UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC., Petitioner,

v.

ETHICON LLC, Patent Owner.

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.

JUDGMENT Final Written Decision Granting Patent Owner's Motion to Amend 35 U.S.C. § 318(a)

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") on the following grounds (Pet. 3):

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

Ethicon LLC ("Patent Owner") filed a Preliminary Response. Paper 9.

On December 4, 2018, we instituted *inter partes* review. Paper 10 ("Dec."). Patent Owner did not file a Patent Owner Response addressing the patentability of claims 1–20. Patent Owner did, however, file a Motion to Amend (Paper 15) and, pursuant to our authorization (Paper 17) filed a Corrected Motion to Amend (Paper 18, "Mot. to Amend" or "Motion to

¹ U.S. Pat. App. 2005/0131390 (Jun. 16, 2005) (Ex. 1005).

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

³ US 5,779,130 (Jul. 14, 1998) (Ex. 1010).

⁴ 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).

Amend"). In its Motion to Amend, Patent Owner requests that we substitute proposed claims 21–40 for original claims 1–20. Mot. to Amend, 1. Patent Owner's Motion to Amend is not contingent on a determination of unpatentability of the original claims.

Petitioner filed an Opposition to Patent Owner's Motion to Amend (Paper 19, "Pet. Opp."); Patent Owner filed a Reply in support of its Motion to Amend (Paper 23, "PO Reply"); and Petitioner filed a Sur-reply in Opposition to the Motion (Paper 27, "Pet. Sur-reply"). Oral argument was held September 5, 2019, and a transcript of the hearing is in the record. Paper 30.

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a). For the reasons discussed below, we hold that Patent Owner's Motion to Amend satisfies the requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. We further hold that Petitioner has not shown by a preponderance of the evidence that proposed claims 21–40 are unpatentable. Accordingly, we grant Patent Owner's Motion to Amend to substitute claims 21–40 for claims 1–20 in the '601 patent.⁵

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

⁵ Because we grant the Motion to Amend, which is a non-contingent motion, and substitute claims 21-40 for challenged claims 1-20, we need not address the patentability of claims 1-20.

petitions for U.S. Patent Nos. 8,991,677 and 8,998,058, which are related to the '601 patent. *Id.* at 2.

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, codes (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." *Id.* at 1001 at Abstract, 1:27–30. Figure 1 of the '601 patent is reproduced below:



Figure 1 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:



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 4:30–35. 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 one of contacts 540, 542, 544 to supply power to the motor. *Id.* at 13:18–23.

D. The Proposed Substitute Claims

Patent Owner proposes a substitute claim for each original claim in the '601 patent. Mot. to Amend, App. (proposing the substitution of new claims 21–40 for original claims 1–20). Patent Owner proposes largely identical changes to independent claims 1, 11, and 17, as exemplified by proposed substitute claim 21, reproduced below with additions to claim 1 underlined and deletions from claim 1 struck through:

21. A surgical cutting and stapling instrument comprising:

a housing including at least one engagement member for removably coupling the housing to an actuator <u>in a surgical</u> <u>instrument system</u> arrangement;

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;

an axial drive assembly movably supported for selective axial travel relative to said first and second jaws;

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 jaws, wherein said motor is coupled to a power source when said housing is not coupled to the surgical instrument system; and

a contact arrangement supported by said housing and configured to permit power to be supplied from said power source to the motor only when the housing is operably attached to the actuator arrangement.

Id. at A-1. Proposed dependent claims 22, 24–30, 33–36, and 38–40

are identical to their counterpart claims, and would be amended only as a

result of the amendment of the independent claims from which they depend.

Id. at A-1–A-5. Proposed dependent claims 23 and 32 would additionally be amended by the deletion of the word "arrangement" from the term "actuator

arrangement," consistent with the deletion of that word from the proposed independent claims. *Id.* at A-2, A-4

II. ANALYSIS

A. Claim Construction

Although the claim construction standard to be employed in an *inter partes* review has changed,⁶ because this Petition was filed on May 22, 2018 before the effective date of the change in claim construction standard, we apply the "broadest reasonable construction" of the claims in light of the specification in which the claims appear. 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" (substitute claim 37), "contact arrangement" (substitute claims 21, 31, and 37), and "means for fastening tissue on each side of a cut line" (substitute claim 28). Pet. 16–18.

⁶ 37 C.F.R. § 42.100(b) (Nov. 2018); *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).

Patent Owner did not file a Patent Owner Response to challenge Petitioner's constructions. Further, Petitioner's proposed constructions are consistent with the Specification. Accordingly, for purposes of this decision and as necessary, we will apply Petitioner's constructions. *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. 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 ¶ 27. While Patent Owner did not file a Response, Patent Owner's declarant, Dr. William Cimino, applies this level of ordinary skill in his analysis. Ex. 2006 ¶ 5. For purposes of this Final Written Decision, we adopt Dr. Fischer's definition of the appropriate level of skill at the time of the invention. We also find that the cited prior art references reflect the appropriate level of ordinary skill. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Whether Patent Owner's Motion to Amend Satisfies Statutory and Regulatory Requirements

Patent Owner must show that the proposed substitute claims satisfy the requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.

Lectrosonics, Inc. v Zaxcom, Inc., IPR2018-01129, -01130, Paper 15 (PTAB Feb. 25, 2019) (precedential). These provisions state that: (1) the number of proposed substitute claims must be "reasonable"; (2) the amendment must respond to a ground of unpatentability involved in the trial; (3) the proposed amendment may not enlarge the scope of the claims; and (4) the proposed amendment may not introduce new matter.

1. Reasonable Number of Substitute Claims

Under 37 C.F.R. § 42.121(a)(3), there is a "presumption that only one substitute claim would be needed to replace each challenged claim." Here, Patent Owner proposes 20 substitute claims, 21–40, to replace the 20 challenged claims, 1–20. PO Mot. to Amend, App. A. Petitioner does not contend that Patent Owner's proposal in that regard is unreasonable. We conclude that this one-for-one substitution presents a reasonable number of substitute claims.

2. Responsive to a Ground of Unpatentability

Patent Owner contends that its substitute claims respond to the proposed grounds of unpatentability because none of the prior-art references on which the grounds are based—Heinrich, Milliman, Alesi, and Tonet—discloses a limitation Patent Owner proposes adding to all three of the independent claims: a motor coupled to a power source when the housing is not coupled to the surgical instrument system. Mot. to Amend, 20. Petitioner does not dispute that substitute claims 21–40 are responsive to the grounds of unpatentability. We conclude that the substitute claims satisfy the requirement that the claims "respond to a ground of unpatentability involved in the trial." *See* 37 C.F.R. § 42.121(2)(i).

3. Scope of Substitute Claims

Under 35 U.S.C. § 316(d)(3) and 37 C.F.R. § 42.121(a)(2)(ii), an amendment may not enlarge the scope of the claims of the patent. Patent Owner contends that "the proposed substitute claims *narrow*—and do not broaden—the original claims." Mot. to Amend, 2. Patent Owner states that substitute independent claims 21, 31, and 37: (1) "include all of the original features of original independent claims 1, 11, and 17, respectively"; (2) are amended to "clarif[y] . . . that the housing includes an engagement member for removably coupling the housing to an actuator in a surgical instrument system," which "address[es] a finding of indefiniteness in a co-pending district court litigation"; and (3) are amended to "clarif[y] that the motor is coupled to a power source when the housing is not coupled to the surgical instrument system and that the power is supplied to the motor from the power source only when the housing is operably attached to the actuator." *Id.*

Petitioner responds that changing "actuator arrangement" to "actuator in a surgical instrument system" impermissibly broadens the scope of the independent claims. Pet. Opp. 1. Petitioner asserts that "[t]he plain meaning of 'arrangement' is 'a structure or combination of things arranged in a particular way or for a specific purpose: combination." *Id.* (citing Ex. 1011, 6). According to Petitioner, "[b]y removing the word 'arrangement,' Patent Owner removed the requirement that the claimed actuator be a 'combination of things arranged in a particular way." *Id.* at 1–2.

In its Reply in support of its Motion to Amend, Patent Owner asserts that the removal of "arrangement" does not expand the scope of the claims, because "the amendment includes a meaningful limitation that narrows the

scope of the claim by confining where the claimed actuator is located." PO Reply 2. Patent Owner also asserts that Petitioner's argument is not based on "the full scope of their cited definition," because the argument disregards "the portion of the definition that allows for an arrangement to be a 'structure." *Id.* (citing Ex. 2014 ¶¶ 8–14); *see* Ex. 2014 ¶ 10 (Patent Owner's declarant asserting that under Petitioner's definition, "arrangement" means "structure arranged in a particular way.").

In its Sur-reply, Petitioner contends that even under Patent Owner's definition of "arrangement"—structure arranged in a particular way—the term "has some meaning, [and] its deletion necessarily broadens the claim." Pet. Sur-reply, 2.

Having carefully considered the positions of both parties, we determine that the proposed changes do not broaden the scope of the existing claims. We credit, as consistent with other evidence of record and our analysis below, Dr. Cimino's testimony to that effect. Ex. 2014 ¶¶ 8–14.

As an initial matter, we do not agree with Petitioner's framing of the issue as simply the removal of the word "arrangement." The proper comparison should be between the entire original term ("actuator arrangement") and the entire amended term ("actuator in a surgical instrument system"), rather than on a single word embedded in the original language. *See IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011) ("Extracting a single word from a claim divorced from the surrounding limitations can lead construction astray.").

Further, the phrase "for removably coupling the housing to an actuator in a surgical instrument system" is a statement of intended use⁷ that modifies the term "engagement member." "An intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). In other words, this limitation does not require "an actuator in a surgical instrument system" *per se*; it requires an engagement member *for removably coupling* the housing to such an actuator. *See Arctic Cat, Inc. v. GEP Power Products, Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019) (holding that term "[a] power distribution module for a personal recreational vehicle" "does not claim the vehicle; it claims only the module").

This term may, however, limit the scope of the claim to the extent that it imposes a structural requirement on the claimed engagement member. *See id.* (stating that Arctic Cat has not demonstrated that the identified use itself imposes any structural requirement on the claimed module). Thus, the question is whether "for removably coupling the housing to an actuator in a surgical instrument system" imposes less of a structural requirement on the engagement member than "for removably coupling the housing to an actuator arrangement." We find nothing in the record to support such a conclusion. In particular, we discern no meaningful difference in scope between "an actuator in a surgical instrument system" and "an actuator

⁷ Although "[s]uch statements often . . . appear in the claim's preamble," a statement of intended use or purpose can appear elsewhere in a claim. *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987).

arrangement," and therefore do not see how the former term can impose less of a structural requirement than the latter term. We assume here that "arrangement" means "structure arranged in a particular way," which is the definition that Patent Owner's expert proposes (Ex. 2014 ¶ 10) and Petitioner does not expressly dispute (Pet. Sur-reply 2). Further, Patent Owner has submitted persuasive evidence that "actuator" means "[a]n electric, hydraulic, mechanical or pneumatic device, or combination of these, to effect some predetermined linear or rotating movement." Ex. 2017, 2. "[E]lectric, hydraulic, mechanical or pneumatic device, or combination of such devices," clearly denotes structure. For that structure to effect some *predetermined* linear or rotating movement, it stands to reason that it would have to be, at a very minimum, pre-*arranged* "in a particular way."

4. New Matter

Pursuant to 35 U.S.C. § 316(d)(3) and "[a]n amendment . . . may not . . . introduce new matter"; *see also* 37 C.F.R. § 42.121(2)(ii) ("[a] motion to amend may be denied where: . . . [t]he amendment seeks to . . . introduce new subject matter.") In order to show that an amendment does not introduce new subject matter, a motion to amend must set forth "[t]he support in the original disclosure of the patent for each claim that is added or amended" and "[t]he support in an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought." 37 C.F.R. § 42.121(b). Patent Owner provides a table indicating where support for the substitute claims can be found in the original disclosure of the '601 patent, U.S. Pat. App. 2013/0200132 (Ex. 2011, "the '132 application"), as well as from the application to which the '601 patent claims priority, U.S.

Pat. Pub. No. 2009/0206136 (Ex. 2010, "the '136 application"). Mot. to Amend, 3–17; *see also* PO Reply, 5–8.

Petitioner responds that:

[E]ach of the substitute claims adds the clause: "wherein said motor is coupled to a power source when said housing is not coupled to the surgical instrument system." MTA at 14, 25, 33. However, this added clause does not have written description support because the '601 patent and all of its priority applications clearly teach the opposite; namely, that the motor is <u>not</u> coupled to the power source when the housing is not coupled to the surgical instrument system, but rather is intentionally decoupled to prevent battery drain when in the detached state."

Pet. Opp. 5.

Patent Owner responds that this argument "is based on the incorrect assumption that, for a motor and power source to be 'coupled,' they must be electrically coupled." PO Reply 6. According to Patent Owner, "coupled" may refer to either physical or electrical coupling. *Id.* (citing Ex. 2015, 5). Patent Owner further asserts that the '601 patent "is clear that coupling does not require 'electrical coupling," and notes several instances where the '601 patent uses the term "coupled" to describe a physical connection. *Id.* (citing Ex. 1001, 13:16–19, 11:25–28, 16:44–46, 17:32–36). Finally, Patent Owner asserts that the '601 patent "plainly teaches that the motor is physically connected to the power source when the housing is not coupled to [the] surgical instrument system." *Id.* at 7 (citing Ex. 1001, 12:4–9, Fig. 3).

In its Sur-reply, Petitioner no longer bases its argument on the term "coupled" referring only to electrical coupling, and thus appears not to dispute that "coupled" may encompass physical connection. Instead, Petitioner asserts that Patent Owner's definition of "coupled" is "absurd" because it "includes *indirect* physical connections regardless of how many

intermediary components are between the two 'coupled' objects." Pet. Surreply 4–5.

New matter is any addition to the claims without written-description support in the original disclosure. *See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("When [an] applicant adds a claim ... the new claim[] ... must find support in the original specification."). To satisfy the written description requirement, a disclosure must reasonably convey to one skilled in the art that the applicant had possession of the subject matter in question when the application was filed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Patent Owner has satisfied its burden of showing that the proposed substitute claims do not add new matter. *See* Mot. to Amend, 3–17; PO Reply, 5–8. For example, with respect to the limitation recited "said motor is coupled to a power source when said housing is not coupled to the surgical instrument system," Figures 2 and 3 (the '132 and '136 applications contain identical versions) illustrate a motor and battery enclosed within the housing of disposable loading unit (DLU) 16, the motor and battery in indirect contact via intervening structure, while (as shown in Figure 3) DLU 16 is disconnected from the surgical instrument. Ex. 2010 ¶¶ 7–8, 28–29, 35, Figs. 2, 3; Ex. 2011 ¶¶ 8–9, 160–161, 166, Figs. 2, 3.

Regarding Petitioner's argument that Patent Owner's definition of "coupled" is "absurd," we are not persuaded that Patent Owner's interpretation of the term is as broad as Petitioner contends. We decline to ascribe to Patent Owner an interpretation that Petitioner derives from an answer given by Patent Owner's declarant in response to a far-fetched

hypothetical. *See* Pet. Sur-reply 5–6. In any event, such an interpretation is not required to support our determination above that Patent Owner's claim amendments do not introduce new matter.

5. Conclusion

For the foregoing reasons, we determine that Patent Owner's motion to amend complies with the statutory and regulatory requirements discussed above.

D. Petitioner's Proposed Ground of Unpatentability for Substitute Claims 21–40

Petitioner contends that proposed substitute claims 21–40 are:

(1) unpatentable under 35 U.S.C. § 112(b) as indefinite; and (2) unpatentable under 35 U.S.C. § 103 over Heinrich and Viola. Pet. Opp. 2–23. Petitioner bears the burden of showing that Patent Owner's substitute claims are unpatentable. *Aqua Products, Inc. v. Joseph Matal*, 872 F.3d 1290, 1327–28 (Fed. Cir. 2017) (*en banc*).

1. Indefiniteness

Petitioner contends that "the substitute term 'actuator' is indefinite for the same reasons the original term 'actuator arrangement' was found to be indefinite in the co-pending litigation—*Ethicon LLC v. Intuitive Surgical, Inc.*, No. CV 17-871-LPS, 2018 WL 6831169, at *11 (D. Del. Dec. 28, 2018)." Pet. Opp. 3 (citing Ex. 1028). According to Petitioner, despite Patent Owner's addition of the words "in a surgical instrument system" after the word "actuator" in the substitute claims, "there still are many possible structures that may be removably coupled to the housing and used with a contact arrangement regulating the supply of power to a motor, and the plain meaning of the term 'actuator' is too vague to differentiate what structure or structures are covered." *Id.* at 4 (citing Ex. 1026 ¶ 51; Ex. 1027, 22–23).

Patent Owner responds that "Petitioner improperly ignores the full scope of the substitute claims." PO Reply 4. According to Patent Owner, the plain meaning of actuator is "[a]n electric, hydraulic, mechanical or pneumatic device, or combinations of these, to effect some predetermined linear or rotating movement." *Id.* (citing Ex. 2017,⁸ 2). Patent Owner asserts that:

Although Patent Owner disagrees with the district court's finding, Patent Owner's substitute claims address the district court's finding by clarifying that the claimed housing includes an engagement member for removably coupling the housing to an actuator *in a surgical instrument system*. Paper 18 at 4. This necessarily limits the scope of possible actuators, and informs a POSITA as to which actuators identified in the specification satisfy the claim language.

Id. at 4–5 (citing Ex. 2014 ¶ 16).

We are not persuaded that the substitute claims are indefinite. As an initial matter, as discussed above, the term "actuator in a surgical instrument system" is part of a statement of intended use—"for removably coupling the housing to an actuator in a surgical instrument system"—that modifies the term "engagement member." As such, the claims do not expressly require "an actuator in a surgical instrument system"; the term is relevant to patentability to the extent that it imposes structural limitations on the claimed "engagement member." *Arctic Cat*, 919 F.3d at 1328. Petitioner's argument fails to consider the claim term in this context.

⁸ DICTIONARY OF MECHANICAL ENGINEERING, 2 (3rd ed. 1985).

In any event, we believe that Patent Owner's amendment of the claim language adequately addresses the District Court's concerns. Patent Owner has provided persuasive evidence that "actuator" is a term known in the art, and means "[a]n electric, hydraulic, mechanical or pneumatic device, or combinations of these, to effect some predetermined linear or rotating movement." Ex. 2017, 2. *See Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 996 (Fed. Cir. 2006) ("Because there is no suggestion that the intrinsic evidence defines the term 'catalyst,' one may look to technical dictionaries for assistance in determining that term's meaning to a person of ordinary skill in the art.") (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc)). The proposed new language limits the particular actuator to a specific technical environment. Even if the term covers "many possible structures," as Petitioner asserts, this would result in a broad claim, not necessarily an indefinite one. *See In re Johnson*, 558 F.2d 1008, 1016 n.17 (CCPA 1977) (breadth is not indefiniteness).

2. *Obviousness*

Petitioner asserts that the proposed substitute claims would have been obvious over Heinrich and Viola. Pet. Opp. 6–22. Patent Owner opposes. PO Reply 8–12.

a. <u>Heinrich (Ex. 1005)</u>

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



Heinrich's Figures 3 and 3a respectively illustrate an endoscopic gastrointestinal anastomotic stapler 300 and an enlarged view of the distal end of stapler 300. *Id.* ¶ 92. The stapler comprises disposable loading unit 316 releasably secured to a distal end of elongated body 314. *Id.* 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:



Figure 7 illustrates robotic surgical system 600 comprising 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:



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." *Id.* ¶ 99. Figure 1 of Milliman appears substantially the same as Figure 3 of Heinrich. *Compare* Ex. 1006, Fig. 1 *with* Ex. 1005, Fig. 3. Accordingly, we discuss Milliman next.

b. <u>Milliman (Ex. 1006)</u>

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:



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.

c. <u>Viola (Ex. 1031)</u>

Viola describes an electrically-powered endoscopic surgical instrument having a motor and power source contained within the instrument's handle. Ex. 1031, 2:23–27. Figure 1, reproduced below, depicts one embodiment of Viola's surgical instrument:



Figure 1 depicts surgical stapler 10, which "is configured to clamp body tissue, apply a plurality of surgical fasteners to the body tissue, and form an incision in the fastened body tissue during a laparoscopic surgical procedure." *Id.* at 4:11–14. Stapler 10 comprises handle portion 12, elongate body portion 14 extending distally from handle portion 12, and cartridge assembly 16 detachably connected to a distal end of body portion 14. *Id.* at 4:14–17. Figure 2a, reproduced below, depicts handle portion 12 in greater detail:



As shown in Figure 2a, handle portion 12 comprises elongated barrel section 18 and handle gripping section 20. *Id.* at 4:18–21. Motor assembly 22, disposed within barrel section 18, drives cartridge assembly 16 via gear set 24 and drive shaft 42. *Id.* at 4:23–38. Motor assembly 22 is powered by power cells 45a-b disposed within handle gripping section 20. *Id.* at 4:21–22, 40–43. Trigger 44 projects from gripping section 20 for controlling motor assembly 22. *Id.* at 4:46–48. Trigger 44 is connected to switching assembly 46 by link bar 48. *Id.* at 4:48–49. When trigger 44 is squeezed, link bar 48 moves proximally to engage the terminals to drive the output shaft of motor assembly 22 in a first direction to fire the staples. *Id.* at 4:64–5:4, Fig. 3. When the trigger is released, link bar 48 returns to a disconnected position. *Id.* at 5:4–6. Motor assembly 22 may be operated in a reverse direction by pulling trigger 44 distally. *Id.* at 5:6–12.

d. <u>Principles of Law</u>

"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.

e. <u>The Parties' Contentions</u>

Petitioner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Heinrich and Viola to achieve the proposed claims. Pet. Opp. 6–22. In particular, Petitioner contends that:

[I]t would have been obvious to (1) incorporate the components inside Viola's handle portion 12 (e.g., motor assembly 22 and power cells 45a-b) into Heinrich's housing, and (2) replace or actuate Viola's trigger 44 with Heinrich's electromechanical assembly 619, which is also included in the housing of disposable loading unit 618 and is controlled by Heinrich's robotic surgical system.

Pet. Opp. 7–8. Petitioner provides a composite image of Heinrich Figure 9 and Viola Figure 1 to illustrate the proposed combination:



The above composite image illustrates Petitioner's proposed combination of Heinrich Figure 9 and Viola Figure 1. *Id.* at 8. Petitioner also provides a detailed claim chart illustrating its proposed combination. *Id.* at 12–22. For example, regarding the limitation in proposed claim 21 requiring the motor to be coupled to a power source when said housing is not coupled to the surgical instrument system, Petitioner provides the following

See, e.g., Viola, 4:40-57, 7:56-8:16, Figs. 2-2a, 5, 8-10; Heinrich, ¶136-37; Fischer Supp. Decl., ¶65-70.



Viola, Fig. 2a



The above image is a portion of Petitioner's claim chart illustrating how Petitioner contends the combination of Heinrich and Viola teaches the motor coupled to a power source when said housing is not coupled to the surgical instrument system. *Id.* at 14. Regarding the claimed "contact arrangement configured to permit power to be supplied from said power source to the motor only when the housing is operably attached to the actuator," Petitioner provides the following:

> See, e.g., Petition at 41-45 (confirming that Heinrich discloses element [21.6]); Fischer Decl., ¶¶ 119-23 (same); see also Viola, 4:48-5:12, Figs. 2a-b; Fischer Supp. Decl., ¶¶71-73.



The above image is a portion of Petitioner's claim chart illustrating how Petitioner contends the combination of Heinrich and Viola teaches the claimed contact arrangement configured to permit power to be supplied from said power source to the motor only when the housing is operably attached to the actuator. *Id.* at 15. Petitioner states that:

Contact arrangement (switching assembly 46) is configured to permit power to be supplied from the power source (45a-b) to the motor (22) only when the housing of the Viola/Heinrich loading unit is operably attached to the actuator (Heinrich's robot 616 and actuation assembly 612) because link bar 48 must be moved to connect the two middle terminals T3, T4 with respective rear terminals T5, T6 (or front terminals T1, T2) to permit power to be supplied from the power source to the motor, but the robotcontrolled electromechanical assembly 619 that moves link bar 48 can only be actuated when the Viola/Heinrich loading unit is attached to the robotic system.

Id. at 16.

Petitioner advances several reasons why one of ordinary skill in the art would have been motivated to combine Viola and Heinrich in the proposed manner. First, Petitioner asserts that "making a handheld surgical stapler compatible with a robotic system was desirable." Pet. Opp. 9 (citing Ex. 1030 ¶¶ 44–47). Second, Petitioner asserts that Heinrich "specifically envisions the use of 'locally powered' surgical instruments, like the instruments disclosed in Viola." *Id.* at 10 (citing Ex. 1005 ¶ 131). Third, Petitioner contends that another prior art reference, U.S. Pat. No. 6,783,524 B2 to Anderson et al. ("Anderson"), "teaches that loading units for robotic systems 'may include OEM parts' from handheld instruments, like the parts disclosed in Viola, "to reduce costs and for manufacturing convenience." *Id.* (quoting Ex. 1013, 7:6–7).

Patent Owner responds that one of ordinary skill in the art would not have had a reason to include Viola's motor assembly 22 and power cells 45a-b in any combination of Viola and Heinrich, because "Heinrich's DLU already contains a motor that is connected to an external power source," and that motor is capable of "driving an attached surgical tool such as Viola's staple cartridge 16." PO Reply 8–9. According to Patent Owner, "Petitioner's proposed combination results in a redundant, over-powered motor used solely to control power to a second motor." *Id.* at 9. Patent Owner also asserts that even if one of ordinary skill in the art would have been motivated to use OEM parts in the combined device to save manufacturing costs, "[t]here is no scenario where it would be *less* expensive to completely re-design Heinrich's DLU to incorporate *additional redundant* components." *Id.* at 10 (citing Ex. 2014 ¶¶ 52–54).

f. <u>Discussion</u>

To prevail in its assertion that the substitute claims are obvious over a combination of references, Petitioner "must demonstrate . . . that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015) (quoting *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014) (alteration in original)). The reason to combine or modify references must be supported by a "rational underpinning." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR*, 550 U.S. at 418).

Petitioner has not demonstrated that one of ordinary skill in the art would have had a reason—supported by a rational underpinning—to combine Viola and Heinrich in the manner that Petitioner proposes.

According to Petitioner, it would have been obvious to one of ordinary skill in the art to combine Viola's cartridge assembly 16, elongate portion 14, motor assembly 22, power cells 45a-b, and switching assembly 46; and Heinrich's head portion 640 and electro-mechanical assembly 619; into a single "Viola/Heinrich loading unit"; which is removably coupled to Heinrich's robot 616 and actuation assembly 612. Pet. Opp. 12–16. So combined, Viola's motor assembly 22, power cells 45a-b, and switch assembly 46 would perform the same function performed by Heinrich's

electromechanical assembly 619, powered and controlled by actuation assembly 612: operating the surgical instrument. Ex. 1005 ¶¶ 134, 136– 137. Thus, Viola's motor assembly 22, power cells 45a-b, and switch assembly 46 would not, in Petitioner's combination, add to the functionality of the surgical instrument device, and would thus appear to be superfluous. This is underscored by the fact that Petitioner proposed a combination of Heinrich and Alesi to obtain a robotically controlled cutter/stapler that has the same functionality as the Heinrich/Viola device, but without motor assembly 22, power cells 45a-b, or switch assembly 46. Pet. 62–70.

One of ordinary skill in the art would ordinarily not combine teachings in a way that results in superfluous components. *See In re NTP, Inc.*, 654 F.3d 1279, 1299 (Fed. Cir. 2011) (holding that claims would not have been obvious based on the combination of two references because the combination would have resulted in two RF networks, one of which would have been superfluous). Further, the inclusion of unnecessary components would likely have increased the cost of the device, without any corresponding benefit. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1353 (Fed. Cir. 2011) ("the fact that a combination is expected to increase cost has some bearing on the obviousness of that combination").

Moreover, none of Petitioner's reasons to combine Heinrich and Viola justifies the inclusion of these components. While we agree that one of ordinary skill in the art would have been motivated to make a hand-held surgical stapler compatible with a robotic system, that combination could have been achieved without Viola's motor assembly 22, power cells 45a-b, and switch assembly 46, as discussed above in connection with the combination of Heinrich and Alesi.

We are also not persuaded that one of ordinary skill in the art would have combined Heinrich and Viola to achieve the claimed invention based on Petitioner's assertion that "Heinrich specifically envisions the use of 'locally powered' surgical instruments, like the instruments disclosed in Viola." Pet. Opp. 10 (citing Ex. 1005 ¶ 131; Ex. 1030 ¶ 46). The cited portion of Heinrich states:

Generally, robotic surgical systems include surgical instrument[s] or systems, either powered locally or remotely, having electronic control systems localized in a console or distributed within or throughout the surgical instrument system.

Ex. 1005 ¶ 131. Heinrich thus teaches that a surgical instrument may be powered locally *or* remotely, whereas Petitioner's proposed combination comprises portions that are powered locally (motor assembly 22, powered by power cells 45a-b) and portions powered remotely (electromechanical assembly 619, powered by actuator assembly 612). Petitioner does not explain the advantage of this bifurcated power-supply arrangement.

Perhaps more importantly, Petitioner also has not established its premise that Viola's surgical instruments are "powered locally." Heinrich describes robotically controlled "surgical instruments" as part of a detachable loading unit. *See* Ex. 1005 ¶ 132, Fig. 7 (describing "surgical instrument 620" as part of loading unit 618). The detachable loading unit of Viola's device is cartridge assembly 16. Ex. 1031, 4:10-17, Fig. 1. Viola's cartridge assembly 16 does not have its own power supply, but rather receives power from power cells 45a-b located in handle portion 12. *Id.* at 4:40–43, Figs. 2, 2a.

Petitioner argues that one of ordinary skill in the art would have included motor assembly 22 and power cells 45a-b based on Anderson's

teaching that robotic systems "may include OEM parts from hand-held instruments, like the parts disclosed in Viola, "to reduce costs and for manufacturing convenience." Pet. Opp. 10 (citing Ex. 1013, 7:6–7). This is not persuasive. We understand Anderson's point to be that it would be more convenient and less expensive to use commercially available parts rather than manufacture new parts. *See* Ex. 1013, 7:6–25. We do not read Anderson as advocating using OEM parts that are not needed, however. Nor does Anderson support Petitioner's and Dr. Fischer's position that "a POSITA modifying Viola's instrument for use with Heinrich's robotic system would not move Viola's power source to Heinrich's robotic system because such a modification would significantly increase the cost and complexity of the task." Pet. Opp. 10–11 (citing Ex. 1030 ¶¶ 48–49). Neither Petitioner nor Dr. Fischer explain why this is so, particularly when Heinrich's robotic system already provides a power source.

g. <u>Conclusion</u>

For the above reasons, we determine that Petitioner has not articulated a reason, supported by a rational underpinning, why one of ordinary skill in the art would have combined Heinrich and Viola to achieve the subject matter of the proposed substitute claims. Accordingly, Petitioner has not shown that the substitute claims would have been obvious over Heinrich and Viola.

III. CONCLUSION

For the foregoing reasons, we determine the following:

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	21–40
Substitute Claims: Motion to Amend Granted	21–40
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	

IV. ORDER

For the reasons given, it is

ORDERED that Patent Owner's Motion to Amend (Paper 18) seeking substitution of claims 21–40 for claims 1–20 in the '601 patent is *granted*; and

FURTHER ORDERED that because this is a Final Written Decision,

parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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