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Paper 9
Date: April 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

REX MEDICAL, L.P.,
Patent Owner.

IPR2020-00152
Patent 9,439,650 B2

Before GEORGE R. HOSKINS, MICHAEL L. WOODS, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner, Intuitive Surgical, Inc., filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 4–24 ("the challenged claims") of U.S. Patent No. 9,439,650 B2 (Ex. 1001, "the '650 patent").[1] Pet. 3. Patent Owner, Rex Medical, L.P., timely filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Pursuant to 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a), we have authority to determine whether to institute review.

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that Petitioner has shown a reasonable likelihood it will prevail in establishing the unpatentability of at least one challenged claim. We, therefore, institute *inter partes* review.

A. RELATED MATTERS

The parties identify the following two related cases as pending before the U.S. District Court for the District of Delaware: *Rex Medical, L.P. v. Intuitive Surgical, Inc., Intuitive Surgical Operations, Inc., and Intuitive Surgical Holdings, Inc.*, 1:19-cv-00005-MN (Del.), filed January 2, 2019, and *Rex Medical, L.P. v. Covidien LP*, 1:19-cv-01092-MN (Del.), filed June 13, 2019. Pet. 1–2; Paper 5, 2. Petitioner also identifies pending U.S. Patent Application Nos. 16/185,506 and 16/564,543 as claiming priority to the application from which the '650 patent issued. Pet. 2.

[1] Petitioner identifies itself as the only real party in interest. Pet. 1.

B. THE '650 PATENT

The '650 patent is titled "Apparatus and Method for Resectioning Gastro-Esophageal Tissue" and describes a system for stapling tissue. Ex. 1001, codes (54), (57). To illustrate an embodiment of the '650 patent's stapler, we reproduce its Figure 3, below:

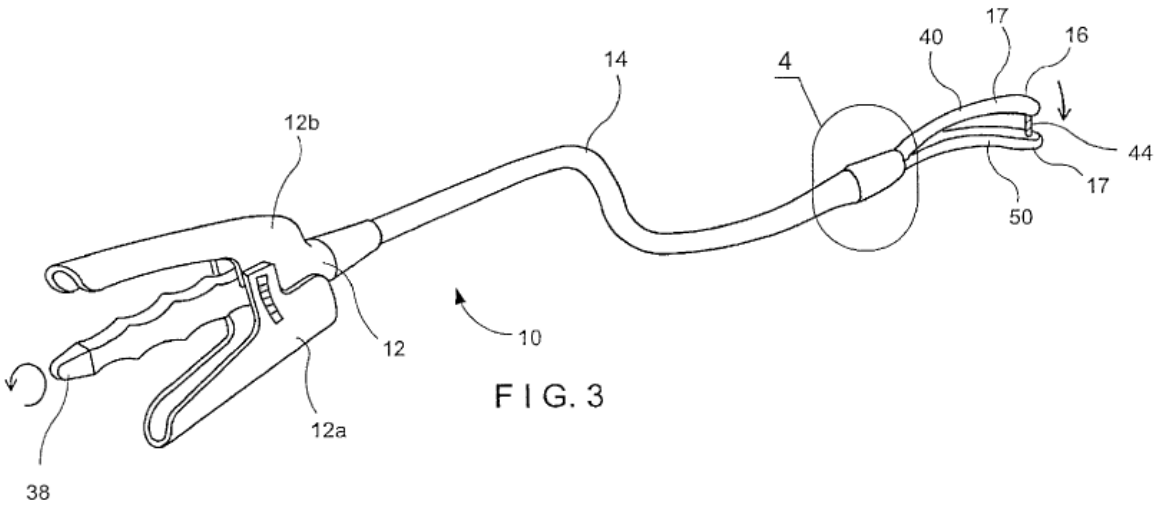


FIG. 3

Figure 3 depicts a perspective view of an illustrative embodiment of the '650 patent's stapling system. Ex. 1001, 2:7–10, 2:19–20. In particular, Figure 3 depicts stapling apparatus 10 with proximal handle portion 12, elongated flexible body portion 14 that extends from handle portion 12, and C-shaped stapling assembly 16 at the distal end of flexible body portion 14. *Id.* at 3:55–59. Apparatus 10 also includes actuation cable 44 and actuation knob 38 that, together, operate jaws 17. *Id.* at 4:61–63. The '650 patent further describes that in at least one embodiment, an I-beam member is used for bringing jaws 17 together. *See id.* at 2:57–59. We further reproduce Figure 14, below:

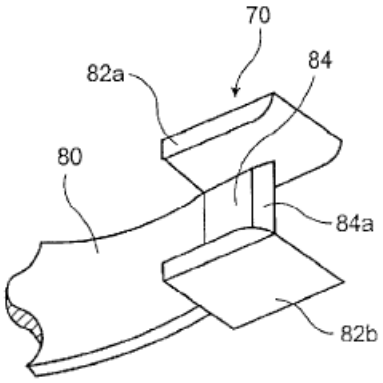


FIG. 14

Figure 14 depicts I-beam member 70 with upper beam portion 82a and lower beam portion 82b, connected via central web portion 84. *Id.* at 5:45–47. As shown, leading edge 84a of central web portion 84 may include a cutting blade for incising tissue as I-beam member 70 moves distally. *Id.* at 5:47–50. To illustrate the location of I-beam member 70 within the distal portion of the stapler, we reproduce Figure 15, below:

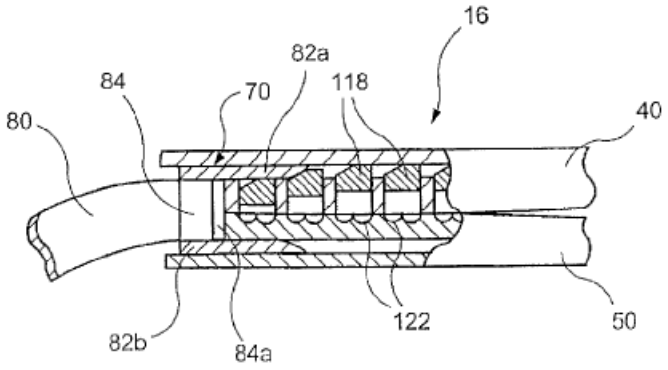


FIG. 15

Figure 15 depicts the jaws as closed by operation of actuation cable 44. *Id.* at 5:36–50, Fig. 3. Once the jaws are closed, I-beam 70 is moved distally along the jaws, during which upper portion 82a of the I-beam rides in a channel in the upper jaw and lower portion 82b of the I-beam rides in a channel of the lower jaw. *Id.* I-beam 70 is driven by pusher 80, and when the I-beam is driven distally, a sloped leading edge of upper portion 82a

(shown above) contacts, sequentially, each of a plurality of staple pushers 118, driving the staples through their respective staple slots out of staple carrying portion 40. *Id.* at 6:26–40.

C. CHALLENGED CLAIMS

Challenged claims 4 and 13 are independent. Ex. 1001, 8:4–10:9. We reproduce these claims, below, and add brackets with numbers that correspond to Petitioner's reference numbers of the claimed limitations (*see, e.g.*, Pet. 19–29):

> 4. **[4.0]** An apparatus for stapling tissue, comprising:
> **[4.1]** a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling,
> **[4.2]** a staple carrying portion of the first jaw defining slots through which staples are configured to pass;
> **[4.3]** an anvil surface defined on the second jaw opposing the first jaw;
> **[4.4]** at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment; and
> **[4.5]** a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion, **[4.6]** the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location.

Id. at 8:4–33 (bolded and bracketed portions added).

13. **[13.0]** An apparatus, comprising:

[13.1] a head portion having a first jaw and a second jaw configured to move between a first configuration for receiving tissue and a second configuration for stapling tissue,

[13.1.1] the first jaw defining a cavity configured to receive a plurality of staples and a plurality of slots configured to pass staples therethrough;

[13.1.2] the second jaw having a staple-forming surface; and

[13.2] a beam whose opposite end portions are connected by a central web portion and are configured to clamp and align the first and second jaws from therewithin when in the second configuration as the beam moves distally along a channel defined in a tissue contacting surface of each of the first and second jaws; and

[13.3] a control handle configured to actuate receiving, clamping and stapling of tissue, and

[13.4] a shaft coupling the control handle to the head portion.

Id. at 8:63–9:14 (bolded and bracketed portions added).

The other challenged claims depend, directly or indirectly, from claim 4 or 13. *See id.* at 8:34–10:9.

D. Prior Art and Asserted Grounds

Petitioner asserts the following ground of unpatentability:

Ground	Claims Challenged	35 U.S.C. §	References/Basis
1A	4, 5, 9–18, 20, 22–24	103	Green 209[2], Green 695[3], Knodel 895[4]
1B	4, 5, 9–18, 20, 22–24	103	Green 695, Green 209, Knodel 895
2	4–8, 10–24	103	Rothfuss[5], Green 209, Knodel 895
3	4–24	103	McGuckin[6], Green 695

Pet. 3. Petitioner also relies on the Declaration testimony of Dr. Bryan Knodel (Ex. 1003). *See id.* Patent Owner submits the competing testimony of Dr. Michael Dolgin (Ex. 2001). *See, e.g.*, Prelim. Resp. 19.

II. ANALYSIS

A. Principles of Law

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Petitioner's challenges are based on obviousness. Pet. 3.

[2] US 5,645,209 (issued July 8, 1997) (Ex. 1004).
[3] US 4,429,695 (issued Feb. 7, 1984) (Ex. 1005).
[4] US 5,465,895 (issued Nov. 14, 1995) (Ex. 1006).
[5] US 4,605,001 (issued Aug. 12, 1986) (Ex. 1007).
[6] US 5,868,760 (issued Feb. 9, 1999) (Ex. 1012).

A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

B. SAS

The Supreme Court has held that a final written decision in an *inter partes* review must decide the patentability of all claims challenged in the corresponding petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018). The USPTO has also provided guidance on implementing *SAS*. *See Guidance on the Impact of SAS on AIA Trial Proceedings* (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial ("*SAS* Guidance") ("As required by [*SAS*] decision, the PTAB will institute as to all claims or none," and "[a]t this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition."); PTAB Consolidated Trial Practice Guide (Nov. 2019) ("Consolidated Guide"), 5–6.

C. Level of Ordinary Skill in the Art

Neither party defines the level of ordinary skill in the art. *See, generally*, Pet.; *see also, generally*, Prelim. Resp. At this time, there is no need to precisely define a level of ordinary skill in the art, and for purposes of this Decision, we consider Petitioner's expert—Dr. Bryan Knodel (Ex. 1003)—and Patent Owner's expert—Dr. Michael Dolgin (Ex. 2001)—as being persons of ordinary skill in the art ("POSITA").

D. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), specifically, that set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

The Petition was filed November 19, 2019. Thus, we apply the claim construction standard as set forth in *Phillips.*

As set forth in *Phillips*, claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Id.* at 1312–1317. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term.

Petitioner submits that no claim requires express construction, and submits that the challenged claims should be given their plain and ordinary

meaning. *See* Pet. 9. Patent Owner also submits that no claim construction is necessary. Prelim. Resp. 1.

We determine that the only limitation that requires construction is 4.4. *See supra* Part I.C.

1. 4.4 "at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment"

As discussed above, Petitioner and Patent Owner each submit that no claim term requires express construction for purposes of this Decision. Pet. 9; Prelim. Resp. 1. Rather, Petitioner proposes that "the challenged claims should be given their plain and ordinary meaning." Pet. 9.

Under Ground 3, however, Petitioner asserts that "McGuckin discloses this limitation *under Patent Owner's apparent construction*." Pet. 74 (emphasis added). Yet, Patent Owner does not expressly construe the claims (*see* Prelim. Resp. 1), and Petitioner's position presumes that Patent Owner will adopt the same construction that Patent Owner proposed in a related district court litigation. *See, e.g.*, Pet. 74 (citing Ex. 1003 ¶¶ 163–67). In point of fact, Petitioner's expert testifies:

> Patent Owner argues in a related litigation that this limitation is broad enough to cover a gear and a cable operatively coupled to the first jaw and the second jaw through a series of intermediary structures that ultimately move the first jaw and the second jaw from the first configuration to the second configuration. If so, McGuckin discloses this limitation under Patent Owner's apparent construction.

Ex. 1003 ¶ 163.

From the record, as best as we can discern, we understand Petitioner's position to be that the plain and ordinary meaning of the claim *may* include

intermediary structures between the gear (or cable) and jaws—as disclosed by McGuckin (Ground 3). So that we may properly analyze Petitioner's challenge under Ground 3, we must expressly construe the meaning of the claimed limitation.

At this stage of the proceeding, and under the plain and ordinary meaning of the claim, we find nothing in the record that precludes intermediary structures from operatively coupling the "at least one of a gear and cable" to "one of the first jaw and second jaw." *Phillips*, 415 F.3d at 1312–1317. In other words, the claim *may* include structure in which the gear and/or the cable is operatively coupled to the first jaw and/or the second jaw *through a series of intermediary structures* that ultimately move the first jaw and the second jaw from the first configuration to the second configuration.

If our understanding of Petitioner's claim construction position is in error, and Petitioner disagrees with our interpretation, Petitioner must clarify its claim construction for Ground 3 in its reply brief. Indeed, our Rules require as much. *See* 37 C.F.R. § 42.104(b)(3) ("the *petition must set forth* . . . a statement of the precise relief requested for each claim challenged . . . [including *h*]*ow the challenged claim is to be construed*" (emphases added)).

2. Other Claim Terms

There are no other terms that require express construction for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

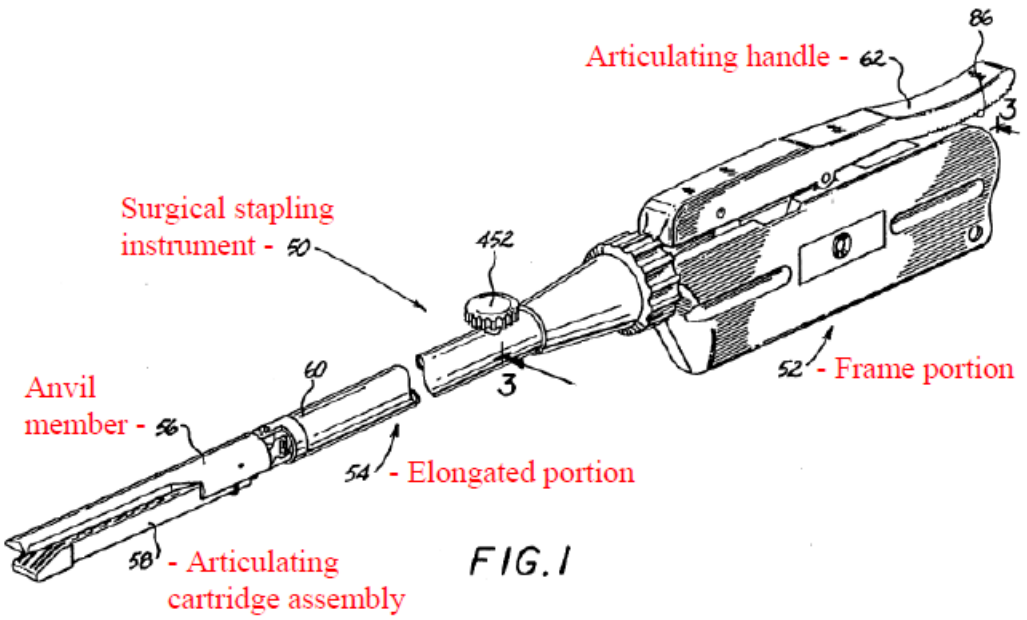
E. GROUND 1A: GREEN 209, GREEN 695, KNODEL

Petitioner submits that claims 4, 5, 9–18, 20, and 22–24 are unpatentable over *Green 209 in view of* Green 695 and Knodel. Pet. 9. Petitioner alternatively contends that these same claims are unpatentable over *Green 695 in view of* Green 209 and Knodel. *Id.* We address Petitioner's first challenge under this heading, "Ground 1A," and address Petitioner's second, alternative challenge under the heading "Ground 1B." *See supra* Part I.D.

Petitioner relies on Green 209 for disclosing the majority of the claimed limitations. *See* Pet. 10–44.

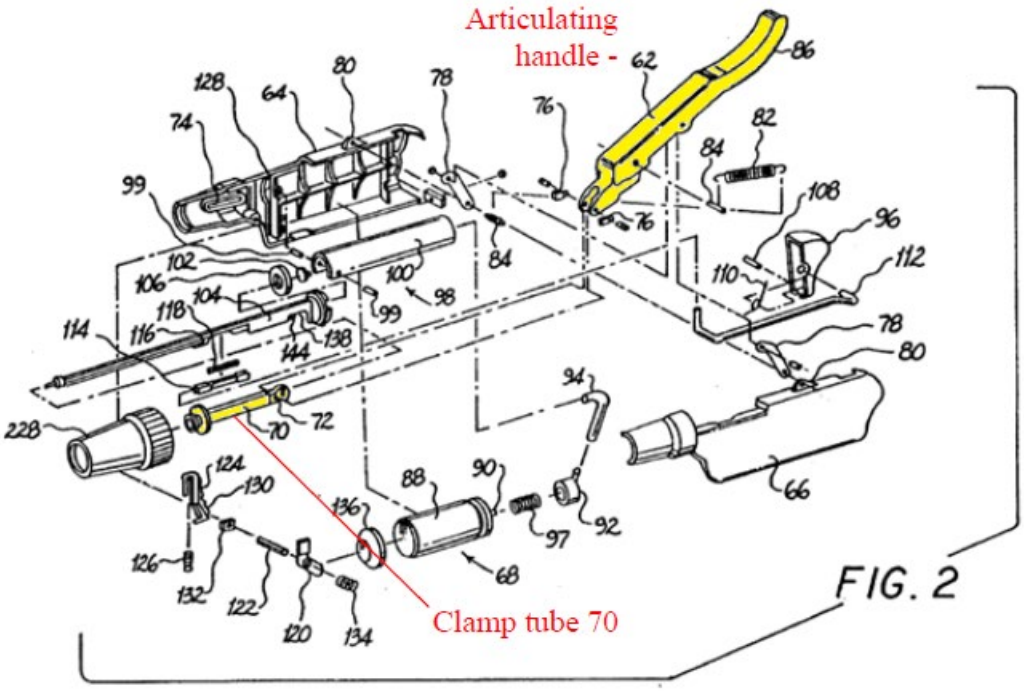
1. Green 209

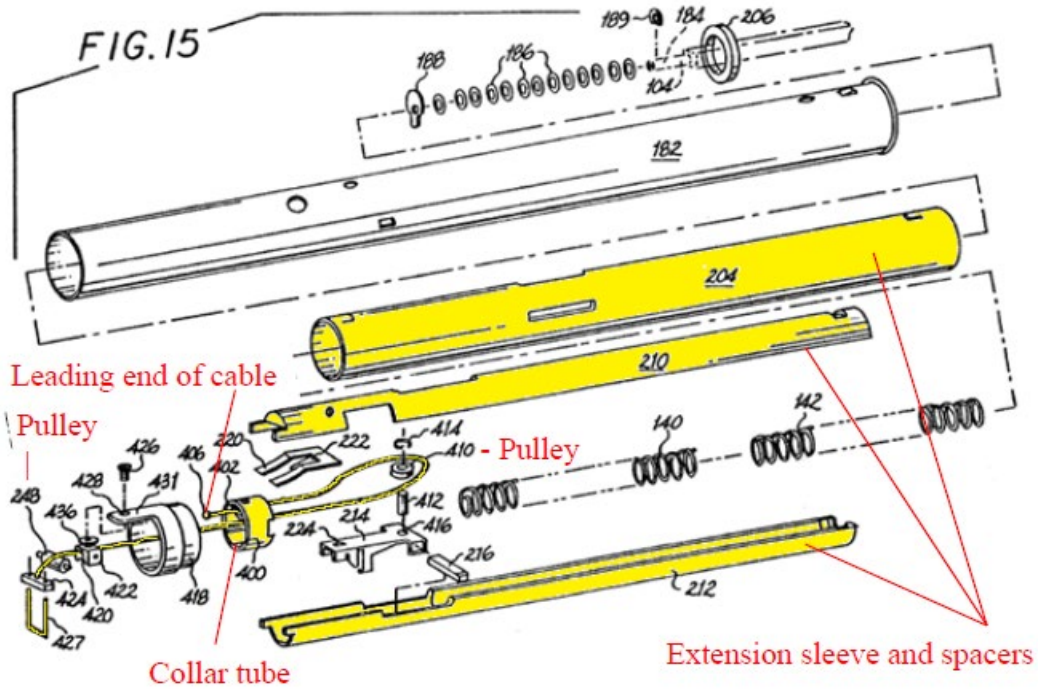
Petitioner submits that Green 209 discloses an apparatus for stapling tissue, providing an annotated version of Green 209's Figure 1 (Pet. 10), which we reproduce, below:



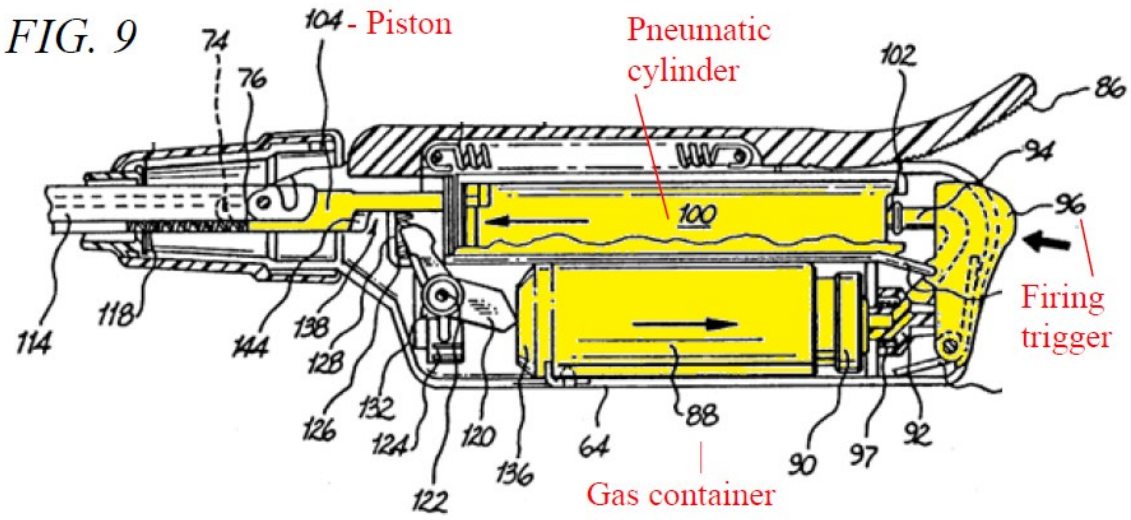
According to Petitioner, and as shown in Figure 1, Green 209 discloses surgical stapling instrument 50 with frame portion 52, elongated portion 54,

anvil member 56, articulating cartridge assembly 58, and articulating handle 62. Pet. 10 (citing Ex. 1004, 11:21–35). Petitioner further provides annotated versions of Green 209's Figures 2 and 15 (Pet. 11), both of which we also reproduce, below:

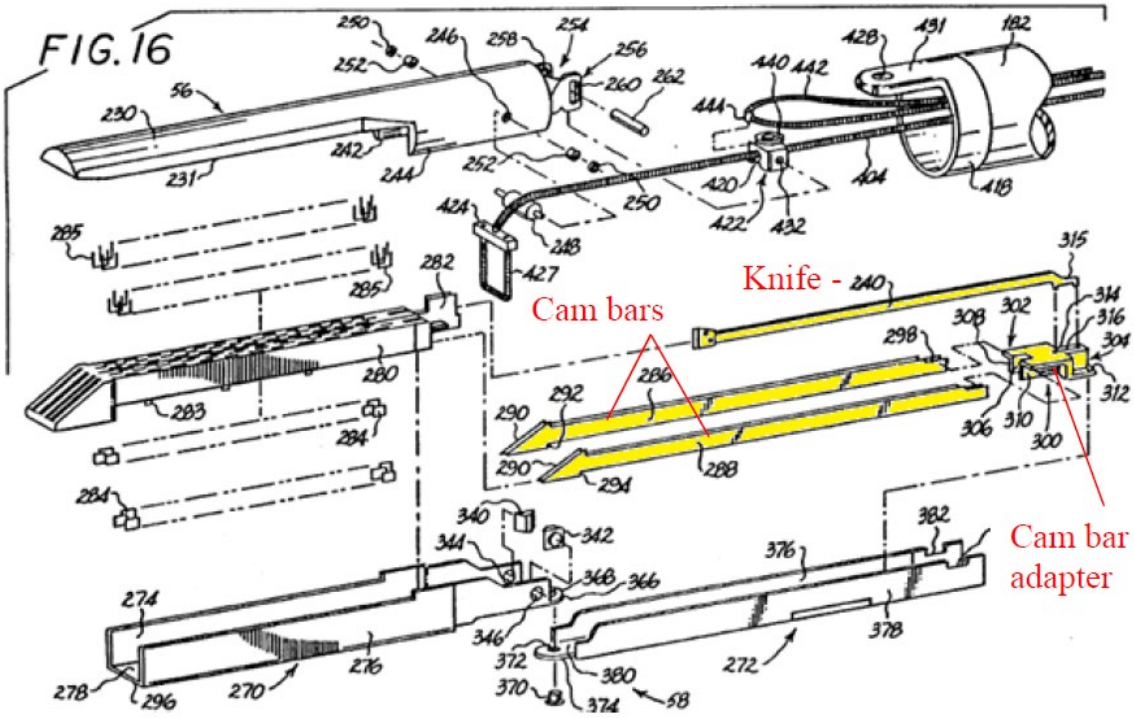




According to Petitioner, and as shown in Figures 2 and 15, the surgeon presses down upon articulating handle member 62 to close the jaws. Pet. 12 (citing Ex. 1004, 19:50–20:2). When the tissue is clamped within the jaws, the instrument can be fired to staple and cut tissue. *Id.* (citing Ex. 1004, 12:40–42). Petitioner also submits an annotated version of Green 209's Figure 9 (Pet. 13), which we also reproduce, below:



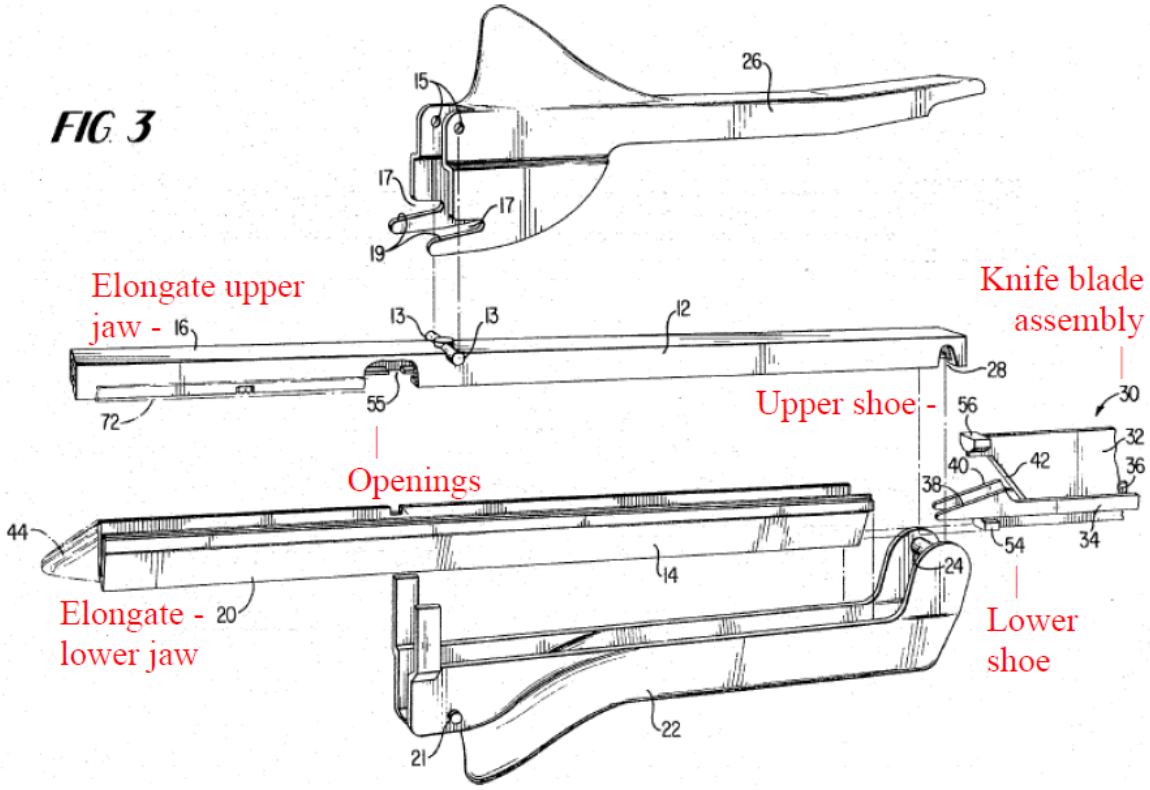
According to Petitioner, and as illustrated in Figure 9, Green 209's instrument also includes firing trigger 96. Pet. 12 (citing Ex. 1004, 12:40–42). After the tissue is clamped between the jaws, depressing firing trigger 96 dispenses a gas to propel a surgical knife in the distal direction via piston. *See id.* (citations omitted). Petitioner also submits an annotated version of Green 209's Figure 16 (Pet. 14), which we reproduce below:



According to Petitioner, and as shown in Figure 16, knife 240 cuts tissue upon depression of firing trigger 96. Pet. 12 (citations omitted). Petitioner acknowledges that knife 240 "is not an I-beam." *Id.* at 14.

2. Green 695

Petitioner submits that Green 695 utilizes an I-beam (knife blade assembly 30) to maintain distance and alignment between jaws of a stapler. Pet. 14 (citations omitted). Petitioner submits an annotated version of Green 695's Figure 3 (*id.* at 15), which we reproduce, below:



According to Petitioner, and as shown in Figure 3, Green 695's knife blade assembly 30 includes upper shoe 56 and lower shoe 54 that fit within passageways to ensure vertical spacing is maintained when upper and lower frame members (12 and 14) are held. *See* Pet. 14–15 (citations omitted). Petitioner also submits an annotated version of Green 695's Figure 6 (*id.* at 16), which we reproduce, below:

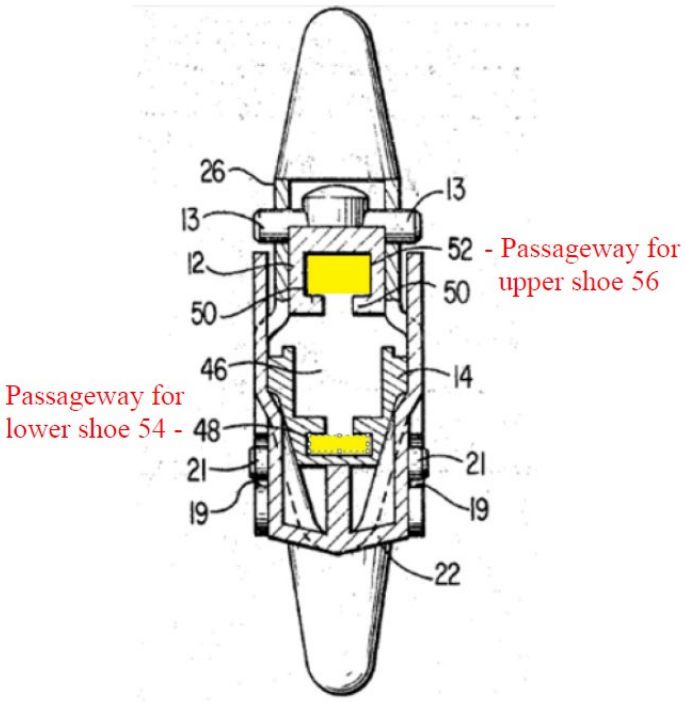
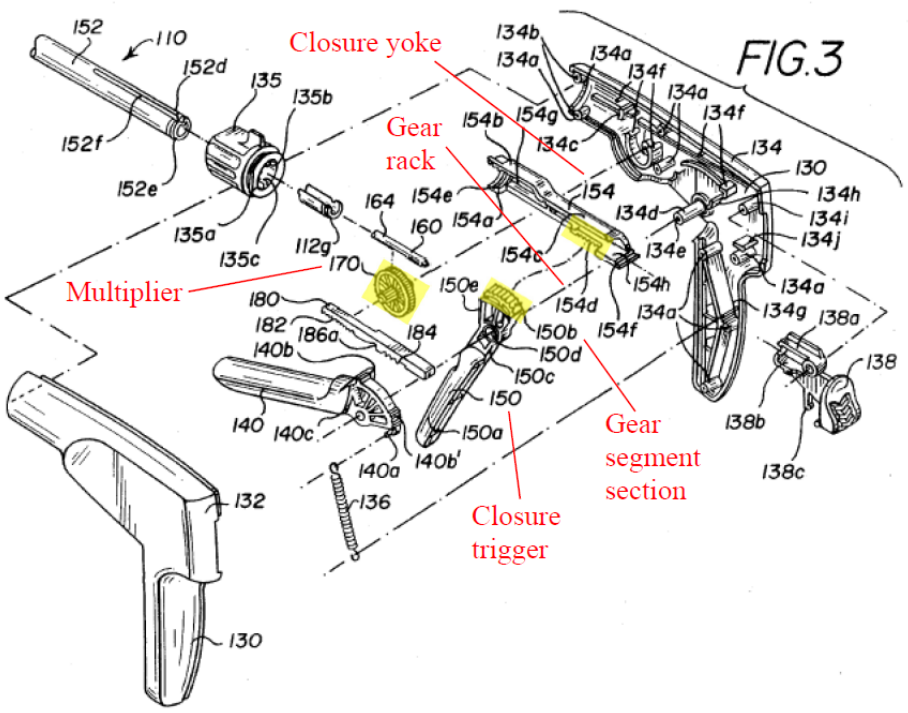


FIG. 6

According to Petitioner, Figure 6 depicts Green 695's upper passageway 52 and lower passageway 48, which receive upper shoe 56 and lower shoe 54, respectively. *See* Pet. 15 (citing Ex. 1005, 4:37–60).

3. Knodel 895

Petitioner relies on Knodel 895 for disclosing a closing trigger with gear system. *See* Pet. 26 (citations omitted). Petitioner submits an annotated version of Knodel 895's Figure 3 (Pet. 27), which we reproduce, below:



According to Petitioner, Knodel 895 discloses closure trigger 150 with gear segment section 150b in meshing engagement with gear track 154d. Pet. 26 (citations omitted). Knodel 895 further discloses firing multiplier 170 comprises first and second integral pinion gears 170a, 170b. *Id.*

4. *Independent Claim 4*

For ease of reference, we map the limitations of claim 4 as Petitioner has done in its Petition. *See* Pet. 19–29; *see also supra* Part I.C.

a. *"[4.0] An apparatus for stapling tissue, comprising:"*

Petitioner submits that Green 209 discloses an apparatus for stapling tissue, submitting an annotated version of Green 209's Figure 1. Pet. 19 (citing in part Ex. 1005, Fig. 1). We reproduce Green 209's Figure 1, as annotated by Petitioner (*id.* at 20), below:

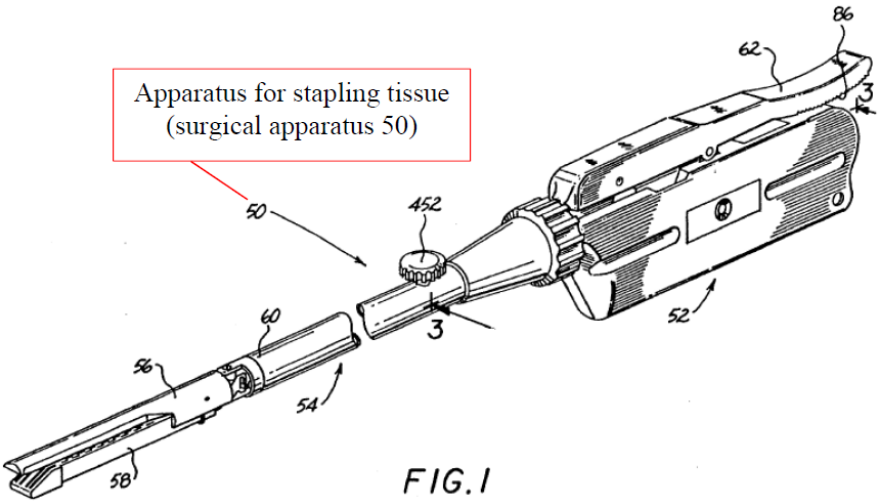


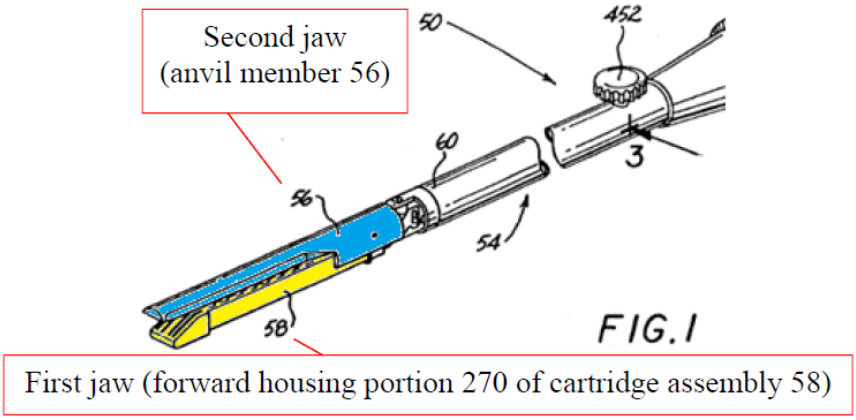
FIG. 1

According to Petitioner, and as shown in Figure 1, Green 209's surgical apparatus 50 is an apparatus for stapling tissue. *Id.* at 19.

Without addressing whether the preamble is limiting, based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses an apparatus for stapling tissue.

b. "[4.1] a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling"

Petitioner submits that Green 209 discloses this limitation, providing another annotated version of Green 209's Figure 1. Pet. 20–21 (citations omitted). We reproduce Petitioner's annotated Figure 1, below:

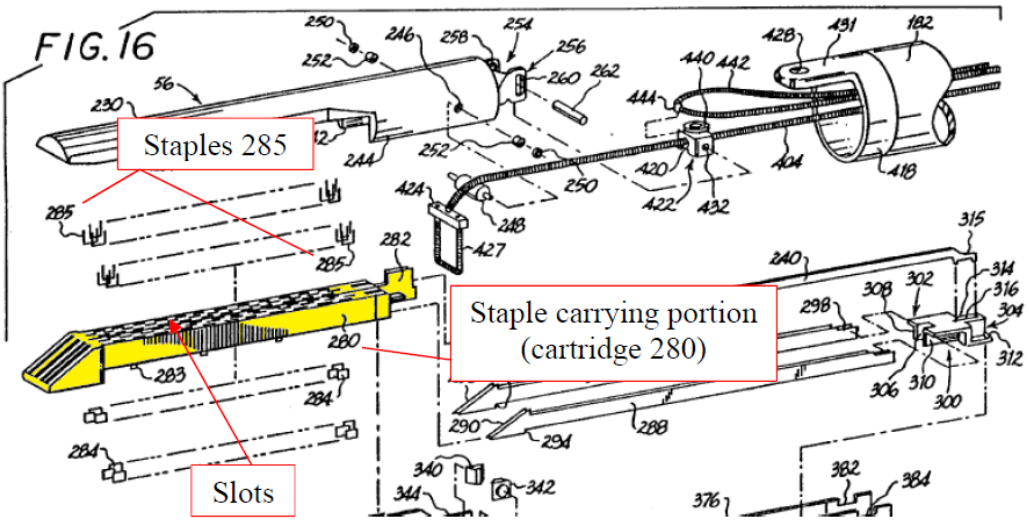


According to Petitioner, Figure 1 of Green 209 depicts first jaw (shown in yellow) and second jaw (shown in blue) that are moveable with respect to each other from a first/open configuration (shown in Green 209's Figure 29) to receive tissue to a second/closed configuration (shown above) to hold tissue for stapling. Pet. 21 (citing in part Ex. 1003 ¶ 65).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses this limitation.

c. *"[4.2] a staple carrying portion of the first jaw defining slots through which staples are configured to pass"*

Petitioner submits that Green 209 discloses this limitation, submitting an annotated version of Green 209's Figure 16. Pet. 22 (citations omitted). Below, we reproduce Petitioner's annotated Figure 16:



According to Petitioner, and as illustrated in Figure 16, Green 209 discloses stapling carrying portion (cartridge 280) of first jaw defining slots (shown in Green 209's Figures 16, 18) through which staples 285 pass. *Id.* (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses this limitation.

d. "[4.3] an anvil surface defined on the second jaw opposing the first jaw"

Petitioner submits that Green 209 discloses this limitation, submitting annotated versions of Green 209's Figures 17 and 30. Pet. 22–23 (citations omitted). We reproduce annotated Figures 17 and 30, below:

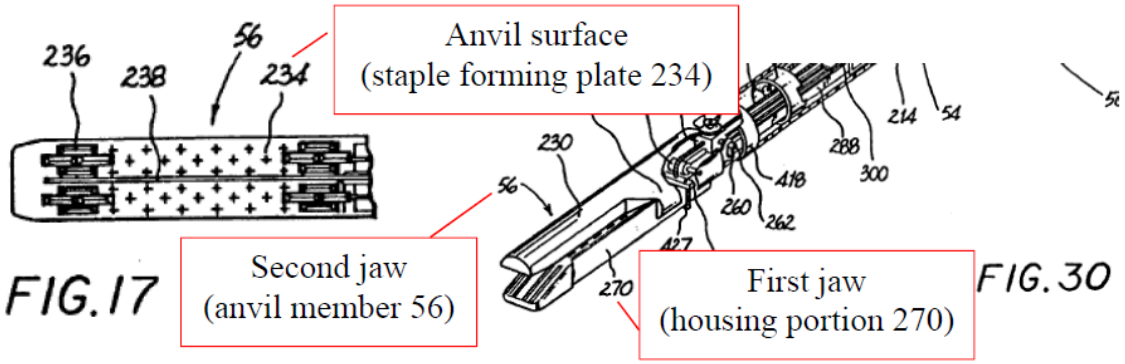


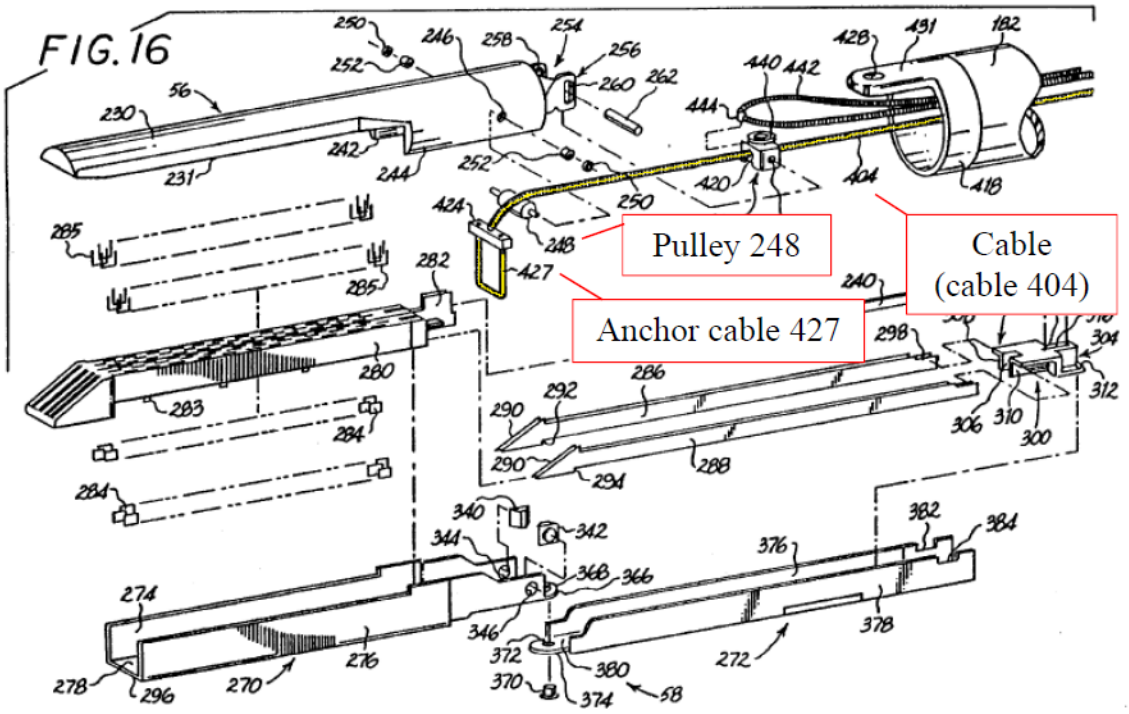
FIG. 17 FIG. 30

According to Petitioner, and as shown in Figures 17 and 30, Green 209 discloses an anvil surface (staple forming plate 234) defined on the second jaw (anvil member 56) and in opposition to the first jaw (housing portion 270). *See* Pet. 23 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses this limitation.

e. "[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment"

Petitioner relies on Green 209, when modified based on Knodel 895's teachings, for satisfying this limitation. *See* Pet. 23, 26. Petitioner submits an annotated version of Green 209's Figure 16 to support its assertions (Pet. 24), a copy of which we reproduce, below:



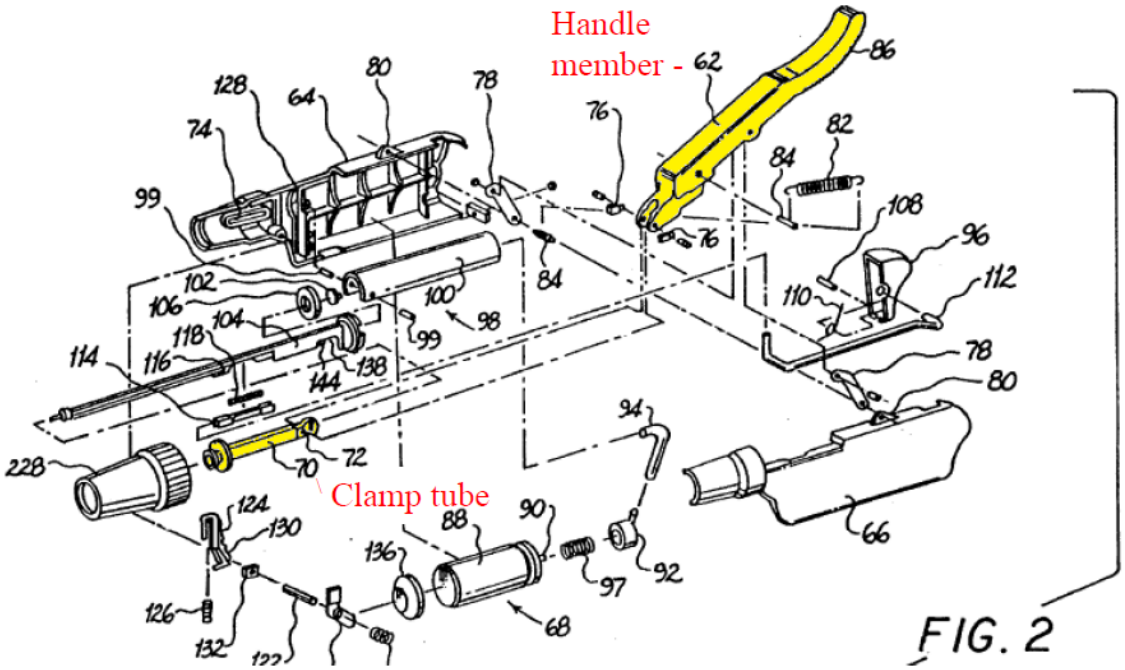
According to Petitioner, and as shown in the above annotated Figure 16, Green 209 discloses a cable (cable 404) that is:

(1) operatively coupled to the first jaw by anchor cable 427;

(2) operatively coupled to the second jaw by pulley 248; and

(3) configured to move at least one of the first jaw and the second jaw (anvil member 56) from the first/open configuration to the second/closed configuration such that the first and second jaws are aligned in the closed position to allow for stapling.

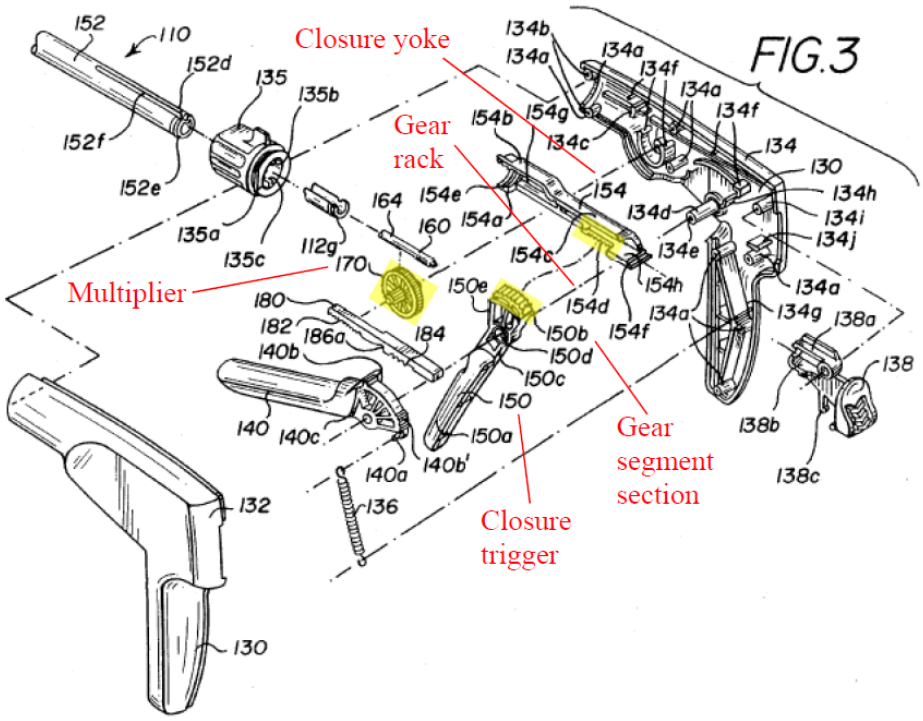
Pet. 23 (citing Ex. 1004, 18:1–41, Figs. 15, 16). Petitioner also submits an annotated version of Green 209's Figure 2 (*id.* at 25), which we reproduce, below:



As shown above in Figure 2, Petitioner asserts that Green 209's jaws are closed by pressing down on articulating handle member 62, driving clamp tube 80 distally. *Id.* at 24 (citations omitted). Petitioner acknowledges that Figure 2 depicts a "palm grip configuration" instead of a "pistol grip configuration." *Id.* at 26.

Petitioner cites to Green 209's disclosure that its "handle portion . . . may have a palm grip configuration or a pistol grip configuration depending on the needs of the surgeon." Pet. 25 (quoting Ex. 1004, 5:53–56, Fig. 90). Petitioner reasons that it would have been obvious to use a pistol grip configuration instead of a palm grip configuration to address the "needs of the surgeon" and to provide the surgeon with "increased range of operability." Pet. 26 (citing in part Ex. 1003 ¶ 71; Ex. 1004, 5:53–56, 36:14–35).

As to Knodel 895's teachings, Petitioner submits an annotated version of Knodel 895's Figure 3 (*id.* at 27), which we reproduce, below:



According to Petitioner, Figure 3 depicts Knodel 895's closure trigger 150 with gear segment section 150b in meshing engagement with gear track 154d. Pet. 26 (citations omitted). Petitioner further submits that Knodel 895 discloses firing multiplier 170 with first and second pinion gears 170a, 170b. *Id.*

In combining Green 209 with Knodel 895, Petitioner reasons that a skilled artisan would have modified Green 209 to use Knodel 895's gears to increase design flexibility. Pet. 27 (citing Ex. 1003 ¶ 27; Ex. 1006, 11:16–25).

In its Preliminary Response, Patent Owner contends that "there is no discussion whatsoever in the Petition regarding *why* it would have been obvious or why there would have been a reasonable expectation of success in combining Green-209 with Knodel-895 **and Green-695**." Prelim. Resp. 13 (citing Pet. 23–28). Patent Owner explains that "[t]here are no arguments addressing the *entire three-reference combination*" to meet this limitation.

Id. (emphasis added). Patent Owner further contends that "Petitioner's reasonable expectation of success arguments [for meeting this limitation] . . . are insufficient to show that the combination of Green-209 and Knodel-895 would have had a reasonable expectation of success." *Id.* (citing Pet. 28).

Patent Owner's arguments are unavailing for the following reasons.

First, Petitioner does not rely on Green 695 for satisfying this limitation, so Patent Owner's argument that Green 695 is not addressed (Prelim. Resp. 13) is not responsive to the proposed combination. *See, e.g.*, Pet. 23 ("Green-209 in view of Knodel-895 discloses this limitation.").

Second, and contrary to Patent Owner's assertion, Petitioner has articulated persuasive reasoning with rational underpinnings to support the legal conclusion that its proffered combination of Green 209's stapler with Knodel 895's gear system would have been obvious to one of ordinary skill in the art. *See KSR*, 550 U.S. at 418.

Dr. Knodel testifies that "increasing the drive system's mechanical advantage would, for example, permit a given input force to produce a larger output force, which may be advantageous for clamping certain tissues with a surgical stapler." Ex. 1003 ¶ 74. In support of this testimony, Knodel 895 discloses,

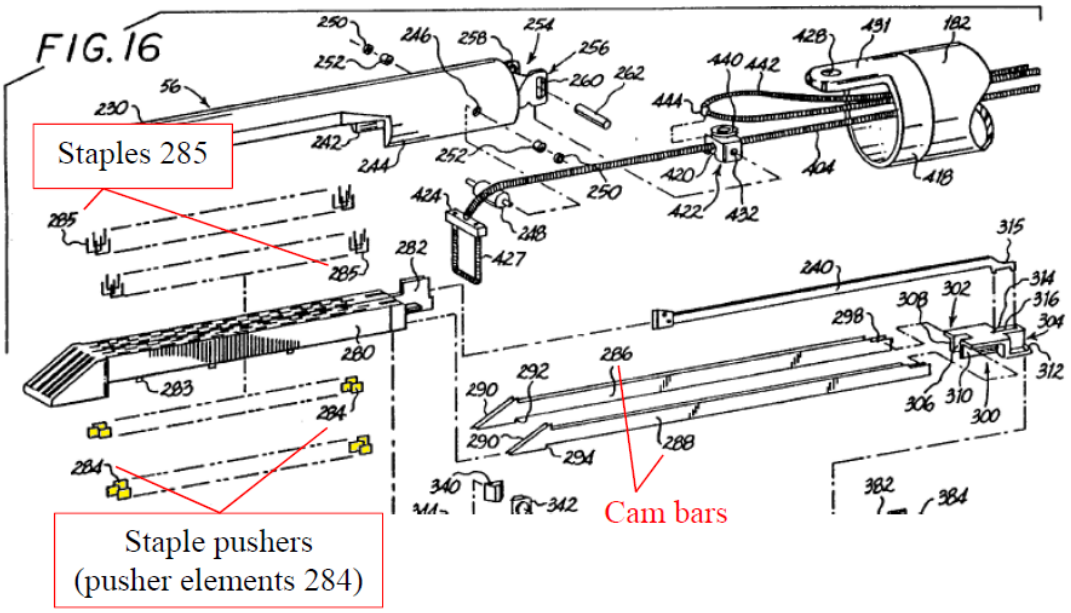
> Because the size of each of the pinion gears **170a** and **170b** may be varied, the motion transfer mechanism **220** of the present invention is easily modifiable for use in stapler instruments having different staple line lengths and/or staple firing force requirements so as to permit, for a given instrument, the length of the stroke of the firing trigger and the force required to move it to be set at ergonomically preferred values.

Ex. 1006, 11:16–25; *see also* Ex. 1003 ¶ 74 (quoting the same).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209, as modified based on Knodel 895's teachings, would have satisfied this limitation.

f. "[4.5] a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion"

Petitioner submits that Green 209 discloses this limitation, submitting an annotated version of Green 209's Figure 16. Pet. 28–29 (citations omitted). Below, we reproduce the annotated version of Figure 16:

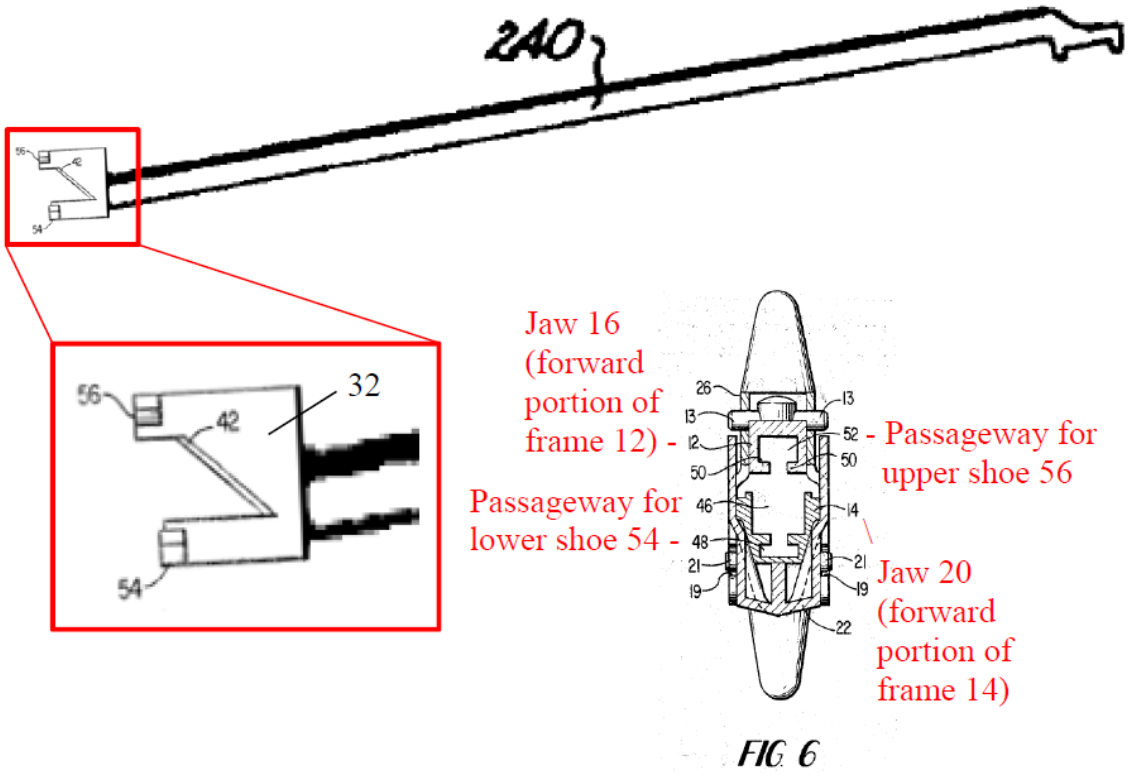


According to Petitioner, and as shown in Figure 16, Green 209 discloses staple pusher (pusher elements 284) configured to cause staple (285) to move from a first position (in which staples 285 are within cartridge 280) to a second, ejected position. Pet. 28 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses this limitation.

g. "[4.6] the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location"

Petitioner relies on Green 209, as modified based on Green 695's teachings, for satisfying this limitation. *See* Pet. 29–30. In particular, Petitioner proposes to modify Green 209's knife 240 to include: (1) an I-beam like that disclosed in Green 695; and (2) Green 695's knife blade carrier 32, lower shoe 54, and upper shoe 56, configured to engage the first and second jaws from within when the jaws are in the second/closed position. *Id.* at 29–30 (citations omitted). Petitioner submits an image to illustrate the resultant structure (*id.* at 30), which we reproduce, below:



As shown in the above figures, Green 209's modified knife 240 includes knife blade carrier 32 with upper shoe 56 and lower shoe 54. Upper shoe 56 fits within passageway 52 of jaw 16, and lower shoe 54 fits within passageway 48 of opposing jaw 20 when jaws 16, 20 are closed.

In modifying Green 209, as shown above, Petitioner reasons that a skilled artisan would have made the modification "to provide . . . optimum alignment and stabilization of the jaws . . . during application and securing of the fasteners" and to "enable the use of lightweight disposable materials for manufacture of the jaws." Pet. 17 (citations omitted).

Dr. Knodel testifies that "a POSITA reading both Green 209 and Green 695 would have been motivated to improve the alignment and clamping capability of Green 209 by using the I-beam disclosed in Green 695." Ex. 1003 ¶ 51.

At this stage of the proceeding, we find Petitioner's reasoning persuasive.

Green 695 discloses:

> By utilizing the aforementioned shoes [on an I-beam] locally to support the jaws and provide both lateral and vertical stabilization in the region of the pusher bar cams and knife blade as these elements ride along the jaws, the adverse effects of the previously mentioned forces are substantially minimized and the jaws themselves can therefore be made of light-weight construction so that an instrument designed in accordance with the invention lends itself to manufacture in disposable materials.

Ex. 1005, 2:48–56.

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209, as modified based on Green 695's I-

beam with upper and lower shoe teachings, would have satisfied this limitation.

h. Summary of Claim 4

Based on the present record, we determine that Petitioner has shown a reasonable likelihood that Green 209, in view of Green 695 and Knodel 895, would have rendered claim 4 unpatentable.

5. Independent Claim 13

Petitioner relies on Green 209, as modified by the teachings of Green 695, for satisfying the limitations of claim 13. *See* Pet. 36–40.

a. Missing Knodel 895

Patent Owner argues that "there are no arguments for Knodel-895 in the Petition for independent claim 13 and its dependent claims 14–18, 20, and 22–24." Prelim. Resp. 14 (emphasis omitted) (citing Pet. 9–19, 39–40). Based on this deficiency, Patent Owner argues that we should deny institution as the Petition fails to identify the specific statutory ground or prior art patents or printed publications relied on under 37 C.F.R. § 42.104(b)(2). *Id.*

We agree with Patent Owner that the Petition does not rely on Knodel 895 for satisfying the limitations of independent claim 13 or any of its challenged dependent claims (claims 14, 18, 20, and 22–24), despite the fact that the heading of the challenge includes Knodel 895. *See* Pet. 3, 36–45. Nevertheless, we do not find the apparent inadvertent addition of Knodel 895 to the challenge of claims 13, 14, 18, 20, and 22–24 as warranting denial

of institution. We find that such a harsh result would not serve the interests of justice.

b. Limitations 13.0, 13.1, 13.1.1, 13.1.2, 13.2

In addressing the limitations that correspond to 13.0, 13.1, 13.1.1, 13.1.2, and 13.2 (*see supra* Part I.C (claim 13)), Petitioner cites to its analysis in addressing similar limitations recited in claim 4. *See* Pet. 36–37.

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 in view of Green 695's teachings would have satisfied these limitations. We address the remaining limitations, below.

c. "[13.3] a control handle configured to actuate receiving, clamping and stapling of tissue, and"

Petitioner submits that Green 209's control handle is configured to actuate receiving, clamping, and stapling of tissue. Pet. 39 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses this limitation.

d. "[13.4] a shaft coupling the control handle to the head portion"

Petitioner submits that Green 209 discloses a shaft (54 or 1044) coupling the control handle to the head portion. Pet. 39–40 (citing Green 209, 11:20–25).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209 discloses this limitation.

e. Summary of Claim 13

Based on the present record, we determine that Petitioner has shown a reasonable likelihood that Green 209, in view of Green 695, would have rendered claim 13 unpatentable.

6. Dependent Claims 5, 9, 10–12, 14–18, 20, 22–24

Petitioner submits that the additional limitations of dependent claims 5, 9–12, 14–18, 20, and 22–24 are satisfied by Green 209, as modified in view of Green 695 and Knodel 895. Pet. 30–36, 41–45. Patent Owner does not specifically address these claims in its Preliminary Response. *See, generally*, Prelim. Resp.

Based on the present record, we determine that Petitioner has shown a reasonable likelihood that Green 209, as modified based on the teachings of Green 695 and Knodel 895, satisfies these additional claim limitations.

7. Summary of Ground 1A

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Green 209, in view of Green 695 and Knodel 895, would have rendered claims 4, 5, 9–18, 20, and 22–24 unpatentable.

Pursuant to *SAS* and the *SAS* Guidance, based on our determination that it is more likely than not that claims 4, 5, 9–18, 20, and 22–24 are unpatentable under Ground 1A, we institute a trial as to all claims and all challenges raised in the Petition.

We also address limited aspects of Petitioner's other grounds of unpatentability based on the present preliminary record, to help guide the parties' efforts during trial. *See* Consolidated Guide, 5–6.

F. GROUND 1B: GREEN 695, GREEN 209, KNODEL 895

1. Petitioner's Challenge

Petitioner's challenge under Ground 1B is similar to Petitioner's challenge under Ground 1A in that both challenges rely on the same three references—Green 209, Green 695, and Knodel 895. *See* Pet. 9. As distinguished from Ground 1A, in which Petitioner proposes to modify Green 209 in view of Green 695 and Knodel 895, Petitioner proposes to modify Green 695's "surgical stapler for use in minimally invasive surgery to create essentially the same device." *Id.*

Petitioner submits that "Green-695's instrument 10 does not include an elongated shaft and therefore could not be used for minimally invasive surgery ('MIS')." *Id.* at 17. Petitioner further submits that Green 695's instrument does not include a power source (separate from the hand-actuated mechanism) for firing the stapling mechanism. *Id.* at 17–18. Based on these perceived shortcomings, Petitioner submits that a skilled artisan would have modified Green 695's instrument to be used for MIS "to produce essentially the same device as discussed in the first combination." *Id.* at 18 (citing Ex. 1003 ¶ 55). In explaining how this structure would look, Petitioner explains, "Green-695's handles 22, 26 are replaced with Green-209's frame 52 and elongated shaft portion 54 . . . [and] Green-695's jaws 16, 20 are opened and closed using the linkage and cable assembly controlled by Green-209's handle 62." *Id.* Petitioner further explains that "Green's 695's [sic] pusher bar and knife assembly 30 are driven by Green 209's pneumatic system." *Id.*

Petitioner reasons that a skilled artisan would have modified Green 695 in such a manner "because the benefits of MIS compared to open surgery (e.g., faster recovery times, less pain, etc.) were well known." *Id.* (citations omitted). As for the modification involving the addition of Green 209's pneumatic system, Petitioner reasons that a skilled artisan would have modified Green 695 to include such a feature "to facilitate fastening and/or cutting tissue." *Id.* (citations omitted).

2. Analysis

Patent Owner contends that by presenting Ground 1B along with Ground 1A, Petitioner conflates and confuses the issues, and makes Petitioner's arguments difficult to follow. Prelim. Resp. 5. Patent Owner submits that "it is not clear how Green-695 is a primary reference at all" as Petitioner fails to "describe the teachings of Green-695 as a primary reference with respect to any claim element." *Id.*

We agree with Patent Owner's assessment that the Petition fails to clearly set forth its challenge under Ground 1B. Although Petitioner submits a detailed claim chart to address the limitations of the challenged claims under Ground 1A (*see* Pet. 19–45), this claim chart fails to support Petitioner's alternative challenge under Ground 1B. Indeed, other than its brief summary on pages 9 and 17–18 of the Petition, Petitioner fails to specify (under Ground 1B) where each element of the challenged claims are found in the prior art. *See* 37 C.F.R. § 42.104(b)(4) ("The petition must specify where each element of the claim is found in the prior art patents or printed publications relied upon.").

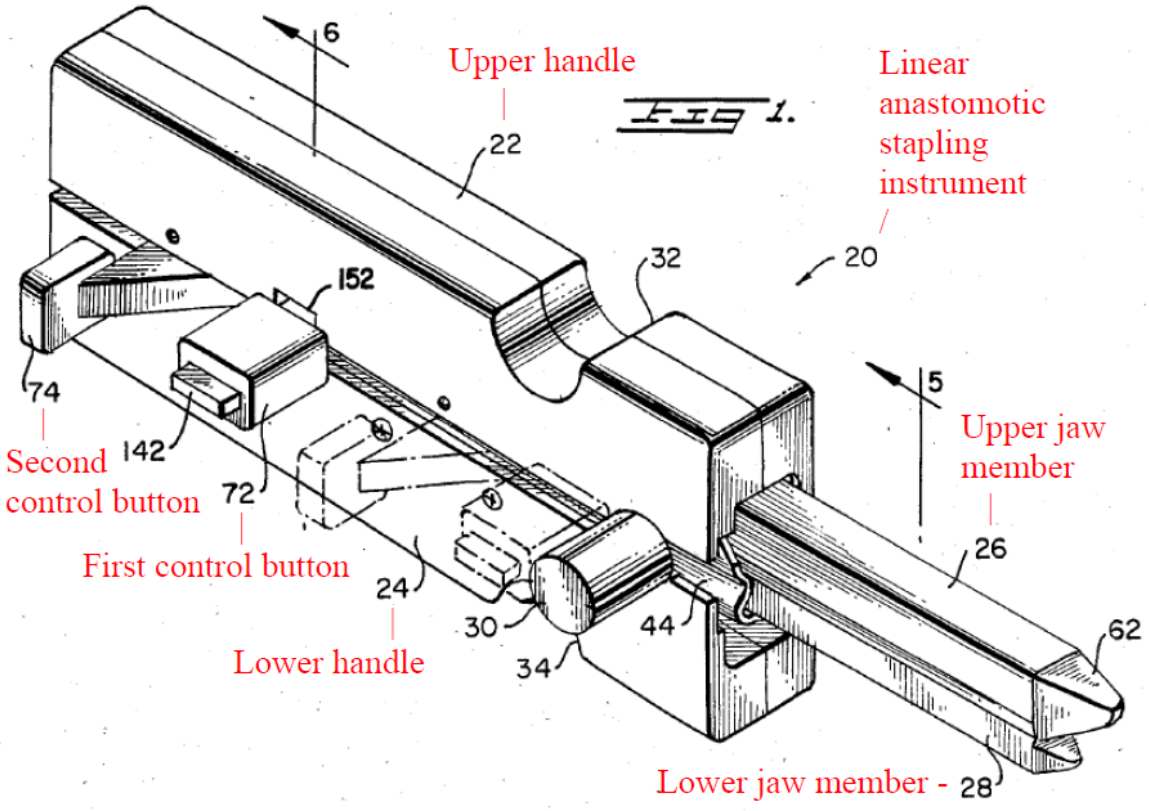
Nevertheless, and pursuant to *SAS* and the *SAS* Guidance, we institute review of claims 4, 5, 9–18, 20, and 22–24 under Ground 1B.

G. GROUND 2: ROTHFUSS, GREEN 209, KNODEL

Petitioner contends that claims 4–8 and 10–24 are unpatentable as obvious over Rothfuss in view of Green 209 and Knodel 895. Pet. 45.

1. Rothfuss

Petitioner submits that Rothfuss discloses a stapling instrument, producing an annotated version of Rothfuss's Figure 1 (Pet. 45), which we reproduce, below:



According to Petitioner, annotated Figure 1 depicts linear anastomotic stapling instrument 20, which includes upper and lower handles 22, 24, upper and lower jaw members 26, 28, and first and second control buttons 72, 74. Pet. 45 (citations omitted).

Petitioner explains that two operations are performed in sequence to complete stapling. *Id.* at 46. First, and "[a]fter the tissue is clamped, first

control button 72 is actuated to advance actuator assembly 70 [shown below in Figure 9] longitudinally along jaw members 26 and 28 into staple cartridge 60 . . . and anvil 80." *Id.* (quoting Ex. 1007, 12:37–40). Next, when "actuator assembly 70 [is] advanced into staple cartridge 60 and anvil 80, its elongated I-beam structure provides support and alignment along the entire operating length of jaw members 26 and 28." *Id.* (quoting Ex. 1007, 12:66–13:2).

Petitioner also submits an annotated version of Rothfuss's Figure 9, which depicts Rothfuss's actuator assembly 70 (Pet. 47), below:

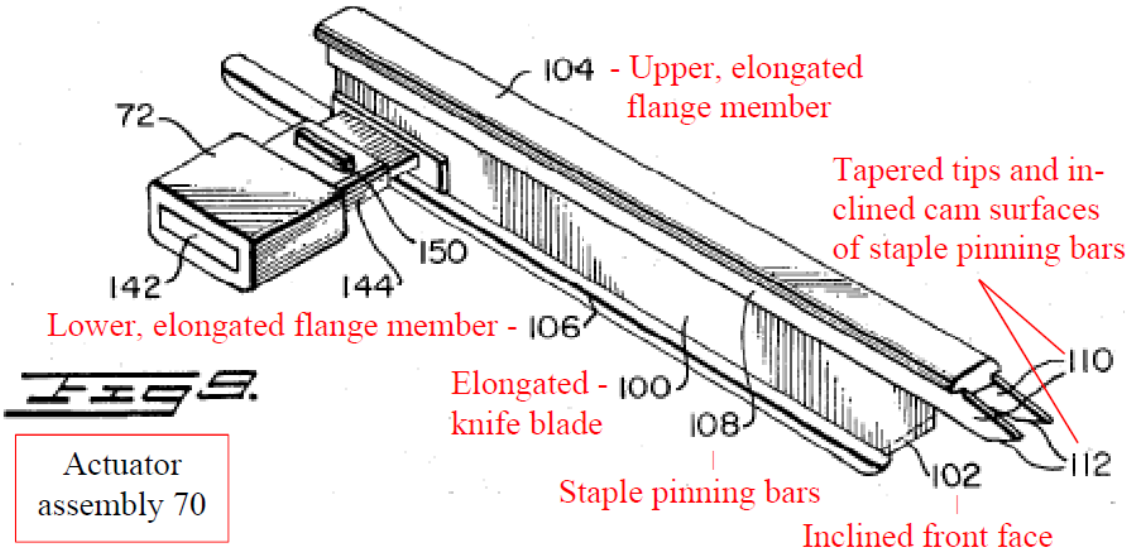
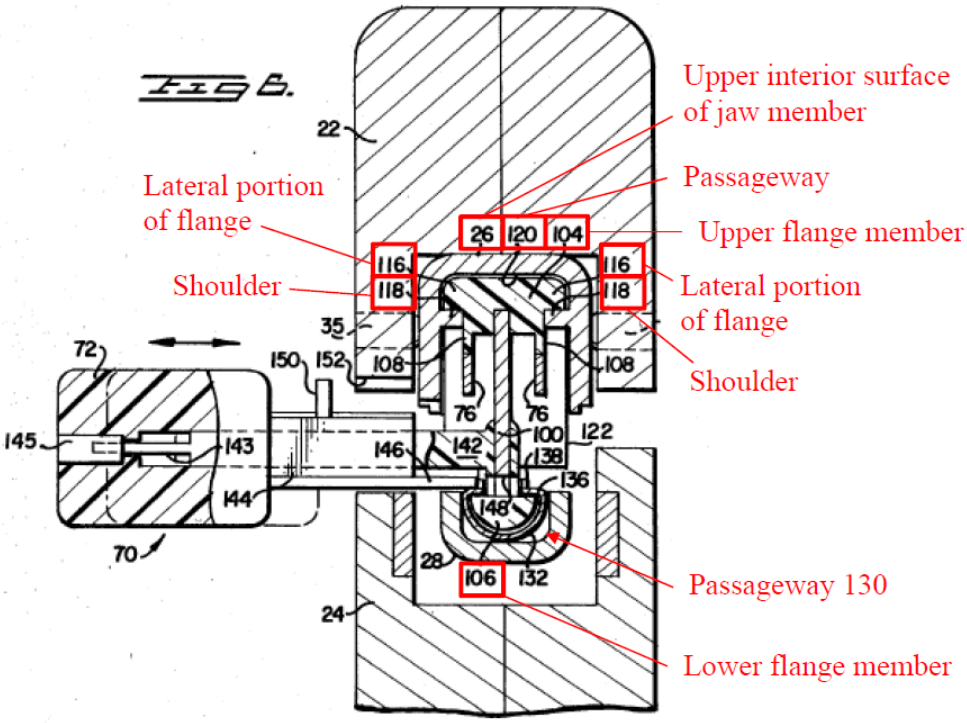


Fig 9.

According to Petitioner, Rothfuss's actuator assembly 70 includes an I-beam with knife blade 100 "having an inclined front face 102 which is beveled to provide a sharp cutting edge." Pet. 47 (quoting Ex. 1007, 8:38–45). Rothfuss further discloses that "upper, elongated flange member 104 extends along the top of knife blade 100 and a lower, elongated flange member 106 extends along the bottom of the knife blade to complete the I-beam structure." *Id.* Rothfuss explains that upper I-beam flange member 104 is provided with staple pinning bars 108, which each include forwarding

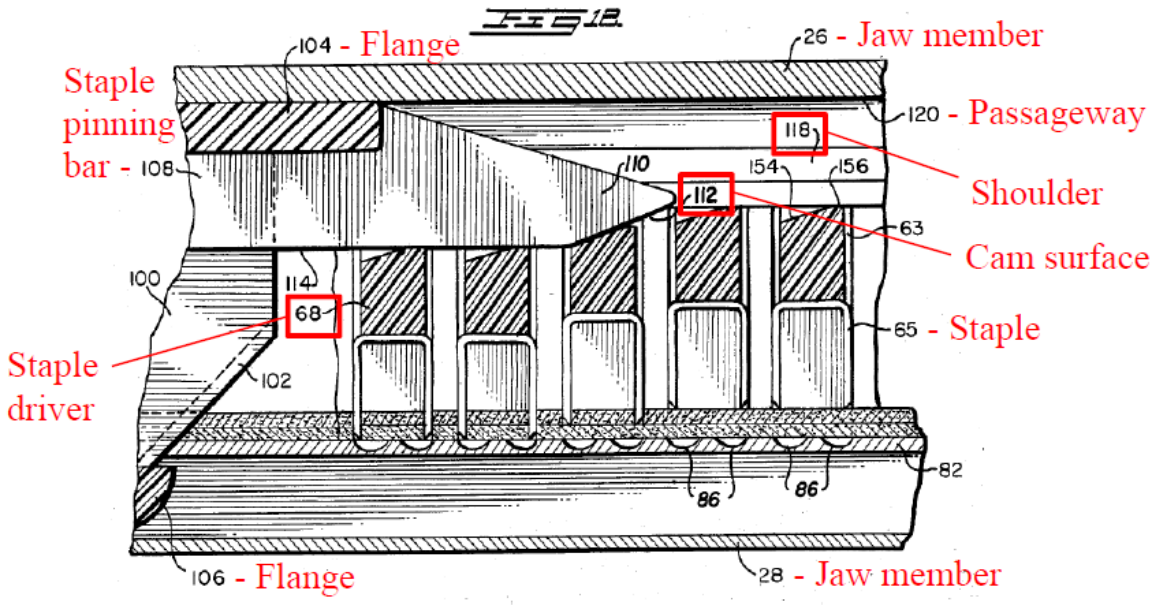
projecting tapered tip 110 and an inclined cam surface 112. *Id.* (citing Ex. 1007, 8:45–56).

Petitioner also submits an annotated version of Rothfuss's Figure 6 (*id.* at 48), which we also reproduce, below:

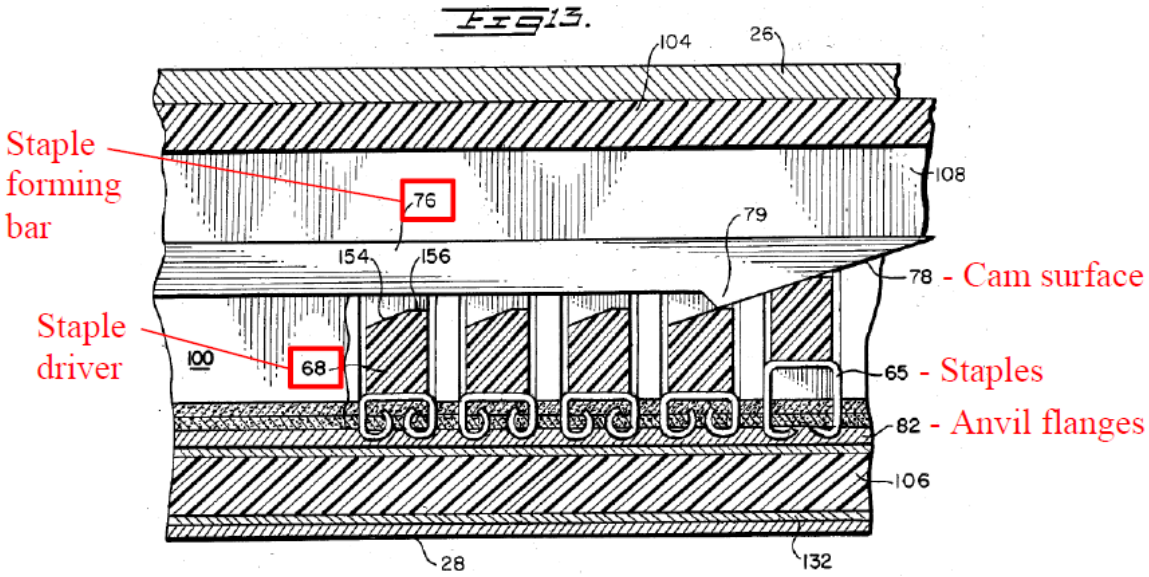


According to Petitioner, and as shown above, upper jaw member 26 includes pair of shoulders 118, which along with upper interior surface of jaw member 26, define passageway 120 in which upper flange 104 is slidably mounted for longitudinal movement relative to the jaw member. Pet. 47 (citing Ex. 1007, 8:62–9:3). As with the upper jaw member, lower jaw member 28 (along with anvil flanges 82) define passageway 130 for slidably receiving lower I-beam flange 106. Pet. 48 (citing Ex. 1007, 9:37–40).

In describing the operation of Rothfuss's stapling, Petitioner submits an annotated version of Rothfuss's Figure 12 (Pet. 49), which we reproduce, below:



According to Petitioner, and as shown above, as actuator assembly 70 is advanced, upper I-beam flange 104 slides into passageway 120, and cam surfaces 112 sequentially engages staple drivers 68. Pet. 48 (citing Ex. 1007, 13:7–28). "As a result, staple drivers 68 are sequentially pushed downward to partially drive each staple 65." *Id.* (quoting Ex. 1007, 13:7–28). Next, second control button 74—of staple pusher bar mechanism 75, shown in Figure 11—is actuated to advance staple forming bars 76 longitudinally into staple cartridge. *Id.* at 50 (citing Ex. 1007, 13:28–30, Fig. 11). Petitioner also submits an annotated version of Rothfuss's Figure 13 to illustrate the ejection of staples by bars 76 (*id.* at 51), which we reproduce, below:

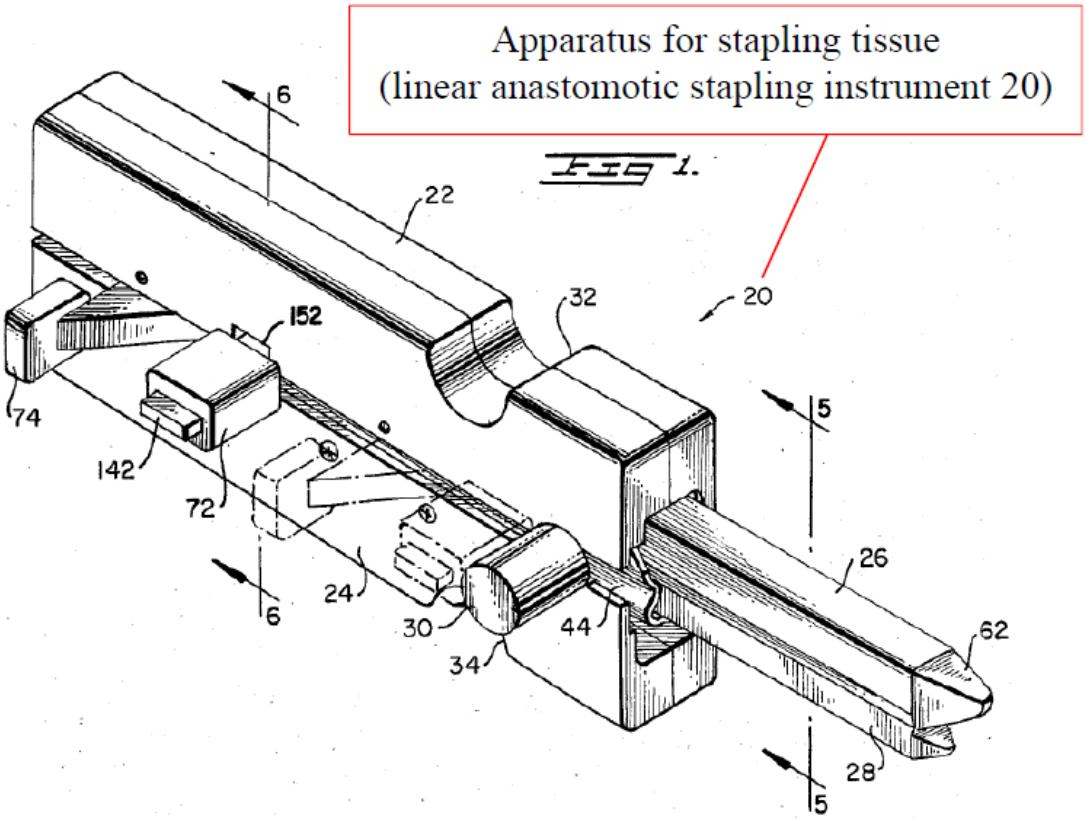


As shown above, cam surfaces 78 of staple forming bars 76 push staple drivers 68 downward to complete ejection of staples 65 from the cartridge and into anvil flanges 82, forming the staples into a B-shaped configuration. Ex. 1007, 13:29–38.

2. *Independent Claim 4*

a. *"[4.0] An apparatus for stapling tissue, comprising:"*

Petitioner submits that Rothfuss discloses an apparatus for stapling tissue, submitting an annotated version of Rothfuss's Figure 1 (Pet. 51), which we reproduce, below:



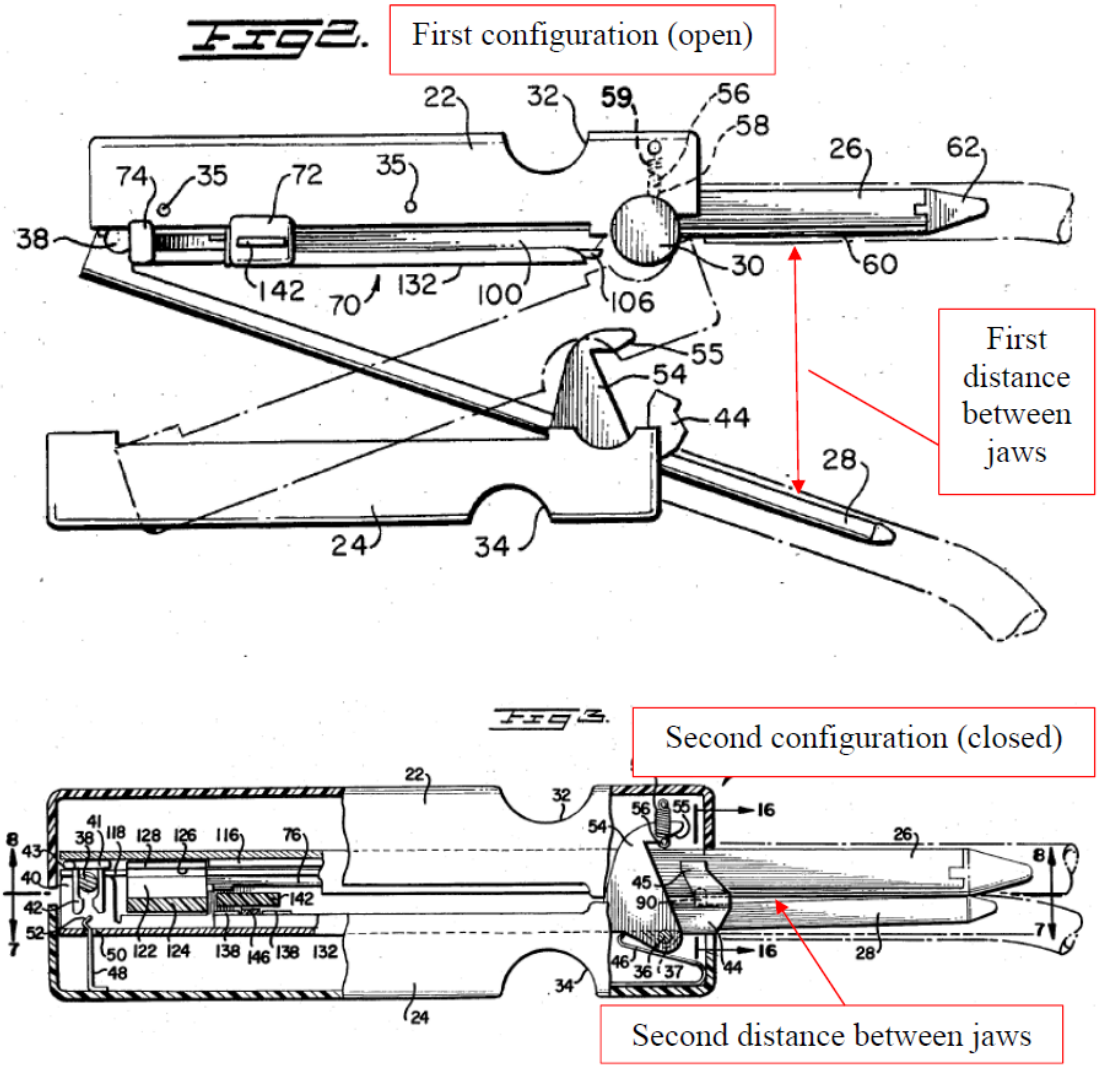
According to Petitioner, and as shown above, Rothfuss's linear anastomotic stapling instrument 20 satisfies the claimed "apparatus for stapling tissue." *Id.* (citing Ex. 1007, 6:8–14).

Without addressing whether the preamble is limiting, based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Rothfuss discloses an apparatus for stapling tissue.

b. "[4.1] a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a

second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling"

Petitioner submits that Rothfuss discloses this limitation, submitting annotated versions of Rothfuss's Figures 2 and 3 (Pet. 53), which we reproduce, below:



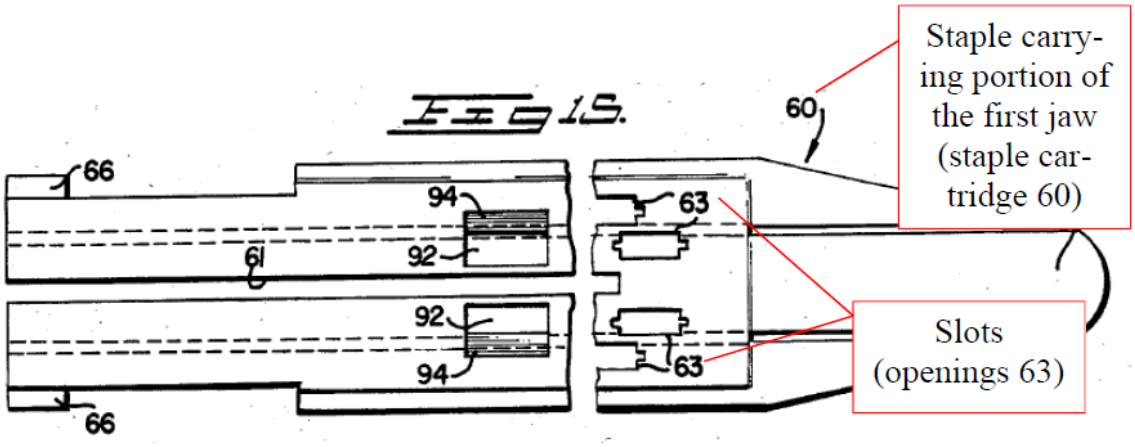
According to Petitioner, and as shown above, Rothfuss's Figure 2 depicts upper/first jaw 26 and lower/second jaw 28 in the first, or open, position, for receiving tissue. *See id.* at 52–53 (citations omitted). As also shown above, Rothfuss's Figure 3 depicts upper/first jaw 26 and

lower/second jaw 28 in a second, or closed, position to hold tissue therebetween. *See id.* (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Rothfuss discloses this limitation.

c. *"[4.2] a staple carrying portion of the first jaw defining slots through which staples are configured to pass"*

Petitioner submits that Rothfuss discloses this limitation, submitting an annotated version of Rothfuss's Figure 15 (Pet. 54), which we reproduce, below:

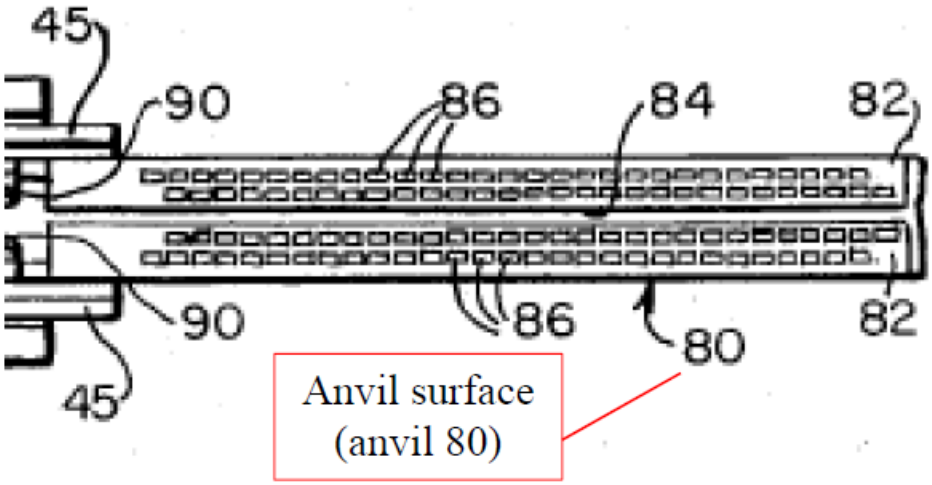


According to Petitioner, and as shown above, Figure 15 depicts a staple carrying portion (staple cartridge 60) of the first jaw defining slots (openings 63) through which staples 65 are configured to pass. *Id.* (citing Ex. 1007, 22–57).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Rothfuss discloses this limitation.

d. "[4.3] an anvil surface defined on the second jaw opposing the first jaw"

Petitioner submits that Rothfuss discloses this limitation, submitting an annotated excerpt from Rothfuss's Figure 7 (Pet. 55), which we reproduce, below:



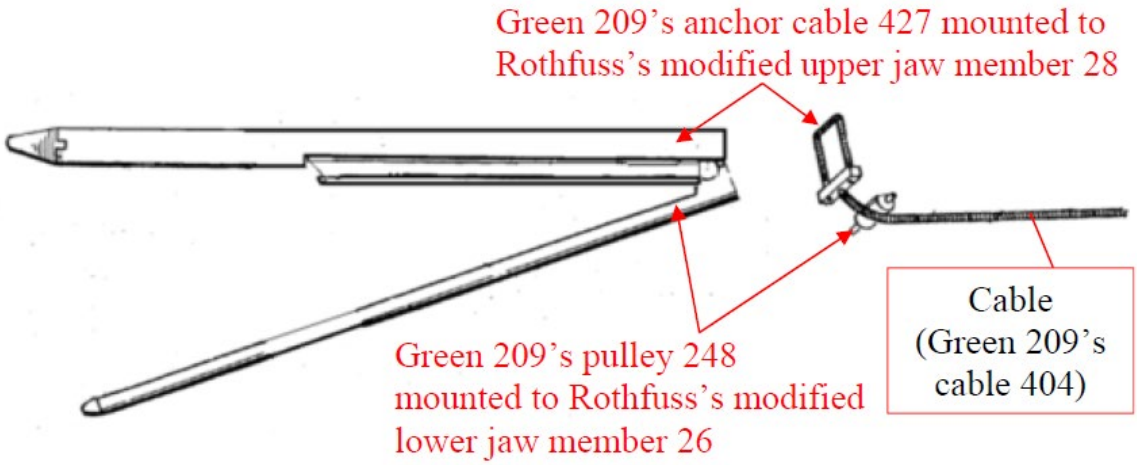
According to Petitioner, and as shown in Figure 7, Rothfuss discloses an anvil surface (anvil 80) defined on the second jaw opposing the first jaw. *Id.* at 54 (citing Ex. 1007, 8:14–22).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Rothfuss discloses this limitation.

e. "[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment"

Petitioner relies on Rothfuss, in view of the teachings of Green 209 and Knodel 895, for satisfying this limitation. Pet. 55. In particular, Petitioner submits that Rothfuss would include two modifications: (1) modified to be used for MIS based on Green 209's teachings; and (2)

modified to include Knodel 895's gears and Green 209's cable which are controlled by Green 209's handle. *See id.* To illustrate the modified structure, Petitioner submits the following figure (Pet. 56):



According to Petitioner, the above figure depicts Rothfuss's upper jaw connected to Green 209's anchor cable with Rothfuss's lower jaw connected to Green 209's pulley. *See id.*

As to the proposed modification of Rothfuss for MIS, Petitioner reasons that a skilled artisan would have modified "Rothfuss's stapler for use in minimally invasive surgery . . . for the same reasons a POSITA would have modified Green 695's stapler for use in MIS." *Id.* at 50 (citing Ex. 1003 ¶ 117). Petitioner explains:

> Rothfuss's handles 22, 24 would be replaced with Green-209's frame portion 52 and elongated shaft portion 54 without or without [sic] Green-209's articulation and rotation functionality. Rothfuss's jaws 26, 28 (reduced in size and modified to resemble Green-209's jaws) would be opened and closed using Green-209's linkage and cable assembly. And at least Rothfuss's staple pusher bar mechanism 75 would be driven by Green-209's pneumatic system 68 to gain the benefit of a powered firing mechanism.

Id. at 50–51.

Patent Owner argues that Rothfuss's "staple drivers 68, however, are operated by the first and second control buttons 72, 74 in Rothfuss, which . . . are rendered inoperable when Rothfuss' handles 22, 24 are replaced with Green-209's frame portion 52 and elongated shaft portion 54." Prelim. Resp. 21 (citing Ex. 1007, 2:58–3:3; Ex. 2001 ¶¶ 32–38). Dr. Dolgin testifies that "Petitioner has . . . failed to explain how the first control button 72 is toggled between its innermost and outermost position and moved along the length of the jaws when the handles 22, 24 are removed." Ex. 2001 ¶ 39. Dr. Dolgin further testifies,

> When Rothfuss' device is modified for use in MIS, the surgeon cannot manually manipulate the jaws or button because the surgeon cannot physically contact the jaws or button. There would have to be some other way of, for example, toggling the first control button 72 to select the staple height and then advancing the button 72 along the assembly 70 to move the staples of the selected height. This is not addressed in any capacity in the Petition, even though these details are critical to the functionality, operation, and intended purpose of Rothfuss' device.

Id.

At this stage of the proceeding, we find Patent Owner's argument persuasive. Petitioner proposes to modify Rothfuss by replacing Rothfuss's handles 22, 24 with Green 209's frame portion 52 and elongated shaft portion 54 for the purpose of making Rothfuss a MIS device, yet it is not clear to us how Rothfuss's buttons 72, 74 would continue to operate within this construct. *See* Pet. 50.

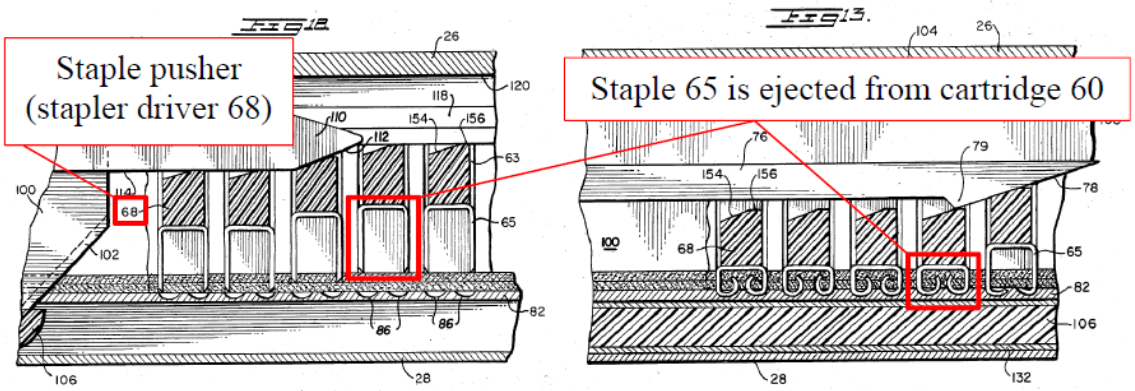
Indeed, Rothfuss, which is titled "Surgical Stapling Instrument with Dual Staple Height Mechanism" (Ex. 1007 code (54)), discloses that its stapling device permits surgeons to select between two different staple

heights to allow the device to be used with tissue of different thicknesses. *Id.* at 2:51–55; *see also* Ex. 2001 ¶ 33 (testifying to the same)). Rothfuss achieves this functionality through its two buttons, 72, 74. *See, e.g.*, Ex. 1007, 7:68–8:2 ("first control button 72 is moveable laterally between different control positions to select the desired staple height to be produced"); *see also* Ex. 2001 ¶ 33 (testifying to the same). Furthermore, Rothfuss's handles 22, 24 (including notch 152 and flange 153) permit the control buttons to be adjusted laterally between their outermost and innermost positions for selection of the desired staple height. *See* Ex. 1007, 10:53–11:3, Figs. 1, 8; *see also* Ex. 2001 ¶ 37 (testifying the same)). Absent any detailed explanation in the Petition (*see* Pet. 50–51, 55–57), it is not clear to us how Petitioner's proposed removal of handles 22, 24 would maintain the functionality of buttons 72, 74, and we are not persuaded that a skilled artisan would have modified Rothfuss as Petitioner proposes.

Based on the present record, we conclude that Petitioner has *not* shown a reasonable likelihood that a skilled artisan would have modified Rothfuss, based on the teachings of Green 209 and Knodel 895, to arrive at the claimed limitation.

f. "[4.5] a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion"

Petitioner submits that Rothfuss discloses this limitation, submitting annotated versions of Rothfuss's Figures 12 and 13 (Pet. 57), which we reproduce, below:



According to Petitioner, and as shown above in Figures 12 and 13, Rothfuss discloses staple pusher (staple drivers 68) configured to cause staples 65 to move from a first position within staple carrying portion (shown in Figure 12) to a second position entirely outside of the staple carrying portion (shown in Figure 13). *Id.* at 56 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Rothfuss discloses this limitation.

g. "[4.6] the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location"

Petitioner submits that Rothfuss discloses this limitation, submitting an annotated version of Rothfuss's Figure 9 (Pet. 58), which we reproduce, below:

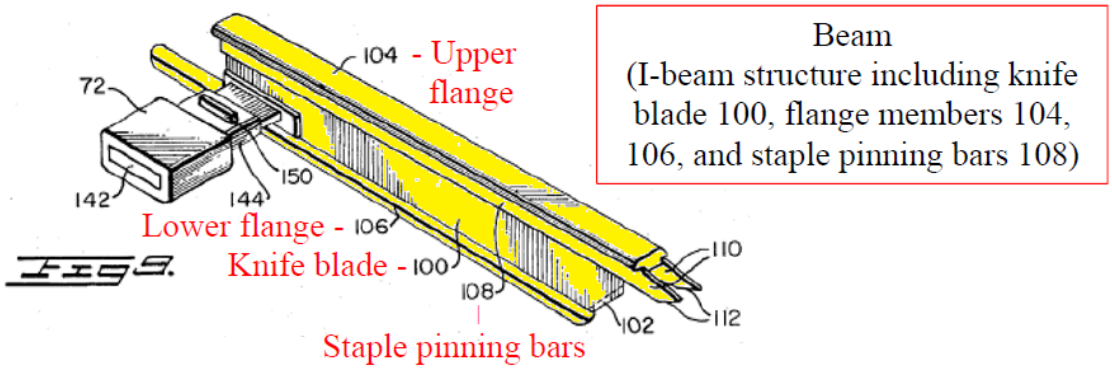


Fig 9.

According to Petitioner, and as shown above in Figure 9, Rothfuss discloses that I-beam structure—including knife blade 100—is configured to engage first and second jaws from within passageways 120, 130 while tissue is stapled from a proximal location to a distal location. Pet. 57 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that Rothfuss discloses this limitation.

h. Summary of Claim 4

Petitioner has not shown a reasonable likelihood that claim 4 is unpatentable over Rothfuss, Green 209, and Knodel 895.

3. Independent Claim 13

As with its challenge of claim 4, in addressing the claimed limitation 13.3, "a control handle configured to actuate receiving, clamping and stapling of tissue," Petitioner proposes to replace Rothfuss's handles with Green 209's control handle. *See* Pet. 66; *see also id.* at 50 ("Rothfuss's handles 22, 24 would be replaced with Green-209's frame portion 52 and elongated shaft portion 54 without or without [sic] Green-209's articulation and rotation functionality.").

As with claim limitation 4.4 of claim 4, however, at this stage of the proceeding, we are not persuaded that a skilled artisan would have replaced Rothfuss's handles 22, 24, as doing so would also impact the operation of Rothfuss's control buttons 72, 74. *Supra* Part II.G.2.e. The Petition fails to adequately address how the proposed modification would maintain the functionality of these buttons, and we are not persuaded that a skilled artisan would have modified Rothfuss as Petitioner proposes. *See id.*

Petitioner has not shown a reasonable likelihood that claim 13 is unpatentable over Rothfuss, Green 209, and Knodel 895.

4. Summary

Although Petitioner has *not shown* a reasonable likelihood that claims 4–8 and 10–24 are unpatentable over Rothfuss, Green 209, and Knodel 895, pursuant to *SAS* and the *SAS* Guidance, we institute review of these claims under Ground 2.

H. GROUND 3: MCGUCKIN, GREEN 695

Petitioner contends that claims 4–24 are unpatentable as obvious over McGuckin in view of Green 695. Pet. 70.

1. McGuckin

McGuckin discloses a surgical apparatus for resectioning diseased tissue. Ex. 1012, 1:5–9. Resection is described as the surgical removal of an organ or structure. *Id.* at 1:44. To illustrate McGuckin's apparatus, we reproduce its Figures 1A and 1B, below:

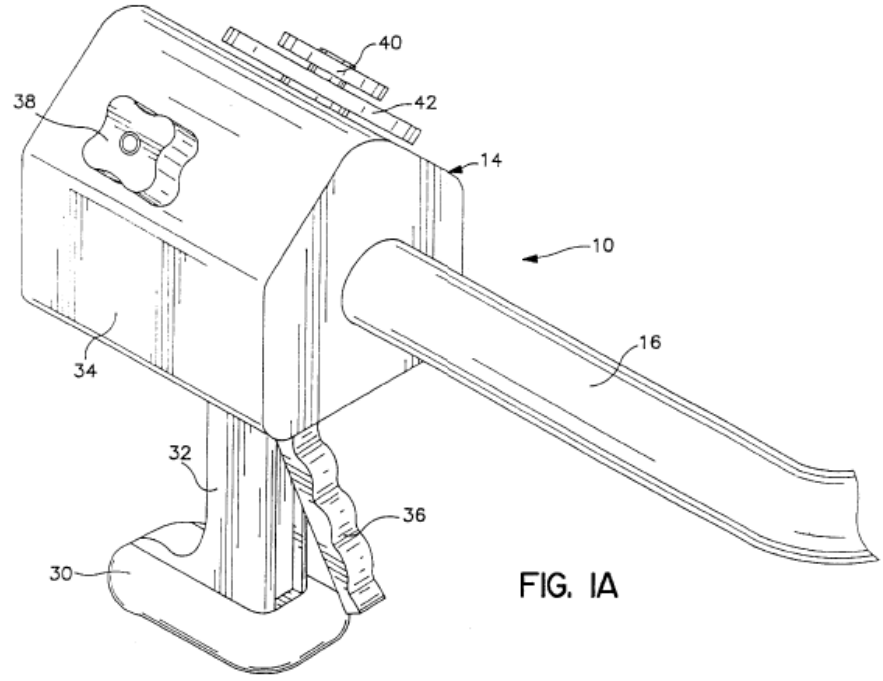


FIG. IA

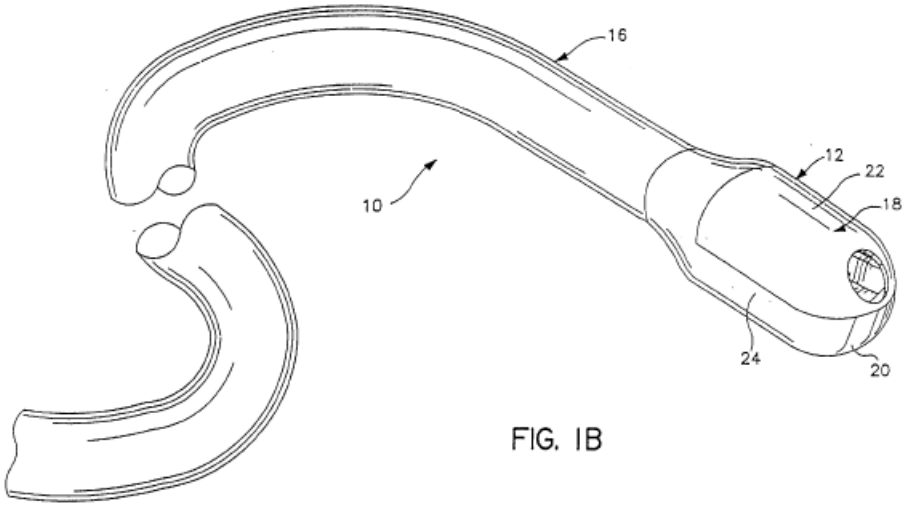


FIG. IB

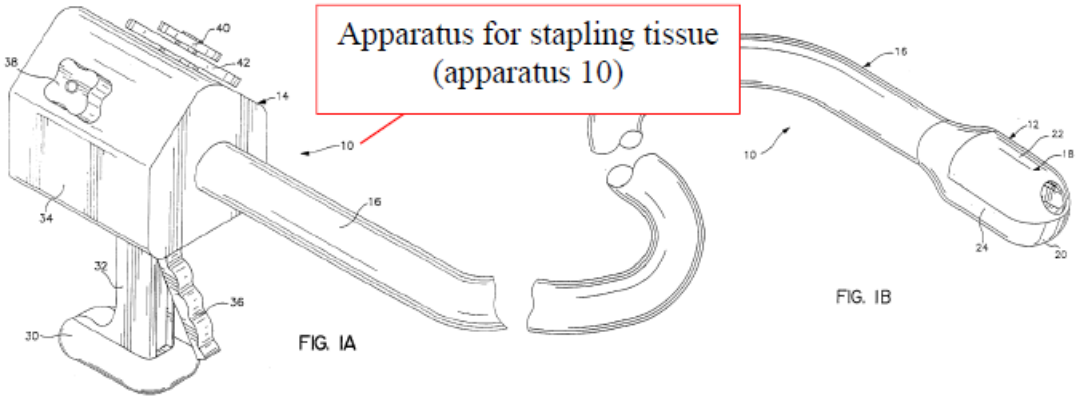
Figures 1A and 1B are isometric views of a preferred embodiment of an apparatus for the removal of malignant or other undesirable tissue. *Id.* at 9:54–56. In particular, Figure 1A (top) depicts the operating control module portion of the apparatus and Figure 1B (bottom) depicts "a longitudinally elongated operating capsule apparatus . . . and the portion of the cable carrying flexible tubular apparatus not shown in FIG. 1A." *Id.* at 9:60–66.

In combination, these figures depict apparatus 10 including longitudinally elongated operating capsule 12, operating control module 14, and cable carrying flexible tubular member 16. *Id.* at 11:62–66.

2. Independent Claim 4

a. "[4.0] An apparatus for stapling tissue, comprising:"

Petitioner submits that McGuckin discloses an apparatus for stapling tissue, submitting an annotated version of McGuckin's Figures 1A and 1B (Pet. 70), which we reproduce, below:



According to Petitioner, McGuckin's apparatus 10 is an apparatus for stapling tissue. *Id.* (citations omitted). McGuckin discloses, "The tissue fastening means portion of the apparatus preferably may further include a plurality of suturing staples and anvils for the fastening, bending or closing of individual suturing staples serially thereagainst." Ex. 1012, 4:34–37.

Without addressing whether the preamble is limiting, based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin discloses an apparatus for stapling tissue.

b. "[4.1] a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second

jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling"

Petitioner submits that McGuckin discloses this limitation, submitting an annotated version of McGuckin's Figures 14 and 15 (Pet. 72), which we reproduce below:

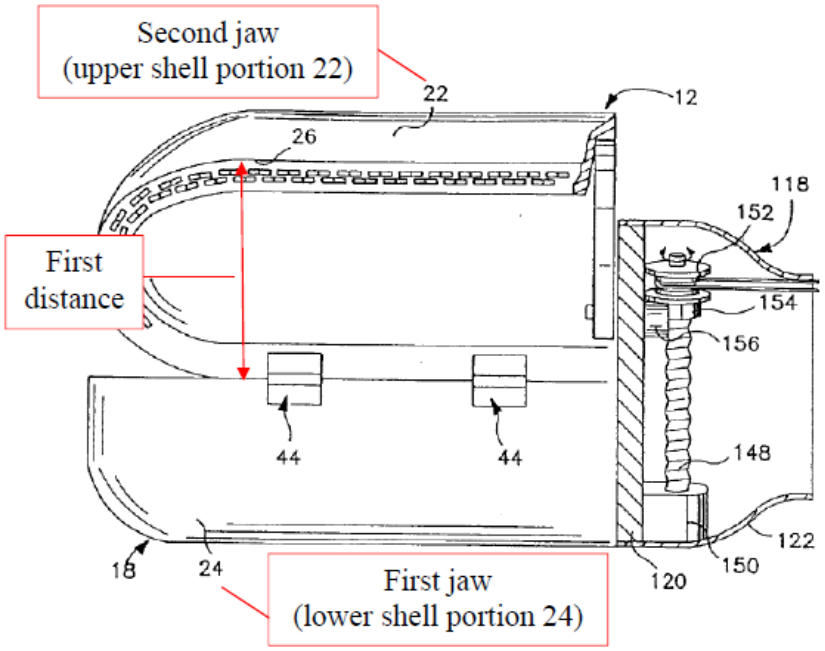


Fig. 15

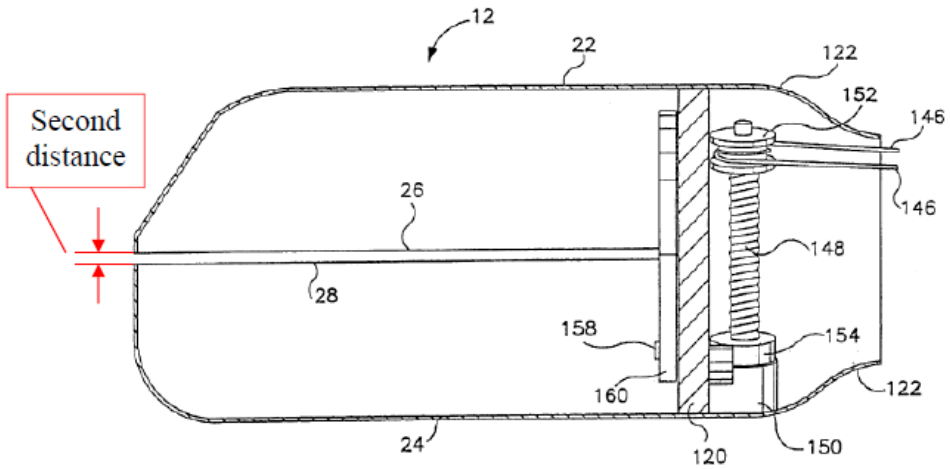


FIG. 14

According to Petitioner, and as shown above in Figures 14 and 15, McGuckin discloses first jaw (lower shell 24) and second jaw (upper shell 22) being movable with respect to the other from a first/open configuration in which the jaws are separated from each other at a first distance (Figure 15) to receive tissue and a second configuration (closed) in which the jaws are clamped together at a second distance (Figure 14) to hold tissue therebetween for stapling, as further shown in Figure 31. Pet. 71 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin discloses this limitation.

c. "[4.2] a staple carrying portion of the first jaw defining slots through which staples are configured to pass"

Petitioner submits that McGuckin discloses this limitation, submitting an annotated version of McGuckin's Figure 23 (Pet 73), which we reproduce, below:

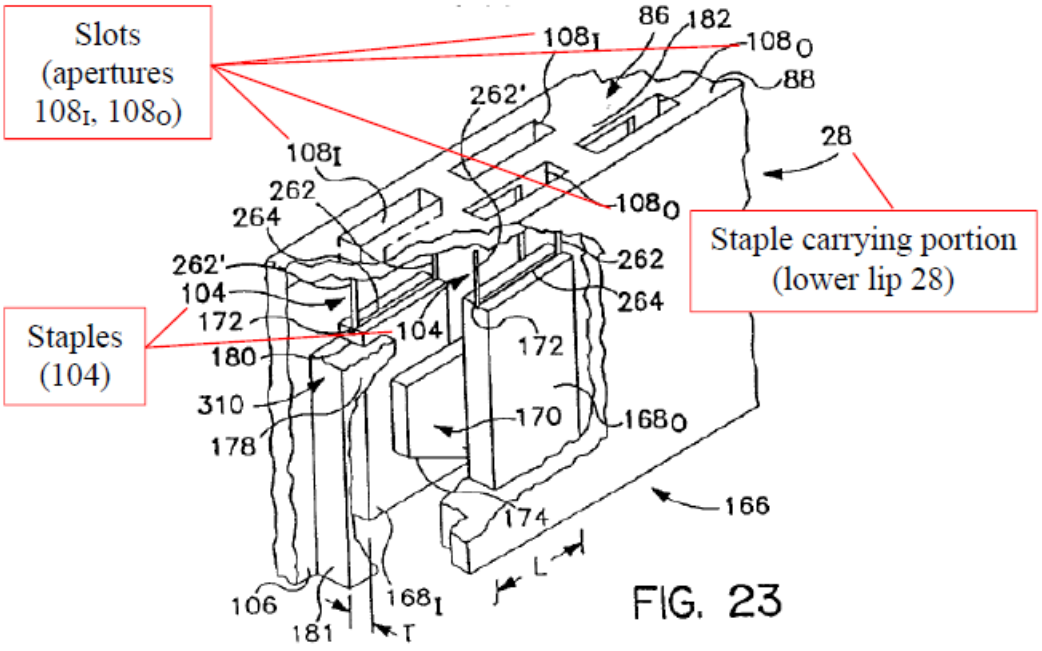


FIG. 23

According to Petitioner, and as shown in Figure 23, McGuckin discloses staple carrying portion (lower lip 28) of the first jaw defining slots (apertures 108_O, 109_I) through which staples 104 are configured to pass. Pet. 73 (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin discloses this limitation.

d. "[4.3] an anvil surface defined on the second jaw opposing the first jaw"

Petitioner submits that McGuckin discloses this limitation, submitting an annotated version of McGuckin's Figure 15 (Pet. 74), which we reproduce, below:

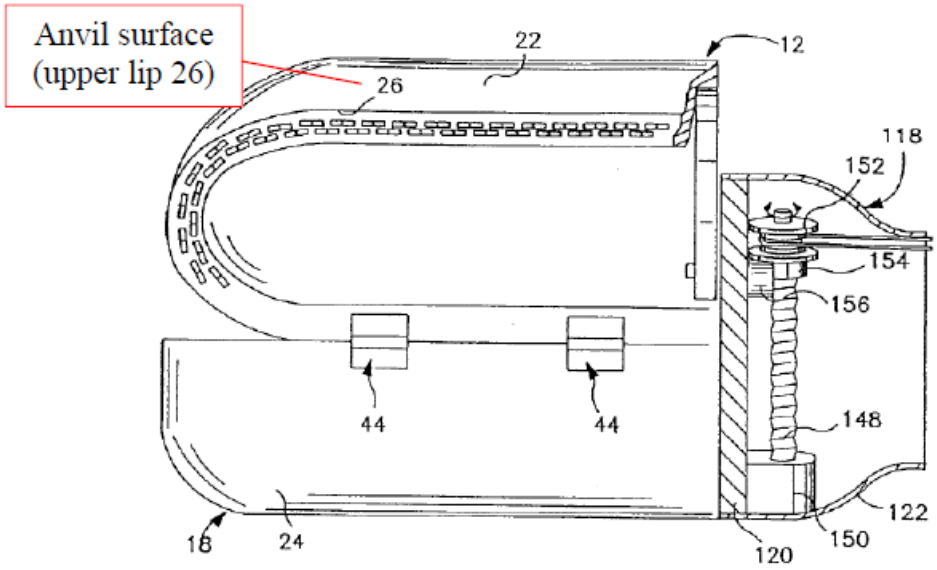


Fig. 15

According to Petitioner, and as shown above in Figure 15, McGuckin discloses anvil surface (upper lip 26) defined on second jaw 22 opposing first jaw 24. *See id.* (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin discloses this limitation.

e. "[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment"

Petitioner submits that McGuckin discloses this limitation (*see supra* Part II.D.1), and provides an annotated version of McGuckin's Figure 13 (Pet. 75) to support its position, which we reproduce below:

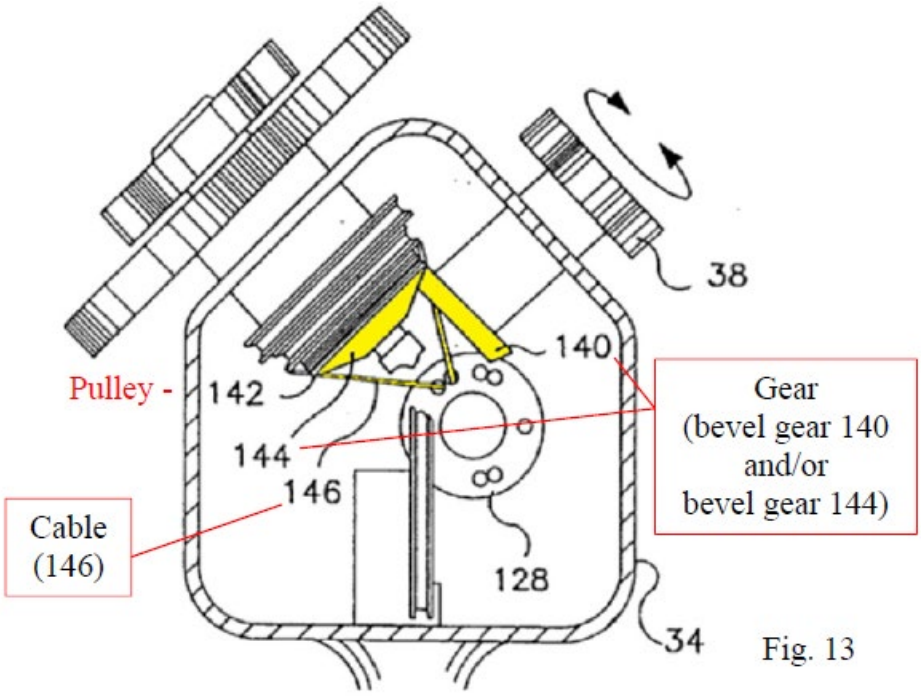


Fig. 13

According to Petitioner, and as shown above, McGuckin discloses at least one gear (bevel gears 140, 144) and cable (146). Pet. 75 (citations omitted). Petitioner explains that bevel gears 140, 144 and cable 146 are operatively coupled to first and second jaws by pulley 142, threaded shaft 148, pedestal block 150, bulkhead 120, drive pulley 152, nut 154, arm 156, pin 158, and lift arm 160. *Id.*

Petitioner also submits an annotated version of McGuckin's Figure 14 (Pet. 76), which we also reproduce, below:

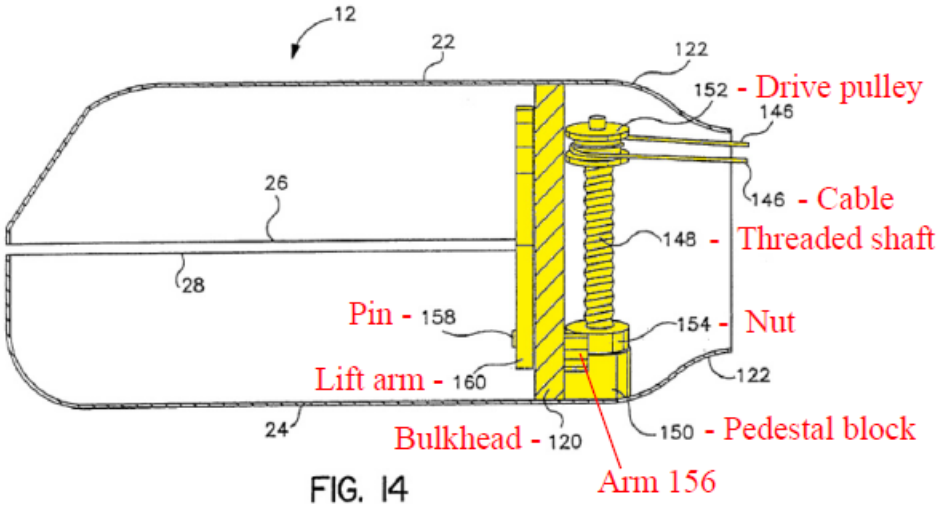


FIG. 14

According to Petitioner, Figure 14 depicts cable 146 configured to move first jaw 24 and second jaw 22 from the first/open configuration to the second/closed configuration such that the first and second jaws are in alignment. *See* Pet. 76.

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin discloses this limitation.

f. "[4.5] a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion"

Petitioner submits that McGuckin discloses this limitation, submitting an annotated version of McGuckin's Figure 24 (Pet. 77), which we reproduce, below:

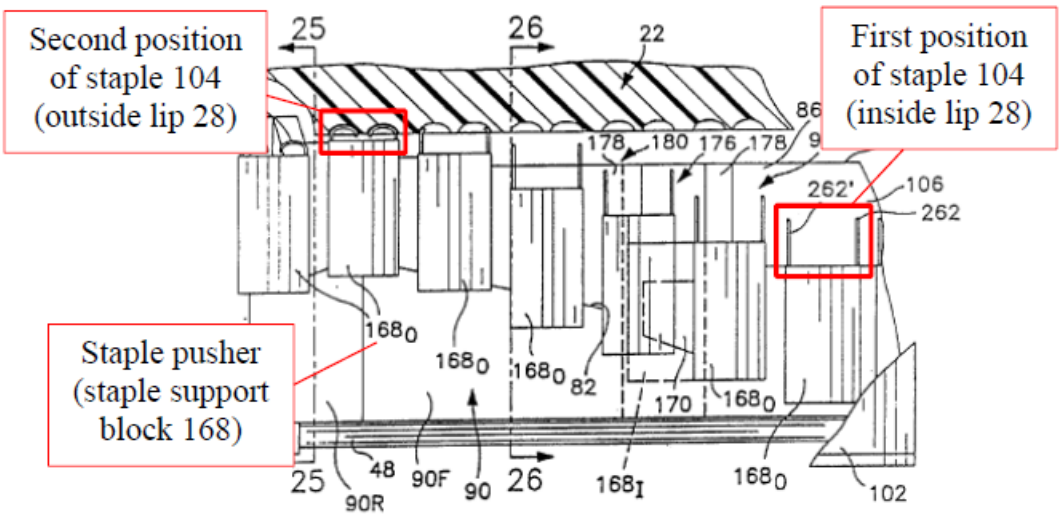


FIG. 24

According to Petitioner, Figure 24 depicts staple pusher (staple support block 168) configured to cause staple (104) to move from a first position at least partially within s staple carrying portion to a second position entirely outside of the staple carrying portion. *Id.* (citations omitted).

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin discloses this limitation.

g. "[4.6] the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location"

Petitioner submits that McGuckin, when modified based on Green 695's teachings, satisfies this limitation. *See* Pet. 77–78. In particular, Petitioner proposes to modify McGuckin in two ways: (1) to modify McGuckin's knife portion 76 to include the upper portion of an I-beam; and (2) to modify McGuckin's first and second jaws to include an internal passageway and opening. *See id.* at 78.

Patent Owner disputes this combination, first asserting that the Petition fails to provide "any reason why a POSITA would have been motivated to make this combination." Prelim. Resp. 22.

We disagree with Patent Owner's first argument. Petitioner references the same reasons as in Ground 1. *See* Pet. 78. As explained above in Ground 1A, Petitioner reasons that a skilled artisan would have made the modifications for at least three reasons: (1) to provide optimum alignment and stabilization of the jaws during application and securing of the fasteners; (2) to enable the use of lightweight disposable materials for manufacture of the jaws; and (3) to enable the use of longer staple cartridges. *See id.* at 17 (citing Ex. 1003 ¶¶ 51, 52). Petitioner's proposed modifications are supported by the testimony of Dr. Knodel (Ex. 1003 ¶¶ 51, 52) and explicitly suggested by Green 695 (*see, e.g.*, Ex. 1005, 4:57–60).

Second, Patent Owner argues that "McGuckin has a rounded, U-shape jaw and Petitioner proposes moving the beam around the perimeter of the jaw so that it traces the U-shape edge of the jaw." Prelim. Resp. 24 (citing Pet. 77–82). Patent Owner points out: "In stark contrast, Green-209 has a straight jaw so that its I-beam moves from front-to-back along a single plane." *Id.* Patent Owner contends that "[t]hese differences, which affect the operation of the devices, are not discussed or even acknowledged by Petitioner." *Id.* (citing Ex. 2001 ¶¶ 42–45).

Patent Owner's second argument is also unpersuasive. Modifying McGuckin's apparatus based on the teachings of Green 695 does not require bodily incorporation of Green 695's straight I-beam into McGuckin's U-shaped jaw. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be

bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."). At this stage of the proceeding, we find persuasive Petitioner's reasoning that a skilled artisan would have modified McGuckin's apparatus to include an I-beam and channels, as generally taught by Green 695, for the reasons stated by Petitioner.

Based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin, as modified based on Green 695's I-beam and upper and lower shoe teachings, would have satisfied this limitation.

3. Summary

Petitioner addresses the limitations of the other challenged claims (*see* Pet. 83–98) and Patent Owner does not contest Petitioner's challenge of these claims apart from those arguments discussed above (*see* Prelim. Resp. 22–25). Accordingly, and based on the present record, we conclude that Petitioner has shown a reasonable likelihood that McGuckin, as modified based on Green 695's teachings, renders claims 4–24 unpatentable.

III. CONCLUSION

For the reasons discussed above, we conclude Petitioner has shown a reasonable likelihood of prevailing with respect to at least one claim. We have evaluated all of the parties' submissions and determine that the record supports institution.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '650 patent is instituted on all claims and all grounds set forth in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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