

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*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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. We issued a decision to institute an *inter partes* review of these claims. Paper 9 (“Institution Decision” or “Inst. Dec.”).

After institution, Rex Medical, L.P. (“Patent Owner”) filed a Patent Owner Response (Paper 13 (“PO Resp.” or “Response”)), to which Petitioner replied (Paper 21 (“Pet. Reply” or “Reply”)). Patent Owner also filed a Sur-Reply to Petitioner’s Reply. Paper 25 (“PO Sur-Reply” or “Sur-Reply”).

Oral argument, or hearing, was held on January 27, 2021, and the transcript of the hearing has been entered as Paper 34.

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown that claims 4, 5, 9–18, 20, and 22–24 of the ’650 patent are unpatentable. Petitioner has not shown that claims 6–8, 19, and 21 of the ’650 patent are unpatentable.

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

A. Related Proceedings

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 U.S. Pat. No. 10,136,892 and pending U.S. Patent Application Nos. 16/185,506 and 16/564,543 as related to the '650 patent. *See* Pet. 1–2.

B. The '650 Patent (Ex. 1001)

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 stapling apparatus, we reproduce its Figure 3, below:

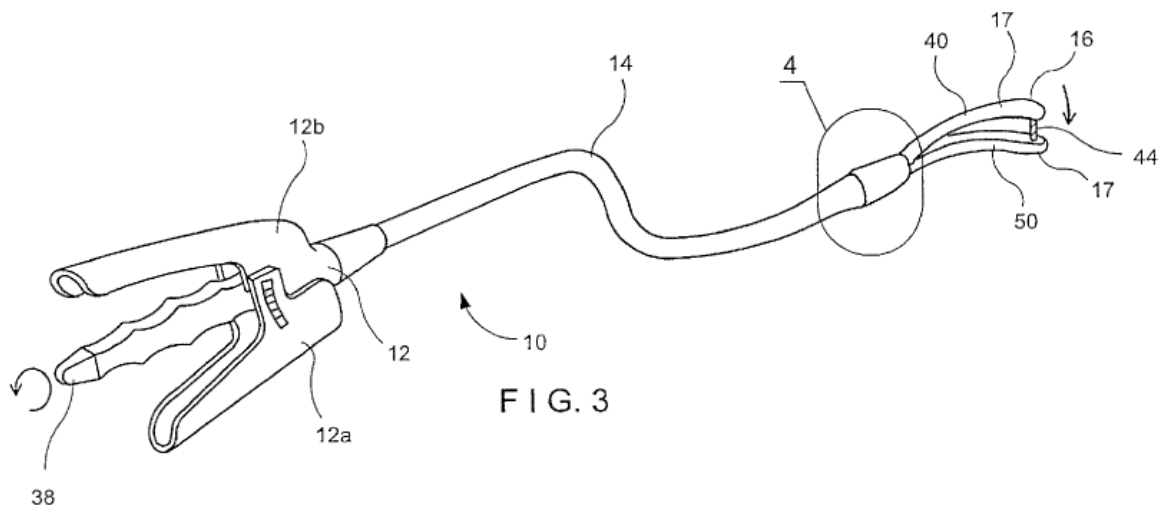


Figure 3 depicts a perspective view of an illustrative embodiment of the '650 patent's stapling system. *Id.* at 2:7–10, 2:19–20. In particular, Figure 3 depicts stapling apparatus 10 with proximal handle portion 12, elongated

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. Stapling 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. To illustrate the I-beam, we reproduce Figure 14, below:

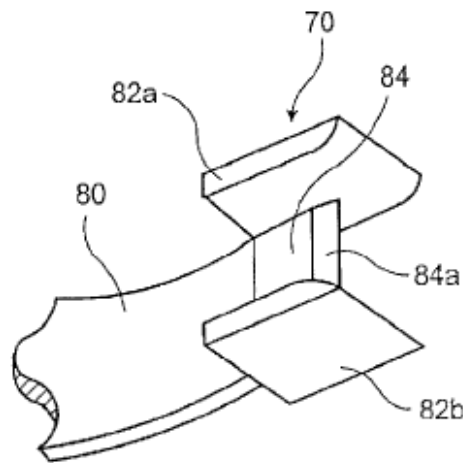


FIG. 14

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 stapling apparatus, we reproduce Figure 15, below:

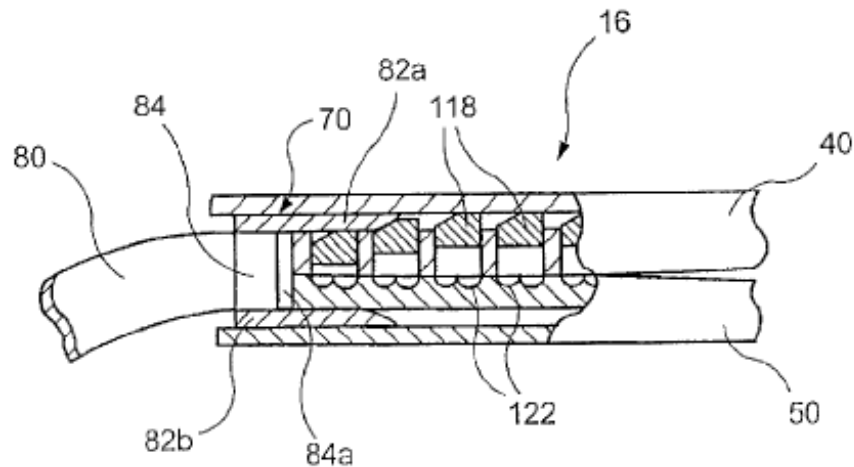


FIG. 15

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 to hold tissue between them, 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.* at 5:36–50. 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, through the tissue, and into staple forming pockets 122 of staple forming portion 50. *Id.* at 6:26–40.

C. Illustrative Claims

Of the challenged claims, 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 8:34–8:62, 9:15–10:9.

D. References Relied Upon

Petitioner’s challenges rely on the following references (Pet. 4–5):

Name	Reference	Ex. No.
Green 209	US Pat. No. 5,645,209, issued July 8, 1997	1004
Green 695	US Pat. No. 4,429,695, issued Feb. 7, 1984	1005
Knodel	US Pat. No. 5,465,895, issued Nov. 14, 1995	1006
Rothfuss	US Pat. No. 4,605,001, issued Aug. 12, 1986	1007
McGuckin	US Pat. No. 5,868,760, issued Feb. 9, 1999	1012

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 4–24 of the '650 patent are unpatentable under the following grounds:

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

Pet. 3. Petitioner also relies on the Declaration testimony of Dr. Bryan Knodel (Exs. 1003, 1025). *See, e.g.*, Pet. Reply iv–v, 7 (referencing Dr. Knodel’s testimony under Exs. 1003, 1025). Patent Owner submits the competing testimony of Dr. Michael Dolgin (Ex. 2001) and Mr. Albert Juergens (Ex. 2002). *See, e.g.*, PO Resp. iv (Exhibit List, referencing Ex. 2002); *see also, e.g., id.* at 29 (referencing Dr. Dolgin’s testimony).

II. ANALYSIS

A. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966).

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity

with which innovations are made; (5) sophistication of the technology, and (6) educational level of workers active in the field. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Petitioner’s expert, Dr. Knodel, testifies that:

A person of ordinary skill in the art [(“POSITA”)] at the time of the alleged invention would have had the equivalent of a Bachelor’s degree or higher in mechanical engineering with at least 3 years working experience in the design of comparable surgical devices. *Additional education in a relevant field, such as mechanical engineering, or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above.*

Ex. 1003 ¶ 26 (emphasis added).

Patent Owner’s expert, Mr. Juergens, testifies that:

The relevant technical field for the ’650 patent is medical staplers. Based on this, and the four factors above, in my opinion a person of ordinary skill in the art as of January 2001 would hold a bachelor’s degree or the equivalent in mechanical engineering (or equivalent degree or experience) *and at least two years of additional product development experience in the area of medical staplers, other regulated products or equivalent work experience.*

Ex. 2002 ¶ 14 (emphasis added).

Based on the sophistication of the technology, as reflected in the prior art, we are not persuaded that product development experience—as opposed to graduate-level research in medical staplers, for example—is *necessary* to qualify a person as a POSITA, as Patent Owner’s expert testifies. *Id.*

Rather, we find Petitioner’s definition to more accurately reflect the level of ordinary skill in the art, as it does not require “at least two years of additional product development experience.” *Compare id., with* Ex. 1003 ¶ 26. Petitioner’s definition is flexible in that it provides that “[a]dditional education in a relevant field, such as mechanical engineering, or industry experience may compensate for a deficit in” the stated work experience. *See* Ex. 1003 ¶ 26.

For this reason, we adopt Petitioner’s proposed level of ordinary skill in the art (*id.*). We also consider Petitioner’s expert—Dr. Bryan Knodel (Exs. 1003, 1025)—and Patent Owner’s experts—Dr. Michael Dolgin (Ex. 2001) and Mr. Albert Juergens (Ex. 2002)—as being POSITAs under our definition. These experts have established, through their own testimony, that they possessed the appropriate education and work experience in the relevant art at the time of the invention. *See* Ex. 1003 ¶¶ 6–14 (Dr. Knodel’s qualifications); *see also* Ex. 2001 ¶¶ 3–11 (Dr. Dolgin’s qualifications); *see also* Ex. 2002 ¶¶ 3–11 (Mr. Juergens’s qualifications).

B. Claim Construction

In an *inter partes* review proceeding for a petition filed on or after November 13, 2018, a patent 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). *See* 37 C.F.R. § 42.100(b) (2019). This rule adopts the same claim construction standard used by Article III federal courts (*see id.*), which follow *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) and its progeny. Under the *Phillips* standard, the words of a claim are generally given their “ordinary and customary meaning,” which is the meaning the term would have to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *See Phillips*, 415 F.3d at 1312–13. “[W]here a party believes that a specific term has meaning other than its plain meaning, the party should provide a statement identifying a proposed construction of the particular term and where the disclosure supports that meaning.” Office Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

1. District Court Claim Construction Order

Patent Owner directs our attention to a related District Court Claim Construction Order (“Order”) that issued after our Institution Decision was entered. PO Resp. 1 (“A claim construction order issued in the corresponding litigation on May 5, 2020.” (citing Ex. 2003)).

Patent Owner “adopts those claim constructions” in this proceeding. *Id.*

Petitioner does not address the Order in its Reply. *See, generally*, Pet. Reply.

We have considered the Order, Patent Owner’s Response, Petitioner’s Reply, and Patent Owner’s Sur-Reply, and determine that the only limitation that requires express construction for purposes of this Final Written Decision is 4.4 of independent claim 4. *See Nidec Motor Corp. v. Zhongshan Broad*

Ocean Motor Co. Ltd., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’”) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

2. 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*”

In our Institution Decision, we expressly construed this limitation. *See* Inst. Dec. 10–11. The District Court also construed this limitation. *See* Order 1–2.

At the institution phase, we determined that under the plain and ordinary meaning of the claim, the limitation 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. *See* Inst. Dec. 11.

Neither Petitioner nor Patent Owner disagrees with our initial proposed construction. *See, generally*, Pet. Reply; *see also* PO Resp. 1 (“PO does not object to the Board’s interpretation of the ‘gear and cable’ limitation of claim 4.”).

The District Court construed “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” to mean “at least one of a gear *or* a cable operatively coupled to at least one of the first jaw *or* the

second jaw and configured to move at least one of the first jaw *or* the second jaw from the first configuration to the second configuration.” Order 1–2 (emphases on the three words “or”).

The District Court’s claim construction is consistent with the construction that we adopted in our Institution Decision. *Compare id.*, with Inst. Dec. 11. In particular, both constructions provide that the claimed gear *or* cable are operatively coupled to the first jaw *or* second jaw.

Absent any argument that our initial construction was in error, and as doing so would be consistent with the District Court’s claim construction, we conclude that limitation [4.4] 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/or* the second jaw from the first configuration to the second configuration.

3. *Other Claim Terms*

There are no other terms that require express construction for purposes of this Decision. *See Nidec*, 868 F.3d at 1017.

C. 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. 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*, 383 U.S. at 17–18.

D. Ground 1A: Green 209, Green 695, and 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 infra* Part II.E.

Under Ground 1A, Petitioner relies on Green 209 for disclosing the majority of the claimed limitations. *See* Pet. 10–44.

1. Green 209 (Ex. 1004)

Green 209 is a U.S. Patent titled "Self Contained Gas Powered Surgical Apparatus." Ex. 1004, code (54). Green 209 discloses that its

“invention relates to surgical stapling apparatus, and more particularly to surgical apparatus which are powered by [self-]contained relatively low pressure gas systems to perform sequential operations such as tissue clamping, staple forming and/or tissue cutting.” *Id.* at 1:20–24.

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:

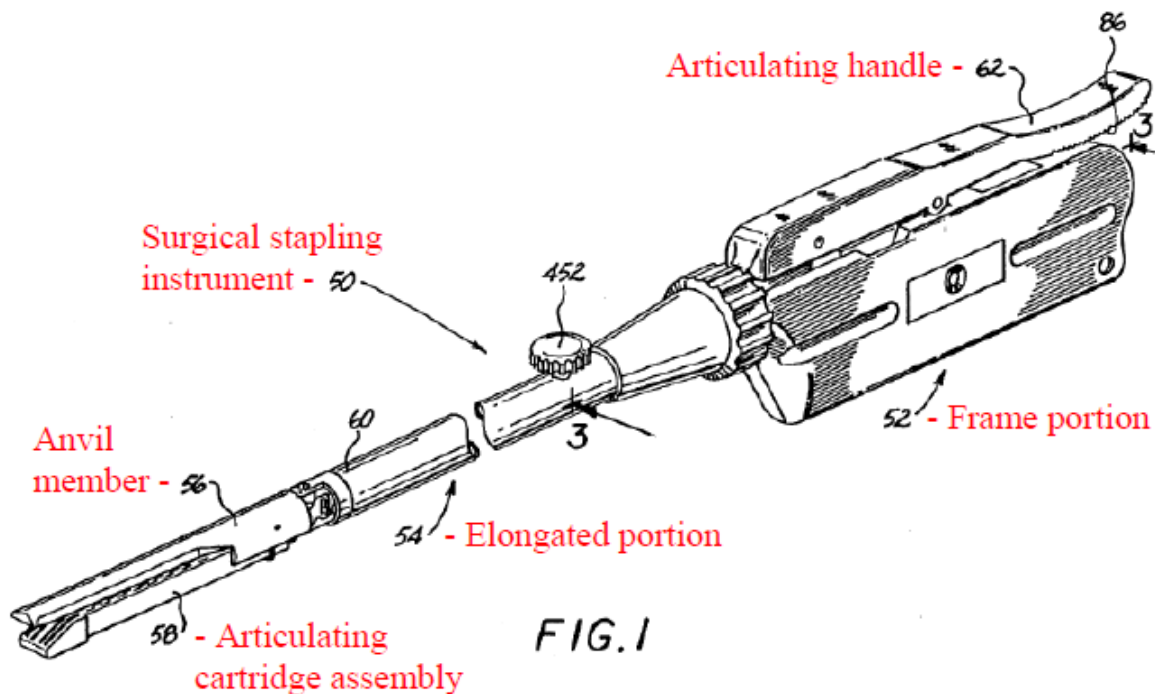


Figure 1 is a “perspective view of a self contained gas powered endoscopic surgical instrument.” Ex. 1004, 6:4–6. According to Petitioner’s annotations, this figure depicts surgical stapling instrument 50 with frame portion 52, elongated portion 54, anvil member 56, articulating cartridge assembly 58, 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 reproduce, below:

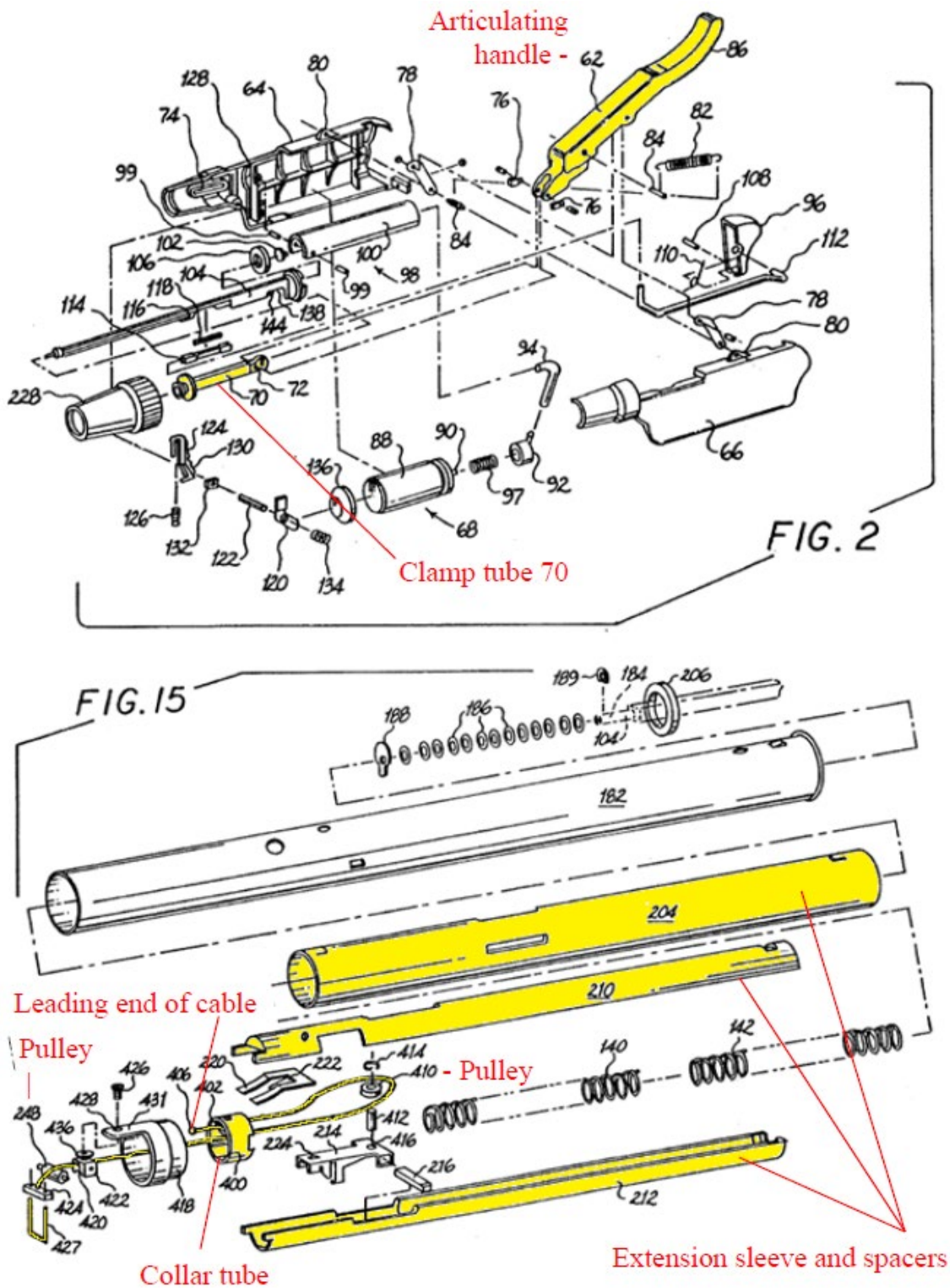


Figure 2 is an “exploded perspective view of the frame and pneumatic assembly of the surgical instrument of” Figure 1. Ex. 1004, 6:7–9. Figure

15 is an “exploded perspective view of the elongated portion of the surgical instrument of” Figure 1. *Id.* at 6:47–47. Petitioner’s annotations to Figure 2 include highlighting in yellow clamp tube 70 and articulating handle member 62.

According to Petitioner, 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:

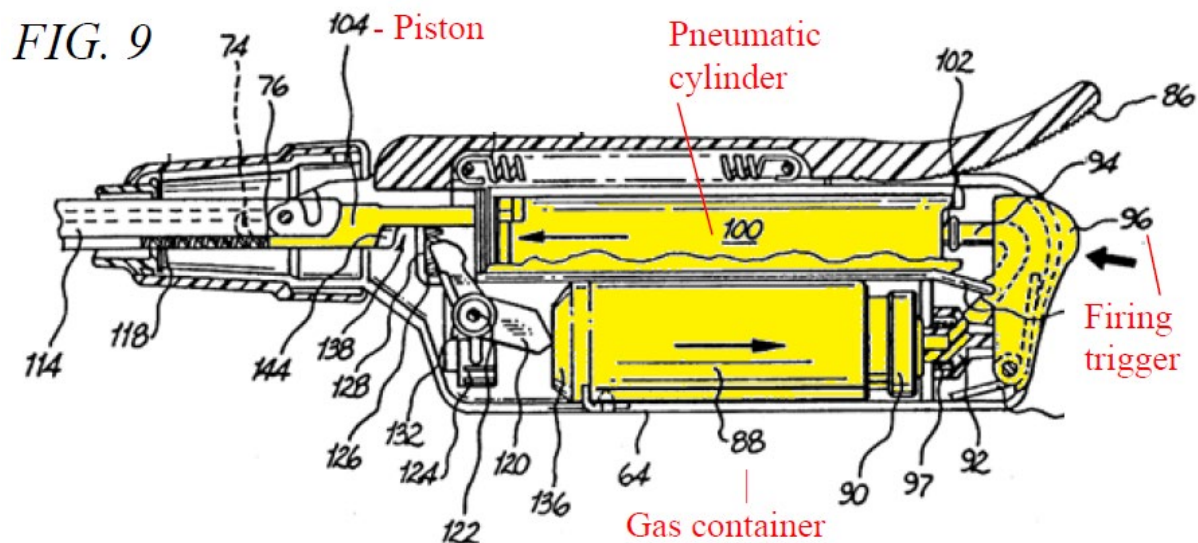


Figure 9 is a “side plan view in cross section showing the frame and pneumatic assembly of the present invention in the clamped and fired position.” Ex. 1004, 6:31–33. Petitioner’s annotation to Figure 9 includes highlighting in yellow gas container 88, firing trigger 96, pneumatic cylinder 100, and piston 104. According to Petitioner, 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 104. *See id.*

(citations omitted). Petitioner also submits an annotated version of Green 209's Figure 16 (Pet. 14), which we reproduce below:

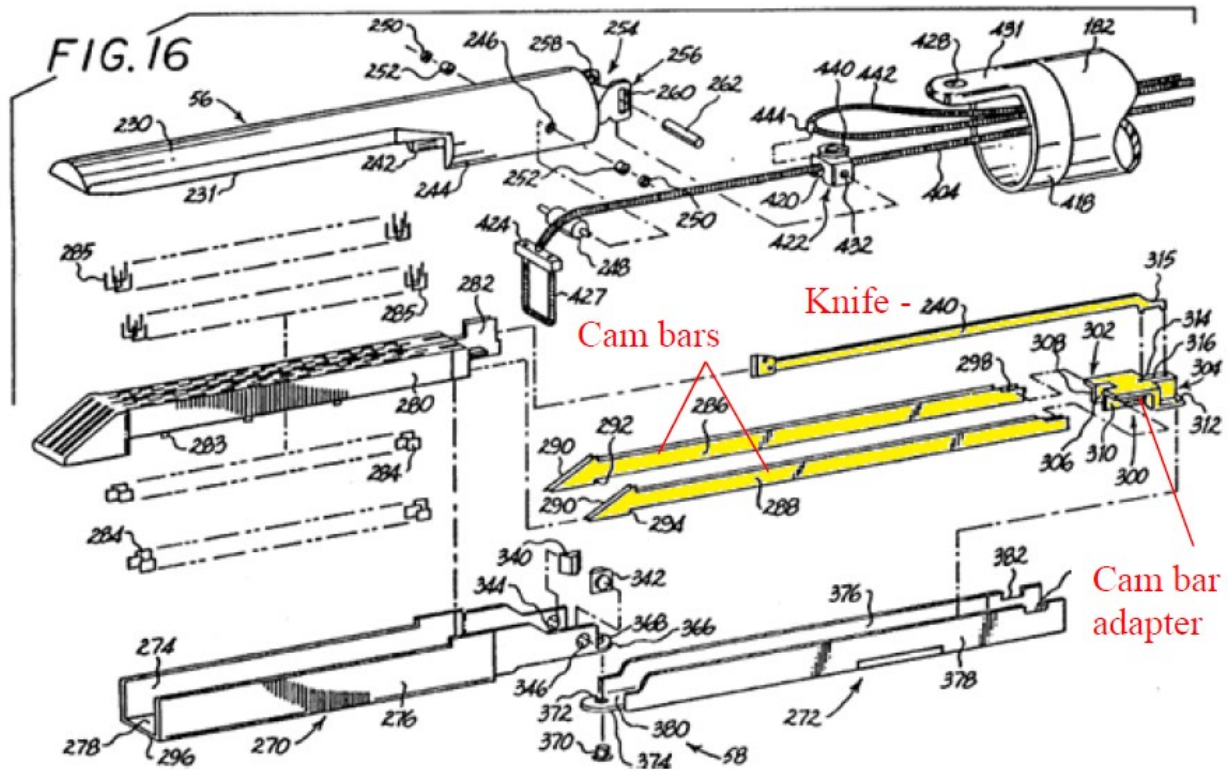


Figure 16 is an “exploded perspective view of the articulating cartridge assembly of the surgical instrument” of Figure 1. Ex. 1004, 48–49.

Petitioner’s annotation to Figure 16 includes highlighting in yellow cam bars 286, 288, knife 240, and cam bar adapter 300. According to Petitioner, knife 240 cuts tissue upon depression of firing trigger 96. Pet. 12 (citations omitted). Petitioner acknowledges, however, that knife 240 “is not an I-beam.” *Id.* at 14.

2. Green 695 (Ex. 1005)

Green 695 is a U.S. Patent titled “Surgical Instruments.” Ex. 1005, code (54). Green 695 describes its invention as relating to “an instrument

for use in applying surgical fasteners such as staples, clips and the like to living tissue.” *Id.* at 1:8–10.

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:

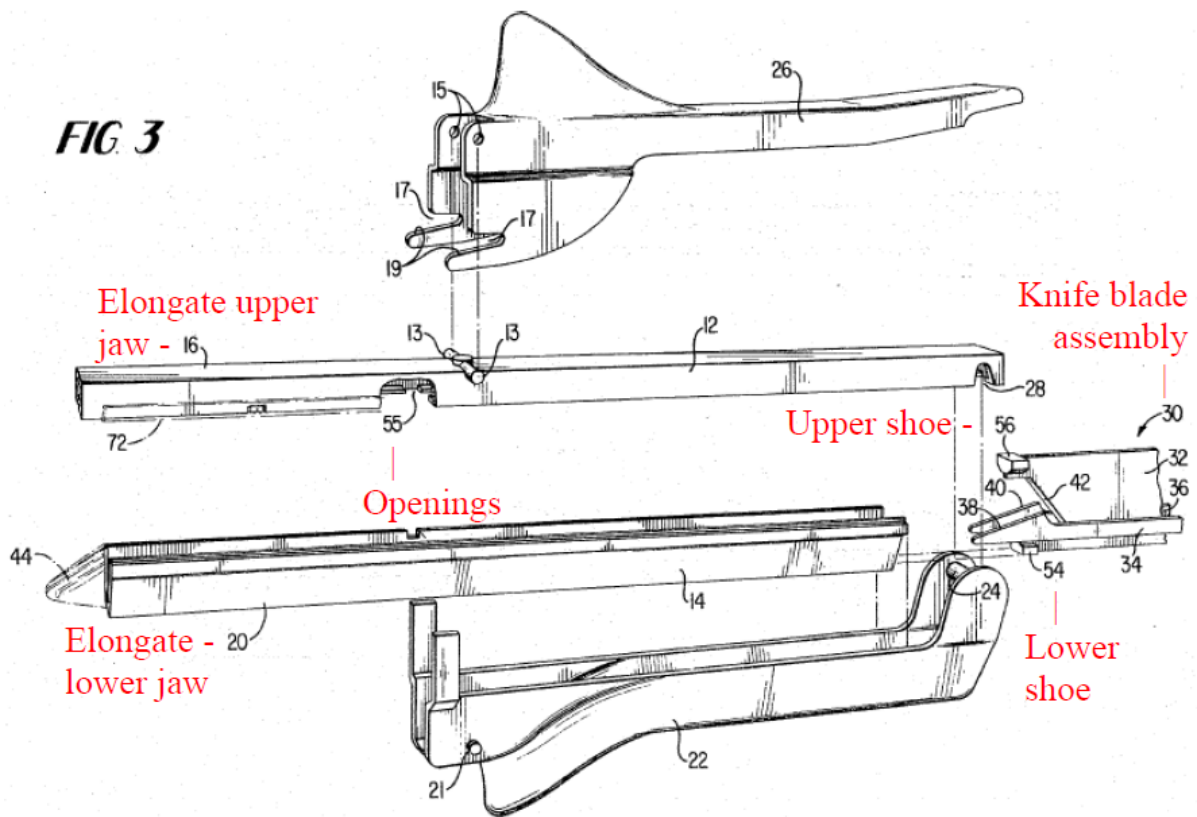


Figure 3 is a “side view of the instrument in an open condition.” Ex. 1005, 2:63. Petitioner’s annotations include identifying in red elongate upper jaw 16, openings 55, upper shoe 56, elongate lower jaw 20, lower shoe 54, and knife blade assembly 30. According to Petitioner, Green 695’s knife blade 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:

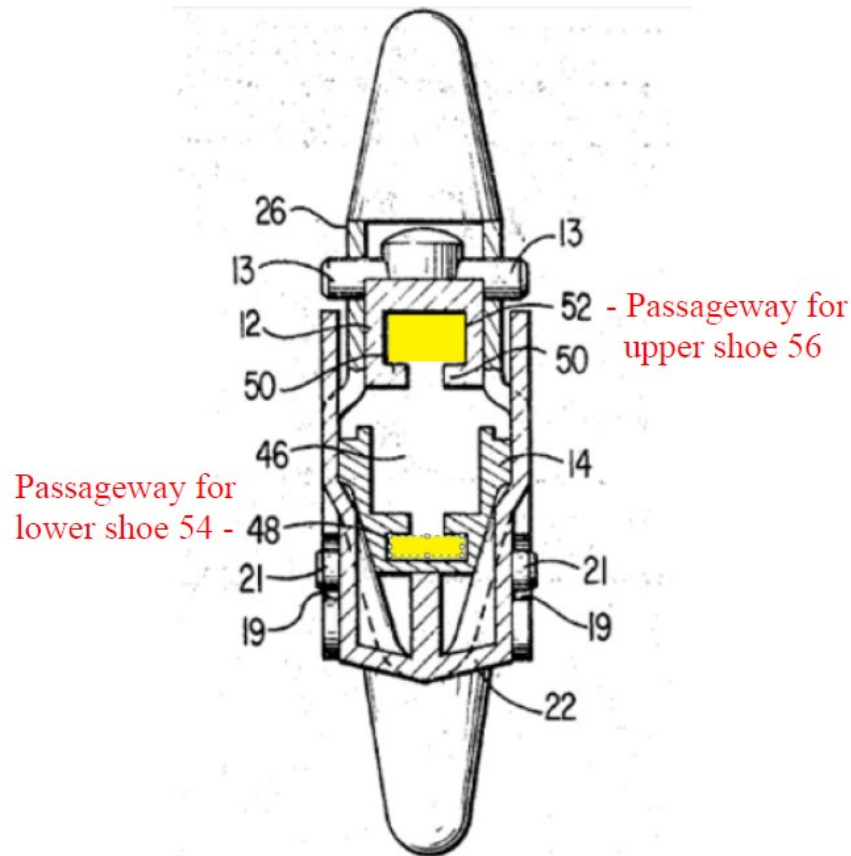


FIG. 6

Figure 6 is a section line of the side view of the surgical instrument in an assembled and closed condition. Ex. 1005, 2:59–60, 2:68. Petitioner's annotations include highlighting in yellow passageway for lower shoe 54 and passageway for upper shoe 56. According to Petitioner, this figure depicts Green 695's upper passageway 52 and lower passageway 48 (both shown in yellow), which receive upper shoe 56 and lower shoe 54, respectively. *See* Pet. 15 (citing Ex. 1005, 4:37–60).

3. *Knodel (Ex. 1006)*

Knodel is a U.S. Patent titled “Surgical Stapler Instrument.”

Ex. 1006, code (54). Knodel discloses that its “invention relates in general to surgical stapler instruments which are capable of applying lines of staples to tissue while cutting the tissue between those staple lines.” *Id.* at 1:5–7.

Petitioner asserts that Knodel discloses a closing trigger with gear system. *See* Pet. 26 (citations omitted). In support of this assertion, Petitioner submits an annotated version of Knodel’s Figure 3 (Pet. 27), which we reproduce, below:

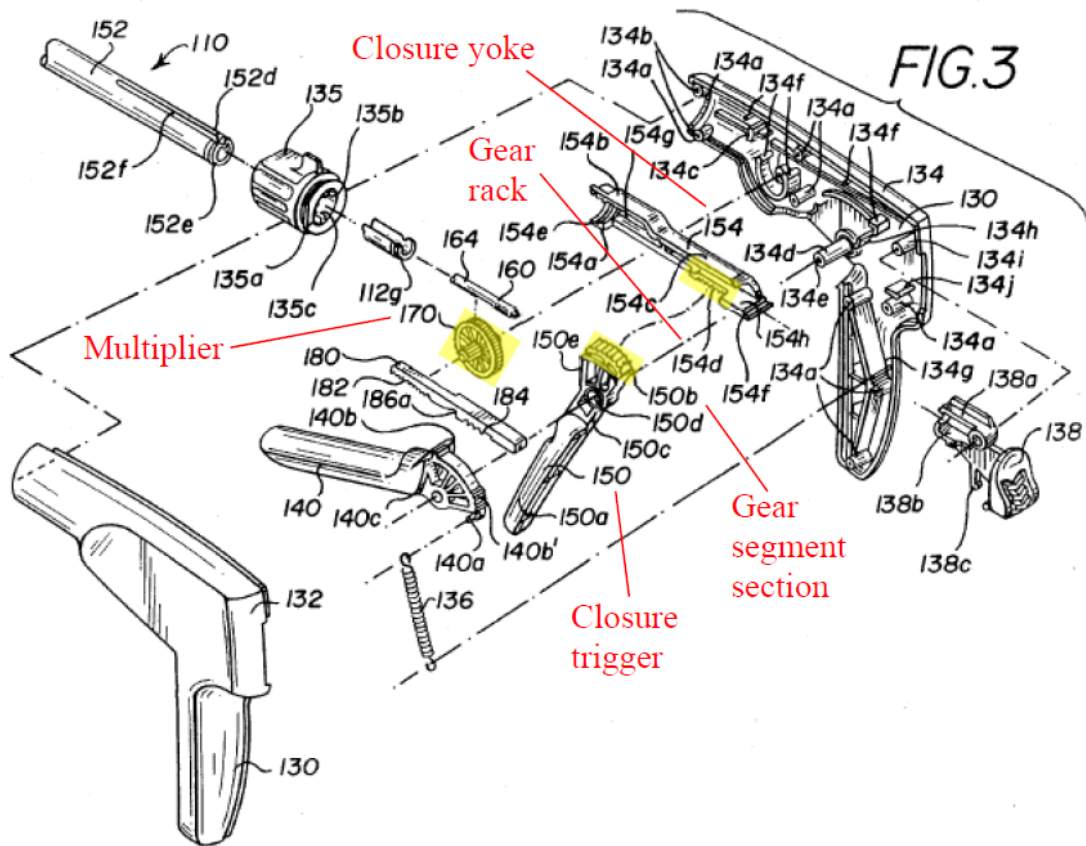


Figure 3 is an “exploded view showing the handle portion, the firing trigger, the closure trigger, the spring, the motion transfer mechanism, the yoke and the release button of the instrument.” Ex. 1006, 4:47–50. Petitioner’s

annotations include calling out multiplier 170, closure trigger 150, gear segment section 150b, gear rack 154d, and closure yoke 154. According to Petitioner, Knodel discloses closure trigger 150 with gear segment section 150b in meshing engagement with gear track 154d. Pet. 26 (citations omitted).

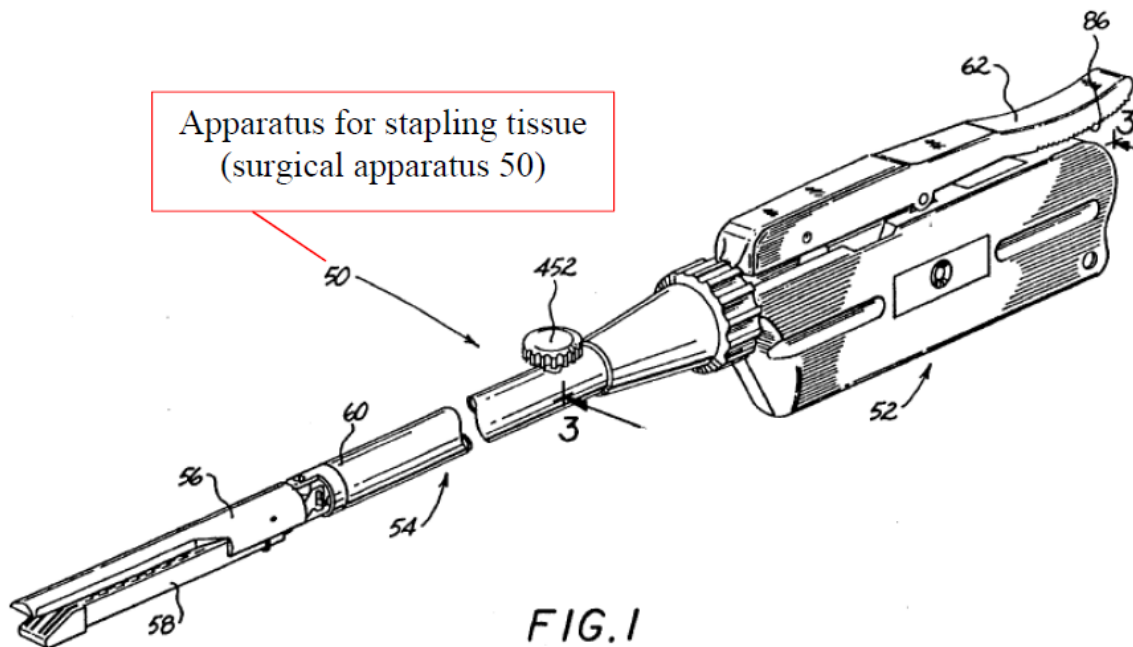
Knodel further discloses firing multiplier 170, which comprises first and second integral pinion gears 170a, 170b, which are shown in Figures 6 and 12. *Id.*

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:*”

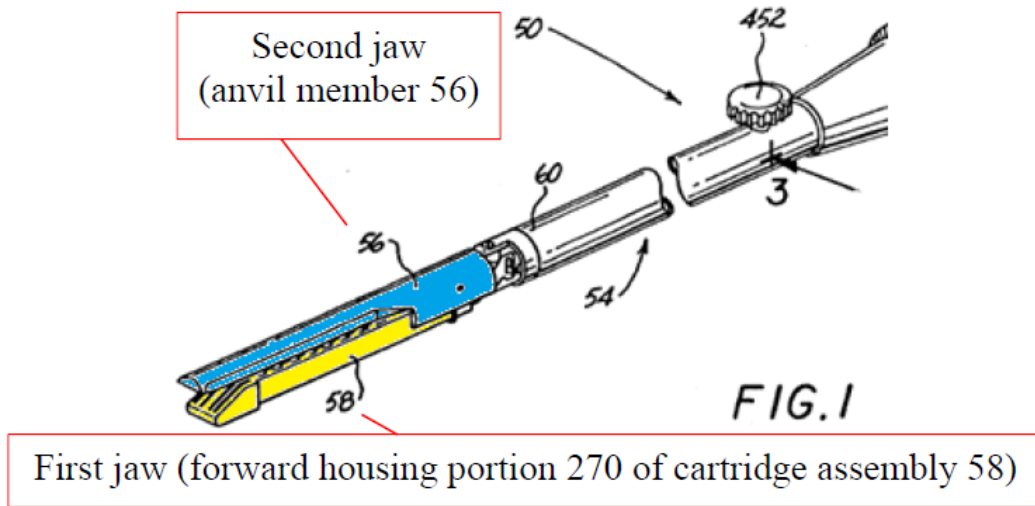
Petitioner submits that Green 209 discloses an apparatus for stapling tissue, submitting an annotated version of Green 209’s Figure 1. Pet. 19 (citing in part Ex. 1004, Fig. 1). We reproduce Green 209’s Figure 1, as annotated by Petitioner (*id.* at 20), below:



As shown above in annotated Figure 1, Petitioner submits that Green 209's surgical apparatus 50 is an apparatus for stapling tissue. *Id.* at 19.

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”

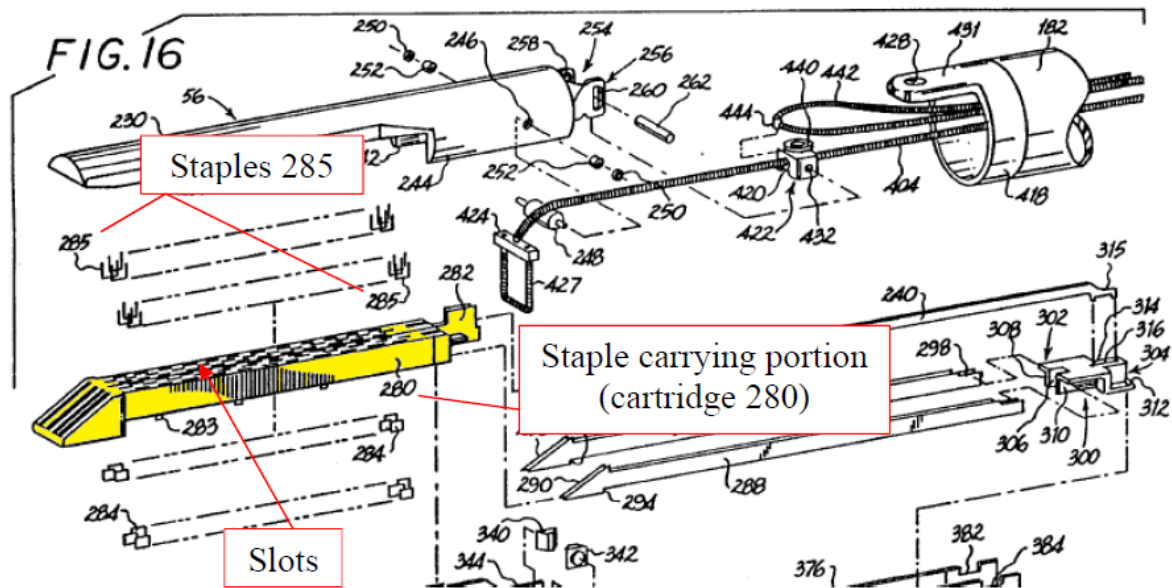
Petitioner asserts that Green 209 discloses this limitation, providing another annotated version of Green 209's Figure 1. Pet. 20–21 (citations omitted). We reproduce Petitioner's annotated Figure 1, below:



As shown in the above annotated Figure 1, Petitioner submits that 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).

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

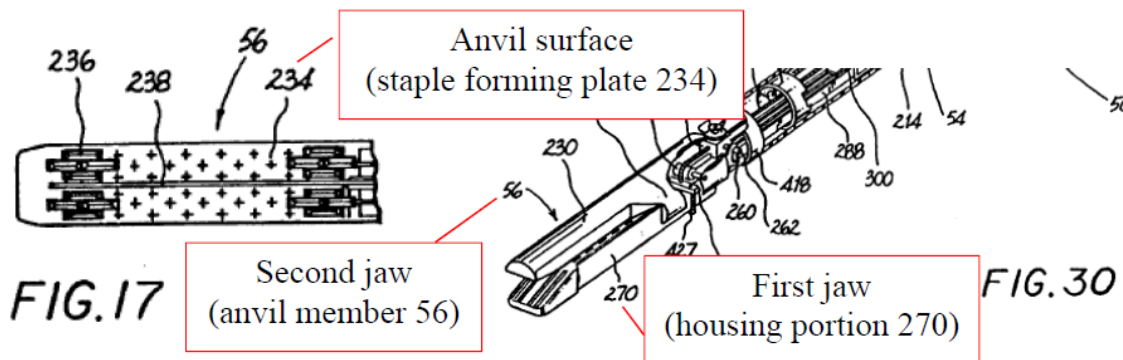
Petitioner asserts that Green 209 discloses this limitation, submitting an annotated version of Green 209's Figure 16. Pet. 22 (citations omitted). Below, we reproduce Petitioner's annotated Figure 16:



As shown above in annotated Figure 16, Petitioner submits that Green 209 discloses stapling carrying portion (cartridge 280, and highlighted in yellow) of first jaw defining slots (shown in Green 209's Figures 16, 18) through which staples 285 pass. *Id.* (citations omitted).

d) “[4.3] an anvil surface defined on the second jaw opposing the first jaw”

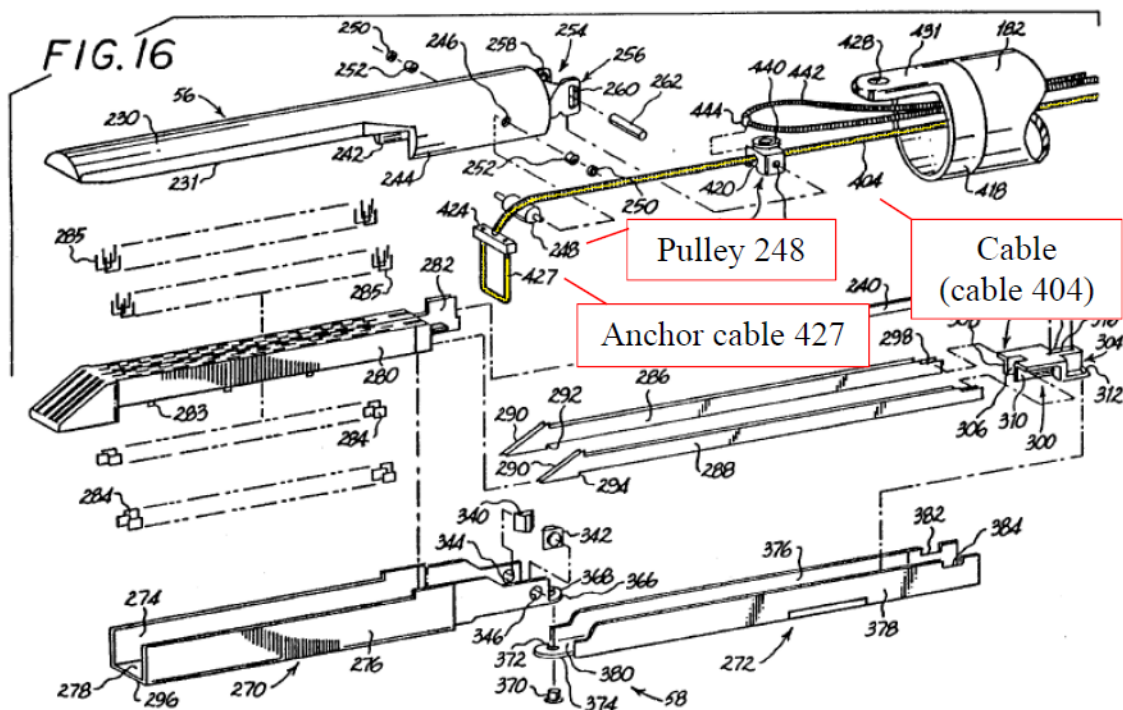
Petitioner asserts that Green 209 discloses this limitation, submitting annotated versions of Green 209's Figures 17 and 30. Pet. 22–23 (citations omitted). We reproduce annotated Figures 17 and 30, below:



As shown above in annotated Figures 17 and 30, Petitioner submits that 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).

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”

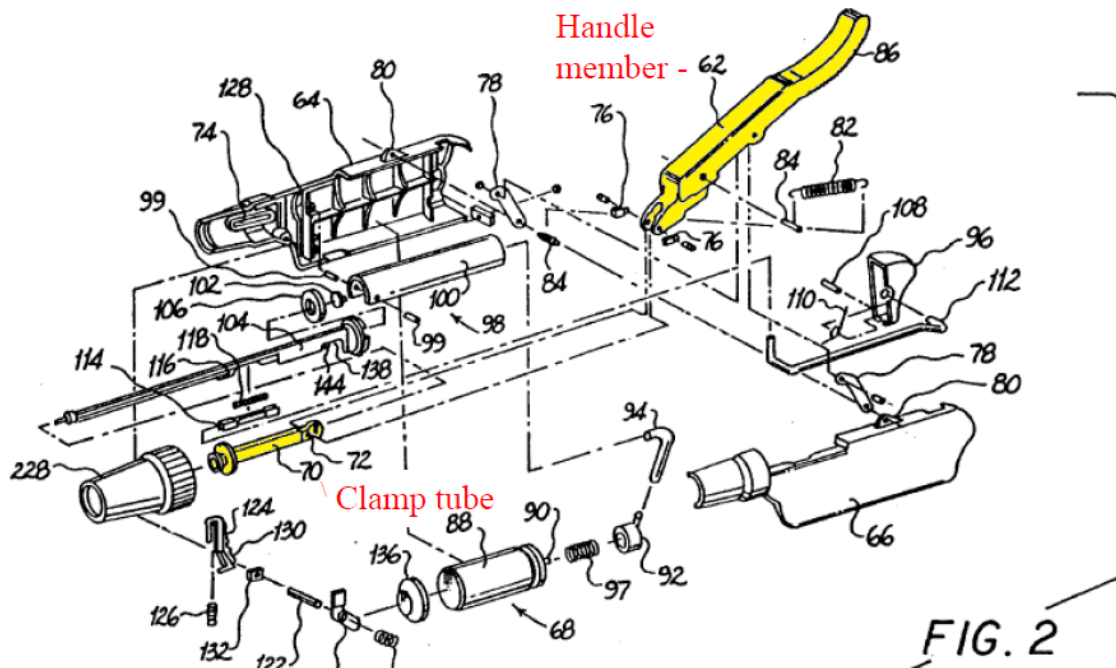
Petitioner relies on Green 209, when modified based on Knodel's teachings, for satisfying this limitation. *See* Pet. 23, 26. Petitioner submits an annotated version of Green 209's Figure 16 to support its assertions (Pet. 24), a copy of which we reproduce, below:



Petitioner calls out pulley 248, anchor cable 427, and cable 404 from Green's Figure 16. As also shown above, Petitioner submits that 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:

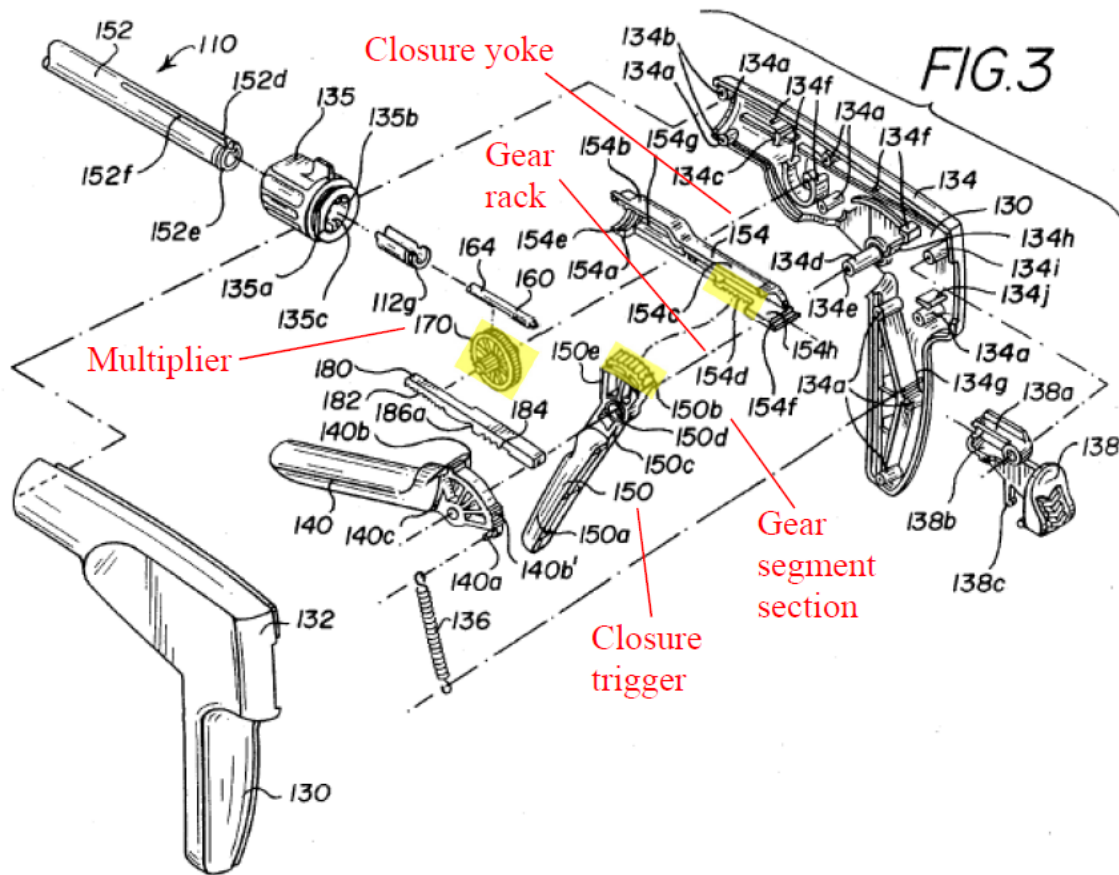


In the above-annotated Figure 2, Petition highlights handle member 62 and clamp tube 70. Petitioner asserts that Green 209's jaws are closed by pressing down on articulating handle member 62, driving clamp tube 70

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



In annotated Figure 3, Petitioner calls attention to closure yoke 154, gear rack 154d, gear segment section 150b, closure trigger 150, and multiplier 170. Petitioner submits that this figure depicts Knodel’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 discloses firing multiplier 170 with first and second pinion gears 170a, 170b identified in Figures 6 and 12. *Id.*

In combining Green 209 with Knodel, Petitioner reasons that a skilled artisan would have been motivated to modify Green 209 to use Knodel’s gears to increase design flexibility. Pet. 27 (citing Ex. 1003 ¶ 74; Ex. 1006, 11:16–25). Dr. Knodel testifies that “increasing the drive system’s mechanical advantage would, for example, permit a given input force to

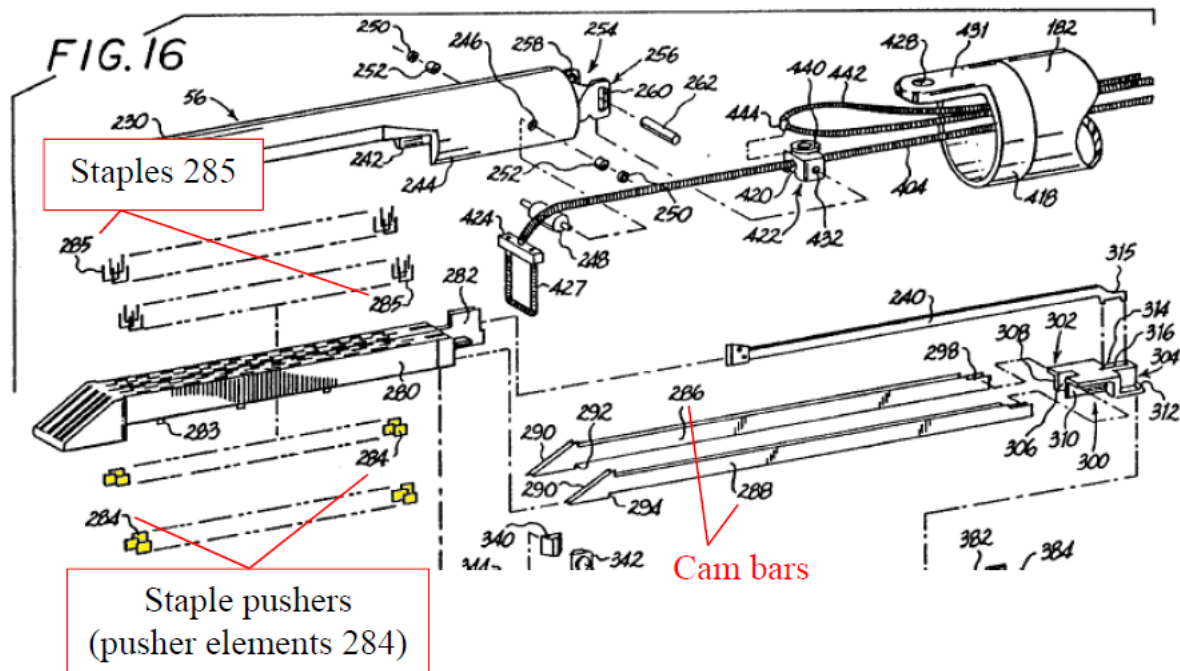
produce a larger output force, which may be advantageous for clamping certain tissues with a surgical stapler.” Ex. 1003 ¶ 74. In support of this testimony, Knodel discloses,

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).

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 asserts 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:

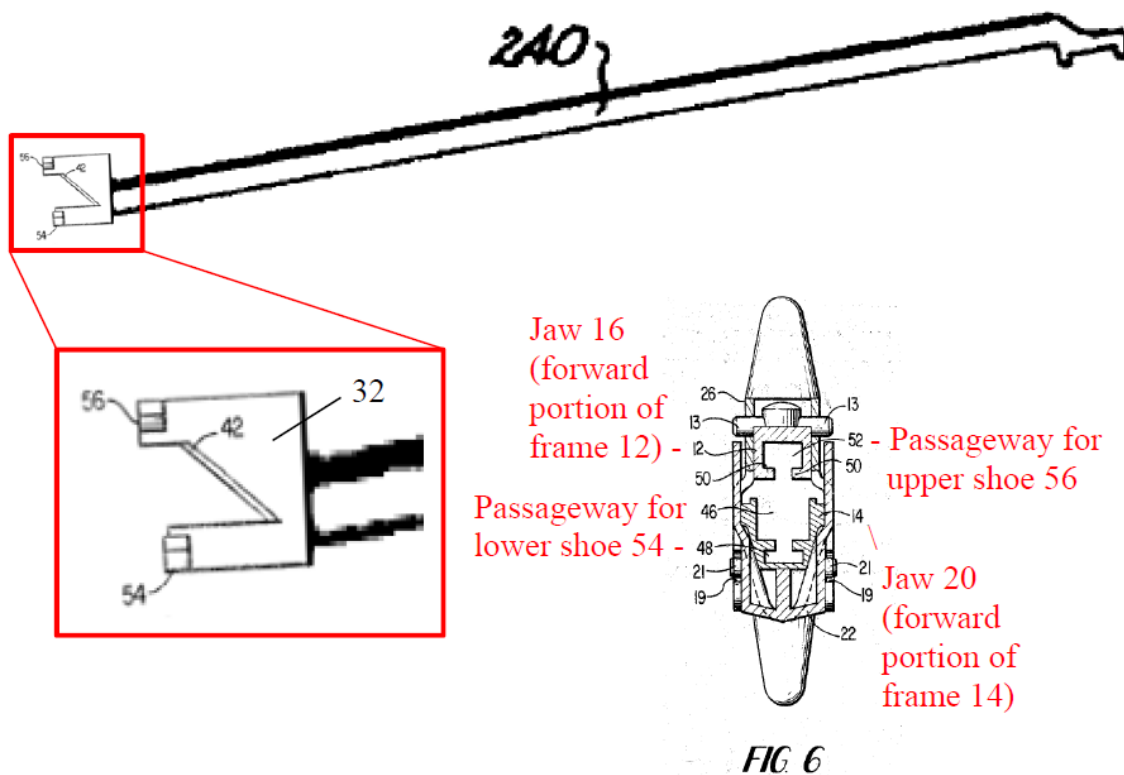


As shown above in annotated Figure 16, Petitioner identifies in red cam bars 286, 288, staples 285, and staple pusher elements 284. Petitioner submits that Green 209 discloses staple pusher (pusher elements 284) configured to cause staples (285) to move from a first position (in which staples 285 are within cartridge 280) to a second, ejected position. Pet. 28 (citations omitted).

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 an I-beam like that disclosed in Green 695, including 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 annotated Figure 6, Petitioner submits that Green 209's modified knife 240 includes knife blade carrier 32 with upper shoe 56 and lower shoe 54. *See id.* 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. *See id.*

In modifying Green 209, as shown above, Petitioner reasons that a skilled artisan would have been motivated to make 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.

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.

h) Patent Owner’s Arguments

Patent Owner argues that a skilled artisan would not have combined Green 209 with Green 695 as Petitioner has done. PO Resp. 2. In support of this argument, Patent Owner presents the following interrelated arguments (*id.* at 2–25):

1. “Adding an I-beam to Green-209’s stapler results in a serious safety issue and would have rendered Green-209’s stapler unsatisfactory for its intended purpose of endoscopic use” (*id.* at 5).
2. “Adding an I-beam to Green-209 is unnecessary and adds duplicative functionality” (*id.* at 11).
3. “Adding an I-beam to Green-209’s stapler would increase the complexity and cost to manufacture and commercialize the stapler” (*id.* at 14).

4. “Adding an I-beam to Green-209’s stapler would require a substantial redesign, which is not accounted for in the Petition” (*id.* at 20).

5. “Petitioner’s motivations to combine Green-209 and Green-695 are unavailing” (*id.* at 22).

We address each of Patent Owner’s arguments separately, below.

i) Analysis

(1) “Adding an I-beam to Green-209’s stapler results in a serious safety issue and would have rendered Green-209’s stapler unsatisfactory for its intended purpose of endoscopic use”

Patent Owner argues that adding an I-beam to Green 209’s stapler would create a *safety issue*. PO Resp. 5. Specifically, Patent Owner contends that adding an I-beam eliminates an inherent safety feature of Green-209’s stapler. *See id.* at 5–6.

As explained by Patent Owner, Green 209’s stapler includes return springs 140, 142 for retracting the knife to its start position after firing. *See id.* at 7 (citations omitted). With Green 209’s stapler, if springs 140, 142 fail to return the knife to its retracted position, “the surgeon can simply open the stapler to release the tissue [and] remove the stapler from the patient.” *Id.* Patent Owner contends that this “failure does not pose any safety issues to Green-209’s design as-is.” *Id.*

Turning to the proposed modification, Patent Owner contends that the addition of an I-beam creates a “serious problem.” *Id.* Patent Owner explains that *if* Green 209’s device failed, the presence of an I-beam “would prevent the jaws of Green-209’s stapler from opening to release the tissue, and the device would literally be stuck inside the patient and need to be

manually excised via an incision.” *See id.* at 8 (citing Ex. 2002 ¶¶ 54–56) (emphasis omitted).

Importantly, Patent Owner’s argument is premised on a *failure* of Green 209’s retraction mechanism. That is, Patent Owner’s safety issue *only arises* if Green 209’s stapler fails in some way. Patent Owner does not argue that Petitioner’s proposed modification (adding an I-beam to Green 209’s stapler) in and of itself prevents Green 209’s retraction springs 140, 142 from working. Rather, Patent Owner’s argument is premised on one of *many possible failures* of Green 209’s retraction mechanism. In particular, Patent Owner’s expert, Mr. Juergens, testifies,

Several different conceivable failures would result in an I-beam preventing the jaws of Green-209’s stapler from opening. For example, Green-209 includes a counter mechanism that “indicate[s] to a user the number of times the instrument has been operated or, alternatively, the number of remaining firings available.” Green-209, 5:34-45. But, like all mechanical and electrical features, there is a potential for failure. For example, the counter could fail to advance so that the surgeon does not know how many firings s/he has left and, as a result, *the stapler could potentially run out of gas* midway through a firing. *The venting valve could malfunction.* It is also possible[] that the stapler may be used to grab more tissue than can be handled by the jaws given the fixed spacing of the I-beam. In this case, *the cutter/stapler mechanism could advance part way or even all the way through the cut but not have enough force in the return springs 140, 142 to overcome stiction between the I-beam and the jaws to push the I-beam back out of the jaws.* Failures like these (and others not mentioned) can have catastrophic effects during surgery, which is why medical device companies regularly validated the designs of their staplers. Here, where Green-209’s stapler is gas powered, there is an increased risk of failure because the pushing and pulling of the I-beam is at the mercy of a part that cannot be manually controlled and is subject to inherent failures.

Ex. 2002 ¶ 55 (emphases added). In summary, Mr. Juergens identifies three possible points of failure: (1) the stapler could “run out of gas” midway through firing; (2) the “venting valve could malfunction”; and (3) return springs 140, 142 may lack sufficient force to overcome the stiction between the I-beam and jaws. *See id.*

Before addressing each of these possible points of failure, we provide a detailed discussion of Green 209’s pneumatic system, starting by reproducing Green 209’s Figure 9, below:

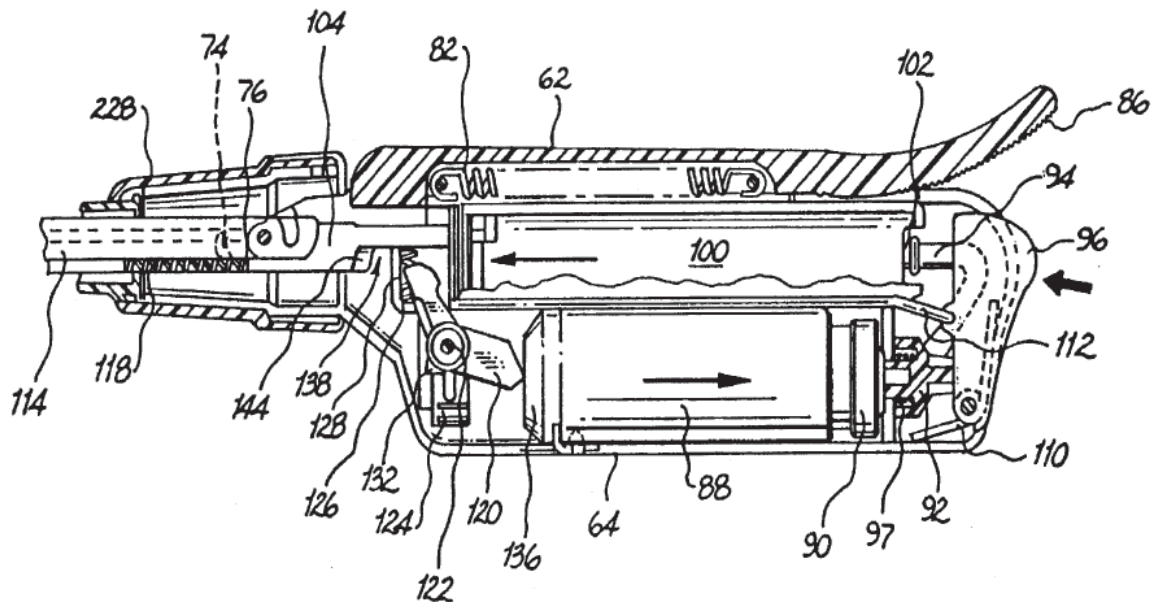


Figure 9 “is a side plan view in cross section showing the frame and pneumatic assembly of the present invention in the clamped and fired position.” Ex. 1004, 6:30–32. Green 209 discloses,

Pneumatic system 68 is wholly contained within housing members 64 and 66 and includes a container 88 of relatively low pressure gas longitudinally slidably mounted therein. The pressure of the gas in container 88 during operation of the stapler is typically less than about 200 p.s.i.g. and preferably in the range of about 80 p.s.i.g. to about 160 p.s.i.g. Container 88 dispenses the relatively low pressure gas through stem 90, valve

92, and gas tube **94** when the firing trigger **96** is depressed. Spring **97** is positioned between container **88** and valve **92** and functions to hold the container **88** in position spaced from valve **92**. Valve **92** is fixed within housing members **64** and **66** and is longitudinally adjustable by means of set screw **93** (see FIG. **11**). This feature permits the position of valve **92** to be longitudinally changed to compensate for manufacturers' variations in length among containers **88** between a distal end and the proximal end of stem **90**. A pneumatic actuator **98** is disposed above container **88** within housing members **64** and **66**. Actuator **98** includes a pneumatic cylinder **100** which is held in place by opposed pins **99**. Cylinder **100** is substantially closed at the proximal end thereof but for a ferrule **102** extending therethrough and is open at its distal end, wherein a pneumatic piston **104** is mounted for reciprocal motion therein on an axis which is parallel to the longitudinal axis of elongated portion **54**.

Ex. 1004, 12:1–29. Green 209 further discloses,

When the instrument is in the clamped configuration, depression of firing trigger **96** moves trigger rod **112** distally in the longitudinal direction causing piston slide **144** to engage and pivot rocking lever **120** which, in turn, engages pusher disk **136** and moves container **88** into contact with valve **92** to dispense gas and propel piston **104** in the distal direction (see FIGS. **9–11**).

As piston **104** moves distally, rocking lever **120** remains in its pivoted firing position by contact with the bottom surface of piston **104**. A gap **138** is formed in the bottom surface of piston **104** adjacent the proximal end thereof which effectively allows rocking lever **120** to disengage from piston **104** and return to a position wherein container **88** is released from engagement with valve **92**, thereby stopping the flow of gas into pneumatic cylinder **100**.

A pair of return springs **140** and **142** disposed in elongated portion **54** drive piston **104** back to its initial prefired position.

Ex. 1004, 13:28–38; *see also id.* at Figs. **9–11** (depicting side cross-sectional views of Green 209's pneumatic firing assembly).

Turning back to Patent Owner’s argument, Patent Owner’s expert speculates that (1) “the stapler could potentially run out of gas midway through the firing,” (2) the “venting valve could malfunction,” or (3) that retraction springs 140, 142 may lack the spring force to overcome the friction between the I-beam and jaws. Ex. 2002 ¶ 55. Having reviewed the evidence of record, however, we are not persuaded with Patent Owner’s theories on failure. After weighing the competing expert testimony, we agree with and credit the testimony of Petitioner’s expert, Dr. Knodel. In particular, *even if* Patent Owner’s problems exist, we agree with Dr. Knodel that they are within a skilled artisan’s abilities to account for. See Ex. 1025 ¶ 18.

As to the first possible point of failure, Mr. Juergens speculates that Green 209’s gas cylinder may “run out of gas midway through the firing.” Ex. 2002 ¶ 55. Mr. Juergens’s testimony presumes, however, that Green 209’s gas cartridge cannot be recharged or replaced, and once the pressure of working gas in container 88 falls below a certain pressure, the I-beam may remain stuck in Green 209’s jaws. This argument is not persuasive for at least two reasons.

First, Green 209 describes gas staplers that use *replaceable* gas supplies. Specifically, Green 209 suggests that gas containers 88 are replaceable, as Green 209 discloses that “the position of valve 92 [may] be longitudinally changed to compensate for *manufacturers’ variations in length among containers 88*.” See *id.* at 12:17–20 (emphasis added); see also *id.* at 2:61–63 (“[E]ven if the gas supply is replaceable, it undesirably increases the frequency with which the gas supply must be replaced.”). Because Green 209 teaches that its gas containers 88 are replaceable, we do

not envision a problem arising if the stapler “runs out of gas midway,” which Patent Owner argues would require the surgeon to perform *another* incision to excise the stapler from the patient. *See* PO Resp. 7–8. Indeed, Green 209’s gas containers 88 are located at the proximal end of the device, near the surgeon, and even if container 88 “ran out of gas,” we do not see why this would require the surgeon to perform an invasive surgical procedure to excise the device from the patient, rather than simply replacing or recharging container 88.

Second, the pressurized gas is used to urge the piston and I-beam from a proximal position to a distal position, not the other way around. *See supra* pp. 34–36. If container 88 “runs out of gas,” we understand that the gas within cylinder 100 will fail to drive piston 104 distally. In this event, the force from springs 140, 142, which are biased to keep the assembly in a retracted position, will be unopposed by a contrary distally-directed force on piston 104. As a result, the springs will maintain piston 104 in a retracted position, and the I-beam will not be stuck within the jaws.

As to Patent Owner’s second possible “failure,” Mr. Juergens speculates that Green 209’s “venting valve could malfunction.” Ex. 2002 ¶ 55. Absent a more detailed explanation, we assume that Patent Owner is referring to valve 92. Having reviewed Green 209, however, we do not envision how malfunction of valve 92 would create the problem that Mr. Juergens testifies to.

Patent Owner’s argument presumes that valve 92 will “malfunction” (Ex. 2002 ¶ 55), thus preventing the I-beam from being retracted and requiring the surgeon to perform an invasive incision to excise the device from the patient (*see* PO Resp. 7–8). Yet, we do not see how a

“malfunction” of valve 92 would result in a scenario where the I-beam remains stuck in Green 209’s jaws. Specifically, forces from springs 140, 142 urge piston 104 to remain in the retracted position, and we do not see how failure of valve 92 would result in a scenario where the I-beam is stuck within Green 209’s jaws. If, for the sake of argument, Mr. Juergens believes that container 88 fails to disengage from valve 92, thereby *locking pressure* within cylinder 100, we do not see why the surgeon would not simply manually slide container 88 longitudinally to disengage container 88 from valve 92, thereby releasing pressurized gas from cylinder 100, and retracting the I-beam from the jaws. As with Mr. Juergens’s first speculated failure (loss of gas pressure), Mr. Juergens’s second speculated failure (malfunction of valve 92) is located at the *proximal end* of Green 209’s stapler, and a surgeon would presumably have access to valve 92 to disengage container 88 from the valve.

As to Patent Owner’s third hypothesized failure, in which return springs 140, 142 lack sufficient force to retract the I-beam, Patent Owner’s argument has some merit. Ex. 2002 ¶ 55. In support of this argument, Patent Owner cites to Dr. Knodel’s cross-examination testimony from a different *inter partes* review challenging a different patent. *See* PO Resp. 8 (referencing Dr. Knodel’s cross-examination testimony in IPR2019-00880, filed as Ex. 2005 in this proceeding, at 47:1–8). In this other *inter partes* review, Dr. Knodel testified in response to the following questions:

Q. Okay. And what’s your experience with respect to retraction springs and how often they don’t work?

A. In the case of a – of endocutters, it is a common issue with endocutters, and you can check the MDR records of the FDA that clamping on too thick of tissue is a continual problem, has been over the entire life of endocut – endoscopic linear

stapling; and when that occurs, you can bind – you can bind the jaw so that the spring will not have sufficient force to pull it back, and, therefore, you – because it would be locked on the tissue, you have to provide some kind of manual retraction because it's not just reliable enough for such a critical function. To leave this device clamped on tissue is a huge – this – and we're not talking about one more step of an operation, we're taking about, you know, cutting a person open to re- -- to be able to get the device, you know, cut out of their body.

So, and by – in my opinion, they, the Swayze and Shelton II references that – that have automatic and – but with lots of provisions for why there's a manual backup, it's very, very clear that that is because the automatic system does not work all the time.

Q. Okay. But that's not something you addressed in designing the EZ 45 or the ETS 45?

A. In the EZ 35 or EZ 45, there's no E-beam and no I-beam; therefore, it doesn't matter if the firing system doesn't retract because you're not locked on tissue; that's the beauty of it. You can unclamp an EZ 45 and EZ 35 even if the firing system has not retracted, and that is a safety feature that was lost with the introduction of I-beams and E-beams.

Ex. 2005, 45:18–47:8.

We agree with Patent Owner that Petitioner's proposed modification *may* make retraction of Green 209's knife/I-beam seemingly more difficult if the forces from springs 140, 142 fail to overcome the frictional forces imposed between Green 209's jaws and the I-beam. *See, e.g.*, Ex. 2002

¶ 54. Indeed, Dr. Knodel's cross-examination testimony in related IPR2019-00880 provides *some support* for this finding. *See* Ex. 2005, 45:18–47:8.

When reviewing the entirety of Dr. Knodel's testimony, however, including his supplemental declaration (Ex. 1025), we are persuaded by Dr. Knodel that Patent Owner fails to fully appreciate the cross-examination

testimony from the related proceeding, as the testimony addresses a skilled artisan's proclivity—to add an I-beam to a spring-loaded retraction mechanism—during a *different time of invention*. See Ex. 1025 ¶¶ 20, 21. In particular, to clarify his cross-examination testimony in IPR2019-00880 (Ex. 2005), Dr. Knodel explains that at the time of the '650 patent, “a spring alone was considered sufficient for I-beam retraction,” whereas, the testimony in IPR2019-00880 addresses a skilled artisan's knowledge as of “2005 (more than four years after the alleged priority date of the '650 patent) [when it became mandatory] to add a backup manual retraction mechanism to a spring return.” *Id.* ¶ 21. Having clarified this point, we agree with Dr. Knodel's testimony that a “spring alone was considered sufficient for I-beam retraction at the time of the '650 patent.” *Id.*

We further agree with Dr. Knodel's testimony that at least U.S. Patent No. 5,507,426 to Young (Ex. 1009, “Young”) disclosed a system with a spring-loaded retraction mechanism and an I-beam. Ex. 1025 ¶ 16 (citing Ex. 1009, Figs. 2, 5, 6). Indeed, Figure 2 of Young depicts “I-beam” (54, 56, 80) and Figures 5 and 6 depict spring 112 within chamber 100 and biased to return piston 98 to return to its proximal direction. See Ex. 1009, 5:37–44; see also *id.* at 6:44–46 (“further comprising a coiled return spring disposed within the piston chamber to bias the piston in a proximal direction”). Dr. Knodel testifies, correctly, that: “Under [Patent Owner's] theory . . . [,] Young's stapler, which uses only a spring to retract the I-beam, would have suffered the same safety issues as the proposed combinations of Green-209 and Green-695. Yet that did not deter the inventors of Young.” Ex. 1025 ¶ 16. We credit Dr. Knodel's testimony that “Young confirms that

a spring alone was considered sufficient for I-beam retraction at the time of the '650 patent.” *Id.* at ¶ 21.

Moreover, and *even if* a spring, by itself, was insufficient for retraction at the time of the '650 patent, we credit Dr. Knodel’s testimony that “the selection of an alternative retraction mechanism (*e.g.*, a manually operated mechanical slide or a reversible motor) would have been well within a POSITA’s abilities.” *Id.* ¶ 18. We are not persuaded that the use of a spring-loaded retraction mechanism with an I-beam would have been so problematic that it would have discouraged a skilled artisan from adding an I-beam to Green 209’s stapler, considering the benefits that the I-beam would have provided. *See* Pet. 17 (identifying multiple benefits to adding an I-beam, including improved alignment and stabilization of the stapler’s jaws).

In summary, even if the addition of an I-beam to Green 209’s stapler *may* have made it more difficult to retract the I-beam from the jaws (in the unlikely event that springs 140, 142 fail to retract the I-beam from the bound jaws), this concern would not have discouraged a skilled artisan from adding an I-beam to Green 209’s spring-loaded retraction mechanism, considering the benefits that adding an I-beam would have provided (*see id.*).

(2) “*Adding an I-beam to Green-209 is unnecessary and adds duplicative functionality*”

Patent Owner asserts that “Green-209’s stapler is stable and aligned without an I-beam.” PO Resp. 11–12 (citing Ex. 2002 ¶¶ 59–71). Patent Owner explains: “Adding an I-beam to Green-209’s stapler therefore does not solve any problem or improve the stapler’s functionality. Rather, adding the I-beam *creates* problems for the stapler.” *Id.* at 12. In explaining why

Green 695 used an I-beam, Patent Owner states that Green 695 had an “unstable pivot point” that would result in its jaws “eventually becom[ing] misaligned due to acting forces as soon as the stapling function was activated.” *Id.* (citing Ex. 2002 ¶¶ 61–64). In differentiating Green 209’s stapler, Patent Owner asserts: “None of these issues, however, are present in Green-209.” *Id.* at 12–13.

Patent Owner’s argument is not persuasive. Having reviewed Green 695, Green 209, and the testimony of Dr. Knodel and Mr. Juergens, we credit Dr. Knodel’s testimony that if “a POSITA used a longer anvil and/or a lightweight material having a thickness that is not sufficient to withstand the clamping and firing forces, then an I-beam (or a similar structure) would have been required to stabilize and align the jaws.” Ex. 1025 ¶ 5.

As to Patent Owner’s assertion that Green 695 has an unstable pivot point, which explains why Green 695 used an I-beam (*see* PO Resp. 11–13), we disagree. Rather, we agree with and credit Dr. Knodel’s testimony that “nothing in Green-695 suggest[s] that the pivot point was unstable or that an I-beam was added to stabilize the pivot mechanism.” Ex. 1025 ¶ 6. In comparing the stability of Green 695’s pivot point with Green 209’s pivot point, we further agree with Dr. Knodel that “Green 695’s pivot point is more stable than Green 209’s pivot point,” because, “unlike Green 209’s pivot point, which moves up and down in slot 260 during operation, Green-695[’s] pivot point is fixed during operation.” *Id.* ¶ 7 (citing Ex. 1005, Figs. 1, 2; citing *also* Ex. 1004, 15:40–48, Figs. 16, 28).

Green 695 further identifies a problem that existed in the prior art with surgical staplers, namely, distortion of the jaws when clamping tissue. *See* Ex. 1005, 1:49–57. Specifically, Green 695 discloses,

With stapling instruments of the type described, relatively large forces are involved in clamping the tissue to be fastened and in ejecting the individual staples, causing these to penetrate the gripped tissue and to be closed against the anvil. Such forces tend both to separate the jaws vertically and to laterally distort the jaws, thereby hindering accurate stapling. This problem is of course accentuated if relatively light-weight disposable materials are to be used for manufacture of the jaw frames.

Id. Green 695 further discloses that if the jaw frames are manufactured from light-weight materials, the problem of jaw distortion is exacerbated. *See id.*

As to Patent Owner’s argument that Green 209’s jaws are already manufactured from light-weight materials (*see* PO Resp. 14 (citing Ex. 1005, 2:40–43)), we disagree.

Although Green 209 discloses that “[u]se of a relatively *low pressure gas is advantageous* to enable a stapler to be made of lighter construction and less expensive materials” (Ex. 1004, 2:40–43 (emphasis added)), Green 209 *does not* disclose or suggest that its *jaws* are made from light-weight materials (*see* Ex. 1025 ¶¶ 9, 10 (confirming the same)). We agree with and credit Dr. Knodel’s understanding of this disclosure that a “POSITA would have understood that the use of a relatively low pressure gas would enable the pneumatic system (e.g., the air tanks and the components actuated by them) to be made of lighter construction and less expensive materials.” *Id.* ¶ 10.

Petitioner’s reasoning that a POSITA would have added an I-beam to Green-209’s stapler to improve alignment and stabilization of the jaws during application and securing of the fasteners, and to enable use of lightweight disposable materials for the manufacture of the jaws, is reasonably supported by the testimony of Dr. Knodel (*see e.g.*, Ex. 1003 ¶¶

51, 52) and the express teachings of Green 695 (*see e.g.*, Ex. 1005, 1:49–62, 2:48–56).

(3) “*Adding an I-beam to Green-209’s stapler would increase the complexity and cost to manufacture and commercialize the stapler*”

Patent Owner argues that Petitioner’s proposed modification of adding passageways in Green 209’s upper and lower jaws for receiving an I-beam, would have been impractical. *See* PO Resp. 14–16. Patent Owner’s expert, Mr. Juergens, testifies: “In my opinion, the modifications that would be required to implement Green-695’s passageways 48, 52 in Green 209’s stapler would have been extremely difficult to implement cost effectively.” Ex. 2002 ¶ 77. Mr. Juergens explains: “[B]ecause these complex and expensive modifications would *not result in any positive benefit* to Green-209’s stapler, a POSITA would not have been motivated to combine Green-209 with Green-695 in the manner suggested.” *Id.* Mr. Juergens further explains that the T-slot passageways that Petitioner proposes to include in Green 209’s jaws are “one of the more difficult cuts to make on a machine because it requires cutting into a thick piece of metal and milling an opening having different widths at different depths to form the ‘T’ shape therein.” *Id.* ¶ 82 (citation omitted). Mr. Juergens testifies, “Implementing the T-slots in a very small device . . . would have been very difficult to do and that would have weighed heavily on a POSITA’s mind and deterred them from making the combination.” *Id.* ¶ 86.

Although we agree that the proposed modification would have likely added costs to the proposed stapler, in that the modified stapler would have

required T-shaped slots in its jaws and an I-beam to engage those slots, nevertheless, it is well established that tradeoffs regarding costs or manufacturability do not necessarily obviate a proposed modification. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”). Patent Owner’s argument and Mr. Juergens’s testimony assumes that the proposed modification provides *no benefit*. *See, e.g.*, Ex. 2002 ¶ 77 (“because these complex and expensive modifications *would not result in any positive benefit* to Green-209’s stapler, a POSITA would not have been motivated to combine Green-209 with Green-695 in the manner suggested”). We disagree with this assumption. Rather, we agree with Petitioner’s reasoning that the proposed modification would have improved alignment and stabilization of Green 209’s jaws, allowing the use of light-weight disposable materials and longer staple cartridges, which may further reduce the number of cartridges used in a procedure. *See* Pet. 17 (citing Ex. 1003 ¶¶ 51, 52). We find that the additional cost incurred from the proposed modification would not have deterred a skilled artisan from making the proposed combination, in light of the extensive improvements realized from the modification. *See* Ex. 1025 ¶ 25 (testifying that the additional cost of adding an I-beam did not deter the inventor of Green 695 from adding an I-beam to a prior art stapler).

(4) “Adding an I-beam to Green-209’s stapler would require a substantial redesign, which is not accounted for in the Petition”

Patent Owner further argues that “[a]dding an I-beam to Green-209’s stapler would require a complete redesign of the pulley system.” PO Resp. 20. To support this assertion, Patent Owner submits an annotated version of Green 209’s Figure 28 (*id.*), which we reproduce, below:

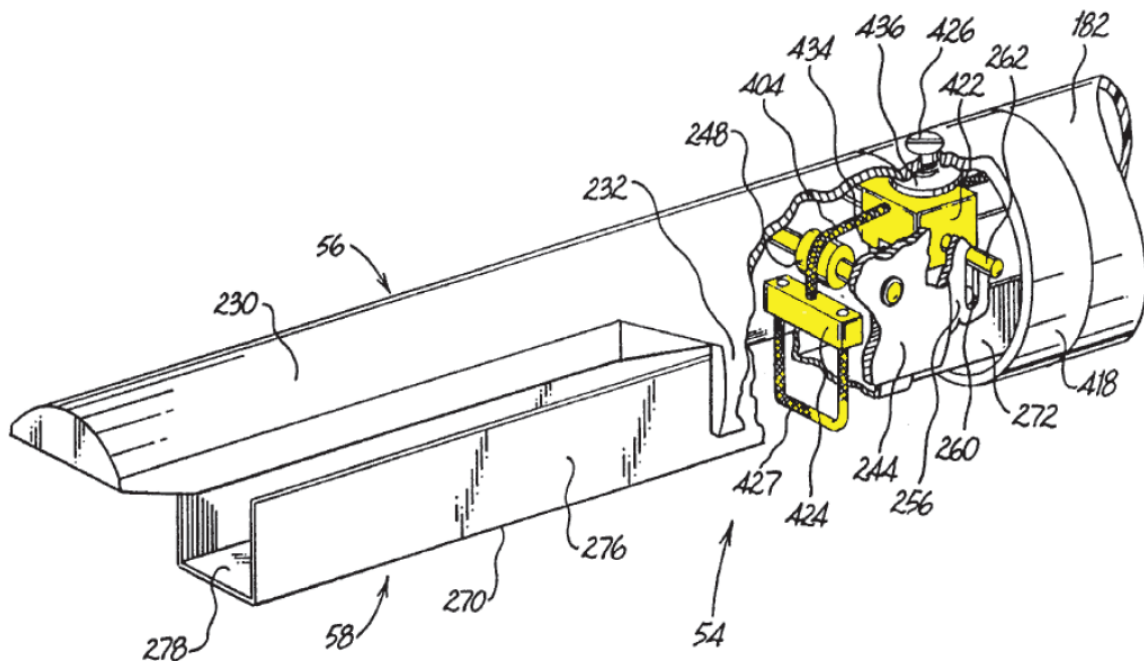


FIG. 28

Figure 28 “is an enlarged perspective view, partially cut-away, of the distal end of the elongated portion of the subject invention showing the mechanism provided therein.” Ex. 1004, 7:12–14. Patent Owner’s annotations highlight Green-209’s pulley system. Patent Owner explains that the system highlighted in yellow “is responsible for closing Green-209’s jaws and serves as the jaws’ pivot point.” PO Resp. 20 (citing Ex. 1004, 15:23–48, 18:1–19:11). Patent Owner submits that adding an I-beam “would not clear

this system because it is much taller than the original knife 240 and must extend past the anvil's staple forming plate 234 to reach the channel formed therein.” *Id.* at 21 (citing Ex. 2002 ¶¶ 96–98). Patent Owner submits that “the system will block the I-beam from moving into the jaws and entering the channels.” *Id.* (emphasis omitted).

Patent Owner's argument that the proposed modification “would require a substantial redesign” (PO Resp. 21) is not persuasive for at least two reasons.

First, the test for obviousness “is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, . . . but rather whether ‘a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention’.” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016); *see also* Pet. Reply 15 (arguing the same).

Second, we disagree with Patent Owner's assertion that adding an I-beam “would not clear this system because it is much taller than the original knife 240.” PO Resp. 21. Instead, we agree with Dr. Knodel's testimony that Patent Owner's argument incorrectly assumes that cable separation block 424 must sit on top of the staple cartridge. Ex. 1025 ¶ 33; *see also* Ex. 1004, Figs. 16, 28. To illustrate this point, Dr. Knodel submits an annotated version of Green 209's Figure 16 (Ex. 1025 ¶ 33), which we reproduce, below:

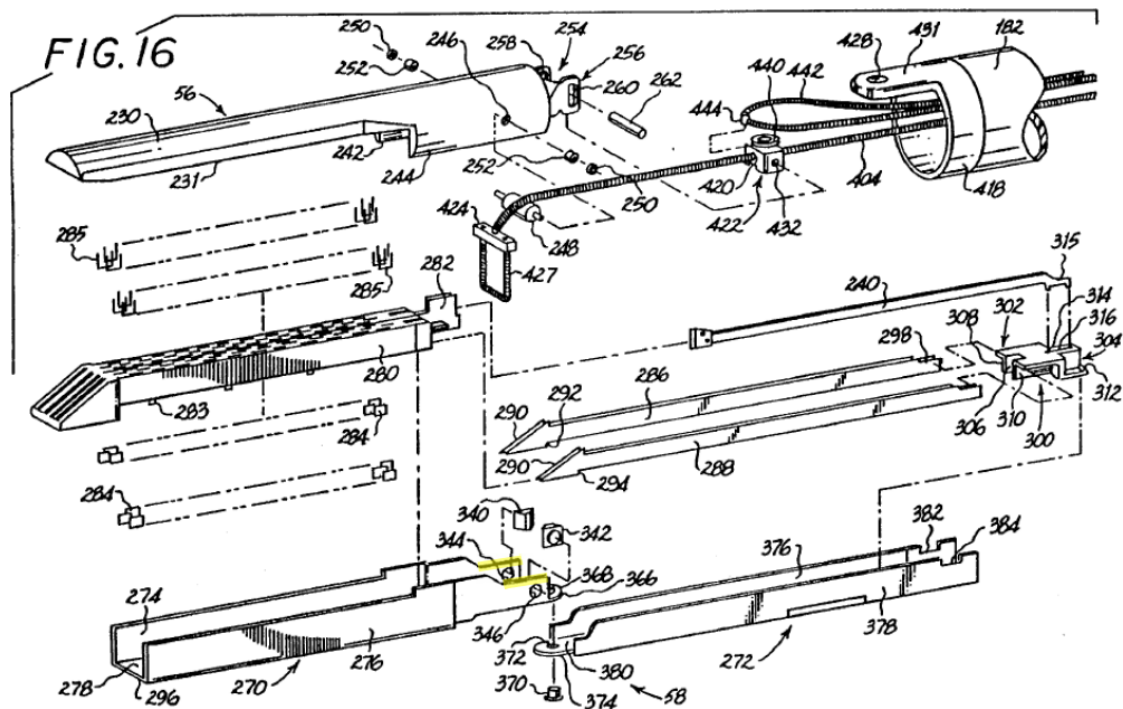


Figure 16 “is an exploded perspective view of the articulating cartridge assembly of the surgical instrument.” Ex. 1004, 6:48–49. Dr. Knodel testifies that “a POSITA would have understood that cable separation block 424 rests on the lowered portion at the proximal end of forward housing portion 270’s sidewalls (highlighted in yellow . . .), which is proximal of the cutting portion of knife 240 positioned in the raised portion of slot 282.” Ex. 1025 ¶ 33. We agree with Dr. Knodel that “pulley 248 is clearly proximal of the cutting portion of knife 240” (*id.* ¶ 34) and credit his testimony that “the I-beam . . . replaces only the distal-most portion of knife 240 that is distal to cable separation block 424 and pulley 248, [and] would not have been blocked by the pulley system” (*id.* ¶ 35). Accordingly, we disagree with Patent Owner’s assertion that the proposed modification would have required a “substantial redesign” of Green 209’s stapler. PO Resp. 20.

(5) *“Petitioner’s motivations to combine
Green-209 and Green-695 are unavailing”*

In rehashing several of the arguments addressed above, Patent Owner contends that “each and every one of Petitioner’s motivations to combine Green-209 with Green-695 fails.” PO Resp. 25; *see also id.* at 22–25. For the reasons discussed above, we disagree with Patent Owner.

Petitioner has established by a preponderance of the evidence that a skilled artisan would have been motivated to modify Green 209’s stapler so that knife 240 includes an I-beam, the jaws include internal passageways for receiving the I-beam, and Green 209’s anvil member 56 includes an opening that allows the I-beam to enter the channel as the instrument is closed. *See* Pet. 14. Having fully considered the evidence of record, including Green 209 and Green 695, and having weighed the competing testimony of Mr. Juergens and Dr. Knodel, we credit Dr. Knodel’s testimony that “A POSITA would have been motivated to make this modification for the reasons provided in Green 695” and 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. Indeed, Green 695 discloses that an object of its invention is “to provide . . . optimum alignment and stabilization of the jaws . . . during application and securing of the fasteners” (Ex. 1005, 1:58–62), and we find that this teaching would have motivated a POSITA to incorporate Green 695’s I-beam into Green 209’s stapler. *See also id.* at 2:48–56 (“By utilizing the aforementioned shoes 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.”). We further find persuasive Petitioner’s reason that the proposed modification would have improved Green 209’s device in other ways, as well, including by (1) allowing the use of lightweight disposable materials for the manufacture of the jaws and (2) allowing for longer staple cartridges, as the jaws of the modified stapler would be less likely to distort when clamping tissue. *See* Pet. 17; *see also* Ex. 1003 ¶ 52.

j) Summary of Independent Claim 4

We are persuaded by Petitioner’s argument and evidence as discussed above, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies all of the limitations of independent claim 4, for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the declarations of Dr. Knodel.

5. Dependent Claim 5

Claim 5 depends from claim 4 and further recites, “wherein the beam is configured to engage the first and second jaws one of entirely or substantially from therewithin to maintain the second distance and the alignment.” Ex. 1001, 8:33–36. In addressing this limitation, Petitioner submits that Green 209 as modified by Green 695 satisfies this limitation. *See* Pet. 31 (citations omitted).

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 5 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

6. *Dependent Claim 9*

Claim 9 depends from claim 4 and further requires, “wherein the first jaw and the second jaw are pivotably coupled at a pivot point, a portion of *the first jaw defining a flange* that extends past a surface of the second jaw when the first jaw and second jaw are in the first configuration and the second configuration.” Ex. 1001, 8:51–55 (emphasis added).

To address this claim, Petitioner submits that Green 209 and Green 695 each discloses this limitation. *See* Pet. 31–33. Petitioner apparently submits these alternative positions to account for the fact that Petitioner presents two alternative grounds: (1) Ground 1A—which relies primarily on Green 209—and (2) Ground 1B—which relies primarily on Green 695. *See id.* at 10 (“Green-209 in view of Green-695” (emphasis omitted)); *see also id.* at 17 (“Green-695 in view of Green-209” (emphasis omitted)).

Under Ground 1A, we understand Petitioner’s position to be that Green 209 discloses this limitation. Whether Green 695 discloses or teaches this limitation is irrelevant under Ground 1A, as Petitioner does not propose to modify Green 209 by adding Green 695’s flange. *See id.* at 14, 31–32.

In addressing claim 9 under Ground 1A, Petitioner submits an annotated version of Green 209's Figure 16 (Pet. 33), which we reproduce, below:

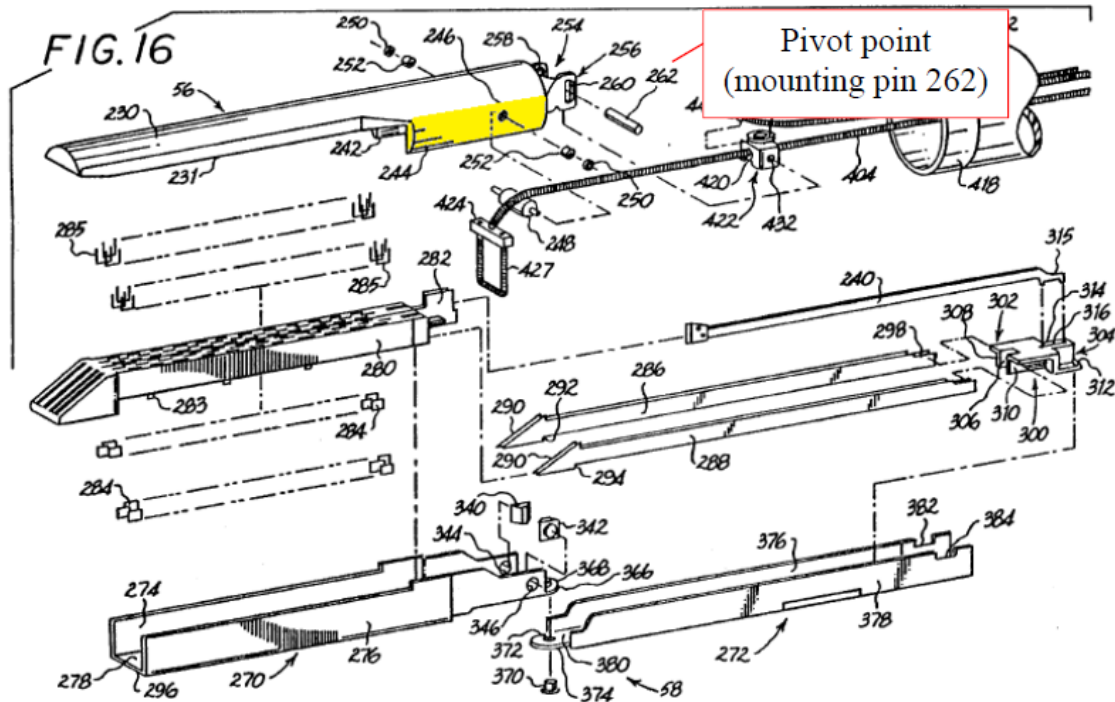


Figure 16 depicts “an exploded perspective view of the articulating cartridge assembly of the surgical instrument.” Ex. 1004, 6:48–49. Petitioner submits that Green 209 discloses a flange, but acknowledges that “Green-209’s second jaw defines the claimed flange (highlighted in yellow), rather than the first jaw,” as required by the claim. *See* Pet. 32–33.

To meet the limitation, Petitioner reasons,

It would have been obvious to move Green-209’s flange from the second jaw to the first jaw because there were a finite number of identified and predictable locations for the flange (e.g., the first jaw, the second jaw, or the shaft housing). . . . A POSITA making this modification would have reasonably expected to succeed because moving the location of the flange from one jaw to the other was well within the level of ordinary skill in the art.

Pet. 33 (citing in relevant part Ex. 1003 ¶¶ 83–86).

Patent Owner responds, “If the flange were moved to the bottom jaw as Petitioner suggests, then a completely different pulley fixation system would be needed to open and close Green-209’s upper jaw, otherwise the open and close functionality of Green-209’s stapler would be lost.” PO Resp. 27 (citing Ex. 2002 ¶¶ 104–108).

Petitioner replies, “The pulley fixation arrangement is the same in the combination as in Green-209.” Pet. Reply 16 (citing Ex. 1025 ¶ 36). Petitioner states that “even if a different pulley fixation arrangement would have been needed (it was not), that would not demonstrate non-obviousness.” *Id.*

We disagree with Patent Owner’s assertion that “a completely different pulley fixation arrangement would be needed to open and close Green-209’s upper jaw, otherwise the open and close functionality of Green-209’s stapler would be lost.” PO Resp. 27 (emphasis omitted). Patent Owner’s argument presumes that the modification requires relocating the pulley system from the upper jaw to the lower jaw. It does not.

Having reviewed the evidence of record, including Green 209 and the competing testimony of Dr. Knodel and Mr. Juergens, we credit Dr. Knodel’s testimony that “the anvil member 56 would still have sidewalls including apertures for mounting ring pairs 250 and 252 and pulley 248. At most, a POSITA might reduce the width of proximal anvil portion to sit inside the relocated flange and/or the length of the sidewalls.” Ex. 1025 ¶ 36.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that

Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 9 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

7. *Dependent Claim 10*

Claim 10 depends from claim 4 and recites, “further comprising one or more actuators including at least one of an actuator handle, a lever, a trigger, a knob or a cable.” Ex. 1001, 8:56–58. In addressing this limitation, Petitioner submits that Green 209 discloses this limitation, identifying Green 209’s frame 52 (the “handle”), handle member 62 (the “lever”), firing trigger 96 (the “trigger”), dial member 452 (the “knob”), and cable 404 (the “cable.”). *See* Pet. 34 (referencing in part Green 209’s Figure 1).

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 10 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

8. *Dependent Claim 11*

Claim 11 depends from claim 4 and further recites, “wherein at least a portion of the apparatus is powered.” Ex. 1001, 8:59–60. In addressing this limitation, Petitioner submits that Green 209 discloses this limitation, citing

the fact that Green 209 describes a pneumatically-powered stapler. *See* Pet. 35 (citations omitted).

Patent Owner does not dispute Petitioner's assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner's argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 11 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

9. *Dependent Claim 12*

Claim 12 depends from claim 4 and further recites, "wherein at least a portion of the first jaw and the second jaw is curved." Ex. 1001, 8:61–62. In addressing this limitation, Petitioner submits that Green 209 discloses this limitation, citing the outer surface of Green 209's anvil member 56 and flange 366 of forward housing 270. *See* Pet. 35–36 (citations omitted).

Patent Owner does not dispute Petitioner's assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner's argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 12 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

10. *Independent Claim 13*

Independent claim 13 is similar to independent claim 4 but further recites, *inter alia*, “a control handle configured to actuate receiving, clamping and stapling of tissue.” *Compare* Ex. 1001, 8:4–32, *with id.* at 8:63–9:13.

To address this particular limitation, Petitioner submits that

Green-209’s control handle (frame 52 or handle assembly 1012) is configured to actuate receiving (via gross manipulation of frame 52/handle assembly 1012 to position the instrument jaws relative to tissue), clamping (via handle member 62 or actuation handle 1018) and stapling of tissue (via firing trigger 96 or 1020).

Pet. 39 (citing in part Ex. 1003 ¶ 96).

Patent Owner argues, “It appears that Petitioner is arguing that simply *pushing* the stapler towards the tissue via *hand* is supposed to satisfy the ‘actuate receiving’ requirement If PO’s assumption is correct, then Petitioner has failed to satisfy the limitation because hand movement itself does not equate to ‘actuating’ anything.” PO Resp. 28.

Patent Owner’s argument is not persuasive. Petitioner and Dr. Knodel sufficiently explain the following: (1) that gross manipulation of Green 209’s frame 52 to position the instrument jaws relative to tissue satisfies the claimed “configured to actuate receiving,” (2) manipulation of handle member 62 satisfies the claimed “configured to actuate . . . clamping,” and (3) actuating firing trigger 92 satisfies the claimed “configured to actuate . . . stapling of tissue.” *See* Ex. 1003 ¶ 96.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies

the limitations of claim 13 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

11. Dependent Claim 14

Claim 14 depends from claim 13 and further recites, “wherein: the beam is configured to enable at least one of firing staples and cutting tissue.” Ex. 1001, 9:15–17. In addressing this limitation, Petitioner references limitation [4.6] and submits that Green 209 as modified by Green 695 satisfies this limitation. *See* Pet. 40 (citations omitted).

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 14 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

12. Dependent Claim 15

Claim 15 depends from claim 13 and further recites, “wherein the slots through which staples are passed are arranged in a first row extending from a proximal end of the first jaw to a distal end thereof such that two or more staples are fired in a row orthogonal to a direction of movement of the beam one of simultaneously or serially.” Ex. 1001, 9:18–23. In addressing this limitation, Petitioner asserts that Green 209 discloses this limitation,

submitting an annotated version of Green 209's Figure 18 (*see* Pet. 41–42), a copy of which we reproduce, below:

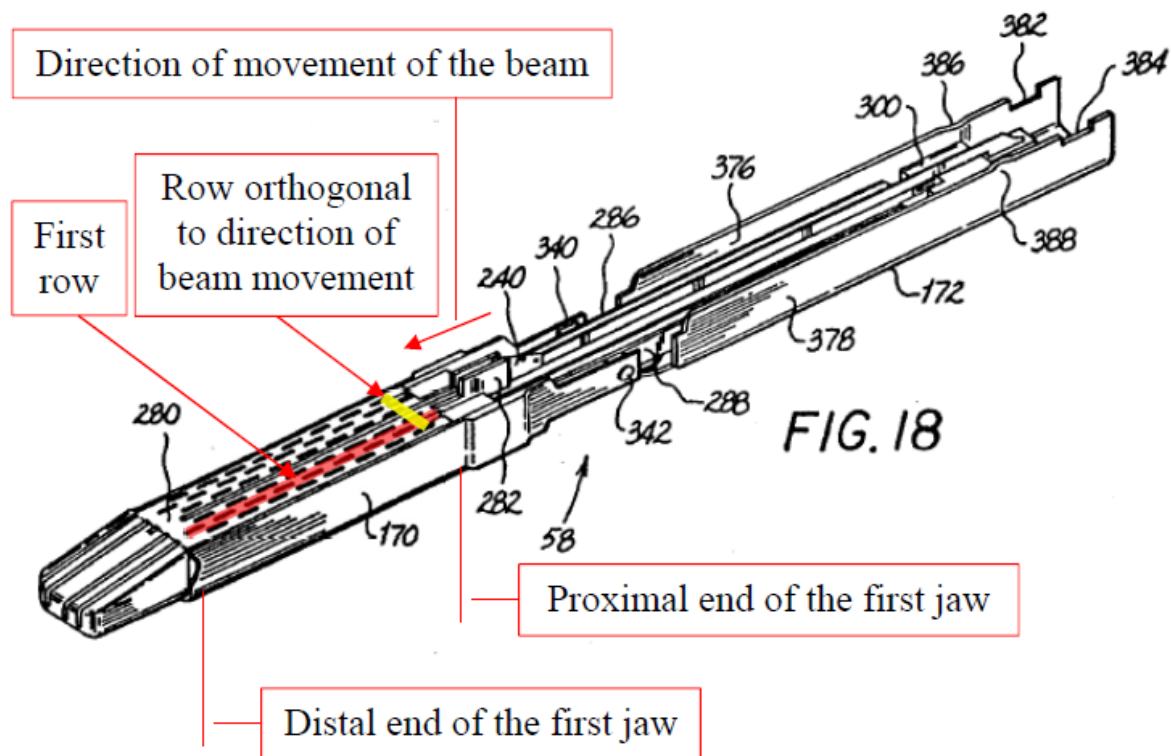


Figure 18 is a “perspective view of the articulating cartridge assembly of the surgical instrument.” Ex. 1004, 6:53–54. Petitioner annotates Figure 18 to highlight the “proximal end of the first jaw,” the “distal end of the first jaw,” the “direction of movement of the beam,” the “row orthogonal to direction of beam movement,” and the “first row.”

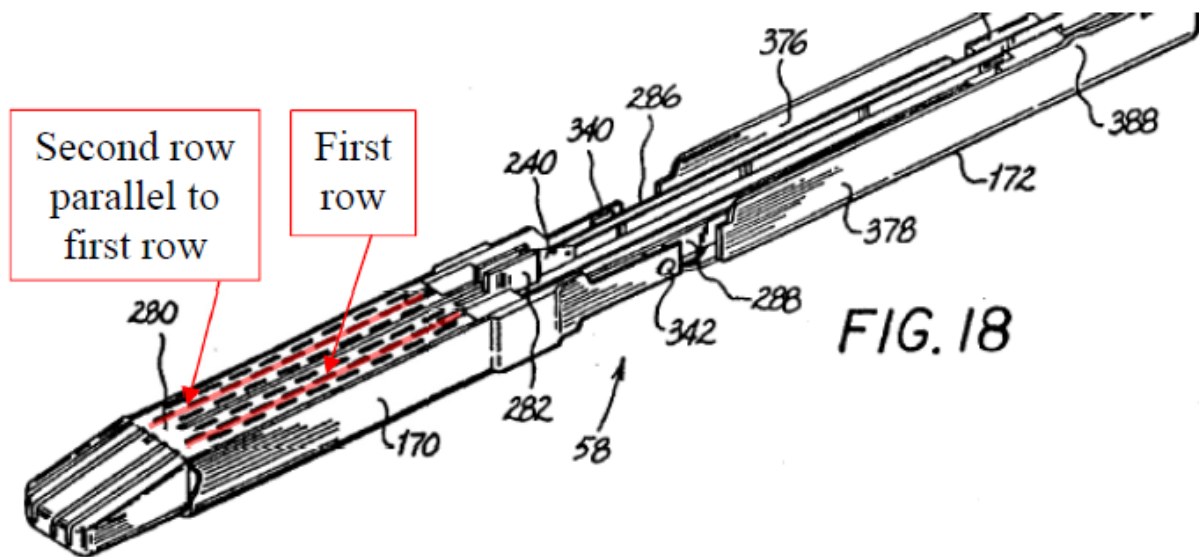
Patent Owner does not dispute Petitioner's assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner's argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 15 for the reasons stated by Petitioner in the Petition,

which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

13. *Dependent Claim 16*

Claim 16 depends from claim 15 and further recites, “wherein additional slots are arranged in a second row substantially parallel to the first row of slots.” Ex. 1001, 9:23–25. In addressing this limitation, Petitioner submits that Green 209 discloses this limitation, presenting another annotated version of Green 209’s Figure 18. *See* Pet. 42 (citations omitted). We reproduce Petitioner’s annotated Figure 18, below:



As shown in the annotated figure, Petitioner calls out the “first row” and the “second row parallel to [the] first row” and submits that Green 209 discloses additional slots arranged in a second row that is substantially parallel to the first row of slots. *See id.*

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 16 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

14. Dependent Claim 17

Claim 17 depends from claim 13 and further recites, “wherein the head portion is one of fixedly coupled or movably coupled to the shaft.” Ex. 1001, 9:27–28. In addressing this limitation, Petitioner asserts that Green 209 discloses this limitation, submitting an annotated version of Green 209’s Figure 31 (*see* Pet. 43 (citations omitted)), a copy of which we reproduce, below:

FIG. 31

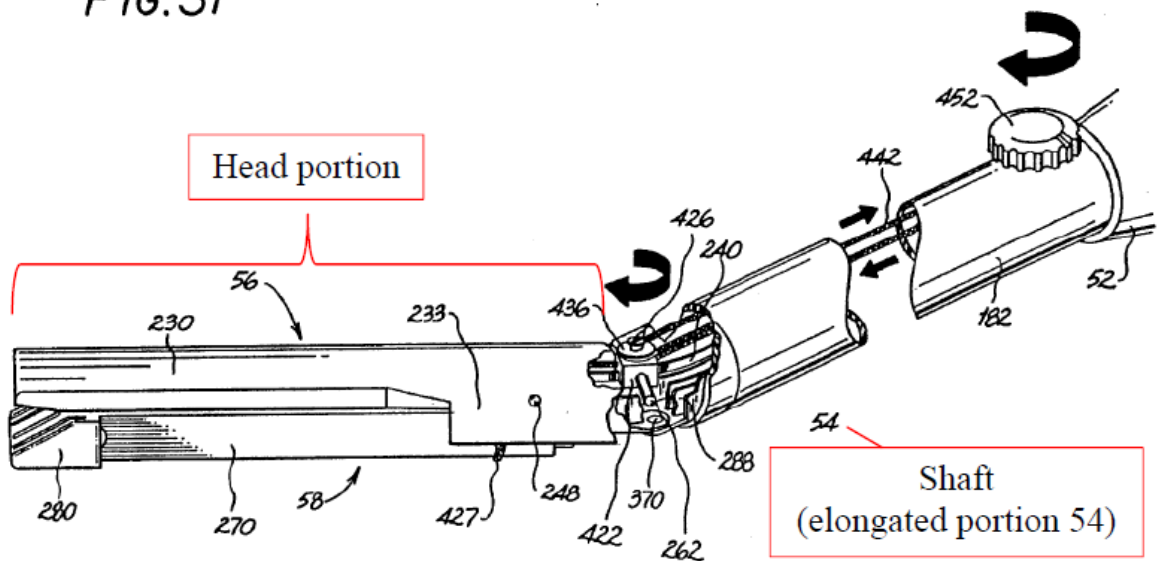


Figure 31 “is an enlarged perspective view, partially cut-away, of [a] cartridge assembly.” Ex. 1004, 7:21–23.

Patent Owner does not dispute Petitioner's assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner's argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 17 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

15. Dependent Claim 18

Claim 18 depends from claim 13 and further recites, "wherein tissue is cut between the first row and the second row upon firing of one or more staples through the slots." Ex. 1001, 9:29–31. In addressing this limitation, Petitioner asserts that Green 209, as modified by the teachings of Green 695, satisfies this limitation. *See* Pet. 44 (citing in relevant part limitations [4.2], [4.6], and claims 14 and 16).

Patent Owner does not dispute Petitioner's assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner's argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 18 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

16. Dependent Claim 20

Claim 20 depends from claim 13 and further recites, “wherein the beam includes a cutting blade and is configured to clamp and align the first and second jaws one of entirely or substantially from therewithin.”

Ex. 1001, 9:35–38. In addressing this limitation, Petitioner references elements [4.2] and [13.2], and asserts that Green 209, as modified by Green 695, satisfies this limitation. *See* Pet. 44.

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 20 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

17. Dependent Claim 22

Claim 22 depends from claim 13 and further recites, “wherein the control handle includes at least one of an actuation handle, a lever, a trigger, a knob and a cable.” Ex. 1001, 10:3–5. In addressing this limitation, Petitioner references the analysis from its claim 10 challenge. *See* Pet. 44; *see also supra* Part II.D.7.

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies

the limitations of claim 22 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

18. Dependent Claim 23

Claim 23 depends from claim 13 and further recites, “wherein at least a portion of the apparatus is powered.” Ex. 1001, 10:6–7. In addressing this limitation, Petitioner references the pneumatically-powered stapler cited in its claim 11 challenge. *See* Pet. 45; *see also supra* Part II.D.8.

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 23 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

19. Dependent Claim 24

Claim 24 depends from claim 13 and further recites, “wherein the apparatus is powered electrically, hydraulically or pneumatically.” Ex. 1001, 10:8–9. In addressing this limitation, Petitioner relies on Green 209’s pneumatically-powered stapler cited during the analysis of claim 11. *See* Pet. 45; *see also supra* Part II.D.8.

Patent Owner does not dispute Petitioner’s assertion. *See, generally*, PO Resp.

We are persuaded by Petitioner’s argument and evidence, and find that Petitioner has established by a preponderance of the evidence that Green 209 as modified by the teachings of Green 695 and Knodel satisfies the limitations of claim 24 for the reasons stated by Petitioner in the Petition, which we adopt as our own findings, as further supported by the testimony of Dr. Knodel.

20. Summary of Ground 1A

Based on the foregoing, we determine Petitioner has proven by a preponderance of the evidence that claims 4, 5, 9–18, 20, and 22–24 are unpatentable in view of Green 209 as modified by the teachings of Green 695 and Knodel.

E. Ground 1B – Green 695, Green 209, and Knodel

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—and both challenge the same claims—namely, claims 4, 5, 9–18, 20, and 22–24. *See* Pet. 9. As distinguished from Ground 1A, in which Petitioner proposes to modify Green 209 in view of Green 695 and Knodel, however, 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 been motivated to modify 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 been motivated to modify 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 been motivated to modify Green 695 to include such a feature “to facilitate fastening and/or cutting tissue.” *Id.* (citations omitted).

2. Analysis

Patent Owner argues: “The Petition is detrimentally silent as to how or why Green 695 satisfies the limitations of the challenged claims.” PO Resp. 28–29. Patent Owner cites to our Institution Decision (*see id.*), in which we explained that Petitioner failed to explain adequately its challenge. *See* Inst. Dec. 33–34. Despite not being persuaded, we nevertheless

instituted Ground 1B under *SAS* Guidance. *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”). *See* Inst. Dec. 34.

Petitioner does not respond to Patent Owner’s argument or otherwise address our Institution Decision in its Reply. *See, generally*, Pet. Reply.

We maintain our initial 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.”).

3. *Summary of Ground 1B*

Based on the foregoing, Petitioner has failed to prove by a preponderance of the evidence that claims 4, 5, 9–18, 20, and 22–24 are unpatentable over Green 695 in view of Green 209 and Knodel.

F. *Ground 2 – Rothfuss, Green 209, and Knodel*

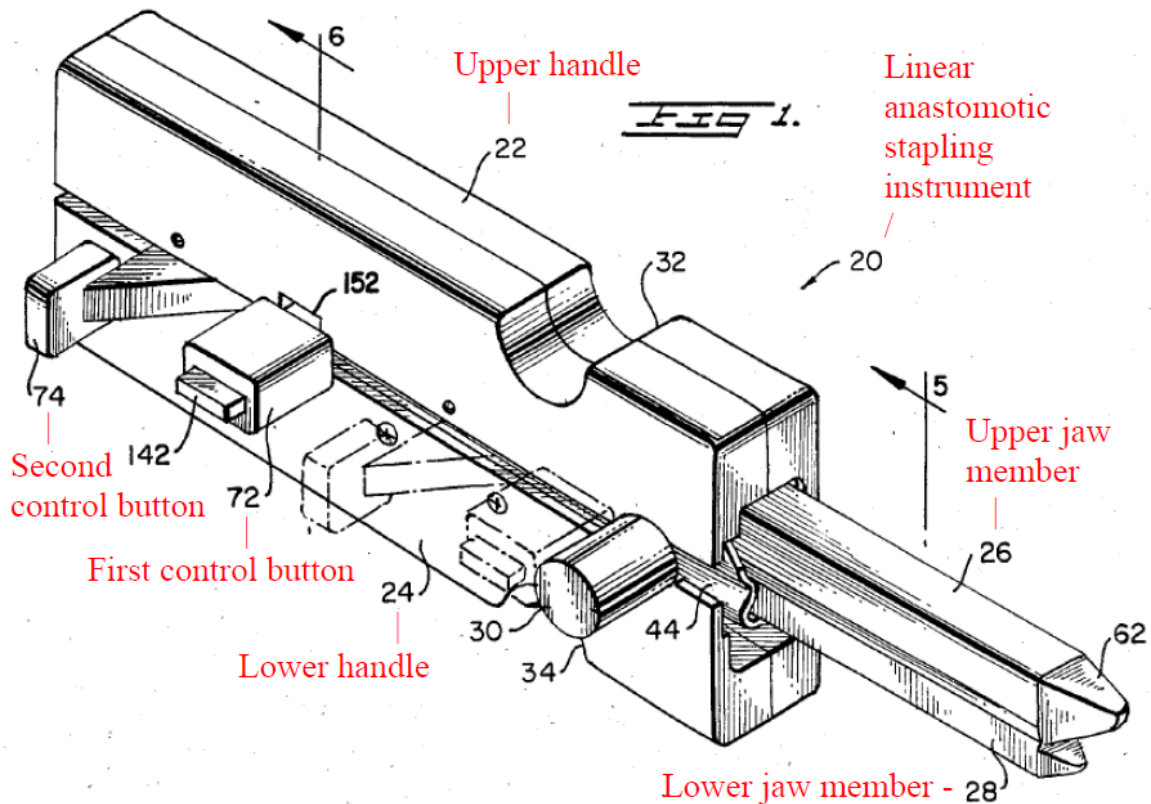
Petitioner contends that claims 4–8 and 10–24 are unpatentable as obvious over Rothfuss in view of Green 209 and Knodel. Pet. 45.

1. *Rothfuss (Ex. 1007)*

Rothfuss is a U.S. Patent titled, “Surgical Stapling Instrument with Dual Staple Height Mechanism.” Ex. 1007, code (54). Rothfuss describes a “surgical stapling instrument suitable for performing a gastrointestinal anastomosis.” *Id.* at code (57).

2. *Petitioner’s Challenge*

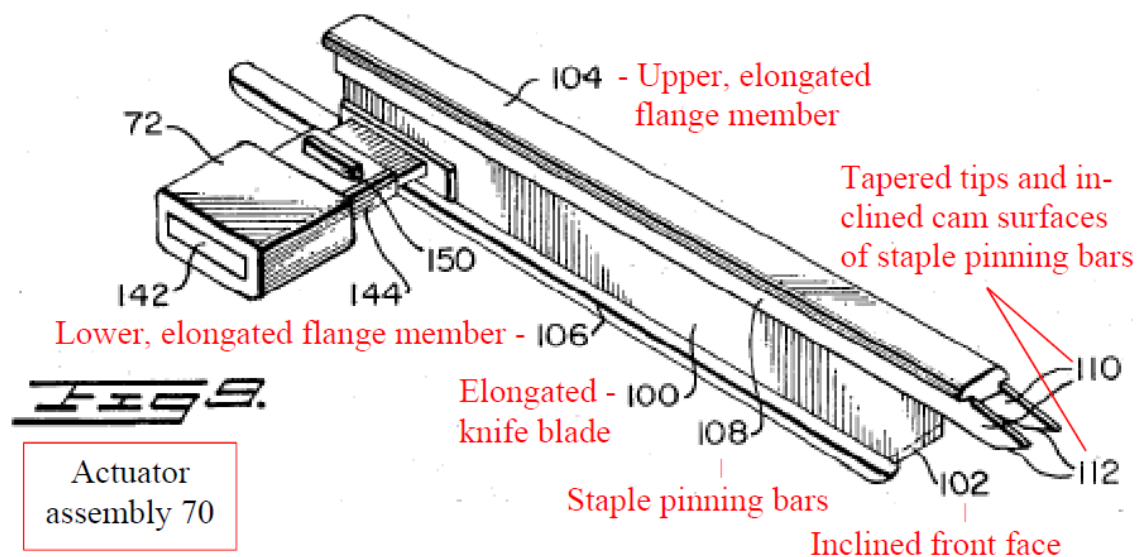
Petitioner produces an annotated version of Rothfuss’s Figure 1 (Pet. 45), which we reproduce, below:



As shown above in annotated Figure 1, Petitioner submits that this figure 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).

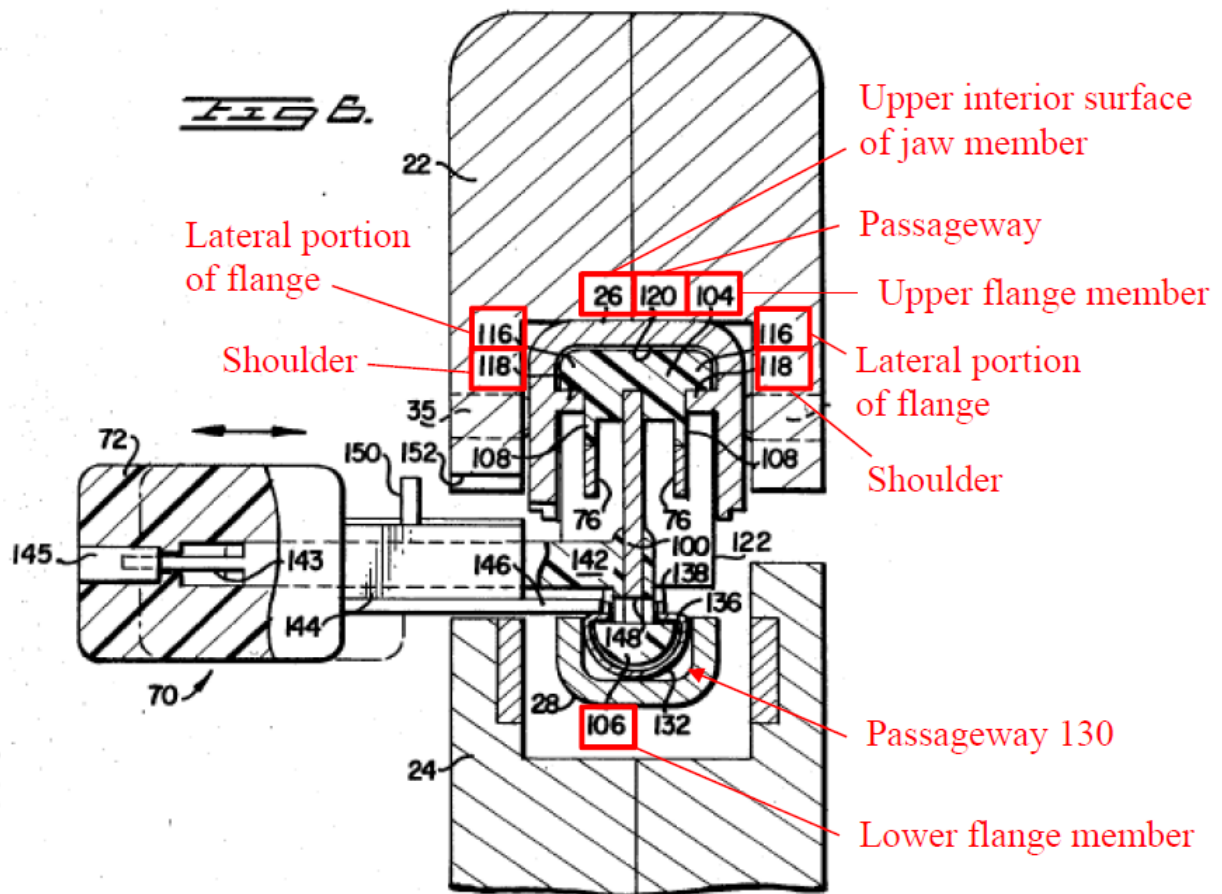
Petitioner also submits an annotated version of Rothfuss’s Figure 9, which depicts Rothfuss’s actuator assembly 70 (Pet. 47), below:



As shown above in annotated Figure 9, Petitioner submits that 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).

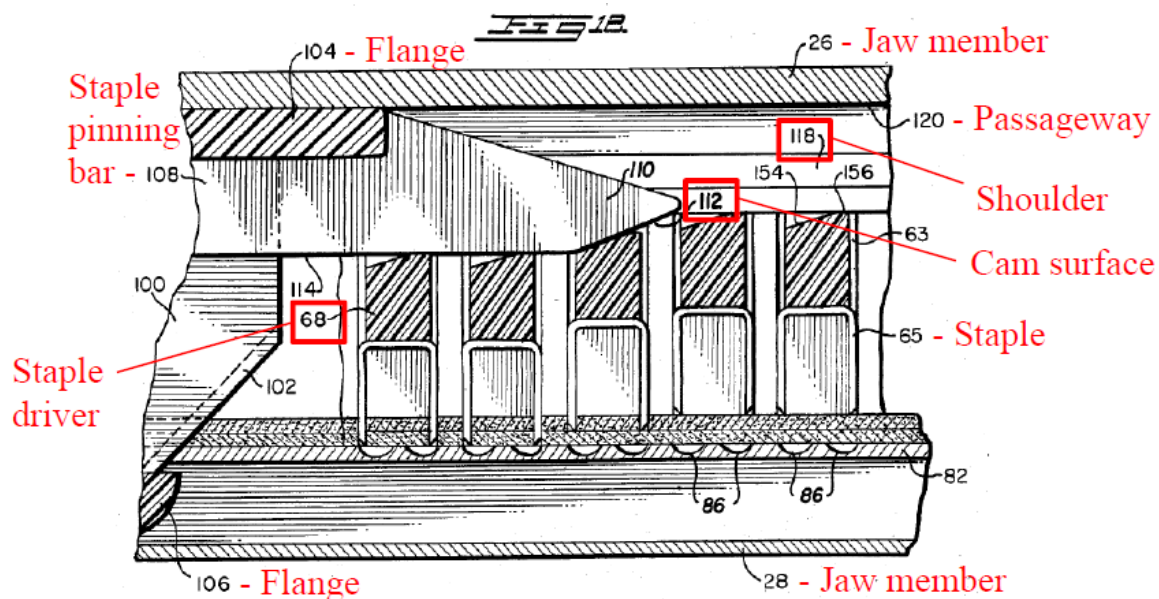
Petitioner also submits an annotated version of Rothfuss’s Figure 6 (*id.* at 48), which is an enlarged vertical section through the handle of Rothfuss’s device (Ex. 1007, 5:40–42), and which we also reproduce, below:



As shown above in annotated Figure 6, Petitioner submits that 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 member 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

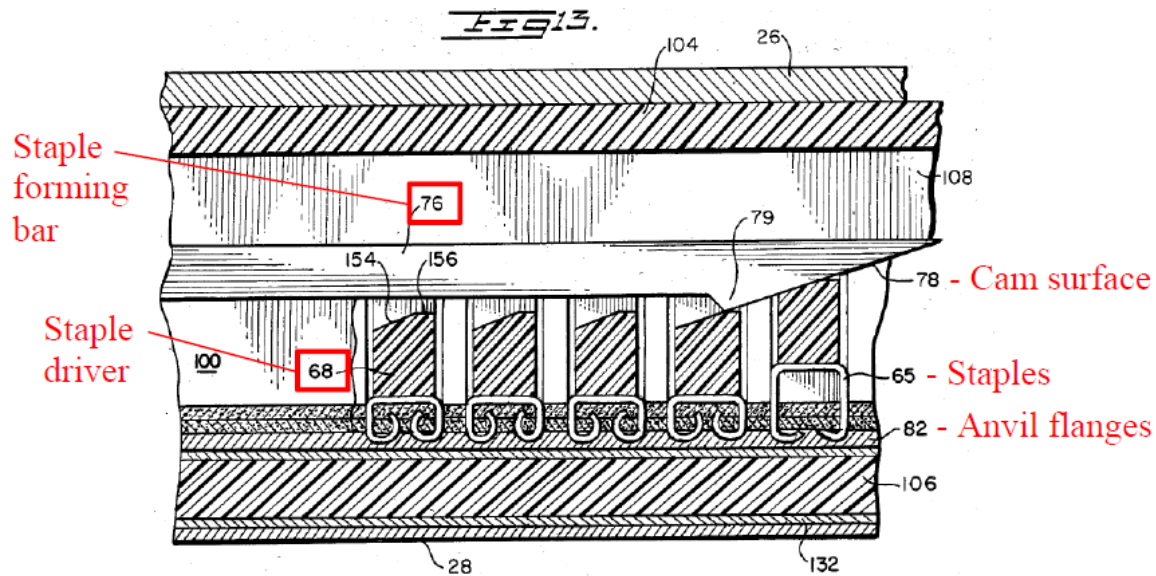
member, lower jaw member 28 (along with anvil flanges 82) define passageway 130 for slidably receiving lower I-beam flange 106. Pet. 48 (citing Ex. 1007, 9:37–40).

In describing the operation of Rothfuss’s stapling, Petitioner submits an annotated version of Rothfuss’s Figure 12 (Pet. 49), which illustrates the operation of Rothfuss’s actuator assembly (Ex. 1007, 5:56–58), and which we reproduce, below:



As shown above in annotated Figure 12, Petitioner submits that as actuator assembly 70 is advanced, upper I-beam flange 104 slides into passageway 120, and cam surfaces 112 sequentially engage 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 in annotated Figure 13, Petitioner submits that 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.

3. Institution Decision

In our Institution Decision, we determined that Petitioner did not show a reasonable likelihood of establishing that any of claims 4–8 or 10–24 are unpatentable over Rothfuss in view of Green 209 and Knodel. *See* Inst. Dec. 49.

Patent Owner argues that Petitioner’s proposed modification of Rothfuss is flawed (*see* PO Resp. 29–36) and requests that we maintain our initial position (*see id.* at 29).

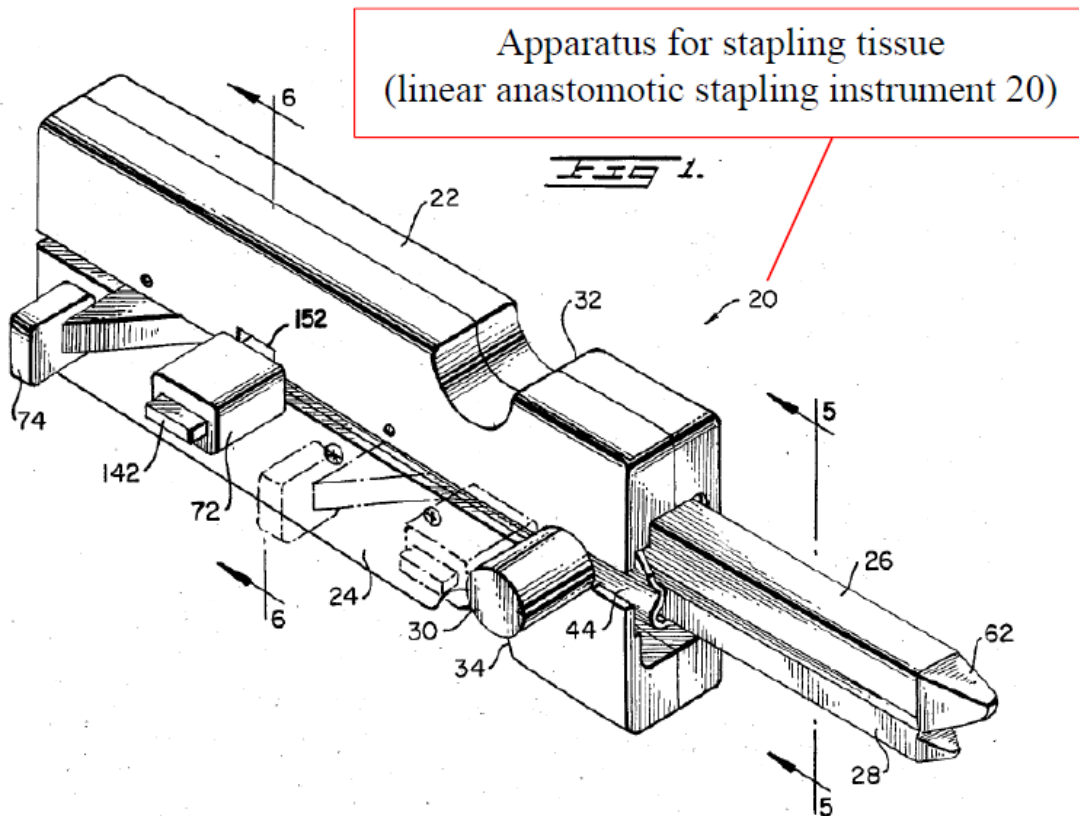
Petitioner did not reply to Patent Owner’s arguments or otherwise address our Institution Decision. *See, generally*, Pet. Reply.

For the reasons below, Petitioner has failed to prove by a preponderance of the evidence that claims 4–8 and 10–24 are unpatentable over Rothfuss in view of Green 209 and Knodel.

4. *Independent Claim 4*

a) “[4.0] *An apparatus for stapling tissue, comprising:*”

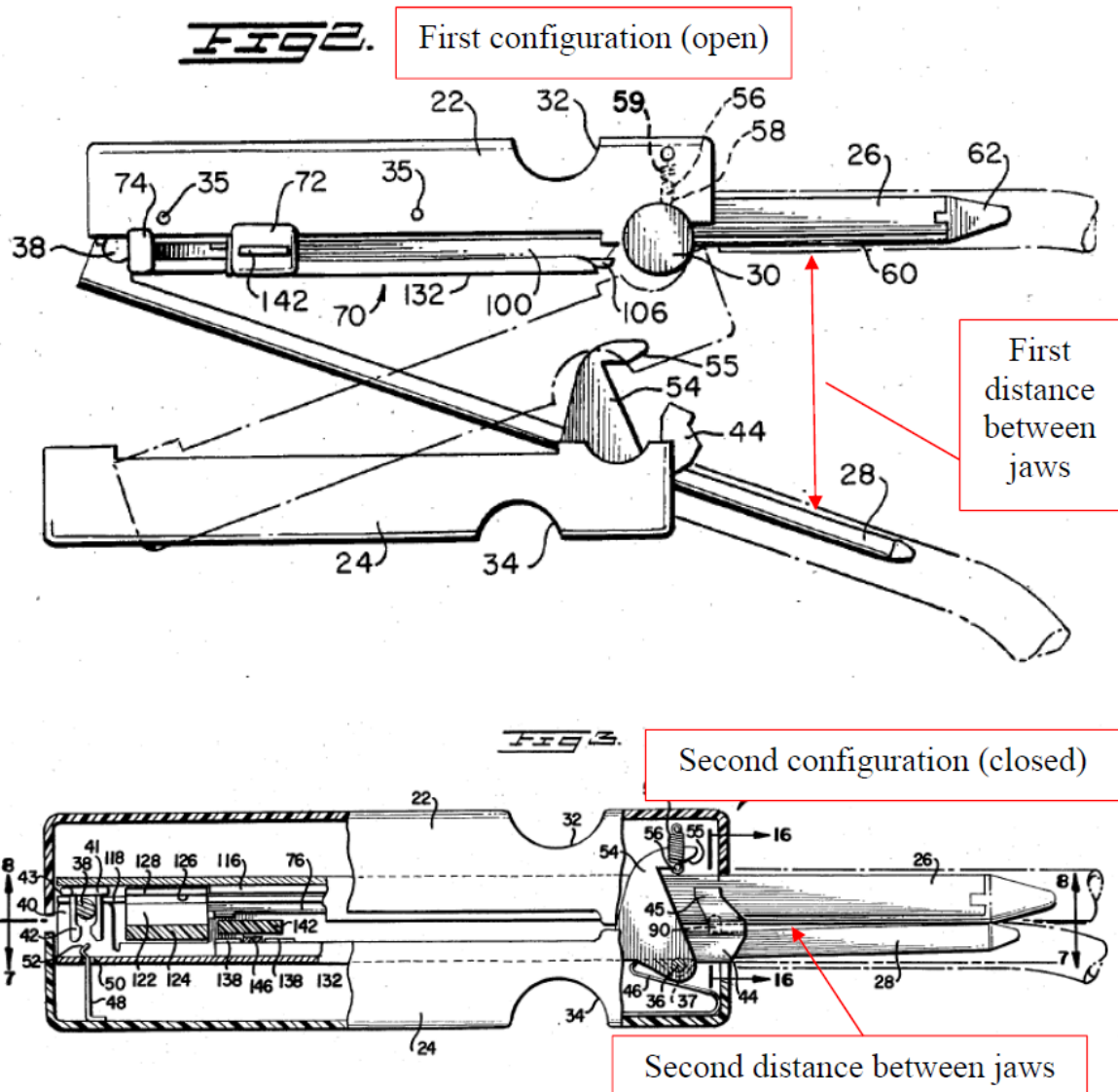
Petitioner submits that Rothfuss discloses an apparatus for stapling tissue, submitting an annotated version of Rothfuss’s Figure 1 (Pet. 51), which we reproduce, below:



As shown above in annotated Figure 1, Petitioner submits that Rothfuss’s linear anastomotic stapling instrument 20 satisfies the claimed “apparatus for stapling tissue.” *Id.* (citing Ex. 1007, 6:8–14).

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

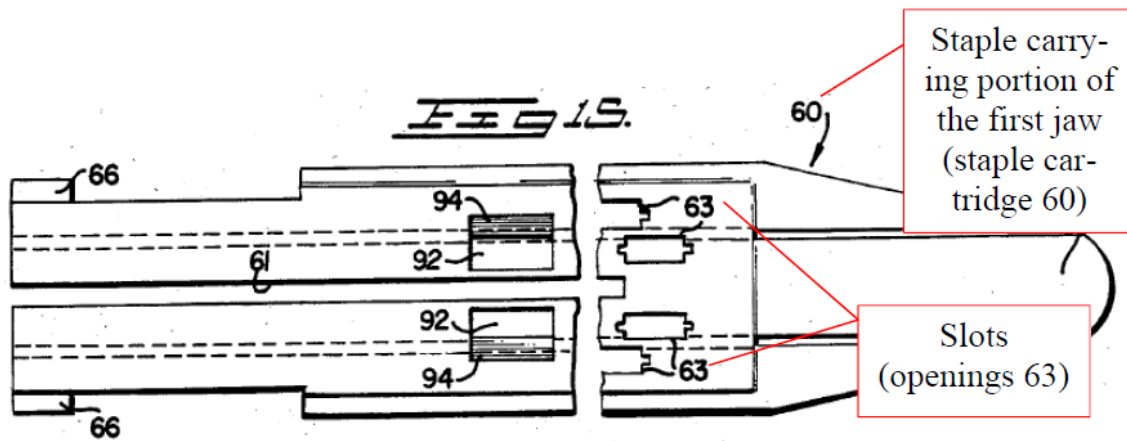


As shown above in the annotated Figure 2, Petitioner highlights the “first configuration” (in which the jaws are open), the “first distance between jaws,” the “second configuration” (in which the jaws are closed), and the “second distance between jaws.” Petitioner submits that this figure depicts Rothfuss’s 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, Petitioner submits that 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).

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

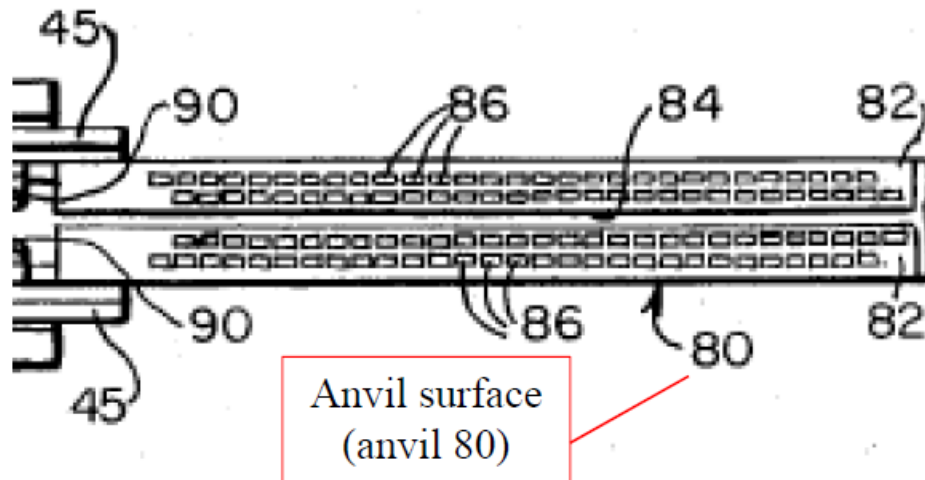
Petitioner asserts that Rothfuss discloses this limitation, submitting an annotated version of Rothfuss’s Figure 15 (Pet. 54), which we reproduce, below:



As shown above in annotated Figure 15, Petitioner submits that this figure 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, 7:22–57).

d) “[4.3] an anvil surface defined on the second jaw opposing the first jaw”

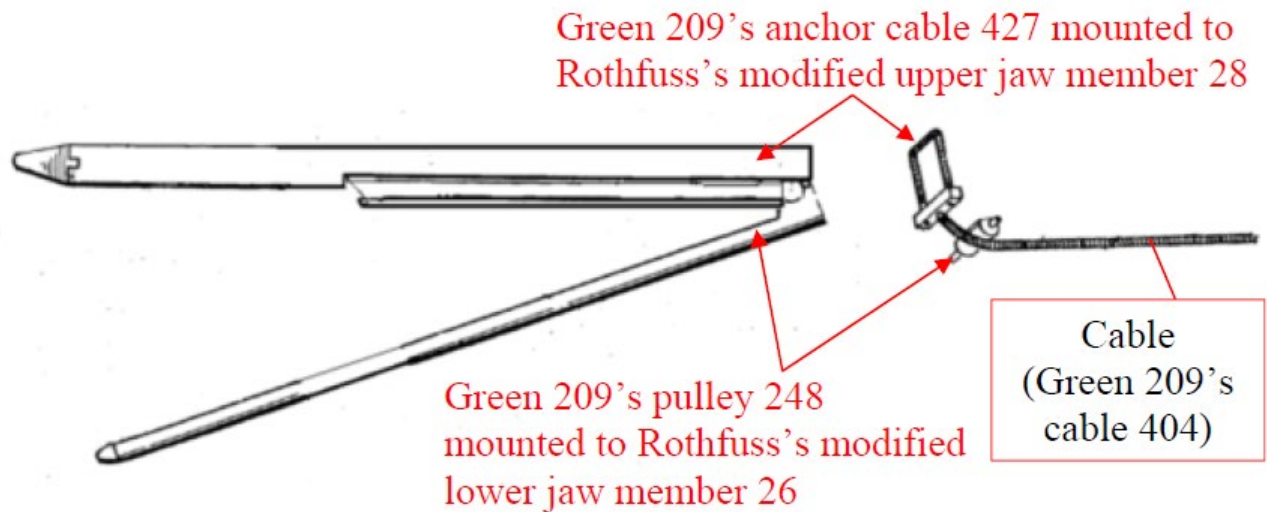
Petitioner asserts that Rothfuss discloses this limitation, submitting an annotated excerpt from Rothfuss’s Figure 7 (Pet. 55), which we reproduce, below:



As shown above in annotated Figure 7, Petitioner submits that 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).

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, 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’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):



As shown above in the annotated Figure Petitioner submits that Rothfuss's upper jaw member 28 is connected to Green 209's anchor cable 427, with Rothfuss's lower jaw member 26 connected to Green 209's pulley 248. *See id.*

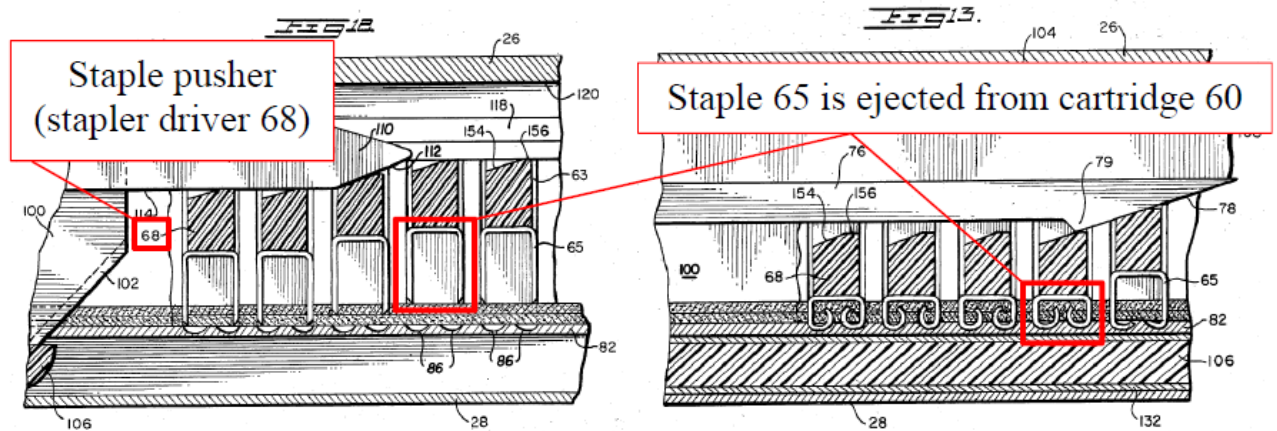
As to the proposed modification of Rothfuss for MIS, Petitioner reasons that a skilled artisan would have been motivated to modify "Rothfuss's stapler for use in minimally invasive surgery . . . for the same reasons a POSITA would have modified Green 695's stapler for use in MIS." *Id.* at 50 (citing 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.

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”

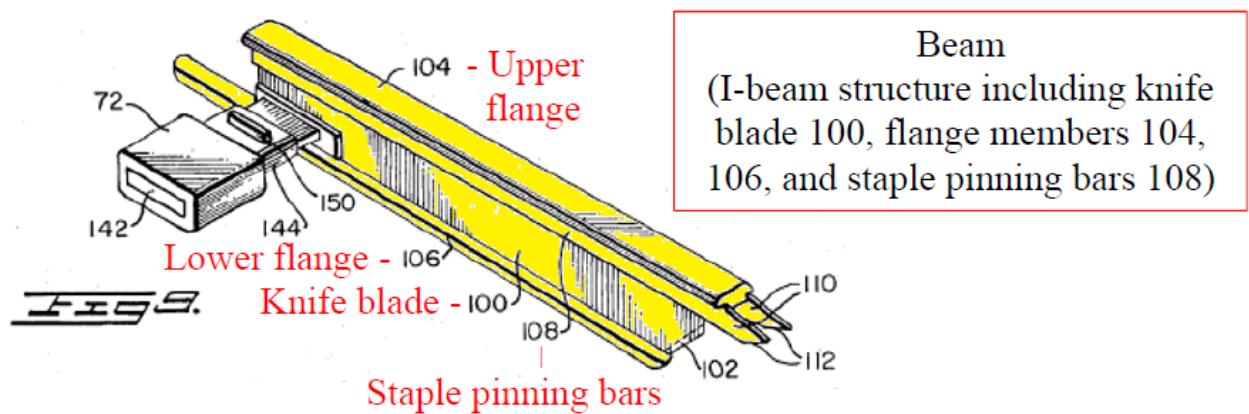
Petitioner asserts that Rothfuss discloses this limitation, submitting annotated versions of Rothfuss’s Figures 12 and 13 (Pet. 57), which we reproduce, below:



As shown above in annotated Figures 12 and 13, Petitioner calls out “staple pusher (or staple driver 68), and staple 65 before and after being ejected from cartridge 60. Petitioner submits that 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).

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:



As shown above in annotated Figure 9, Petitioner calls out upper flange 104, lower flange 144, knife blade 100, and staple pinning bars 108. Petitioner submits that 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).

h) *Patent Owner’s Argument*

In addressing limitation 4.4, Patent Owner argues that “Petitioner has not provided any explanation as to how control button 72 operates when upper handle 22 is replaced with Green-209’s frame portion 52 and elongated shaft portion 54.” PO Resp. 33. Patent Owner explains that “[t]he

buttons 72, 74 in Rothfuss are *manually* operated because the device [] is used in open surgeries.” *Id.* (citations omitted).

Patent Owner’s argument is persuasive.

i) Analysis

The burden is on Petitioner to clearly set forth the basis for its challenge in its Petition. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)).

Here, 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 minimally-invasive surgical 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 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. Ex. 1007, 2:51–55. Rothfuss achieves this functionality through control buttons 72, 74. *See, e.g., id.* at 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 id.* at 8:3–6 (“The stapling instrument includes a second control button **74** which is actuated after the tissue is initially pinned and cut by actuator assembly **70** to operate a staple pusher bar mechanism **75**”). Rothfuss discloses, “After the stapling of the tissue is completed, control buttons 72 and 74 are retracted to allow jaw members 26 and 28 to pivot apart for removal of the stapled tissue

from the jaw members.” *Id.* at 8:10–13. Furthermore, Rothfuss’s handles 22, 24 (including notch 152 and flange 153) permit the control buttons to adjust laterally between their outermost and innermost positions for selection of the desired staple height. *See id.* at 10:53–11:3, Figs. 1, 8. Absent any 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 allow Rothfuss’s device to maintain the varying height-adjustable staple functionality of buttons 72, 74, and we are not persuaded that a skilled artisan would have been motivated to modify Rothfuss as Petitioner proposes. Petitioner’s proposed modification leaves the Board to speculate about how Rothfuss’s control buttons 72, 74 would continue to adjust laterally for selecting staples of varying heights. *See Harmonic*, 815 F.3d at 1363.

Absent any meaningful explanation in the Petition, Patent Owner’s argument that the “proposed modifications to Rothfuss’[s] device render the height staple selection functionality insufficient or inoperable” is persuasive. PO Resp. 33.

Petitioner has failed to prove by a preponderance of the evidence that Rothfuss in view of Green 209 and Knodel satisfies limitation [4.4]. As such, Petitioner has failed to prove that claim 4 is unpatentable over Rothfuss in view of Green 209 and Knodel.

5. *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], however, Petitioner has failed to prove by a preponderance of the evidence that a skilled artisan would have been motivated to replace Rothfuss's handles 22, 24, as doing so would also impact the operation of Rothfuss's control buttons 72, 74. *See supra* Part II.F.4.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 been motivated to modify Rothfuss as Petitioner proposes. *See id.*

Petitioner has failed to prove by a preponderance of the evidence that claim 13 is unpatentable over Rothfuss in view of Green 209 and Knodel.

6. *Dependent Claims 5–8, 10–12, and 14–24*

Claims 5–8, 10–12, and 14–24 depend from either claim 4 or 13, and Petitioner's challenge to these claims inherit the same infirmity as its challenge under claim 4. *See* Pet. 59–70. For the same reasons that Petitioner has failed to prove by a preponderance of the evidence that a skilled artisan would have been motivated to modify Rothfuss's handles, Petitioner has failed to prove that dependent claims 5–8, 10–12, and 14–24 are unpatentable over Rothfuss in view of Green 209 and Knodel.

7. *Summary of Ground 2*

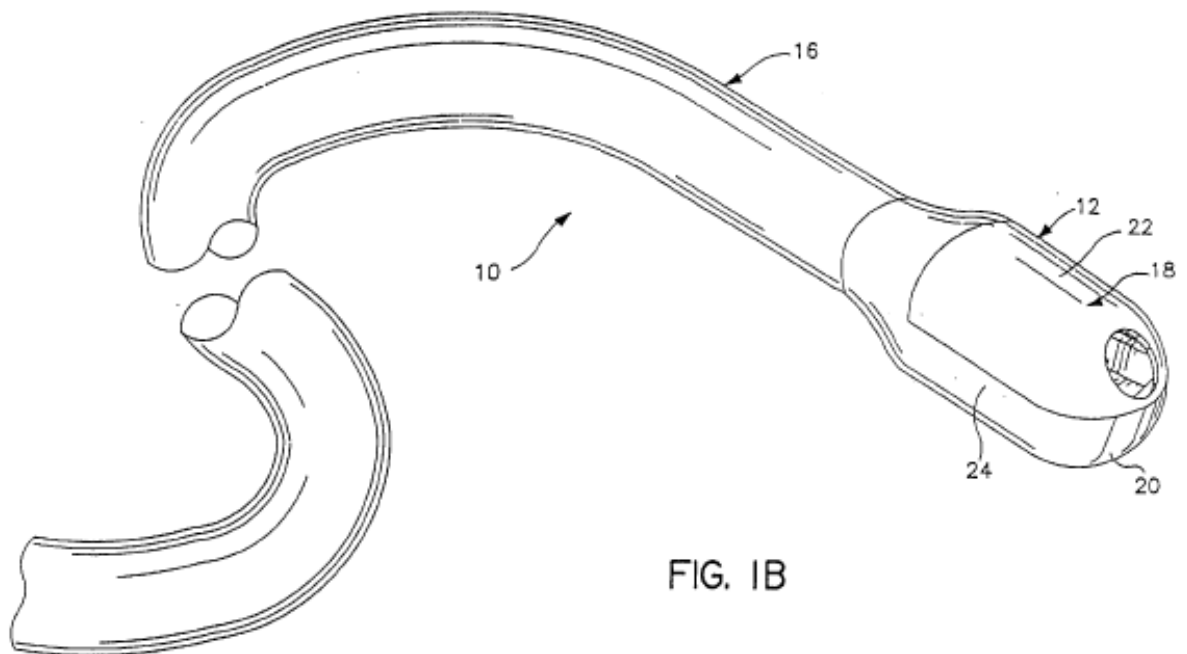
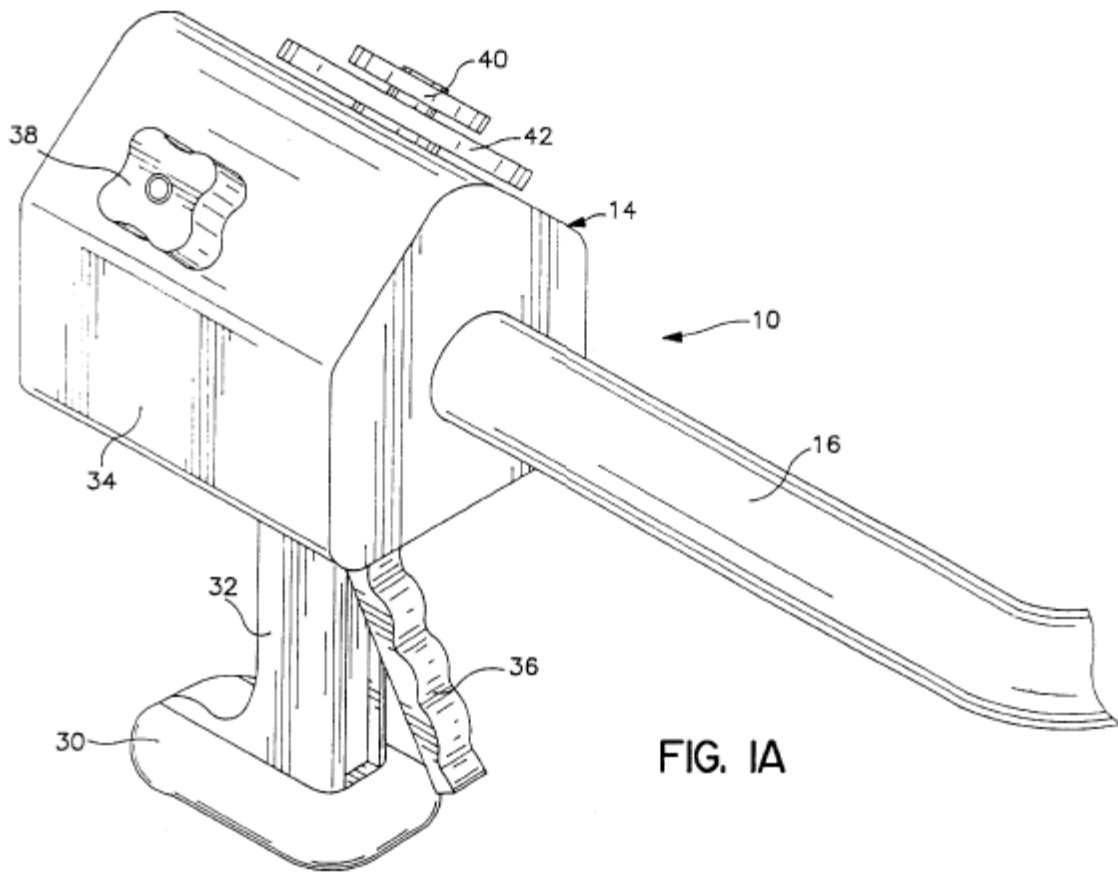
Petitioner has failed to prove by a preponderance of the evidence that claims 4–8 and 10–24 are unpatentable over Rothfuss in view of Green 209 and Knodel.

G. Ground 3 – McGuckin and Green 695

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

1. McGuckin (Ex. 1012)

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:

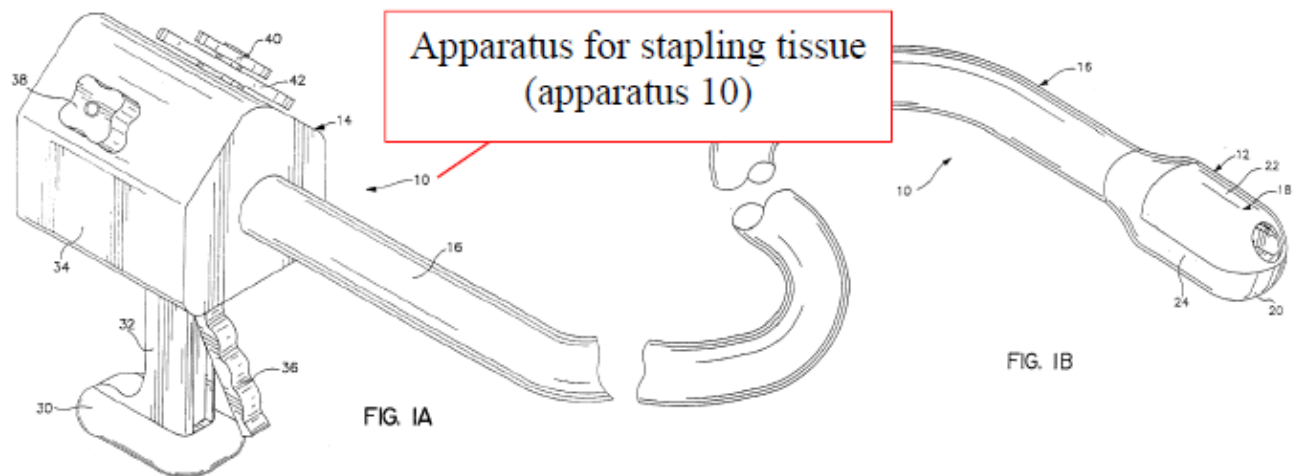


Figures 1A and 1B are isometric views of a preferred embodiment of an apparatus for the removal of malignant or other undesirable tissue. *Id.* at 9:54–56. In particular, Figure 1A (top) depicts the operating control module portion of the apparatus and Figure 1B (bottom) depicts “a longitudinally elongated 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:



As shown above in annotated Figures 1A and 1B, Petitioner submits that 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.

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

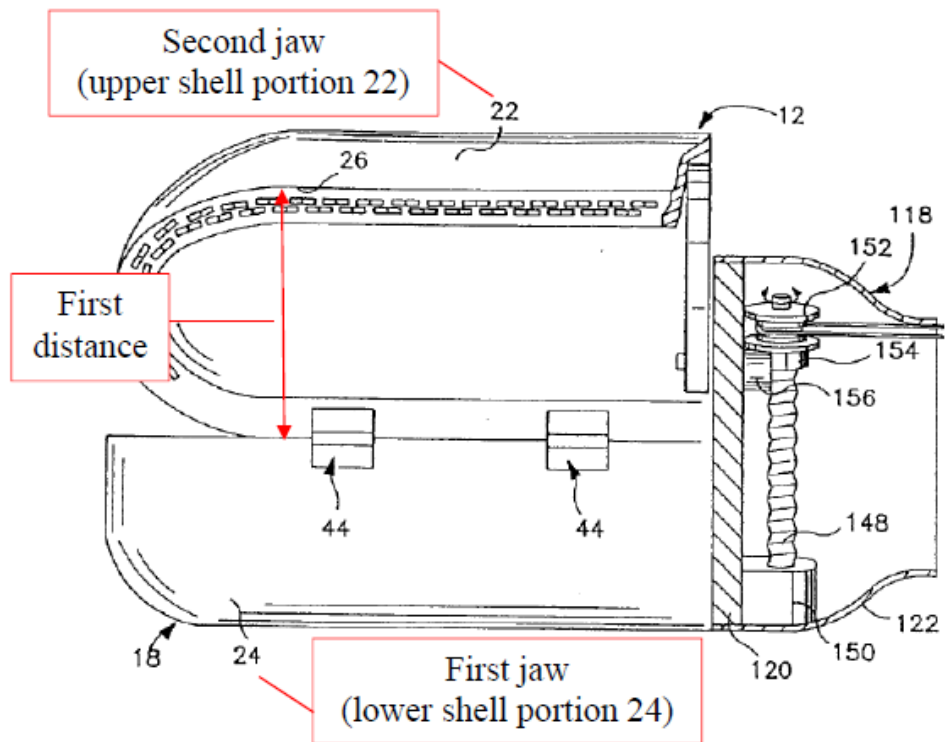


Fig. 15

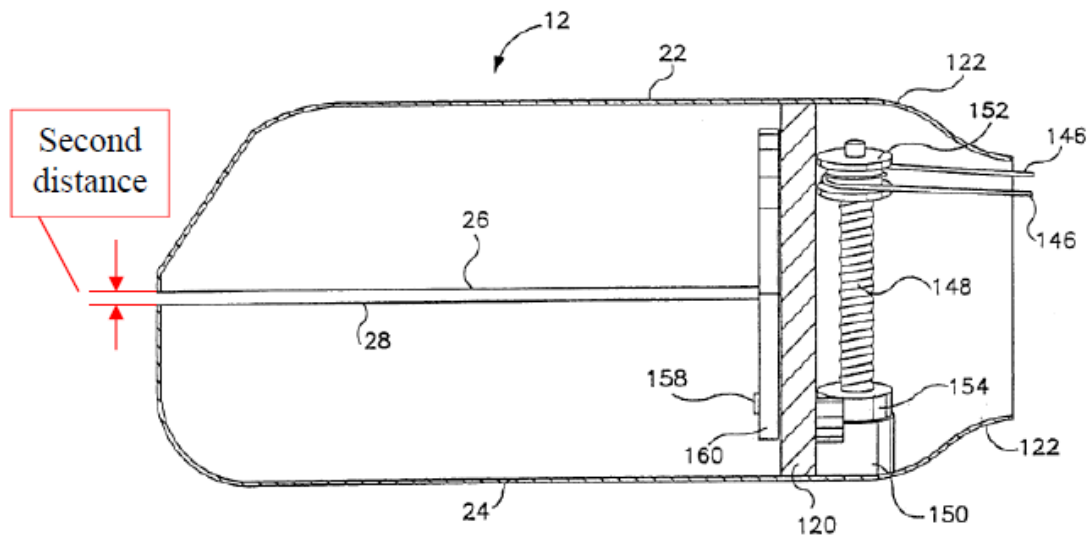


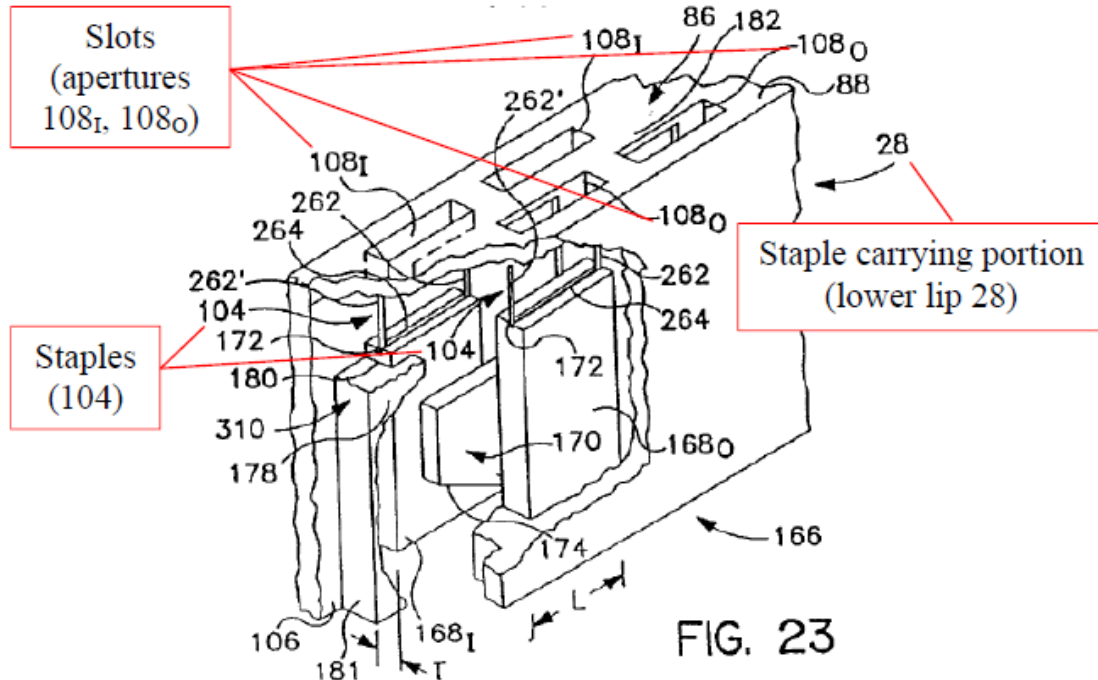
FIG. 14

As shown above in Figures 14 and 15, Petitioner identifies a “first distance” and a “second distance” between “first jaw” 24 and “second jaw” 22. Petitioner submits that 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).

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

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



As shown above in annotated Figure 23, Petitioner submits that 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).

d) “[4.3] an anvil surface defined on the second jaw opposing the first jaw”

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

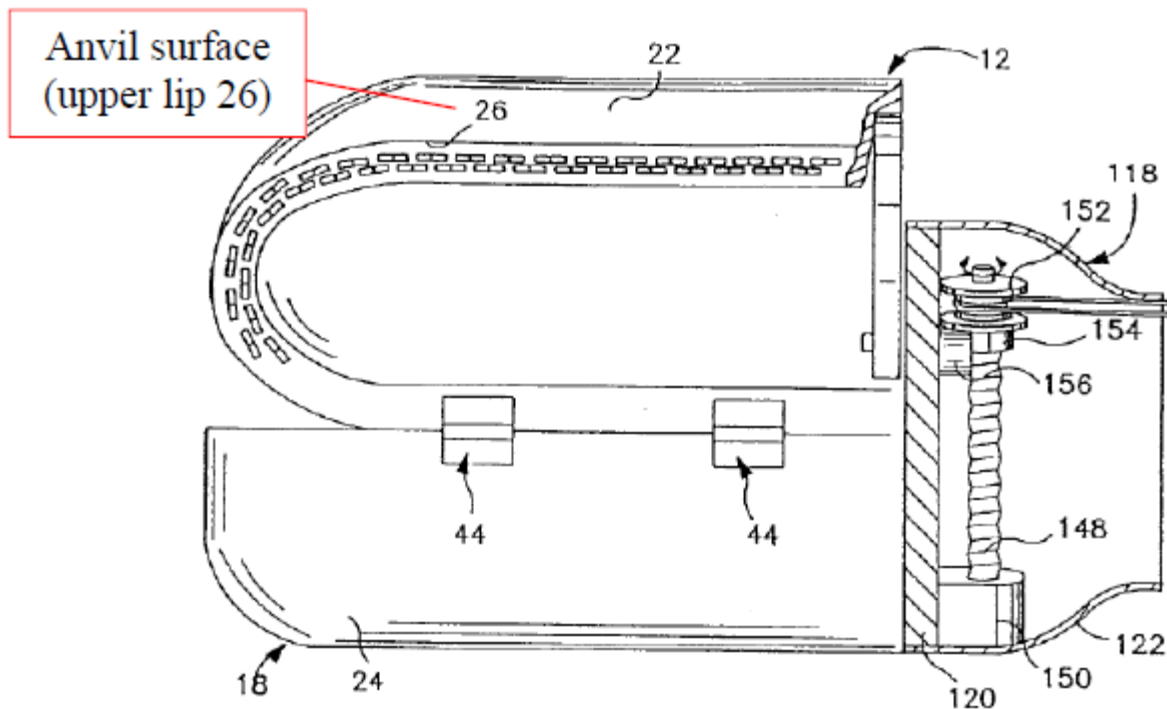
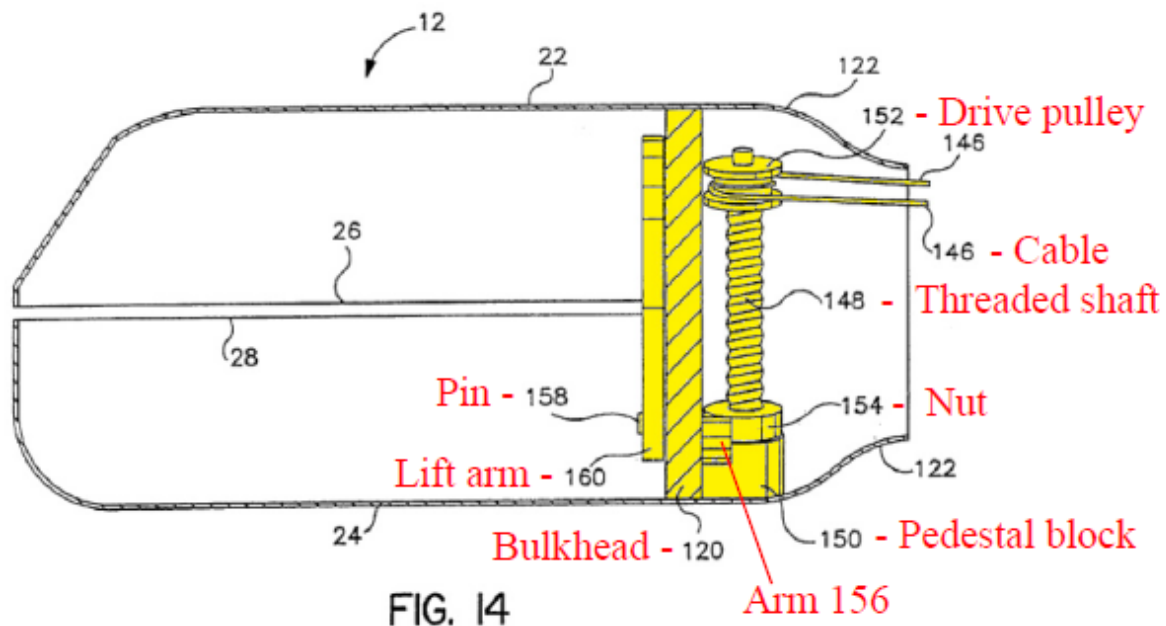


Fig. 15

As shown above in annotated Figure 15, Petitioner submits that McGuckin discloses anvil surface (upper lip 26) defined on second jaw 22 opposing first jaw 24. *See id.* (citations omitted).

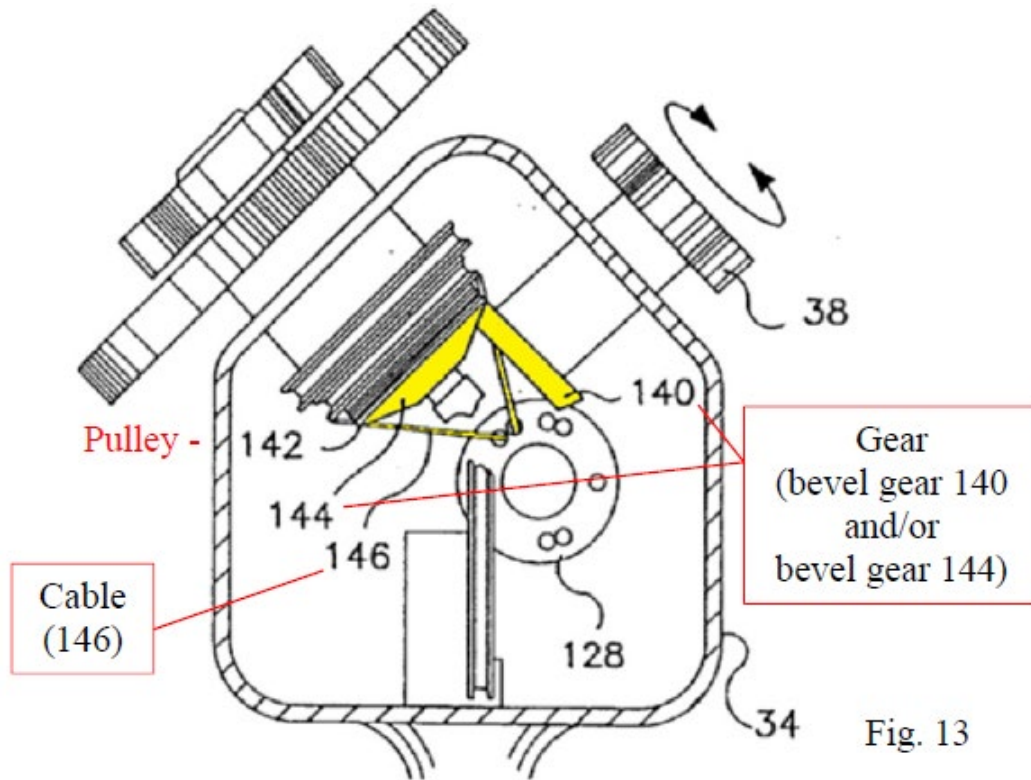
e) “[4.4] at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment”

Petitioner submits that McGuckin discloses this limitation (*see supra* Part II.G.1), and provides annotated versions of McGuckin’s Figures 13 and 14 to support its position. Pet. 75–76. We reproduce Petitioner’s annotated Figure 14, below:



As shown above in annotated Figure 14, Petitioner highlights threaded shaft 148, bulkhead 120, arm 156, pedestal block 150, pin 158, drive pulley 152, nut 154, and cable 146. Petitioner submits that McGuckin 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 id.* at 76.

We also reproduce Petitioner’s annotated Figure 13, below:



As shown above in annotated Figure 13, Petitioner submits that McGuckin discloses at least one gear (bevel gears 140, 144, highlighted in yellow) and cable (146, also highlighted in yellow). 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 (shown in Figure 14). *Id.*

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

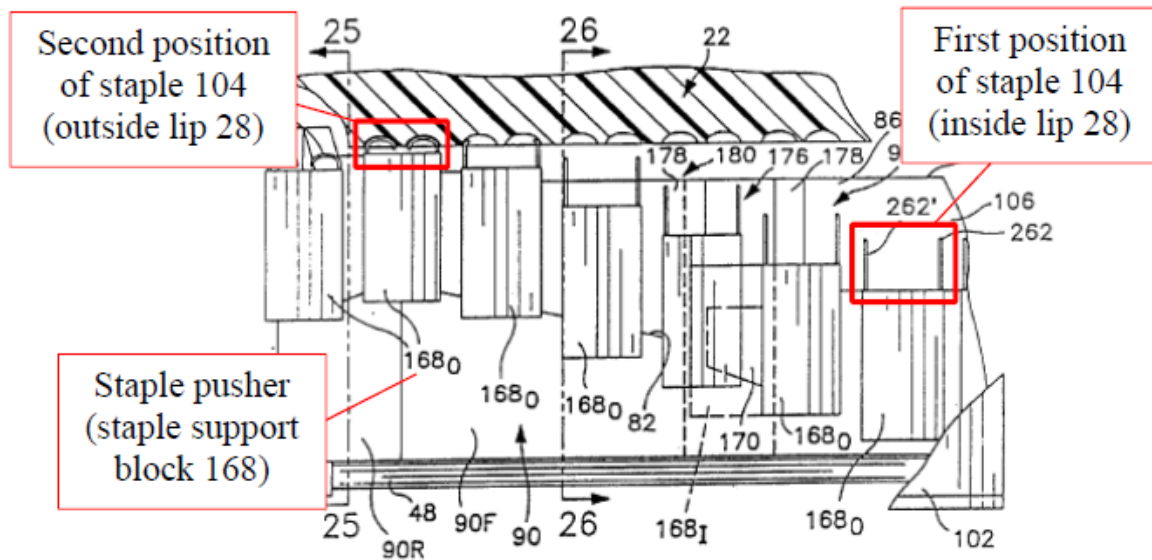


FIG. 24

As shown above in annotated Figure 24, Petitioner submits that this figure depicts staple pusher (staple support block 168) configured to cause staple (104) to move from a first position at least partially within a staple carrying portion to a second position entirely outside of the staple carrying portion. *Id.* (citations omitted).

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’s knife portion 76 to include the upper portion of an I-beam, and to modify McGuckin’s first and second jaws to include an internal passageway and opening. *See id.* at 78.

h) Patent Owner’s Argument

Patent Owner argues that a POSITA would *not* have modified McGuckin based on Green 695’s teachings. *See* PO Resp. 40–45. Patent Owner explains that the McGuckin stapler is “very different” from the staplers described in Green 695 and Green 209 and Petitioner “ignor[es] existing features of McGuckin . . . already providing alignment and stability.” *Id.* at 41. Specifically, Patent Owner identifies McGuckin’s hinges as creating a solid anchor point whereby longitudinal distortion of the jaws is prevented. *Id.* at 43 (citing Ex. 2002 ¶ 133); *see also* PO Sur-Reply 17 (“In McGuckin, longitudinal movement is restricted by two hinges 44 along the length of the shells. . . . Having two pivot points is significant.”).

We agree.

i) Analysis

Having reviewed the evidence of record, namely, McGuckin, Green 695, and the competing testimony of Mr. Juergens and Dr. Knodel, we credit

Mr. Juergens’s testimony that a POSITA would not have modified McGuckin by adding an I-beam taught by Green 695. *See* Ex. 2002 ¶ 132. To illustrate this point, Mr. Juergens produces an annotated version of McGuckin’s Figure 15 (*id.* ¶ 133), a copy of which we reproduce, below:

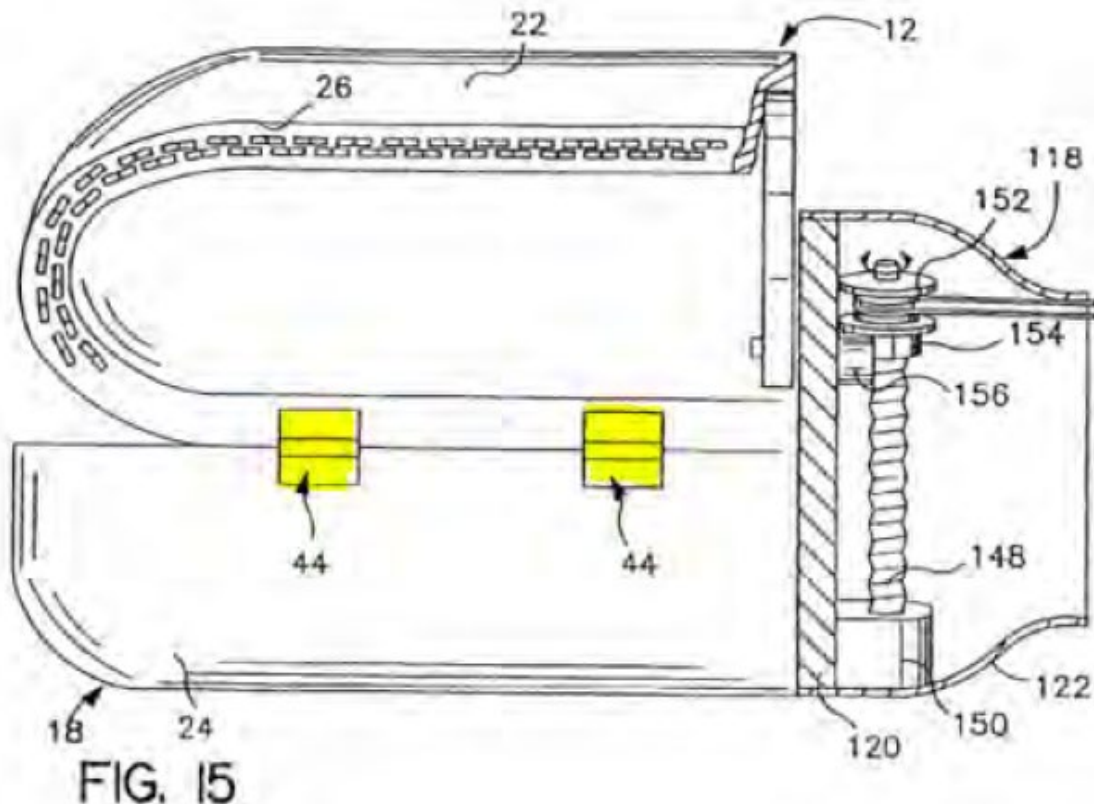


Figure 15 depicts a “partially sectioned side view of the operating capsule apparatus manifesting aspects of the invention with the operating capsule illustrated in the open position.” Ex. 1012, 10:50–52. Specifically, Figure 15 discloses upper shell portion 22 and lower shell portion 24 “longitudinally aligned and movable relative to one another about hinges 44 [highlighted in yellow] . . . so that upper and lower shell portions 22, 24 can move, thereby to open shell 18.” *Id.* at 13:29–34.

We credit Mr. Juergens’s testimony that McGuckin’s hinges 44 “are widely spaced by virtue of being on the *long side of the shell*. This makes

them particularly stable as they define a pivot line that is long when compared to the length of the rotating shell.” Ex. 2002 ¶ 135 (emphasis added).

Although we agree with Petitioner’s similar reasoning for modifying Green 209 based on Green 695’s I-beam (*see supra* Part II.D.4.i), we find that the differences between Green 209’s stapler and McGuckin’s resectioning apparatus would have led a POSITA to different results.

Green 209’s stapler includes elongated jaws (56, 58) with a pivot point located at one end of the elongation. *See, e.g.*, Ex. 1004, Fig. 1.

McGuckin’s device, on the other hand, is not elongated like Green 209’s and Green 695’s staplers, and McGuckin’s shell pivots along the longitudinal side of the shell. *See, e.g.*, Ex. 1012, Figs. 15, 18; *see also* PO Sur-Reply 16 (“McGuckin’s jaws pivot longitudinally”). We agree with Mr. Juergens’s testimony that the “hinges 44 in McGuckin . . . are widely spaced by virtue of being on the long side of the shell [and that this] makes them particularly stable as they define a pivot line that is long when compared to the length of the rotating shell.” Ex. 2002 ¶ 135.

The record supports our legal conclusion that Green 209’s elongated jaws, but not McGuckin’s relatively short jaws, would have benefited from adding an I-beam. We credit Mr. Juergens’s testimony that McGuckin’s hinges “are disposed along the length of jaws 22, 24, creating a solid anchor and pivot point [axis] about which jaws 22, 24 can rotate but longitudinal movement is prevented.” Ex. 2002 ¶ 133. Indeed, even Dr. Knodel’s testimony confirms our understanding that a longer anvil, or longer jaws, “would have been required to stabilize and align the jaws.” *See* Ex. 1025 ¶ 5 (“If, however, a POSITA used a longer anvil . . . then an I-beam (or a similar

structure) would have been required to stabilize and align the jaws.”). Yet, McGuckin’s jaws are not elongated like Green 209’s jaws or Green 695’s jaws.

Furthermore, we are not persuaded by Dr. Knodel’s testimony that “a POSITA would have understood that McGuckin’s jaws could have various lengths.” Ex. 1025 ¶ 42. Petitioner’s attempt to reconstruct the shape and length of McGuckin’s jaws for the purpose of supporting its proposed modification is a bridge too far; this is precisely the type of impermissible hindsight reconstruction that we have been cautioned to avoid. *See Grain Processing Corp. v. Am.-Maize Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (“Care must be taken to avoid hindsight reconstruction by using ‘the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.’” (quoting *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983))).

For the foregoing reasons, Petitioner has failed to prove by a preponderance of the evidence that a skilled artisan would have been motivated to modify McGuckin to include an I-beam in view of Green 695’s teachings. As such, Petitioner has failed to prove that claim 4 is unpatentable over McGuckin in view of Green 695.

3. *Independent Claim 13*

As with its challenge of claim 4, Petitioner relies on the same unsupportable modification of adding an I-beam to McGuckin based on Green 695’s teachings. *See* Pet. 91 (referencing limitation [4.6] in addressing “a beam . . . configured to clamp and align the first and second jaws . . .”). For the same reasons that Petitioner has failed to prove by a

preponderance of the evidence that a skilled artisan would have been motivated to modify McGuckin to include an I-beam in view of Green 695's teachings, Petitioner has failed to prove that independent claim 13 is unpatentable over McGuckin in view of Green 695.

4. *Dependent Claims 5–12 and 14–24*

Claims 5–12 and 14–24 depend from claim 4 or 13, respectively, and Petitioner's challenge to these claims inherit the same infirmity as its challenge under claim 4. *See* Pet. 83–98. For the same reasons that Petitioner has failed to prove by a preponderance of the evidence that a skilled artisan would have been motivated to modify McGuckin to include an I-beam in view of Green 695's teachings, Petitioner has failed to prove that claims 5–12 and 14–24 are unpatentable over McGuckin in view of Green 695.

5. *Summary of Ground 3*

Petitioner has failed to prove by a preponderance of the evidence that claims 4–24 are unpatentable over McGuckin in view of Green 695.

III. CONCLUSION

Weighing the evidence of the disclosure of the references, the competing testimony, and the reasoning to combine the references, we determine that Petitioner has shown by a preponderance of the evidence that claims 4, 5, 9–18, 20, and 22–24 of the '650 patent are unpatentable. Petitioner has not shown that claims 6–8, 19, and 21 of the '650 patent are unpatentable.

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
4, 5, 9–18, 20, 22–24	103	Green 209, Green 695, Knodel (Ground 1A)	4, 5, 9–18, 20, 22–24	
4, 5, 9–18, 20, 22–24	103	Green 209, Green 695, Knodel (Ground 1B)		4, 5, 9–18, 20, 22–24
4–8, 10–24	103	Rothfuss, Green 209, Knodel		4–8, 10–24
4–24	103	McGuckin, Green 695		4–24
Overall Outcome			4, 5, 9–18, 20, 22–24	6–8, 19, 21

IV. ORDER

Accordingly, it is:

ORDERED that claims 4, 5, 9–18, 20, and 22–24 of the '650 patent have been shown to be unpatentable;

FURTHER ORDERED that claims 6–8, 19, and 21 of the '650 patent have not been shown to be unpatentable; and

FURTHER ORDERED that any party seeking judicial review must comply with the notice and service requirements of 37 C.F.R. § 90.2.²

² Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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For PETITIONER:

Steven Katz

John Phillips

Ryan O'Connor

FISH & RICHARDSON P.C.

katz@fr.com

phillips@fr.com

oconnor@fr.com

For PATENT OWNER:

Erik Milch

Jennifer Volk-Fortier

Frank Pietrantonio

Joseph Van Tassel

COOLEY LLP

emilch@cooley.com

jvolkfortier@cooley.com

fpietrantonio@cooley.com

jvantassel@cooley.com