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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTUITIVE SURGICAL, INC., Petitioner,

v.

ETHICON LLC, Patent Owner.

Case IPR2019-00880 Patent 7,490,749 B2

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

WOOD, Administrative Patent Judge.

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

I. INTRODUCTION

A. Background

Intuitive Surgical, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1 and 3 of U.S. Patent No. 7,490,749 B2 (Ex. 1001, "the '749 patent"). Ethicon LLC ("Patent Owner") did not file a Preliminary Response.

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we authorize an *inter partes* review to be instituted as to all challenged claims of the '749 patent on all grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of the challenged claims. Any final decision will be based on the record as fully developed during trial.

B. Related Proceedings

The parties state that the '749 patent is the subject of Civil Action No. 1:18-cv-01325 filed August 27, 2018 in the U.S. District Court for the District of Delaware. Pet. 1; Paper 5, 2. Petitioner also states that it has filed other petitions for *inter partes* review of patents owned by Patent Owner and asserted against Petitioner in the District of Delaware. *Id*.

C. The '749 Patent

The '749 patent issued February 17, 2009 from an application filed March 28, 2007, and is titled "Surgical Stapling and Cutting Instrument with Manually Retractable Firing Member." Ex. 1001, at codes (45), (22), (54). The '749 patent describes a surgical stapler that applies lines of staples to tissue and cuts the tissue between the staple lines, and particularly to such staplers with manual retraction capabilities. *Id.* at 1:17–24. Figure 1, reproduced below, depicts a surgical stapler according to the '749 patent:



FIG. 1

Figure 1, reproduced above, depicts surgical stapling and severing instrument 10 comprising end effector 12 coupled to elongate shaft assembly 18, which in turn is coupled to handle 20. *Id.* at 5:36–43. End effector 12 comprises anvil 14 pivotally attached to elongate channel 16 to form opposing jaws for clamping tissue. *Id.* at 5:39–41. Closure tube 24 of shaft assembly 18 is coupled between closure trigger 26 and anvil 14. *Id.* at 5:60–

61. Firing rod 32^1 is positioned for longitudinal movement and coupled between anvil 14 and multiple-stroke firing trigger 34. *Id.* at 6:6:-8.

In an endoscopic operation, a surgeon first inserts end effector 12 and shaft assembly 18 in the surgical site and positions the end effector around the tissue to be stapled and severed. The surgeon then depresses closure trigger 26 fully toward pistol grip 36 to move closure tube 24 distally to push anvil 14 pivotally toward elongate channel 16, thereby clamping the tissue between the anvil and elongate channel. *Id.* at 6:19–22, 7:20–23.

The surgeon then fires the instrument. *Id.* at 6:26–30. Figures 7 and 9, reproduced below, depict portions of the instrument's firing mechanism:



Figures 7 and 9, reproduced above, provide left and right views, respectively, of portions of linked transmission firing drive 150. Upper portion 204 of firing trigger 34 engages each of links 196a-d of linked rack 200 (shown more clearly in Figures 8 and 10) during each firing stroke depression, incrementally advancing linked rack 200 distally. *Id.* at 10:19– 43. Because firing rod 32 is attached to linked rack 200, it also advances

¹ The '749 patent also refers to this structure as "firing bar 32." *See, e.g.*, Ex. 1001, 12:11, 56–57.

distally, causing a wedge-shaped sled and cutting blade to simultaneously staple and cut the tissue. *Id.* at 6:26–35, 7:24–8:18.

Instrument 10 also comprises a manual retraction system that allows the surgeon to retract firing rod 32 after the firing operation. The manual retraction system is depicted in Figures 16 and 17, reproduced below:



Figures 16 and 17, reproduced above, depict retraction assembly 500. *Id.* at 12:9–10. First gear 220 meshes with toothed upper surface 222 of linked rack 200. *Id.* at 12:16–18. First gear 220 also engages second gear 230, which is attached to smaller right-side ratchet gear 231. Ratchet gear 231 fits into handle 42 and engages with pawl 516, which is fitted into upper recess 512 of the handle. *Id.* at 12:37–45.

After the firing sequence has been completed, the surgeon can retract firing rod 32 by sequentially depressing and releasing manual retraction lever 42. *Id.* at 12:55–59. When handle 42 is depressed, pawl 516 drives ratchet gear 231, and thus second gear 230, clockwise when viewed from the left. *Id.* at 12:59–64. This drives first gear 220 counterclockwise, which moves linked rack 200 and firing rod 32 longitudinally in the proximal direction until it is fully retracted. *Id.* at 12:64–13:6. Retraction assembly 500 generates a "sole" retraction motion because it is "configured to enable

the surgeon to manually retract firing rod 32 without any other assistance from springs or other retraction arrangements that serve to place a drag on the firing system and which ultimately require the generation of higher firing forces to actuate the firing mechanism." *Id.* at 12:9–15, 16:23–28.

D. The Challenged Claims

Petitioner challenges claims 1 and 3 of the '749 patent. Pet. 1. Claim 1 is independent and claim 3 depends from claim 1. Claim 1 is reproduced below:

1. A surgical instrument, comprising:

a handle assembly;

an end effector for performing a surgical operation, said end effector operably coupled to said handle assembly and operably supporting a firing member that is movable from a retracted position to a fired position in response to a longitudinal firing motion applied thereto;

a firing drive supported by said handle assembly and configured to selectively generate said longitudinal firing motion upon actuation of a firing trigger operably coupled to said handle assembly; and

a retraction assembly supported by said handle assembly and interfacing with said firing drive such that manual actuation of said retraction assembly causes said firing drive to generate a sole retraction motion which is communicated to said firing member to cause said firing member to move from said fired position to said retracted position.

E. Asserted Grounds of Unpatentability

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

No.	Claims	Basis	Reference
1	1 and 3	§ 102/103	Shelton II ²
2	1 and 3	§ 102/103	Swayze ³
3	1 and 3	§ 102	Shelton I ⁴

In support of its proposed grounds, Petitioner relies on the Declaration of Dr. Bryan Knodel (Ex. 1003).

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art at the time of the invention "would have had the equivalent of a Bachelor's degree or higher in mechanical engineering, or a related field directed towards medical mechanical systems, and at least 3 years working experience in research and development for surgical instruments." Pet. 23 (citing Ex. 1003 \P 25). On this record and for purposes of this decision, we adopt Petitioner's definition. Further, we presume that the cited prior art references reflect the level of ordinary skill at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

² U.S. Pat. Publ. No. 2006/0175375 (pub. Aug. 10, 2006) (Ex. 1004).

³ U.S. Pat. Publ. No. 2005/0178813 (pub. Aug. 18, 2005) (Ex. 1005).

⁴ U.S. Pat. No. 8,322,455 (iss. Dec. 4, 2012) (Ex. 1006).

B. Claim Construction

We construe the claims "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), including construing the claim 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." 37 C.F.R. § 42.100(b) (Nov. 2018); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005). Any special definitions for claim terms must be set forth in the Specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner asserts that claim terms "should generally be given their plain and ordinary meaning consistent with the '749 Patent's specification." Pet. 15. Petitioner further asserts that four claim terms require construction under 35 U.S.C. § 112, paragraph 6⁵: "firing member," "retraction assembly," "firing drive," and "closure drive." *Id.* at 15–23. Patent Owner has not filed a Preliminary Response, and therefore has not proposed any constructions for any claim terms, or responded to Petitioner's proposed constructions.

For the purpose of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges, we determine that no express construction is required for any claim term. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that

⁵ Because the '749 patent issued from an application that claims priority to a date before the effective dates of the amendments to the Patent Statute enacted by the Leahy-Smith America Invents Act (AIA), we apply the pre-AIA version of the statute. *See* Leahy-Smith America Invents Act (AIA), Pub. L. No. 112–29, §§ 3(n)(1), 4(e), 125 Stat. 284, 293, 297 (2011).

only terms that are in controversy need to be construed, and "only to the extent necessary to resolve the controversy"); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

C. Ground 1: Claims 1 and 3—Anticipated by or Obvious over Shelton II

Petitioner alleges that claims 1 and 3 are anticipated by or would have been obvious over Shelton II. Pet. 24–50.

1. Shelton II (Ex. 1004)

Shelton II describes a surgical stapling and cutting instrument that may be equipped with a manual retraction mechanism. Ex. 1004 ¶¶ 2, 14. Figure 31 is reproduced below:



FIG. 31

Figure 31, reproduced above, depicts surgical stapling and severing instrument 1010 comprising staple applying apparatus 1012 coupled to elongate shaft 1018, which in turn is attached to handle 1020. *Id.* ¶ 125. Staple applying apparatus 1012 comprises anvil 1014 pivotally attached to

elongate (staple) channel 1016. *Id.* Closure tube 1024 is coupled between closure trigger 1026 and anvil 1014. *Id.* ¶ 1027. Closure trigger 1026 may be depressed against pistol grip 1036 to move closure tube 1024 distally to push anvil 1014 pivotally toward elongate channel 1016. *Id.* ¶¶ 1026–1027. Multiple stroke firing trigger 1034 can then be depressed against the pistol grip, which moves linked rack 1200 distally to transfer a firing force to the staple applying apparatus via firing rod 1032. *Id.* ¶¶ 130, 132, Figs. 33–37.

Figure 31 also depicts manual firing release lever 1042, which is part of a manual retraction mechanism. Figures 42 and 44, reproduced below, depict this mechanism:



Figures 42 and 44, reproduced above, depict manual retraction mechanism 1500. *Id.* ¶ 142. Front idler gear 1220 engages a toothed upper, left surface 1222 of linked rack 1200 (shown in Figure 33). *Id.* Front idler gear 1220 also engages aft transmission gear 1230 having a smaller right-side ratchet gear 1231. *Id.* The smaller right-side ratchet gear 1231 extends into hub 1506 of manual retraction lever 1024. *Id.* ¶ 143. Locking pawl 1516, located in upper recess 1512, is urged downward into engagement with ratchet gear 1231 by L-shaped spring tab 1522. *Id.*; *see also id.*,

Fig. 43. As manual retraction lever 1042 is sequentially raised and lowered, locking pawl 1516 rotates clockwise and engages ratcheting gear 1231, rotating aft transmission gear 1230 clockwise. *Id.* ¶ 144. This causes forward idler gear 1220 to rotate counterclockwise, which retracts linked rack 1200. *Id.* Combination tension/compression spring 1184 also provides a retraction force. *Id.* ¶ 133. Manual retraction mechanism may operate without the assistance of a retraction spring, however. *Id.* ¶¶ 144, 154.

2. Principles of Law

a. <u>Anticipation</u>

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997); *see also Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984) ("Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.").

b. <u>Obviousness</u>

"A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in [35 U.S.C. § 102], if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Obviousness is a question of law based on underlying findings of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The underlying factual considerations "include the scope and

content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations" of non-obviousness, including commercial success of the patented product or method, a long-felt but unmet need for the functionality of the patented invention, and the failure of others who have unsuccessfully attempted to accomplish what the patentee has achieved. *Id.* at 17–18. The obviousness analysis should not be conducted "in a narrow, rigid manner," but should instead focus on whether a claimed invention is merely "the result[] of ordinary innovation," which is not entitled to patent protection. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

3. Discussion

Petitioner asserts that Shelton II discloses all the limitations of independent claim 1. Pet. 24–44. In particular, Petitioner contends that Shelton II discloses: (1) a handle assembly (Pet. 27–28 (citing Ex. 1004 ¶¶ 125–126, Figs. 31–37; Ex. 1003 ¶ 91)); (2) an end effector (Pet. 28–29 (citing Ex. 1004 ¶¶ 76–82, 125–126, Figs. 2–6, 31–33; Ex. 1003 ¶¶ 92–94)); (3) the end effector supporting a firing member (Pet. 29–31 (citing Ex. 1004 ¶¶ 77–80, Figs. 2, 5, 6; Ex. 1003 ¶¶ 95–98)); (4) a firing drive (Pet. 31–35 (citing Ex. 1004 ¶¶ 126, 128, 130–132, 138–142, Figs. 31–37, 39, 40; Ex. 1003 ¶¶ 99–104)); and (5) a manual retraction assembly that causes the firing drive to "generate a sole retraction motion" (Pet. 35–44 (citing Ex. 1004 ¶¶ 142–144, 154, Figs. 33, 35, 40, 42–45; Ex. 1003 ¶¶ 105–112)).

Patent Owner has not yet presented arguments or evidence regarding Petitioner's challenge to independent claim 1. Based on our review of Petitioner's arguments and evidence at this stage of the proceeding, however, we determine that Petitioner has demonstrated a reasonable

likelihood that it would prevail with respect to independent claim 1. Accordingly, Petitioner's arguments and evidence are sufficient for instituting *inter partes* review of all challenged claims on all proposed grounds. *See* Trial Practice Guide Update (July 2019)⁶ at 31 ("The Board will not institute on fewer than all claims or all challenges in a petition.").

D. Remaining Grounds

Petitioner additionally contends that (1) Shelton II anticipates or renders obvious claim 3; (2) Swayze anticipates or renders obvious claims 1 and 3; and (3) Shelton I anticipates claims 1 and 3. Pet. 3. Petitioner sets forth these contentions in detail, and supports them with citations to record evidence and declarant testimony. *Id.* at 44–85.

Having already determined that institution of *inter partes* review of all challenged claims on all grounds is appropriate based on Petitioner's arguments and evidence regarding the anticipation or obviousness of claim 1 over Shelton II, and considering that Patent Owner has not yet presented its arguments and evidence against any of Petitioner's challenges, we determine that further analysis of Petitioner's challenges is best left for trial after full development of the record.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with regard to at least one of the claims challenged in the Petition. Accordingly, we institute *inter partes* review. 35 U.S.C. § 314(a). At this stage of the proceeding, we have

⁶ Available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trial-practice-guide-july-2019-update.

not made a final determination as to the patentability of any challenged claim or any underlying factual or legal issue.

IV. ORDER

For the reasons given, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1 and 3 of U.S. Patent 7,490,749 B2 is instituted on all grounds asserted in the Petition; and

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

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