

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETHICON, INC.,
Petitioner,

v.

ENDOEVOLUTION, LLC,
Patent Owner.

Case IPR2016-00071
Patent 6,923,819 B2

Before ERICA A. FRANKLIN, RICHARD E. RICE, and
JEREMY M. PLENZLER, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Ethicon, Inc. (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1, 2, 6–10, 15–17, 25–31, 40, 46–52, and 59–62 of U.S. Patent No. 6,923,819 B2 (Ex. 1001, “the ’819 patent”). Paper 1 (“Pet.”). EndoEvolution, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

We have jurisdiction 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 and Preliminary Response, we determine that the Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we decline to institute an *inter partes* review of any challenged claim.

A. *Related Proceedings*

Petitioner and Patent Owner have identified no related matters that would affect, or be affected by, a decision in this proceeding. Pet. 57; Paper 5, 2.

B. *The ’819 Patent (Ex. 1001)*

The ’819 patent relates to a suturing device and methods of using the device for suturing tissue. Ex. 1001, 1:12–13. The Specification explains that the suturing device provides greater ease of use and allows better visualization for the user during its operation than prior art devices and methods. *Id.* at 2:44–47. The Specification explains also that the suturing needle is protected by a housing cartridge such that the needle is not exposed

to or handled directly by the user, thereby precluding inadvertent needle sticks. *Id.* at 3:2–5. According to the Specification, “[t]he needle normally resides in a ‘home’ position in its track such that the gap in the arcuate suturing needle is in alignment with the aperture in the cartridge housing.” *Id.* at 4:3–5. The Specification describes the “sharp, pointed end of the needle” as being “situated on one side and entirely within the confines of the housing aperture; the pointed end is, therefore, always shielded by the cartridge housing.” *Id.* at 4:5–9. In this manner, the sharp, pointed end of the needle is “wholly contained within the cartridge and does not protrude and [is not] exposed to the user.” *Id.* at 4:11–13.

C. Illustrative Claims

Independent claims 1 and 40 of the ’819 patent are illustrative and reproduced below:

1. A suturing device comprising:
 - a cartridge having a protective housing and a suturing needle having a pointed end and a blunt end, the suturing needle capable of rotating about an axis, *wherein the pointed end of the suturing needle is positioned within the protective housing after a complete rotation of the suturing needle about the axis;*
 - a pusher assembly comprising a cartridge holder assembly having a needle rotation drive, the cartridge holder assembly capable of releasably engaging the cartridge to bring the needle rotation drive into operational contact with the suturing needle wherein the needle rotation drive releasably engages the suturing needle to rotate the suturing needle; and
 - an actuator capable of engaging the needle rotation drive to rotate the needle rotation drive and the suturing needle.

40. A method for suturing tissue comprising the steps of:
releasably engaging a cartridge to a cartridge holder
assembly of a suturing device;
placing the suturing device having the cartridge with
a protective housing and a suturing needle to cause an
aperture in the cartridge to span a plurality of separated
tissue segments, *wherein a pointed end of the suturing
needle is positioned within the protective housing after
a complete rotation of the suturing needle about a
rotational axis*;
activating an actuator coupled to a needle rotation drive
that releasably engages the suturing needle to cause
rotational movement of the suturing needle across the
aperture and advance the suturing needle through the
plurality of separated tissue segments; and
deactivating the actuator to stop an advancing movement
of the suturing needle to cause a suturing material
attached to the suturing needle to be pulled through the
plurality of separated tissue segments forming a stitch.

Ex. 1001, 16:30–46, 19:61–20:12; (emphasis added to identify dispositive limitations).

D. The Cited References and Declaration

Petitioner relies upon the following references:

Meade	US Patent No. 5,437,681, issued Aug. 1, 1995	Ex. 1004
Beurrier	US Patent No. 5,306,281, issued Apr. 26, 1994	Ex. 1005
Andersson	US Patent No. 4,557,265, issued Dec. 10, 1985	Ex. 1006
Taylor	US Patent No. 5,911,727, issued June 15, 1999	Ex. 1008
Chironis	MECHANISMS, LINKAGES, AND MECHANICAL CONTROL (Nicholas P. Chironis ed., 5 th ed. 1965)	Ex. 1009

Petitioner relies also upon the Declaration of Kevin L. Houser, M.S. (Ex. 1003).

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 2, 6–10, 15–17, 25–31, 40, 46–52, and 59–62 of the ’819 patent on the following grounds (Pet. 1, 14–15):

Claim(s) Challenged	Basis	Reference(s)
1, 2, 6–10, 16, 17, 25–31	§ 102	Meade
1, 2, 6–10, 16, 17, 25–31	§ 103	Meade and Beurrier
15	§ 103	Meade and Chironis
15	§ 103	Meade, Chironis, and Beurrier
40, 51	§ 103	Andersson, Taylor, and Beurrier
40, 51	§ 103	Andersson, Taylor, and Beurrier
40, 46–52, 59–62	§ 102	Meade
40, 46–52, 59–62	§ 103	Meade and Beurrier

The Petitioner explains that grounds directed to the same claims are presented contingent upon whether we adopt a “proposed” or an “alternative” claim construction. Pet. 15–16.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R.

§ 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 890 (mem.) (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Only terms which are in controversy need to 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). For this reason, we construe only the following claim phrase recited by each of the challenged independent claims.

“wherein the pointed end of the suturing needle is positioned within the protected housing after a complete rotation of the suturing needle about the axis”

Petitioner asserts that the broadest reasonable construction of the claim phrase “positioned within the protective housing” is that “the pointed end of the suturing needle ‘*does not project materially outside of the protective housing*’ after a complete rotation.” Pet. 9 (citing Ex. 1003 ¶¶ 48–53). In support of this proposed construction, Petitioner and its declarant, Mr. Houser, rely upon the Specification description that “when the needle 26 is in the ‘home’ position . . . it *does not project materially* into the aperture 56,” and that “[s]uch an alignment causes the needle to reside *entirely* within the needle cartridge.” Pet. 8–9 (citing Ex. 1001, 10:48–50).

Patent Owner disagrees with Petitioner and asserts that the claim phrase “wherein the pointed end of the suturing needle is positioned within the protected housing after a complete rotation of the suturing needle about the axis” means “the sharp, pointed end of the needle does not protrude [from] and is protected by the housing after a complete rotation.” Prelim. Resp. 11. According to Patent Owner, “every portion of the [] ’819 patent that discusses the ‘sharp’ or ‘pointed end’ of the needle indicates that the sharp, pointed end of the needle does not protrude from, and is protected by, the cartridge housing.” *Id.* at 12 (citing Ex. 1001, 4:3–13; 10:50–56; 15:65–67). Patent Owner asserts that Petitioner’s proposed construction relies upon a disclosure of the ’819 patent that does not refer to the “pointed end” of the needle. *Id.* at 13.

We agree with Patent Owner that the Specification does not support Petitioner’s proposed construction. The Specification describes that after advancing through a complete circular arc of about 360°, i.e., “after a complete rotation of the suturing needle about the axis,” the needle comes to rest at its original “home” position within the cartridge holder track. Ex. 1001, 15:63–65. Although the Specification generally states that “when the needle 26 is in the ‘home’ position . . . it does not project materially into the aperture 56,” *id.* at 10:48–50, the Specification is more explicit when describing the position of the pointed end of the needle. In particular, the Specification states that the “*sharp, pointed end* of the needle is situated on one side and *entirely within the confines of the housing aperture*; the *pointed end* is, therefore, always shielded by the cartridge housing” and that the “*sharp pointed end* of the needle is, therefore, *wholly contained within the cartridge* and does not protrude and [is not] exposed to the user.” *Id.* at 4:3–

13 (emphasis added); *see also id.* at 15:65–67 (explaining that in the “home” position, the needle, “including the *sharp, pointed end* 102 remains *entirely contained within the cartridge* 84”) (emphasis added). Based on those descriptions, we find that the Specification explains that “after complete rotation of the suturing needle about the axis,” the pointed end of the suturing needle is positioned “entirely” within the protective housing cartridge. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1320–21 (Fed. Cir. 2005) (en banc) (the specification is “the single best guide to the meaning of a disputed term”); *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1149 (Fed. Cir. 2012) (explaining that any broadest reasonable construction must be consistent with the specification, and claim language should be read in light of the specification).

Accordingly, in view of the Specification, we determine that the broadest reasonable interpretation of the claim phrase “wherein the pointed end of the suturing needle is positioned within the protected housing after a complete rotation of the suturing needle about the axis” is “wherein the pointed end of the suturing needle is positioned *entirely* within the protected housing after a complete rotation of the suturing needle about the axis.”

B. Petitioner’s Presentation of Alternative Grounds

Petitioner explains that “grounds directed to the same claims are only presented contingent upon whether a ‘proposed’ or an ‘alternative’ claim construction for a given claim term is adopted by the Board.” Pet. 15–16. In particular, Petitioner asserts that, “[i]n the event the Board does not accept Petitioner’s construction of ‘*positioned within the protective housing*,’ but concludes instead that this term means ‘*does not project at all outside of the protective housing*,’” i.e., “the pointed end of the suturing needle is

positioned *entirely within* the protective housing,” Petitioner presents grounds addressing that alternative construction. Pet. 9, 14–16. In the table set forth above, those alternative grounds are presented as the second ground for each claim grouping. *Id.*

Accordingly, our analysis proceeds only with respect to those applicable grounds.

C. Obviousness over Meade and Beurrier

Petitioner contends that, in view of our construction of the claim phrase “positioned within the protective housing,” claims 1, 2, 6–10, 16, 17, 25–31, 40, 46–52, and 59–62 would have been obvious over the combination of Meade and Beurrier. Pet. 35–38, 55–56. Patent Owner disagrees. Prelim. Resp. 27–32.

1. Meade

Meade discloses a suturing instrument that maintains positive control over the suturing needle and thread during the suturing process. Ex. 1004, 1:5–8. The two inventors of Meade are also included among the inventors listed for the ’819 patent. The ’819 patent addresses Meade in the “Background of the Invention” section and describes its limitations with respect to “efficient operability.” Ex. 1001, 2:11–39. Meade describes its suturing instrument as having a disposable needle cartridge releasably mounted to its distal end. Ex. 1004, 2:51–53. The cartridge housing is comparable to the width of the gap in the needle so that when the needle is positioned at a home position, “it does not project materially into the aperture 28, i.e., it may project slightly.” *Id.* at 5:30–34.

2. Beurrier

Beurrier discloses a suturing cassette device comprising a driving mechanism and a cassette, wherein the cassette provides a housing containing a mechanism for guiding and driving an arcuate suturing needle through a 360° suturing rotation. Ex. 1005, 3:27–32. Beurrier describes an embodiment of the invention comprising a knob drive attachment fitted with a pin that engages a slot located on the backside of the cassette. *Id.* at 5:38–40, 56–57. The slot defines an arc slightly less than about 180° and therefore restricts rotation of the knob to just less than one-half of a revolution. *Id.* at 5:57–60. Beurrier explains that by restricting the needle from making a complete revolution, the point of the needle is “safely protected in cassette 101 avoiding injury or the spread of infection to a user of the device.” *Id.* at 5:64–68.

3. Analysis

A conclusion that the claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Obviousness grounds must be supported with “articulated reasoning with some underpinning” and not by “mere conclusory statements.” *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S 398, 418 (2007).

Petitioner asserts that Meade discloses each limitation of claims 1, 2, 6–10, 16, 17, 25–31, 40, 46–52, and 59–62, except for “the pointed end of the suturing needle being positioned entirely within the protective housing after a complete rotation of the suturing needle about the axis.” Pet. 18, 37,

50, 56. For that requirement, Petitioner relies on Beurrier’s teaching that the point of the needle in its suturing device is safely protected in the cassette, avoiding injury or the spread of infection to a user of the device. Pet. 35 (citing Ex. 1003 ¶¶ 83–87). According to Petitioner, a person of ordinary skill in the art would have been motivated to combine the teachings of Meade and Beurrier because each reference discloses a suturing device with common features, such as an arcuate suturing needle that rotates about an axis, and a housing that coincides with the aperture in the suturing needle. *Id.* at 36. In particular, Petitioner asserts that “[b]oth Meade and Beurrier also recognize that accidental needle pricks increase the risk of infection during surgery and both references disclose designs that minimize this risk.” *Id.*

In particular, Petitioner asserts that “[a] person of ordinary skill in the art would have been motivated to modify the ‘home position’ of Meade so that the pointed end of the needle did not protrude *at all* outside the cartridge after a complete rotation.” *Id.* at 37. In support of that assertion, Petitioner cites the Declaration of Mr. Houser. *Id.* (citing Ex. 1003 ¶ 111). Petitioner asserts further that its proposed modification “would have included, for example, shortening the arcuate extent of the needle, or extending the arcuate extent of the needle cartridge.” *Id.*

Patent Owner asserts a number of reasons why Petitioner has not established that a person of skill in the art would have found it obvious to modify Meade so that the pointed end of the suturing needle is positioned entirely within the protective housing after a complete rotation of the suturing needle about a rotational axis. Prelim. Resp. 27–32. In particular, Patent Owner asserts that Petitioner’s reliance upon the Declaration of Mr.

Houser for its proposed modification of Meade is insufficient because Mr. Houser “merely speculates” as to possible modifications without demonstrating that the proposed modifications would have been obvious to a person of ordinary skill in the art. *Id.* at 28–29.

We agree with Patent Owner. At best, Petitioner has established that Beurrier recognized a potential problem of inadvertent needle pricks when using a suturing device comprising a needle and provided a solution for that problem. However, Petitioner’s proposed modification to Meade does not implement Beurrier’s solution, i.e., including a knob drive attachment fitted with a pin that engages a slot located on the backside of the cassette (which prevents the needle from making a complete revolution and thus keeps the needle safely protected in the cassette). Pet. 37; Ex. 1005, 5:38–40, 56–57. Moreover, implementing Beurrier’s solution on Meade’s device would not yield the invention of the ’819 patent, as Beurrier’s approach restricts the needle from making a *complete rotation*. Ex. 1005, 5:57–60.¹

Petitioner instead proposes a modification to Meade that is not taught by a cited reference, i.e., shortening the arcuate extent of the needle or lengthening the arcuate extent of the cartridge’s protective housing. Pet. 37. In support of that proposed modification, Petitioner relies on the declaration

¹ Further, we note that during the prosecution of the application that issued as the ’819 patent, the Examiner determined that the claim amendment adding the phrase “wherein the pointed end of the suturing needle is positioned within the protective housing after a complete rotation of the suturing needle about the axis” overcame Beurrier. Ex. 1002, Prosecution History of US Application No. 10/127,254, by Meade et al., published on Apr. 22, 2002, 210 (Interview Summary) and 275 (Amendment); Prelim. Resp. 31–32.

of Mr. Houser. *Id.* (citing Ex. 1003 ¶ 111). Mr. Houser’s opinion on this matter, however, amounts to a conclusory statement, unsupported by any fact. *See Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48763 (Aug. 14, 2012) (a declaration expressing an opinion of an expert without disclosing underlying facts may be given no weight). Indeed, Mr. Houser does not assert or establish that his proposed modification to Meade’s device would have been, for example, a predictable variation to a skilled artisan, *see KSR*, 550 U.S. at 417 (“If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.”), or implemented with a reasonable expectation of success, *see In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (obviousness requires a reasonable expectation of success).

Thus, Petitioner has not established persuasively that a person of ordinary skill in the art would have found it obvious to modify Meade by shortening the arcuate extent of the needle or lengthening the arcuate extent of the cartridge’s protective housing to ensure that the pointed end of the needle does not project at all outside of the protective housing.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that that it would prevail in showing the unpatentability of claims 1, 2, 6–10, 16, 17, 25–31, 40, 46–52, and 59–62 over Meade and Beurrier.

D. Obviousness over Meade, Chironis, and Beurrier

Petitioner contends that, in view of our construction of the claim phrase “positioned within the protective housing,” claim 15 would have been obvious over the combination of Meade, Chironis, and Beurrier. Pet. 41. Patent Owner disagrees. Prelim. Resp. 32.

1. *Chironis*

Chironis is a book characterized as “a compilation of classical and modern mechanisms and devices for providing a wide variety of motions and functions.” Ex. 1009, Preface. In particular, Chironis describes “practical devices for locating or holding mechanical movements,” including one wherein automatic release occurs in one direction, and manual release is needed in the other direction. *Id.* at 150–151, Figure 12.

2. *Analysis*

Claim 15 recites, “[t]he suturing device of claim 1 wherein the cartridge holder assembly further comprises at least one mounting clip whereby the cartridge holder assembly releasably engages the cartridge having the suturing needle.” Ex. 1001, 17:52–55. Petitioner asserts that Meade’s suturing device includes a cartridge holder assembly comprising a spring button mounted in the barrel “adapted to engage in a dimple formed in the housing 22 of cartridge 14.” Pet. 38–39, 41. According to Petitioner, a person of ordinary skill would have found it obvious to replace the fixing mechanism of Meade with another suitable mechanism, such as the mounting-clip-slot mechanism disclosed by Chironis. *Id.* at 39, 41.

Petitioner relies on Beurrier and Dr. Houser’s declaration to modify Meade’s device so that the pointed end of the needle does not protrude at all outside of the protective housing after a complete rotation, in the same manner discussed, *supra*, regarding Petitioner’s proposed combination of Meade and Beurrier. *Id.* at 41 (citing Ex. 1005, 5:66–68; Ex. 1003 ¶¶ 107–111).

Consequently, for the same reasons discussed regarding the proposed combination of Meade and Beurrier, we agree with Patent Owner that

Petitioner has not established persuasively that a person of ordinary skill in the art would have found it obvious to modify Meade by shortening the arcuate extent of the needle or lengthening the arcuate extent of the cartridge's protective housing to ensure that the pointed end of the needle does not project at all outside of the protective housing.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that that it would prevail in showing the unpatentability of claim 15 over a combination of Meade, Chironis and Beurrier.

E. Obviousness over Andersson, Taylor, and Beurrier

Petitioner contends that, in view of our construction of the claim phrase “positioned within the protective housing,” method claims 40 and 51 would have been obvious over the combination of Andersson, Taylor, and Beurrier. Pet. 50. Patent Owner disagrees. Prelim. Resp. 32–41.

1. Andersson

Andersson discloses a suturing instrument for joining together two edges of biological tissue. Ex. 1006, 1:4–5. Andersson's suturing instrument comprises a housing for a movably-arranged arcuate suturing needle having a sharp point, a suture thread, and a drive means for moving the needle. *Id.* at 1:4–10.

2. Taylor

Taylor discloses an automated stitching or suturing device having an arcuate suturing needle that is positively driven in a circular path to suture tissues. Ex. 1008, 1:53–56. Taylor explains that the distal portion of the stitcher may comprise a removable and disposable cartridge containing at least a needle and attached thread. *Id.* at 7:37–40.

3. *Analysis*

Independent claims 40 and 51 recite methods for suturing tissue using a suturing device “wherein a pointed end of the suturing needle is positioned within the protective housing after a complete rotation of the suturing needle about a rotational axis.” Ex. 1001, 19:67–20:3, 21:11–14. Petitioner asserts that the combination of Andersson and Taylor teaches each limitation of claims 40 and 51, except for the pointed end of the suturing needle being positioned entirely within the protective housing. Pet. 44–50. Petitioner relies on Beurrier and Dr. Houser’s Declaration to modify the combination of Andersson and Taylor so that the pointed end of the needle does not protrude at all outside of the protective housing after a complete rotation, in the same manner discussed, *supra*, with respect to the other challenged claims. *Id.* at 50 (citing Ex. 1003 ¶ 117) (Dr. Houser opining that “modifications may include, for instance, shortening the arcuate extent of the needle or lengthening the arcuate extent of the cartridge’s protective housing”).

Consequently, for the same reasons discussed regarding the other challenged claims, we agree with Patent Owner that Petitioner has not established persuasively that a person of ordinary skill in the art would have found it obvious to modify the combination of Andersson and Taylor by shortening the arcuate extent of the needle or lengthening the arcuate extent of the cartridge’s protective housing to ensure that the pointed end of the needle does not project at all outside of the protective housing.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that it would prevail in showing the unpatentability of claims 40 and 51 over a combination of Andersson, Taylor, and Beurrier.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition does not establish that there is a reasonable likelihood that Petitioner would prevail in showing that any of the challenged claims are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*.

FOR PETITIONER:

Dianne B. Elderkin
Ruben H. Munoz
Akin Gump Strauss Hauer & Feld LLP
delderkin@akingump.com
rmunoz@akingump.com

FOR PATENT OWNER:

Dorothy P. Whelan
Michael J. Kane
Patrick J. Bisenius
Brian R. Pollack
Fish & Richardson P.C.
IPR42638-0002IP1@fr.com
PTABInbound@fr.com
bpollack@daypitney.com