

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

ETHICON LLC,
Patent Owner.

IPR2020-00050
IPR2020-00051¹
Patent 9,844,379 B2

Before JOSIAH C. COCKS, FRANCES L. IPPOLITO, and
MATTHEW S. MEYERS, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Granting Parties' Motions to Seal
35 U.S.C. § 318(a)

¹ As set forth herein, we exercise our discretion under 35 U.S.C. § 315(d) to consolidate the two proceedings.

I. INTRODUCTION

A. Consolidation

Pursuant to 35 U.S.C. § 315(d):

[D]uring the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review of other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

Here, each of IPR2020-00050 and IPR2020-00051 involves challenges to claims 1–3 (“the challenged claims”) of U.S. Patent No. 9,844,379 B2 (Ex. 1001 (both proceedings), “the ’379 patent”). We exercise our discretion to consolidate the proceedings and enter a single final written decision pertaining to both proceedings.²

B. Background

Intuitive Surgical, Inc. (“Petitioner”) filed a Petition (IPR2020-00050, Paper 3, “’050 Pet.”; IPR2020-00051, Paper 3, “’051 Pet.”) in each proceeding to institute an *inter partes* review of the challenged claims. *See*

² During a conference call on September 18, 2020, Petitioner requested that the two proceedings be consolidated into a single proceeding with a single final written decision. *See* IPR2020-00051, Ex. 1026, 7–10. At the time, the panel and Patent Owner contemplated that there may be logistical issues, including, for instance, concerns as to the effect of consolidation on briefing submitted during trial, were the cases to then be consolidated. *See id.* At this advanced stage of the proceedings, the panel considers entry of a single final written decision to be appropriate.

35 U.S.C. § 311. We instituted trial in each proceeding, to determine whether the challenged claims were unpatentable as follows:

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–3	102	Shelton '562 ³

IPR2020-00050, Paper 15 (“’050 Dec. on Inst.”).

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–3	102	Shelton '818 ^{4,5}

³ Shelton '562, US 2005/0263562 A1 published Dec. 1, 2005 (IPR2020-00050, Ex. 1004).

⁴ Shelton '818, US 7,000,818 B2 issued Feb. 21, 2006 (IPR2020-00051, Ex. 1014).

⁵ Petitioner contends that Shelton '818 incorporates by reference the entirety of another document that Petitioner identifies as “U.S. Patent Application Publication No. 2004/0232195 (‘Shelton '195,’ [Ex. 1013]).” ’051 Pet. 19 (citing Ex. 1014, 1:8–26, 9:35–38). Shelton '818, itself, does not reference the particular application publication number that Petitioner terms “Shelton '195,” and instead incorporates by reference four applications identified by their titles and the names of their inventors. IPR2020-00051, Ex. 1014, 1:13–26. Petitioner relies on the Declaration testimony of Dr. Bryan Knodel (Ex. 1003) to support that Shelton '195 constitutes subject matter of one of those four applications. ’051 Pet. 19 (citing Ex. 1003 ¶ 57, n.2). On the record before us, we discern no reason to doubt Petitioner’s and Dr. Knodel’s contention that one of the patent applications identified expressly in Shelton '818 is Shelton '195 and is incorporated by reference in its entirety as a part of Shelton '818’s disclosure. Patent Owner also does not contest that Shelton '195 is incorporated by reference. Petitioner relies on content of Shelton '195 as a part of its proposed ground of anticipation based on Shelton '818.

IPR2020-00050
IPR2020-00051
Patent 9,844,379 B2

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–3	103	Green, ⁶ Solyntjes ⁷

IPR2020-00051, Paper 15 (“’051 Dec. on Inst.”).⁸

In IPR2020-00050, Ethicon LLC, (“Patent Owner”) timely filed a Patent Owner’s Response. Paper 21 (“’050 PO Resp.”).⁹ Petitioner filed a Reply. Papers 28, 29 (“’050 Pet. Reply”).¹⁰ Patent Owner subsequently filed a Sur-Reply (Paper 38, “’050 Sur-Reply”) and Petitioner filed a Sur-Sur-Reply (Paper 46, “’050 Sur-Sur-Reply”).¹¹ A consolidated oral hearing for both IPR2020-00050 and IPR2020-00051 occurred on January 12, 2021.

⁶ Green, US 4,429,695 issued Feb. 7, 1984 (IPR2020-00051, Ex. 1015).

⁷ Solyntjes, US 5,413,267 issued May 9, 1995 (IPR2020-00051, Ex. 1011).

⁸ Prior to our Decisions on Institution, and as was authorized by the panel (Paper 9 in each proceeding), Patent Owner filed a “Motion Requesting Leave to Petition the Director for a Certificate of Correction” (Paper 10 in each proceeding). Although Petitioner opposed (Paper 11 in each proceeding), we granted the Motion (Paper 13 in each proceeding). During trial, on April 21, 2020, the Director issued a Certificate of Correction. *See* Ex. 2004 (each proceeding).

⁹ Along with the Response, Patent Owner filed a “Motion to Seal and For Entry of a Protective Order.” Paper 20.

¹⁰ Paper 28 is a version of the Reply designated “Protective Order Material - Confidential.” IPR2020-00050, Paper 28; *see also* Paper 27 (Petitioner’s Motion to Seal). Paper 29 is a redacted, public version.

¹¹ Petitioner’s Sur-Sur-Reply was authorized by the panel. Paper 46.

A transcript of the oral hearing appears in the record. IPR2020-00050, Paper 49, Ex. 2102; IPR2020-00051, Paper 50, Ex. 2102.¹²

In IPR2020-00051, Patent Owner timely filed a Patent Owner's Response. Papers 21, 22 ("051 PO Resp."). Petitioner filed a Reply. Papers 29, 30 ("051 Pet. Reply").¹³ Patent Owner subsequently filed a Sur-Reply (Papers 39, 40, "051 Sur-Reply")¹⁴ and Petitioner filed a Sur-Sur-Reply (Paper 47, "051 Sur-Sur-Reply").¹⁵

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that the challenged claims of the '379 patent are unpatentable.

¹² The parties had represented that confidential material may be discussed during the oral hearing. Accordingly, the hearing was closed to the public. A non-public version of the transcript of the hearing was entered into the record. IPR2020-00050, Paper 49; IPR2020-00050, Paper 50. The parties were invited to submit jointly a public, redacted version of the transcript. IPR2020-00050, Paper 50; IPR2020-00051, Paper 51. They did so (IPR2020-00050, Paper 51; IPR2020-00051, Paper 52), and the parties' joint submission now appears in the record (IPR2020-00050, Ex. 2012; IPR2020-00051, Ex. 2102).

¹³ Paper 29 is a version of the Reply designated "Protective Order Material - Confidential." Paper 29; *see also* Paper 28 (Petitioner's Motion to Seal). Paper 30 is a redacted, public version.

¹⁴ Paper 39 is a version of the Sur-Reply designated "Protective Order Material." Paper 39; *see also* Paper 38 (Patent Owner's second Motion to Seal). Paper 40 is a redacted, public version.

¹⁵ Petitioner's Sur-Sur-Reply was authorized by the panel. Paper 46.

C. Related Matters

The parties identify *Ethicon LLC et al. v. Intuitive Surgical, Inc. et al.*, C.A. No. 1:18-cv-01325-LPS (D. Del.) as a proceeding in which Patent Owner moved to amend its complaint to assert the '379 patent against Petitioner. Paper 6, 2 (each proceeding); *see* Pet. 2 (each proceeding). Patent Owner explains that “[o]n July 17, 2019, Patent Owner’s motion was denied without prejudice in light of the parties’ joint stipulation to stay that litigation.” Paper 6, 2. The parties also refer to a United States International Trade Commission proceeding alleging infringement of the '379 patent by Petitioner. Pet. 2; Paper 6, 2 (identifying *Certain Reload Cartridges for Laparoscopic Surgical Staplers*, Inv. No. 337-TA-1167). Petitioner further identifies several other *inter partes* review (“IPR”) proceedings involving other U.S. patents that Patent Owner has asserted against Petitioner in district court. Pet. 2–3. Patent Owner additionally references numerous other U.S. patents and patent applications that it contends “claim priority to one of more of the same applications(s) to which the '379 patent claims priority.” Paper 6, 3–7.

D. The '379 Patent

The '379 patent is titled “Surgical Stapling Instrument Having Clearanced Opening,” and relates to “surgical instruments that are suitable for endoscopically inserting an end effector that is actuated by a longitudinally driven firing member.” Ex. 1001, code (54); 1:51–54. The Abstract of the '379 patent sets forth the following:

A stapling assembly comprising a first jaw and a second jaw, wherein the first jaw is rotatable relative to the second jaw. The

stapling assembly comprises a detachable cartridge portion comprising a plurality of staples and an anvil configured to deform the staples. The stapling assembly comprises a staple firing member comprising a first cam configured to engage the first jaw and a second cam configured to engage the second jaw when the staple firing member is advanced from an initial position, and wherein the first jaw comprises a clearanced opening configured to receive the first cam when the staple firing member is in the initial position such that the first cam is not engaged with the first jaw when the staple firing member is in the initial position.

Id. at code (57).

Figure 1 of the '379 patent is reproduced below.

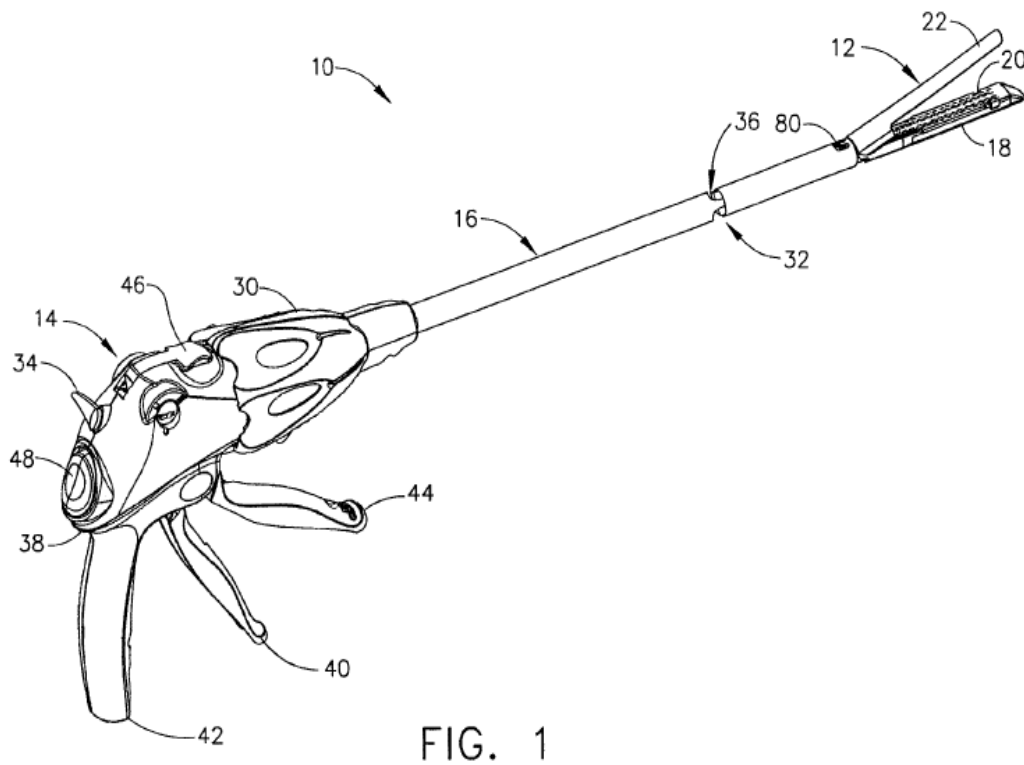


FIG. 1

Figure 1 above shows “a perspective view of an endoscopic surgical stapling instrument for surgical stapling and severing in an open, unarticulated state.” *Id.* at 3:44–46. Surgical stapling instrument 10

includes handle 14 and staple applying assembly 12 spaced from the handle by elongate shaft 16. *Id.* at 4:58–61.

Figure 2 of the '379 patent is reproduced below.

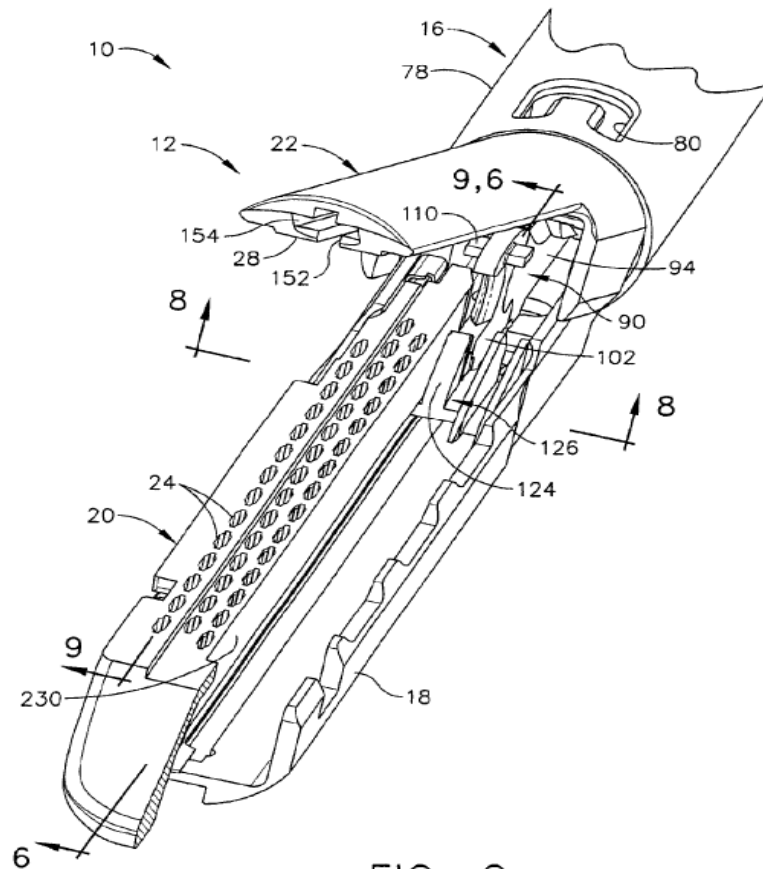


FIG. 2

Figure 2 above “is a left front perspective view of an open staple applying assembly of the surgical stapling instrument of FIG. 1 with a right half portion of a replaceable staple cartridge included in a staple channel.” *Id.* at 3:47–50. Staple receiving assembly 12 includes staple channel 18 for receiving staple cartridge 20. *Id.* at 4:61–63. “Pivotally attached to the staple channel 18 is an anvil 22 that clamps tissue to the staple cartridge 20 and serves to deform staples 23 [not shown in Figure 2] driven up from

staple holes 24 in the staple cartridge 20 against staple forming recesses [not shown in Figure 2] in an anvil undersurface 28 into a closed shape.” *Id.* at 4:63–5:1. “An E-beam 102 is the distal portion of the two-piece knife and firing bar 90, which facilitates separate closure and firing as well as spacing of the anvil 22 from the elongate staple channel 18 during firing.” *Id.* at 6:28–31.

Figure 6 of the '379 patent is reproduced below.

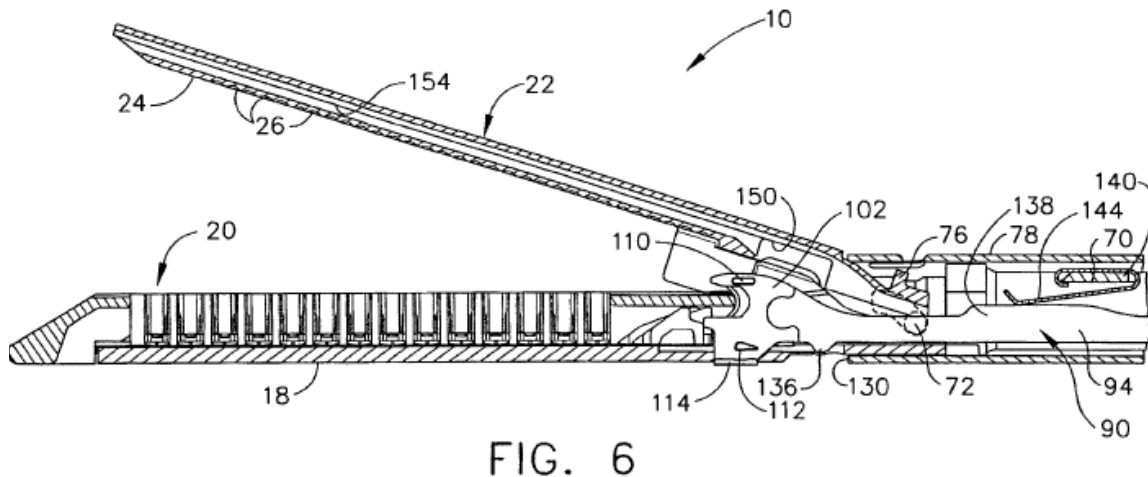


Figure 6 above “is a left side view [] taken in longitudinal cross section along a centerline line 6-6 of the staple applying assembly of FIG. 2.” *Id.* at 3:60–63. In Figure 6, surgical stapling instrument is shown in an open state with E-Beam 102 fully retracted. *Id.* at 6:61–62. “E-beam 102 is retracted with the top pins 110 thereof residing with an anvil pocket 150 near the pivoting proximal end of the anvil 22.” *Id.* at 7:29–31.

Figure 8 of the '379 patent is reproduced below.

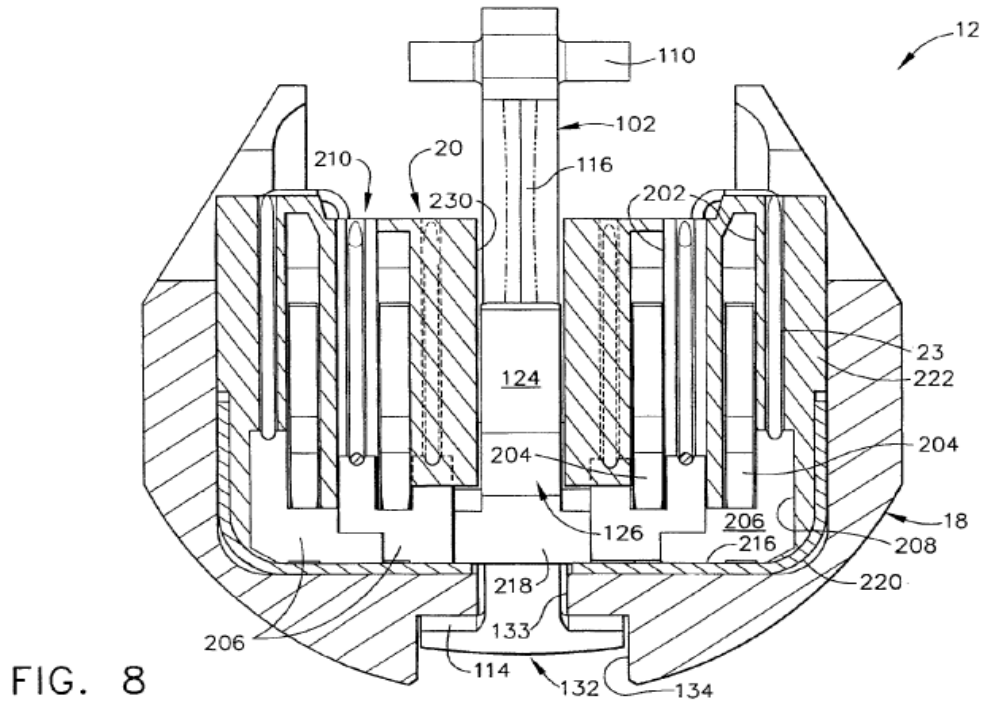


Figure 8 above “is a front view in elevation taken in cross section along line 8-8 of the staple applying assembly of FIG. 2 depicting internal staple drivers of the staple cartridge and portions of the two-piece knife and firing bar.” *Id.* at 4:1–4. “Longitudinally aligned and parallel plurality of downwardly open wedge slots 202 (FIG. 8) receive respective wedges 204 integral to the wedge sled 126.” *Id.* at 7:44–47.

Figures 13 and 14 of the '379 patent are reproduced below.

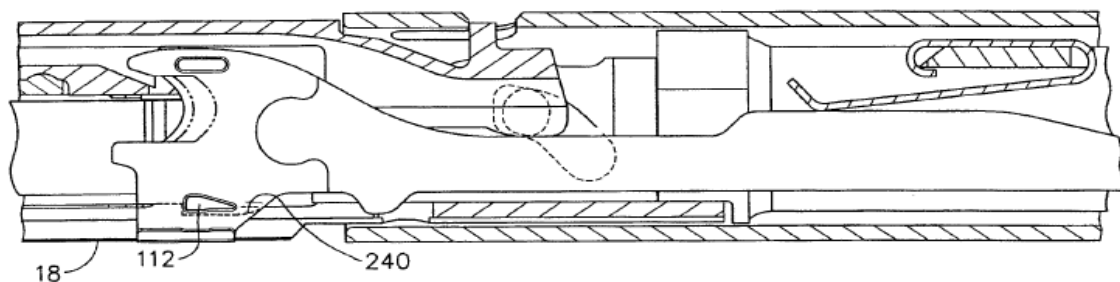
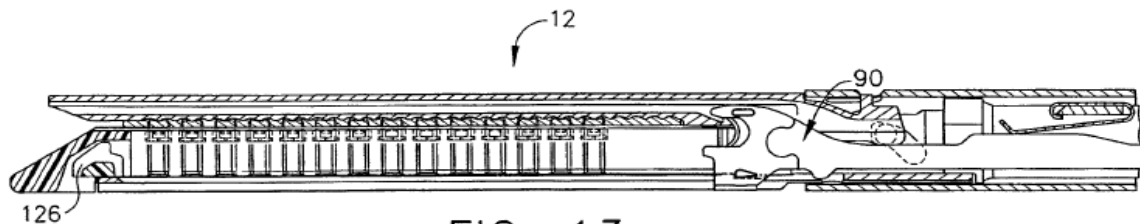


Figure 13 above is a left view cross-sectional view in elevation of a closed staple applying assembly “after firing of the staple cartridge and retraction of the two-piece knife.” *Id.* at 4:22–23. Figure 14 above is “a left side cross-sectional detail view in elevation of the staple applying assembly of FIG. 13 with the two-piece knife allowed to drop into a lockout position.” *Id.* at 4:25–27. After firing, firing bar 90 is retracted leaving wedge sled 126 in a distal position. *Id.* at 8:18–19. The '379 patent further states the following:

In FIG. 14, the middle pin 112 is allowed to translate down into a lockout recess 240 formed in the staple channel 18 Thus, the operator would receive a tactile indication as the middle pin 112 encounters the distal edge of the lockout recess 240 when the wedge sled 126 (not shown in FIG. 14) is not

proximally positioned (i.e., missing staple cartridge 20 or spent staple cartridge 20).

Id. at 8:20–26.

E. Illustrative Claim

Each of claims 1–3 is independent. Claim 1 is illustrative and is reproduced below.

1. A stapling assembly, comprising:
 - a frame;
 - a distal end;
 - a first jaw comprising a channel;
 - a channel retainer, wherein said channel is slidably attachable to said channel retainer;
 - a second jaw extending from said frame;
 - a plurality of staples;
 - a staple firing member comprising a first cam configured to engage said first jaw and a second cam configured to engage said second jaw when said staple firing member is advanced from an unadvanced position toward said distal end, wherein one of said first jaw and said second jaw comprises a clearanced opening configured to permit said firing member to be unengaged with one of said first jaw and said second jaw when said firing member is in said unadvanced position; and
 - a lockout configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.

Ex. 1001, 8:60–9:11.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b).” 37 C.F.R. § 42.100(b) (2019).

Under this standard, claim terms are given their ordinary and customary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). We determine that it is unnecessary to provide an explicit construction of any additional claim term in order to resolve the issues in dispute in this proceeding. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (explaining that claim terms need to be construed “only to the extent necessary to resolve the controversy” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Proposed Ground of Obviousness Based on Green and Solyntjes

1. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 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 such subject matter pertains.” 35 U.S.C. § 103(a). The question of obviousness under 35 U.S.C. § 103 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) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–

18 (1966).¹⁶ “While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

2. *Level of Ordinary Skill in the Art*

Patent Owner expresses the following as to the level of ordinary skill in the art:

Patent Owner’s expert, Dr. Fronczak, has opined that a person of ordinary skill in the art (“POSITA”) with respect to the 379 Patent would include someone who has a Bachelor’s degree in Mechanical Engineering or an equivalent branch of engineering, as well as 3 years of experience in the design and analysis of minimally invasive surgical instruments or comparable surgical devices. [IPR2020-00051,] Ex. 2094 ¶ 33. Petitioner’s expert, Dr. Knodel, has opined that a POSITA would include someone who 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. [IPR2020-00051,] IS1003 ¶¶ 25–26. Accordingly, there does not appear to be a material dispute between the parties regarding the level of ordinary skill in the art.

’051 PO Resp. 15.

Petitioner does not challenge Patent Owner’s explanation of the parties’ positions with respect to the level of ordinary skill in the art. We agree that there is no material dispute between the parties’ experts in that respect, and adopt the proposed assessments. We also discern that the applied prior art reflects the appropriate level of skill at the time of the

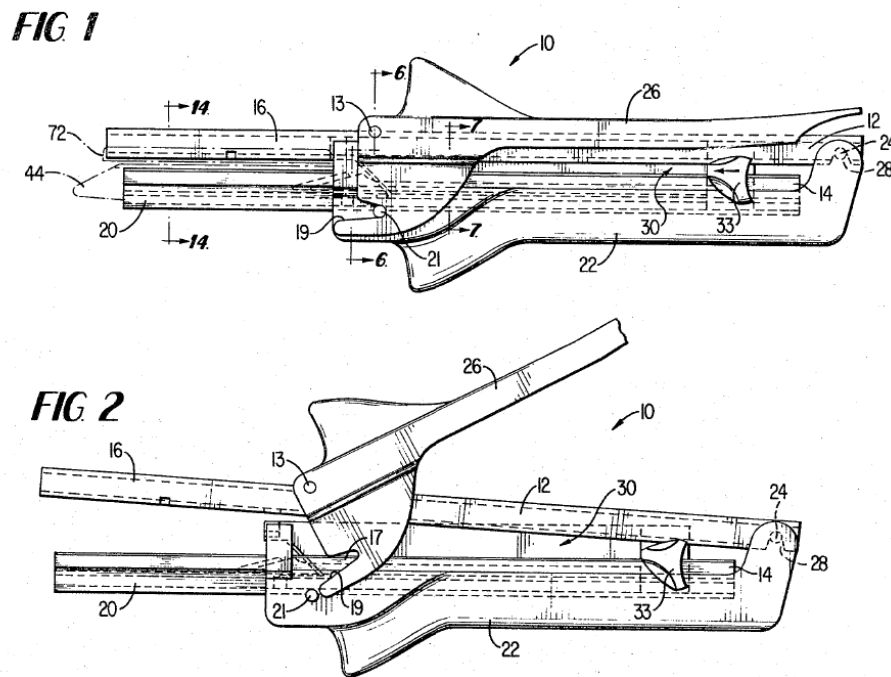
¹⁶ Neither party has submitted or relied on any objective evidence of non-obviousness.

claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

3. Overview of Green

Green is titled “Surgical Instruments.” IPR2020-00051, Ex. 1015, code (54). Green describes “[a] surgical stapling instrument [that] has upper and lower elongate jaws for receiving a staple cartridge and an anvil respectively.” *Id.* at code (57).

Green’s Figures 1 and 2 are reproduced below:



Figures 1 and 2 above illustrate a surgical stapling instrument in a closed position (Figure 1) and an open position (Figure 2). *Id.* at 2:59–62. Surgical stapling instrument 10 includes upper frame 12 defining elongate upper jaw 16 and lower frame 14 defining elongate lower jaw 20. *Id.* at 3:23–27. Handle 26 operates to open and close the frames about pivot

means 24, 28. *Id.* at 3:34–37.

Green's Figure 3 is reproduced below:

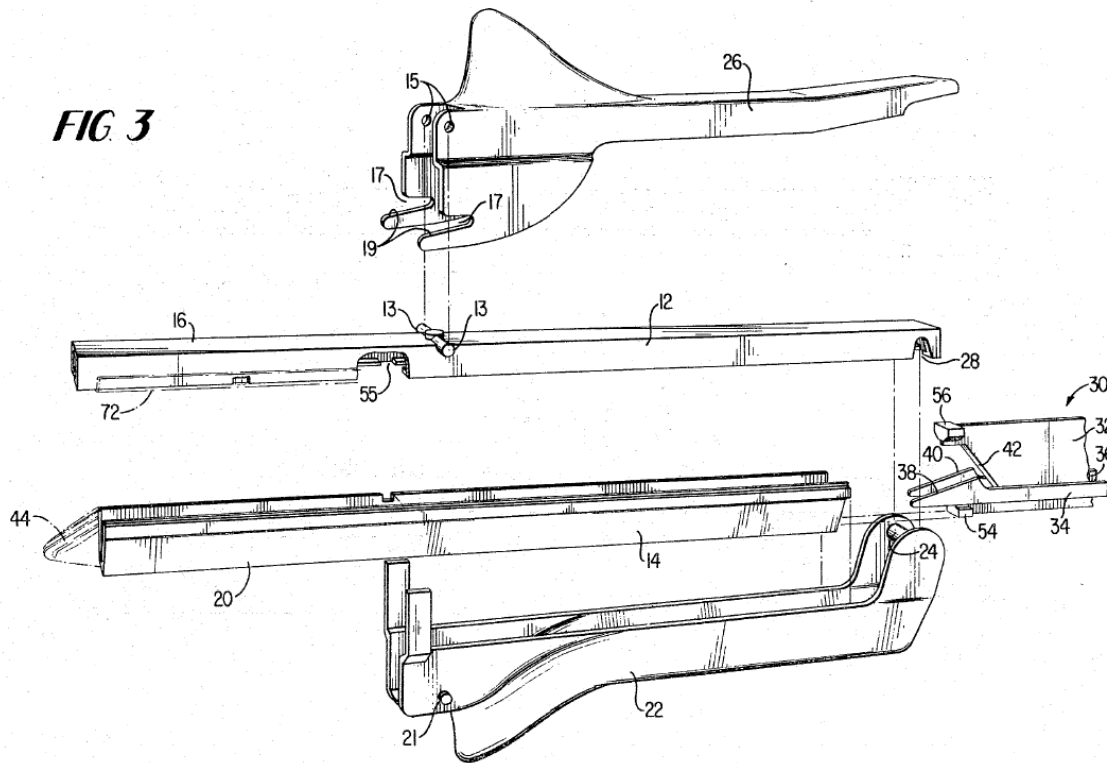


Figure 3 depicts an “exploded view of the instrument.” *Id.* at 2:63. The surgical stapler instrument includes sliding pusher bar and knife assembly 30 with knife 42 that is situated to the rear of pusher bar cams 38 and 40. *Id.* at 3:40–47 Green explains the following:

In use, a disposable staple cartridge 44, containing four laterally spaced longitudinal rows of staples is inserted into the lower jaw 20 while two anvil members 72 having staple shaping depressions in their outer surfaces, complimentary to the positioning of the individual staples in the staple cartridge, are placed on the upper jaw 16. The instrument is inserted into a patient's body and manipulated such that tissue to be cut and sutured is inserted between the jaws, and incision to receive one of the jaws having previously been made in the tissue if required. The jaws are then closed and locked by handle 26 to firmly grip

the tissue between the opposing staple cartridge and anvil surface. The pusher bar and knife assembly, which is initially in a rearward position relative to the jaws, is then pushed forward causing the pusher bar cams to enter longitudinal slits in the staple cartridge, in which slits are accommodated rows of individual stapler pushers. The pusher bar cams cooperate sequentially with camming surfaces on the individual staple pushers to force the staples successively from the cartridge, through the gripped tissue and into engagement with the anvil depressions which thereby, in conjunction with the cams, produce staple-closing forces.

Id. at 3:48–4:3.

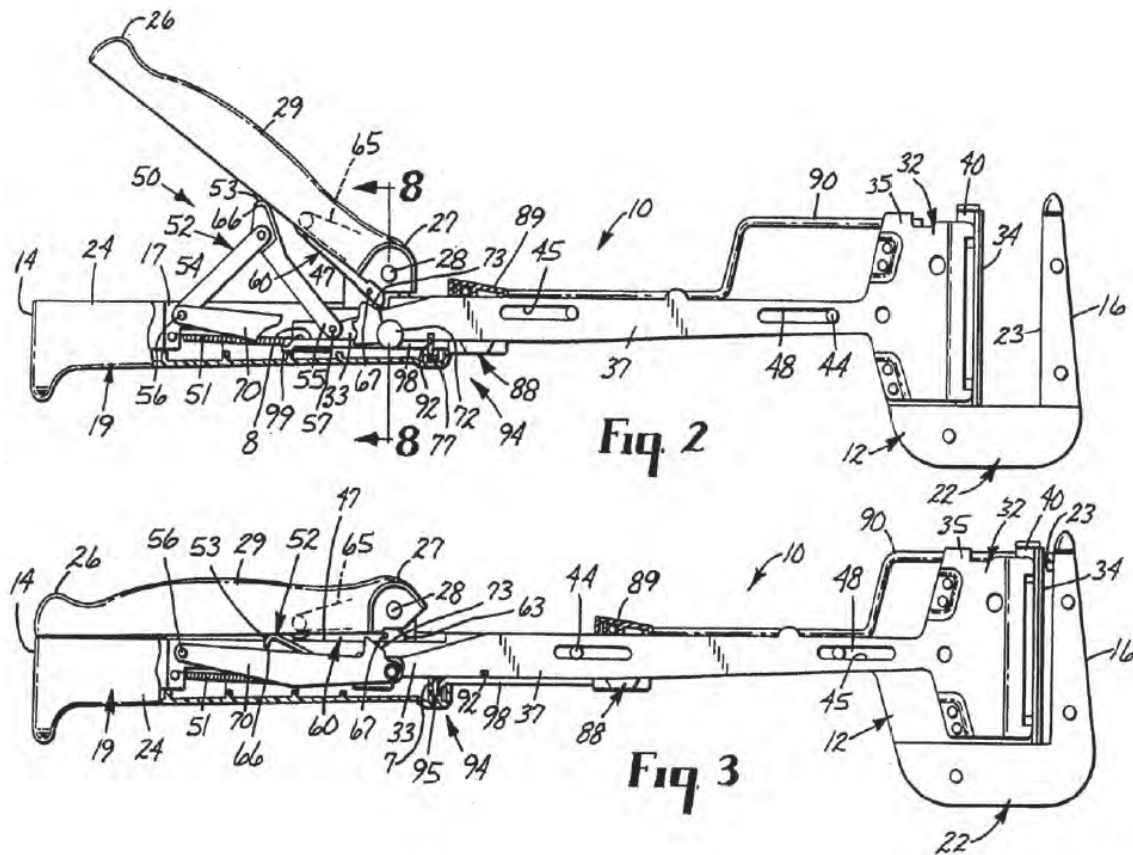
4. Overview of Solyntjes

Solyntjes is titled “Surgical Stapler with Spent Cartridge Sensing and Lockout Means.” IPR2020-00051, Ex. 1011, code (54). Solyntjes’s Abstract reads as follows:

A stapler is disclosed that includes a mechanism for sensing whether the stapler is loaded with a fire cartridge housing and for preventing the stapler from being closed or fired when loaded with the fired cartridge. The mechanism also prevents the stapler from firing or clamping on tissue when the stapler is not loaded with a stapler cartridge.

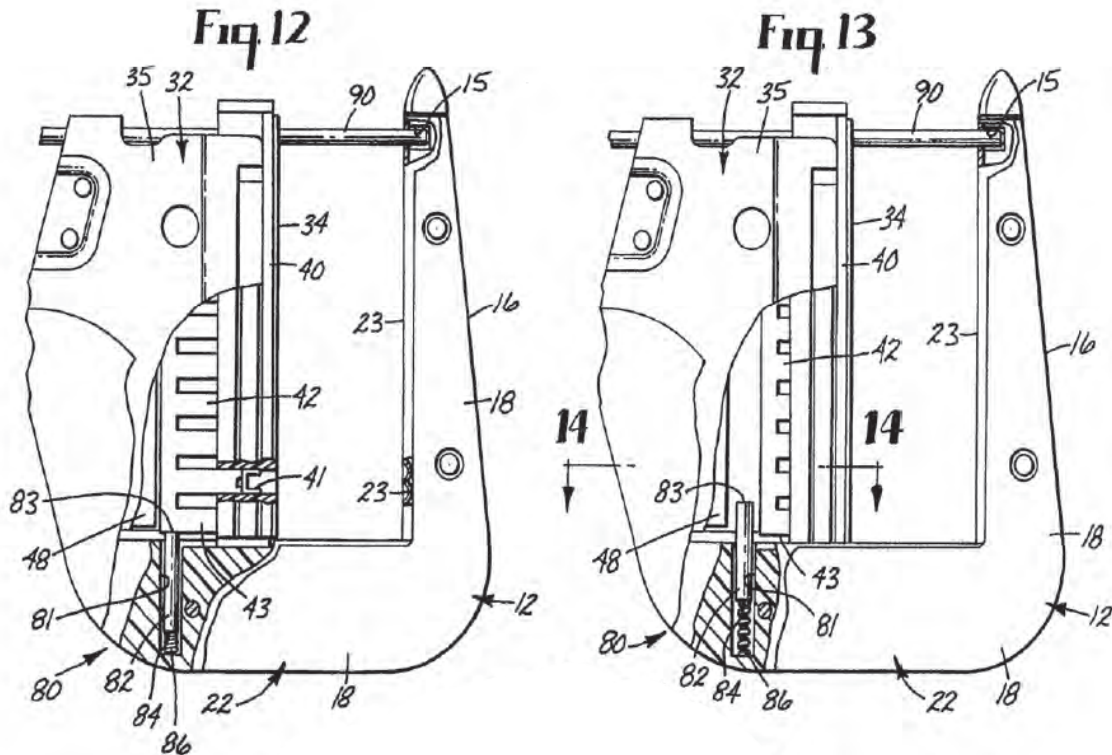
Id. at code (57).

Solyntjes's Figures 2 and 3 are reproduced below:



Figures 2 and 3 above illustrate operation of stapler 10 in an open position (Figure 2) and a closed position (Figure 3). *Id.* at 8:13–18. Actuation means 50 operates to transition cartridge assembly 32 from an open to a closed position. *Id.*

Solyntjes's Figures 12 and 13 are reproduced below:



Figures 12 and 13 above illustrate enlarged views of the distal end of a stapler in a pre-fired position (Figure 12) and a fired position (Figure 13). *Id.* at 6:8–13. The stapler includes a means for preventing cartridge assembly 32 from moving from an open to a closed position. *Id.* at 10:64–66. That means comprises anvil frame 12 defining safety aperture 81 and locking plate or pin 82 residing in the safety aperture. *Id.* at 10:66–11:2. Locking pin 82 is biased by coil spring 86 to move into the path of ram 48 to block movement of cartridge assembly 32 when the assembly is not loaded with a ready-to-fire staple cartridge. *Id.* at 10:48–11:18. In that regard, Solyntjes describes that “pin 82 prevents firing of the stapler 10 should the fired cartridge housing be replaced with another fired cartridge.” *Id.* at 12:67–13:3. Solyntjes also specifies that “pin 82 will not only prevent the

stapler 10 from firing when loaded with a spent cartridge, but will also prevent the firing of the stapler 10 when the stapler is not loaded with a cartridge housing 40 at all.” *Id.* at 12:62–66.

Solyntjes summarizes the benefits of its means for preventing cartridge assembly movement as follows:

The means for preventing the cartridge assembly from moving from the open to the closed position (1) prevents approximation and clamping of living tissue between anvil and cartridge components of the stapler when the stapler is loaded with a spent stapler cartridge, (2) prevents the user from attempting to refire the stapler, and (3) provides a stapler that reduces the chances of unnecessary tissue trauma, blood loss, inadequate hemostasis, and squandered time during surgery.

Id. at 2:59–68.

5. Discussion

Petitioner proposes that Green and Solyntjes disclose all the features of the challenged claims. ’051 Pet. 59–86. More specifically, Petitioner contends that the stapling assembly of Green accounts for the majority of the claim features including a frame, a distal end, a first jaw with a channel, a channel retainer, a second jaw, a plurality of staples, and a staple firing member. *See generally id.* Petitioner points to Solyntjes as teaching the claim element of “a lockout” that is “configured to block the advancement of said staple firing member when said channel is not attached to said channel retainer.” *Id.* at 69–75. Petitioner contends that a person of ordinary skill in the art would have had multiple reasons to implement a Solyntjes’s locking mechanism in Green’s surgical stapling device as one of ordinary skill in the art would have recognized that such a locking mechanism “would

advantageously prevent the inadvertent severing of tissue when the device is loaded with a spent cartridge or no cartridge,” and “would have made Green’s instrument safer and more efficient.” *Id.* at 75–77. Petitioner also reasons that a skilled artisan would have recognized Green’s stapling instrument as being “ready for improvement to yield predictable results.” *Id.* at 77–78 (citing *KSR*, 550 U.S. at 417). Petitioner supports its position as to its proposed combination of Green and Solyntjes with citation to the testimony of Dr. Knodel. *Id.* at 75–78 (citing Ex. 1003 ¶¶ 157–171).

Patent Owner does not dispute that all of the features required by the challenged claims are found in the prior art teachings of Green and Solyntjes. Rather, Patent Owner takes the position that a person of ordinary skill in the art neither would have been motivated to combine those teachings nor would have had a reasonable expectation of success in doing so. ’051 PO Resp. 57–85; ’051 Sur-Sur-Reply 3–38. Patent Owner offers a variety of arguments in support of its position, but for the reasons that follow we find them all unpersuasive.

For instance, Patent Owner argues that Green “already provides the user with tactile and visual feedback as to the presence or absence of a staple cartridge.” ’051 PO Resp. 59. Thus, in Patent Owner’s view, a skilled artisan would have regarded Green’s disclosure as “negat[ing] the need for a no-cartridge lockout in Green[.]” *Id.* at 62. Patent Owner bases that view almost entirely on the testimony of Dr. Fronczak. *Id.* at 59–64 (citing Ex. 2094 ¶¶ 258–265). In reviewing that testimony, we discern that it is generally premised on Dr. Fronczak’s speculation as to a user’s awareness or cognizance during use of Green’s surgical stapler instrument as to the

presence or absence of a stapler cartridge. We find that speculation unpersuasive.

In that respect, Dr. Fronczak does not explain persuasively why the prospect that a user might happen to recognize that a stapler instrument is missing a staple cartridge eliminates motivation to employ a locking mechanism, as in Solyntjes, which is an assembly dedicated to preventing the instrument's firing in the very circumstance of the absence of a cartridge. Solyntjes's teachings as to the safety benefit of a locking mechanism as a part of a stapler instrument are unambiguous. In particular, Solyntjes clearly sets forth that a locking mechanism is valuable, as the dangers of firing a surgical stapler instrument without a staple cartridge being present are significant, including the risk of "unnecessary tissue trauma, blood loss, inadequate hemostasis, and squandered time during surgery." IPR2020-00051, Ex. 1011, 2:65–68. Indeed, as noted by Petitioner ('051 Sur-Sur-Reply 2), on cross examination, Patent Owner's own declarant, Dr. Fronczak, himself expressed that firing of an instrument in that scenario would be "catastrophic" and presents a "hazard." *See, e.g.*, Ex. 1019, 101:20–102:56; Ex. 1027, 21:11–22:1. It defies reason to conclude that a skilled artisan would not have recognized readily the benefit of employing a locking mechanism specifically directed to preventing such firing. That is logically so even if a user may already have an avenue to recognize the presence or absence of a staple cartridge, such as through visual or tactile feedback, as mere recognition in that regard is not understood to actually prevent the firing of a cartridge-less stapler. *See, e.g.*, Ex. 1025 (Supplemental Declaration of Dr. Knodel) ¶¶ 15–20) (Dr. Knodel testifying

that Green's visual or tactile feedback indications do not prevent a user from firing a stapler that does not have a staple cartridge). We credit Dr. Knodel's testimony on this matter.

Patent Owner also contends that combining Solyntjes's teachings of a locking mechanism with Green would require "substantial modifications" because the two references disclose "fundamentally different architectures." *See, e.g.*, '051 PO Resp. 65; '051 Sur-Reply 14–15. At the outset, we observe that the stapler instruments of Green and Solyntjes hardly seem "fundamentally different," as even a casual review of the two references reveals that they include similar structures to accomplish a staple firing operation, and perform similar functions of stapling tissue. For example, both devices include jaw portions with anvil surfaces that operate by virtue of a pivoting lever to bring the jaws from an open to a closed position for the purpose of firing staplers from a staple cartridge into tissue. *Compare, e.g.*, IPR2020-00051, Ex. 1011, 8:14–52, Figs 2, 3, *with* IPR2020-00051, Ex. 1015, 3:23–4:9, Figs. 1, 2. Nevertheless, even considering that some modification of Green's instrument is necessary to implement Solyntjes's teachings of a locking mechanism, such modification is not an anathema to the obviousness inquiry.

A showing of obviousness does not require that references be physically combinable, without change. *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). Indeed, "[c]laims may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference." *Orthopedic Equipment Co., Inc. v. U.S.*, 702 F.2d 1005, 1013 (Fed. Cir. 1983). Thus,

the obviousness inquiry does not turn on whether modifications to a surgical stapling instrument, such as Green's, in view of Solyntjes's teachings of a locking mechanism, may require something more than direct physical insertion of one structure into another. Furthermore, Patent Owner does not assert that any necessary change to the structure or arrangement of Green's surgical stapling instrument, even if substantial, is beyond the skill or ability of one of ordinary skill in the art. It is well settled that a person of ordinary skill in the art is also a person of ordinary creativity. *KSR*, 550 U.S. at 421. A skilled artisan of ordinary creativity reasonably would appreciate necessary design modifications or adjustments to implement a known safety component for a surgical implement, i.e., Solyntjes's locking mechanism, into a surgical implement, as in Green, that is missing such a component but is ripe for its implementation. We credit Dr. Knodel's testimony to that effect. *See, e.g.*, IPR2020-00051, Ex. 1003 ¶¶ 154–171.

Patent Owner additionally argues that a person of ordinary skill in the art would have lacked a reasonable expectation of success in combining Green and Solyntjes. '051 PO Resp. 79–87; '051 Sur-Reply 21–38.

Generally, Patent Owner bases that argument on two theories, as follows:

First, a [person of ordinary skill in the art] would not expect there to be sufficient space to add a spring-and-pin lockout mechanism to Green's stapler jaws. Ex. 2094 ¶ 290. Second, a [person of ordinary skill in the art] would not expect a spring fitted into Green's stapler's jaws, if it could be made to work at all, to be able to withstand user applied force. Ex. 2094 ¶ 296.

'051 PO Resp. 80.

We do not find either of Patent Owner's theories persuasive. The general assumption underscoring those theories is that a skilled artisan in the

area of surgical staplers would be incapable of implementing a “spring –and-pin lockout mechanism,” such as that disclosed in Solyntjes, into a surgical stapler instrument having the particular structural characteristics of Green’s instrument. In offering that assumption, Patent Owner relies extensively on the testimony of Dr. Fronczak. ’051 Pet. 79–87 (citing Ex. 2094 ¶¶ 288–302). That testimony, however, is based on little evidentiary support in the record, and is instead largely premised on Dr. Fronczak’s speculation that physical difficulties or impediments in modifying Green’s instrument would have been insurmountable for a skilled artisan to produce a functional instrument that incorporates Solyntjes’s locking pin mechanism. What a reference teaches, however, must be taken in the context of the knowledge, skill and reasoning ability of one with ordinary skill in the art. *Syntex (U.S.A) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005).

Moreover, a skilled artisan is presumed to know something about the art apart from what the reference expressly discloses. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962); *see also DyStar Textilfarben GmbH & Co. v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) (explaining that “the prior art” includes basic principles unlikely to be restated in cited references). We are not persuaded that Dr. Fronczak’s speculation adequately takes into account what a skilled artisan in the art of surgical stapler devices would have appreciated from the teachings of the prior art.

“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 US at 417. In this case,

Solyntjes is unmistakable in its teachings that there are notable, recognized benefits in equipping a surgical stapler instrument with a particular locking pin assembly for preventing the firing of the instrument when a staple cartridge is either empty or absent. *See, e.g.*, IPR2020-00051, Ex. 1011, 2:59–68. For example, as noted above, those benefits include “prevent[ing] the user from attempting to refire the stapler” and “provid[ing] a stapler that reduces the chances of unnecessary tissue trauma, blood loss, inadequate hemostasis, and squandered time during surgery.” *Id.* at 2:64–68. It follows readily that a person of ordinary skill in the art would have appreciated that such benefits would also be desirable in other types of stapler instruments that involve firing staples from a staple cartridge into tissue, but do not provide for the prevention of such firing in the circumstance of a missing staple cartridge, *e.g.*, Green’s surgical stapler instrument.

Both parties agree that the level of ordinary skill in the relevant art includes someone with a degree in mechanical engineering and at least three years of design experience in surgical instruments. *See, e.g.*, ’051 PO Resp. 15; IPR2020-00051, Ex. 2094 ¶ 33; IPR2020-00051, Ex. 1003 ¶¶ 25–26. Dr. Knodel testifies that a person with such a background would be guided by the teachings of Solyntjes to modify Green’s stapler so as to result in an instrument that accounts for the challenged claims. *See, e.g.*, IPR2020-00051, Ex. 1003 ¶¶ 154–206. In our view, Dr. Knodel’s testimony is logical and credible and appropriately reflects the types of design assessments that such a skilled artisan would have employed in seeking to improve Green’s instrument based on Solyntjes’s teachings as to a locking pin mechanism so as to harness the benefits of such a mechanism. We are not persuaded that

such design assessments would be deficient or inadequate to account for routine considerations, e.g., location, positioning, and robustness of a locking mechanism, as a part of Green's instrument. We determine that Dr. Knodel's testimony on the matter is more persuasive than the countervailing testimony of Dr. Fronczak, and we therefore credit Dr. Knodel's testimony over that of Dr. Fronczak.¹⁷

We have considered all of Patent Owner's arguments challenging the ground of unpatentability of the challenged claims based on Green and Solyntjes, but find them unavailing. We conclude that the record before us reflects that Petitioner has made the requisite showing that the challenged claims would have been unpatentable for obviousness.

C. Proposed Grounds of Anticipation

Petitioner proposes grounds of anticipation to the challenged claims based on each of Shelton '818 and Shelton '562. Because we conclude above that all of the challenged claims of the '379 patent are unpatentable

¹⁷ Patent Owner contends that Dr. Knodel's testimony is unreliable. '051 PO Resp. 87–88. That contention is based on testimony from Dr. Knodel, at his deposition on June 3, 2020, in which he apparently characterized a type of "ETS 45 stapler" that he had designed while an engineer for Ethicon in the 1990s as including a no-cartridge lockout. *Id.* Patent Owner challenges the accuracy of that testimony. In a supplemental declaration (Ex. 1025), Dr. Knodel testifies that during his deposition he confused one type of stapler he had previously designed, the "ETS 45 stapler," with another "EZ 45 stapler" that he had also designed, and which he testifies includes a "no-cartridge lockout." IPR2020-00051, Ex. 1025 ¶ 36. We find Dr. Knodel's explanation in his supplemental declaration sufficient and credible and conclude that Dr. Knodel's testimony is reliable.

IPR2020-00050
IPR2020-00051
Patent 9,844,379 B2

based on Green and Solyntjes, we determine that it is unnecessary to reach the merits of either of the proposed anticipation grounds.

III. MOTIONS TO SEAL

A. Listing of the Motions

Both parties have filed Motions to Seal. Neither party has filed an opposition to any of the Motions. The Motions to Seal are summarized below.

Petitioner's Motions To Seal	
Proceeding and Paper No.	Documents sought to be sealed
IPR2020-00050, Paper 27	Paper 28 (Petitioner's Reply); Exhibit 1012
IPR2020-00051, Paper 28	Paper 29 (Petitioner's Reply); Exhibit 1025

Patent Owner's Motions To Seal	
Proceeding and Paper No.	Documents sought to be sealed
IPR2020-00050, Paper 20	Exhibit 2094
IPR2020-00051, Paper 20	Exhibits 2012–2014, 2017–2050, 2052–2070, 2072–2085, 2094, 2095
IPR2020-00051, Paper 38	Paper 39 (Patent Owner's Sur- Reply); Exhibit 2099

B. Consideration of the Motions

There is a strong public policy in favor of making information filed in an *inter partes* review open to the public, especially because the proceeding determines the patentability of claims in an issued patent and, therefore, affects the rights of the public. Under 35 U.S.C. § 316(a)(1) and 37 C.F.R.

§ 42.14, the default rule is that all papers filed in an *inter partes* review are open and available for access by the public; a party, however, may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion. It is, however, only “confidential information” that is protected from disclosure. 35 U.S.C. § 316(a)(7); *see* Trial Practice Guide, 77 Fed. Reg. at 48,760. The standard for granting a motion to seal is “for good cause.” 37 C.F.R. § 42.54(a). The party moving to seal bears the burden of proof in showing entitlement to the requested relief, and must explain why the information sought to be sealed constitutes confidential information. 37 C.F.R. § 42.20(c).

We have reviewed all the parties’ Motions to Seal. On the record before us, we conclude that both parties have shown that the documents sought to be sealed contain confidential information.

We further note that in the Scheduling Order of each proceeding, we expressed to the parties the following: “[r]edactions to documents filed in this proceeding should be limited to the minimum amount necessary to protect confidential information, and the thrust of the underlying argument or evidence must be clearly discernible from the redacted versions.”

See, e.g., IPR2020-00050, Paper 16, 2–3; IPR2020-00051, Paper 16, 2–3. We discern that the parties have largely complied with that requirement. To that end, the record as a whole provides a clear and understandable basis for an adequate appreciation of the issues that were developed and resolved during the course of this *inter partes* review, without the need to make public any of the material that the parties seek to be maintained under seal.

We conclude that the parties have established sufficiently good cause

to grant the Motions to Seal that are before us. Furthermore, in each of IPR2020-00050 and IPR2020-00051, as a part of Paper 20, Patent Owner expresses that “[b]y agreement of the parties, Patent Owner also requests entry of the Proposed Protective Order (Attachment 1). In each case, Attachment 1 to Paper 20 is titled “[Stipulated] Protective Order.” There is also an “Attachment 2” to Paper 20 in each case that is a redlined version of the Stipulated Protective Order showing the proposed variations from the Board’s default Protective Order (*see* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, App. B (Aug. 14, 2012)). Attachment 1 and Attachment 2 of Paper 20 in each of IPR2020-00050 and IPR2020-00050 are identical. We grant each of the parties’ Motions to Seal and enter the Stipulated Protective Order (each proceeding, Paper 20, Attachment 1). Furthermore, until further notice from the Board, the record will be preserved in its current form.

IV. CONCLUSION¹⁸

For the foregoing reasons, we conclude that Petitioner has shown by a preponderance of the evidence that claims 1–3 of the ’379 patent are unpatentable for obviousness based on Green and Solyntjes. We do not

¹⁸ 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).

reach the merits of the anticipation grounds based on Shelton '818 or Shelton '562.

In summary,

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3	103	Green, Solyntjes	1–3	
1–3	102	Shelton '818 ¹⁹		
1–3	102	Shelton '562		
Overall Outcome			1–3	

V. ORDER

It is

ORDERED that Petitioner has established by a preponderance of the evidence that claims 1–3 of U.S. Patent 9,844,379 B2 are unpatentable;

FURTHER ORDERED that Petitioner's Motions to Seal (IPR2020-00050, Paper 27; IPR2020-00051, Papers 28) are *granted*;

FURTHER ORDERED that Patent Owner's Motions to Seal (IPR2020-00050, Paper 20; IPR2020-00051, Papers 20, 38) are *granted*; and

¹⁹ As noted above, because we conclude that all of the challenged claims of the '379 patent are unpatentable based on Green and Solyntjes, we do not reach the merits of either of the proposed anticipation grounds.

IPR2020-00050
IPR2020-00051
Patent 9,844,379 B2

FURTHER ORDERED because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2020-00050
IPR2020-00051
Patent 9,844,379 B2

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