotic instrument embodiment, which is configured to be attached to a robotic surgical system and actuated via a remote console:

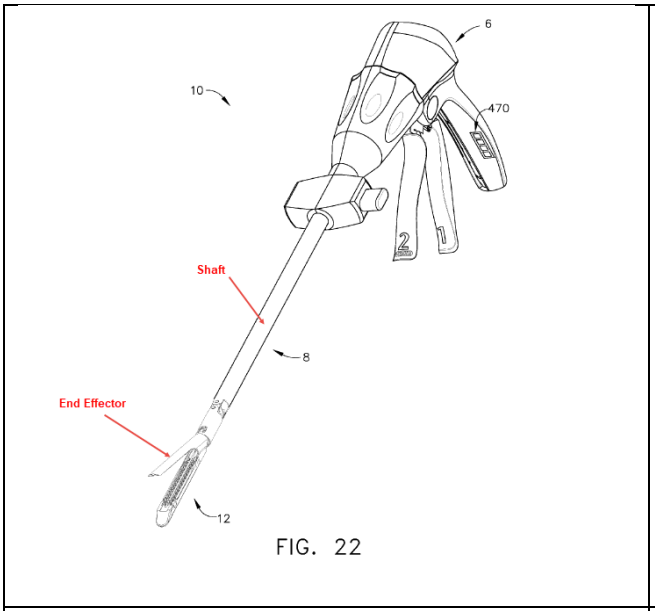


FIG. 22

Ex. 1001 at Figure 22

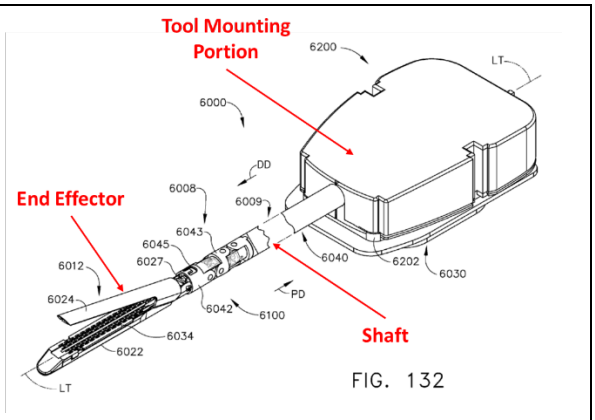


FIG. 132

Ex. 1001 at Figure 132

19. In either embodiment, the end effector is operably coupled to an elongate shaft. This arrangement facilitates insertion of the end effector into the body in a minimally invasive manner.

20. The 969 Patent is further directed to implementations of a "surgical instrument for use with a robotic system." Ex. 1001, Abstract. The surgical tool of

independent claim 24, for example, includes, a transmission assembly in meshing engagement with a gear-driven portion to apply control motions to a selectively moveable component of an end effector. *See, e.g.*, Ex. 1001 at 34:36-43 ("[A] knife drive gear 2432 is attached to the drive shaft segment 2430 and is meshing engagement with a drive knife gear 2434 that is attached to the end effector drive shaft 2336. Thus, rotation of the drive shaft segment 2430 will result in the rotation of the end effector drive shaft 2336 to drive the cutting instrument 2332 and sled 2333 distally through the surgical staple cartridge…."); *id.* at 85:4-8 ("In various embodiments, the gears of the knife gear assembly 6560 are sized to generate the forces needed to drive the cutting instrument through the tissue clamped in the surgical end effector 6012 and actuate staples therein."). As shown below in Figure 132, the claimed surgical instrument includes a tool mounting portion that is operably coupled to the shaft, and is configured to operably interface with a tool drive assembly of a robotic system. Also shown below is Figure 136, which illustrates a transmission that includes a plurality of gears that are in meshing engagement with a gear driven knife bar to apply control motions to the cutting instrument and sled of an end effector. Ex. 1001 at 84:38-85:16.

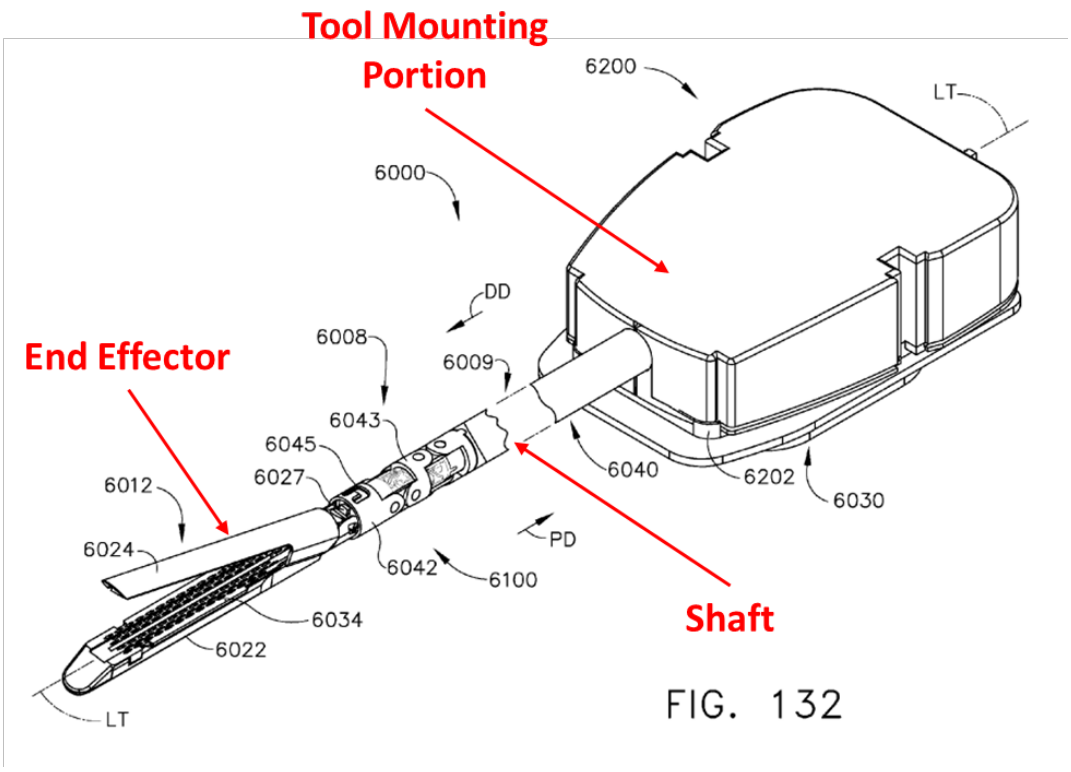


FIG. 132

Ex. 1001 at Fig. 132

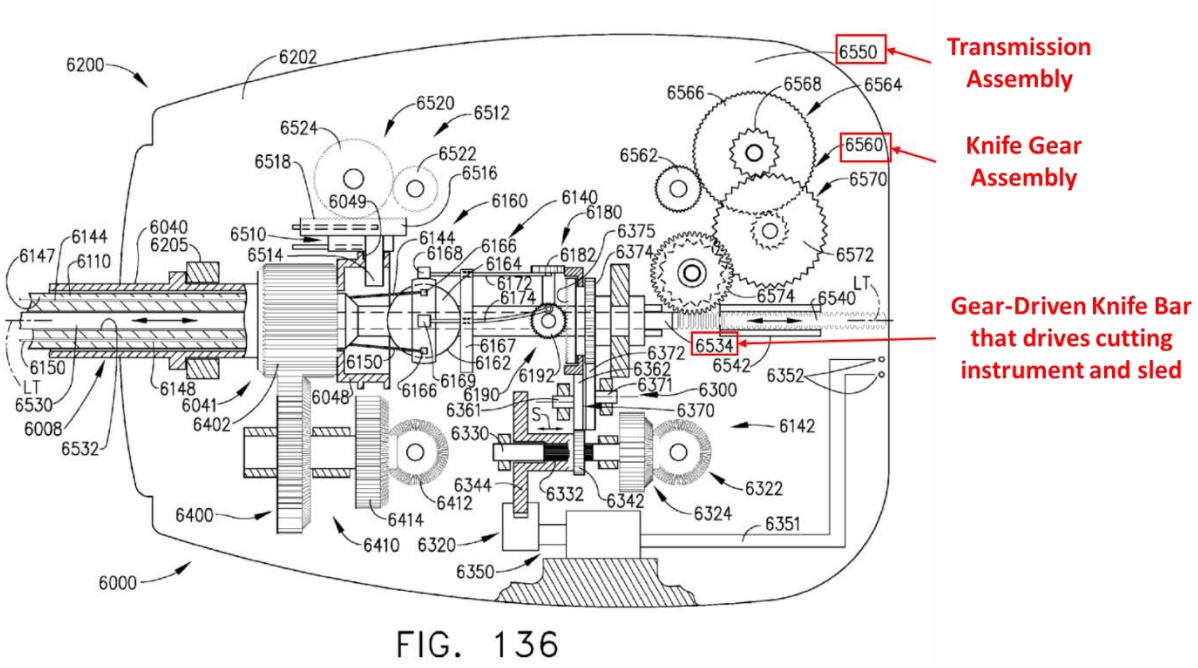


FIG. 136

Ex. 1001 at Fig. 136

21. 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. *See* Ex. 1001at Claim 24. The 969 Patent also discloses exemplary articulation joints that facilitate articulation about one or two axes. In each of these exemplary embodiments, the articulation joint is operably coupled to the tool mounting portion, such that the rotary members, which are controlled remotely from the surgeon's console, control the articulation about the articulation joint. Figure 35, for example, illustrates an articulation joint that facilitates articulation about a single axis transverse the longitudinal axis of the elongate shaft. *See* Ex. 1001at 27:19-47.

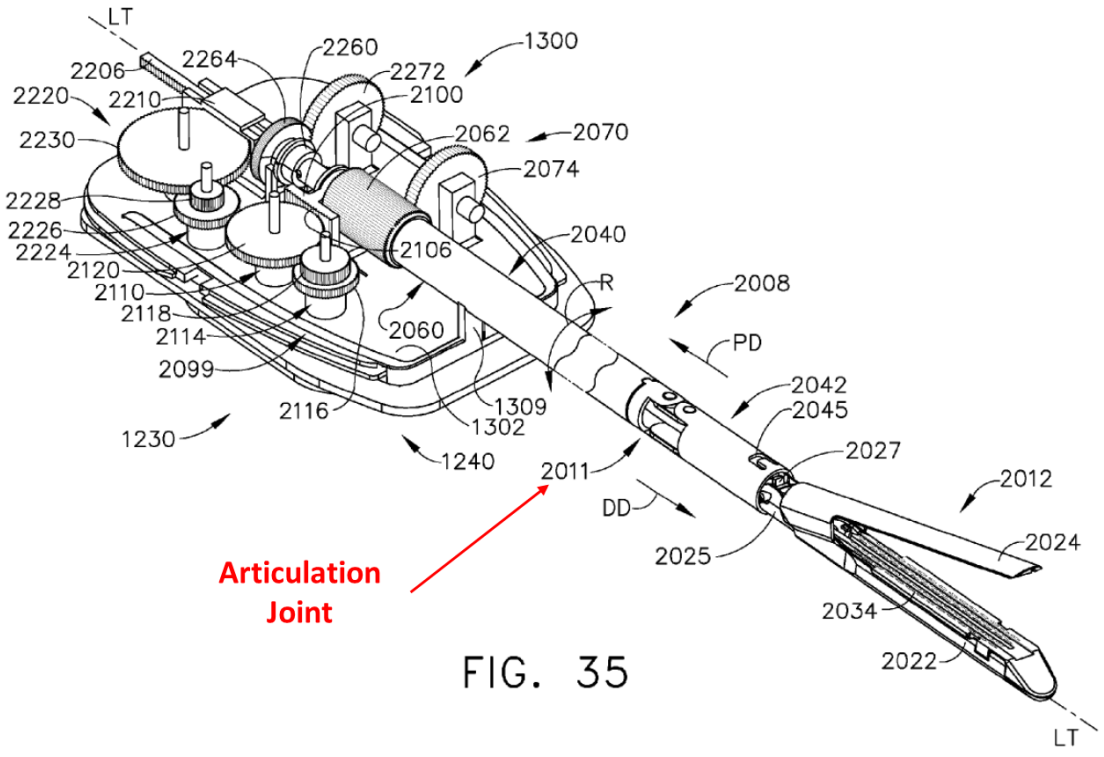


FIG. 35

Ex. 1001 at Fig. 35.

As shown in Figure 34, which depicts the same embodiment viewed from behind the tool mounting portion, the articulation joint is controlled by articulation nut 2260 at the proximal end of the shaft. *Id*. at 30:65-31:3. The articulation nut 2260 is, in turn, driven by the rotary motion of articulation drive gear 2274, which receives rotary motion from articulation gear 2272, which in turn receives rotary motion from the robotic system through a driven element on the adapter side of the tool mounting portion. *Id*. at 31:3-16.

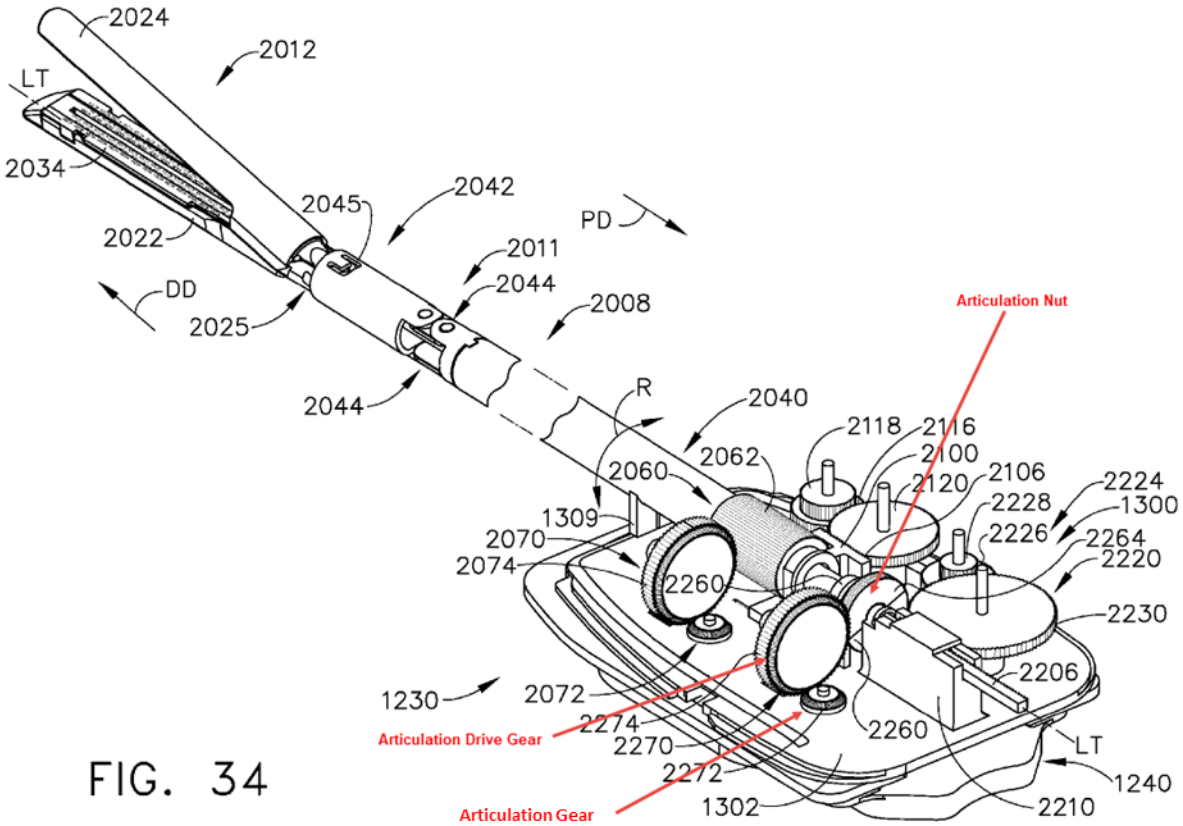


FIG. 34

Ex. 1001 at Fig. 34

22. Figure 133 illustrates articulation about 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. Ex. 1001at 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 seen in Figure 133, this embodiment of the articulation joint is controlled by two pairs of articulation cables, designated 6144, 6146, 6150, and 6152.

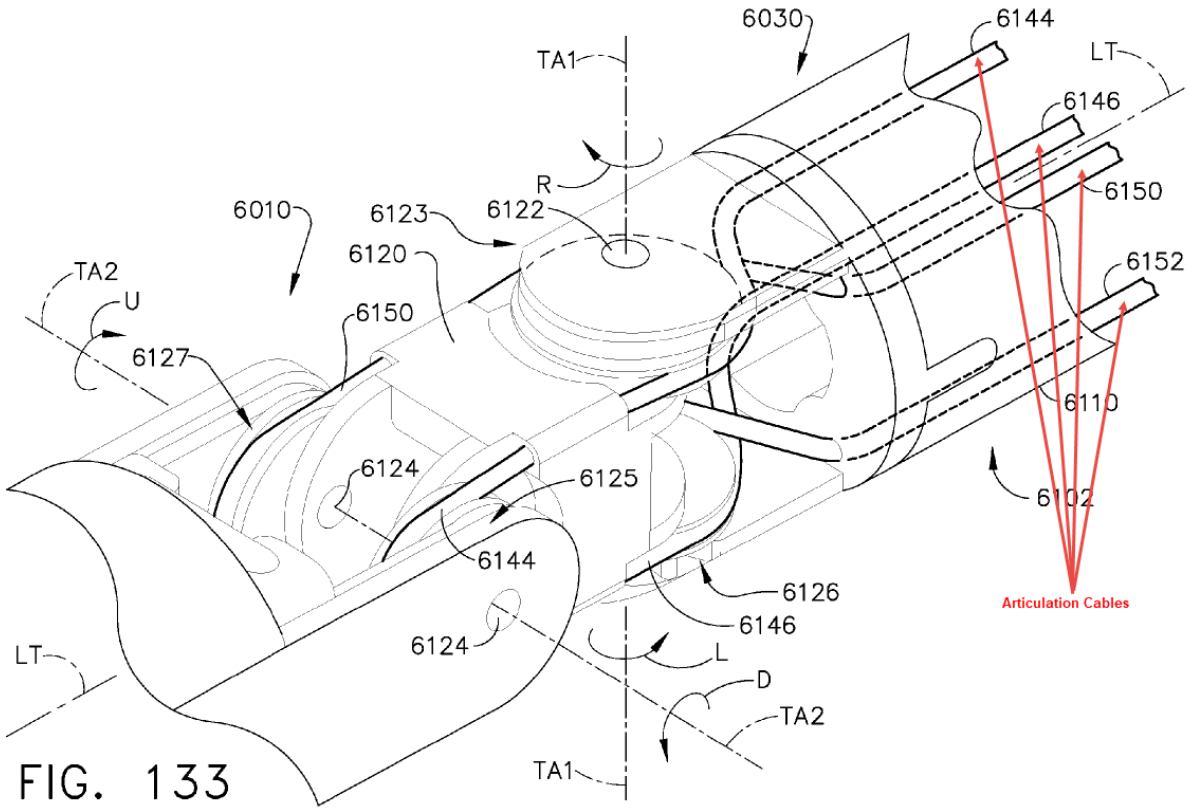


FIG. 133

969 Patent at Fig. 133

Like the articulation joint of the embodiments in Figures 34-35, the articulation joint in Figure 133 is operably coupled to the tool mounting portion by the articulation cables 6144, 6146, 6150, and 6152, allowing the articulation joint to be operated by rotary motion received from the robotic system. 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 run parallel to 6144 and 6150, are not visible in this perspective). *Id*. at 78:51-67.

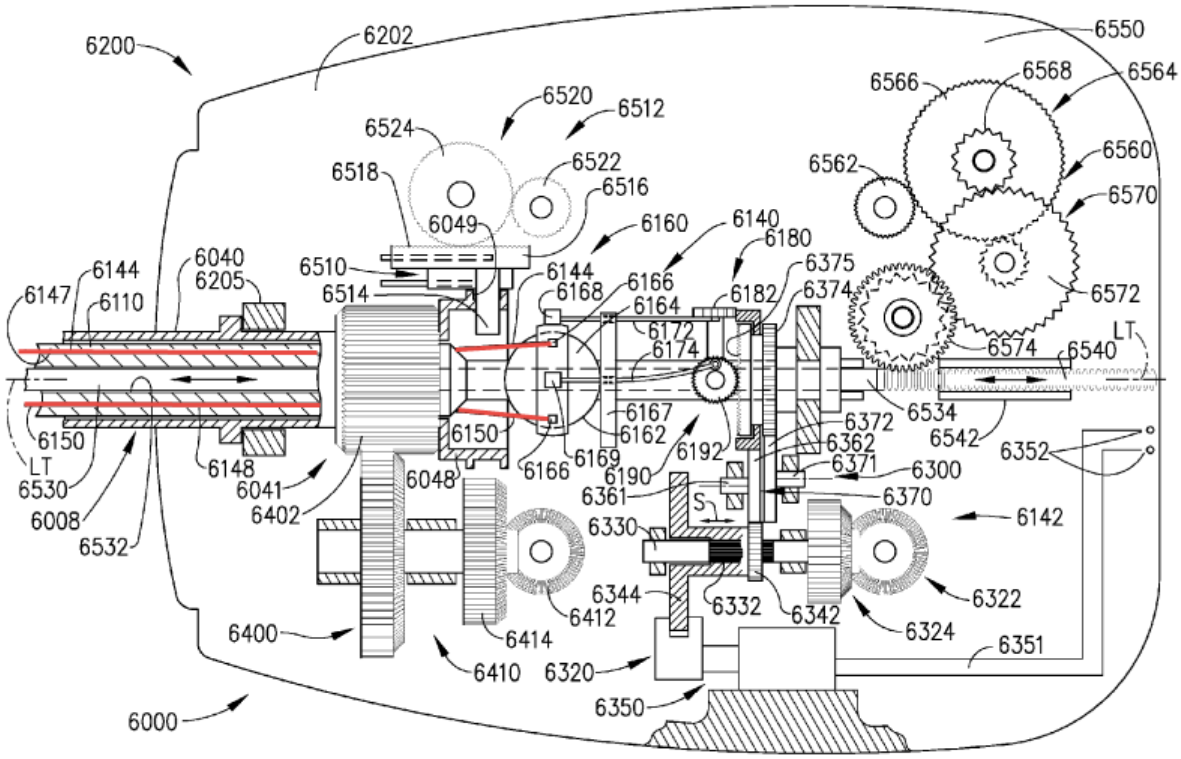


FIG. 136

Ex. 1001 at Fig. 136

23. As shown in Figure 137, below, the articulation cables couple to an articulation control arrangement 6160 on the tool mounting portion. *Id*. at 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*. at 79:54-80:39.

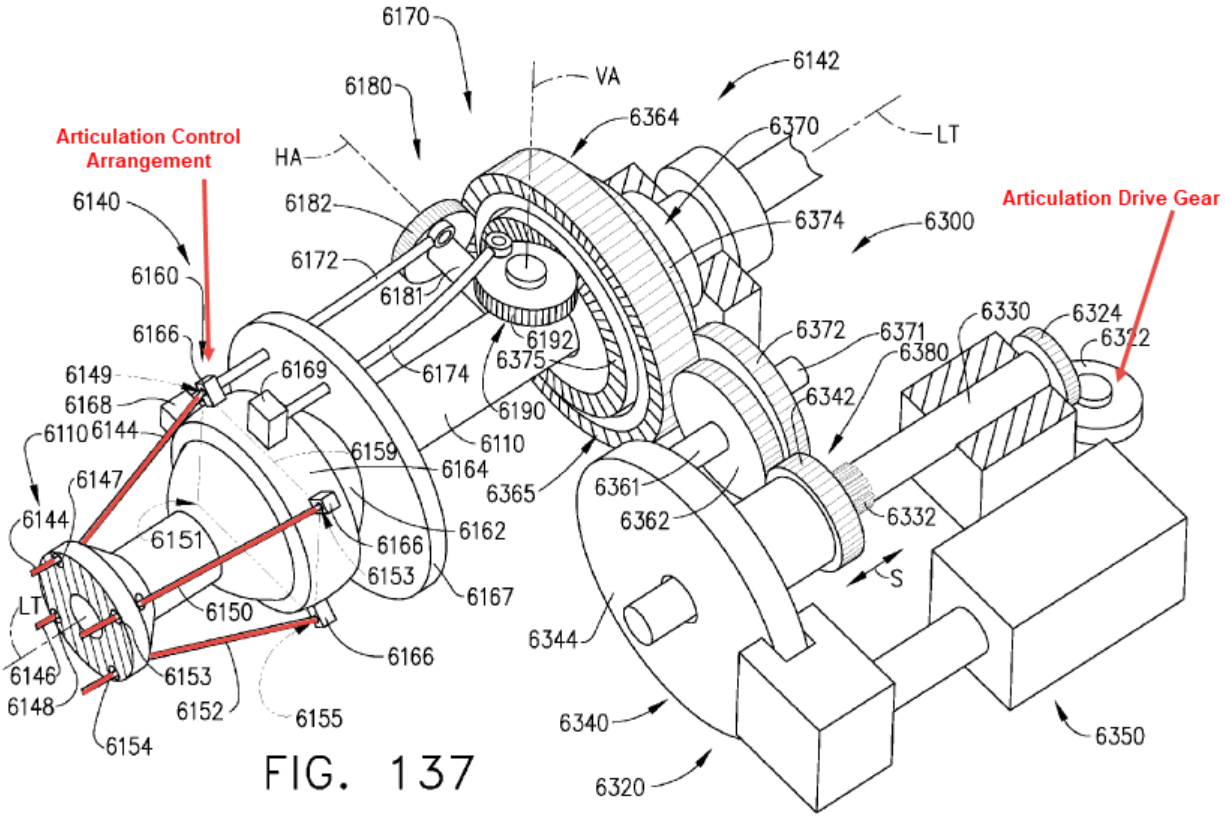


FIG. 137

Ex. 1001 at Fig. 137

24. The 969 Patent describes that the claimed invention provides several advantages. In particular, the disclosed transmission arrangement enables an instrument that can (i) articulate about two different axes that are substantially transverse to each other and the longitudinal tool axis: (ii) rotate the end effector about the longitudinal tool axis; (iii) open and close the end effector anvil to clamp tissue; and (iv) fire the device to cut and staple tissue. Ex. 1001 at 85:19-32. The 969 Patent describes that the disclosed gear-driven system improves upon the prior art

by enabling a surgical instrument that can generate the magnitude of forces required to effectively cut and fasten tissue, which is critical for surgical staplers. *Id.* at 23:6-29, 84:20-26, 85:4-10.

VI. PROSECUTION HISTORY OF THE 969 PATENT

25. Ethicon filed Application No. 13/369,609 on February 9, 2012, which ultimately issued as the 969 Patent on July 9, 2013. The 969 Patent is a continuation of application No. 13/118,259, which was filed on May 27, 2011, and is a continuation in part of application No. 11/651/807, which was filed on January 10, 2007.

26. The originally filed claims in the application that resulted in the 969 Patent were initially rejected by the examiner. *See* Ex. 1002 at p. 280-4, 8-30-2012 Non-Final Rejection. In response to the rejection, Ethicon added a new claim that ultimately issued as Claim 24. *See id.* at p. 289-317, 11-13-2012 Amendment After Non-Final Rejection. Claim 24 of the 969 Patent was never the subject of a rejection, and was ultimately allowed by the examiner without amendment. *See id.* at p. 328, 12-11-2012 Notice of Allowance.

VII. CLAIM CONSTRUCTION

27. I have been informed that the claims of the 969 Patent should be construed using the broadest reasonable construction in light of the specification of the patent. I have been informed that the broadest reasonable construction is an

interpretation that corresponds with what and how an inventor describes his invention in the specification, meaning that the interpretation must be consistent with the specification.

28. In rendering my opinions, to the extent that I do not provide a construction for a term, I have applied that term's ordinary meaning to a person of ordinary skill in the art, in light of the specification.

VIII. OVERVIEW OF THE PRIOR ART CITED BY PETITIONER

29. I understand that Petitioner has asserted that claims 19-22 and 24-26 of the 969 Patent are invalid as obvious based on various prior art references. Below I provide a brief description of each reference that Petitioner has relied on.

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

30. U.S. Patent No. 6,784,524 ("Anderson") was filed on April 18, 2002 and issued on August 31, 2004. The named inventors are Stephen C. Anderson and Christopher A. Julian, and the patent was originally assigned to Petitioner here, Intuitive Surgical, Inc. Anderson is discussed and incorporated by reference in the 969 Patent. Ex. 1001, 23:6-29; 85:51-64.

31. Anderson discloses a robotic surgical tool that has 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. Anderson's surgical

instrument attaches to the robotic surgical system through instrument base 34. Ex. 1010, 11:66-12:11.

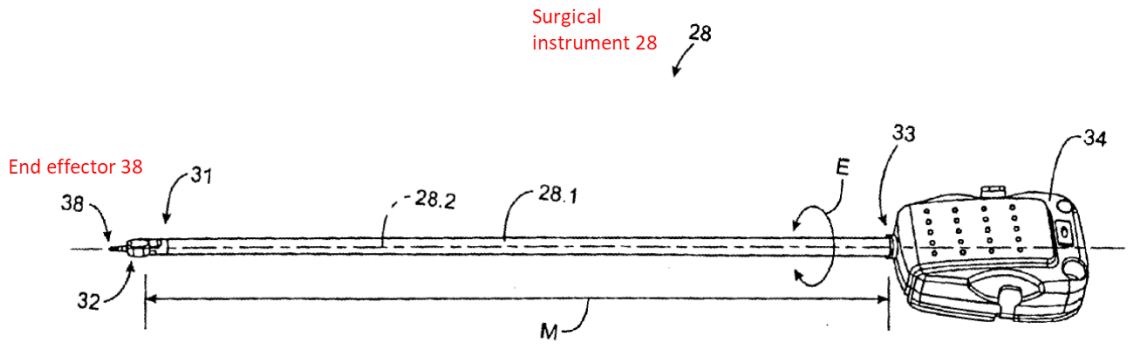
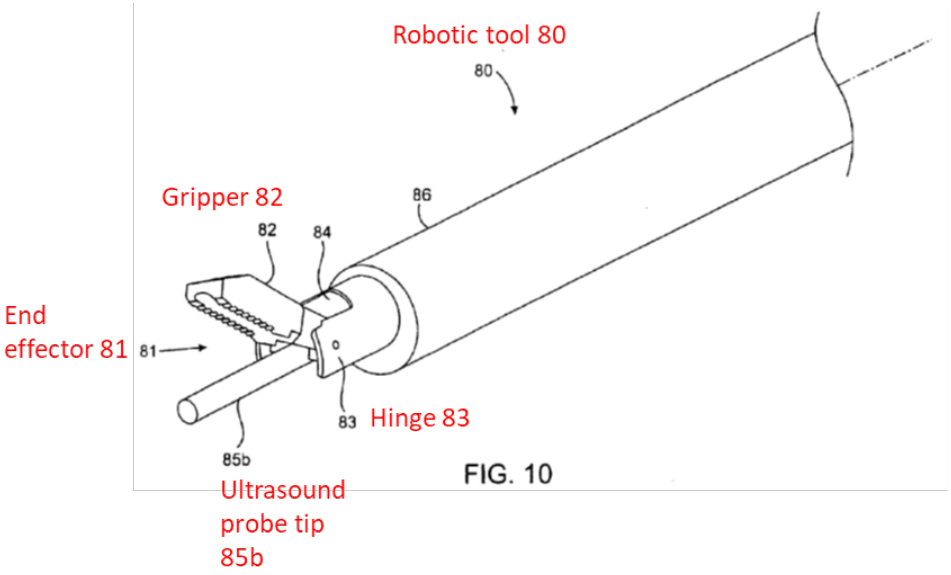


FIG. 2

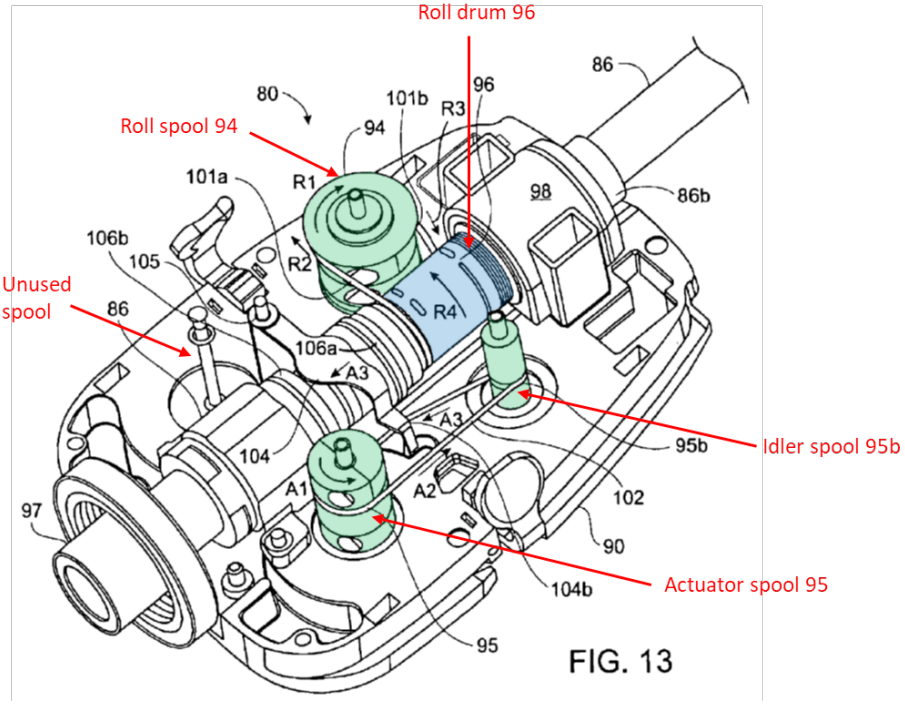
Ex. 1010 at Fig. 2 (annotated)

32. Figures 10-19 of the Anderson reference 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 robotic tool's end effector 81 includes gripper 82 and ultrasound probe tip 85b. Ex. 1010, 15:29-60. Figure 10 is annotated below.



Ex. 1010 at Fig. 10 (annotated)

33. Anderson's instrument base is illustrated in greater detail in Figure 13. Relevant components of the tool base are annotated in the illustration below:



Ex. 1010 at Fig. 13 (annotated)

34. As illustrated in Figure 13, the instrument base includes roll spool 94, actuator spool 95, idler spool 95b, roll drum 96, and an unused spool. Roll cable 101a/b runs between roll spool 94 and roll drum 96 to rotate the instrument shaft. Ex. 1010, 16:45-61. Cable loop 102 connects the actuator spool 95 and idler spool 95b. These components control the gripper 82 of end effector 81 (the end effector is 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) to control two instrument motions (shaft rotation and gripper open/close). Anderson also discloses one additional spool that is unused. This spool could be utilized for an additional control motion.

35. In the 969 Patent, Anderson is cited as an example of a prior art robotic system. The 969 Patent discloses 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):

> 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" … <u>Many of such systems, however, have in the past been unable to generate the magnitude of forces required to effectively cut and fasten tissue</u>.**

Ex. 1001, 23:6-29.[2]

36. The Petitioner has noted that Anderson suggests that "stapler probes" may be used with its system. *See* Petition at 31. However, in my opinion, the passing reference to stapler probes in Anderson does not indicate that a surgical cutting and stapling device such as an endocutter may be utilized with the Anderson robotic system. A surgical "stapler probe" may refer to a device that simply applies staples and does not cut tissue at all. On this point, I note that Dr. Knodel has agreed that a device that simply staples is a "vastly different" device from an endocutter. *See, e.g.*:

> 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.
> Q. All right. So there are staplers that just staple. They don't cut and staple tissue; right?
> A. The simple answer would be yes, but I want to clarify. Endoscopic -- endoscopic staplers, linear staplers, they're

[2] All emphasis is added in this declaration unless otherwise noted.

-- there's a subset, I believe, that some companies have that they call a no knife. But generally, devices that only staple aren't endoscopic. They look like a C-clamp. They're used in open procedures.

Q. Okay. So you're saying when somebody uses the word "stapler" in the context of an endoscopic device, it means a device that cuts and staples tissue?

A. No, I'm not saying that either.

Q. Okay.

A. No. There's endoscopic staplers that just apply a staple on the end of an endoscopic tube, for example.

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.

Ex. 2010 at 24:12-25:24.

Q. So this is a Patent No. US 7,473,258, that we've marked as Exhibit 2004, and it is in your C.V. in the list of patents. And you are the Bryan Knodel –

A. I am –

Q. -- on this patent?

A. -- in fact, that Bryan Knodel. I'm not sure if it's in my list. I may have forgot to put it in.

Q. It's on the second page, page 104.

A. Okay. Yes. I see it. Mm-hmm.

Q. Okay. And this is -- again, you were named an inventor on this patent; right?

A. Yes, I am.

Q. And this 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.

Ex. 2010 at 28:7-29:6.

37. In my opinion, and as I discuss further below in Section IX in the context of Petitioner's combinations of Anderson, a POSITA reviewing the Anderson reference would have understood that the reference does not disclose a tool base that would be capable of driving an endocutter that articulates.

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

38. U.S. Patent No. 7,510,107 ("Timm") was filed on June 18, 2007 and issued on March 31, 2009. The named inventors are Richard W. Timm and

Frederick E. Shelton, IV. The patent was originally assigned to Ethicon Endo-Surgery, Inc. and is now assigned to Patent Owner Ethicon LLC.

39. Timm relates to a handheld endocutter. *See*, *e.g.*, Ex. 1011, Abstract; Fig. 1. Timm's handheld endocutter also includes an articulation joint, and Timm discloses two separate types of articulation joints: (1) "passive" articulation joints (*see* Figures 52-72); and (2) "active" articulation joints (*see* Figures 73-89).

40. Timm's passive articulation joint is described as a "lockable articulation joint." 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**.").

41. Timm explains that passive articulation requires the surgeon to press the end effector against another instrument or structure in the body to articulate it. Once the end effector is in the desired orientation, the surgeon locks the

articulation joint in place. 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 (describing Figs. 62-64); *see also id.* 30:44-57 (Figs. 55-57), 31:36-51 (Figs. 58-61), 33:5-19 (Figs. 65-67), 33:61-34:9 (Figs. 68-70), 34:46-57 (Fig. 71), 35:24-35 (Fig. 72).

42. Separate from these passive articulation embodiments, Timm discloses embodiments with active articulation in Figures 73-89. Ex. 1011, 37:55-58 ("[T]he present invention may further include an active articulation system"); *id.* at 42:37-39 ("FIGS. 85-89 illustrate another surgical instrument embodiment 6000 that employs an active or controllable articulation joint").

43. In the active articulation joint embodiments, a joystick assembly is included at the back end of the handle assembly and push/pull wires couple the joystick assembly to the articulation joint. *See, e.g.*:

> 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 at 40:34-63.

44. Timm does not describe these active articulation embodiments as including a "lockable articulation joint." Based on my review of the Petition and Dr. Knodel's declaration, Petitioner and Dr. Knodel do not rely on the active articulation embodiments in the obviousness analysis of claim 24. The only substantive discussion of active articulation appears in Dr. Knodel's declaration when discussing claims 25-26. There, Dr. Knodel opined that active articulation

embodiments are not applicable in the context of a robotic system and should not be combined with Anderson.

> 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.

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

45. U.S. Patent No. 6,699,235 ("Wallace") was filed on June 28, 2002 and issued on March 2, 2004. The named inventors are Daniel T. Wallace, S. Christopher Anderson, and Scott Manzo, and the patent was originally assigned to the Petitioner here, Intuitive Surgical, Inc.

46. Wallace alleges that existing tools for minimally invasive surgery (which Wallace refers to as "MIS") often denied the surgeon the flexibility of tool placement that surgeons were used to in open surgery. Ex. 1008 at 2:31-34. The rigid shafts found on many laparoscopic tools, for example, made it difficult to approach the surgical site through small incisions. *Id*. at 2:34-36. When such instruments are

used with robotic surgical systems, manipulation and control of the end effectors is a critical aspect. *Id*. at 2:60-61.

47. Accordingly, Wallace sought to provide surgical tools that included mechanisms for "three degrees of rotational movement of an end effector around three perpendicular axes to mimic the natural action of a surgeon's wrist." *Id*. at 2:61-65. Wallace's approach to such a mechanism was a rod-based articulation mechanism, shown in Figures 2A and 3:

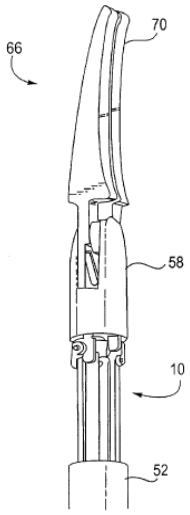


Fig. 2A

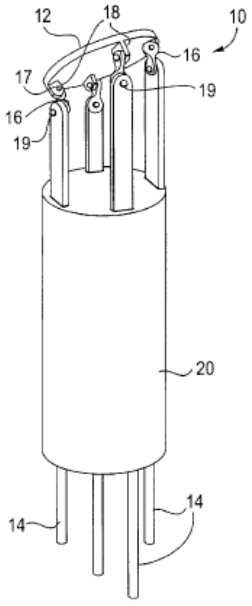


Fig. 3

Ex. 1008 at Figs. 2A and 3

48. The rods of the wrist mechanism are controlled by a robotic tool base 62, to which the instrument is coupled. Ex. 1008 at 7:37-40. The tool base is shown in Figure 30.

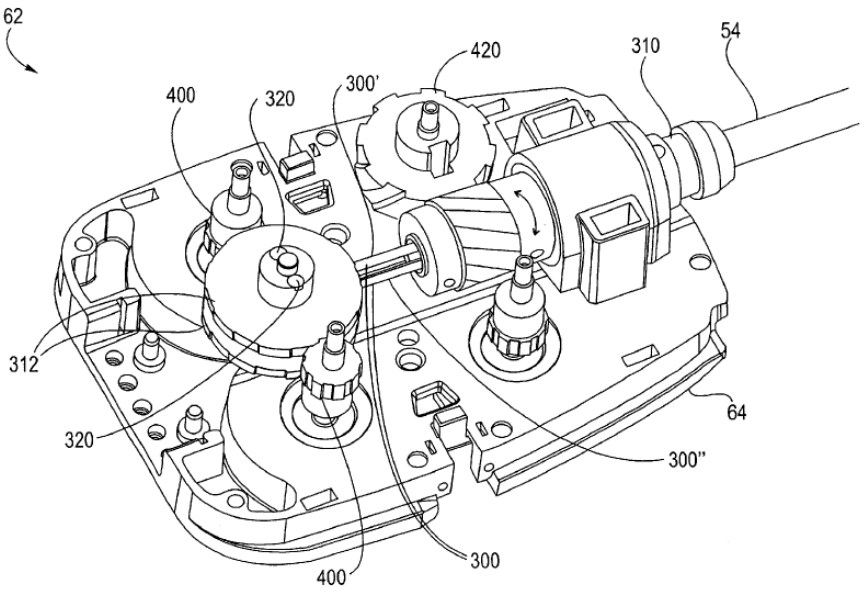


Fig. 30

Ex. 1008 at Fig. 30

49. The articulation rods 14 in Figures 2A and 3 extend through the shaft of the instrument, and emerge in the tool base as rods 300. Ex. 1008 at 13:44-45. On the tool base, the rods are coupled to sector gears 312, which rotate under the control of gears 400. *Id*. at 13:47-54. This rotational input causes individual rods to advance or retract as needed, allowing the instrument to articulate freely in three dimensions around the wrist joint. *Id*.

50. The tool base also includes a gear 420, which rotates pull pulley 310 to generate shaft rotation. *Id*. at 13:66-14:10.

51. As is evident from the description above, and as a person of ordinary skill in the art would have understood, Wallace's system uses three input motions to

control two instrument functions: rotation of the two gears 400 to control articulation, and rotation of gear 420 to control shaft rotation. As shown in Figure 30, the tool base can accept a total of four input motions, thus leaving one additional input motion available to control an additional instrument function.

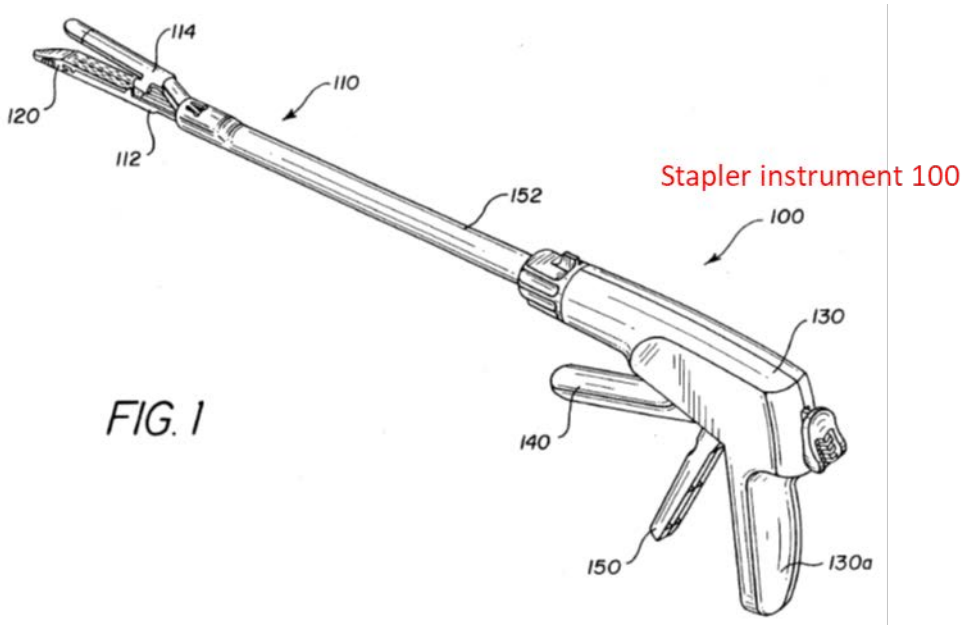
52. While Wallace contemplates that its tool base and articulation mechanism may be used with a number of different end effectors, including scalpels, blades, electrodes, forceps, graspers, scissors, or clip appliers, it does not disclose any embodiments in which the end effector is an endocutter. *See* Ex. 1008 at 3:46-50, 7:50-53. The end effectors illustrated in the figures are a grasper and a cautery isolation effector. *Id.* at 7:47-50. Additionally, Wallace includes no disclosures about how to provide control motions through the articulation joint for the end effectors that it does disclose; the figures (including Figures 2A, 3, and 30 shown above) and text do not show depict any mechanisms for controlling the end effector.

53. I understand that in IPR2018-1254, Dr. Knodel has expressed the opinion that Wallace incorporates by reference the entirety of another prior art reference, U.S. Patent No. 6,331,181 ("Tierney"). *See* IPR2018-1254, Ex. 1005 at ¶ 43. Because the opinions I express regarding the validity of the claims of the 969 Patent do not depend on whether or not Tierney is wholly incorporated by reference into Wallace, I offer no opinion at this time about whether Dr. Knodel's position on incorporation by reference is correct.

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

54. U.S. Patent No. 5,465,895 ("Knodel") is an expired patent filed on February 3, 1994 and issued on November 14, 1995. The named inventors are Bryan D. Knodel, Richard O. Nuchols, and Warren P. Williamson. The patent was originally assigned to Ethicon Endo-Surgery, Inc. The Knodel reference is relied on solely for Ground 4 (claims 19-20).

55. Knodel relates to a handheld surgical stapler. Ex. 1012, Abstract. Knodel's handheld surgical stapler comprises an end effector at the distal end of an elongated shaft that is coupled to a handle. This is illustrated in Figure 1, below:



Ex. 1012 at Fig. 1

56. Knodel 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. The

surgeon pulls the closure trigger 150 to close the instrument on tissue and then actuates the firing mechanism by pulling the firing trigger 140.

> 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.

Ex. 1012, 11:40-45.

> 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.

Ex. 1012, 11:40-12:6.

57. Knodel is cited in the 969 Patent specification and described as an endocutter with "distinct closing and firing motions":

> An example of a surgical stapler suitable for endoscopic applications is described in U.S. Pat. No. 5,465,895, which discloses an endocutter with distinct closing and firing actions. A clinician using this device is able to close the jaw members upon tissue to position the tissue prior to firing. Once the clinician has determined that the jaw members are properly gripping tissue, the clinician can then fire the surgical stapler with a single firing stroke, thereby severing and stapling the tissue. The simultaneous severing and stapling avoids complications that may arise

when performing such actions sequentially with different surgical tools that respectively only sever and staple.

Ex. 1012, 2:13-24.

58. Knodel does not disclose any mechanisms for articulation. It also does not disclose tools designed for robotic surgical systems.

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

59. U.S. Patent No. 5,954,259 ("Viola") is an expired patent filed on June 27, 1997 (claiming priority to earlier applications) and issued on September 21, 1999. The named inventors are Frank J. Viola, Daniel E. Alesi, Dominick L. Mastri, Wayne P. Young, Richard N. Granger, and Kenneth E. Toso. The patent was originally assigned to United States Surgical Corporation. The Viola reference is relied on solely for Ground 5 (claims 21-22).

60. Viola is directed to a handheld endocutter that includes a drive screw that is located proximal (closer to the handle) to the device's end effector (i.e., the portion of the instrument that engages tissue). This is illustrated in Figures 9 and 10 below:

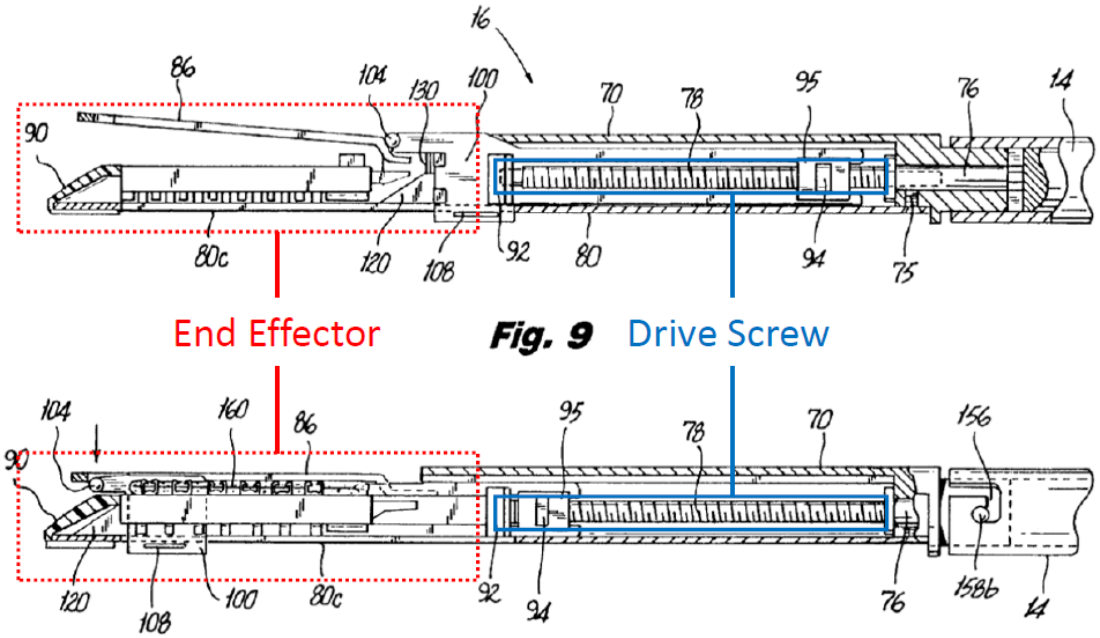
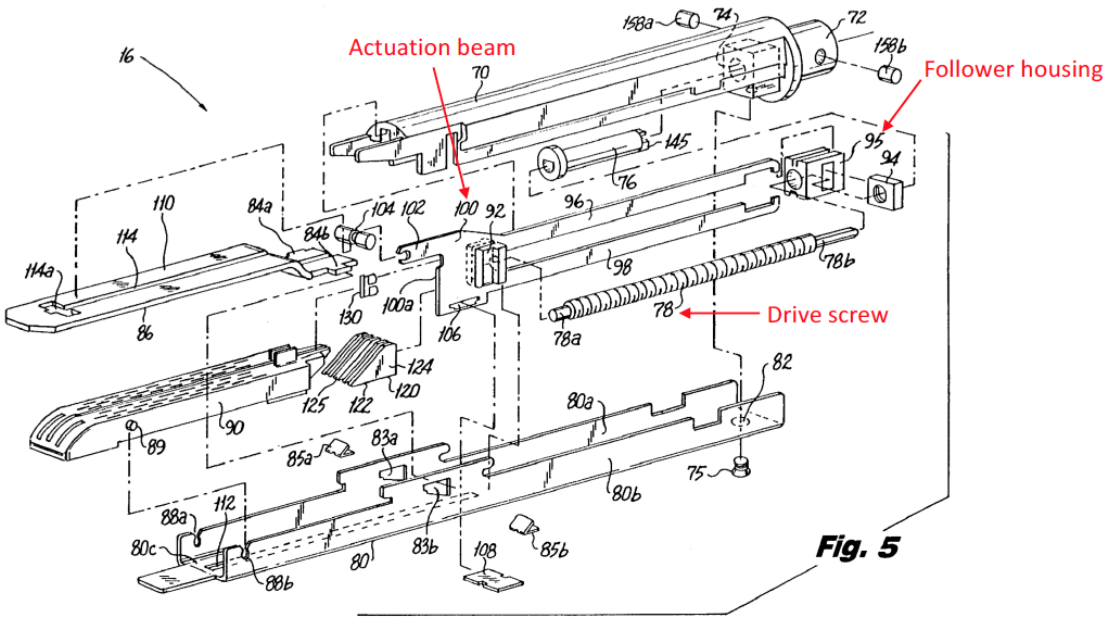


Fig. 9

Fig. 10

Ex. 1013 at Figs. 9-10 (annotations in red and blue)

61. With respect to the drive screw, Viola discloses that it is threadedly engaged with a nut 94 mounted within follower housing 95. Viola discloses that the follower housing 95 is operatively connected to actuation beam 100. The actuation beam 100 includes a cutting blade and is operatively connected to the follower housing via beam extensions 96 and 98. This is illustrated in Figure 5 and described in the specification text below.



Ex. 1013 at Fig. 5 (annotated)

> 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.

Ex. 1013, 6:50-55.

> 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. 1011, 6:55-59.

62. Viola does not disclose any mechanisms for articulation. It also does not disclose tools designed for robotic surgical systems.

IX. PETITIONER HAS NOT DEMONSTRATED THAT ANDERSON IN COMBINATION WITH ANY OF THE REMAINING PRIOR ART REFERENCES RENDERS OBVIOUS THE CHALLENGED CLAIMS OF THE 969 PATENT

63. I have reviewed Grounds 2-5[3] set forth in the Petition and Dr. Knodel's declaration. 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

64. For the reasons discussed in the sections that follow, it is my opinion that none of Intuitive's proposed obviousness combinations (and therefore none of the instituted grounds) render obvious any of the challenged claims of the 969 Patent.

A. Petitioner Has Not Demonstrated Anderson in View of Timm Renders Obvious Claim 24 of the 969 Patent (Ground 2)

[3] As noted above, I understand that Ground 1 is no longer at issue.

65. It is my opinion that Petitioner has not demonstrated that the combination of Anderson and Timm renders claim 24 obvious for the reasons below.

1. Petitioner Has Not Demonstrated That The Combination Of Anderson And Timm Discloses "A Tool Mounting Portion Operably Coupled To A Distal End Of Said Proximal Spine Portion" (Ground 2, claim 24)

66. 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. I understand that a certificate of correction issued in January 2018 "tool mounting portion operably coupled to a proximal end of said proximal spine portion." I further understand that a District Court has held the certificate of correction invalid. *See* Ex. 2013, Ethicon LLC et al. v. Intuitive Surgical, Inc. et al., C.A. 17-871, D.I. 292 (D. Del. Feb. 11, 2019). I have been asked by counsel to evaluate Petitioner's analysis of the uncorrected language.

67. Petitioner's analysis 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. Ex. 1004, ¶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 <u>via the structure of the distal spine portion itself</u>.

Petition at 52.

68. This analysis does not explain how any portion of the proximal spine is operably coupled to the tool mounting portion "via the structure of the distal spine portion itself." Paragraph 105 of Dr. Knodel's declaration does not relate to this issue. To the extent the citation was intended to be to paragraph 104, this paragraph does not add any explanation, and in fact adds confusion because Dr. Knodel substitutes "via the structure of the proximal spine portion itself" for "via the structure of the distal spine portion itself." Ex. 1004 at ¶ 104.

69. Indeed, as discussed in Section IX.A.2 below, Petitioner's Anderson/Timm combination relies on the passive articulation joint of the Timm reference to disclose this limitation. A passive articulation joint, however, does not involve a distal end of a proximal spine that is "operably coupled" to the tool mounting portion. In the context of the 969 Patent, it is clear that the operable coupling between the tool mounting portion and the spine portion is referring to an active articulation joint that is operated via the tool mounting portion. Ex. 1001 at 30:26-31:43, 78:19-79:53. In contrast, a passive articulation joint is manipulated by external forces, not the tool mounting portion, and therefore, would not involve an operable coupling to a tool mounting portion.

2. A POSITA Would Not Have Utilized Timm's Passive Articulation Joint In The Robotic System Of Anderson (Ground 2, Claim 24)

70. Claim 24 recites a "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.

71. Petitioner relies on a passive articulation joint to meet this limitation. In particular, Petitioner and Dr. Knodel rely on Figure 52 and Figures 66 (the passive "lockable articulation joint"). Petition at 36-27; Ex. 1004 at ¶¶ 88-89.

72. Later in his declaration, Dr. Knodel affirmatively opines that the "active articulation" mechanisms in Timm are "only relevant to handheld" devices because they are manually operated.

> [O]ne 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.

Ex. 1004, ¶ 118.

73. It is my opinion that a POSITA would have been strongly discouraged from combining Anderson with Timm's passive articulation joint. In reaching this

conclusion, I note that a POSITA would have been aware of the capabilities of the existing da Vinci robotic systems (which are the robotic systems disclosed in Anderson) in the 2011 timeframe and the prevailing opinions of surgeons regarding passive articulation mechanisms.

74. I have reviewed the declaration of Dr. Elliott Fegelman, who I understand was a practicing general surgeon in the 2011 timeframe and had experience with both laparoscopic and robotic surgical tools. I understand that Dr. Fegelman's declaration is being submitted contemporaneously with this declaration. Consistent with the description in Timm, Dr. Fegelman explains that passive articulation requires pressing the exterior of the end effector of a surgical tool against another structure. Ex. 2007 at ¶ 17. Thus, performing passive articulation safely and effectively requires real-time, tactile feedback to ensure that excessive forces are not applied to the instrument or another structure. Ex. 2007 at ¶ 19. Video feedback alone would have been unacceptable because it does not indicate the forces being applied. Ex. 2007 at ¶¶ 19, 24. While real-time, tactile feedback was and is available through the surgeon's grip on the hand-held portion of a laparoscopic instrument, it would not have been available in a robotic system in the 2011 timeframe. Ex. 2007 at ¶ 23. 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. Indeed,

robotic systems were not even capable at this time of providing haptic feedback concerning gripping force. *See, e.g.*:

> Due to the lack of haptic feedback, visual cues are necessary to estimate grip forces and tissue tensions during surgery.

Ex. 2009 at 523, 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).

> The current robotic platforms do not employ the use of haptic feedback.

Ex. 2009 at 526.

> 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.

Ex. 2009 at 527.

75. And, as Dr. Fegelman explains, a key perceived benefit of robotic tools in the 2011 timeframe was the surgeon's ability to have complete control over the tool. To use a passive articulation mechanism in a robotic tool, the surgeon would relinquish this complete control. As a result, this would negate a key perceived benefit of robotics. Ex. 2007 at ¶ 25.

76. Thus, 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. Indeed, I was personally aware of these facts in 2011. Further, Dr. Fegelman's declaration underscores my opinion that a POSITA would not have proceeded with combining Anderson and Timm.

3. A POSITA Would Not Have Had A Reasonable Expectation Of Success In Combining Anderson's Tool Base With A Handheld Endocutter As Disclosed In Timm (Ground 2, Claim 24)

77. Petitioner's analysis of claim 24 proposes the following combination of elements: (1) the end effector and shaft from Timm; (2) the tool base from Anderson (which was designed to drive a harmonic tool); and (3) re-designing the tool base from Anderson to drive Timm's components. *See, e.g.*:

> A POSITA would have been motivated to use Timm's end effector with Anderson for several reasons.

Petition at 31.

> Multiple reasons would have prompted a POSITA to modify Anderson to include pivotally coupled distal and proximal spine portions (as suggested by Timm).

Petition at 38.

> A POSITA would have understood that the combination of Anderson and Timm would include Timm's surgical stapler end effector and shaft (as described above), and would have included part or all of any of the specific gear-driven actuation assemblies described by Timm to drive the motions of Timm's surgical tool. IS1004, ¶99. This is

> especially true given that Anderson contemplates "other actuation interface devices," such as "a gear train or other mechanical transmission means," and Timm discloses that its surgical instrument "may be supported [by] any one of a number of known arrangements," including being "removably associated with" a "robotic or computer" actuator such as that which Anderson describes. IS1010, 23:25-36; IS1011, 28:45-49; 8:3-7; see also 12:1-3 ("[U]se of the above described tool assembly 100 as part of a robotic system is also envisioned."); IS1004, ¶99.

Petition at 45.

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

Petition at 46-47.

> Furthermore, a POSITA would have understood that in the combination of Anderson and Timm, the surgical stapler

> end effector, closure tube, and actuation assemblies of Timm (as described above) would be driven by Anderson's rotary robotic interface in the tool mounting portion. IS1004, ¶104.

Petition at 50-51.

> A POSITA implementing the system resulting from the combination of Anderson with Timm would have recognized that the shafts extending from the base of Anderson's surgical instrument would be used to drive the gear assemblies of the embodiments disclosed by Timm. IS1004, ¶108. *See also* discussion of the tool mounting portion and tool drive assembly in element [23.3] above.

Petition at 54.

> In the combination, Timm's end effector, shaft, and transmission assembly are modified to replace the Timm handle with the Anderson base (robotic surgical system interface with driven elements) so that the Anderson transmission members impart rotary motion to the transmission assembly.

Petition at 54-55.

> With respect to the **first** exemplary selectively movable component of Timm, the combination would have the transmission assembly of Timm driven by one of Anderson's transmission members to drive the knife and dynamic clamping member.

Petition at 55.

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

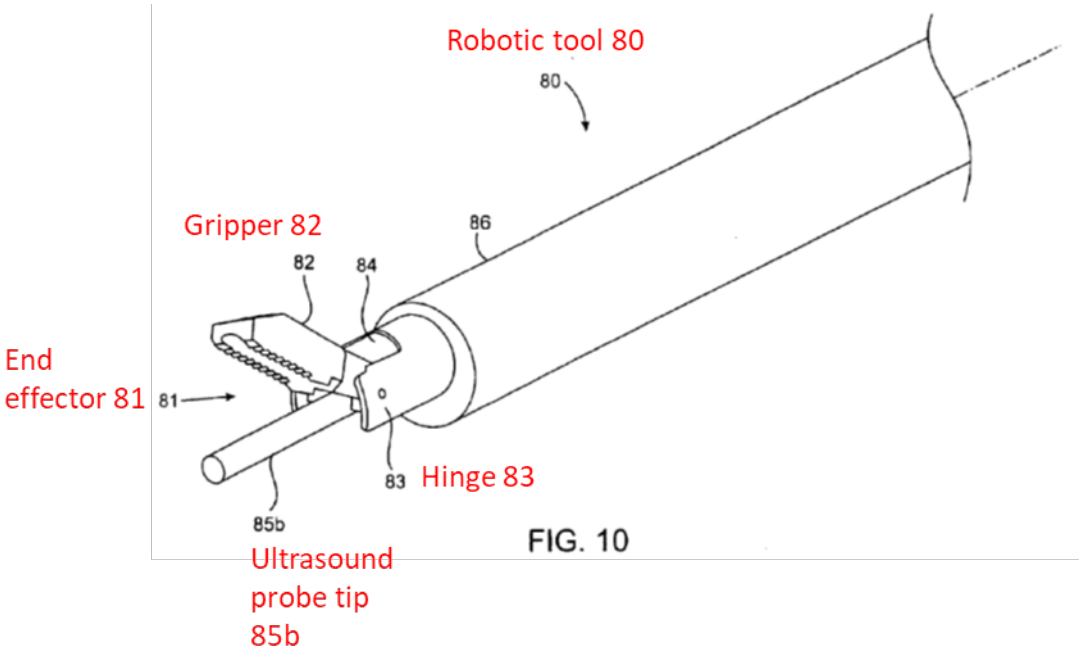
Petition at 56.

78. It is my opinion that a POSITA would not have had a reasonable expectation of success in combining Anderson's tool base with Timm's handheld endocutter, for the reasons explained below.

a) A POSITA Would Have Recognized That the Combination of Anderson with Timm's Endocutter Would Require a Re-Design to Provide Sufficient Forces to Drive the Endocutter

79. As an initial matter, a harmonic end effector is fundamentally different from an endocutter. 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 to cut and/or coagulate it. It is only physically

possible to vibrate the probe tip at frequencies that are sufficiently high to cut/coagulate tissue if the vibration is along the longitudinal axis of the device. A non-articulating ultrasound probe tip is illustrated in Figure 10 of Anderson, below.



Ex. 1010 at Fig. 10.

80. The gripping force required for a harmonic tool (such as the tool shown in Figure 10 above) is far less than for an endocutter. As the 969 Patent discloses, in embodiments where its drive system powers an endocutter, the gears in the closure gear assembly were sized to generate "approximately 70-120 pounds of closure forces." Ex. 1001 at 84:20-26.

81. 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 (the examples include graspers, retractors, bipolar forceps,

scissors, needle drivers, clip appliers, etc.). The forces reported in that study were at least one order of magnitude smaller than 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.

b) Handheld Endocutters That Are Manually Actuated Operate on Fundamentally Different Principles Than Robotic Tools

82. It is my opinion that a POSITA would have encountered substantial challenges in attempting to adapt Timm's endocutter for use with Anderson's robotic system. Timm's handheld endocutter and Anderson's robotic system used fundamentally different systems for transferring force to their end effectors.

83. Petitioner relies primarily on an embodiment that is actuated by a manual trigger 1004. A POSITA would have understood that such a trigger is a relatively low-speed, high-torque mechanism because the mechanism requires the surgeon to exert a relatively large amount of force (force is proportional to torque) to move the handle over a relatively short distance (i.e., moving at a low speed).

84. Figure 17 of Timm, for example, shows firing trigger 1004, which only pivots a short distance at a low speed when actuated by a surgeon to fire the device.

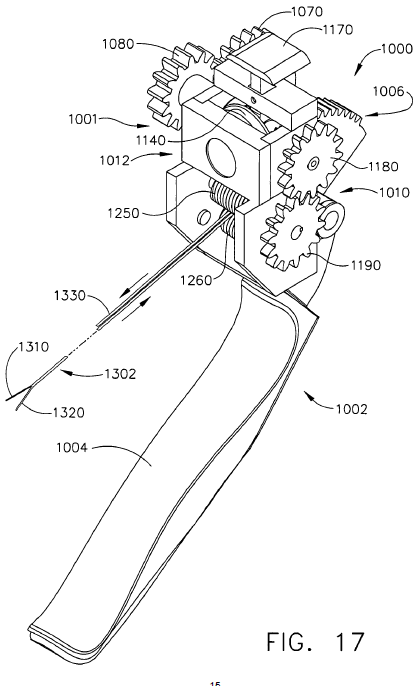


FIG. 17

Ex. 1011 at Fig. 17

85. 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. These factors include how to achieve the mechanical advantage that is necessary to produce the relatively high forces required for an endocutter. As I discuss above, these forces could be one order of magnitude or more greater than the forces required for the types of instruments that Anderson identifies for use with its system while maintaining the compact size required for minimally invasive surgery. Theoretically, a gear drive could achieve such a mechanical advantage,

but the speed reduction (or torque amplification) at a single gear stage is limited due to practical considerations—such as size and strength of the gears and gear teeth. Thus, a gear drive system for driving an endocutter would likely require multiple stages, which would complicate the design for the compact envelope required of a minimally invasive instrument. Furthermore, such a gearing system, while amplifying torque (and associated forces) to levels necessary for an endocutter, would correspondingly reduce the actuation speed. Dr. Knodel has not explained how or whether a person of ordinary skill in the art could have addressed these and other considerations associated with combining the handheld endocutter from Timm with the robotic system from Anderson.

c) The Publications of Both Patent Owner and Petitioner Confirm that a POSITA Would Not Have Had a Reasonable Expectation of Success

86. Ethicon's and Intuitive's publications similarly describe that robotic instrument drive systems that were known as of 2011 were insufficient to cut and staple tissue.

87. As an initial matter, the 969 Patent identifies Anderson's robotic system as one of many prior art robotic surgical systems that were unable to generate the forces required to effectively 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

88. Petitioner's publications also confirm that known robotic systems were unable to drive instruments that cut and staple tissue. U.S. Patent No. 8,640,788 was filed by Petitioner in 2010 and initially published on May 19, 2011 as Application Publication No. 2011/0118754. This patent describes that known drive systems for robotic instruments, including graspers and needle drivers (i.e., instruments with opposing jaws), were incapable of providing the high forces necessary for a device that clamps, staples, and cuts tissue (such as 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.

89. In 2011, Petitioner filed an application that published in 2012 as U.S. Patent Application Publication No. 2012/0209314. This publication also admitted

that adapting handheld endocutter technology to be used with robotic systems (such as the robotic system of 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 at [0008].

B. Petitioner Has Not Demonstrated That The Combination Of Anderson, Timm, And Wallace Renders Obvious Claims 25-26 Of The 969 Patent (Ground 3)

90. Claims 25 and 26 are dependent on claim 24. Claim 25 requires a gear-driven articulation system. Claim 26 further requires that the articulation is driven by first and second articulation bars.

1. Petitioner Has Not Demonstrated That Claim 24 Is Obvious, And Therefore Cannot Demonstrate That Its Dependent Claims Are Obvious

91. Petitioner's analysis in Ground 3 does not present a separate analysis of claim 24. *See* Petition at 57-64 (only addressing claims 25 and 26 in the combination of Anderson, Timm, and Wallace). For the reasons discussed in Section IX.A, it is my opinion that 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. Timm's Passive Articulation Joint is Not Compatible With Wallace's Active Articulation System

92. Petitioner's proposed combination adds Wallace's active articulation system to Anderson/Timm combination in order to disclose a gear-driven articulation system (claims 25) and articulation that is driven by first/second articulation bars (claim 26). However, as I discussed in Section IX.A.1 and Section IX.A.2, Petitioner relies on Timm's passive articulation joint in the

Anderson/Timm combination for claim 24. Dr. Knodel's analysis confirms that Petitioner does not rely on Timm's active articulation mechanisms:

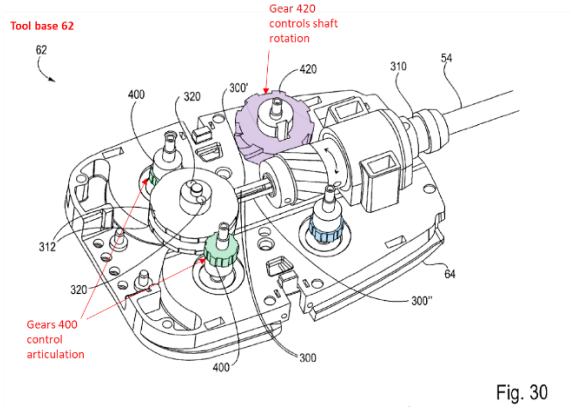
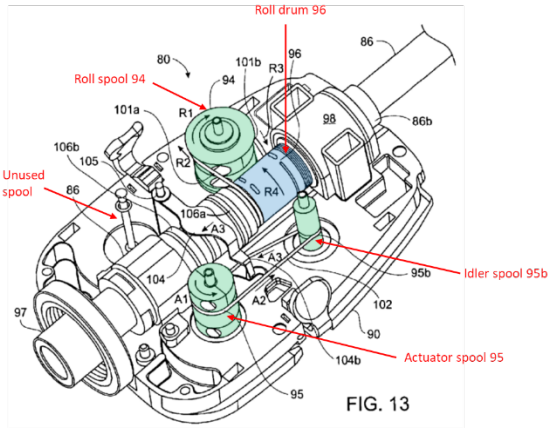
> First, one of skill in the art would have seen that while **Timm contemplates use with "a robotic system", it's disclosure of an active articulation system only details the implementation of an active articulation system relevant to handheld (and manually-operated) surgical instruments and that Wallace 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 at ¶ 118.

93. The passive articulation joint relied on for purposes of claim 24 is not compatible with the active articulation joint relied on for purposes of claims 25-26. The two types of articulation joints are mutually exclusive and are incompatible with each other. In particular, when a passive articulation joint is used, the entire purpose of the mechanism is to allow it to articulate freely when it is unlocked and external forces are applied. This purpose would be negated by adding active articulation systems to control the joint.

3. The Combination Of Timm's Endocutter With Wallace's Wrist Requires More Control Inputs Than Are Available In Wallace And Anderson

94. Petitioner's proposed combination of Anderson/Timm/Wallace requires more inputs than are available in these Anderson and Wallace robotic systems. As discussed above, Anderson and Wallace contain four available rotary mechanisms for controlling actuations. This is illustrated in the figures below:

Wallace	Anderson
 Fig. 30	 FIG. 13
Ex. 1008 at Fig. 30	**Ex. 1010 at Fig. 13**

95. As illustrated above, Wallace's wrist requires two control inputs for articulation (gears 400) and a third input for shaft roll (gear 420). Moreover, Wallace does not explain how its rotary inputs can control an end effector at the end of its articulating wrist joint. Meanwhile, Anderson discloses two control inputs for gripping (spool 95 and 95b) and one control input for shaft roll (roll

spool 94). Therefore, both of these tool bases have at most one additional rotary input that could be utilized to perform an additional actuation motion.

96. Timm's endocutter requires the additional control motions of both clamping and firing. It is my opinion that a POSITA would have been deterred from combining Timm and Anderson/Wallace as Petitioner proposes, for the reasons explained below.

97. As an initial matter, none of Petitioner's proposed references disclose controlling multiple control motions with a single rotary input. For example, Timm specifically discloses that firing and closing are controlled separately. *See, e.g.*, Ex. 1011, 14:39-15:25 (disclosing firing trigger 1004, which drives a component containing a knife ("dynamic clamping member") through the elongate channel assembly and is a separate motion from closing the anvil). Timm's disclosure is consistent with the prior art concept that it is advantageous to separate closing and firing motions. Ex. 2020 at 2:36-50.

98. Moreover, a Petitioner publication has explained that modifying robotic systems to add motor outputs (and therefore additional available control inputs) is cost prohibitive. Thus, in my opinion, this would not be a viable option that a POSITA would pursue when designing a robotic tool. The same publication further explained that there was a need to adapt surgical tools for use with robotic

systems without modifying the systems themselves. This was a need that the 969 Patent addresses.

> 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 at [0007].

99. I note that Dr. Knodel's deposition testimony indicates that the analysis of dependent claims 25-26 may not actually involve Timm's endocutter. However, this is inconsistent with the analysis in the Petition. Moreover, Timm is necessarily a part of the combination because Petitioner has relied on Timm for its analysis of claim 24 (from which claims 25-26 depend).

> 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 at 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).

C. Petitioner Has Not Demonstrated That The Combination Of Anderson And Knodel Renders Obvious Claims 19-20 Of The 969 Patent (Ground 4)

100. Claim 19 is directed to a surgical tool for use with a robotic system that includes, among other things, 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.

101. Petitioner's analysis combines the teachings of Anderson with Knodel. Knodel concerns to a non-articulating, handheld endocutter with a gear-driven knife bar (knife member 161).

102. It is my opinion that Petitioner has not demonstrated that claims 19-20 are obvious for the reasons discussed below.

1. A POSITA Would Have Been Dissuaded From the Combination of Anderson's Robotic System with Knodel's Handheld Endocutter

103. As discussed above, there is no suggestion that Knodel's handheld endocutter could or should be utilized in a robotic system. It is my opinion that a POSITA would have recognized that tactile feedback is critical when firing and clamping a handheld endocutter such as the device disclosed in Knodel.

104. For example, U.S. Patent No. 8,186,555 (the 555 Patent) (Ex. 2015), published as an application on August 2, 2007. The 555 Patent 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 2:62-3:14; *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.").

105. Petitioner's proposed combination removes the handheld instrument from the surgeon's hand and instead places it on the Anderson robotic system where it is remotely-controlled by the surgeon. As a result, the surgeon would not experience any forces through gripping the instrument. This would result in a loss of tactile feedback, which would be undesirable for surgeons who rely on such feedback to ensure proper staple formation and avoid tissue trauma.

106. 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, because surgeons relied on tactile feedback to understand when the patient might be at risk of tissue trauma and structural damage. This is described in numerous publications concerning robotic surgical systems:

> 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. 2017.002.

> **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. 2018.001.

107. Thus, given that the advantages associated with tactile feedback were known to be critical to the user of an endocutter such as that disclosed in 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 Petitioner proposes.

2. A POSITA Would Have Lacked A Reasonable Expectation Of Success In Combining Anderson With Knodel

108. Petitioner proposes to combine the following: (1) Knodel's endocutter end effector and shaft; (2) Anderson's tool base designed to drive a harmonic tool; and (3) a re-designed tool base from Anderson to drive components in Knodel. For the same reasons discussed in Section IX.A.3, a POSITA would have lacked a reasonable expectation of success in the combination of Knodel's manually-actuated, handheld endocutter and Anderson's tool base designed for a harmonic device.

D. Petitioner Has Not Demonstrated That The Combination Of Anderson And Viola Renders Obvious Claims 21-22 Of The 969 Patent (Ground 5)

109. Claim 21 is directed to a surgical tool for use with a robotic system that includes, among other things, a "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. Claim 22 is dependent on claim 21.

110. Viola relates to a handheld, non-articulating endocutter with a knife member that is driven by a rotary shaft (drive screw 78). Petitioner's analysis relies solely on Viola for the "rotary end effector drive shaft" and "knife member having a tissue-cutting portion thereon threadedly received on said rotary drive shaft"

limitations. *See* Petition at 82-84. Petitioner has not demonstrated that Viola discloses either of these limitations.

111. First, the "rotary end effector drive shaft" that Petitioner relies on is not part of the end effector. This is in contrast to the end effector drive shaft disclosed in the 969 Patent, which is illustrated below as a component of the end effector:

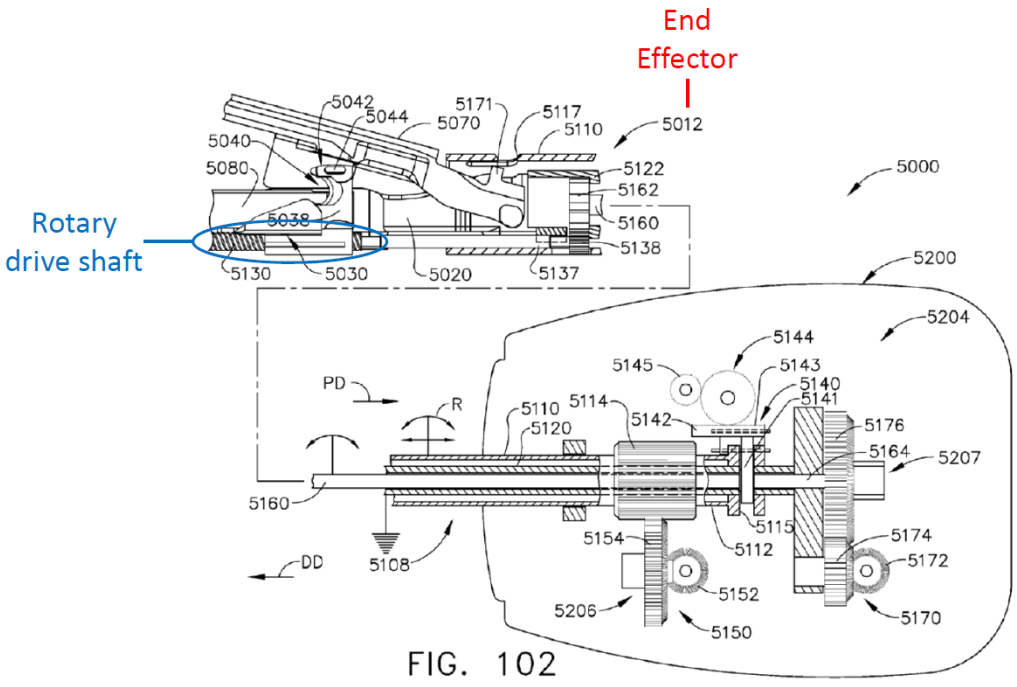


FIG. 102

Ex. 1001 at Fig. 102 (annotations in color)

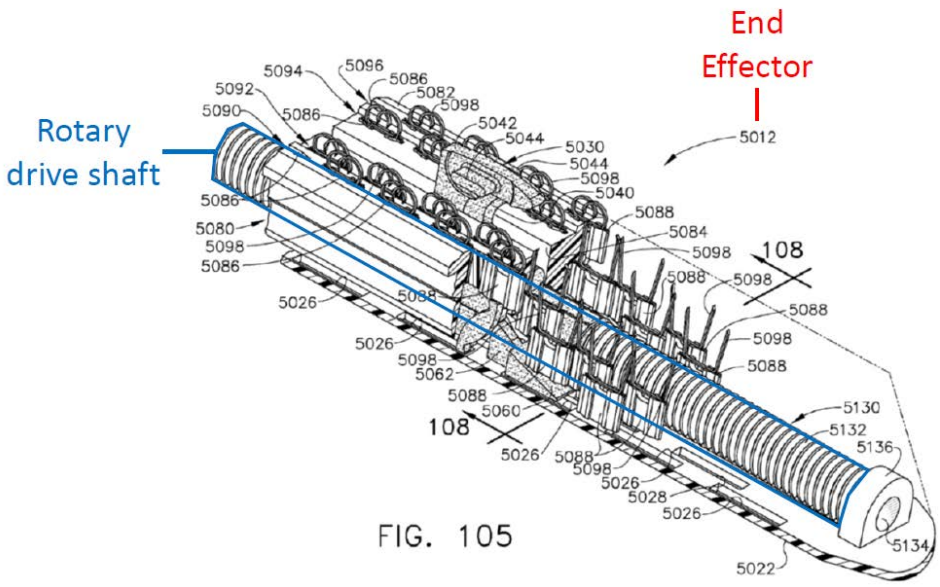


FIG. 105

Ex. 1001 at Fig. 105 (annotations in color)

112. In Viola, the drive screw that Petitioner relies on as the "rotary end effector drive shaft" is located proximal to the end effector (i.e., the portion of the device that engages tissue). This is illustrated in Figure 9 (which shows the device before clamping and firing) and Figure 10 (which shows the device after clamping and firing). In both figures, the drive screw is proximal to, and terminates before, the end effector. *See also* Ex. 1013 at Fig. 3:45-50, 7:56-8:15.

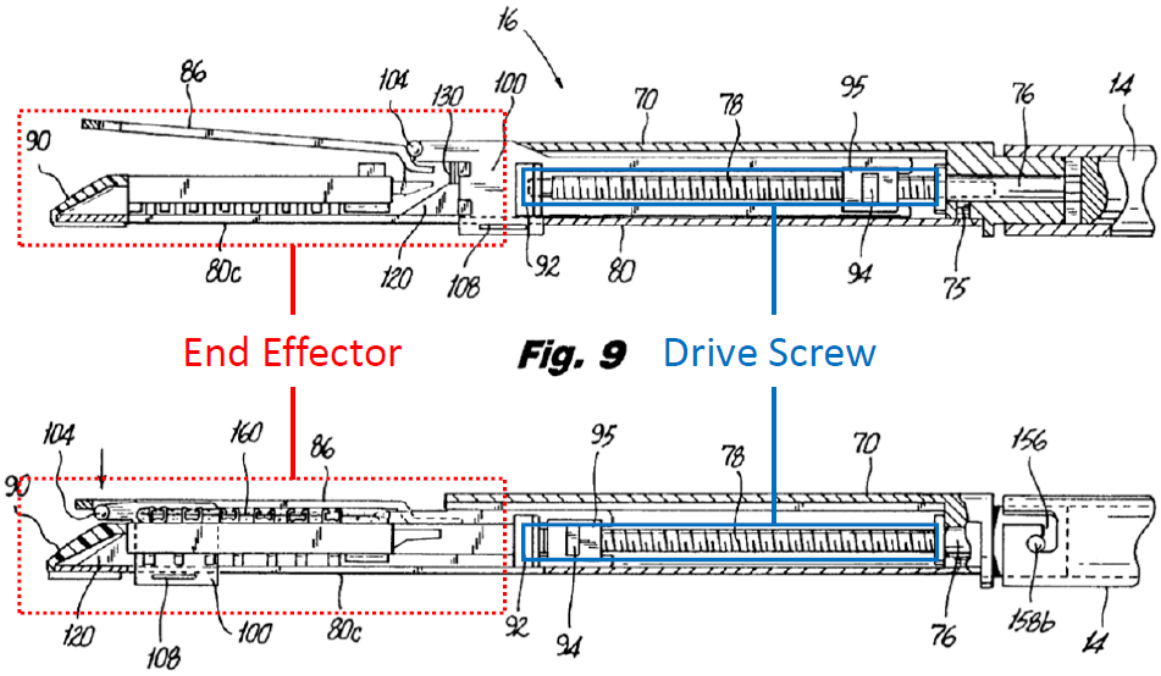


Fig. 9

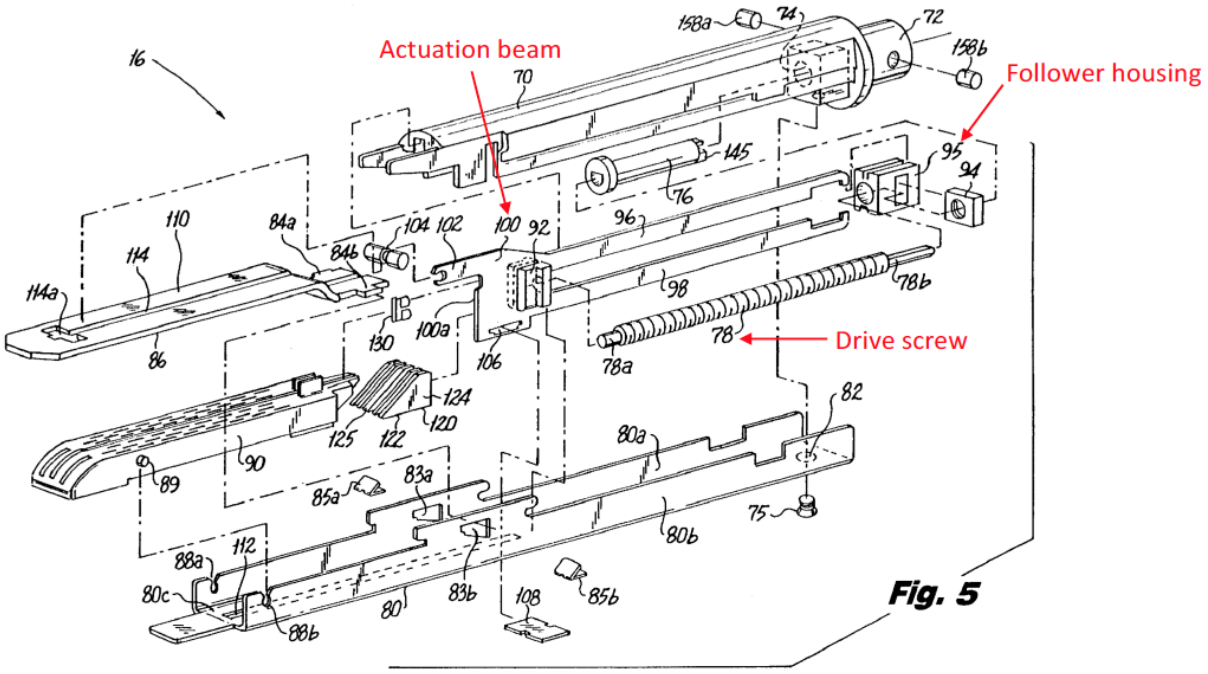
Fig. 10

113. Ex. 1013 at Figs. 9 and 10 (annotations in color)

114. Thus, it is my opinion that Viola does not disclose an end effector comprising a "rotary end effector drive shaft."

115. Second, the "knife member" that Intuitive relies on is not "threadedly received on said rotary drive shaft." In particular, Intuitive relies on a cutting blade on actuation beam 100 as disclosing this limitation. *See* Petition at 83-84 ("Viola discloses a knife member in the form of a cutting blade on an actuation beam 100 that is threadedly coupled to the drive screw 78 (e.g., the rotary end effector drive shaft) by a follower nut as shown in FIGs. 9-10."). However, the actuation beam 100 is not threadedly received on drive screw 78. Rather, Viola discloses that the

drive screw is threadedly engaged with a follower nut that is mounted in follower housing. Ex. 1013 at 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."). Figure 5 is illustrated below:



Ex. 1013 at Fig. 5 (annotated)

116. In contrast, the 969 Patent discloses a claimed embodiment of the knife member that is threadedly engaged with the rotary end effector drive shaft. This is illustrated in Figures 107 and 108.

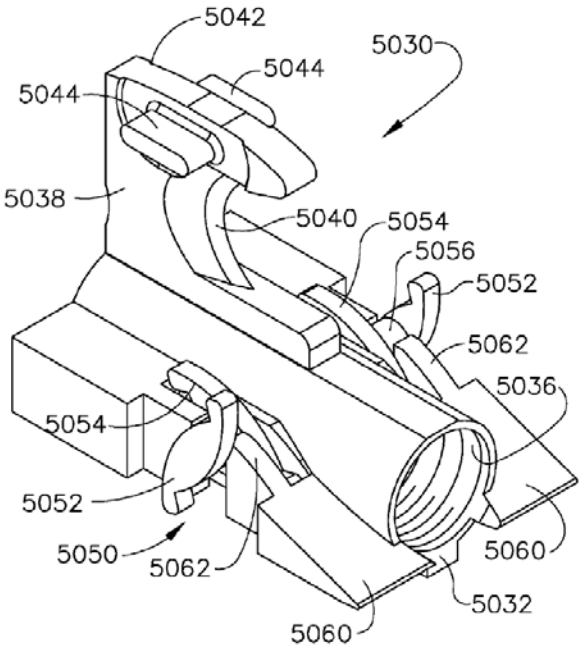


FIG. 107

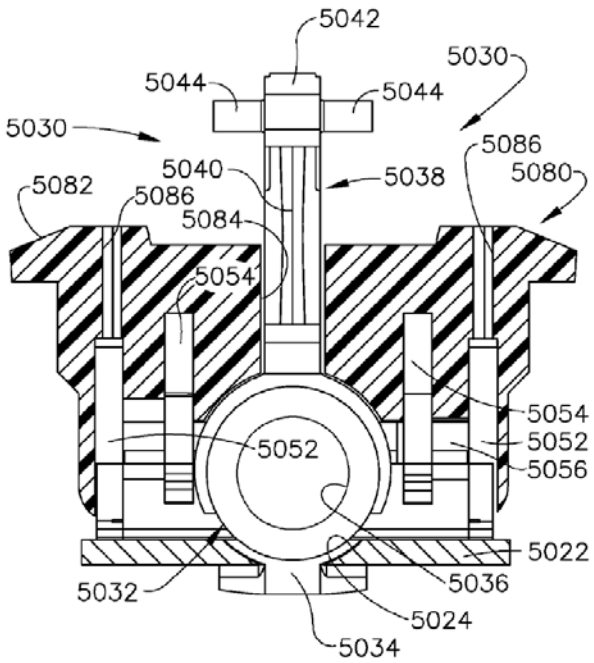


FIG. 108

Ex. 1001 at Figs. 107 and 108

117. Thus, it is my opinion that Viola does not disclose "a knife member having a tissue-cutting portion thereon threadedly received on said rotary drive shaft."

XI. JURAT

118. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

119. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on April 19, 2019

Shorya Awtar

Dr. Shorya Awtar

Appendix A

Shorya Awtar

Associate Professor of Mechanical Engineering, University of Michigan
Director, Precision Systems Design Laboratory (psdl.engin.umich.edu)
Co-Founder and Chief Technology Officer, FlexDex Surgical (www.flexdex.com)
awtar@umich.edu, shorya.awtar@flexdex.com, 518-577-5500 (C)

PROFESSIONAL INTERESTS

Shorya Awtar, Sc.D., is an Associate Professor of Mechanical Engineering at the University of Michigan, and the Chief Technology Officer of FlexDex Surgical. His research interests include machine design, flexure mechanisms, parallel kinematics, mechatronic systems, flexible system dynamics and controls, and precision engineering. Application areas include medical devices for minimally invasive surgery, motion stages for metrology and manufacturing, electromagnetic and electrostatic actuators, and micro-electromechanical systems. He earned his engineering degrees from the Indian Institute of Technology Kanpur (B.Tech., 1998), Rensselaer Polytechnic Institute (M.S., 2000), and the Massachusetts Institute of Technology (Sc.D., 2004). Prof. Awtar has started two companies, FlexDex Surgical and HiperNap, to commercialize the technologies developed in his research lab. He has published more than 60 peer-reviewed conferences and journal articles and has three-dozen inventions that are either patented or patent-pending. He has received the National Science Foundation's CAREER Award, the Society of Manufacturing Engineers' Outstanding Young Manufacturing Engineer Award, the American Society of Mechanical Engineers' Leonardo daVinci Award, the General Motors Young Investigator Award, and multiple R&D100 Awards, among several others, for his innovations in machine and mechanism design. Prof. Awtar is a Fellow of the American Society of Mechanical Engineers. He teaches graduate and undergraduate courses as well as professional tutorials in machine design, mechanism design, and mechatronic systems. He actively works with the Ann Arbor Hands-on Museum to create educational exhibits for K-12 children.

EDUCATION

Massachusetts Institute of Technology, Cambridge MA — *08/2000 – 12/2003*
Sc. D., Mechanical Engineering
Thesis: Analysis and Synthesis of Parallel Kinematic XY Flexure Mechanisms
Advisor: Prof. Alexander H. Slocum

Rensselaer Polytechnic Institute, Troy NY — *09/1998 – 07/2000*
M.S., Mechanical Engineering
Thesis: Electromagnetic Coupling in DC Motor and Tachometer and its Effect on Motion Control
Advisor: Prof. Kevin C. Craig

Indian Institute of Technology, Kanpur INDIA — *08/1994 – 05/1998*
B.Tech. in Mechanical Engineering

EXPERIENCE

Co-Founder, Chief Technology Officer, and Board Director — *2014 – present*
FlexDex Surgical, Brighton MI

Associate Professor of Mechanical Engineering — *2013 – present*
University of Michigan, Ann Arbor MI

Member, Board of Trustees — *2014 – 2016*
Ann Arbor Hands-on Museum, Ann Arbor MI

Summer Faculty Fellow, Aerospace Systems Directorate — *2011*
Wright Patterson Air-Force Research Lab, Dayton OH

Assistant Professor of Mechanical Engineering — *2007 – 2013*
University of Michigan, Ann Arbor MI

Mechanical Engineer, Energy and Propulsion Technology Organization — *2004 – 2006*
General Electric – Global Research Center, Niskayuna NY

Visiting Scientist, Manufacturing Engineering Laboratory *2003*
National Institute of Standards & Technology, Gaithersburg MD

AWARDS/HONORS

- American Society of Mechanical Engineers (ASME) Fellow, 2017
- 2017 ASME DSCD Best Conference Paper on Mechatronics award for the best original paper in the area of mechatronics presented at any of the DSCD-sponsored conferences in 2016 including the IEEE/ASME International Conference on Advanced Intelligent Mechatronics (AIM), the American Control Conference (ACC), and the ASME Dynamic Systems and Control Conference (DSCC)
- College of Engineering Rexford E. Hall Innovation Excellence Award in recognition of developing a breakthrough technology and demonstrating its transformational potential in the marketplace, engineering practice, and for societal good, 2017.
- Best Student Paper Award at the 2016 ASME Dynamics Systems and Controls Conference (DSCC)
- Best Paper Award in Micro and Nano Systems at the 7th International Conference on Micro and Nano Systems, ASME International Design Engineering Technical Conferences (IDETC) 2013, Award by the Mechanisms and Robotics Committee of the ASME Design Engineering Division
- Best Paper Award in Compliant Mechanisms at the 37th Mechanisms and Robotics Conference, ASME International Design Engineering Technical Conferences (IDETC) 2013
- R&D 100 Award for one of the 100 most innovative and significant technologies of the year, High Performance Electrostatic Comb-drive Micro-Actuators, R&D Magazine, 2013
- College of Engineering 1938E Award, 2013, in recognition of an outstanding teacher in elementary as well as advanced courses, an understanding counselor of students, a contributor to the educational growth of his College, and a teacher whose scholarly integrity pervades his service to the University and the profession of Engineering. This is the highest honor awarded by the University of Michigan to an Assistant Professor across the College of Engineering.
- Ralph R. Teetor Award for outstanding contributions to engineering education, Society for Automotive Engineers (SAE), 2012
- Best 2010 Conference Paper on Mechatronics in the American Controls Conference, the Dynamic Systems and Control Conference, the IFAC Symposium on Mechatronics, and Advanced Intelligent Mechatronics. Awarded by the ASME Dynamic Systems and Controls Division's Mechatronics Technical Committee, 2011
- Leonardo da Vinci Award for eminent achievement and important advances in the field of machine design, American Society of Mechanical Engineers (ASME), 2011.
- Freudenstein / General Motors Young Investigator Award for significant original contribution to the theory of mechanisms and the potential to enhance the public good, ASME, 2011
- Selected by National Academy of Engineering to attend the US Frontiers of Engineering Symposium, 2011
- ASEE / Air Force Summer Faculty Fellowship, 2011
- Mechanical Engineering Department Achievement Award for outstanding contributions to research, teaching, and service, University of Michigan, 2011
- Outstanding Young Manufacturing Engineer Award, Society of Manufacturing Engineers, 2011
- NSF CAREER Award, National Science Foundation, 2009
- FlexDex Minimally Invasive Surgical Tool technology selected as one of the top six inventions out of more than 300 invention disclosures in year 2008 and show-cased at the *Celebrate Invention* Event, Technology Transfer Office, University of Michigan, 2009
- R&D 100 Award for one of the 100 most innovative and significant technologies of the year, XY HiPER-NaP: High Precision Extended Range Nano Positioner, R&D Magazine, 2008. Video Demonstration
- Inventor's Medal, General Electric, 2005
- Rosenblith Fellowship for graduate studies, Massachusetts Institute of Technology, 2000-01
- Selected for Stanford Graduate Fellowship, 2000

- Michael A. Sadowsky Award for best M.S. thesis in Mechanical Engineering, Rensselaer Polytechnic Institute (RPI), 2000
- Founder's Award for academic excellence and leadership, Rensselaer Polytechnic Institute (RPI), 1999
- Mark Darlow Memorial Award for outstanding achievement in Mechatronics, RPI, 1999
- Institute Awards for academic excellence, Indian Institute of Technology - Kanpur, 1996, 1997
- National Talent Search Scholarship, Government of India, 1992-1998

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CONFERENCE ARTICLES

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[32] Awtar, S. and Slocum, A.H., 2005, "Design of Flexure Stages based on a Symmetric Diaphragm Flexure", *Proc. ASPE Annual Meeting*, Norfolk, VA, Paper No. 1803

[33] Sutin J., Awtar S. et al, 2005, "Improving the Optical Performance of the Optical Microscope via Modern Opto and Optomechanical Design", *Focus on Microscopy 2005 Conference*, Jena, Germany

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PATENTS

Granted (US). Several of the following US patents have foreign counterparts.

[1] End-Effector Jaw Closure Transmission Systems for Remote Access Tools, US 9,869,339, Jan 2018

[2] Skin Tissue Biopsy Device, US 9,861,345, Jan 2018

[3] Handle Mechanism Providing Unlimited Roll, US 9,814,451, Nov 2017

[4] Electromagnetic Actuators and Component Designs Therefor, US 9,814,451, Oct 2017

[5] Minimal Access Tool, US 9,675,370, Jun 2017

[6] Attachment Apparatus for Remote Access Tools, US 9,629,689, Apr 2017

[7] Single Axis Flexure Bearing Configurations, Dec 2015

[8] Minimal Access Tool, US 8,668,702, Mar 2014

[9] Active Retractable Seal for Turbo-machinery and Related Method, US 8,540,479, Sep 2013

[10] Compliant Plate Seals for Turbomachinery, US 8,382,119, Feb 2013

[11] Fluidic Actuator for Application inside Turbomachinery, US 8,327,752, Dec 2012

[12] Compliant Plate Seal with an Annular Ring for Turbomachinery and Methods of Assembling the Same, US 8,162,324, Apr 2012

[13] Spring System Designs for Active and Passive Retractable Seals, US 8,113,771, Feb 2012

[14] Multiple Degrees of Freedom Motion System, US 8,072,120, Dec 2011

[15] Methods and Apparatus to Facilitate Sealing in Rotary Machines, US 7,976,026, Jul 2011

[16] Retractable Compliant Plate Seals, US 7,909,335, Mar 2011

[17] Shaft Seal using Shingle Members, US 7,703,774, Apr 2010

[18] Compliant Plate Seals for Turbomachinery, US 7,651,101, Jan 2010

[19] Actuation Pressure Control for Adjustable Seals in Turbomachinery, US 7,549,834, Jun 2009

[20] Compliant Plate Seals for Turbomachinery, US 7,419,164, Sep 2008

[21] Compliant Seal and System and Method Thereof, US 7,229,246, Jun 2007

[22] Material Transportation System, US 6,886,651, May 2005

[23] Apparatus Having Motion with Pre-Determined Degrees of Freedom, US 6,688,183, Feb 2004

Pending Applications (US)

[24] Medical Devices having Smoothly Articulating Multi-Cluster Joints, US 15/286,489, 2016

[25] Parallel Kinematic Mechanisms with Decoupled Rotational Motions, US 20160256232, 2016

[26] Tension Management Apparatus for Cable-driven Transmission, PCT/US2016/025926, 2016

Abandoned Applications (US)

[27] Endo-illuminator and Apparatus and Systems for use Therewith, US Application 61/829,758

[28] Active Retractable Seals for Bucket Tip and Interstage Locations in Steam Turbines, US 20100078893

[29] Axially Oriented Shingle Face Seal for Turbine Rotor and Related Method, US Application US 12/155,728

[30] Compliant Plate Seal Assembly Apparatus and Assembly Method Thereof, US Application 20080169614

[31] Shaft Seal formed of Tapered Compliant Plate Members, US Application 20080107525

[32] Pressurized Gas Supply and Control System for Actuation of Active Seals in Turbomachinery, US 20070295402

[33] Mechanisms having Motion with Constrained Degrees of Freedom, US Application 20040037626

[34] Characterization of Compliant Structure Force-Displacement Behavior, US Application 20030009898

More than a dozen pending Provisional Patent Applications and Invention Disclosures

START-UP COMPANIES

FlexDex Surgical, C-Corp Founded: 2014

FlexDex Surgical (www.flexdex.com), a University of Michigan start-up based on research and innovations in the Precision Systems Design Lab, is developing and commercializing a suite of articulating laparoscopic instruments that enable minimally invasive surgery at an affordable cost. Via fundamental innovations in mechanical design, these instruments provide enhanced dexterity, intuitive control, and ergonomics – functionality so far seen only in multi-million dollar robotic surgical systems. FlexDex's mission is to democratize minimally invasive surgery around the world.

HIPERNAP, Michigan LLC Founded: 2011

HIPERNAP was founded to develop and commercialize XY nanopositioning systems (based on research and innovations in the Precision Systems Design Lab) that provide 100 times greater motion range per axis, compared to existing competing products. While existing XY nanopositioning systems typically offer a motion range of 100μm x 100μm, HIPERNAP's products (winner of an RD100 Award in 2008) are targeted to provide a motion range of 10mm x 10mm, which represents 10,000 times greater area-coverage in scanning. Additionally, HIPERNAP's technology focusses on scanning speeds to maintain high process throughput and compact desk-top architectures to ensure affordability. These nanopositioning systems are currently being developed in collaboration with a leading semiconductor equipment manufacturer for next-generation wafer inspection and defect review machines. HIPERNAP has been funded by the NSF Small Business Innovation Research (SBIR) program. HIPERNAP Technology Demo.

UNIVERSITY COURSES TAUGHT

ME350, Design and Manufacturing II

This junior-level class covers the design, analysis, and selection of mechanical and electromechanical components in the context of system-level machine design. Specific topics include mechanisms, bearings, transmissions, joining methods, structures, springs, sensors, actuators, and manufacturing, and are taught via lectures, recitations, and hands-on labs. These topics are further reinforced via hands-on lab exercises and class projects that emphasize system-level design. In the first project, student teams design, build, and test golf-club swinging machines that compete at the local driving range. A second project covers the design, assembly, and testing of an inverted pendulum system, and emphasizes the principles of mechatronic design and systems integration.

Class Project Video: http://www.youtube.com/watch?v=YCuh54ohj3k

ME450, Design and Manufacturing III

This senior-level class provides students a complete capstone design and manufacturing experience via an open-ended real world engineering project. Projects are solicited from the industry as well as research labs, and involve the design, fabrication, and testing of a new device, machine, or system. Student teams carry out a systematic design process, all the way from identifying customer needs to delivering a working prototype. Particular emphasis is placed on model-based design, project planning and management, and professional engineering practices. Several highly successful projects have come out of this class including the above described start-up FlexDex Surgical and a new interactive, mechatronic exhibit for the Ann Arbor Hand-on Museum (video below).

Project Video: http://www.youtube.com/watch?v=iM5ya5v-Pz8

ME552, Mechatronic Systems Design

This graduate level class covers the synergistic integration of mechanical disciplines, controls, electronics and computers in the design of high-performance systems. Case studies, hands-on lab exercises, and design projects

provide a practical exposure to machine design, multi-domain dynamic systems modeling, controls theory, sensors and actuators, electrical drives and circuits, simulation tools, DAQ hardware/software, and real-time controls implementation using microprocessors. The class project involves the design, fabrication, and demonstration of full-size, fully functional, two-wheeled electric transporters, like the Segway, from scratch in less than a semester (video below).

Project Video: http://www.youtube.com/watch?v=5VdKVvBeQIY

SERVICE / PROFESSIONAL ACTIVITIES

- Collaboration with the Ann Arbor Hands-on Science Museum to develop new educational exhibits. Served on the Board of Directors from 2014 to 2016.
- Design & Manufacturing Division Coordinator, Mechanical Engineering, University of Michigan, 2012 – 2014, 2016 – present
- University of Michigan Solar Car Team, Faculty Advisor, 2014 – 2015
- Associate Editor, ASME Journal of Mechanical Design, 2014 – 2015
- Course Leader: ME350 (Design & Manufacturing) and ME552 (Mechatronic Systems Design), 2007 – 2010
- Guest Editor for the special issue on the "Future Directions in Compliant Mechanisms" in *Mechanical Sciences (MS): An Open Access Journal for Theoretical and Applied Mechanics*, 2011
- Professional Tutorials on Flexure Mechanism Design, American Society for Precision Engineering Annual Meetings and ASME International Design Engineering Technical Conferences, 2007-present
- Reviewer for Review of Scientific Instruments, Mechanics Based Design of Structures and Machine, ASME Journal of Mechanisms and Robotics, ASME Journal of Medical Devices, ASME Journal of Mechanical Design, ASME Journal of Dynamic Systems, Measurement, and Control, IEEE/ASME Journal of MEMS, IEEE/ASME Transactions on Mechatronics, IEEE Transactions on Robotics, Mechatronics Journal, Precision Engineering Journal, ASME International Design Engineering Technical Conferences.
- Symposium Organizer, Compliant Mechanisms, ASME IDETC 2006, 2010, 2012, 2013**;** Session Chair, Compliant Mechanisms, IDETC 2005, 2009 – 2012; Session Chair, Novel Actuators, ASME DSCC 2011
- Member of Mechanisms and Robotics Technical Committee and Micro and Nano Systems Technical Committee, ASME Design Engineering Division, 2012 – 2016
- Member of Mechatronics Technical Committee, ASME Dynamic Systems and Controls Division, 2012 – 2014
- Faculty Advisor to the student team that won the second place in ASME Student Mechanism Design Competition (Graduate Level), ASME IDETC, 35th Mechanisms and Robotics Conference, 2011
- Faculty Advisor to the student team that won the first place in ASME Student Mechanism Design Competition (Graduate Level), ASME IDETC, 34th Mechanisms and Robotics Conference, 2010
- Faculty Advisor to student teams that won the first place in the *Spotlight* event (engineering/business project competition) organized by the Tauber Institute for Global Operations, University of Michigan, 2009 and 2010
- Expert Witness on litigations pertaining to Intellectual Property, US Customs, and Product Liability