UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

ETHICON LLC,
Patent Owner.

Case IPR2018-00933
Patent 9,084,601 B2

Before JOSIAH C. COCKS, BENJAMIN D. M. WOOD, and MATTHEW S. MEYERS, *Administrative Patent Judges.*

WOOD, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Intuitive Surgical, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–20 of U.S. Patent No. 9,084,601 B2 (Ex. 1001, "the '601 patent"). Ethicon LLC ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Moreover, a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Upon considering the Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we authorize an *inter partes* review to be instituted as to all challenged claims of the '601 patent on all grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of the challenged claims. Any final decision will be based on the record as fully developed during trial.

B. Related Proceedings

Petitioner states that the ’601 patent is the subject of Civil Action No. 1:17-cv-00871-LPS, filed on June 30, 2017 in the U.S. District Court for the District of Delaware. Pet. 1–2. Petitioner also states that it has filed IPR petitions for U.S. Patent Nos. 8,991,677 and 8,998,058, which are related to the ’601 patent. *Id.*

C. The ’601 Patent

The ’601 patent issued July 21, 2015 from an application filed March 15, 2013, and claims priority to an application filed February 14, 2008. Ex. 1001, [45], [22], [63]. The ’601 patent describes a “detachable motor-powered surgical instrument,” and, in particular, an endoscopic surgical cutting and stapling apparatus having a “disposable loading unit.” Ex. 1001, Abstract, 1:27–30. Figure 1 of the ’601 patent is reproduced below:

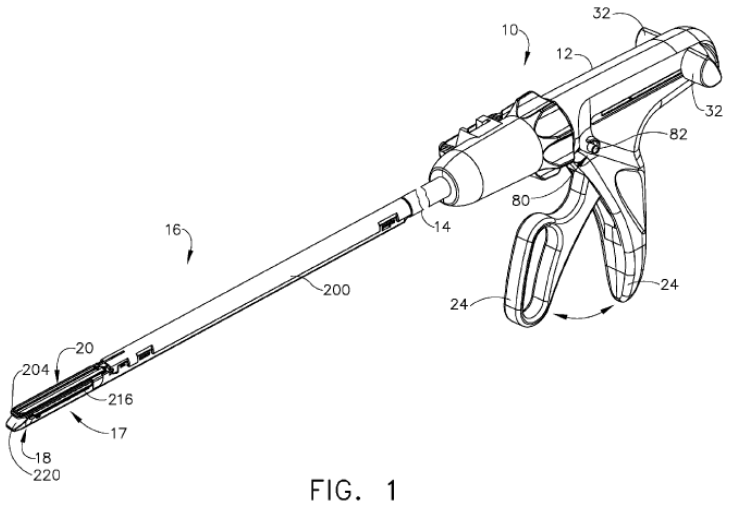

FIG. 1

Figure 1, reproduced above, depicts a perspective view of disposable loading unit 16 coupled to conventional surgical cutting and stapling apparatus 10. *Id.* at 10:64–67. Disposable loading unit 16 comprises tool assembly 17 that includes a pair of cooperating jaw members—staple

cartridge assembly 18 and anvil 20—coupled to carrier 216. *Id.* at 1:51–58, 11:20–28. Housing 200 connects carrier 216 to elongated body 14 of the surgical cutting and stapling apparatus. *Id.* at 11:63–12:1

Figures 2 and 3 of the '601 patent are reproduced below:

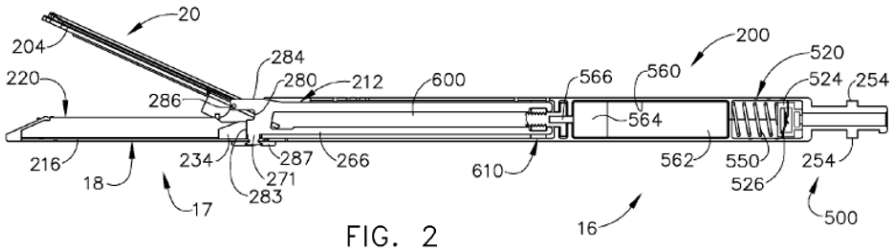

FIG. 2

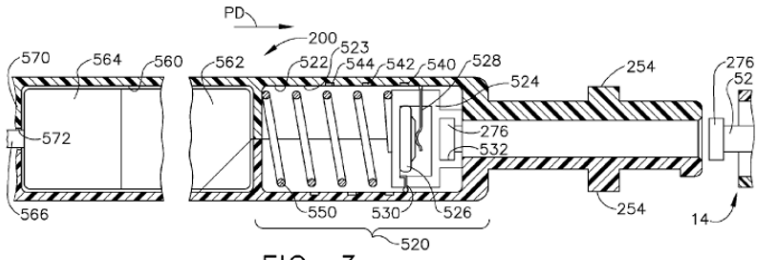

FIG. 3

Figure 2 depicts a cross-section of disposable loading unit 16, and Figure 3 depicts the proximal end of the disposable loading unit. *Id.* at 10:30–35. As shown in these figures, housing 200 includes battery cavity 522 that movably supports battery holder 524, which in turn houses battery 526. *Id.* at 12:4–8. Battery 526 supplies power to motor 562. *Id.* at 2:27–31. First and second battery contacts 528, 530 are in electrical contact with battery 526 and protrude from battery holder 524 to engage inside wall 523 of battery cavity 522. *Id.* at 12:9–16. A series of contacts 540, 542, 544 are also located within wall 523. *Id.* at 12:21–23. When the disposable loading unit is disconnected from the surgical cutting and stapling assembly, first and second battery contacts 528, 530 are out of alignment with contacts 540, 542, 544, and power is not supplied to the motor, thus preventing battery

526 from being drained during non-use. *Id.* at 12:30–34. When the disposable loading unit is connected to the surgical apparatus, battery holder 524 is pushed distally, which allows contacts 528, 530 to connect with contacts 540, 542, 544 to supply power to the motor. *Id.* at 13:18–23.

D. The Challenged Claims

Petitioner challenges claims 1–20 of the '601 patent. Pet. 3. Claims 1, 11, and 17 are independent. Claim 1 is reproduced below:[1]

> 1. [1.1] A surgical cutting and stapling instrument comprising:
>
> [1.2] a housing including at least one engagement member for removably coupling the housing to an actuator arrangement;
>
> [1.3] first and second jaws operably coupled to the housing such that at least one said jaw is selectively movable relative to the other said jaw;
>
> [1.4] an axial drive assembly movably supported for selective axial travel relative to said first and second jaws;
>
> [1.5] a motor supported by said housing and operably interfacing with the axial drive assembly to selectively move said axial drive assembly between a starting position and an ending position relative to the first and second parts; and
>
> [1.6] a contact arrangement supported by said housing and configured to permit power to be supplied to the motor only when the housing is operably attached to the actuator arrangement.

E. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 3):

[1] We include Petitioner's limitation labels for convenience. *See* Pet. 22–72.

Reference[s]	Basis	Claims Challenged
Heinrich[2]	§ 102	1, 2, 4–6, 8–11, 13, 15–20
Heinrich and Milliman[3]	§ 103	1, 2, 4–6, 8–11, 13, 15–20
Heinrich and Alesi[4]	§ 103	1, 2, 4–11, 13–20
Heinrich, Alesi, Milliman	§ 103	1, 2, 4–11, 13–20
Heinrich and Tonet[5]	§ 103	3, 12
Heinrich, Tonet, Milliman	§ 103	3, 12

In support of its proposed grounds, Petitioner relies on the Declaration of Dr. Gregory S. Fischer (Ex. 1003).

II. ANALYSIS

A. Claim Construction

The claim construction standard to be employed in an *inter partes* review has changed. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Nov. 13, 2018). Based on when the Petition in this proceeding was filed, however, we determine whether to institute *inter partes* review of the claims based on the "broadest reasonable construction" of the claims in light of the specification in which the claims appear.

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[2] U.S. Pat. App. 2005/0131390 (Jun. 16, 2005) (Ex. 1005).

[3] US 5,865,361 (Feb. 2, 1999) (Ex. 1006).

[4] US 5,779,130 (Jul. 14, 1998) (Ex. 1010).

[5] Oliver Tonet *et al.*, *Comparison of Control Modes of a Hand-Held Robot for Laparoscopic Surgery*, MICCAI 2006, Lecture Notes in Computer Science, vol. 4190, pp. 429–36 (Springer, Berlin, Heidelberg 2006).

37 C.F.R. § 42.100(b) (2016); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). Under this standard, claim terms are generally given their ordinary and accustomed meaning as understood by one of ordinary skill in the art, unless it appears from the specification, the file history, or other evidence asserted by the parties that the inventor used them differently. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Id.*

Petitioner proposes constructions for the terms "means for removably coupling the housing to an actuator arrangement" (claim 17), "contact arrangement" (claims 1, 11, and 17), and "means for fastening tissue on each side of a cut line" (claim 8). Pet. 16–18. For purposes of its preliminary response, Patent Owner does not dispute Petitioner's constructions. Accordingly, we will apply Petitioner's constructions as necessary and for purposes of this decision only. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that only terms that are in controversy need to be construed, and "only to the extent necessary to resolve the controversy").

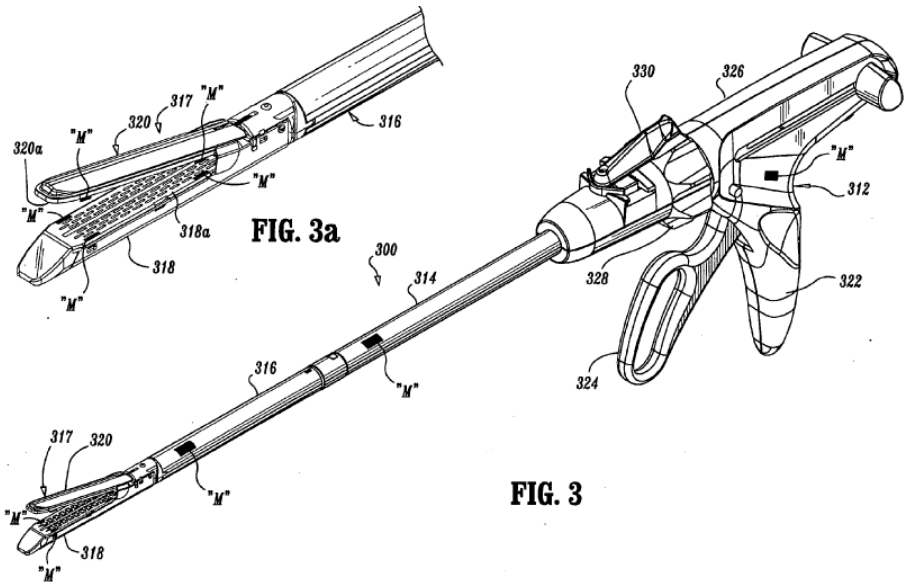
B. Ground 1: Claims 1, 2, 4–6, 8–11, 13, and 15–20—Anticipation—Heinrich

Petitioner alleges that Heinrich anticipates claims 1, 2, 4–6, 8–11, 13, and 15–20. Pet. 22–59. Patent Owner opposes. Prelim. Resp. 25–42.

1. Heinrich(Ex. 1005)

Heinrich is directed to "surgical instruments including an end effector configured and adapted to engage tissue, and at least one micro-

electromechanical system (MEMS) device operatively connected to the surgical instrument." Ex. 1005 ¶ 13. Heinrich describes several surgical instruments, including the stapler illustrated in Figures 3 and 3a of Heinrich, reproduced below:



Figures 3 and 3a, reproduced above, respectively illustrate an endoscopic gastrointestinal anastomotic stapler 300 and an enlarged view of the distal end of stapler 300. The stapler comprises disposable loading unit 316 releasably secured to a distal end of elongated body 314. *Id.* ¶ 92. Disposable loading unit 316 includes end effector 317 having staple cartridge assembly 318 secured to anvil 320. *Id.*

Heinrich states that "it is envisioned that the above described surgical instruments . . . can be employed with or interface directly with a robotic surgical system 600." *Id.* ¶ 130. This system is depicted in Figure 7, reproduced below:

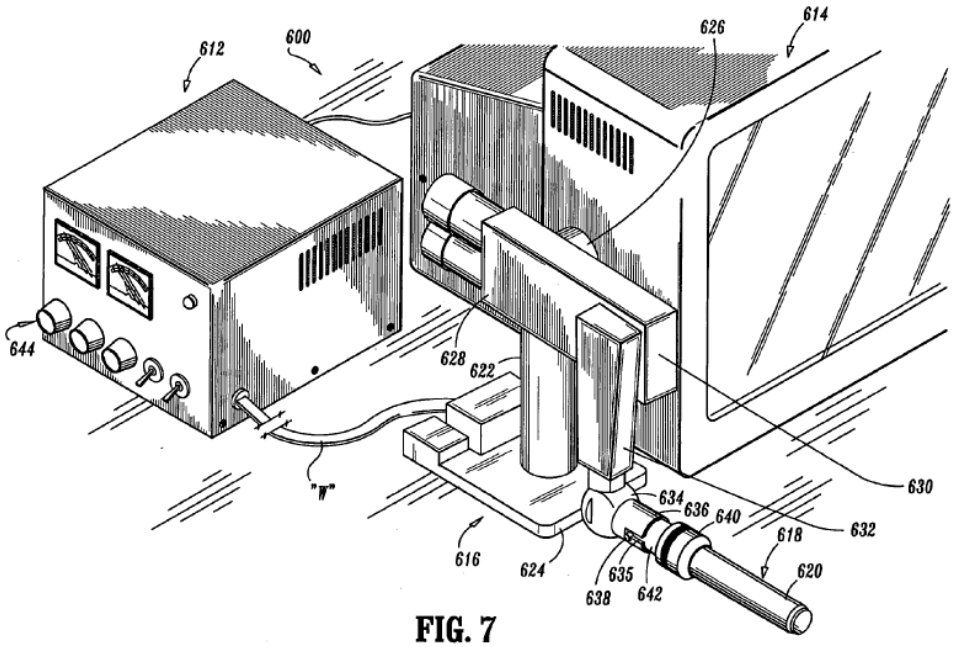


FIG. 7

Figure 7, reproduced above, illustrates robotic surgical system 600. The system comprises actuation assembly 612, monitor 614, robot 616, and "loading unit 618 releasably attached to robot 616 and having at least one surgical instrument 620 for performing at least one surgical task operatively connected thereto." *Id.* ¶ 132. According to Heinrich, the term "loading unit" includes disposable loading units (DLUs) and single use loading units (SULUs), which, in turn, include "removable units, e.g., those having a shaft 316, a cartridge assembly 318 and an anvil 317 [sic, 320]." *Id.* ¶ 133.

One example of one of the "above described surgical instruments" connected to the robotic surgical system is provided in Figure 9 of Heinrich, reproduced below:

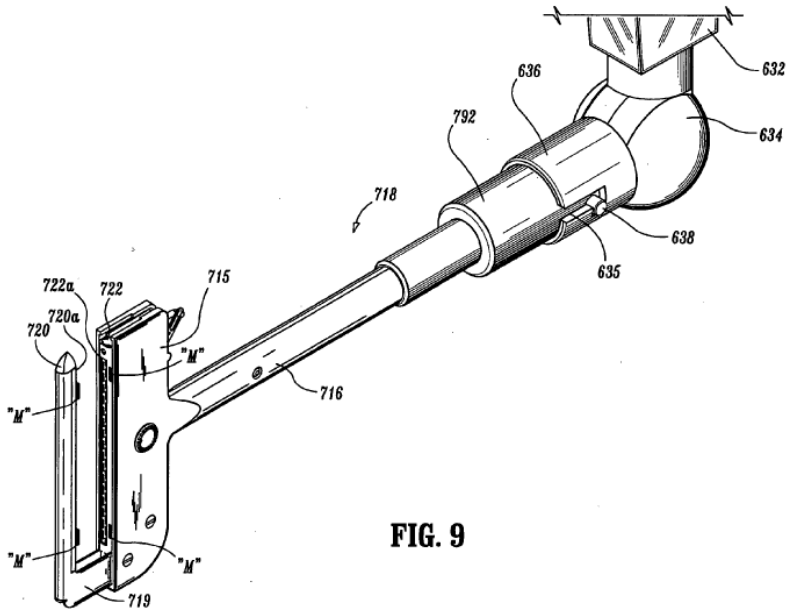


FIG. 9

Figure 9 of Heinrich, reproduced above, depicts disposable loading unit 718—including an end effector of a surgical stapler similar to the end effector of surgical stapler 100 depicted in Figure 1—operatively connected to robot 616. *Id.* ¶ 139.

Heinrich incorporates Milliman by reference "to provide a more detailed explanation of the operation of surgical stapler 300." Indeed, Figure 1 of Milliman is substantially the same as Figure 3 of Heinrich. *Compare* Milliam, Fig. 1 *with* Heinrich, Fig. 3. Accordingly, we discuss Milliman next.

2. Milliman (Ex. 1006)

Milliman discusses a surgical stapling and cutting apparatus. Ex. 1006, 1:6–10. Like Heinrich's surgical stapler 300, Milliman's stapler comprises a disposable loading unit that includes a tool assembly having a staple cartridge assembly secured to an anvil. *Id.* at 6:29–32. Figure 21 of Milliman, reproduced below, provides a more detailed view of the tool assembly.

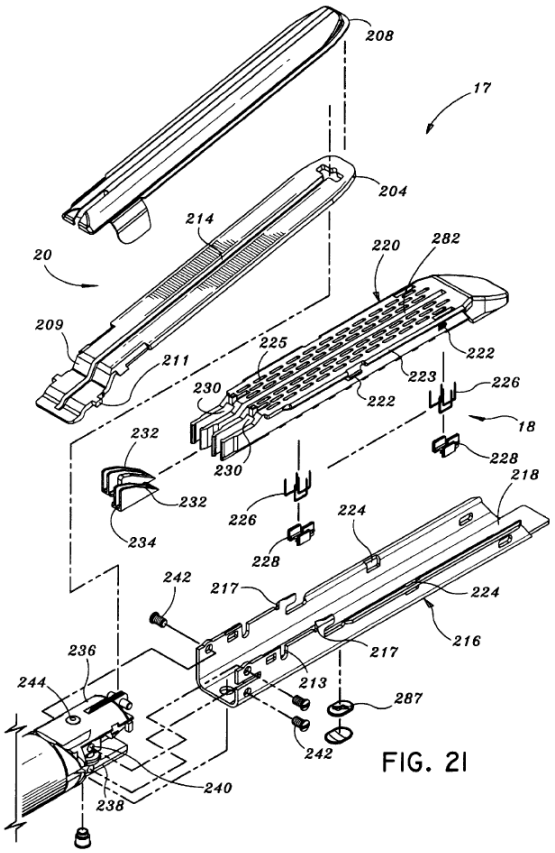
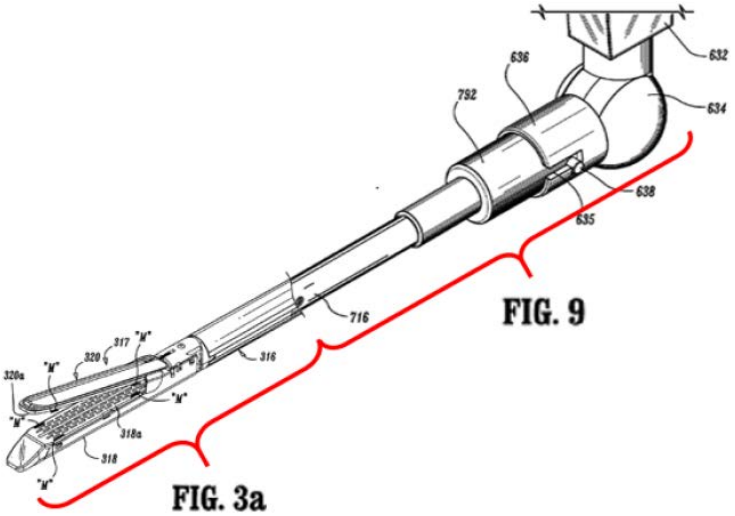


FIG. 21

As shown in Figure 21, reproduced above, tool assembly 17 includes anvil assembly 20 and cartridge assembly 18. *Id.* at 11:24–25. Camming surface 209 formed on anvil portion 204 engages axial drive assembly 212 (Figure 27) to close the anvil and cartridge assembly together to clamp tissue. *Id.* at 11:35–38. Actuation sled 234 then translates through longitudinal slots 230 of staple cartridge 220 to advance cam wedges 232 to move pushers 228 vertically within slots 224 to urge fasteners 226 into staple deforming cavities 206 to staple the clamped tissue. *Id.* at 11:61–67. Knife blade 280 translates slightly behind actuation sled 234 through central longitudinal slot 282 (Figure 30) to form an incision between rows of stapled body tissue. *Id.* at 12:59–62.

3. Discussion

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984). In support of its assertion that Heinrich anticipates claims 1, 2, 4–6, 8–11, 13, and 15–20, Petitioner discusses the teachings of Heinrich—as well as the teachings of Milliman, which Heinrich incorporates by reference—and explains how each claim limitation is disclosed in Heinrich/Milliman. Pet. 22–45. In particular, Petitioner contends that Heinrich teaches that surgical stapler 300 can be used with robotic surgical system 600, and more particularly that "a loading unit 618 'having a shaft 316, a cartridge assembly 318 and an anvil [320]' could be operatively connected to robot 616." *Id.* at 25 (quoting Ex. 1005 ¶ 133). Petitioner has created a composite of Figures 3a and 9 that Petitioner contends illustrates the resulting device. Petitioner's composite drawing is reproduced below:



The illustration reproduced above depicts Petitioner's composite of Figures 3a and 9 of Heinrich, which represents the embodiment that Petitioner contends corresponds to the surgical cutting and stapling instrument of claim 1. *Id.* at 22–27. According to Petitioner, "a POSITA would have understood that Heinrich discloses this device and would have been able to implement it." *Id.* at 26 (citing Ex. 1003 ¶ 77, 97). Petitioner supports these contentions with the declaration of Dr. Fischer. Ex. 1003.

Patent Owner disputes that Heinrich discloses and enables an embodiment that combines the surgical instrument shown in Figure 3 with the robotic surgical system shown in Figures 7–9. First, Patent Owner asserts that "Heinrich expressly states which surgical instruments it believes can be combined with 'a robotic surgical system 600,' and those are 'seen in FIGS.7–12.'" Prelim. Resp. 38 (citing Ex. 1005 ¶ 130). Patent Owner notes that the surgical stapler illustrated in Figure 3 of Heinrich "does not appear in Figures 7–12." *Id.* at 38–39 (citing Ex. 1005 ¶¶ 139–151, Figs. 7–12). The excerpt on which Patent Owner relies, paragraph 130 of Heinrich, reads in relevant part: "In accordance with the principles of the present disclosure, as seen in Figures 7–12, it is envisioned that the above described surgical instruments . . . can be employed with or interface directly with a robotic surgical system 600." Ex. 1005 ¶ 130. At this stage of the proceeding, we do not read this excerpt as excluding the surgical instrument depicted in Figure 3 from those instruments that Heinrich envisions being employed with robotic surgical system 600. Heinrich states that "above described" surgical instruments can be used with the robotic system, and the surgical device of Figure 3 is one of the "above described" devices. See Ex. 1005 ¶¶ 92–99. Moreover, other excerpts from Heinrich support the notion that

Heinrich envisions using the instrument shown in Figure 3 with the robotic system of Figures 7–9. For example, Heinrich specifically discloses using the disposable loading unit of the Figure 3 device as loading unit 618 of the robotic device. Ex. 1005 ¶ 133; *see also id.* ¶ 135 ("potential surgical instruments or systems which can interface with robotic system 600 include . . . stapling or fastener applying instruments . . . cutting instruments . . . and/or any combination thereof).

Next, Patent Owner argues that Heinrich "provides no description of how such a combination might be achieved." Prelim. Resp. 39. According to Patent Owner, the stapler depicted in Figure 3 and the stapler depicted in Figure 1—Heinrich depicts in Figure 9 connected to robotic surgical system 600—are "fundamentally different." *Id.* In Patent Owner's view, the differences between the two instruments calls into question whether one of ordinary skill in the art would have been able to create the composite embodiment without further guidance. *Id.* at 40.

The Federal Circuit has held that "a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016). Petitioner asserts that one of ordinary skill in the art would at once envisage the surgical instrument of Figure 3 used with the robotic system of Figures 7–9, and supports that assertion with citations to Heinrich and with testimony from Dr. Fischer. We deem this a sufficient showing at this stage of the proceeding that one of ordinary skill in the art would at once envisage this combination. The fact that the Figure 3 instrument operates differently

than the Figure 1 instrument, by itself, does not persuade us that one of ordinary skill in the art would not be able to envisage both instruments used with the robotic system. The extent to which the differences between the Figure 1 embodiment and the Figure 3 embodiment differ, and the significance of those differences in determining whether one of ordinary skill in the art would have envisaged using the Figure 3 instrument with the robotic system, can be evaluated on a complete record after trial.

Patent Owner also disputes that Heinrich discloses the claimed contact arrangement. Prelim. Resp. 25–32. For purposes of its Preliminary Response, Patent Owner assumes that Petitioner's proposed construction of "contact arrangement"—a combination of junctions or touching surfaces of electrical conductors through which an electrical current passes—is proper, but contends that Heinrich does not disclose a contact arrangement under this construction. *Id.* at 10, 25. Petitioner relies on electrical connection 633, which Petitioner contends "is at least two electrical contacts 'provided between slots 635 and protrusions 638' (i.e., located at predetermined locations relative to each other)." Pet. 41 (quoting Ex. 1005 ¶ 134) (citing Ex. 1003 ¶¶ 119–123). Petitioner notes that the housing of loading unit 618 houses electro-mechanical assembly 619—which corresponds to the claimed motor—but the power supply for electro-mechanical assembly 619 resides in actuation assembly 612. *Id.* at 42 (citing Ex. 1005 ¶ 134, Fig. 8). Thus, according to Petitioner, "because the housing of loading unit 618 is detachable from the robotic surgical system 600, power can be supplied to electro-mechanical assembly 619 (i.e., the motor) only when the housing unit 618 is "operably attached" to the robotic surgical system 600." *Id.* at 43 (citing Ex. 1003 ¶ 121). Petitioner asserts, alternatively, that "if electrical

connection 633 is deemed not to be an explicit disclosure of the claimed contact arrangement, Heinrich inherently discloses the claimed contact arrangement." *Id.* Petitioner contends that electrical connection 633 must necessarily include at least one contact to transmit power to electro-mechanical assembly 619, a second contact to send "electrical signals" to actuate electro-mechanical assembly 619, and a third contact to transmit "feedback signals" from MEMS devices to the actuation assembly via "wire leads 560" or "transmission wires 'W'. *Id.* (citing Ex. 1005 ¶¶ 86, 134 Figs 6–8; Ex. 1003 ¶¶ 122–123).

Patent Owner responds that Heinrich does not disclose "a combination of junctions or touching surfaces of electrical conductors through which an electrical current passes," because "Heinrich discloses one, and only one, electrical connection 633, which could be a junction or a touching surface of an electrical conductor, or could be a different from of connection such as a transmission line." *Id.* at 27–28. Patent Owner also finds fault with Petitioner's inherency argument, asserting that neither wire leads 560 nor transmission wires W are supported by the housing or configured to permit power to be supplied to the motor only when the housing is operably attached to the actuator arrangement. *Id.* at 29–31.

Patent Owner does not appear to dispute, at this stage of the proceeding, that electrical connection 633 is configured to permit power to be supplied to the motor (electro-mechanical assembly 619) only when housing 618 is operably attached to robot 616. Patent Owner does dispute, however, that electrical connection 633 is "a combination of junctions or touching surfaces of electrical conductors," because, as we understand Patent Owner's position, electrical connection 633 may be only one contact.

For purposes of this institution decision, however, we accept Dr. Fischer's testimony that Heinrich's electrical connection 633 comprises "at least two contacts." Ex. 1003 ¶ 119.

On the other hand, we do not find Petitioner's alternative inherency argument to be persuasive on this record. Petitioner has not explained how the purportedly inherent second and third contacts are configured to permit power to be supplied to electromechanical assembly 619 only when the housing 618 is operably attached to the actuator arrangement. Nevertheless, we determine that Petitioner has made a sufficient showing that Heinrich teaches the contact-arrangement limitation based on Petitioner's primary argument, which relies on electrical connection 633.

a. Conclusion With Respect to Ground 1

Based on the current record, and for purposes of this decision, we determine that Petitioner has sufficiently shown that Heinrich, which incorporates Milliman by reference, discloses all of the limitations of claims 1, 2, 4–6, 8–11, 13, and 15–20, arranged as claimed.

C. Ground 2: Claims 1, 2, 4–6, 8–11, 13, and 15–20—Obvious over Heinrich and Milliman

Petitioner contends that claims 1, 2, 4–6, 8–11, 13, and 15–20 would have been obvious over Heinrich and Milliman. Pet. 59–62. Patent Owner opposes. Prelim. Resp. 42–47.

1. Principles of Law

"A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in [35 U.S.C. § 102], if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have

been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Obviousness is a question of law based on underlying findings of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The underlying factual considerations "include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations" of nonobviousness, including commercial success of the patented product or method, a long-felt but unmet need for the functionality of the patented invention, and the failure of others who have unsuccessfully attempted to accomplish what the patentee has achieved. *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 736 (Fed. Cir. 2013) (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007); *Graham*, 383 U.S. at 17–18). The obviousness analysis should not be conducted "in a narrow, rigid manner," but should instead focus on whether a claimed invention is merely "the result[ ] of ordinary innovation," which is not entitled to patent protection. *KSR*, 550 U.S. at 427.

2. Level of Ordinary Skill in the Art

Petitioner's declarant, Dr. Fischer, asserts that:

> A person of ordinary skill in the art at the time of the claimed invention ("POSITA") would have had the equivalent of a Bachelor's degree or higher in mechanical engineering, electrical engineering, biomedical engineering, or a related field directed towards medical electro-mechanical systems and at least 3 years working experience in research and development for surgical instruments. Experience could take the place of some formal training, as relevant skills may be learned on the job.

Ex. 1003 ¶ 26. At this stage, Patent Owner does not dispute this assertion. For purposes of this decision, we adopt Dr. Fischer's definition of the appropriate level of skill at the time of the invention. The cited prior art references also reflect the appropriate level of ordinary skill. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

3. Discussion

Petitioner states that "[i]f Heinrich is deemed not to disclose the Milliman subject matter incorporated by reference, it would have been obvious to combine Heinrich and Milliman to arrive at the same subject matter." Pet. 59 (citing Ex. 1003 ¶¶ 99–101). In other words, Petitioner asserts that Heinrich either incorporates Milliman by reference or expressly teaches combining the two references.

At this stage of the proceeding, Patent Owner does not dispute that Heinrich incorporates Milliman's teachings by reference. Further, we agree with Petitioner that Heinrich unambiguously incorporates Milliman by reference. *See* Ex. 1005 ¶ 99 ("Reference is made to commonly assigned U.S. Pat. No. 5,865,361 . . . to Milliman et al., the entire contents of which [is] incorporated herein by reference, for a more detailed explanation of the operation of surgical stapler 300."). The Federal Circuit has deemed similar language as constituting an incorporation by reference. *See Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 907 (Fed. Cir. 2018) (holding the statement "[patent] . . . is incorporated herein by reference" is "broad and unambiguous," and "identifies with detailed particularity the specific material subject to incorporation," i.e., the entire patent); *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011) (holding the statement "[t]he disclosures of the two [patent] applications are hereby incorporate[d] by reference" is

sufficient to incorporate by reference the disclosures of the two patent applications in their entirety).

Patent Owner argues that "Petitioner provides no motivation to combine Heinrich and Milliman to incorporate the teachings of Milliman into the embodiment of Figure 9." This argument is likely moot in view of our determination that Heinrich expressly incorporates Milliman by reference. In any event, we understand Petitioner's position to be that Milliman is relied upon to provide details of the operation of stapler 300 depicted in Figure 3, and on Heinrich to teach combining stapler 300 with robotic system 600.

4. Grounds 3 and 4: Claims 1, 2, 4–11, and 13–20—Obviousness—Heinrich (or Heinrich and Milliman) and Alexi

For Ground 3, Petitioner asserts that claims 1, 2, 4–11, and 13–20 would have been obvious over Heinrich and Alexi (Ex. 1010). Pet. 62–70. For Ground 4, Petitioner adds the Milliman reference for reasons discussed above with respect to ground 2. *Id.* at 70.

a. Alesi (Ex. 1010)

Alesi discloses a self-contained powered surgical stapling and cutting apparatus. Ex. 1010, 1:13–16. In one embodiment, Alesi's apparatus comprises a disposable cartridge assembly connected to the distal end of an elongate instrument body. *Id.* at 9:31–35, Fig. 13. Figures 14 and 15 of Alesi are reproduced below:

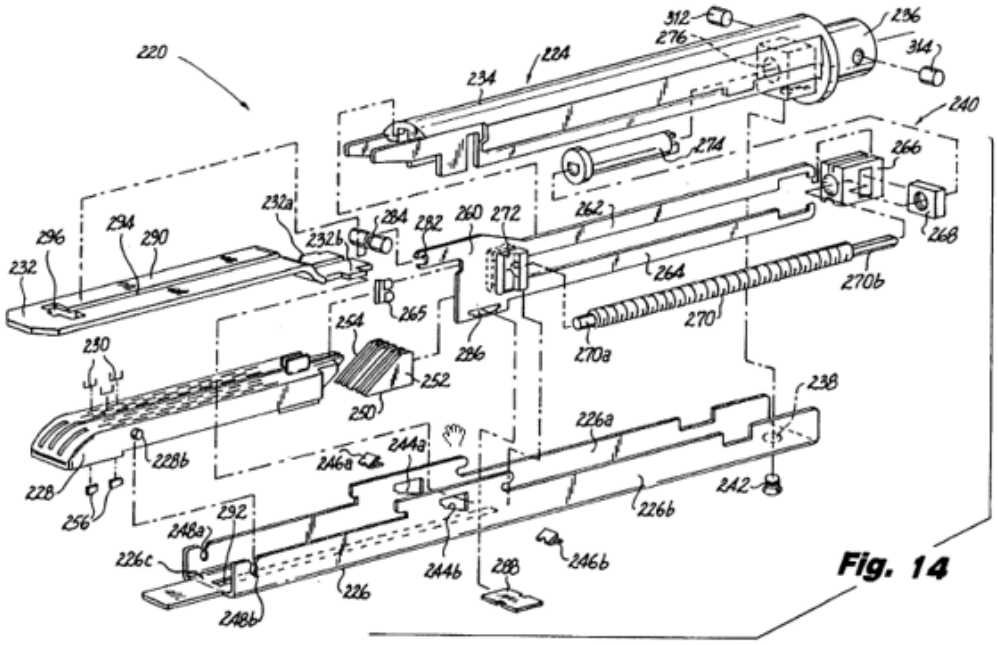


Fig. 14

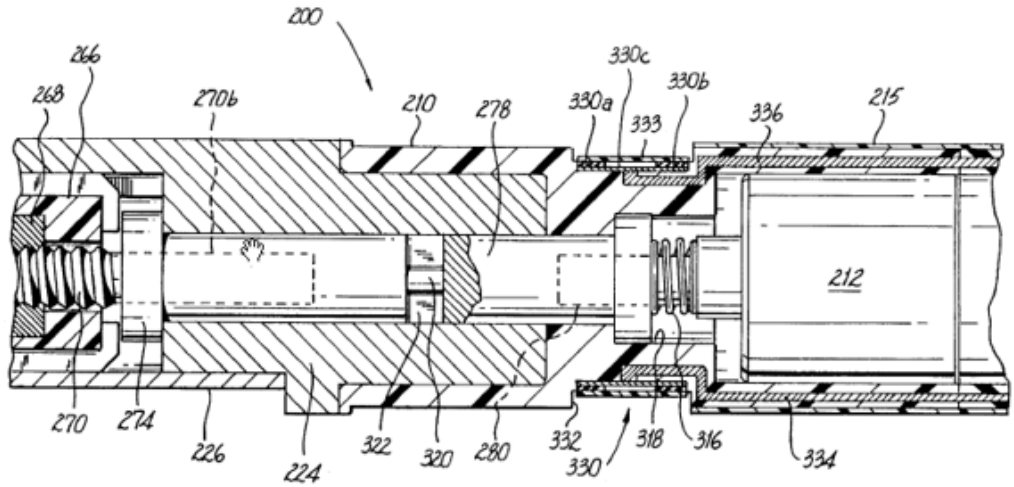


Fig. 15

Figure 14, reproduced above, is an exploded view of cartridge assembly 220, and Figure 15, also reproduced above, illustrates how cartridge assembly 220 is coupled to motor assembly 212 housed in instrument body 210. *Id.* at 4:18–24. Cartridge assembly 220 comprises anvil 232 pivotably mounted to housing channel 226, and actuation assembly 240 that is driven by motor assembly 212 to move anvil 232. *Id.* at 9:50–59. Motor assembly 212 causes drive screw 270 to rotate, which in turn causes longitudinal

translation of actuation beam 260 via drive nut 268 and follower housing 266. The longitudinal translation of actuation beam 260: (1) causes anvil to move from an open position to a closed position; (2) ejects surgical fasteners 230; and (3) cuts tissue with knife blade 265. *Id.* at 9:54–59, 10:23–42.

b. Discussion

Petitioner relies on Alesi for two reasons: (1) to teach the drive-screw limitations of claims 7, 10, 14, 16, and 20 (Pet. 63–65); and (2) to teach a motor operably interfacing with an axial drive assembly, to the extent this teaching is not found in Heinrich (*id.* at 70). Petitioner contends that one of ordinary skill in the art would have combined Alesi with Heinrich for a number of reasons, including that Alesi teaches that its drive-screw implementation is "compact, lightweight and easy to manufacture." *Id.* at 65 (quoting Ex. 1010, 2:18–19).

Patent Owner raises two argument against this ground. First, Patent Owner asserts that Petitioner fails to show that one of ordinary skill in the art would have had a reasonable expectation of success in combining Heinrich with Alesi. Prelim. Resp. 43. Second, Patent Owner asserts that the combination of Heinrich and Alesi is premised on Heinrich disclosing "a screw rod for firing staples," but Heinrich makes no such disclosure. *Id.* at 47–48.

Patent Owner is correct that Petitioner does not use the term "reasonable expectation of success" in its analysis. However, Petitioner does contend that combining Heinrich and Alesi would have achieved "entirely predictable results," and that one of ordinary skill in the art could have "easily" combined Heinrich and Alesi. Pet. 67 (citing Ex. 1003 ¶ 171). We consider these contentions, which Petitioner supports with testimony

from its declarant, to suffice, on this record and at this stage of the proceeding, as a showing of reasonable expectation of success.

As to Patent Owner's second argument, we agree that Heinrich does not disclose a "drive screw implementation" per se. Heinrich only tangentially refers to a "drive rod" or "screw rod." Ex. 1005 ¶ 141. But Petitioner makes reasonably clear that it is Alesi, not Heinrich, that is relied on for implementing a screw-rod drive mechanism in a powered surgical stapler. See, e.g., Pet. 63–65 (acknowledging that Heinrich "does not explicitly disclose" a screw rod rotatably supported within the housing in operable engagement with the motor and in threaded engagement with a portion of the drive beam," and explaining how Alesi discloses this limitation). For grounds 3 and 4, we understand Petitioner to be relying on Heinrich (or Heinrich and Milliman) for its teaching of surgical stapler 300 combined with robotic surgical system 600, and on Alesi to teach using a drive screw mechanism to actuate the stapler.

5. Grounds 5 and 6: Claims 3 and 12—Obviousness—Heinrich (or Heinrich and Milliman) and Tonet

Claim 3 depends from claim 1 and additionally recites "wherein the actuator arrangement comprises a portion of a handheld surgical instrument." Ex. 1001, 80:50–52. Claim 12 depends from claim 11 and contains the same limitation. *Id.* at 81:32–34. For grounds 5 and 6, Petitioner alleges that claims 3 and 12 would have been obvious over Heinrich (or Heinrich and Milliman) and Tonet (Ex. 1014). Pet. 70–73. Tonet is an academic article that describes an experiment to determine the most intuitive and efficient way to map the degrees of freedom (DoFs) of the handle of a surgical device to the DoFs of the tip of the surgical device. Ex.

1014, 2. Petitioner asserts that "Tonet discloses replacing a robotic arm like Heinrich's with a hand-held robot" for positioning a surgical instrument. Pet. 70–71. Petitioner further asserts that one of ordinary skill in the art would have modified Heinrich in view of Tonet to avoid certain problems that surgeons face when using teleoperated robots during surgery, such as the lose of direct contact with the patient and hampered perception and motor skills. *Id.* at 71 (citing Ex. 1003 ¶¶ 183–84). According to Petitioner, Tonet teaches a "known technique," and "Tonet's handle" would perform the same "predictable function" combined with Heinrich that it does separately "without significantly altering or hindering the functions performed by Heinrich's disposable loading unit 618." *Id.* at 72.

Patent Owner responds that "Tonet is a highly speculative article that merely hints at future possible solutions to a problem." Prelim. Resp. 48. According to Patent Owner, "[t]he entire point of Tonet is that the use of a hand-held robot to perform laparoscopic surgery was not well known as a technique, and further experimentation was required to determine the best mode to accomplish such a feat." *Id.* at 53 (citing Ex. 1014, 1–4, 8).

The system that Tonet describes appears to have been developed solely for the described experiment and is used in a computer-simulated environment to perform non-surgical tasks (knot-tying). Ex. 1014, 3–4. The goal of the experiment was to aid in developing a lightweight hand-held robot for laparoscopic surgery, but the instrument itself was, at the time the article was published, still in development. *Id.* at 8. It is unclear on the present record whether combining Tonet with Heinrich would, as Petitioner's allege, be the combination of prior art elements according to known methods to yield predictable results.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with regard to at least one of the claims challenged in the Petition. Accordingly, we institute *inter partes* review. 35 U.S.C. § 314(a). At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim or any underlying factual or legal issue.

IV. ORDER

For the reasons given, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of U.S. Patent 9,084,601 B2 is instituted on all grounds;

and

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

PETITIONER:

John C. Phillips
Steven R. Katz
Ryan P. O'Connor
Fish & Richardson
phillips@fr.com
katz@fr.com
oconnor@fr.com

PATENT OWNER:

Anish R. Desai
Elizabeth Stotland Weiswasser
Adrian Percer
Christopher T. Marando
Christoper M. Pepe
Weil, Gotschal & Manges LLP
anish.desai@weil.com
elizabeth.weiswasser@weil.com
adrian.percer@weil.com
christopher.marando@weil.com
christopher.pepe@weil.com