

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC.,
Petitioner,

v.

ETHICON LLC,
Patent Owner.

IPR2019-01110
Patent 8,602,288 B2

Before JOSIAH C. COCKS, ZHENYU YANG, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

A. *Background and Summary*

Intuitive Surgical, Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 10 and 11 of U.S. Patent No. 8,602,288 B2 (“the ’288 patent”). Paper 2 (“Pet.”). Ethicon LLC (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

We have authority to determine whether to institute *inter partes* review under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the information presented in the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Having considered the arguments and the evidence presented, for the reasons described below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged by the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

B. *Real Parties in Interest*

Pursuant to 37 C.F.R. §42.8(b)(1), Petitioner, Intuitive Surgical, Inc. identifies itself as the real-party-in-interest. Pet. 2.

Patent Owner states that it is an indirect subsidiary of Johnson and Johnson. Paper 5, 2. Patent Owner also states that the ’288 patent is licensed to Ethicon Endo-Surgery, Inc. which has, in turn sublicensed the ’288 patent to Ethicon US, LLC. *Id.* Patent Owner states that Ethicon Endo Surgery, Inc. and Ethicon US, LLC are also indirect subsidiaries of Johnson & Johnson. *Id.*

C. Related Matters

The parties have indicated that the '288 patent is involved in the following litigation: *Ethicon LLC et al. v. Intuitive Surgical, Inc. et al.*, C.A. No. 1:18-cv-01325-LPS (D. Del.). Pet. 2; Paper 5, 2.

Patent Owner also represents that patents assigned to Patent Owner and asserted against Petitioner in the litigation listed above are involved in the following IPRs: IPR2018-00933, -934, -935, -936, -938, -1247, -1248, -1254, -1703, IPR2019-00880, -00991, and -01066. *Id.*

D. The '288 Patent

The '288 patent is entitled Robotically-Controlled Motorized surgical-end Effector System with Rotary Actuated Closure Systems Having Variable Actuation Speeds. Ex. 1001 (54). The '288 patent issued from U.S. App. No. 13/369,588, filed on Feb. 9, 2012, which is a continuation of U.S. App. No. 13/118,253, filed on May 27, 2011, which is a continuation-in-part of U.S. App. No. 12/235,972, filed on Sep. 23, 2008. Ex. 1001, (21), (45), and (63).

The '288 patent generally relates to motorized surgical instruments. Ex. 1001, col. 1, ll. 62–66. In one embodiment, the instrument comprises an end effector which include a component or part which can be selectively moved between first and second position where the movement of the component occurs in two phases and where the rate of movement during one phase is different from the rate of movement in the other phase. *Id.* Abstr. The end effector may comprise “graspers, cutters, staplers, clip applicators, access devices, drug/gene therapy devices, ultrasound, RF or laser devices” and the like. *Id.*, col. 9, ll. 46–52. In one embodiment, the moveable component is an anvil of a surgical stapler. *Id.* col. 10, ll. 1–19.

The '288 patent discloses at least two methods for controlling the rate at which the anvil is closed. The first involves the use of a variable pitch groove/thread arrangement to close the anvil at two different rates. *Id.* col. 53, ll. 50–64; Pet. 7–8. The second involves the use of a trunnion which engages a slot having a steeper proximal portion and a shallower distal portion. Ex. 1001, Figure 57 and 58, col. 50, ll. 15–18; col. 4, ll. 60–63; Pet. 9–10.

E. Illustrative Claims

Petitioner has challenged claims 10 and 11 which read as follow:

10. A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator, said surgical tool comprising:

- a surgical end effector comprising at least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof; and

- an elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising:

- an axially movable portion in operable communication with said at least one selectively movable component portion of said surgical end effector; and

- a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector

from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.

11. A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator, said surgical tool comprising:

- a surgical end effector comprising at least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof; and

- an elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising:

- an axially movable portion in operable communication with said at least one selectively movable component portion of said surgical end effector; and

- a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion.

F. Evidence

Petitioner relies on the following references:

Heinrich et al., US 2005/0131390 A1, published June 16, 2005.
 (“Heinrich”) (Ex. 1004).

Viola et al., US 5,915,616, issued June 29, 1999. (“Viola”) (Ex. 1005).

Timm et al., US 7,510,107 B2, issued March 31, 2009. (“Timm”) (Ex. 1006).

Schulze et al., US 5,632,432, issued May 27, 1997. (“Schulze”) (Ex. 1007).

Anderson et al., US 6,783,534 B2, issued August 31, 2004.
 (“Anderson”) (Ex. 1008).

Petitioner also relies on the Declaration of Dr. Gregory S. Fischer.
 (Ex. 1003).

G. Prior Art and Asserted Grounds

Petitioner asserts that claims 10 and 11 would have been unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)
10 and 11	102	Heinrich
10 and 11	102	Timm
10 and 11	103	Timm and Viola
10 and 11	103	Timm and Schulze
10 and 11	103	Timm and Anderson and, if needed, Viola and Schulze
10 and 11	103	Heinrich and Anderson
10 and 11	103	Heinrich and Viola and, if needed, Anderson

II. DISCRETIONARY DENIAL

Patent Owner argues that the Board should deny the Petition because the Petition contains voluminous or excessive grounds and fails to state at least some of them asserted grounds with particularity. Prelim. Resp. 2. Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review, and that discretion has been delegated to the Board. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”); 37 C.F.R. § 42.4(a). For the reasons discussed below, we do not deny institution under § 314(a).

Patent Owner argues that the Board should exercise its discretion and deny the Petition as the Petition presents “voluminous grounds” prohibiting Patent Owner from adequately responding to each argument advanced by Petitioner. Prelim. Resp. 2–3. Patent Owner contends that while the Petition lists seven grounds of invalidity, the petition actually presents nine different grounds. *Id.* In support of its contention, Patent Owner points to Grounds 5 and 7 where it states that the proposed combination of references may be supplemented by additional references “if necessary.” *Id.* at 5–6. Patent Owner contends that each of these grounds is in fact two separate grounds bringing the total number of grounds to nine. *Id.* Patent Owner contends that it is impossible for Patent Owner to adequately respond to each of the grounds given the limitation imposed on any response Patent Owner might chose to file. *Id.*

Patent Owner contends that the present case is similar to that in *Adaptics Ltd. v. Perfect Co.*, Case IPR2018-01596, Paper 20 (P.T.A.B. Mar.

6, 2019) (Informative). Prelim. Resp. 4. Patent Owner contends that like the petition in *Adaptics*, the present Petition contains voluminous grounds making a response onerous and warranting denial of the petition especially given the lack of particularity in the petition. *Id.*

We have considered Patent Owner’s argument and are not persuaded that we should exercise our discretion under 35 U.S.C. § 314)(a).

In *Adaptics*, the Board found that one of the grounds advanced in the petition relied on six different secondary references and another ground relied on another seven secondary references. *Adaptics* at 21. The Board also found that petitioner’s declarant relied on additional references to support the conclusion of obviousness. *Id.* at 22. The petition also included a third ground which the Board found encompassed “hundreds of possible combinations.” *Id.* at 19. In *Adaptics*, the Board also found that Petitioner’s obviousness analysis did not state which limitations were missing from the primary references nor did Petitioner limit its analysis to those specific limitations.

In contrast, the present petition relies on only two primary references, Heinrich and Timm, and three secondary references, Viola, Schulze and Anderson. Pet. 3–4. In the present Petition, the analysis of the secondary references is limited to two claim elements, movement of the selectively moveable component at two different rates and use of the claimed surgical tool with a robotic system. *See, e.g.*, Pet. 78–86.

Petitioner’s use of the term “if necessary” does not create a situation akin to that in *Adaptics*. In *Adaptics*, the Board found the use of the term “and/or” coupled with the recitation of up to ten references yielded hundreds of possible combinations. *Adaptics* at 19. In the present case, accepting

Patent Owner's contention, the use of the term "if necessary" only adds two possible grounds for a total of nine. Prelim. Resp. 2.

With respect to lack of particularity, we are not persuaded by Patent Owner's argument. As noted above, the discussion of the secondary references, Viola, Schulze, and Anderson, is limited to two specific elements in the claims. The Petition also states which elements are missing from the primary references and how the secondary references correct the alleged deficiency. For example, in the discussion of Schulze, the Petition identifies the element that may be missing from Timm – closure of the moveable portion at two different rates – and then discusses how Schulze teaches that element. Pet. 78–80. Moreover, as discussed more fully below, the present Petition fully maps each primary reference to the claim limitations. This is in stark contrast to the petition in *Adaptics* where the Board found that Petition did not map out the primary references to the limitations nor did the Petition make clear how the secondary references were being applied. *See Adaptics* 19–10

Based on the foregoing, we conclude that the present Petition does not present voluminous grounds, nor does it fail to state the grounds with particularity. We find that the Petition does not present Patent Owner with a "high hurdle" sufficient to warrant denial of the petition. Therefore, we decline to exercise our discretion to deny the petition under 35 U.S.C. §314(a).

III. ANALYSIS

A. *Legal Standards*

1. *Anticipation*

Section 102(b) provides that “a person shall be entitled to a patent unless the invention was patented or described in a printed publication . . . more than one year prior to the date of the application.” 35 U.S.C. § 102(b) (2002).¹ Accordingly, invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation. *See Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994). Material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. *See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed. Cir. 1997) (holding that material incorporated by reference into a document may be considered in an anticipation determination).

Incorporation by reference provides a method for integrating material from various documents into a host document — a patent or printed publication in an anticipation determination — by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein. *Advanced Display*

¹ The provisions of the America Invents Act regarding novelty and obviousness applies to patents containing at least one claims having an effective filing date on or after March 16, 2013. Pub L. 112–29. Petitioner contends and Patent Owner does not contest that the ’288 patent has an effective filing date of at least May 27, 2011. Pet. 4. Therefore, the Pre-AIA provisions of 35 U.S.C. §§ 102 and 103 apply to this decision.

Systems, Inc. v. Kent State University, 212 F.3d 1272, 1281 (Fed. Cir. 2000). To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents. *See In re Seversky*, 474 F.2d 671, 674 (CCPA 1973) (providing that incorporation by reference requires a statement “clearly identifying the subject matter which is incorporated and where it is to be found”).

2. *Obviousness*

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham vs. John Deere Co.*, 383 U.S. 1, 17–18(1966). If the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains, the claim is unpatentable under 35 U.S.C. § 103(a). *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination.” *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). “Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner, through its declarant, Dr. Fischer, contends that

A person of ordinary skill in the art at the time of the claimed invention (“POSITA”) would have had the equivalent of a Master’s degree or higher in mechanical engineering, electrical engineering, biomedical engineering, or a related field directed towards medical electro-mechanical systems and at least 2-3 years working experience in research and development for surgical instruments. Experience could take the place of some formal training, as relevant skills may be learned on the job. This description is approximate, and a higher level of education might make up for less experience, and vice versa.

Ex. 1003 ¶30. For purposes of this decision, we adopt Dr. Fischer’s description of the level of ordinary skill in the art.

We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Claim Construction

We interpret a 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).² Under this standard, we construe the claim

² The Office has changed the claim construction standard in AIA proceedings to replace the broadest reasonable interpretation standard with the same claim construction standard used in a civil action in federal district courts. Changes to the Claim Construction Standard for

“in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy. . . .’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Construing a means-plus-function claim limitation is a two-step process. First, the claim must be analyzed to determine whether the claim language actually invokes the provisions of 35 U.S.C. § 112, sixth paragraph. *See Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 1364 (Fed. Cir. 2000) (“If a claim element contains the word ‘means’ and recites a function, th[e] court presumes that element is a means-plus-function element under § 112, ¶ 6. . . . That presumption falls, however, if the claim itself recites sufficient structure to perform the claimed function.”). The second step is to “determine what structures have been disclosed in the specification that correspond to the means for performing that function.” *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1361 (Fed. Cir. 2000).

Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). The change applies to petitions filed on or after November 13, 2018. *Id.* Because the present Petition was filed on March 9, 2019, we construe the claims in accordance with the federal district court standard, now codified at 37 C.F.R. § 42.100(b).

Petitioner contends that the terms “component portion,” “axially moveable portion,” and “rotatably moveable portion” should be construed as means-plus-function limitation and be limited to the specific embodiments recited in the specification. Pet. 12–23.

We have considered Petitioner’s arguments and conclude that, at this stage of the proceeding, we need not construe any of the terms proposed by Petitioner.

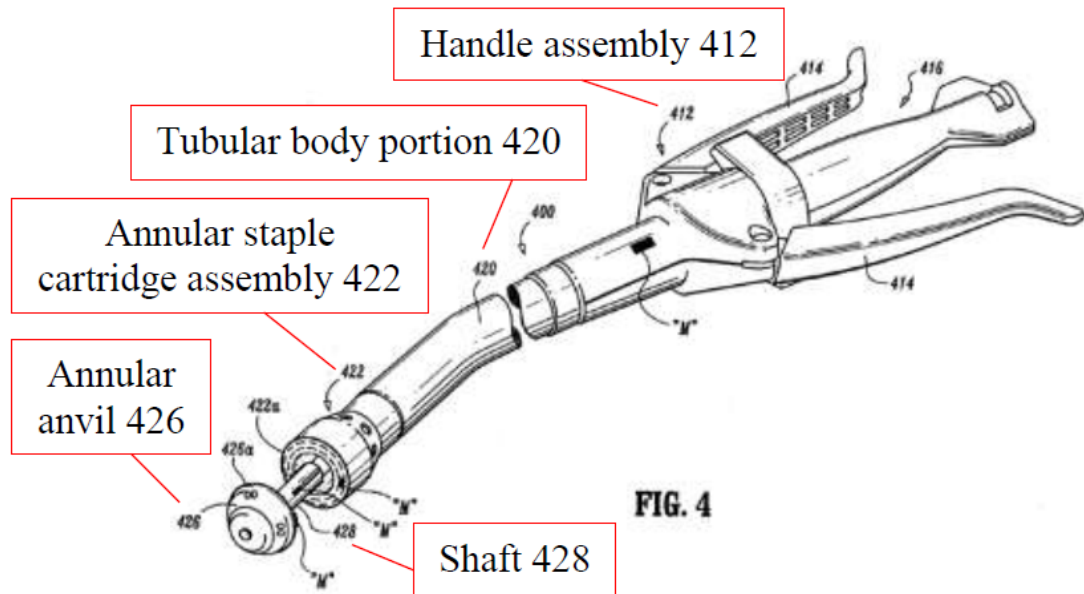
D. Unpatentability based on Heinrich

Petitioner contends that claims 10 and 11 are unpatentable as either anticipated by Heinrich or obvious over Heinrich in view of Anderson, Viola, or Viola and Anderson together. Pet. 37–55 and 87–90.

1. Heinrich

Heinrich relates to surgical systems and instruments, and more specifically, surgical stapler instruments and systems. Ex. 1004 ¶ 4. Heinrich discloses the use of a robotic system to perform various surgical tasks including operation of an end effector such as a surgical stapler. *Id.* ¶¶ 21, 28. In one embodiment Heinrich discloses a surgical stapler which includes a handle assembly to open and close the stapler. As shown in Figure 4 below, the stapler of Heinrich also comprises a tubular body portion 420 extending from handle assembly 412, and annular staple cartridge assembly 422 operatively connected to a distal end of the tubular body portion 420, and an annular anvil 426 positioned opposite staple cartridge assembly 422 and connected to surgical stapler 400 by a shaft 428. Ex. 1004 ¶¶ 100, 103.

Figure 4 of Heinrich illustrates a surgical stapler and is reproduced below.



2. *Viola*

Viola discloses

A surgical apparatus for applying staples or fasteners to tissue to form a circular anastomosis having an adjustable closure mechanism to rapidly approximate the distance between the anvil member and the fastener assembly of the instrument. The adjustable closure mechanism provides for rapid approximation during an initial movement and for fine adjustment of the distance between the anvil member and the fastener assembly upon subsequent movement of the closure mechanism. The closure mechanism consists of an advancing mechanism which operates in a two stage advancement, such that initial movement of the advancing mechanism moves the anvil member a greater distance than a subsequent movement of the advancing mechanism.

Ex. 1005, Abstr.

Viola discloses the use of a cam that engages grooves within a rotatable sleeve member to control the movement of the anvil relative to the fastener assembly. Ex. 1005, col. 9, ll. 21–51, Figures 9 and 11.

3. *Anderson*

Anderson discloses an apparatus for enhancing robotic surgery. Ex. 1008, col. 3, ll. 64–65. The apparatus of Anderson comprises a tool drive assembly coupled to a control station that is operated by a surgeon or other user. Ex. 1008, col. 10, l. 40 – col. 12, l. 22; col. 15, ll. 3–8; col. 21, l. 66 – col. 22, l. 19; col. 31, ll. 31–45; and Figure 1, 2, 12A–D, and 20.

4. *Analysis*

Petitioner contends that Heinrich, through its incorporation by reference of the teachings of Viola, anticipates claims 10 and 11. Pet. 37–55. Alternatively, Petitioner contends that the subject matter of claims 10

and 11 would have been obvious over Heinrich combined with Anderson, Viola or Viola combined with Anderson. *Id.* at 87–90.

- a) *A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to control unit of the robotic system that is operable by inputs from an operator, said surgical tool comprising.*

Petitioner contends that if the preamble of claims 10 and 11 is limiting, Heinrich teaches this element. Petitioner contends that Heinrich discloses a surgical tool which can be used with a robotic system having a tool drive assembly. Pet. 37; Ex. 1003 ¶¶ 65–97; Ex. 1004 ¶¶ 100–103. Petitioner also contends that Heinrich discloses that the robotic system is operated by inputs from a user such as a surgeon, nurse or technician. Pet. 37; Ex. 1003 ¶¶ 65–97; Ex. 1004 ¶¶ 100–103.

Alternatively, Petitioner contends that the combination of Heinrich and Anderson renders this element obvious. Pet. 87. Petitioner contends that Anderson discloses the use of a robotic system to operate surgical instruments. Pet. 84.

We have considered Petitioner’s arguments and the evidence of record and conclude that, for purposes of this decision, the preamble of the claims is not limiting. The preamble does not recite any essential structure, provide antecedent basis for any elements in the body of the claim, recite any structure that is underscored as important by the specification, or distinguish the claimed invention from the prior art relied on by the examiner during prosecution. *Georgetown Rail Equipment Co. v. Holland L.P.*, 867 F.3d 1229, 1236–38 (Fed. Cir. 2017). It merely recites a purpose or intended use of the structurally complete surgical tool defined by the body of the claim. *Id.*

We also conclude that, for purposes of this decision, Petitioner has demonstrated that Heinrich discloses a surgical instrument.

- b) *A surgical end effector comprising at least one component portion that is moveable between first and second positions relative to at least one other component portion thereof.*

Petitioner contends that this element is disclosed by Heinrich. Pet. 40. Petitioner contends that Heinrich discloses a surgical end effector that comprises a staple cartridge and an anvil where the anvil moves between an open and closed position. *Id.* at 40–43.

We have considered Petitioner's argument and the evidence of record and conclude, for purposes of this decision, Petitioner has demonstrated that Heinrich teaches the element. Heinrich teaches that the surgical stapler can move from an open to a closed position. Ex. 1004 ¶ 100. Dr. Fischer testifies that one skilled in the art would understand that this paragraph refers to the anvil of the stapler moving relative to the staple cartridge thus meeting the requirement that the moveable portion move from a first to a second position relative to a second portion of the component. Ex. 1003 ¶ 104.

- c) *An elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising:*

Petitioner contends that Heinrich discloses this element. Pet. 43–45. Petitioner contends that by incorporating the teachings of Viola by reference, Heinrich discloses a surgical instrument that comprises an elongate shaft assembly operably coupled to the end effector. *Id.* at 43. Petitioner contends that by incorporation of the teachings of Viola, Heinrich teaches that the shaft assembly comprises the combination of a rotatable bushing, rotation pin, rotatable sleeve member, cam member, inner rod, pin, and flexible member which are connected to the anvil as shown in Figure below.

Id. at 44–45; Ex. 1003 ¶ 108; Ex. 1004, ¶ 103; Ex. 1005, col. 7, ll. 34–39; col. 8, ll. 64–65; col. 9, ll. 21–52 and Figures 1, 11, and 12.

Figure 11 of Viola illustrates a surgical stapler and is reproduced below.

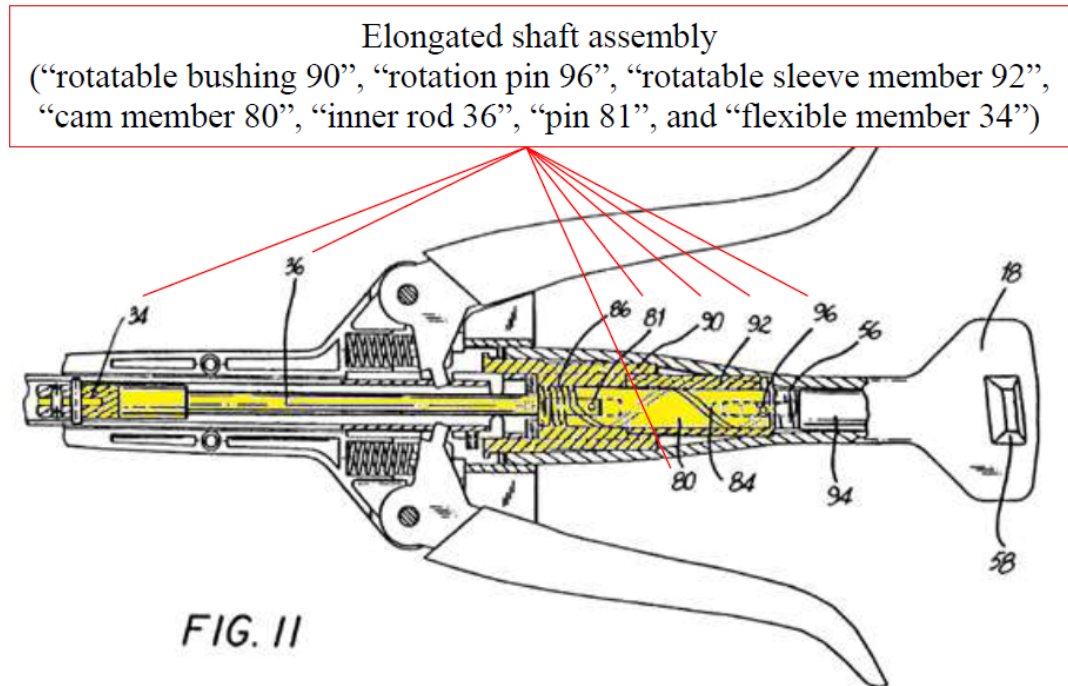


Figure 11 of Viola as highlighted and annotated by Petitioner showing a cross section of a surgical stapler. Pet. 45.

Alternatively, Petitioner contends that if Heinrich does not disclose this element, the combination of Heinrich and Viola teaches this element. *Id.* at 87–89. Petitioner contends Heinrich’s reference to the teachings of Viola for the workings of the stapler disclosed in Heinrich would have lead one skilled in the art to use the teachings of Viola to construct the instrument. *Id.*

We have considered Petitioner’s argument and the evidence of record and conclude that, for purposes of this decision, Petitioner has demonstrated

that Heinrich, either alone or in combination with Viola, teaches this element. Heinrich states “Reference is made to commonly assigned U.S. Pat. No. 5,915,616 to Viola et al., the entire content of which is incorporated herein by reference, for a more detailed explanation of the operation of surgical stapler.” This statement of incorporation makes it clear that the subject matter being incorporated into Heinrich is the discussion of the operation of the stapler which necessarily include the various components of the stapler and how they interact. Thus, the disclosure of Viola is effectively part of Heinrich as if it were explicitly contained therein. *Advanced Display*, 212 F. 3d at 1281.

Even if we were to conclude that Heinrich’s incorporation by reference did not include the structure of Viola’s stapler, we would agree with Petitioner that the combination of Heinrich and Viola teaches this element. Heinrich discloses a tubular body 420 that connects to the stapler assembly. Ex. 1004, Figure 4.

Figure 4 of Heinrich illustrates a portion of a surgical instrument and is reproduced below:

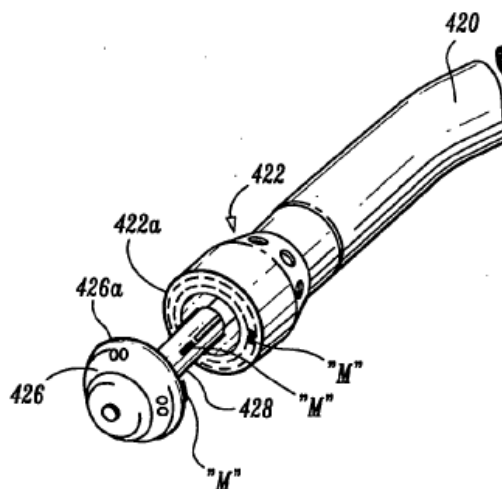


Figure 4 of Heinrich showing a perspective view of a surgical stapling instrument.

As Petitioner points out, Heinrich is silent as to the inner structure of the instrument. Pet. 88. We agree with Petitioner that one skilled in the art would have turned to a reference such as Viola for the details of how to design and construct the instrument. *Id.* Heinrich's specific reference to Viola would have lead one skilled in the art to consult the teachings of Viola. An axially moveable portion in operable communication with said at least one selectively moveable component of said surgical end effector.

Petitioner contends that Heinrich discloses this element via its incorporation by reference of Viola. Pet. 46–50. Petitioner contends that Viola discloses that the flexible member of Viola “slides rearward in the bore drawing the inner rod and flexible member in a proximal direction” and that this is the same as moving axially. *Id.* at 49; Ex. 1005, col. 9, ll. 40–42. Petitioner also contends that flexible member of Viola is coupled to the anvil satisfying the requirement that the axially moveable member in in operable communication with the selectively moveable member. Pet. 50; Ex. 1005, Col. 7, ll. 34–39, Figure 1 and 11; Ex. 1003 ¶ 118.

We have considered Petitioner's argument and the evidence of record and conclude that, for purposes of this decision, Petitioner has demonstrated that Heinrich, either alone or in combination with Viola, discloses this element. Viola discloses that the movement of the inner rod and the flexible member controls the movement of the anvil relative to the staple cartridge. Ex. 1005, col. 7, ll. 34–39. Viola also discloses that the inner rod and flexible member move in a proximal direction, which is the same as moving axially. Ex. 1005, col. 9, ll. 40–42. We agree with Dr. Fischer that the inner rod and flexible member of Viola form an axially moveable portion in

operable communication with said at least one selectively moveable portion of said surgical end effector. Ex. 1003 ¶ 117.

- d) *a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.*

Petitioner contends that Heinrich discloses this element via its incorporation by reference of Viola. Pet. 50–55.

Petitioner contends that the rotation pin and rotatable sleeve member of Viola constitutes a rotatably moveable portion as recited in claims 10. *Id.* at 53; Ex. 1003 ¶ 125; Ex. 1005 col. 9, ll. 21–51. Petitioner contends that the rotation pin and rotatable sleeve member can be rotated so as to cause the axially moveable portion to open and close. Pet. 53–54; Ex. 1003 ¶ 125; Ex. 1005 col. 9, ll. 35–52 and Figures 10–12. Petitioner also contends that Viola teaches the use of a helical groove in the cam which is engaged by the rotatable pin. Pet. 52–53; Ex. 1005, col. 9, ll. 21–52 and Figures 10–12. Petitioner contends that Viola teaches that the helical groove has regions with two different pitches which, in combination with the rotation pin and rotatable sleeve, cause the closing of the end effector from a first position to an intermediate position and from the intermediate position to a second position at two different rates, where the first rate is faster than the second rate. *Id.*

We have considered Petitioner’s arguments and the evidence of record and conclude that, for purposes of this decision, Petitioner has demonstrated

that Heinrich, either alone or in combination with Viola, teaches the element calling for

a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.

Ex. 1001, col. 93, ll. 1–13.

Viola teaches

As seen in FIG. 11 [reproduced below], cam member 80 is positioned within rotatable bushing 90 and rotatable sleeve member 92. Cam member 80 is secured to inner rod 36 as described above, such as by pin 81. A rotation pin 96 is provided which is operably secured to rotatable sleeve 92, so that upon rotation of grip member 18, helical groove 82 begins to ride over pin member 96 at first pitch 84. Cam member 80 begins to slide rearwardly in bore 94, thus drawing inner rod member 36 and flexible member 34 in a proximal direction. As cam member 80 reaches a point where rotation pin 96 is at the end of first pitch 84, anvil member 26 is positioned adjacent staple pusher member 22. Further rotation of grip member 18, as seen in FIG. 12, causes second pitch 86 to ride over pin 96 to provide for fine adjustment of the distance between anvil member 26 and staple pusher member 22.

Ex. 1005, col. 9, ll. 34–52.

Figure 11 of Viola illustrates a surgical stapler and is reproduced below:

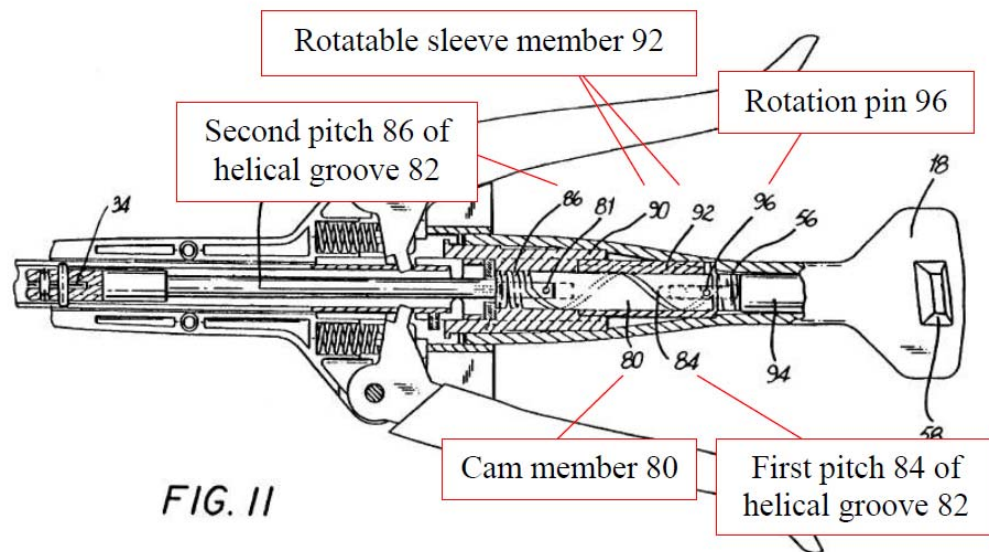


Figure 11 of Viola as annotated by Petitioner showing a cross section view of a surgical stapler. Pet. 54.

f. Claim 11

Claim 11 is similar to claim 10 except that it does not call for the first rate of movement to be greater than the first and adds the element that “said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion.” Ex. 1001, col. 94, ll. 7–20.

Petitioner contends that Heinrich anticipates claim 11 or that the subject matter of claim 11 would have been obvious over Heinrich combined with Viola. Pet. 55, 87–90. Petitioner contends that Viola’s combination of a rotatable bushing, rotation pin, and rotatable sleeve member form a closure member which is in threaded engagement with the threaded cam of the axially moveable portion. *Id.* at 55, Ex. 1003 ¶ 128.

We have considered Petitioner’s argument and the evidence of record and agree with Petitioner that Heinrich alone or in combination with Viola discloses this element. Viola discloses that the rotation pin engages the helical grooves of the cam causing the cam and the drawing rod member and

flexible rod to move in a proximal direction. Ex. 1005, col. 9, ll. 34–41. Dr. Fischer testified that this represents a threaded engagement. Ex. 1003 ¶ 128.

5. Conclusion

Based upon our review of the current record, we discern no deficiency in Petitioner’s characterization of the cited references and the knowledge in the art, or in Petitioner’s assertions as to the reasonable inferences an ordinary artisan would make from those references. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in establishing the unpatentability of claims 10 and 11 over Heinrich alone or in combination with Viola, Anderson or Viola and Anderson.

E. Unpatentability based on Timm

Petitioner contends that claims 10 and 11 are unpatentable as either anticipated by Timm or obvious over Timm combined with Viola, Schulze, Anderson or Anderson, combined with Viola and Schulze.

1. Timm

Timm relates to a surgical instrument such as a surgical stapler. Ex. 1006, col. 1, ll. 8–13. Referring to Figure 73A, reproduced below, in one embodiment, the opening and closing of the stapler is accomplished using a closure ring which engages a ramp at the end of the anvil. Ex. 1006, col. 36, ll. 18–24. As the closure ring is moved forward, the anvil is moved relative to the staple cartridge. *Id.* The movement of the closure ring is controlled by the rotation of a closure tube, which is threadably connected to the closure ring. *Id.* In this embodiment, the anvil includes a pair of trunnions which engage slots in the device which regulate the rate at which the anvil moves. Ex. 1006, col. 35, l. 64 – col. 36, l. 3; col. 45, ll. 45–55; Ex. 1003 ¶ 89.

Figure 73A of Timm illustrates a portion of a surgical stapler and is reproduced below:

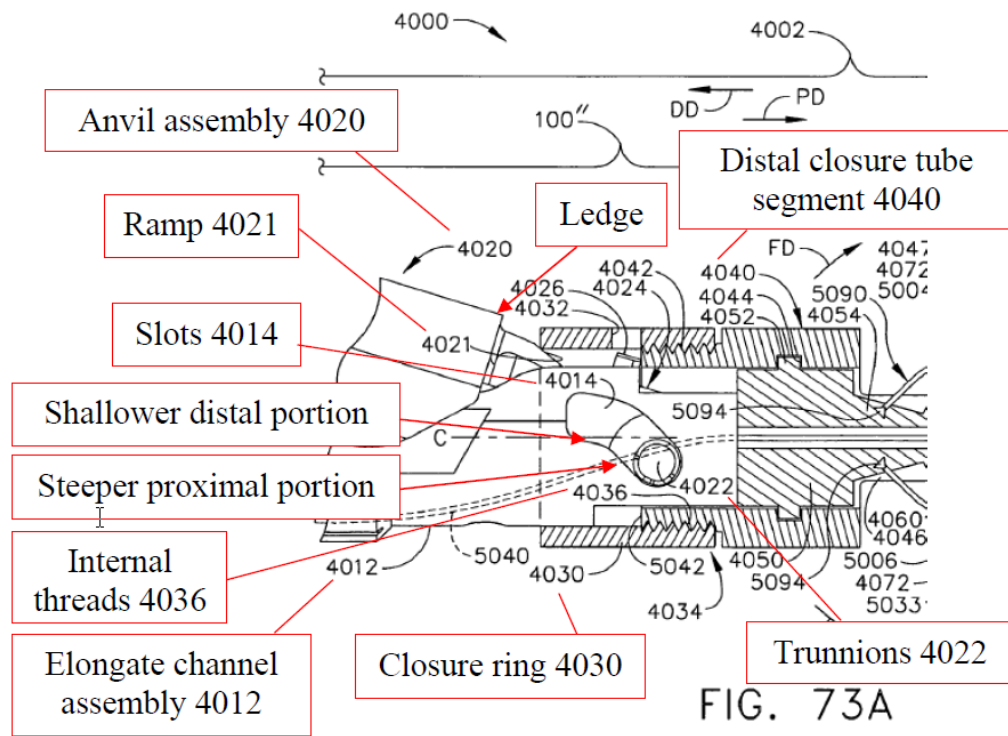


Figure 73A of Timm as annotated by Petitioner showing a partial cross-section of a surgical instrument. Pet. 33.

2. Schulze

Schulze relates to a surgical stapler. Ex. 1007, col. 2, l. 66 – col. 3, l. 6. In one embodiment, the anvil has a rear cam surface and a closure sheath which operates with the cam to close the anvil. Ex. 1007, col. 13, ll. 4–6; col. 14, ll. 38–56. As show in Figure 13 below, Schulze teaches that the cam mechanism is designed with a multiple angel with a steeper proximate portion of the angle [that] allows faster closing of the anvil against the staple cartridge assembly and a “distal or more shallow angle.” Ex. 1007, col. 14, ll. 45–56.

3. Analysis

Petitioner contends that claims 10 and 11 are anticipated by Timm as Tim discloses all of the elements of claims 10 and 11. Pet. 55–68.

Alternatively, Petitioner contends that if all of the elements of claims 10 and 11 are not disclosed by Timm, the missing elements are taught by Timm combined with Viola, Schulze, Anderson or the combination of Anderson, Viola and Schulze. *Id.* at 68–86.

- a) *A surgical tool for use with a robotic system that has a tool drive assembly that is operatively coupled to a control unit of the robotic system that is operable by inputs from an operator, said surgical tool comprising*

Petitioner contends that Timm meets this element as Timm discloses a surgical tool. Pet. 55; Ex. 1006, col. 35, l. 44–col. 41, l. 18; Ex. 1003 ¶ 129. Petitioner contends that, with respect to the remainder of the preamble, the terms are not limiting as the language merely recited an intended use of the surgical tool. Pet. 56.

Alternatively, Petitioner contends that if the requirement for a robotic system is deemed to be a claimed element, Timm combined with Anderson teaches that element. *Id.* at 80–86.

As discussed above, we conclude that the preamble of the claims is not limiting, rather it recites an intended use of the surgical tool. Timm states “[t]he present invention relates in general to endoscopic surgical instruments.” Ex. 1006, col. 1, ll. 8–9. Timm discloses a surgical tool.

- b) *a surgical end effector comprising at least one component portion that is selectively movable between first and second positions relative to at least one other component portion thereof*

Petitioner contends that Timm discloses this element. Pet. 57.
Petitioner contends that Timm discloses a surgical end effector in that Timm

discloses the combination of an anvil and an elongate channel assembly. Pet. 57; Ex. 1006, col. 35, ll. 64–67. Petitioner also contends that Timm discloses that the anvil is selectively moveable between an open and a closed position relative to the elongate channel assembly. Pet. 59; Ex. 1006, col. 35, l. 64 – col. 36, l. 24; Ex. 1003, ¶ 136.

We have considered Petitioner’s argument and the evidence of records and concluded that Timm discloses this element. Timm discloses a surgical stapling instrument which is a type of “surgical end effector.” Ex. 1006, col. 35, l. 36; *see* Ex. 1003 ¶ 132. Timm also teaches that the stapling instrument comprises an anvil and an elongate channel assembly, where the anvil can be moved relative to the elongate channel assembly. Ex. 1006, col. 35, l. 64 – col. 36, l. 24; Ex. 1003, ¶ 136.

c) an elongated shaft assembly operably coupled to said surgical end effector, said elongated shaft assembly comprising

Petitioner contends that Timm discloses this element. Pet. 59. Petitioner contends that the closure ring and distal closure tube segment forms an elongate shaft assembly. Pet. 59; Ex. 1006, col. 36, ll. 3–21; Ex. 1003 ¶¶ 137–138. Petitioner contends that the combination of the closure ring and distal closure tube are operably coupled to the end effector in that the closure ring rides up a ramp at the end of the anvil causing the anvil to pivot to a closed position. Pet. 60; Ex. 1006, col. 35, l. 64 – col. 36, l. 24; Ex. 1003 ¶ 138.

We have considered the argument advanced by Petitioner and conclude, for purposes of this decision, Petitioner has demonstrated that Timm discloses this element. Dr. Fischer has testified that the closure ring and distal closure tube of Timm shown in Figure 73A form an elongated shaft assembly. Ex. 1003 ¶¶ 137–138.

- d) *an axially movable portion in operable communication with said at least one selectively movable component portion of said surgical end effector*

Petitioner contends that Timm discloses this element. Pet. 61.

Petitioner contends that Timm teaches that the closure ring moves axially such that it engages the ramp on the anvil causing the anvil to close. Pet. 62–63; Ex. 1006, col. 36, ll. 16–18; Ex. 1003 ¶ 145.

We have considered Petitioner’s arguments as well as the evidence of record and concluded, for purposes of this decision, that Petitioner has demonstrated that Timm discloses this element.

- e) *a rotatably movable portion in operable engagement with said axially movable portion wherein an initial rotation of said rotatably movable portion causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said first position into an intermediate position at a first rate, wherein a subsequent rotation of said rotatably movable portion in a same direction causes said axially movable portion to move said selectively movable component portion of said surgical end effector from said intermediate position to said second position at a second rate, and wherein said first rate is greater than said second rate.*

Petitioner contend that this element is disclose by Timm or, in the alternative, taught by Timm combined with Viola or Schulze. Pet. 64–86.

(1) *Timm*

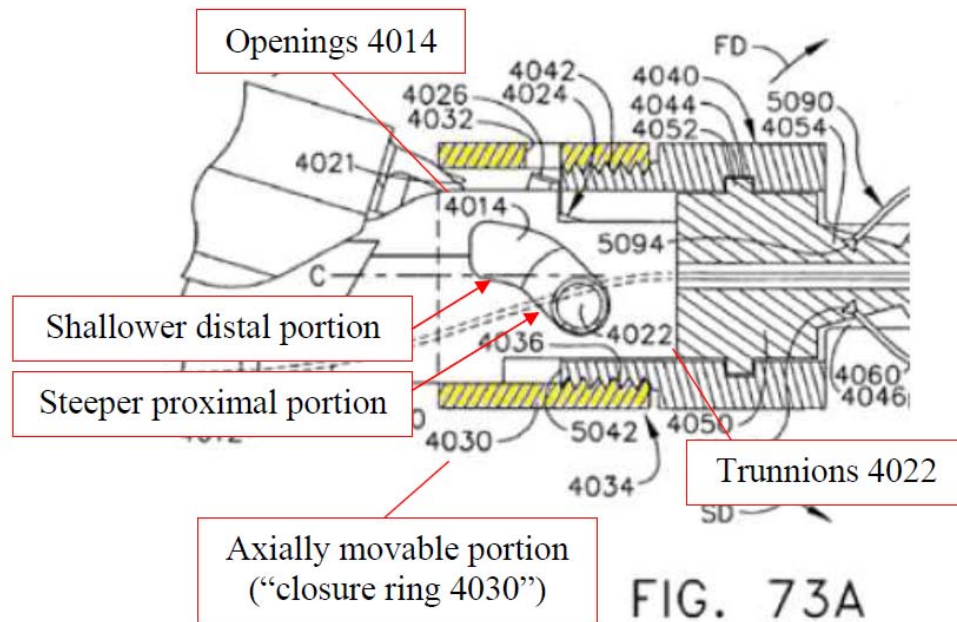
Petitioner contends that distal closure tube of Timm constitutes a rotatably moveable portion. Pet. 65–66. Petitioner contends that Timm teaches that the distal closure tube operates by rotating thus causing the closure ring to move axially. *Id.* at 65–67; Ex. 1006, col. 36, ll. 12–21; Ex. 1003 ¶ 151.

Petitioner contends that as the distal closure tube rotates, the tube causes the closure ring to move axially at a first rate up to an intermediate

position that then at a second rate from the intermediate position to a second position at a second rate. Pet. 65–66; Ex. 1006, col. 36, ll. 12–21, Figs. 73A, 74A, 104–105; *see also Id.*, at col. 25:51–28:40, col. 46:22–39, and Figs. 47–51, 90–91. Petitioner contends that the rate of closure is controlled by the use of trunnions which engage slots having multiple camming angles. Pet 62–63; Ex. 1006, col. 36, ll. 12–21, Figs. 73A, 74A, 104–105; Ex. 1003 ¶ 142; *see also Id.*, at col. 25:51–28:40, col. 46: 22–39, and Figs. 47–51, 90–91. Petitioner contends that the differing camming angles cause the anvil to close at different rates, with the first rate being higher than the second. *Id.*

We have considered the arguments advanced by Petitioner and the evidence of record and conclude that, for purposes of this decision, Petitioner has demonstrated that Timm discloses this element. Timm teaches that the distal closure tube rotates such as to cause the closure ring to move axially thereby causing the anvil to move to the closed position. Ex. 1006, col. 36, ll. 12–21. Timm also discloses that the trunnion and slot arrangement also controls the movement of the anvil. *See* Ex. 1006; col. 35, l. 67 – col. 36, l. 3, and Figure 73A. While the cited portion of Timm does not expressly discuss moving the anvil at two rates, Petitioner’s declarant, Dr. Fischer, testified that the slot groove arrangement described in Timm and shown in Figure 73A below, would operate to cause the anvil to move at two different rates. *See* Ex. 1003 ¶ 170.

Figure 73A illustrates a portion of a surgical stapler and is reproduced below.



A portion of Figure 73A of Timm as annotated by Petitioner showing a cross section of a surgical instrument. Pet. 62.

(2) *Timm Combined with Viola*

Petitioner contends Timm combined with Viola teaches the fourth and fifth elements of claim 10. Petitioner contends that Timm teaches that the distal closure tube and closure ring are in threaded engagement such that the rotation of the closure tube causes the axial movement of the closure ring. Pet. 69–70. Petitioner contends that it would have been obvious to one of ordinary skill in the art to replace the threaded engagement between the closure tube and closure ring with the pin and dual pitch slot arrangement of Viola. Pet. 70. Petitioner contends that this combination would yield the same result – axial movement of the closure ring – and add the feature of having the closure ring move at two different rates. *Id.*

Petitioner contends that one skilled in the art would have been motivated to make the proposed modification in order to expedite the surgical procedure. Pet. 71; Ex. 1005, col. 2, ll. 28–45; col. 3, ll. 10–15; Ex. 1003 ¶ 163. Petitioner contends that one skilled in the art would have had a reasonable expectation of success in that the modification merely involves the application of a known technique with a known system. Pet. 72; Ex. 1003 ¶ 165.

We have considered Petitioner’s arguments and the evidence of record and conclude that, for purpose of this decision, Petitioner has demonstrated a reasonable likelihood that these elements are taught by Timm combined with Viola.

(3) Timm combined with Schulze

Petitioner contends that

If Timm is deemed to not disclose that closure ring moves anvil from the first position into the intermediate position at a first rate, and from the intermediate position to the second position at a second rate, wherein the first rate is greater than the second rate, then it would have been obvious in view of Schulze to modify Timm’s anvil to include a camming surface with multiple angles that performs these claimed functions.

Pet. 78 (reference numerals omitted). Petitioner contends that as shown in Figure 19 below, Schulze teaches a surgical stapler with an anvil that has a cam mechanism on the rear of the anvil which has multiple angles. Pet. 78; Ex. 1007, col. 14, ll. 38–56. Petitioner contends that Schulze teaches that the steeper proximal portion of the cam causes the anvil to close faster than the distal or more shallow angle. Pet. 78–79; Ex. 1007, col. 14, ll. 38–56.

Figure 19 of Schulze illustrates a portion of a surgical stapler and is reproduced below:

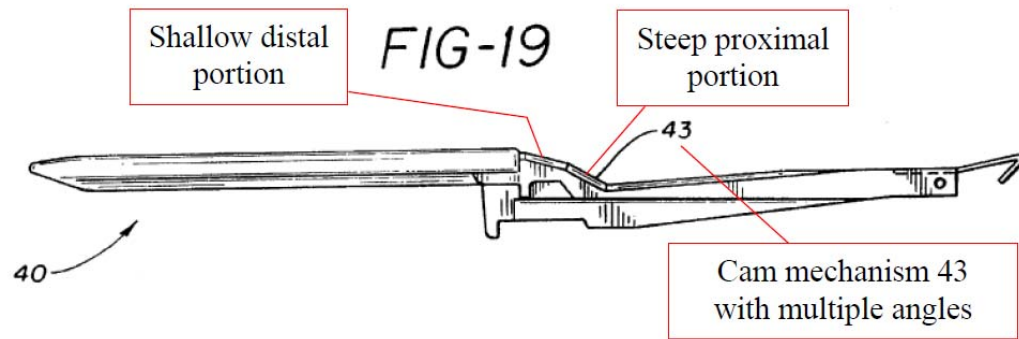


Figure 19 of Schulze as annotated by Petitioner showing a side view of an anvil of the surgical stapler. Pet. 79.

Petitioner contends that one skilled in the art would have been motivated to combine the teachings of Timm and Schulze because Schulze teaches that the “compound angles are specifically designed to give higher mechanical advantage when needed and faster closure and wider opening when needed.” Ex. 1007 col. 14, ll. 38–45; Pet. 79; Ex. 1003 ¶ 178.

We have considered Petitioner’s arguments and the evidence of record and conclude that, for purposes of this decision, Petitioner has demonstrated that claim 10 would have been obvious over Timm combined with Schulze.

f. Claim 11

As discussed above, claim 11 adds an element calling for said rotatably movable portion comprises a closure member in threaded engagement with said axially movable portion. Ex.1001, col. 94, ll. 18–20. Petitioner contends that this element is disclosed by Timm which teaches that the distal closure tube is engaged to the closure ring via threads. Pet. 67–68; Ex. 1003 ¶ 152.

We have considered Petitioner’s arguments and the evidence of record and conclude that, for purposes of this decision, Petitioner has demonstrated that Timm discloses this element. Referring to Figure 73A below, Timm states “a ‘series of internal threads 4036 may be provided in the proximal

end 4034 of the non-rotating closure ring 4030 for threadably receiving a threaded distal end 4042 of a distal closure tube segment 4040.” Cite.

Figure 73A illustrates a portion of a surgical stapler and is reproduced below.

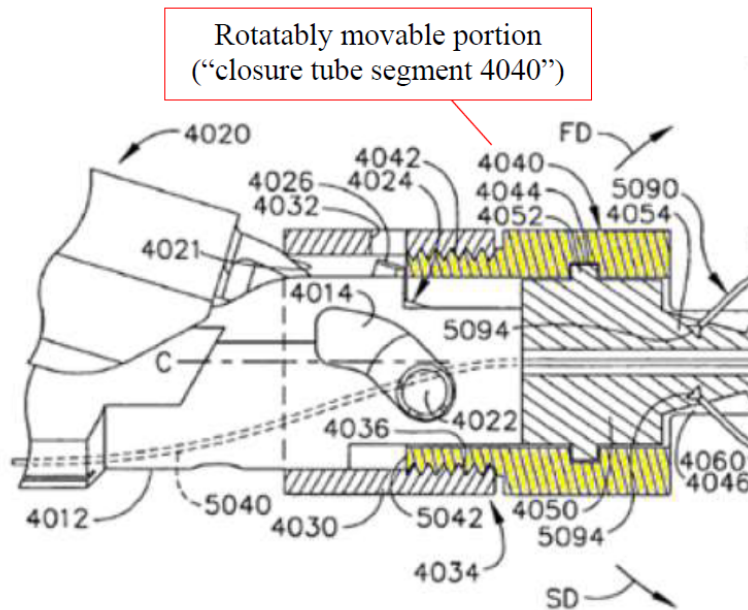


FIG. 73A

A portion of Figure 73A of Timm as annotated by Petitioner showing a cross section of a surgical instrument. Pet. 75.

g. Conclusion

Based upon our review of the current record, we discern no deficiency in Petitioner’s characterization of the cited references and the knowledge in the art, or in Petitioner’s assertions as to the reasonable inferences an ordinary artisan would make from those references. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in establishing the unpatentability of claims 10 and 11 over Timm, either alone or in combination with Viola or Schulze.

IV. CONCLUSION

After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that claims 10 and 11 of the '288 patent are unpatentable. Accordingly, we institute an *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 10 and 11 of the '288 patent on the grounds recited in the Petition; and

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

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
10, 11	102	Heinrich
10, 11	102	Timm
10, 11	103	Timm, Viola
10, 11	103	Timm, Schulze
10, 11	103	Timm, Anderson, Viola, Schulze
10, 11	103	Heinrich, Anderson
10, 11	103	Heinrich, Viola, Anderson

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Patent 8,602,288 B2

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