PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN LAPAROSCOPIC SURGICAL STAPLERS, RELOAD CARTRIDGES, AND COMPONENTS THEREOF**	**Inv. No. 337-TA-1167**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Chief Administrative Law Judge Charles E. Bullock

(June 8, 2021)

Appearances:

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LIST OF ABBREVIATIONS

The following abbreviations may be used in this Initial Determination:

CDX	Complainants' demonstrative exhibit
CPX	Complainants' physical exhibit
CX	Complainants' exhibit
CIB	Complainants' initial post-hearing brief
CRB	Complainants' reply post-hearing brief
CPHB	Complainants' pre-hearing brief
Dep.	Deposition
JX	Joint Exhibit
RDX	Respondents' demonstrative exhibit
RPX	Respondents' physical exhibit
RX	Respondents' exhibit
RIB	Respondents' initial post-hearing brief
RRB	Respondents' reply post-hearing brief
RPHB	Respondents' pre-hearing brief
Tr.	Transcript

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Chief Administrative Law Judge Charles E. Bullock

(June 8, 2021)

Pursuant to the Notice of Investigation, this is the final Initial Determination in the Matter of Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof, Investigation No. 337-TA-1167.

For the reasons stated herein, the undersigned has determined a violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain laparoscopic surgical staples, reload cartridges, and components thereof alleged to infringe U.S. Patent Nos. 9,844,369 and 9,844,379. The undersigned has also determined that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred with respect to U.S. Patent Nos. 8,479,969 and 9,113,874.

I. INTRODUCTION

A. Procedural History

Complainants Ethicon LLC, Ethicon Endo-Surgery, Inc., and Ethicon US, LLC (collectively, "Ethicon") filed a complaint on May 30, 2019. 84 Fed. Reg. 32,220-221 (July 5, 2019). Letters supplementing the complaint were filed on June 7 and 17, 2019. *Id*. The complaint alleged violations of section 337 based on the importation and sale of certain reload cartridges for laparoscopic surgical staplers that purportedly infringe U.S. Patent Nos. 9,844,379 ("the '379 patent"); 9,844,369 ("the '369 patent"); 7,490,749 ("the '749 patent"); 8,479,969 ("the '969 patent"); and 9,113,874 ("the '874 patent"). *Id*. The investigation was instituted on July 5, 2019. *Id.* Intuitive Surgical, Inc., Intuitive Surgical Operations, Inc., Intuitive Surgical Holdings, LLC, and Intuitive Surgical S. De R.L. De C.V. are the named Respondents. The Office of Unfair Import Investigations is not a party to the Investigation.

On October 23, 2020, the undersigned granted Ethicon's motion for leave to amend the complaint, case caption, and Notice of Investigation to reinstate the original plain English statement of the category of accused products, as well as the original case caption, and to reincorporate Intuitive's laparoscopic surgical staplers and components thereof as articles to be excluded. Order No. 14, *not reviewed* by Comm'n Notice (Nov. 21, 2019). On November 5, 2019, Ethicon filed its amended complaint. CX-0478C.

On March 5, 2020, claim 1 of the '379 patent and the '749 patent were terminated from the Investigation. *See* Order No. 21, *not reviewed* by Comm'n Notice (Mar. 25, 2020).

On April 21, 2020, Ethicon moved for leave to file a second amended complaint to include the Certificate of Correction for the '379 patent. The motion was granted on May 6, 2020, and Ethicon filed its second amended complaint on May 7, 2020. *See* Order No. 36; Doc. ID 709878.

The evidentiary hearing was originally scheduled to commence on April 20, 2020, but was postponed due to the COVID pandemic. Order No. 28 (Mar. 18, 2020). The virtual hearing was held February 8–12, 2021.

B. The Private Parties

1. Ethicon Complainants[1]

a) Ethicon LLC

Ethicon LLC[2] is a limited liability company organized under the laws of the State of Delaware. Ethicon LLC is headquartered in Guaynabo, Puerto Rico. CIB at 6. Ethicon LLC is the owner by assignment of the entire right, title and interest in the Asserted Patents. *Id*. Ethicon LLC funds research and development ("R&D") activities relating to laparoscopic surgical staplers (*i.e.*, endocutters), reload cartridges, and components thereof. *Id*. These R&D activities are conducted by Ethicon Endo-Surgery, Inc. employees at facilities in the United States. *Id*.

b) Ethicon Endo-Surgery, Inc.

Ethicon Endo-Surgery, Inc. is an Ohio corporation with its principal place of business at 4545 Creek Road, Cincinnati, OH 45242. *Id*. at 7. Ethicon LLC has exclusively licensed Ethicon Endo-Surgery, Inc. to sell products in the United States that would infringe the Asserted Patents absent a license. *Id*. at 6. Ethicon Endo-Surgery, Inc. has exclusively sublicensed that right to Ethicon US, LLC. *Id*.

Ethicon Endo-Surgery, Inc. engages in research and development, manufacturing, sterilization, training, and marketing activities in its United States facilities concerning endocutters, reload cartridges, and components thereof, as well as other surgical devices. *Id*. at 7.

[1] Complainants are part of the Johnson & Johnson family of companies. *See* 2d Am. Compl. at ¶ 1.
[2] Ethicon LLC formerly did business as Ethicon Endo-Surgery, LLC. 2d Am. Compl. at ¶ 13.

c) Ethicon US, LLC

Ethicon US, LLC is a limited liability company organized under the laws of the State of Texas having its headquarters and principal place of business at 4545 Creek Road, Cincinnati, OH 45242. *Id*. Ethicon US, LLC is a wholly-owned subsidiary of Ethicon Endo-Surgery, Inc. *Id*. Ethicon US, LLC engages in marketing and sales of endocutters, reload cartridges, and components thereof, as well as other surgical devices in the United States. *Id*.

2. Intuitive Respondents

a) Intuitive Surgical, Inc.

Intuitive Surgical, Inc. is a Delaware corporation with its principal place of business in Sunnyvale, California. RIB at 10; CIB at 7.

b) Intuitive Surgical Operations, Inc.

Intuitive Surgical Operations, Inc. is a Delaware corporation with its principal place of business in Sunnyvale, California. RIB at 10; CIB at 7. Intuitive Surgical Operations, Inc. is a wholly-owned subsidiary of Intuitive Surgical, Inc. RIB at 10. Intuitive Surgical Operations, Inc. designs and develops the accused SureForm Staplers and accused EndoWrist Xi Staplers. CIB at 7.

c) Intuitive Surgical Holdings LLC

Intuitive Surgical Holdings, LLC is a Delaware corporation with its principal place of business in Sunnyvale, California. RIB at 10; CIB at 7. Intuitive Surgical Holdings, LLC is a wholly-owned subsidiary of Intuitive Surgical, Inc. RIB at 10.

d) Intuitive Surgical S. De R.L. De C.V.

Intuitive Surgical S. De R.L. De C.V. is a Mexican corporation with it principal place

of business in Mexicali, Baja California, Mexico. RIB at 10; CIB at 7. Intuitive Surgical S. De R.L. De C.V. is a wholly-owned subsidiary of Intuitive Surgical, Inc. RIB at 10.

C. Overview of the Technology

The technology at issue in this Investigation relates to surgical instruments and systems. RIB at 11. More specifically, this Investigation concerns laparoscopic surgical staplers and associated reload cartridges that are used to cut and staple tissue during minimally invasive procedures. CIB at 8. Ethicon refers to these instruments and systems as endocutters, staplers, linear staplers, or linear cutters. *Id*. at 8-9. Intuitive refers to them as staplers. RIB at 11.

D. Products at Issue

1. The Accused Products

The accused products are Intuitive's 3rd generation stapler and reload cartridges ("SureForm Staplers") and 2nd generation stapler and reload cartridges ("EndoWrist Staplers"). CIB at 19. The SureForm Staplers are available in 60mm and 45mm sizes, while the EndoWrist Staplers are available in 45mm and 30mm sizes. *Id*. Both types of staplers are designed for use with Intuitive's da Vinci X/Xi Surgical System. *Id*.

The accused SureForm Products are: SureForm 60 (480460), SureForm 45 (480445), SureForm 45 (480545), SureForm 60 Green Reload (48360G), SureForm 60 White Reload (48360W), SureForm 60 Blue Reload (48360B), SureForm 60 Black Reload (48360T), SureForm 45 White Reload (48345W), SureForm 45 Blue Reload (48345B), SureForm 45 Green Reload (48345G), SureForm 45 Black Reload (48345T), and SureForm 45 Gray Reload (48345M). RIB at 12. The accused EndoWrist Staplers are: Xi EndoWrist 45 (470298), Xi EndoWrist 45 (470545), Xi EndoWrist 30 (470430), Xi EndoWrist 30 (470530), Xi EndoWrist 45 Green Reload (48445G), Xi EndoWrist 45 White Reload (48645W), Xi EndoWrist 45 Blue Reload (48645B), Xi EndoWrist

30 Blue Reload (48630B), Xi EndoWrist 30 Gray Reload (48630M), Xi EndoWrist 30 White Reload (48630W), and Xi EndoWrist 30 Green Reload (48630G). *Id*. at 13.

Ethicon and Intuitive have agreed to consolidate the accused products into groups where each product is representative of the others in the same category, as set forth below.

Accused Product(s)	Asserted Patents and Claims
• SureForm Staplers (480460, 480445, 480545) • SureForm Reloads (48360G, 48360W, 48360B, 48360T, 48345W, 48345B, 48345G, 48345T, 48345M)	'369 patent, claims 22-23
• SureForm Staplers (480460, 480445, 480545) • SureForm Reloads (48360G, 48360W, 48360B, 48360T, 48345W, 48345B, 48345G, 48345T, 48345M)	'379 patent, claims 2-3
• SureForm Staplers (480460, 480445, 480545) • SureForm Reloads (48360G, 48360W, 48360B, 48360T, 48345W, 48345B, 48345G, 48345T, 48345M) • Xi EndoWrist Staplers (470298, 470545, 470430, 470530) • Xi EndoWrist Reloads (48445G, 48645W, 48645B, 48630B, 48630M, 48630W, 48630G)	'969 patent, claim 24
• Xi EndoWrist Staplers (470298, 470545, 470430, 470530) • Xi EndoWrist Reloads (48445G, 48645W, 48645B, 48630B, 48630M, 48630W, 48630G)	'874 patent, claim 19

RIB at 12; CIB at 20.

2. The Domestic Industry Products

Ethicon contends that its domestic industry products and prototypes (collectively, "DI products") fall into three categories: (1) Handheld motor-powered staplers: the Echelon FLEX™ Powered Plus Staplers, Echelon FLEX™ Powered Staplers; [redacted] Staplers, and [redacted] Staplers; (2) Handheld non-powered staplers: Echelon FLEX™ Non-Powered Staplers; and (3) [redacted] Staplers. CIB at 16 (citing

CX-0009C at Q/As 30-37, 70-74; CX-0013C at Q/A 13; CX-0002C at Q/A 30.) All of these staplers are designed for use with Ethicon's GST and ECR reload cartridges. *Id*.

Ethicon and Intuitive have agreed to consolidate the DI products into groups where each product is representative of the others in the same category, as set forth below.

DI Product(s)	Compatible Reloads	Asserted Patents and Claims
• Echelon FLEX™ Powered Plus Staplers (PSEE60A, PCEE60A, PLEE60A, PSEE45A, PCEE45A, PLEE45A) • [redacted] • [redacted] • [redacted]	• GST Reloads (GST60G, GST60W, GST60B, GST60D, GST60T, GST45W, GST45B, GST45D, GST45G, GST645T) • ECR Reloads (ECR60W, ECR60B, ECR60D, ECR60G, ECR60M, ECR45W, ECR45B, ECR45D, ECR45G, ECR45M)	'369 patent, claims 22-23
• Echelon FLEX™ Powered Plus Staplers (PSEE60A, PCEE60A, PLEE60A, PSEE45A, PCEE45A, PLEE45A) • Echelon FLEX™ Powered Staplers (PSE60A PCE60A, PLE60A, PSE45A, PCE45A, PLE45A) • Echelon FLEX™ Non-Powered Staplers (EC60A, SC60A, LONG60A, EC45A, SC45A, EC45AL) • [redacted] • [redacted] • [redacted]	• GST Reloads (GST60G, GST60W, GST60B, GST60D, GST60T, GST45W, GST45B, GST45D, GST45G, GST645T) • ECR Reloads (ECR60W, ECR60B, ECR60D, ECR60G, ECR60M, ECR45W, ECR45B, ECR45D, ECR45G, ECR45M)	'379 patent, claims 2-3

DI Product(s)	Compatible Reloads	Asserted Patents and Claims
• [redacted]	• GST Reloads (GST60G, GST60W, GST60B, GST60D, GST60T, GST45W, GST45B, GST45D, GST45G, GST645T) • ECR Reloads (ECR60W, ECR60B, ECR60D, ECR60G, ECR60M, ECR45W, ECR45B, ECR45D, ECR45G, ECR45M)	'969 patent, claim 24
• [redacted]	• GST Reloads (GST60G, GST60W, GST60B, GST60D, GST60T, GST45W, GST45B, GST45D, GST45G, GST645T) • ECR Reloads (ECR60W, ECR60B, ECR60D, ECR60G, ECR60M, ECR45W, ECR45B, ECR45D, ECR45G, ECR45M)	'874 patent, claim 19

RIB at 14-15; CIB at 16.

II. JURISDICTION AND IMPORTATION

A. Subject Matter Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation, the sale for importation, or the sale after importation of articles into the United States. *See* 19 U.S.C. §§ 1337(a)(1)(B) and (a)(2). Ethicon filed a complaint alleging a violation of this subsection. Accordingly, the Commission has subject matter jurisdiction over this Investigation under section 337 of the Tariff Act of 1930. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

Intuitive has appeared and participated in this Investigation. The Commission therefore has personal jurisdiction over Intuitive. *See, e.g., Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players & PC Optical Storage Devices*, Inv. No. 337-TA-506, Initial Determination at 4-5 (May 16, 2005) (unreviewed in relevant part).

C. *In Rem* Jurisdiction

Intuitive does not contest the Commission's *in rem* jurisdiction over the accused products and components thereof. RIB at 15. Intuitive has stipulated that at least one unit of the SureForm 60 stapler, SureForm 60 reloads, sub-assemblies of the SureForm 45 reloads, various components of the SureForm 60 and 45 staplers, EndoWrist Xi 45 reloads, EndoWrist Xi 30 reloads, and various components of the EndoWrist Xi 45 and 30 staplers were imported into the United States. CX-0589C.0002-.0003. Intuitive has also stipulated that at least one unit of the SureForm 45 stapler (curved and straight tipped) has been imported for sale in the United States. *Id*.

III. STANDING

To establish standing, Ethicon must demonstrate that it is the owner or exclusive licensee of the Asserted Patents. 19 C.F.R. § 210.12(a)(7). The assignments of the Asserted Patents to Ethicon LLC establish Ethicon's standing as to each of the Asserted Patents. JX-0011; JX-0012; JX-0014; JX-0015; *see also SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1327-28 (Fed. Cir. 2010) ("The recording of an assignment with the PTO…creates a presumption of validity as to the assignment."). Ethicon LLC has exclusively licensed the Asserted Patents to Ethicon Endo-Surgery Inc., which has exclusively sub-licensed the Asserted Patents to Ethicon US, LLC, all of whom are named Complainants in this Investigation. *See* Section I.B.1.

IV. ORDINARY SKILL IN THE ART[3]

The undersigned has previously determined that: (1) a person of ordinary skill in the art with respect to the '874 and '969 patents would have at least (a) a bachelor's degree or higher in mechanical engineering and (b) at least 3 years of work experience in the design of surgical devices; and (2) that a person of ordinary skill in the art with respect to the '369 and '379 patents would have at least (a) a Bachelor's degree or higher in mechanical engineering and (b) at least 3 years working experience in the design of comparable surgical devices. Order No. 15 at 5 (Jan. 7, 2020). The undersigned also found that, with respect to the Asserted Patents, additional graduate education could substitute for professional experience and significant work experience could substitute for formal education. *Id*.

V. RELEVANT LAW

A. Infringement

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc*., 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

1. Literal Infringement

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is

[3] Ethicon briefed this issue for each of the Asserted Patents. *See, e.g.*, CIB at 39, 87, 120-121, 176-177. As noted above, however, the undersigned has already decided what the appropriate level of skill in the art is for the Asserted Patents.

no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp*., 212 F.3d 1241, 1247 (Fed. Cir. 2000).

2. Indirect Infringement

Indirect infringement may be either induced or contributory. Direct infringement must first be established in order for a claim of indirect infringement to prevail. *BMC Res. v. Paymentech,* 498 F.3d 1373, 1379 (Fed. Cir. 2007).

a) Induced Infringement

Section 271(b) of the Patent Act provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. §271(b) (2008). To establish liability, the patent holder must prove that "once the defendants knew of the patent, they 'actively and knowingly aid[ed] and abett[ed] another's direct infringement.'" *DSU Med. Corp. v. JMS Co., Ltd*. 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc) (citations omitted). A finding of induced infringement requires "evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." *Id.* at 1306. Although §271(b) requires knowledge that the induced acts constitute patent infringement, the Supreme Court has held that liability will also attach when the defendant is willfully blind. *Global-Tech Appliances, Inc. v. SEB S.A*., 131 S. Ct. 2060, 2068-2069 (2011). The burden is on the complainant to prove that the respondent had the specific intent and took action to induce infringement. *DSU*, 471 F.3d at 1305-06. Intent may be proven by circumstantial evidence. *Lucent Tech., Inc. v. Gateway, Inc*., 580 F.3d 1301, 1322 (Fed. Cir. 2009).

b) Contributory Infringement

A finding of contributory infringement under 35 U.S.C. § 271(c) requires (1) direct infringement; (2) that the contributory infringer had knowledge of the patent; and (3) that the

component part had no substantial non-infringing use. *Fujitsu Ltd. v. Netgear Inc.,* 620 F.3d 1321, 1326 (Fed Cir. 2010). In a section 337 case, a complainant alleging contributory infringement must also show "the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

B. Validity

A patent is presumed valid. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft,* 564 U.S. at 95.

1. 35 U.S.C. § 102 (Anticipation)

Under 35 U.S.C. § 102, a claim is anticipated and therefore invalid when "the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 904 (2001). To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

2. 35 U.S.C. § 103 (Obviousness)

Under 35 U.S.C. §103, a patent may be found invalid for obviousness if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person

having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. §103. Because obviousness is determined at the time of invention, rather than the date of application or litigation, "[t]he great challenge of the obviousness judgment is proceeding without any hint of hindsight." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 655 F.3d 1364, 1375 (Fed. Cir. 2011) ("*Star II*").

When a patent is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l Co. v. Teleflex, Inc*., 550 U.S. 398, 417-418 (2007). The Federal Circuit has since held that when a patent is challenged as obvious, based on a combination of several prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

Obviousness is a determination of law based on underlying determinations of fact. *Star II*, 655 F.3d at 1374. The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR,* 550 U.S. at 399 (citing *Graham v. John Deere Co*., 383 U.S. 1, 17 (1966)). These factual determinations are referred to collectively as the "*Graham* factors." Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, and the failure of others. *Id.* When present, secondary considerations "give light to the circumstances surrounding the origin of the subject matter sought to be patented," but they are not dispositive on

the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l.*, 618 F.3d 1294, 1304-06 (Fed. Cir. 2010). A court must consider all of the evidence from the *Graham* factors before reaching a decision on obviousness. For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.,* 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

C. Domestic Industry

For a patent-based complaint, a violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). This domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, USITC Pub. 4120, 2009 WL 5134139 (Dec. 2009), Comm'n Op. at 12-14. The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes & Components Thereof*, Inv. No. 337-TA-454, ID at 294, 2002 WL 31556392 (June 21, 2002) (unreviewed by Commission in relevant part).

1. Economic Prong

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

> (A) significant investment in plant and equipment;
> (B) significant employment of labor or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). Thus, section 337(a)(3) requires that investments be either "significant" or "substantial." The Federal Circuit has clarified that a quantitative analysis must be performed in order to make this determination. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883 (Fed. Cir. 2015) ("The plain text of § 337 requires a quantitative analysis in determining whether a [complainant] has demonstrated a 'significant investment in plant and equipment' or 'significant employment of labor or capital.'"). There is no threshold amount that a complainant must meet. *See Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 25-26 (May 16, 2008) ("We emphasize that there is no minimum monetary expenditure that a complainant must demonstrate to qualify as a domestic industry under the 'substantial investment' requirement of this section."); *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007) ("*Male Prophylactic Devices*") ("[T]here is no mathematical threshold test."). Rather, the inquiry depends on "the facts in each investigation, the article of commerce, and the realities of the marketplace." *Certain Printing & Imaging Devices & Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 27 (Feb. 17, 2011). As such, "[t]he determination takes into account the nature of the investment and/or employment activities, the industry in question, and the complainant's relative size." *Id.*

2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same & Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-

366, Comm'n Op. at 8, 1996 WL 1056095 (Jan. 16, 1996). "The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 38 (Aug. 1, 2007).

D. Unenforceability

A patent is unenforceable on grounds of inequitable conduct if the patentee withheld material information from the PTO with intent to mislead or deceive the PTO into allowing the claims. *LaBounty Mfr. Inc. v. U.S. Int'l Trade Comm'n,* 958 F.2d 1066, 1070 (Fed. Cir. 1992). "The accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011).

Information that is withheld or misrepresented to the PTO is considered material if it satisfies a "but for" test:

> When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.

Id. at 1291-92.

To satisfy the clear and convincing evidence standard, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." *Therasense*, 649 F.3d at 1290 (citing *Star Scientific, Inc., v. R.J. Reynolds Tobacco Co.,* 537 F.3d 1357, 1366 (Fed. Cir. 2008)). When there are multiple reasonable inferences that can be drawn as reasons for withholding a reference, deceptive intent cannot be found. *Id.* at 1290-91. A finding that a patentee was negligent or grossly negligent regarding an omission or misrepresentation to the PTO does not satisfy the intent requirement. *Id.* Specific intent to deceive can be inferred from indirect or circumstantial evidence; it cannot, however, be inferred from the materiality of the omitted or misrepresented reference. *Id.*; *see also Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.,* 559 F.3d 1317, 1340 (Fed. Cir. 2009).

VI. U.S. PATENT NO. 8,479,969

A. Overview

The '969 patent, entitled "Drive Interface for Operably Coupling a Manipulatable Surgical Tool to a Robot," issued on July 9, 2013 to Frederick E. Shelton, IV. The '969 patent is assigned on its face to Ethicon Endo-Surgery, Inc. and was subsequently assigned to Ethicon LLC. 2d Am. Compl. at ¶ 40; *see also* Section III. The '969 patent generally relates to "a drive interface for coupling an articulating surgical tool to a robotic system." *Id*. at ¶ 43.

1. Asserted Claim

Ethicon is asserting claim 24, which reads as follows[4]:

24. [24.1] A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator and is configured to provide at least one rotary output motion to at least one rotatable body portion supported on the tool drive assembly, said surgical tool comprising:

[4] The parties use different numbers to refer to the same claim limitations. The undersigned has adopted Intuitive's numbering system.

[24.2] a surgical end effector comprising at least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof in response to control motions applied to said selectively movable component portion;

[24.3] an elongated shaft assembly defining a longitudinal tool axis and comprising:

[24.3.1] a distal spine portion operably coupled to said end effector;

[24.3.2] and a proximal spine portion pivotally coupled to said distal spine portion at an articulation joint to facilitate articulation of said surgical end effector about an articulation axis that is substantially transverse to said longitudinal tool axis;

[24.3.3] and at least one gear-driven portion that is in operable communication with said at least one selectively movable component portion of said surgical end effector

[24.4] and wherein said surgical tool further comprises: a tool mounting portion operably coupled to a distal end of said proximal spine portion, said tool mounting portion being configured to operably interface with the tool drive assembly when coupled thereto, said tool mounting portion comprising:

[24.4.1] a driven element rotatably supported on said tool mounting portion and configured for driving engagement with a corresponding one of the at least one rotatable body portions of the tool drive assembly to receive corresponding rotary output motions therefrom;

[24.4.2] and a transmission assembly in operable engagement with said driven element and in meshing engagement with a corresponding one of said at least one gear-driven portions to apply actuation motions thereto to cause said corresponding one of said at least one gear driven portions to apply at least one control motion to said selectively movable component.

2. Claim Construction

The undersigned has construed the following terms from claim 24 of the '969 patent:

TERM	CLAIM(S)	CLAIM CONSTRUCTION
Preamble	24	The preamble is limiting.
"distal spine portion"	24	structural member within distal portion of elongated shaft assembly
"proximal spine portion"	24	structural member within proximal portion of elongated shaft assembly
"tool mounting portion operably coupled to a proximal end of said proximal spine portion"	24	Plain and ordinary meaning

Order No. 15 at 10, 28.

B. Infringement

1. Direct Infringement

a) SureForm Staplers and Reloads

Ethicon argues that "[t]he SureForm Staplers and Reload Cartridges meet every limitation of claim 24 of the 969 Patent." CIB at 121. Intuitive disagrees and asserts that these products do not include the claimed gear-driven portion or a transmission assembly in meshing engaging with a gear-driven portion. RIB at 88. Intuitive does not dispute that the SureForm Staplers and Reload Cartridges meet the remaining limitations. RLUL at 3-4; RIB at 88.

i. Limitation 24.3.3

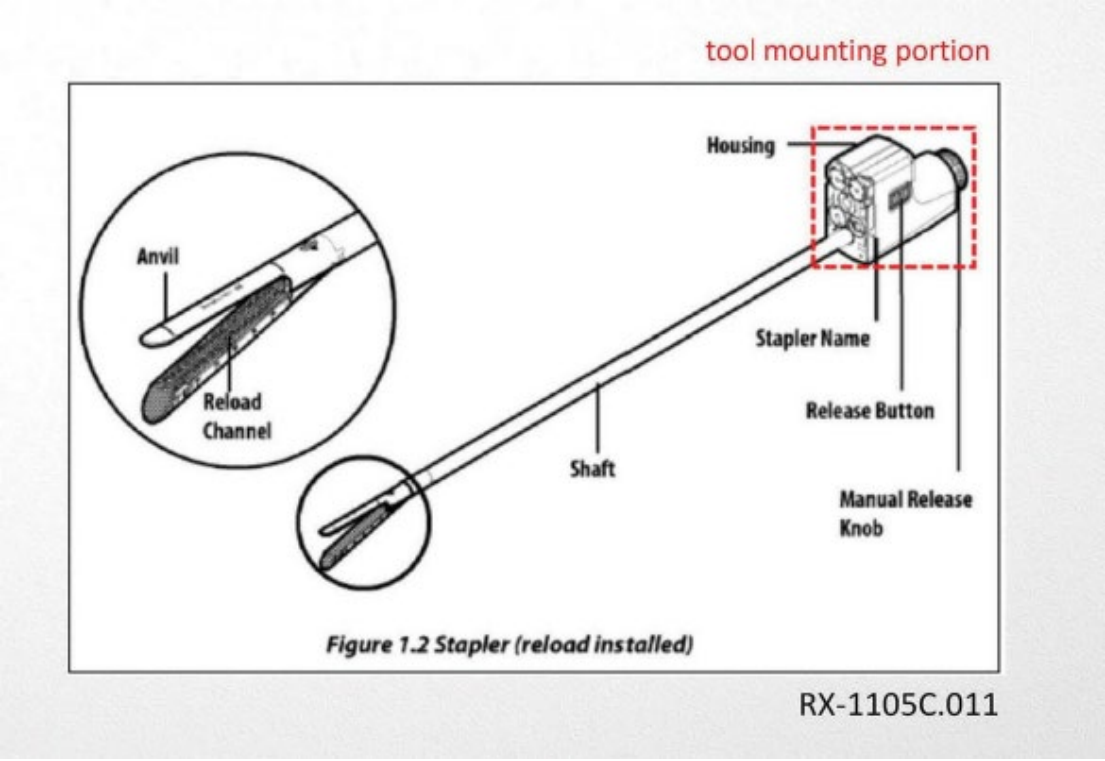
Claim 24 includes the limitation "an elongated shaft assembly defining a longitudinal tool axis and comprising . . . and at least one gear-driven portion that is in operable communication with said at least one selectively movable component portion of said surgical end effector." JX-0004, cl. 24.

Ethicon argues that "[t]he claimed gear-driven portion is a drive train that is part of the elongated shaft assembly that is gear-driven and is in operable communication with the I-beam, the reload channel and the shuttle." CIB at 127. Specifically, "[t]he I-beam drive is driven by the drive gear, and therefore, it is a gear-driven portion." *Id.* Ethicon acknowledges that the gear-driven portion of the I-beam drive resides within the tool mounting portion, but asserts that components of the elongated shaft assembly can extend into the tool mounting portion. *Id.* at 128-129. Ethicon explains that "[c]laim 24 and the 969 Patent specification clearly encompass the gear-driven portion of the elongated shaft assembly residing within the tool mounting portion (*i.e.*, a housing)." *Id.* at 129. Ethicon notes: "Indeed, the claim specifically requires that the gear-driven

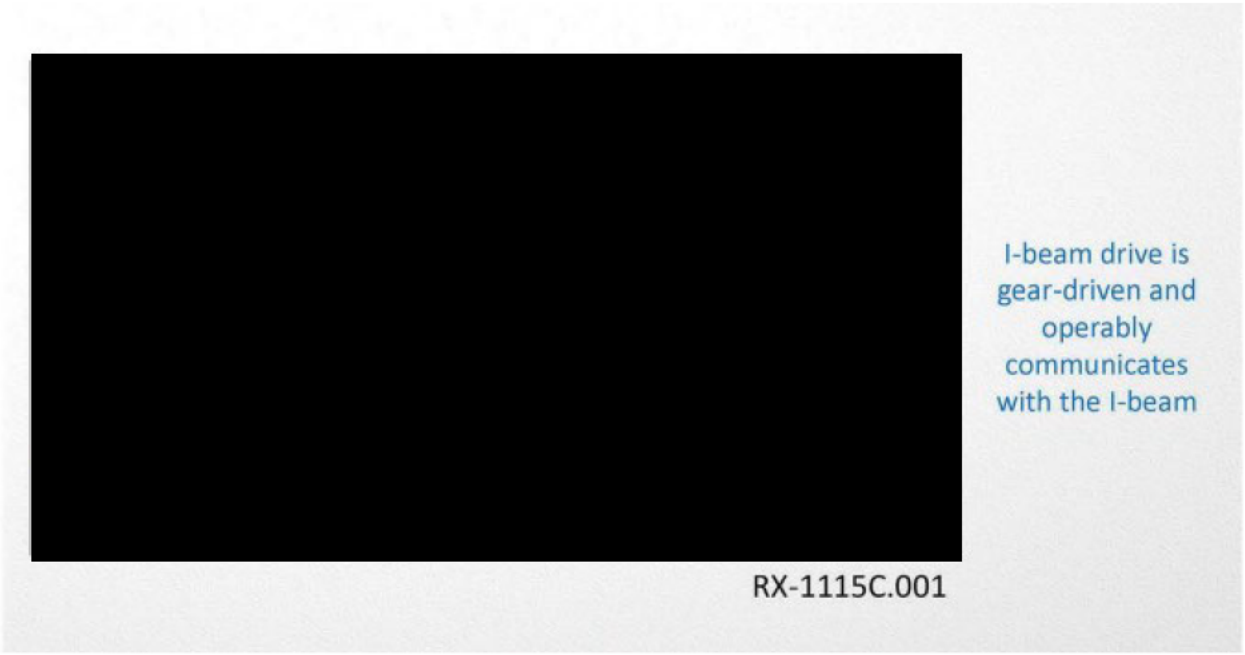
portion of the elongated shaft assembly meshes with the transmission assembly of the tool mounting portion, which by definition means the gear-driven portion interfaces with the transmission assembly within the tool mounting portion." *Id.* Thus, "the elongated shaft assembly can comprise a gear-driven portion and at the same time the gear-driven portion can reside within the tool mounting portion (in order to mesh with the transmission assembly)." *Id*

Intuitive argues that "the alleged 'gear-driven portion' of the SureForm is not a portion of the elongated shaft assembly." RIB at 97. Rather, "the gears in the SureForm . . . are part of the SureForm's transmission assembly." *Id.* Intuitive explains that "the SureForm's gears are rotatably mounted to the tool mounting portion (not the elongated shaft assembly), and all three gears are required to reduce the speed and increase the torque transmitted from the driven element to the portion of the elongated shaft assembly in operable communication with the I-beam." *Id.* at 98.

Ethicon identifies the shaft of the SureForm Staplers and Reloads as the elongated shaft assembly and the housing as the tool-mounting portion:



CX-0001C at Q/As 70-71; 104; CDX-0001C.0017 (annotation of RX-1105C.0011 by Dr. Awtar). Ethicon further identifies the I-beam drive as the gear-driven portion that is part of the shaft and explains that the combo gear is part of this gear-driven portion. CX-0001C at Q/As 93, 100. The below image is of a stapler in which the shaft cover and housing cover are removed. The I-beam drive is depicted in the blue box:



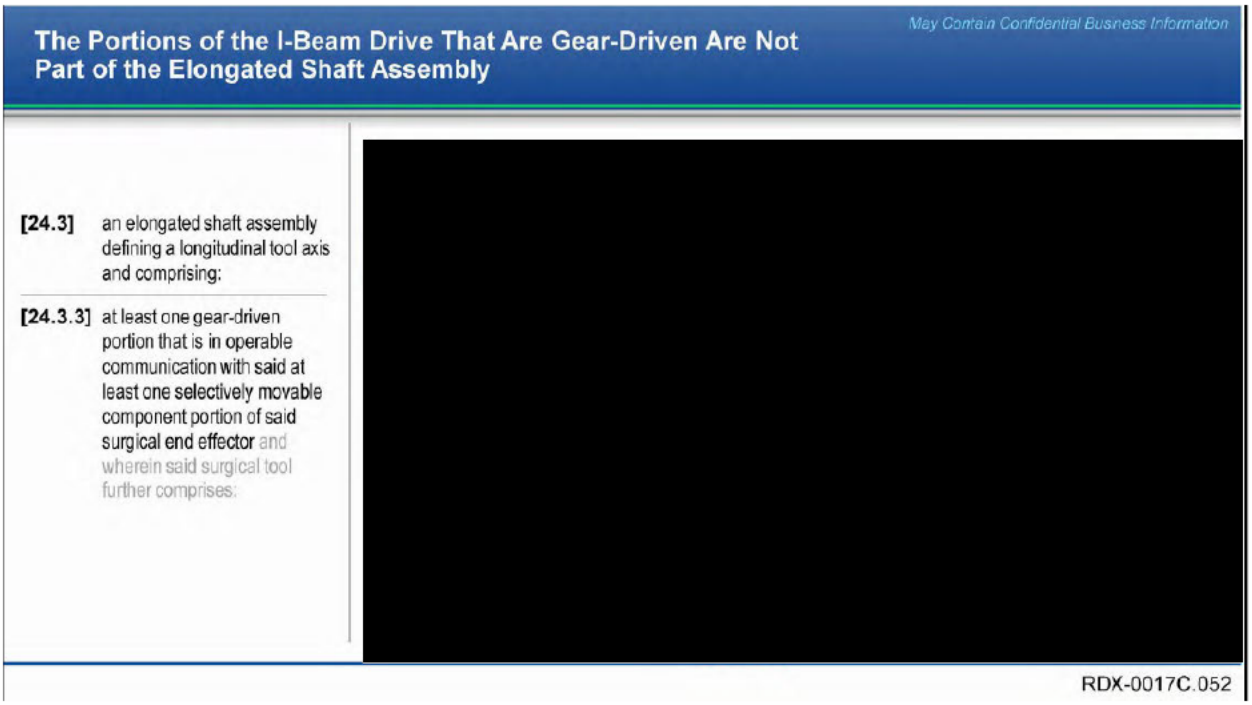
CDX-0001.0014 (annotation of RX-1115C.001 by Dr. Awtar).

Intuitive agrees that a portion of the I-beam drive is part of the elongated shaft assembly. *See* RX-0017C at Q/As 95, 114 (opining that the I-beam drive includes drive cables and noting that "[p]ortions of each drive cable extend through the elongated shaft and therefore may be considered part of the 'elongated shaft assembly"). Intuitive further agrees that the '969 patent contemplates that the elongated shaft assembly can extend into the housing. *See* RRB at 51; *see also* Vaitekunas, Tr. at 668:14-669:8. Intuitive is not, therefore, arguing that the I-beam drive cannot be the claimed gear-driven portion simply because part of it resides in the housing. Rather, it asserts that the part of the I-beam drive that resides within the housing is not part of the elongated

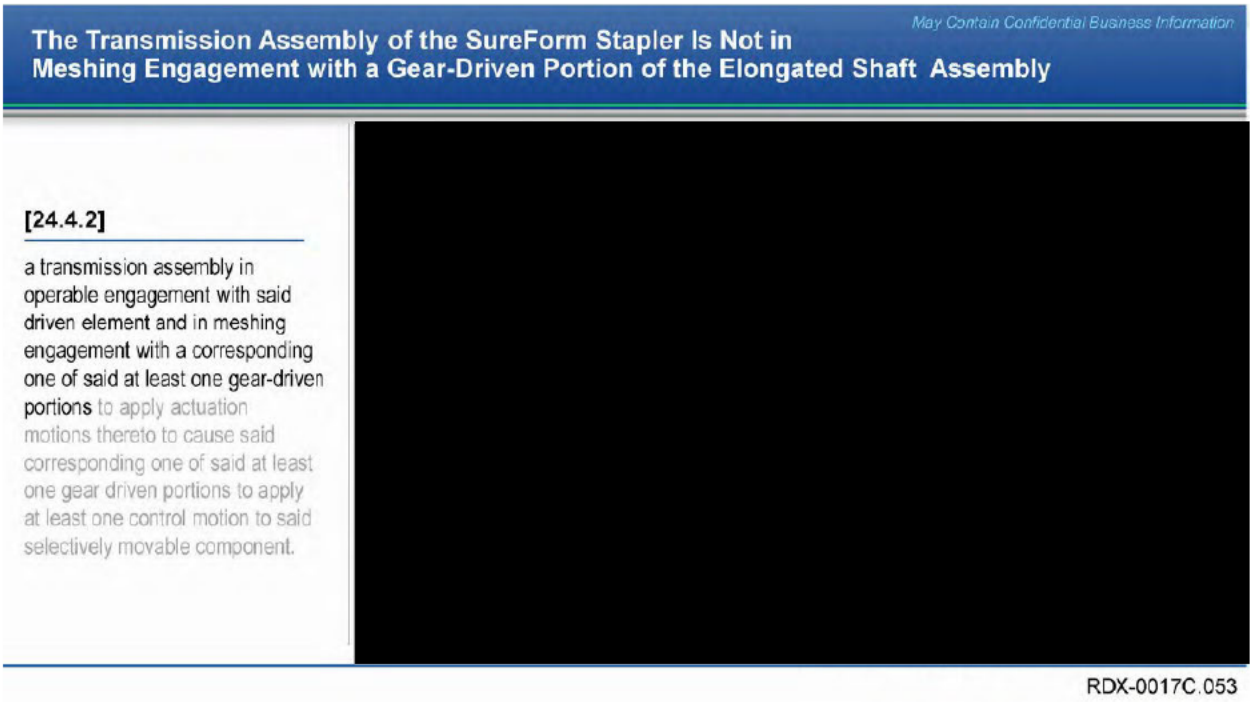
shaft assembly. As Intuitive explains: "[T]he fact that the elongated shaft assembly can extend into the housing does not make everything in the housing part of the elongated shaft assembly." RRB at 51.

The undersigned agrees with Intuitive that Ethicon has failed to show that the portion of the I-beam drive that Ethicon identifies as the "gear-driven portion" is part of the elongated shaft assembly. Dr. Awtar testifies that the gear-driven portion of the I-beam drive includes "a combo gear." CX-0001C at Q/A 100. Dr. Vaitekunas explains, however, that the combo gear is not "mounted to or part of the elongated shaft assembly, as required by claim 24."[5] RX-0017C at Q/A 122. The evidence supports Dr. Vaitekunas' opinion. For example, RDX-0017C.0052 shows that the combo gear is not part of the shaft:

[5] Dr. Vaitekunas also testifies that the bevel gear is not part of the elongated shaft assembly. RX-0017C at Q/A 122. Although the bevel gear is not mentioned in Dr. Awtar's witness statement, he acknowledged during cross-examination that he considered the bevel gear to be part of the elongated shaft assembly. Awtar, Tr. at 159:4-7. The undersigned finds that the bevel gear is not part of the elongated shaft assembly for the same reasons as those for the combo gear.



RDX-0017C.0052 (annotated version of RPX-1792C). Likewise, RDX-0017C.053 shows the same:



RDX-0017C.0053 (annotated versions of RX-01115C.002 and RPX-1792C).

Dr. Awtar does not cite to any evidence which would allow one to conclude otherwise. In testifying that the I-beam drive includes a gear-driven portion that is part of the shaft, Dr. Awtar offers only the following testimony:

> In the SureForm Stapler, the I-beam drive extends into the housing, but it is still part of the elongate[d] shaft assembly. And as I explain later with respect to the 'transmission assembly' limitation, the I-beam drive includes a combo gear that is in meshing engagement with a transmission assembly of the tool mounting portion.

CX-0001C at Q/A 100. This testimony is conclusory and does not explain how the combo gear is part of the shaft. Thus, the evidence does not support a finding that the portion of the I-beam drive that includes the combo gear qualifies as part of the "elongated shaft assembly" of the SureForm Staplers and Reloads.

Because the portion of the I-beam drive identified by Ethicon as the "gear-driven portion" is not part of the elongated shaft assembly, the undersigned finds that the SureForm Staplers and Reloads do not meet this limitation.

ii. Limitation 24.4.2

Claim 24 includes the limitation "and a transmission assembly in operable engagement with said driven element and in meshing engagement with a corresponding one of said at least one gear-driven portions to apply actuation motions thereto to cause said corresponding one of said at least one gear driven portions to apply at least one control motion to said selectively movable component." JX-0004, cl. 24.

Ethicon argues that the transmission assembly includes a shaft and a drive spur gear. CIB at 132. Ethicon asserts that "Dr. Vaitekunas's non-infringement position with respect to this limitation hinges on his incorrect position . . . that the SureForm Stapler does not have an elongate shaft assembly comprising a gear-driven portion." *Id.* at 133. Specifically, "Dr. Vaitekunas has arbitrarily determined that the 'combo gear' of the I-beam drive is not part of the elongate shaft

assembly, and on that basis, argues that there is no gear-driven portion of a shaft assembly in meshing engagement with a transmission assembly." *Id.* Ethicon also argues that Intuitive's position that the transmission assembly requires multiple gears is both meritless and waived. CRB at 60-64.

Intuitive argues that the alleged "transmission assembly" is not in meshing engagement with the gear-driven portion. RIB at 99. Intuitive explains that the combo gear "is part of the SureForm's transmission assembly - not part of the SureForm's elongated shaft assembly." *Id.* Intuitive also argues that the transmission assembly must include more than one gear. *Id.* Intuitive notes that "[t]he SureForm's drive spur gear alone cannot generate" the forces necessary to cut and staple tissue. *Id.* at 99-100. "Thus, the single gear alleged to be the 'transmission assembly' is not, in fact, the SureForm's transmission assembly. It is only part of the transmission assembly." *Id.* at 100.

As noted above, the undersigned found that the combo gear of the SureForm Staplers and Reload Cartridges is not part of the "elongated shaft assembly" and thus cannot serve as the "gear-driven portion." As such, the undersigned cannot find that the transmission assembly is in meshing engagement with at least one gear-driven portion.

Accordingly, the undersigned finds that the SureForm Staplers and Reloads do not meet this limitation.[6]

iii. Conclusion

Accordingly, for the reasons set forth above, the undersigned finds that the SureForm Staplers and Reloads do not infringe claim 24 of the '969 patent.

[6] The undersigned also agrees that Intuitive's argument that the transmission assembly requires multiple gears is waived per Ground Rule 9.2.

b) EndoWrist Xi Staplers and Cartridges

Ethicon argues that "[t]he EndoWrist Xi Staplers and Reload Cartridges meet every limitation of claim 24 of the 969 Patent." CIB at 136. Intuitive disagrees and asserts that these products do not include either a distal spine portion or a proximal spine portion. RIB at 100. Intuitive does not dispute that the EndoWrist Xi Staplers and Reload Cartridges meet the remaining limitations. RLUL at 3-4; RIB at 100.

i. Limitations 24.3.1 and 24.3.2

Claim 24 includes the limitation: "a distal spine portion operably coupled to said end effector and a proximal spine portion pivotally coupled to said distal spine portion at an articulation joint to facilitate articulation of said surgical end effector about an articulation axis that is substantially transverse to said longitudinal tool axis." JX-0004, cl. 24.

Ethicon identifies the pivot plate as the distal portion and the pivot tube as the proximal portion. CIB at 138. Ethicon explains that the pivot plate is on the distal side of the articulation joint and the pivot tube is on the proximal side of the articulation joint. *Id.* at 140. As such, the pivot plate and pivot tube are "within" the elongated shaft assembly. *Id.* Ethicon also asserts that the pivot plate and pivot tube are interior components "because they are covered by a sheath." *Id.* at 142.; *see also* CRB at 67.[7] According to Ethicon, Dr. Vaitekunas' opinion that the sheath is not part of the instrument "is plainly inconsistent with his previous testimony concerning invalidity, where he argued that covering an articulation joint with a sheath would result in interior components of a shaft assembly." CIB at 143.

[7] Ethicon also argues that the "distal spine portion is deemed to be part of the claimed 'elongated shaft assembly' even though it is also coupled to the end effector." CIB at 139; *see also id.* at 140-142; CRB at 66, 68-69. Intuitive does not, however, assert a noninfringement position on this ground. *See* RRB at 53. Rather, it argues that the distal spine portion is not *within* the elongated shaft assembly. *Id.*

Intuitive asserts that the distal spine portion and proximal spine portion "must be interior to the elongated shaft assembly." RIB at 100. Intuitive explains that the Xi EndoWrist Staplers do not meet this requirement because they do not include a structural member that is within either a distal or proximal portion of the elongated shaft assembly. *Id.* at 101. Instead, the pivot plate and pivot tube are on the distal and proximal sides of the articulation joints, respectively. RRB at 52. Intuitive notes that "rather than applying the CALJ's construction of 'distal spine portion,' Ethicon has adopted its own claim construction to require a 'structural member ~~**within**~~ **that is part of** distal portion of the elongated shaft assembly." RIB at 106 (emphasis in original). Additionally, Intuitive argues that "Ethicon's alternative infringement theory that relies on a sheath accessory . . . runs afoul of the CALJ's construction" and "is completely unsupported" by the evidence. *Id.* at 107.

Intuitive does not dispute that the pivot plate is "operably coupled to the end effector" and the pivot tube is "pivotally coupled to the [pivot plate] at an articulation joint to facilitate articulation of the surgical end effector about an articulation axis that is substantially transverse to said longitudinal tool axis." RLUL at 3-4. Instead, Intuitive disputes that the pivot plate and pivot tube qualify as a distal spine portion and proximal spine portion, respectively.

In the *Markman* Order, the undersigned adopted the parties' agreed constructions of these terms: "Distal spine portion" was construed as "structural member within distal portion of elongated shaft assembly" and "proximal spine portion" was construed as "structural member within proximal portion of elongated shaft assembly." Order 15 at 10. The parties' dispute centers around the meaning of the word "within" as used in these constructions.

The word "within" is not used in the claim itself, but is instead used only by the parties in the agreed-upon constructions. The undersigned does not see a reason to depart from the plain and ordinary meaning of this word, especially since Ethicon previously agreed to this construction and

did not assert that "within" had a specialized meaning. The undersigned finds that the plain and ordinary meaning of "within" is "interior to." RX-0017C at Q/A 57[8]. This construction is also consistent with the '969 patent, which depicts the distal spine portion as interior to the elongated shaft in each of the relevant embodiments. JX-0004 at 27:28-38, 76:65-68, 78:37-39, Fig. 32, Fig. 135; RX-0001C at Q/A 57; Vaitekunas, Tr. at 705:22-706:1.

Ethicon has not established that the pivot plate and pivot tube in the Xi Endo Wrist Stapler are "interior to" the elongated shaft assembly. With respect to this limitation, Ethicon argues:

> In the EndoWrist Xi stapler, the pivot tube is on the proximal side of the articulation joint meaning it is within the proximal portion of the elongated shaft assembly. The pivot plate is on the distal side of the articulation joint meaning it is within the distal portion of the elongated shaft assembly.

CIB at 140.[9] In other words, Ethicon argues that the pivot plate and pivot tube are on the sides of the articulation joint. Being on the sides of the articulation joint does not qualify as being "interior to" the elongated shaft assembly.

Ethicon also asserts that the pivot plate and pivot tube "are both interior components of the shaft assembly at least because they are covered by a sheath." CIB at 142. Ethicon does not cite to any expert testimony in support of this argument, nor does its expert offer this opinion in his witness statement. *Id.*; *see also* CRB at 67-68; *see generally* CX-0001C. Instead, Ethicon cites to the testimony of Intuitive's expert, claiming that Dr. Vaitekunas contends that the "addition of a sheath covering an articulation joint would result in interior components of shaft assembly." CIB at 142 (citing RX-0001C at Q/A 274). Dr. Vaitekunas makes no such statement. Rather, he testifies that a prior art device that includes a sheath would *not* be within the elongated shaft assembly. RX-

[8] Dr. Awtar did not offer his own definition of the word "within." *See generally* CX-0001.
[9] Ethicon also cites to Dr. Awtar's witness statement. This testimony is identical to the cited potion of Ethicon's brief. CX-0001C at Q/A 139.

0001C at Q/A 274.[10] Thus, the only evidence in the record establishes that the inclusion of a sheath does not result in the pivot plate and pivot tube meeting the definition of "distal spine portion" and "proximal spine portion." Therefore, the undersigned finds that Ethicon has not established that the EndoWrist Xi Staplers and Reload Cartridges meet these limitations.

ii. Conclusion

Accordingly, for the reasons set forth above, the undersigned finds that the EndoWrist Xi Staplers do not infringe claim 24 of the '969 patent.

2. Indirect Infringement

Ethicon alleges that "Intuitive indirectly infringes claim 24 of the 969 Patent by committing acts of induced and contributory infringement of claim 24 of the 969 Patent with respect to the SureForm Staplers and Reloads and the EndoWrist Xi Staplers and Reloads." CIB at 146. However, the undersigned has found hereinabove that neither the SureForm Staplers and Reloads nor the EndoWrist Xi Staplers and Reloads directly infringe claim 24. Ethicon therefore cannot, as a matter of law, prove indirect infringement. *See Novartis Pharm. Corp. v. Eon Labs Mfg. Inc.,* 363 F.3d 1306, 1308 (Fed. Cir. 2004) ("When indirect infringement is at issue, it is well settled that there can be no inducement or contributory infringement absent an underlying direct infringement.").

C. Technical Prong of the Domestic Industry Requirement

Ethicon asserts that its "[redacted] and GST/ECR Reloads practice claim 24." CIB at 119. Intuitive does not dispute that the technical prong of the domestic industry is met. RLUL at 3-4. Additionally, the evidence shows that the [redacted] and GST/ECR

[10] Dr. Vaitekunas acknowledged that, if the undersigned found that the distal and proximal portions need not be "interior to" the elongated shaft assembly, the inclusion of a sheath would allow the limitation to be met. RX-0001C at Q/A 274. As noted above, the undersigned did not reach this conclusion.

Reloads practice claim 24. CX-0001C at Q/As 175-207. Accordingly, the undersigned finds that Ethicon has satisfied the technical prong of the domestic industry requirement for the '969 patent.

D. Validity

Intuitive argues that claim 24 of the '969 patent is invalid due to either anticipation or obviousness. RIB at 109. Intuitive also argues that claim 24 fails to claim the subject matter which the applicants regarded as their invention. *Id.*

1. Anticipation

Intuitive asserts that "Intuitive's da Vinci Si System with the EndoWrist One Vessel Sealer anticipates claim 24 under Ethicon's theory of infringement."[11] RIB at 109; *see also* RX-0001C at Q/A 265 (opining that the da Vinci System with the EndoWrist One Vessel Sealer includes each limitation of claim 24 "[o]nly under Ethicon's theory of infringement"). As explained above, however, the undersigned did not adopt Ethicon's theory of infringement. As such, the undersigned finds that the da Vinci Si System with the EndoWrist One Vessel Sealer does not anticipate claim 24 of the '969 patent.

2. Obviousness

Intuitive argues that claim 24 is rendered obvious by: "(1) the da Vinci Si System with the EndoWrist One Vessel Sealer alone or in view of U.S. Patent No. 6,817,974 ('Cooper') under Ethicon's theory of infringement; (2) U.S. Patent No. 8,545,515 ('Prisco') in view of the da Vinci Si System under Ethicon's theory of infringement; and (3) Power Medical Interventions, Inc.'s i60 Stapler ('the PMI i60 Stapler') in view of the da Vinci Si System."[12] RIB at 109.

[11] Intuitive contends that the da Vinci Si System with the EndoWrist One Vessel Sealer is prior art under pre-AIA 35 U.S.C. § 102(g)(2). RIB at 110.

[12] Intuitive contends that Prisco, which was filed on November 13, 2009, is prior art under pre-AIA 35 U.S.C. § 102(e); Cooper, which was filed on November 16, 2004, is prior art under pre-AIA 35 U.S.C. § 102(b); and the PMI i60 System received 510(k) FDA marketing clearance in 2007 and was sold more than one year before the earliest alleged priority date of the '969 patent and is prior art under pre-AIA 35 U.S.C. § 102(b). RIB at 111, 113, 116. Ethicon does not dispute this. *See* CIB at 107-119; CRB at 44-52.

a) Da Vinci Alone or with Cooper

Intuitive asserts that "[i]t would have been obvious in view of the da Vinci Si System with the EndoWrist One Vessel sealer alone or in view of Cooper to cover the EndoWrist One Vessel Sealer's multi-disk wrist with a sheath." RIB at 110. Intuitive further argues that "the resulting instrument would include the claimed 'distal spine portion' and 'proximal spine portion' under Ethicon's alternative theory of infringement." *Id.* at 111. As noted above, the undersigned did not adopt Ethicon's theory of infringement and instead found that the inclusion of a sheath does not result in the system meeting the distal and proximal spine portions of claim 24. As such, the undersigned finds that the da Vinci Si System with the EndoWrist One Vessel Sealer alone or in view of Cooper does not render obvious claim 24 of the '969 patent.

b) Da Vinci with Prisco

Intuitive argues that "Prisco in view of the da Vinci Si System renders claim 24 of the '969 patent obvious." RIB at 111. Intuitive notes, however, that its invalidity theory mirrors Ethicon's theory of infringement. *See* RIB at 109 (asserting that claim 24 is rendered obvious by Prisco in view of the da Vinci Si System "under Ethicon's theory of infringement"); *see also id.* at 113 ("Ethicon does not dispute that the proposed combination includes every limitation of claim 24 under its theory of infringement."). As explained above, however, the undersigned did not adopt Ethicon's theory of infringement. As such, the undersigned finds that the da Vinci Si System with the Prisco does not render obvious claim 24 of the '969 patent.

c) PMI i60 Stapler

Intuitive argues that "[t]he PMI i60 System in view of the da Vinci Si System renders claim 24 of the '969 patent obvious." RIB at 116. Ethicon does not dispute that the PMI i60 Stapler in view of the da Vinci Si System discloses each and every limitation of claim 24. *See* CLUL at 3.

Rather, Ethicon argues that a person of ordinary skill in the art would not be motivated to combine the references and would not have a reasonable expectation of success. CIB at 163-169.

i. Motivation to Combine

Intuitive asserts that "[i]t would have been obvious to modify the PMI i60 Stapler so that it could be used with the da Vinci Si robotic system." RIB at 117. Intuitive explains: "In fact, in September 2008 (approximately three years before the alleged priority date of the '969 patent), Intuitive entered into a joint development agreement with PMI specifically for the purpose of combining the PMI i60 stapler with the da Vinci Si System; the Si EndoWrist 45 Stapler was the direct product of that joint development effort." *Id.* Intuitive asserts, therefore, that "[i]t cannot be reasonably disputed that a POSITA would have been motivated to combine the PMI i60 Stapler with the da Vinci Si System because the POSITAs at Intuitive did just that." *Id.* at 118.

Ethicon asserts that "[a] POSITA would not have been motivated to combine the PMI i60 Stapler and the commercial da Vinci Si System because the PMI i60 Stapler could only articulate in one plane and lacked any shaft roll capability." CIB at 163. Ethicon further asserts that "disclosures concerning the PMI i60 Stapler and Whitman 692 . . . demonstrate that a POSITA would not have been motivated to combine the PMI i60 Stapler with the da Vinci Si Surgical System." *Id.* at 164. Additionally, Ethicon notes that the PMI i60 Stapler was the subject of a voluntary FDA recall in 2009 and that adapting the PMI i60 Stapler for use with the da Vinci Si System would involve substantial engineering challenges. *Id.* at 165. Finally, Ethicon argues that Intuitive's licensing agreement with PMI i60 does not support a motivation to combine. *Id.* at 166.

The evidence shows that a person of ordinary skill in the art would have been motivated to combine the PMI i60 Stapler with the da Vinci Si System to achieve the claimed invention. Three years before the priority date of the '969 patent, Intuitive and PMI entered into an agreement to

combine the PMI i60 Stapler with the da Vinci Si System. RX-1069C; RX-1070C; CX-0985C; RX-0009C at Q/As 19-53; RX-0011C at Q/As 34-35, 43-44, 109-110, RX-0001C at Q/A 351; Vaitekunas, Tr. at 351:16-23; DeSantis, Tr. at 227:15-18, 235:22-236:8, 238:12-24, 244:10-19, 278:14-279:17. The fact that persons of ordinary skill in the art were actually motivated to combine the references at issue is highly persuasive evidence of a motivation to combine. Even Dr. Awtar acknowledges, that the fact that Intuitive obtained a license to use PMI's stapling technology in order to develop a stapler for the da Vinci Si System "is a clear indication of the intent to – to combine the two technologies and bring a robotic version of staplers to the market." Awtar, Tr. at 599:17-23.

Other evidence confirms a motivation to combine. First, "[i]t was well known in the art that robotic systems, like the da Vinci Si system, provided increased dexterity, and more intuitive control compared to handheld laparoscopic instruments like the PMI i60 Stapler." RX-0001C at 351; *see also id.* at Q/As 196-201, 297-299; RX-1654 at Q/As 35-41; RX-0231 at 2:37-40; JX-0157 at 2:42-45; RX-0207 at 2:50-53; RX-0050 at [0003], [0043]. The '969 patent itself acknowledges that "[o]ver 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." JX-0004 at 23:6-9; *see also id.* at 23:9-29. Additionally, in a paper co-authored by Dr. Awtar, he acknowledges that robotic systems offer "several outstanding features, including high dexterity . . . , a highly intuitive input/output motion mapping, variable motion scaling and unprecedented hand tremor reduction." RX-0867; Awtar, Tr. at 590:10-14, 593:5-17.

Second, a "person of ordinary skill in the art would have understood that Intuitive contemplated use of its robotic surgical systems with any suitable end effector, include[ing] a

surgical stapler." RX-0001C at Q/A 351; *see also* JX-0157 at 2:18-21; JX-0154 at 6:22-28; RX-0231 at 7:6-25. "Thus, a person of ordinary skill in the art would have been motivated to identify instruments, like the PMI i60 Stapler, that could be modified for use with the da Vinci Si system to increase the number of uses of the da Vinci Si System." RX-0001C at Q/A 351. It was also well-known in the art to modify handheld surgical instruments for use with a robotic system. *Id.*

Additionally, the PMI i60 Stapler and the da Vinci Si Systems are in the same technical field and concern aspects of surgical instrument systems. RX-0001C at Q/A 351. "The fact that the references are directed to the same field of art helps to support [a] finding that a person of ordinary skill in the art would have been motivated to combine their teachings." *LG Elecs., Inc. v. Conversant Wireless Licensing S.A.R.L.*, 759 Fed. App'x 917, 2019 WL 343152, *4-5 (Fed. Cir. 2019).

Ethicon presents several arguments for why a person of ordinary skill in the art would lack motivation, despite this evidence. First, it argues that the undersigned should ignore the agreement between Intuitive and PMI, asserting that Intuitive "ultimately rejected [the combination] because the PMI i60 Stapler was unsuitable due to its limited movement, such as the lack of shaft roll." CIB at 166. As Intuitive notes, however, "numerous aspects of PMI's stapler technology were, in fact, incorporated into Intuitive's Si EndoWrist Stapler 45, including: a printed circuit board chip in the reload cartridge, leadscrew-driven clamping and firing mechanisms, and a motor to drive the leadscrews." RRB at 74 (citing Awtar, Tr. at 607:20-609:14; RX-0009C at Q/As 51-53, RX-0011C at Q/A 110; DeSantis, Tr. at 240:9-22, 244:10-19, 278:20-279:17). Additionally, the fact that the combination did not work out exactly as planned does not mean that one of skill would have lacked motivation to try the combination. Thus, the undersigned does not agree with Ethicon that it should ignore the agreement between Intuitive and PMI when considering motivation.

Next, Ethicon argues that the fact that "Intuitive's management decided to devote significant resources to this project does not reflect the motivations of a POSITA." CIB at 166. As Intuitive recognizes, however, "Ethicon's argument is based solely on Dr. Awtar's vague testimony about how, in general, business executives in companies supposedly make strategic decisions regarding technology transfer. The business practices of business executives in other companies has no bearing on what Intuitive and its POSITAs did here." RRB at 74.

Finally, Ethicon makes several arguments as to why a person of ordinary skill in the art would not, in fact, combine the references. Given that the evidence shows that persons of ordinary skill in the art were actually motivated to combine the references, the undersigned is not persuaded by any of these arguments grounded in hindsight reasoning.[13] Additionally, Dr. Vaitekunas' testimony shows that these concerns are unfounded. RX-0001C at Q/A 352.

For the above reasons, the undersigned finds that a person of ordinary skill in the art would have been motivated to combine the PMI i60 System with the da Vinci Si System.

ii. Reasonable Expectation of Success

Intuitive argues that "[a] POSITA would have reasonably expected to succeed in combining the PMI i60 Stapler with the da Vinci Si System." RIB at 120. "A POSITA would have understood that the modification of the PMI i60 Stapler for use with the da Vinci Si System would have been merely the application of a known technique (modifying a handheld surgical instrument, like the PMI i60 Stapler) for use with a known system (the da Vinci Si System) ready for improvement." *Id.* "And the result of the combination, which would have been entirely predictable, would not significantly alter or hinder the functions performed by the PMI i60 Stapler and the da Vinci Si System." *Id.*

[13] For example, a person of ordinary skill in the art would not have known about the 2009 voluntary FDA recall when considering whether to combine the references in 2008, as was the case with Intuitive and PMI.

Ethicon argues that a person of ordinary skill in the art would not have a reasonable expectation of success because "the clamping and firing requirements of the PMI i60 Stapler are not compatible with the limited capabilities of the rotatable bodies on the instrument arm of the da Vinci Si Surgical System." CIB at 167. Ethicon asserts that "Intuitive's counterarguments regarding this issue are meritless." *Id.*

The evidence shows that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the PMI i60 System and the da Vinci Si System. First, as noted above, Intuitive did, in fact, combine the PMI i60 Stapler with the da Vinci Si System and succeeded in doing so. RX-0009C at Q/As 19-23, 51-53; RX-0011C at Q/As 34-44, 108-110, Vaitekunas, Tr. at 351:16-23. Additionally, Dr. Vaitekunas testified at length as to how the components are complementary and readily adapted to work together. RX-0001C at Q/A 352.

The evidence also shows that a person of ordinary skill in the art would have used well-known solutions, such as the ratcheting mechanism, to drive the leadscrews of the modified PMI i60 Stapler. While Ethicon asserts that "there is no evidence or prior art that discloses a mechanism that accomplishes" the desired result, the evidence shows that such systems did exist. CIB at 167. For example, Computer Motion, Inc. recognized that a robotic surgical instrument could be modified to include a ratcheting mechanism to achieve greater stroke. RX-0005C at Q/As 40-57; RX-1074C.0002; *see also* RX-0001C at Q/ 352. Ethicon's own prior art confirms that ratcheting mechanisms could be implemented in surgical staplers with manually operated triggers which are limited to less than one rotation and apply limited force. JX-0003 at 2:27-31; RX-1638 at 14:25-42, 14:57-67, Fig. 46; *see also* RX-0001C at Q/A 352.

Additionally, the evidence shows that the use of the da Vinci Si System's motor pack would eliminate any need to modify the PMI i60 Stapler's drive train for use with the rotatable bodies on

the da Vinci Si System's robotic arm. RX-0001C at Q/A 300. The use of a motor pack was known in the art. *Id.*; *see also* RX-0231 at 23:31-45; CX-1797 at [0084]-[0093], Figs. 11a-14; CX-1787 at [0168]-[0177], Figs. 27a-30; RX-0005C at Q/As 14, 20, 25, 28-31. Further, using a motor pack would not constitute a "significant alteration," as Ethicon alleges. Intuitive's own design history demonstrates that a motor pack could be developed and used in the da Vinci Si System. RX-0009C at Q/As 72-77, 87, 97, 100, 107-11, 118-119, 121-124; RX-1012C.0054, .0062, .0063; RX-1098C.0046-.0048, .0053-.0063.

Accordingly, the undersigned finds that a person of ordinary skill in the art would have had a reasonable expectation of success at combining the PMI i60 Stapler with the da Vinci Si System.

iii. Conclusion

For the reasons set forth above, the undersigned finds that the '969 patent is invalid as obvious due to the combination of the PMI i60 Stapler with the da Vinci Si System.[14]

3. 35 U.S.C. § 112, ¶ 2

Claim 24 of the '969 patent issued with the language "tool mounting portion operably coupled to a **distal** end of said proximal spine portion." JX-0004, cl. 24 (emphasis added). Ethicon subsequently filed a Request for a Certificate of Correction to "delete 'distal' and insert . . . proximal." JX-0009.19036-.19037. The PTO granted this request. *Id.* at .19061. In a case pending in the District of Delaware, the court found that the Certificate of Correction was invalid. RX-1541. Ethicon waived its right to appeal that decision. RX-1487. Likewise, in this Investigation, the undersigned found the certificate invalid and that the original claim language should apply. Order No. 15 at 28.

[14] The parties do not discuss secondary considerations with respect to the '969 patent.

Intuitive argues that claim 24 is invalid under the first prong of 35 U.S.C. § 112, ¶ 2. RIB at 126. Intuitive explains that "[c]laim 24 is invalid because the original, as-issued (and currently asserted) claim language . . . does not claim the subject matter which the inventor regarded as his invention." *Id.* Intuitive asserts that "there is a direct contradiction between the claims and the intrinsic evidence." *Id*. Intuitive further asserts that "Ethicon in this case clearly recognized that claim 24 does not say what it should have." *Id.*

Ethicon argues that Intuitive's position "is clearly wrong." CIB at 169. Ethicon asserts that "[e]nablement and written description support for" claim 24 as written can be found in the specification. *Id*. Ethicon further asserts that "Frederick Shelton, the sole inventor of the 969 Patent, testified that both the original claim language and corrected claim language is described in the specification." *Id.* Ethicon also asserts that "Intuitive is judicially estopped from making a § 112 argument concerning the original claim language in this Investigation after prevailing in invalidating the corrected claim language in district court." *Id.*

Section 112, paragraph 2 requires that a claim "must set forth what the applicant regards as his invention." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002) (internal quotations and citations omitted). "Where it would be apparent to one of skill in the art, based on the specification, that the invention set forth in a claim is not what the patentee regarded as his invention" the claim is invalid under § 112, paragraph 2. *Id.* at 1349.

Intuitive has not met its burden of proving that claim 24 is invalid. The only evidence that Intuitive introduces to demonstrate that the invention set forth in claim 24 is not what the patentee regarded as his invention is the fact that Ethicon previously argued that claim 24 contained a mistake. This is not enough evidence for the undersigned to conclusively find that the patentee regarded his invention in the same manner. Indeed, the evidence from the record contradicts this

belief. JX-0242C at 226:11-227:5 (testimony from the sole inventor that both the original and corrected claim language is supported by the specification and that he prefers the original claim language). As such, the undersigned cannot conclude that claim 24 is invalid based on § 112, ¶ 2.

E. Unenforceability

Intuitive argues that "[c]laim 24 of the '969 patent is unenforceable because it contains an error in a material limitation that is not clear from the face of the patent." RIB at 133. According to Intuitive, "[w]hen . . . a claim issues that omits a material limitation, and such omission is not evident on the face of the patent, the patentee cannot assert that claim until it has been corrected by the PTO." *Id.* (quoting *H-W Technology, L.C. v. Overstock.com*, 758 F.3d 1329, 1335 (Fed. Cir. 2014)).

Ethicon responds that "[t]he original language of claim 24 is plainly enforceable." CIB at 173. Ethicon explains: "Indeed, the Federal Circuit has expressly allowed for infringement claims to proceed on original claim language after invalidation of a certificate of correction." *Id.* Finally, Ethicon asserts that Intuitive is judicially estopped from asserting that claim 24 is unenforceable. *Id.* at 173-174.[15]

Intuitive's argument is premised on the condition that the patent, as issued, contains an error. The evidence does not support such a finding. Instead, the patent specification supports both the original and "corrected" versions. *See* CX-1863.0007-.8; *see also id.* at CX-1863.0006 (opinion in District of Delaware noting that "the presence of an error is subject to reasonable debate"). Even Intuitive acknowledges this fact, arguing that "[s]omeone looking at this patent would find both in

[15] Ethicon also asserts that this argument was raised for the first time in Intuitive's pre-trial brief. CIB at 173-174. Ethicon does not, however, support this allegation with any citations to the invalidity contentions. As such, the undersigned is unable to confirm that Intuitive had not previously made this argument.

other claims and in the specification support for the language as originally issued." CX-3279.0022 at 22:18-20. As such, the undersigned cannot find that claim 24 is unenforceable based on an error.

VII. U.S. PATENT NO. 9,113,874

A. Overview

The '874 patent, entitled "Surgical Instrument System," issued on August 25, 2015 to Frederick E. Shelton, IV, James R. Giordano, and Jeffrey S. Swayze. The '874 patent is assigned on its face to Ethicon Endo-Surgery, Inc. and was subsequently assigned to Ethicon LLC. 2d Am. Compl. at ¶ 45; *see also* Section III. The '874 patent generally relates to "surgical instruments, and more particularly to minimally invasive surgical instruments capable of recording various conditions of the instrument." JX-0005 at 2:45-48.

1. Asserted Claims

Ethicon asserts that its DI product practices claim 9, and is asserting that Intuitive infringes claim 19. These claims read as follows[16]:

9. [9.1] A surgical instrument comprising:

[9.2] a surgical end effector comprising:

[9.2.1] a first jaw;

[9.2.2] a second jar, wherein said first and second jaws are unsupported relative to each other such that one of said first and second jaws is movable between open and closed positions relative to the other of said first and second jaws in response to opening and closing motions applied thereto; and

[9.2.3] a driver element supported for axial travel through the surgical end effector in response to firing motions applied thereto

[9.3] and wherein said surgical instrument further comprises: a motor powered firing element configured to apply said firing motions to said driver element;

[16] The parties use different numbers to refer to the same claim limitations. The undersigned has adopted Intuitive's numbering system.

[9.4] a remotely user-controlled console electrically coupled to said surgical instrument; and

[9.5] a reciprocatable closure element configured to apply said opening and closing motions to said one of said first and second jaws.

19. [19.1] A surgical instrument system, comprising:

[19.2] an end effector, comprising:

[19.2.1] an anvil;

[19.2.2] a cartridge including staples that can be ejected out of said cartridge with a distal actuation of a firing member:

[19.2.3] and at least one sensor;
[19.3] an assembly, comprising:

[19.3.1] an elongate shaft including a longitudinal axis:

[19.3.2] a motor;

[19.3.3] and an articulation joint for positioning said cartridge at an angle to said longitudinal axis of said elongate shaft;

[19.4] a remote user-controllable actuation console electrically coupled to said motor;

[19.5] and a motion converter configured to convert a rotary drive motion produced by said motor to a linear drive motion.

2. Claim Construction

The undersigned has construed the following terms from claim 19 of the '874 patent:

TERM	CLAIM	CLAIM CONSTRUCTION
"remote user-controllable actuation console"	19	console that allows a user to control and actuate the surgical instrument
"motion converter configured to convert a rotary drive motion produced by said motor to a linear drive motion"	19	Subject to 35 U.S.C. § 112(6) Function: converting a rotary drive motion to a linear drive motion Structure: Helical screw shaft 36 (with a threaded engagement)

Order No. 15 at 10, 30. Additionally, the parties have agreed upon the definition of two other terms:

TERM	CLAIM	CLAIM CONSTRUCTION
"remotely user-controlled console"	9	Console that allows a user to control and actuate the surgical instrument
"reciprocatable closure element configured to apply said opening and closing motions to said one of said first and second jaws"	9	Subject to 35 U.S.C. § 112(6) Function: to apply opening and closing motions to one of said first and second jaws Structure: distal closure tube 42 and proximate closure tube 40 (Fig. 4)
"driver element"	9	Subject to 35 U.S.C. § 112(6) Function: imparting motion onto another component Structure: sled 33

CIB at 176; RIB at 137-138. The undersigned hereby adopts the parties' proposed constructions and shall construe the terms set forth above according to their agreed-to definitions.

B. Infringement

Ethicon argues that "[t]he EndoWrist Xi Staplers and Reloads in combination with the da Vinci Xi/X Surgical System directly infringe claim 19 of the 874 Patent." CIB at 177. Intuitive disagrees and asserts that "[t]he Xi EndoWrist staplers and reloads lack 'an end effector, comprising . . . at least one sensor' as required by asserted claim 19." RIB at 136. Intuitive does not dispute that the EndoWrist Xi Staplers and Reloads in combination with the da Vinci Xi/X Surgical System meet the remaining limitations. RLUL at 5.

1. Direct Infringement

a) Limitation 19.2.3

Claim 19 includes the limitation "an end effector comprising . . . at least one sensor." JX-0005, cl. 19.

Ethicon argues that "[t]he EndoWrist Xi Staplers include Dallas Connectors, which are a cartridge presence sensor as described in the 874 Patent." CIB at 178. Ethicon explains that "[t]he Dallas Connectors . . . are electrical contacts that sense the presence of a reload cartridge." *Id.* Ethicon asserts that "the Dallas Connectors detect a physical property, which is the presence or absence of a reload in the end effector, and indicate that physical property by the output of the connectors (*e.g.*, no information output means no reload is present)." *Id.* at 179.

Intuitive asserts that the end effector of the EndoWrist Xi Staplers does not include a sensor. "[T]he accused Dallas connector does not detect, discover, identify or measure anything." RIB at 141. "Nor does the Dallas connector output, generate, or otherwise modify any electrical signal, such as a logic zero or logic one, in response to the presence or absence of a staple reload cartridge." *Id.* "Instead, the accused Dallas connector is nothing more than two pieces of metal that provide an interface to passively transmit electrical signals, without modifying them, between the Dallas memory chip in the reload cartridge and the wires that connect the Dallas chip to the da Vinci robotic system." *Id.*

According to Intuitive, a person of ordinary skill in the art would understand that the plain and ordinary meaning of "sensor" is "a device that detects or measures a physical property and records, indicates, or otherwise responds to it." RIB at 138 (citing RX-0017C at Q/A 21; RX-1653.003-.0004). Ethicon does not indicate that it disagrees with this position nor does it offer its own definition in its briefs. *See* CIB at 179; CX-0001C at Q/A 238. As such, the undersigned will

apply this definition when determining whether or not the end effector of the Xi EndoWrist Staplers includes at least one sensor.

The Dallas connectors are electrical contacts. CX-0001C at Q/A 235. When a reload cartridge is installed, the Dallas connectors make electrical contact with a Dallas chip in the reload cartridge. *Id.*; *see also* RX-0021C at Q/A 7. Dr. Awtar opines that, through this contact, "information gets passed to the system" and informs it that a reload is attached. CX-0001C at Q/A 235. Intuitive asserts, however, that the Dallas connectors are not sensors because they "passively transmit electrical signals, without modifying them." RIB at 141.

The undersigned agrees with Intuitive that the Dallas connector does not qualify as a sensor. Intuitive's Principal Mechanical Engineer,[17] Mr. Burbank, testified that "[t]he Dallas connector consists of pieces of metal that passively transmit electrical signals. . . It does not generate any signal that is communicated to either the Dallas chip in the reload cartridge or the da Vinci Xi system." RX-0021C at Q/A 8. Mr. Burbank also testified that the Dallas connector does not modify electrical signals, nor does it detect or measure anything. *Id.* at Q/As 9-11. Finally, he testified that the Dallas connector does not react in any way to the presence or absence of the reload cartridge. *Id.* at Q/A 12.

Ethicon does not address this testimony in its briefs. *See* CIB at 178-180; CRB 92-96. Thus, it stands unrebutted. Additionally, even Ethicon's expert seems to acknowledge that the Dallas connectors only passively transmit the signals *See* CX-0001 at Q/A 225 (opining that "information gets passed to the system" from the Dallas connectors). As such, the undersigned cannot conclude that the Dallas connectors are devices that detect or measure a physical property and record, indicate, or otherwise respond to it.

[17] *See* RX-0009C at Q/As 1-5 for information about Mr. Burbank's background.

The undersigned therefore finds that Ethicon has not established that the EndoWrist Xi Staplers and Reloads in combination with the da Vinci Xi/X Surgical System meet this limitation. Accordingly, the undersigned finds that these products do not infringe claim 19 of the '874 patent.

2. Indirect Infringement

Ethicon alleges that "Intuitive indirectly infringes claim 19 of the '874 Patent by committing acts of induced and contributory infringement." CIB at 182. However, the undersigned has found hereinabove that the EndoWrist Xi Staplers and Reloads in combination with the da Vinci Xi/X Surgical System do not directly infringe claim 19. Ethicon therefore cannot, as a matter of law, prove indirect infringement. *See Novartis*, 363 F.3d at 1308 ("When indirect infringement is at issue, it is well settled that there can be no inducement or contributory infringement absent an underlying direct infringement.").

C. Technical Prong of the Domestic Industry Requirement

Ethicon asserts that its "[redacted] GST/ECR Reloads in combination with the [redacted] practice claim 9 of the 874 Patent." CIB at 183-184. Intuitive asserts that "the alleged DI product does not practice claim 9 because it does not include the claimed 'remotely user-controlled console electrically coupled to said surgical instrument." RIB at 145. Intuitive does not dispute that the remaining limitations of claim 19 are met. RLUL at 5.

Ethicon asserts that "[t]he [redacted] includes a Surgeon Console, which is a remotely user-controlled console that allows a user to control [redacted]." CIB at 185. Ethicon also asserts that "[t]he Surgeon Console is electrically coupled to the surgical instrument." *Id.* at 185-186. Specifically, "[t]he Surgeon Console is electrically coupled to the 'surgical instrument' because it is electrically coupled to the motors on the instrument arm." *Id.*

Intuitive argues that the undersigned must reject Ethicon's theory. According to Intuitive, "[t]he CALJ . . . has already found that Ethicon's contention with respect to the 'surgical instrument' . . . is limited to the [redacted] alone" and cannot include the instrument arm. RRB at 86. Intuitive asserts that, without this theory, Ethicon cannot show that [redacted] is electrically coupled to the [redacted] surgeon console. *Id.*

The undersigned did not limit Ethicon to asserting that the [redacted] alone is the surgical instrument. In fact, the undersigned declined to strike the portion of Dr. Awtar's expert report in which he opined that the [redacted] is electrically coupled to at least the motors on the instrument arm. Order No. 31 at 8-9 (Mar. 20, 2020). Thus, Ethicon was permitted to proceed on its theory that the Surgeon Console is electrically coupled to the surgical instrument because it is electrically coupled to the motors of the instrument arm.

The evidence shows that the Surgeon Console is electrically coupled to the surgical instrument because it is electrically coupled to the motors of the instrument arm. CX-0001C at Q/As 296-299; CX-0013C at Q/As 56-58; CX-0054C; CX-0219C; CX-3269C.002. Intuitive does not present any evidence to the contrary. *See* RIB at 145-146; RRB at 86. Accordingly, the undersigned finds that the [redacted] and GST/ECR Reloads in combination with the [redacted] practice claim 9 of the '874 patent.

D. Validity

Intuitive argues that claim 19 of the '874 patent is invalid due to either anticipation or obviousness. RIB at 146. Intuitive also argues that claim 24 fails to claim the subject matter which the applicants regarded as their invention. *Id.*

1. Anticipation

Intuitive argues that claim 19 is anticipated by U.S. Pat. App. Pub. No. 2007/0023477 ("Whitman 477"), which incorporates U.S. Patent No. 7,695,485 ("Whitman 485"). RIB at 137. Ethicon disputes that Whitman 477 discloses limitations 19.2.2 and 19.2.3, but does not dispute the remaining limitations. CLUL at 3.

a) Limitation 19.2.2

Claim 19 includes the limitation: "an end effector, comprising . . . a cartridge including staples that can be ejected out of said cartridge with a distal actuation of a firing member." JX-0005, cl. 19.

Intuitive asserts that "Whitman 477 expressly discloses distal actuation of the firing member (wedge 603) that ejects staples 606 from the staple cartridge 600." RIB at 149. Intuitive explains that the staple cartridge 600 "comprises a wedge 603" that "has 'disposed thereon a blade 51' to cut tissue." *Id.* at 148 (quoting JX-0141 at [0072], [0074], [0091]). According to Intuitive, "[b]ecause the wedge 603 and the blade 51 are coupled together, 'wherever [wedge] 603 goes, that's where the blade goes.'" *Id.* (quoting Awtar, Tr. at 632:15-24). Intuitive further asserts that "Whitman 477 discloses that the 'wedge 603 may be moved in either a proximal or a distal direction,' and that 'any mechanical arrangement that is configured to move the blade 51 and the wedge 603 in order to cut and/or staple tissue disposed between the first jaw 50 and the second jaw 80 may be employed." *Id.*

Ethicon asserts that "while Whitman 477 discloses various embodiments . . . Whitman 477 only discloses a stapling and cutting end effector designed to eject staples out of a staple cartridge in response to a ***proximal*** actuation of a firing member." CIB at 189 (emphasis in original). Ethicon further asserts that "Intuitive has failed to identify any disclosure in Whitman 477 that discloses

distal actuation of a firing member that ejects staples." *Id.* Instead, the "evidence shows that Whitman 477 only discloses ***cutting tissue*** in response to distal actuation of wedge 603." *Id.* (emphasis in original).

The undersigned finds that Whitman 477 discloses a cartridge with a distal actuation of a firing member. Whitman 477 discloses that the wedge 603 (the firing member) "may be moved in either a proximal or a distal direction in order to cut a section of tissue disposed between the first jaw 50 and the second jaw 80." JX-0141 at [0098]; *see also* RX-0001C at Q/A 100. While this passage specifically relates to cutting tissue, Whitman 477 also states: "[I]t should be recognized that, according to various embodiments of the present invention, any mechanical arrangement that is configured to move the blade 51 and the wedge 603 in order to cut and/or staple a section of the tissue disposed between the first jaw 50 and the second jaw 80 may be employed." *Id.* The evidence shows that a person of ordinary skill in the art would understand that the wedge can also move distally to eject staples. As Dr. Vaitekunas explains, "[c]learly, distal actuation of a firing member was a well-known mechanical arrangement to cut and/or staple tissue." RX-0001C at Q/A 100.

Ethicon does not dispute that distal actuation of a firing member is a well-known mechanical arrangement to staple tissue. *See* CIB at 190-191; CRB at 97-98. Instead, it argues that "Whitman 485 explicitly teaches away from ejecting staples using a distal actuation of a firing member." CIB at 191. As Intuitive notes, however, this argument "is factually irrelevant because Intuitive does not rely on Whitman 485 for its disclosure of ejecting staples with a distal actuation of a firing member." RRB at 90. So long as distal actuation is disclosed in Whitman 477 itself, it is irrelevant that an incorporated reference teaches away from the disclosure. Moreover, in an anticipation analysis, the Federal Circuit has found that "[a] reference is no less anticipatory if, after disclosing the invention, the reference then disparages it." *Celeritas Techs., Ltd. v. Rockwell*

Int'l Corp. 150 F.3d 1354, 1361 (Fed. Cir. 1998). "Thus the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." *Id.*

Accordingly, the undersigned finds that Whitman 477 discloses this limitation.

b) Limitation 19.2.3

Claim 19 includes the limitation: "an end effector, comprising . . . at least one sensor;. " JX-0005, cl. 19.

Intuitive argues that "Whitman 477, through its incorporation of Whitman 485, also discloses 'an end effector, comprising . . . at least one sensor.'" RIB at 149. According to Intuitive, "Whitman 485 discloses a first sensor electrode 182 and a second sensor electrode 184 in the end effector." *Id.* "As explained by Dr. Vaitekunas, a POSITA would have understood that Whitman 477 discloses the use of Whitman 485's sensor electrodes in Whitman 477's similar end effector." *Id.*

According to Ethicon, "Intuitive's anticipation argument fails because it is attempting to stitch together the claimed surgical instrument from different embodiments in Whitman 477 and Whitman 485." CIB at 192. Ethicon asserts that Intuitive "has failed to provide an adequate motivation as to why a POSITA would" modify the end effector of the Whitman 477 with the sensors of Whitman 485. *Id.* at 193. "As Dr. Awtar explains, because Whitman 477's stapler already uses encoders to determine whether the jaws are sufficiently closed to initiate stapling and cutting, a POSITA would see no reason to incorporate additional sensors into the end effector of Whitman 477's stapler to perform the same function." *Id.* at 194.

Ethicon does not dispute that Whitman 485 is incorporated into Whitman 477. The undersigned agrees with Ethicon, however, that, even with this incorporation, Whitman 477 does not disclose an end effector with at least one sensor. Under Intuitive's theory, a person of ordinary

skill in the art would need to incorporate the sensor of Whitman 485 into the end effector of Whitman 477. "It is not enough," however, "that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Further, a person of ordinary skill in the art would not be motivated to make such a combination. The sensor in Whitman 485 is used to determine whether the jaws are sufficiently closed, but, in Whitman 477, there is already a sensor used to make this determination. CX-03275C at Q/As 29, 32. Thus, as Dr. Awtar explains: "[T]here is no need to incorporate a sensor into the Whitman 477 stapler to determine whether to commence the stapling and cutting process," since "the Whitman 477 stapler already uses encoders outside of the end effector to determine whether the jaws are sufficiently closed to initiate stapling and cutting." *Id.* at Q/A 32.

As such, the undersigned cannot find that Whitman 477 discloses this limitation.[18]

c) Conclusion

Accordingly, for the reasons set forth above, the undersigned finds that the Whitman 477 does not anticipate claim 19 of the '874 patent.

2. Obviousness

Intuitive argues that claim 19 is rendered obvious by: (1) Whitman 477 in view of Whitman 485; (2) U.S. Pat. App. Pub. No. 2005/0131390 ("Heinrich") in view of U.S. Pat No. 5,779,130 ("Alesi"); and (3) U.S. Pat. App. Pub. No. 2008/167671 ("Giordano 671") in view of Heinrich and

[18] Intuitive also asserts that the Whitman 477 encoders provide only indirect information about the position of the jaws in the end effector. *See* RIB at 150; RRB at 91-92. Intuitive waived this argument by failing to assert it in its pre-hearing brief. Ground Rule 9.2. Thus, the undersigned will not consider it.

U.S. Patent No. 6,783,524 ("Anderson"). RIB at 137. Intuitive also argues that "[c]laim 9 is invalid because it is rendered obvious by Giordano 671 in view of Heinrich and/or Anderson." *Id.*

a) Whitman 477 and Whitman 485

Intuitive asserts that "it would have been obvious in view of Whitman 485 to modify 477's end effector (jaw portion 11a) to include sensor electrodes." RIB at 150. Ethicon disputes that Whitman 477 discloses limitations 19.2.2 and 19.2.3, but does not dispute the remaining limitations. CLUL at 3.

As noted above, the undersigned found that a person of ordinary skill in the art would not have been motivated to combine the sensor of Whitman 485 with the end effector of Whitman 477. As such, the undersigned also finds that claim 19 is not rendered obvious by Whitman 477 in view of Whitman 485.

b) Heinrich in view of Alesi

Intuitive asserts that claim 19 is rendered obvious by Heinrich in view of Alesi. RIB at 152. Ethicon disputes that Heinrich in view of Alesi discloses limitations 19.3.3 and 19.5, but does not dispute the remaining limitations. CLUL at 3.

Claim 19 includes the limitations: (1) "an articulation joint for positioning said cartridge at an angle to said longitudinal axis of said elongate shaft" and (2) "and a motion converter configured to convert a rotary drive motion produced by said motor to a linear drive motion." The parties address these limitations together.

Intuitive asserts that "[i]t is undisputed that Heinrich's surgical stapler 300 includes an articulation joint." RIB at 154. Intuitive also explains that "[i]t is undisputed that Heinrich's linear stapler loading unit includes surgical stapler 300's shaft 316, cartridge assembly 318, and anvil 317." *Id.* "And it is undisputed that surgical stapler 300's cartridge assembly 318 is coupled to

shaft 316 by an articulation joint that is manually actuated by an articulation lever." *Id.* According to Intuitive, "a POSITA would have" therefore "understood that Heinrich's linear stapler loading unit includes surgical stapler 300's articulation joint, which is the claim 'articulation joint for positioning said cartridge at an angle to said longitudinal axis of said elongate shaft.'" *Id.* Intuitive also argues that "a POSITA would have understood that the electromechanical assembly of Heinrich's linear stapler loading unit operates the articulation joint in the same manner as the handle portion of surgical stapler 300." *Id.* at 155.

Ethicon argues that "[t]he proposed combination of Alesi and Heinrich would fail to meet both the articulation joint . . . and motion converter . . . limitations of claim 19." *Id.* at 196. Ethicon argues that a person of ordinary skill in the art would not have combined Alesi's helical screw shaft with the stapler in figure 3 of Heinrich. *Id.* at 195. "As Dr. Awtar explains, a POSITA would have understood that these two drive systems are not interchangeable and it is not possible to insert Alesi's drive screw 270 into Heinrich's assembly, without additional significant modifications." *Id.* at 196.

The undersigned first finds that the combination of Alesi and Heinrich discloses an articulation joint. It is undisputed that Heinrich's surgical stapler 300's cartridge assembly is coupled to shaft 316 by an articulation joint that is manually actuated by an articulation lever. JX-0138 at [0093], Fig. 3; RX-0001C at Q/A 147; CX-3275C at Q/A 37. The evidence also demonstrates that, when manually operated instruments are adapted to the robotic surgical system, the manually actuated components of the instrument, like the articulation lever on surgical stapler 300's handle portion, are "incorporated within the structure and construction of the electro-mechanical assembly" of the loading unit for "operating the body portion components in the same

manner as the hand[le] portion operates the body portion components." RX-0203 at 5:39-46[19]; RX-0001C at Q/As 124-131. Accordingly, a person of ordinary skill in the art would have understood that the electromechanical assembly of Heinrich's linear stapler loading unit operates the articulation joint in the same manner as the handle portion of surgical stapler 300. RX-0001C at Q/As 124-131, 147; JX-0138 at [0130], Figs. 1-6, 9-11.

Ethicon also disputes that the combined system meets the "motion converter" limitation. The undersigned construed the term "motion converter configured to convert a rotary drive motion produced by said motor to a linear drive motion" as having the function of "converting a rotary drive motion to a linear drive motion" and the structure of "a helical screw shaft 36 (with a threaded engagement)." Order No. 15 at 30.

The evidence shows that Alesi discloses a motion converter. Dr. Vaitekunas testified that Alesi's drive screw 270 with threaded engagement is a helical screw with a threaded engagement and is an equivalent structure to that disclosed in the '874 patent. RX-0001C at Q/As 159-160; *see also* CX-3275C at Q/A 50 (testifying that Alesi's self-contained stapler includes a helical screw shaft). Dr. Vaitekunas further testified that the drive screw 270 with threaded engagement "performs the claimed function of converting a rotary drive motion to a linear drive motion." RX-0001C at Q/A 161. He also testified that "[a] person of ordinary skill in the art would have been motivated to combine Heinrich's motor powered surgical stapler with Alesi's motor powered motion converter." *Id.* at Q/A 165.

Ethicon argues that a person of ordinary skill in the art would not have been motivated to combine the systems because Alesi "relies on rotary motion of a drive screw 270," while Heinrich "relies on linear motivation of an actuation shaft 46." CIB at 196. According to Ethicon, "a

[19] Heinrich incorporates this reference. JX-0138 at [0130]; *see also* RX-0001C at Q/A 128.