IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Peter Emmanuel Petros	
U.S. Patent No.:	10,925,715	Attorney Docket No.: 48122-0013IP1
Issue Date:	February 23, 2021	
Appl. Serial No.:	16/784,603	
Filing Date:	February 7, 2020	
Title:	ANCHORING DEVICE AND ITS IMPLEMENTATION	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 10,925,715 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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Coloplast A/S (the parent of Coloplast Corp., each referred to as "Coloplast" or "Petitioner") petitions for *inter partes* review ("IPR") of claims 1-4, 6-7, 9-14, 16-17, and 19-20 ("the Challenged Claims") of U.S. Patent No. 10,925,715 ("the '715 patent").

The '715 patent is an overly-broad patent that goes too far, with the allowed claims now reading on old-in-the-art sling implants. When filing the continuation application in 2020 for the '715 patent, Patent Owner removed the purported inventive concept from the claims that was once at the heart of the claims in every issued patent in the family with the goal, presumably, of bringing a lawsuit against Coloplast for its near decade-long sale of medical sling products.[1] However, Patent Owner's new claims are so broad that they include only features that were already well-known. Thus, Patent Owner's overly broad claims are unpatentable over prior art.

I. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Coloplast certifies that the '715 Patent is available for IPR. The present petition is being filed within one year of service of a complaint against Coloplast

[1] The lawsuit was filed on February 23, 2021. COLOPLAST-1018.

Corp. in the district of Delaware. Coloplast is not barred or estopped from requesting this review challenging the Challenged Claims on the below-identified grounds.

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

Based on the evidence presented herein, including the expert testimony of Dr. Ty B. Erickson, M.D. (COLOPLAST-1003, ¶¶1-163), Coloplast requests IPR of the Challenged Claims of the '715 patent on the grounds listed below:

Ground	'715 Patent Claims	Basis for Rejection
1	1-4, 6-7, 9-14, 16-17, and 19-20	US Pub. No. 2002/0161382 ("Neisz") in view of US 6,500,194 ("Benderev") under §103
2	1-4, 6-7, 9-14, 16-17, and 19-20	WO 98/19606 ("Brenneman") in view of US 6,039,686 ("Kovac") under §103

The earliest possible priority date ("Critical Date") for the '715 patent is 8/23/2002, based on AU2002951024.[2] The earliest effective filing date for the '715 patent is 10/15/2003. The references below are prior art under at least 35 U.S.C. §102(e):

Reference	§102(e) Date
Neisz	3/25/2002
Benderev	3/14/1997
Brenneman	11/6/1997

[2] Petitioner does not concede that the '715 patent is entitled to this priority date.

Kovac	7/8/1998

II. SUMMARY OF THE '715 PATENT

A. Brief Description

Generally, the '715 patent describes a method of "providing ligamentory like support between two spaced locations in the body of a patient." COLOPLAST-1001, 1:43-45; COLOPLAST-1003, ¶¶36-38. More specifically, the method describes fixing "filamentary element[s]" to "ligaments" with "a pair of anchors 15" that "receive the ends…of [the] filament[.]" *Id*., 5:51-62.

Importantly, the '715 method describes using a specific anchor design having a "locking member" "**to prevent movement of the filamentary element … in [one] direction**." *Id*., 6:59-7:10. All the embodiments disclosed in the '715 specification include the locking member, or an equivalent structure, *id.*, *passim*, and every claim of the earlier filed patents (U.S. Pat. Nos. 8,753,372 and 10,426,594) recites a locking member or a similar structure. COLOPLAST-1012, 11:40-13:10; COLOPLAST-1013, 11:49-14:60. But unlike its earlier filings, the overly-broad '715 patent has omitted this presumably key feature—the locking member—and its function from all of the Challenged Claims. Thus, these broadened claims go too far—covering that which was already well-known in the prior art.

B. The Prosecution History

U.S. 10,925,715 issued on February 23, 2021, from U.S. Patent Application No. 16/784,603 ("the '603 application"), which was filed on February 7, 2020. *See* COLOPLAST-1002 (the '715 prosecution history), 257.

There were multiple office actions and claim amendments during the '603 application's prosecution. COLOPLAST-1002, *passim*; COLOPLAST-1003, ¶¶39-40. The Examiner's stated reasons for allowance were that the prior art failed to disclose "a method…providing a filament between a first anchor and a second anchor, adjusting a tension of the filament between the two anchors by moving the filament through an aperture of the second anchor" and "introducing the filament into a fascial tissue so that the filament will be embodied with the fascial tissue over time." COLOPLAST-1002, 14-15. But such a method was already an old approach before the Critical Date, as demonstrated by the prior art references in this Petition. Consequently, the Challenged Claims are obvious.

C. Claim Construction under 37 C.F.R. §§ 42.104(b)(3)

A claim subject to IPR "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. §42.100(b). Thus, all terms should be given their plain meaning. COLOPLAST-

1003, ¶¶44, 33-34; *see also* ¶¶15-32. Coloplast submits the following constructions as being consistent with the plain meaning of the terms.

"the filamentary element will become embodied with fascia in the fascial tissue" (claims 1, 11) – *fascial tissue grows into the filamentary element during healing.* COLOPLAST-1003, ¶¶45-46. This interpretation is consistent with the specification of the '715 patent. *Id.* For example, the '715 patent describes that "the filamentary element…is adapted to **facilitate the growth of tissue** between the locations to provide said ligamentory support between the locations." COLOPLAST-1001, 1:67-2:3. Furthermore, the '715 patent discloses that "**[w]ith the healing** of the incisions the **filamentary element becomes embodied** into the fascial tissue on the anterior and posterior sides of the vaginal walls" and "introducing the filamentary element into the fascial tissue such that with time it will become embodied with the fascia." COLOPLAST-1001, 6:4-7; 2:60-64.

"lateral" (claims 1, 11) – *to one side of*.[3] COLOPLAST-1003, ¶47. This interpretation is consistent with the specification of the '715 patent. *Id.* For

[3] Because the '715 patent also recites that the support be "sling-like," a POSITA would have understood that anchors can be positioned at locations that are both "lateral" and above to achieve the "sling-like" orientation described and claimed in the '715 patent. COLOPLAST-1003 (Expert Declaration), ¶47.

example, the '715 patent describes that "anchors 15 on each length of filamentary element 13 are embedded into the recto-vaginal ligaments in opposed relationship **to each side of** the vagina." COLOPLAST-1001, 5:63-66; *see also* abstract.

D. Level of Ordinary Skill

For purposes of this IPR, a POSITA would have had a doctor of medicine (M.D.) in an area emphasizing female pelvic surgery, or an equivalent field, or a bachelor of science and/or an advanced degree in an academic area emphasizing biomedical engineering, bioengineering, mechanical engineering, medical device design, or an equivalent field. COLOPLAST-1003, ¶¶41-43. Additionally, a POSITA would have had five or more years of experience in the area of female pelvic medicine or reconstructive surgery, or an equivalent field, or a bachelor of science and/or an advanced degree in an academic area emphasizing biomedical engineering, bioengineering, mechanical engineering, medical device design, or an equivalent field. *Id*.

III. THE CHALLENGED CLAIMS ARE UNPATENTABLE

This request shows how the primary references above, alone or in combination with other references, disclose or render obvious the limitations of the Challenged Claims. COLOPLAST-1003, ¶¶48-40; *see also* ¶35. While some of the prior art discussed below were *cited* during prosecution along with many other references, none were specifically *considered* during prosecution of the '715

patent, let alone considered in the combinations proposed herein. As detailed below, this request shows a reasonable likelihood that Petitioner will prevail with respect to Challenge Claims of the '715 patent.

A. GROUND 1

1. Combination of Neisz and Benderev

Neisz is a prior art patent application that teaches a variety of implant features, including implantable slings, and methods of providing support for the urethra to treat female urinary incontinence. COLOPLAST-1004 (Neisz), *passim*; COLOPLAST-1003, ¶¶51-59; *see also* COLOPLAST-1004, [0031]; [0131], [0036]; *see also* [0127]-[0138].

Neisz's implant "comprises a thin, flexible structure," e.g., a "rectangular" structure. COLOPLAST-1004, [0082]. Neisz also uses anchors, e.g., "deployable members" (shown below) "to implant the implant 10" that "may take several different forms." COLOPLAST-1004, [0092], [0101], [0132].

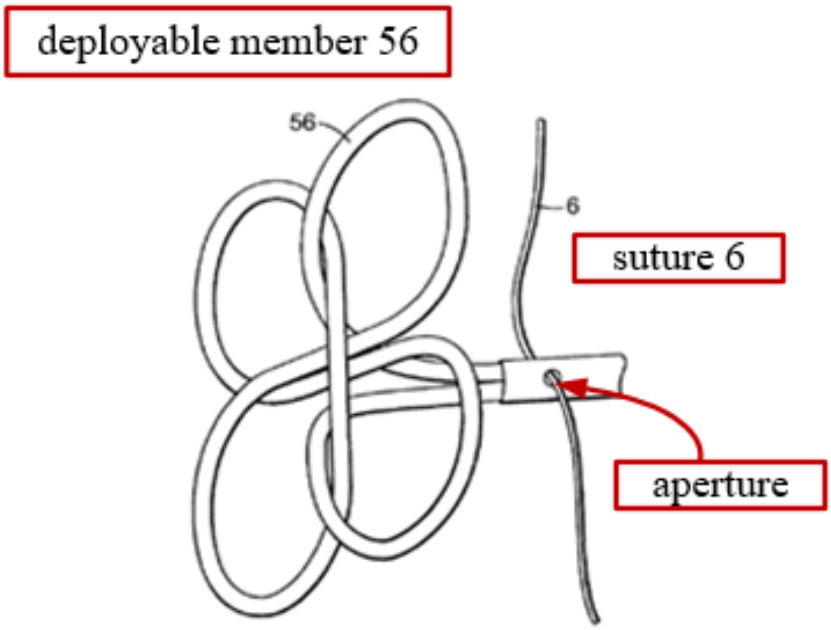


Fig. 9

COLOPLAST-1004, FIG. 9 (annotated).

As shown below in FIG. 4, Neisz discloses "placing the implant 10…in a therapeutically effective position relative to the patient's urethra 16." COLOPLAST-1004, [0131]. Neisz's method includes "pass[ing] a deployable anchoring member 56 with an associated suture 6 through endopelvic fascia 15" and deploying the anchor and the implant in endopelvic fascia. COLOPLAST-1004, [0132]-[0134], [0097].

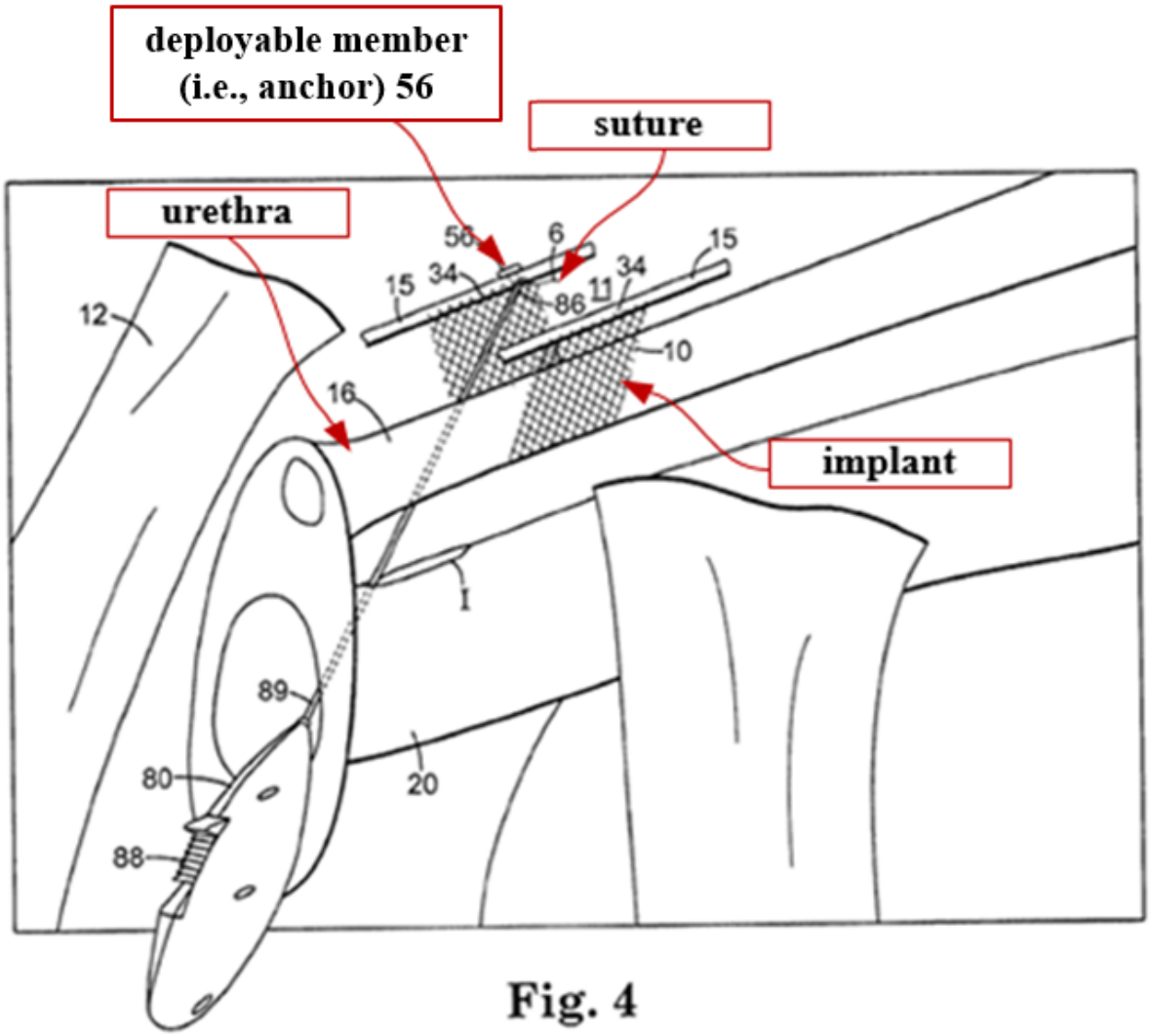


Fig. 4

COLOPLAST-1004, FIG. 4 (annotated).

Neisz discloses that the "implant 10 is secured by tying the suture 6 to the implant 10." COLOPLAST-1004, [0135]. Specifically, Neisz discloses that the "suture…is…used to secure one end of the implant 10 to the anchor 56" and the "steps…are repeated…for a second side of the implant 10 on the other side of the urethra 16." COLOPLAST-1004, [0135]-[0136]. Furthermore, Neisz's method "extend[s] the implant 10 from the endopelvic fascia on one side of the patient's

urethra 16…and to the endopelvic fascia 15 on the other side of the patient's urethra 16" to provide support. COLOPLAST-1004, [0136]; [0022].

Neisz also teaches adjusting tension of the sling to provide sling-like support by moving the suture through an aperture in Neisz's anchor. COLOPLAST-1003, ¶55. Specifically, Neisz's Figure 9 shows suture 6 loosely extending through an aperture in the anchor when in a collapsed orientation during insertion via an insertion tool, and a deployed orientation during anchoring. COLOPLAST-1004, [0097], [0098], FIGS. 5, 8, 9; *see also* [0101], FIGS. 10-11; COLOPLAST-1003 (Expert Declaration), ¶55.

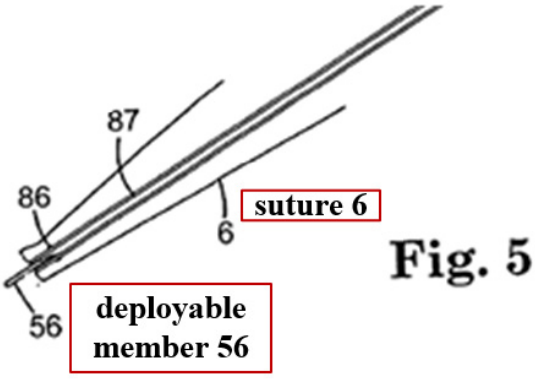


Fig. 5

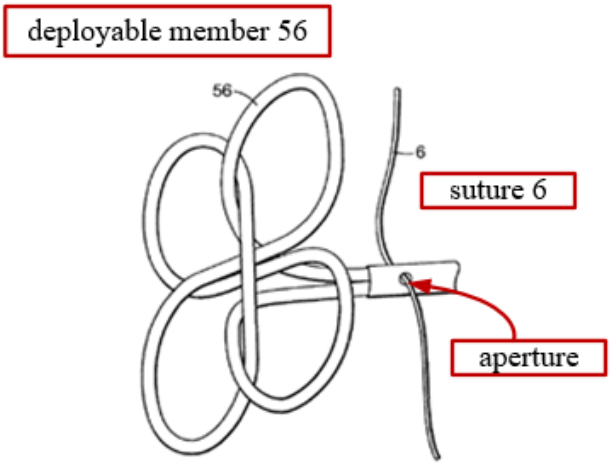
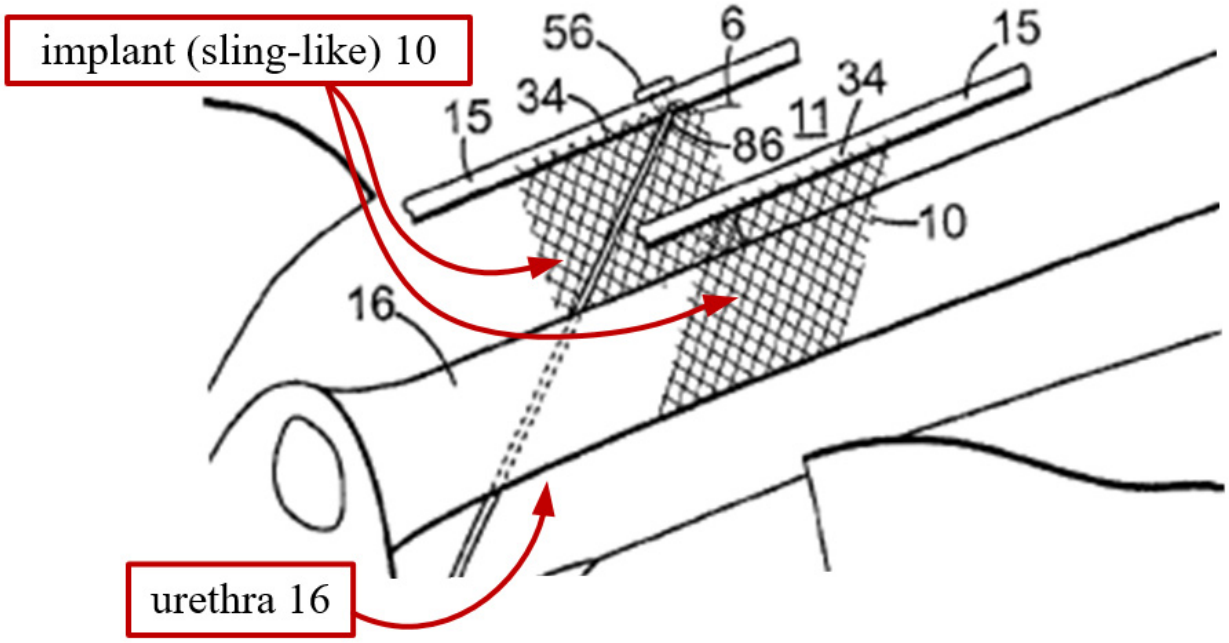


Fig. 9

COLOPLAST-1004, Fig. 5 (left, annotated), Fig. 9 (right, annotated).

Neisz's Figure 4 shows that implant 10 is eventually tightened to support the urethra 16. COLOPLAST-1004, FIG. 4; COLOPLAST-1003 (Expert Declaration), ¶56. Furthermore, Neisz discloses "[t]he implant is preferably placed

mid-urethra as shown in FIG. 4." COLOPLAST-1004, [0133]. Based on Neisz's FIG. 4 (shown below), it would have been obvious to a POSITA to loop an implant (e.g., a filamentary element) between two anchoring locations after introducing the filamentary element into fascial tissue. COLOPLAST-1003, ¶56.



COLOPLAST-1004, FIG. 4 (annotated).

A POSITA would have found it obvious to adjust the tension of the central portion between the first and second anchors so that the central portion provides at least a sling-like support for the urethra between the first and second locations based on Neisz's disclosure. COLOPLAST-1003, ¶¶56-57. For example, Neisz's repeated use of "sling" and "support" teaches that implant 10 should be tightened enough to provide sling-like support to the urethra. COLOPLAST-1004, [0008], [0014], [0015], [0027], [0031]; COLOPLAST-1003, ¶57.

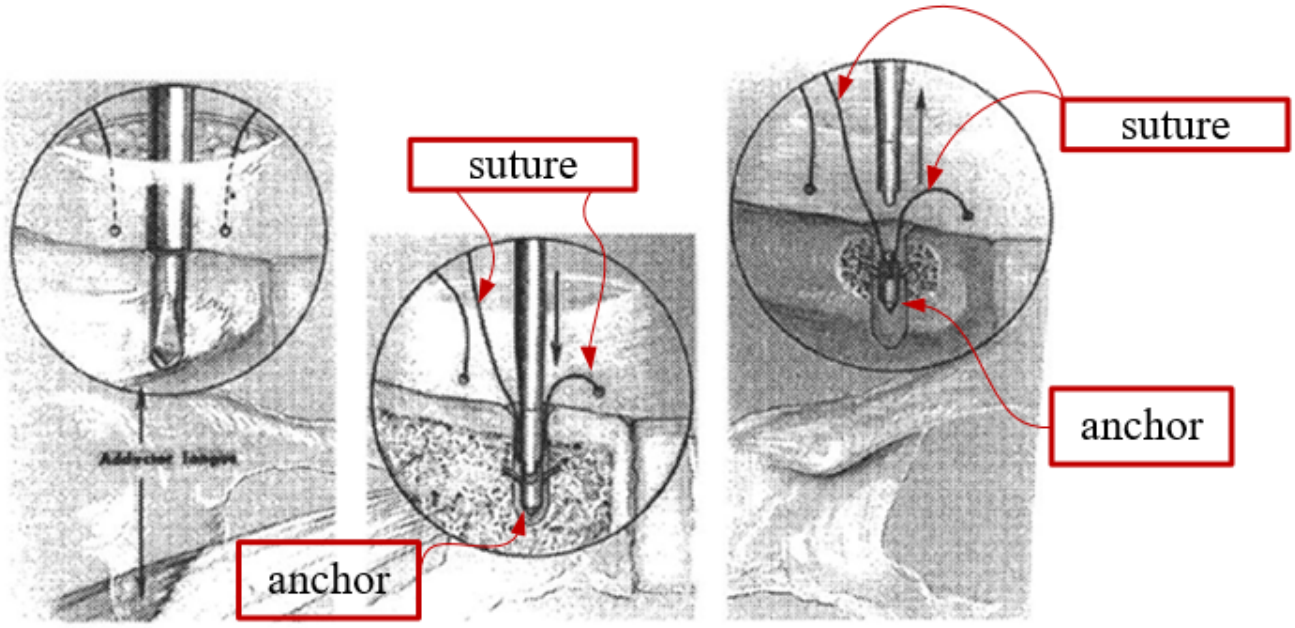
Moreover, Neisz also discusses adjusting the sling tension in numerous embodiments. COLOPLAST-1004, [0106], [0107], [0124]. In one example, Neisz discloses an embodiment that allows "adjustment of sling tension ***even after*** the suture 6E is tied to sling 10," which would have further suggested to a POSITA that sling tension is normally adjusted before and/or while the suture is tied to the sling. COLOPLAST-1004, [0107]; COLOPLAST-1003, ¶58.

Furthermore, when Neisz teaches that "[t]he implant 10 is secured by tying the suture 6 to the implant 10," a POSITA would have understood that the loose suture would have been pulled tight and tied as was conventionally done with sutures, which would have caused the suture to move through the aperture in the anchor (e.g., deployable member) at least slightly in one direction. COLOPLAST-1004, [0135]; COLOPLAST-1003, ¶59. Indeed, as shown above in FIGS. 5 and 9, Neisz's suture is threaded through anchor's aperture and hangs from the aperture in a free manner with slack depicted in those figures. COLOPLAST-1004, FIGS. 5, 9; COLOPLAST-1003, ¶59. It would have been obvious to a POSITA that any slack present in the thread would be addressed by pulling the suture through the anchor's aperture to tighten and/or shorten the suture lines and thereby ensuring that proper tension is applied to the sling once the anchors are positioned in the tissue. COLOPLAST-1003, ¶59. Such a tightening step would be necessary to ensure that unnecessary slack between the implant and the anchor is removed since

too much slack in the suture would prevent the urethra from being properly supported. *Id*. Accordingly, it would have been well understood that, in such sling-type urinary incontinence procedures, such an adjustment of the suture would be necessary because a POSITA would have known that adjusting suture length after implantation was easier and less prone to error as compared to adjusting suture length prior to insertion. COLOPLAST-1003, ¶59; *see also* COLOPLAST-1007 (Browning), [0043] (contemporary prior art explaining the well-known surgical concept: "it is difficult to predetermine what length the [sutures] must be to position the suburethral support loosely under the urethra as desired"). Indeed, Dr. Erickson explains: "A POSITA would have understood that tying a suture to attach a sling to an anchor like in Neisz would have either inherently or at least obviously slid the suture either a little or a lot through the aperture in Neisz's anchor when the suture is being pulled tight. That is just how tying a suture works—it moves in the direction of tightening." COLOPLAST-1003, ¶59.

To the extent that Neisz is deemed to not explicitly teach or render obvious adjusting the tension by moving the second portion through the aperture of the second anchor so that the central portion provides at least a sling-like support for the urethra between the first and second locations, a POSITA would have considered that technique obvious based on well-known techniques disclosed by other prior art. COLOPLAST-1003, ¶60. For example, such a tensioning

technique was taught by Benderev, entitled "Surgical treatment of stress foreign patent documents urinary incontinence," which discloses the "capture of the pubocervical fascia lateral to the bladder neck and urethra," "anchor fixation of the suspending sutures," and "a simple and reproducible technique to set a limited tension of the suspending sutures." COLOPLAST-1005 (Benderev), Title, Abstract; COLOPLAST-1003, ¶60. As shown in the figures below, Benderev teaches that "[o]ne anchor for each side…was loaded with a medical suture end" and that "**[t]raction was placed on the sutures**." COLOPLAST-1005 (Benderev), 36:15-29.



COLOPLAST-1005 (Benderev), Figs. 12a-12c (annotated). Benderev explains that the sutures are pulled to tighten the sutures enough to provide tension, stating:

"[t]he sutures on each side were then tied down with **sufficient tension**." COLOPLAST-1005 (Benderev), 36:30-37.

Multiple reasons would have motivated a POSITA to apply Benderev's tensioning techniques to Neisz's implant by drawing a suture through the aperture of the anchor when adjusting the tension of the sling underneath urethra to ensure that sufficient tension was being applied to the urethra. COLOPLAST-1003, ¶61.

First, a POSITA would have been prompted to move the suture through the aperture of the second anchor of Neisz's implant to apply sufficient tension, as taught by Benderev, to provide sling-like support for the urethra. *Id*. Benderev explicitly explains that "[t]he sutures on each side [are] tied down with sufficient tension **so as to develop a gentle elevation and cradle-like support**" of the urethra or bladder neck. COLOPLAST-1005 (Benderev), 36:30-37; *see also* abstract ("to provide a more accurate and reproducible capture of the pubocervical fascia lateral to the bladder neck **and urethra**."). In multiple embodiments, Neisz recognizes need to "adjust the tension of the sling underneath urethra." COLOPLAST-1004, [0124]; *see also* [0016], [0107]. Thus, a POSITA would have recognized that applying a well-known technique of adjusting the tension through the movement of the sutures, as described by Benderev, in Neisz's device would have resulted in achieving proper support of the urethra. COLOPLAST-1003, ¶61.

Second, a POSITA would have been prompted to pull the suture through the aperture of Neisz's second anchor in order to ensure that the anchor was properly attached to an implant location. COLOPLAST-1003, ¶61. Benderev teaches that, after an "anchor for each side…[is] loaded with a medical suture end," "[t]raction [is] placed on the sutures **to assure adequate fixation of the anchors**." COLOPLAST-1005 (Benderev), 36:22-29; *see also* Figs. 11a-11b, 12a-12c. A POSITA would have understood that by pulling the suture through the aperture of the second anchor until the suture was taut would allow a medical practitioner to tactilely determine whether the anchor was properly engaged in the implant location to provide adequate fixation of that anchor. COLOPLAST-1003, ¶61.

Third, a POSITA would have been prompted to move Neisz's suture through the second anchor's aperture to beneficially shorten the implant to a suitable length to reduce or eliminate unnecessary slack in the sutures and to properly position the sling in the patient. COLOPLAST-1003, ¶61. Both Neisz and Benderev illustrate loosely attaching suture to the anchor while the anchor is attached to an introducer device and during the securement of the anchor to the implantation location. *See* COLOPLAST-1004, FIGS. 4-5, 9; COLOPLAST-1005 (Benderev), FIGS. 11a-11b, 12a-12c. A POSITA would have understood that having some degree of slack in the sutures during placement of the anchors would allow a medical practitioner to implant the anchors without interference from the

attached sutures. COLOPLAST-1003, ¶61. Similarly, both references illustrate that the suture line becomes tautly attached to the anchors once the implants are properly tensioned. *See* COLOPLAST-1004, FIG. 8; COLOPLAST-1005 (Benderev), FIG. 13a-13b, 14. For this reason, a POSITA would have readily understood that pulling a suture (depicted in numerous embodiments) through the anchor's aperture to shorten the overall length of Neisz's implant would result in changing the tension applied on an implant positioned underneath the urethra (to support and/or prevent the urethra from descending). COLOPLAST-1003, ¶61.

Fourth, a POSITA would have been prompted to modify Neisz's method to adjust the tension of its implant by moving the second portion (e.g., suture, implant 10) through the aperture of the second anchor so that the implant provides at least a sling-like support for the urethra between the first and second locations because doing so would be merely the application of known techniques (applying traction on a suture) to a known system (Neisz's implant system) to yield predictable results. COLOPLAST-1003 (Expert Declaration), ¶61; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (a supposed invention that "simply arranges old elements with each performing the same function it had been known to perform" is obvious). A POSITA would have recognized that applying Bendrev's tensioning technique would have led to predictable results without significantly altering or

hindering the Neisz's method of providing support for the urethra to treat female urinary incontinence. COLOPLAST-1003, ¶61.

2. Analysis

[1pre] A method of providing support for the urethra to treat female urinary incontinence comprising:

To the extent that the preamble serves as a limitation, Neisz teaches element [1pre]. COLOPLAST-1003, ¶63. Neisz explains: "The present invention is directed to methods…for treating incontinence." COLOPLAST-1004, [0031]; *see also* [0003], [0021], [0041]. Neisz's "methods of use…generally relate to **female incontinence** conditions and treatments/procedures" and can "be utilized to support a variety of structures at different anatomical locations," e.g., the "**urethra**", "**mid-urethra**" and "bladder neck." COLOPLAST-1004, [0127]. "[T]he method includes the step of extending the implant from the…fascia on one side of the patient's urethra, **underneath approximately the mid-urethra**, and to the…fascia on the other side of the patient's urethra" to support the urethra. COLOPLAST-1004, [0036]; *see also* [0131]. Thus, Neisz teaches [1pre].

[1a] providing a support element having a first portion coupled to a first anchor, a second portion coupled to a second anchor through an aperture, and a central portion between the first and second portions and comprising a ribbon-like filamentary element;

Neisz teaches element [1a]. COLOPLAST-1003, ¶¶64-67. Neisz discloses "an implant for treating incontinence in a patient." COLOPLAST-1004, [0041].

Neisz's "implant 10 comprises a thin, flexible structure that has a geometry, size and shape suitable for placement" in the patient's anatomy. COLOPLAST-1004, [0082]. "[T]the implant 10 is rectangular with a pair of sides and a pair of ends 34." COLOPLAST-1004, [0082]; *see also* [0083], [0041]. As shown below, Neisz's implant 10 (and "sling 10B") teaches a ribbon-like shape.

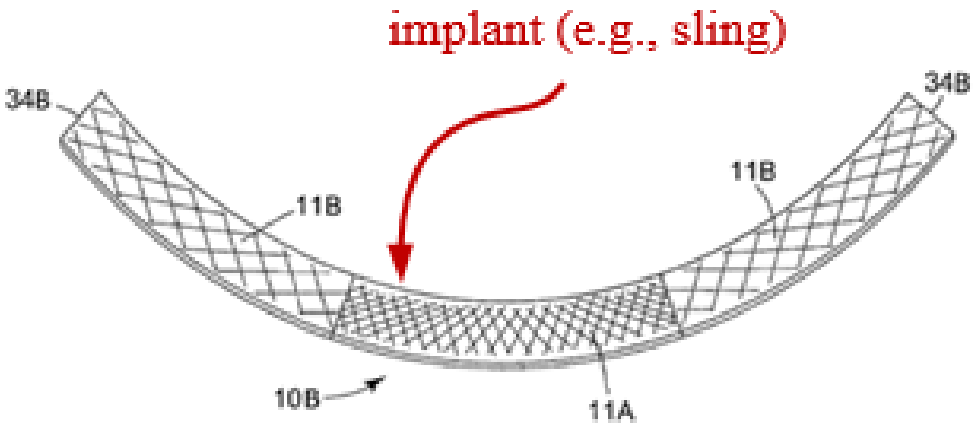


Fig. 32

COLOPLAST-1004, FIG. 32 (annotated), *see also* FIG. 4; COLOPLAST-1003, ¶64.

As Dr. Erickson explains, Neisz's Figure 4 shows and describes a support element having a first portion (including a first end of the implant 10 and a suture 6, colored blue), a second portion (including a second end of the implant 10 and another suture 6, colored yellow) and a central portion (including the portion of the

implant 10 between the first and second portions, colored green).[4] COLOPLAST-1004, [0132], FIG. 4; COLOPLAST-1003, ¶65.

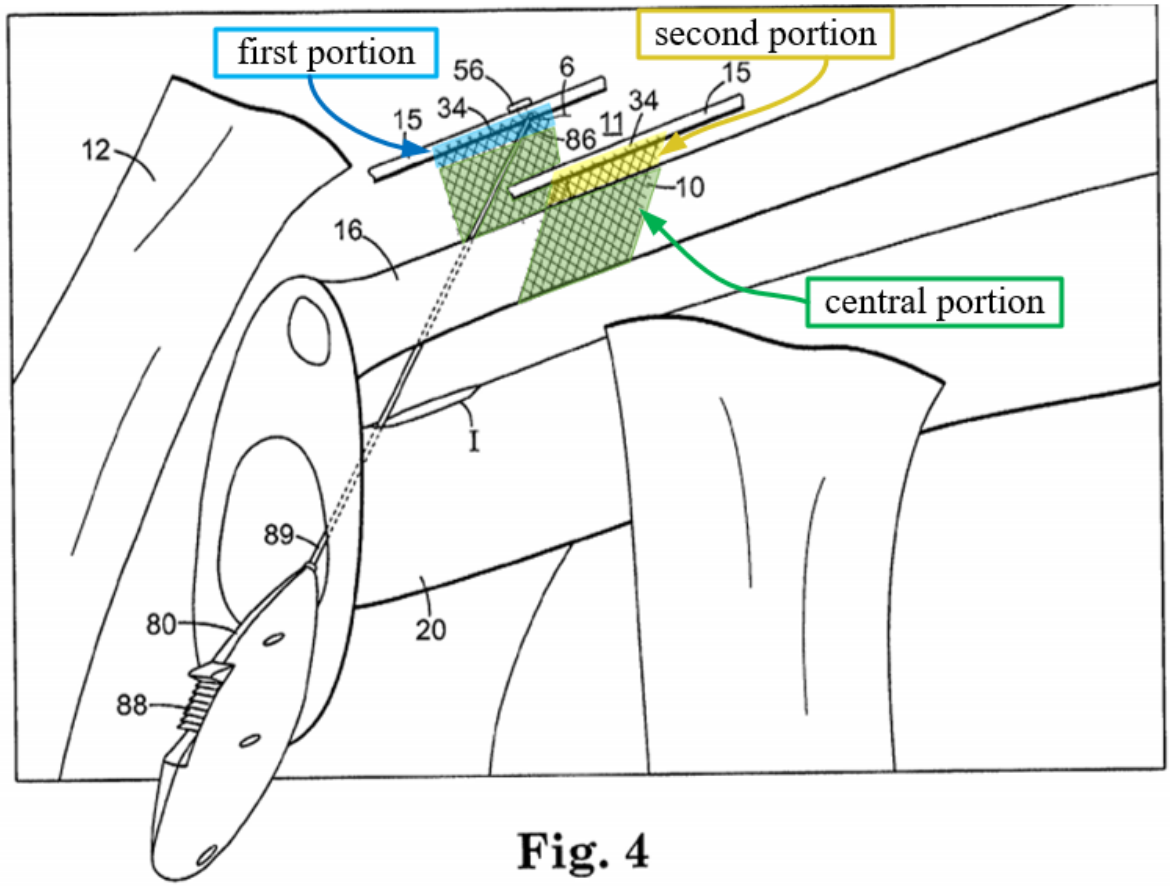


Fig. 4

COLOPLAST-1003, ¶65 (annotated).

[4] As Dr. Erickson explains in his declaration, Neisz discloses that anchors are used to anchor **both** sides of the implant, even though FIG. 4 depicts only one of the two anchors. COLOPLAST-1004 (Neisz), [0132] (describes using "anchors (e.g., 56)" to "anchor[] the second end 34 of the implant 10 with endopelvic fascia 15 on the other side of the patient's urethra 16."); COLOPLAST-1003, ¶65.

Neisz also "recognizes that an implantable article…may be anchored to structure" within the patient's anatomy. COLOPLAST-1004, [0027]. Thus, "[i]n a preferred embodiment, the present invention includes **deployable members** used to implant the implant 10." COLOPLAST-1004, [0092]; *see also* FIGS. 3-5, 9 ("deployable members 56"). As shown below in FIG. 4, Neisz discloses an implant 10 with first and second ends 34, each attached to an anchor (e.g., deployable member 56) by an associated suture 6.

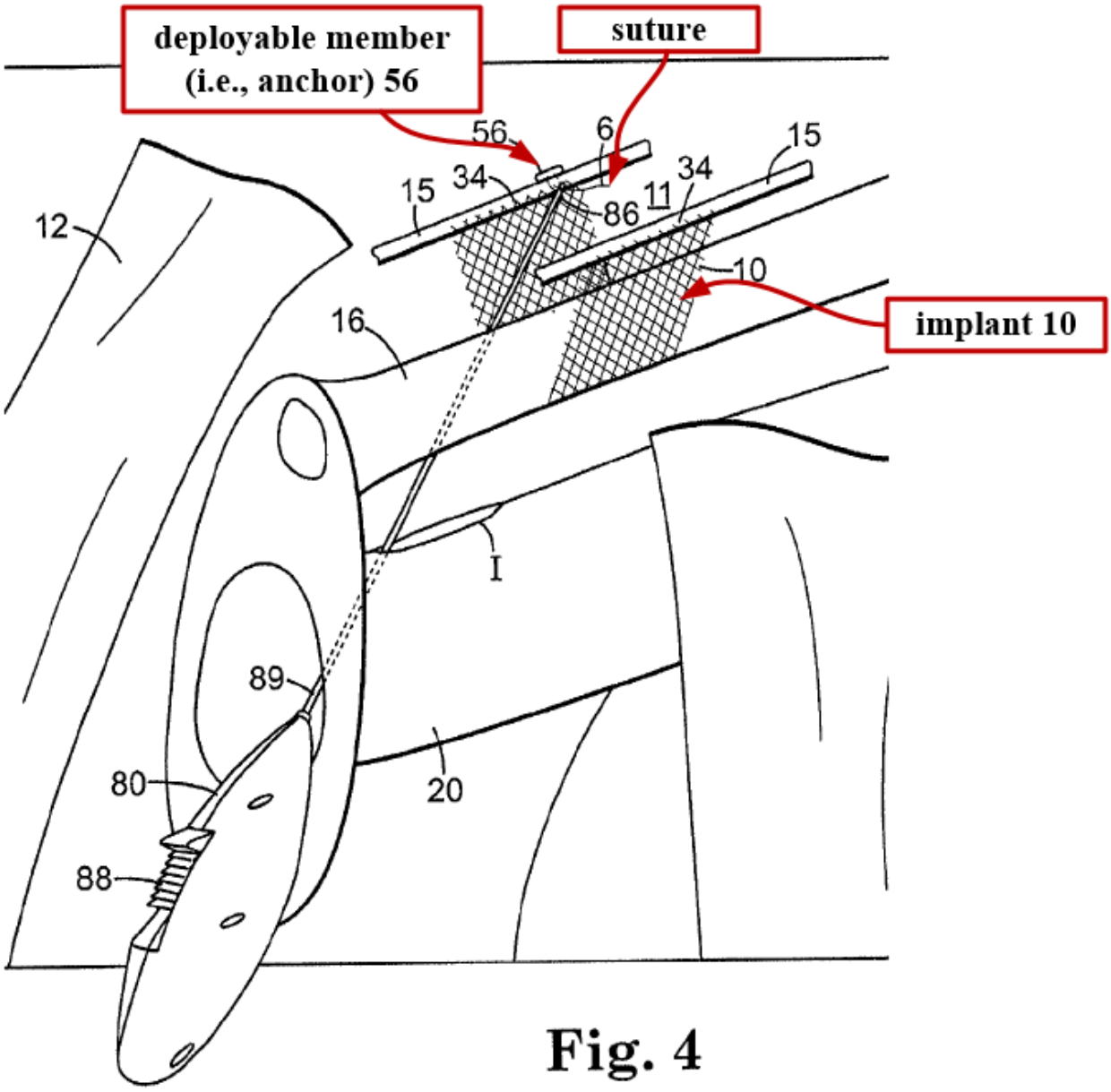


Fig. 4

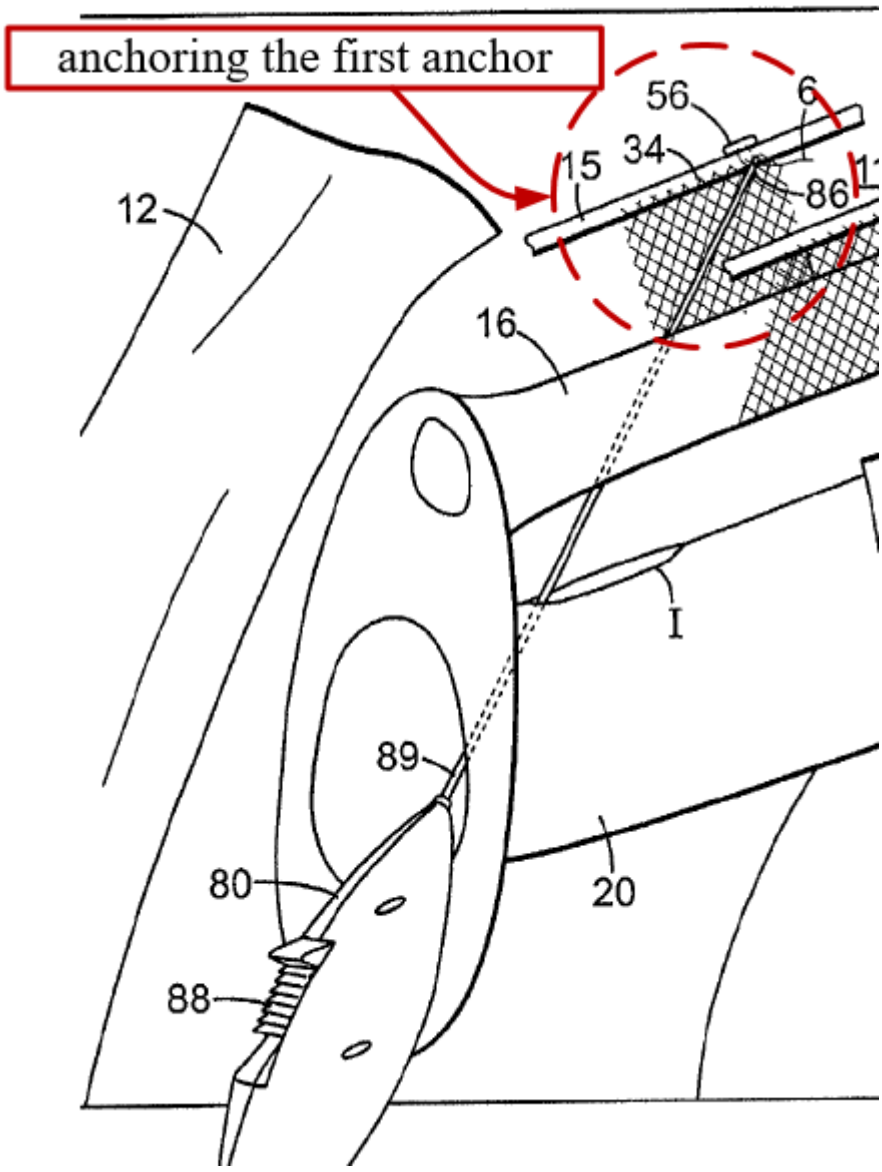
COLOPLAST-1004, FIG. 4 (annotated). As shown above, the "suture…is…used to secure one end of the implant 10 to the anchor 56." COLOPLAST-1004, [0135]; *see also* FIG. 4, 5, and 8-9. Either the suture alone, or the suture and the end portions of the implant 10 coupled thereto, can serve as the first (or second)

portion coupled to a respective anchor. COLOPLAST-1003, ¶66. Based on Neisz's disclosure, implant 10 spans between two anchors via a suture connection, thus the implant 10 (or at least a central portion thereof) serves as a central portion between the first and second portions. COLOPLAST-1004, [0135]-[0136]; FIGS. 4, 8; COLOPLAST-1003, ¶66.

In sum, Neisz teaches that its implant and the sutures collectively serve as a support element. COLOPLAST-1003, ¶67.

[1b] attaching the first anchor to a first tissue portion at a first location lateral to the urethra;

Neisz teaches element [1b]. COLOPLAST-1003 (Expert Declaration), ¶68. As explained above (§II.C, *supra*), "lateral" within the meaning of the '715 patent means "to one side of." *Id*., ¶¶45-46. As illustrated below, Neisz describes that "[p]referably, the step of placing the implant includes the step of **anchoring a first end of the implant with endopelvic fascia on one side of the patient's urethra**." COLOPLAST-1004, [0035]; *see also* [0132], [0036], [0136], FIG. 4; COLOPLAST-1003, ¶68.



COLOPLAST-1004, FIG. 4 (annotated).

[1c] attaching the second anchor to a second tissue portion at a second location lateral to the urethra;

Neisz teaches element [1c]. COLOPLAST-1003, ¶69. Specifically, Neisz says that "[p]referably, the step of placing the implant includes …**anchoring a second end of the implant with endopelvic fascia on the other side of the**

patient's urethra." COLOPLAST-1004, [0035]; *see also* [0132], [0036], [0136], FIG. 4; COLOPLAST-1003, ¶69.

[1d] introducing the filamentary element into fascial tissue; and

Neisz teaches element [1d]. COLOPLAST-1003, ¶¶70-74. Facial tissue is present at a number of locations in the pelvic region.[5] Indeed, there are multiple regions of fascial tissue disclosed by Neisz. COLOPLAST-1003, ¶¶70-73. In one example, Neisz teaches that "endopelvic fascia can include pubocervical fascia," an "**anterior vaginal fascia that fuses with vaginal tissue.**" COLOPLAST-1004, [0028]-[0030]. In another example, Neisz illustrates exemplary fascial tissue in the retropubic space in multiple figures. COLOPLAST-1004, [0092] ("associating the implant 10 with **endopelvic fascia 15 of the retropubic space 11**"), FIGS. 4, 2, 31. Neisz also generally describes broad regions of fascia, stating that

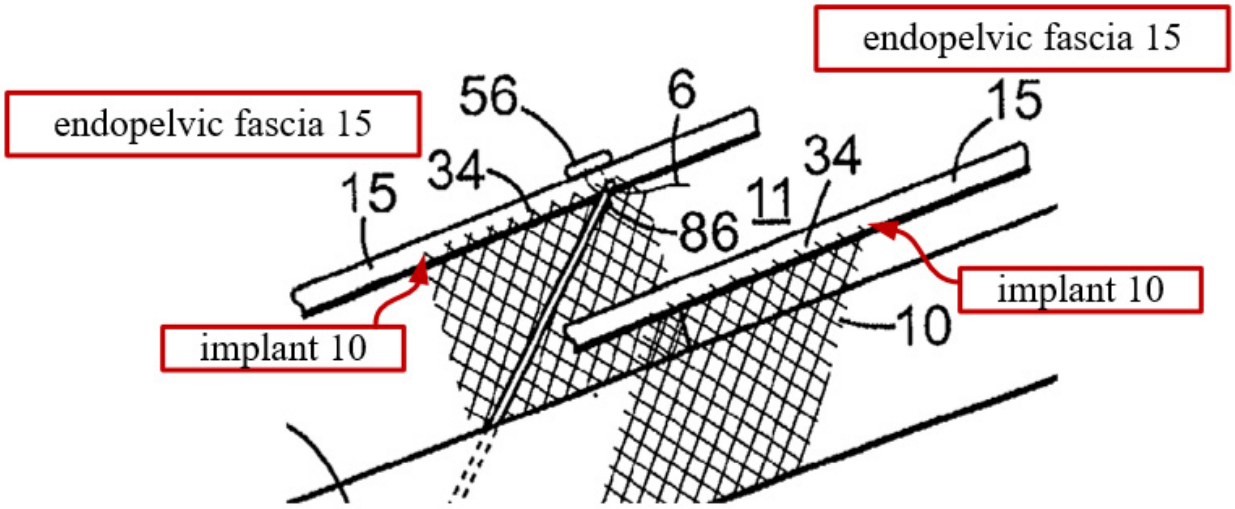
[5] There is some dispute in the industry as to whether the phrase "fascial tissue" is a colloquial or anatomical phrase. Petitioner reserves the right to argue in litigation that arguments made during prosecution of the '715 patent acts as a disclaimer on this issue. *See* COLOPLAST-1002, 60-61 (Applicant argues that "Benderev teaches away from the claimed method, emphasizing instead that intervening fascia is not penetrated"). However, that dispute is moot for purposes of this IPR because the cited references meet this limitation under either view.

"[e]ndopelvic fascia includes collagen, elastin and smooth muscle," which are "structures [that] **surround and support the viscera in the pelvic cavity** and **extend from the pelvic floor to the rectus fascia and respiratory diaphragm**." COLOPLAST-1004, [0028]. Accordingly, Neisz alone, or the Neisz-Benderev combination, teaches introducing the filamentary element into fascial tissue in at least three different ways. COLOPLAST-1003, ¶70

As a first example, to the extent that this claim element ("introducing… into fascial tissue") covers filamentary sutures penetrating and extending though endopelvic fascia, Neisz teaches such a structure. COLOPLAST-1004, FIG. 4, [0036] ("**passing**…**an associated suture through endopelvic fascia**"); [0115]; COLOPLAST-1003, ¶71.

As a second example, to the extent that this claim element ("introducing… into fascial tissue") covers positioning an implant (e.g., implant 10) adjacent to and/or penetrating fascia, Neisz teaches anchoring implant 10 to the endopelvic fascia 15 on either side of the urethra in the retropubic space. COLOPLAST-1004, FIG. 4; COLOPLAST-1003, ¶72. Generally, Neisz discloses "anchoring a[n]…**implant** in **tissue such as endopelvic fascia**." COLOPLAST-1004, [0115]; *see also* [0132], [0034]. Neisz says "deployable members 56 are particularly suitable for **associating the implant 10 with endopelvic fascia 15**[.]"

COLOPLAST-1004, [0092]. In FIG. 4, end portions of implant 10 extend into endopelvic fascia 15.



COLOPLAST-1004, FIG. 4 (select portion, annotated). The above depiction is consistent with Neisz's disclosure that, in some certain embodiments, "an implant 10 with ends 34 project[s] slightly **through endopelvic fascia 15 and into endopelvic fascia**." COLOPLAST-1004, [0087]; COLOPLAST-1003, ¶72.

As a third example, to the extent that element [1d] covers placing an implant adjacent or into fascia, Neisz first expressly describes various fascia in the region of the vagina including: "anterior vaginal fascia that fuses with vaginal tissue" and "providing a hammock for the urethra and bladder" (COLOPLAST-1004, [0028]-[0029]); and then inserting an implant through a vaginal incision to treat incontinence (COLOPLAST-1004, [0032]-[0033]). COLOPLAST-1003, ¶73. Specifically, Neisz discloses "anchoring a[n]…implant in tissue such as endopelvic

fascia," (COLOPLAST-1004, [0115]), while also describing that "endopelvic fascia can include pubocervical fascia," which "is anterior vaginal fascia" (COLOPLAST-1004, [0029]).

Thus, Neisz alone teaches (and the Neisz-Benderev combination certainly teaches) introducing the filamentary element (e.g., implant 10) into fascial tissue in at least three different ways. COLOPLAST-1003, ¶74. A POSITA would have understood that there was nothing new or inventive about such implants being introduced into fascial tissue. *Id*., (explaining "it is just patient anatomy").

To the extent that Patent Owner disputes whether Neisz alone (or Neisz in view of Benderev) teaches limitation [1d], the three reasons provided above are consistent with Patent Owner's own arguments provided in its complaint, which alleges that a sling with sutures placed in this region of the anatomy necessarily meets the claim element for introducing the filamentary element into fascial tissue. COLOPLAST-1018, 7-8.

[1e] after the step of introducing the filamentary element into the fascial tissue adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor so that the central portion provides at least a sling-like support for the urethra between the first and second locations;

Neisz alone, or alternatively, Neisz in view of Benderev teaches element [1e]. COLOPLAST-1003, ¶¶75-80. Specifically, as described above (*supra,* [1d]), Neisz describes the step of introducing the filamentary element into the fascial

tissue. COLOPLAST-1004, [0028], [0028]-[0029], [0032]-[0034], [0036], [0087], [0092], [0115], [0132], FIGS. 4, 2, 31; COLOPLAST-1003, ¶¶70-74.

As explained in §III.A.1, *supra*, Neisz alone teaches adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor so that the central portion provides at least a sling-like support for the urethra between the first and second locations, and that this is done after introducing the filamentary element into fascial tissue. COLOPLAST-1004 (Neisz), [0097], [0098], [0133], [0008], [0013]-[0015], [0027], [0031], [0107], [0135], FIGS. 4-5, 8-9; COLOPLAST-1003, ¶¶51-62. Indeed, Neisz shows and describes extending a suture loosely from an aperture in the anchor during insertion and deployment, followed by positioning the sling (implant 10) beneath the urethra to provide a sling-like support for the urethra by securing tying the sutures to the sling.

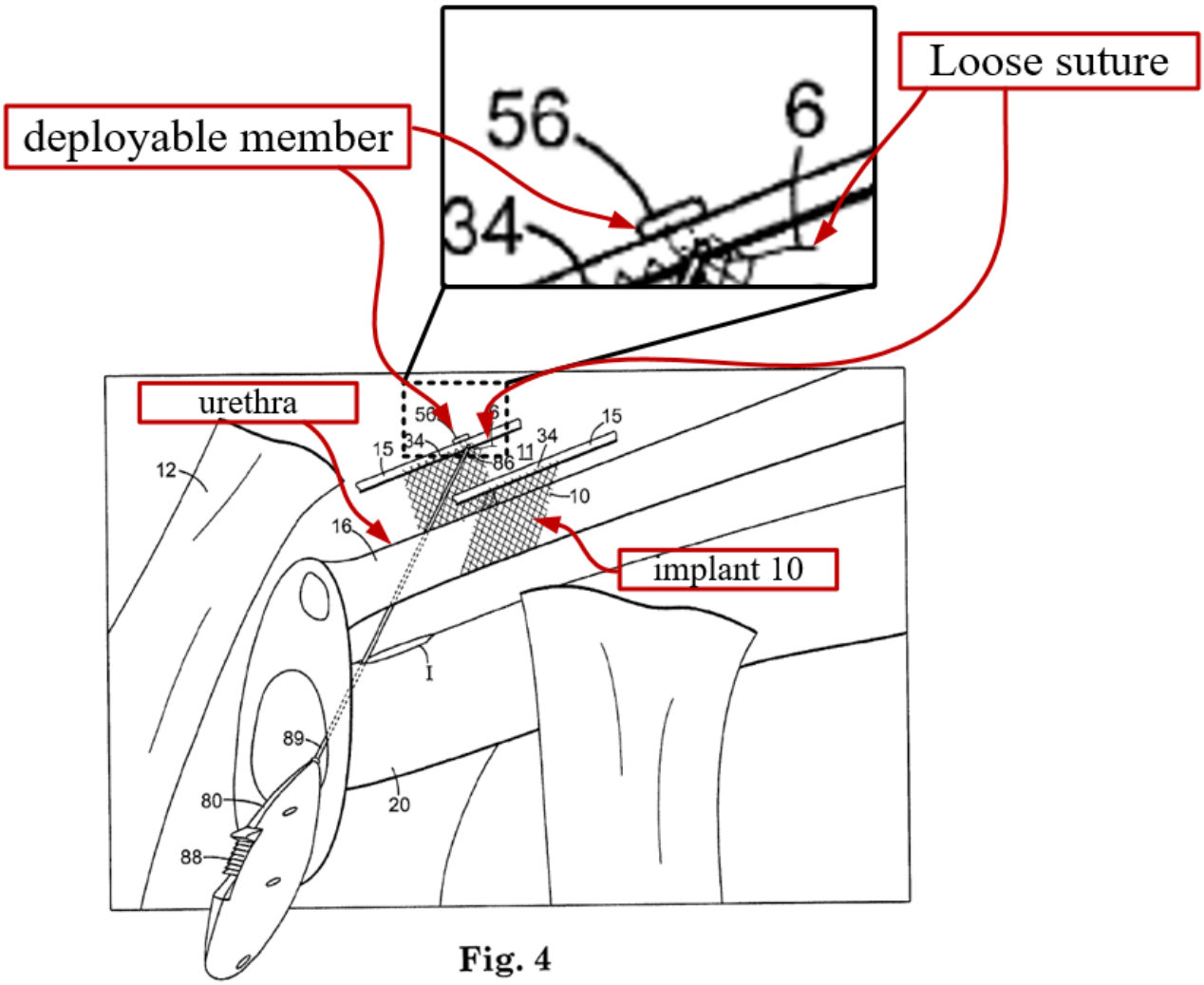


Fig. 4

COLOPLAST-1003, ¶77 (annotated); *see also* COLOPLAST-1004, FIGS. 4, 9, [0027], [0031], [0090], [0097]. As Dr. Erickson explains, it would have been obvious that any slack in the suture, shown in Neisz's FIGS. 4 and 9, would be removed by pulling the suture through the aperture of the anchor, when tightening and/or shortening the suture line, to ensure that proper tension is applied to the urethra by the sling. COLOPLAST-1003, ¶77. Accordingly, a POSITA would have found it obvious to adjust the tension of the central portion between the first

and second anchors so that the central portion provides at least a sling-like support for the urethra between the first and second locations based on Neisz's disclosure. COLOPLAST-1003, ¶¶76-77.

Furthermore, as explained above (§III.A.1, *supra*), Neisz-Benderev also renders this limitation obvious. COLOPLAST-1004, [0135], FIG. 4; COLOPLAST-1005 (Benderev), Title, Abstract, 36:15-29, Figs. 11a-11b, 12a-12c, 13a-13b, 14; COLOPLAST-1003, ¶¶59-61. Indeed, to the extent that Neisz alone does not explicitly disclose adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor, it would have been obvious to have applied this surgical technique to Neisz's method in view of Benderev's teachings. COLOPLAST-1003, ¶¶60-61. A POSITA would have found it obvious to apply Benderev's tensioning techniques to Neisz's implant by drawing a suture through the aperture of the anchor, as taught by Benderev, when adjusting the tension of the sling underneath urethra to ensure that sufficient tension was being applied to the urethra. COLOPLAST-1005 (Benderev), 36:15-29, FIGS. 12a-c; COLOPLAST-1003, ¶¶78-80.

Accordingly, Neisz alone as well as Neisz-Benderev teaches, after the step of introducing the filamentary element into the fascial tissue, adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor so that the central portion

provides a sling-like support for the urethra between the first and second locations. COLOPLAST-1004, [0008], [0014]-[0016], [0022], [0027], [0031], [0036], [0082], [0092], [0097]-[0098], [0101], [0106]-[0107], [0124], [0131]-[0136], FIGS. 4, 5, 8-11; COLOPLAST-1005, title, abstract, 36:15-37, FIGS. 11a-11b, 12a-12c, 13a-13b, 14; COLOPLAST-1003, ¶¶75-80, 55-62; *see also* COLOPLAST-1007, [0043].

[1f] wherein the filamentary element will become embodied with fascia in the fascial tissue over time.

To the extent that this wherein clause simply expresses an intended result of the claimed method (e.g., intended result of "introducing the filamentary element into fascial tissue" in element [1d]), element [1f] should not be given patentable weight. *See Minton v. Nat'l Ass'n of Sec. Dealers, Inc*., 336 F.3d 1373, 1381 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses **the intended result** of a process step positively recited.").

Alternatively, to the extent that element [1f] is further limiting, Neisz-Benderev teaches element [1f]. COLOPLAST-1003, ¶¶139-141. As discussed above (element [1d], *supra*), Neisz-Benderev teaches introducing the "filamentary element into fascial tissue." COLOPLAST-1003, ¶¶70-74. Furthermore, Neisz describes that its "implant comprises" "a synthetic mesh material having a plurality of holes, the holes being sized and shaped **to afford tissue ingrowth** to anchor the implant." COLOPLAST-1004, [0041]; *see also* [0086]; [0087], [0090], [0091].

As explained above (§II.C, *supra*), "the filamentary element will become embodied with fascia in the fascial tissue" within the meaning of the '715 patent means that "fascial tissue grows into the filamentary element during healing." Neisz's teachings about tissue ingrowth are consistent with what is taught in the '715 patent. COLOPLAST-1003, ¶¶45-46. For instance, the '715 patent admits that the natural healing process causes fascial tissue to become embedded in a filamentary sling, by stating: "[w]ith the **healing of the incisions** the filamentary element becomes embodied into the fascial tissue." COLOPLAST-1001, 6:4-7. This is consistent with what was already taught in Neisz and well-known to a POSITA—that the ingrowth of tissue occurs due to a body's reaction to the surgery, e.g., healing of incised tissue located adjacent to the implanted device. COLOPLAST-1003, ¶82. Indeed, Neisz explains that "when disturbed by an implantable material," the "body['s] reaction" "will generate tough fibrous tissue, providing substantial holding power for an implant placed in that space." COLOPLAST-1004, [0026]. Neisz explicitly discloses placing the implant in "endopelvic fascia" on either side of the urethra where the implant is capable of eliciting a foreign body response "to afford tissue ingrowth to anchor the implant in the retropubic space." COLOPLAST-1004, [0035], [0041], [0087], [0090]; Claim 27. Thus, like the '715 patent, Neisz discloses that "tissue reaction (e.g., ingrowth) may be relied upon to secure the sling 10 in place." COLOPLAST-

1004, [0090]. Accordingly, a POSITA would have understood that Neisz's sling (e.g., a filamentary element since Neisz teaches implants formed of monofilament at [0088]) would become embodied with fascia since, like the '715 patent, Neisz's sling is embodied with any fascia tissue contacting the sling. COLOPLAST-1001, 6:4-7; COLOPLAST-1003, ¶82.

As discussed above (element [1d]), Neisz teaches multiple regions of fascial tissue. COLOPLAST-1004, [0028]-[0029], FIG. 4; COLOPLAST-1003, ¶¶70-74. Thus, based on Neisz's disclosure of multiple regions of endopelvic fascia and of healing that would be prompted by surrounding fascia tissue "disturbed by an implantable material", a POSITA would have understood that Neisz teaches that fascial tissue ingrowth would occur at the ends of the implant contacting endopelvic fascial tissue 15 (shown in green), depicted in FIG. 4, as well as any other portion (e.g., the mid portion) along the entire length of implant 10 in the retropubic space, which also, according to Neisz, contacts fascial tissue. COLOPLAST-1004, [0026], [0028], [0029]-[0030]; COLOPLAST-1003, ¶83.

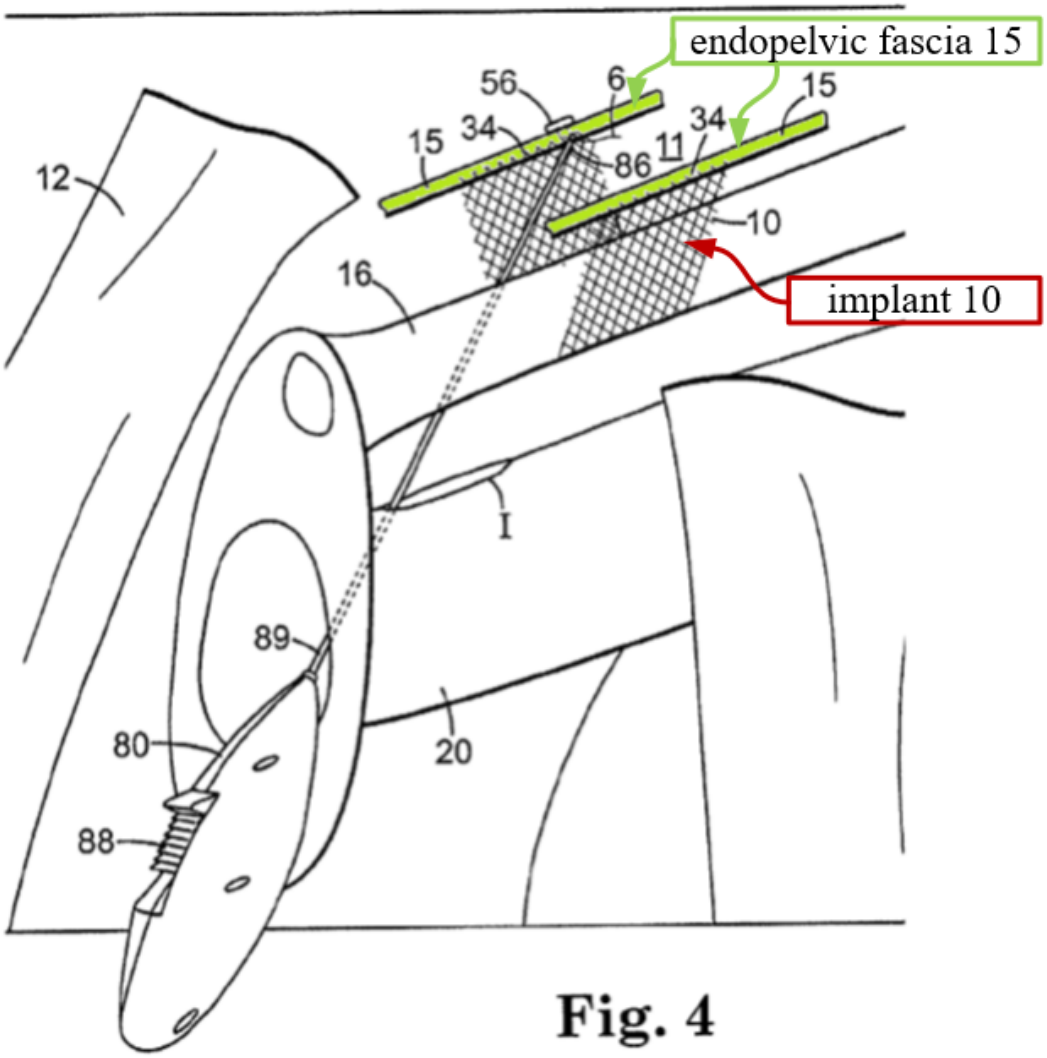


Fig. 4

COLOPLAST-1004, FIG. 4 (annotated). A POSITA would have understood that there was nothing new or inventive about this well-known biological response to mesh slings. COLOPLAST-1003, ¶83.

[2] The method of claim 1, wherein the second location is on a side opposite from the first location.

Neisz-Benderev teaches element [2]. COLOPLAST-1003, ¶84. Specifically, Neisz shows and describes that "[p]referably, the step of placing the

implant includes the step of anchoring a first end of the implant with endopelvic fascia on one side of the patient's urethra and anchoring a second end of the implant with endopelvic fascia on the **other side** of the patient's urethra" in opposite locations with respect to the urethra. COLOPLAST-1004, [0035]-[0036], [0132], [0136], Fig. 4; COLOPLAST-1003, ¶84.

[3] The method of claim 1, wherein each respective anchor has a body elongated along a longitudinal axis and with first and second ends and a plurality of flexible prongs extending radially outwards from the first end.

Neisz-Benderev teaches element [3]. COLOPLAST-1003, ¶85. Specifically, as shown below in FIG. 9, Neisz shows and describes an anchor (e.g., deployable member 56) having a body elongated in a longitudinal axis, first and second ends, and a plurality of flexible prongs extending radially outwards (depicted by blue arrows) from the first end.

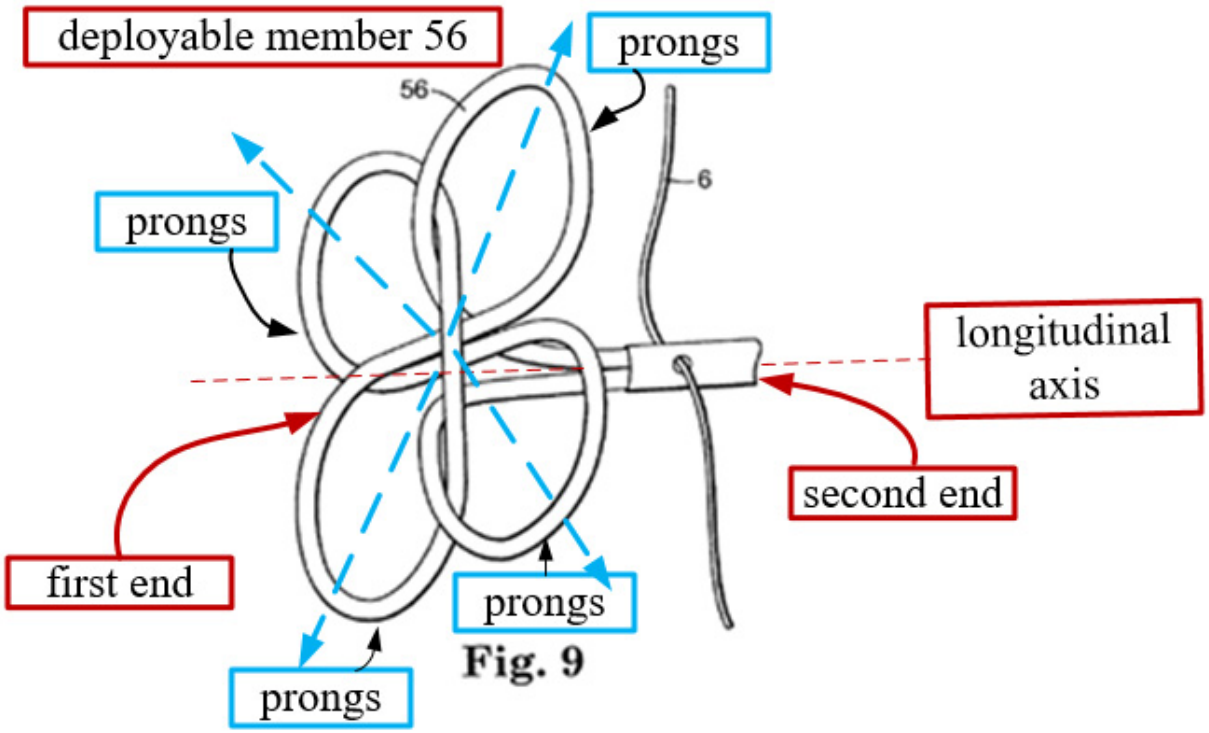
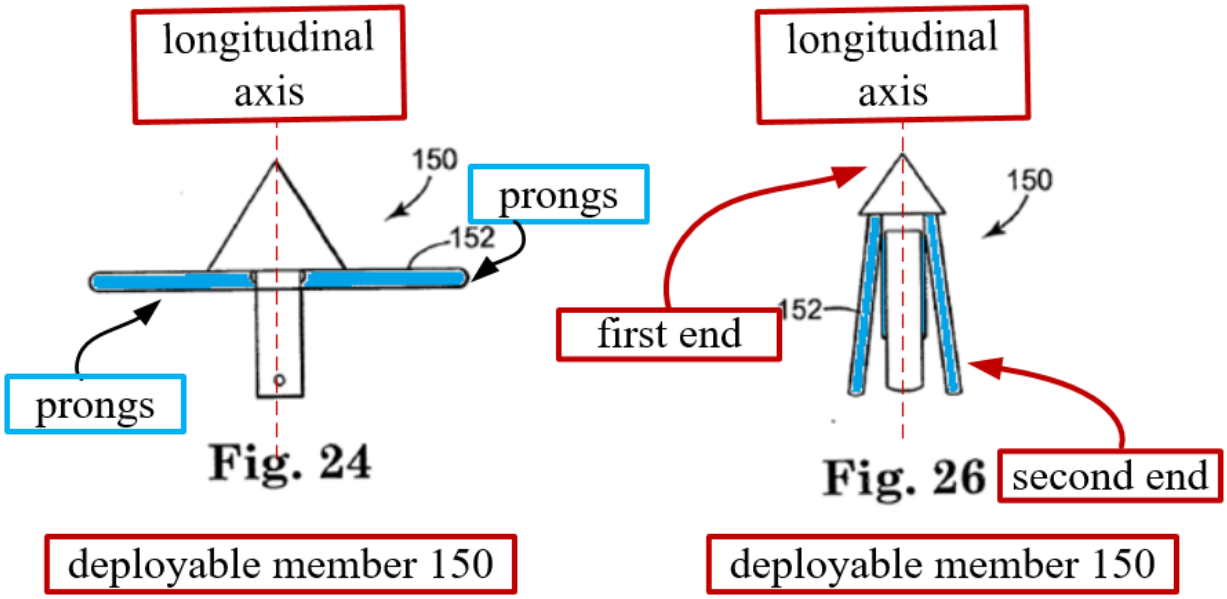


Fig. 9

COLOPLAST-1004, Fig. 9 (annotated); *see also* COLOPLAST-1004, [0055], [0096]-[0098].

Alternatively, the proposed combination could be further modified to include other anchor designs disclosed by Neisz. COLOPLAST-1003, ¶¶86-87. For example, as shown below, Neisz discloses that "FIGS. 24 through 26 show another embodiment of [the] deployable member 150" that includes a body elongated along a longitudinal axis and with first and second ends and a plurality of flexible prongs extending radially outwards from the first end. COLOPLAST-1004, [0113]-[0115], FIGS. 24-26. Specifically, "deployable member 150 [] includes a plurality of movable arms" (shown in blue) such that "**[a]rms 152** [are]

pinned and hang in a collapsed position and **when deployed are pushed up and outward** being held outward in an umbrella-like fashion." COLOPLAST-1004, [0113]-[0114].



COLOPLAST-1004, FIGS. 24 (left, annotated), 26 (right, annotated); COLOPLAST-1003, ¶86.

It would have been obvious to a POSITA to have incorporated anchor 150 of FIGS. 24 and 26 for multiple reasons. COLOPLAST-1003, ¶87.

First, it would have been obvious to have implemented anchor 150 (of FIGS. 24 and 26) in Neisz's method because both anchor embodiments (e.g., deployable members 56 and 150) are disclosed in its specification. COLOPLAST-1004, [0113]-[0115]; COLOPLAST-1003, ¶87. Furthermore, Neisz also teaches that these embodiments can be combined by explaining that "deployable members

according to the present invention may take several different forms." COLOPLAST-1004, [0113], [0040]; COLOPLAST-1003, ¶87.

Second, it would have been obvious to have implemented anchor 150 in the method of FIG. 4 because a POSITA would have been motivated to use anchor 150, which has moveable arms 152 that allow for the anchor 150 to be inserted relatively easily and then advantageously deploy to resist retraction. COLOPLAST-1004, [0113]-[0114]; COLOPLAST-1003, ¶87.

Third, a POSITA would have been motivated to incorporate anchor 150 of FIGS. 24 and 26 in Neisz's method as depicted in FIG. 4 because doing so would be merely the application of known techniques (applying known anchor designs) to a known system (Neisz's implant system and method) to yield predictable results. COLOPLAST-1003 (Expert Declaration), ¶87; *KSR*, 550 U.S. at 417.

[4] The method of claim 3, wherein the aperture in the second anchor is transverse to a longitudinal axis of the second anchor.

Neisz-Benderev teaches element [4]. COLOPLAST-1003, ¶88. Specifically, Neisz discloses that its anchor "stem includes a passage that anchors a suture 6." COLOPLAST-1004, [0097], FIGS. 5, 9. Further, in various embodiments, Neisz shows that the aperture of the anchor is transverse to a longitudinal axis of the anchor.

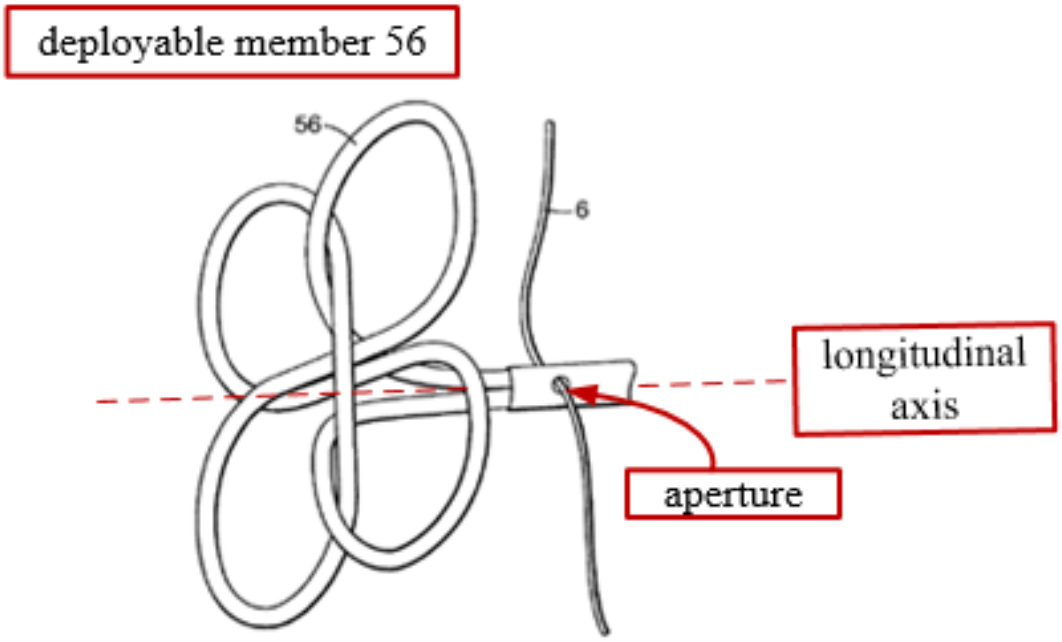


Fig. 9

COLOPLAST-1004, FIG. 9 (annotated); *see also* FIGS. 5, 10-11, 24, 28-29; COLOPLAST-1003, ¶88.

[6] The method of claim 1, further comprising mounting the second anchor on an insertion tool, wherein attaching the second anchor to the second portion comprises using the insertion tool to position the second anchor at the second location.

Neisz-Benderev teaches element [6]. COLOPLAST-1003, ¶¶89-90. Specifically, Neisz shows and describes mounting the second anchor on an insertion tool. COLOPLAST-1004, [0038]-[0040]; *see also* FIGS. 3-6, 10, *supra*, element [1c].

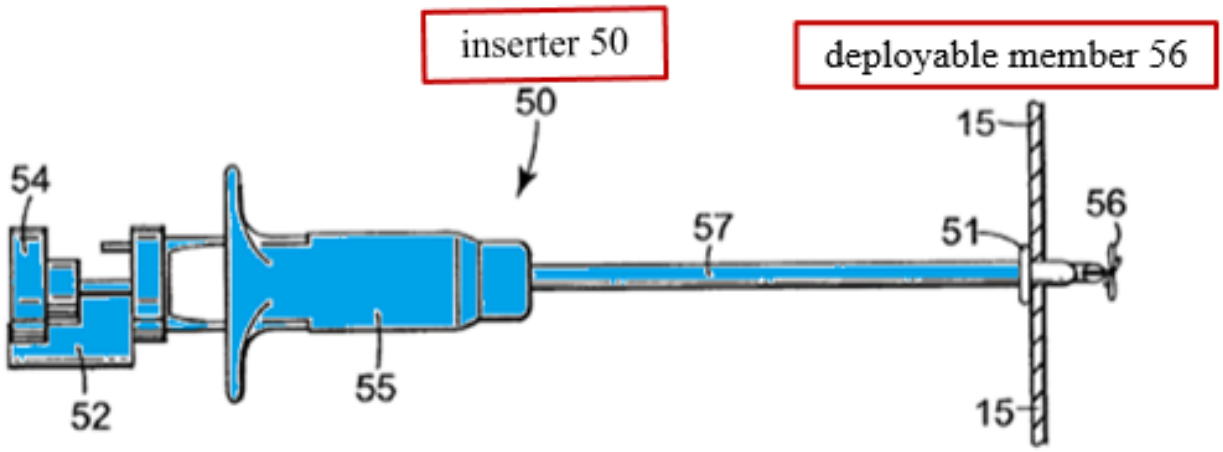


Fig. 7

COLOPLAST-1004, FIG. 7 (annotated), *see also* FIG. 4, [0095] ("the inserter 80 is sized and shaped to associate the deployable members 56 with endopelvic fascia 15"), [0096]; COLOPLAST-1003, ¶89.

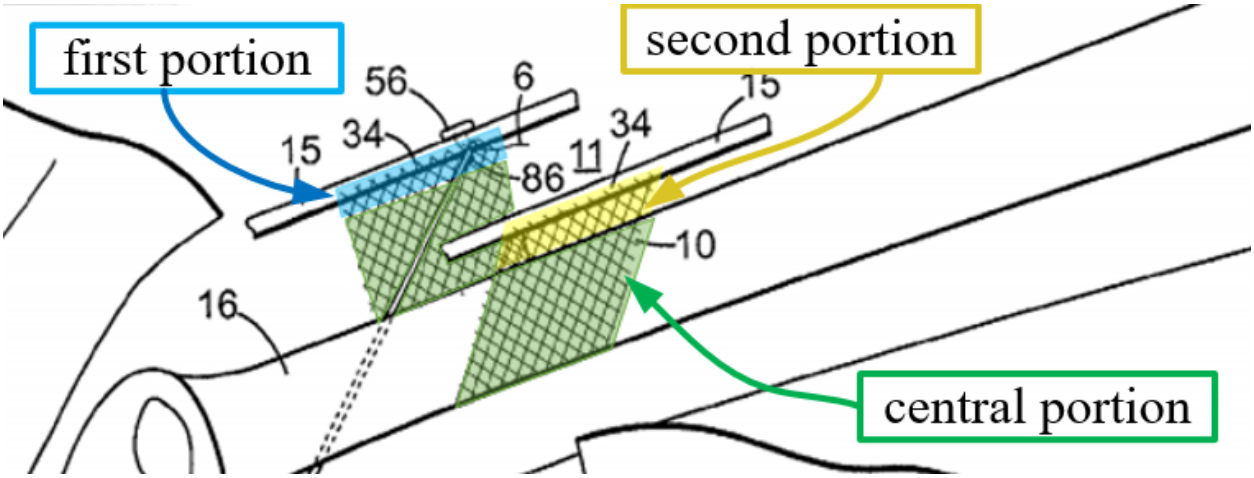
Neisz also discloses using the insertion tool to position the second anchor at the second location. *See e.g.,* COLOPLAST-1004, [0095], [0096], [0132], FIGS. 4-5; COLOPLAST-1003, ¶90.

[7] The method of claim 1, wherein the first and the second portions of the support element comprise ribbon like filamentary elements.

Neisz-Benderev teaches element [7]. COLOPLAST-1003, ¶¶91-93. As discussed above (element [1a]), Neisz teaches a support element (e.g., implantable article) comprising a central portion (e.g., implant 10 or portions thereof) between the first and second portions and comprising a ribbon-like filamentary element

(e.g., implant with a "rectangular," and "thin, flexible structure"). COLOPLAST-1004, [0027], [0035]-[0036], [0041], [0082], [0131]-0136], FIG. 4.

As explained above with respect to element [1a], *supra*, Neisz teaches the first portion (colored blue) and the second portion (colored yellow) comprise ribbon like filamentary elements. COLOPLAST-1003, ¶92. As illustrated below, Dr. Erickson explains in his declaration that Neisz's first portion and the second portion can include the suture as well as end portions of the implant.



COLOPLAST-1003, ¶92 (annotated).

Thus, Neisz-Benderev teaches the limitations of claim 7. COLOPLAST-1003, ¶¶91-93.

[9] The method of claim 1, wherein the filamentary element is adapted to facilitate the growth of scar-like tissue upon the filament.

Neisz-Benderev teaches element [9]. COLOPLAST-1003, ¶94. Specifically, Neisz's "invention comprises a method of treating incontinence in a patient comprising the steps of…providing an implant capable of eliciting a

foreign body response." COLOPLAST-1004, [0033]; *see also* [0035], [0041], [0087], [0089], [0091]. Neisz explains that promoting scarring is one form of eliciting a foreign body response. COLOPLAST-1004, [0091] ("elicit a foreign body response (e.g., **promote scarring**"). Thus, a POSITA would have understood that "elicit[ing] a foreign body response" facilitates the growth of scar-like tissue since Neisz teaches that the foreign body response promotes scarring. COLOPLAST-1004, [0091]; COLOPLAST-1003, ¶94. Indeed, a POSITA would have understood that adapting the filamentary element to elicit such a foreign body response and its subsequent scarring effect would "secure anchoring of the sling," as taught by Neisz. COLOPLAST-1004, [0091]; COLOPLAST-1003, ¶94.

[10] The method of claim 1, wherein the filamentary element is one of a knitted material or a woven material.

Neisz-Benderev teaches element [10]. COLOPLAST-1003, ¶95. Specifically, Neisz discloses that its "implant comprises a substantially thin, flexible sheet" "compris[ing] a synthetic mesh material having a plurality of holes" "sized and shaped to afford tissue ingrowth to anchor the implant[.]" COLOPLAST-1004, [0041]. Neisz further discloses that "**woven and/or knitted** polypropylene mesh materials are believed suitable" exemplary mesh materials. COLOPLAST-1004, [0041], *see also* [0086], [0088].

[11pre] A method of providing support for the urethra to treat female urinary incontinence comprising:

To the extent that the preamble is limiting, Neisz teaches element [11pre]. *Supra* [1pre] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63, 96.

[11a] providing a support element having a first portion coupled to a first anchor, a second portion coupled to a second anchor through an aperture, and a central portion between the first and second portions and comprising a ribbon-like filamentary element;

Neisz teaches element [11a]. *Supra* [1pre]-[1a] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63-67, 97.

[11b] performing during a medical procedure steps comprising: attaching the first anchor to a first tissue portion at a first location lateral to the urethra;

Neisz teaches element [11b]. *Supra* [1pre]-[1b] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63-68, 98.

[11c] attaching the second anchor to a second tissue portion at a second location lateral to the urethra;

Neisz teaches element [11c]. *Supra* [1pre]-[1c] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63-74, 99.

[11d] introducing the filamentary element into fascial tissue; and

Neisz teaches element [11d]. *Supra* [1pre]-[1d] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63-74, 100.

[11e] adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor so that the central portion provides at least a sling-like support for the urethra between the first and second locations;

Neisz-Benderev teaches element [11e]. *Supra* [1pre]-[1e] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63-80, 101.

[11f] wherein after the medical procedure the filamentary element will become embodied with fascia in the fascial tissue over time.

Neisz-Benderev teaches element [11f]. *Supra* [1pre]-[1f] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶63-83, 102.

[12] The method of claim 11, wherein the second location is on a side opposite from the first location.

Neisz-Benderev teaches element [12]. *Supra* [2] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶84, 103.

[13] The method of claim 11, wherein each respective anchor has a body elongated along a longitudinal axis and with first and second ends and a plurality of flexible prongs extending radially outwards from the first end.

Neisz-Benderev teaches element [13]. *Supra* [3] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶85-87, 104.

[14] The method of claim 13, wherein the aperture in the second anchor is transverse to a longitudinal axis of the second anchor.

Neisz-Benderev teaches element [14]. *Supra* [4] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶88, 105.

[16] The method of claim 1, further comprising mounting the second anchor on an insertion tool, wherein attaching the second anchor to the second portion comprises using the insertion tool to position the second anchor at the second location.

Neisz-Benderev teaches element [16]. *Supra* [6] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶89-90, 106.

[17] The method of claim 11, wherein the first and the second portions of the support element comprise ribbon like filamentary elements.

Neisz-Benderev teaches element [17]. *Supra* [7] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶91-93, 107.

[19] The method of claim 11, wherein the filamentary element is adapted to facilitate the growth of scar-like tissue upon the filament.

Neisz-Benderev teaches element [19]. *Supra* [9] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶94, 108.

[20] The method of claim 1, wherein the filamentary element is one of a knitted material or a woven material.

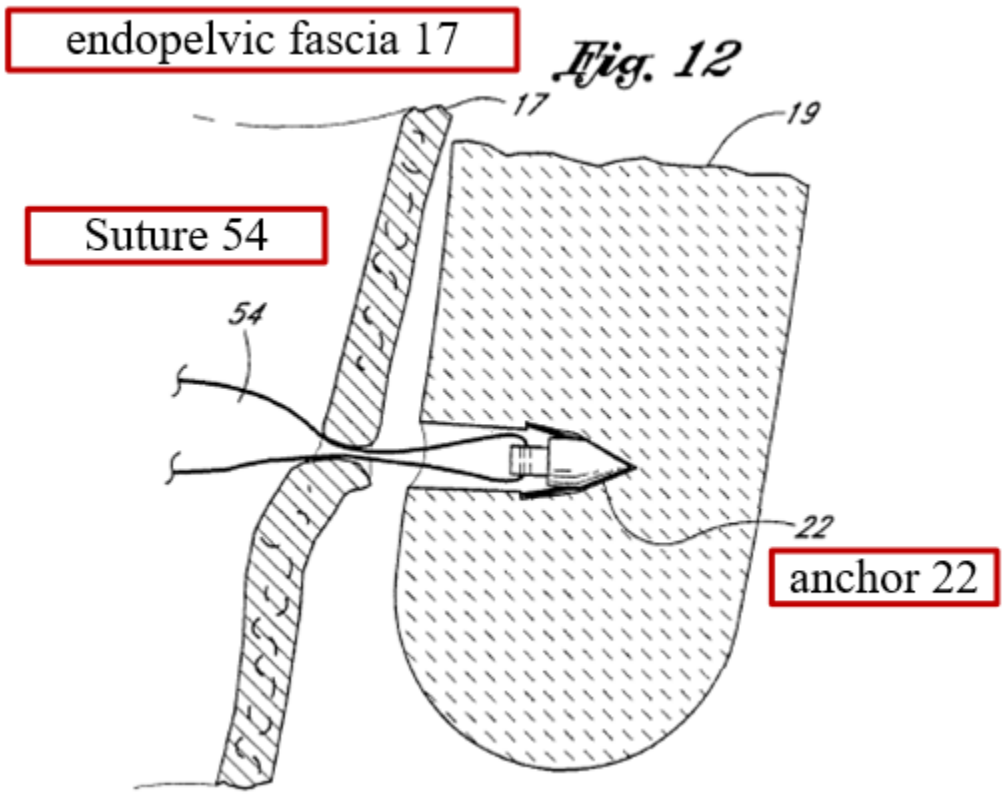
Neisz-Benderev teaches element [20]. *Supra* [10] and §III.A.1-2 (incorporated here). COLOPLAST-1003, ¶¶95, 109.

B. GROUND 2

1. Combination of Brenneman and Kovac

Brenneman is a patent application that "relates to devices and methods for inserting anchors…into a bone or tissue." COLOPLAST-1006 (Brenneman), 1:27-28, Title; COLOPLAST-1003, ¶¶110-111. Brenneman discloses that "sutures attached to the…anchors extend through the vaginal wall and…attach[] to the endopelvic fascia…a sling, or other material" to "stabilize and/or slightly compress the urethra, thereby improving or maintaining the patient's urinary continence."

COLOPLAST-1006, 5:33-6:3, 12:20-23. Brenneman describes: "two...anchors are implanted on each side of the urethra" and "one…anchor on each side of the urethra." COLOPLAST-1006, 3:11-13, 3:6, 5:35-36, 12:18-30.



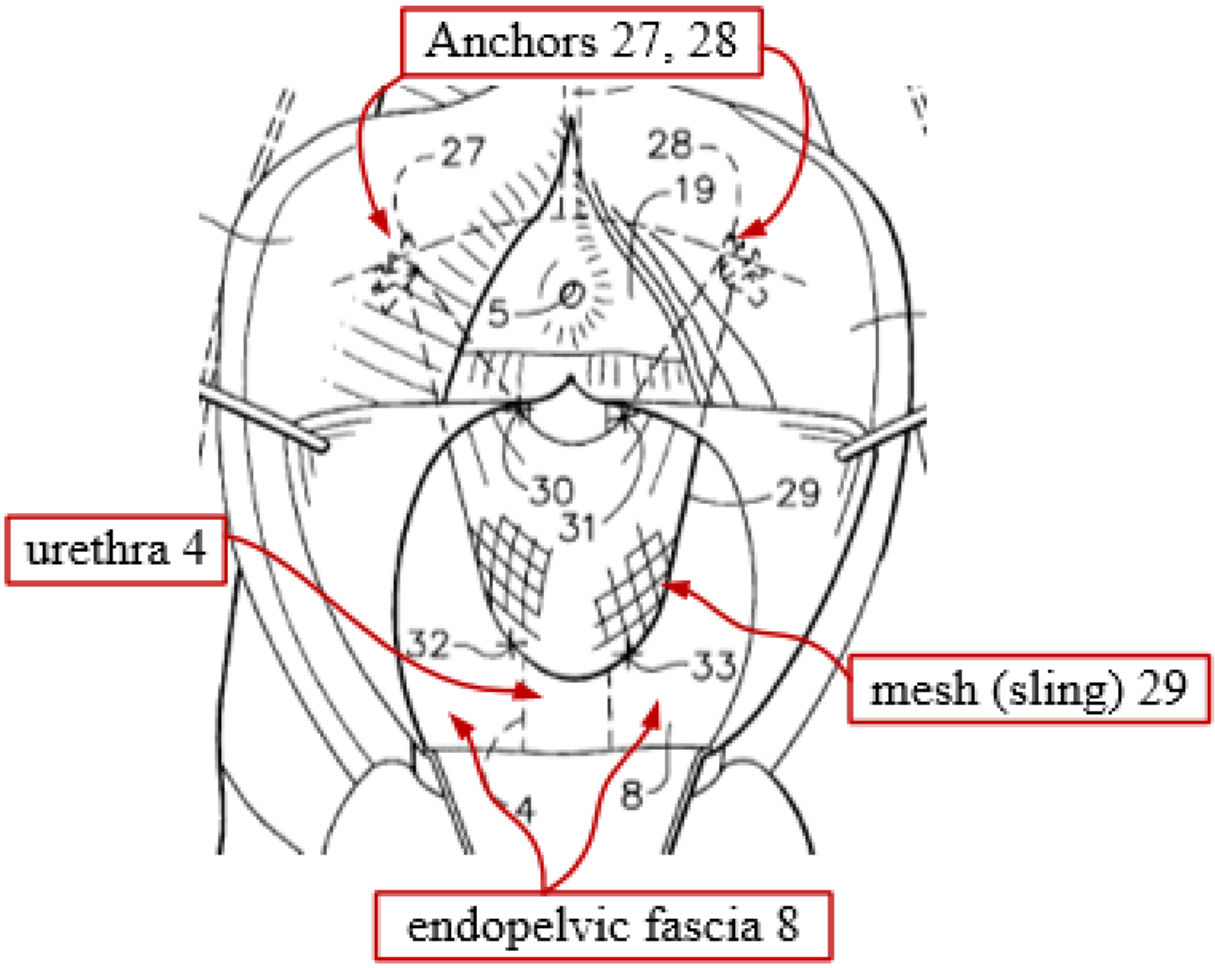
COLOPLAST-1006, FIG. 12 (annotated).

Brenneman also discloses that "stabilizing and/or slightly compressing the urethra" "prevent[s] the leakage of urine" and that "[t]he stabilizing or compressive force…may be applied by means of a sling suspended by sutures." COLOPLAST-1006, 1:17-24, 3:7-10, 5:36-4:3, 12:24-30. In particular, Brenneman describes that "[t]he free ends of suture from the two anchors on each side of the urethra are…tied to the corresponding corners of the sling" and the "tension on the sling

provided by the sutures is adjusted to provide the appropriate biasing force to the urethra." COLOPLAST-1006, 14:31-36, 12:29-30.

Based on Brenneman's disclosure of teaching a method of treating urinary incontinence that utilizes a sling to stabilize the bladder neck with anchors on either side of the urethra, it would have been obvious to a POSITA to look to the known prior art for sling shapes and materials suitable for supporting the urethra. COLOPLAST-1006, 3:7-13; COLOPLAST-1003, ¶112. For example, Kovac discloses "a urethra stabilization and support system" and related methods. COLOPLAST-1010 (Kovac), Title, 1:13-15.

Kovac teaches using a rectangular, ribbon-like sling. COLOPLAST-1010, 7:8-10, *see also* 3:53-54 ("A sling…can be…rectangular"), 7:3-4, 4:38-42, 3:53-56, FIGS. 7-10; COLOPLAST-1003, ¶113. Kovac's sling "mesh 29 is laid upon the endopelvic fascia 8 with its longitudinal edges 29a and 29b extending transversely of the urethra 4 beneath the endopelvic fascia 8." COLOPLAST-1010, 7:10-12, FIG. 7. As shown below, Kovac's sling has an elongate shape that supports the urethra and surrounding tissue and extends from beneath the urethra up to the anchors 27, 28 attached to the pubic bone. COLOPLAST-1010, FIG. 9; COLOPLAST-1003, ¶113. A POSITA would have understood that a long, flat surgical mesh as shown and described in Kovac as being ribbon-like as well as a conventional example of the kind of sling suggested in Brenneman. *Id*.



COLOPLAST-1010, FIG. 9 (annotated).

There are multiple reasons that would have motivated a POSITA to apply the incontinence sling features (such as its size, shape and materials) of Kovac to the incontinence sling of Brenneman's implant system. COLOPLAST-1003, ¶¶114-116.

First, a POSTA would have been prompted to incorporate Kovac's sling (or obvious variants thereof) into Brenneman's implant because Brenneman specifically suggests using a "sling" and Kovac discloses a suitable example of a

sling that would work in Brenneman's application. COLOPLAST-1006, 5:33-6:3, 12:24-30, 13:33-14:26; COLOPLAST-1003, ¶114. Brenneman's teaching to use a sling to improve urinary continence without disclosing a specific sling would have prompted a POSITA to look for known slings. COLOPLAST-1003, ¶114. Kovac discloses such a sling, and POSITA would have understood that Kovac's sling could be used either directly in Brenneman's system or could be modified as appropriate for a given application. COLOPLAST-1010, abstract, 3:11-31, 3:54-67, 6:49-60, 7:3-45, 7:66-8:51; COLOPLAST-1003, ¶114.

Second, a POSITA would have been prompted to incorporate features of Kovac's sling (or obvious variants thereof) in Brenneman's implant based on the clear similarities between these two systems and their associated components. COLOPLAST-1003, ¶114. For example, both Brenneman and Kovac describe using a "sling to restore, support and stabilize functional urethral continence anatomy." COLOPLAST-1010, Abstract, 3:25-31; COLOPLAST-1006, 13:1-2. Furthermore, like Brenneman, Kovac's "system comprises a pair of anchors" as well as "sutures attached to the anchors." COLOPLAST-1010, 3:11-13; COLOPLAST-1006, 13:4-5. Additionally, both Kovac and Brenneman's components are similarly connected. COLOPLAST-1003, ¶114. For example, like Brenneman, Kovac's "mesh sling…ha[s] ends attached to the anchors by the anchor-mounted sutures." COLOPLAST-1010, 3:13-16; COLOPLAST-1006,

14:33-35. For the reasons above, it would have been obvious for a POSITA to have relied on Kovac's disclosure to incorporate suitable features of a sling, such as its material, size and shape, in Brenneman's system. COLOPLAST-1003, ¶114.

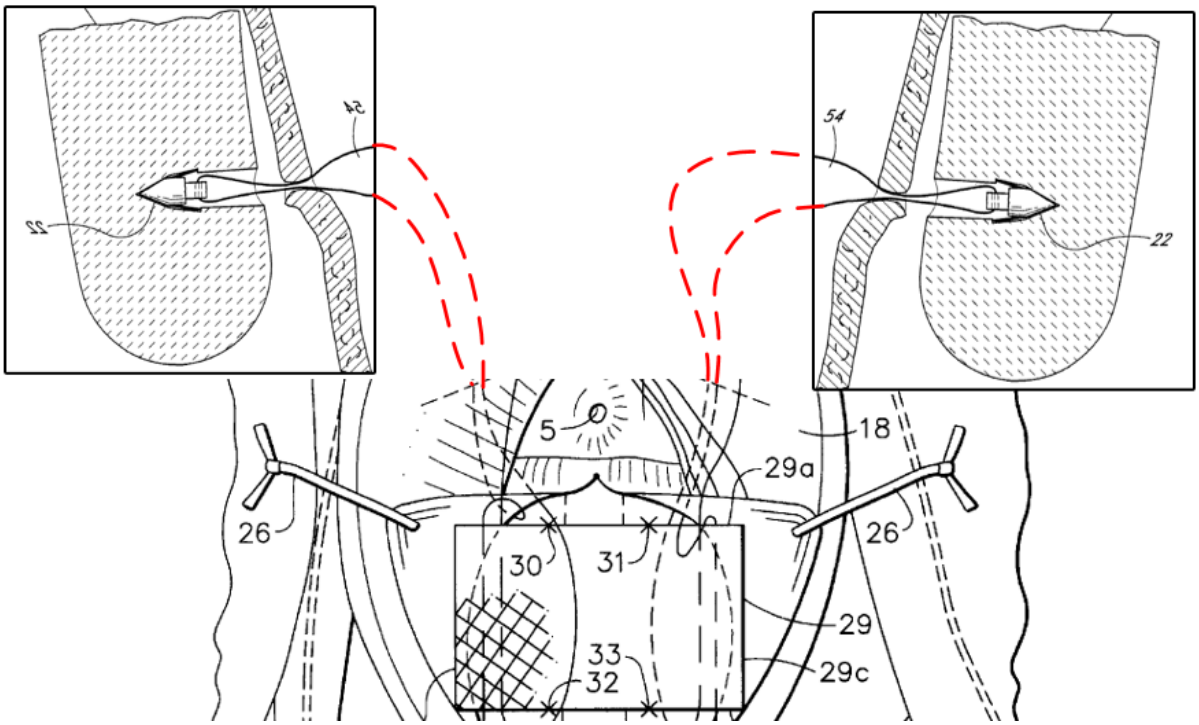
Third, a POSITA would have been prompted to incorporate features of Kovac's sling, or obvious variants thereof, into Brenneman's implant based on their common surgical techniques. COLOPLAST-1003, ¶114. For example, similar to Brenneman, Kovac's "mesh sling pass[es] behind and about the urethra and the adjacent endopelvic fascia" and "[s]utures connect the anchor…to the mesh sling" so that the sling can "directly support[ ] the urethra by its placement on the endopelvic fascia." COLOPLAST-1010, 3-3:19; COLOPLAST-1006, 12:29-30 ("the sling…is adjusted to provide the appropriate biasing force to the urethra"). Furthermore, like Brenneman, Kovac describes that its "system comprises a pair of anchors affixed to the posterior/inferior pubic bone." COLOPLAST-1010, 3:11-12, abstract; COLOPLAST-1006, 12:7-8; COLOPLAST-1003, ¶114. These surgical similarities would have further prompted a POSITA to look to Kovac for a suitable sling for use in Brenneman. COLOPLAST-1003, ¶114.

Fourth, a POSITA would have been motivated to incorporate sling features described by Kovac (or obvious variants thereof) into Brenneman's implant because Kovac describes that "[e]xcellent results have been achieved by using [its

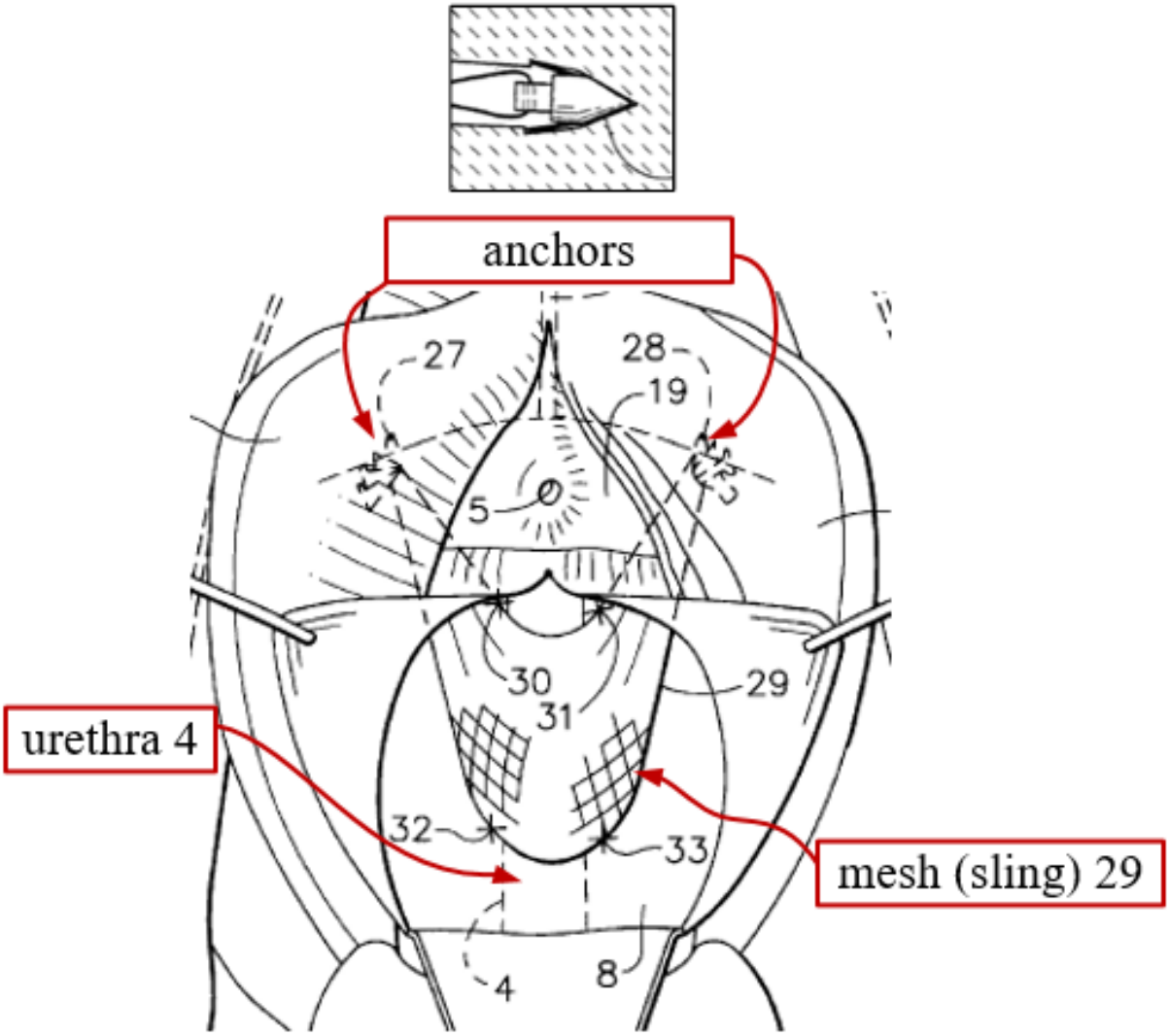
recommended] surgical mesh." COLOPLAST-1010, 7:5-7; COLOPLAST-1003, ¶114. Thus, based on Kovac's teaching, a POSITA would have expected "excellent results" by using the same or similar features of Kovac's sling. *Id.*

Fifth, a POSITA would have been prompted to modify Brenneman's method to apply the sling features of Kovac's sling (or its obvious variants) because doing so would be merely the application of known techniques (applying the sling size, shape and material) to a known system (Brenneman's implant system) to yield predictable results. COLOPLAST-1003 (Expert Declaration), ¶114; *KSR*, 550 U.S. at 417. A POSITA would have recognized that applying Kovac's sling features (or obvious variants thereof) would have led to predictable results without significantly altering or hindering the Brenneman's method of providing support for the urethra to treat female urinary incontinence. COLOPLAST-1003, ¶114.

Dr. Erickson included a schematic image in his declaration, showing an example of what Brenneman's system would look like as modified to include Kovac's sling. COLOPLAST-1003, ¶115. Dr. Erickson explains "This annotated figure is just one example of how a POSITA would have predictably added a mesh sling to Brenneman's system." *Id*.



COLOPLAST-1003 (Expert Declaration), ¶115 (annotated). Dr. Erickson also further explains in his declaration, once the sutures are tensioned and tied, the sling is pulled about the urethra to form the sling-like structure as shown below.



COLOPLAST-1010, FIG. 9 (annotated); COLOPLAST-1003, ¶¶115-116.

2. Analysis

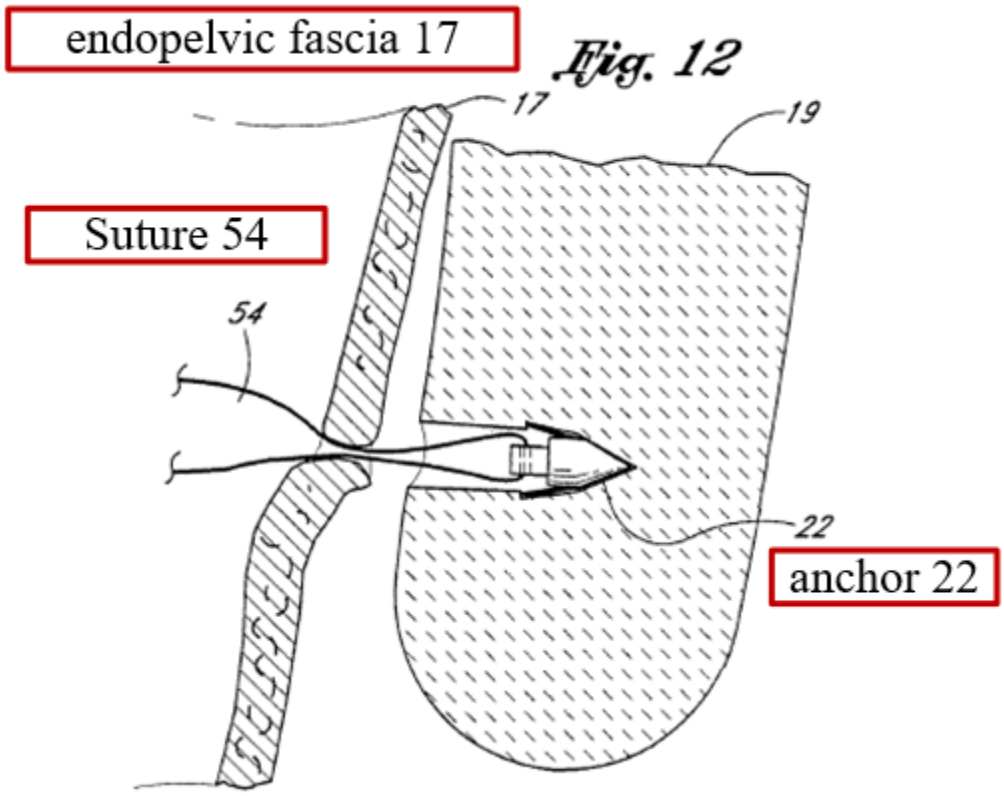
[1pre] A method of providing support for the urethra to treat female urinary incontinence comprising:

To the extent that the preamble serves as a limitation, Brenneman teaches element [1pre]. COLOPLAST-1003, ¶117. Brenneman generally discloses that "[n]umerous approaches for treating urinary incontinence are available," "[f]or

example, several procedures for stabilizing and/or slightly compressing the urethra so as to prevent the leakage of urine have been developed." COLOPLAST-1006, 1:17-24. Brenneman further discloses that "[t]he stabilizing or compressive force may be applied directly by sutures passing through the soft tissue surrounding the urethra or, alternatively, may be applied by means of a sling suspended by sutures." COLOPLAST-1006, 1:17-24. Specifically, Brenneman's method includes "**stabiliz[ing] and/or slightly compress[ing] the urethra**" to "**improv[e] or maintain[] the patient's urinary continence**." COLOPLAST-1006, 5:33-6:3; *see also* 3:6-8, 12:24-30, 13:33-14:36.

[1a] providing a support element having a first portion coupled to a first anchor, a second portion coupled to a second anchor through an aperture, and a central portion between the first and second portions and comprising a ribbon-like filamentary element;

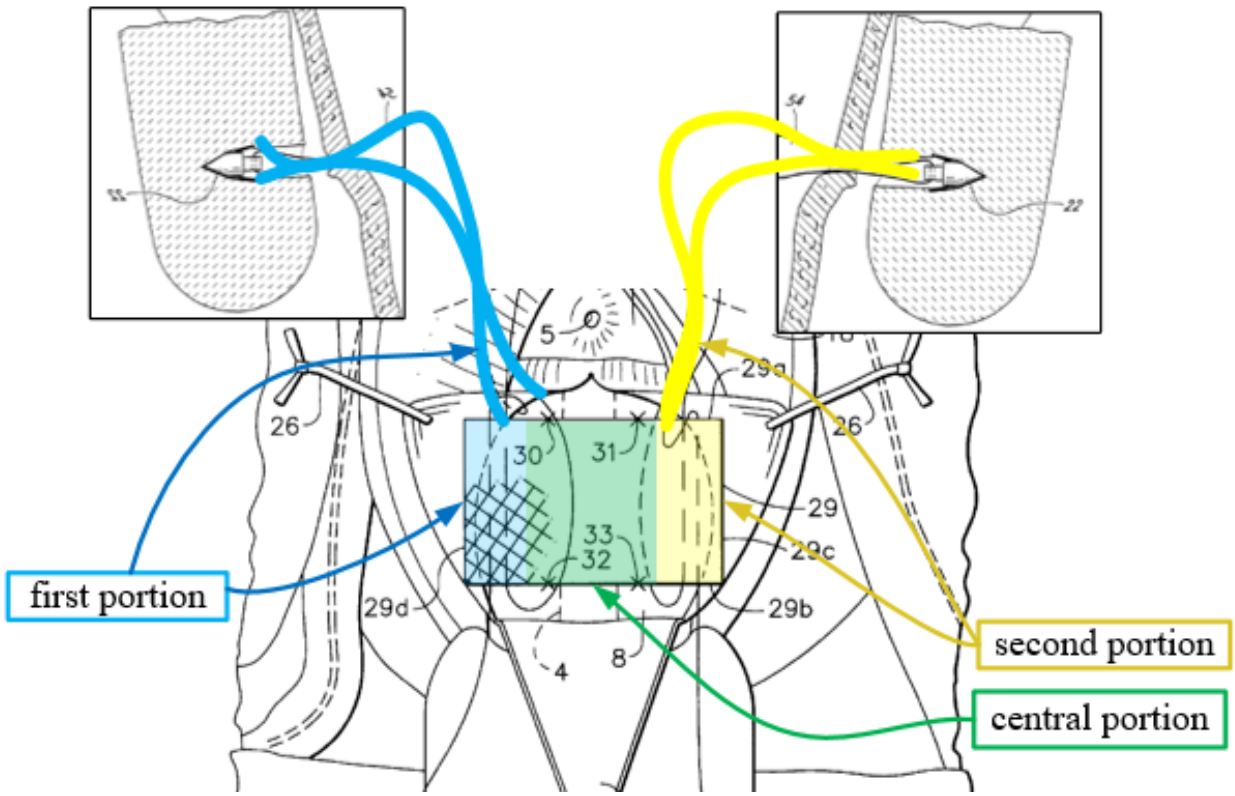
Brenneman-Kovac teaches element [1a]. COLOPLAST-1003, ¶¶118-122. Brenneman shows and discloses a support element having a first portion coupled to a first anchor, a second portion coupled to a second anchor. COLOPLAST-1003, ¶118. Brenneman's method describes using "two…anchors…implanted on each side of the urethra." COLOPLAST-1006, 3:11-14. As shown below, Brenneman discloses "methods and devices" that include using an "**anchor with at least one suture attached thereto**." COLOPLAST-1006, FIGS. 1-14,16-24.



COLOPLAST-1006, FIG. 12 (annotated). As depicted above, Brenneman's suture is coupled to the anchor through an aperture. *Id.*

Brenneman teaches that its sling (or other material), anchors, and attached sutures collectively serve as a support element. COLOPLAST-1003, ¶119. For example, Brenneman discloses that "[t]he free ends of **suture from the two anchors** on each side of the urethra are…**tied to**…**the sling**." COLOPLAST-1006, 14:31-36; *see also* 14:31-36. Thus, Brenneman teaches that its first portion includes either: (i) only the suture of the first anchor, or, alternatively, (ii) the suture of the second anchor and at least a portion of the sling or other material that the suture attaches thereto. COLOPLAST-1003, ¶119. Similarly, Brenneman

teaches a second portion that includes either: (i) only the suture of the second anchor, or, alternatively, (ii) the suture of the second anchor and at least a portion of the sling or other material that the suture attaches thereto. COLOPLAST-1003, ¶119. Since Brenneman's "sutures [are] connected between the sling and the…anchors," the sling (or portions thereof) provides a central portion between the first and second portions. COLOPLAST-1006, 3:9-10; COLOPLAST-1003, ¶119. For example, as illustrated by Dr. Erickson in his declaration, the below annotated figure shows that the first (blue) and second (yellow) portions each include a suture and at least a portion of the sling of the proposed combination. COLOPLAST-1003, ¶119.



COLOPLAST-1003 (Expert Declaration), ¶119 (annotated).

As discussed in §III.B.1, *supra*, a POSITA would have been motivated to incorporate Kovac's ribbon-like sling shape in Brenneman's sling. COLOPLAST-1003, ¶¶110-116. As Dr. Erickson explains, a POSITA would have recognized that Kovac's sling shape is a ribbon-like sling shape. COLOPLAST-1003, ¶120. Accordingly, the modified Brenneman-Kovac system includes ribbon-like filamentary element, as claimed. COLOPLAST-1003, ¶¶120.

To the extent that Kovac's sling is deemed not to be sufficiently long or narrow to be considered "ribbon like," a POSITA would have considered it obvious to modify the sling of Brenneman-Kovac to be longer and/or narrower for multiple reasons. COLOPLAST-1003, ¶¶121-122.

First, a POSITA would have been prompted to modify the sling of Brenneman-Kovac to be narrower in order to use less material. COLOPLAST-1003, ¶121. As Dr. Erickson discussed, a POSITA would have been prompted to incorporate obvious variants of Kovac's sling to further narrow the sling shape to advantageously "pass[] around the urethra with a minimum of excess material" to avoid unnecessary foreign body reactions. COLOPLAST-1003 (Expert Declaration), ¶121; *see also* COLOPLAST-1007, [0124], [0039], [0008]. Specifically, Dr. Erickson explains that it would have been well-known, and thus obvious, to have used a sling in the form of a narrower piece of mesh in

Brenneman's system to advantageously reduce or eliminate potential excess material. COLOPLAST-1003, ¶121. Indeed, a POSITA would have been motivated to incorporate narrow pieces (e.g., strips) of mesh with the minimum (or near minimum) dimensions suitable to effectively achieve the surgical purpose. COLOPLAST-1003 (Expert Declaration), ¶121; *see also* COLOPLAST-1007, [0039], [0124] (contemporary prior art explaining the well-known sizing concept: "dimensions sufficient only to pass around the urethra" and to "pass[] around the urethra with a minimum of excess material" to avoid implanting a device that "comprises a relatively large foreign body mass to be retained within the patient.").

Also, as Dr. Erickson further explains, a POSITA would have known that a large foreign body mass "can lead to related inflammation, infection translocation, erosion, fistula and such like," and thus would have looked to ways to mitigate these issues. COLOPLAST-1003 (Expert Declaration), ¶121; *see also* COLOPLAST-1007, [0008], [0124]. Thus, a POSITA would have recognized that implementing a narrow form of Kovac's sling in Brenneman's implant would have provided proper support of the urethra while minimizing or preventing adverse body reactions as well as minimize potential patient discomfort and use of excess sling material. COLOPLAST-1003, ¶121.

Second, and in the alternative, a POSITA would have been prompted to modify the sling of Brenneman-Kovac to be either longer or narrower because

modifying dimensions was known to be obvious. *In Gardner v. TEC Syst., Inc.,* 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984) (the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.). Indeed, this is particularly true for medical devices inserted into patient anatomy, because it was well-known to POSITAs that different sized and shaped implants are appropriate for patients having different sized and shaped anatomy. COLOPLAST-1003, ¶121.

Third, a POSITA would have been prompted to modify the sling of Brenneman-Kovac to be either longer or narrower because doing so would be merely the application of known techniques (e.g., sizing an implantable sling) to a known system (e.g., Brenneman's implant system with Kovac's sling) to yield predictable results. COLOPLAST-1003 (Expert Declaration), ¶121; *KSR*, 550 U.S. at 417. A POSITA would have recognized that sizing a sling to be ribbon-like would have led to predictable results without significantly altering or hindering the Brenneman's method of providing support for the urethra to treat female urinary incontinence. COLOPLAST-1003, ¶121.

In sum, the Brenneman-Kovac combination teaches element [1a]. COLOPLAST-1003, ¶¶118-122.

[1b] attaching the first anchor to a first tissue portion at a first location lateral to the urethra;

Brenneman-Kovac teaches element [1b]. COLOPLAST-1003, ¶¶123-125. As explained above (§II.C, *supra*), "lateral" within the meaning of the '715 patent means "to one side of." COLOPLAST-1003, ¶47. Specifically, Brenneman discloses that "at least one…anchor is implanted on either side of the urethra." COLOPLAST-1006, 3:6. Furthermore, Brenneman's Figures 9-12 shows an example of attaching the anchor 22 to tissue (the endopelvic fascia 17 and the pubic bone 19), which a POSITA would have understood is a location lateral to the urethra. COLOPLAST-1003, ¶123. Brenneman also describes incising and suturing at locations lateral to the urethra. COLOPLAST-1006, 3:3-5; *see also* 13:22-23, 3:29; 14:7-8, 14:13-16 , 11:28-33.

Brenneman also teaches that the first anchor is attached a first tissue portion. COLOPLAST-1003, ¶124. Specifically, Brenneman discloses that its "invention relates to devices and methods for inserting anchors…**into a bone or tissue**." COLOPLAST-1006, 1:27-28. Indeed, it was well-known prior to the Critical Date that "bone" is a form of tissue. COLOPLAST-1015, 3 ("bone….a specialized form of dense connective tissue consisting of bone cells (osteocytes)"). COLOPLAST-1003, ¶124.

Thus, Brenneman teaches attaching the first anchor at a first location lateral to the urethra. COLOPLAST-1003, ¶¶123-125.

[1c] attaching the second anchor to a second tissue portion at a second location lateral to the urethra;

Brenneman-Kovac teaches element [1c]. COLOPLAST-1003, ¶¶126. Brenneman teaches attaching the second anchor to a second tissue portion at a second location by describing that "two…anchors are placed on either side of the urethra." COLOPLAST-1006, 14:1-5, 3:11-14, 14:25-26. Therefore, and for the reasons provided above (element [1b], *supra*), Brenneman alone discloses or the combination renders obvious attaching a second anchor to a second tissue portion at a second location lateral to the urethra. COLOPLAST-1003, ¶¶126, 123-125.

[1d] introducing the filamentary element into fascial tissue; and

Brenneman-Kovac teaches element [1d]. COLOPLAST-1003, ¶¶127-135. As discussed above, facial tissue is present at a number of locations in the pelvic region.[6] For example, as discussed further below, there are at least two regions of fascial tissue disclosed by Brenneman and Kovac. COLOPLAST-1003, ¶¶127-129. Accordingly, the Brenneman-Kovac combination discloses introducing the filamentary element into fascial tissue in multiple ways. COLOPLAST-1003, ¶127.

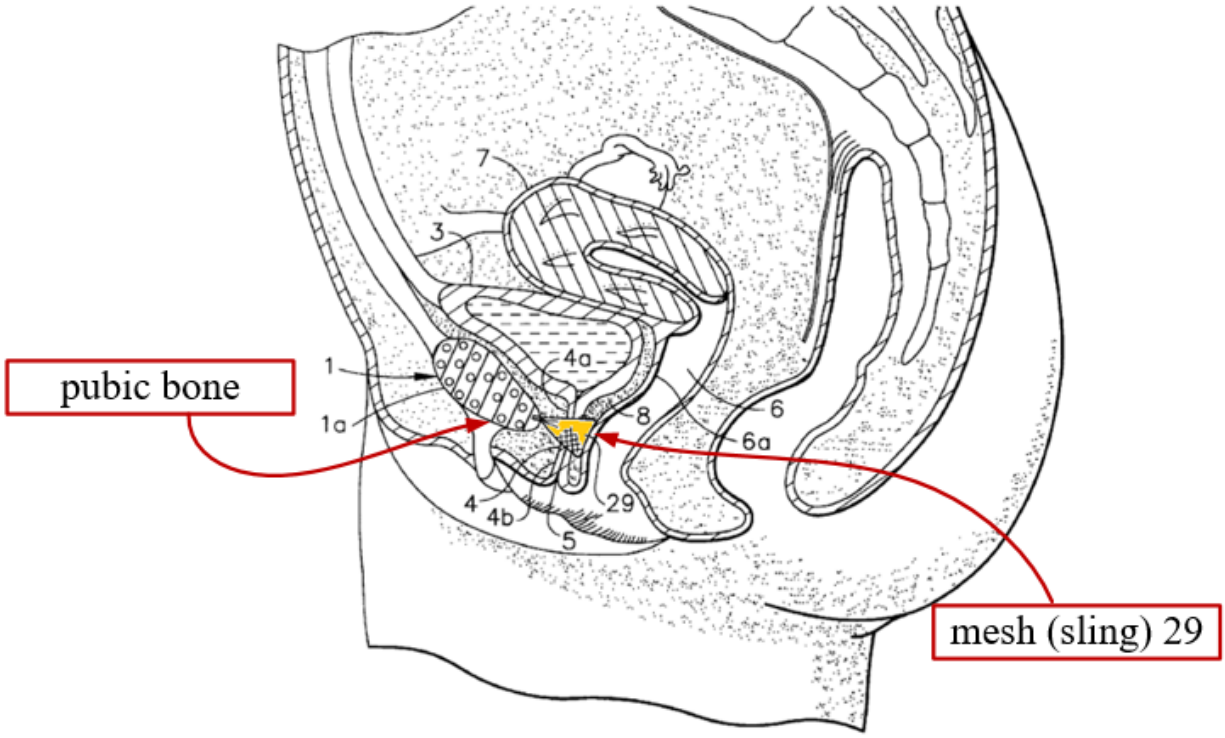
[6] *See* FN6.

As a first example, to the extent that this claim element covers filamentary sutures penetrating and extending though endopelvic fascia, Brenneman discloses or renders obvious such a structure. COLOPLAST-1006, 14:22-23 ("the two free ends of suture exit[ ] the endopelvic fascia"), 5:33-6:3 ("The sutures …attached to the endopelvic fascia"), 12:15-17; COLOPLAST-1003, ¶128.

As a second example, to the extent that this claim element covers the mesh sling material being positioned adjacent to and/or penetrating into the endopelvic fascia 17 adjacent to the pubic bone, as shown in Brenneman's FIG. 12, that too is taught by the Brenneman-Kovac combination. COLOPLAST-1003, ¶129. As Dr. Erickson explains in his declaration, Brenneman shows in FIG. 12 that an anchor can be attached to tissue (e.g., pubic bone) with its suture extending through the endopelvic fascia prior to tensioning the sutures and sling. COLOPLAST-1006, 14:22-23 ("The bone anchor…is withdrawn leaving the two free ends of suture exiting the endopelvic fascia"), FIG. 12; COLOPLAST-1003, ¶129. Brenneman also discloses that "[t]he free ends of suture from the two anchors…are then tied to the corresponding corners of the sling" and "sutures are then tied off with the appropriate amount of tension to suspend…the bladder neck" with the sling. COLOPLAST-1006, 14:33-36. Based on Brenneman's disclosure, it would have been obvious that, once the suture is pulled taut, the suture length would shorten and the end portions of the sling would advance towards the endopelvic fascia such

that the sling end portions would penetrate into and/or lay adjacent to the endopelvic fascia depicted in Brenneman. COLOPLAST-1003, ¶129.

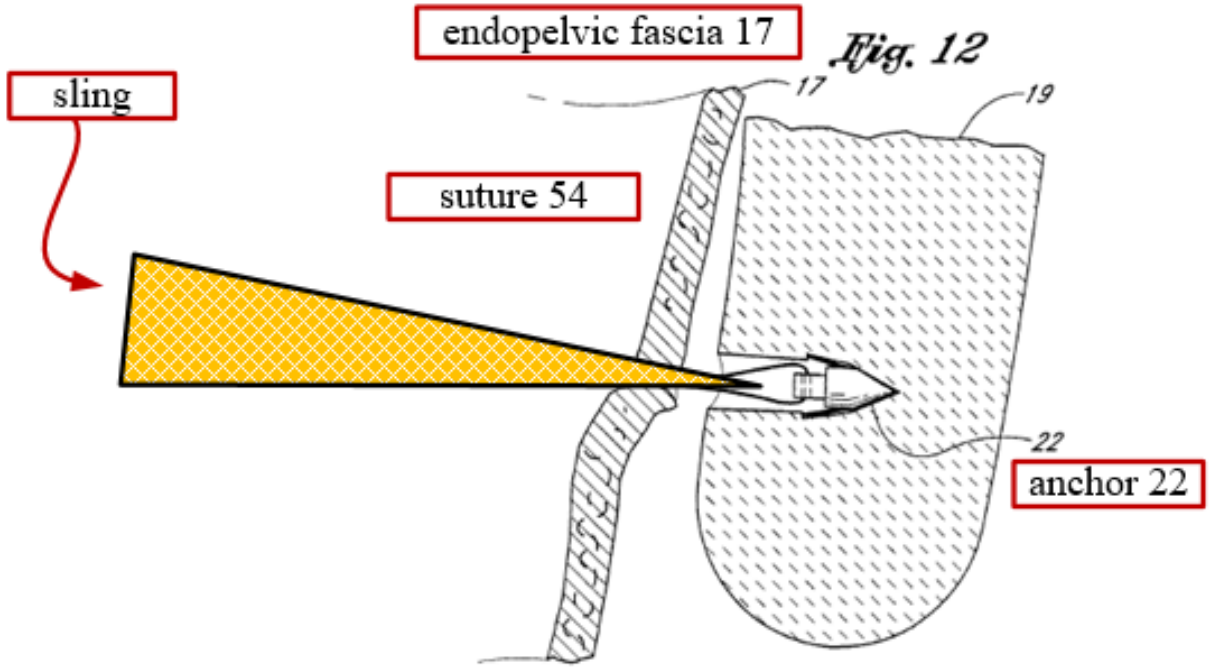
Indeed, as shown below by Kovac, a tensioned sling (shown in orange) extends from the vaginal wall to the pubic bone.



COLOPLAST-1010, FIG 10 (annotated). As discussed in §III.B.1, *supra*, since both Brenneman and Kovac describes attaching anchors in an anatomically similar location and use similar device components (e.g., anchor, suture, sling, etc.), it would have been obvious to a POSITA that Brenneman's sling would be similarly positioned within an anatomy and extend to the pubic bone. COLOPLAST-1010,

3:11-15; COLOPLAST-1006, 12:29-30, 12:7-8; COLOPLAST-1003, ¶¶129-130, 110-116.

Further, as illustrated in Dr. Erickson's declaration, since Brenneman discloses that the endopelvic fascia is located adjacent to the pubic bone (*see* Fig. 12), it would have been obvious to a POSITA that end portions of the sling that extends to the pubic bone (as disclosed in Kovac) would penetrate through the endopelvic fascia layer 17, as disclosed by Brenneman, following tensioning of the sling. COLOPLAST-1003, ¶131.



COLOPLAST-1003 (Expert Declaration), ¶¶131 (annotated).

Furthermore, a POSITA would have understood that the female pelvic anatomy is a small region with essentially no space between adjacent anatomy.

COLOPLAST-1003, ¶132. As Dr. Erickson explains more clearly: "[w]hile patent drawings sometimes show space between patient anatomy for illustrative purposes, there are actually no pockets of space in the lower abdomen—everything is touching." *Id*. Accordingly, based on the anatomy shown in Figure 12 of Brenneman and Figure 10 of Kovac, a POSITA would have understood that portions of the mesh sling material would have been adjacent to and in contact with the endopelvic fascia 17 for the vast majority of (if not all) people. *Id*.

As a third example, to the extent that element [1d] covers the mesh sling being positioned adjacent to what Kovac refers to as "a hammock-like supportive layer comprising the web of endopelvic fascia 8 and the anterior vaginal wall 6a" (COLOPLAST-1010, 5:24-29), that too was taught by the Brenneman and Kovac combination. COLOPLAST-1003, ¶133. Specifically, Brenneman discloses that in its procedure, "an incision is made midline to the urethra" and "[a]n opening or pocket for receiving the sling is created in the tissue between the urethra and the upper vaginal wall." COLOPLAST-1006, 12:12-13. Brenneman states that "[t]he sling is introduced into the opening or pocket and attached to the sutures." COLOPLAST-1006, 12:28-30. It would have been obvious to POSITA that the "tissue between the urethra and the upper vaginal wall," described by Brenneman, is fascial tissue because Brenneman discloses that "[t]he vaginal wall is retracted to allow access to the endopelvic fascia," and that "[a]fter making an incision in the

anterior vaginal wall, the endopelvic fascia is accessed." COLOPLAST-1006, 13:4-11:28-29; COLOPLAST-1003, ¶133.

Furthermore, it would have been well-known before the Critical Date that the tissue present from the urethra to the upper vaginal wall is fascial tissue. COLOPLAST-1003, ¶134. As Dr. Erickson explains in his declaration, the area between the vaginal wall and the urethra would have been readily recognized as fascia, or, more specifically, endopelvic fascia. COLOPLAST-1003, ¶134. Such knowledge would have been corroborated by the prior art that existed before the Critical Date. For example, Kovac discloses that "the urethra and bladder are separated from the extra abdominal area by a hammock-like supportive layer comprising the web of endopelvic fascia 8 and the anterior vaginal wall 6a." COLOPLAST-1010, 5:24-29. As Dr. Erickson illustrates in his declaration, Kovac discloses that the endopelvic fascia 8 (highlighted in yellow) spans between the urethra 4 and anterior vaginal wall 6a.

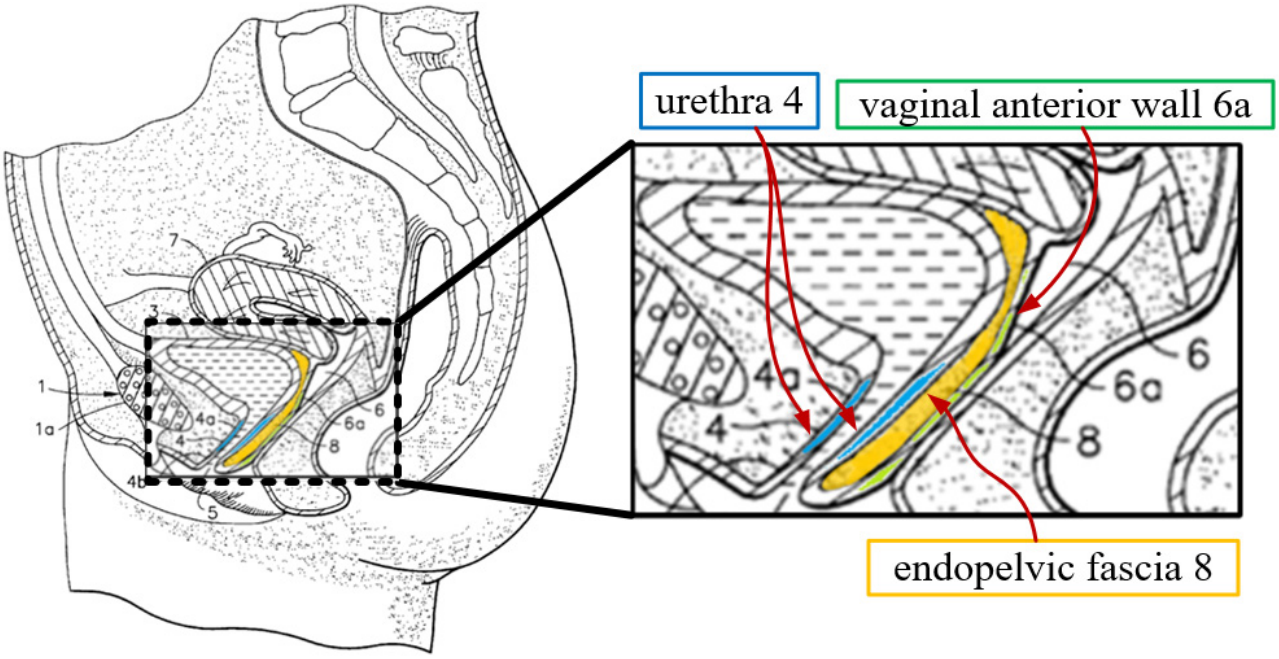


FIG. 3

COLOPLAST-1003 (Expert Declaration), ¶134 (annotated). Thus, based on at least Dr. Erickson's testimony and the teachings of Kovac, a POSITA would have understood that when a sling that is introduced into "tissue between the urethra and the upper vaginal wall," the sling is introduced into fascial tissue. COLOPLAST-1003, ¶134.

Thus, Brenneman-Kovac discloses or suggests introducing the filamentary element into fascial tissue at least three different ways, as described above. COLOPLAST-1003, ¶¶127-135. A POSITA would have understood that there was nothing novel or inventive about such implants being introduced into fascial tissue. *Id.* (explaining "it is just patient anatomy").

To the extent that Patent Owner disputes whether Brenneman-Kovac teaches limitation [1d], the three reasons provided above are consistent with Patent Owner's own arguments provided in its complaint, which alleges that a sling with sutures placed in this region of the anatomy necessarily meets the claim element for introducing the filamentary element into fascial tissue. COLOPLAST-1018, 7-8.

[1e] after the step of introducing the filamentary element into the fascial tissue adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor so that the central portion provides at least a sling-like support for the urethra between the first and second locations;

Brenneman-Kovac teaches element [1e]. COLOPLAST-1003, ¶¶136-138. Specifically, as described above (*supra,* [1d]), Brenneman-Kovac describes the step of introducing the filamentary element into the fascial tissue. COLOPLAST-1003, ¶¶127-135. Brenneman teaches and/or renders obvious adjusting the tension of the central portion between the first and second anchors so that the central portion provides at least a sling-like support for the urethra between the first and second locations after introducing the filamentary element into the fascial tissue. COLOPLAST-1003, ¶136. Indeed, Brenneman shows and describes extending a suture loosely from an aperture in the anchor during insertion and deployment, followed by positioning the sling beneath the urethra to provide a sling-like support for the urethra by securing tying the sutures to the sling. COLOPLAST-

1006, 15:33-36, 14:31-36, 12:29-30, FIGS. 9-12. Specifically, Brenneman states that "the two anchors on each side of the urethra **are then** tied to…the sling" and "[t]he sutures **are then** tied off with the appropriate **amount of tension** to suspend or stabilize the bladder neck."

COLOPLAST-1006, 15:33-36. The sequence of steps indicated by the "are then…" phrases used in the Brenneman disclosure teaches that the tying and tensioning of Brenneman's sling (e.g., filamentary element) occurs after the sling is introduced into the fascial tissue (e.g., placed in the pocket). COLOPLAST-1003, ¶137. Accordingly, a POSITA would have found it obvious to adjust the tension of the central portion between the first and second anchors after introduction so that the central portion provides at least a sling-like support for the urethra between the first and second locations based on Brenneman's disclosure. *Id.*

For the reasons above, Brenneman-Kovac renders obvious element [1e]. *Id.*, ¶¶136-138.

[1f] wherein the filamentary element will become embodied with fascia in the fascial tissue over time.

To the extent that this wherein clause simply expresses an intended result of the claimed method, element [1f] should not be given patentable weight. *See Minton*, 336 F.3d 1373 at 1381.

Alternatively, to the extent that this limitation has patentable weight, Brenneman-Kovac teaches element [1f]. COLOPLAST-1003, ¶¶139-141. As explained above (§II.C, *supra*), "the filamentary element will become embodied with fascia in the fascial tissue" within the meaning of the '715 patent is "fascial tissue grows into the filamentary element during healing." As described above (elements [1a] and [1d], *supra*), Brenneman-Kovac renders obvious providing a support element comprising a ribbon-like filamentary element, introducing the support element into facial tissue such that Kovac's sling would have become embodied with fascia. COLOPLAST-1003, ¶¶118-122, 127-135.

Specifically, Kovac teaches that "[e]xcellent results have been achieved by using a surgical mesh manufactured by Ethicon, Inc. of Summerville, N.J. and sold under the registered trademark Mersilene®." COLOPLAST-1010, 7:5-7. Furthermore, as Dr. Erickson explains in his declaration, it would have been obvious, based on existing prior art, that a Mersilene mesh allows tissue ingrowth to occur over time. COLOPLAST-1003, ¶140. Indeed, it was well-known before the Critical Date that Mersilene® was a commercially available polyester fiber mesh that "display[s] excellent tissue ingrowth and fixation" characteristics. COLOPLAST-1019, 15; COLOPLAST-1020, 1 ("Fibrovascular tissue grows through the [Mersilene] mesh's interstices so embedding the mesh with its

contacting tissues."), *id.* ("Mersilene mesh…can be used for a variety of surgical problems."); COLOPLAST-1003, ¶140.

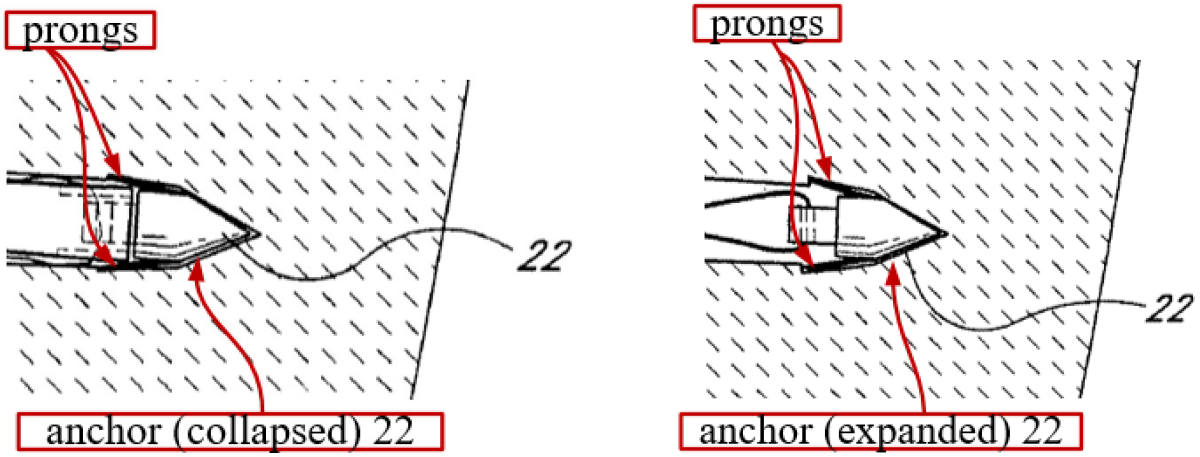
Furthermore, Dr. Erickson explains that the teachings of Brenneman and Kovac render obvious that the ingrowth tissue would be fascia. COLOPLAST-1003, ¶141. As discussed above ([1d], *supra*), Brenneman's implant is placed into fascial tissue. COLOPLAST-1006, 12:24-26 ([a]n opening or pocket for receiving the sling," is "created in the tissue between the urethra and the upper vaginal wall" and the "implantation device is inserted…into the pocket"). And because Brenneman teaches that a pocket is created by making an incision between the urethra and the vaginal, a POSITA would have understood that Brenneman's sling (e.g., filamentary element) would become embodied with fascia, that is, the same tissue that surrounds the sling once it is placed into the pocket. COLOPLAST-1003, ¶141. In other words, consistent with '715 patent's disclosure that "[w]ith the healing of the incisions the filamentary element becomes embodied into the fascial tissue," it would have been obvious that any tissue ingrowth on an implanted device (e.g., Mersilene mesh) would be the same tissue (e.g., fascia) as the healing tissue (e.g., fascia) surrounding the implant. *Id*. A POSITA would have understood that there was nothing novel or inventive about this well-known biological response to mesh slings. *Id*.

[2] The method of claim 1, wherein the second location is on a side opposite from the first location.

Brenneman-Kovac teaches element [2]. COLOPLAST-1003, ¶142. Specifically, Brenneman describes that "[p]referably, at least one…anchor is implanted on either side of the urethra." COLOPLAST-1006, 5:6; COLOPLAST-1003, ¶142. Furthermore, Brenneman's "bone anchor implantation procedure is repeated to implant a second bone anchor on the **opposite side of the urethra** from the first bone anchor." COLOPLAST-1006, 12:18-19.

[3] The method of claim 1, wherein each respective anchor has a body elongated along a longitudinal axis and with first and second ends and a plurality of flexible prongs extending radially outwards from the first end.

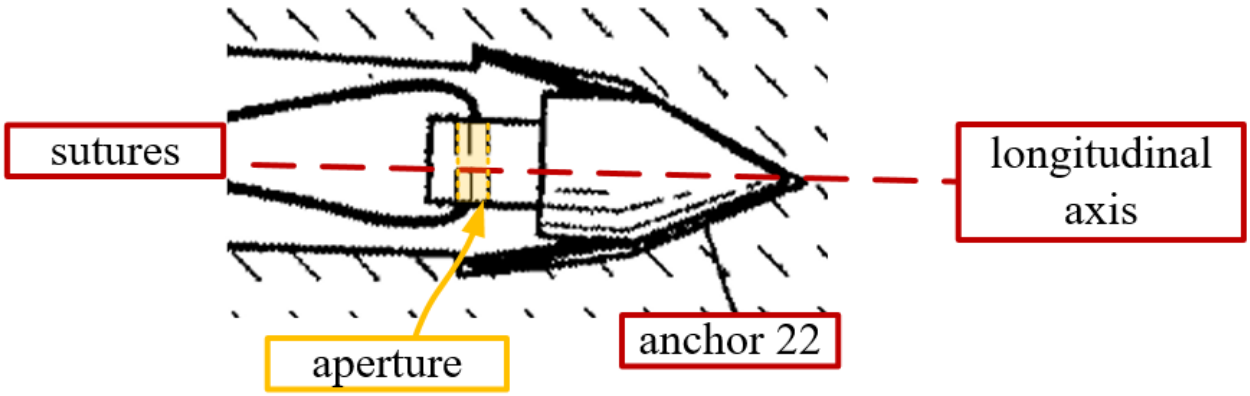
Brenneman-Kovac teaches element [3]. COLOPLAST-1003, ¶143. Specifically, Brenneman shows and describes an anchor having a body elongated in a longitudinal axis, first and second ends, and a plurality of flexible prongs extending radially outwards from the first end. COLOPLAST-1003, ¶143. For example, as shown in FIGS. 11-12, Brenneman shows an exemplary "releasable bone anchor" having multiple prongs that flex outwardly as the anchor transitions from a collapsed state to an expanded state of the prongs. COLOPLAST-1006, 5:3.



Compare COLOPLAST-1004, FIG. 11 (partial, annotated, left) with FIG. 12 (partial, annotated, right), *see also* FIG. 3; COLOPLAST-1003, ¶143. The above figures illustrate that the anchor's prongs radially extend outwardly from its first end once the anchor is implanted into tissue. COLOPLAST-1003, ¶143.

[4] The method of claim 3, wherein the aperture in the second anchor is transverse to a longitudinal axis of the second anchor.

Brenneman-Kovac teaches element [4]. COLOPLAST-1003, ¶144. Specifically, Brenneman's "Figure 12 shows the…anchor with sutures extending therefrom after implantation into the bone." COLOPLAST-1006, 5:3, FIG. 12.



COLOPLAST-1006, FIG. 12 (partial, annotated). Brenneman's above depiction shows an aperture (orange) extending through a base portion of the anchor and transverse to a longitudinal axis of the anchor. COLOPLAST-1006, FIG. 12; COLOPLAST-1003, ¶144.

[6] The method of claim 1, further comprising mounting the second anchor on an insertion tool, wherein attaching the second anchor to the second portion comprises using the insertion tool to position the second anchor at the second location.

Brenneman-Kovac teaches element [6]. COLOPLAST-1003, ¶145. Specifically, Brenneman shows and describes mounting the second anchor on an insertion tool, wherein attaching the second anchor to the second portion comprises using the insertion tool to position the second anchor at the second location. COLOPLAST-1003, ¶145. For example, as shown below in FIG. 1, Brenneman discloses that its "anchor implantation device [shown in blue] has a first handle having an inserter shaft attached thereto" that is "adapted to releasably engage or attach to a bone anchor." COLOPLAST-1006, 6:6-12, FIGS. 1-5; *see also* FIGS. 6-24. Brenneman also teaches that "the inserter shaft...eject[s] the...anchor from the inserter shaft with sufficient force to implant the...anchor." COLOPLAST-1006, 10:12-18.

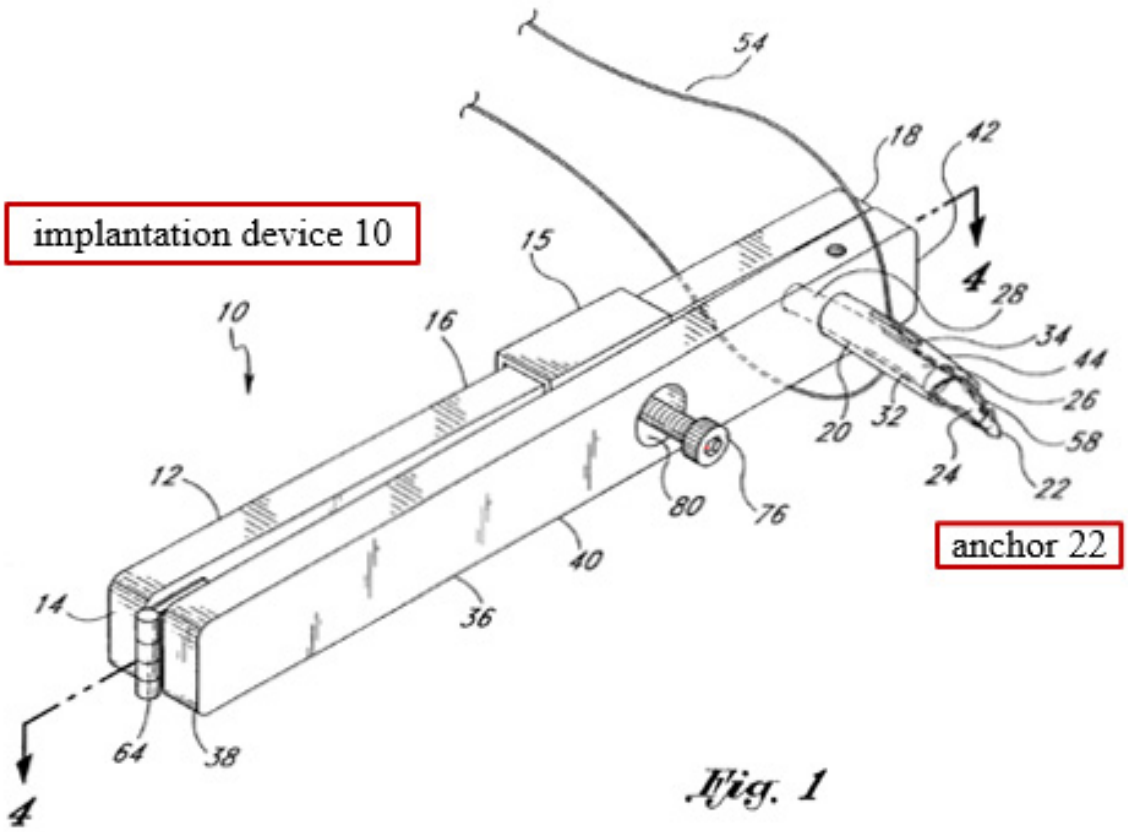


Fig. 1

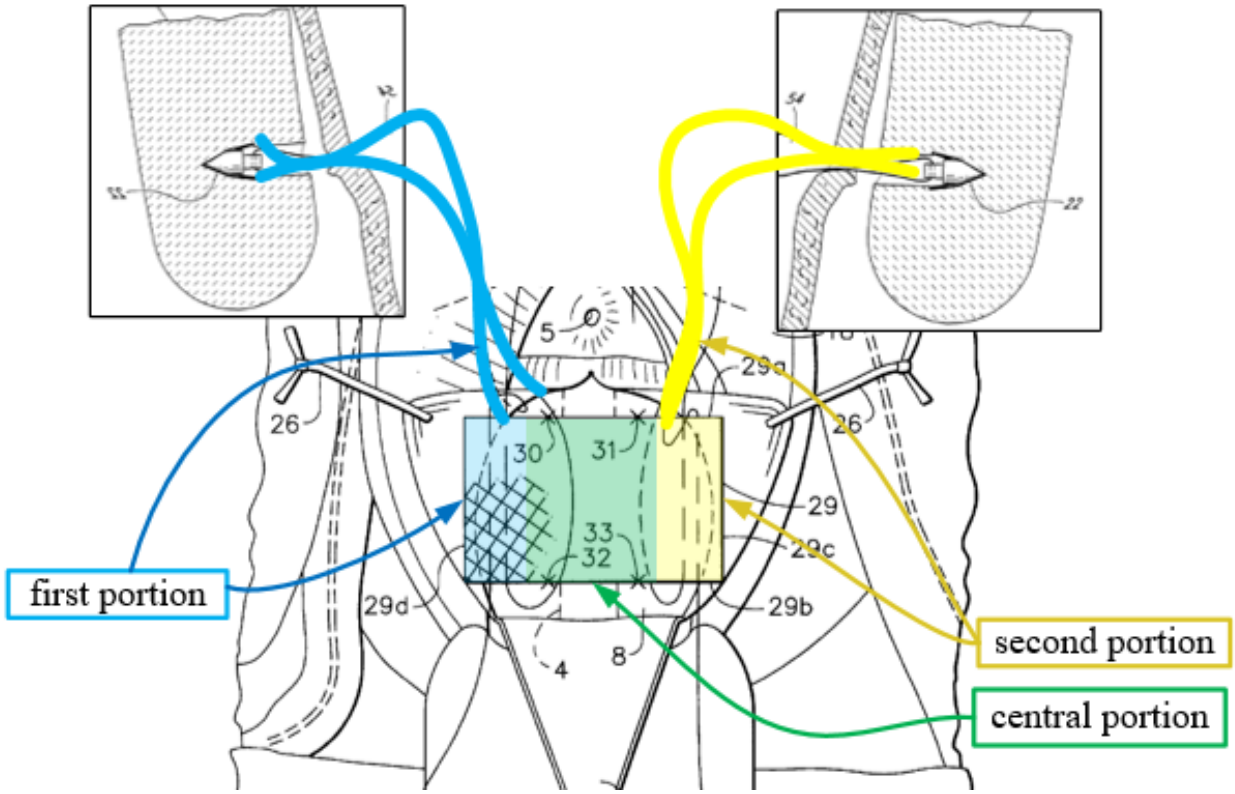
COLOPLAST-1006, FIG. 1 (annotated); COLOPLAST-1003, ¶145.

[7] The method of claim 1, wherein the first and the second portions of the support element comprise ribbon like filamentary elements.

Brenneman-Kovac teaches element [7]. COLOPLAST-1003, ¶¶146-147. As discussed above (element [1a], *supra*) and as depicted below, Brenneman-Kovac teaches a support element comprising a central portion (e.g., sling or portions thereof) between the first and second portions and comprising a ribbon-like filamentary element. COLOPLAST-1003, ¶¶118-122.

As discussed above with respect to element [1a], *supra*, Dr. Erickson explains in his declaration that the Brenneman-Kovac combination includes the

first portion (colored blue) and the second portion (colored yellow) comprise ribbon like filamentary elements. COLOPLAST-1003, ¶147. Specifically, Dr. Erickson explains that the combination's first portion and the second portion can each include the suture as well as an end portion of the sling.



COLOPLAST-1003 (Expert Declaration), ¶147 (annotated).

Thus, Brenneman-Kovac teaches the limitations of claim 7. COLOPLAST-1003, ¶¶146-148.

[9] The method of claim 1, wherein the filamentary element is adapted to facilitate the growth of scar-like tissue upon the filament.

Brenneman-Kovac teaches element [9]. COLOPLAST-1003, ¶149. As discussed above (element [1f], *supra*), Brenneman-Kovac renders obvious that the

filamentary element will become embodied with fascia in the fascial tissue over time. COLOPLAST-1003, ¶¶139-141. A POSITA would have understood that when filamentary element becomes embodied with fascia due to tissue growth during a healing process, this also facilitates the growth of scar-like tissue on the filamentary element because, as explained by Dr. Erickson, it was well-known in the prior art that scar tissue forms when tissue is injured during a surgery. COLOPLAST-1003, ¶149; *see also* COLOPLAST-1015, 6 (a "scar [is]…left in the skin or an internal organ by the healing of a wound…or injury because of replacement by connective tissue of the injured tissue" and "result[s] from wounds that have healed…or surgical operations."); COLOPLAST-1021, 2:1-7 ("The mesh is simply a scaffold upon which the scar tissue may form" and "**the mesh effectively becomes embedded within the scar itself**").

[10] The method of claim 1, wherein the filamentary element is one of a knitted material or a woven material.

Brenneman-Kovac teaches element [10]. COLOPLAST-1003, ¶150. As discussed above (element [1f], *supra*), it would have been obvious to have incorporated Kovac's sling mesh features, such as its specific sling material (e.g., a polyester mesh) into Brenneman's implant system. COLOPLAST-1003, ¶¶139-141. Furthermore, it would have been obvious that the filament element of Brenneman's system would have been made of a knitted or woven material in the combination device based on at least Kovac's teachings and the known prior art.

COLOPLAST-1003, ¶150. For example, Kovac discloses that Mersilene® is a suitable surgical mesh. COLOPLAST-1010, 7:5-7. Furthermore, as Dr. Erickson explains in his declaration, it was well-known prior to the Critical Date that Mersilene® was a woven mesh. COLOPLAST-1003, ¶150; *see also* COLOPLAST-1020, 1 ("Mersilene mesh (Ethicon)…is **woven with an interlocking weave** which permits cutting to any shape without weakening or fraying of the edges.")

[11pre] A method of providing support for the urethra to treat female urinary incontinence comprising:

To the extent that the preamble serves as a limitation, Brenneman teaches element [11pre]. *Supra* [1pre] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶117, 151.

[11a] providing a support element having a first portion coupled to a first anchor, a second portion coupled to a second anchor through an aperture, and a central portion between the first and second portions and comprising a ribbon-like filamentary element;

As explained above for element [1a], Brenneman teaches element [11a]. *Supra* [1pre]-[1a] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶117-122, 152.

[11b] performing during a medical procedure steps comprising: attaching the first anchor to a first tissue portion at a first location lateral to the urethra;

Brenneman teaches element [11b]. *Supra* [1pre]-[1b] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶117-125, 153.

[11c] attaching the second anchor to a second tissue portion at a second location lateral to the urethra;

Brenneman teaches element [11c]. *Supra* [1pre]-[1c] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶117-126, 154.

[11d] introducing the filamentary element into fascial tissue; and

Brenneman-Kovac teaches element [11d]. *Supra* [1pre]-[1d] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶117-135, 155.

[11e] adjusting the tension of the central portion between the first and second anchors by moving the second portion through the aperture of the second anchor so that the central portion provides at least a sling-like support for the urethra between the first and second locations;

Brenneman-Kovac teaches element [11e]. *Supra* [1pre]-[13] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶117-138, 156.

[11f] wherein after the medical procedure the filamentary element will become embodied with fascia in the fascial tissue over time.

Brenneman-Kovac teaches element [11f]. *Supra* [1pre]-[1f] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶139-143, 157.

[12] The method of claim 11, wherein the second location is on a side opposite from the first location.

Brenneman-Kovac teaches element [12]. *Supra* [2] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶142, 158.

[13] The method of claim 11, wherein each respective anchor has a body elongated along a longitudinal axis and with first and second ends and a plurality of flexible prongs extending radially outwards from the first end.

Brenneman-Kovac teaches element [13]. *Supra* [3] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶143, 159.

[14] The method of claim 13, wherein the aperture in the second anchor is transverse to a longitudinal axis of the second anchor.

Brenneman-Kovac teaches element [14]. *Supra* [4] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶144, 160.

[16] The method of claim 1, further comprising mounting the second anchor on an insertion tool, wherein attaching the second anchor to the second portion comprises using the insertion tool to position the second anchor at the second location.

Brenneman-Kovac teaches element [16]. *Supra* [6] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶145, 161.

[17] The method of claim 11, wherein the first and the second portions of the support element comprise ribbon like filamentary elements.

Brenneman-Kovac teaches element [17]. *Supra* [7] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶146-148, 162.

[19] The method of claim 11, wherein the filamentary element is adapted to facilitate the growth of scar-like tissue upon the filament.

Brenneman-Kovac teaches element [19]. *Supra* [9] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶149, 163.

[20] The method of claim 1, wherein the filamentary element is one of a knitted material or a woven material.

Brenneman-Kovac teaches element [20]. *Supra* [10] and §III.B.1-2 (incorporated here). COLOPLAST-1003, ¶¶150, 164.

IV. PTAB DISCRETION SHOULD NOT PRECLUDE INSTITUTION

A. Board Should Not Exercise Discretion Under 35 U.S.C. § 314(a)

The *Fintiv* factors weigh against discretionary denial. IPR2020-00019, Paper 11 at 2-3 (PTAB "precedential" Mar. 20, 2020) ("Fintiv I").

Relevant Facts—On 2/23/2021, Patent Owner filed an infringement action against Petitioner involving the '715 patent ("Litigation"). *See* COLOPLAST-1018. No scheduling conference has yet been held and no trial date has yet been set. Given the filing date of this Petition, the Board's Institution Decision and Final Written Decision will likely issue in March of 2022 and 2023, respectively.

Factor 1 (Stay)— Factor 1 is neutral because neither party in the Litigation has, as of yet, requested a stay (e.g., pending the result of IPR).

Factor 2 (Trial Date)—Factor 2 favors institution because the Court has not set a trial date in the Litigation. Thus, there can be no reasonable assertion that a district court trial might precede the conclusion of this proceeding and its concomitant estoppels under 35 U.S.C. §315(e)(2).

Factor 3 (Investment)—Factor 3 favors institution because the Litigation is currently in its infancy, and neither the parties nor the Court have invested

significant resources relating to the '715 patent.

Factor 4 (Overlap)— Factor 4 favors institution because the Board's final written decision can be expected well in advance of a jury trial, and §315(e)(2) estoppel would prevent Petitioner from asserting in the Court any ground that was raised or reasonably could have been raised in IPR.

Factor 5 (Parties)— Factor 5 favors denial if trial precedes the Board's FWD and favors institution if the opposite is true (due to the 35 U.S.C. 315(e)(2) estoppel provision). *Google LLC, et al. v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at 20–21 (PTAB Oct. 21, 2020).

Factor 6 (Merits and Other Circumstances)— Factor 6 favors institution because the merits of this Petition are particularly strong. As demonstrated in the Petition with reference to Dr. Erickson's testimony and additional evidence, institution would result in invalidation of the Challenged Claims, which are obvious based on prior art references that materially differ from those considered by the Examiner during prosecution.

B. Discretion Under §325(d)

Discretionary denial under §325(d) is not warranted in this IPR, and the Board should not exercise discretion here for several reasons. None of Neisz, Benderev, Brenneman, or Kovac were considered during prosecution of the '715 patent (*supra*, §II.B), nor were they even cited during examination of the '715

patent. Coloplast-1001, Cover pp. 1-2. Notably, the Benderev reference cited herein in Ground 1 is not cumulative of a different, later-filed "Benderev" patent (U.S. Pat. No. 6,200,330) that was mentioned during prosecution. COLOPLAST-1005, 5:63-6:11. All of the *Becton, Dickinson* factors weigh against discretionary denial under §325(d). For example, the prior art asserted in Grounds 1-2: (a) has material differences from and (b) is not cumulative of the art asserted during examination, and (c) was not evaluated during examination. Moreover, this Petition (d) does not rely on overlapping arguments, (e) includes arguments not presented to the Examiner amidst the references cited during examination, and (f) includes the supporting declaration of Dr. Erickson, which was not present during examination.

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

Coloplast authorizes the Patent and Trademark Office to charge Deposit Account No. 06-1050 for the fee set in 37 C.F.R. § 42.15(a) for this Petition and further authorizes payment for any additional fees to be charged to this Deposit Account.

VI. CONCLUSION

Coloplast requests *inter partes* review of these Challenged Claims pursuant to Grounds 1 and 2.

VII. 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)

Coloplast A/S (and Coloplast Corp., its wholly-owned subsidiary) are the real parties-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 *inter partes* review for the '715 Patent. The '715 patent is the subject of civil action C.A. No. 21-265-LPS, *Pamarope Pty Ltd. v. Coloplast Corp*.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Coloplast provides the following designation of counsel.

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D. Service Information

Please address all correspondence and service to the address listed above. Petitioner consents to electronic service by email at IPR48122-0013IP1@fr.com

(referencing No. IPR48122-0013IP1 and cc'ing PTABInbound@fr.com).

Respectfully submitted,

Dated 8/31/2021

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Attorneys for Petitioner

CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter partes* Review totals 13,901 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated: August 31, 2021

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on August 31, 2021, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via Federal Express, to the Patent Owner by serving the correspondence address of record as follows:

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