UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

COMMISSION OPINION

CONTENTS

I. INTRODUCTION

On August 16, 2021, the Commission determined to review in part the final initial determination ("ID") of the presiding Chief Administrative Law Judge ("CALJ") in this investigation, which issued on June 8, 2021. 86 Fed. Reg. 46882 (Aug. 20, 2021), *as corrected*, 86 Fed. Reg. 47521 (Aug. 25, 2021). On review, the Commission has determined to affirm in part, modify in part, reverse in part, and take no position on certain issues in the ID. Consistent with these findings, the Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, as amended, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain laparoscopic surgical staplers, reload cartridges, and components thereof by reason of infringement of claims 2 and 3 of U.S. Patent No. 9,844,379 ("the '379 patent"). The Commission has further determined that that there has been no violation of section 337 in connection with U.S. Patent No. 8,479,969 ("the '969 patent"); U.S. Patent No. 9,113,874 ("the '874 patent"); and U.S. Patent No. 9,844,369 ("the '369 patent"). This opinion sets forth the Commission's reasoning in support of its determination. The Commission adopts the findings in the ID that are not inconsistent with this opinion.

II. BACKGROUND

A. Procedural History

The Commission instituted this investigation on July 5, 2019, based on a complaint filed by Ethicon LLC of Guaynabo, Puerto Rico; Ethicon Endo-Surgery, Inc. of Cincinnati, Ohio; and Ethicon US, LLC of Cincinnati, Ohio (collectively, "Ethicon"). 84 Fed. Reg. 32220 (July 5, 2019). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain reload cartridges for laparoscopic surgical staplers by reason of infringement of certain claims of the '379,

'369, '969 and '874 patents.[1] 84 Fed. Reg. at 32220. The Commission's notice of investigation named four respondents: Intuitive Surgical Inc., of Sunnyvale, California; Intuitive Surgical Operations, Inc., of Sunnyvale, California; Intuitive Surgical Holdings, LLC, of Sunnyvale, California; and Intuitive Surgical S. De R.L. De C.V. of Mexicali, Mexico (collectively, "Intuitive"). *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

As initially instituted, the investigation covered reload cartridges for laparoscopic staplers, but not the staplers themselves. *See* 84 Fed. Reg. at 32220. However, on October 23, 2020, the CALJ granted Ethicon's motion for leave to amend the complaint, case caption, and notice of investigation to change the scope of the investigation to encompass Intuitive's laparoscopic surgical staplers and components thereof, in addition to their associated reload cartridges. Order No. 14, *unreviewed by* Comm'n Notice (Nov. 21, 2019); *see also* 84 Fed. Reg. 65174 (Nov. 26, 2019), *as corrected*, 84 Fed. Reg. 67295 (Dec. 9, 2019).

The CALJ issued the final ID in this investigation on June 8, 2021. The ID found a violation of section 337 based on infringement of the '369 and '379 patents. The ID found that no violation of section 337 occurred with respect to the '969 and '874 patents, finding that the asserted claims of both patents were not infringed and were invalid as obvious.

[1] The Complaint also asserted U.S Patent No. 7,490,749, but that patent was terminated from the investigation and is not relevant to any issue on review. *See* Order No. 21, *unreviewed by* Comm'n Notice (Mar. 25, 2020).

Ethicon and Intuitive both filed petitions for review on June 21, 2021, encompassing issues across all four of the remaining patents in this investigation.[2] Each filed a response to the other's petition on June 29, 2021.[3]

On August 20, 2021, the Commission published notice in the *Federal Register* of its determination to review parts of the ID. Comm'n Notice, 86 Fed. Reg. 46882 (Aug. 20, 2021), *as corrected*, 86 Fed. Reg. 47521 (Aug. 25, 2021) ("Notice of Review"). The Commission determined to review the ID with respect to (1) the ID's findings on claim construction, infringement, anticipation, obviousness, and enforceability of the '969 patent; and (2) the ID's findings on claim construction, infringement, and obviousness of the '369 patent. 86 Fed. Reg. at 46883. The Commission sought briefing on nine questions related to the issues under review. *Id.* at 46883–84. The Commission did not review any findings related to the '379 patent and the '874 patent. Accordingly, the ID's findings of violation based on the '379 patent and no violation based on the '874 patent, including its related subsidiary findings, became the Commission's final determinations on those issues. 19 C.F.R. § 210.42(h)(2).

[2] Ethicon Complainants' Petition for Review of Initial Determination on Violation of Section 337, EDIS Doc. ID 745168 ("Ethicon Pet."); Respondent's Petition for Review of Initial Determination on Violation of Section 337, EDIS Doc. ID 745192 ("Intuitive Pet.").

[3] Ethicon Complainants' Response to Intuitive's Petition for Review of Initial Determination on Violation of Section 337, EDIS Doc. ID 745721 ("Ethicon Resp."); Respondent's Opposition to Ethicon Complainants' Petition for Review of Initial Determination on Violation of Section 337, EDIS Doc. ID 745720 ("Intuitive Resp.")

On August 23, 2021, Ethicon and Intuitive submitted briefs responding to the questions posed in the Commission's Notice of Review.[4] Thereafter, on August 30, 2021, each submitted a reply to the other's brief on review.[5]

B. The Technology & Asserted Patents

This investigation is about surgical staplers used for cutting and stapling tissue during minimally invasive laparoscopic surgery. The parties to the investigation use various terms to refer to such staplers, including staplers, endocutters, linear staplers, and linear cutters. ID at 4. The two patents at issue on review, as well as the patent on which the Commission's determination of violation is based, all relate to such staplers and have distinct specifications.

1. The '969 Patent

The '969 patent is titled "Drive Interface for Operably Coupling a Manipulatable Surgical Tool to a Robot," and issued on July 9, 2013, from application number 13/369,609, which was filed on February 9, 2012. The application claims priority through continuation and continuation-in-part applications to application No. 11/651,807, which was filed on January 10, 2007. Frederick E. Shelton, IV, of Hillsboro, Ohio, is listed as the sole inventor, and Ethicon Endo-Surgery, Inc. is listed as the assignee.

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[4] Ethicon Complainants' Opening Brief in Response to Commission's Notice of Review, EDIS Doc. ID 750133 ("Ethicon Br. on Review"); Respondent's Response to Commission Questions, EDIS Doc. ID 750140 ("Intuitive Br. on Review").

[5] Ethicon Complainants' Reply Brief in Response to Commission's Notice of Review, EDIS Doc. ID 750562 ("Ethicon Reply on Review"); Respondents' Reply to Ethicon Complainants' Opening Brief in Response to Commission's Notice of Review, EDIS Doc. ID 750556 ("Intuitive Reply on Review").

2. The '369 Patent

The '369 patent is titled "Surgical End Effectors with Firing Element Monitoring Arrangements," and issued on December 19, 2017, from application number 14/319,004, which was filed on June 30, 2014. The application claims priority to provisional application No. 61/980,293, which was filed on April 16, 2014. Thomas W. Huitema of Cincinnati, Ohio, Charles J. Schelb of Loveland, Ohio, Cortney E. Henderson of Wilmington, Ohio, Frederick E. Shelton, IV, of Hillsboro, Ohio, and Jason L. Harris of Lebanon, Ohio are listed as the inventors. Ethicon Endo-Surgery, Inc. is listed as the applicant and Ethicon LLC of Guaynabo, Puerto Rico is listed as the assignee.

3. The '379 Patent

The '379 patent is titled "Surgical Stapling Instrument Having a Clearanced Opening," and issued on December 19, 2017, from application number 15/064,075, which was filed on March 8, 2016. The application claims priority through continuation and continuation-in-part applications to application No. 11/141,753, which was filed on June 1, 2005 and to provisional application No. 60/591,694, which was filed on July 28, 2004. Frederick E. Shelton, IV, of Hillsboro, Ohio, Michael E. Setser of Burlington, Kentucky, and William B. Weisenburgh of Mainville, Ohio are listed as the inventors. Ethicon Endo-Surgery, LLC is listed as the applicant and Ethicon LLC of Guaynabo, Puerto Rico is listed as the assignee.

C. The Products at Issue

The products at issue in this investigation are laparoscopic surgical staplers and their reload cartridges. Intuitive's 3rd generation stapler and reload cartridges ("SureForm products") are accused of infringing the '369, '379, and '969 patents. Intuitive's 2nd generation stapler and reload cartridges ("EndoWrist Xi products") are accused of infringing the '969 and '874 patents. The

following is an image captured from an animation of one of Intuitive's SureForm laparoscopic staplers:

RDX-24C (image captured from animation at time 00:01). Ethicon and Intuitive agreed to consolidate the accused products into groups where each product listed therein is representative of the others in that group, as set forth here:

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

ID at 5.

III. COMMISSION REVIEW OF THE FINAL ID

When the Commission decides to review an initial determination, it reviews the determination *de novo*. *Certain Polyethylene Terephthalate Yarn & Prods. Containing Same*, Inv. No. 337-TA-457, Comm'n Op. at 9 (June 18, 2002). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits & Prods. Containing Same*, Inv.

No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 9–10 (July 1997) (quoting *Certain Acid-Washed Denim Garments & Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). Commission practice in this regard is consistent with the Administrative Procedure Act. *Certain EPROM, EEPROM, Flash Memory, & Flash Microcontroller Semiconductor Devices & Prods. Containing Same*, Inv. No. 337-TA-395 (Reconsideration), Comm'n Op. at 6 (Dec. 11, 2000); *see also* 5 U.S.C. § 557(b).

On review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any finding or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS

A. The '969 Patent

The Commission determined to review the ID's findings on claim construction, infringement, anticipation, obviousness, and enforceability of the '969 patent. The disputes as to the ID's findings on claim construction, infringement, and anticipation all relate to the proper construction of the term "elongated shaft assembly" in asserted claim 24. Claim 24 provides:

> [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:
>
> > [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; and

[24.3.2] 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; and

[24.3.3] 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.

JX-4 at cl. 24 (emphasis added to disputed limitations).

1. The Scope and Application of "Elongated Shaft Assembly"

The claim construction and infringement issues on review concerning the '969 patent relate to the proper scope of the term "elongated shaft assembly" and that term's application to the accused SureForm staplers.

The embodiments disclosed in the '969 patent are generally of two types. In the first type, as shown in Figures 52, 58, and 136, the "elongated shaft assembly" includes a threaded component at one end that meshes with a transmission assembly gear to actuate the firing motion of the effector at the opposite end of the elongated shaft assembly. In Figure 52, for example, "fourth rotary driven gear assembly **2658** is in meshing engagement with threaded portion **2644**":

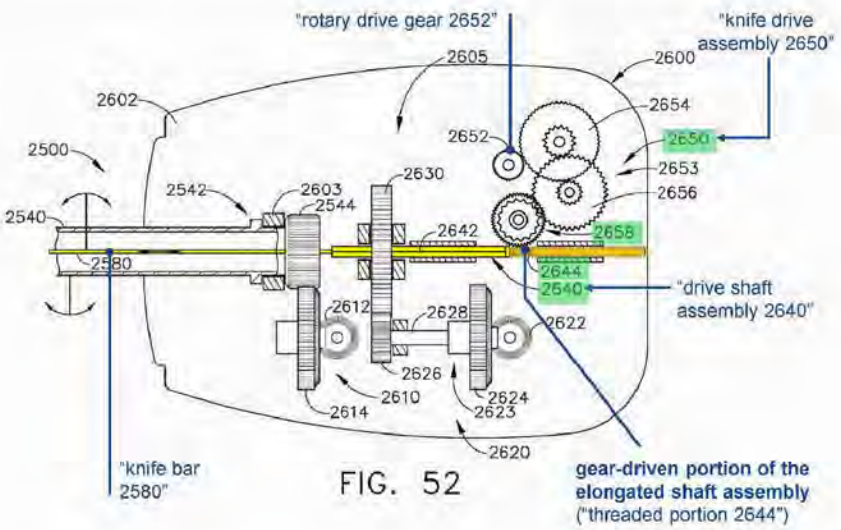


FIG. 52

RDX-17C at 37 (green highlighting added by the Commission; all other annotations added by Intuitive); JX-4 at Fig. 52, 40:31–64. Threaded portion **2644** is part of "drive shaft assembly **2640**," while fourth rotary driven gear assembly **2658** is part of "knife drive assembly **2650**." JX-4 at 40:31–64. "The drive shaft assembly **2640** is axially advanced in the distal and proximal directions by [the] knife drive assembly **2650**." *Id.* at 40:39–41.

Figure 58 provides a second example of this type of stapler where "fourth rotary driven gear assembly **2948** [] is in meshing engagement with the threaded portion **2786** of the knife bar **2780**":

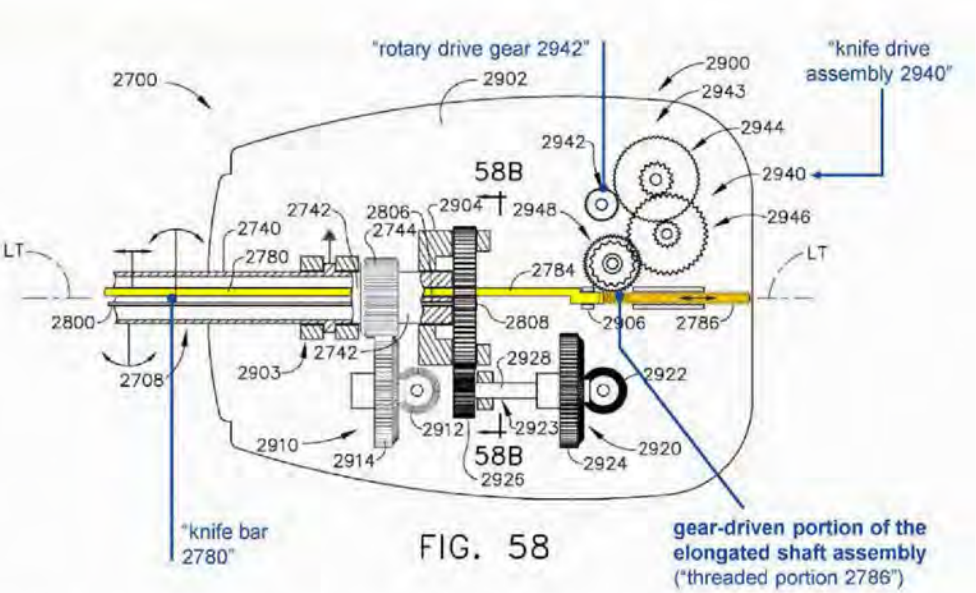


FIG. 58

RDX-17C at 39 (annotating Fig. 58); JX-4 at 45:49–51. Here, fourth rotary driven gear assembly **2948** is a part of "knife drive assembly **2940**." JX-4 at 45:35–51.

Figure 136 provides a third example of a gear-driven firing mechanism, where "fifth knife driven gear assembly **6574** [] is in meshing engagement with knife rack gear **6540**":

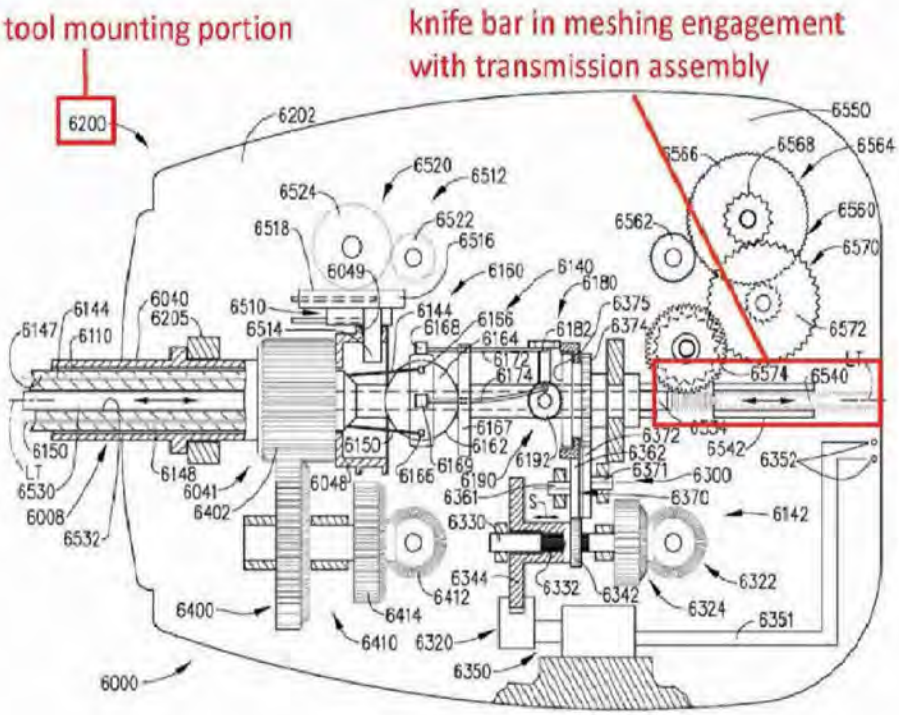


FIG. 136

CDX-1C at 8 (annotating Fig. 136); JX-4 at 85:2–4. According to Ethicon's expert, Dr. Awtar, knife rack gear **6540** is part of the elongated shaft assembly in Figure 136, while the gear it meshes with, fifth knife driven gear assembly **6574**, is part of the transmission assembly. *See* CX-1C at Q/A 100 (explaining annotated Figure 136 reproduced above).

Distinct from the staplers with gear-driven firing mechanisms, the specification of the '969 patent also teaches cable-driven firing mechanisms. JX-4 at Figs. 88–97, 8:4–27, 58:1–19, 59:51–60:25, 60:39–61:25; *see also* RX-17C at Q/A 87. Particularly, Figures 88, 92, and 95 show a stapler with a cable-driven firing mechanism, which includes an "elongated shaft assembly **3808**" and a "cable drive transmission **3920**":

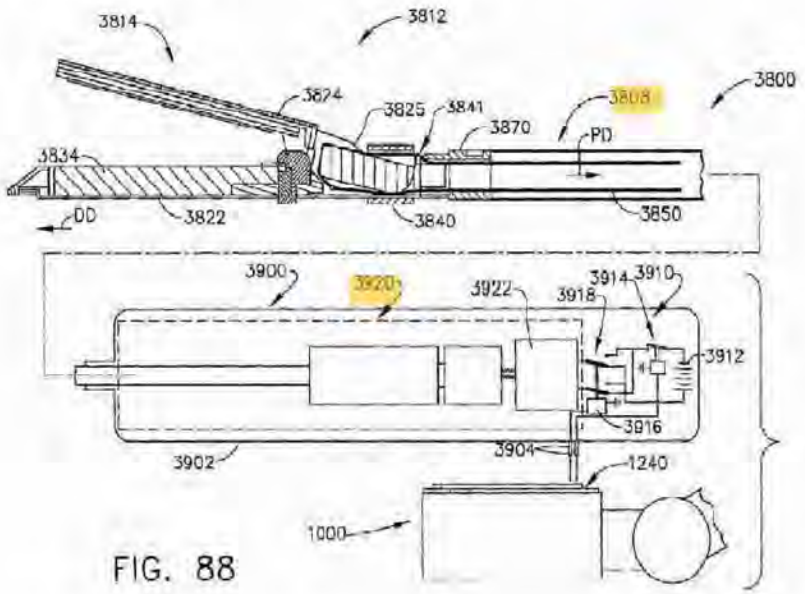


FIG. 88

* * *

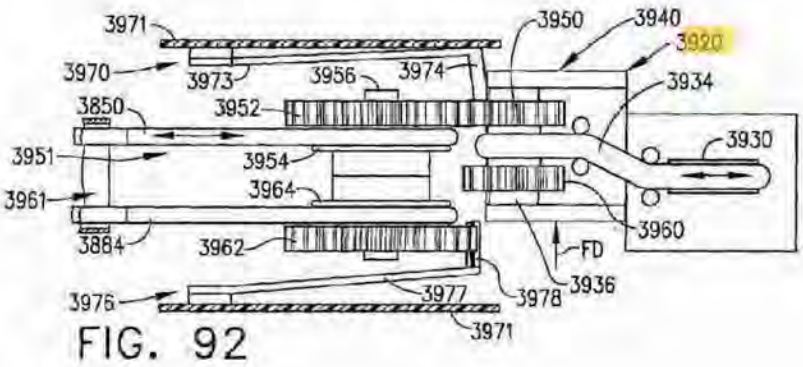


FIG. 92

* * *

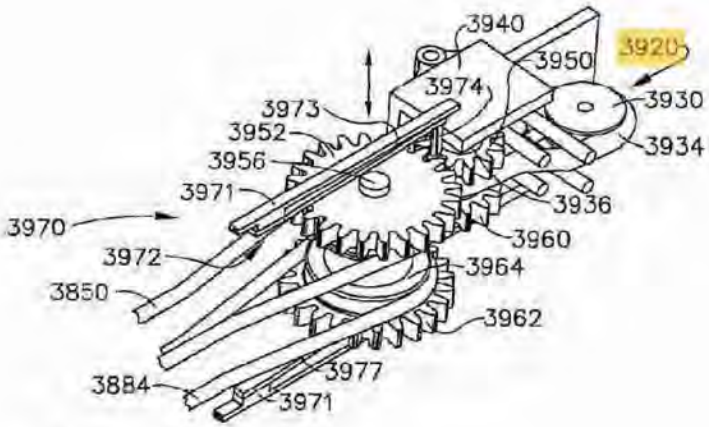
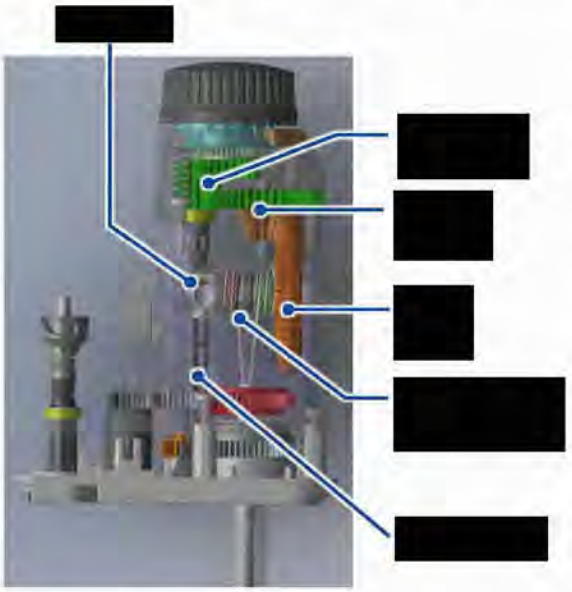


FIG. 95

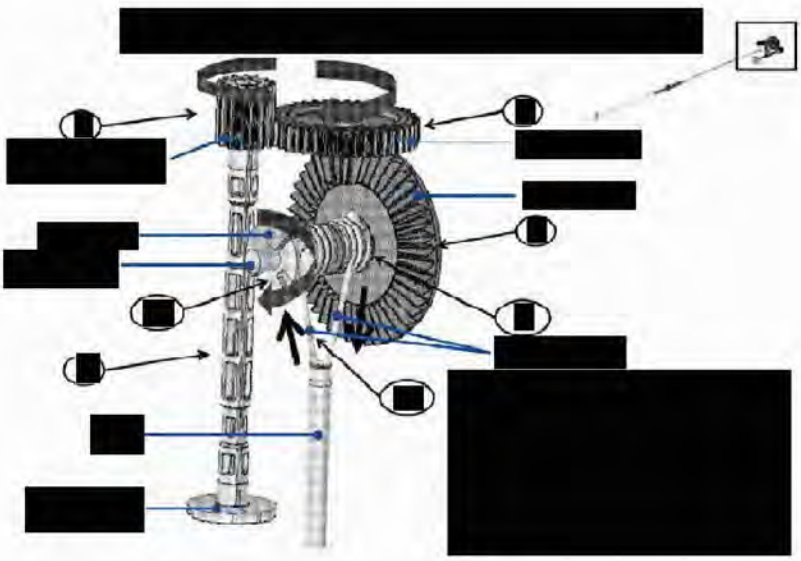
JX-4 at Figs. 88, 92, 95 (highlighting added by Commission); *see also id.* at 8:16–17, 8:22–23 (describing Figures 92 and 95 as views of the "cable drive transmission"). Unlike the staplers of Figures 52, 58, and 136, there is no gear-driven portion of the elongated shaft assembly **3808** in "meshing engagement" with a part of cable drive transmission **3920**. While the cable-driven embodiment disclosed in the '969 patent does include gears, as shown in Figures 88, 92, and 95, they are part of the cable drive transmission **3920**, not part of elongated shaft assembly **3808**. The portions of the elongated shaft assembly in this embodiment that engage with the transmission are "closure cable **3850**" and "firing cable **3884**," unlike the invention of claim 24 and the gear-driven embodiments in the specification where a portion of the elongated shaft assembly itself is in

meshing engagement with the transmission assembly. *See* JX-4 at 60:67–61:13. In other words, this cable-driven embodiment does not fall within the scope of claim 24 at least because it lacks an elongated shaft assembly with the gear-driven portion of limitation 24.3.3.

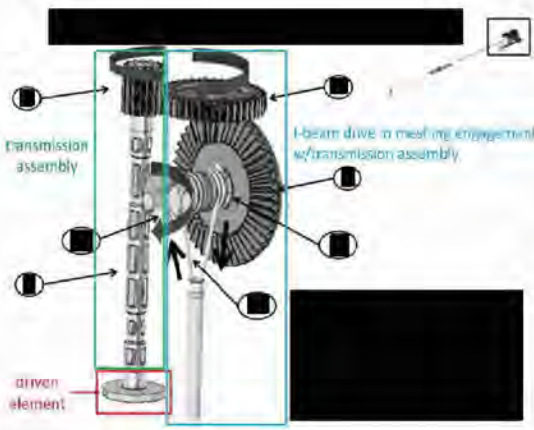
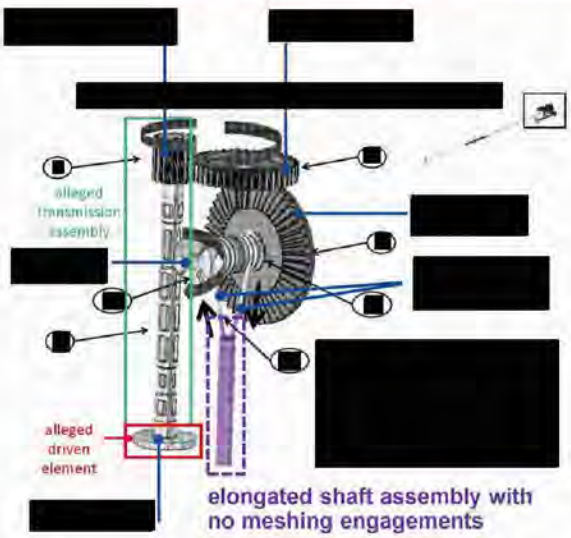
The following annotated CAD model identifies the SureForm stapler components that are relevant to the parties' dispute over the scope of the "elongated shaft assembly":



RDX-17C at 53 (annotating RPX-1792C). The following annotated illustration shows the same mechanism, but without several components that are not relevant to the parties' dispute:



Id. at 50 (annotating RX-1115C at 2). Both Ethicon and Intuitive annotated this latter illustration to explain how they read the term "elongated shaft assembly" onto the SureForm staplers. A side-by-side comparison of their annotations reveals the crux of their dispute:

Ethicon's Position	Intuitive's Position
	
CDX-1C at 22 (annotating RX-1115C at 2)	RDX-17C at 53 (annotating RX-1115C at 2)

Ethicon argued that the SureForm staplers meet the limitations of claim 24 by asserting that everything inside the blue box in its annotation of the illustration is part of the claimed "elongated shaft assembly" of limitation 24.3. Ethicon further asserted that the [redacted] (numbered part "3") is the gear-driven portion of the elongated shaft assembly required by limitation 24.3.3. By contrast, Intuitive argued that the elongated shaft assembly is limited to the elements in the purple dashed box of its annotation of the illustration (plus other elements not shown in the illustration and not relevant to the instant dispute). Accordingly, Intuitive asserted that its SureForm staplers lack an elongated shaft assembly with a gear-driven portion, as required by limitation 24.3.3. Thus, Ethicon and Intuitive's dispute boils down to whether the [redacted]

in the SureForm staplers is part of an "elongated shaft assembly." That dispute necessarily implicates the scope of the term "elongated shaft assembly."

a) Claim Construction of "Elongated Shaft Assembly"

In its notice of review, the Commission asked two questions concerning the proper construction of "elongated shaft assembly" and the related term "transmission assembly":

> 1. Claim 24 of the '969 patent includes the terms "elongated shaft assembly" and "transmission assembly." Concerning these terms, identify where in the record, if anywhere:
>
> a. The parties proposed constructions for these terms;
>
> b. The parties argued in support of any constructions proposed; and
>
> c. The ALJ construed these terms.
>
> 2. Concerning the terms "elongated shaft assembly" and "transmission assembly," indicate whether these terms should be construed according to their plain and ordinary meaning. If these terms should be construed according to their plain and ordinary meaning, what is the plain and ordinary meaning of each term? If these terms should be construed otherwise, identify the correct mode of construction and the corresponding construction for each term. Identify with specificity the evidence of record that supports your contentions with particular emphasis on evidence intrinsic to the '969 patent.

86 Fed. Reg. 46883. In response to the first question, Ethicon and Intuitive confirmed that they did not propose constructions for the terms "elongated shaft assembly" and "transmission assembly," did not argue for construction of those terms, and that the CALJ did not construe those terms.

For the second question, Ethicon and Intuitive agree that the terms should be construed according to their plain and ordinary meanings. Ethicon Br. on Review at 1, 7; Intuitive Br. on Review at 2, 10. They disagree, however, on what the plain and ordinary meanings of these terms are and propose the following competing formulations:

	Ethicon's Construction	Intuitive's Construction
"elongated shaft assembly"	"an assembly of components defining a longitudinal tool axis and including at least an elongate shaft, a distal spine portion, a proximal spine portion, and a gear-driven portion (all as further defined in the claim)"	"a collection of components that makes up the long, narrow cylindrical part of the surgical tool and includes mechanisms which transmit power or motion from the transmission assembly of the tool mounting portion to the selectively movable component portion of the surgical end effector"
"transmission assembly"	"an assembly of components that transmits mechanical power"	"a collection of components that transmits power and torque from the driven element of the tool mounting portion to the gear driven portion of the elongated shaft assembly"

Ethicon Br. on Review at 1, 7; Intuitive Br. on Review at 2–3, 10. We focus our attention on the construction of "elongated shaft assembly" because, as explained *infra*, that term is ultimately outcome determinative of the parties' infringement dispute.

The Commission finds that Intuitive's proposal to construe "elongated shaft assembly" to mean: "a collection of components that makes up the long, narrow, cylindrical part of the surgical tool and includes mechanisms which transmit power or motion from the transmission assembly of the tool mounting portion to the selectively movable component portion of the surgical end effector," correctly captures the plain and ordinary meaning of that term. This construction is consistent with the language of the claims and the specification of the '969 patent, and also remains faithful to the ordinary meaning of simple non-technical terms like "elongated" and "shaft."

As Intuitive asserts, the claim language makes it "clear that the 'elongated shaft assembly' comprises multiple components that transmit power or motion from the transmission assembly of the tool mounting portion to the selectively movable component portion of the surgical end effector

of the surgical tool." Intuitive Br. on Review at 4. The use of the term "elongated shaft assembly" in asserted claim 24, and unasserted claims 17, 19, and 23, is consistent with this construction. *See* JX-4 at Cls. 17, 19, 23, 24; Intuitive Br. on Review at 4–5. It is also consistent with the use of the term "elongated shaft assembly" throughout the specification and in the Figures. Intuitive Br. on Review at 5–7. Notably, Figures 33, 53, 58, 132, and 136 show elongated shaft assemblies that are formed of a collection of components that makes up the long, narrow cylindrical part of the surgical tool. JX-4 at Figs. 33, 53, 58, 132, 136; *see also supra* pp. 10, 11.

The Commission also notes that the adopted construction for "elongated shaft assembly" is consistent with the embodiments in the '969 patent describing gear-driven firing mechanisms as well as cable-driven firing mechanisms, both of which have "elongated shaft assemblies." This is because, under the adopted construction, "elongated shaft assembly" retains the full breadth of its ordinary meaning without being limited to the specific "elongated shaft assembly" of claim 24, which has been narrowed by the addition of limitations such as the "gear-driven portion" limitation 24.3.3. As such, the adopted construction reads on all types of "elongated shaft assemblies" disclosed in the '969 patent, including the one described in the cable-driven firing mechanism embodiment, which lacks the gear-driven portion of limitation 24.3.3.

The Commission does not find persuasive Ethicon's arguments in opposition to this construction. First, Ethicon argues that the claims of the '969 patent lack the words "long," "narrow," and "cylindrical" precludes the adopted construction, presupposing some rule of law that restricts the words available to construe a claim term to only those words that are already in the claims. Ethicon cites no authority establishing such a rule and we are aware of none. To the contrary, construing terms by circular reference to those same terms is, in many cases, unhelpful. *See, e.g.*, *Apple, Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846-LHK, 2012 WL 2993856, at *6

(N.D. Cal. July 20, 2012) ("[T]he Court finds Samsung's construction ultimately unhelpful for the jury to understand the term. Samsung's construction includes the disputed claim term itself ('structural') and does not clarify its meaning."); *see also* Intuitive Reply on Review at 4 (citing same).

Moreover, Ethicon contends that the absence of those words means that "there is no claim language that supports Intuitive's position that each component of the elongated shaft assembly must be part of 'the long, narrow cylindrical part of the surgical tool.'" *Id.* at 8. But the words "elongated shaft," which do appear in the claim, are sufficiently synonymous in common parlance with "long," "narrow," and "cylindrical" to provide support for Intuitive's construction. Thus, contrary to Ethicon's assertion, Intuitive's construction is supported by the language of the claims.

Ethicon's arguments based on the specification are also unpersuasive and misinterpret the Commission's adopted construction in an attempt to create conflicts with the specification. For example, Ethicon argues that the adopted construction requires that all components of an elongated shaft assembly reside inside a hollow tube, such as "hollow spine tube **2740**" in Figure 58. *See* Ethicon Reply on Review at 8–10. But the adopted construction requires only that components of the elongated shaft assembly ***make up*** the long, narrow, and cylindrical part of the surgical tool. As can be seen from the orange and yellow highlighting in the following illustration, both the "knife bar **2780"** (yellow) and its "threaded shaft portion **2786"** (orange) are components of the long, narrow, and cylindrical part of the surgical instrument:

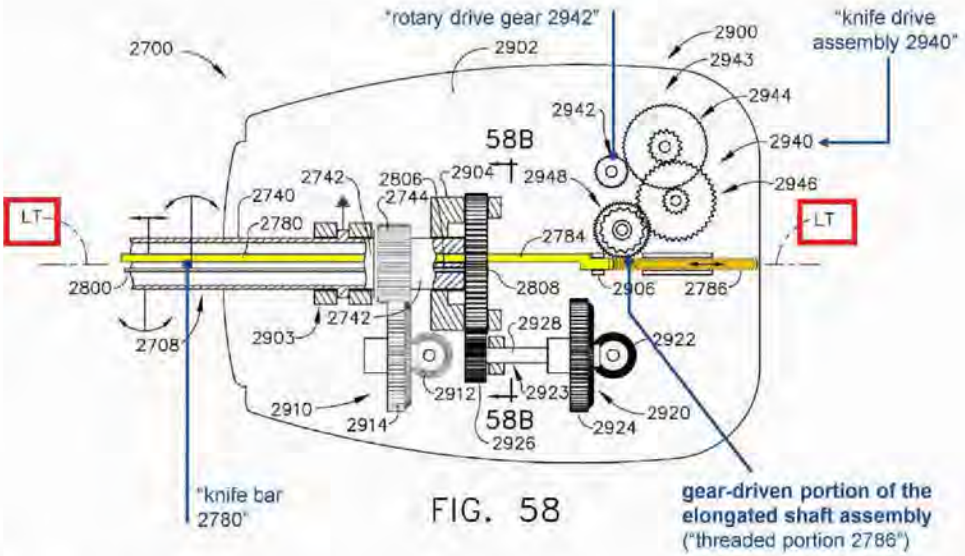


FIG. 58

See id. at 9.[6] The Commission's construction does not require every component of the elongated shaft assembly to reside inside a cylindrical tube such as the one Ethicon points to in Figure 58.

The Commission also finds that Ethicon's own proposed construction is flawed because it essentially re-writes limitation 24.3 to recite a generic assembly of components defining a longitudinal tool axis of which an elongate shaft is one such component. Ethicon's construction alters the plain language of limitation 24.3 as follows:

> [24.3] an ~~elongated shaft~~ assembly defining a longitudinal tool axis and comprising:
>
> [24.3.*] an elongate shaft;
>
> [24.3.1] a distal spine portion operably coupled to said end effector; and
>
> [24.3.2] 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; and

[6] This image of Figure 58 has been annotated by both Intuitive and Ethicon. Intuitive added the yellow and orange highlighting when it included this image in RDX-17C (p. 39), and then Ethicon further annotated the image in its reply to add the red boxes.

> [24.3.3] 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.

By recasting the claim in this way, the components of limitations 24.3.1, 24.3.2, and 24.3.3 need not bear any relation to the elongated shaft. Those components need only be part of "an assembly of components defining a longitudinal tool axis." Ethicon Br. on Review at 1. Accordingly, Ethicon's proposed construction conflicts with the plain language of limitation 24.3.

Ethicon's proposed construction also makes the "gear-driven portion" limitation 24.3.3 inherent in the plain and ordinary meaning of "elongated shaft assembly." As such, the "elongated shaft assembly **3808**," which is part of the cable-driven embodiment lacking a gear-driven firing mechanism, would fall outside the scope of the ordinary meaning of "elongated shaft assembly" under Ethicon's proposed construction. Thus, the term "elongated shaft assembly" would have to be given a different meaning in connection with the cable-driven embodiment than with the gear-driven firing mechanism embodiments in the specification. Accordingly, Ethicon's proposed construction is inconsistent with the Federal Circuit's guidance that claim terms are typically used consistently throughout a patent. *See Gillespie v. Dywidag Sys. Int'l, USA*, 501 F.3d 1285, 1291 (Fed. Cir. 2007).

Still further, if adopted, Ethicon's construction would create additional conflict with the cable-driven firing mechanism embodiments disclosed in the '969 patent insomuch as it would transform components such as the "closure driven gear **3952**," which is part of the "cable drive transmission **3920,**" into components of the elongated shaft assembly in those embodiments. This follows from Ethicon's application of its construction to the SureForm staplers to argue that the combo gear therein is part of an "elongated shaft assembly." Applying that construction in the same way to the cable-driven embodiment in the '969 patent would expand the elongated shaft

assembly of that embodiment to include elements of its transmission assembly, despite the contrary descriptions in the specification.[7]

Ethicon's argument that Intuitive waived its claim construction argument is also meritless. Both Ethicon and Intuitive, in response to the Commission's first question on review, agree that the parties did not identify "elongated shaft assembly" for construction, did not advance constructions for the term, and that the CALJ did not construe the term. Ethicon Br. on Review at 1 ("The parties did not propose constructions for 'elongated shaft assembly' or 'transmission assembly.' As a result, the CALJ did not construe these terms."); Intuitive Br. on Review at 1 ("The terms 'elongated shaft assembly' and 'transmission assembly' in claim 24 of the '969 patent were not proposed for construction or otherwise addressed by the parties as part of the claim construction process in this Investigation. The CALJ therefore did not expressly construe either term."). It necessarily follows that the claim construction arguments the Commission invited the parties to make in its second question on review are new, but both parties were provided sufficient opportunity to proffer their own constructions, and address each other's. Under the facts here, the

[7] The Commission declines to rely on the dictionary definitions of the word "shaft" offered by Intuitive. Intuitive Br. on Review at Ex. 3 (pdf page no. 253); *id.* at Ex. 4 (pdf page no. 257). Neither the dictionaries nor the excerpts Intuitive relies on are in the evidentiary record of this investigation. Instead, Intuitive attached those materials to its brief on review. Intuitive does not request that the Commission take judicial notice of the definitions, nor does it move to re-open the record to admit its belated exhibits. Under these circumstances, the Commission declines to consider Intuitive's dictionary definitions. Still further, the definitions add little value given that "shaft," is an ordinary word used in its ordinary sense in the '969 patent. As *Phillips* recognized, "[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). Here, the words "elongated" and "shaft" are used in their ordinary sense, understandings of which are well within the grasp of even lay judges. The Commission need not consult a dictionary to recognize that the use of the words "long" and "narrow" in our adopted construction is consistent with the ordinary meaning of "elongated shaft."

Commission declines to find that Intuitive waived claim construction arguments that Intuitive was invited to make in response to the Commission's Notice of Review.

Both parties failed to identify for the CALJ a material dispute between them about the plain and ordinary meaning of the term "elongated shaft assembly." As such, at the *Markman* phase of the investigation, the CALJ had no reason to construe the term. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (explaining that trial judges are not obligated to construe terms for which the meaning is not in material dispute). However, when the parties presented their infringement arguments at the hearing and in post-hearing briefing, these arguments revealed that there was indeed a material dispute over the meaning of "elongated shaft assembly." At that point, *O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.* required resolution of the parties' claim construction dispute. 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it."). As *O2 Micro* explains, this is true even if, as here, the parties contend that the disputed term has an ordinary meaning:

> A determination that a claim term "needs no construction" or has the "plain and ordinary meaning" may be inadequate when a term has more than one "ordinary" meaning or when reliance on a term's "ordinary" meaning does not resolve the parties' dispute. In this case, for example, the parties agreed that "only if" has a common meaning, but then proceeded to dispute the scope of that claim term, each party providing an argument identifying the alleged circumstances when the requirement specified by the claim term must be satisfied (e.g., at all times or during steady state operation). In this case, the "ordinary" meaning of a term does not resolve the parties' dispute, and claim construction requires the court to determine what claim scope is appropriate in the context of the patents-in-suit. This court has construed other "ordinary" words for these and other related reasons.

Id. at 1361. Accordingly, here, the parties' dispute over the scope of "elongated shaft assembly" compels the Commission to review the ID and resolve the parties' claim construction dispute.

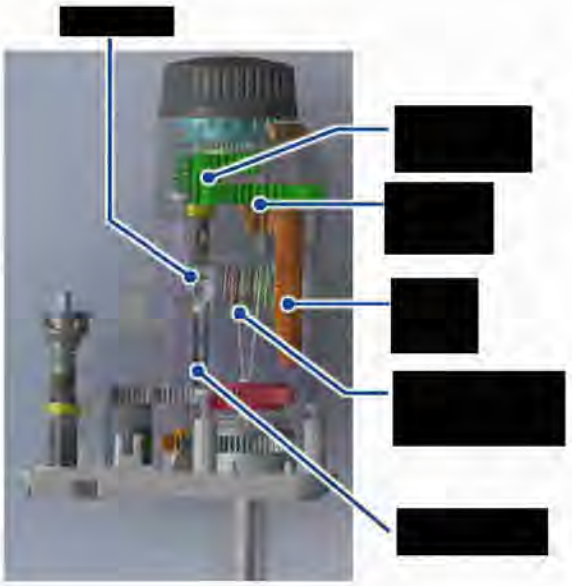
b) Direct Infringement of "Elongated Shaft Assembly" by the SureForm Products

In addition to the proper construction of "elongated shaft assembly," the Commission also sought briefing from the parties on whether the SureForm products practice that limitation under the parties' proposed constructions. 86 Fed. Reg. 46883. As explained above, the Commission has determined to adopt Intuitive's proposal and construe "elongated shaft assembly" to mean: "a collection of components that makes up the long, narrow, cylindrical part of the surgical tool and includes mechanisms which transmit power or motion from the transmission assembly of the tool mounting portion to the selectively movable component portion of the surgical end effector." The next question is whether the SureForm products infringe asserted claim 24 under the adopted construction.

Intuitive argues that the long, narrow, cylindrical part of the SureForm stapler does not include a gear-driven portion in meshing engagement with a transmission assembly. Intuitive instead asserts that the long, narrow, cylindrical part of the SureForm stapler is made up of a "[redacted]" none of which are a "gear-driven portion" of the "elongated shaft assembly" as recited in limitation 24.3.3. Intuitive Br. on Review at 21–22. Intuitive emphasizes that the SureForm stapler is cable-driven and thus "[t]here simply is no gear-driven component in the SureForm's elongated shaft assembly." *Id.* at 22.

Intuitive argues that the [redacted] and [redacted] of the SureForm stapler are part of the SureForm stapler's transmission assembly, not the elongated shaft assembly, because "neither the combo gear nor the bevel gear is part of the collection of components that forms the long, narrow cylindrical part of the surgical tool." *Id.* at 23. Moreover, Intuitive asserts that the [redacted] and [redacted], shown below, cannot be part of the elongated shaft assembly because they are

mounted to the tool mounting plate of the SureForm stapler. *Id.* Per Intuitive, the '969 patent treats the tool mounting portion of the stapler as distinct from the elongated shaft assembly. *Id.*



RDX-17C at 53 (annotating RPX-1792C).

Ethicon *does not* argue that the SureForm staplers infringe under the Commission's adopted construction. Where Ethicon responds to Intuitive's noninfringement arguments, its response is based entirely on arguing that Intuitive's claim construction is wrong. *See* Ethicon Reply on Review at 20 ("Intuitive's noninfringement argument hinges on its incorrect position that the elongated shaft assembly in the SureForm is limited to the components that 'make[] up the long, narrow cylindrical part of the surgical tool.'").

The Commission finds that the SureForm products lack an "elongated shaft assembly" with a "gear-driven portion" as recited in limitation 24.3.3 and thus affirms the ID's finding that the SureForm products do not infringe claim 24 of the '969 patent. The Commission finds that the SureForm product's [redacted] and [redacted], are not among the collection of components that make up the long, narrow, cylindrical part of the surgical tool that constitute the "elongated shaft assembly," and Ethicon has presented no evidence or argument that the SureForm products

infringe under the construction of "elongated shaft assembly" proposed by Intuitive and adopted by the Commission.

c) Indirect Infringement of "Elongated Shaft Assembly" by the SureForm Products

The ID also found that Intuitive did not indirectly infringe claim 24 of the '969 in connection with the SureForm products. ID at 28. The ID's finding rests on the fact that, absent a showing of direct infringement, there can be no indirect infringement.[8] *Id.* Because the Commission has determined to affirm the ID's finding that the SureForm products do not directly infringe claim 24 of the '969 patent—subject to the reasoning in this opinion *supra*—the Commission likewise affirms the ID's finding that Intuitive does not indirectly infringe claim 24 of the '969 patent due to the absence of a showing of direct infringement.

2. Obviousness of Claim 24

The ID considered three prior art combinations that Intuitive alleged render claim 24 of the '969 patent obvious. As to the first two combinations—(1) the da Vinci Si System with the EndoWrist One Vessel Sealer alone or in view of U.S. Patent No. 6,817,974; and (2) U.S. Patent No. 8,545,515 in view of the da Vinci Si System—the Commission has determined to take no position on whether those prior art combinations render claim 24 of the '969 patent obvious. *Beloit*, 742 F.2d at 1423.

For third prior art combination—Power Medical Interventions, Inc.'s i60 Stapler ("the PMI i60 Stapler") in view of the da Vinci Si System—the Commission has determined to affirm, with modified reasoning, the ID's finding that claim 24 is obvious in view of that combination. The

[8] That indirect infringement requires a showing of direct infringement is settled law. *See Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1348 (Fed. Cir. 2015) ("For contributory infringement, as for inducement, direct infringement is necessary and will typically take place later than the accused indirect infringer's act.").

ID's finding that the combination of the PMI i60 Stapler and the da Vinci Si System rendered claim 24 obvious turned on two subsidiary issues: (1) whether a person of ordinary skill in the art would have been motivated to combine the PMI i60 Stapler and the da Vinci Si System; and (2) whether a person of ordinary skill in the art would have had a reasonable expectation of success in doing so. ID at 30–31. The ID answered both of those questions in the affirmative, and thus found claim 24 invalid as obvious.

The ID found that a prior joint agreement between Intuitive and PMI to work towards combining the PMI i60 Stapler with the da Vinci Si System was "highly persuasive evidence" demonstrating both a motivation to combine and a reasonable expectation of success. ID at 32. The ID treated the Intuitive/PMI agreement as indicative of "[t]he fact that persons of ordinary skill in the art were actually motivated to combine the [PMI i60 Stapler and the da Vinci Si System]," but did not cite evidence from which the Commission could conclude that the decision to enter into the Intuitive/PMI agreement can be attributed to a person of ordinary skill in the art. *Id.* Ethicon raised that omission explicitly in its petition for review of the ID's obviousness determination. Ethicon Pet. at 34–35. The Commission requested briefing from Ethicon and Intuitive on the following question via its notice of review:

> 3. Does the evidence of record support the conclusion that persons of ordinary skill in the art with respect to the '969 patent were responsible for the decision to create a joint venture between PMI and Intuitive for the purpose of modifying the PMI i60 stapler to work with the da Vinci Si surgical system? Provide any citations to the record that support your contention.

86 Fed. Reg. at 46883. Both Ethicon and Intuitive agreed that the evidence of record does not support attributing the origin of the Intuitive/PMI agreement to persons of ordinary skill in the art. Ethicon Br. on Review at 15; Intuitive Br. on Review at 26–27. Based on the parties' responses, as well as our own review of the record, the Commission has determined to take no position on

whether the Intuitive/PMI agreement is probative of an ordinary artisan's motivation to combine the PMI i60 Stapler with the da Vinci Si System and the reasonable expectation of success.

The Commission also declines to apply waiver, as urged by Intuitive, to Ethicon's argument that the Intuitive/PMI agreement is attributable to persons with skill exceeding that of ordinary artisans. *See* Intuitive Br. on Review at 29. As Intuitive concedes, Ethicon raised its argument at least as early as the evidentiary hearing before the CALJ. *Id.* at 27. The Commission further notes that, even if Ethicon waived its argument that the PMI/Intuitive agreement was attributable to persons exceeding the ordinary level of skill in the art, Ethicon has no burden to establish this fact to preserve the validity of claim 24. Here, where Intuitive wholly failed to introduce evidence connecting the PMI/Intuitive agreement to decisions made by ordinary artisans, whether Ethicon can prove that the agreement was ***not*** attributable to ordinary artisans is irrelevant.

Intuitive also now requests that the Commission re-open the record and receive into evidence additional testimony given by an Intuitive employee named Salvatore Brogna during his deposition in a related matter.[9] Intuitive Br, on Review at 27–28. Intuitive contends that the additional testimony by Mr. Brogna would establish that the origin of the Intuitive/PMI agreement is attributable to persons of ordinary skill in the art—specifically, Mr. Brogna himself, Mr. Dave Rosa (Intuitive's Executive Vice President and Chief Business Officer), and Dr. Gary S. Guthart (Intuitive's Chief Executive Officer). *Id.* at 28. To prove that each of these individuals possessed ordinary skill in the art during the relevant time period, Intuitive relies on portions of Mr. Brogna's deposition that are in evidence, as well as the company profiles of Mr. Rosa and Dr. Guthart, which are not in evidence. *Id.*

[9] Portions of Mr. Brogna's deposition that were timely designated by the parties are already in the record. *See* CX-975C.

Intuitive's request to re-open the record and admit Mr. Brogna's additional deposition testimony is denied. Intuitive has not shown that good cause exists to re-open the evidentiary record at this late stage of the proceeding. Rather, Intuitive seeks to re-open the record in an attempt to rectify a deficiency in its reliance on the Intuitive/PMI agreement as evidence of obviousness. Intuitive would have the Commission believe that the deficiency in its argument is Ethicon's fault for not pointing it out sooner. But the burden lies with Intuitive to establish its prima facie case of obviousness. Intuitive's failure to introduce evidence to connect the Intuitive/PMI agreement to ordinarily skilled artisans as part of its affirmative obviousness case is of its own making, and, absent good cause for doing so at this late stage, the Commission declines to reopen the record.

Moreover, the Commission further finds that Intuitive's reliance on the additional portions of Mr. Brogna's deposition would not establish that the Intuitive/PMI agreement was attributable to ordinary artisans. The ID found, and the parties do not dispute, that a person of ordinary skill in the art with respect to the '969 patent "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 that "additional graduate education could substitute for professional experience and significant work experience could substitute for formal education." ID at 9. Mr. Brogna, Mr. Rosa, and Dr. Guthart all possess master's degrees or higher and have considerably more than three years of experience designing surgical devices just based on how long each has been at Intuitive. *See* Ethicon Reply on Review at 26. *See* CX-975C at 18:11–25, 24:19–25; Intuitive Br. on Review at Ex. 7 (Mr. Rosa's company profile); Intuitive Br. on Review at Ex. 8 (Dr. Guthart's company profile). Their levels of skill are thus beyond the level of ordinary skill in the art for the

'969 patent[10] and as such their involvement in the creation of the Intuitive/PMI agreement is not probative of obviousness. *See Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 1340 (Fed. Cir. 2010) (rejecting reliance on motivations of scientists exceeding ordinary skill in the art to establish obviousness).

Nonetheless, the Commission finds that the other evidence of obviousness cited and discussed in the ID is sufficient to support the conclusion that claim 24 is obvious in view of the combination of the PMI i60 Stapler and the da Vinci Si System. *See* ID at 32–36. Accordingly, the Commission affirms the ID's finding that claim 24 of the '969 patent is obvious.

3. Findings Concerning the '969 Patent on Which the Commission Takes No Position

In addition to the Commission's determinations detailed *supra*, the Commission has further determined to take no position on certain of the ID's findings concerning the '969 patent. *Beloit*, 742 F.2d at 1423. Specifically, the Commission takes no position on (1) whether claim 24 of the '969 patent is infringed, directly or indirectly, in connection with the EndoWrist Xi products; (2) whether claim 24 of the '969 patent is anticipated by Intuitive's da Vinci Si System with the EndoWrist One Vessel Sealer; and (3) whether claim 24 is unenforceable. The Commission notes that Ethicon has specifically stated that it does not seek to exclude the EndoWrist Xi products. Ethicon Br. on Review at 34. Accordingly, there is no reason for the Commission to take a position on infringement by the EndoWrist Xi products. The Commission's orders do not cover the EndoWrist Xi products as discussed in more detail below.

[10] To the extent that the ID's use of the phrase "at least" could be read as permitting the ordinary level of skill to extend upward without limit, the Commission declines to adopt that reading. The Commission interprets that phrase only as placing a lower limit on the level of ordinary skill. There is no basis in the record here to conclude that individuals with the breadth of skill and education held by Mr. Brogna, Mr. Rosa, and Dr. Guthart qualify as "ordinary" artisans in the context of the '969 patent.

B. The '369 Patent

The Commission determined to review the ID's findings on claim construction, infringement, and obviousness for the '369 patent. Claims 22 and 23 were asserted from the '369 patent, and the ID found both claims infringed by the SureForm products and not invalid. Claims 22 and 23 provide:

> 22. A surgical end effector, comprising:
>
> [22.1] an elongate channel including a bottom including a proximal end and a distal end, the elongate channel being configured to operably support a staple cartridge therein;
>
> [22.2] a firing element configured to translate between a first position adjacent the proximal end of the bottom of the elongate channel and an ending position adjacent the distal end of the bottom of the elongate channel, the firing element including a vertical portion and at least one laterally extending lower foot;
>
> [22.3] **an internal passage** extending within the elongate channel and configured to receive the at least one laterally extending lower foot when the firing element moves between the first position and ending position;
>
> [22.4] **a proximal channel opening** through the proximal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the first position, the proximal channel opening sized to receive therein the at least one laterally extending lower foot on the firing element; and
>
> [22.5] **means for guiding** the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element.
>
> 23. The surgical end effector of claim 22, wherein said means for guiding comprises at least one ramped surface provided on at least one of the at least one lower foot and a portion of the elongate channel defining the proximal channel opening.

JX-2 at Cls. 22–23 (emphasis added).

The ID's claim construction and infringement findings on review implicate limitations 22.4 ("the proximal channel opening limitation") and 22.5 ("the means for guiding limitation"). The

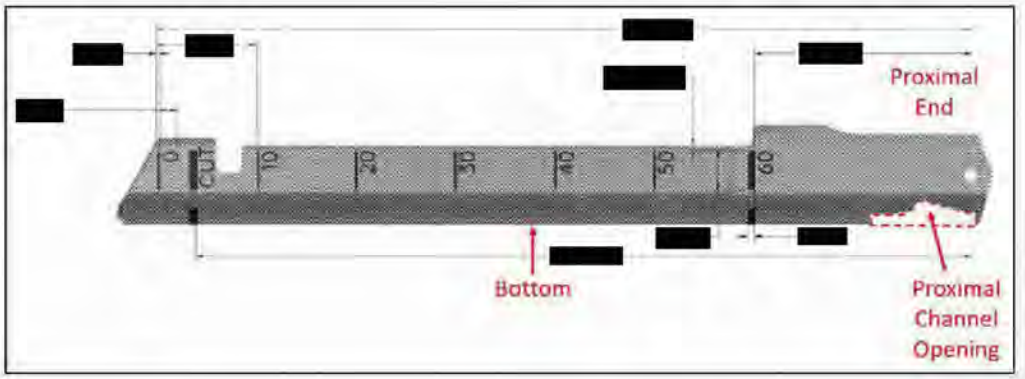
ID's obviousness findings on review implicate limitation 22.3 ("the internal passage"). None of the ID's findings turned on disputes related to the other limitations of claim 23.

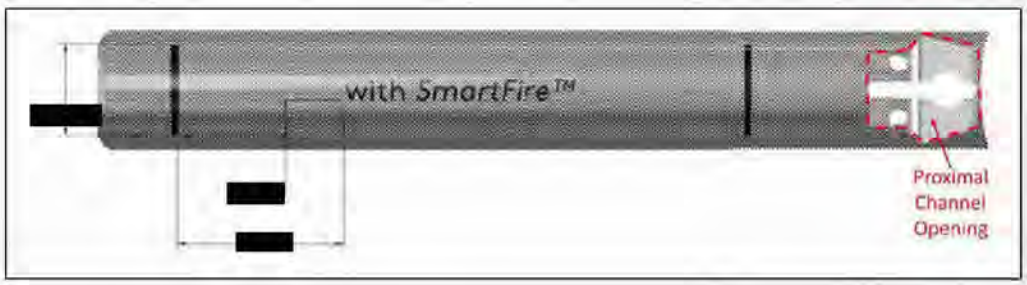
1. The Scope and Application of the "Proximal Channel Opening" Limitation

Limitation 22.4 requires an elongate channel with:

> a proximal channel opening through the proximal end of the bottom of the elongate channel to facilitate viewing of the firing element therethrough when the firing element is in the first position, the proximal channel opening sized to receive therein the at least one laterally extending lower foot on the firing element.

JX-2 at Cl. 22. Thus, the "proximal channel opening" of limitation 22.4 must have three characteristics: (1) it must be an opening through the proximal end of the bottom of the elongate channel; (2) it must facilitate viewing of the firing element through the opening; and (3) it must be sized to receive a laterally extending lower foot of a firing element. *See id.* In the SureForm products, there is a channel that looks like this:





CDX-2C at 20 (annotating RX-339C at 3); *see also* ID at 62 (reproducing same). In the image above, Ethicon's expert, Dr. Fronczak, has identified the proximal channel opening on which Ethicon relies to show infringement. ID at 62. The ID found that this opening meets all three requirements of limitation 22.4, and thus found that the SureForm products meet the proximal channel opening limitation of claim 22. *Id.* at 63.

The Commission notes, as did the ID, that there is a cover attached over the proximal channel opening in the final assembled SureForm stapler. *Id.* at 62. With the cover attached, the channel looks like this:

RPX-4 at 3. As seen in this image, the cover over the proximal channel opening includes a small oblong opening in its center. *See id.* Before the CALJ, Intuitive argued that this oblong opening is the only opening *through* the bottom of the elongate channel in the SureForm products and thus is the only opening that could practice the "proximal channel opening" limitation. *See* ID at 61. Because the opening in the cover is too small to receive the lower foot of the SureForm stapler's firing element, Intuitive argued that the SureForm staplers lack a proximal channel opening meeting all of the requirements of limitation 22.4. *See id.* The ID rejected Intuitive's argument, reasoning that "the opening identified by Intuitive is an opening in the cover, which is not part of the channel, but rather, is a separate component added to the channel." ID at 62.

Intuitive petitioned for review of the ID's findings on limitation 22.4 and argued that the ID incorrectly identified the cover as a component separate from the elongate channel. In support

of that point, Intuitive emphasized that the cover is welded in place during the manufacturing process and is not removeable thereafter. *See* Intuitive Pet. at 10–11. The Commission determined to review the ID's findings on whether the SureForm products practice limitation 22.4 and sought briefing on the following questions in connection with its review:

5. Claim 22 of the '369 patent includes the term "elongate channel." Concerning that term, identify where in the record, if anywhere:

    a. The parties proposed constructions for that term;

    b. The parties argued in support of any constructions proposed; and

    c. The ALJ construed that term.

6. Concerning the term "elongate channel," indicate whether these terms should be construed according to its plain and ordinary meaning? If this term should be construed according to its plain and ordinary meaning, what is the plain and ordinary meaning of the term? If the term should be construed otherwise, identify the correct mode of construction and the corresponding construction. Identify with specificity the evidence of record that supports your contentions with particular emphasis on evidence intrinsic to the '369 patent.

    a. Explain whether the SureForm products meet this limitation under the parties' proposed constructions.

86 Fed. Reg. 46883.

In response, the parties indicated that neither had proposed a construction for elongate channel to the CALJ and that the CALJ did not construe the term. The parties agreed that "elongate channel" should have its plain and ordinary meaning and proposed the following definitions of the plain and ordinary meaning:

	Ethicon's Construction	Intuitive's Construction
"elongate channel"	"an elongate component that forms the shape of a channel"	"the jaw of the stapler into which the staple cartridge is inserted"

Ethicon Br. on Review at 19; Intuitive Br. on Review at 31. The Commission notes that Intuitive asserted in its opening brief that the "elongate channel" need not be construed "because the parties' infringement dispute does not depend on the meaning of this term." Intuitive Br. on Review at 30. Consistent with that assertion, Ethicon submitted that "the party's [*sic*] proposed meanings of 'elongate channel' do not affect the infringement analysis." Ethicon Reply on Review at 30, n.5. Upon review, the Commission agrees that construing "elongate channel" will not bring any additional clarity to the instant infringement dispute. Accordingly, the Commission need not provide additional construction of the term "elongate channel." *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."). We thus turn to the parties' infringement dispute concerning the "proximal channel opening" limitation.

a) Whether the SureForm Staplers Practice the "Proximal Channel Opening" Limitation

On review, the Commission has determined to affirm the ID's finding that the cover is a separate component from the elongate channel for purposes of infringement, and further affirms the ID's finding that the opening in the channel identified by Ethicon meets all of the requirements of the "proximal channel opening" limitation. Intuitive frames this dispute as a question about finished versus unfinished products. To the contrary, the dispute is more aptly framed as whether the addition of an unclaimed component (the cover) to an otherwise infringing structure (the

elongate channel having a proximal channel opening) can convert the infringing product to a noninfringing one. In this instance, the answer is "no."

Intuitive does not argue, and the Commission is aware of no reason, that the channel of the SureForm products, absent the cover, does not infringe limitation 22.4. Accordingly, Intuitive must necessarily concede that if the SureForm staplers simply omitted the cover, it would have no noninfringement argument at all for this limitation.[11] The relevant question then is whether the addition of that cover to the SureForm stapler's otherwise infringing channel makes the channel noninfringing. "It is well settled that if a patent claim uses open language in its claim, such as 'comprising' or 'having,' patent infringement cannot be avoided by simply adding extraneous features or components to an accused device." 2 Annotated Patent Digest (Matthews) § 12:6 (Aug. 2021 Update).[12] Per the Federal Circuit:

> It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device. For example, a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write. Neither would infringement be negated simply because the patentee failed to contemplate use of the pencil in that environment.

A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703 (Fed. Cir. 1983).

[11] The record indicates that the channel cover was added to [redacted]. CX-924C at 75:5–9, 77:2–5. Nonetheless, intent is not relevant to the relevant inquiry.

[12] "Including," which is the term used in conjunction with "elongate channel" in claim 22, is also considered an open transition term. *SanDisk Corp. v. Memorex Prod., Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005) ("As a patent law term of art, 'includes' means 'comprising.' Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations.").

While examples applying that rule are plentiful, the rule is not totally unbounded. Where the addition of an unrecited component alters an infringing structure in a way that renders it noninfringing, the rule will not apply. *See Outside Box Innovations, LLC v. Travel Caddy, Inc.*, 260 F. App'x 316, 321 (Fed. Cir. 2008) (unpublished) ("Travel Caddy's argument that when the open transition term 'comprising' is used the addition of an unclaimed element does not mandate a finding of noninfringement is well taken. However, in this case the inclusion of an additional element changed the structure of the purported infringing object such that it could not infringe."). Examples of this exception to the general rule include claims to "flexible" fabric panels where the inclusion of an inflexible sheet between flexible fabric sheets defeated infringement, *Outside Box Innovations*, F. App'x at 321, claims to a mount that permits pivoting "through an arc of at least about 90°" where the addition of a safety stop prevented the mount from pivoting ninety degrees, *Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1327 (Fed. Cir. 2013), claims to a method of placing stock trades with a graphical user interface where automatic price updates in the accused device negated a claimed requirement for the "static display of prices," *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1354 (Fed. Cir. 2010), and claims directed to a "planar back face" where the addition of ribs to an otherwise planar surface precluded the ribbed surface from reading on the claim, *In re Vagedes*, 976 F.2d 748 (Fed. Cir. 1992) (unpublished).

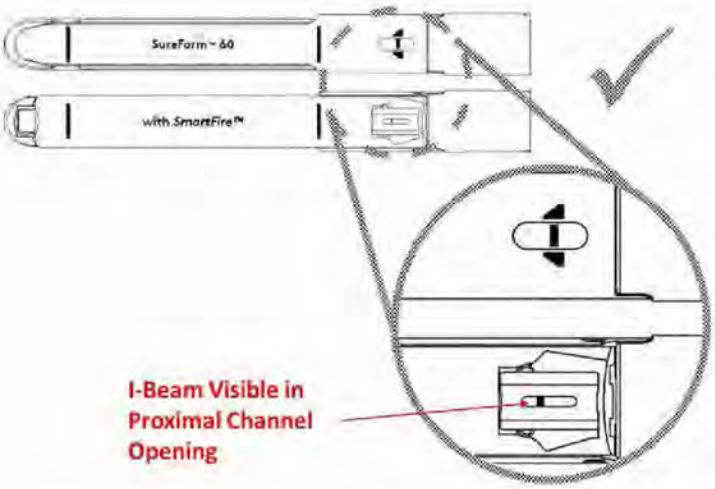
Concerning the dispute over the SureForm product, the Commission finds that the general rule that the additional components do not negate infringement applies. The addition of the cover to the opening in the channel of the SureForm products does not negate any of the features required of the "proximal channel opening" recited in limitation 22.4. With the cover attached, there remains a "proximal channel opening through the proximal end of the bottom of the elongate

channel." As can be seen in the following images, the cover does not fill or otherwise remove the opening in the bottom of the channel:

RPX-4 at 3; RX-341C. To the extent Intuitive has argued that the opening relied on by the ID is not through the bottom of the elongate channel because of the cover, Intuitive conflates the elongate channel with the final product. Limitation 22.4 requires only that the opening be through the bottom of the channel; it does not require that the opening continue through any other components attached to the channel, or that opening of the channel be an unobstructed opening to the outside of the device.

Similarly, the attachment of the cover does not negate the fact that the channel opening in the SureForm products facilitates viewing of the firing element therethrough, as required by limitation 22.4. Indeed, the firing element can be viewed through the opening in the cover, a fact not in dispute:

3. If either the top of the anvil or the bottom of the channel are visible, keep turning the Manual Release Knob until the I-beam has returned to the home position, which indicates that the jaws are fully opened. See Figure 3.11.



CDX-2C at 21 (annotating RX-1105C at 34). This follows from the arrangement of the cover, the channel opening, and the firing element. Because the channel opening is between the cover and the firing element, the channel opening must permit viewing of the firing element for the opening in the cover to be able to do so. Here, however, with or without the cover, the firing element is viewable through the opening in the bottom of the SureForm stapler's channel.

So too the opening in the SureForm stapler's channel is sized to receive therein the lower foot on the SureForm's firing element, regardless of the presence or absence of the cover. Indeed, the record includes CAD models of the SureForm stapler that show the lower foot (in green) received in the channel opening with the cover attached:

[redacted]

RX-1651C at 4. Intuitive's noninfringement arguments rely on comparing the size of the lower foot to the size of the opening in the cover, but those arguments fail because, as the ID found, the cover is a separate component from the SureForm stapler's channel. Accordingly, whether the opening in the cover is sized to receive the lower foot of the firing element is irrelevant to whether the SureForm products infringe limitation 22.4.

Intuitive focuses on the fact that the cover is welded in place, is not removeable, and is [redacted]. However, the ID's finding that the cover is separate from the channel is well supported by the evidence. For example, as seen in all of the pictures reproduced above, the cover is readily distinguishable from the channel. Moreover, [redacted]. *See* RX-341C at 1. By contrast, Intuitive's focus on the method and permanence of the cover's attachment suggests a rule whereby two structures lose their separate identities if they are permanently attached to each other. Intuitive cites no case enunciating such a rule though, and to the extent the Commission is aware of a case touching on

that idea, it stands for the opposite proposition, *i.e.*, that attachment does not cause two components to lose their separate identities. *Cf. Maxill, Inc. v. Loops, LLC*, 838 F. App'x 534, 537 (Fed. Cir. 2020) (unpublished) ("Claim 1 also describes the physical relationship between the head and the elongated body in which the head is 'disposed in and molded to' the elongated body's head portion. This insertion, however, does not mean that the head loses its identity as a separately identifiable component of the claimed toothbrush and somehow merges into becoming a part of the elongated body.").

For the reasons discussed above, the Commission has determined to affirm the ID's finding that the SureForm products practice limitation 22.4 of the '369 patent.

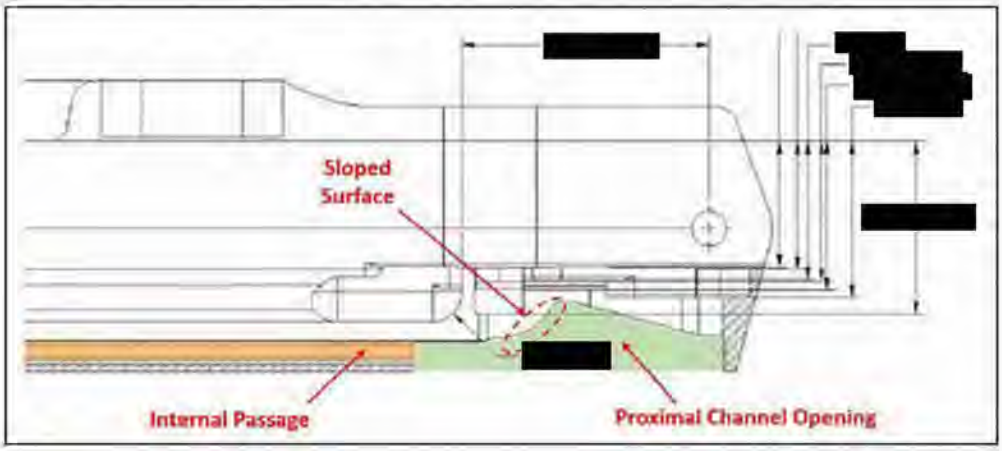
b) Whether the SureForm Staplers Practice the "Means for Guiding" Limitation[13]

Limitation 22.5 is a means-plus-function limitation, which the ID construed as follows:

[13] Vice Chair Stayin would affirm the ID's construction of "means for guiding," the finding of infringement, and ultimately, a violation of section 337 as to the '369 patent. In his view, the Commission's identification of the corresponding structure for the agreed upon function is overly narrow, and properly construed, the "means for guiding" limitation reads on the sloped surface of the SureForm products as found by the ID.

TERM	CONSTRUCTION
"means for guiding the at least one lower foot on the firing element out of the proximal channel opening and into the internal passage upon initial application of a firing motion to the firing element"	Function: Guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element Structure: (i) a chamfer or otherwise sloped surface on the foot of the firing element, and/or (ii) a chamfer or otherwise sloped surface on a portion of the elongate channel defining (a) the proximal end of the internal passage or (b) the proximal channel opening

ID at 58–59. The main dispute that the ID addressed regarding whether the required structure is present in the SureForm products was whether the "chamfer or otherwise sloped surface" must be flat or instead can be curved. As seen in the image below, the structure Ethicon pointed to in the SureForm products for infringement are curved surfaces, thus satisfaction of this limitation required the FID to find that a curved surface is within the scope of "a chamfer or otherwise sloped surface":



CDX-2C at 23 (annotating RX-339C at 2); *see also* CX-2C at Q/A 108 (referencing same). Pointing to a portion of the specification that stated that a "sloped surface" could comprise one or more "curved surfaces," the ID found that the curved surfaces in SureForm's products meet the structural definition of this limitation.[14] ID at 66–67. On review, the Commission has determined to reverse the ID's finding that the corresponding structure for limitation 22.5 includes sloped surfaces that are curved.

"The construction of a means-plus-function limitation includes two steps." *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1330 (Fed. Cir. 2005). The Commission first must "determine the claimed function," and second must "identify the corresponding structure in the written description that performs that function." *Id.* On review, neither Ethicon nor Intuitive assert that the ID erred in determining the function of the "means for guiding" limitation to be "guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to

[14] The ID also rejected an additional argument from Intuitive regarding the location of the sloped surface, finding that nothing "requires the sloped surface to be located on the bottom of the internal passage or on the bottom of the foot of the firing element." ID at 67, n.29.

the firing element." ID at 58–59. So too the Commission finds no error in the ID's determination of the function of the "means for guiding" limitation, which we affirm here.

With respect to the second step of construing a means-plus-function term, identifying corresponding structure, the Federal Circuit has held that "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *B. Braun Med., Inc. v. Abbott Lab'ys*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). Here, the Commission finds that the sole discussion of structure that is clearly linked to the function recited in limitation 22.5 appears at column 77, lines 24–29, which is reproduced below along with the preceding paragraph for context:

> FIG. **40** illustrates the position of the cutting head **6050** and firing bar **6080** when an unspent surgical staple cartridge has been operably supported within the elongate channel **6122.** Although the body of the surgical staple cartridge is not shown in FIG. **40,** a wedge sled assembly **6078** is shown. It will be understood that the wedge sled assembly **6078** will be in the position shown in FIG. **40** in an unfired or unspent staple cartridge. When in that position, the wedge sled assembly **6078** engages with the hook portion **6056** on the cutting head **6050** to raise the cutting head **6050** in an upward direction (arrow "U" in FIG. **40)** to a point wherein, when the cutting head **6050** is advanced distally, the feet **6070** thereon will enter the internal passage **6030** in the elongate channel **6122.** When employing the elongate channels that have closed bottoms or substantially closed bottoms such as those described herein, a dimensional stack situation could conceivably occur wherein interference between the channel bottom and the knife foot or feet could occur when the end effector is used to cut and staple extremely thin tissue. If the tissue is too thin, for example, the tissue compression resistance may not be enough to push the anvil away from the elongate channel and load those two components against the cutting head tabs. If this situation occurs, the knife foot or feet could extend below the bottom of the elongate channel far enough so that the cutting head could not be distally advanced. The cutting head assembly **6050** and elongate channel arrangement **6122** depicted in FIGS. **40** and **41** may prevent this from happening.
>
> As can be seen in FIGS. **40** and **41**, for example, the distal end of each foot **6070** may have a chamfer **6072** formed thereon. The chamfer **6072** is configured to engage corresponding portions of the

> elongate channel **6122** as the cutting head **6050** is advanced distally to cause the feet 6070 to enter the internal passage **6030.** Thus the chamfers **6072** form small "lead-in" ramps which help to guide the feet **6070** into the passage **6030.** ***As can also be seen in FIGS. 40 and 41, the portion of the elongate channel 6122 defining the proximal end 6131 of the internal passage 6030 may have a chamfer 6133 thereon or otherwise be sloped as shown.*** In alternative arrangements, the feet **6070** (or single foot) may be provided with the chamfer **6072** or the proximal end portion **6131** of the internal passage **6030** may be provided with the chamfer **6133** or both chamfer arrangements may be provided ***as shown in FIGS. 40 and 41.***

JX-2 at 76:39–77:39 (emphasis added). The ID's analysis relied heavily on the sentence we have emphasized in the above passage. *Id.* at 77:31–34. Focusing on the word "sloped," the ID reasoned that because other portions of the specification described sloped or ramped surfaces that could be curved, the word "sloped" here must imply the same. ID at 65–66 (citing JX-2 at 25:17–20, 26:12–15). Here the ID erred insomuch as it relied on structures in the specification that do not perform the function of "guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element" to expand the scope of the corresponding structure for the "means for guiding" limitation. Specifically, the ID relied on the "sloped surface **208** in Figure 10," and on the "ridge **615** in Figure 18," which the specification indicates can comprise a "ramped surface." *Id.* But neither the sloped surface **208** nor the ridge **615** perform the function of "guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element." The sloped surface **208** describes a part of the staple cartridge and is not clearly linked to any function, let alone the guiding function of the "means for guiding" limitation. *See* JX-2 at 25:14–20. The ridge **615** similarly describes a part of the staple cartridge and ascribes it two possible functions: (1) "facilitate the sliding of tissue across the staple cartridge **642** when the tissue is positioned in the end effector"; and (2) "increase

the strength and/or stiffness of the cartridge body **685**." *Id.* at 26:15–25. Neither of those functions is the function of the "means for guiding" limitation.

As the Federal Circuit found under analogous facts in *B. Braun Medical*, it is inappropriate to expand the scope of the structure that is clearly linked to a claimed function with alternative structure disclosed in the specification that is not so linked. *See* 124 F.3d at 1424–25. In *B. Braun Medical*, the Federal Circuit was called on to decide the scope of the corresponding structure for the claimed function of "holding said disc firmly against said first means in such a manner that said disc is restrained from sideways movement." *Id.* at 1424. While there was no dispute that a "traverse cross bar," was clearly linked structure that performed the claimed function, Braun, like Ethicon here, argued that the asserted patent contained additional corresponding structure. *See id.* Specifically, Braun pointed to a "valve seat" identified in the asserted patent as additional corresponding structure. *Id.* The Court rejected Braun's argument, explaining that "[a]lthough Fig. 3 of the patent shows a valve seat, neither the specification nor the prosecution history contains *any* indication that the valve seat structure corresponds to the recited function." *Id.* at 1425. Going a step further, the Court explained that the "lack of association between the valve seat and the recited function is especially striking given the explicitly clear association provided between the traverse cross bar and the recited function." *Id.* Applying the reasoning of *B. Braun Medical*, the Commission finds that the absence of any indication that the sloped surface **208** or the ridge **615** corresponds to the function of "guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element" precludes reliance on those structures to expand the scope the corresponding structure for the "means for guiding" limitation.

The ID's contrary conclusion appears to stem from an erroneous interpretation of the above-quoted portion of the specification. Specifically, the ID appears to read that portion of the specification as linking any sloped surface (or ramped surface) to the guiding function of the "means for guiding" limitation. *See* ID at 66 ("[O]ne of ordinary skill in the art would understand that a 'sloped surface' or 'ramped surface' could encompass flat surfaces, curved surfaces, concave surfaces, and convex surfaces."). The specification does not link all sloped or ramped surfaces generally to the claimed guiding function though. Rather, it points only to Figures 40 and 41 and states, "[a]s can be seen in FIGS. **40** and **41**, for example, the distal end of each foot **6070** may have a chamfer **6072** formed thereon." It further discloses a surface that is chamfered "or otherwise sloped ***as shown***" in Figures 40 and 41. JX-2 at 77:34. Figures 40 and 41, the relevant portions of which are reproduced below, show only flat surfaces, not show curved surfaces:

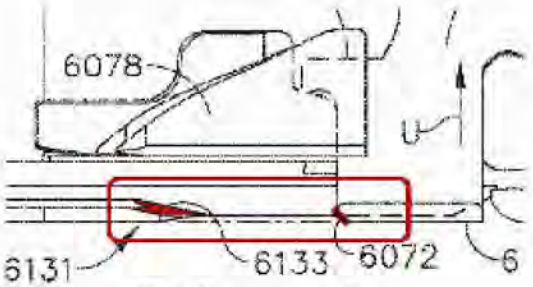


FIG. 40

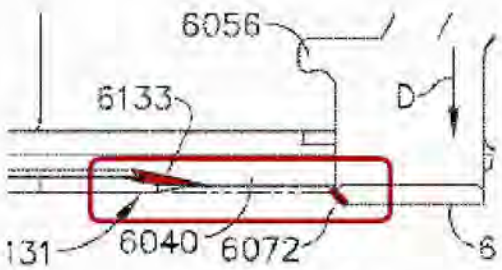


FIG. 41

Intuitive Pet. at 22 (annotations added by Intuitive). The ID's reliance on sloped surface **208** and ridge **615**, shown below, to expand the scope of the corresponding structure for limitation 22.5 to include curved surfaces was error, and we reverse it as such:

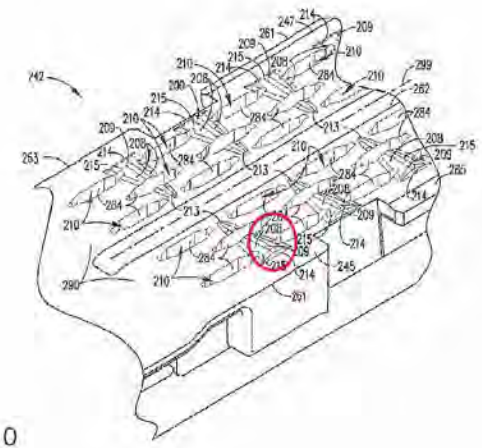


FIG. 10

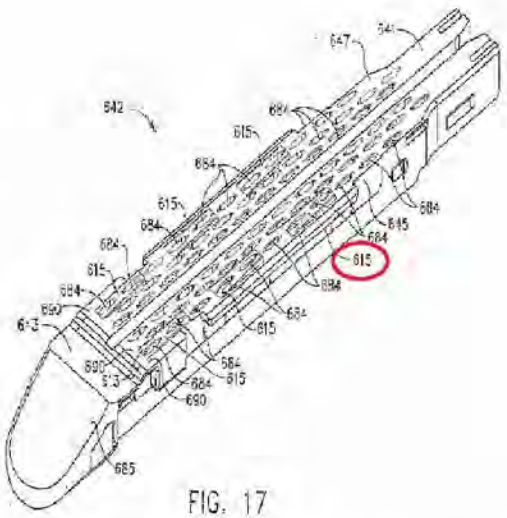


FIG. 17

JX-2 at Figs. 10, 17 (annotations added by Commission). Accordingly, curved surfaces, whether characterized as slopes, ramps, or chamfers, are not corresponding structure for the function recited by limitation 22.5. While a person of ordinary skill in the art may well understand the word "sloped," in its general sense, to be broad enough to encompass curved surfaces, that is beside the point here where the term is further limited by the phrases "as shown" and "[a]s can be seen in FIGS. **40** and **41**." Because the only guiding surfaces shown in Figures 40 and 41 are flat, the Commission finds that the corresponding structure for limitation 22.5 is limited to flat surfaces such as those shown in Figures 40 and 41.[15]

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[15] The Commission notes that while section 112, ¶ 6 sets the scope of means-plus-function elements to corresponding structure described in the specification and "equivalents thereof," it is nonetheless improper to adopt a broad definition of the corresponding structure under the guise of equivalency. Structural equivalence is a separate issue from the identification of "the structure disclosed in the written description as corresponding to the recited function." *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1213 (Fed. Cir. 2002), *abrogated on other grounds by Phillips*, 415 F.3d at 1303. Moreover, structural equivalence is a question of fact on which Ethicon bears the burden of proof, *Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1373 (Fed. Cir. 2001); *see also* 19 C.F.R. § 210.37(a) ("The proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto."). Because Ethicon has at no point in this investigation argued or adduced evidence that the curved surfaces in the SureForm staplers are structural equivalents of the flat surfaces shown in Figures 40 and 41 that correspond to the

Because the Commission has modified the ID's construction of limitation 22.5, we must address whether the SureForm products practice that limitation under that modified construction.[16] In anticipation of this possibility, the Commission posed the following question to the parties in our Notice of Review:

> 7. Claim 22 of the '369 patent includes the limitation: "means for guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element." If the Commission determines that the corresponding structure for that limitation is limited to flat, as opposed to curved, chamfers and slopes, would the accused products practice this limitation?

86 Fed. Reg. at 46883. In response to this question, Ethicon argued that the "SureForm Staplers meet the means for guiding limitation even if the Commission determines that the corresponding structure for the means for guiding limitation is limited to flat chamfers and slopes." Ethicon Br. on Review at 28. The reasoning behind Ethicon's argument is that it can subdivide the relevant sloped surface in the SureForm products into a curved portion and a flat portion. *Id.* at 28–29. Per Ethicon, the flat portion practices limitation 22.5, while the curved portion is merely an additional unrecited element, which, due to the use of the word "comprised" in the preamble of the claim, will not defeat infringement. *Id.* at 29–30. Intuitive disagrees with Ethicon and argues, essentially, that the flat portion of the guiding surface in the '369 patent cannot be considered separately from the curved portion. Intuitive Reply on Review at 34–36. Concerning Ethicon's reliance on the open-ended language of claim 22, Intuitive argues that the term "comprising" cannot be used to

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claimed guiding function of limitation 22.5, a finding of structural equivalence would be inappropriate here.

[16] Vice Chair Stayin would affirm the ID's finding of infringement, and thus would not reach the question of whether the SureForm products infringe the "means for guiding" limitation if it does not encompass curved surfaces. Accordingly, Vice Chair Stayin does not join the Commission's analysis of this question, including the legal discussion, *infra*, pp. 50–54.

broaden the corresponding structure for limitation 22.5 to include curved surfaces. *Id.* at 40–41 (citing *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1376 (Fed. Cir. 2005) ("[C]omprising is not a weasel word with which to abrogate claim limitations . . . or to impermissibly expand a claim's scope."); *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998) (rejecting an attempt to use "the term 'comprising' [to] alter the scope of the . . . element in the claim at issue")).

Based on the parties' briefs, the Commission views the primary dispute concerning limitation 22.5 to be whether or not to apply the general rule that additional unclaimed elements in an accused device will not defeat infringement of a claim that uses the open-ended transition term "comprised." The dispute is similar to the one concerning limitation 22.4 and the effect of attaching a cover to the SureForm stapler's elongate channel, but it is not identical. The dispute over limitation 22.4 dealt with the addition of a wholly separate component—the cover—to an otherwise infringing structure—the elongate channel. Here, there is a single structure in the SureForm products that includes both curved portions and flat portions. Thus, the question is not so much whether an additional unrecited element defeats infringement as it is whether Ethicon can parse the sloped surface of the SureForm stapler into flat and curved portions and rely on the flat portion only to establish infringement. The Commission finds that Ethicon cannot, and thus finds that the SureForm products do not practice limitation 22.5 and therefore do not infringe claim 22.

The leading case on the issue of finding infringement based on only a portion of an accused device is *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999). In *SunTiger*, the asserted patent was directed to "optical lenses for sunglasses that screen out certain wavelengths of visible light that may cause harm to human eyes after extended exposure. The lenses covered by the '046 patent incorporate an orange-colored, sharp cut-on dye

that blocks out blue light while allowing other colors of light to be transmitted." *Id.* at 1329–30. The particular claim at issue claimed, *inter alia*, lenses comprised of:

> (a) a transparent, organic plastic matrix material, and (b) a sharp cut-on orange dye incorporated into said material that allows the lens to transmit at least 90% of the visible sunlight with wavelengths longer than 636 nm and block more than 99% of all sunlight with wavelengths shorter than 515 nm.

Id. at 1331. The evidence in *SunTiger* showed that the accused lenses included an orange layer that met these limitations. *Id.* "However, in addition to the orange dye, the accused lens also incorporate[d] a gray gradient surface coating that reduce[d] the amount of visible light transmitted by the accused lens." *Id.* The effect of the gray coating was that "no part of the accused lens met the transmission limitations of claim 1 except for the 'right bottom' portion of the accused lens where the gray gradient coating was lightest and allowed for the transmission of the most visible light." *Id.* The question before the Court on appeal thus was whether the fact that a portion of the lenses met the transmission requirements of claim 1 was sufficient to find infringement. The Court concluded that it was, explaining:

> Reasoning that the gray coating that BluBlocker applied to its accused orange-dyed lens changes the transmission characteristics of the lens such that it is outside the scope of the asserted claims, the district court granted summary judgment of non-infringement to BluBlocker. This conclusion was reached despite the evidence that the "right bottom" of the accused lens met the claim limitations.
>
> The district court was persuaded that the gray coating on the BluBlocker lens changed an inherent property, thereby removing the accused lens from infringement. The district court's error lies in the fact that we have never required that a claim read on the entirety of an accused device in order to infringe. If a claim reads merely on a part of an accused device, that is enough for infringement. As we explained in *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991):
>
> > It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device. For example, a pencil

> structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.
>
> (quoting *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703, (Fed.Cir.1983)). *Cf. Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 623 (Fed. Cir. 1995) (holding that part-time infringement is nonetheless infringement). Any other reasoning would allow an infringer to avoid infringement merely by adding additional elements to an infringing device.

Id. at 1336. However, the Court went on to acknowledge that "in certain instances adding elements may allow a product to avoid infringing a claim." *Id.* (discussing *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098 (Fed. Cir. 1996)).

Vagedes illustrates one example where the general rule regarding the effect of additional unclaimed structures in a device did not apply. There, the issue was whether a prior art device disclosed in a reference called "White" included "a structure having a main panel with a planar back face," as recited in the relevant claim. *Vagedes*, 1992 WL 196739 at *1. The Patent and Trademark Office Board of Patent Appeals and Interferences ("Board") sustained an examiner's rejection of that claim as anticipated by White, explaining that:

> The claims are drafted as open-ended claims in the use of the word "including" to list the elements of each claim and do not preclude ribs on an otherwise planar back face. Stated differently, the apparatus of White includes a main panel having a planar back face and raised ribs on the planar back face and, accordingly, corresponds to the literal language of the claims.

Id. In other words, the Board applied the conventional rule that the presence of additional unclaimed structures in a device that is otherwise within the scope of a claim does not take that device outside the scope of the claim. The Court rejected the Board's reliance on that rule and reversed its decision. The Court explained:

> We are convinced that the "planar back face" limitation is not itself an element but a limitation to the "main panel" element. *See Corning Glass Works v. Sumitomo Elec. U.S.A.*, 868 F.2d 1251,

> 1259 (Fed. Cir. 1989). Even though an open ended claim may permit additional elements, these additional elements cannot result in the modification of an explicit limitation of the claims. In this case, if raised ribs were added to the back surface of the "main panel" referred to in the claims, it would no longer have a planar face. In that event the "planar back face" limitation would be changed.

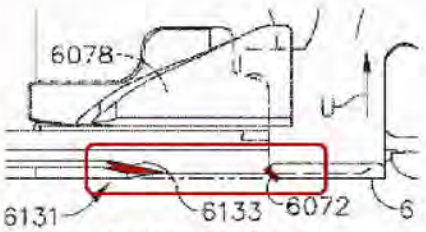
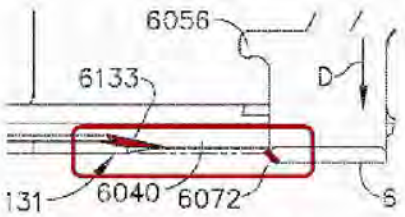
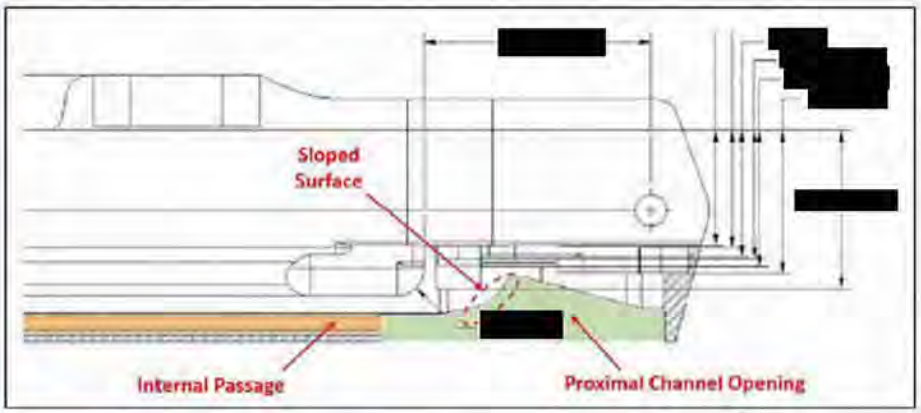
Id. We understand *Vagedes* to illustrate a distinction between adding unclaimed structures to a device—whether accused or prior-art—that is within the scope of a claim, which will not take the device outside the scope of the claim, and dissecting a structure that is not within the scope of a claim into isolated parts to create a structure that *is* within the scope of that claim. Since *Vagedes*, this idea has been reiterated. For example, in *Slot Speaker Techs., Inc. v. Apple, Inc.*, No. 13-CV-01161-HSG, 2018 WL 1581985, at *3 (N.D. Cal. Mar. 27, 2018), *aff'd*, 776 F. App'x 709 (Fed. Cir. 2019), concerning a claim limitation requiring sound waves to travel in a "straight path," the district court explained:

> SST contends that under *SunTiger, Inc. v. Scientific Res. Funding Grp.*, 189 F. 3d 1327, 1336 (Fed. Cir. 1999), a specific portion of the sound path in the accused products may be isolated to find infringement. *See* SST Opp. Mot. at 20. The Court is not persuaded. *SunTiger* involved sunglasses that blocked visible sunlight. Part of the accused lenses contained infringing transmission rates, but other parts were affected by an additional element: a coating that altered the transmission rates such that those parts did not infringe. Here, in contrast, SST cannot point to a portion of the accused products that meets every limitation of an asserted claim. The sound waves emitted from the output aperture cannot be segregated into those that followed a straight path and those that did not, because to engage in that type of strategic box-drawing would vitiate the purported invention of the patent.

2018 WL 1581985, at *3; *see also, e.g.*, *Vita-Mix Corp. v. Blendtec, Inc.*, No. 1:15 CV 1118, 2017 WL 3425286, at *5 (N.D. Ohio Aug. 9, 2017) ("The Court rejects plaintiff's argument that the ridges are an added feature that should be ignored in assessing infringement. As defendant aptly

notes, this doctrine applies where an element is added to a product that *otherwise* meets each claim element.").

Ethicon's infringement argument based on a flat portion of the sloped surface in the SureForm products is more like the failed arguments of *Vagedes*, *Slot Speaker Techs.*, and *Vita-Mix* than it is like the prevailing argument in *SunTiger*. Whereas the patentee in *SunTiger* pointed to a portion of the accused lens that met every limitation of its asserted claim, Ethicon here advances an argument like the one in *Slot Speaker Techs.* insomuch as it seeks to isolate a select portion of the accused curved surface in the SureForm products to create a flat, and therefore infringing, surface out of the otherwise noninfringing curved surface of the SureForm stapler. However, Ethicon's focus on an isolated portion of the sloped surface in the SureForm product cannot change the fact that the sloped surface is not chamfered or otherwise sloped as shown in Figures 40 and 41. A simple side-by-side comparison confirms as much:

Figures 40 and 41	 FIG. 40  FIG. 41
SureForm Stapler	

There can be no reasonable dispute that the sloped surface in the SureForm products is curved and unlike the sloped surfaces "as shown" in Figures 40 and 41. Ethicon has failed to point to any precedent that supports reaching a different conclusion by focusing on an isolated portion of the SureForm stapler's sloped surface to the exclusion of the rest of the surface, which is indisputably curved.

The testimony of Ethicon's own expert, Dr. Fronczak, also undermines its attempt to establish that the sloped surface in the SureForm products is composed of two separate structures, one being flat and the other curved. For example, in his testimony concerning limitation 22.5, Dr. Fronczak consistently refers to a singular "sloped surface" in the SureForm products, including when testifying that the SureForm products would infringe even if the guiding means of limitation

22.5 were restricted to flat surfaces. *See, e.g.*, CX-2C at Q/A 108 ("As I explained previously, the proximal channel opening includes a sloped surface. That sloped surface comprises a portion that has a constant slope of [redacted], which is a flat surface."). In so doing, his testimony reinforces the fact that the SureForm products have a single sloped surface, which is unlike the sloped surfaces shown in Figures 40 and 41. Accordingly, the Commission finds, as a factual matter, that the SureForm staplers do not include a surface that is chamfered or sloped "as shown" in Figures 40 and 41.

Separate from Ethicon's failure to identify structure in the SureForm products that matches the structure of limitation 22.5, Ethicon has also failed to identify evidence establishing that the flat portion of the sloped surface in the SureForm products, on its own, performs the guiding function of limitation 22.5. Where Dr. Fronczak addresses the claimed guiding function in his testimony, he refers only to the "sloped surface" of the SureForm staplers as a whole, not to a flat portion or curved portion of the "sloped surface." *See id.* at Q/A 110. Thus, even if the Commission were to agree with Ethicon that a flat portion of the sloped surface in the SureForm products is identical to the structure of limitation 22.5, the Commission would still be compelled to find that the SureForm products do not practice limitation 22.5 due to an absence of evidence showing that the flat portion of the curved surface on which Ethicon relies performs the guiding function of limitation 22.5.

Consistent with our findings detailed above, the Commission finds that the SureForm products do not practice limitation 22.5 of claim 22 of the '369 patent and thus do not infringe that claim. Because the only other asserted claim of the '369 patent—claim 23—depends from claim 22, the Commission necessarily also finds that the SureForm products do not infringe claim 23

either. The effect of these findings is to reverse the ID's finding of violation of section 337 based on infringement of the '369 patent.

2. Findings Concerning the '369 Patent on Which the Commission Takes No Position

In addition to the Commission's findings and determination on infringement detailed *supra*, the Commission has further determined to take no position on the ID's obviousness findings concerning the '369 patent. *Beloit*, 742 F.2d at 1423.

C. Remedy

The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. US. Int'1 Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

1. Limited Exclusion Order

Section 337(d)(1) provides that "[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1).

The RD recommended that the Commission issue a limited exclusion order ("LEO") in this investigation covering any products and components found to infringe the asserted patents. ID at 114–15. The RD further recommended that the limited exclusion order not include numerous carve outs requested by Intuitive due to a lack of record support for those carve outs. *Id.* at 115. The RD also explained, in response to Intuitive's post hearing arguments, that "limited exclusion orders need not be limited to those articles named as accused products in the complaint, and they can also cover products and components of products that indirectly infringe the asserted patents." *Id.*

Ethicon agrees with the RD that a limited exclusion order should issue in this investigation.[17] Ethicon Br. on Review at 39–40. Presently, Intuitive's primary argument on remedy is that the Commission should suspend any remedial orders based on the '379 patent pending the Federal Circuit's review of the Patent Trial and Appeal Board's ("PTAB") consolidated Final Written Decision in two *inter partes* reviews ("IPR") finding that the asserted claims of the '379 patent are invalid. Intuitive Br. on Review at 66–70; *see also Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2020-00050 and IPR2020-00051, Patent 9,844,379, Final Written Decision Determining All Challenged Claims Unpatentable (Mar. 26, 2021) ("Final Written Decision").[18] That issue, which is relevant to any remedial orders issued in this investigation is addressed separately below. Intuitive's only other arguments concerning the issuance of a limited exclusion order are that it should contain a certification provision, that it should be narrowly tailored, and that articles that do not infringe should not be excluded from importation. Intuitive Br. on Review at 70–71; Intuitive Reply on Review at 55–58.

Intuitive's certification provision request seeks a certification provision allowing it to certify, pursuant to U.S. Customs and Border Protections' ("CBP") procedures, that it is familiar with the terms of the order, has made appropriate inquiry, and to the best of its knowledge and belief, the products being imported are not excluded. Intuitive Br. on Review at 70–71. Ethicon opposes Intuitive's request for a certification provision on the basis that CBP will be able to readily

[17] Ethicon's initial brief on review includes responses to several arguments that Intuitive raised before the CALJ, but that the RD did not adopt, and that Intuitive appears to have abandoned before the Commission. *See id.* at 40–47.

[18] The appeals from the consolidated Final Written Decision IPR2020-00050 and IPR2020-00051 were docketed as *Ethicon LLC v. Intuitive Surgical, Inc.*, Fed. Cir. Dkt. Nos. 21-1995 and 21-1997, respectively. The Federal Circuit consolidated those appeals with No. 21-1995 as the lead appeal. Ethicon filed its opening brief in the consolidated appeals on September 10, 2021.

identify Intuitive's infringing products through a visual inspection such that certification is unnecessary. Ethicon Reply on Review at 53. Ethicon also asserts that "Intuitive has provided no evidence that it intends to modify any of the Accused SureForm Products in a non-infringing manner such that Customs [CBP] will be confused by the proposed import, so its request is premature." *Id.* at 53–54. Moreover, Ethicon asserts that a Part 177 adjudication before CBP or a Commission ancillary proceeding (*e.g.,* modification or advisory) will adequately protect Intuitive's ability to import any future product that does not infringe. *Id.* at 54.

Intuitive's request that any limited exclusion order be narrowly tailored is vague, and it is unclear whether Intuitive's request seeks anything other than a standard LEO. *See* Intuitive Reply on Review at 55. Intuitive asserts that "[a]ny remedial order issued by the Commission should be tailored to those specific products or specific components which were found to infringe a valid and enforceable claim" and that "any articles that are not found to infringe, either directly or indirectly, … should not be deemed within the scope of any remedial order the Commission may issue." *Id.* Thus, it is unclear if Intuitive is requesting that the Commission's exclusion order be limited to the specific models and components of surgical staplers adjudicated in this investigation, or if it is merely requesting that the Commission ensure its exclusion order not ensnare staplers and components found noninfringing in this investigation. Complicating the issue, because this argument appears in Intuitive's reply brief, the Commission lacks any context that could be gleaned from a response by Ethicon.

Turning to Intuitive's request that articles that do not infringe should not be excluded, the Commission notes that such a request is unremarkable on its face. However, the portion of Intuitive's brief in which that request appears is actually dedicated to revisiting its argument that the "elongated channel" of the SureForm products ceases to meet the requirements of limitation

22.4 once the cover is welded to it. *Id.* at 56–58. Relying on that theory, which the Commission has rejected, Intuitive argues that because the cover is added to the elongated channel [redacted], the SureForm stapler, as imported, does not infringe and should not be excluded. As explained, Intuitive's argument necessarily fails in light of the Commission's rejection of the same argument in the context of infringement.

As to Intuitive's "narrowly tailored" request, to the extent Intuitive is attempting to restrict the scope of the exclusion order to the specific model names or numbers of SureForm staplers adjudicated in this investigation, it is well-settled that the Commission's orders are not to be so limited. *See Hardware Logic Emulation Systems and Components Thereof* ("*Hardware Logic*"), Inv. No. 337-TA-383, USTIC Pub. 3089, Comm'n Opinion on Remedy, the Public Interest, and Bonding at 16 (Mar. 1998). As the Commission explained in *Hardware Logic*:

> The Commission's long-standing practice is to direct its remedial orders to all products covered by the patent claims as to which a violation has been found, rather than limiting its orders to only those specific models selected for the infringement analysis.[] … [W]hile individual models may be evaluated to determine importation and infringement, the Commission's jurisdiction extends to all models of infringing products that are imported at the time of the Commission's determination and to all such products that will be imported during the life of the remedial orders.")..

Id. (omitting footnote collecting exemplary investigations). If instead Intuitive is requesting that the order not cover noninfringing products, a standard LEO will not, by its plain terms, cover a noninfringing product. Should Intuitive consider importation of redesigned products or models that have not been adjudicated here, those products cannot enter the United States under certification until such products have been adjudicated to be outside the scope of the LEO. Intuitive can obtain such a ruling *inter alia* through procedures available under Commission Rules 210.76 (modification proceeding) or 210.79 (advisory opinion). *See* 19 C.F.R. §§ 210.76, 210.79. The Commission notes that Ethicon has indicated in its briefing that it does not seek exclusion

orders against the EndoWrist products despite having accused them in this investigation, *see* Ethicon Br. on Review at 34, and further that the Commission's sole determination of violation is based on infringement of the '379 patent, for which the EndoWrist staplers are not accused products. Accordingly, the Commission's remedial orders do not cover the EndoWrist staplers.

Concerning Intuitive's request for a certification provision and Ethicon's opposition to the same, as the Commission recently explained, it "no longer limits the inclusion of certification provisions to only situations where [CBP] might not be able to readily ascertain whether an incoming product is subject to the order." *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm'n Op. at 45–46 (Sep. 29, 2021). Rather, the Commission now "consistently include[s] certification provisions in exclusion orders to prevent an importer from avoiding exclusion by simply stating that an article being imported is not subject to the order." *Id.* Accordingly, the Commission finds that the LEO in this investigation should include the standard certification provision where, at the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles that are potentially subject to the LEO may be required to certify that they are familiar with the terms of the LEO, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under the LEO. Certification is acceptable for those articles that were previously determined by the Commission not to violate the LEO. *See Automated Teller Machines, ATM Modules, Components Thereof, & Prods. Containing the Same*, Inv. No. 337- TA-972, Comm'n Op., 2017 WL 11198798, *17 (June 12, 2017) ("The standard certification language does not apply to redesigns that have not been adjudicated as non-infringing.") (quotation omitted).

In sum, the Commission has determined to issue a standard limited exclusion order directed to Intuitive's laparoscopic surgical staplers, reload cartridges, and components thereof that infringe '379 patent that includes the standard certification language.

2. Cease and Desist Order

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order ("CDO") as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.[19] *See, e.g.*, *Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof* ("*Table Saws*"), Inv. No. 337-TA-965, Comm'n Op. at 4-6 (Feb. 1, 2017); *Certain Protective Cases & Components Thereof*, Inv. No. 337-TA-780, USITC Pub. No. 4405, Comm'n Op. at 28 (Nov. 19, 2012) (citing *Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-551, Comm'n Op. at 22 (June 24, 2007)). Complainants bear the burden on this issue. *Table Saws*, Comm'n Op. at 5 (citing *Certain Integrated Repeaters, Switches, Transceivers, & Prods. Containing Same*, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm'n Op. at 27 (Aug. 16, 2002); *see also* H.R. REP. No. 100-40, at 160 (1987)).

[19] When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations needs to be "commercially significant" in order to issue the CDO. *See, e.g.*, *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65, n.24 (Mar. 25, 2019); *Table Saws*, Comm'n Op. at 6-7, n.2 (Feb. 1, 2017). In Commissioner Schmidtlein's view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a cease and desist order. *Id.*

The RD found that Intuitive maintains commercially significant quantities of SureForm products in the United States and on that basis recommended issuance of cease and desist orders.[20] As with the limited exclusion order, the RD declined to recommend carve outs to the CDOs that Intuitive pressed before the CALJ, but has now abandoned. Ethicon agrees with the RD that CDOs are appropriate. Ethicon Br. on Review at 47–49. Intuitive does not address the RD's recommendation on CDOs at all in its briefing except through its generic assertions that "[a]ny remedial order issued by the Commission should be tailored to those specific products or specific components which were found to infringe a valid and enforceable claim" and that "any articles that are not found to infringe, either directly or indirectly, do not have such a relationship and should not be deemed within the scope of any remedial order." Intuitive Reply on Review at 55.

Because Intuitive's only statements that could be read to bear on the issuance of CDOs are coextensive with its request that the limited exclusion order be "narrowly tailored," we reject those statements as they pertain to the issuance of CDOs for the same reasons as we did with respect to the LEO. Intuitive's maintenance of commercially significant inventories in the United States establishes that CDOs directed to Intuitive are appropriate. The Commission therefore agrees with the RD that CDOs should issue in this investigation. Accordingly, the Commission has determined to issue CDOs directed to Intuitive in connection with its laparoscopic surgical staplers, reload cartridges, and components thereof that infringe '379 patent.

3. Suspension of the Remedial Orders

The Commission has found a violation and determined that issuance of an LEO and CDOs is warranted. However, the Commission has determined to exercise its discretion to suspend

[20] The RD indicated that the parties jointly stipulated that Intuitive's domestic inventory related to the SureForm products was: [redacted]. ID at 116, citing CX-0589C.

enforcement of those remedial orders pending resolution of Ethicon's appeal of the PTAB's Final Written Decision finding all claims of the '379 patent to be unpatentable. *See Viscofan*, 787 F.2d at 548 (finding that the Commission has "broad discretion in selecting the form, scope, and extent of the remedy"). Suspension of the remedial orders pending resolution of the PTAB's Final Written Decision is consistent with the Commission's past practice on this issue. *See, e.g.*, *Certain Unmanned Aerial Vehicles and Components Thereof* (*"Unmanned Aerial Vehicles"*), 337-TA-1133, Comm'n Op. at 35 (Sep. 8, 2020); *Certain Magnetic Tape Cartridges and Tape Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 62-63 (Apr. 9, 2019); *Certain Three-Dimensional Cinema Systems and Components Thereof*, Inv. No. 337-TA-939, Comm'n Op. at 60 (July 21, 2016). Indeed, as the Commission explained at length under similar circumstances in *Unmanned Aerial Vehicles*, suspended enforcement of remedial orders is within the Commission's discretion over the form, scope, and extent of its remedy and may be appropriate where, as here, the PTAB issues a final written decision of unpatentability concerning certain claims before the Commission issues remedial orders based on those same claims. *Unmanned Aerial Vehicles*, Comm'n Op. at 35–38.

Ethicon, which opposes suspension of the remedial orders in this investigation during the pendency of the appeal from the PTAB's Final Written Decision, acknowledges that the Commission has suspended its orders in similar circumstances, but submits that the Commission lacked authority to do so in those instances. Ethicon Reply on Review at 51–52. However, that assertion relies on Ethicon's related assertion that the statutory provisions of section 337 preclude the Commission from tailoring the scope of its remedy to a particular period of time. *See id.* at 49–50 (arguing that section 337 requires the Commission to issue orders that are immediately enforceable upon their issuance). The language of section 337 does not so restrict the Commission,

and Ethicon's assertion to the contrary directly conflicts with *Viscofan*'s recognition that the Commission maintains "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan*, 787 F.2d at 548. Indeed, as even Ethicon acknowledges, *Viscofan* expressly confirmed the Commission's discretion to limit the duration of time during which its order would be enforced. *Id.* at 549–550 (discussing Commission's selection of a ten-year duration for the exclusion order); *see also* Ethicon Reply on Review at 51 ("[T]he accused infringer in *Viscofan* challenged the Commission's form of remedy—an exclusion order—***and the scope and extent of that order—10-year duration of the products excluded***." (emphasis added)). Ethicon fails to explain why the scope and extent of the enforceable duration of the orders in *Viscofan* was within the Commission's discretion, but the scope and extent of the enforceable duration of the orders in this investigation is not.

Ethicon also argues that suspending the enforcement of the remedial orders in this investigation would be inconsistent with the Commission's refusal in prior investigations to stay its orders pending the appeal of its own decisions. Ethicon Reply at 52–53. Specifically, Ethicon argues that a "suspension pending appeal of the PTAB's finding of unpatentability is no more justifiable than a stay pending appeal of the Commission's finding of [a rejection of a defense of] invalidity." *Id.* at 53. That argument is based on a false equivalence between a final written decision of unpatentability by the PTAB and a final determination of violation of section 337 by the Commission. When the PTAB issues a final written decision of unpatentability, as it did here, the successful challenger in that *inter partes* review ("IPR") is estopped by statute from raising the same invalidity arguments before the Commission. 35 U.S.C. § 315(e)(2). Indeed, that is exactly what happened in this investigation—a result which Ethicon actively advocated. ID at 101–02; *see also* Ethicon Resp. at 40–47. Absent the same invalidity arguments being raised before the

Commission by another party not estopped under § 315(e)(2), the Commission would render its determination on violation of section 337 without consideration of the IPR petitioner's arguments that led to the PTAB's determination of unpatentability. That scenario shares little in common with the prior Commission precedents cited by Ethicon where the Commission refused to stay its orders pending appeals of its own determinations of violation in investigations where it made no finding that the patent was *invalid* and there was no corresponding PTAB determination that would have estopped the respondent from raising invalidity arguments before the Commission. *See id.* at 53 (citing *Certain EPROM, EEPROM, Flash Memory, and Flash Microcontroller Semiconductor Devices and Prods. Containing the Same*, Inv. No. 337-TA-395, USITC Pub. No. 3392 (Feb. 2001), Comm'n Op. at 90 (Dec. 11, 2000); *Certain Agricultural Tractors Under 50 Power Take-off Horsepower*, Inv. No. 337-TA-380, Comm'n Op. at 17 (Apr. 25, 1997).

Accordingly, the Commission has determined that it is appropriate under the facts in this investigation to suspend enforcement of the limited exclusion order and cease and desist orders, including the bond provision, pending final resolution of the PTAB's Final Written Decision finding all claims of the '379 patent unpatentable.

D. The Public Interest

Upon finding a violation, section 337 requires the Commission to issue an exclusion order "unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(l). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g.*, *Certain Fluidized*

Supporting Apparatus & Components Thereof, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm'n Op. at 1–2, 23–25 (Oct. 1984) (finding that the public interest warranted denying complainant's requested relief). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. For example, the Commission has allowed continued importation for ongoing medical research, exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third-party consumers to transition to non-infringing products. *E.g.*, *Certain Microfluidic Devices*, Inv. No. 337-TA-1068 Comm'n Op. at 1, 22–48, 53–54 (analyzing the public interest, discussing applicable precedent, and ultimately issuing a tailored LEO and a tailored CDO); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm'n Op. at 32–33 (July 18, 2019) (exempting service parts); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, Comm'n Op. at 150–51 (Oct. 2011) (grandfathering certain products); *Certain Personal Data & Mobile Comm'n Devices & Related Software*, 337-TA-710, USITC Pub. No. 4331, Comm'n Op. at 72–73, 80–81 (June 2012) (delaying effective date of remedy).

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. 19 U.S.C. § 1337(d)(l), (f)(l). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in an investigation. 19 U.S.C. § 1337(d)(l) & (f)(l).

On June 14, 2021, the Commission issued a notice via the *Federal Register* soliciting comments on public interest issues raised by the relief recommended in the CALJ's recommended determination ("RD") on remedy and bond. 86 Fed. Reg. 31536 (June 14, 2021). The Commission received twelve submissions from the public in response to that notice. On July 8, 2021, pursuant to Commission Rule 210.50(a)(4), Ethicon and Intuitive each filed submissions addressing the effect the RD's proposed remedies would have on the public interest. The parties also addressed the public interest in their briefs in response to the Commission's Notice of Review.[21] We address the public's and the parties' submissions in turn below.

1. Responses from the Public

The submissions on the public interest from the public come from a number of surgeons who perform procedures that utilize laparoscopic staplers. The surgeons that currently use the Intuitive SureForm staplers posit a detrimental effect on the public interest if the staplers are excluded. The surgeons that do not use the SureForm staplers do not foresee such a detrimental effect. We briefly summarize each response here.

- Dr. Alan C. Wittgrove identifies himself as a surgeon "who has performed thousands of bariatric procedures, including what is regarded as the world's first laparoscopic gastric bypass surgery." Wittgrove PI Statement at 1. Dr. Wittgrove indicates that he is a consultant of Ethicon's and is being paid for his time but is nonetheless expressing his own opinions. Dr. Wittgrove states that he does not believe "there is a patient benefit associated with performing bariatric surgery with Intuitive's robotic surgical systems." *Id.* at 2. He also states that "there is to date no reliable clinical evidence showing that there is a benefit to patients or surgeons in using Intuitive's robotic systems or robotic linear staplers in bariatric procedures." *Id.* at 3. Dr. Wittgrove also states that handheld staplers such as those made by Ethicon can and are used in combination with Intuitive's robotic surgery systems by having a second clinician fire the stapler manually at the direction of the surgeon controlling the robot. *Id.* at 3–4. Dr. Wittgrove opines that "performing bariatric surgeries with Intuitive' s robotic surgical systems and a secondary clinician firing a

[21] The Commission did not delegate responsibility to the CALJ for taking evidence and making findings concerning the effect of a remedy on the public interest in this investigation.

handheld linear stapler does not pose any additional risk to a patient when compared to the same surgery performed with a robotic mounted linear stapler.

- Dr. William B. Tisol identifies himself as "a cardiothoracic surgeon and regular user of Intuitive's *da Vinci* system and Intuitive's EndoWrist and SureForm robotic staplers." Tisol PI Statement at 1. Dr. Tisol indicates that he uses Intuitive's robotic surgical system extensively and that the SureForm stapler is his preferred stapler. *Id.* at 2. He also expresses a preference for fully robotic procedures over hybrid procedures, which he argues are slower and less efficient than fully robotic procedures. *Id.* at 2–3. Dr. Tisol posits that the use of SureForm staplers improves patient outcomes. Dr. Tisol identifies several benefits of the SureForm staplers, including superior stapler formation and extended range of motion. *Id.* at 3–4. Dr. Tisol summarizes that "Robotic surgery using the SureForm stapler has shortened recovery times, decreased pain, lowered blood utilization during surgery, decreased surgery times, and minimized the frequency and severity of complications. *Id.* at 4.

- Dr. Harmik J. Soukiasian identifies himself as "a surgeon specializing in robotic-assisted thoracic surgery using the Intuitive *da Vinci* surgical system and robotic SureForm staplers." Soukiasian PI Statement at 1. Dr. Soukiasian opines that "the public health and welfare will suffer greatly if I and other surgeons performing robotic thoracic surgery can no longer use Intuitive's SureForm robotic staplers." *Id.* Dr. Soukiasian identifies several purported advantages attributable to the SureForm staplers, including increased precision, increased stability, and increased sensory feedback. *Id.* at 2–3. Dr. Soukiasian indicates that he has performed one hybrid surgery using a robotic system with a manual stapler and would prefer to return to fully manual surgery rather than use that procedure if SureForm staplers are not available. *Id.* at 4.

- Dr. Eric Smith identifies himself as "a surgeon who has performed hundreds of operations using the Intuitive *da Vinci* surgical system with the Intuitive EndoWrist 45 and SureForm 60 surgical staplers and reload cartridges." Smith PI Statement at 1. Dr. Smith explains that when he began using robotic surgery systems, he used hybrid procedures because the 45mm staplers available for the robotic system were not long enough for the bariatric procedures he was conducting. *Id.* Dr. Smith further explains that when a 60mm stapler was released for the robotic platform, he abandoned the hybrid procedure in favor of a fully robotic one and has observed improved patient outcomes as a result. *Id.* at 1–2. A particular advantage over manual staplers that Dr. Smith points to is the ability of the stapler to measure tissue thickness in real time, which in turn allows the surgeon to select a staple of appropriate thickness with more precision than is possible with a manual stapler. *Id.* at 2. Dr. Smith opines that if the SureForm stapler were not available, he would have to use an inferior stapler such as that made by Ethicon. *Id.* at 2–3.

- Dr. Sharona B. Ross identifies herself as "surgeon who has performed hundreds of operations using the Intuitive *da Vinci* surgical system with the Intuitive EndoWrist and SureForm surgical staplers and reload cartridges." Ross PI Statement at 1. Dr. Ross indicates that she has "experience using handheld staplers manufactured by both Ethicon and Medtronic, and robotic surgical staplers manufactured by Intuitive." *Id.* at 2. Dr. Ross opines that "the Intuitive robotic staplers, used with the Intuitive *da Vinci* platform, are

superior to their handheld counterparts and result in better outcomes for my patients." *Id.* at 2. Dr. Ross indicates that she has experience using the *da Vinci* system in hybrid procedures with manual staplers, with the EndoWrist 45 stapler, and with the SureForm 60 stapler. *Id.* Dr. Ross identifies several reasons that hybrid procedures with the *da Vinci* system are inferior to fully robotic procedures with the EndoWrist and SureForm staplers, including the need to rely on another person to operate the manual stapler, substantial grip strength required to fire manual staplers, increased size of powered manual staplers, and less stability. Dr. Ross notes improved patient outcomes with the use of robotic staplers, particularly identifying lesser occurrences of staple line leakage and bleeding. *Id.* at 5. We note that Dr. Ross does not distinguish between the EndoWrist and SureForm staplers in discussing the advantages of robotic staplers.

- Dr. Daryl S. Marx identifies himself as "a general surgeon specializing in general, bariatric, and robotic-assisted surgery using advanced minimally invasive techniques." Marx PI Statement at 1. Dr. Marx indicates that if he "were unable to deploy and use Intuitive's SureForm staplers in the surgeries I perform, many of my patients would needlessly suffer moderate to serious consequences." *Id.* Notably, Dr. Marx only identifies manual staplers as alternatives to the SureForm stapler. He does not mention the EndoWrist stapler. Dr. Marx points to many of the same advantages of the SureForm staplers as the other surgeons who use those staplers, including increased precision and control as well as reduced incidences of staple line leakage and bleeding. *Id.* at 3–4. Like Dr. Ross, Dr. Marx's remarks focus on advantages of the SureForm stapler over manual staplers, not other robotic staplers such as the EndoWrist stapler.

- Dr. M. Brian Harkins identifies himself as "surgeon who has performed nearly two thousand surgeries using the Intuitive *da Vinci* surgical system including many with the Intuitive EndoWrist and SureForm surgical staplers and reload cartridges." Harkins PI Statement at 1. Dr. Harkins opines that "Intuitive robotic surgical staplers are superior to traditional handheld staplers and offer improved results for my patients." *Id.* at 2. Dr. Harkins indicates that he has experience with hybrid procedures using the *da Vinci* system but prefers fully robotic procedures. *Id.* Like others, Dr. Harkins explains that he finds hybrid procedures less desirable because of the reduced control he has over the procedure and the increased time necessary to complete the procedure. *Id.* at 3. Dr. Harkins identifies similar advantages to robotic staplers as other surgeons who use them. *Id.* at 3–5. Dr. Harkins concludes by stating that "some or all of the benefits that I have described would be lost if I were unable to use the Intuitive EndoWrist and SureForm staplers and were required to use handheld staplers instead." *Id.* at 5.

- Dr. Reza Gamagami identifies himself as "a surgeon who regularly performs minimally-invasive surgery using Intuitive SureForm staplers." Gamagami PI Statement at 1. Dr. Gamagami opines that a "significant number of my patients, and many of the patients of other surgeons who regularly use Intuitive SureForm staplers and reloads, are likely to suffer adverse consequences if we are forced to use different instruments" from the SureForm staplers. *Id.* Dr. Gamagami goes on to detail advantages of the SureForm stapler in line with those mentioned by other surgeons, including increased sensory feedback, increased range of motion, lower incidences of bleeding and leakage, and shorter hospital stays for patients. *Id.* at 2–4.

- Dr. Andrew J. Duffy identifies himself as "surgeon and an educator who has performed more than 800 operations using the Intuitive *da Vinci* surgical system, and have used the Intuitive EndoWrist and SureForm surgical staplers and reload cartridges in the majority of these surgeries." Duffy PI Statement at 1. Dr. Duffy explains that he relies on "the SureForm and EndoWrist surgical staplers for a significant portion of my cases." *Id.* at 2. Like other surgeons who use the Intuitive's robotic staplers, Dr. Duffy identifies advantages such as increased precision, accuracy, speed, lesser bleeding and leakage, and fewer complications. *Id.* at 4–5.

- Dr. Elizabeth A. Dovec identifies herself as "a bariatric surgeon who has experience with both laparoscopic and robotic procedures." Dovec PI Statement at 1. Dr. Dovec indicates that she is a consultant of Ethicon's and is being paid for her time but is nonetheless expressing her own opinions. Dr. Dovec identifies the "primary clinical benefit of Intuitive's robotic surgical systems [as] enabling the conversion of open surgery to minimally invasive surgery for certain types of surgeries," and thus distinguishes between space constrained procedures where that benefit is realized and non-space constrained procedures. *Id.* at 3. Dr. Dovec identifies her specialty, bariatric surgery, as non-space constrained. Dr. Dovec indicates that she experiences no issues firing or articulating manual staplers such as those made by Ethicon, and further sees no advantage to the SureForm's sensory feedback over the physical feedback she experiences gripping a manual stapler. *Id.* at 3–4. Dr. Dovec indicates that she is "not aware of any clinical evidence that bariatric procedures with Intuitive robotic surgical systems or robotic-mounted linear staplers can improve patient outcomes," and that she uses laparoscopic techniques in her practice as opposed to robotic techniques. Dr. Dovec asserts that "it is well known that robotic bariatric surgery with Intuitive's systems takes longer than laparoscopic bariatric surgery." *Id.* at 4. Dr. Dovec agrees that shorter surgery times benefit patients, but because she believes robotic surgeries take more time than laparoscopic surgeries, she sees operation time as a factor in laparoscopic surgery's favor. *Id.* at 4–5. Dr. Dovec concludes that she does "not believe that Intuitive's robotic systems and robotic-mounted linear staplers, including their SureForm products, provide a benefit to patient outcomes over existing laparoscopic procedures and handheld linear staplers." *Id.* at 5.

- Dr. Dale D. Burleson identifies himself as "a surgeon who has performed over six hundred robotic surgeries using the Intuitive *da Vinci* surgical system with the Intuitive SureForm surgical staplers and reload cartridges." Burleson PI Statement at 1. Dr. Burleson's asserts that his comments are submitted on his behalf as well as 18 other surgeons at his practice. *Id.* at 1–2. Dr. Burleson prefers SureForm staplers over manual staplers for many of the reasons other surgeons using robotic surgical systems have already mentioned. *Id.* at 2–5. Dr. Burleson also indicates that hybrid procedures with the *da Vinci* system are not preferred due to the extended surgical time that process entails. *Id.* at 3.

- Dr. Collin E.M. Brathwaite identifies himself as "Chairman of Surgery and the Chief of the Division of Minimally Invasive Surgery and Director of the Bariatric Surgery Program at NYU Langone Hospital—Long Island on Long Island, New York, and a Professor of Surgery at the NYU Long Island School of Medicine in Mineola, New York." Brathwaite PI Statement at 1. A significant portion of Dr. Brathwaite's statement is devoted to

explaining his view that robotic surgery is superior to laparoscopic surgery. *Id.* at 2–5. Dr. Brathwaite does not address the advantages or disadvantages of using the SureForm staplers versus the EndoWrist staplers or either of those robotic staplers versus a manual stapler in a hybrid procedure.

These submissions demonstrate that surgeons who have committed to using a *da Vinci* system in their practices strongly prefer using robotic staplers that can be controlled from the *da Vinci* console as opposed to manual staplers controlled by a surgical assistant in a so-called "hybrid procedure." These surgeons' preferences are based in part on their professional judgment that the use of robotic staplers leads to improved patient outcomes. The ability to use any robotic stapler with the *da Vinci* system appears more important than the ability to use a particular stapler. The comments do not support the conclusion that the SureForm stapler is particularly superior to the EndoWrist stapler as only one of the multiple robotic surgical system users identified specific advantages of the SureForm stapler over the EndoWrist stapler. As noted above, the EndoWrist products are not covered by the Commission's remedial orders. Accordingly, even if the SureForm staplers are excluded, the EndoWrist products would appear to provide a viable alternative for these surgeons. The public submissions also show that some surgeons do not believe robotic surgical systems provide better patient outcomes over laparoscopic surgeries and thus have opted not to use robotic systems.

2. Analysis

a) Public Health and Welfare

Ethicon contends that exclusion of the SureForm staplers does not implicate any public health or welfare concerns in the United States. Ethicon Br. on Review at 35. The basis of Ethicon's contention is that manual staplers used in a hybrid procedure with a robotic surgical system or Intuitive's own EndoWrist staplers will provide adequate substitutes for surgeons who prefer to perform robotic surgery. *Id.* Additionally, Ethicon argues that studies exist showing that

surgeries performed with the *da Vinci* robotic system result in longer operating times and increased cost compared to traditional laparoscopic methods. *Id.* at 35–37. Ethicon asserts that these studies also support the conclusion that there is no observed clinical benefit to robotic surgery over traditional laparoscopic surgery. Ethicon goes on to point out that for all but the last three years of the *da Vinci* system's 20+ year existence, stapling procedures with the *da Vinci* system were conducted with either manual staplers such as Ethicon's or with Intuitive's EndoWrist stapler. *Id.* at 37–38. Ethicon also argues that surgeon preference is not the same as a patient safety issue. *Id.* at 38.

Intuitive disagrees with Ethicon that the EndoWrist robotic staplers or manual staplers used in hybrid procedures are comparable substitutes for the SureForm stapler. Intuitive Br. on Review at 54. Concerning the EndoWrist staplers specifically, Intuitive points to portions of public interest submissions by three surgeons as evidence of the superiority of the SureForm stapler over the EndoWrist stapler. *Id.* at 54–55. Intuitive goes on to allege five advantages the SureForm staplers have over the EndoWrist staplers, which are: (1) that the SureForm staplers are available in sizes up to 60mm in length versus the maximum 45mm length of the EndoWrist staplers, thus permitting use in a wider array of operations; (2) that the 60mm length SureForm stapler allows for fewer staple figures over the EndoWrist alternative, and thus shorter surgery times; (3) that the I-beam architecture of the SureForm staplers is superior to the cantilever architecture of the EndoWrist staplers; (4) that only the SureForm staplers utilize "SmartFire" technology to dynamically adjust the speed the I-beam moves during the stapling procedure, which improves staple formation; and (5) that the SureForm is for single-patient use only as opposed to the EndoWrist that is intended to be re-used, which necessitates reprocessing. *Id.* at 55–56.

Intuitive criticizes the public interest submissions from Drs. Wittgrove and Dovec based on their compensation by Ethicon and their limited experience using robotic surgery systems. *Id.* at 59, n.7, 60. Intuitive also argues that Drs. Wittgrove's and Dovec's opinions fail to address the importance of robotic surgery in fields other than bariatric surgery. Concerning the studies attributing higher costs and operating time to robotic surgeries, Intuitive argues that those studies failed to consider downstream costs, which it contends are lower in robotic surgeries due to fewer complications and argues that Ethicon artificially inflated operating times for robotic staplers by including machine setup time. *Id.* at 62. Finally, Intuitive dismisses the timing of its release of the SureForm stapler as irrelevant. *Id.* at 62–63.

The Commission finds that the record of this investigation demonstrates that the exclusion of SureForm robotic staplers will have some effect on the public health and welfare insomuch as some surgeons currently use and prefer the SureForm staplers over manual staplers. We find, based largely on the public interest submissions of the surgeons using robotic surgical systems, that handheld staplers are not comparable substitutes for robotic staplers in all circumstances. However, we also find that the continued availability of Intuitive's own EndoWrist robotic staplers will mitigate whatever detrimental effects are associated with excluding the SureForm staplers. Here too we rely on the public interest submissions of the surgeons using robotic surgical systems insomuch as those submissions evince substantial differences between robotic staplers and manual staplers for use in robotic laparoscopic surgery, but at the same time evince only a single difference in available tool length between the SureForm and EndoWrist staplers for use in robotic laparoscopic surgery.

Of the surgeons who prefer robotic surgery with Intuitive's staplers, only one, Dr. Smith, identifies a specific advantage of the SureForm staplers over the EndoWrist staplers. *See* Smith

PI Statement at 1–2 (identifying the additional length of a 60mm robotic stapler, such as the SureForm 60, as an advantage of shorter 45mm staplers, such as the EndoWrist 45, in certain bariatric procedures). While Intuitive cites portions of three other surgeons' public interest comments for the proposition that the SureForm staplers are superior to the EndoWrist staplers, in each case the surgeon merely states his or her preference for the SureForm stapler. *See* Intuitive Br. on Review at 55. By way of example, Dr. Tisol, who has used handheld staplers, the EndoWrist stapler, and the SureForm stapler, states his preference for the SureForm stapler. Tisol PI Statement at 2. However, when he elaborates on his reasons for preferring the SureForm stapler, he is comparing it to handheld staplers, not the EndoWrist stapler. *See id.* at 3–4. Nothing in Dr. Tisol's statement identifies an advantage conveyed by the SureForm stapler but not the EndoWrist stapler. Similarly, the portion of Dr. Marx's statement that Intuitive relies on is clearly comparing the SureForm stapler with handheld staplers, not the EndoWrist stapler. Marx PI Statement at 3. And the same is true of the portion of Dr. Gamagami's statement that Intuitive cites. *See* Gamagami PI Statement at 2. Concerning the five advantages of the SureForm staplers over the EndoWrist staplers that Intuitive lists on pages 55–56 of its brief, we note, as does Ethicon in its reply, that Intuitive points to no supporting evidence for those advantages. *See* Ethicon Reply on Review at 45.

The Commission is not persuaded by Intuitive's suggestion that Drs. Dovec's and Wittgrove's comments should be afforded less weight because they were compensated by Ethicon for their time. Surgeons who currently use robotic surgical systems with the SureForm staplers had an inherent motivation to submit public interest comments in this investigation because the possibility of remedial orders barring Intuitive's robotic staplers stood to directly impact their practices. The same is not true for surgeons who have opted not to perform robotic surgeries like

Drs. Dovec and Wittgrove. There is no indication in the record that the fact that these surgeons have been paid for their time compromised the veracity of their professional opinions as to the benefits or lack thereof to patient outcomes with respect to the use of robotic staplers as compared to conventional staplers. Further, Ethicon's reply brief on review includes public data showing that 24 of the 26 doctors who submitted public interest comments in Intuitive's favor have also received payments from Intuitive at some point between 2014 and 2020. *Id.* at 40–41. In some instances, those payments are quite small (~$1000), and in other cases they are quite large, the largest being more than $2.3M. *Id.* Accordingly, we note that, in terms of party compensation received by the surgeons who submitted public interest statements in this investigation, the record indicates whether each professional surgeon has received compensation either from Ethicon or Intuitive. The Commission sees no reason to disparage the motivations of any of the surgeons who submitted public interest comments in this investigation on this basis and declines to do so.[22, 23]

At bottom, the Commission finds that the potential effect of an exclusion order and CDOs directed to only the SureForm products on the public health and welfare does not justify

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[22] Commissioners Schmidtlein and Johanson do not join this paragraph. *See Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm'n Op. at 58, n.44 (Sep. 29, 2021) (adopting the ALJ's finding that public interest submissions should be accorded less weight because the filers were compensated in the form of trips and experiences in exchange for their public interest comments).

[23] The Commission finds that the record of this investigation is distinguishable from *Tobacco Heating Articles*, in which the ALJ found "the majority of the public comments were unreliable, failed to account for the scientific evidence evaluated by the FDA, and were tainted by bias due to Philip Morris's coordination." *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm'n Op. at 58 (Sept. 29, 2021) (citing ID at 110-116). The Commission agreed with the ALJ in that case that "the evidence supports the ALJ's conclusion that the doctors' and other entities' public interest statements were tarnished by Phillip Morris' actions and lack credibility." *Id.* at 58 n.44. In contrast, the evidence of record here is insufficient to conclude that the information submitted by the surgeons is unreliable based only on the fact that they received compensation from Ethicon or Intuitive.

withholding such orders. The Commission sees no need to tailor or withhold the orders given the continued availability of the EndoWrist staplers.

b) Competitive Conditions in the U.S. Economy

Turning to the competitive conditions in the U.S. economy, Ethicon asserts that its requested exclusion order would not have an adverse effect on competitive conditions because its handheld staplers, as well as those made by Medtronic, comprise [redacted] of the market for staplers and reloads, and that the EndoWrist staplers comprise a portion of the remaining [redacted] of the market. Ethicon Br. on Review at 38. Accordingly, Ethicon submits that "consumers will still have several competitive products available to them" if the SureForm staplers are excluded. *Id.*

Intuitive asserts that "the main concern here is public health and welfare, not competitiveness."[24] Intuitive Br. on Review at 63–64. Intuitive goes on to argue that handheld staplers and even its own EndoWrist staplers are not direct competitors to the SureForm staplers for the reasons explained in its comments on the public health and welfare. *Id.* at 64.

The record in this investigation does not indicate that that competitive conditions in the U.S. would be adversely impacted by the exclusion of the SureForm products. For the reasons given above in the public health and welfare context, the Commission disagrees with Intuitive that the record establishes that the SureForm and EndoWrist staplers are not comparable products. Because Intuitive will be able to continue selling the EndoWrist stapler, the effect on competitive conditions from the exclusion of the SureForm stapler will be small given that Intuitive will still have a comparable product on the market in the EndoWrist stapler. Further, to the extent Intuitive

[24] Intuitive essentially focuses exclusively on harm to the public health and welfare in its public interest briefing.

was the sole supplier of robotic staplers for use with the *da Vinci* system, it will remain so even after exclusion of the SureForm staplers, in supplying the EndoWrist staplers for use in this system.

Accordingly, the Commission finds that the potential effect of an exclusion order and CDOs directed to only the SureForm products on competitive conditions in the U.S. economy does not justify withholding such orders.

c) U.S. Production of Articles That Are Like or Directly Competitive with Those That Are Subject to Investigation

On the effect of a remedial order on U.S. production of like or directly competitive articles, Ethicon submits there will be no such adverse effects because staplers made by itself, competitor Medtronic, and Intuitive will provide an adequate supply of substitute products. Ethicon Br. on Review at 38–39. Ethicon further submits that it "is unaware of any limitations that would impact its ability to supply replacement products in a commercially reasonable time." *Id.* at 39.

In response, Intuitive argues that handheld staplers from Medtronic and Ethicon are not substitutes for the SureForm staplers, and also that even its own EndoWrist stapler is not a substitute for the SureForm stapler. Intuitive Br. on Review at 64–66; Intuitive Reply on Review at 54.

Intuitive's arguments that there are no substitutes for the SureForm staplers does not address how *U.S. production* of like or directly competitive articles would be affected. Moreover, consistent with the Commission findings above, while handheld staplers are not directly competitive with the SureForm staplers, the Commission disagrees with Intuitive's contention that its own robotic EndoWrist staplers are not directly competitive articles. Accordingly, the Commission finds that the potential effect of an exclusion order directed to only the SureForm products on U.S. production of like or directly competitive articles does not justify withholding such an order.

d) U.S. Consumers

Ethicon states that "[t]he recommended remedial orders will have no adverse impact on United States consumers" because "Ethicon and (if necessary) Medtronic and Intuitive can supply consumers in the United States with competing replacement products." Ethicon Br. on Review at 39. Intuitive replies that handheld staplers are not comparable to the SureForm staplers and thus would not serve as substitutes to ameliorate harm to U.S. consumers. Intuitive Br. on Review at 66; Intuitive Reply on Review at 54.

Here again, given the continued availability of the EndoWrist robotic staplers, which are comparable to the SureForm robotic staplers, the Commission finds that the potential effect of an exclusion order and CDOs directed to only the SureForm products on U.S. consumers does not justify withholding such orders.

3. Conclusion on Public Interest

In sum, the Commission finds that the potential effects of an exclusion order and CDOs directed to only the SureForm products on the public interest, as considered according to the statutory public interest factors, do not warrant withholding such orders.

E. Bonding

If the Commission enters an exclusion order or a CDO, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); see also 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, & Prods. Containing Same, Including Self-stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 2949,

Comm'n Op. at 24 (Jan. 16, 1996). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same*, Inv. No. 337-TA-499, Comm'n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a one hundred percent bond. *See, e.g., Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm'n Op. at 6-7 (Nov. 24, 2009). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm'n Op. at 40 (July 21, 2006).

The CALJ's RD recommended that the Commission set the bond amount at zero percent (0%) (*i.e.*, no bond) of the entered value of the SureForm products. ID at 118. The RD reached that recommendation by applying a price differential approach, where, because the SureForm products are more expensive than Ethicon's domestic industry staplers, it found that a zero percent bond was appropriate. *Id.* at 117. Intuitive agrees with the RD's recommendation of a zero percent bond and defends the RD's use of a price differential and its recognition that the Intuitive products are more expensive than the domestic industry products. Intuitive Br. on Review at 71–77. By contrast, Ethicon urges a bond set at one hundred percent (100%) of entered value based on its assertion that the SureForm staplers are in competition with its own staplers, a price comparison is not practical, and no licensing data exists to support a reasonable royalty rate. Ethicon Br. on Review at 49–52.

The Commission has determined to adopt the RD's recommendation and set the bond rate at zero percent (0%) (*i.e.*, no bond) of the entered value of the SureForm products. Although Ethicon argues that a price comparison is not practical in this investigation, it does not explain why it is impractical other than the accused products are sold at a higher price than the domestic industry products. *See* Ethicon Br. on Review at 51. Contrary to Ethicon's statement otherwise, we find that a price comparison is practical here because the parties and their experts did conduct such a comparison. The result formed the basis for the RD's finding that the SureForm products are more expensive than the domestic industry products. The RD's conclusion that a bond of zero percent is appropriate under those facts is consistent with the Commission's determination on bond in *Table Saws*, Comm'n Op. at 13–15, on which the RD explicitly relied. The Commission sees, and Ethicon offers, no reason to depart from the RD's recommendation and create inconsistency with a prior decision.[25] Accordingly, the Commission has determined to set the bond rate at zero percent (0%) (*i.e.*, no bond) of the entered value of the SureForm products.

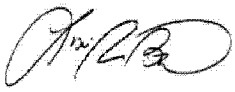
V. CONCLUSION

For the reasons set forth herein, the Commission has determined that Ethicon has established a violation of section 337 by Intuitive with respect to claims 2 and 3 of the '379 patent, but no violation with respect to the other three asserted patents. Accordingly, the investigation is terminated with a finding of violation of section 337. The Commission has determined that the appropriate remedy is a limited exclusion order and cease and desist orders, the public interest

[25] The sole precedent on which Ethicon relies to support its position for a one hundred percent bond under these facts is the RD in *Certain Switches and Prods. Containing Same*, Inv. No. 337-TA-589, Recommended Determination on Remedy and Bonding at 7 & n.3 (Nov. 21, 2007). However, the Commission did not find a violation in that investigation and thus did not address the ALJ's recommendation on bond.

does not preclude that remedy, and the bond during the Presidential review period is set at zero percent (0%) of entered value (*i.e.*, no bond). Finally, the Commission has determined to suspend the orders pending resolution of the PTAB's Final Written Decision finding all claims of the '379 patent unpatentable.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: December 20, 2021

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached document has been served via EDIS upon the Commission OUII Investigative Attorney and the following parties as indicated, upon the date listed below.

Document	Security	Document Type	Official Rec'd Date	Title
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/s/

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