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POSITA would have understood that these two drive systems are not interchangeable and it is not possible to insert Alesi's drive screw 270 into Heinrich's assembly, without additional significant motivations." *Id.* Intuitive notes, however, that "the proposed combination involves implementing Alesi's drive screw in Heinrich's robotic linear stapler loading unit" – not into the surgical stapler in Figure 3 of Heinrich. RRB at 96. Thus, Ethicon's concerns are not relevant. Additionally, Dr. Vaitekunas testifies that incorporating Alesi's drive screw into Heinrich's stapler loading unit is "simply the application of a known technique to a known system." RX-0001C at Q/A 170; *see also id.* at Q/As 171-172. Thus, the undersigned finds that that a person of ordinary skill in the art would have motivated to combine the systems and further finds that the resulting system would meet the "motion converter" limitation.

The undersigned also finds that there is other evidence of motivation to combine Heinrich and Alesi. Alesi teaches that its design is "compact, lightweight, and easy to manufacture." JX-0150 at 2:18-19. Thus, a person of ordinary skill in the art "would have been motivated to use Alesi's drive screw with Heinrich's linear stapler loading unit to realize these advantages." RX-0001C at Q/A 167. Additionally, as Dr. Vaitekunas notes:

[A] person of ordinary skill in the art would have understood that Heinrich contemplates use of its robotic system 600 with a motor powered 'stapling or fastener applying instrument[]' and that Alesi provides details on a motor powered 'surgical stapling device.' Furthermore, as Dr. Awtar notes in his rebuttal report, Heinrich does not disclose exactly how the surgical stapler disclosed in paragraphs 92-99 of Heinrich and also through Heinrich's incorporation of Milliman 139's is employed with or interfaced directly with Heinrich's robotic system as taught by Heinrich. Thus, a person of ordinary skill in the art would have turned to Alesi for details on how to implement Heinrich's robotic motor powered surgical stapler.

RX-0001C at Q/A 168. The evidence further shows that a person of ordinary skill in the art would have reasonably expected to succeed. Implementing Heinrich's screw rod as taught by Alesi is simply the application of a known technique ("[u]tilizing a drive screw and a drive nut to actuate

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the firing mechanism in a motor powered surgical stapler”) to a known system (“Heinrich’s robotic surgical stapler”). *Id.* at Q/As 170-172. Additionally, the results would have been predictable “without altering or hindering the functionality of Heinrich’s instrument.” *Id.* at 170.

Ethicon’s only argument to the contrary is that Alesi “teaches away” from the proposed combination. The evidence does not support a view the Alesi teaches away from *all* externally-powered surgical devices. Alesi’s self-contained powered surgical apparatus was designed to solve a specific problem faced by some surgeons using handled instruments that were connected to power sources by conductive cables. JX-0150 at 2:12-14 (noting that “cables could . . . become entangled during a surgical procedure, thereby complicating the operations”); RX-0001C at Q/A 173. Heinrich’s robotic system “also avoids the problems associated with the entanglement of power cables by allowing a surgeon to operate remotely by controlling and actuating a surgical instrument via a console.” RX-0001C at Q/A 173. In fact, “[t]here are no cables connecting Heinrich’s loading units to the robotic arm.” *Id.*

Accordingly, the undersigned finds that claim 19 is rendered obvious by Heinrich in view of Alesi.<sup>20</sup>

### **c) Giordano 671 in view of Heinrich and Anderson**

Intuitive argues that Giordano 671 in view of Heinrich and/or Anderson renders claims 9 and 19 obvious. RIB at 157. Ethicon disputes that Giordano 671 in view of Heinrich and/or Anderson discloses limitation 19.3.3<sup>21</sup>, but does not dispute the remaining limitations. CLUL at 4. As for claim 9, Ethicon disputes that a person of ordinary skill in the art would be motivated to combine the references, but “does not specifically dispute any limitation.” *Id.*

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<sup>20</sup> The parties do not discuss secondary considerations with respect to the ’874 patent.

<sup>21</sup> Ethicon does not specifically address this limitation in its briefs and instead focuses on a lack of motivation to combine. CIB at 197-206.

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Intuitive argues that it “would have been obvious to combine Giordano 671’s stapler with a remote user-controllable actuation console/remotely user-controlled console as disclosed in Heinrich and/or Anderson.” RIB at 157. Intuitive asserts that there are five reasons why a person of ordinary skill in the art would have been motivated to combine the systems: (1) “First, Giordano 671 specifically states that its stapler has applicability to ‘robotic-assisted surgery.’” *Id.* at 159; (2) “Second, Heinrich and Anderson each expressly state that their robotic systems can be used with a variety of instruments, including surgical staplers.” *Id.* at 160; (3) “Third, the automation of mechanical equipment once operated manually, like Giordano 671’s stapler, is commonplace and reasonably obvious to one of ordinary skill.” *Id.* at 161; (4) “Fourth, robotic surgical systems, like those disclosed in Heinrich and Anderson, provided well-known advantages and benefits.” *Id.* at 162; and (5) “Finally, moving high-cost components like processor and power supplies from Giordano 671’s stapler to a robotic system would have allowed those components to be reused and reduced the number of parts in the stapler, which would reduce its cost and complexity.” *Id.* at 165. Intuitive also argues that a person of ordinary skill in the art would have “reasonably expected to succeed when modifying Giordano 671’s stapler for use with a robotic system.” *Id.* at 165.

Ethicon asserts that “Intuitive has failed to demonstrate why a POSITA would have been motivated to modify Giordano 671 for use with Heinrich or Anderson.” CIB at 197. Ethicon disputes each of the rationales by Intuitive and offers reasons of its own why a person of ordinary skill in the art would not have been motivated to combine the references. *Id.* at 197-199. First, Ethicon explains that “Giordano 671 and Heinrich . . . disclose fundamentally different stapler architectures that are not interchangeable.” *Id.* at 199. Ethicon also asserts that Giordano 671 and Anderson each disclose “completely different surgical tools.” *Id.* at 202. Finally, Ethicon asserts

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that “the loss of tactile feedback that would have resulted from combining Giordano 671 with Heinrich or Anderson would have deterred a POSITA from making” the combination. *Id.* at 204.

The record contains testimony as to why a person of ordinary skill in the art would be motivated to combine these references. *See* RX-0001C at Q/As 193-208. The record also, however, contains testimony as to why a person would *not* be so motivated. First, Dr. Awtar opines that Giordano 671 and Heinrich “use fundamentally different architectures that are not interchangeable. Giordano 671 utilizes a replaceable staple cartridge architecture, whereas Heinrich’s robotic system is premised on the use of loading unit architecture.” CX-3275C at Q/A 55; *see also id.* at Q/As 56-57. He also testifies that “[a] POSITA would have understood the Heinrich robotic system is designed specifically for loading unit architecture, which has a fundamentally different principle of operation than the removable staple cartridge architecture disclosed in Giordano 671.” *Id.* at Q/A 58. As to Anderson, Dr. Awtar notes that the tool in Anderson is a “completely different tool[]” than that of Giordano 671. *Id.* at Q/A 60. Dr. Awtar explains:

The robotic ultrasound cauterizing tool in Anderson utilizes low force gripping and probe tip that is vibrated at high frequency to impart sufficient energy onto tissue to cut and/or coagulate it. This tool is incapable of articulation because it was only physically possible to vibrate the probe tip at frequencies that are sufficiently high to cut or coagulate tissue if the vibration is along the longitudinal axis of the device.

In contrast, the tool in Giordano 671 is a handheld articulating instrument that utilizes high force clamping followed by a firing sequence that results in staples being ejected and tissue being cut by a knife.

*Id.*; *see also id.* at Q/A 61. Thus, the evidence in the record suggests both that the systems use fundamentally different architectures and disclose fundamentally different instruments.

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Although Intuitive makes arguments for why the undersigned should reject Dr. Awtar's opinions, Dr. Vaitekunas, in turn, does not address this testimony.<sup>22</sup> See RRB at 96-98. As such, the undersigned cannot find that there is clear and convincing evidence that a person of ordinary skill in the art would be motivated to combine Giordano 671 with Heinrich and/or Alesi.<sup>23</sup> See *Acoustic Tech, Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1375 (Fed. Cir. 2020) (“conclusory expert testimony and attorney argument cannot constitute substantial evidence of a motivation to combine”).

Accordingly, the undersigned finds that claim 9 and 19 are not rendered obvious by Giordano 671 in view of Heinrich and/or Alesi.

### **VIII. U.S. PATENT NO. 9,844,369**

#### **A. Overview**

The '369 patent, entitled “Surgical End Effectors with Firing Element Monitoring Arrangements,” issued on December 19, 2017 to Thomas W. Huitema, Charles J. Scheib, Cortney E. Henderson, Frederick E. Shelton, IV, and Jason L. Harris. The '369 patent is assigned to Ethicon LLC. See 2d Am. Compl at ¶ 30; see also Section III. The '369 patent generally relates to “stapling instruments and, in various embodiments, to a surgical stapling instrument for producing one or more rows of staplers.” JX-0002 at 1:16-18.

#### **1. Asserted Claims**

Ethicon is asserting claims 22 and 23 of the '369 patent against Intuitive. CIB at 85. These claims read as follows:

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<sup>22</sup> Dr. Vaitekunas does assert that Anderson “discloses modifying a variety of surgical instruments, including staplers, for use with a robotic system.” RX-0001 at Q/A 195. Such testimony is conclusory, however, and does not address the specific concerns raised by Dr. Awtar.

<sup>23</sup> The undersigned notes that this is particularly true for claim 9. Dr. Vaitekunas did not offer any opinion as to how this combination renders claim 9 obvious. RX-0001C at Q/A 83 (“I have not offered any opinions regarding the validity of claim 9.”); see also *id.* at 174-211 (explaining only how claim 19 is obvious).

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22. [22.0] 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.

### 2. Claim Construction

The undersigned construed the following terms from the asserted claims as follows:

TERM	CLAIM	CLAIM CONSTRUCTION
<b>“first position”</b>	22	Plain and ordinary meaning
<b>“firing motion”</b>	22	Plain and ordinary meaning
<b>“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”</b>	22	<u>Function:</u> 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  <u>Structure:</u> (i) a chamfer or otherwise sloped surface on the foot of the firing element, and/or

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TERM	CLAIM	CLAIM CONSTRUCTION
		(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

Order No. 15 at 30-43.

**B. Infringement**

Ethicon asserts that Intuitive’s SureForm 60, SureForm 45, and compatible SureForm 60 Reloads and SureForm 45 Reloads directly infringe claims 22 and 23 of the ’369 patent.<sup>24</sup> CIB at 20, 85. Ethicon further asserts that Intuitive commits acts of induced and contributory infringement of claims 22 and 23 by importing SureForm Staplers into the U.S., supplying them to end users, and providing instruction and training regarding their use. *Id.* at 85-86.

**1. Direct Infringement**

**a) Claim 22**

Ethicon asserts that Intuitive’s SureForm Staplers meet every limitation of claim 22 of the ’369 patent. CIB at 87.

Intuitive contends that the SureForm Staplers do not have “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” or “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.”

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<sup>24</sup> Ethicon contends that the “SureForm 60 and SureForm 45 have the same design architecture.” CIB at 20; CX-0002C at Q/A 20-23. As previously noted, Intuitive agrees that the various SureForm Staplers are representative of each other. RIB at 13.

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RIB at 52. Intuitive does not dispute that the SureForm Staplers meet the remaining limitations of claim 22. RLUL at 2-3; RIB at 52.

### i. Limitation 22.4

Claim 22 includes the limitation “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-0002, cl. 22.

Ethicon argues that the reload channel of the SureForm Staplers has a proximal channel opening through the proximal end of the bottom of the reload channel, which facilitates viewing of the I-beam when it is in the first position, and is also sized to receive the laterally extending feet of the I-beam. CIB at 89-90. Ethicon contends that when the I-beam is in the first position (*i.e.*, home position), the bottom foot is positioned in the proximal channel opening and is visible. *Id.* at 90.

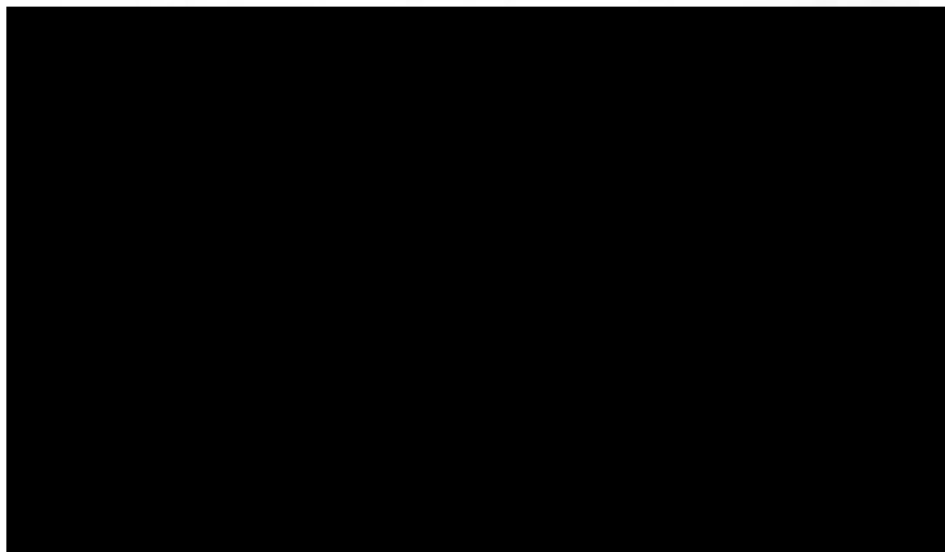
Ethicon disagrees with Intuitive’s assertion that an opening in the middle of a cover that is welded to the reload channel is the proximal channel opening. *Id.* Ethicon argues that the cover is not part of the reload channel. *Id.* at 91-92. Instead, Ethicon asserts that Intuitive’s documentation demonstrates that the cover is part of the [REDACTED] which is separate from the channel component. *Id.* at 32-33. In addition, Ethicon contends that even if the cover were considered part of the reload channel, the limitation is still met because the proximal channel opening identified by Dr. Fronczak extends through the middle and around the sides of the cover. CIB at 92-93; CRB at 33-34. Lastly, Ethicon submits that Dr. Howe admitted that the opening identified by Dr. Fronczak is sized to receive the I-beam lower foot. CIB at 93; CRB at 35.



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Intuitive argues that while the SureForm Staplers have an opening through the bottom of the elongate channel, it is too small for the I-beam to fit and is therefore not sized to receive the lower foot of the I-beam. RIB at 55-57. Intuitive contends that the portion Ethicon identifies as the proximal channel opening is incorrect because it is not an opening through the bottom of the channel, but rather, is inside the channel and above the bottom of the channel. *Id.* at 58-59; RRB at 33. Intuitive argues that the claim requires an opening through the bottom of the channel, and not a volume in the interior of the channel. RIB at 59. According to Intuitive, [REDACTED] *Id.* at 61-62. Intuitive submits that only a “fully-assembled end effector” can satisfy this limitation. RRB at 34.

At issue is which opening in the SureForm Staplers is the proximal channel opening. Below is an excerpt from Dr. Fronczak’s demonstrative illustrating the area Ethicon identifies as the proximal channel opening (outlined in a blue dashed line), the area Intuitive identifies as the proximal channel opening (outlined in a yellow solid line), and the cover on the channel (outlined in a red dashed line).



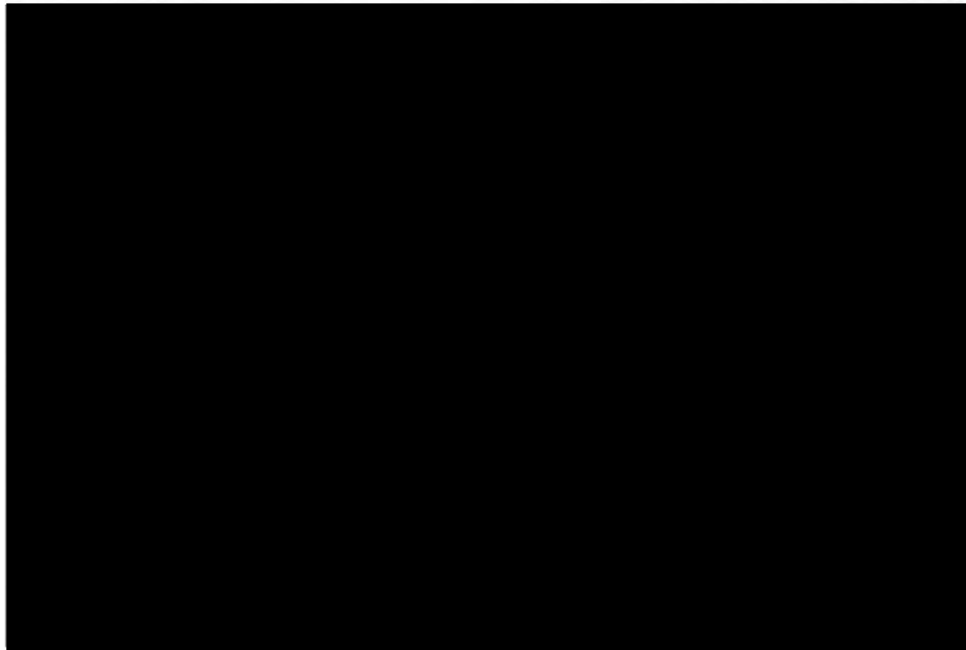
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CDX-0002C at 22; *see also* CX-0002C at Q/A 98; RX-0019C at Q/A 32. First, the undersigned finds that the area identified by Intuitive is not the proximal channel opening. The evidence shows that the opening identified by Intuitive is an opening in the cover, which is not part of the channel, but rather, is a separate component added to the channel. *See* RX-0019C at Q/A 32 (describing opening as “a small opening in the cover portion of the channel”). For example, the part drawing for the channel does not include the cover as being part of the channel. *See* RX-0339C. In addition,

[REDACTED]

[REDACTED] *See* RX-0341C. Therefore, because the cover is not part of the channel, the opening that Intuitive identifies in the cover is not “a proximal channel opening through the proximal end of the bottom of the elongate channel” as required by this claim limitation.

Turning to the area that Ethicon identifies as the proximal channel opening (as shown below in Dr. Fronczak’s annotation of the part drawing of the channel), the reload channel in the SureForm Stapler has an opening through the proximal end of the bottom of the elongate channel.



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*See* CDX-0002C at 20 (annotating RX-0339C at 3); *see also* CX-0002C at Q/As 90-100. The evidence also shows that this opening facilitates viewing of the firing element when it is in the first position. For example, when the I-beam (firing element) is in the home position (first position), the bottom of the I-beam is positioned in the proximal channel opening and is visible to the user. *See* CX-0002C at Q/As 91-93; RX-1105C at 34. In addition, when the I-beam is in the home position, the bottom foot of the I-beam is in the opening, thus demonstrating that it is sized to receive the foot. *See* CX-0002C at Q/A 91; Howe, Tr. at 725:3-5 (“Q: Okay. And you would agree that that blue opening is sized to receive the I-beam lower foot, right? A: Yes.”). The undersigned therefore finds that the SureForm Staplers meet this limitation.

### **ii. Limitation 22.5**

Claim 22 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.” JX-0002, cl. 22.

#### **(a) Structure**

Ethicon argues that the SureForm Staplers include the required structure for this limitation in two ways: (1) a sloped surface on the foot of the I-beam firing element, and (2) a sloped surface on the portion of the elongate channel defining the proximal channel opening. CIB at 93-94. Ethicon disputes Intuitive’s contention that these are not sloped surfaces because they are curved. *Id.* at 94. In particular, Ethicon asserts that Intuitive’s argument that a “chamfer or otherwise sloped surface” should be limited to the exact surfaces shown in Figures 40 and 41 of the ’369 patent was rejected during claim construction. *Id.* at 95. Ethicon contends that Intuitive’s attempt to limit the

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structure to a flat surface is inconsistent with the claim construction order and that a “sloped surface” can have a variable slope.<sup>25, 26</sup> *Id.*

In addition, Ethicon argues that Intuitive incorrectly identifies what portion of the reload channel constitutes the proximal channel opening. *Id.* Ethicon also claims that Intuitive’s argument regarding the location of the surfaces is irrelevant to the issue of infringement. *Id.* at 96; *see also* CRB at 40. Ethicon argues that the undersigned’s claim construction only requires that the sloped surface be located on the foot of the I-beam, on the proximal end of the internal passage, and/or on a portion of the elongate channel that defines the proximal channel opening. CIB at 96; CRB at 39-40.

Intuitive argues that in the ’369 patent, the chamfers or otherwise sloped surfaces are “flat, planar surfaces” that are located on the cover of the internal passage and on the bottom of the lower foot of the firing element.<sup>27</sup> RIB at 63-64. Intuitive contends that the features identified by Ethicon are not flat surfaces like the chamfers or otherwise sloped surfaces disclosed in the ’369 patent, but instead, comprise a radius or curved surface. *Id.* at 65-66. Intuitive disputes Ethicon’s contention that it is limiting the claims to the exact surfaces illustrated in Figures 40 and 41 of the ’369 patent. RRB at 36. Instead, Intuitive argues that it is using those figures as examples of the corresponding structure, supporting its expert’s opinion that a person of ordinary skill in the art would have understood that the “otherwise sloped surfaces” in the ’369 patent are flat surfaces. *Id.*

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<sup>25</sup> Ethicon submits that Intuitive’s position renders a portion of the undersigned’s claim construction superfluous since Dr. Howe claims that a “chamfer” refers to a surface with a constant slope, while an “otherwise sloped surface” also refers to a surface with a constant slope. CRB at 38 (citing Howe, Tr. at 738:4-12).

<sup>26</sup> In addition, Ethicon asserts that in Intuitive’s Petition for *Inter Partes* Review of the ’369 Patent, it took the position that a curved surface was a ramped surface. *Id.*

<sup>27</sup> Intuitive notes that Ethicon has never attempted to argue that the features it has identified are equivalent to the structures disclosed in the specification of the ’369 patent. RIB at 68; RRB at 35. Intuitive also notes that Ethicon has never attempted to argue that the features it has identified are “chamfers.” RRB at 35.

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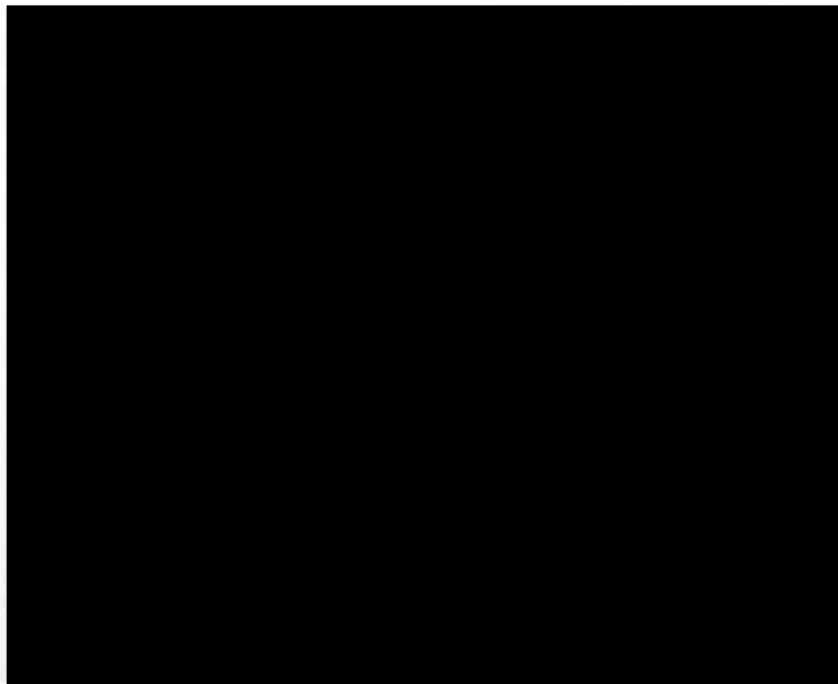
Intuitive also argues that the features Ethicon identifies are not located in the same locations as the structures disclosed in the '369 patent. RIB at 66. Intuitive contends that the structures in the '369 patent are on the bottom of the leading edge of the lower foot of the E-beam and on the cover of the stapler's channel, while in the SureForm, the structures identified by Ethicon are located on the top of the leading edge of the lower foot of the I-beam and on an interior surface of the channel. *Id.* at 66-67. In addition, Intuitive asserts that the structure Ethicon identifies does not define the proximal end of the internal passage because it is physically separated from what Ethicon has identified as the internal passage. *Id.* at 67. Intuitive also contends that the structure Ethicon identifies does not define the proximal channel opening because the SureForm does not have the claimed proximal channel opening. *Id.* at 68.

As an initial matter, the undersigned finds that "a chamfer or otherwise sloped surface" need not be a flat, planar surface. The undersigned previously found that the structure for this means plus function term included "(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." Order No. 15 at 43. In addition, the undersigned noted that "the specification explicitly indicates that the chamfer may 'otherwise be sloped as shown' or may be a 'ramped surface.'" *Id.* at 42 (citing JX-0002 at 77:24-39, cl. 23). While the portion of the specification describing the required structure for this limitation does not expand on the meaning of "chamfer" or "otherwise sloped surface," other portions of the specification provide some guidance. For example, in describing sloped surface 208 in Figure 10, the specification states that "[i]n certain embodiments, each sloped surface 208 can comprise one or more flat surfaces, curved surfaces, concave surfaces, and/or convex surfaces, for example." JX-0002 at 25:17-20. Similarly, in describing ridge 615 in

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Figure 18, the specification states that “each ridge 615 can comprise a ramped surface which can comprise one or more flat surfaces, curved surfaces, concave surfaces, and/or convex surfaces, for example.” *Id.* at 26:12-15. While these portions of the specification are not describing the exact structure at issue in this limitation of claim 22, they demonstrate that one 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.

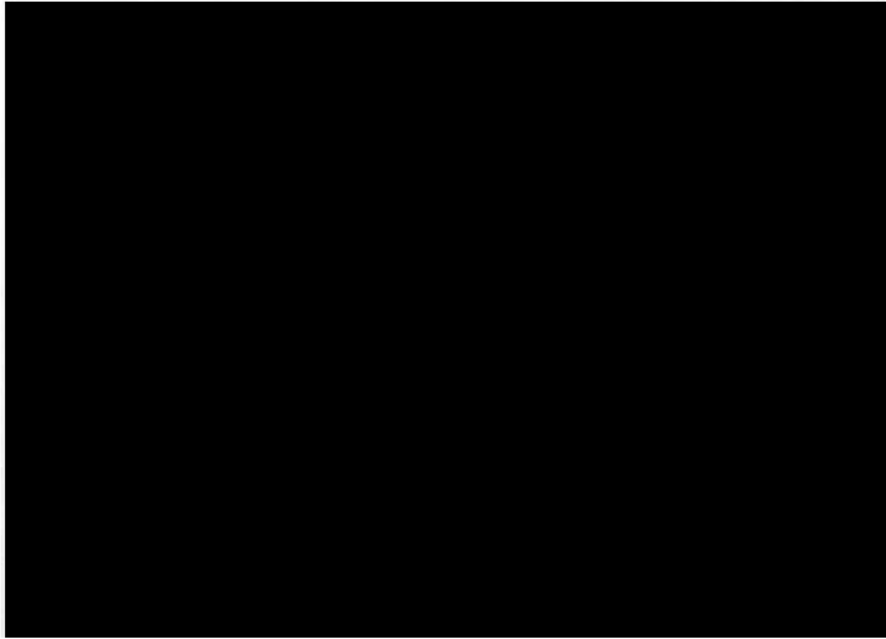
Next, the undersigned must determine whether the two structures identified by Ethicon are corresponding structures for this means plus function term. First, as seen below in Dr. Fronczak’s annotation of the I-beam part drawing, the lower foot of the I-beam of the SureForm Stapler has a sloped or ramped surface.



*See* CDX-0002C at 24; *see also* RX-0334C; CX-0002C at Q/As 102, 105. Thus, the sloped surface on the foot of the I-beam is the corresponding structure because it is “a chamfer or otherwise sloped surface on the foot of the firing element.” Second, as seen below in Dr. Fronczak’s annotation of

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the channel part drawing, the proximal channel opening<sup>28</sup> of the reload channel in the SureForm Stapler has a sloped or ramped surface.



*See* CDX-0002C at 23; *see also* RX-0339C; CX-0002C at Q/As 102-104. Thus, the sloped surface on the portion of the elongate channel defining the proximal channel opening is the corresponding structure because it is “a chamfer or otherwise sloped surface on a portion of the elongate channel defining . . . the proximal channel opening.” Therefore, the undersigned finds that both of these are corresponding structure for this claim limitation.<sup>29</sup>

**(b) Function**

Ethicon contends that when the I-beam is in its initial position, the user can initiate distal movement of the I-beam by providing a grip command at the surgeon’s console, which is the initial application of the firing motion. CIB at 96. Ethicon asserts that when this happens, the sloped

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<sup>28</sup> The undersigned has already rejected Intuitive’s argument regarding the proximal channel opening limitation. *See supra* at Section VIII.B.1.a.i.

<sup>29</sup> Contrary to Intuitive’s assertion, nothing in the language of claim 22 nor the construction of this term 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. *See* JX-0002, cl. 22; Order No. 15 at 43.

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surface on the foot of the I-beam engages the sloped surface on the proximal channel opening. *Id.* at 96-97. According to Ethicon, as the I-beam continues to move distally, the engagement between the sloped surfaces guides the foot of the I-beam out of the proximal channel opening into the internal passage of the reload channel. *Id.* at 97. Ethicon argues that claim 22 does not require the firing element to move vertically, but instead, only requires that the foot of the firing element is guided out of the proximal channel opening and into the internal passage. *Id.* at 98. Ethicon argues that the claimed “guidance” occurs when the sloped surface on the proximal channel opening engages the sloped surface on the I-beam foot, which causes the reload channel to move vertically as the I-beam moves distally and into the internal passage. *Id.*

Ethicon asserts that Dr. Howe confirmed that the sloped surfaces on the SureForm Staplers guide the I-beam lower foot out of the proximal channel opening and into the internal passage. CIB at 98; CRB at 41. In addition, Ethicon asserts that Intuitive’s argument that the term “firing motion” should be limited to a “motion applied during the firing operation” was already rejected during claim construction. CIB at 99. Ethicon contends that neither the plain language of claim 22 nor the specification of the ’369 patent require that the firing motion be associated with the deployment of staples or a firing operation. *Id.* Ethicon argues that the plain meaning of “firing motion” is clearly set forth in claim 22. *Id.* More specifically, Ethicon submits that “the firing motion is the motion of the firing element that moves it between the first position and the ending position, while the initial application of the firing motion is the motion of the firing element associated with moving the foot out of the proximal channel opening and into the internal passage.” *Id.* at 99-100.

Intuitive argues that the features Ethicon identified do not perform the claimed function because they do not guide the I-beam, but rather, the I-beam stays in a fixed vertical position while



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the allegedly sloped surfaces close the stapler's jaws. RIB at 68-69. Thus, Intuitive argues that if anything is guided when the allegedly sloped surfaces interact, it is the channel, not the I-beam. *Id.* at 69. According to Intuitive, the claimed guiding function in the '369 patent refers to guiding the E-beam in a vertical direction up out of the proximal channel opening. *Id.* However, Intuitive contends that in the SureForm, the I-beam only moves along the horizontal axis, and it cannot move vertically like the E-beam in the '369 patent. *Id.* at 70-71. Thus, Intuitive argues that the features identified by Ethicon do not guide the I-beam at all, but rather, "serve to aid the I-beam as the I-beam guides closed the jaws of the stapler during the SureForm's 'grasp' and 'clamp' operations." RRB at 37. In other words, Intuitive claims that the I-beam is not guided by something, but rather, it is the guide. *Id.*

In addition, Intuitive argues that the alleged guiding does not occur upon initial application of a firing motion to the firing element. RIB at 71. Rather, Intuitive asserts that the alleged guiding occurs before the firing motion begins – *i.e.*, during the "grasp" and "clamp" steps. *Id.* Intuitive contends that the plain meaning of "initial application of the firing motion" refers to the beginning of the firing step when the surgeon initiates firing. *Id.* at 73. Intuitive argues that this does not refer to the separate and distinct closure step, not does it refer generically to movement of the E-beam. *Id.* According to Intuitive, in the SureForm Stapler, both the grasp and clamp modes correspond to certain ranges of motion of the I-beam, neither of which results in advancement of the I-beam to any location that would result in the lower foot on the firing element moving out of an opening through the proximal end of the bottom of the elongate channel and into an internal passage in the elongate channel to deploy staples. *Id.* at 75. In fact, Intuitive contends that excerpts of a SureForm CAD file show that the guiding occurs during the "grasp" and "clamp" steps, before the firing motion is applied to the firing element. *Id.* at 77-78.

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The undersigned disagrees with Intuitive's argument that "firing motion" is defined by the deployment of staples. *See* RIB at 73; RX-0019C at Q/A 81. During the claim construction phase of this Investigation, Intuitive argued that "firing motion" meant "motion applied during the firing operation." *See* Order No. 15 at 34. The undersigned, however, rejected that position. *See id.* at 36-38 ("While it is true that the specification describes an embodiment where a firing force or motion is applied once the anvil has been close, it would be improper to limit the claims to any particular embodiment."). Thus, the undersigned finds that in the SureForm Staplers, initial application of a firing motion to the firing element occurs when a user initiates a grip command at the surgeon's console. *See* CX-0002C at Q/As 110, 118; CX-0075C at 4; *see also* RX-0019C at Q/A 79 ("the alleged 'guiding' function occurs upon initial application of a gripping or clamping motion to the I-beam").

The evidence shows that when the I-beam is in the home position in the proximal channel opening and the jaws are open, a user can initiate distal movement of the I-beam toward the distal end of the instrument by implementing this grip command at the surgeon's console using hand controls. *See id.* In response to the grip command, the I-beam moves distally and the sloped surface on the foot of the I-beam engages the sloped surface on the proximal channel opening. *See id.*; CX-0924C at 124:24-125:12; CX-0909C; JX-0280C at 178:3-6; CX-0890C; CX-0002C at Q/As 110-112; CX-0036C; CX-0055C; CX-0056C; CX-0057C; CDX-0002 at 25-26. The engagement between the sloped surface on the foot of the I-beam and the sloped surface on the proximal channel opening guides the lower foot of the I-beam out of the proximal channel opening and into the internal passage as the I-beam moves distally.<sup>30</sup> *See id.*

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<sup>30</sup> The function for this term is "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." Order No. 15 at 43. Nothing requires the I-beam to move vertically, as Intuitive suggests. *See id.*

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The undersigned therefore finds that Ethicon provided sufficient evidence demonstrating that the SureForm Staplers perform the identical function recited in this means limitation and perform that function using the corresponding structure disclosed in the specification, as construed. *See Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1548 n.8 (Fed. Cir. 1994) (quoting *Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.*, 15 F.3d 1573, 1578 (Fed. Cir. 1993)).

### iii. Conclusion

Accordingly, for the reasons set forth above, the undersigned finds that the SureForm Staplers infringe claim 22 of the '369 patent.

### b) Claim 23

Ethicon asserts that the SureForm Staplers have a reload channel that includes a sloped surface on a portion of the channel defining the proximal channel opening [REDACTED], which is a ramped surface. CIB at 100. Intuitive does not dispute that the SureForm Staplers meet the additional limitations of dependent claim 23, but contends that the SureForm Staplers do not infringe claim 23 for the same reasons as claim 22. RLUL at 3; RIB at 53-54.

In addition, the evidence shows that the SureForm Staplers meet the limitations of claim 23. CX-0002C at Q/As 189-190; CDX-0002C at 41. Accordingly, the undersigned finds that the SureForm Staplers infringe claim 23 of the '369 patent.

## 2. Indirect Infringement

Ethicon asserts that Intuitive commits acts of induced and contributory infringement of claims 22-23 by importing SureForm Staplers into the United States, supplying them to end users, and providing instruction and training regarding their use. CIB at 85-86. Intuitive does not address indirect infringement in its briefs and has therefore waived its arguments. *See generally* RIB at 53-78; RRB at 32-39; Ground Rule 13.1.

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### **a) Induced Infringement**

Ethicon argues that Intuitive has had knowledge of the '369 patent since August 2018, which is before Ethicon filed its Complaint in this Investigation. CIB at 100. Ethicon contends that Intuitive induces infringement of claims 22 and 23 because the SureForm Staplers directly infringe claims 22 and 23, and Intuitive provides instruction and operating manuals that affirmatively instruct end users to use the SureForm staplers in combination with compatible SureForm reloads. *Id.* In addition, Ethicon asserts that Intuitive provides training and assistance to end users about how to use SureForm Staplers. *Id.*

Intuitive had actual knowledge of the '369 patent at least since August 27, 2018, prior to when Ethicon filed its Complaint in this Investigation. CX-1893 at 4. The undersigned, however, finds that Ethicon has not shown that Intuitive had actual knowledge of infringement or was willfully blind to infringement *See Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639-642 (2015) (rejecting the argument that mere knowledge of the patent is sufficient to show induced infringement).

Accordingly, the undersigned finds that Ethicon failed to prove that Intuitive induced infringement of claims 22 and 23 of the '369 patent.

### **b) Contributory Infringement**

Ethicon argues that Intuitive commits acts of contributory infringement by importing SureForm Staplers and components thereof into the United States, and then providing them to customers who directly infringe claims 22 and 23. CIB at 100. Ethicon submits that neither the SureForm Staplers nor the compatible reloads are staple articles of commerce that are suitable for non-infringing uses. *Id.* at 100-01. In fact, Ethicon asserts that the User Manual describes that the staplers are designed solely for use with compatible reloads and are incompatible with third-party

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reloads. *Id.* at 101. Ethicon also argues that both the imported SureForm staplers and SureForm reloads constitute material parts of the invention of claims 22 and 23. *Id.* at 101. For example, Ethicon contends that claim 22 is specifically directed to an end effector comprising an elongate channel configured to support a staple cartridge and the SureForm 60 reloads and sub-assemblies of the SureForm 45 reloads are staple cartridges. *Id.* at 102. In addition, Ethicon argues that the I-beam firing element in the SureForm Staplers is configured to translate between a first position and ending position when a compatible SureForm reload cartridge is installed, as described in claim 22. *Id.*

First, the undersigned has already determined that there is direct infringement of claims 22 and 23 of the '369 patent. *See supra* at Section VIII.B.1. Second, Ethicon has made a *prima facie* showing that the accused components do not have any substantial non-infringing uses, which Intuitive does not dispute. In particular, the user manual for the SureForm staplers explains that they are designed to only be compatible with their respective SureForm reloads and the da Vinci Xi and X Surgical Systems. *See CX-0002C* at Q/A 136; *RX-0335C* at 6, 10. The SureForm staplers and SureForm reloads also constitute material parts of the invention of claims 22 and 23. *See CX-0002C* at Q/A 137; *JX-0002*, cls. 22-23. Third, there is no dispute that the accused components have been imported, sold for importation, or sold after importation in the United States by Intuitive. *See CX-0002C* at Q/A 136; *CX-0589C*; *see also supra* at Section II. As to the requisite knowledge, the threshold is lower than for inducement. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) (“One who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent.”). Therefore, because the evidence shows that the SureForm staplers are designed solely to be used with

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compatible SureForm reloads and are incompatible with third-party reloads, then the knowledge requirement has been satisfied.<sup>31</sup> See CX-0002C at Q/A 136; RX-0335C at 6, 10.

Accordingly, the undersigned finds that Intuitive has contributorily infringed claims 22 and 23 of the '369 patent.

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

Ethicon asserts that the Echelon FLEX™ Powered Plus Staplers, [REDACTED], and compatible ECR and GST reloads (“the '369 DI Products”) satisfy the technical prong of the domestic industry requirement for claims 22 and 23 of the '369 patent. CIB at 16, 102. Intuitive does not dispute that the technical prong of the domestic industry is met. RLUL at 2-3.

Additionally, the evidence shows that Ethicon’s '369 DI Products practice claims 22 and 23. CX-0002C at Q/As 26-27, 30-46, 52, 138-181, 189-190; CX-0022 at 12, 20; CX-0146C; CX-0159C; CX-0148C; CPX-0010C; CDX-0002C at 33, 34, 36, 37, 41; CX-0009C at Q/As 54-69; CX-0004C at Q/As 79-89; CX-0647C at 49:5-50:19; JX-0214C at 116:22-117: 19; JX-0242C at 137:19-138:5; CDX-0004C at 3; CX-0046C at 2-3.

Accordingly, the undersigned finds that Ethicon has satisfied the technical prong of the domestic industry requirement for the '369 patent.

### D. Validity

Intuitive asserts that claims 22 and 23 are rendered obvious by Kostrzewski in view of Green 695, Scirica, and/or Zemlok.<sup>32</sup> RIB at 78.

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<sup>31</sup> In addition, as previously noted, Intuitive had actual knowledge of the '369 patent at least since August 27, 2018. CX-1893 at 4.

<sup>32</sup> Intuitive contends that U.S. Patent Pub. No. 2013/0098965A1 (“Kostrzewski”), which was filed on October 25, 2011 and published on April 25, 2013, is prior art under AIA 35 U.S.C. § 102(a)(1); U.S. Patent No. 4,429,695 (“Green 695”), which issued on February 7, 1984, is prior art under AIA 35 U.S.C. § 102(a)(1); U.S. Patent No. 8,973,805 (“Scirica”), which was filed on May 25, 2012, is prior art under AIA 35 U.S.C. § 102(a)(2); and U.S. Patent Pub. No. 2011/0036891A1 (“Zemlok”), which published February 17, 2011, is prior art under AIA 35 U.S.C. § 102(a)(1). RIB

**1. Claim 22**

Intuitive asserts that Kostrzewski discloses a surgical stapler substantially similar to the accused SureForm Stapler, except with an open-bottom channel. RIB at 78. Intuitive submits that it would have been obvious, in view of Green 695, Scirica, and/or Zemlok, to cover the portion of Kostrzewski's exposed passage, and that the resulting instrument would include each limitation of the asserted claims under Ethicon's theory of infringement. *Id.* at 78-79; *see also* Appx. D.

Ethicon states that "[t]o the extent the references are combined as Intuitive proposes, Ethicon does not specifically dispute any limitation." CIB at 108. Ethicon, however, disputes that Kostrzewski, or Zemlok and Scirica disclose limitations 22.3 and 22.4. *Id.* at 108-109.

**a) Limitation 22.3**

Intuitive asserts that while Kostrzewski has an open-bottom channel, it would have been obvious in view of Green 695, Scirica, and/or Zemlok to cover the portion of Kostrzewski's exposed passage where the tissue is stapled and cut. RIB at 78. Intuitive asserts that Green 695 discloses a surgical stapler with an internal passage in the elongate channel that is configured to receive the laterally extending lower foot (lower shoe 54) of the I-beam. *Id.* at 79-80. Intuitive argues that Green 695 teaches a closed channel, which is more effective at aligning and stabilizing the jaws, and thus, one of ordinary skill would have been motivated to combine Green 695 with Kostrzewski's open channel to increase stability. RRB at 41. In addition, Intuitive asserts that Scirica discloses a stapler with an enclosed I-beam, showing the firing element with a lower foot that moves within an internal passage. RIB at 80-81. Intuitive also contends that Zemlok discloses an endoscopic surgical stapler with an enclosed I-beam, showing that the firing element has a lower foot. *Id.* at 81.

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at 78-79 n.7; JX-0144; JX-0145; JX-0163; JX-0142. Ethicon does not dispute this. *See* CIB at 107-119; CRB at 44-52.

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Intuitive argues that neither Kostrzewski nor the asserted claims of the '369 patent limit the overall dimensions of the end effector and thus, one of ordinary skill would not have been deterred from making a slightly larger stapler. RRB at 43. In addition, Intuitive disputes that covering the channel would make the instrument more complex to manufacture. *Id.* at 43-44. Intuitive contends that, as shown in Scirica, “visibility of the I-beam was not a required feature of surgical staplers and therefore the purported lack of visibility throughout the I-beam’s path of travel would not have deterred a POSITA from covering Kostrzewski’s channel.” *Id.* at 44. Moreover, Intuitive asserts that if visibility were desired, a person of ordinary skill could include viewing holes as taught by Zemlok. *Id.*

Ethicon argues that Kostrzewski discloses an elongate channel with an open passageway. CIB at 109. Ethicon claims that Dr. Howe failed to set forth any evidence that a person of ordinary skill would have recognized a problem in Kostrzewski that would have prompted a motivation to create an internal passage to increase its strength and protect external tissue from damage. *Id.* at 110. Ethicon asserts that a person of ordinary skill would not have recognized a problem with strength or tissue damage with respect to Kostrzewski, as evidenced by Covidien’s use of an elongate channel with an open bottom in its commercial products. *Id.* at 110-112. Ethicon argues that Green 695, Zemlok, and Scirica also fail to provide a motivation to modify Kostrzewski to include an internal passage. *Id.* at 112. For example, Ethicon contends that Green 695 teaches the combination of an I-beam and corresponding passageways to maintain alignment of the jaws. *Id.* Ethicon claims that this would not have motivated a person of ordinary skill to modify Kostrzewski, which already had the combination of passageways and an I-beam to maintain alignment of the jaws during use. *Id.*; *see also* CRB at 45-46. Similarly, Ethicon asserts that neither Zemlok nor Scirica disclose the claimed internal passage. CIB at 113-114. In addition, Ethicon



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argues that a person of ordinary skill would have been deterred from modifying Kostrzewski to include the claimed internal passage because it would increase the diameter of the instrument, would make the instrument more complex to manufacture, and would eliminate visibility of the I-beam throughout its path of travel. *Id.* at 114.

At issue is whether it would have been obvious to one of ordinary skill in the art, in view of Green 695, Scirica, and/or Zemlok, to cover Kostrzewski's exposed passage to achieve the claimed internal passage. Intuitive maintains that it would have been obvious because there were "known disadvantages of having an open bottom channel." *See* RX-0003C at Q/A 425. Intuitive's expert cites to a portion of the following passage in Green 695 and alleges that it explains the problems associated with open channels as well as the benefit of internal passages. *See id.* at Q/As 429-430; JX-0145 at 6:26-36. Green 695 states:

It will be appreciated, since the shoes 54 and 56 are accurately laterally aligned and carried by a relatively rigid member, that during stapling, as the shoes move along the passageways 48 and 52 with minimal clearance, they provide adequate localized support to the jaws in the region of operation of the pusher bar cams and the particular individual staple pushers being actuated. Due to the cross-sectional shape of the shoes and passageways, such support resists forces tending both laterally to distort the jaws and to open the jaws vertically, and accordingly the present construction lends itself to manufacturing the jaws in relatively light weight disposable materials. It is to be understood, however, that the construction can also be used in instruments manufactured from more conventional materials.

JX-0145 at 6:26-41. Contrary to what Intuitive's expert alleges, however, this passage does not indicate that the internal passages in Green 695 provide adequate localized support to the jaws. *See id.*; RX-0003C at Q/A 430. Rather, Green 695 teaches that the shoes 54 and 56 provide adequate localized support to the jaws, and that due to the cross-sectional shape of the shoes and passageways, such support resists forces on the jaws. *See* JX-0145 at 6:26-41. Thus, Intuitive

misinterprets the teachings of Green 695. Moreover, Intuitive does not point to anything in Scirica or Zemlok, let alone Kostrzewski itself, demonstrating that one of ordinary skill in the art would have a reason to modify Kostrzewski to create a closed bottom internal passage.<sup>33, 34</sup> See RX-0003C at Q/As 425-441. The undersigned therefore finds that Intuitive has not met its burden to prove that the proposed combination teaches this claim limitation.

**b) Limitation 22.4**

Intuitive argues that the proposed combination discloses this limitation under Ethicon's theory of infringement, and that the accused SureForm Stapler and the proposed combination contain "nearly identical structures." RIB Appx. D (citing RX-0003C at Q/As 482-483; JX-0144 at Fig. 15). Thus, Intuitive contends that if the undersigned agrees with Ethicon's identification of the proximal channel opening in the SureForm Staplers, then the proposed combination also has the same proximal channel opening. *Id.* (citing RX-0003C at Q/As 482-483; RDX-0003C at 293; Fronczak, Tr. at 535:3-10). Intuitive claims that Zemlok discloses closed bottom cartridge housing 116 (elongate channel), which includes openings in the bottom to facilitate viewing of the firing element when the firing element is in the first position. RIB at 82 (citing JX-0142 at Figs. 4, 6). According to Intuitive, Zemlok confirms that a person of ordinary skill would have been motivated to only cover a portion of the channel because it "teaches the importance of 'provid[ing] the

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<sup>33</sup> Dr. Howe states that "[a] POSITA would have also understood that enclosing the passage would provide more protection from external tissue and other material than that provided by an open passage." RX-0003C at Q/A 441. Given that the evidence shows that Covidien used an elongate channel with an open bottom in its commercial products, the undersigned gives little weight to such a conclusory argument. See CX-3276C at Q/As 187-190, 250-262; Fronczak, Tr. at 541:7-542:4.

<sup>34</sup> In addition, Intuitive relies on the testimony of Ethicon engineer, Kevin Doll, to assert that open bottom channels had known disadvantages. See RIB at 82-83. However, this is unconvincing for several reasons. First, Intuitive did not establish Mr. Doll as one of ordinary skill in the art for purposes of the '369 patent. Second, rather than being definitive, Mr. Doll testified that without running a test, he would not know whether closing off the channel would make it stronger. See RX-1399C at 111:5-112:11.

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surgeon with information concerning one or more of the following: clamp position, overall travel distance, proximal limit, and distal limit.” *Id.* at 84 (quoting JX-0142 at [0012]).

Ethicon argues that Intuitive offered no legitimate reason why a person of ordinary skill would have modified Kostrzewski to include a proximal channel opening meeting the limitations of this claim because Kostrzewski’s instrument already provides visual indication of the I-beam through its path of travel. CIB at 115 (citing CX-3276C at Q/A 270). Ethicon claims that Intuitive’s rationale for why a person of ordinary skill would have left the proximal end of the internal passage in Kostrzewski uncovered was conclusory and “clearly a hindsight reconstruction of claim 22.” *Id.* (citing RX-0003C at Q/A 480; CX-3276C at Q/A 270). In addition, Ethicon contends that Green 695, Zemlok, and Scirica do not disclose or suggest a proximal channel opening that is sized to receive the foot of a firing element. *Id.* at 115-116 (citing CX-3276C at Q/A 271; CDX-0006C at 49-50).

The undersigned finds that Intuitive does not sufficiently demonstrate that one of ordinary skill in the art would have a reason to modify Kostrzewski to achieve the claimed proximal channel opening to facilitate viewing of the firing element. As Dr. Fronczak points out, Kostrzewski’s design already provides for visual indication of the firing element due to the open bottom channel design. *See* CX-3276C at Q/A 270; JX-0144 at Figs. 14, 15. Therefore, the undersigned finds that Intuitive has not met its burden to prove that the proposed combination teaches this claim limitation.

### **c) Conclusion**

The undersigned found that Intuitive has not met its burden to prove that Kostrzewski in view of Green 695, Zemlok, and/or Scirica teaches limitations 22.3 and 22.4. Accordingly, the undersigned finds that Intuitive has failed to establish, by clear and convincing evidence, that claim

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22 of the '369 patent is rendered obvious by Kostrzewski in view of Green 695, Zemlok, and/or Scirica.

### 2. Claim 23

Claim 23 depends from claim 22. Because claim 22 is not rendered obvious by Kostrzewski in view of Green 695, Zemlok, and/or Scirica, then claim 23 is also not rendered obvious by Kostrzewski in view of Green 695, Zemlok, and/or Scirica.

### 3. Secondary Considerations

Intuitive contends that secondary considerations do not support the validity of the '369 patent. RIB at 168-171; RRB at 110-111. Secondary considerations of nonobviousness may rebut a *prima facie* case of obviousness. Here, where Intuitive has not made out a *prima facie* case of obviousness, there is no showing to rebut. Accordingly, the undersigned need not consider any secondary considerations of nonobviousness.

## IX. U.S. PATENT NO. 9,844,379

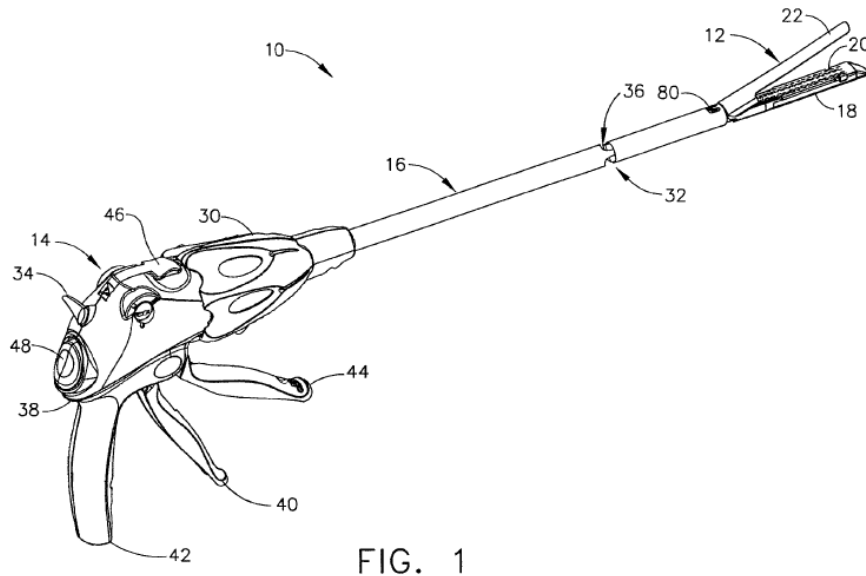
### A. Overview

The '379 patent, entitled “Surgical Stapling Instrument Having a Clearanced Opening,” issued on December 19, 2017 to Frederick E. Shelton, IV, Michael E. Setser, and William B. Weisenburgh II. The '379 patent is assigned on its face to Ethicon Endo-Surgery LLC and was subsequently assigned to Ethicon LLC. JX-0001; *see also* Section III. The '379 patent generally relates to “surgical instruments that are suitable for endoscopically inserting an end effector that is actuated by a longitudinally driven firing member<sup>35</sup>, and more particularly a surgical stapling and

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<sup>35</sup> Ethicon refers to the firing member as an E-beam. Intuitive’s documentation uses the term “I-beam.” Mr. Shelton explained: “An I-beam is a mechanism that generally forms the shape of the letter I. The I-beam advances through the jaws of the instrument to push a sled that ejects staples from the staple cartridge. The upper and lower horizontal portions of the I-beam engage the jaws of the stapler as the I-beam advances, which ensures that the jaws are properly spaced when staples are ejected.” CX-0004C at Q/A 16.

severing instrument that has an articulating shaft.”<sup>36</sup> *Id.* at 1:51-55. Figure 1 of the ’379 patent is reproduced below.



*Id.* at Fig. 1, 3:44-46 (showing a “perspective view of an endoscopic surgical stapling instruments for surgical stapling and severing in an open, unarticulated state.”).

## 1. Asserted Claims

Ethicon is asserting claims 2 and 3, which read as follows:<sup>37</sup>

2. [2.p] A stapling assembly, comprising:
  - [2.1] a frame;
  - [2.2] a distal end;
  - [2.3] a first jaw comprising a channel;
  - [2.4] a channel retainer, wherein said channel is slidably attachable to said channel retainer;
  - [2.5] a second jaw extending from said frame;

<sup>36</sup> In non-technical terms, the ’379 patent is directed to a surgical stapler with a lockout mechanism that blocks advancement of the firing member when a staple cartridge has not been installed in the stapler. 2d Am. Compl at ¶ 28; CX-0004C at Q/A 33; CX-0005C at Q/A 60.

<sup>37</sup> The parties use different numbers to refer to the same claim limitations. The undersigned has adopted a modified version of Intuitive’s numbering system.

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- [2.6] a plurality of staples;
  - [2.7] 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,
    - [2.7.1] wherein said first cam and said second cam are configured to cooperatively hold said first jaw and said second jaw relative to one another when said staple firing member is advanced toward said distal end, and
    - [2.7.2] wherein one of said first jaw and said second jaw comprises a clearanced opening configured to receive one of said first cam and said second cam such that said first jaw is not held to said second jaw when said staple firing member is in said unadvanced position; and
  - [2.8] a lockout configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.
3. [3.p] A stapling assembly, comprising:
- [3.1] a first jaw;
  - [3.2] a second jaw, wherein said first jaw is rotatable relative to said second jaw;
  - [3.3] a detachable cartridge portion comprising a plurality of staples;
  - [3.4] an anvil configured to deform said staples; and
  - [3.5] 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 initial position, and
    - [3.5.1] wherein said first jaw comprises a clearanced opening 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 firing member is in said initial position; and
  - [3.6] a lockout configured to block the advancement of said staple firing member when said detachable cartridge portion is not attached to said stapling assembly.

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### 2. Claim Construction

The undersigned has construed the following terms from claims 2 and 3 as follows:

TERM	CLAIM	CLAIM CONSTRUCTION
“said first jaw is not held to said second jaw”	2	Plain and ordinary meaning <sup>38</sup>
“not engaged with”	3	Plain and ordinary meaning <sup>39</sup>

Order No. 15 at 43-49.

#### B. Infringement

##### 1. Direct Infringement

Ethicon alleges that Intuitive directly infringes claims 2 and 3 of the '379 patent by making and selling the SureForm Staplers and compatible SureForm Reloads to end users. CIB at 38

##### a) Claim 2

Ethicon asserts that the SureForm Staplers and Reloads meet every limitation of claim 2 of the '379 patent. CIB at 39-48. 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 2. RLUL at 1; *see generally* RIB at 17-28.

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<sup>38</sup> Order No. 15 provides additional context, stating: “The specification of the '379 patent confirms the plain meaning of ‘said first jaw is not held to said second jaw’ in claim 2. It explains that when the E-beam staple firing member is advanced, a first jaw is held to a second jaw such that the jaws are affirmatively spaced. . . . The specification then describes that with the E-beam staple firing member retracted, the jaws are no longer held to each other such that the jaws can be opened or closed.” Order No. 15 at 48-49 (citing '379 patent at 7:29-36).

<sup>39</sup> In reaching this construction, the undersigned stated: “The specification explains that when an E-beam is advanced distally from its initial position, 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. . . . The specification further explains that when the E-beam is in a retracted position, the upper pin of the E-beam is unengaged with the anvil such that the firing member does not affirmatively space the jaws and the anvil can move relative to the lower jaw . . . . *Id.* at 45 (citing '379 patent at 3:18-27, 7:29-38).

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### i. Limitation 2.7.2

Claim 2 includes the limitation “wherein one of said first jaw and said second jaw comprises a clearanced opening configured to receive one of said first cam and said second cam such that said first jaw is not held to said second jaw when said staple firing member is in said unadvanced position.” JX-0001, cl. 2.

Ethicon explains that the reload channel of the accused SureForm Staplers includes a clearanced opening that receives the cam on the lower portion of the I-beam when the I-beam is in an unadvanced position. CIB at 42-44; CRB at 7-8. Ethicon contends that the jaws of the SureForm Staplers are able to open and close relative to one another when the I-beam is positioned in the clearanced opening in an unadvanced position. CIB at 42-44. According to Ethicon, the fact that a user can pinch the jaws shut confirms that the reload channel can close relative to the anvil when the I-beam is in an unadvanced position. *Id.* at 45-46. Ethicon asserts that Intuitive’s non-infringement arguments are “untethered from the plain language of the claims and/or were already rejected by the CALJ during claim construction.” CRB at 9-10.

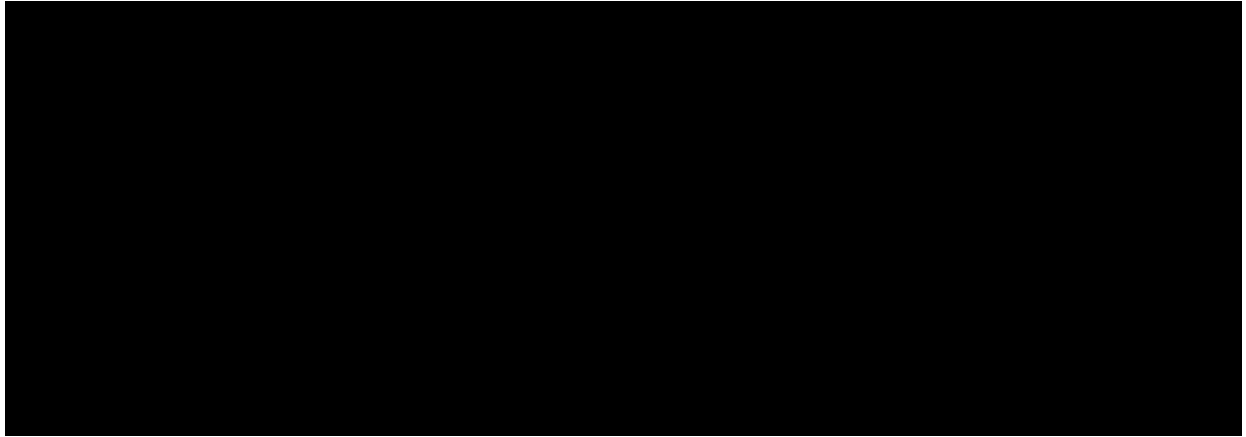
Intuitive insists that the accused SureForm staplers do not contain the claimed “clearanced opening” limitation, and thus, do not infringe the ’379 patent. RIB at 86-90. Intuitive writes: “In the SureForm stapler . . . there is no closure tube, and it is the I-beam that actually opens and closes the jaws.” RRB at 5. Intuitive further contends that “when the I-beam is in its unadvanced/initial position, it affirmatively engages and holds the jaws in the open position; the jaws cannot freely open and close.” *Id.*

The undersigned agrees with Ethicon that the SureForm Staplers include a clearanced opening. Specifically, the evidence shows that the reload channel of the SureForm Staplers has a clearanced opening that receives the cam on the lower portion of the I-beam when the I-beam is in



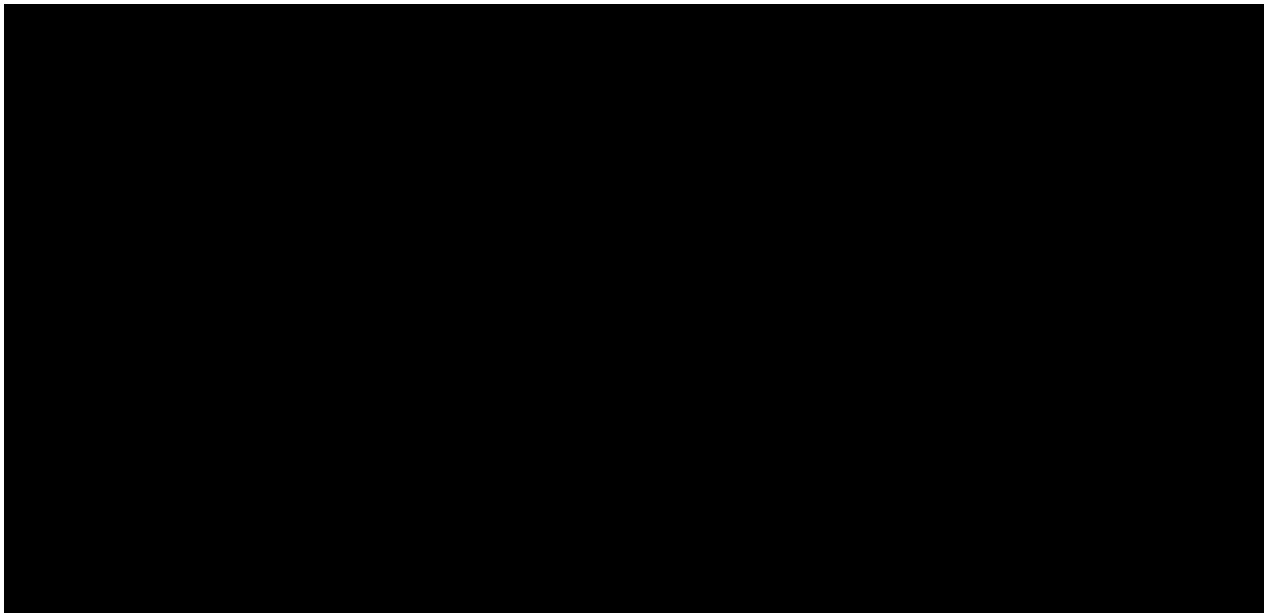
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an unadvanced position. CX-0002C at Q/As 234-235. The cleared opening in the SureForm Staplers is illustrated below:



CDX-0002C.0053 (annotated excerpt of RX-0339C); RX-0339C; *see also* CX-0002C at Q/A 237.

The opening can also be seen in a CT scan of the SureForm 60 Stapler, as set forth below:



CDX-0002C.0054 (annotated CX-0036C); CX-0036C. As the CT scan evidences, when the I-beam is in an unadvanced position, the lower portion of the I-beam (which includes a first cam) is in the opening. CX-0002C at Q/As 238-240; CDX-0002C.0054 (annotating CX-0036C); CX-0036. This opening provides clearance for the jaws to open and close when the I-beam (*i.e.*, firing

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member) is retracted.<sup>40</sup> CX-0002C at Q/As 234-235; CX-0924C (Wixey) at 113:114:10 (

). By contrast, the jaws of the SureForm Stapler cannot be opened when the I-beam is advanced because the I-beam affirmatively spaces the jaw. CX-0002C at Q/A 233; Howe, Tr. at 760:8-19 (agreeing that when the I-beam is in the advanced position, the jaws cannot be opened and closed relative to one another).

CDX-0002C.052 (annotated version of CT scan of a SureForm 60 Stapler); CX-0061C.

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<sup>40</sup> One of Intuitive's noninfringement arguments is that the SureForm Staplers do not infringe because they do not utilize a closure tube to open and close the jaws. RIB at 18-22. While the specification describes an embodiment comprising a "closure tube 78" that opens and closes the jaws, claim 2 does not require a closure tube nor does it specify what mechanism in the stapler causes the jaws to open or close when the firing member is unadvanced. JX-0001, cl. 2. Rather, claim 2 only requires that the "opening" provides clearance so that the jaws can open and close when the firing member is retracted. *Id.*; see also 7:29-38 ("E-beam 102 is retracted with the top pins 110 thereof residing within an anvil pocket 150 . . . Thus, with the E-beam 102 retracted, the surgeon is able to repeatedly open and close the staple applying assembly 12 . . ."). As discussed, the accused SureForm Staplers have this functionality.

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Intuitive contends that the SureForm Staplers do not meet the clearanced opening limitation because the I-beam “holds the jaws of the stapler open when it is in its unadvanced position.”<sup>41, 42</sup> RIB at 23. To the contrary, the evidence establishes that when the I-beam is unadvanced, the first and second jaws are “no longer held to each other” because the jaws can be opened and closed.<sup>43, 44</sup> As Dr. Fronczak explained: “The reload channel can close relative to the anvil when the I-beam is in an unadvanced position when the user pinches the jaws shut with his or her fingers or hands.” CX-0002C at Q/A 236. At the hearing, Dr. Fronczak demonstrated how the jaws of the SureForm Staplers close when minimal force is exerted, such as by pinching. Fronczak, Tr. at 112:13-117:19; *see also* Howe, Tr. at 765:23–766:23 (acknowledging that the I-beam does not prevent the jaws from being closed when it is in an unadvanced position), 837:20-838:3 (closing the jaws by pinching them shut). In fact, the User Manual of the SureForm Staplers directs a user to close the jaws with his/her hands when installing the stapler. *See* RX-0335C.019 (“Always use two hands when installing the stapler; ***one hand holding the jaws closed.*** . . .”) (emphasis added). Dr. Fronczak further testified: “Conversely, the reload channel can open relative to the anvil once

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<sup>41</sup> Intuitive has also argued that the “not held to” language of claim 2 means that the jaws are not held “in a fixed position relative to each other.” RIB at 18. Intuitive made this same argument during claim construction. It was rejected then and is similarly rejected now. *See* Order No. 15 at 46-49 (“Intuitive’s construction merely replaces ‘not held to’ with ‘not kept or sustained in a specified position.’ The undersigned fails to see how this clarifies the meaning of readily understandable claim language.”).

<sup>42</sup> Intuitive has asserted that the claimed “clearanced opening” requires “the stapler’s jaws to ***freely open and close, without interference from the firing member,*** when the firing member is in the unadvanced/initial position.” RIB at 17 (emphasis added). Nothing in the claims, the specification, or the *Markman* order requires that the jaws “freely open and close” or open and close “without interference from the firing member.” *See generally* JX-0001; Order No. 15 at 46-49. As the Federal Circuit has expressly stated: “[U]nless required by the specification, limitations that do not otherwise appear in the claims should not be imported into the claims.” *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1348 (Fed. Cir. 2005); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) (“Where a specification does not require a[n] extraneous limitation, that limitation should not be read from the specification into the claims.”).

<sup>43</sup> The specification discusses how when the E-beam is retracted, the jaws are no longer held to each other such that the jaws can be opened or closed. JX-0001 at 7:29-38; *see also* Order No. 15 at 48-49.

<sup>44</sup> The I-beam may contribute to opening the jaws by contacting the back of the reload channel. That contact alone does not hold the jaws open, however. CX-0002C at Q/As 243, 245. If the I-beam held the jaws open, a user would not be able to pinch the jaws closed. *Id.*; *see also* CX-0924C (Wixey) at 134:2-19 (“Q. Okay. But – but I could pinch it -- pinch the jaws closed with my fingers, right? . . . A. Yes.”); RX-0335C.0019 (directing user to hold jaws closed to install the SureForm Stapler).