

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.
Petitioner

v.

ETHICON LLC
Patent Owner

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

**PETITIONER'S REPLY TO
PATENT OWNER'S
RESPONSE**

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EXHIBITS

IS1001	U.S. Pat. No. 8,479,969 to Shelton, IV (“the ’969 Patent”)
IS1002	Prosecution History of the ’969 Patent (Serial No. 13/369,609)
IS1003	Reserved
IS1004	Declaration of Dr. Bryan Knodel (Anderson as Primary Reference)
IS1005	Reserved
IS1006	Reserved
IS1007	U.S. Patent No. 6,817,974 to Cooper et al. (“Cooper”)
IS1008	U.S. Patent No. 6,699,235 to Wallace et al. (“Wallace”)
IS1009	U.S. Patent No. 6,331,181 to Tierney et al. (“Tierney”)
IS1010	U.S. Patent No. 6,783,524 to Anderson et al. (“Anderson”)
IS1011	U.S. Patent No. 7,510,107 to Timm et al. (“Timm”)
IS1012	U.S. Patent No. 5,465,895 to Knodel et al. (“Knodel”)
IS1013	U.S. Patent No. 5,954,259 to Viola et al. (“Viola”)
IS1014	U.S. Patent App. No. 2008/0167672 to Giordano et al. (“Giordano”)
IS1015	Reserved
IS1016	Reserved

IS1017	Supplemental Declaration of Dr. Bryan Knodel (“Knodel Supp. Decl.”)
IS1018	Reserved
IS1019	June 17, 2019 Deposition of Shorya Awtar for IPR2018-01247 (“Awtar Dep. I”)
IS1020	U.S. Pat. No. 9,820,768 to Gee et al. (“Gee”)
IS1021	Reserved
IS1022	Reserved
IS1023	June 6, 2019 Deposition of Frank Fronczak for IPR2018-00936 (“Fronczak Dep.”)
IS1024	Reserved
IS1025	Reserved
IS1026	District Court Complaint in <i>Ethicon LLC et al. v. Intuitive Surgical, Inc. et al.</i> , 1:17-cv-00871-LPS filed June 30, 2017
IS1027	U.S. Pat. No. 7,524,320 to Tierney et al. (“Tierney 320”)

I. Introduction

The challenged claims in the '969 Patent combine prior art surgical instruments with a prior art surgical robot in a predictable manner. As established in the Petition, a POSITA would readily adapt Timm (a surgical stapler) for use with Anderson (a surgical robot). Anderson provides rotary control motions through the robot arm interface and Timm's instrument is powered by rotary input motions. A POSITA would have readily been able to put Anderson and Timm together.

Patent Owner's Response fails to point out anything unique or novel about the claimed "invention." Instead, Patent Owner makes a number of unsubstantiated arguments about what a POSITA would or would not have done, and a number of incorrect arguments about the prior art disclosures and the scope of the claims. However, as shown in this Reply, Patent Owner's own experts contradict and undermine Patent Owner's arguments at virtually every turn.

II. Ground 2: The Combination of Anderson and Timm Discloses Claim 24

A. Claim 24 Now Requires "A Tool Mounting Portion Operably Coupled to a Proximal End of Said Proximal Spine Portion"

Claim 24 of the '969 Patent issued with a defect, and the Patent Owner requested a Certificate of Correction to address that defect. Specifically, as issued, claim 24 required "a tool mounting portion operably coupled to a **distal** end of said

proximal spine portion.” (Emphasis added throughout) On January 23, 2018, the United States Patent and Trademark Office issued a Certificate of Correction stating: “In the Claims – In Column 95, Line 59, in Claim 24, delete “distal”; and insert --proximal--.” IS1002 at 686.

Accordingly, in view of the Certificate of Correction, claim 24 of the ’969 Patent now reads: “a tool mounting portion operably coupled to a **proximal** end of said proximal spine portion.” *See* 37 CFR 1.323; 35 U.S.C. § 255 (“Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.”) The petition for this proceeding was filed and these proceedings were instituted **after** the Certificate of Correction issued. *See* Paper 2 (Petition), filed on June 14, 2018 and Paper 7 (Institution Decision), entered on January 15, 2019. Thus, the trial having arisen thereafter, the Certificate of Correction applies to these proceedings.

Because the Certificate of Correction applies, the Petition largely addresses claim 24 in view of the Certificate of Correction. However, the Petition also provides a backup argument under the original claim language (although the backup argument should be moot in view of the Certificate of Correction). Accordingly, the Petition’s primary argument establishes that claim 24 is invalid

because the prior art teaches “a tool mounting portion operably coupled to a **proximal** end of said proximal spine portion.” Petition, 51.

In fact, nowhere in the Response, does Patent Owner dispute that the prior art discloses this limitation. Instead, Patent Owner’s lead argument in its Response is that the Certificate of Correction should be ignored. In support, Patent Owner points to Exhibit 2013, which is an interlocutory order from a District Court holding the Certificate of Correction invalid. POR, 25-26.

However, Patent Owner does not—and cannot—establish that the interlocutory order by the District Court applies to this proceeding. In fact, beyond citing to the interlocutory order, Patent Owner makes no attempt to establish its applicability here—and with good reason.

First, the Certificate of Correction issued and remains in the file history and has not been superseded by any subsequent paper in the file. IS1002, 686.

Second, Patent Owner fails to present a legal argument for applying issue preclusion. Issue preclusion does not apply here because there is no final judgment from the District Court, which is a prerequisite for issue preclusion. Nor will there be a final judgment during this proceeding because the District Court action has been stayed until after resolution of this and other *inter partes* proceedings.

“When an issue of fact or law is actually litigated and **determined by a valid and final judgment**, and the determination is essential to the judgment, the

determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.” *Worlds Inc. v. Bungie, Inc.*, 903 F.3d 1237, 1247 (Fed. Cir. 2018) (quoting Restatement (Second) of Judgments § 27 (1982)).

Accordingly, absent a final judgment, issue preclusion does not apply, and the District Court’s interlocutory order is not relevant to these proceedings.

Third, the interlocutory order in question will be subject to appeal if and when the District Court renders judgment, and Patent Owner has specifically reserved the right to appeal the interlocutory order. Exhibit 2013 at fn1.

Fourth, as part of its Response, Patent Owner did not file a motion to cancel the Certificate of Correction or seek any similar remedy (and nor did Petitioner). Therefore, the question of the propriety of the Certificate of Correction is not before the Board. *See* 37 C.F.R. § 1.323.

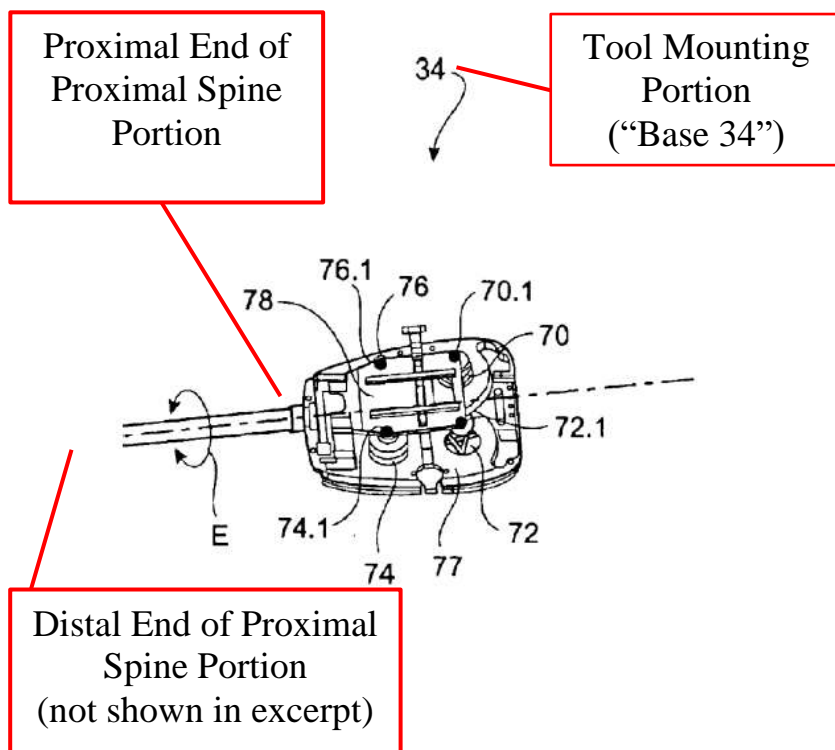
And finally, fifth, the petition was filed and these proceedings were instituted before the Delaware District Court issued the interlocutory order— institution was on January 15, 2019 and the interlocutory order issued on February 11, 2019. It is now too late to alter the claims, which would place these proceedings on shifting sands. This proceeding should proceed on the basis of the claims as they existed at the time of institution (if not at the time of the petition). *C.f. Emerson Electric Co. v. Sipco*, No. CBM2016-00095, 2018 WL 446681, at *3 (P.T.A.B. Jan. 16, 2018) (covered business method patent review is conducted

based on claims as they exist at time of decision to institute, regardless of post-institution disclaimer).

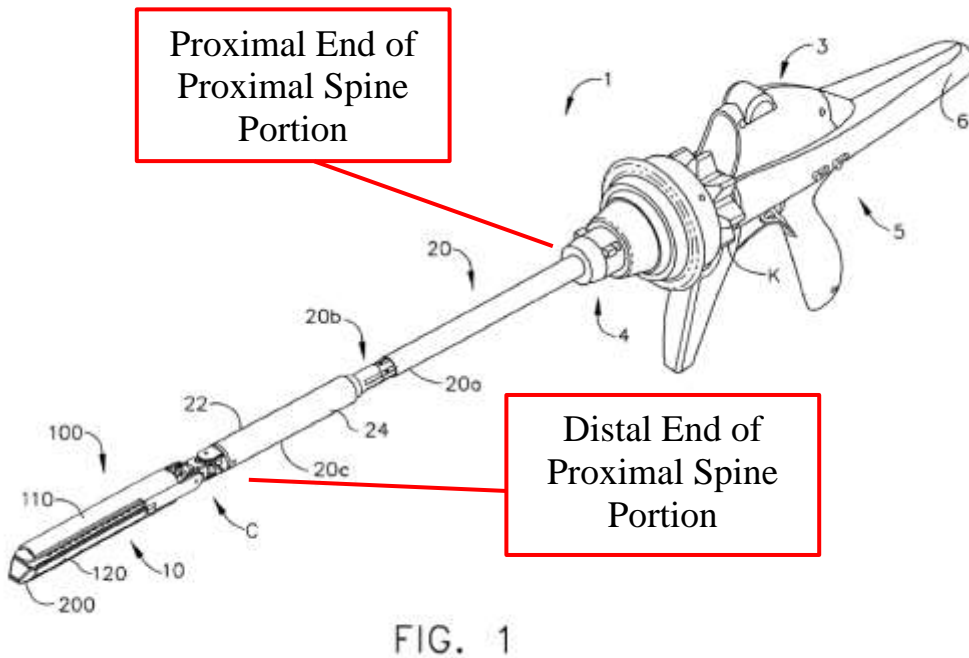
Accordingly, Section V.A.1 of Patent Owner's Response is moot because the Certificate of Correction applies to these proceedings.

B. As a Backup Argument, Petitioner Established That the Tool Mounting Portion in the Prior Art was Also Coupled to the Distal End of the Proximal Spine Portion

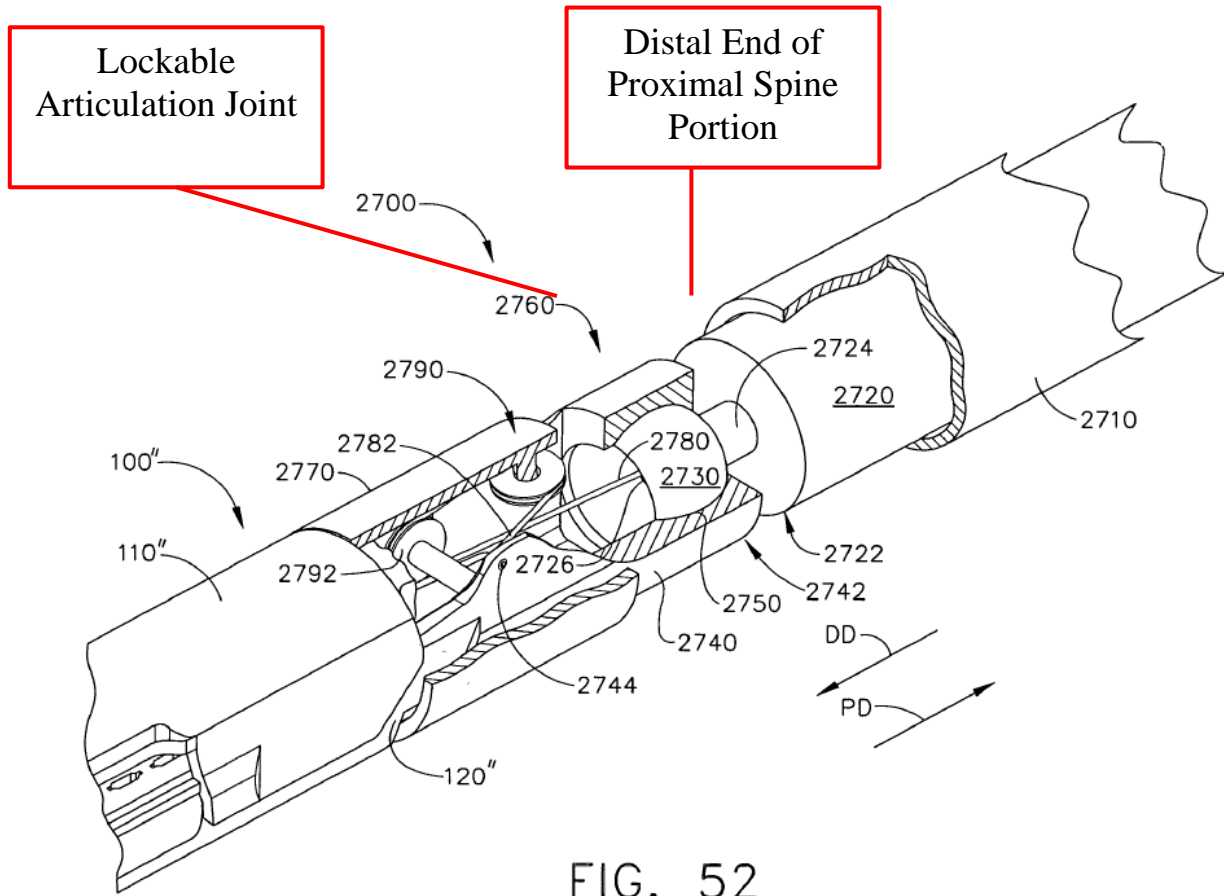
As Dr. Knodel explained in his Declaration, "Specifically, in the combination, Anderson's tool mounting portion would be operably coupled to the distal end of the proximal spine portion of Timm's shaft via the proximal spine portion itself." Knodel Dec., ¶104. Dr. Knodel explained that the "tool mounting portion" of Anderson was "base 34." Knodel Dec., ¶63. Dr. Knodel included the following figure, which we annotate to show the relevant parts:



In the Anderson/Timm combination, the shaft and end effector of Anderson is replaced with the shaft and end effector of Timm. Dr. Knodel refers to FIG. 1 of Timm, which shows “a surgical stapler with an articulation joint.”



Referring to FIG. 52, Dr. Knodel explains that the proximal spine portion includes a “proximal spine segment 2720” coupled to an “articulation ball joint 2760” at the distal end. The “articulation ball joint 2760” is coupled to “a distal spine segment 2740.” Knodel Dec., at ¶36.



Dr. Knodel further identified a “lockable articulation joint” at the distal end of the proximal spine portion, citing to Timm, 31:62-32:31, which explains that “[v]arious trigger and locking arrangements (not shown) in the handle may be employed to selectively axially move the actuation member in the proximal PD and distal DD directions and lock the actuation member 3050 in position to retain the ball-shaped member 3016 in an expanded/locked condition.” Knodel Dec., ¶89. Thus, as Dr. Knodel testified, the tool mounting portion is operably coupled to the distal end of the proximal spine portion via the structure of the proximal

spine portion itself. *See* Knodel Dec., ¶¶36, 89, and 104; Awtar Dep., 45:4-47:7 (discussing meaning of operable coupling). Petitioner has met its burden.

Patent Owner further attempts to exclude passive articulation joints from the claims, arguing that “it is clear ... that operable coupling between the tool mounting portion and the spine portion refers to an active articulation joint that is operated via the tool mounting portion.” POR, 27-28. However, Patent Owner is mistaken. The cited passages do not even mention “operable coupling” or “operably coupled.” Moreover, claim 24 merely requires an “articulation joint” and does not require “active articulation.” An “articulation joint” may be either active or passive. Knodel Dec., ¶89 (reading the articulation limitation of claim 24 on the “lockable articulation joint” of Timm). Notably, Patent Owner did not seek a construction of “articulation joint” in claim 24 as being limited to an “active articulation joint.”

Moreover, the cable that locks the joint from the handle undeniably operably couples the handle to the articulation joint (Awtar Dep. 49:14-50:3), and in the combination, the handle becomes the tool mounting portion. Even setting aside the locking feature, the articulation joint is still operably coupled to the tool mounting portion. As Patent Owner admits, the passive articulation joint of the Anderson/Timm combination is operated from the handle/tool mounting portion when the joint is articulated because a surgeon would articulate the instrument by

“pressing the end effector against another structure in order to articulate it.” POR,

2. As Patent Owner’s own expert admits: “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.**” Awtar Dec., ¶41.

This action requires the claimed operable coupling.

Patent Owner’s expert further admits that Timm discloses both passive articulation and active articulation, and thus there is no question that the ’969 Patent was not the first patent to disclose active articulation or operable coupling to an articulation joint. Awtar Dec., ¶¶42 and 43 (“In the active articulation joint embodiments [of Timm], 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.”); *accord* POR at 16 (“The description in Timm plainly divides the articulation joints into two categories: passive joints and active joints.”); POR, 18 (“Timm also discloses ‘active articulation’ joints in the embodiments of Figures 73-89. Ex. 1011, 37:55-58”); *accord* Knodel Dec., ¶118 (referring to Timm’s active manually operated articulation system).

Accordingly, the Anderson/Timm combination discloses a tool mounting portion coupled to the distal end of a proximal spine portion because (i) the Anderson/Timm articulation joint is disposed at the distal end of the proximal

spine portion, and (ii) the Anderson/Timm tool mounting portion is used to articulate (by pressing distal end of the instrument against another instrument or nearby anatomy) and is used to lock the joint.

C. As Dr. Knodel Testified, a POSITA Would Have Been Motivated To Combine Anderson With Timm (Including Timm's Lockable Articulation Joint)

In paragraphs 83-114 of his Declaration, Dr. Knodel explains why claim 24 would have been obvious to a POSITA in light of the Anderson/Timm combination, and provides the motivation for the combination.

In its Response, Patent Owner raises a new issue related to “tactile feedback.” Patent Owner argues that “performing passive articulation safely and [sic] requires real-time, tactile feedback to ensure that excessive forces are not applied to the instrument or another structure, such as an internal body part” and that “video feedback alone would have been unacceptable.” POR, 29. Patent Owner further asserts that “tactile feedback” was “not available” in the robotic prior art. *Id.* Patent Owner’s argument is wrong for two independent reasons: First, there is no credible evidence that “tactile feedback” is required, and second, the Anderson/Timm combination has tactile feedback. We will address the second point first.

D. Even if Tactile Feedback Were a Requirement, Anderson Discloses It

In a robotic system, there are various forms of possible feedback, including, as Patent Owner states, “video feedback” and “tactile feedback.” POR, 29. As the ’969 Patent itself confirms, “tactile feedback” includes feedback to the “control members.” ’969 Patent, 67:35-36; see also ’969 Patent, 86:30-32) (“master controllers . . . grasped by the surgeon and manipulated in space while the surgeon views the procedure via a stereo display.”) As described in the ’969 Patent itself, video feedback is provided by the stereo display and tactile feedback is provided to the controllers grasped by the surgeon.

With regard to the prior art, Patent Owner does not allege that Anderson fails to disclose tactile feedback, but merely alleges that Petitioner’s actual commercial robots allegedly lacked tactile feedback. POR, 29. Of course, in this proceeding, where prior art must consist of patents and printed publications, and cannot include commercial embodiments, it is curious and telling that Patent Owner discusses commercial embodiments not of record in these proceedings, and ignores the teachings of the actual prior art references.

In fact, Anderson, the primary robotic reference for Ground 2 does in fact disclose tactile feedback (which it must be remembered, is not a limitation of the claims). Anderson teaches that “[t]he control system typically includes at least one processor which relays [information] . . . from the arm and instrument assemblies

to the associated master control devices in the case of, *e.g.*, **force feedback**, or the like.” Anderson, 2:63-3:1. The force feedback is created by a “motor pack” that “may include . . . **feedback sensors**, and the like, and may transmit feedback or sensor signals to the robotic surgical system via the interface.” Anderson, 6:33-37. The sensors in the motor pack can provide tactile feedback because as force is applied to the instrument, the motors sense the resistance, and can provide that force feedback to the master controllers. Knodel Supp. Dec., ¶15. Accordingly, Anderson discloses tactile feedback that would transmit forces from the instrument to the surgeon via the associated master control device. Knodel Supp. Dec., ¶¶13-15. Accordingly, even if a POSITA would want to see a disclosure of tactile feedback in the robotic references, Anderson discloses it.

E. Tactile Feedback Is Not a Requirement for Use of Passive Articulation with a Robotic System

Setting aside the fact that Anderson does, in fact, disclose tactile feedback, a POSITA would have been motivated to make the Anderson/Timm combination regardless because a POSITA would not require “tactile feedback” with a passive articulation joint. As Timm states, and as Patent Owner admits, passive articulation of a joint can be performed in at least two ways: (1) by pressing the end effector against an organ in the body and (2) by having the clinician apply “an articulation force to the tool assembly **with another surgical instrument**.” POR, 17 (quoting Timm, 32:32-46). In the latter approach, the risk of damaging an

organ is not present. Accordingly, a POSITA would have been motivated to use Timm's passive articulation with a robot that lacked tactile feedback with the understanding that the surgeon would use another surgical tool to apply the articulation force rather than a sensitive body organ. Knodel Supp. Dec., ¶8. This is confirmed by Ethicon's expert, Dr. Fegelman, who focuses on the first (body) option rather than the second (instrument) option: "this [risk of injury] is particularly true when the exterior of the end effector is **being pressed against a structure in the body**." Fegelman Dec., ¶19.¹ In addition, as Dr. Knodel states, a skilled surgeon can articulate the instrument against a resilient part of the body without tactile feedback. Knodel Supp. Dec., ¶11. Patent Owner's own patents belie Patent Owner's position that nobody would be motivated to combine passive articulation with a robot. Gee discloses an "embodiment of a passive articulation mechanism for use with a robotic surgical system and/or manual surgical instrument." Gee, 5:11-13; *see also* Awtar Dep., 60:4-63:10 ("I am not making the

¹ Patent Owner also argues that passive articulation relinquishes "complete control" over the tool. POR, 30. On the contrary, the surgeon would control the two robotic tools used to articulate, and thus has complete control over the process. Knodel Supp. Dec., ¶9.

statement at all that there is no surgeon in 2011 who would have found passive articulation acceptable.”)

Finally, Patent Owner’s argument, if assumed correct, leads to an inescapable conclusion: adding tactile feedback to a robot lacking it would have been obvious in view of general knowledge of the art. Patent Owner’s expert, Dr. Fegelman, asserts that “passive articulation **requires** nearly instantaneous, tactile feedback.” Fegelman Dec., ¶19. If this were true, then a POSITA, recognizing this alleged requirement, would have been motivated to add such tactile feedback to the Anderson/Timm system. This is confirmed by at least one of the prior art articles on which Patent Owner relies. Exhibit 2017 is a 2007 article entitled “Haptic Feedback in a Telepresence System for Endoscopic Heart Surgery.” In that article, the authors noted that the “lack of haptic feedback may cause damage to tissue” and their solution was simply to build a “telem manipulator for endoscopic surgery that provides . . . **force-feedback** (in order to improve the feeling of immersion).” Mayer (Exhibit 2017), 1. In sum, if tactile feedback was a requirement, a POSITA would simply add it to the robot—Patent Owner’s own evidence shows that this was done before the priority date.

F. As Established in the Petition, a POSITA Would Have Had a Reasonable Expectation of Success

1. *Anderson Has Sufficient Transmission Members to Drive Timm*

For Ground 2, Petitioner combines Anderson and Timm. Anderson provides the teachings for the surgical robot and the tool mounting portion (“instrument base 34”), which includes “transmission members 70, 72, 74, and 76” each of which includes a “spool.” Anderson, 11:66-12:22; Petition, 11, 15, 25-38, 52. Although four transmission members are shown, Anderson states that “[w]here more or fewer degrees of freedom are desired, the number of spools may be decreased or increased.” Anderson, 11:66-12:22. Both sides’ experts have confirmed that Anderson contemplates more or fewer rotary drives than four. Awtar Dep., 32:8-33:16; Ex. 2010 (Knodel Dep.), 85:22-86:19. Therefore, the number of transmission members is not a stumbling block in making the combination.

2. *Anderson Can Generate Sufficient Forces to Drive Timm*

The ’969 Patent itself admits that the robot disclosed in Anderson generates sufficient forces to drive a linear stapler/cutter, thus further confirming that a POSITA would have an expectation of success. For details about the robotic interface, Anderson repeatedly refers to and incorporates by reference Tierney. Anderson, 16:17-24, 22:61-68, and 23:31-45. And, there is no question that Tierney is capable of driving the linear stapler/cutter of the ’969 Patent because in the ’969 Patent, Patent Owner did not disclose a new surgical robot. Rather, the ’969 Patent is admittedly built upon the prior art robotic patents **of Petitioner**.

Specifically, the '969 Patent discloses “robotic system 1000” to which surgical instruments may be attached. The '969 Patent then identifies Tierney 320,² a prior art robotic patent of Petitioner, as an example of “robotic system 1000”.

'969 Patent, 23:32-38, 31:56-59; Petition, 1-3, 6-7.

Moreover, Patent Owner's expert admitted that Tierney was an example of robotic system 1000, and that robotic system 1000 was capable of driving a linear stapler/cutter. Fronczak Dep., 123:15-125:11. Thus, any suggestion by Patent Owner that Tierney (or Anderson, which incorporates Tierney) is incapable of driving a linear stapler/cutter is contradicted by Patent Owner's own expert.

Thus, in both the '969 Patent and in the Anderson/Timm combination, the motor generates sufficient forces because the motor is powering gears. As was well-known in the prior art, gears are used to reduce speed and increase torque (as in any power tool). The '969 Patent discloses nothing new in this regard:

In various embodiments, the various gears of the closure gear assembly 6520 are sized to generate the necessary closure forces needed to satisfactorily close the anvil 6024 onto the tissue to be cut and stapled by the surgical end effector 601. For example, the gears of

² The Tierney 320 reference is related to, and has the same disclosure as, the Tierney reference incorporated into Anderson.

the closure transmission 6520 **may be sized** to generate approximately 70-120 pounds of closure force.

'969 Patent, 84:20-26; POR at 34; *see also* '969 Patent, 85:4-8. Critically, the '969 Patent does not state what that “sizing” is. Rather, a POSITA **would know how to choose the right gears** to generate the required forces, a point confirmed by Patent Owner’s expert, Dr. Fronczak. *See* Knodel Dec., ¶60; Fronczak Dep., 27:8-31:14.

Accordingly, as stated in the Petition, connecting a motor to an instrument via the gears in the Anderson/Timm combination is merely an application of a known technique to a known system that would certainly yield predictable results. Petition, 45-46, 55-56. In sum, Patent Owner’s argument that Anderson cannot drive Timm because it allegedly has “high speed, low torque” motors is baseless. It has the same motor disclosure as the '969 Patent and Timm’s gears would adjust the torque as needed. Moreover, the conclusory statements to the contrary in Patent Owner’s expert declarations were debunked at deposition. Fronczak Dep., 27:8-31:14; Awtar Dep., 116:8-119:1; *compare* Timm, 19:22-27 (“Those of ordinary skill in the art will understand that changes in the gear ratios-either in the transmission or rack and pinion could be used to attain improved mechanical advantages for driving the knife assembly 170”).

G. Anderson Provides a Generic Robotic Foundation For a Variety of Tools

Patent Owner next argues that Anderson cannot drive an “endocutter” such as Timm because Anderson’s tool base “is designed to control a harmonic end effector.” POR, 33. As shown above, this is incorrect. First, Anderson provides a generic robotic foundation to which a variety of tools may be attached, including “stapler probes, tissue grasping and cutting probes, and the like.” Anderson, 7:1-25; Petition at 70-71. Thus, Anderson provides rotary “transmission members” (four in the exemplary embodiment) that can provide rotary motion to any tool function that requires it. Accordingly, even though the focus of Anderson’s preferred embodiments may be harmonic tools, Anderson’s transmission members can drive any tool requiring rotary controls. Knodel Dec., ¶¶64-75, Petition, 1, 18-29, 69, 80 (discussing Anderson’s rotary controls and tools), 45-51 (discussing Anderson’s interface with Timm’s gears).

Patent Owner also argues that “harmonic devices are incapable of articulation.” POR, 34. This is irrelevant as Anderson specifically discloses non-harmonic tools and also discloses articulating surgical instruments. Anderson, 6:47-58 (disclosing “alternative embodiments” with a “wrist-like . . . pivotal joint.”); *see also* Petition, 1, 38.

Patent Owner also argues that a POSITA would face “substantial challenges” in attempting to “adapt Timm’s endocutter for use with Anderson’s

robotic system.” POR, 35. As a threshold matter, the existence of “substantial challenges” does not negate an expectation of success. It is the job of design engineers to address challenges. Moreover, the alleged “challenges” are greatly exaggerated. First, Dr. Knodel has testified that a POSITA would easily make the necessary adjustments to couple the rotary output of Anderson to the rotary input of Timm. Knodel Dec., ¶¶92-103; Petition at 55-56. Patent Owner offers no rebuttal to this specific issue. Instead, Patent Owner makes a series of vague assertions divorced from Dr. Knodel’s actual testimony.

Patent Owner makes its “low speed, high torque” argument again. POR, 36. As discussed above, using gears to convert motor power to a lower speed and higher torque is well within a POSITA’s skill—as admitted by both of Patent Owner’s experts. Fronczak Dep., 27:8-31:14; Awtar Dep., 116:8-119:1.

Also, Patent Owner asserts a POSITA must determine “how to achieve the mechanical advantage needed to produce the relatively high forces required of an endocutter while maintaining the compact size needed for a minimally invasive instrument.” POR, 36. This is a variation of its “low speed, high torque argument.” As Dr. Awtar admitted, a POSITA would know how to size the gears appropriately and Dr. Awtar further admitted that Anderson specifies no size constraints that would preclude appropriate gears from being included in the tool mounting portion of the Anderson/Timm instrument. Awtar Dep., 111:9-112:4. In

fact, Patent Owner admits in its Response that gears would solve the alleged problem when it states that “a gear drive could achieve such a mechanical advantage.”³ POR, 36; compare Timm, 19:22-27.

H. The Unrelated Publications Cited by Patent Owner Fail to Address the Anderson / Timm Combination and Are Thus Irrelevant

On pages 37-40 of its Response, Patent Owner cites to the '969 Patent and two publications. None of which supports its argument that known robotic instruments in 2011 were incapable of driving a linear stapler/cutter. First, Patent Owner alleges that the '969 Patent “specifically identifies” Anderson as a system that was “**unable to generate the forces** required to cut and fasten tissue.” POR, 37. This is a gross mischaracterization of the quoted passage. The passage actually says that “**many** of such systems,” **not all** of such systems, “have in the past been unable to generate the magnitude of forces required.” '969 Patent, 23:6-29. As Patent Owner’s own expert admitted, this passage does **not** state that Anderson’s robotic system was incapable of generating the forces required. Fronczak Dep., 117:6-118:14.

³ Patent Owner then questions whether a “single gear stage” would work, but this is irrelevant. Neither Anderson nor Timm precludes multiple gear stages, as would be known to a POSITA. Awtar Dep., 116:8-119:1.

Moreover, (1) the passage is an unsupported statement in Patent Owner's patent. (2) the passage appears to be referring to actual systems, and not publications. As Patent Owner's expert admitted, the system disclosed in Anderson does not have a maximum torque limit. Fronczak Dep., 94:8-96:6 (discussing Tierney robot which disclosure is incorporated into Anderson). (3) the forces from Anderson's disclosed tools are not relevant. Rather, the relevant tool is the Timm tool, which uses gears to generate high torque, modified for Anderson. And (4), and perhaps most significantly, Patent Owner has not provided any explanation why a robot that admittedly drives the '969 Patent cannot drive Timm.

Patent Owner next cites to Exhibit 2012, a prior art patent assigned to Petitioner filed in 2010. This patent is irrelevant. It did not discuss Timm or the proposed Anderson/Timm combination, and thus was certainly not commenting on the forces needed to actuate the Anderson/Timm combination instrument.

Patent Owner also cites Exhibit 2019, which is equally irrelevant. It states that adapting "open surgical clamping devices" to "minimally invasive settings may be more challenging than expected." POR, 39. It also states that "[t]ransferring the advantages available from surgical staplers, linear cutters, and surgical clamping tools to robotic surgical settings may involve even more challenges." POR, 40. In context, it is clear that the discussion is about moving

open surgical tools to robotic settings. Like the previous publication, this publication is not discussing Timm or the proposed Anderson/Timm combination.

III. Ground 3: The Articulation Bars of Wallace Are Compatible with the Anderson/Timm Combination

A. In the Proposed Combination for Ground 3, the Articulation Mechanism of Timm Is Replaced with the Articulation Mechanism of Wallace

Claims 25 and 26 of the '969 Patent add the additional limitations that the articulation system use “gears” (claim 25) and use two “articulation bars” (claim 26). For these claims, Petitioner relies on a combination of Anderson, Timm, and Wallace. Petition, 57-65. In the combination, Timm’s lockable articulation mechanism is **replaced** by the articulation mechanism of Wallace, which has the advantage of providing active articulation via the articulation bars. Petition, 59. Accordingly, Patent Owner’s argument that the combination would employ both active and passive articulation in the same mechanism is incorrect and moot. POR, 41-42. Ex. 2010 (Knodel Dep.), 79:14-80:19 (confirming that in the combination, articulation is provided by the Wallace structure).

B. Anderson Can Accommodate Additional Controls as Necessary to Operate the Wallace Articulation Mechanism

Patent Owner next argues that Anderson “plainly disclose[s] four available control inputs” and that the proposed combination requires at least five inputs and perhaps six (the POR is unclear on this point): two for articulation, one for shaft

roll, one or two for gripping, and one for firing the stapler. POR, 42-43. Thus, Patent Owner concludes, the combination “requires more control inputs than are available.” POR, 42 (section heading). Patent Owner is mistaken because Anderson discloses multiple “control inputs” without a specific maximum. Petition, 11, 15, 25, 51-52. The figures in Anderson disclose four control inputs, but Anderson explicitly states that more or less could be provided. Anderson, 11:66-12:22; Awtar Dep., 32:8-33:16; Ex. 2010 (Knodel Dep.), 85:22-86:19. Accordingly, a POSITA would design a system with the number of inputs required.⁴

Second, even with only four inputs, the combination meets the limitations of the claims. The claims do not require articulation in two directions and therefore, in the combination, only two of the four articulation bars of Wallace need to be

⁴ Ethicon here cites to an unrelated publication for the proposition that four control inputs is the limit. First, even if the publication made such a statement, it would have no bearing on the teaching of Anderson, which permits more than four. Second, Exhibit 2014 states that in the real world, one would not want to design a brand new robotic system for a particular application. The proposed combination is not a single function robot. Moreover, the expense of an invention is not a factor in an obviousness analysis. *In re Farrenkopf*, 713 F.2d 714, 718 (Fed. Cir. 1983)

used, and only a single articulation control would be required. Petition, 60, 62-65. Similarly, although Anderson discloses embodiments of grippers with two control inputs (one for each jaw), Timm's instrument only requires a single control input for clamping. Petition, 55.

Finally, the claims do not require a linear stapler/cutter. Rather, the claims only require an articulating end effector with at least one movable component. Thus, to the extent that the number of control inputs was limited to four (it is not), a POSITA would be motivated to simply adapt Timm to use fewer control inputs by removing functionality (e.g., "firing" such that Timm's end effector would act as a gripper). Petition at 39-55 (one alternative does not require knife), 60 (gripper only); POR, 45. Such a device would be useful and meet the claim language.

IV. Ground 4: Claims 19 and 20 Would Have Been Obvious over Anderson and Knodel

A. Petitioner Has Already Addressed Patent Owner's "Tactile Feedback" Argument

For Ground 2, Patent Owner argued that tactile feedback was "critical" to passive articulation. For this Ground, Patent Owner ups the ante and argues that tactile feedback is "critical" to any robotic linear stapler/cutter (which it calls an "endocutter.") POR, 46-48. This argument is baseless and contradicted by the very lawsuit that triggered this IPR petition. As Patent Owner's related patent infringement lawsuit confirms, it is undisputed that Petitioner has—and sells—

linear staplers that staple and cut tissue even without the type of tactile feedback that Patent Owner asserts is “critical.” IS1026; Fronczak Dep., 144:13-19; Awtar Dep., 37:1-37:11.

Of course, as discussed in section II.D, this argument is also moot because Anderson discloses tactile feedback.

B. A POSITA Would Have Had a Reasonable Expectation of Success

In this combination, the handheld gear-driven linear stapler of Knodel is modified to adapt to the Anderson system. As explained in the Petition, a POSITA would know how to do this because it merely involves the coupling of rotary drives to rotary inputs, using, e.g., gears. Petition, 75-76. Such coupling is well within the skill of the art, as discussed previously. Patent Owner presents no new arguments, but again asserts that it would be too difficult to combine a handheld instrument to a “harmonic” tool base. POR at 49. Petitioner has already responded to these arguments in Section II.G, above.

V. Ground 5: Claims 21 and 22 Are Obvious over Anderson in view of Viola

For this Ground, Patent Owner argues that Viola’s drive screw is in the wrong place. The claims require the “rotary end effector drive shaft” (Viola’s drive screw) to be in the end effector. And Patent Owner asserts that Viola’s drive screw is not in the end effector, but somewhere else. POR, 49-51.

Patent Owner is wrong. Viola's drive screw is in Viola's "cartridge assembly 16," which is part of Viola's "end effector." Petition, 80-81; Knodel Dec., ¶157. Patent Owner's argument relies on Patent Owner's arbitrary box drawing that contradicts the '969 Patent's disclosure. The '969 Patent has a detachable embodiment similar to Viola's. For that embodiment, the '969 Patent calls the **entire** disposable loading unit the "end effector": "As can be seen in FIG. 74, the tool 3600 includes an **end effector in the form of a disposable loading unit 3612**." '969 Patent, 54:1-5. Compare '969 Patent, FIGs. 74-76 with Viola, FIGs. 1, 5, 9, and 10.

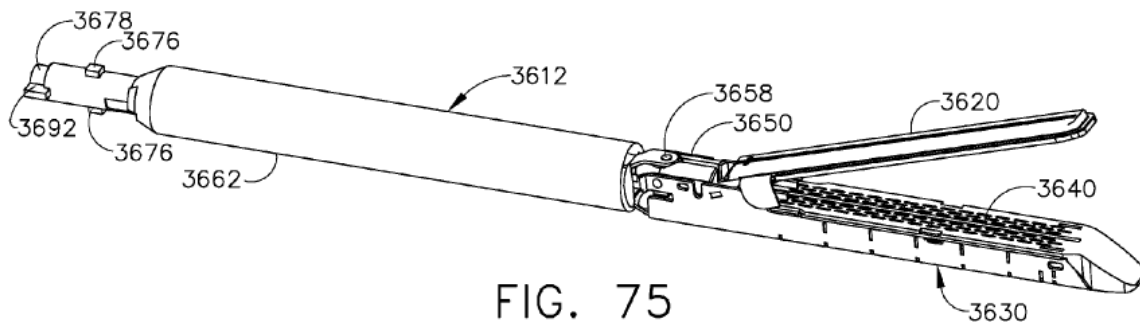


FIG. 75 of '969 Patent with end effector 3612.

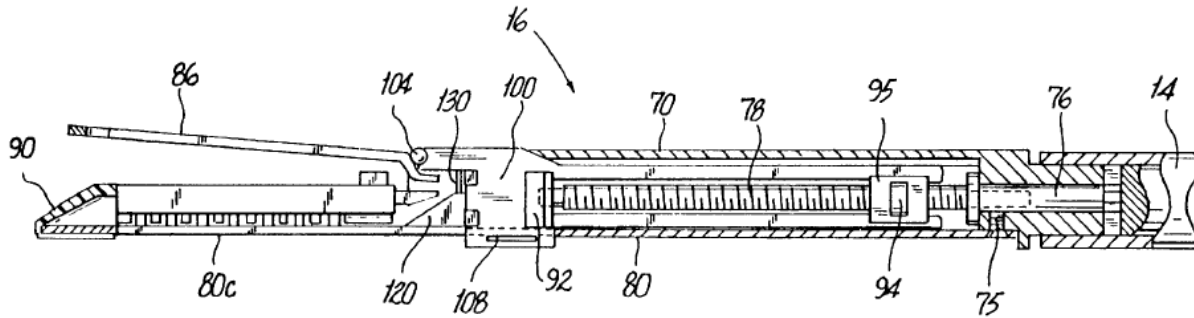


Fig. 9

FIG. 9 of Viola with cartridge assembly 16 (the end effector).

Likewise, Patent Owner arbitrarily excludes Viola's "follower nut 94" from the "knife member" and argues that the "knife member" lacks a threaded engagement. POR, 51-52. The Petition properly maps the entire knife structure, including the follower nut, to the claimed "knife member," given that the entire structure moves as one. Petition, 83-85. Patent Owner offers no basis for its arbitrary box drawing.

VI. Conclusion

For the foregoing reasons and the reasons expressed in the Petition, the challenged claims should be held unpatentable.

Date: July 15, 2019

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petitioner's Reply to Patent Owner's Response totals 5,569, which is less than the 5,600 allowed under 37 CFR § 42.24

Date: July 15, 2019

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(1) and 42.6(e)(4)(iii), the undersigned certifies that on July 15, 2019, a complete and entire copy of this Petitioner's Reply to Patent Owner's Response and Accompanying Exhibits were provided via email to the Patent Owner by serving the email correspondence addresses of record as follows:

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