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the user no longer pinches the jaws shut because a spring biases the reload channel to the open position.” CX-0002C at Q/A 236; CX-0075C.013 (“When the I-beam is fully retracted, the jaws shall spring open.”); CX-0924C (Wixey) at 83:14-85:4 (admitting that a spring in the SureForm Staplers biases the jaws to the open position); Fronczak, Tr. at 116:15-25. Thus, if the I-beam was holding the jaws open as Intuitive and Dr. Howe contend, a user would not be able to pinch the jaws shut without breaking the instrument. CX-0002C at Q/A 243.

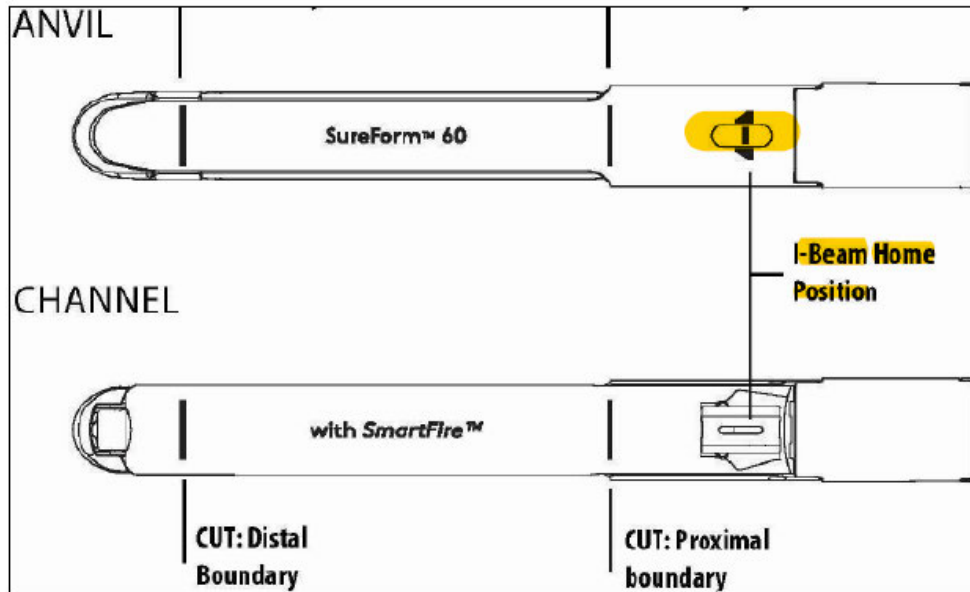
Intuitive next argues that when the jaws of a SureForm Stapler are pinched shut, the I-beam moves distally such that the I-beam is no longer in an advanced position.<sup>45</sup> RIB at 27-28. There is no dispute that when a user pinches the jaws closed, the I-beam moves slightly. CIB at 46; CX-0002C at Q/A 243; Fronczak, Tr. at 115:13-15; RIB at 27; Howe, Tr. at 836:5-21. Rather, the dispute centers on whether the I-beam remains in an “unadvanced” position, after the forward movement. The undersigned finds that even though the I-beam moves slightly, it is still in an “unadvanced” position. First, the claim language makes clear that the I-beam is not in an advanced position until the cams of the firing member engage the first and second jaws. JX-0001, cl. 2 (“a staple firing member comprising a first cam configured to engage said first jaw and a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position toward said distal end.”). So, even though there is distal movement, the cams

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<sup>45</sup> In support, Intuitive cites to a portion of the specification, claiming that it describes the position of the firing member as “advanced” even when the firing member has moved forward only a “small distance.” RRB at 8 (citing JX-0001 at 8:5-10). While Intuitive is correct that the specification does describe the firing member as having “distally advanced a small distance,” the specification does not provide guidance as to when the firing member is in an “unadvanced” versus “advanced” position. *See generally* JX-0001 (using “advanced” as a descriptor for forward movement, not as a way to delineate between the “unadvanced” and “advanced” positions). Rather, a person of ordinary skill in the art must turn to the claim language, which states, in relevant part: “a staple firing member comprising **a first cam configured to engage said first jaw and a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position** toward said distal end.” *Id.* at cl. 2. Moreover, as was demonstrated at the hearing, slight distal movement does not advance the I-beam beyond its “home” (or unadvanced) position. Fronczak, Tr. at 115:7-116:3.

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of the I-beam have yet to engage, meaning that the I-beam is still in an unadvanced position. CX-0002C at Q/A 245. Second, the marking on the top of the I-beam remains positioned between the triangles on the top of the anvil, as shown below:



**RX-0335C.0013 (annotations in yellow)**

RX-0335C.013. This is confirmation that the I-beam remains in the home position. Fronczak, Tr. at 115:7-116:3. Thus, the slight movement from pinching the jaws closed did not move the I-beam out of the unadvanced position. Fronczak, Tr. at 115:7-116:3. Lastly, as Dr. Fronczak testified: “Even if the I-beam moves forward slightly when the user pinches the jaws closed, the I-beam was not holding the jaws to each other because it did not prevent an external force from changing the relative position of the jaws. CX-0002C.0053 (Fronczak) at Q/A 245.

The undersigned therefore finds that accused SureForm Staplers and Reloads meet this limitation.

**ii. Conclusion**

Accordingly, for the reasons set forth above, the undersigned finds that the accused SureForm Staplers and Reloads infringe claim 2

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### b) Claim 3

Ethicon asserts that the SureForm Staplers and Reloads meet every limitation of claim 3 of the '379 patent. CIB at 48-54. Intuitive disagrees and asserts that these products do not include the “clearanced opening” limitation. RIB at 15, 17. Intuitive does not dispute that the SureForm Staplers and Reloads meet the remaining limitations of claim 3. RLUL at 1; *see generally* RIB at 17-28.

#### i. Limitation 3.5.1

Ethicon contends that the SureForm Staplers include a first cam that is not engaged with said first jaw when said staple firing member is in said initial position, as required by claim 3. CIB at 49-53; CRB at 12-17. Ethicon claims that “[t]he reload channel of the SureForm Staplers includes a clearanced opening that receives the cam on the lower portion of the I-beam when it is in an initial position, such that the cam is unengaged from the reload channel.” CIB at 49. Ethicon explains that this opening is what enables the reload channel to open and close relative to the anvil. *Id.* Ethicon further states that “the reload channel can close when the user pinches the jaws shut, while the reload channel can also open due to the biasing force of a spring in the end effector.” *Id.* at 44.

Intuitive asserts that the SureForm Staplers and Reloads do not meet this limitation “for similar reasons that it does not meet the ‘clearanced opening’ limitation of claim 2.” RIB at 28-32; RRB at 8-10. According to Intuitive, “when the SureForm’s I-beam is in the unadvanced position, the lower foot of the I-beam *is engaged* with the channel such that it *does affirmatively space* the jaws of the stapler and the *jaws cannot move relative to each other.*” RIB at 28 (emphasis in original).

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The parties agree that this limitation is nearly identical to the “clearanced opening” limitation for claim 2. RIB at 28; CX-0002 at Q/A 261; CPHB at 82-83. As Dr. Fronczak explained:

The only difference is that claim 2 refers to the staple firing member being advanced from an unadvanced position toward the distal end, while claim 3 refers to the staple firing member being advanced from an initial position. Both of the phrases, however, refer to the 1-beam advancing distally from a position at or near its home position . . .

CX-0002C at Q/A 261. Intuitive and Ethicon also appear to agree that the analysis for this limitation is the same or similar to the analysis for claim 2’s “clearanced opening” limitation.<sup>46</sup> See RIB at 28 (“The SureForm does not meet the ‘clearanced opening’ limitation of claim 3 for similar reasons that it does not meet the ‘clearanced opening’ limitation of claim 2.”); CPHB at 82083 (“This element is similar to the clearanced opening limitation for claim 2 (element [2.9]), so the analysis and evidence presented in Section III.C.1.j is applicable to this limitation, and is incorporated by reference”); CX-0002C at Q/A 261 (explaining that his analysis of claim 2 also applies to his analysis of this limitation for claim 3); RX-0019C at Q/As 159-166 (opining that the SureForm Stapler does not infringe claim 3 for the same reasons that it does not infringe claim 2).

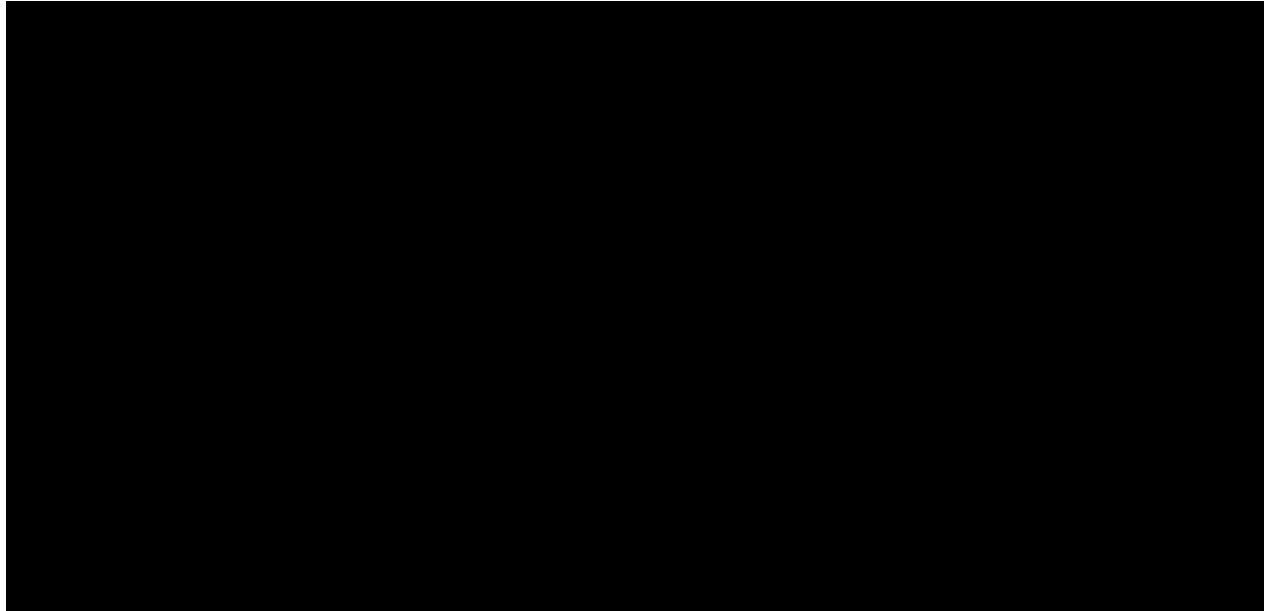
The undersigned has already determined that the SureForm Staplers include a “clearanced opening.” See Section IX.B.1.a., *supra*; see also CX-0002C at Q/As 262; CDX-0002C.60; RX-0339C.003 The undersigned finds that the SureForm Staplers also include a first cam that is not engaged with said first jaw when said staple firing member is in said initial position, as required by claim 3. See JX-0001, cl. 3 (“configured to receive said first cam when said staple firing member is in said initial position such that said first cam is not engaged with said first jaw when said staple

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<sup>46</sup> Intuitive’s arguments were rejected for the “clearanced opening” of claim 2. See Section IX.B.1.a.i. Intuitive’s arguments similarly fail for the “clearanced opening” of claim 3.

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firing member is in said initial position.”). The evidence shows that when the I-beam is in an initial position, the cam on the lower portion of the I-beam is unengaged from the reload channel:



CDX-0002C.0061 (annotated CX-0036C); *see also* CX-0002 at Q/A 264. As the CT scan above clearly demonstrates, the first cam – the distal end of the lower portion/foot of the I-beam – is unengaged from the reload channel.<sup>47</sup> CX-0002C at Q/As 267-268. This is all that is required by the claim language.

Despite this fact, Intuitive asserts that the SureForm Staplers do not infringe because the lower foot of the I-beam engages with the channel jaw when it is in the retracted position. RX-0019C at Q/As 161-162. Intuitive also claims that Ethicon and Dr. Fronczak are “artificially dividing the lower foot of the I-beam.” RIB at 29; *see also* RX-0019C at Q/A 163. The undersigned

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<sup>47</sup> Intuitive contends that Ethicon’s arguments are inconsistent with the *Markman* order. The undersigned does not agree. In the *Markman* Order, the undersigned explained that the specification describes that “an upper pin of the E-beam (*i.e.*, a first cam) engages the anvil, while a lower cap of the E-beam (*i.e.*, a second cam) engages the lower jaw to affirmatively space the jaws.” Order 15 at 45. Consistent with the *Markman* order, Ethicon has identified these elements/features in the accused SureForm Staplers – *i.e.*, the first and second cams on a staple firing member that engage the jaws to affirmatively space the jaws.

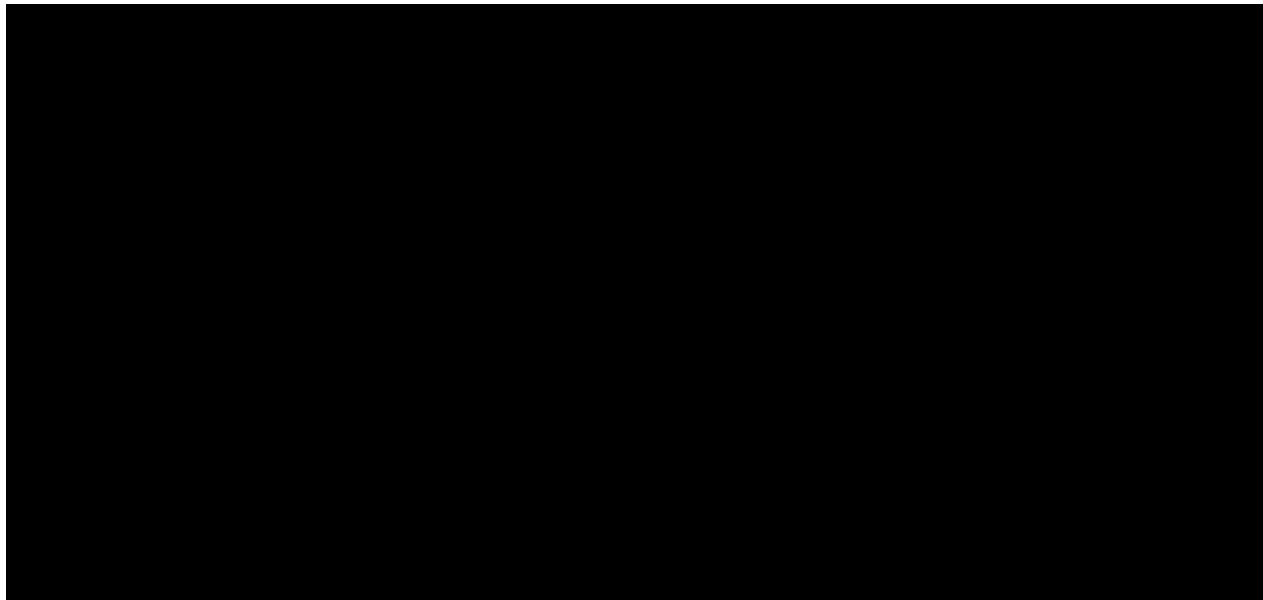
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disagrees. First, both experts agree that the lower foot of the I-beam is a cam with multiple camming surfaces. CX-0002C at Q/A 268; Howe, Tr. at 750:10-752:11 (“Q: Now, you agree, in your opinion is that the lower foot of the SureForm I-beam is one cam with multiple camming surfaces, right? A: Yes, that's a reasonable characterization. Q: That's -- that is a characterization that you have made, the lower foot of the I-beam is one cam with multiple camming surfaces, right? A: That's fine. Q: Okay. Now, if we stay on the slide here, let's identify those multiple camming surfaces. So the feature circled on the left that we were talking about that Dr. Fronczak has identified as the first cam, you agree that is one camming surface, right? A: Yes, that is a camming surface.”). In other words, different portions of the lower foot can perform different functions.<sup>48, 49</sup> See CX-0002C at Q/A 268 (explaining that although the distal end and proximal end of the lower portion are both part of the I-beam, they perform different functions). Thus, “the fact that a different portion of the I-beam is contacting the reload channel does not matter.” *Id.* at Q/A 267.

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<sup>48</sup> CDX-0002C.00063 is an annotated CT scan of the SureForm Stapler. It shows that when the I-beam advances and the distal end of the lower portion of the I-beam engages the reload channel, the proximal end of the reload channel is not in contact with the reload channel. See CX-0002C at Q/A 269. This confirms that the proximal end of the lower portion of the I-beam is not the “first cam” since it neither affirmatively spaces the jaws or cams them closed. *Id.* at Q/As 268-269.

<sup>49</sup> This is also consistent with the claim language. JX-0001, cl. 3 (describing the firing member as including two different cams – the first cam and the second cam).



CDX-0002C.0062 (annotated CX-0036C); *see also* CX-0002C at Q/As 267-268.

Second, Intuitive’s own expert acknowledged that the distal face of the lower foot of the I-beam is not engaged with a jaw when in the retracted position. Howe, Tr. at 750:10-14. Dr. Howe also conceded that the distal face of the lower foot is what engages when the I-beam moves forward and what cams the jaws close. *Id.* at 750:15-22 (“Q: Okay. And you also agree that this distal face of the lower foot of the I-beam when the I-beam moves forward, that distal face is what engages the jaw, right? A: Yes, that part of the cam then engages the jaw. Q: And that distal face is what cams the jaw 20 closed, right? A: I will agree that interaction is what closes the jaw, yes.”). Both experts therefore agree that the distal end of the lower foot of the I-beam corresponds to the “first cam configured to engage said first jaw . . . when said staple firing member is advanced.” *See* CX-0002C at Q/As 268-269 (opining that the first cam is the distal end of the lower foot of the I-beam because it is what engages the reload channel when the I-beam advances distally).

The undersigned therefore finds that the SureForm Staplers and Reloads practice this limitation.

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### ii. Conclusion

Accordingly, for the reasons set forth above, the undersigned finds that the accused SureForm Staplers and Reloads infringe claim 3.

### 2. Indirect Infringement

Ethicon asserts that Intuitive indirectly infringes claims 2 and 3 of the '379 patent by committing acts of induced and contributory infringement. CIB at 54-56. Intuitive did not address indirect infringement in its briefs and has therefore waived any arguments that it does not indirectly infringe the accused SureForm Staplers and Reloads. *See generally* RIB at 15-32; Ground Rule 13.1.

#### a) Induced Infringement

Ethicon contends that Intuitive has had knowledge of the '379 patent since March 12, 2019 when Ethicon filed its Motion for Leave to File First Amended Complaint in *Ethicon LLC, et al. v. Intuitive Surgical, Inc., et al.*, Case No. 18-1325-LPS-CJB (D. Del. Mar. 12, 2019). CIB at 54. Ethicon claims that Intuitive induces infringement by selling SureForm Staplers and Reloads with instructions and operating manuals that instruct end-users to use the SureForm Staplers, and by providing training and assistance to end user regarding their use. *Id.* (citing CX-0002C at Q/As 271-280; RX-0335C.0005, .0007, 0016-.0028; CX-0923C at 143:2-145:2, 148:13-150:2; CX-0076C).

Like with the '369 patent, Intuitive had actual knowledge of the '379 patent prior to Ethicon filing its Complaint in this Investigation. CX-0470.0005. Specifically, Intuitive has had knowledge of the '379 patent since at least March 12, 2019. *Id.* Ethicon, however, has not presented any evidence that Intuitive knew the alleged “induced acts” constituted patent infringement. *DSU Med. Corp.*, 471 F.3d at 1306. Ethicon has therefore failed to show that Intuitive had actual knowledge



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of infringement or was willfully blind to infringement *See Global-Tech Appliances*, 563 U.S. at 766; *Commil USA*, 575 U.S. at 639-642.

Accordingly, the undersigned finds that Ethicon has not shown Intuitive induced infringement of claims 2 and 3 of the '379 patent.

### **b) Contributory Infringement**

Ethicon alleges that Intuitive commits acts of contributory infringement by importing SureForm Staplers and Reloads into the United States, and providing them to customers who directly infringe claims 2 and 3 by using the SureForm Staplers. CIB at 55. Ethicon contends that neither the SureForm Staplers nor the compatible reloads are staple articles of commerce that are suitable for non-infringing uses. *Id.* (citing CX-0002C at Q/As 275-280). According to Ethicon, the SureForm Reloads are designed solely for use with SureForm Staplers. *Id.*

Ethicon also asserts that the imported SureForm Staplers constitute a material part of the invention of claims 2 and 3 “because the SureForm Staplers with compatible SureForm Reloads include components that satisfy all limitations of claims 2 and 3.” *Id.* (citing CX-0002C at Q/A 279). Similarly, Ethicon argues that the imported SureForm Reloads constitute a material part of the invention of claims 2 and 3 because “the reloads include components that comprise the ‘channel’ limitation of claim 2 and the ‘detachable cartridge’ limitation of claim 3, and the ‘plurality of staples’ limitations in both claims.” *Id.* (citing CX-0002C at Q/A 280). Lastly, Ethicon contends that the imported I-beam lock component also constitutes a material part of the claimed invention as it “meets the lockout limitation of claims 2 and 3, which is central to the invention.” *Id.* at 55-56.

The undersigned has already determined that Intuitive directly infringes claims 2 and 3 of the '379 patent. *See supra* at Section IX.B.1. Based on the evidence of record, Ethicon has made

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a *prima facie* showing that the components of the SureForm Staplers and Reloads do not have any substantial non-infringing uses. CX-0002C at Q/A 278; RX-0335.0006, .0010. For example, the user manual states that the staplers are designed solely for use with compatible SureForm Reloads and the da Vinci Xi and X surgical systems. RX-0335.0006, .0010. The SureForm Staplers and Reloads also constitute material parts of the invention of claims 2 and 3. *See* CX-0002C at Q/As 279-280; JX-0001, cls. 2-3. Finally, Intuitive has admitted that the components of the accused SureForm Staplers and Reload have been imported, sold for importation, or sold after importation in the United States by Intuitive. CX-0589C. As noted above (*see* Section VIII.B.2.b), the knowledge required for contributory infringement is lower than for inducement. *See Metro-Goldwyn-Mayer Studios*, 545 U.S. at 932 (2005). Because the evidence shows that the SureForm Reloads are designed solely for use with SureForm Staplers, the knowledge requirement has been satisfied.<sup>50</sup> *See* CX-0002C at Q/A 278; RX-0335C at .0006, .0010.

Accordingly, the undersigned finds that Intuitive contributorily infringes claims 2 and 3 of the '379 patent.

### C. Technical Prong of the Domestic Industry Requirement

Ethicon asserts that the '379 DI Products practice all limitations of claim 3. CIB at 56-59. Intuitive does not dispute that Ethicon's '379 DI Products (*i.e.*, Echelon FLEX™ Non-Powered Staplers, Echelon FLEX™ Powered Staplers, Echelon FLEX™ Powered Plus Staplers, [REDACTED], [REDACTED], ECR Reloads, and GST Reloads) practice claim 3 of the '379 patent. RLUL at 1-2.

Additionally, the evidence shows that Ethicon's '379 DI Products practice claim 3. CX-0002C at Q/As 53, 281, 283-312; CX-0149C.0001; CX-0025.0004, .0006; CX-0020.0004-.0006;

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<sup>50</sup> Intuitive had actual knowledge of the '379 patent at least since March 12, 2019. CX-0470.0005

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CX-0155C; CX-0147C; CX-0157C; CX-0046C.0006; CX-0159C; CX-0027; CDX-0002C.0064-.0069, 00072. Accordingly, the undersigned finds that Ethicon has satisfied the technical prong of the domestic industry requirement for the '379 patent.

### **D. Validity**

Intuitive asserts the following invalidity grounds: (1) U.S. Patent No. 4,520,817 to Green ("Green 817") anticipates claims 2 and 3; (2) U.S. Patent Application Publication No. 2005/0263562 to Shelton<sup>51</sup> ("Shelton 562") anticipates claims 2 and 3; and Green 817 combined with U.S. Patent No. 5,413,267 to Solyntjes et al. ("Solyntjes 267") renders the asserted claims obvious. RIB at 32-33; JX-0146; JX-0139; JX-0147. More specifically, Intuitive contends that claims 2 and 3 are anticipated by "(1) Green 817's instrument 200; and (2) Shelton 562's instrument 10" and rendered obvious by "Green 817's stapler 10 in view of Solyntjes." *Id.* at 33-45; *see also* RRB at 13-29.

#### **1. Estoppel – 35 U.S.C. § 315(e)(2)**

In this Investigation, Intuitive has challenged the validity of claims 2–3 of the '379 patent based on Shelton 562, Green 817, and Solyntjes 267. *See supra*. Intuitive has also challenged the validity of claims 1–3 of the '379 patent in *inter partes* review ("IPR") proceedings IPR2020-00050 and IPR2020-00051 based on many of the same patents and patent publications. CX-0470

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<sup>51</sup> Ethicon contends that the asserted claims of the '379 patent are entitled to an effective filing date of July 28, 2004, which predates the September 30, 2004 filing date of the Shelton 562. CIB at 73; *see also id.* at 59-67. Thus, in Ethicon's view, Shelton 562 is not prior art and cannot anticipate claims 2 and 3. *Id.* Intuitive, on the other hand, believes that Ethicon is trying to avoid the Shelton 562 reference by claiming that the '379 patent is entitled to an earlier effective filing date. RIB at 33, 36-42. Intuitive submits that several of the priority claims in the '379 patent contain errors that violate 35 U.S.C. § 120 and prevent the '379 patent from claiming the benefit of a filing date before February 7, 2014. *Id.* In response, Ethicon asserts that Intuitive's argument is moot given that a certificate of correction fixed this error by correcting the labeling of the two applications in the '379 patent's priority chain from "continuation" to "continuation-in-part." CIB at 66, 78-82. Intuitive, however, disputes the validity of the certificate of correction Ethicon obtained. RIB at 41-42. Because the undersigned has determined (Section IX.D.1, *infra*) that Intuitive is estopped from asserting Shelton 562 pursuant to 35 U.S.C. § 315(e)(2), the undersigned need not reach the issues of whether [1] Shelton 562 qualifies as prior art or [2] the certificate of correction is valid.

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(IPR2020-00050); CX-1897 (IPR2020-00051). In IPR2020-00050, Intuitive asserted one ground of invalidity based on anticipation by Shelton 562, which is also asserted in this Investigation. CX-0470. In IPR2020-00051, Intuitive asserted two grounds of invalidity: (1) anticipation by U.S. Pat. No. 7,000,818 and (2) obviousness over U.S. Pat. No. 4,429,695 (“Green 695”) in combination with Solyntjes 267. While the combination of Green 695 with Solyntjes 267 is not asserted in this Investigation, Intuitive has asserted obviousness of claims 2 and 3 over Green 817 with Solyntjes 267. RIB at 42-45. At the time of post-trial briefing, the final written decisions (“FWDs”) were due to issue from the Patent Trial and Appeal Board (“PTAB”) no later than March 31, 2021.

Ethicon contends that the FWDs will trigger the estoppel provision of 35 U.S.C. § 315(e)(2) against Intuitive for any ground that Intuitive raised or could have raised in the co-pending IPRs. CIB at 67-69 (citing *Certain Memory Modules & Components Thereof*, Order No. 51 at 7–8 (June 26, 2019) (hereinafter “*Memory Modules*”).) Ethicon therefore asserts that once the FWDs issue, § 315(e)(2) bars Intuitive from maintaining these invalidity grounds (Shelton 562, Green 817, and Solyntjes 267) in this Investigation. *Id.*

Intuitive does not believe the IPR estoppel provision of 35 U.S.C. § 315(e)(2) applies to the ‘379 patent “because there was no Final Written Decision from the PTAB at the time of the trial and Intuitive has no other role in ‘asserting’ its arguments in advance of the Initial Determination.” RRB at 10-13. Even if IPR estoppel were to apply to Respondents, Intuitive asserts that “estoppel does not apply to the CALJ and therefore does not prevent the CALJ from issuing an Initial Determination on the record here.” *Id.* at 10, 12-13.

35 U.S.C. § 315(e)(2) states:

The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International

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Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that *inter partes* review.

*Id.* Thus, “[b]y its plain and unambiguous language, the statute prevents a party from asserting that a patent claim is invalid in any Section 337 investigation on grounds that were raised or reasonably could have been raised in an *inter partes* review which resulted in a final written decision.” *Memory Modules*, Order No. 51 at 6-7 (June 26, 2019); *see also id.*, Initial Determination on Violation (“ID”) at 104-112 (Oct. 21, 2019) (finding invalidity theories not raised before the PTAB estopped because Respondents reasonably could have raised them). An “aim of this estoppel is to prevent serial challenges to patent validity to the detriment of patent owners.” *Memory Modules*, Order No. 51 at 7 (citing 157 Cong. Rec. S936, S952 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley)).

Intuitive does not dispute that the invalidating references it relies on in this Investigation to contend that claims 2 and 3 of the ’379 patent are invalid were raised<sup>52</sup> or reasonably could have been raised<sup>53</sup> in the IPR challenges to the ’379 patent. *See generally* RRB at 10-13. Rather, Intuitive asserts that IPR estoppel should not apply because there was no FWD at the time of the evidentiary hearing and that when the FWD did issue, Intuitive’s invalidity arguments in this Investigation were fully briefed. *Id.* at 11-12.

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<sup>52</sup> Intuitive’s obviousness argument in this Investigation is based on the combination of Solyntjes 267 and Green 817, as opposed to Green 695. RIB at 42-45. Green 695 and Green 817 disclose very similar instrument architectures. CX-3276C at Q/As 33-34. Arguably, Intuitive therefore raised Green 817 in the co-pending IPR because the embodiment from Green 817 that Intuitive is relying on in this Investigation is the same as the embodiment in Green 695 that Intuitive relied upon in IPR2020-00051. *Compare* RX-0226, with CX-1897C at 26-28; CX-3276C at Q/As 32-34 (testifying that Intuitive’s invalidity arguments with respect to Green 817 and Green 695 are substantially the same).

<sup>53</sup> Intuitive filed two petitions for IPR against the ’379 patent on October 16, 2019. CX-1897; CX-0470. Five days later, Intuitive served its Notice of Prior Art and its invalidity contentions in this Investigation, which included all of the invalidity grounds currently being asserted against the ’379 patent. *See, e.g.*, Order No. 8 (Aug. 5, 2019) (setting the procedural schedule); EDIS Doc. ID 691788 (Intuitive’s Notice of Prior Art). Intuitive clearly had knowledge of the Green 817 reference and could have raised it in the IPRs filed less than a week earlier.

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The undersigned previously considered estoppel under 35 U.S.C. § 315(e)(2) in *Memory Modules*. In *Memory Modules*, Respondents had filed numerous petitions for *inter partes* review on the validity of the asserted patents. ID at 104. Prior to the hearing, a FWD issued regarding U.S. Patent 9,535,623, and the undersigned determined Respondents to be estopped from asserting invalidity based on those same grounds at the hearing. *Id.* at 62; *see also* Order No. 51 (June 26, 2019). At the time of the final initial determination, two IPR petitions regarding U.S. Patent No. 9,606,907 had resulted in a FWD from the PTAB. *Id.* at 104. In the ID, the undersigned determined that “[t]his circumstance implicate[d] 35 U.S.C. § 315(e)(2)” and found Respondents estopped from asserting that the ‘907 patent claims are invalid based on the same grounds as in the IPR petitions. *Id.* at 104-112.

The situation here is no different. Like the Respondents in *Memory Modules*, Intuitive filed several petitions for *inter partes* review at the PTAB. Prior to the commencement of the evidentiary hearing, Ethicon and Intuitive acknowledged that a FWD would issue after the hearing, but before the final initial determination, and the parties agreed to brief the issue of IPR estoppel in their post-hearing briefs. The FWDs issued on March 26, 2021, finding claims 1–3 of the ’379 unpatentable. EDIS Doc. ID 738746, Exs. A and B. Thus, just like in *Memory Modules*, at the time of this final initial determination, FWDs have issued from the PTAB and the parties had fully briefed the issues of IPR estoppel and validity. Because a decision had yet to be rendered in this Investigation, the undersigned finds that issuance of the FWDs triggers 35 U.S.C. § 315(e)(2). All three asserted invalidity grounds in this Investigation were raised or could have been raised in the co-pending IPRs. As such, 35 U.S.C. § 315(e)(2) bars Intuitive from asserting that claims 2 and 3 of the ’379 patent are invalid based on those grounds – [1] anticipated by Green 817 under 35 U.S.C. § 102;

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[2] anticipated by Shelton 562 under 35 U.S.C. § 102; and [3] obviousness over Green 817 and Solyntjes 267 under 35 U.S.C. § 103.<sup>54</sup>

### 2. Conclusion

Intuitive has not asserted any other invalidity grounds than those that have been estopped. Accordingly, for the reasons set forth above, the validity of the '379 patent is no longer at issue in this Investigation.

#### E. Unenforceability

Intuitive asserts that the '379 patent is unenforceable because the prosecuting attorney, [REDACTED], committed inequitable conduct “to obtain the certificate of correction that attempted to change [Ethicon’s] priority claims to antedate Shelton 562.” RIB at 46-52; RRB at 29-31. According to Intuitive, the '379 patent’s incorrect priority claims were “because of deliberate decisions that [REDACTED] made based on his understanding of the law.” RIB at 46, 48-49. Nevertheless, when [REDACTED] secured the certificate of correction for Ethicon, he represented to the USPTO that the errors in the priority chain of the '379 patent were “clerical in nature.” *Id.* Intuitive contends that this intentional misrepresentation was “an affirmative act of egregious misconduct that is *per se* material.” *Id.* at 48 (citing *Therasense*, 649 F.3d at 1291-92). Intuitive also contends that “[t]he single most reasonable inference that can be drawn from [REDACTED] conduct is that he intended to defraud the USPTO into granting a certificate of correction on the basis that a clerical error had been made.” *Id.* at 49-50; *see also* RRB at 30-31. Intuitive further

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<sup>54</sup> If IPR estoppel applies, Intuitive submits that the undersigned should still decide the issue of invalidity. RRB at 12-13 (citing *Certain Magnetic Tape Cartridges & Components Thereof*, Inv. No. 337-TA-1058, ID, 2018 WL 4943753, at \*73–74 (Aug. 17, 2018) (hereinafter “*Magnetic Tapes*”).) In *Magnetic Tapes*, the Commission Investigative Staff (“Staff”) was a party to the Investigation and as such, IPR estoppel did not apply to Staff. *Magnetic Tapes*, Initial Determination on Violation at 106-107 (Aug. 17, 2018). Staff could therefore raise the same invalidity grounds that the 1058 Respondents were estopped from asserting. *Id.* That is not the case here, though. With Intuitive being estopped, the undersigned need not consider Intuitive’s invalidity arguments, “fully developed” or not, as they are no longer before him.

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alleges that litigation misconduct by Ethicon in this Investigation and in the co-pending IPR further supports the inference that [REDACTED] intended to defraud the USPTO. *Id.* at 50-52.

Ethicon asserts that Intuitive has failed to demonstrate inequitable conduct by [REDACTED]. CIB at 82-85 (arguing that Intuitive has not set forth any evidence of materiality or intent to deceive). First, Ethicon contends that there is no evidence of materiality and disputes that [REDACTED] committed an affirmative act of egregious misconduct that should be deemed *per se* material. *Id.* at 82-84. Ethicon explains that [REDACTED] representation to the USPTO (that the errors were clerical) was correct and “even if the errors are determined not to be clerical, the certificate still would have issued because the errors were of minor character. *Id.* (“In other words, Respondents [*sic*] inequitable conduct allegation necessarily fails because the Certificate is valid.”) Next, Ethicon asserts that [REDACTED] informed the USPTO that the ’379 patent’s priority chain errors were clerical in nature because “he believed that they were in fact clerical in nature.” CRB at 30; *see also* CIB at 84-85. Ethicon insists that “[t]his undisputed fact forecloses any argument that [REDACTED] intended to deceive the Patent Office.” CRB at 26. Lastly, Ethicon submits that Intuitive’s request for an adverse inference of inequitable conduct based on litigation misconduct is baseless. *Id.* at 27-30 (“Respondents did not send Ethicon a single letter or email regarding purported deficiencies in its discovery responses, let alone put Ethicon on notice that it would seek discovery sanctions in the form of an adverse inference. Raising this issue for the first time after discovery closed is clearly improper.”).

To establish unenforceability based on inequitable conduct, materiality and intent must be shown by clear and convincing evidence. For the reasons set forth below, the undersigned finds that Intuitive has failed to demonstrate by clear and convincing evidence that [REDACTED] possessed the requisite intent.



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Intent to deceive to deceive requires “knowledge and deliberate action.” *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1290 (Fed. Cir. 2012). Intuitive must therefore show that [REDACTED] knew his errors could not be considered “clerical in nature.”<sup>55</sup> The evidence does not support such a finding.

It is undisputed that [REDACTED] made an error during the initial prosecution of the ’379 patent when labeling Application No. 14/175,148 (the “148 Application”) as a continuation, rather than a continuation-in-part.<sup>56, 57</sup> *See, e.g.*, CIB at 78-79; RIB at 42; CX-3287C at Q/As 16-21. [REDACTED] testified that at the time, he believed this was the “correct way to characterize the relationship.” CX-3287C at Q/As 18-19; *see also* [REDACTED]r, Tr. at 477:4-15. It is also undisputed that [REDACTED] learned of his error shortly after Intuitive filed its IPR petitions. *Id.* at Q/As 20-21. Ethicon also became aware of the error on October 16, 2019, when Intuitive filed its IPR petitions. *See, e.g.*, CX-0470; CX-1897. Ethicon then requested leave from the PTAB to file a certificate of correction. CX-3286.0010-.0019. Intuitive opposed Ethicon’s motion for leave, arguing that the priority errors were not clerical, typographical, or of minor character. *Id.* at .0020-.0031. Intuitive also insisted that the PTAB require Ethicon to submit Intuitive’s opposition briefing to the Director if the PTAB granted Ethicon’s request. *Id.* at .0022. Ethicon filed a reply to Intuitive’s opposition. In its reply, Ethicon asserted that the priority chain errors were clerical in nature because the labeling of applications serves an administrative function. *Id.* at .0032-.0038. Ethicon also asserted that the requested corrections were of minor character “because they merely

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<sup>55</sup> While intent can be inferred, it must be the single most reasonable inference. *Therasense*, 649 F.3d at 1290. That is simply not the case here.

<sup>56</sup> The 148 Application included content from both Application No. 13/369,601 (the “601 Application”) and Application No. 11/141,753 (the “753 Application”). The 148 Application therefore claims priority to both the 601 and 753 Applications. JX-0001. During prosecution, [REDACTED] identified the 148 Application as a “continuation” of both the 601 Application and 753 Application. CX-3287C at Q/A 17.

<sup>57</sup> Intuitive characterizes this as a “deliberate” decision by [REDACTED]. RRB at 30-31. It was a decision made in good faith, nevertheless. CX- 3287C at Q/As 16-19; [REDACTED], Tr. at 479:16-481:11.

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correct the relationship between applications already identified in the priority data.” *Id.* The PTAB granted Ethicon’s motion for leave to seek correction of the ’379 patent on February 26, 2020. *Id.* at .0039-.0045.

That same day, Ethicon submitted its request for a certificate of correction to the Director.<sup>58</sup> *Id.* at .0001. [REDACTED] was responsible for prosecuting the certificate of correction. CX-3287C at Q/A 23. Along with the request for correction, [REDACTED] also submitted Intuitive’s opposition briefing and Ethicon’s reply to the Director. *Id.* at Q/A 28. [REDACTED] informed the Director of Ethicon’s legal position that the mistakes were “clerical in nature” and that the mistakes were of “minor character” because they did not “materially affect the scope or meaning” of the ’379 patent. CX-3286.001; CX-3287C at Q/As 29-35; M.P.E.P. § 1481. The Director subsequently issued the certificate of correction.<sup>59</sup> CX-3281.

As explained above, after reviewing the briefing, which included Ethicon’s legal position that the correction was clerical in nature, the PTAB authorized Ethicon to seek a certificate of correction. *See* CX-3286 at .0039-.0045. It was therefore reasonable for [REDACTED] to believe that the priority chain error made during prosecution was “clerical in nature” under 35 U.S.C. § 255 when he submitted the request to the Director because the PTAB had authorized Ethicon’s request to seek correction.<sup>60</sup> [REDACTED] has also testified that he believed – and continues to believe – the error was clerical in nature and of minor character. CX-3287C at Q/As 33-39. He provided several

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<sup>58</sup> Pursuant to 35 U.S.C. § 255, the Director may issue a certificate of correction to correct “a mistake of a clerical or typographical nature, or of minor character,” if the mistake occurred in good faith and “if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination.” *Id.*

<sup>59</sup> Because Ethicon submitted the parties’ briefing before the PTAB with its request for correction, the Director was in possession of the basis for Ethicon’s legal position that the priority chain errors in the ’379 patent were both clerical in nature and of minor character. The Director was also in possession of Intuitive’s arguments in opposition. *See* CX-3286.0020-0031 (asserting that the mistakes were not clerical in nature or of minor character).

<sup>60</sup> Even if it is ultimately determined that [REDACTED]’s (and Ethicon’s) legal position is incorrect, the Federal Circuit has made clear that what a person should have known is insufficient to demonstrate intent to deceive. *Therasense*, 649 F.3d at 1290 (“A finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.”); *see also Outside the Box*, 695 F.3d at 1292.

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reasons for why he believed the errors were clerical in nature. *Id.* at Q/A 36. For example, he explained that an error in identifying an application as a continuation instead of a continuation-in-part is clerical in nature because such designations serve an administrative function. *Id.* [REDACTED] further testified that he did not intend to deceive the Patent Office and that he believes that the certificate of correction was properly issued. *Id.* at Q/As 37, 39 (“I indicated in the request for connection of the 379 Patent that the errors in the priority chain were clerical in nature because I believed that they were clerical in nature.”).

Accordingly, the requirements of *Therasense* are not met here because there was no clear and convincing evidence of intent to deceive.<sup>61, 62</sup>

### X. ECONOMIC PRONG OF THE DOMESTIC INDUSTRY REQUIREMENT

Ethicon argues, among other things, that its engineering plus research and development (“R&D”) expenditures are substantial, and that there is a nexus between the R&D expenditures and the Asserted Patents, sufficient to meet its economic prong requirement under 19 U.S.C §

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<sup>61</sup> Because Intuitive has not shown intent to deceive by clear and convincing evidence, the undersigned need not reach the materiality prong. The undersigned notes, however, that the evidence of record does not appear to support Intuitive’s assertion that [REDACTED] alleged misrepresentation was material. As the Federal Circuit has made clear, “the materiality required to establish inequitable conduct is but-for materiality.” *Therasense*, 649 F.3d at 1291. Thus, Intuitive would need to show that the certificate of correction would not have issued but-for [REDACTED] representation that the priority chain errors were clerical in nature. Even if [REDACTED] (and Ethicon’s) legal position is deemed to be incorrect, the certificate of correction would still be valid because the errors are of minor character. As to Intuitive’s allegation that [REDACTED] committed an affirmative act of egregious misconduct that should be deemed *per se* material, the undersigned notes that to prevail, Intuitive must show – by clear and convincing evidence – that [REDACTED] submitted an unmistakably false affidavit. *Id.* at 1292. The fact that Intuitive disagrees with [REDACTED] position does not make his submission to the Patent Office an unmistakably false statement, however. Furthermore, as discussed with respect to the intent prong, [REDACTED] informed the Patent Office that the errors were clerical in nature because that is what he believed. CX-3287C at Q/As 33-38.

<sup>62</sup> Intuitive requests an adverse inference of inequitable conduct based on litigation misconduct by Ethicon. Yet, Intuitive never raised any issues with the Court concerning purported deficiencies in Ethicon’s discovery responses. Similarly, Intuitive’s complaints regarding the deposition of Ethicon’s corporate representative do not justify such a severe sanction. Intuitive claims that Mr. Garner “did not explain the true circumstances of the error.” RIB at 52. To the contrary, Mr. Garner made quite clear that the priority chain error was made by outside counsel and that no one at Ethicon were aware of the error because priority determinations were handled by prosecution counsel. RX-1865C at 46:9-23.

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1337(a)(3)(C). CIB at 206-242; CRB at 104-113. Intuitive asserts that Ethicon has not supported its economic prong requirement. RIB at 172-192; RRB at 111-119. Intuitive disputes that Ethicon's R&D expenditures are substantial and that there is a nexus between those expenditures and the Asserted Patents. *Id.*

For the reasons set forth below, the undersigned finds that Ethicon's engineering plus R&D expenditures satisfy the economic prong requirement under subsection (C). Ethicon's DI products and the patents they practice are set forth in the following table ("Table A"):

<b>Domestic Industry Endocutters</b>	<b>Product Type</b>	<b>Embodying Patents</b>
Echelon Flex Powered Plus 60 and 45 Endocutters	"Powered Plus" handheld stapler	379, 369
Echelon Flex Powered ENDOPATH 60 and 45 Endocutters	"Powered" handheld stapler	379
Echelon Flex ENDOPATH 60 and 45 Endocutters	"Non-Powered" handheld stapler	379
<b>Domestic Industry Reloads</b>	<b>Product Type</b>	<b>Embodying Patents</b>
GST 60 and 45 Reload Cartridges	Stapler reloads	379, 369, 874, 969
ECR 60 and 45 Reload Cartridges	Stapler reloads	379, 369, 874, 969
<b>Domestic Industry Prototypes</b>	<b>Product Type</b>	<b>Embodying Patents</b>
[REDACTED]	[REDACTED]	379, 369
[REDACTED]	[REDACTED]	379, 369
[REDACTED]	[REDACTED]	379, 369, 874, 969

CIB at 214; *see also* CX-0003C at Q/As 25, 32; Section I.D.2. The following table ("Table B") identifies how certain of the above DI products are grouped for purposes of how Ethicon tracks certain of its product investments.

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<b>Project Name</b>	<b>Domestic Industry Products</b>
Endocutter Life Cycle <sup>63</sup>	Echelon Flex Powered Plus, Powered, and Non-Powered 45 and 60 Endocutters and associated Reloads
██████████ 45	Echelon Flex Powered Plus 45 Endocutters and GST 45 Reloads
██████████ 60	Echelon Flex Powered Plus 60 Endocutters and GST 60 Reloads

CIB at 214-215; *see also* CX-0005C at Q/As 69, 84; CX-0003C at Q/A 122; CX-0009C at Q/A 43.

Since 2016, Ethicon’s expenditures on labor for R&D have exceeded \$23.5 million, as set forth in the below table (“Table C”):

<b>Domestic Industry Products</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019 FY (Latest Estimate)</b>	<b>2019 (Q3 YTD Actuals)</b>
██████████ r 45	██████████ <sup>64</sup>	██████████	██████████	-	-
██████████ 45 - Endocutters	-	██████████	██████████	-	-
██████████ 45 – Reloads	-	██████████	██████████	-	-
██████████	-	-	██████████	██████████	██████████
██████████	██████████	██████████	██████████	██████████	██████████
██████████	-	-	-	██████████	██████████
Endocutter Life Cycle	██████████	██████████	██████████	██████████	██████████
Life Cycle – Endocutters	██████████	██████████	██████████	██████████	██████████
Life Cycle – Reloads	██████████	██████████	██████████	██████████	██████████
<b>Total</b>	██████████	██████████	██████████	██████████	██████████
				<b>Grand Total</b>	██████████

CX-0003C at Q/A 153; CX-0393C; CX-0385C. In addition to the above labor costs, Ethicon has also invested in non-labor costs for the R&D of the DI products. These include costs for tooling, design work, samples and supplies, and testing work done in-house and through vendors. CX-0003C at Q/A 154; CX-0005C at Q/As 69, 92. However, these payments do not include in-house

<sup>63</sup> Ethicon represents that the “Endocutter Life Cycle spend includes any endocutter-related product that is currently on the market. . . . The Echelon Flex Powered Plus, Echelon Flex Powered, Echelon Flex non-powered, GST reloads, and ECR reloads constitute the vast majority of the Endocutter Life Cycle spend from 2016 to [the] present.” CIB at 214-215 n.18.”

<sup>64</sup> 2016 Net Trade Sales for ██████████ 45 products are unavailable, so no apportioning between endocutters and reloads is available for that year. CIB at 232 n.32.

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plant and equipment or in-house capital expenditures. *Id.* The below table (“Table D”) summarizes these investments in R&D for the DI products:

Domestic Industry Products	2016	2017	2018	2019FY (Latest Estimate)	2019 (Q3 YTD Actuals)
45				-	-
45 - Endocutters	-			-	-
45 - Reloads	-			-	-
	-	-			
	-	-	-		
Endocutter Life Cycle					
Life Cycle - Endocutters					
Life Cycle - Reloads					
<b>Total</b>					
				<b>Grand Total</b>	

CX-0003C at Q/As 155-157; CX-0393C; CX-0385C. Thus, considering Ethicon’s non-labor and labor costs together, Ethicon has invested over [REDACTED] in R&D for the DI products between 2016 and the third quarter of 2019. In addition, Ethicon’s foreign-based investments in R&D for the DI products from 2016 thru 2019 were virtually zero. CX-0003C at Q/A 181. Thus, Ethicon’s investments in R&D are substantial when viewed in the proper context.

As required by paragraph C, there is also a nexus between Ethicon’s investments in R&D and the asserted patents because the DI products are the commercial embodiment of those patents. CX-0003C at Q/A 164; CX-0002C at Q/As 26-53; CX-0001C at Q/As 175, 274; *see also* Tables C, D. As noted above, Table A identifies the DI products and the Asserted Patents that they practice. CX-0003C Q/As 25, 32, 163-165.<sup>66</sup>

<sup>65</sup> As with the above table, 2016 Net Trade Sales for [REDACTED] 45 products are unavailable, so no apportioning between Endocutters and reloads is available for that year. CIB at 233 n.33.

<sup>66</sup> The undersigned further notes that Intuitive did not dispute that Ethicon satisfied the technical prong of the domestic industry requirement for the ’369, ’379, and ’969 patents. RLUL at 1-4; *see also* Sections VI.C, VII.C, VIII.C, IX.C.

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Intuitive's criticisms of Ethicon's presentation are not persuasive. For example, Dr. Vander Veen asserts that Ethicon's R&D expenditures are only [REDACTED] of Ethicon's worldwide expenditures on R&D for all products and services. RRB at 119. Besides Intuitive not providing a reasonable basis for this assertion, it is not appropriate to compare the worldwide R&D spending for *all* products to the domestic R&D spent for only the DI products. As noted above, Ethicon's foreign-based expenditures on R&D for the DI products is near zero. CX-0003C at Q/A 181. It is this comparison that is the relevant one. *See, e.g., Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 19 (Oct. 28, 2019) ("*Carburetors*") ("The Commission has also assessed the relative domestic contribution to the protected article by comparing complainant's product-related domestic activities to its product-related foreign activities").

Intuitive also argues that "the alleged research and development expenses as a proportion of sales of the Domestic Industry Products is only about [REDACTED]." RIB at 190. There is no precise formula for determining whether domestic industry expenditures are reasonable and substantial. *Certain Stringed Musical Instruments*, Comm'n Op., 2008 WL 2139143, at \*8 (May 16, 2008). Thus, a complainant is not required to establish that its DI investments are high in comparison to its sales. Rather, the complainant must provide evidence to place the investments in context. *Carburetors*, Comm'n Op. at 19. As noted above, Ethicon did that by introducing evidence of its foreign R&D investments for the DI products.

Accordingly, for the reasons stated above, the undersigned finds that Ethicon has satisfied the economic prong of the domestic industry requirement.<sup>67</sup>

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<sup>67</sup> The undersigned has already determined that Ethicon satisfies the economic prong under section 337(a)(3)(C). Accordingly, the undersigned need not decide whether Ethicon meets the economic prong under sections 337(a)(3)(A) or (B).

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### **XI. CONCLUSIONS OF LAW**

1. The importation or sale requirement of section 337 is satisfied.
2. Ethicon has standing to assert U.S. Patent Nos. 9,113,874; 8,479,969; 9,844,369; and 9,844,379.
3. Intuitive does not infringe claim 24 of U.S. Patent No. 8,479,969.
4. The technical prong of the domestic industry requirement for U.S. Patent No. 8,479,969 has been satisfied.
5. Claim 24 of U.S. Patent No. 8,479,969 is not invalid under 35 U.S.C. § 102 for anticipation.
6. Claim 24 of U.S. Patent No. 8,479,969 is invalid under 35 U.S.C. § 103 for obviousness.
7. Claim 24 of U.S. Patent No. 8,479,969 is not invalid based on § 112, ¶ 2.
8. Claim 24 of U.S. Patent No. 8,479,969 is not unenforceable based on an error.
9. Intuitive does not infringe claim 19 of U.S. Patent No. 9,113,874.
10. The technical prong of the domestic industry requirement for U.S. Patent No. 9,113,874 has been satisfied.
11. Claim 19 of U.S. Patent No. 9,113,874 is not invalid under 35 U.S.C. § 102 for anticipation.
12. Claim 19 of U.S. Patent No. 9,113,874 is invalid under 35 U.S.C. § 103 for obviousness.
13. Intuitive infringes claims 22 and 23 of U.S. Patent No. 9,844,369.
14. Intuitive does not induce infringement of claims 22 and 23 of U.S. Patent No. 9,844,369.
15. Intuitive does contributorily infringe claims 22 and 23 of U.S. Patent No. 9,844,369.
16. The technical prong of the domestic industry requirement for U.S. Patent No. 9,844,369 has been satisfied.
17. Claims 22 and 23 are not invalid under 35 U.S.C. § 103 for obviousness.



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18. Intuitive infringes claims 2 and 3 of U.S. Patent No. 9,844,379.
19. Intuitive does not induce infringement of claims 2 and 3 of U.S. Patent No. 9,844,379.
20. Intuitive does contributorily infringe claims 2 and 3 of U.S. Patent No. 9,844,379.
21. The technical prong of the domestic industry requirement for U.S. Patent No. 9,844,379 has been satisfied.
22. Intuitive is estopped under 35 U.S.C. § 315(e)(2) from asserting that U.S. Patent No. 9,844,379 is invalid under 35 U.S.C. § 102 and § 103.
23. U.S. Patent No. 9,844,379 is not unenforceable based on inequitable conduct.
24. The economic prong of the domestic industry requirement has been satisfied.

## **XII. RECOMMENDED DETERMINATION ON REMEDY AND BOND**

The Commission's Rules provide that subsequent to an initial determination on violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii). The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

### **A. Limited Exclusion Order**

Under section 337(d), if the Commission determines that there is a violation of section 337, the Commission may issue a limited exclusion order directed to a respondent's infringing products. 19 U.S.C. § 1337(d). A limited exclusion order instructs the U.S. Customs and Border Protection to exclude from entry all articles that are covered by the patent at issue that originate from a named

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respondent in the investigation. *Fuji Photo Film Co. Ltd. v. Int’l Trade Comm’n*, 474 F.3d 1281, 1286 (Fed. Cir. 2007).

Ethicon requests a permanent limited exclusion order excluding from entry all Accused Products and components that infringe the Asserted Patents and that are imported, sold for importation, or sold after importation by a named Respondent. CIB at 243. Ethicon contends that “[t]he exclusion order should extend to each of the named Respondents as Intuitive has admitted that each plays a role in these activities.” *Id.* Ethicon argues that the limited exclusion order should not contain a carve out for imported components of U.S. manufactured products or for the accused SureForm Staplers. CRB at 114. Ethicon contends that an argument that components should be exempt because they do not infringe at the time of importation “has been flatly rejected by both the Federal Circuit and the Commission.” *Id.* (citing *Certain Blood Cholesterol Testing Strips & Associated Sys. Containing the Same*, Inv. No. 337-TA-1116, Comm’n Op., 2020 WL 2617310, at \*16-19 (May 1, 2020)).

In addition, Ethicon disputes Intuitive’s assertion that the SureForm Staplers are not imported into the U.S., and instead contends that they are manufactured in Mexico. *Id.* at 115. Ethicon asserts that the parties’ joint stipulation demonstrates that at least one unit of the SureForm 60 stapler was imported into the U.S. and that Intuitive intends to import at least one unit of the SureForm 45 stapler for sale into the U.S. *Id.* Ethicon also argues that imported components accused of indirect infringement are subject to an exclusion order. *Id.* at 115-116 (citing *Cisco Sys., Inc. v. Int’l Trade Comm’n*, 873 F.3d 1354, 1362-63 (Fed. Cir. 2017)). Ethicon argues that the limited exclusion order should not include carve outs for reload cartridges for existing Intuitive customers. *Id.* at 117. Ethicon contends that “Intuitive’s own delay in bringing its robotic staplers to market indicates that surgeons and patients will not be harmed by the exclusion order.” *Id.* at

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117-118. Moreover, Ethicon asserts that if the accused products are excluded, handheld staplers offered by either Ethicon or Medtronic<sup>68</sup> can continue to fill that need because it is well established that a robotic surgeon can use an Ethicon or Medtronic endocutter through an ancillary port of the robotic system. *Id.* at 118-119.

Intuitive asserts that a limited exclusion order should carve out unaccused components. RIB at 193. For example, Intuitive argues that, although certain components of the accused EndoWrist staplers are imported into the United States, they were not accused of infringement. *Id.* Additionally, Intuitive contends that, while certain components of the accused SureForm Staplers are imported into the United States, they have only been accused of contributory infringement. *Id.* at 193-194. Intuitive argues that “[a]s these components are used to manufacture the SureForm staplers exclusively in Sunnyvale, California, these components should therefore also not be included in any exclusion order.” *Id.* at 194. Intuitive also asserts that a limited exclusion order should not include non-imported staplers and reload cartridges, such as the EndoWrist 30 and 45 staplers, the SureForm staplers, and SureForm 45 reloads. *Id.* at 195. Lastly, Intuitive asserts that a limited exclusion order should carve out reload cartridges for existing Intuitive customers because they will suffer “significant harm” without continued access to Intuitive’s reload cartridges. *Id.* at 195-196. Intuitive claims that such an exception is warranted given its customers’ investment in their prior purchases of Intuitive products, the reasonable expectation of continued availability of those reload cartridges, and the lack of alternate products. *Id.* at 196-197.

Should the Commission determine there is a violation, the undersigned recommends the issuance of a limited exclusion order covering Intuitive’s products and components found to infringe the asserted patents. As an initial matter, limited exclusion orders, by definition, are

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<sup>68</sup> According to Ethicon, “Ethicon and Medtronic historically have been the two primary manufacturers of laparoscopic endocutters in the United States.” CIB at 216.

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directed to articles imported into the United States and thus, would not be directed to non-imported articles, such as the ones about which Intuitive appears to be concerned. *See* 19 U.S.C. § 1337(d). The undersigned does not recommend that the limited exclusion order include Intuitive’s requested carve outs, as the record does not support them.<sup>69</sup> In addition, 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. *See Cisco Sys., Inc.*, 873 F.3d at 1362-63.

### **B. Cease and Desist Order**

Under section 337(f)(1), the Commission may issue a cease and desist order in addition to, or instead of, an exclusion order. 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a “commercially significant” amount of infringing, imported product in the United States that could be sold, thereby undercutting the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293 USITC Pub. 2391, Comm’n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof & Prods. Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334 (Remand), Comm’n Op. at 26-28, 1997 WL 817767 at \*11-12 (U.S.I.T.C. Sept. 10, 1997).

Ethicon requests a cease and desist order and asserts that “Intuitive maintains a commercially significant domestic inventory of the Accused Products.” CIB at 245. In fact, Ethicon contends that the parties entered into a joint stipulation demonstrating Intuitive’s domestic inventory. *Id.* at 245-246.

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<sup>69</sup> Although Intuitive presents arguments relying on public interest rationale, the Commission did not order the undersigned to take evidence on the issue of the public interest for the purposes of the recommended determination under § 210.42(a)(1)(ii). *See* 84 Fed. Reg. 32,220-21; 19 C.F.R. § 210.50(b)(1).

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Intuitive argues that a cease and desist order should contain the same carve outs as a limited exclusion order. RIB at 200.

The undersigned recommends that cease and desist orders issue as to the Intuitive Respondents found to infringe by the Commission. The parties' Joint Stipulation demonstrates Intuitive's inventory of accused products in the United States as of November 15, 2019. *See* CX-0589C. Specifically, the evidence shows Intuitive's domestic inventory is as follows: 14,514 units of SureForm 60 staplers; 138,936 units of SureForm 60 reloads; 3,432 units of SureForm 45 staplers; 50,076 units of SureForm 45 reloads; 558 units of EndoWrist 45 staplers; 48,300 units of EndoWrist 45 reloads; 812 units of EndoWrist 30 staplers; and 40,548 units of EndoWrist 30 reloads. *See id.* Thus, the evidence demonstrates that Intuitive maintains a "commercially significant" inventory of Accused Products in the United States. The undersigned does not recommend any carve outs for the cease and desist orders.

### C. Bonding

Pursuant to section 337(j)(3), the Administrative Law Judge and the Commission must determine the amount of bond to be required of a respondent during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. 19 U.S.C. § 1337(j)(3). The purpose of the bond is to protect the complainant from any injury. 19 C.F.R. § 210.42(a)(1)(ii), § 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Microsphere Adhesives, Processes for Making Same, & Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. 2949, Comm'n Op. at 24 (Dec. 8, 1995). In other cases, the Commission has turned to alternative approaches, especially when the

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level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit Telecomm. Chips & Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n Op. at 41, 1993 WL 13033517, at \*24 (U.S.I.T.C. June 22, 1993). A 100 percent bond has been required when no effective alternative existed. *See, e.g., Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (imposing a 100% bond when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

Ethicon claims that a bond should be imposed because the Accused Products are in direct competition with the DI products. CIB at 246. Ethicon submits that the bond should be set at 100% of the price of the excluded Accused Products because a price comparison is not practical and licensing data does not exist. *Id.* at 248.

Intuitive argues that a bond of zero percent is economically reasonable. RIB at 201. Intuitive contends that the Accused Products are more expensive than Ethicon's DI Products. *Id.* at 201-203. Intuitive therefore argues that a reasonable royalty rate for purposes of calculating bond in these circumstances is zero. *Id.* at 204 (citing *Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op., 2017 WL 1476193, at \*8-9 (Feb. 1, 2017)). In addition, Intuitive contends that Ethicon would not be injured by a zero bond. *Id.* at 204-206.

The parties do not dispute that the Accused Products are more expensive than the DI Products. *See* CX-0003C at Q/A 225; RX-0015C at Q/As 137-142. Therefore, using the price differential method, the bond rate should be zero. *See Certain Table Saws Incorporating Active*

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*Injury Mitigation Tech. & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 13-15 (Feb. 1, 2017).

Accordingly, the undersigned recommends that the Commission set the bond value at zero percent.

### **XIII. INITIAL DETERMINATION**

Based on the foregoing, it is the Initial Determination of the undersigned that Respondents Intuitive Surgical, Inc., Intuitive Surgical Operations, Inc., Intuitive Surgical Holdings, LLC, and Intuitive Surgical S. De R.L. De C.V. infringe claims 22 and 23 of U.S. Patent No. 9,844,369 and claims 2 and 3 of U.S. Patent No. 9,844,379, but do not infringe the asserted claims of U.S. Patent Nos. 9,113,874 and 8,479,969. The undersigned further determines that U.S. Patent Nos. 9,113,874 and 8,479,969 are invalid, and that the domestic industry requirement has been satisfied for the Asserted Patents.<sup>70</sup>

The undersigned hereby certifies to the Commission this Initial Determination and the Recommended Determination. The parties' briefs, which include the final exhibits lists, are not certified as they are already in the Commission's possession in accordance with Commission rules. 19 C.F.R. § 210.38(a).

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation. A public version will be served at a later date.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R.

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<sup>70</sup> Any arguments from the parties' pre-hearing briefs incorporated by reference into the parties' post-hearing briefs are stricken, unless otherwise discussed herein, as an improper attempt to circumvent the page limits imposed for post-hearing briefing.

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§ 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within ten days of the date of this document, the parties must jointly submit a statement to Bullock337@ustic.gov stating whether they seek to have any portion of this document redacted from the public version. The parties shall attach to the statement a copy of a joint proposed public version of this document indicating with red brackets any portion asserted to contain confidential business.<sup>71</sup> To the extent possible, the proposed redacting should be made electronically, in a PDF of the issued order, using the “Redact Tool” within Adobe Acrobat, wherein the proposed redactions are submitted as “marked” but not yet “applied.” The parties’ submission concerning the public version of this document should not be filed with the Commission Secretary.

**SO ORDERED.**

  
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Charles E. Bullock  
Chief Administrative Law Judge

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<sup>71</sup> If the parties submit excessive redactions, they may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).



**CERTAIN LAPAROSCOPIC SURGICAL STAPLERS,  
RELOAD CARTRIDGES, AND COMPONENTS THEREOF**

**Inv. No. 337-TA-1167**

**PUBLIC CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served upon the following parties as indicated, on **June 29, 2021**.



Lisa R. Barton, Secretary  
U.S. International Trade Commission  
500 E Street, SW, Room 112  
Washington, DC 20436

**On Behalf of Complainants Ethicon LLC, Ethicon Endo-Surgery,  
Inc., and Ethicon US, LLC:**

Anish R. Desai, Esq.  
**WEIL, GOTSHAL & MANGES LLP**  
765 5<sup>th</sup> Avenue  
New York, NY 10153  
Email: anish.desai@weil.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification of  
Availability for Download

**On Behalf of Respondents Intuitive Surgical Inc., Intuitive Surgical  
Operations, Inc., Intuitive Surgical Holdings, LLC, and Intuitive  
Surgical S.DE R.L. DE C.V:**

Richard A. Sterba, Esq.  
**FISH & RICHARDSON P.C.**  
1000 Maine Avenue, SW, 1000  
Washington, D.C. 20024  
Email: sterba@fr.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
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