

Paper No. ____
Date Filed: Oct. 22, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETHICON, INC.

Petitioner

v.

ENDOEVOLUTION, LLC

Patent Owner

Case IPR: Unassigned

Patent No. 6,923,819

Title: Apparatus and Method for Surgical
Suturing with Thread Management

**PETITION FOR *INTER PARTES* REVIEW OF
UNITED STATES PATENT NO. 6,923,819**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	SUMMARY OF THE '819 PATENT	2
	A. The '819 Patent	2
	B. Prosecution History of the '819 Patent	3
	C. The Purported Improvements of the '819 Patent Over the Prior Art	4
	D. The Challenged Claims of the '819 Patent	5
III.	CLAIM CONSTRUCTION	6
	A. Level of Ordinary Skill in the Art	6
	B. Terms to be Construed Under 37 C.F.R. § 42.100(b)	6
	1. “positioned within the protective housing” (all Challenged Claims)	7
	2. “deactivating the actuator . . . to cause” (claims 40 and 51)	9
	3. “cartridge holder assembly” (all Challenged Claims)	13
IV.	CHALLENGE UNDER § 42.104(b) AND RELIEF REQUESTED	13
V.	NO REDUNDANCY	15
VI.	EACH CHALLENGED CLAIM OF THE '819 PATENT IS UNPATENTABLE	16
	A. The Prior Art References	16
	B. Detailed Explanation of Grounds of Unpatentability	17
	1. Ground 1: Meade Anticipates Claims 1, 2, 6-10, 16, 17, and 25-31	17
	2. Ground 2: Under an Alternative Construction of the Term “ <i>positioned within the protective housing</i> ,” Meade in View of Beurrier Renders Obvious Claims 1, 2, 6-10, 16, 17, and 25-31	35
	3. Ground 3: Meade in View of Chironis Renders Obvious Claim 15	38
	4. Ground 4: Under an Alternative Construction of the Term “ <i>positioned within the protective housing</i> ,” Meade in View of Chironis in View of Beurrier Renders Obvious Claim 15	41
	5. Ground 5: Andersson in View of Taylor in View of Beurrier Renders Obvious Claims 40 and 51	41
	6. Ground 6: Under an Alternative Construction of the Term “ <i>positioned within the protective housing</i> ,” Andersson in View of Taylor in View of Beurrier Renders Obvious Claims 40 and 51	50

7.	Ground 7: Under an Alternative Construction of the Term “deactivating the actuator . . . to cause,” Meade Anticipates Claims 40, 46-52, and 59-62	50
8.	Ground 8: Under Alternative Constructions of the Terms “positioned within the protective housing” and “deactivating the actuator . . . to cause,” Meade in View of Beurrier Renders Obvious Claims 40, 46-52, and 59-62	55
VII.	SECONDARY CONSIDERATIONS	56
VIII.	MANDATORY NOTICES UNDER 37 C.F.R § 42.8(a)(1).....	57
	A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1).....	57
	B. Related Matters Under 37 C.F.R. § 42.8(b)(2).....	57
	C. Lead and Back-Up Counsel and Service Information	57
IX.	GROUNDS FOR STANDING UNDER § 42.104(a)	58
X.	PAYMENT OF FEES – 37 C.F.R. § 42.103.....	58
XI.	CONCLUSION.....	58

LIST OF EXHIBITS

Exhibit No.	Description
Ex. 1001	U.S. Patent Number 6,168,819 (the “’819 Patent”)
Ex. 1002	Excerpts from the Prosecution History of Application No. 10/127,254 (the “’254 Application”) that led to the ’819 Patent
Ex. 1003	Declaration of Kevin L. Houser, M.S.
Ex. 1004	U.S. Patent Number 5,437,681 (“Meade”)
Ex. 1005	U.S. Patent Number 5,306,281 (“Beurrier”)
Ex. 1006	U.S. Patent Number 4,557,265 (“Andersson”)
Ex. 1007	U.S. Patent Number 6,053,908 (“Crainich”)
Ex. 1008	U.S. Patent Number 5,911,727 (“Taylor”)
Ex. 1009	Mechanisms, Linkages, and Mechanical Control, Nicholas P. Chironis, Ed. (1965) (“Chironis”)
Ex. 1010	Webster’s New Universal Unabridged Dictionary, 1972

Petitioner Ethicon, Inc. respectfully requests *inter partes* review (“IPR”) of claims 1, 2, 6-10, 15-17, 25-31, 40, 46-52, and 59-62 (the “Challenged Claims”) of U.S. Patent No. 6,923,819 (the “’819 Patent”) (**Ex. 1001**), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*

I. INTRODUCTION

The Challenged Claims of the ’819 Patent are directed to a suturing device that was disclosed more than two decades ago in U.S. Patent No. 5,437,681 (**Ex. 1004**, “Meade”). Although cited on the face of the ’819 Patent—and in fact discussed in its background section—Meade was never substantively considered during prosecution of the ’819 Patent. As explained in this petition, Meade anticipates the vast majority of the Challenged Claims and renders obvious the remaining ones. The fact that the Challenged Claims are identically disclosed in Meade is not surprising considering that both patents share common inventors and were both originally assigned to the same company (SuturTek Inc.). Undoubtedly, had Meade been considered during prosecution of the ’819 Patent, the Challenged Claims would have never been issued. Their existence amounts to an impermissible extension of exclusionary rights that should have ended on January 13, 2014—the day that Meade expired. Petitioner submits that this petition establishes by a preponderance of the evidence that the Challenged Claims are unpatentable and respectfully requests a ruling from the Board to that effect.

II. SUMMARY OF THE '819 PATENT

A. The '819 Patent

The '819 Patent discloses “an apparatus and a method for surgical suturing.”

Ex. 1001, Abstract. As will be explained in detail below, the Challenged Claims generally recite a suturing device and a method of suturing tissue. The claimed *suturing device (1)* of the '819 Patent generally comprises an *actuator* (trigger, 16), a *cartridge holder assembly (20)* that holds a disposable *needle cartridge (24)*,

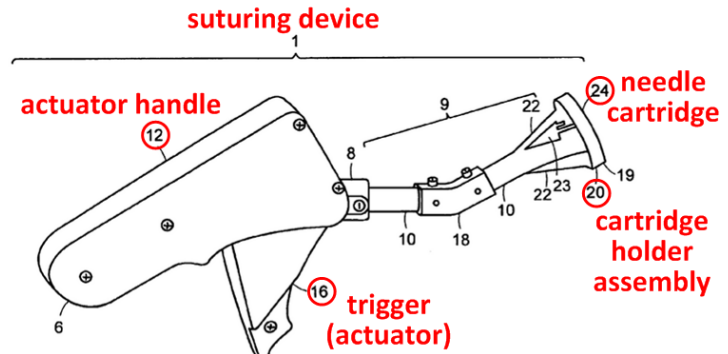


FIG. 1

an arcuate (e.g., curved) **suturing needle (26)** (contained in cartridge (24)), and a **needle rotation drive** through which motion is transferred from the trigger to the needle to cause it to rotate. *See* **Ex. 1001**, independent claims 1 (apparatus), 40 (method), and 51 (method); *see also id.*, 3:9-15 (explaining that by actuating trigger (16) in the actuator handle (12), a user can apply “a torquing force to the suturing needle to cause the needle to advance through tissue during a suturing process . . .”); *see also* **Ex. 1003**, ¶¶ 17-19. The ’819 Patent further explains that “[t]he rotatory movement of the needle within the needle cartridge is accomplished by a needle driver that may be operated by the user by holding the suturing device with one hand in a pistol-like grip around the handle, and using at least one finger of

that hand to activate a triggering lever.” *Id.*, 4:42-46. Furthermore, “[a] continued rotatory movement of the needle causes it to return it to its original ‘home’ position, and thereby causes the suturing thread attached to the needle to be pulled into and through the tissue” *Id.*, 4:24-29. According to the ’819 Patent, “the suture follows the curved path of the needle to bind the tissues together with a stitch of thread across the incision in a manner identical to that of a surgeon suturing manually, wherein the needle is ‘pushed’ from the tail and then ‘pulled’ from the point by the drive mechanism.” *Id.*, 4:30-34.

As explained in detail below, none of these components (or their combination) were new at the time of the alleged invention. Nearly six years before the earliest priority date of the ’819 Patent, the same lead inventor and assignee of the ’819 Patent had obtained U.S. Patent No. 5,437,681 (**Ex. 1004**, “Meade”). Meade, which was not substantively considered during prosecution, disclosed these elements in the same combination.

B. Prosecution History of the ’819 Patent

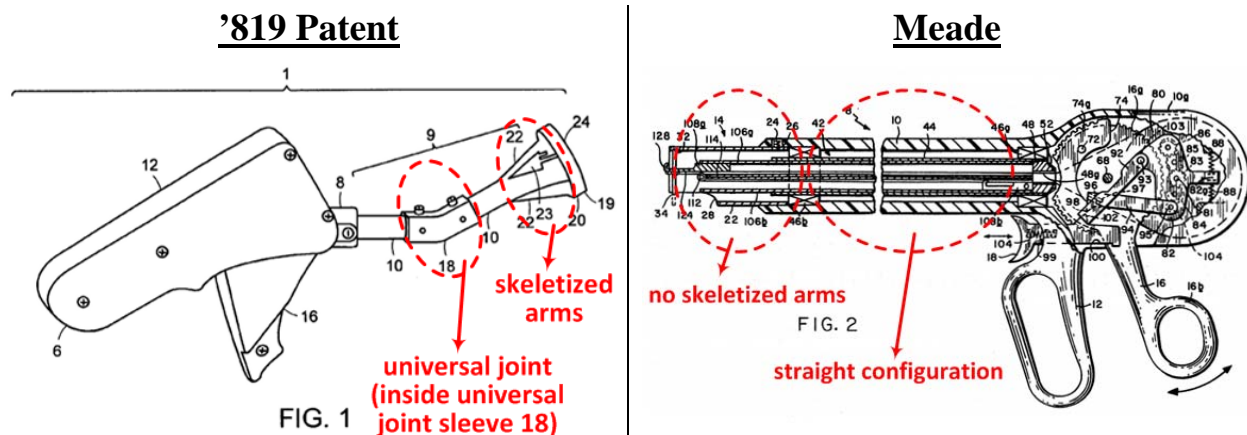
The ’819 Patent issued from Application No. 10/127,254 (the “’254 Application”), which was filed on April 22, 2002 and claims priority to a provisional application (No. 60/298,281) filed on June 14, 2001. **Ex. 1001**, Cover Sheet. Of the prior art references presented in this petition, only Beurrier (**Ex. 1005**) was addressed during prosecution, but neither its disclosure nor the reasons why it was

introduced by the examiner were described in the prosecution history. **Ex. 1002**, 210, 244-246, 276-278. Importantly, however, Beurrier was never considered during prosecution in the obviousness combinations presented in this petition. *Id.*

C. The Purported Improvements of the '819 Patent Over the Prior Art

According to the '819 patent, the suturing devices of the prior art, including Meade, suffered from three shortcomings: 1) “difficult[y] to manipulate and control” the device because “the rotational direction of the needle and the drive shaft is in a direction that is perpendicular to the device actuating handles[;]” 2) difficulty in “view[ing] the needle and its progress through the tissue during the suturing operation” because “the barrel containing the drive shaft leading to the needle cartridge does not have an open construction[;]” and 3) difficulty in obtaining “uniform needle rotation, tissue penetration and suture advancement . . .” **Ex. 1001**, 2:20-39. To address these purported shortcomings of Meade and other prior art, the '819 Patent discloses a surgical device configured with universal joints and a plurality of support arms. *See e.g., id.*, 7:41-52. According to the '819 Patent, the “minimalized structural design of the support arms enables the user to have a clear, unobstructed view of the suturing needle as it advances through the tissue segments during the course of a suturing operation, thereby enabling precise placement of the suturing device to provide uniform sutures” *Id.*, 4:63-5:1. According to the '819 Patent, some of the shortcomings of Meade are attributable to

what the '819 Patent describes as a design having “a linear drive shaft encased in a barrel,” and that is what the '819 patent purportedly improves upon through the use of universal joints and “skeletalized” support arms. *Id.*, 2:16-17, 4:61-5:3, 7:41-52, 8:62-9:6; *see also* **Ex. 1003**, ¶¶ 69-72.



D. The Challenged Claims of the '819 Patent

Although the universal joints and support arms of the '819 Patent are elements of some of the '819 Patent claims, this petition is *not* directed to those claims. Nor is this petition focused on whether the incorporation of universal joints and/or support arms is a novel or nonobvious improvement over Meade. Instead, this petition challenges the patentability of the '819 Patent claims that do not recite universal joints or support arms—that is, claims that essentially attempt to claim embodiments that were either explicitly disclosed in Meade or are obvious variations of the embodiments disclosed in Meade. The claim charts and explanations in Section VI.B. describe in detail how numerous elements of the Challenged Claims are disclosed by Meade and how the Challenged Claims are anticipated by,

and/or rendered obvious in view of, the prior art.

III. CLAIM CONSTRUCTION

A. Level of Ordinary Skill in the Art

Claim terms are given their ordinary and customary meaning as understood by one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). With regards to the '819 Patent, a person of ordinary skill in the art at the time of the alleged invention would have had a bachelor's degree in mechanical engineering or a related engineering discipline and at least four years of industry experience in the design of surgical devices, or equivalent experience, education, or both. *See Ex. 1003*, ¶¶ 43-46.

B. Terms to be Construed Under 37 C.F.R. § 42.100(b)

Each term of a claim of an unexpired patent subject to IPR is given its “broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b). Accordingly, for purposes of this proceeding only, Petitioner submits constructions under the broadest reasonable interpretation (“BRI”) for the following terms, and submits that all remaining terms should be given their ordinary and customary meaning.¹

¹ These claim constructions are not, and should not be viewed as, a concession by Petitioner as to the proper scope of any claim term in any litigation. For example, these proposed constructions are not a waiver of any argument in any litigation that

1. “positioned within the protective housing” (all Challenged Claims)

Independent claims 1, 40, and 51 of the '819 Patent recite “a cartridge” having “a protective housing and a suturing needle. . . , wherein” the “pointed end of the suturing needle is *positioned within the protective housing* after a complete rotation of the suturing needle”² The applicant added this claim limitation (among others) during the prosecution of the '254 Application in an attempt to overcome obviousness rejections in light of the prior art. **Ex. 1002**, 200-08, 223-45, 255-77;³ *see also id.*, 210 (summarizing amendments discussed between applicant and examiner after an in-person interview during prosecution).

According to the '819 Patent “when the needle 26 is in the ‘home’ position (as shown in FIG. 7A) it *does not project materially into the aperture 56.*” **Ex. 1001**, 10:48-50. The '819 Patent further explains that this is desirable because “[s]uch an alignment causes the needle to reside *entirely* within the cartridge holder 20, thereby preventing inadvertent contact of the sharp pointed end 60 with the user's fingers during handling” *Id.*, 10:50-

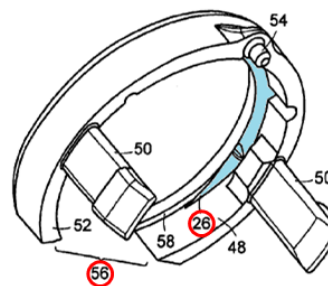


FIG. 7A

claim terms in the '819 Patent fail to meet the requirements of 35 U.S.C. § 112.

² All emphases in this petition are added unless otherwise noted.

³ Claims 1, 40, and 51 correspond to original claims 1, 37, and 45, respectively.

See Ex. 1002, 321.

53. During prosecution of the '254 Application, the applicant pointed to precisely this language in the specification of the '819 Patent in support of the claim amendment reciting that the pointed end of the suturing needle is “*positioned within the protective housing* after a complete rotation.” **Ex. 1002**, 244-45, 276-77.

For additional support, the applicant pointed to the portion of the specification that explains that “[s]uch protection of the needle 26 in the suturing device . . . prevents accidental ‘needle-pricks’ from occurring, thereby substantially reducing the risk of infection caused by pathogenic bacteria or viruses that may contaminate the needle during or after its use prior to its disposal.” *Id.* (citing to current **Ex. 1001**, 10:56-61). The applicant further supported its amendment by pointing to a portion of the specification that describes another embodiment of the claimed suturing device. *See Ex. 1002*, 244-45, 276-77 (citing to current **Ex. 1001**, 15:63-67). In this regard, the '819 Patent explains that, after a complete rotation, “[t]he needle 102 comes to rest at its original ‘home’ position . . . ” and that “[t]he needle 102 including the sharp, pointed end 102 [sic, 108] remains entirely contained within the cartridge 84.”). *Id.*

The intrinsic evidence discussed above makes clear that after a complete rotation, the needle is at its “home” position. Furthermore, according to the '819 Patent, when the needle is in its “home” position, “it *does not project materially* into the [cartridge housing] aperture 56” and “[s]uch an alignment causes the needle to

reside *entirely* within the needle cartridge.” **Ex. 1001**, 10:48-53. Thus, under the BRI, the term “*positioned within the protective housing*” means that the pointed end of the suturing needle “*does not project materially outside of the protective housing*” after a complete rotation. **Ex. 1003**, ¶¶ 48-53. This construction comports with the broadest reasonable breath of the term as described in the specification.

In the event that 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*,” then Petitioner also presents grounds of unpatentability addressing this alternative construction. In Petitioner’s view, however, this alternative construction is unduly narrow and contradicts the intrinsic evidence. **Ex. 1003**, ¶ 54.

2. “deactivating the actuator . . . to cause” (claims 40 and 51)

Claims 40 and 51 of the ’819 Patent recite “*deactivating the actuator . . . to cause*.” A comparison of the recited language in these claims is shown in the table below, with the differences in claim language underlined.

Claim 40 language	Claim 51 language
“ <i>deactivating the actuator</i> <u>to stop an</u> advancing movement of the suturing	“ <i>deactivating the actuator</i> <u>at the completion of</u> advancing movement of the

Claim 40 language	Claim 51 language
needle to cause a suturing material attached to the suturing needle to be pulled through the <u>plurality of separated tissue segments forming a stitch.</u>	suturing needle to cause a suturing material attached to the suturing needle to be pulled through the tissue <u>of the wound or incision site.</u>

The '819 Patent nowhere describes “**deactivating**” the device’s actuator “**to cause**” any type of resulting action, as recited in claims 40 and 51. The '819 Patent only describes the manner in which to **activate** an actuator (e.g., a triggering lever) to cause the rotary movement of the needle. *See id.*, 4:42-46 (explaining that “the rotatory movement of the needle within the needle cartridge is accomplished by a needle driver that may be operated by the user by holding the suturing device with one hand in a pistol-like grip around the handle, and using at least one finger of that hand to **activate** a triggering lever.”). To a person of ordinary skill in the art, the word “deactivating” a device’s actuator means the opposite of “activating” it—that is, “returning” or “resetting” the device’s actuator. *See Ex. 1003*, ¶¶ 55-58. The word “deactivating” in the above claim term, therefore, should be construed as simply “returning” or “resetting” the actuator. *Id.*

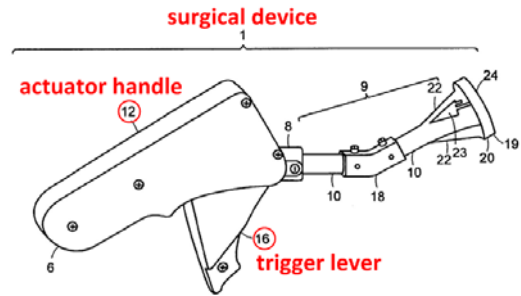


FIG. 1

The plain reading of the claim requires that the term “to cause” qualify the action “deactivating the actuator.” The ’819 Patent uses the phrase “*to cause*” twice in the specification. *See, Ex. 1001*, 3:11-15 (stating that “[t]he present invention . . . provides an actuating means and a shaft and drive assembly that provides a torquing force to the suturing needle *to cause* the needle to advance through tissue during a suturing process”); *id.*, 4:47-52 (referring to “a finger operated trigger lever . . . , which when actuated, operates a driveshaft . . . through a drive mechanism so as *to cause* the drive shaft to undergo a rotatory motion”). In each instance, the ’819 Patent uses the phrase “to cause” to describe a first action, which may be carried out by the user, that results in a direct second action by the suturing device—without any further intermediate action by the user.

Although the phrase “*deactivating the actuator . . . to cause*” is not explicitly used in the specification, it should be interpreted in a manner that is consistent with the teachings of the ’819 Patent which describe the term “*to cause*” as linking a user action with a direct action by the device without any further intermediate steps by the user. This understanding of the term “*to cause*” also comports with the extrinsic evidence. In this regard, Webster’s New Unabridged Dictionary defines “cause” to mean to “bring about,” “make happen,” “effect,” “induce,” or “produce.” *Ex. 1010*, p. 288. Thus, under the BRI, “*deactivating the actuator . . .*

to cause” means “*returning or resetting the actuator . . . to produce.*” Ex. 1003, ¶¶ 55-60.

Petitioner acknowledges that the ’819 Patent nowhere describes “returning or resetting the actuator . . . to produce” suturing material attached to the suturing needle to be pulled through: “the plurality of separated tissue segments forming a stitch” (*see* claim 40), or “the tissue of the wound or incision site” (*see* claim 51). Thus, adoption of this construction raises issues under 35 U.S.C. § 112 for claims 40 and 51, which are outside the statutory scope of this proceeding. But the plain reading of the claim language requires the term “to cause” to qualify the step of “deactivating,” which mandates the proposed claim construction.

In the event that the Board does not accept Petitioner’s proposed construction of “*deactivating the actuator . . . to cause,*” but concludes instead that this term means “*returning or resetting the actuator . . . to permit, allow, or enable*” then Petitioner also present alternative grounds of unpatentability. In Petitioner’s view, however, this alternative construction is unreasonably broad and not supported by the intrinsic or extrinsic evidence.⁴ Ex. 1003, ¶ 61.

⁴ Under either construction, the term “*deactivating the actuator . . . to cause*” fails to comply with one or more of the requirements of 35 U.S.C. § 112. Petitioner’s proposed construction in this proceeding is not an admission to the contrary.

3. “cartridge holder assembly” (all Challenged Claims)

To the extent that this term needs construction, it should be construed to mean “*an assembly for releasably attaching the cartridge.*” See **Ex. 1001**, 3:52-56 (“A *cartridge holder* is . . . attached to the distal end of the barrel assembly . . . to which is *releasably* mounted a disposable cartridge that is capable of accommodating a suturing needle and a suturing thread material.”); *id.*, 7:65-66 (describing “a cartridge holder assembly 20 with an *attached* disposable needle cartridge 24”); *id.*, 12:12-13 (describing a “cartridge holder assembly 82 with the *attached* disposable needle cartridge 84.”); *id.*, 10:53-54 (describing “the disposable needle cartridge 24 for its *placement on* the cartridge holder 20”); *id.*, 8:1-6 (“FIGS. 3A and 3B provide detailed segmental views of the suturing device working-end 19 showing the disposable needle cartridge 24 in a *disengaged* mode and a curved suturing needle 26 separated from the needle cartridge 24 to illustrate the relative configuration of these segments with respect to the cartridge holder assembly 20”). See also, **Ex. 1003**, ¶¶ 62-64.

IV. CHALLENGE UNDER § 42.104(b) AND RELIEF REQUESTED

Petitioner requests IPR of the Challenged Claims on the grounds set forth in the table below, and requests that each of the Challenged Claims be found unpatentable. An explanation of unpatentability under the identified grounds is provided in the form of the detailed description that follows, indicating where each el-

ement can be found in the cited prior art, and the relevance of each prior art reference. Additional explanation and support for each ground of unpatentability is set forth in the Expert Declaration of Kevin L. Houser, M.S. (**Ex. 1003**).

Ground	'819 Patent Claims	Basis of Unpatentability
1	Claims 1, 2, 6-10, 16, 17, 25-31	Anticipated under 35 U.S.C. § 102 by Meade
2	Claims 1, 2, 6-10, 16, 17, 25-31	Obvious under 35 U.S.C. § 103 over Meade in view of Beurrier
3	Claim 15	Obvious under 35 U.S.C. § 103 over Meade in view of Chironis
4	Claim 15	Obvious under 35 U.S.C. § 103 over Meade in view of Chironis in view of Beurrier
5	Claims 40 and 51	Obvious under 35 U.S.C. § 103 over Ander-sson in view of Taylor in view of Beurrier
6	Claims 40 and 51	Obvious under 35 U.S.C. § 103 over Ander-sson in view of Taylor in view of Beurrier ⁵

⁵ Grounds 5 and 6 address the same claims with the same prior art references under two different constructions for the term “positioned within the protective housing.”

Ground	'819 Patent Claims	Basis of Unpatentability
7	Claims 40, 46-52, and 59-62	Anticipated under 35 U.S.C. § 102 by Meade
8	Claims 40, 46-52, and 59-62	Obvious under 35 U.S.C. § 103 over Meade in view of Beurrier

The earliest date to which the '819 Patent claims priority is June 14, 2001 (the "Priority Date"). **Ex. 1001**, Cover Sheet. Thus, U.S. Patent Nos. 5,437,681 ("**Meade**"), 5,306,281 ("**Beurrier**"), 4,557,265 ("**Andersson**"), and 5,911,727 ("**Taylor**") are prior art at least under 35 U.S.C. § 102(b) because they are U.S. patents that issued more than one year before the Priority Date. Meade issued on Aug. 1, 1995. *See* **Ex. 1004**, Cover Sheet. Beurrier issued on Apr. 26, 1994. *See* **Ex. 1005**, Cover Sheet. Andersson issued on Dec. 10, 1985. *See* **Ex. 1006**, Cover Sheet. Taylor issued on Jun. 15, 1999. *See* **Ex. 1008**, Cover Sheet. Furthermore, Chironis is also prior art under 35 U.S.C. § 102(b) because it is a printed publication that was published in 1965. **Ex. 1009** (*see* third excerpted page).

V. NO REDUNDANCY

None of the grounds of unpatentability presented in Section VI.B. are redundant. As shown in the table below, grounds directed to the same claims are only

See Section VI.B.5. and VI.B.6.

presented contingent upon whether a “**proposed**” or an “**alternative**” claim construction for a given claim term is adopted by the Board.

“positioned within the protective housing”	“deactivating the actuator . . . to cause”	Ground
proposed	not applicable	Grounds 1, 3, and 5
alternative	proposed	Grounds 2, 4, and 6
proposed	alternative	Ground 7
alternative	alternative	Ground 8

VI. EACH CHALLENGED CLAIM OF THE ’819 PATENT IS UN-PATENTABLE

A. The Prior Art References

This petition shows how Meade anticipates certain claims of the ’819 Patent and how all the Challenged Claims are obvious in view of Beurrier, Andersson, Taylor, and Chironis. Although Meade, Andersson, as well as a patent related to Taylor (with similar disclosure) were cited during the prosecution of the ’819 Patent, they were not substantively addressed by either the applicant or the examiner. Chironis was never considered by the Patent Office. Beurrier was made of record during prosecution, but it was never considered in combination with Meade, Andersson, or Taylor, as presented in this petition.

B. Detailed Explanation of Grounds of Unpatentability

1. Ground 1: Meade Anticipates Claims 1, 2, 6-10, 16, 17, and 25-31

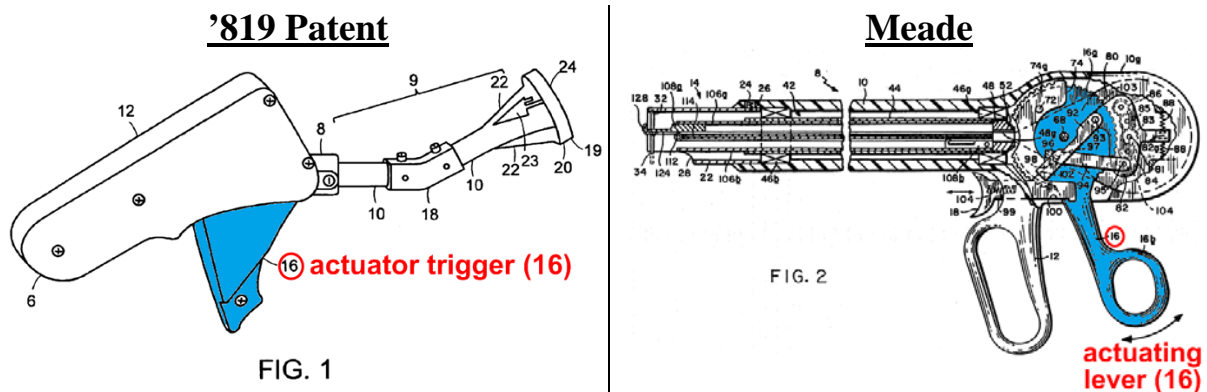
Meade: Meade is explicitly addressed in the “Background of the Invention” section of the ’819 Patent. The ’819 Patent states that Meade discloses “[a] suturing device that maintains a positive control over the suturing needle and is capable of providing uniform stitches.” **Ex. 1001**, 2:11-13. The ’819 Patent also explains that Meade discloses a device that is operated via a “drive mechanism that causes rotation of a linear drive shaft encased in a barrel, which in turn causes a *suturing needle* encased in a *disposable cartridge* mounted at the distal end of the barrel to rotate in an advancing motion through the tissue.” *Id.* at 2:16-20. *See also Ex. 1003*, ¶¶ 66-82.

Meade Anticipates Claims 1, 2, 6-10, 16, 17, and 25-31: For purposes of Ground 1, Petitioner has applied the proposed claim constructions set forth in Section III.B. where the term “*positioned within the protective housing*” (see claim 1[a] in the chart below) means “*does not project materially outside of the protective housing*,” and the term “cartridge holder assembly means “*an assembly for releasably attaching the cartridge*” (see claim 1[b] in the chart below).

Independent claim 1 of the ’819 Patent recites four main components, namely, an *actuator*, a *cartridge*, a *suturing needle*, and a *pusher assembly*. **Ex. 1003**, ¶ 18. Claim 1 further recites that the cartridge has a *protective housing*, and that

the pusher assembly comprises two subcomponents, namely, a *cartridge holder assembly* having a *needle rotation drive*. **Ex. 1003**, ¶ 18, 20-35. As explained below, Meade discloses all of these components and subcomponents.

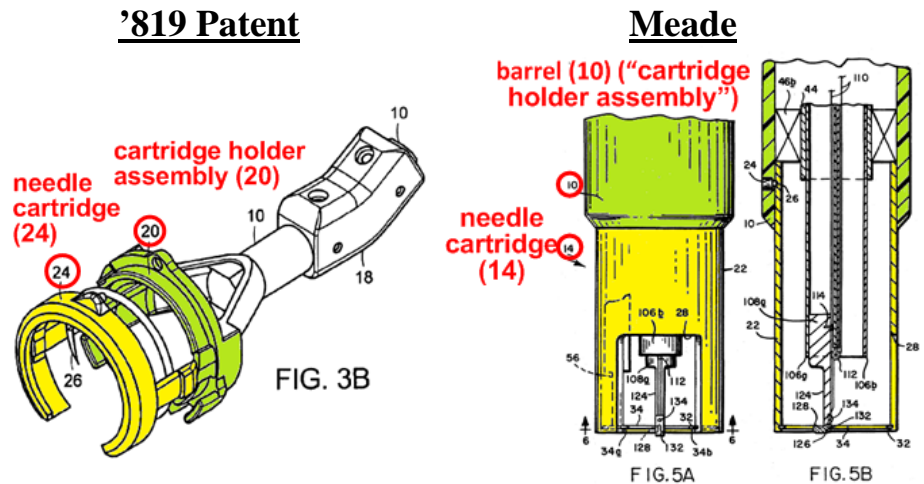
Actuator: An example of an *actuator* according to the '819 Patent is shown as *actuator trigger (16)* in Figure 1. **Ex. 1001**, 15:36-41; **Ex. 1003**, ¶ 21. The '819 Patent explains that an actuator may take the form of “a trigger, a push button, a lever, [or] a pedal[,]” among others. **Ex. 1001**, 19:40-42, 20:44-46, 22:21-23; **Ex. 1003**, ¶ 91. Meade discloses an *actuator* in the form of “lever (16).” **Ex. 1004**, 6:27-29; **Ex. 1003**, ¶ 74.



Cartridge and Cartridge Holder Assembly: The '819 Patent discloses in Figure 3B an embodiment of a *cartridge having a protective housing (24)* and a corresponding *cartridge holder assembly (20)* to which the cartridge attaches. **Ex. 1001**, 3:43-48, 7:52-55, 9:21-27, 9:66-67, Figs. 3B and 7A; **Ex. 1003**, ¶¶ 75-76. The walls of the needle cartridge (24) (shown in yellow) constitute its protective

housing. **Ex. 1003**, ¶ 75. Meade also discloses a *cartridge having a protective housing* and a *cartridge holder assembly*. **Ex. 1003**, ¶¶ 75-76. The needle cartridge (14) of

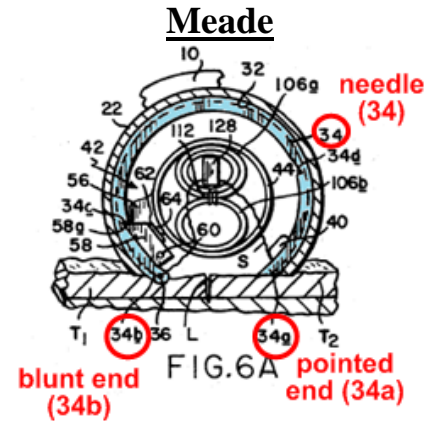
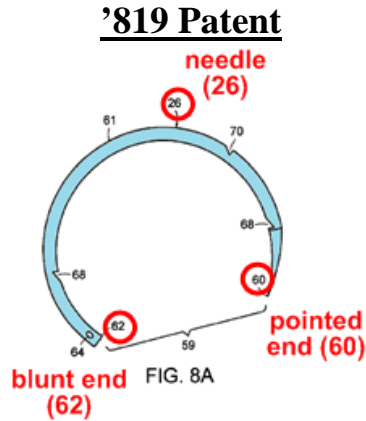
Meade is shown in Figures 5A and 5B and its walls (22) (shown in yellow) constitute its pro-



TECTIVE housing. **Ex. 1004**, 5:1-5; **Ex. 1003**, ¶ 75. Like in the '819 Patent, the needle cartridge (14) may be attached to a corresponding structure (barrel 10). **Ex. 1004**, 4:46-48, 12:22-27; **Ex. 1003**, Appendix B (pp. 69-70). Under the BRI of the term “cartridge holder assembly” (i.e., “*an assembly for releasably attaching the cartridge*”) (see Section III.B.3.), barrel 10 and spring button 24 comprise such an assembly. **Ex. 1003**, ¶ 76; see also **Ex. 1004**, 5:10-12. Barrel 10 is designed to releasably engage the needle cartridge (14) and “spring button 24” is designed to “fix[] both the longitudinal and rotational positions of the cartridge 14 in the barrel 10.” **Ex. 1004**, 5:6-12.

Needle: An embodiment of the arcuate *suturing needle* of the '819 Patent is shown in Figure 8A. Like the '819 Patent, Meade discloses a *suturing needle* having a *pointed end* and a *blunt end*, as shown in Figure 6A. **Ex. 1003**, ¶¶ 77-78.

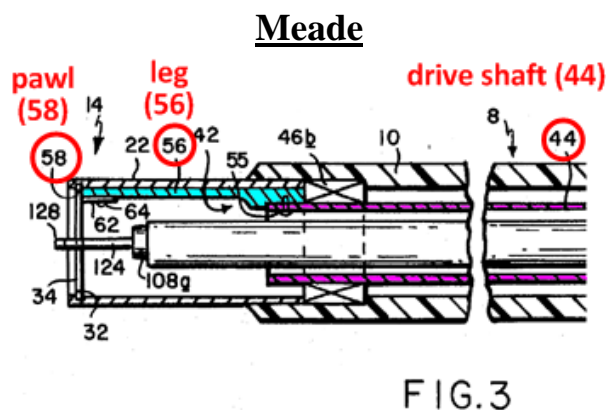
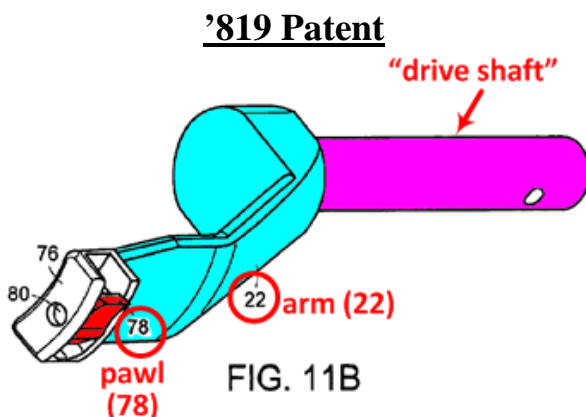
Like the claimed suturing needle of the '819 Patent, the suturing needle of Meade “*does not project materially outside of the*



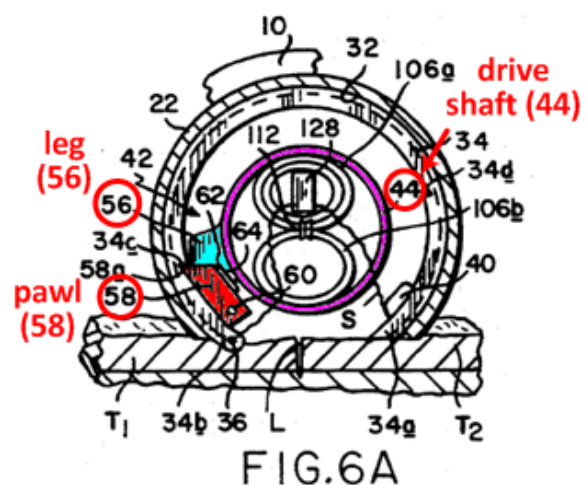
protective housing” after a complete rotation, as required under the BRI of the term “positioned within the protective housing.” See Section III.B.1., above; **Ex. 1003**, ¶¶ 48-53. In this regard, Meade states that “when the needle is positioned at [its] home position . . . , *it does not project materially into the aperture . . .*” **Ex. 1004**, 5:30-34. The suturing needle of Meade is at its “home” position after a complete rotation. *Id.*, 6:13-26.

Pusher Assembly and Needle Rotation Drive: The '819 Patent states that “FIG. 11B shows an expanded view of a *pusher assembly*.” **Ex. 1001**, 11:30; **Ex. 1003**, ¶¶ 24-29. Although the '819 Patent does not define the term “pusher assembly,” claim 1 of the '819 Patent is instructive in this regard. Claim 1 recites a pusher assembly comprising “a cartridge holder assembly” and “a needle rotation drive.” Figure 11B shows a pusher assembly comprising a *needle rotation drive* without a cartridge holder assembly. **Ex. 1003**, ¶ 24-29. Although the term “needle rotation drive” is not defined in the '819 Patent, claim 16 is instructive in that it recites a needle rotation drive comprising a “rotatable needle driver” and a “drive

shaft.” **Ex. 1003**, ¶¶ 33-35. Claim 16 further states that “rotation of the rotatable needle driver causes rotation of the suturing needle.” **Ex. 1001**, 17:61-62. In light of these disclosures in the ’819 Patent, a person of ordinary skill in the art would understand that the needle rotation drive may include the components shown in annotated Figure 11B below—namely, a drive shaft, arm (22), and a rotatable needle driver such as pawl (78). **Ex. 1003**, ¶¶ 33-35. This understanding is in accord with the interpretation of the term “pusher assembly,” which, as described above, may comprise the components of a needle rotation drive as shown in the annotated Figure 11B below. As shown in Figures 3 and 6A of Meade, Meade discloses a



pusher assembly comprising a *needle rotation drive*, which itself comprises a drive shaft (44), a leg (56), and a pawl (58). **Ex. 1003**, ¶¶ 78-81. These are the same structures in the same combination as disclosed and claimed in the ’819 Patent. *Id.*

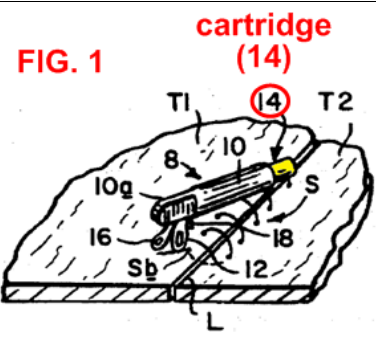
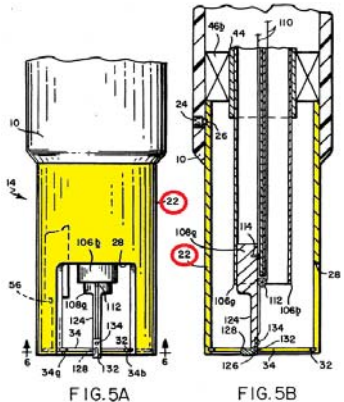
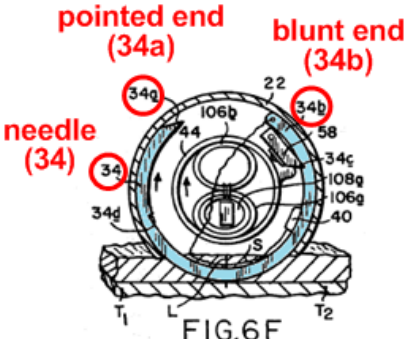


In addition to disclosing all of the components and subcomponents discussed above, Meade discloses each additional element of claims 1, 2, 6-10, 16, 17, and 25-31 as described in detail in the claim chart that follows and in **Ex. 1003**, Appendix B (Ground 1, pp. 63-88). With respect to claims 25 and 26, the following additional explanations are provided.

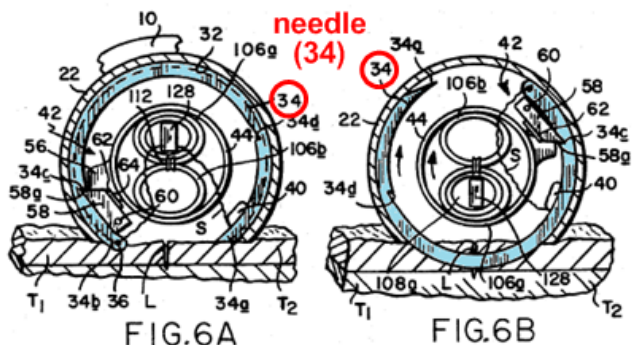
Claim 25 recites “providing a pushing force and a pulling force” to the needle. In this regard, Meade discloses a suturing device wherein the needle rotation drive causes rotation of the suturing needle by providing a “*pushing force*” adjacent to the blunt end of the suturing needle and a “*pulling force*” adjacent to the sharp pointed end of the suturing needle. *See Ex. 1003*, Appendix B (pp. 84-85). Specifically, Meade explains that “[t]o enable the needle to penetrate tissue to the required depth, the needle should have an arcuate extent between 180° and 330°” **Ex. 1004**, 5:27-29. According to Meade, the notches on the suturing needle on which the pulling and pushing forces are applied “are spaced about 180° apart around the needle.” *Id.*, 6:1-2. Thus, at the lower arcuate extent (i.e., 180°) of the suturing needle, the notches disclosed in Meade are “adjacent” to the blunt end and the sharp pointed end of the suturing needle. *See Ex. 1003*, Appendix B (pp. 84-85).

Claim 26 recites “an actuator that is a manually operable trigger, button or switch” The term trigger and lever are used interchangeably in the ’819 Pa-

tent. *See* **Ex. 1001**, 7:32-35 (“The suturing device 1 includes an actuator handle 12 comprising . . . a *trigger lever 16*.”). Meade discloses an actuator in the form of “lever 16” or a “*trigger*” or “*switch*.” **Ex. 1003**, ¶ 74, **Ex. 1004**, 6:27-29, 12:49-53.

Claim	Prior Art
1. A suturing device comprising:	Ex. 1004 , Abstract.
[a] a cartridge	<p>Meade discloses that “[t]he instrument also includes a disposable suturing needle-and-thread <i>cartridge 14</i> releasably plugged into the distal end of barrel 10.” Ex. 1004, 4:46-48; <i>see also id.</i> Fig. 1.</p> 
having a protective housing	<p>Meade discloses that “[t]he cartridge comprises a generally cylindrical tubular <i>housing 22</i> which may be formed of a suitable rigid, medical grade, sterilizable metal or plastic material.” Ex. 1004, 5:2-5; <i>see also id.</i>, Figs. 5A, 5B.</p> 
and a suturing needle having a pointed end and a blunt end,	<p>Meade discloses that “[t]he disposable cartridge has a generally cylindrical housing with an aperture in the sidewall of the housing at the distal or working end thereof. Slidably mounted in a circular track at the distal end of the housing opposite the aperture is an <i>arcuate suturing needle having a pointed tip at one end of the needle, the opposite or blunt end</i> of the needle being connected to one end of a suturing thread contained in the cartridge.”); Ex. 1004, 2:54-61; <i>see also id.</i>, Fig. 6F.</p> 

Claim	Prior Art
<p>the suturing needle capable of rotating about an axis,</p>	<p>Meade discloses that “[t]he needle 34 may be rotated in its curved track 32 about the instrument's longitudinal axis to advance the pointed needle tip 34a so that the needle first spans the aperture 28 as shown, for example, in FIG. 6B and then returns to its original or home position illustrated in FIGS. 5A and 6A.” Ex. 1004, 5:34-40; <i>id.</i>, 10:18 (“needle 34 . . . will rotate”); <i>see also</i> Ex. 1004, Figs. 6A, 6B.</p>
<p>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;</p>	<p>Meade discloses that “[t]he width of the aperture 28 in the cartridge housing 22 is comprable [sic] to the width of the gap in needle 34 so that when the needle is positioned at a home position as shown in those figures, it does not project materially into the aperture 28, i.e., it may project slightly.”). Ex. 1004, 5:30-34; <i>see also</i> <i>Id.</i>, Figs. 6A through 6D, 6:13-26 (“[W]ith the pawl 58 engaged in the needle notch 34c, when the drive shaft 44 is at a home position shown in FIG. 6A, shaft 44 may be rotated from that position approximately 180° so as to rotate needle 34 from its home position by the same amount; see FIG. 6B. This places the needle notch 34d at the location formerly occupied by notch 34c. Shaft 44 may then be turned in the opposite direction to its original position whereupon pawl 58 will engage in the needle notch 34d; see FIG. 6C. Shaft 44 may then be rotated in the original direction again through 180° carrying needle 34 along with it so that the needle is returned to its original or home position; see FIG. 6D.”)</p>

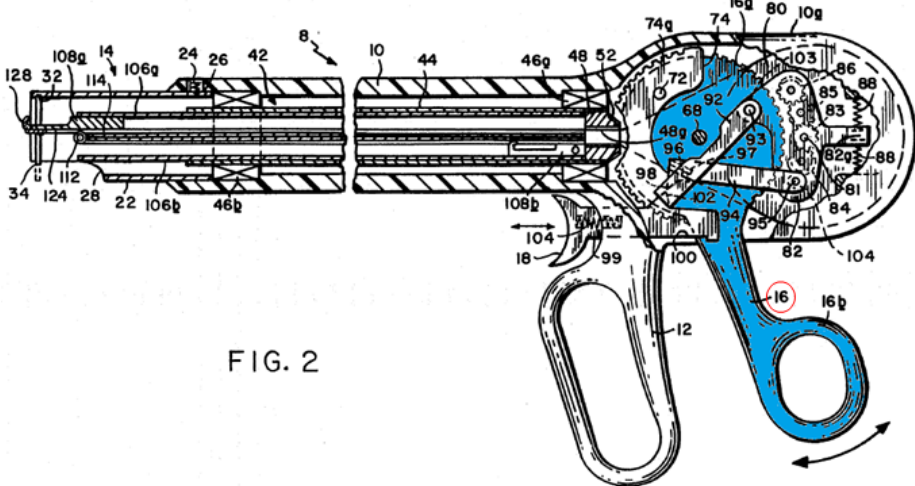


Claim	Prior Art
	<p>FIG. 6A</p> <p>FIG. 6B</p> <p>FIG. 6C</p> <p>FIG. 6D</p> <p>pointed end (34a) at starting position</p> <p>pointed end after a complete rotation</p>
<p>[b] a pusher assembly comprising a cartridge holder assembly having a needle rotation drive,</p>	<p>Meade discloses that “[t]he instrument includes an actuator shown generally at 8 which is shaped like a pistol in that it has a generally <i>cylindrical barrel 10</i> with a hand grip 12 extending from a housing 10a at the proximal end of the barrel.” Ex. 1004, 4:43-46, Figs. 5A and 5B; <i>id.</i>, 5:48-61 (“Referring now to FIGS. 2 and 3, the needle 34 is rotated about the axis of cartridge 14 by a <i>driver mechanism shown generally at 42</i>. While the mechanism 42 may take a variety of forms, the illustrated one comprises a <i>tubular shaft 44</i> which is rotatably mounted coaxially in barrel 10 by means of bearing units 46a and 46b located adjacent to opposite ends of shaft 44. The proximal end of shaft 44 is closed by a tubular plug 48 having an axial passage 48a and an exposed end surface formed as a bevel gear 52. The <i>distal end of shaft 44</i></p> <p>FIG. 3</p> <p>pawl (58)</p> <p>leg (56)</p> <p>barrel (10)</p> <p>drive shaft (44)</p>

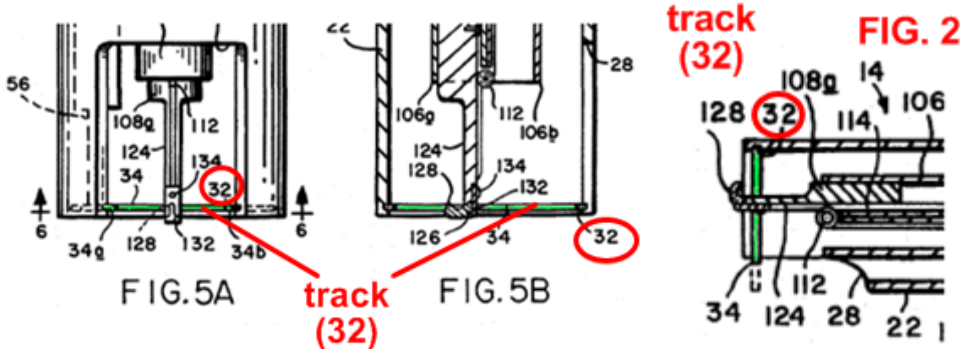
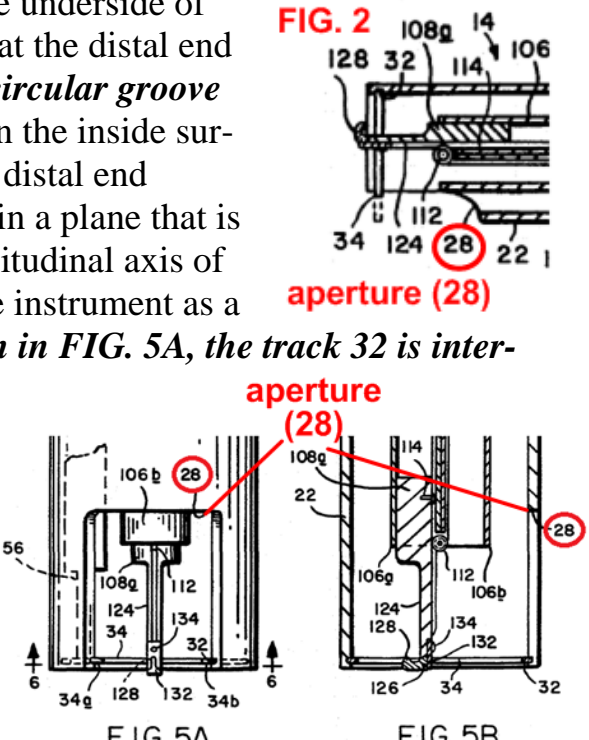
Claim	Prior Art
	<p>which projects beyond the bearing unit 46b <i>is connected at one</i> side by pins 55 <i>to a straight leg 56</i> which extends from the end of barrel 10 along the cartridge housing 22 to the needle track or groove 32 therein.”); <i>id.</i>, 5:62-64 (“As best seen in FIGS. 2 and 6A, a <i>pawl 58 is connected</i> at one end by a pivot pin 60 <i>to the free end of leg 56</i> radially inboard needle 34.”); <i>id.</i>, Figs. 2, 3, 5A, 5B, 6A, and 6B.</p> <div data-bbox="479 535 1437 1060"> <p>FIG. 5A and FIG. 5B are cross-sectional views of a surgical instrument assembly. FIG. 5A shows a barrel (10) with a cartridge (14) inserted into its distal end. The cartridge (14) contains a needle (34) and a leg (56). FIG. 5B shows the barrel (10) with the cartridge (14) removed, revealing the internal components including the needle (34) and the leg (56). FIG. 6A is a top-down view of the assembly, showing the barrel (10), the leg (56), the needle (34), and the pawl (58) connected to the leg (56) by a pivot pin (60). The drive shaft (44) is also shown. Various components are labeled with reference numerals: 10, 14, 22, 24, 26, 28, 32, 34, 36, 38, 40, 42, 44, 46b, 55, 56, 58, 60, 62, 64, 106g, 106b, 108g, 108b, 110, 112, 124, 126, 128, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 190, 192, 194, 196, 198, 200.</p> </div>

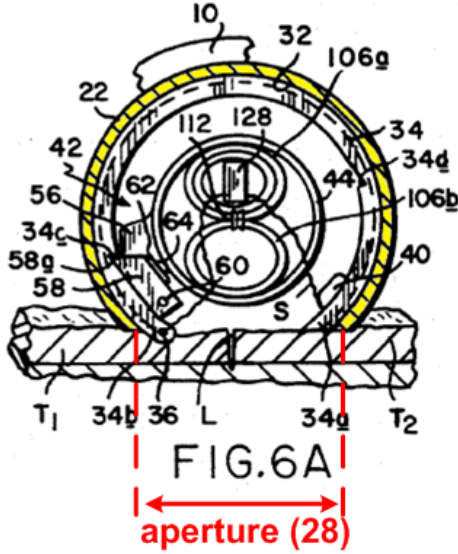
Claim	Prior Art
<p>to bring the needle rotation drive into operational contact with the suturing needle</p>	<p>Meade discloses that “[a]s best seen in FIGS. 2 and 6A, a pawl 58 is connected at one end by a pivot pin 60 to the free end of leg 56 radially inboard needle 34. The opposite or free end of pawl 58 is cut to form a sharp outside edge 58a. That <i>pawl edge 58a is arranged to engage in a pair of notches 34c and 34d in the radially inner edge of needle 34</i> and located adjacent to the opposite ends of the needle. Preferably, the notches are spaced about 180° apart around the needle.” Ex. 1004, 5:62-6:2.</p> <div data-bbox="535 588 1364 976"> <p>FIG. 6A and FIG. 6B are cross-sectional views of a surgical instrument. FIG. 6A shows the instrument in a first position where a pawl (58) is engaged with a needle (34). FIG. 6B shows the instrument in a second position where the pawl (58) is disengaged from the needle (34). The diagrams illustrate the mechanical components and their interaction during the suturing process.</p> </div>
<p>wherein the needle rotation drive releasably engages the suturing needle to rotate the suturing needle; and</p>	<p>Meade discloses that “[t]o commence suturing, the surgeon, holding the instrument by means of the grip 12, moves lever 16 rearwardly with the thumb without squeezing trigger 18. Under these conditions, the bevel gear segment 74 engaged to bevel gear 52 will <i>rotate the drive shaft 44</i> and foot 56 <i>clockwise as viewed in FIG. 6A so that needle 34, which is engaged by the pawl 58, will rotate with the shaft approximately 180° to the position shown in FIG. 6B</i>. This motion of the needle causes the needle tip 34a to penetrate down through the tissue T2 and tap through the tissue T1 following a curved path as</p> <div data-bbox="909 1050 1429 1890"> <p>FIG. 6A and FIG. 6B are cross-sectional views of a surgical instrument. FIG. 6A shows the instrument in a first position where a pawl (58) is engaged with a needle (34). FIG. 6B shows the instrument in a second position where the pawl (58) is disengaged from the needle (34). The diagrams illustrate the mechanical components and their interaction during the suturing process.</p> </div>

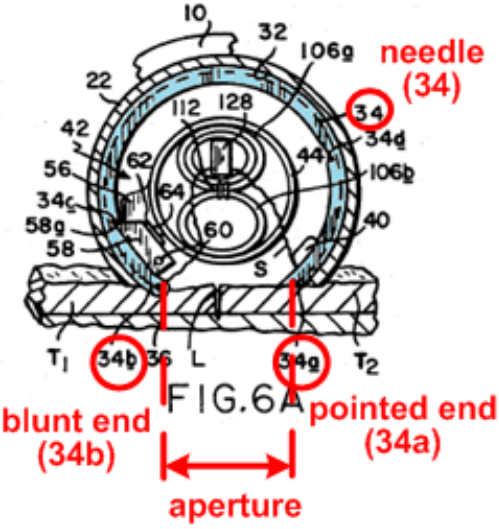
Claim	Prior Art
	<p>shown in FIG. 6B. At this point, <i>the surgeon moves the lever 16 forwardly so as to rotate the drive shaft 44 and the attached foot 56 in the opposite or counter clockwise direction to the position shown in FIG. 6C until the pawl 58 snaps into the needle notch 34d</i> which is now situated at substantially the same location formally occupied by notch 34c. <i>Next, the surgeon moves lever 16 rearwardly again so as to rotate the drive shaft 44 and foot 56 clockwise through 180° to the position shown in FIG. 6D.</i> This motion of the drive shaft moves the needle through an additional 180° so that it advances completely through the tissues T1 and T2 and returns to its original or home position. In doing this, the needle pulls the leading end of the suture S along the same path through the tissues as shown in FIG. 6D, the suture being paid out from pouch 40. Thus, the needle 34 behaves in the same way as a conventional suturing needle wielded by a surgeon.” See Ex. 1004, 10:12-41, Figs. 6A through 6D.</p> <div data-bbox="922 367 1388 766"> <p>FIG. 6C</p> </div> <div data-bbox="922 871 1421 1270"> <p>FIG. 6D</p> </div>
[c] an actuator	<p>Meade discloses that “[t]o commence suturing, the surgeon, holding the instrument by means of the grip 12, moves <i>lever 16</i> rearwardly with the thumb.”). Ex. 1004, 10:12-14, Fig. 2 (lever 16).</p>

Claim	Prior Art
	 <p style="text-align: center;">FIG. 2</p>
capable of engaging the needle rotation drive	<p>Meade discloses that “[r]eferring again to FIGS. 1 and 2, <i>the drive shaft 44 is rotated by moving the lever 16</i> which extends down from the actuator housing 10a.” Ex. 1004, 6:27-29; <i>see also id.</i>, 6:29-40; <i>id.</i>, 6:40-47 (“Thus, <i>when the lever 16 is moved rearwardly away from grip 12, the drive shaft 44 and the leg 56 attached to that shaft will be moved about the instrument's axis in the clockwise direction as viewed in FIG. 6A.</i> On the other hand, <i>when the lever 16 is moved in the opposite direction toward the finger grip 12, shaft 44 and leg 56 will be rotated in the counter clockwise direction</i> about that axis.”); <i>see also id.</i>, 6:47-52; Figs. 6A-6F.</p>
to rotate the needle rotation drive and the suturing needle.	<p>Meade discloses that “[t]o commence suturing, <i>the surgeon, holding the instrument by means of the grip 12, moves lever 16 rearwardly with the thumb</i> without squeezing trigger 18. Under these conditions, the bevel gear segment 74 engaged to bevel gear 52 will <i>rotate the drive shaft 44 and foot 56 clockwise as viewed in FIG. 6A so that needle 34, which is engaged by the pawl 58, will rotate with the shaft approximately 180° to the position shown in FIG. 6B.</i>”); Ex. 1004, 10:12-20; <i>see also id.</i>, 10:20-58; Figs. 6A-6G.</p>
2. The suturing device of claim 1 wherein the cartridge further comprises:	<p>Ex. 1004, 4:46-48; <i>see also id.</i>, Fig. 1.</p>

Claim	Prior Art
<p>[a] a curved lip covering an arc greater than about 180° and less than about 330°;</p>	<p>Meade discloses that “Fig[.] 6A [is a] sectional view[] taken along line 6--6 of FIG. 5A, illustrating the operation of the instrument”. Ex. 1004, 4:33-35.</p> <p>“To enable the needle to penetrate tissue to the required depth, the <i>needle should have an arcuate extent between 180° and 330°</i>, 330° being preferred.” <i>Id.</i>, 5:27-29.</p> <p>“The disposable <i>cartridge has</i> a generally cylindrical housing with <i>an aperture in the sidewall of the housing at the distal or working end</i> thereof. Slidably mounted in a circular track at the distal end of the housing opposite the aperture is an arcuate suturing needle having a pointed tip at one end of the needle, the opposite or blunt end of the needle being connected to one end of a suturing thread contained in the cartridge. <i>The circumference of the suturing needle is more or less equal to the circumference to the cartridge housing at the aperture therein</i> and the needle normally reposes in a home position in its track such that the gap in the arcuate suturing needle is in register with the aperture in the cartridge housing.” <i>Id.</i>, 2:54-67.</p> <div data-bbox="483 1024 1372 1711"> <p>FIG. 5A</p> <p>FIG. 6A</p> </div>

Claim	Prior Art
<p>[b] a track in a wall whereby the suturing needle follows a curved path along the track during needle rotation; and</p>	<p>Meade discloses that “[r]eferring to FIGS. 2, 5A and 5B, an aperture 28 is formed in the underside of the cartridge housing 22 at the distal end of the cartridge. Also, a circular groove or track 32 is inscribed in the inside surface of housing 22 at the distal end thereof, which track lies in a plane that is perpendicular to the longitudinal axis of the housing 22 and of the instrument as a whole. Thus, as best seen in FIG. 5A, the track 32 is interrupted by the aperture 28. Slidably positioned in the groove or track 32 is a curved medical grade stainless steel suturing needle 34.” Ex. 1004, 5:13-23, Figs. 5A, 5B, and 2.</p>  <p>The diagrams illustrate the mechanical components of the instrument. FIG. 5A and FIG. 5B are cross-sectional views of the distal end of the cartridge housing 22. FIG. 5A shows a track 32 (a circular groove) inscribed in the inner wall of the housing, which is interrupted by an aperture 28. A suturing needle 34 is shown positioned within the track. FIG. 5B shows a similar view from a different angle. FIG. 2 is a side view showing the needle 34 sliding within the track 32. Red circles and arrows highlight the track 32 and aperture 28 in the original image.</p>
<p>[c] an aperture in the curved lip which intercepts the track</p>	<p>Meade discloses that “[r]eferring to FIGS. 2, 5A and 5B, an aperture 28 is formed in the underside of the cartridge housing 22 at the distal end of the cartridge. Also, a circular groove or track 32 is inscribed in the inside surface of housing 22 at the distal end thereof, which track lies in a plane that is perpendicular to the longitudinal axis of the housing 22 and of the instrument as a whole. Thus, <i>as best seen in FIG. 5A, the track 32 is interrupted by the aperture 28.</i>” Ex. 1004, 5:13-21 Figs. 5A, 5B, Fig. 2.</p>  <p>The diagrams illustrate the mechanical components of the instrument. FIG. 2 is a side view showing the needle 34 sliding within the track 32. FIG. 5A and FIG. 5B are cross-sectional views of the distal end of the cartridge housing 22. FIG. 5A shows a track 32 (a circular groove) inscribed in the inner wall of the housing, which is interrupted by an aperture 28. A suturing needle 34 is shown positioned within the track. FIG. 5B shows a similar view from a different angle. Red circles and arrows highlight the aperture 28 and track 32 in the original image.</p>

Claim	Prior Art
<p>whereby the pointed end of the suturing needle traverses the aperture during each revolution of the suturing needle along the path.</p>	<p>Meade discloses “[a suturing instrument . . . comprising . . . a curved suturing needle . . . [s]aid needle has circular curvature, and said support means include a cylindrical wall, means defining <i>a circular track in the cylindrical wall that constrains the needle to follow a circular path</i> about said axis, and <i>an aperture in said wall which intercepts said track whereby the pointed end of the needle traverses the aperture during each revolution</i> of the needle so that when the housing one end is placed against tissue so that the aperture faces the tissue, said needle can follow a curved path through the tissue.” Ex. 1004, 14:42-68; <i>id.</i>, Fig. 6A.</p> 
<p>6. The suturing device of claim 1 wherein the suturing needle covers an arc greater than about 180° and less than about 330°</p>	<p>Meade discloses that “[t]o enable the needle to penetrate tissue to the required depth, <i>the needle should have an arcuate extent between 180° and 330°</i>, 330° being preferred.” Ex. 1004, 5:26-29, Figs. 6A-6I.</p>
<p>having an aperture located adjacent to the blunt end for engaging a suturing material.</p>	<p>Meade discloses that “[t]he illustrated needle is formed as a circular split ring, one end 34a of which is pointed and the opposite end 34b of which contains an <i>opening or eye 36 by which the leading end of suture S may be attached to the needle.</i>” Ex. 1004, 5:23-27 <i>see also id.</i>, Fig. 6A.</p>

Claim	Prior Art
<p>7. The suturing device of claim 1 wherein the suturing needle comprises an aperture between the pointed end and blunt end.</p>	<p>Meade discloses that “[r]eferring to FIGS. 2, 5A and 5B, an aperture 28 is formed in the underside of the cartridge housing 22 at the distal end of the cartridge. . . . <i>The width of the aperture 28 in the cartridge housing 22 is comprable [sic] to the width of the gap in needle 34</i> so that when the needle is positioned at a home position as shown in those figures, it does not project materially into the aperture 28.” Ex. 1004, 5:13-34, Fig. 6A.</p> 
<p>8. The suturing device of claim 1 further comprising an interlocking mechanism capable of releasably locking the suturing needle with the needle rotation drive</p>	<p>Meade discloses that “[i]n accordance with the invention, the needle may be releasably engaged by a driver rotatably mounted in the barrel of the instrument so that the needle can be rotated from its home position 360° about the cartridge axis.” Ex. 1004, 3:3-7; 5:65-6:4.</p>
<p>whereby rotational movement of the needle rotation drive causes the suturing needle to rotate.</p>	<p>Meade discloses that “[a]s best seen in FIGS. 2 and 6A, a pawl 58 is connected at one end by a pivot pin 60 to the free end of leg 56 radially inboard needle 34.” Ex. 1004, 5:62-64; 3:3-7; <i>id.</i>, 5:65-6:4; 6:4-8 (“Thus, <i>when drive shaft 44 is rotated about its longitudinal axis in the clockwise direction as viewed in FIG. 6A, pawl 58 will engage in notch 34c or 34d so as to advance needle 34 in the same direction.</i>”); <i>id.</i>, 6:8-12.</p>
<p>9. The suturing device of claim 8 wherein the interlocking mechanism further comprises a plurality of engagement notches that interfit with the needle rotation drive whereby the suturing needle is rotated by said needle rotation drive in a direction which advances the pointed end of the suturing needle.</p>	<p>See claim 8. Meade discloses “[t]hat <i>pawl edge 58a is arranged to engage in a pair of notches 34c and 34d in the radially inner edge of needle 34</i> and located adjacent to the opposite ends of the needle. Preferably, the notches are spaced about 180° apart around the needle.” Ex. 1004, 5:65-6:8; <i>see also id.</i> 5:62-65.</p>

Claim	Prior Art
10. The suturing device of claim 9 wherein the interlocking mechanism engages at least one notch on a surface of the suturing needle.	See claim 9 (Ex. 1004 , 5:62-6:2).
16. The suturing device of claim 1 wherein the needle rotation drive comprises:	See claim 1[b].
[a] a rotatable needle driver mounted in a terminally located housing capable of coupling to a cartridge capable of releasably engaging a suturing needle contained therein whereby rotation of the rotatable needle driver causes rotation of the suturing needle; and	See claim 1[b] (Ex. 1004 , 4:43-46, 5:48-64).
[b] a drive shaft attaching to an end of the housing capable of rotating the rotatable needle driver.	See claim 1[b] (Ex. 1004 , 5:48-61)
17. The suturing device of claim 16 wherein the drive shaft couples the needle driver to an actuator to rotate the needle driver about an axis.	See claim 1[b] (Ex. 1004 , 5:48-64); See claim 1[c] (Ex. 1004 , Fig. 2 (lever 16); <i>id.</i> , 6:27-29; 6:40-47, 10:20-58, Figs. 6A-6G).
25. The suturing device of claim 1 wherein the needle rotation drive causes rotation of the suturing needle comprising a blunt end and a sharp pointed end by providing a pushing force adjacent to said blunt end and a pulling force adjacent to said sharp pointed end.	See claim 1[b]. See also Ex. 1004 , 5:62-68 (“As best seen in FIGS. 2 and 6A, a pawl 58 is connected at one end by a pivot pin 60 to the free end of leg 56 radially inboard needle 34. The opposite or free end of pawl 58 is cut to form a sharp outside edge 58a. That pawl edge 58a is arranged to engage in a pair of notches 34c and 34d in the radially inner edge of needle 34 and located <i>adjacent</i> to the opposite ends of the needle.”); <i>id.</i> , 6:1-2 (“Preferably, the notches are spaced about 180° apart around the needle.”); <i>id.</i> , 9:59-67; 9:67-10:3 (“Also, the lever 16 is moved to its forward position so that the driver mechanism 42, including foot 56, is located at the home position as shown in FIG. 6A such that the pawl 58 is engaged in the needle notch 34c <i>adjacent</i> to the rear end 34b of the needle 34.”).
26. The suturing device of claim 1 wherein the actuator is a manually operable trigger, button or switch.	Meade discloses that “[t]he surgeon, using only one hand, may manipulate the instrument while actuating a lever 16.” Ex. 1004 , 4:52-53; see also Ex. 1004 , 12:49-53 (“trigger . . . or switch”).
27. The suturing device of claim 1 wherein the actuator is mechanically opera-	Meade discloses that “in some applications it may be <i>desirable to rotate drive shaft 44</i> by means of a conventional pneumatic hydraulic or <i>electric</i> reversible

Claim	Prior Art
ble by an electrical device or a fuel driven device.	rotary <i>actuator or motor</i> (not shown) controlled by a trigger activated valve or switch.” Ex. 1004 , 12:49-53.
28. The suturing device of claim 1 wherein the actuator is activated by automation using a power source selected from the group consisting of <i>electrical</i> , electromagnetic, compressed air, compressed gas, hydraulic, vacuum and hydrocarbon fuels.	<i>See claim 27 (Ex. 1004, 12:49-53).</i>
29. The suturing device of claim 1 further comprising a curved track on an inner surface of the cartridge wherein the suturing needle moves in the curved track during rotation of the suturing needle.	<i>See claim 2[b] (Ex. 1004, 5:13-23, Figs. 5A, 5B, and 2).</i>
30. The suturing device of claim 1 further comprising a curved track on an inner surface of the cartridge that contains the pointed end of the suturing needle prior to and after rotation of the suturing needle.	<i>See claim 1[a] (Ex. 1004, 5:30-34; see also id., Figs. 6A through 6D, 6:13-26; See claim 29 (Ex. 1004, 5:13-23, Figs. 5A, 5B, and 2).</i>
31. The suturing device of claim 1 wherein the suturing needle is slidably positioned in a curved track of the cartridge.	<i>See claim 1[a] (Ex. 1004, 2:54-61; see also id., Fig. 6F); See claim 29 (Ex. 1004, 5:13-23, Figs. 5A, 5B, and 2).</i>

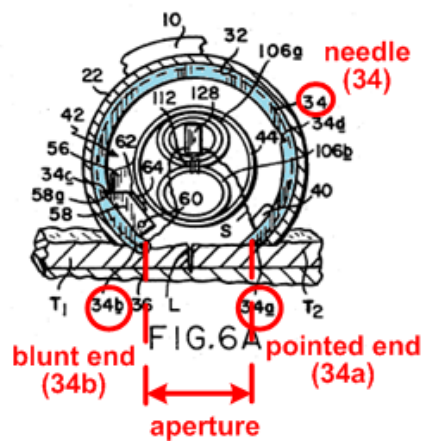
2. Ground 2: Under an Alternative Construction of the Term “*positioned within the protective housing*,” Meade in View of Beurrier Renders Obvious Claims 1, 2, 6-10, 16, 17, and 25-31

Beurrier: Beurrier discloses a suturing device with an arcuate needle mounted within a cassette for 360° rotation. **Ex. 1005**, Abstract; Fig. 1. Among other things, Beurrier discloses that “the *point of needle 102 is . . . safely protected in cassette 101 avoiding injury or the spread of infection to a user* of the device.” *Id.* at 5:66-68. *See also Ex. 1003*, ¶¶ 83-87.

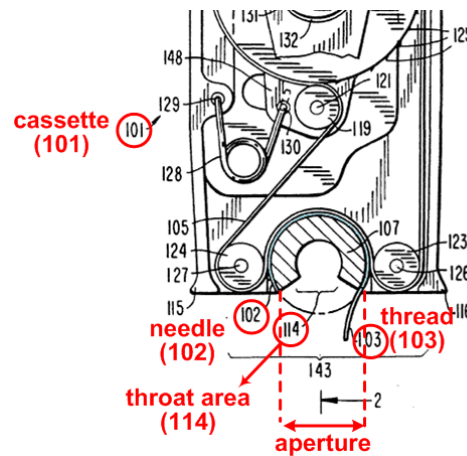
Motivation to Combine Meade and Beurrier: Meade and Beurrier disclose suturing devices with many features in common. For example, both Meade

and Beurrier teach suturing devices with arcuate suturing needles that rotate about an axis; **Ex. 1003**, ¶ 107; **Ex. 1004**, Abstract; **Ex. 1005**, Abstract. The suturing needles in both devices are within housings with apertures that coincide with the aperture in the suturing needles. **Ex. 1003**, ¶ 108; **Ex. 1004**, 2:63-67; **Ex. 1005**, 3:66-4:2. In addition, both Meade and Beurrier recognize “needle slippage” as a

Meade (Fig. 6A)



Beurrier (portion of Fig. 1)



problem in the prior art and both references address the problem by the use of “positive needle control,” through drive mechanisms that minimize the potential for slippage. **Ex. 1003**, ¶ 109; **Ex. 1004**, 1:57-63, 2:10-13; **Ex. 1005**, 1:61-64, 2:5-12. Both 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. **Ex. 1003**, ¶ 110; **Ex. 1004**, 1:39-44; **Ex. 1005**, 2:30-34, 5:66-68. Because both Meade and Beurrier discloses suturing devices with several features in common, and they both address the same problems encountered in the prior art, a person of ordinary skill in the art would have been motivated to combine the

teachings of Meade and Beurrier. **Ex. 1003**, ¶ 111.

Claims 1, 2, 6-10, 16, 17, 25-31 are Obvious: For purposes of Ground 2, Petitioner has applied an alternative claim construction to the term “*positioned within the protective housing*.” Under this alternative construction, this term means “*does not project at all outside of the protective housing*.” As explained in Ground 1, Meade discloses all the limitations recited in claims 1, 2, 6-10, 16, 17, 25-31 of the ’819 Patent, except that Meade does not explicitly describe a suturing device “wherein the pointed end of the suturing needle [*does not project at all outside of the protective housing*] after a complete rotation of the suturing needle about the axis.” However, Beurrier teaches that the pointed end of its arcuate needle is “safely protected” in its housing to “avoid[] injury or the spread of infection to a user of the device” (**Ex. 1005**, 5:66-68). 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. **Ex. 1003**, ¶ 111. Such modifications would have included, for example, shortening the arcuate extent of the needle, or extending the arcuate extent of the needle cartridge so as to ensure that the pointed end of the suturing needle does not project at all outside of the protective housing after a complete rotation. *Id.*

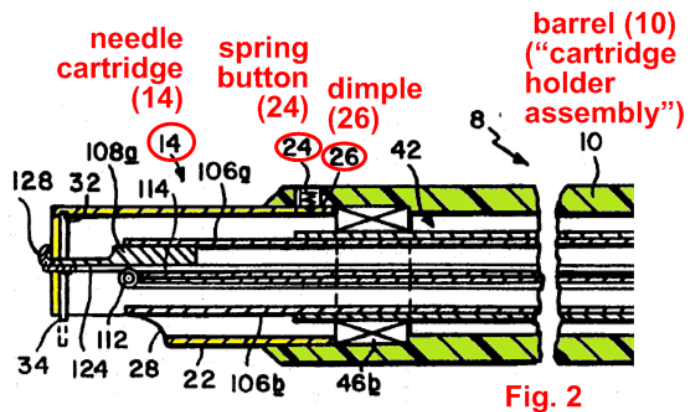
Thus, as explained above in the Meade claim chart of Ground 1, which is incorporated in Ground 2 in its entirety—except as to the limitation “positioned within the protective housing”—the combination of Meade and Bearrier renders obvious claims 1, 2, 6-10, 16, 17, 25-31. *See also* **Ex. 1003**, Appendix B (Ground 2, pp. 63-88).

3. Ground 3: Meade in View of Chironis Renders Obvious Claim 15

Chironis: Chironis is an engineering handbook that discloses a compilation of mechanisms and devices for a wide variety of functions, including the fixing or locking of components relative to each other. **Ex. 1009**, 150-152 (disclosing “devices for . . . holding mechanical movements”). The mechanisms disclosed in Chironis were well known to persons of ordinary skill in the art at the time of the invention of the ’819 Patent. **Ex. 1003**, ¶ 102-103.

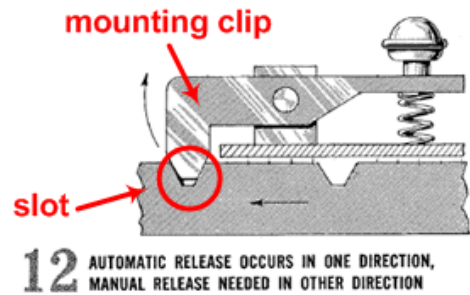
Motivation to Combine Meade

and Chironis: The suturing device disclosed in Meade, which was described in Ground 1 (*see* Section V.B.1), discloses a car-



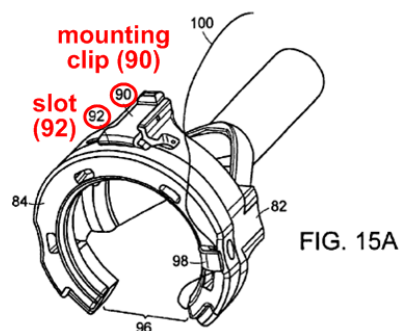
tridge holder assembly that comprises barrel 10 and spring button 24. **Ex. 1003**, ¶ 76; **Ex. 1004**, 5:6-12. Spring button 24 is part of a mechanism for fixing the longitudinal and rotational positions of barrel 10 relative to cartridge 14. **Ex. 1003**, ¶

119; **Ex. 1004**, 5:6-12. Specifically, spring button 24 mounted in barrel 10 is adapted to engage in a dimple formed in the housing 22 of cartridge 14. **Ex. 1004**, 5:6-12. A person of ordinary skill in the art would have found it obvious to replace the fixing mechanism of Meade with any other suitable mechanism disclosed in Chironis, including, for example, a mounting-clip-slot mechanism such as the one disclosed in Figure 12 of Chironis.



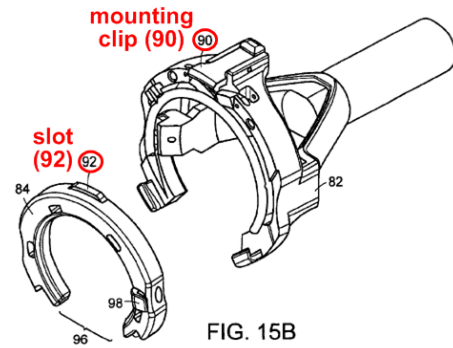
Such replacement would have been a simple substitution of known elements to obtain the predictable result of securing two components relative to each other. **Ex. 1003**, ¶¶ 120-121.

Claim 15 is Obvious: Claim 15 of the '819 Patent recites the 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.*” An



embodiment of this mechanism (comprising a mounting clip 90 and a slot 92) is shown, for example, in Figs. 15A and 15B of the '819 Patent. See **Ex. 1003**, Appendix B (pp. 81-83); **Ex. 1001**, 12:21-35. Likewise, Meade teaches that the car-

tridge (comprising housing 22) may be releasably retained in the distal end of barrel 10 by any “*known means*,” such as, for example, the spring-button-dimple mechanism described in Meade. *See* Meade 5:1-12 (“The disposable



cartridge 14 . . . comprises a generally cylindrical tubular housing 22 ***Housing 22 may be releasably retained in the distal end of barrel 10 by known means*** such as a spring button 24 mounted in barrel 10 and adapted to engage in a dimple 26 formed in the side wall of cartridge housing 22, as best seen in FIGS. 2 and 5B. ***The spring button 24 fixes both the longitudinal and rotational positions of the cartridge 14 in the barrel 10.***”). As explained above, numerous means for releasably engaging two components, such as the cartridge holder assembly (comprising barrel 10) and the cartridge 14 of Meade, were well known in the art. Chironis discloses many of them. **Ex. 1003**, ¶¶ 102-103, 118-121; **Ex. 1009**, 150-151. One such mechanism disclosed in Chironis is the mounting-clip-stop mechanism (shown in Figure 12). Thus, under Petitioner’s proposed constructions, it would have been obvious to a person of ordinary skill in the art to use the retaining means disclosed in Chironis and apply them to the suturing device of Meade to releasably engage the cartridge to the cartridge holder assembly, which comprises barrel 10. **Ex. 1003**, ¶ 121.

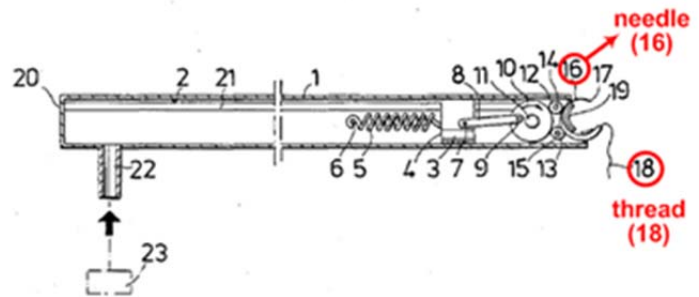
4. Ground 4: Under an Alternative Construction of the Term “*positioned within the protective housing*,” Meade in View of Chironis in View of Beurrier Renders Obvious Claim 15

To the extent that it is determined that the term “positioned within the protective housing” means that the pointed end of the needle “*does not project at all outside of the protective housing*,” Meade and Chironis in view of Beurrier renders of obvious claim 15 for the same reasons described under Ground 3, which is incorporated herein, except for this claim term. As explained in Section VI.B.2. (which is also incorporated herein), Beurrier’s teaching that the pointed end of its arcuate needle be “safely protected” in its housing to “avoid[] injury or the spread of infection to a user of the device” (**Ex. 1005**, 5:66-68) would motivate a person of ordinary skill in the art to modify a suturing device according to the teachings of Meade and Beurrier so that the pointed end of the needle did not protrude *at all* outside of the protective housing after a complete rotation. **Ex. 1003**, ¶¶ 107-111. Thus, Meade and Chironis in view of Beurrier render obvious claim 15. *See also* **Ex. 1003**, Appendix B (Ground 4, p. 83).

5. Ground 5: Andersson in View of Taylor in View of Beurrier Renders Obvious Claims 40 and 51

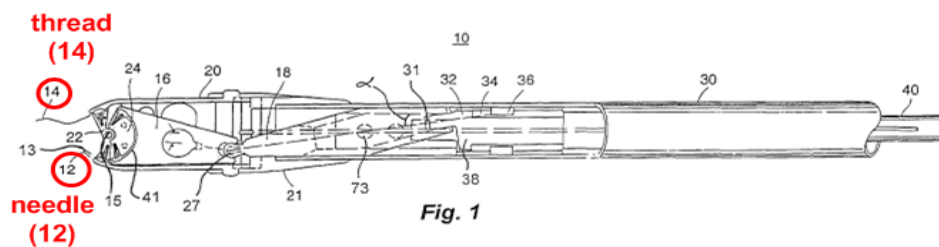
Andersson: Andersson discloses a suturing device with an arcuate needle capable of rotating about an axis. **Ex. 1006**, Abstract; **Ex. 1003**, ¶¶ 88-94. The “circular-arcuate suture needle 16” of Andersson has “a sharp point 17 on one end .

... and a suture thread 18 connected to the other end ... [that] can be driven around a circular part [sic, path] with the pointed end 17



of the needle in the driving direction.” **Ex. 1006**, 1:63-2:1. **Ex. 1003**, ¶ 90.

Taylor: Taylor discloses a suturing device having an arcuate suturing needle that rotates about an axis. **Ex. 1008**, Abstract; **Ex. 1003**, ¶¶ 95-101. The suturing device of Taylor “may comprise a *removable cartridge* containing at least needle 12 and attached thread 14 ... which may be disposable.” **Ex. 1008**, 7:37-40.



Beurrier: Beurrier was described in Ground 2 (*see* Section VI.B.2).

Motivation to Combine Andersson, Taylor, and Beurrier: Andersson, Taylor, and Beurrier disclose suturing devices with many features in common. **Ex. 1003**, ¶¶ 112-117. All three references disclose suturing devices with arcuate needles that rotate about an axis. **Ex. 1003**, ¶ 112. Both Taylor and Beurrier explicitly discuss Andersson. **Ex. 1003**, ¶ 113; **Ex. 1005**, 1:18-21; **Ex. 1008**, 1:25-28, 1:41-50. Specifically, Taylor and Beurrier recognize the potential for needle

slippage in Andersson's design, and each proposes solutions to overcome this potential shortcoming in Andersson's design. **Ex. 1003**, ¶ 113. Additionally, both Taylor and Beurrier disclose suturing needles contained in disposable housings. **Ex. 1003**, ¶ 115; **Ex. 1005**, 5:31-34; **Ex. 1008**, 7:36-40. Furthermore, Andersson and Taylor disclose drive mechanisms that may generate continuous needle rotation of the suturing needle. **Ex. 1003**, ¶ 114; **Ex. 1006**, 2:24-32; **Ex. 1008**, 7:41-45. Both Andersson and Taylor also disclose actuators that may be in the form of foot pedals to trigger the rotation of the suturing needle. **Ex. 1003**, ¶¶ 91, 99, 116; **Ex. 1006**, 2:9-12; **Ex. 1008**, 6:39-42. In light of these teachings, a person of ordinary skill in the art would have been motivated to combine features disclosed in each of Andersson, Taylor, and Beurrier to improve upon known problems or shortcomings in the art. **Ex. 1003**, ¶ 117. Specifically, a person of ordinary skill in the art would have been motivated to incorporate a needle cartridge such as the one disclosed in Taylor into the suturing device of Andersson in order to prevent the known problem of accidental needle pricks described in Beurrier and Taylor by ensuring that the needle does not project materially outside of the protective housing of the cartridge after a complete rotation. *Id.* This can be accomplished by shortening the arcuate extent of the needle or extending the arcuate extent of the cartridge's protective housing. *Id.*; *see also id.*, ¶ 86-87, 117.

Claims 40 and 51 are Obvious: Method claims 40 and 51 of the '819 Patent recite the same components (a *cartridge having a protective housing*, a *suturing needle*, and an *actuator*) recited in claim 1 (*see* Section VI.B.1) of the '819 Patent, except that claims 40 and 51 do not recite a pusher assembly. **Ex. 1003**, ¶¶ 19, 36-42. Nevertheless, claims 40 and 51 recite the two subcomponents (a *cartridge holder assembly* having a *needle rotation drive*) that claim 1 recites as being comprised in the pusher assembly (*see* Section VI.B.1). **Ex. 1003**, ¶¶ 19, 30-35. With respect to these components and subcomponents, Andersson discloses a *suturing needle*, an *actuator*, and a *needle rotation drive*. **Ex. 1003**, ¶¶ 88-93. Andersson also teaches the limitation “*deactivating the actuator . . . to cause*” under Petitioner’s proposed construction. *See* Section III.B.2.; **Ex. 1003**, ¶ 94. Andersson does not explicitly disclose a cartridge or a cartridge holder assembly. **Ex. 1003**, ¶ 94. Taylor discloses all the physical components and subcomponents recited in claims 40 and 51, but it does not teach the limitation “deactivating the actuator . . . to cause” under Petitioner’s proposed construction. **Ex. 1003**, ¶¶ 95-101. Andersson and Taylor in view of Beurrier teach the limitation “positioned within the protective housing” under Petitioner’s proposed construction for this term. *See* Section III.B.1.

Suturing Needle, Needle Rotation Drive, and Actuator: Andersson discloses a “suturing needle 16,” an actuator in the form of “a foot pedal” (*see* Section

VI.B.1.; **Ex. 1003**, ¶ 91; **Ex. 1006**, 2:9-12), and a needle rotation drive (i.e., a mechanism that drives the rotation of the suturing needle) comprising plunger 3, plunger rod 8, flywheel 10, and roller 12. **Ex. 1003**, ¶¶92-93; **Ex. 1006**, 2:9-16.

Taylor discloses needle 12,

an actuator in the form of “a foot pedal,” and a needle rotation drive comprising drive shaft 40, crank shaft 38, and the combina-

tion of toggle 18

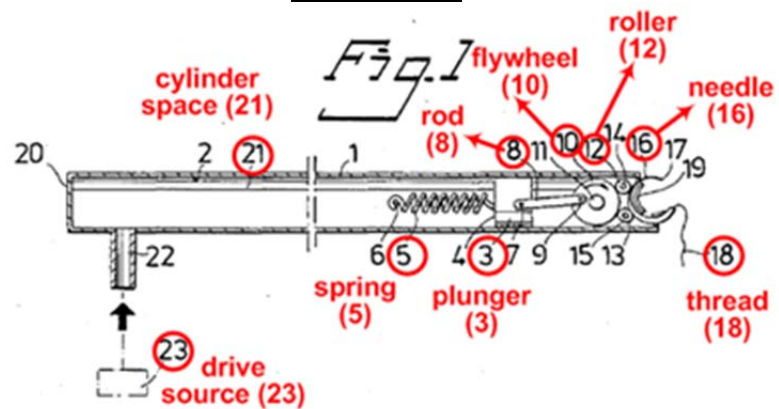
and drive plate

16. **Ex. 1003**, ¶¶

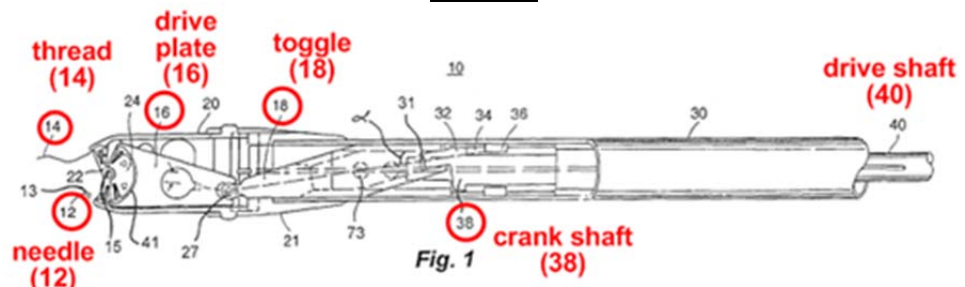
95-100. **Ex.**

1008, 3:66-4:24, 4:32-39, Figure 1.

Andersson



Taylor



Needle Cartridge and Cartridge Holder Assembly: Taylor discloses a sutur-

ing device that “may comprise a removable cartridge containing at least needle 12 .

. . which may be disposable.” **Ex. 1008**, 7:37-40; **Ex. 1003**, ¶ 101. Because Taylor

teaches a “removable cartridge,” it also necessarily discloses a corresponding

structure to which it releaseably attaches (i.e., “an assembly for releasably attach-

ing the cartridge,” in accord with Petitioner’s construction of “cartridge holder as-

sembly.”). **Ex. 1003**, Appendix B (pp. 90-91). **Ex. 1008**, 7:37-40. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194–96 (Fed. Cir. 2014) (“[I]nherency may supply a missing claim limitation in an obviousness analysis . . .” if “the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.”) (citations omitted).

The “deactivating the actuator . . . to cause” Limitation: Andersson teaches that “deactivating the actuator” causes a corresponding action by the suturing device as required by Petitioner’s proposed construction of this claim term. *See* Section III.B.2. When the foot pedal of Andersson is deactivated (i.e., reset or returned), a “pressure surge is interrupted

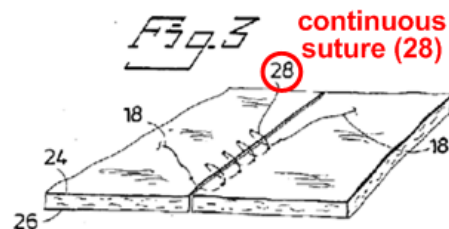
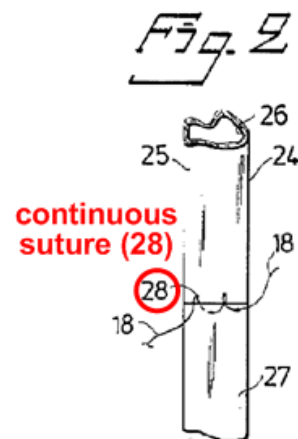
and the pressure in the cylinder space 21 will fall, *whereupon the return spring 5 . . . will function to withdraw the plunger 10 back to its inner position.*” **Ex. 1006**, 2:19-24;

Ex. 1003, ¶ 94. This causes the “suture thread [to] form[] a

loop through the two tissue parts and, as illustrated in FIGS. 2 and 3, forms a continuous suture 28 by repeating the aforescribed working

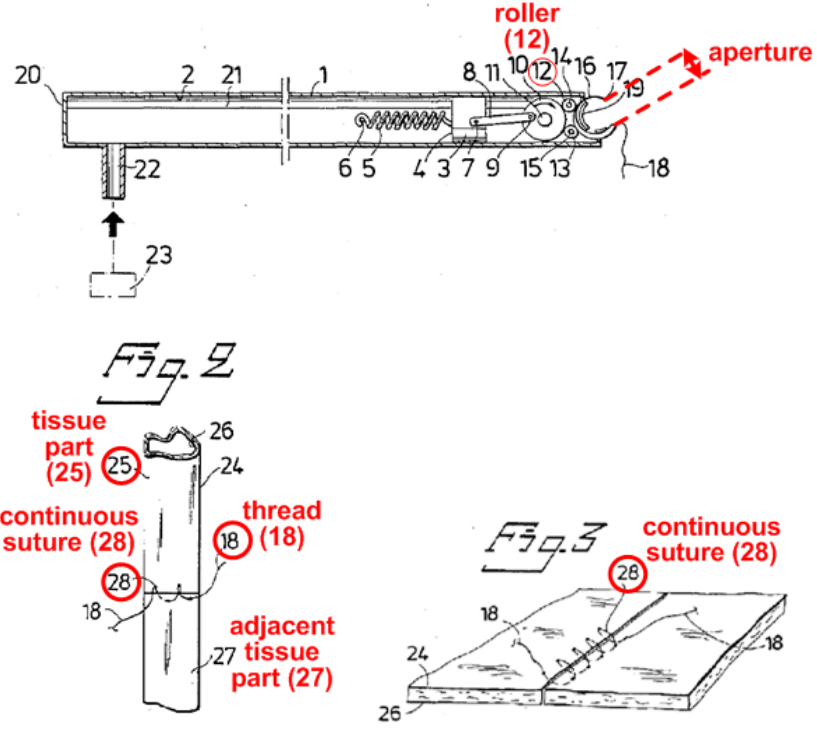
cycle.” **Ex. 1006**, 2:24-36. **Ex. 1003**, ¶ 94, Appendix B, Ground 5 (pp. 95-96).

In addition to the components, subcomponents, and the limitation “deactivating the actuator . . . to cause” described above, the claim chart that follows indi-



cates where Andersson, Taylor, and Beurrier disclose each element of claims 40 and 51. *See also* **Ex. 1003**, ¶¶ 88-94, Appendix B (Ground 5, pp. 89-96, and 99-101). For purposes of Ground 5, Petitioner has applied the proposed constructions for the terms “*positioned within the protective housing*,” “*deactivating the actuator . . . to cause*,” and “*cartridge holder assembly*.” *See* Section III.B.

Claim	Prior Art
40. [preamble] A method for suturing tissue comprising the steps of:	<i>See</i> Ex. 1006 , Abstract (“The invention relates to <i>suturing instrument for joining two edges of biological tissue together</i> . The instrument includes a housing (1) in which there is movably arranged an <i>arcuate suture needle</i> (16) having a point (17) arranged to penetrate the tissue, and the suture thread (18) connected to the suture needle. ”); Ex. 1008 , Abstract (“An automated stitching device having a ‘C’-shaped <i>arcuate needle which is incrementally advanced in a circular path</i> .”); Ex. 1005 , Abstract (“A mechanical apparatus for suturing biological tissue including a cassette housing, a continuous loop belt mounted for circulation therein, an <i>arcuate needle mounted within the cassette for 360° rotation</i> ”).
[a] releasably engaging a cartridge to a cartridge holder assembly of a suturing device;	<i>See</i> Ex. 1006 , Figure 1; Ex. 1008 , Figure 1. <i>See</i> Ex. 1008 , 7:37-40. (“Some or all of the distal portion of the stitcher 10 may comprise a <i>removable cartridge containing at least needle 12</i> and attached thread 14 and <i>which may be disposable</i> .”).
[b] 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 protec-	<i>See</i> Ex. 1006 , Figures 1, 2, and 3. <i>Id.</i> 1:35-39 (“FIG. 1 is a simplified view of a suturing instrument according to the invention; FIG. 2 illustrates the joining of a blood vessel; FIG. 3 illustrates the mode of the instrument in sewing two edges of tissue together”).

Claim	Prior Art
<p>tive housing after a complete rotation of the suturing needle about a rotational axis;</p>	 <p>Ex. 1005, 5:66-68 (“The point of needle 102 is also safely protected in cassette 101 avoiding injury or the spread of infection to a user of the device.”).</p>
<p>[c] 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</p>	<p>See Ex. 1006, 2:12-19 (“When the plunger moves towards the needle 16, under the action of the increased pressure in the cylinder space 21, <i>the flywheel 10 will rotate and its rotary motion transmitted to the two friction rollers 12 and 13 abutting the suture needle 16. As a result hereof, the circular-arcuate suture needle 16 is rotated about its centre axis</i>, with the point 17 of the needle in the rotating direction.”); <i>id.</i>, Figs. 1, 2, and 3.</p>
<p>[d] deactivating the actuator to stop an advancing movement of the suturing needle to cause a suturing material attached to</p>	<p>See Ex. 1006, 2:6-9 (“The drive source 23 is arranged to deliver a pressure surge to the cylinder space 21 at, for example, predetermined or randomly selected time intervals, whereupon the plunger 3 is urged forwards.”). <i>Id.</i>, 2:12-19 (“When the plunger moves towards the needle 16, under the action of the increased pressure in the cylinder space 21, the flywheel 10 will rotate and its rotary motion transmitted to the two friction rollers 12 and 13 abutting the suture needle 16. As a result hereof, the circular-</p>

Claim	Prior Art
the suturing needle to be pulled through the plurality of separated tissue segments forming a <u>stitch</u> .	arcuate suture needle 16 is rotated about its centre axis, with the point 17 of the needle in the rotating direction.”). <i>Id.</i> , 2:19-24 (“As soon as the plunger rod 8 reaches its top-dead-centre position, the pressure surge is interrupted and the pressure in the cylinder space 21 will fall, whereupon the return spring 5, which is now tensioned, will function to withdraw the plunger 10 back to its inner position.”).
51. A method for suturing tissue at a wound or incision site comprising the steps of:	<i>See</i> claim 40 [preamble] (Ex. 1006 , Abstract; Ex. 1008 , Abstract; Ex. 1005 , Abstract).
[a] releasably engaging a cartridge to a cartridge holder assembly of a suturing device;	<i>See</i> claim 40[a] (Ex. 1006 , Figure 1; Ex. 1008 , Figure 1; <i>See</i> Ex. 1008 , 7:37-40).
[b] placing a suturing device having a cartridge with a protective housing and a suturing needle at the wound site or incision site to cause an aperture in the cartridge to span a tissue of the wound or incision site, 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;	<i>See</i> claim 40[b] (Ex. 1006 , Figures 1, 2, and 3. <i>Id.</i> 1:35-39; Ex. 1005 , 5:66-68).
[c] 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 suture needle through the tissue of the wound or incision site; and	<i>See</i> claim 40[c] (Ex. 1006 , 2:12-19; <i>id.</i> , Figs. 1, 2, and 3).
[d] deactivating the actuator at the completion of advancing movement of the suturing needle to cause a suturing material attached to the suturing needle to be pulled through the tissue of the wound or incision site; and	<i>See</i> claim 40[d] (Ex. 1006 , 2:6-9; <i>Id.</i> , 2:12-24).
[e] repeating steps B through D to cause a plurality of stitches to be placed through the tissue of the wound or incision site.	<i>See</i> claim 40[b] (Ex. 1006 , Figures 1, 2, and 3. <i>Id.</i> 1:35-39; Ex. 1005 , 5:66-68). <i>See</i> claim 40[c] (Ex. 1006 , 2:12-19; <i>id.</i> , Figs. 1, 2, and 3.) Ex. 1006 , 2:24-36 (“By suitable adjustment of the duration of the pressure surge . . . the needle will carry out one revolution for each pressure surge Thus, <i>the suture thread . . . forms a continuous suture 28 by repeating the aforescribed working cycle.</i> ”).

6. Ground 6: Under an Alternative Construction of the Term “*positioned within the protective housing*,” Andersson in View of Taylor in View of Beurrier Renders Obvious Claims 40 and 51

To the extent that it is determined that the term “positioned within the protective housing” means that the pointed end of the needle “*does not project at all outside of the protective housing*,” Andersson and Taylor in view of Beurrier render obvious claims 40 and 51 for the same reasons described under Ground 5, which is incorporated herein. As explained in Section VI.B.2., Beurrier’s teaching that the pointed end of its arcuate needle be “safely protected” in its housing to “avoid[] injury or the spread of infection to a user of the device” (**Ex. 1005**, 5:66-68) would motivate a person of ordinary skill in the art to modify a suturing device according to the teachings of Andersson and Taylor so that the pointed end of the needle did not protrude *at all* outside the cartridge after a complete rotation. **Ex. 1003**, ¶ 117. Thus, Andersson and Taylor in view of Beurrier render obvious claims 40 and 51. *See also* **Ex. 1003**, Appendix B (Ground 6, pp. 89-96, and 99-101).

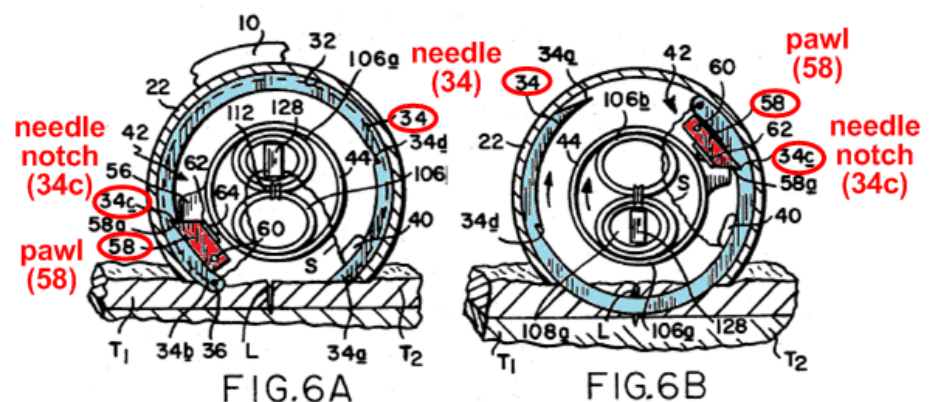
7. Ground 7: Under an Alternative Construction of the Term “*deactivating the actuator . . . to cause*,” Meade Anticipates Claims 40, 46-52, and 59-62

Meade: Meade was described in Ground 1 (*see* Section VI.B.1.).

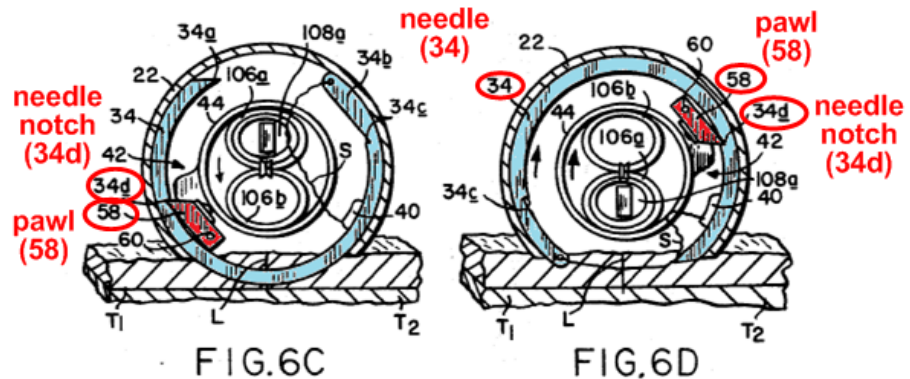
Claims 40, 46-52, 59-62 are Anticipated: As explained in Section VI.B.1. (which is incorporated herein to the extent described below and in the claim chart

that follows) Meade discloses all the physical components recited in independent claims 40, and 51 (namely, a cartridge having a protective housing, a needle, a cartridge holder assembly, a needle rotation drive, and an actuator). *See* Section VI.B.1. **Ex. 1003**, ¶¶ 19-35.

The “deactivating the actuator . . . to cause” Limitation: Under an alternative construction of this term, i.e., “*returning or resetting the actuator . . . to permit, allow, or enable,*” Meade discloses this limitation. In fact, as explained below and in the claim chart that follows, under this construction, Meade discloses the identical steps for operating an actuator to cause the rotation of a suturing needle as those claimed in the ’819 Patent. In this regard, when the lever 16 moves away from grip 12, the drive mechanism engages the needle via the pawl 58 and moves it 180 degrees in the clockwise direction (the movement of the needle is shown by comparing Figs. 6A and 6B). **Ex. 1004**, 10:12-23. By “returning” or “resetting” lever 16 (i.e., moving it back towards grip 12), the drive mechanism disengages the needle and the pawl rotates in the counterclockwise direction for the pawl to engage the needle once again. *Id.*, 10:24-30. Under this construction, the step carried out in



moving the needle rotation drive from Fig. 6B to Fig. 6C is the “deactivating” step claimed in the ’819 Patent. **Ex. 1003**, Appendix B (Ground 7, pp. 95-96). This step “stops an advancing movement” of the suturing needle (as recited in claim 40) and it occurs “at the completion of an advancing movement” of the suturing needle (as recited in claim 51). Once this step is completed, it “permits,” “allows,” or “enables” a user to move lever 16 away from grip 12 to cause (once again) the clockwise rotation of the drive mechanism with the engaged needle and in doing so it cause the suturing material attached to the suturing needle to be passed through tissue. **Ex. 1004**,



and “*cartridge holder assembly*,” and the alternative construction (see Section III.B.2.) of the term “*deactivating the actuator . . . to cause*.”

Claim	Prior Art
40. [preamble] A method for suturing tissue comprising the steps of:	Meade discloses that “[t]o commence suturing, the surgeon, holding the instrument by means of the grip 12, moves lever 16 rearwardly with the thumb Under these conditions, the bevel gear[s] . . . will rotate the drive shaft 44 . . . so that needle 34 . . . will rotate This motion of the needle causes the needle tip 34a to penetrate down through the tissue T2 and tap through the tissue T1 following a curved path as shown in FIG. 6B.” Ex. 1004 , 10:12-23; <i>see also id.</i> , 12:1-21.
[a] releasably engaging a cartridge to a cartridge holder assembly of a suturing device;	<i>See</i> Ground 1 claim 1[a] (Ex. 1004 , 4:46-48; <i>id.</i> , Fig. 1). <i>See</i> Ground 1 claim 1[b] (Ex. 1004 , 12:22-27, Figs. 5A and 5B).
[b] 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;	<i>See</i> Ground 1 claim 1[a] (Ex. 1004 , 4:46-48; <i>see also id.</i> Fig. 1, 5:2-5, Figs. 5A, 5B; Ex. 1004 , 5:30-34, Figs. 6A through 6D, 6:13-26). Meade discloses that “when the instrument is positioned so that the tissues to be sutured are situated at the housing aperture, the needle will penetrate the tissues and span the incision between them.” Ex. 1004 , 3:9-12.
[c] 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	<i>See</i> Ground 1 claim 1[c]. Ex. 1004 , Fig. 2 (lever 16), 10:12-14, 6:27-47. <i>See</i> Ground 1 claim 1[b]. Ex. 1004 , 10:12-23, Figs. 6A-6B.
[d] 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.	<i>See</i> Ground 1 claim 1[b] (Ex. 1004 , 10:24-45, Figs. 6B through 6D, 6:20-26).
46. The method of claim 40 wherein the needle rotation drive causes rotation of the suturing needle com-	<i>See</i> Ground 1 claim 25 (Ex. 1004 , 5:62-6:2, 9:59-

Claim	Prior Art	
	prising a blunt end and a sharp pointed end by providing a pushing force adjacent to said blunt end and a pulling force adjacent to said sharp pointed end.	10:3).
47. The method of claim 40 wherein the tissue is mammalian tissue.	Meade discloses that “[a] further object of the invention is to provide a suturing instrument which incorporates a unique thread management system which controlledly pulls the thread entirely through the <i>patient's tissues</i> following each stitch.” Ex. 1004 , 2:18-22.	
48. The method of claim 40 further comprising moving the suturing needle in a curved track on an inner surface of the cartridge during rotation of the suturing needle.	See Ground 1 claim 29 (Ex. 1004 , 5:13-23, Figs. 5A, 5B, and 2).	
49. The method of claim 40 further comprising positioning the pointed end of the suturing needle within a curved track of the cartridge prior to and after rotation of the suturing needle.	See Ground 1 claim 29 (Ex. 1004 , 5:13-23, 5:30-34, Figs. 5A, 5B, and 2).	
50. The method of claim 40 further comprising slidably positioning the suturing needle in a curved track of the cartridge.	See claim 49 (Ex. 1004 , 5:13-23, 5:30-34, Figs. 5A, 5B, and 2).	
51. A method for suturing tissue at a wound or incision site comprising the steps of:	See claim 40 [preamble] (Ex. 1004 , 10:12-23; <i>see also id.</i> , 12:1-21).	
[a] releasably engaging a cartridge to a cartridge holder assembly of a suturing device;	See claim 40[a] (Ex. 1004 , 4:46-48; <i>id.</i> Fig. 1, 12:22-27, Figs. 5A and 5B).	
[b] placing a suturing device having a cartridge with a protective housing and a suturing needle at the wound site or incision site to cause an aperture in the cartridge to span a tissue of the wound or incision site, 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;	See claim 40[b] (Ex. 1004 , 4:46-48; <i>see also id.</i> Fig. 1, 5:2-5, Figs. 5A, 5B; Ex. 1004 , 5:30-34, Figs. 6A through 6D, 6:13-26; Ex. 1004 , 3:9-12).	
[c] activating an actuator coupled to a needle rotation drive that releasably engages the suturing needle to cause rotational movement of the suturing needle across	See claim 40[c] (Ex. 1004 , Fig. 2 (lever 16), 10:12-14, 6:27-47.	

the aperture and advance the suture needle through the tissue of the wound or incision site; and	Ex. 1004 , 10:12-23, Figs. 6A-6B
[d] deactivating the actuator at the completion of advancing movement of the suturing needle to cause a suturing material attached to the suturing needle to be pulled through the tissue of the wound or incision site; and	<i>See</i> claim 40[d] (Ex. 1004 , 10:24-45, Figs. 6B through 6D, 6:20-26).
[e] repeating steps B through D to cause a plurality of stitches to be placed through the tissue of the wound or incision site.	Meade discloses that “[t]he surgeon continues to manipulate the instrument, alternately advancing and rotating the needle about an axis that is generally parallel to the direction of advancement <i>to create a continuous suture which may extend the entire length of the incision.</i> ” Ex. 1004 , 3:30-34. <i>See also. Ex. 1004</i> , 4:6-10 (“[The apparatus and method disclosed in Meade] should find wide application wherever sutures consisting of <i>single stitches or continuous stitches . . .</i> ”).
52. The method of claim 51 for obtaining a series of continuous sutures to close the wound or incision site.	<i>See</i> claim 51[e] (Ex. 1004 , 3:30-34, 4:6-10).
59. The method of claim 51 wherein the tissue is mammalian tissue.	<i>See</i> claim 47 (Ex. 1004 , 2:18-22).
60. The method of claim 51 further comprising moving the suturing needle in a curved track on an inner surface of the cartridge during rotation of the suturing needle.	<i>See</i> claim 48 (Ex. 1004 , 5:13-23, Figs. 5A, 5B, and 2).
61. The method of claim 51 further comprising positioning the pointed end of the suturing needle within a curved track of the cartridge prior to and after rotation of the suturing needle.	<i>See</i> claim 49 (Ex. 1004 , 5:13-23, 5:30-34, Figs. 5A, 5B, and 2).
62. The method of claim 51 further comprising slidably positioning the suturing needle in a curved track of the cartridge.	<i>See</i> claim 50 (Ex. 1004 , 5:13-23, 5:30-34, Figs. 5A, 5B, and 2).

8. Ground 8: Under Alternative Constructions of the Terms “*positioned within the protective housing*” and “*deactivating the actuator . . . to cause,*” Meade in View of Beurrier Renders Obvious Claims 40, 46-52, and 59-62

To the extent that it is determined that the term “positioned within the pro-

tective housing” means that the pointed end of the needle “does not project at all outside of the protective housing,” Meade in view of Beurrier renders obvious claims 40, 46-52, 59-62 for the same reasons described under Ground 7, which is incorporated herein, except as to this claim term. As explained in Section VI.B.2., Beurrier’s teaching that the pointed end of its arcuate needle be “safely protected” in its housing to “avoid[] injury or the spread of infection to a user of the device” (Ex. 1005, 5:66-68) would have motivated a person of ordinary skill in the art 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. Ex. 1003, ¶ 111. Thus, Meade in view of Beurrier renders obvious claims 40, 46-52, and 59-62. *See also* Ex. 1003, Appendix B, Ground 8 (pp. 89-102).

VII. SECONDARY CONSIDERATIONS

For evidence of commercial success to be pertinent to an evaluation of obviousness, there must be a nexus between the commercial success and the merits of the claimed invention. That is, the commercial success must be shown to be due to the nature of the invention as claimed, as opposed to other factors, such as economic and commercial factors that are unrelated to the technical quality of the patented invention. There is no evidence that any product on the market has received any industry recognition attributable to the features claimed in the Challenged Claims of the ’819 Patent. *See* Ex. 1003, ¶ 133-134. There is no evidence that any

product on the market has achieved any unexpected results or recognition attributable to the features claimed in the Challenged Claims of the '819 Patent. *Id.*, ¶ 137-138. Moreover, the features claimed in the Challenged Claims were well known in the art and are not attributable to any alleged unexpected, or superior properties. *Id.* Finally, there is no evidence that prior to the purported invention of the '819 Patent, there existed a long-felt need for the invention claimed in the Challenged Claims. *Id.*, ¶ 136.

VIII. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner Ethicon, Inc. is a real party-in-interest. Ethicon Endo-Surgery, Inc. is also a real party-in-interest. Ethicon, Inc. and Ethicon Endo-Surgery, Inc. are wholly-owned subsidiaries of Johnson & Johnson, which is also a real party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Petitioner is not aware of any disclaimers, reexamination certificates or petitions for IPR for the '819 Patent. Patent Application No. 13/197,870, which is a child of the '254 Application may be affected by this proceeding.

C. Lead and Back-Up Counsel and Service Information

The signature block of this petition designates lead counsel, backup counsel, and service information for Petitioner.

IX. GROUNDS FOR STANDING UNDER § 42.104(a)

Petitioner certifies that the '819 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the claims of the '819 Patent on the grounds identified in this petition. Specifically, Petitioner states that: (1) Petitioner is not the owner of the '819 Patent; (2) Petitioner has not filed a civil action challenging the validity of any claim of the '819 Patent; and (3) Petitioner has not been served with a complaint alleging infringement of the '819 Patent.

X. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 50-2310 for the fee set in 37 C.F.R. § 42.15(a) for this petition and further authorizes for any additional fees to be charged to this account.

XI. CONCLUSION

The prior art identified in this petition provides new, non-cumulative teachings which show a reasonable likelihood of success as to Petitioner's assertion that the Challenged Claims of the '819 Patent are unpatentable pursuant to the grounds presented. Petitioner respectfully requests institution of IPR for the Challenged Claims of the '819 Patent.

Dated: October 22, 2015

Respectfully submitted,

By: /Dianne B. Elderkin /
Dianne B. Elderkin (Lead Counsel)
Reg. No. 28,598
Ruben H. Munoz (Backup Counsel)
Reg. No. 66,998

**Akin Gump Strauss Hauer & Feld
LLP**

Two Commerce Square

2001 Market Street

Suite 4100

Philadelphia, PA 19103-7013

Tel: 215-965-1200

Fax: 215-965-1210

Email: ETHI-ENDO@akingump.com

Attorneys for Petitioner Ethicon, Inc.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e) and 42.105(a), the undersigned certifies that it caused to be served a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,923,819** (including accompanying Exhibits 1001-1010) by Priority Mail Express[®], on October 22, 2015, on the Patent Owner at the correspondence address of record for the subject patent:

Edwards Angell Palmer & Dodge LLP
P.O. Box 55874
Boston MA 02205

The undersigned further certifies that it caused to be served a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,923,819** (including accompanying Exhibits 1001-1010) by Federal Express, on October 22, 2015, on the following address, which is likely to effect service on the Patent Owner:

Ron Rudowsky, President/CEO
EndoEvolution, LLC
10 Commerce Way, Suite 5
Raynham, MA 02767 USA

Date: October 22, 2015

/Dianne B. Elderkin /
Dianne B. Elderkin
Reg. No. 28,598