# UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC., Petitioner,

v.

P TECH, LLC, Patent Owner.

IPR2020-01687 Patent 10,368,953 B2

Before SHERIDAN K. SNEDDEN, MICHELLE N. WORMMEESTER, and CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, Administrative Patent Judge.

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

#### I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–4, 6–20, 22–25, 27, 29, and 30 of U.S. Patent No. 10,368,953 B2 ("the '953 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

In general terms, the technology at issue relates to a method of fastening body tissue, e.g., by suturing or stapling, using a robotic surgical system having one or more adaptive arms. Petitioner Intuitive Surgical, Inc. contends that the challenged claims are unpatentable as obvious over the combination of Tierney (which teaches a robotic surgical system) with Bonutti or Hooven (which respectively teach a suture securing system and stapler). With respect to the Tierney/Bonutti combination, Patent Owner P Tech LLC argues that it does not teach or suggest each limitation of the challenged claims. With respect to both asserted combinations, Patent Owner argues that Petitioner has not demonstrated an adequate motivation to combine the asserted prior art with a reasonable expectation of success.

Petitioner has the burden of proving unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Having reviewed the parties' arguments and supporting evidence, for the reasons discussed below, we find that Petitioner demonstrates by a preponderance of the evidence that claims 1–4, 6–20, 22–25, 27, 29, and 30 are unpatentable as obvious over the asserted prior art.

#### A. Procedural History

On October 1, 2020, Petitioner filed its Petition for *inter partes* review. Paper 2 ("Pet."). On April 20, 2021, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims on

all grounds asserted in the Petition. Paper 7 ("Dec. Inst."). Patent Owner subsequently filed a Patent Owner Response (Paper 11, "PO Resp.");

Petitioner filed a Reply (Paper 13, "Reply"); and Patent Owner filed a Surreply (Paper 17, "Sur-reply").

We heard oral argument on February 15, 2022, and a transcript of the hearing is in the record. Paper 22.

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

B. Real Parties in Interest

Petitioner and Patent Owner each identify themselves as the sole real party in interest. Pet. 1; Paper 4, 2.

C. Related Matters

The '953 patent is asserted in P Tech LLC v. Intuitive Surgical, Inc.,

1:19-cv-00525-RGA (D. Del.), which Petitioner indicates is stayed. Pet. 1– 2; Paper 4, 2.

Petitioner has also filed petitions for *inter partes* review of related U.S. Patent Nos. 9,149,281 and 9,192,395. Pet. 2; Paper 4, 2; IPR2020-00650; IPR2020-00649. Although not identified by either party, we note that Patent Owner has appealed the Board's final written decisions in IPR2020-00650 and IPR2020-00649 to the United States Court of Appeals for the Federal Circuit.<sup>1</sup> *See* Case Nos. 2022-1102, -1115 (CAFC).

<sup>&</sup>lt;sup>1</sup> We remind the parties of their continuing obligation to update their Mandatory Notices. 37 C.F.R. § 42.8(a)(3).

# D. The '953 Patent

The '953 patent issued on August 6, 2019 and through a series of continuation applications, claims priority to an application filed on March 20, 2002. Ex. 1001, codes (22), (45), (63).

The '953 patent is generally directed to a robotic surgical system and its use in a "method of securing either hard or soft body tissue." *Id.* at 1:41–42. Figure 1, reproduced below, illustrates the robotic surgical system:

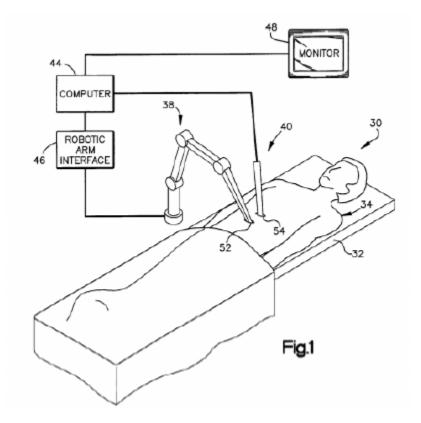
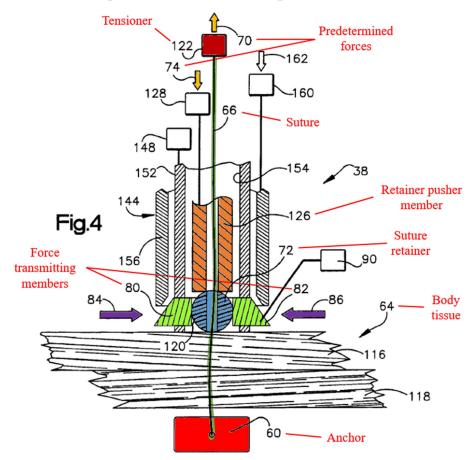


Figure 1 above depicts a robotic mechanism 38 used to position a fastener (e.g., a suture, staple, screw, etc.) relative to body tissue at a desired location within patient 34. *Id.* at 1:44–45, 5:11–14, 5:57–58. Robotic mechanism 38 includes one or more adaptive arms, and is guided by automatic controls including computer 44 and robotic arm interface 46. *Id.* at 5:25–29, 5:40–49.

In one embodiment, the robotic surgical system fastens body tissue using a suture. Ex. 1001, 8:65–9:3. Petitioner's annotated version of Figure 4 of the '953 patent (*see* Pet. 6) is reproduced below:



Annotated Figure 4, reproduced above, is a schematic illustration depicting a suture assembly for use with the robotic surgical system. *Id.* at 2:56–60. Petitioner highlights various components including anchor 60, suture retainer 72, retainer pusher member 126, suture 66, tensioner 122, and force transmitting members 80, 82.

After robotic mechanism 38 moves anchor 60 into position (e.g., underneath two layers of body tissue 116, 118 as depicted in Figure 4), tensioner 122 grips suture 66 and tensions it (e.g., upward as illustrated by arrow 70), with a predetermined force. *Id.* at 11:10–19, 11:30–31. "While

the suture 66 is tensioned . . . , a retainer pusher member 126 is pressed against the retainer 72 with a predetermined force [74]," which "presses the retainer 72 against the upper layer 116 of body tissue  $64."^2$  *Id.* at 11:47–56. This "results in the two layers 116 and 118 of body tissue being clamped between the suture [anchor] 60 and retainer 72 with a predetermined force." *Id.* at 11:65–67. While the tissue is clamped, robotic mechanism 38 operates to plastically deform retainer 72 to grip suture 66. *Id.* at 12:24–37. In particular, "force transmitting members 80 and 82" of robotic mechanism 38 press "radially inward against the suture retainer 72," causing "the material of the suture retainer 72 to move into engagement with and grip the suture 66." *Id.* at 12:45–13:6.

E. Illustrative Claim

Of the challenged claims, claims 1 and 6 are independent. Claim 1, reproduced below with Petitioner's bracketed numbering added, is illustrative:

1. [1.1] A method of fastening at least first and second portions of body tissue together, the method comprising:

[1.2] imparting, using an adaptive arm of a robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another;

[1.3] generating, using a force measurement system associated with the adaptive arm, a clamping force signal indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue;

[1.4] receiving, using a computer in communication with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system;

<sup>&</sup>lt;sup>2</sup> Throughout this Decision, we omit bolding of reference numbers in quotes from the '953 patent and prior art patents.

[1.5] determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude; and

[1.6] fastening, after said determining and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude, the first and second portions of body tissue together using the adaptive arm.

# Ex. 1001, 45:43–65; Pet. 20–42.

# F. Asserted Challenges to Patentability

We instituted trial on the following grounds (Pet. 3; Dec. Inst. 45):

Claim(s) Challenged	35 U.S.C. § <sup>3</sup>	References
1, 2, 4, 6, 8–20, 22–25, 27, 29, 30	103	Bonutti, <sup>4</sup> Tierney <sup>5</sup>
1, 2, 4, 6, 8–20, 22–25, 27, 29, 30	103	Bonutti, Tierney, Cooper, <sup>6</sup> Madhani <sup>7</sup>

<sup>3</sup> Petitioner contends that the America Invents Act ("AIA") applies to the '953 patent, but notes that the cited references are prior art under both the AIA and pre-AIA statutes. Pet. 3 n.1. Patent Owner does not dispute Petitioner's contentions, or explicitly address the proper priority date of the challenged claims. Although we apply the AIA versions of 35 U.S.C. §§ 102 and 103 herein, on this record we agree with Petitioner that the asserted prior art references qualify as prior art to the challenged claims under both the AIA and pre-AIA statutes. Our analysis and conclusions would be the same under the pre-AIA versions of 35 U.S.C. §§ 102 and 103. <sup>4</sup> US 6,159,234, issued December 12, 2000 ("Bonutti," Ex. 1004). The parties sometimes refer to this reference as "Bonutti-'234."

<sup>&</sup>lt;sup>5</sup> US 6,331,181 B1, issued December 18, 2001 ("Tierney," Ex. 1005).

<sup>&</sup>lt;sup>6</sup> WO 98/25666, published June 18, 1998 ("Cooper," Ex. 1007).

<sup>&</sup>lt;sup>7</sup> US 5,792,135, issued August 11, 1998 ("Madhani," Ex. 1013). Although Petitioner's summary of its grounds does not mention Madhani as part of Ground 3, this is an obvious typographical error because the Petition later

Claim(s) Challenged	35 U.S.C. § <sup>3</sup>	References
24	103	Bonutti, Tierney, Bonutti-986 <sup>8</sup>
1-4, 6-8, 24	103	Hooven, <sup>9</sup> Tierney

Petitioner supports its challenges with the Declaration of Dr. Gregory Fischer (Ex. 1003).

## II. ANALYSIS

#### A. Legal Principles

A patent may not be obtained "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 (2018). An obviousness analysis involves underlying factual inquiries including (1) the scope and content of the prior art; (2) differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) where in evidence, objective indicia of nonobviousness, such as commercial success, long-felt but unsolved needs, and failure of others.<sup>10</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17–18, 35–36 (1966). An obviousness determination requires finding "a motivation to combine accompanied by a reasonable expectation

explains that Madhani is part of this challenge. *Compare* Pet. 3, *with* Pet. 78; Dec. Inst. 5 n.7.

<sup>&</sup>lt;sup>8</sup> US 5,921,986, issued July 13, 1999 ("Bonutti-986," Ex. 1008).

<sup>&</sup>lt;sup>9</sup> US 5,518,163, issued May 21, 1996 ("Hooven," Ex. 1006).

<sup>&</sup>lt;sup>10</sup> On the full trial record, neither party relies on evidence of objective indicia.

of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016).

B. Level of Ordinary Skill in the Art

Factors pertinent to determining the level of ordinary skill in the art include the types of problems encountered in the art and prior art solutions to those problems. *See Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–97 (Fed. Cir. 1983).

Patent Owner proposes that a person of ordinary skill in the art

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 electromechanical systems and at least 3 years of experience working with robotic surgical instruments. Experience with robotic surgical instruments could take the place of formal training, as relevant skills may be learned on the job or through practical experience, and *vice versa*.

PO Resp. 30. Petitioner's declarant Dr. Fischer provides a similar proposal, except he cites experience with "surgical instruments" instead of "robotic surgical instruments" as Patent Owner proposes. Ex. 1003 ¶ 32.

Based on our review of the '953 patent and the types of problems and solutions described in the '953 patent and cited prior art, we adopt Patent Owner's proposal for a person of ordinary skill in the art (sometimes referred to herein as a "skilled artisan" or "POSITA").

C. Claim Construction

In an *inter partes* review, we construe a patent claim "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) (2020). Therefore, we construe the claims under the framework in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this

framework, claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id*.

Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Below we address the parties' arguments regarding two claim terms. *1. "determining, using the computer"* 

Petitioner argues that the limitations in independent claims 1 and 6 that recite "determining, using the computer"<sup>11</sup> "encompass mental steps that are not entitled to patentable weight" because they "do not exclude the situation where the surgeon, using the computer to display a force readout, performs the 'determining' step." Pet. 9 (citing *In re Venner*, 262 F.2d 91, 95 (CCPA 1958) ("Patentability cannot be predicated upon a mental step."); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1378 (Fed. Cir. 2016) (mental step of "detect[ing] the allele" did not supply inventive concept necessary for patent eligibility under § 101); Ex. 1001, 11:20–29); Reply 28.

Patent Owner responds that "[t]he plain language of these steps makes clear that it is the computer that performs the 'determining'." PO Resp. 31.

<sup>&</sup>lt;sup>11</sup> The full limitation in claim 1 recites: "determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude." Ex. 1001, 45:57–60. The full limitation in claim 6 recites: "determining, using the computer and the received fastening signal, that the first and second portions of body tissue are suitable for being fastened to one another." *Id.* at 46:29–32.

Although Petitioner argues that the "determining, using the computer" limitations are not entitled to patentable weight, it nevertheless demonstrates that the cited prior art teaches or suggests these limitations. *See infra* Sections II.D.3(e), II.E.2(e). Patent Owner does not dispute Petitioner's showings. *See generally* PO Resp. Accordingly, as we found in our Decision on Institution, to resolve the parties' disputes we need not expressly decide whether these limitations are entitled to patentable weight.<sup>12</sup> Dec. Inst. 8–9; *Vivid Techs., Inc.*, 200 F.3d at 803.

#### 2. "an adaptive arm"

Patent Owner argues that independent claim 1 and dependent claims 2 and 4 are limited to robotic systems having a "*single* adaptive arm" for clamping and fastening the body tissue. PO Resp. 40; *see also* Sur-reply 10–11. This is because, Patent Owner contends, limitation [1.2] "recite[s] '*an* adaptive arm,' and all further mention of 'adaptive arm' is as '*the* adaptive arm.'" PO Resp. 40. Patent Owner thus contends that "there is only antecedent basis for the *same* adaptive arm in these claims." *Id*.

Petitioner responds that the claims do not expressly recite a "single" adaptive arm.<sup>13</sup> Reply 15.

<sup>&</sup>lt;sup>12</sup> The parties also dispute whether the '953 patent discloses a stapler embodiment that practices the "determining" and "fastening" limitations. Pet. 9–11; PO Resp. 31–32; Reply 29. Neither party, however, requests or proposes any claim construction based on its arguments, nor do we perceive any dispute that requires us to decide whether the '953 patent discloses any stapler embodiment that practices these limitations. Thus, as we stated in our Decision on Institution, we need not address these arguments. Dec. Inst. 9 n.14; *see also Vivid Techs., Inc.*, 200 F.3d at 803.

<sup>&</sup>lt;sup>13</sup> In contrast, claims 14, 16–19, and 30 recite a "single adaptive arm," either expressly or through dependence.

We disagree with Patent Owner that claims 1, 2, and 4 are limited to systems having a single adaptive arm for clamping and fastening the body tissue. Unlike claims such as claim 14, claims 1, 2, and 4 do not expressly recite a single adaptive arm. Patent Owner's proposal to read in the word "single" based on use of the indefinite article "a" to introduce the "adaptive arm" term, followed by subsequent use of the definite article "the" to refer back to the adaptive arm, is inconsistent with controlling Federal Circuit case law. *See* PO Resp. 40; Sur-reply 10–11.

The Federal Circuit has explained that subject to very limited exceptions, in claims that use the open-ended "comprising" transition, there is a "general rule" that "a" or "an" means "more than one," and "[t]he subsequent use of definite articles 'the' or 'said' in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). "An exception to the general rule that 'a' or 'an' means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule." *Id.* at 1342–43.

On this record we have not been directed to, nor do we discern, any portion of the claim language, '953 patent specification, or prosecution history that compels a departure from the general rule. Accordingly, we find that the term "an adaptive arm" encompasses one or more adaptive arms, and that claims 1, 2, and 4 are not limited to a single adaptive arm as Patent Owner contends.

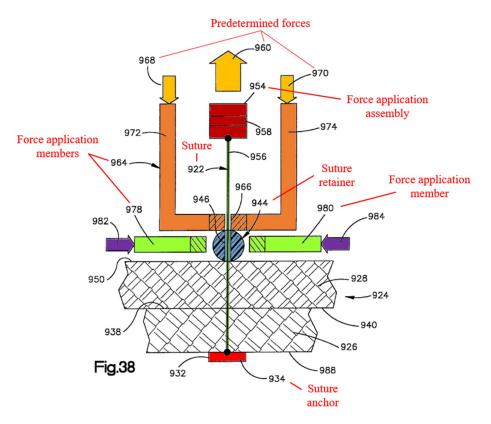
# D. Alleged Obviousness Over Bonutti and Tierney

Petitioner contends that claims 1, 2, 4, 6, 8–20, 22–25, 27, 29, and 30 are unpatentable as obvious over the combination of Bonutti (which teaches a handheld suture securing system) and Tierney (which teaches a robotic surgical system). Pet. 20–59. Patent Owner opposes. *See, e.g.*, PO Resp. 32–55.

For the reasons explained below, we find that Petitioner establishes by a preponderance of the evidence that claims 1, 2, 4, 6, 8–20, 22–25, 27, 29, and 30 are unpatentable as obvious over Bonutti and Tierney. We begin by summarizing Bonutti and Tierney, then turn to the parties' arguments.

1. Bonutti (Ex. 1004)

Bonutti discloses a system for securing body tissue using a suture and suture retainer, as illustrated in Petitioner's annotated version of Bonutti's Figure 38, reproduced below:



As shown in the annotated version of Bonutti's Figure 38 reproduced above, the suture securing system comprises "force application assembly 954," which applies "predetermined" force 960 on suture 922, causing it to become "tensioned" and pull up on suture anchor 934. Pet. 12; Ex. 1004, 41:41–53, 42:19–23, 42:42–45. The system further comprises "force application member 964," which applies "predetermined" forces 968 and 970 to the top of suture retainer 944 so that it "press[es] . . . directly against the outer layer 928 of body tissue." Ex. 1004, 41:58–59, 42:1–11, 42:33– 39. "[W]hile the suture retainer 944 is being pressed against the outer layer 928 of body tissue 924 under the combined forces 968 and 970 and while the suture 922 is being tensioned by the force 960, a pair of force application members 978 and 980 are pressed against opposite sides of the suture retainer 944." Id. at 42:51-56. "The force applied against the suture retainer 944 by the force application members 978 and 980 plastically deforms the material of the suture retainer" to grip the suture. Id. at 42:56-59, 1:46–47. "The plastic deformation of the material of the suture retainer may be performed while transmitting a predetermined force from the suture retainer to the body tissue." Id. at 1:50–53.

## 2. Tierney (Ex. 1005)

Tierney teaches a robotic surgical system for minimally invasive and other robotically enhanced surgical procedures. Ex. 1005, 1:12–15. The system comprises multiple robotic arms, which support surgical tools such as jaws, scissors, graspers, needle holders, staple appliers, tackers, cutting blades, and irrigators. *Id.* at 6:20–37.

Petitioner's annotated version of Tierney's Figure 1 is reproduced below:

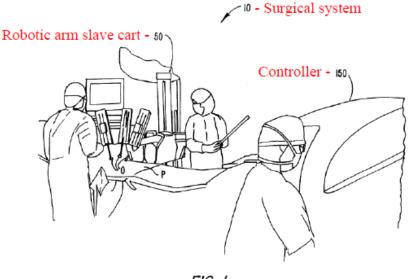


FIG. 1.

Petitioner's annotated version of Tierney's Figure 1, reproduced above, shows a surgical system 10 comprising controller 150, which controls robotic arms on cart 50. Pet. 14; Ex. 1005, 6:61–63. Petitioner's annotations label the surgical system 10, robotic arm cart 50, and controller 150. In this system,

controller 150 generally includes master controllers (not shown) which are grasped by the surgeon and manipulated in space while the surgeon views the procedure . . . [on] a stereo display. The master controllers are manual input devices which preferably move with six degrees of freedom, and which often further have an actuatable handle for actuating tools (for example, for closing grasping saws, applying an electrical potential to an electrode, or the like).

Ex. 1005, 6:63–7:4.

Tierney's Figure 2 is reproduced below:

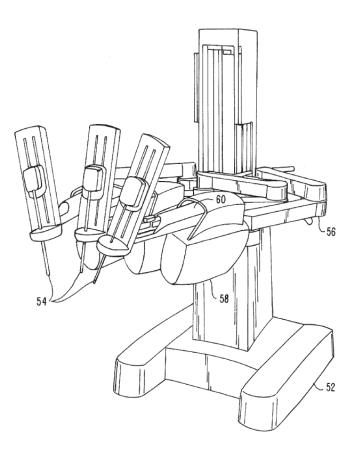


Figure 2 "is a perspective view of a robotic surgical arm cart system [50]," and "includes a base 52 from which three surgical tools 54 are supported." *Id.* at 5:29–32, 7:16–18. In the cart, "robotic manipulators 58 preferably include a linkage 62 [not shown] that constrains movement of tool 54." *Id.* at 7:41–48. Tierney describes manipulation of the tools as follows:

Linkage 62 . . . is driven by a series of motors 70. . . . Motors 70 are further coupled to tool 54 so as to rotate the tool about axis 66, and often to articulate a wrist at the distal end of the tool about at least one, and often two, degrees of freedom. Additionally, motors 70 can be used to actuate an articulatable end effector of the tool for grasping tissues in the jaws of a forceps or the like. Motors 70 may be coupled to at least some of the joints of tool 54 using cables, as more fully described in U.S. Pat. No. 5,792,135 [Madhani], the full disclosure of which

> is also incorporated herein by reference. As described in that reference, the manipulator will often include flexible members for transferring motion from the drive components to the surgical tool.

*Id.* at 7:63–8:10. Tierney states that "[a] wide variety of alternative drive systems might be employed, including alternative cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like." *Id.* at 9:31–34.

Tierney also teaches that "a wide variety of alternative end effectors for differing tool-types may be provided," such that "the tools of the present invention may incorporate any of the illustrated end effectors, or any other end effector which is useful for surgery, particularly at an internal surgical site." *Id.* at 10:5–11. For example, the tool "will often comprise a surgical instrument suitable for manipulating tissue," and can be "articulated (such as jaws, scissors, graspers, needle holders, microdissectors, staple appliers, tackers, suction/irrigation tools, clip appliers, or the like) or non-articulated (such as cutting blades, cautery probes, irrigators, catheters, suction orifices, or the like)." *Id.* at 3:18–20; 6:22–28.

Tierney incorporates Cooper by reference. *Id.* at 1:60–2:11. Cooper teaches a robotic surgical system that includes force and torque feedback sensors and a safety controller that can freeze all robot motion if excessive force is exerted on the patient. Ex. 1007, 1:17–21, 9:22–26, 16:38–17:3.<sup>14</sup>

3. Analysis of Claim 1

We begin by analyzing the parties' arguments regarding whether the cited prior art combination teaches or suggests each limitation of claim 1.

<sup>&</sup>lt;sup>14</sup> We cite Cooper's intrinsic page numbering, rather than Petitioner's added page numbering.

We then turn to the parties' arguments regarding motivation to combine and reasonable expectation of success.

(a) Preamble [1.1]: A method of fastening at least first and second portions of body tissue together, the method comprising:

Petitioner persuasively demonstrates that Bonutti discloses a method of fastening two layers of body tissue together with a suture.<sup>15</sup> *See* Pet. 20–21 (citing, e.g., Ex. 1004, Fig. 38, 40:33–37). Patent Owner does not dispute Petitioner's showing.

(b) Limitation [1.2]: imparting, using an adaptive arm of a robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another;

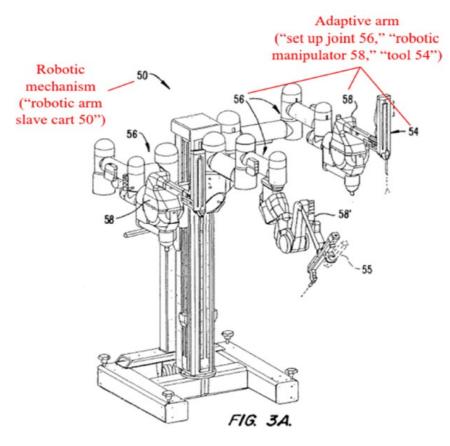
Petitioner persuasively demonstrates that a person of ordinary skill in the art would have been motivated to modify Tierney's robotic system to accommodate Bonutti's suture securing system, and that the resulting system would have used an adaptive arm of a robotic mechanism to impart a clamping force to body tissue as recited in limitation [1.2].<sup>16</sup> See Pet. 21–34.

Petitioner demonstrates that Tierney's robotic surgical system comprises an adaptive arm as claimed. Petitioner's annotated version of

<sup>&</sup>lt;sup>15</sup> Generally, a preamble does not limit a claim. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). The parties do not address whether the preamble is limiting. We need not decide whether it is limiting because Petitioner sufficiently demonstrates that Bonutti discloses the preamble.

<sup>&</sup>lt;sup>16</sup> Following Petitioner's convention, we sometimes refer to the combination of Bonutti's suture securing system and Tierney's robotic system as the "Bonutti/Tierney robotic system." *See* Pet. 28. We further discuss motivation to combine these systems in Section II.D.3(g) below.

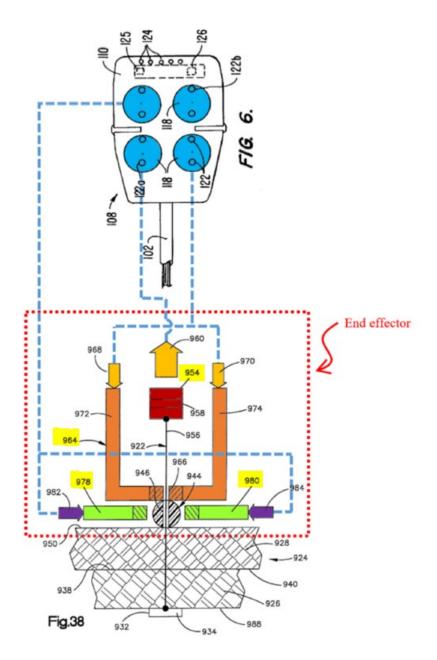
Tierney's Figure 3A, which exemplifies a portion of Tierney's robotic surgical system, is reproduced below:



Annotated Figure 3A reproduced above shows robotic cart 50. Pet. 24. Petitioner labels set up joint 56, robotic manipulator 58, and surgical tool 54, and persuasively maps these features to the "adaptive arm" recited in claim 1. Ex. 1005, 5:39–41, 7:16–20, 7:41–43; Pet. 23–24; Ex. 1003 ¶¶ 71–72. Patent Owner does not dispute this mapping.

Petitioner also establishes that a person of ordinary skill in the art would have been motivated to use Tierney's driven elements to control the movable components of Bonutti's suture securing system. Pet. 22–34; *see also infra* Section II.D.3(g) (further discussing motivation to combine); Pet. 24 (noting that Tierney teaches using "any . . . end effector . . . which is useful for surgery"); Ex. 1005, 10:5–11, 6:22–28 (providing examples of

articulated and non-articulated surgical tools). Petitioner and Dr. Fischer provide the following composite of Tierney's Figure 6 and Bonutti's Figure 38 to show one example of how a skilled artisan would have integrated the two systems:



Ex. 1003 ¶ 74; Pet. 25–26. The composite figure reproduced above shows Tierney's tool on top and Bonutti's suture securing system on the bottom,

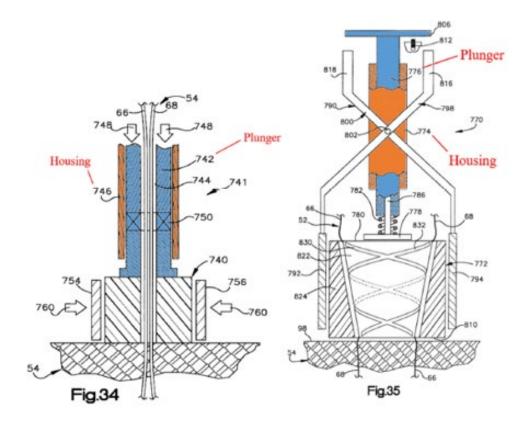
with dotted blue lines denoting the mechanical linkages that would couple Tierney's driven elements to Bonutti's moveable components.<sup>17</sup> Pet. 25–27; Ex. 1003 ¶¶ 74–85, 103–107. The mechanical linkages can be "cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like." Pet. 27 (quoting Ex. 1005, 9:31–45); *see also* Ex. 1005, 8:4–7, 9:18–20 (disclosing "cables" and the drive system of Madhani, and incorporating Madhani by reference), 9:16–18, 10:13–15; Pet. 25–27; Ex. 1003 ¶¶ 104–107.

Petitioner's composite figure reproduced above shows one exemplary way of coupling Bonutti and Tierney. In this example, Petitioner shows that all of Bonutti's moveable components (i.e., force application assembly 954 and force application members 964, 978, 980) are integrated into a single end effector on a single adaptive arm in Tierney's robotic system. Pet. 24– 27; Ex. 1003 ¶ 77. Petitioner demonstrates that "[o]ther obvious configurations exist," including one where Bonutti's moveable components are integrated into separate end effectors and tools on separate arms of Tierney's robotic system.<sup>18</sup> Pet. 25 n.4, 42–44; Ex. 1003 ¶¶ 77–85, 128–32.

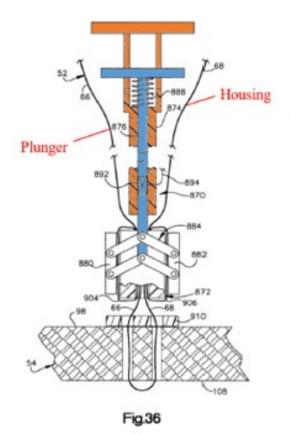
<sup>&</sup>lt;sup>17</sup> We added yellow highlights to this figure to call out the reference numerals for Bonutti's moveable components (i.e., force application assembly 954 and force application members 964, 978, and 980).

<sup>&</sup>lt;sup>18</sup> Patent Owner refers to Petitioner's proposed configuration where all of Bonutti's moveable components are integrated into a single adaptive arm as "Option A," and the configuration where Bonutti's moveable components are integrated into separate adaptive arms as "Option C." PO Resp. 40. In its Patent Owner Response, Patent Owner asserted that "[t]he Petition only discloses Option A." *See* PO Resp. 47; *see also id.* at 40. In its Sur-reply Patent Owner acknowledges that the Petition also discloses Option C, but asserts that Petitioner disclosed this option only for claim 2. *See* Sur-reply 9 n.1. We disagree with Patent Owner's contentions. Petitioner pointed to the separate-arm configuration ("Option C") in the Petition in connection with claim 1, not just claim 2. *See* Pet. 25 n.4; Ex. 1003

Dr. Fischer states that although Bonutti depicts its moveable components as mere "black boxes," to move the components a skilled artisan would have envisioned specific physical structures based on Bonutti's other embodiments. Ex. 1003 ¶ 76; *see also* Pet. 27. For example, regarding structure to move force application member 964 and force application assembly 954, Dr. Fischer establishes that a "POSITA would have envisioned, e.g., a plunger and plunger housing similar to those shown in Figures 34–36 of Bonutti-'234." Ex. 1003 ¶ 76; *see also* Pet. 27. We reproduce Petitioner's annotated versions of Bonutti's Figures 34–36 below:



<sup>¶¶ 77–85.</sup> Patent Owner addressed Option C in its Patent Owner Response. *See, e.g.*, PO Resp. 46, 47–49.



Ex. 1003 ¶ 76. These figures depict apparatuses used to install a suture retainer. *See, e.g.*, Ex. 1004, 34:26–33; 35:7–11, 38:15–18. Petitioner's annotations label the plunger and housing. Dr. Fischer explains that

[i]n operation, the suture 922 would be secured (e.g., by tying) to the portion of the instrument (*e.g.*, the plunger housing) that would be pulled upward (away from the body tissue) to tension the suture while the plunger is pushed downward (towards the body tissue) to press the suture retainer 944 against the body tissue.

Ex. 1003 ¶ 76; *see also* Pet. 27. Regarding structure to move force application members 978 and 980, Dr. Fischer establishes that "a POSITA would have envisioned, *e.g.*, a 'gripper' like in [Bonutti's] Figure 35" or as

disclosed by Tierney. Ex. 1003 ¶ 76; Ex. 1005, 2:38–3:6, 6:20–37; *see also* Pet. 27.

Based on the arguments and evidence of record, we find that the Bonutti/Tierney robotic system would have enabled a surgeon to suture two layers of body tissue together using an arm or arms of Tierney's robotic system. Pet. 28; Ex. 1003 ¶ 85. In this system, an arm or arms of Tierney's robotic system would impart a clamping force (e.g., a combination of upward force 960 and opposing downward forces 968 and 970) suitable to press body tissue layers 926, 928 together, as recited in limitation [1.2]. Pet. 21–22, 28; Ex. 1004, 39:62–40:32, 41:41–42:59, 43:59–64, Fig. 38; Ex. 1003 ¶¶ 67, 77–85, 128–32.

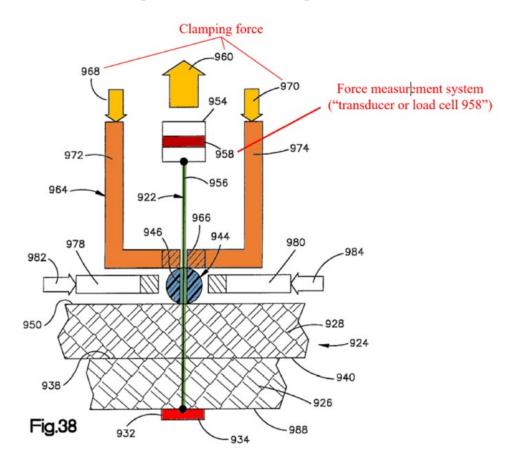
Patent Owner responds to some of Petitioner's arguments summarized above. *See generally* PO Resp. 32–56. We address Patent Owner's arguments in Section II.D.3(g)(iii) below.

> (c) Limitation [1.3]: generating, using a force measurement system associated with the adaptive arm, a clamping force signal indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue;

Petitioner shows that the Bonutti/Tierney robotic system "generates, using a force measurement system (Bonutti-'234's 'transducer or load cell 958') associated with Tierney's adaptive arm, a clamping force signal ('output signal' of Bonutti-'234's transducer or load cell 958) indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue" sufficient to teach or suggest limitation [1.3]. Pet. 34 (citing Ex. 1003 ¶ 109); *see also* Ex. 1004, 41:43–47 (indicating, in connection with Figures 37 and 38, that "[t]he force application assembly

954 includes a transducer or load cell 958 which provides an output signal indicative of a force").

Petitioner's annotated version of Bonutti's Figure 38 (different than the annotated version presented above) is reproduced below:



The annotated version of Bonutti's Figure 38 above shows Bonutti's suture securing system. Ex. 1003 ¶ 110. It includes Petitioner's labels for the "force measurement system" (i.e., Bonutti's transducer or load cell 958) and the "clamping force," which is generated by upward force 960 and downward forces 968, 970. *Id.* As Dr. Fischer establishes, "transducer or load cell 958 provides an output signal indicative of force 960, which applies the upward component of the clamping force and 'is contemplated'

to be equal to forces 968 and 970, which apply the downward component of the clamping force." *Id.* (citing Ex. 1004, 41:41–42:16, Fig. 38).

Dr. Fischer also persuasively establishes that Tierney's robotic system can receive and process the output signal of a force measurement system like Bonutti's transducer 958, including because Tierney discloses (via incorporation of Cooper) that the drive motors preferably include sensors for transmitting force and torque feedback to the surgeon. *Id.* ¶¶ 111–13; Pet. 35–36.

In view of the above, Petitioner persuasively shows that Bonutti and Tierney teach or suggest limitation [1.3]. Patent Owner does not dispute Petitioner's showing.

> (d) Limitation [1.4]: receiving, using a computer in communication with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system;

Petitioner persuasively establishes that Tierney teaches or suggests limitation [1.4]. Specifically, Petitioner explains that controller 150 would receive information about the tools attached to the robotic mechanism, including the clamping force signal from the force measurement system (i.e., Bonutti's transducer 958). Pet. 36–38; Ex. 1003 ¶¶ 115–17. Patent Owner does not dispute Petitioner's showing.

(e) Limitation [1.5]: determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude; and

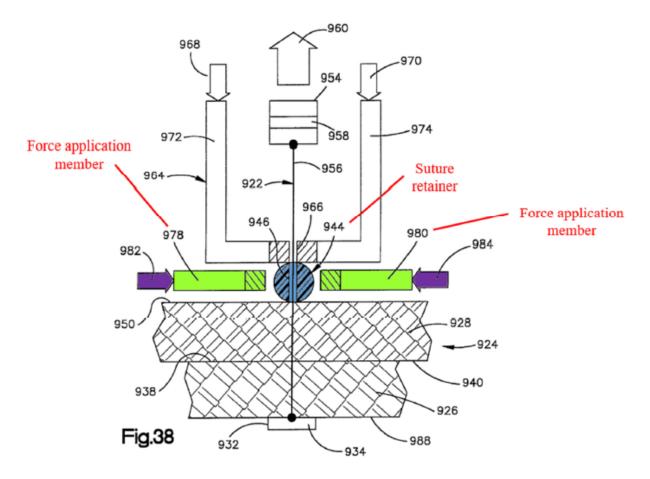
Petitioner persuasively demonstrates that Bonutti and Tierney teach or suggest this limitation. Pet. 38–40. Dr. Fischer explains that after Bonutti's suture retainer is positioned against the outer layer of body tissue, the

system "increases the clamping force until it is determined, based on the clamping force signal, that the clamping force is 'equal to a predetermined function of the strength of the suture 922'." Ex. 1003 ¶ 119 (quoting Ex. 1004, 42:33–39, 42:11–14; citing Ex. 1004, 42:28–45, 42:1–16, 41:41–53); *see also* Pet. 39–40; Ex. 1003 ¶¶ 120–25 (discussing motivation to use Tierney's computer to determine whether the clamping force has a predetermined magnitude). Petitioner also demonstrates that Tierney's controller 150 would store information about the strength of the suture, and the controller would determine (or display the necessary information so the surgeon could determine) whether the clamping force is equal to the predetermined function. Pet. 39; Ex. 1003 ¶ 119.

Patent Owner disputes that in the Bonutti/Tierney robotic system the fastening step (limitation [1.6]) occurs after the determining step (limitation [1.5]), as required by limitation [1.6]. PO Resp. 44–45; Sur-reply 6–9. We address this argument below in Section II.D.3(g)(iii).

(f) Limitation [1.6]: fastening, after said determining and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude, the first and second portions of body tissue together using the adaptive arm.

Petitioner persuasively shows that Bonutti and Tierney teach or suggest this limitation. In particular, Petitioner shows that the Bonutti/Tierney robotic system fastens the first and second portions of body tissue together by plastically deforming the suture retainer. Pet. 40–42 (citing, e.g., Ex. 1003 ¶ 126; Ex. 1004, 42:28–59). To illustrate, reproduced below is another version of Bonutti's Figure 38 annotated by Petitioner (different than the two annotated versions presented above):



With reference to the annotated version of Figure 38 above, Dr. Fischer establishes that a pair of force application members 978 and 980 (green) are pressed against opposite sides of suture retainer 944 (blue), such that "suture retainer 944 is plastically deformed to firmly grip the suture 922." Ex. 1003 ¶ 126 (quoting Ex. 1004, 42:50–51). Dr. Fischer further establishes that in the Bonutti/Tierney robotic system, Bonutti's force application members 978 and 980 are integrated into Tierney's adaptive arm, such that the robotic system fastens the first and second portions of body tissue together using the adaptive arm. *Id*.

Petitioner shows that the fastening occurs after the determining step and simultaneously with application of the clamping force having the predetermined magnitude. Pet. 41–42. Specifically, determining whether the clamping force has a predetermined magnitude occurs before deforming suture retainer 944. *Id.* at 41 (citing Ex. 1004, 42:28–59; Ex. 1005, 15:59–16:19). "[T]he suture retainer is deformed '[w]hile the suture is tensioned' with the predetermined clamping force so it 'maintain[s] the tension in the suture [922]." *Id.* at 42 (quoting Ex. 1004, 2:6–10). Thus, "at the time of fastening, the adaptive arm simultaneously imparts the predetermined clamping force." *Id.*; *see also* Ex. 1003 ¶ 127.

As noted above, Patent Owner disputes that the fastening step occurs after the determining step. PO Resp. 44–45; Sur-reply 6–9. We address this argument below in Section II.D.3(g)(iii).

## (g) Motivation to Combine Bonutti and Tierney with a Reasonable Expectation of Success

#### (i) <u>Petitioner's Motivations to Combine are Persuasive</u>

Petitioner provides several reasons why a person of ordinary skill in the art would have been motivated to combine Bonutti's suture securing system with Tierney's robotic surgical system. *See* Pet. 28–32. For example, Petitioner asserts that Tierney teaches using its robotic system with "any . . . end effector which is useful for surgery," including end effectors for suturing, i.e., "needle drivers," "needle graspers," and "needle holders." *Id.* at 28 (quoting Ex. 1005, 10:8–11); *see also* Ex. 1003 ¶¶ 87–88; Ex. 1005, 1:30–37, 2:47–52, 6:22–28. Petitioner asserts that because Tierney does not detail how to make and use an end effector for securing a suture, a person of ordinary skill in the art would have turned to Bonutti for such details. Pet. 28; *see also* Ex. 1003 ¶¶ 87–88.

Petitioner also asserts that a person of ordinary skill in the art would have known the benefits of using Tierney's robotic system, including increased accuracy, surgical dexterity, and safety. Pet. 28–31 (citing, e.g., Ex. 1003 ¶¶ 89–92, 97; Ex. 1005, 15:59–66; Ex. 1019, 2:16–55; Ex. 1013, 2:24–26, 2:33–38). Petitioner also asserts that adaptation of handheld surgical tools like Bonutti's for use with robotic systems like Tierney's was well known in the art, and that using parts from existing handheld tools (which Petitioner calls "OEM parts") would have offered convenience and reduced costs. *Id.* at 30–31; Ex. 1003 ¶¶ 93–96 (discussing prior art examples of adapting handheld tools for use with robotic surgical systems).

Petitioner also asserts that Bonutti "does not explicitly describe how to generate the forces necessary to operate its suture securing system," and Tierney discloses one of a finite number of predictable solutions, i.e., using a robotic arm. Pet. 32 (citing Ex. 1003 ¶ 100). Thus, Petitioner argues that a person of ordinary skill in the art had a good reason to pursue Tierney's known option, and the resulting combination would have been the product not of innovation, but of ordinary skill and common sense. *Id.* (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)).

Petitioner asserts that a person of ordinary skill in the art would have reasonably expected success in combining Tierney and Bonutti, including because Tierney discloses multiple means of coupling its robotic system to Bonutti's suturing system (e.g., "cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like"). Pet. 32 (quoting Ex. 1005, 9:31–34); Ex. 1003 ¶¶ 101, 103. Additionally, Dr. Fischer testifies that adapting a surgical instrument for use with a robotic system was well within the level of ordinary skill in the art, and merely the application of a known technique (e.g., adapting manually controlled components for use with a robotic system) with known devices (Bonutti's suture securing system and Tierney's surgical robot), where each device in

the combined system performs the same predictable function as it does separately (i.e., securing a suture and robotically positioning and controlling a surgical tool). Ex. 1003 ¶ 102 (discussing prior art examples of converting handheld tools for robotic surgical systems); *id.* ¶¶ 103–08; *see also* Pet. 33– 34.

On the full trial record, and taking into consideration Patent Owner's arguments (discussed further below), we find Petitioner's rationales regarding why a person of ordinary skill in the art would have been motivated to combine Bonutti's and Tierney's teachings with a reasonable expectation of success to be credible and supported by the cited evidence, including Dr. Fischer's testimony.

# (ii) <u>Analysis of Patent Owner's Responses to Petitioner's</u> <u>Motivations to Combine</u>

Patent Owner makes a number of arguments as to why a person of ordinary skill in the art would have lacked a motivation to combine Bonutti and Tierney with a reasonable expectation of success. *See* PO Resp. 33–53. We address each argument below.

First, Patent Owner argues that skilled artisans would have had no motivation to combine Bonutti and Tierney because "[n]one of Tierney's end effectors is designed for suture <u>securing</u>," and because "Bonutti's rigid suture securing apparatus teaches away from a combination with Tierney as it would frustrate the very purpose of Tierney's intricate system." PO Resp. 50, 33. These arguments are unavailing. Tierney teaches that its system is broadly useful with "*any* . . . end effector"—rigid or not. Ex. 1005, 10:8–11 (emphasis added). Tierney specifically teaches use of its system for suturing, e.g., by calling out needle drivers, holders, and graspers, which are devices used in suturing. *Id.* at 1:30–37, 2:47–52, 6:22– 28; Pet. 28; Ex. 1003 ¶¶ 87, 102. To the extent Tierney does not disclose "suture <u>securing</u>" tools, this is immaterial because Petitioner relies on Bonutti, not Tierney, for disclosure of a suture securing system. *See, e.g.*, Pet. 21–22; Reply 16–17. One cannot show nonobviousness by attacking references individually where the obviousness argument is based on a combination of references. *See Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019).

Second, Patent Owner argues a lack of motivation to combine because Bonutti's system is too large for endoscopic surgery. PO Resp. 51 (citing Ex. 1004, Figs. 35, 36). As an initial matter, in support of this argument Patent Owner cites the apparatuses in Bonutti's Figures 35 and 36. However, as discussed below (*see infra* Section II.D.3(g)(iii)(1)), Petitioner's proposed combination is based on the suture securing system depicted in Bonutti's Figure 38, rather than the complete apparatuses shown in Bonutti's Figures 35 and 36. Patent Owner does not allege that the suture securing system depicted in Bonutti's Figure 38 is too large for endoscopic surgery.

However, even if the complete apparatuses in Figures 35 and 36 were part of Petitioner's proposed combination, Patent Owner's argument is unavailing because Patent Owner has not established the size of those apparatuses. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000). Patent Owner has not identified, nor do we discern, any portion of Bonutti indicating that its figures are drawn to scale. Moreover, Dr.

Fischer testifies that it was well within the level of skill in the art to adapt handheld tools for use with a robotic system, and skilled artisans "would have known that the various disclosed physical structures could be modified to suit the needs of a particular application." Ex. 1003 ¶ 93; *see also id.* ¶¶ 89, 93–96, 101–03. This includes scaling down the size of the structures as needed. Indeed, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co.*, 550 U.S. at 421. Additionally, Dr. Fischer testifies that Bonutti's system would have been used for both open surgery and endoscopic surgery. Ex. 1003 ¶ 89; Reply 17. Patent Owner's attorney argument is insufficient to overcome this testimony.

Third, Patent Owner asserts that there is no evidence that Bonutti's suture securing system includes OEM parts. PO Resp. 52 (citing Ex. 2002, 47:21–48:6). This misunderstands Petitioner's argument. Bonutti's system **is** the OEM part. Reply 17–18. Dr. Fischer persuasively testifies that a skilled artisan "attempting to develop new instruments for Tierney's robotic system would have understood that using Bonutti-'234's design to the extent practicable would have reduced development costs compared to developing a new suturing instrument from scratch." Ex. 1003 ¶ 94; Ex. 1019, 7:6–13; Pet. 30–31.

Fourth, Patent Owner asserts that skilled artisans would not have been motivated to make the combination to achieve safety benefits, because "Bonutti already had its own force limitation mechanism when tensioning a suture and so Tierney provides no additional safety benefit." PO Resp. 52 (citing Ex. 1004, 42:28–45). This argument overlooks the additional safety benefits provided by Tierney, including a tool memory and safety monitoring controller that could freeze all robot movement. Pet. 31 (citing,

e.g., Ex. 1003 ¶ 97; Ex. 1005, 15:59–66); *see also* Ex. 1003 ¶¶ 35, 97–99, 123; Ex. 1005, 1:60–66 (incorporating Cooper); Ex. 1007, 9:22–26; Reply 18.

Fifth, Patent Owner argues that Dr. Fischer is wrong in stating that Bonutti "does not explicitly describe how to generate the forces necessary to articulate its moveable components," because Bonutti teaches using manual force to move the components. PO Resp. 53 (quoting Ex. 1003 ¶ 100). This argument does not undermine Petitioner's motivations to combine. Dr. Fischer's statement addresses Bonutti's force application assembly 954 and force application members 964, 978, and 980, which appear in Bonutti's Figure 38. Ex. 1003 ¶ 100. Patent Owner, in contrast, cites portions of Bonutti relating to Figures 35 and 36. PO Resp. 53 (citing Ex. 1004, 35:46-49, 35:63–36:7; 37:10–13, 37:38–43; 39:14–16, 39:38–41). Figures 35 and 36 relate to specific apparatuses for installing a suture retainer (see Ex. 1004, 38:16–20), and do not depict the movable components Dr. Fischer's statement addresses. In any event, Petitioner adequately supports its argument that a skilled artisan would have been motivated to combine Bonutti and Tierney to obtain the benefits a robotic system provides over manually operated instruments, such as increased accuracy (e.g., tremor reduction and more precise movement), ergonomics, surgical dexterity, and safety. See, e.g., Pet. 28–31; Ex. 1003 ¶¶ 89–92, 97; Reply 18–19.

Sixth, Patent Owner argues that a skilled artisan would not have been motivated to place moving parts outside of Tierney's tool shaft because doing so would be dangerous. PO Resp. 45–46. Patent Owner, however, provides no citation to record evidence to support that such an arrangement would be dangerous. Indeed, this argument is inconsistent with the record.

Petitioner establishes that the prior art is replete with examples of moving tool parts outside the tool shaft. *See* Reply 13–14 (citing examples taught by Tierney, Hooven, and Tovey).

Seventh, Patent Owner argues that Petitioner's argument regarding motivation to make the proposed Bonutti/Tierney robotic system using separate adaptive arms (i.e., "Option C") "shows that a POSITA would <u>NOT</u> be motivated to make the proposed combination of Bonutti and Tierney with only a single adaptive arm." PO Resp. 46. We disagree. That a skilled artisan would have had a motivation to make a system with either one or more adaptive arms does not make any one of these systems less obvious. *Cf. Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (finding that a prior art patent that "discloses a multitude of effective combinations does not render any particular formulation less obvious").

In sum, we find that Patent Owner's arguments do not undermine Petitioner's persuasive showing that a person of ordinary skill in the art would have been motivated to combine the teachings of Bonutti and Tierney with a reasonable expectation of success of achieving the claimed method.

## (iii) Patent Owner's Additional Arguments

In addition to addressing Petitioner's proffered motivations to combine, Patent Owner raises several additional arguments regarding alleged shortcomings in Petitioner's arguments. We address these arguments below.

# 1. <u>Whether Petitioner Proposed Viable Structure for</u> <u>Bonutti's Moveable Components</u>

Patent Owner argues that at deposition, Dr. Fischer repudiated his reliance on certain aspects of Bonutti, leaving no working combination.

PO Resp. 34–39. Specifically, as discussed above in connection with limitation [1.2], in his Declaration Dr. Fischer opined that although Bonutti depicts its moveable components as mere "black boxes," to move the components a skilled artisan would have envisioned physical structures such as the plunger, housing, and gripper shown in Bonutti's Figures 34–36. *See supra* Section II.D.3(b); *see also* Ex. 1003 ¶ 76. Patent Owner contends that at deposition, Dr. Fischer repudiated his reliance on the structures in Bonutti's Figures 34–36, and "proposed no other structures in place of the ones he rejected." PO Resp. 37, 38; *see also* Sur-reply 3. Thus, Patent Owner contends that Petitioner has failed to propose a structure for the proposed combination. PO Resp. 39.

We disagree with Patent Owner's interpretation of Dr. Fischer's deposition testimony. The cited testimony reads as follows (with emphases added):

Q. So are you saying here in this paragraph 76 that a POSITA would have envisioned one of the three structures shown on page 62 of your declaration for purposes of building an end effector combination?

A. I believe *I'm showing those as examples* that are depicted within Bonutti-'234. That's not to say that a person of ordinary skill in the art combining Bonutti-'234 with Tierney would necessarily select one of these configurations.

Q. Well, you don't show any other configuration in your declaration than these three; correct?

A. I do not recall if there are other configurations that are shown there, but as I've noted in the body of the text there are a number of very viable solutions in which a person of ordinary skill in the art would implement this and hence, why I showed a schematic figure followed by a detailed description of various embodiments.

• • •

Q. So if we look at the two arrows in Figure 34 on page 62 of your declaration, those are marked 745. Do you see those two arrows?

A. Yes.

Q. Those arrows indicate movement of the plunger downward, is that a fair statement, or pressure on the plunger to move downward?

A. I would need to analyze this more thoroughly. Again, *these were depicted purely as examples of physical structures that were within Bonutti*. There is no reason to believe again that these are necessarily the ones that would be identified or necessarily the ones that I would find to be optimal. These are really the only structures that I had specifically shown within Bonutti that I wanted to reproduce in the declaration.

PO Resp. 37–38 (quoting Ex. 2002, 24:20–25:14, 27:3–19) (emphases added). As the emphasized language demonstrates, a fair reading of this testimony is that Dr. Fischer cited Bonutti's plunger, housing, and gripper as examples of physical structures a skilled artisan may have used to move the force application members of the suture assembly. Patent Owner does not adequately explain how this testimony amounts to Dr. Fischer's repudiation or rejection of those structures or how it negates a motivation to combine Bonutti and Tierney.

We also disagree with Patent Owner that Petitioner's statement that "[t]he proposed combination is **Figure 38** with Tierney, and not Figures 34-36 with Tierney" demonstrates that Petitioner "was abandoning its original arguments." PO Resp. 4 (quoting Reply 7) (emphasis Petitioner's). Petitioner's statement is consistent with the argument in the Petition, which proposes adapting the suture securing system in Bonutti's Figure 38 for use in Tierney's robotic system. *See, e.g.*, Pet. 25–26 (depicting combination of Tierney's tool and the suture securing system in Bonutti's Figure 38). In the

Petition, Petitioner cites Bonutti's Figures 34–36 as showing examples of specific structures (plunger, plunger housing, and gripper). *Id.* at 27 (citing Bonutti's Figures 34–36 for example structures that could impart force to the moving components of the system depicted in Bonutti's Figure 38); Reply 7–8. The Petition does not propose to adapt the complete apparatuses in Bonutti's Figures 34–36 for use in Tierney's robotic system.

For a similar reason, Patent Owner's arguments that (i) Dr. Fischer did not propose feasible structure for connecting Bonutti's apparatus to Tierney's tool shaft, and (ii) it would be problematic to wrap a suture around the suture retainers depicted in Bonutti's Figures 35 and 36 while the robotic system is inside the patient's body, are unavailing. PO Resp. 45–46; Surreply 5. These arguments are based on bodily incorporation of the specific apparatuses in Bonutti's Figures 35 and 36 into Tierney's system, but as discussed, Petitioner's proposed combination is centered on the suture securing system depicted in Bonutti's Figure 38.

# 2. <u>Whether Petitioner's Proposed Combination Would be</u> <u>Inoperable</u>

Patent Owner contends that "the Bonutti/Tierney tool(s) cannot operate as described in the Petition or by Dr. Fischer." PO Resp. 39 (quote altered to remove title case). In particular, Patent Owner argues that Petitioner's "Option A" (i.e., where Bonutti's moveable components all are in the same adaptive arm) fails for four reasons.<sup>19</sup> We address each argument in turn.

<sup>&</sup>lt;sup>19</sup> Patent Owner also discusses Options B and D (PO Resp. 40), but because Petitioner focuses only on Options A and C (*see, e.g.*, Tr. 49:19–26; Reply 8), we do the same.

First, Patent Owner argues that in the proposed combination no clamping force could be generated because the suture cannot be tensioned. PO Resp. 41–42. This is because, Patent Owner argues, the suture would be tied to Bonutti's plunger housing, but that housing is stationary. *Id.* Downward movement on the plunger relative to the stationary housing would create slack, not tension, on the suture. *Id.* 

This argument is unavailing because Patent Owner has not established that in the asserted combination the plunger housing would remain stationary. Patent Owner cites portions of Bonutti that indicate the plunger is moved downward relative to the housing (PO Resp. 41 (citing Ex. 1004, 34:34–36; 35:57–62; 39:38–41)), but these portions do not state that the housing must remain stationary. Moreover, Dr. Fischer expressly testifies that the plunger housing would be "pulled upward" while the plunger is "pushed downward," such that the suture would be tensioned. Ex. 1003 ¶ 76; Reply 10. This testimony is consistent with Bonutti's Figure 38, which shows both an upward force (arrow 960) and downward forces (arrows 968, 970) operating on the suture.

Second, Patent Owner argues that even if a skilled artisan "would have been inclined to move the plunger housing upward . . . Option A would have failed" if a skilled artisan used the apparatuses depicted in Bonutti's Figures 35 and 36. PO Resp. 42–43. This is because, Patent Owner argues, the upward movement would prevent application of downward forces on the body tissue, and would result in inadequate fastening because only the top portion of the suture retainer would be compressed and/or there would be slack in the suture. *Id*.

This argument is unavailing. As just explained, Petitioner asserts that when the plunger housing is moved upward, the plunger is separately pushed downward, thereby applying downward forces on the body tissue and tensioning the suture. Ex. 1003 ¶ 76; Reply 10; Ex. 1004, Fig. 38. Additionally, in Bonutti's Figure 35 the bottom of the gripper is not aligned with the bottom edge of the suture retainer, yet Bonutti states that the gripper works as intended. *See* Ex. 1004, Fig. 35; 35:32–33, 36:7–11; Reply 11. We agree with Petitioner that Patent Owner has not established "how much alleged 'misalignment' would allegedly occur or would have been needed to cause an alleged failure." Reply 11.

Moreover, as discussed above, in Petitioner's proposed combination the gripper in Bonutti's Figure 35 is not bodily incorporated into the combination. *Id.*; Ex. 1003 ¶ 76; Ex. 2002, 32:16–33:16 (explaining that the apparatuses in Bonutti's Figures 34–36 would provide "inspiration or example for how one can essentially apply a force to the tissue while tensioning the suture"). Given the level of skill in the art and scope and content of the prior art (which includes a prior art suturing tool coupled to a surgical robot, *see* Ex. 1003 ¶ 102), the record supports Dr. Fischer's testimony that a skilled artisan would have understood how to adapt prior art grippers so that they function properly in the proposed combination. Ex. 1003 ¶¶ 76, 93; *see also id.* ¶ 107 (discussing a cable-actuated gripper made up of jaws 978 and 980); Reply 11–12; *supra* Section II.B; *KSR Int'l Co.*, 550 U.S. at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

Third, Patent Owner makes arguments related to tying the suture to the robotic tool. With respect to Bonutti's Figure 34, Patent Owner argues

that the walls of the tool shaft are smooth, such that "the suture would simply slide down the smooth walls instead of being tensioned." PO Resp. 43–44 (citing Ex. 2002, 30:21–31:8); Sur-reply 6, 8. This is unavailing because there is no requirement that the shaft have smooth walls. Reply 12. Dr. Fischer testifies that "the suture would be 'secured (*e.g.* by tying) to the portion of the instrument that would be pulled upward (away from the body)," and that "a POSITA would have known that the various disclosed physical structures could be modified to suit the needs of a particular application." Ex. 1003 ¶¶ 76, 93; Reply 12.

With respect to the apparatuses in Bonutti's Figures 35 and 36, Patent Owner argues that the housing would not move during use, so tying the suture to the housing will not tension the suture. PO Resp. 44; Sur-reply 7– 8. As discussed above, however, Patent Owner has not established that the housing would be stationary in the proposed combination.

Fourth and finally, Patent Owner contends that the proposed combination fails if Bonutti's suture apparatus is positioned inside Tierney's tool shaft because the suture would be unreachable and could not be tensioned. PO Resp. 45. This argument is unavailing. Dr. Fischer testified that the suture would be secured, e.g., by tying to the portion of the instrument that is pulled upward (away from the body). Ex. 1003 ¶ 76. Given that adaptation of handheld tools was well-known in the art, it would have been within the skill in the art to appropriately secure the suture to the tool shaft. *See, e.g., id.* ¶ 93.

# 3. <u>Whether the "Determining" and "Fastening" Steps are</u> <u>Missing</u>

Patent Owner argues that the Bonutti/Tierney robotic system fails to teach or suggest the "determining" and "fastening" steps recited in

independent claim 1 (i.e., limitations [1.5] and [1.6], respectively).<sup>20</sup> PO Resp. 44–45; Sur-reply 6–9. Together, these steps require determining that the clamping force has a predetermined magnitude *before* fastening the body tissue. *See* Ex. 1001, 45:57–65. According to Patent Owner, Petitioner's "proposal to tension the sutures by tying them to a stationary housing . . . attempts to tension the sutures *while* they are being fastened," instead of first tensioning the suture to a predetermined magnitude, and thereafter fastening the tissue by securing the suture. PO Resp. 44–45.

Patent Owner's argument is not consistent with Petitioner's proposal. In Petitioner's proposal, the fastening step results from deforming the suture retainer to grip the suture. *See* Pet. 40–41; Ex. 1003 ¶ 126. This fastening step happens only after the system determines that the clamping force has a predetermined magnitude. *See* Pet. 41; Ex. 1003 ¶ 127. That is, Bonutti teaches that the suture is first tensioned to a predetermined magnitude based on the strength of the suture, and thereafter the suture retainer is plastically deformed to grip the suture. Ex. 1004, 42:28–59; *see also* Pet. 12–13. Additionally, as shown in Petitioner's composite of Bonutti's Figure 38 and Tierney's Figure 6 (reproduced above in Section II.D.3(b)), Petitioner proposes separate mechanical linkages for the components that tension the suture and the components that deform the suture retainer, meaning that there is no impediment to independently and sequentially moving these components. *See also* Pet. 25–27 (discussing the mechanical linkages); Tr. 14:13–21.

<sup>&</sup>lt;sup>20</sup> Patent Owner applies the same arguments to the analogous limitations of independent claim 6. PO Resp. 44–45; Sur-reply 6–9. Our analysis applies equally to claim 6.

Furthermore, to the extent Patent Owner's argument relies on the housing being stationary (*see* PO Resp. 44–45), it is unavailing for the additional reason that in the asserted combination the plunger housing is not stationary, as discussed above. To the extent Patent Owner's argument relies on moving the housing upward (away from the patient's body) to tension the suture (*see* Sur-reply 8), as explained above, Petitioner proposes separate mechanical linkages for the components that tension the suture and the components that deform the suture retainer, meaning that there is no impediment to independently and sequentially moving these components.

#### 4. Whether Dr. Fischer's Testimony Lacks Credibility

Patent Owner argues that Dr. Fischer's testimony is conclusory and lacks credibility because at deposition, he was "unwilling[] to take a position" on the Bonutti/Tierney robotic system and could not answer several questions. PO Resp. 35, 53–56; Sur-reply 11–15. We have reviewed the testimony Patent Owner cites and find that it largely relates to questions Patent Owner's counsel posed to Dr. Fischer regarding embodiments in Bonutti on which he did not rely. *See also* Reply 15.

For example, Patent Owner asserts that Dr. Fischer had no answer about how Tierney's robot could wind a suture in a helical pattern as shown in Bonutti's Figure 35, or how Bonutti's conical suture retainer in that figure would work in the robotic system. PO Resp. 54–55 (citing, e.g., Ex. 2002, 60:22–61:23, 63:4–22); *see also id.* at 54 (arguing that Dr. Fischer "abandoned" a combination using Bonutti's Figure 35; citing Ex. 2002, 63:4–22). However, although Dr. Fischer relied on the gripper in Bonutti's Figure 35 as one example of structure that could impart forces to tension the suture, he explained that he did not rely on the helical suture pattern or

conical suture retainer in that figure. For example, in response to questions about the helical suture pattern and conical suture retainer in Bonutti's Figure 35, he stated:

So that is a very, very specific embodiment. *It is not necessarily what my arguments are based upon* and I cannot comment offhand exactly how the suture would pass through that shape.

•••

It is not required with Bonutti-'234 to wrap a suture around a helical shape. Figure 35 shows one specific example of a configuration where it does so. *I do not recall specifically analyzing how one would feed a suture through that helical shape if you were using this particular embodiment.* 

I don't recall specifically analyzing how that particular embodiment has a suture fed through it.

. . .

A person of ordinary skill in the art trying to implement Bonutti-'234 would not necessarily be trying to implement it the way it's shown in Figure 34 through 36 and, in fact, *the composite figure that I show in Figure 38 does not even have a loop of suture. It has a single strand 16 of suture with an anchor that stays on one side of the tissue.* So simply you apply a suture that already has an anchor attached to one end, you pass it through and then effectively you couple that with the force applying element, I think it's 954, to tension that suture. So there's no reason even to have a loop of tissue to *implement Bonutti-'234.* 

Ex. 2002, 60:22-61:23, 63:4-22 (emphases added); see also Reply 14-15.

This testimony is consistent with Dr. Fischer's Declaration, which does not propose a combination that employs a helical suture pattern or conical suture retainer.

Patent Owner also contends that Dr. Fischer could not explain how Tierney's robot would operate with the suture retainer shown in Bonutti's Figure 36. PO Resp. 54–55 (citing, e.g., Ex. 2002, 62:12–17, 63:4–22, 64:4–66:15, 70:4–71:2). This argument is similarly unavailing, because as Dr. Fischer testified, he did not rely on the suture retainer in Figure 36:

If you look at my composite figure on page 60 of my declaration that is not the same configuration that I am connecting with Tierney so I just want to be very, very clear that that is not the configuration that I am arguing necessarily would be combined with Tierney but I don't see a reason why you could not use a configuration like that with Tierney.

Ex. 2002, 70:20–71:2. Patent Owner also argues that Dr. Fischer misunderstood the linkages in Figure 36, but on this record Patent Owner does not adequately explain how this undermines Dr. Fischer's Declaration testimony, which does not rely on those linkages. PO Resp. 55 (citing Ex. 2002, 66:16–68:19). Patent Owner also relies on testimony at Ex. 2002, 17:–18:3 to argue that Dr. Fischer "never put forth any complete design for any proposed combination." PO Resp. 55–56. The cited testimony, however, relates to whether Dr. Fischer has an opinion on the "most suitable" design approaches, and does not indicate that he lacked a complete design.

We find the cited portions of Dr. Fischer's deposition testimony to be consistent with his Declaration. Patent Owner has not pointed us to anything in Dr. Fischer's Declaration indicating that he relied on the suture retainers (as opposed to the plungers and housings) in Bonutti's Figures 35 and 36. We also find that the cases Patent Owner cites in its Sur-reply at pages 14–15 are inapposite because Dr. Fischer's Declaration provides meaningful explanation for why a person of ordinary skill in the art would

have combined the prior art in the way he proposes, as discussed in our analysis above. We also disagree with Patent Owner's argument that paragraph 76 of Dr. Fischer's Declaration "was copied from the Petition . . . and so is nothing more than (erroneous) legal argument." Sur-reply 11–12. We find that paragraph 76 of Dr. Fischer's Declaration is appropriate technical opinion testimony informed by Dr. Fischer's understanding of the prior art.

#### (h) Summary as to Claim 1

As discussed above, Petitioner's analysis addresses every limitation of claim 1 and provides reasons with rational underpinnings why a person of ordinary skill would have been motivated to combine the teachings of Bonutti and Tierney with a reasonable expectation of success. Thus, based on the entire record, and taking into account Patent Owner's arguments, we find that Petitioner has established that claim 1 is unpatentable under § 103 as obvious over Bonutti and Tierney.

#### 4. Claims 2, 4, 6, 8–20, 22–25, 27, 29, and 30

We have reviewed Petitioner's contentions regarding claims 2, 4, 6, 8–20, 22–25, 27, 29, and 30. *See* Pet. 42–59. We are persuaded on the full trial record, including consideration of Patent Owner's arguments, that Petitioner has shown by a preponderance of the evidence that these claims are unpatentable as obvious over Bonutti and Tierney. *Id.* To the extent Patent Owner specifically argues any of these claims, we address those arguments below.

Patent Owner contends that challenged claims 2 and 4 "require a *single* adaptive arm for applying the clamping force to the body tissue and fastening the body tissue," and thus "Option C" is "not possible" for these

claims. PO Resp. 40. Patent Owner's argument is based on its proposed claim construction discussed above in Section II.C.2. *Id.* For the reasons discussed there, we disagree with Patent Owner's proposed claim construction, and thus disagree that Option C is inapplicable to claims 2 and 4.

Patent Owner argues that dependent claims 14, 16–19, and 30 expressly recite a "single adaptive arm" for applying the clamping force to the body tissue and fastening the body tissue, and thus Option C is likewise "not possible" for these claims. PO Resp. 40. Petitioner, however, does not argue Option C for these claims.<sup>21</sup> *See, e.g.*, Pet. 49 ("[T]he Bonutti-'234/Tierney robotic system integrates Bonutti-'234's movable components, which apply the force (forces 960, 968, and 970) to the body tissue and perform the fastening (by plastically deforming the suture retainer), *into a single adaptive arm*.") (emphasis added); Ex. 1003 ¶ 149. Accordingly, Patent Owner's argument is not responsive to the arguments raised in the Petition.

Finally, Patent Owner argues that Option C "fail[s] because no structure is described in the Petition or in Dr. Fischer's Declaration of a

<sup>&</sup>lt;sup>21</sup> In its Reply, Petitioner argues that Option C is permitted by all claims challenged in Ground 1. Reply 16. We acknowledge that Petitioner proposed a two-arm configuration with respect to Ground 1. *See* Pet. 25 n.4. Petitioner, however, did not clearly argue this configuration for claims 14, 16–19, and 30. Instead, in its contentions for these claims, Petitioner specifically argues that force 960 (the upward tensioning force) and forces 968 and 970 (the downward forces) are located in "*a single adaptive arm*." Pet. 49 (claim 14) (emphasis added); *see also id.* at 50 (claim 16) and 59 (claim 30) (both referring back to claim 14); Ex. 1003 ¶¶ 149, 168. Neither the Petition nor Dr. Fischer clearly asserts that the upward tensioning force could be located in a separate adaptive arm and still meet the "single adaptive arm" limitation of these claims.

force application assembly 954 that would work to both insert the suture 922 and suture anchor 934 into the body tissue and maintain the upward force 960 on suture 922." PO Resp. 48. We disagree. Petitioner and Dr. Fischer adequately explain that in this configuration, one arm would both position the suture and suture anchor, e.g., using a "needle holder[]" as disclosed in Tierney, and impart the upward force tensioning force. *See* Pet. 25 n.4, 42– 43; Ex. 1003 ¶¶ 77–84, 130; Ex. 1005, 6:20–37; Reply 16. Dr. Fischer establishes that adapting Bonutti's suture securing system for use in such a configuration is well within the skill in the art, including because Tierney's needle holder already has force sensing capabilities, which could be used to regulate the tension. *See, e.g.*, Ex. 1003 ¶¶ 79, 85, 101–08, 130–32; Ex. 1005, 1:60–66 (incorporating Cooper by reference); Ex. 1007, 16:38– 17:3 (discussing force sensing capabilities); Reply 16.

In sum, we are persuaded on the full trial record, including consideration of Patent Owner's arguments, that Petitioner has shown by a preponderance of the evidence that claims 2, 4, 6, 8–20, 22–25, 27, 29, and 30 are unpatentable as obvious over Bonutti and Tierney.

E. Alleged Obviousness Over Hooven and Tierney

Petitioner contends that claims 1–4, 6–8, and 24 are unpatentable as obvious over the combination of Hooven (which teaches a handheld surgical stapler) and Tierney (which teaches a robotic surgical system). Pet. 59–78. Patent Owner opposes. *See, e.g.*, PO Resp. 56–71.

For the reasons explained below, we find that Petitioner has established by a preponderance of the evidence that claims 1–4, 6–8, and 24 are unpatentable as obvious over Hooven and Tierney. We begin by summarizing Hooven, then turn to the parties' arguments.

## 1. Hooven (Ex. 1006)

Hooven discloses an endoscopic stapling and cutting instrument, interconnected with a controller and a video display monitor. Ex. 1006, 4:6–8. Hooven's device "staples tissue together and cuts that tissue between the stapled portions." *Id.* at 4:39–40. Hooven's Figures 1 and 3, annotated by Petitioner and reproduced below, illustrate several components of the system.

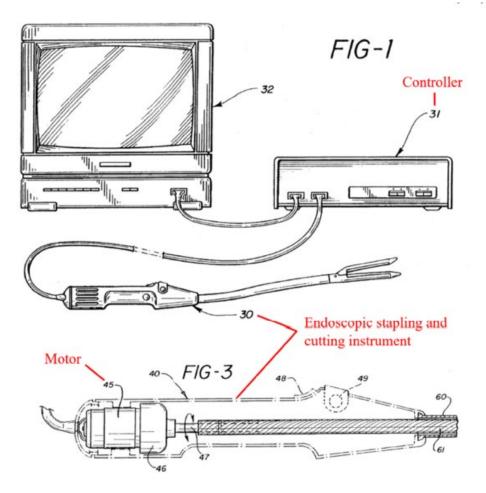
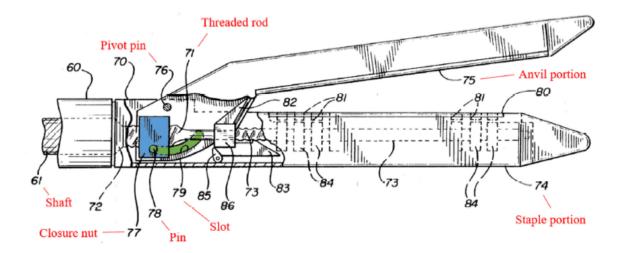


Figure 1 is a schematic view of Hooven's endoscopic surgical system, and Figure 3 "is a longitudinal cross-sectional view of the handle portion of one embodiment of [Hooven's] endoscopic stapling and cutting system." *Id.* at 3:14–16, 3:19–21; Pet. 17. Petitioner's annotation of Figure 1 highlights

controller 31, and its annotations of Figure 3 highlight endoscopic stapling and cutting instrument 30 having motor 45.

In Hooven's system, "information is fed to a video display screen" so that "the surgeon using the instrument will instantaneously receive information as to the placement of the staples, the cutting of the tissue, the presence of staples in the cartridge, etc." Ex. 1006, 8:45–49, 6:33–47. Controller 31 may determine "the thickness of tissue between the anvil and the staple portion" and "inform the surgeon as to whether or not he has the appropriate amount of tissue between the anvil portion and the staple portion . . . or whether he has too much or too little tissue and should remanipulate the instrument." *Id.* at 5:39–48. Hooven's stapler also "includes miniature sensors to detect the power and/or force being used" by the motor. *Id.* at 8:29–32.

Petitioner's annotated version of Hooven's Figure 6 is reproduced below:



Hooven's Figure 6, reproduced above with Petitioner's annotations, is a "longitudinal cross-sectional view of the active or business head" of Hooven's system. Ex. 1006, 3:29–30; Pet. 61. Petitioner's annotations of

Figure 6 highlight (among other things) that the stapler includes closure nut 77 and threaded rod 71. Pet. 61. Figure 6 also depicts firing nut 86 and driving wedge member 83. *Id.* Closure nut 77, firing nut 86, and driving wedge member 83 are driven by motor-powered threaded rod 71. Ex. 1006, 6:9-22; *see also* Ex. 1003 ¶ 62. "To prepare the instrument for firing, motor 45 rotates threaded rod 71 to advance closure nut 77, causing anvil 75 to close and clamp body tissue against staple portion 74 (*i.e.*, the portion containing staples 81)." Ex. 1003 ¶ 62. "Once anvil 75 is closed, threaded rod 71 engages firing nut 86 to drive wedge member 83 along the length of staple portion 74, thereby pushing staple drivers 84 and staples 81 toward anvil 75." *Id.* "As a result, staples are ejected and formed against the recesses located on the anvil, causing the two legs of each staple 81 to be forced toward each other, securing the body tissue." *Id.* 

#### 2. Analysis of Claim 1

We begin by analyzing Petitioner's arguments that the combination of Hooven and Tierney teaches or suggests each limitation of claim 1. Patent Owner does not dispute that the proposed combination teaches or suggests each limitation. *See generally* PO Resp. 56–71. We then turn to the parties' arguments regarding motivation to combine and reasonable expectation of success.

# (a) Preamble [1.1]: A method of fastening at least first and second portions of body tissue together, the method comprising:

To the extent the preamble is limiting, Petitioner sufficiently demonstrates that Hooven discloses a method of fastening portions of body tissue together using a surgical stapler. *See* Pet. 59–60 (citing, e.g.,

Ex. 1006, 4:33–41); Ex. 1003 ¶ 169. Patent Owner does not dispute that the proposed combination teaches or suggests the preamble.

(b) Limitation [1.2]: imparting, using an adaptive arm of a robotic mechanism, a clamping force to the first and second portions of body tissue suitable to press the first and second portions against one another;

Petitioner sufficiently demonstrates that Hooven and Tierney together teach or suggest this limitation. Pet. 61–66. With reference to Petitioner's annotated version of Hooven's Figure 6 (reproduced above), Petitioner demonstrates that the stapler imparts a clamping force—applied by closing anvil portion 75 against staple portion 74—to first and second portions of body tissue, suitable to press the tissue portions against one another. Pet. 61; Ex. 1003 ¶ 170.

As discussed in more detail in Section II.E.2(g) below, Petitioner also demonstrates that a person of ordinary skill in the art would have been motivated to use an adaptive arm of Tierney's robotic system to control Hooven's stapler, including because Tierney teaches using any end effector in its robotic system, including "staple appliers."<sup>22</sup> Ex. 1005, 6:22–28; Pet. 1–65; Ex. 1003 ¶ 171.

Patent Owner does not dispute that the proposed combination teaches or suggests this limitation.

<sup>&</sup>lt;sup>22</sup> Following Petitioner's convention, we sometimes refer to the combination of Hooven's stapler and Tierney's robotic system as the "Hooven/Tierney robotic system." *See* Pet. 63.

> (c) Limitation [1.3]: generating, using a force measurement system associated with the adaptive arm, a clamping force signal indicative of the clamping force imparted by the adaptive arm to the first and second portions of body tissue;

Petitioner establishes that "[t]he Hooven/Tierney robotic system generates, using a force measurement system (*e.g.*, Hooven's 'miniature sensors') associated with the adaptive arm, a clamping force signal (sensor output signal) indicative of the clamping force ('the power and/or force being used' by Hooven's motor 45 to close anvil portion 75) imparted by the adaptive arm to the first and second portions of body tissue." Pet. 66–67 (citing Ex. 1003 ¶ 197; Ex. 1006, 8:18–49, 5:9–53, 9:21–22, 3:2–8). More specifically, Hooven's "miniature sensors" detect the "the amount of torque required to pivot the anvil portion about the pivot pin," enabling "the thickness of the tissue between the anvil and the staple portion [to be] determined." Ex. 1006, 5:39–43; Ex. 1003 ¶ 198. As Dr. Fischer explains, a person of ordinary skill in the art would have understood that the force used to close anvil portion 75 against staple portion 74 indicates the clamping force imparted by the adaptive arm to the first and second portions of body tissue. Ex. 1003 ¶ 198–200.

Patent Owner does not dispute that the proposed combination teaches or suggests this limitation. Based on the arguments and evidence of record, Petitioner establishes that Hooven and Tierney together disclose limitation [1.3].

(d) Limitation [1.4]: receiving, using a computer in communication with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system;

Hooven discloses that its stapler is interconnected with a controller, which "can accept, store, manipulate, and present data," and that sensors in the stapler are connected to the controller via interface cable 205. Ex. 1006, 4:9–11, 8:36–49; *see also* Ex. 1003 ¶ 203. Petitioner demonstrates that "[i]n the Hooven/Tierney robotic system, Tierney's computer (controller 150) and 'remote interface adaptor' replace Hooven's computer (controller) and interface cable 205, respectively." Pet. 69; Ex. 1003 ¶ 204. In this way, "[t]he Hooven/Tierney robotic system receives, using a computer (Tierney's controller 150) in communication (via the 'remote interface adaptor') with the force measurement system and the robotic mechanism, the clamping force signal from the force measurement system." Pet. 67; Ex. 1003 ¶ 201–04.

Patent Owner does not dispute that the proposed combination teaches or suggests this limitation. Based on the arguments and evidence of record, Petitioner sufficiently establishes that Hooven and Tierney together teach or suggest limitation [1.4].

(e) Limitation [1.5]: determining, using the computer and the received clamping force signal, that the clamping force imparted by the adaptive arm to the first and second portions of body tissue has a predetermined magnitude; and

Hooven teaches that "the amount of torque required to pivot the anvil portion about the pivot pin can be sensed and the thickness of tissue between the anvil and the staple portion determined," and the controller can manipulate this information to inform the surgeon as to whether he or she

has the appropriate amount of tissue in the stapler. Ex. 1006, 5:35–48; Pet. 70. Dr. Fischer explains that a person of ordinary skill in the art would

have understood that

for the controller to "inform the surgeon" as to whether they have clamped "too much" tissue in the jaws based on "the amount of torque required to pivot the anvil portion," the controller must at least determine if the force applied to the tissues when the jaws are closed is more than a predetermined magnitude indicative of there being "too much" tissue.

Ex. 1003 ¶ 205 (quoting Ex. 1006, 5:39–48).

Patent Owner does not dispute that the proposed combination teaches or suggests this limitation. Based on the arguments and evidence of record, Petitioner sufficiently demonstrates that Hooven teaches or suggests limitation [1.5]. *See* Pet. 69–70.

> (f) Limitation [1.6]: fastening, after said determining and simultaneously with the clamping force imparted by the adaptive arm to the first and second portions of body tissue having the predetermined magnitude, the first and second portions of body tissue together using the adaptive arm.

Petitioner sufficiently shows that the Hooven/Tierney robotic system teaches or suggests this limitation. Pet. 70–73. As discussed above, Hooven's controller "inform[s] the surgeon as to whether or not he has the appropriate amount of tissue between the anvil portion and the staple portion of the head of the instrument upon closure." Ex. 1006, 5:43–48; *see also id.* at 8:52–56 ("From the sensor input from the specific endoscopic instrument used, the control logic can make decisions and/or actions on things such as tissue compression . . . ."). Hooven's system also receives signals from sensors to determine whether the system is "in range to fire," and if it is, the system will "enable [the] 'fire' button for physician," such that when the

"fire" button is pressed, the system will "fire" the staples to secure portions of body tissue together. *Id.* at Fig. 20A; Ex. 1003  $\P$  206.

Dr. Fischer testifies that "Hooven confirms that the system is 'in range to fire' only if the force applied to the tissues when the jaws are closed is less than a predetermined magnitude indicative of there being 'too much' tissue." Ex. 1003 ¶ 206. Dr. Fischer also testifies that a person of ordinary skill in the art "would have understood that Hooven teaches fastening tissue only after it is determined that the jaws are in 'the closed position ready for firing' and the force applied to tissues by the jaws is less than a predetermined magnitude." *Id.*; *see also* Pet. 70–72. Thus, Petitioner establishes that Hooven and Tierney teach or suggest that the fastening step occurs after the determining step.

Petitioner also establishes that Hooven "discloses [that] the firing (*i.e.*, fastening) occurs simultaneously with the jaws being closed and applying the clamping force." Pet. 72 (citing Ex. 1003  $\P$  207). In particular, as Dr. Fischer explains:

Hooven discloses: (1) that firing nut 86, which performs the firing, does not engage threaded rod 71 until *after* closure nut 77 fully closes the anvil, thereby applying the clamping force; and (2) that closure nut 77 does not "retract and open the anvil," thereby removing the clamping force, until *after* firing nut 86 has "drive[n] and form[ed] all of the staples."

Ex. 1003 ¶ 207 (quoting Ex. 1006, 6:9–47, Fig. 20B). Thus, Petitioner also establishes that the fastening step occurs simultaneously with the application of the clamping force.

Patent Owner does not dispute that the proposed combination teaches or suggests this limitation. Based on the arguments and evidence of record,

Petitioner sufficiently demonstrates that Hooven and Tierney teach or suggest limitation [1.6].

# (g) Motivation to Combine Hooven and Tierney with a Reasonable Expectation of Success

Petitioner persuasively establishes that a person of ordinary skill in the art would have been motivated to modify Tierney's robotic system to accommodate Hooven's stapler with a reasonable expectation of success of achieving the claimed method. See Pet. 61-65. As discussed above, Tierney teaches a robotic system with adaptive arms to control surgical tools, including "staple appliers." Ex. 1005, 6:22-28; see also Pet. 61-62; Ex. 1003 ¶ 171, 176–77. Petitioner argues, and we agree, that the same reasons discussed above that would have motivated a person of ordinary skill to combine Bonutti's suture securing system with Tierney's robotic system also apply to Hooven's stapler, including to obtain the benefits robotic systems offer for handheld surgical tools. See supra Section II.D.3(g); see also Pet. 64; Ex. 1003 ¶¶ 176–88. Petitioner also persuasively establishes that Tierney and Hooven have the common objectives of allowing for a high degree of control of end effectors, which would have motivated a person of ordinary skill in the art to implement the computercontrol features of Hooven's stapler in Tierney's robotic system, to obtain a high degree of control (and the ensuing safety benefits) over the resulting robotic surgical stapler. Pet. 64-65; Ex. 1003 ¶¶ 189-90; Ex. 1005, 1:12-16; Ex. 1006, 2:24–27.

Petitioner also persuasively establishes that a person of ordinary skill in the art would have reasonably expected the combination of Tierney and Hooven to be successful, including because Tierney discloses multiple means of coupling its robotic system to Hooven's stapler (e.g., "cabling

arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like"), and because adapting handheld surgical instruments like Hooven's stapler for use with a robotic system was well within the level of skill in the art. Pet. 65 (quoting Ex. 1005, 9:31–34); Ex. 1003 ¶¶ 191–96. Dr. Fischer provides several exemplary ways of integrating Hooven's stapler into Tierney's robotic system, and establishes that an ordinarily skilled artisan would have known how to appropriately modify each component to enable the robotic system to drive the stapler. Ex. 1003 ¶¶ 172–74, 193–96; *see also* Pet. 61–64.

#### (h) Patent Owner's Arguments

Patent Owner's arguments on this ground of unpatentability are directed to whether a skilled artisan would have been motivated to combine Hooven and Tierney with a reasonable expectation of success. PO Resp. 56–71.

Patent Owner argues a lack of motivation to combine because in the resulting system the stapler would be unable to articulate or rotate. *See, e.g., id.* at 58–60. As an initial matter, as Petitioner correctly notes, the challenged claims require neither articulation nor rotation. Reply 21. Nor did Petitioner rely on the ability of the stapler to articulate or rotate as part of its asserted motivation to combine. *Cf. Cook Grp. Inc. v. Boston Sci. Scimed, Inc.,* 809 F. App'x 990, 1001 (Fed. Cir. 2020) (non-precedential) (noting that "where the motivation to combine rests on a modification alleged to improve the primary reference . . . the Board may consider whether the modification renders the reference inoperable for its intended function in deciding whether a POSA [person of ordinary skill in the art]

would have a motivation to combine the references, even if that function is not a feature of the claimed device at issue").

Nevertheless, Patent Owner asserts that inability to articulate or rotate "would have rendered Hooven inoperable for its intended purpose of providing a high degree of control in the manipulation of the business end of an endoscopic stapler." PO Resp. 61 (citing, e.g., Ex. 1006, 2:24–27). This argument is unavailing. The cited portion of Hooven states that "the present invention provides a system allowing for a high degree of control in the manipulation of the active part or business head of an endoscopic instrument." Ex. 1006, 2:24–27. Patent Owner, however, does not point us to, nor do we discern, any disclosure in the record that suggests articulation or rotation is a necessary part of Hooven's "high degree of control in the manipulation" of the stapler. PO Resp. 61. Moreover, features of Hooven's system that provide control over the stapler, such as the miniature sensors that act as a force measurement system, are retained in the proposed combination, and additional functionality, including tremor reduction and the ability to perform procedures remotely, is gained. See supra Section II.E.2(c) (discussing Hooven's miniature sensors); Reply 24–25; Ex. 1003 ¶ 91, 92 (addressing benefits of robotic surgical systems); Ex. 1013, 2:24– 38 (same); Ex. 1019, 2:37–55 (same). Thus, we do not agree with Patent Owner that the combination would have rendered Hooven inoperable for its intended purpose of providing a high degree of control over the stapler.

Patent Owner also contends that "a linear stapler fixedly connected to the end of a shaft would be worthless during surgery inside of a patient's body." PO Resp. 61. This contention is not supported by citation to the

record or to any testimony from a skilled artisan or surgeon.<sup>23</sup> It is also inconsistent with the record, which discloses robotic linear surgical tools, including a linear stapler. *See, e.g.*, Ex. 1018, Fig. 4, 3:9–11, 3:21–22, 5:26–45; Reply 21, 24; Ex. 1003 ¶¶ 181, 183. Additionally, Tierney does not require rotation or articulation of the end effector. *See* Reply 21 (citing Ex. 1005, 7:65–8:1 (indicating that motors "often" (but not always) "articulate a wrist at the distal end of the tool"), 9:16–33 (teaching that a cable/pulley drive system, which would permit rotation of the end effector, is optional)); *see also* Ex. 1005, 6:22–28 (indicating that tools may be articulated or non-articulated), claims 5, 8, 16, 25 (dependent claims directed to a robotic surgical tool with a wrist, where independent claim does not recite a wrist). We see no evidence of record that negates a motivation to provide a linear stapler.

Additionally, Petitioner establishes that to the extent a skilled artisan would have desired rotation and articulation, Tierney's robot could provide rotation, and using Hooven's flexible shaft instead of Tierney's rigid shaft would permit articulation. Reply 21–24; *see also* Ex. 1003 ¶ 174; Ex. 1005, 8:11–13, 9:25–28. Patent Owner's contention that using another arm of the robotic system to position Hooven's flexible shaft would be "clumsy" and "dangerous" (PO Resp. 60) is not supported by, and is indeed contrary to, evidence of record. The record shows that robotic arms were used for many

<sup>&</sup>lt;sup>23</sup> Patent Owner asserts that a Food and Drug Administration ("FDA") guidance letter "not[es] several serious problems attributed to surgical staplers, including: opening of the staple line or malformation of the staples, misfires, difficulty in firing, and failure to fire." PO Resp. 56 (citing Ex. 2001); *see also* Sur-reply 17. Patent Owner, however, has not established that FDA attributed these problems to a lack of rotation or articulation of the stapler.

tasks, including placement of surgical tools having flexible shafts. Reply 21 (citing Ex. 2004 ¶¶ 99–100).

Patent Owner asserts that rotation and articulation is critical to the operation of Hooven's stapler because without it, creating the square staple pattern shown in Figure 29 of the challenged patent would have been impossible. PO Resp. 61-62. Patent Owner suggests that an inability to create this staple pattern negates any motivation to combine. Id. at 62-63. We disagree. First, as Petitioner correctly states, the challenged claims do not require such a staple pattern. Reply 24 n.3. Second, Petitioner did not rely on ability to make such a staple pattern as part of its asserted motivation to combine. Cf. Cook Grp. Inc., 809 F. App'x at 1001. Finally, Patent Owner has not established with evidence of record either the importance of this staple pattern, or that a purported inability to create it would have overridden the other anticipated benefits of the proposed combination. See supra Section II.E.2(g); see also Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.").

Patent Owner next argues that the proposed Hooven/Tierney robotic system lacks the tactile feedback that each of Hooven and Tierney purportedly require. PO Resp. 63. Patent Owner, however, has not established that either Hooven or Tierney requires tactile feedback. Hooven's system expressly provides "*sensing feedback* to the surgeon to compensate for the *loss of tactile feedback*." Ex. 1006 at 2:38–40 (emphases added); *see also id.* at 2:51–54; 8:27–57. Importantly, this sensing feedback is *retained* in the proposed combination of Tierney and

Hooven.<sup>24</sup> Reply 25–26; Ex. 1003 ¶¶ 197–204; Pet. 66–69; *supra* Section II.E.2(d)–(e).

Regarding Tierney's purported requirement of tactile feedback, Patent Owner points solely to disclosure in Madhani. PO Resp. 63 (citing Ex. 1013, 5:62–64, 3:1–4, 18–21; 6:34–38, 11:2–4). Tierney does call out Madhani's cabling system and incorporates Madhani by reference, but Tierney expressly indicates that a cabling arrangement like Madhani's is merely one possible drive system. Ex. 1005, 8:4–7, 9:18–45. Thus, Tierney does not indicate that any aspect of Madhani—including any tactile feedback provided by Madhani's system—is mandatory. Accordingly, the record does not support that Tierney's system requires tactile feedback. Nevertheless, if tactile feedback were desired, Madhani (which is incorporated into Tierney) teaches the same. Ex. 1003 ¶ 59; Ex. 1013, 5:62–64; Reply 25–26; Pet. 27.

Patent Owner also argues that "Petitioner's expert proposes a larger tool shaft diameter than Madhani or Hooven allow." PO Resp. 63 (quote altered to remove title case). This argument is not sufficiently developed because Patent Owner has not established that Dr. Fischer proposes a tool shaft diameter for the combination. Patent Owner relies on Dr. Fischer's deposition testimony, but that testimony generally discusses shaft sizes that are acceptable for endoscopic surgery. PO Resp. 64 (citing Ex. 2002,

<sup>&</sup>lt;sup>24</sup> In asserting that the Hooven/Tierney robotic system lacks tactile feedback, Patent Owner mischaracterizes Dr. Fischer's testimony. PO Resp. 63 (citing Ex. 2002, 93:20–94:24); *see also* Sur-reply (citing Ex. 2002, 95:17–24). Our review of the cited testimony indicates that Dr. Fischer was *not* discussing whether the proposed Hooven/Tierney system had tactile feedback, but rather was discussing tactile feedback in general and in Tierney's 2002 commercial robotic system. Ex. 2002, 93:20–95:24; Reply 26.

92:23–93:16). It does not address the size of the shaft in the proposed Hooven/Tierney robotic system. Patent Owner also cites Dr. Fischer's testimony from IPR2020-00649. *Id.* That testimony discusses the existence of instruments for minimally invasive surgery having diameters of 30mm and larger (Ex. 2004 ¶ 49; Ex. 2005, 30:13–32:11), but also does not address the size of the shaft in the proposed Hooven/Tierney robotic system. In any event, we find that even if the shaft in the proposed Hooven/Tierney robotic system were too large, "a POSITA would have known that the various disclosed physical structures could be modified to suit the needs of a particular application." Ex. 1003 ¶ 93; *see also* Reply 26–27 (citing Ex. 2004 ¶¶ 44, 48, 49, 105); *KSR*, 550 U.S. at 421.

Patent Owner argues that a skilled artisan would not have been motivated to replace Tierney's cable and pulley system with Hooven's gear system because "[d]oing so would . . . violate the principles of operation of the Tierney/Madhani system." PO Resp. 65; *see also id.* at 69–70. Patent Owner argues that "[t]here is no disclosure in Tierney and Madhani which would have motivated a POSITA to use any drive system other than a cable and pulley drive system," and that Tierney/Madhani teach away from replacing a cable/pulley system with a different drive system, given that cables and pulleys provide benefits such as low friction, high sensitivity, dexterity, and feedback. *Id.* at 68, 64–70.

This argument is unavailing because it mischaracterizes Petitioner's proposal. Petitioner did not propose complete removal of Tierney/Madhani's cable/pulley system. Instead, Petitioner asserted that a skilled artisan would have contemplated the use of cables, among other means of combining Hooven's stapler with Tierney's robot. Pet. 65;

Ex. 1003 ¶¶ 191, 194. Moreover, Patent Owner's arguments contradict Tierney's express teachings. Tierney teaches that Madhani's cable/pulley system is but one option, and that "[a] wide variety of alternative drive systems might be employed, including alternative cabling arrangements, drive chains or belts, hydraulic drive systems, gear trains, or the like." Ex. 1005, 9:31–34; Reply 28. Thus, Tierney cannot teach away from gears, because it expressly teaches use of gears. Finally, even if a cable-based system offered better dexterity than a gear-based system, "just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012).

# (i) Summary as to Claim 1

As discussed above, Petitioner's analysis addresses every limitation in claim 1 and provides reasons with rational underpinnings why a person of ordinary skill in the art would have been motivated to combine the teachings of Hooven and Tierney with a reasonable expectation of success. Thus, based on the entire record, and taking into account Patent Owner's arguments, we find that Petitioner has established that claim 1 is unpatentable under § 103 as obvious over Hooven and Tierney.

3. Analysis of Claims 2–4, 6–8, and 24

We have reviewed Petitioner's contentions regarding claims 2–4, 6–8, and 24. *See* Pet. 73–78. Patent Owner did not make any arguments specific to any of these claims. We are persuaded on the full trial record, including consideration of Patent Owner's arguments discussed above, that Petitioner has shown by a preponderance of the evidence that claims 2–4, 6–8, and 24 are unpatentable as obvious over Hooven and Tierney. *Id*.

# F. Additional Grounds

Petitioner contends that (1) claims 1, 2, 4, 6, 8–20, 22–25, 27, 29, and 30 would have been obvious over the combination of Bonutti, Tierney, Cooper, and Madhani; and (2) claim 24 would have been obvious over the combination of Bonutti, Tierney, and Bonutti-986. Pet. 78–81.

In view of our determinations that these same claims would have been obvious over Bonutti and Tierney and/or Hooven and Tierney as discussed above, we need not address these grounds of unpatentability. *See, e.g., SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

## III. CONCLUSION<sup>25</sup>

Petitioner has shown by a preponderance of the evidence that claims 1-4, 6-20, 22-25, 27, 29, and 30 of the '953 patent are unpatentable under 35 U.S.C. § 103 as obvious. In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1, 2, 4, 6, 8–20, 22– 25, 27, 29, 30	103	Bonutti, Tierney	1, 2, 4, 6, 8–20, 22–25, 27, 29, 30	•
1, 2, 4, 6, 8–20, 22– 25, 27, 29, 30	103 <sup>26</sup>	Bonutti, Tierney, Cooper, Madhani		
24	103 <sup>27</sup>	Bonutti, Tierney, Bonutti-986		
1–4, 6–8, 24	103	Hooven, Tierney	1-4, 6-8, 24	
Overall Outcome			1-4, 6-20, 22- 25, 27, 29, 30	

<sup>&</sup>lt;sup>25</sup> 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).

<sup>&</sup>lt;sup>26</sup> As explained above in Section II.F, we need not reach this ground. <sup>27</sup> As explained above in Section II.F, we need not reach this ground.

#### IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1–4, 6–20, 22–25, 27, 29, and 30 of U.S. Patent No. 10,368,953 B2 are unpatentable as obvious; and

FURTHER ORDERED that, because this is a final written decision, 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.

## For PETITIONER:

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