

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

ETHICON LLC,
Patent Owner.

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

PATENT OWNER ETHICON LLC'S SUR-REPLY

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EXHIBIT LIST FOR IPR2018-01247

Exhibit #	Description
Ex. 2001	Excerpts of a technology tutorial filed in <i>Ethicon v. Intuitive Surgical</i> , C.A. No. 1-17-cv-871 (LPS) (CJB) (D. Del. June 28, 2018)
Ex. 2002	Patent Statutory Disclaimer for U.S. Patent No. 8,479,969 filed on October 15, 2018
Ex. 2003	U.S. Patent No. 7,524,320
Ex. 2004	U.S. Patent No. 7,473,258
Ex. 2005	[Reserved]
Ex. 2006	Declaration of Dr. Shorya Awtar
Ex. 2007	Declaration of Dr. Elliott Fegelman
Ex. 2008	Additional excerpts from technology tutorial
Ex. 2009	Mucksavage et al., Differences in Grip Forces Among Various Robotic Instruments and da Vinci Surgical Platforms, <i>Journal Of Endourology</i> , Vol. 25, No. 3 (March 2011)
Ex. 2010	Deposition Transcript of Bryan Knodel, IPR2018-01247 (April 3, 2019)
Ex. 2011	Deposition Transcript of Bryan Knodel, IPR2018-01254 (April 4, 2019)
Ex. 2012	U.S. Patent No. 8,640,788
Ex. 2013	Order Invalidating the January 2018 Certificate of Correction Relating to U.S. Patent No. 8,479,969, <i>Ethicon v. Intuitive Surgical, Inc.</i> , C.A. No. 17-871 (D. Del. Feb. 11, 2019)
Ex. 2014	WIPO Publication No. 2015/153642 A1
Ex. 2015	U.S. Patent No. 8,186,555

Exhibit #	Description
Ex. 2016	U.S. Patent No. 5,307,976
Ex. 2017	Hermann Mayer et al., <i>Haptic Feedback in a Telepresence System for Endoscopic Heart Surgery</i> , Presence, Vol. 16, No. 5, pp. 459-470 (October 2007)
Ex. 2018	Allison M. Okamura, <i>Haptic feedback in robot-assisted minimally invasive surgery</i> , Current Opinion in Urology, 19:102-107 (2009)
Ex. 2019	U.S. Patent Application Publication No. 2012/0209314
Ex. 2020	U.S. Patent No. 6,978,921
Ex. 2021	[Reserved]
Ex. 2022	[Reserved]
Ex. 2023	Defendants' Opening Claim Construction Brief, <i>Ethicon v. Intuitive Surgical, Inc.</i> , C.A. 17-871, D.I. 116 (D. Del. June 28, 2018)
Ex. 2024	Defendants' Responsive Claim Construction Brief, <i>Ethicon v. Intuitive Surgical, Inc.</i> , C.A. 17-871, D.I. 127 (D. Del. Aug. 1, 2018)
Ex. 2025	Deposition of Dr. Bryan Knodel in IPR2018-01247 and IPR2018-01254 (August 12, 2019)
Ex. 2026	[Reserved]
Ex. 2027	Notice of Waiver of Appeal Regarding the Court's Order Invalidating the January 2018 Certificate of Correction Relating to U.S. Patent No. 8,479,969, <i>Ethicon v. Intuitive Surgical, Inc.</i> , C.A. 17-871, D.I. 311 (D. Del.)

I. INTRODUCTION

Patent Owner's Response ("POR") provided multiple, independent reasons why Petitioner's unpatentability grounds should be denied. Petitioner's reply arguments fail to remedy the Petition's deficiencies.

For Grounds 2-3, the single, conclusory sentence in the Petition and supporting expert declaration failed to demonstrate that the Anderson/Timm combination discloses limitation [24.4] as originally filed ("a tool mounting portion operably coupled to a distal end of said proximal spine portion"). Recognizing this failure of proof, Petitioner erroneously urges the Board to apply the Certificate of Correction to limitation [24.4] in these proceedings. However, the District of Delaware invalidated this certificate *at Petitioner's urging*, and Ethicon has waived its right to appeal that decision. Accordingly, both issue preclusion and judicial estoppel bar Petitioner from changing its position on the certificate's applicability. Furthermore, Petitioner's Reply raises an entirely new argument to attempt to meet its burden that the primary combination discloses limitation [24.4] as originally filed. But the new arguments are contradicted by Petitioner's own characterization of the primary combination in the Petition and its expert declaration.

The POR also conclusively established for Grounds 2-3 that a POSITA would not have utilized a passive articulation joint in a robotic endocutter because

robotic surgical tools lack the tactile feedback that is necessary to perform passive articulation safely and effectively. Petitioner's Reply and supplemental declaration from Dr. Knodel fail to rebut this argument. First, Dr. Knodel agreed that tactile feedback for passive articulation was not disclosed in the prior art. Second, Dr. Knodel's conclusory testimony that tactile feedback is not needed for passive articulation cannot outweigh the testimony of Dr. Fegelman, who unlike Dr. Knodel, actually has experience with the use of both (1) passively-articulated handheld tools and (2) robotic tools. Finally, Petitioner has no response to the testimony of Dr. Fegelman that using passive articulation would take away complete control of the device from a surgeon, negating the key perceived benefit of a robotic tool.

Also, for Grounds 2-3, Petitioner has not demonstrated that a POSITA would have had a reasonable expectation of success combining Anderson and Timm. Petitioner has assumed that a POSITA would have been able to design a new instrument drive system to provide power from Anderson's robot to Timm's end effector, without any evidence or explanation. In contrast, Patent Owner's expert Dr. Awatar provided a detailed analysis regarding the challenges a POSITA would have faced, and why one would have lacked a reasonable expectation of success. Dr. Awatar's testimony is confirmed by Petitioner's own contemporaneous patent applications, which describe that adapting a handheld endocutter for use

with a robotic system was extremely challenging. In light of Dr. Awtar's testimony and Petitioner's patent applications, the bare assumption in the Petition that a POSITA would expect success in combining Anderson and Timm is insufficient.

Finally, Petitioner's specific Reply arguments concerning Ground 3 and its Reply arguments concerning Grounds 4-5 fail to remedy the deficiencies identified in the POR.

Accordingly, for the reasons set forth in the POR and this Sur-Reply, Patent Owner respectfully submits that Petitioner has failed to demonstrate that the challenged claims are obvious.

II. GROUND 2, CLAIM 24: PETITIONER HAS NOT DEMONSTRATED THAT THE ANDERSON/TIMM COMBINATION RENDERS OBVIOUS LIMITATION [24.4]

The Certificate of Correction is invalid and cannot apply in this proceeding. As explained below, Petitioner has failed to show that limitation [24.4], as originally filed, is disclosed by the Anderson/Timm combination.

A. The Certificate of Correction Is Invalid and Does Not Apply in This Proceeding

In litigation between the parties in the District of Delaware, Petitioner urged the Court to invalidate the Certificate of Correction. The Court did so in an order issued on February 11, 2019. Ex. 2013. Ethicon has waived its right to appeal this

decision. Ex. 2027. Accordingly, Petitioner is precluded by both collateral estoppel and judicial estoppel from now advocating that the Certificate should be applied.¹

1. Collateral estoppel bars application of the Certificate

Collateral estoppel applies when an issue of fact or law is (1) “actually litigated and determined,” (2) “by a valid and final judgment,” and (3) “the determination is essential to the judgment.” *Worlds Inc. v. Bungie, Inc.*, 903 F.3d 1237, 1247 (Fed. Cir. 2018). Here, there is no dispute that the validity of the Certificate of Correction was actually litigated before and determined by the District of Delaware, and that the determination was essential to the Court’s order; indeed, the Court’s order was directed solely to the issue of the validity of the Certificate, and evidences that the issue was fully litigated to the Court through “the parties’ claim construction briefing and joint status report.” Ex. 2013, p.1.

¹ Petitioner is also foreclosed from arguing that the original claim language is defective or lacks support in the specification. Petitioner argued exactly the opposite to the District of Delaware. Ex. 2023, p.4; Ex. 2024, p.1 (“As set forth in Intuitive’s opening papers, the as-printed original claim language is typographically and grammatically correct, and reads logically in the context of the surrounding claim language, the specification, and the other claims of the ’969 Patent.”).

Petitioner, however, contends that “[i]ssue preclusion does not apply here because there is no final judgment from the District Court,” and argues that “Patent Owner has specifically reserved the right to appeal” the order. Reply, p.4. Ethicon, however, has waived its right to appeal the Court’s decision. Ex. 2027. Thus, the District Court’s decision invalidating the Certificate of Correction is sufficiently “procedurally definite” to be deemed final for purposes of collateral estoppel because it cannot be modified or reversed on appeal. Restatement (Second) of Judgments § 13 (1982) (“The test of finality, however, is whether the conclusion in question is procedurally definite and not whether the court might have had doubts in reaching the decision.”). Accordingly, collateral estoppel applies to this issue, barring Petitioner from relitigating the question of whether the Certificate applies.

2. Judicial estoppel bars application of the Certificate

Judicial estoppel also bars Petitioner from now asserting that the Certificate applies. Judicial estoppel applies where (1) a party’s later position is “clearly inconsistent” with that party’s earlier litigation position; (2) “the party has succeeded in persuading a court to accept that party’s earlier position,” such that “judicial acceptance of an inconsistent position in a later proceeding would create the perception that either the first or the second court was misled”; and (3) “the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.” *New Hampshire*

v. Maine, 532 U.S. 742, 750-51 (2001). The purpose of the doctrine is to protect the integrity of the judicial process by prohibiting parties from deliberately changing positions according to the exigencies of the moment. *Id.*, 749-50.

“Judicial estoppel applies just as much when one of the tribunals is an administrative agency as it does when both tribunals are courts.” *Trustees in Bankr. of N. Am. Rubber Thread Co. v. U.S.*, 593 F.3d 1346, 1354 (Fed. Cir. 2010).

Here, all three elements of judicial estoppel are met. First, Petitioner’s position now – that the Board should apply the Certificate – is clearly inconsistent with its earlier positions before both the District of Delaware and the Board. Specifically, Petitioner expressly argued in its district court claim construction briefing that the Certificate “is invalid as a matter of law.” Ex. 2023, p.2. Likewise, Petitioner expressly told the Board in its Petition, *in this very proceeding*, that “Petitioner contends the Certificate was not effective.” Petition, p.51, n.3. These unequivocal assertions that the Certificate is not applicable are clearly inconsistent with Petitioner’s new position that the Board should apply the Certificate in this proceeding. Second, Petitioner succeeded in persuading the District of Delaware to accept its earlier position that the Certificate is invalid, as evidenced by the Court’s order. Ex. 2013. In view of the District Court’s order, acceptance by the Board now that the Certificate is operative and in force for this proceeding would invariably create the perception that either the District Court or the Board was

misled as to the Certificate's validity. Finally, Petitioner would derive an unfair advantage over Ethicon if not estopped because Ethicon justifiably relied on Petitioner's prior position and the District Court's order in preparing its POR in this proceeding.

Accordingly, the Board should apply judicial estoppel to bar Petitioner from asserting that the Certificate of Correction applies in this proceeding.

B. The Petition's Conclusory Analysis of Limitation [24.4] Failed to Meet Petitioner's *Prima Facie* Burden

The Petition fails entirely to explain how this limitation is met in the Anderson/Timm combination. POR, p.25-28. Petitioner's analysis in the Petition is reproduced below:

If the January 23, 2018 Certificate of Correction is not effective, then Anderson in view of Timm still discloses this limitation. IS1004, ¶105. Specifically, in the combination, Anderson's tool mounting portion would be operably coupled to the distal end of the proximal spine portion of Timm's shaft assembly via the structure of the distal spine portion itself.

Petition, p.52; *see also* Ex. 1004, ¶104 (same conclusory assertion, except stating "via the proximal spine portion itself" instead of "via the structure of the distal spine portion itself"). This conclusory assertion that the combination discloses an operable coupling between the tool mounting portion and the distal end of the

proximal spine portion as required by limitation [24.4] does not satisfy Petitioner's *prima facie* burden to demonstrate obviousness. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363-64 (Fed. Cir. 2016).

C. Section II.B of the Reply Raises New, Impermissible Arguments Concerning Limitation [24.4] That Should be Disregarded

Section II.B of Petitioner's Reply attempts to overcome the Petition's deficiencies by asserting new arguments that were not previously disclosed in the Petition and should be disregarded. Notably, this section does not cite a single sentence *in the Petition*. Petitioner attempts to stitch together several unrelated statements from Dr. Knodel's declaration to fill the Petition's gaps. But none of these statements are cited in the Petition's analysis of limitation [24.4]'s uncorrected language. Petition, p.51-52 (citing *only* paragraph 105, and not paragraph 104 as may have been intended, of Dr. Knodel's declaration).

Petitioner's scattershot citations only confirm that the arguments in Section II.B should be struck as an improper attempt to substitute Petitioner's original, flawed analysis with a new theory for the first time on Reply. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016) ("[T]he Board did not err in refusing the reply brief as improper under 37 C.F.R. § 42.23(b) because IBS relied on an entirely new rationale to explain why [a POSITA] would have been motivated to combine [the prior art]."); August 2018 Trial Practice

Guide Update, p.14-15 (“Examples of new issues are new theories or arguments necessary to make out petitioner’s case-in-chief”).

First, Petitioner states that “Dr. Knodel explained that the ‘tool mounting portion’ of Anderson was ‘base 34.’” Reply, p.5 (citing Ex. 1004, ¶63). Paragraph 63 of Dr. Knodel’s declaration is an analysis of claim 23, not claim 24. This paragraph is not cited in the Petition’s section regarding the uncorrected language of [24.4].

Second, Petitioner argues that “[i]n 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.’” Reply, p.6 (citing Ex. 1004, ¶36). Paragraph 36 of Dr. Knodel’s declaration is a background discussion of the Timm reference, does not concern an analysis of claim 24, and is not cited in the Petition’s section regarding the uncorrected language of [24.4].

Third, Petitioner argues that “Dr. Knodel further identified a ‘lockable articulation joint’ at the distal end of the proximal spine portion, citing to Timm, 31:62-32:31.” Reply, p.7-8 (citing Ex. 1004, ¶¶36, 89). As noted above, paragraph 36 is a background discussion of Timm, and paragraph 89 is a discussion of a different claim 24 limitation ([24.2]). Neither of these paragraphs is cited in the Petition’s section regarding the uncorrected language of [24.4].

Fourth, Petitioner argues that “the cable that locks the joint from the handle undeniably operably couples the handle to the articulation joint, and in the combination, the handle becomes the tool mounting portion.” Reply, p.8-9. This is neither in the Petition nor Dr. Knodel’s declaration.

Finally,² Petitioner concludes that “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.” Reply, p.9-10. Petitioner cites to neither the Petition nor Dr. Knodel’s declaration.

Not one of these arguments was included in the Petition’s analysis of the uncorrected language of [24.4]. Petition, p.51-52. Petitioner’s attempt at a do over should be rejected.

² Petitioner interposes its contention that the 969 Patent was not the first to disclose active articulation. Reply, p.9. This is irrelevant.

III. GROUND 2, CLAIM 24: A POSITA WOULD NOT HAVE UTILIZED TIMM'S PASSIVE ARTICULATION JOINT IN ANDERSON'S ROBOTIC SYSTEM

A. Petitioner's Combination Eliminates the Tactile Feedback That Is Critical to the Operation of Timm's Endocutter and Changes the Design Principles of the Anderson/Timm Surgical Tools

A POSITA would not have been motivated to combine a robotic system with Timm's passively-articulated endocutter. POR, p.28-31. By proposing to convert Timm's passively-articulated handheld endocutter into a robotic endocutter, Petitioner is proposing modifications that change the basic principles under which Timm's handheld endocutter is designed to operate. As Dr. Fegelman explained, a surgeon's grip on a hand-held endocutter is critical to the use of passive articulation. *See* Ex. 2007, ¶19 (“Thus, *the tactile feedback provided through the surgeon's grip on the hand-held portion is critical to the use of passive articulation.*”)³; *see also id.*, ¶22.

Moreover, Dr. Fegelman's testimony is that “from a surgeon's perspective in the 2011 timeframe, one of the key perceived benefits of a robotic tool was the ability to have complete control over the movement of the tool from the surgeon console. Passive articulation relinquishes this control and instead requires external forces to control the movement of the tool. As a result, passive articulation would

³ All emphasis added unless otherwise noted.

negate this key perceived benefit of robotic surgery tools.” Ex. 2007, ¶25.

Intuitive’s argument that the surgeon would still have complete control because the surgeon would be pressing one tool against the other (Reply, p.13, n.1 (citing Ex. 1017, ¶9)) misses the point because the surgeon is not directly controlling the articulation of the tool in this situation. Moreover, unlike Dr. Fegelman, Dr. Knodel admittedly has essentially no experience with passively articulating tools and has never discussed the issue with surgeons. Ex. 2025, p.20:22-22:24. Thus, Dr. Knodel’s unsupported assertions cannot overcome the testimony of Dr. Fegelman. The Anderson/Timm combination therefore also changes the fundamental operating principle of Anderson’s robotic tools by creating a situation where the surgeon does not directly control the tool’s movement. It is well-established that combinations that change the fundamental design principle may fail to support a conclusion of obviousness. *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App’x 755, 757-758 (Fed. Cir. 2015); *Fisher & Paykel Healthcare Ltd. v. ResMed Pty Ltd.*, IPR2017-00059, 2018 WL 1193320 (P.T.A.B. Mar. 7, 2018); *Adidas AG v. Nike, Inc.*, IPR2016-00922, 2019 WL 764425 (P.T.A.B. Feb. 19, 2019).

B. Passively-Articulated Robotic Tools Have Not Been Introduced Even Today, Confirming That a POSITA Would Not Have Designed Such a Tool in 2011

Petitioner has not disputed Dr. Fegelman's testimony that he is unaware of any passively articulating robotic tools in the past or even today. Ex. 2007, ¶21; Ex. 2025, p.22:23-25 (Dr. Knodel testifying that he has never seen a passively-articulated robotic tool). Intuitive's robotic system was FDA-approved in 2000 (*see* <https://www.intuitive.com/en-us/about-us/company>).

Intuitive, however, has never introduced a passively-articulated robotic tool. This confirms Patent Owner's position, as supported by Dr. Awtar and Dr. Fegelman, that a POSITA would not have found a passively-articulated robotic tool to be clinically acceptable. POR, p.29-31; Ex. 2006, ¶¶73-76; Ex. 2007, ¶¶22-26.

C. Petitioner's Counter-Arguments Are Unpersuasive

Faced with compelling evidence that a POSITA would not have made the proposed combination, Petitioner argues that (1) "there is no credible evidence that 'tactile feedback is required'; and (2) "the Anderson/Timm combination has tactile feedback." Both arguments are meritless and are addressed in reverse order.

1. The Anderson/Timm combination does not disclose tactile feedback relating to forces applied to the exterior of the end effector

Petitioner argues that Anderson discloses tactile feedback. Reply, p.11-12.

However, the tactile feedback that is necessary to perform passive articulation requires detecting the forces that are applied to the exterior of the end effector. *See, e.g.,* POR, p.29 (“Dr. Fegelman explains that passive articulation requires pressing the exterior of the end effector of a surgical tool against another structure. Ex. 2007, ¶17.”). Petitioner’s expert confirmed that the prior art does not disclose this type of tactile feedback in a robotic system. Ex. 2025, p.34:6-9 (“[A]re you aware of any prior art that describes a system for feedback associated with a passive articulating tool? A. [I]’m not aware of that, no.”).

a. The 969 Patent does not disclose tactile feedback for passive articulation

Petitioner cites the 969 Patent at 67:35-36 and 86:30-32 for its disclosure that “video feedback is provided by the stereo display and tactile feedback is provided to the controllers grasped by the surgeon.” Reply, p.11. This disclosure has nothing to do with passive articulation, which Dr. Knodel confirmed at deposition. *See* Ex. 2025, p.17:8-18:6.

b. Anderson does not disclose tactile feedback for passive articulation

Petitioner cites Anderson at 6:33-37, which relates to an embodiment that includes a motor pack on the surgical instrument that may include “feedback sensors ... [that] may transmit feedback or sensor signals to the robotic surgical system via the interface.” Reply, p.11-12 (citing Ex. 1017, ¶¶13-15). Dr. Knodel confirmed at deposition that these disclosures do not concern tactile feedback for passive articulation. *See* Ex. 2025, p.26:7-27:2, p.33:23-34:9.

2. Petitioner’s argument that tactile feedback is not a requirement for use of passive articulation with a robotic system is meritless

Petitioner contends that there are situations under which tactile feedback is not required for performing passive articulation, *e.g.*, when pressing against another surgical instrument or when a “skilled” surgeon presses a tool against a “resilient” body structure.⁴ Reply, p.12-13. Petitioner’s only support is its expert’s *ipse dixit*. *See* Ex. 1017, ¶¶7-11. Dr. Knodel admittedly has essentially no experience with passive articulation and has never discussed the issue with surgeons. Ex. 2025, p.20:22-22:24. Petitioner’s arguments based on Dr. Knodel’s

⁴ Notably, Dr. Knodel “agree[s] that passive articulation against a structure in the body raises concerns of damaging tissue due to excessive force.” Ex. 1017, ¶7.

opinions are thus entitled to no weight. Moreover, to the extent Petitioner contends that Patent Owner conceded that there is no safety risk when performing passive articulation against another instrument, this is wrong. Dr. Fegelman, who unlike Dr. Knodel does have experience with both (1) handheld, passively-articulating tools and (2) robotic tools, did ***not*** opine that it would be clinically acceptable for a surgeon to perform passive articulation against another tool without tactile feedback. Instead, Dr. Fegelman explained that tactile feedback is necessary “to prevent damage to ***both the surgical tool itself as well as the structure that is providing the articulation force.***” Ex. 2007, ¶22. The risk of damage to the surgical tool is present regardless of the structure against which the tool is articulated.

Second, Petitioner cites a patent application that Patent Owner filed in 2012 that allegedly discloses a passively-articulated robotic tool. Reply, p.13-14. This reference is not prior art and is thus not relevant to the issue of whether a POSITA would have combined Timm’s passively-articulated endocutter with Anderson.⁵

Finally, Petitioner cites Dr. Awtar’s testimony where he stated that “I am not making the statement at all that there is no surgeon in 2011 who would have found

⁵ Moreover, the patent concerns an ultrasonic tool, which is vastly different from an endocutter.

passive articulation acceptable.” Reply, p.13-14. This testimony is entirely consistent with Dr. Awtar’s position that “a POSITA would have been aware ... in the 2011 timeframe ... [of] the *prevailing opinions* of surgeons regarding passive articulation mechanisms.” Ex. 2006, ¶73.

3. Petitioner’s argument that a POSITA would have added tactile feedback to the Anderson/Timm combination is meritless

Petitioner asserts that “adding tactile feedback to a robot lacking it would have been obvious in view of the general knowledge of the art.” Reply, p.14. Petitioner cites Ex. 2017, arguing that “the authors noted that the ‘lack of haptic feedback may cause damages to tissue’ and their solution was simply to build a “telemanipulator for endoscopic surgery that provides ... **force-feedback**.” *Id.* (emphasis in original) (citing Ex. 2017, p.1). Dr. Knodel provides no testimony concerning this article, and Petitioner’s attorney argument is entitled to no weight. Dr. Knodel admitted at his deposition that he was not aware of any prior art that discloses a system that provides tactile feedback for a passively articulated tool. Ex. 2025, p.34:6-9. Furthermore, the notion that a POSITA would “simply” add feedback for passive articulation is contradicted by objective evidence. Patent Owner cited publications demonstrating that the lack of tactile feedback in general was a major limitation of robotic systems, and even Dr. Knodel testified at this deposition that tactile feedback is very desirable for surgeons to have. Ex. 2025,

p.8:7-12. Yet, as Dr. Fegelman's testimony confirms, this type of tactile feedback is still not available on robotic systems. Ex. 2007, ¶21. It logically follows that since tactile feedback was considered a major limitation of robotic systems and is desirable for surgeons to have, the absence of it for many years confirms that it is no simple task.

IV. GROUND 2, CLAIM 24: A POSITA WOULD NOT HAVE HAD A REASONABLE EXPECTATION OF SUCCESS IN COMBINING ANDERSON'S TOOL BASE WITH TIMM'S HANDHELD ENDOCUTTER

The POR established that harmonic and endocutter technology are fundamentally different, handheld endocutters operate on different fundamental principles from robotic endocutters, and publications confirm the difficulty in adapting an endocutter for robotic applications. POR, p.31-40. Petitioner's counter-arguments are unpersuasive.

A. Anderson Does Not Disclose a Drive System for a Surgical Instrument Capable of Driving an Endocutter

First,⁶ Petitioner incorrectly argues that the 969 Patent admits that Anderson's robot (and an incorporated Tierney patent) can drive an endocutter because these are essentially no different from the robotic systems disclosed in the

⁶ Petitioner argues that Anderson discloses that transmission members can be added to its system. Reply, p.14-15. This is addressed with respect to Ground 3.

969 Patent. Reply, p.15-16. Petitioner appears to contend that because the 969 Patent did not disclose a new robot, a POSITA would have had a reasonable expectation of success in adapting a handheld endocutter for use with a robot such as the Anderson or Tierney robotic systems. This is wrong. As Dr. Awtar explained, the issue is not whether a POSITA would have expected that Anderson/Tierney's robot could provide enough force, but whether a POSITA would have been able to design an instrument having a drive system capable of transferring power from the robot to the endocutter's end effector. *See e.g.*, Ex. 2006, ¶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."). Indeed, the evidence demonstrates that minimally-invasive endocutters provide a unique challenge because of the requirement to transmit high forces for clamping and firing through a size-restricted device while also providing sufficient maneuverability. *Id.*, ¶¶86-89. Dr. Awtar clearly explained why a POSITA would not have expected to succeed in designing the instrument drive system, while Dr. Knodel simply assumed that a POSITA could do so. *Compare* Ex. 2006, ¶¶77-89 *with* Ex. 1004, ¶¶72-114. Even assuming Anderson's/Tierney's robot motors can provide sufficient power, this does not demonstrate that a POSITA would have expected to succeed in designing a new drive system for an endocutter for use with that system.

Relatedly, Petitioner argues that “though the focus of Anderson’s preferred embodiments may be harmonic tools, Anderson’s transmission members can drive any tool requiring rotary controls.” Reply, p.18. This ignores Patent Owner’s cited evidence demonstrating that harmonic tools are fundamentally different from endocutters, which require forces that are at least one order of magnitude greater than harmonic tools. *See* POR, p.33-35 (citing Ex. 2006, ¶¶79-81). Dr. Knodel’s supplemental declaration does not address this issue.

B. Expert Testimony Concerning Gears Does Not Demonstrate a Reasonable Expectation of Success

The POR explained the substantial challenges in adapting Timm’s handheld endocutter for use with Anderson’s robot. POR, p.33-40. Dr. Awtar further described the challenges a POSITA would have faced in adapting the high torque-low speed handheld drive system of Timm for use with a relatively high speed-low torque system such as Anderson. Ex. 2006, ¶¶79-85. Statements from Petitioner’s patent applications fully support Dr. Awtar’s testimony. Ex. 2006, ¶¶86-89.

Petitioner nevertheless argues that the robot in Anderson/Tierney can drive an endocutter with gears, that Anderson’s “high speed, low torque” motors would simply be adjusted by Timm’s gears to provide the required torque, and that “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.” Reply, p.16-17.

Neither Dr. Fronczak's nor Dr. Awtar's testimony supports Petitioner's argument. First, Dr. Fronczak's agreement that engineering students would understand that gears transmit rotary motion and torque does not demonstrate that a POSITA would have had a reasonable expectation of success in adapting an endocutter for use with a robotic system, which would clearly involve more than knowledge of basic concepts regarding gears. *Schenck, A.G. v. Norton Corp.*, 713 F.2d 782, 785 (Fed. Cir. 1983) ("the statute ... **requires that an invention be considered 'as a whole'**") (citation omitted). Second, Dr. Awtar's declaration explains why a POSITA, without knowledge of the claimed inventions, would have lacked a reasonable expectation of success in combining Anderson/Timm, with support from statements from Petitioner's own (later) patent applications regarding robotic endocutters. Ex. 2006, ¶¶77-89. That Dr. Awtar agreed that a POSITA, *with* knowledge of the 969 Patent's disclosures, would have been able to choose the right gears to practice the 969 Patent's claims (*i.e.*, that the 969 Patent specification enabled the claims) does not demonstrate that a POSITA would have had a reasonable expectation of success in adapting an endocutter for use with a robotic system without the benefit of the 969 Patent's teachings. Petitioner presents nothing more than a classic, impermissible hindsight analysis. Petitioner's assumption that a POSITA would have reasonably expected to succeed in achieving the proposed combination is insufficient.

C. Petitioner Fails To Rebut Evidence From Its Own Patent Applications

Publications from both Petitioner and Patent Owner demonstrate that drive systems for other robotic instruments known in or before 2011 (including the robotic system disclosed in Anderson) were insufficient to power an endocutter end effector, such as the one disclosed in Timm. POR, p.37. The cited applications submitted by Petitioner's own employees represent objective and compelling evidence regarding the complexities associated with adapting a handheld endocutter for use with a robotic system.

Dr. Knodel failed to provide any rebuttal to Dr. Awatar's analysis of Petitioner's own patent applications that provide objective evidence that a POSITA would lack a reasonable expectation of success in converting a handheld endocutter to a robotic endocutter. Instead, Petitioner's attorneys argue that they are irrelevant because they do not explicitly mention the references at issue. Reply, p.20-22. This is meritless. Petitioner's patent applications describe adapting a handheld endocutter for use with a robotic system, which is the exact combination proposed by Petitioner. Ex. 2019, [0008] (“***Transferring*** the advantages available ***from*** surgical staplers, ***linear cutters***, and surgical clamping tools ***to robotic surgical settings***....”). Moreover, Petitioner asserted in these applications that adapting open tools for minimally invasive procedures “has proven quite difficult,”

and that adapting linear cutters for use with robotic systems may “involve even more challenges.” *Id.* Petitioner’s statement in a 2011 publication that “there is believed to be a need for a surgical end effector with high actuation force, for example, high clamping force” also underscores that in 2011 a POSITA would not have had a reasonable expectation of success converting a handheld endocutter to a robotic endocutter. Ex. 2012, 2:4-39. Petitioner’s unsupported assertion that a POSITA would have expected to succeed in combining Anderson and Timm is insufficient to satisfy Petitioner’s burden in light of the complexities of the proposed combination, as Petitioner itself described.

V. GROUND 3: PETITIONER HAS NOT DEMONSTRATED THAT THE ANDERSON/TIMM/WALLACE COMBINATION RENDERS CLAIMS 25-26 OBVIOUS

Petitioner’s analysis of Ground 3 only addresses dependent claims 25-26, and does not separately analyze each of the limitations of independent claim 24. Accordingly, Ground 3 fails for the reasons stated above regarding Ground 2. In addition, the combination of Timm’s endocutter with Wallace’s wrist requires more control inputs than are available in the combination. POR, p.40-45.

Petitioner first argues that Timm’s passive articulation mechanism is replaced with Wallace’s active mechanism. Reply, p.22. However, Petitioner’s analysis of claim 24 in Ground 2 was based solely on Anderson/Timm. Ground 3 does not perform a separate analysis showing how each limitation of claim 24

would be met if Wallace replaces Timm. Thus, Petitioner has failed to meet its burden with respect to the Anderson/Timm/Wallace combination. *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724 (Fed. Cir. 1990) (stating that it is legally improper to “[f]ocus[] on the obviousness of substitutions and differences, instead of on the invention as a whole”) (citations omitted).

Next, Petitioner argues that more than 4 control inputs may be provided. Reply, p.22-23. Yet, there is no teaching in Anderson of how one would add a control input. Moreover, this ignores evidence demonstrating that adding rotary drives to the robotic system itself would be cost prohibitive. POR, p.43-44 (citing Ex. 2014, [0007]). *See Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1353 (Fed. Cir. 2011) (“[T]he fact that a combination is expected to increase cost has some bearing on the obviousness of that combination.”).

Finally, Petitioner argues that the combination would work even with 4 inputs because only 2 of 4 articulation bars of Wallace need to be used. Petitioner further argues that other functionality may be removed, since the claims do not require 2-plane articulation or firing. Reply, p.22-24. However, removing 2-plane articulation or firing contradicts Petitioner’s analysis (which relied on an endocutter in its combination). *See also, e.g.*, Petition, p.61 (arguing a motivation to combine because “Wallace’s articulation wrist assembly ‘allows ease of assembly, reduction of parts and ***an increased*** range of motion.’”). Patent Owner

has demonstrated that the proposed combination presented in the Petition would not be made. *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, 925 F.3d 1373, 1382-83 (Fed. Cir. 2019) (“Petitioners also argue the Board improperly required proof that unclaimed elements were combinable. ... We will not fault the Board for analyzing Petitioners’ obviousness grounds in the way presented in the Petition.”).

VI. GROUND 4: PETITIONER HAS NOT DEMONSTRATED THAT THE ANDERSON/KNODEL COMBINATION RENDERS CLAIMS 19-20 OBVIOUS

A POSITA would have been deterred from combining Anderson with Knodel’s endocutter because of the loss of tactile feedback and would have lacked a reasonable expectation of success. POR, p.46-49. Petitioner argues that (1) the lack of tactile feedback would not deter a POSITA as evidenced by its stapler sales; and (2) that Anderson discloses tactile feedback. Reply, p.24-25. First, Petitioner’s conclusory assertion regarding its stapler sales, unsupported by evidence, does not address a POSITA’s motivations in the 2011 timeframe. Second, Anderson states that “force feedback” could be provided (Ex. 1010, p.2:62-3:1) without providing implementation or any other details. Dr. Knodel’s conclusory statement that a POSITA would understand that this discloses tactile feedback (Ex. 1017, ¶15) is belied by his admission that he has not examined the state of the art in 2011 with respect to tactile feedback. Ex. 2025, p.43:12-14.

Finally, as explained above, Petitioner's reasonable expectation of success argument (Reply, p.25) vastly oversimplifies the complexities involved.

VII. GROUND 5: PETITIONER HAS NOT DEMONSTRATED THAT THE ANDERSON/VIOLA COMBINATION RENDERS CLAIMS 21-22 OBVIOUS

Petitioner's combination does not disclose the claimed (1) "rotary end effector drive shaft" or (2) "knife member" that is "threadedly received on said rotary end effector drive shaft." POR, p.49-53. First, Petitioner contends that the 969 Patent discloses that an entire disposable loading unit is an end effector (citing element 3612; Fig. 75). Reply, p.26. This embodiment does not include a rotary end effector drive shaft and is irrelevant. Moreover, this single reference to element 3612 as an end effector is the only instance where it is described as anything other than a "disposable loading unit." Petitioner has not cited any other disclosure where the end effector is described or illustrated as anything other than the portion engaging tissue.

Second, Petitioner argues that the Petition maps the "entire knife structure, including the follower nut, to the claimed 'knife member.'" Reply, p.27. Unlike the knife member described and claimed in the 969 Patent, Viola's follower nut/knife are separate components. Only the follower nut is threadedly received on Viola's alleged "rotary end effector drive shaft."

VIII. CONCLUSION

For the reasons stated in the POR and above, Intuitive has failed to carry its burden to establish that any of the challenged claims of the 969 Patent are invalid over the prior art. The claims should be upheld as patentable.

Dated: August 19, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Patent Owner Sur-Reply, exclusive of the exempted portions as provided in 37 C.F.R. § 42.24(a), contains no more than 5,596 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(b) and the August 2018 Trial Practice Guide Update. In preparing this certificate, counsel has relied on the word count of the word-processing system used to prepare the paper (Microsoft Word).

Dated: August 19, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2019, a copy of **PATENT OWNER ETHICON LLC'S SUR-REPLY** and any accompanying exhibits was served by filing this document through the PTAB's E2E Filing System as well as delivering a copy via electronic mail upon the following:

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