UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cook Group Incorporated and Cook Medical LLC,

Petitioners

v.

Boston Scientific Scimed, Incorporated,

Patent Owner

Patent No. 9,271,731
Issue Date: March 1, 2016

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,271,731

Case No. IPR 2017-00435

TABLE OF CONTENTS

TABLE OF EXHIBITS

Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners") respectfully request *inter partes* review of claims 1-20 of U.S. Patent No. 9,271,731 ("the '731 patent") (Ex. 1033). The USPTO assignment records show that the Patent Owner is Boston Scientific Scimed, Inc. ("BSSI").

I. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Parties-in-Interest (§ 42.8(b)(1))

Petitioners, Cook Group Incorporated and Cook Medical LLC, along with Cook Incorporated and Cook Medical Technologies LLC are the real parties-in-interest.

B. Related Matters (§ 42.8(b)(2))

1. Pending District Court Litigation

The '731 patent is the subject of litigation in the U.S. District Court for the District of Delaware in *Boston Scientific Corp. et al. v. Cook Group Inc. et al.*, No. 15-980-LPS-CJB (the "Litigation"). Petitioners were served with an amended Complaint asserting the '731 patent on March 9, 2016.

2. Related *Inter Partes* Review Petitions

This Petition is being filed and served concurrently with a petition for *inter partes* review in IPR No. 2017-00440, which also challenges the patentability of claims 1-20 of the ’731 patent. Petitioners have also filed and served petitions for *inter partes* review in IPR Nos. 2017-00131, 2017-00132, 2017-00133, and 2017-00134, which challenge the patentability of the claims of related patents, U.S. Patent Nos. 8,685,048 and 8,709,027.

3. Related Pending Applications

The following patent applications are related to the ’731 patent, and are currently pending before the U.S. Patent Office: U.S. Patent Application Nos. 14/988,447; 15/009,358; and 15/091,147.

C. Lead and Back-Up Counsel (§ 42.8(b)(3))

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D. Service Information (§ 42.8(b)(4))

Service of any documents via hand delivery, express mail, or regular mail may be made to the lead and backup counsel at the postal mailing address above. Petitioners also consent to service by email at the above-designated email addresses.

II. FEE FOR INTER PARTES REVIEW (37 C.F.R. § 42.103)

The Office is authorized to charge the filing fees specified by 37 C.F.R. § 42.15(a), as well as any other necessary fee, to Deposit Account No. 231925.

III. SUMMARY OF THE RELEVANT TECHNOLOGY AND THE '731 PATENT

The '731 patent relates generally to compression clips that can be used "to cause hemostasis of blood vessels located along the gastrointestinal tract." (Ex. 1033, 1:25-26; Ex. 1037, ¶18). The clips stop internal bleeding by clamping together the edge of a wound to achieve "hemostasis." (*Id*. at 2:62-66). The patent acknowledges that such clipping devices were known in the art before the '731 patent was filed. (*See id.*, pp. 1-2 (citing numerous prior art references); 1:53-55 (describing "Olympus Endoclips"); 2:32-38 (describing prior art "clamps, clips, staples, sutures" that are "able to apply sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow")). (Ex. 1037, ¶18).

Besides this knowledge of the prior art clipping devices, a person of ordinary skill in the art also would have been familiar with prior art clip devices in the form

of forceps. (Ex. 1037, ¶19). Annotated Figures 1 and 2, below, depict an example of a prior art forceps disclosed in U.S. Patent No. 5,645,075 ("Palmer"). (Ex. 1017; Ex. 1037, ¶19).[1]

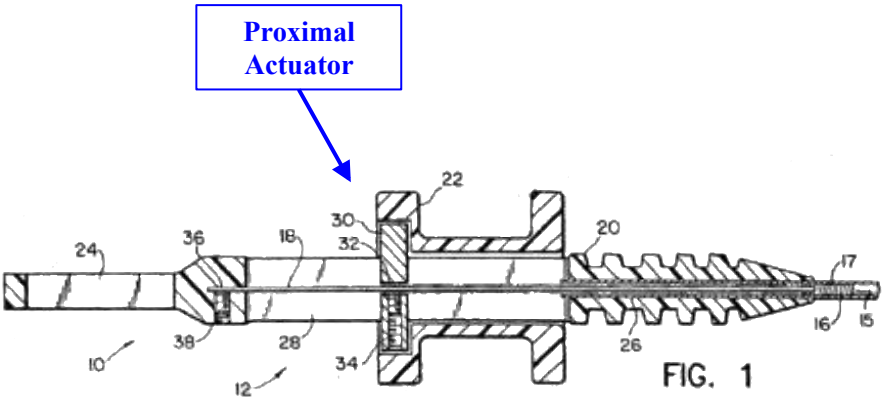


FIG. 1

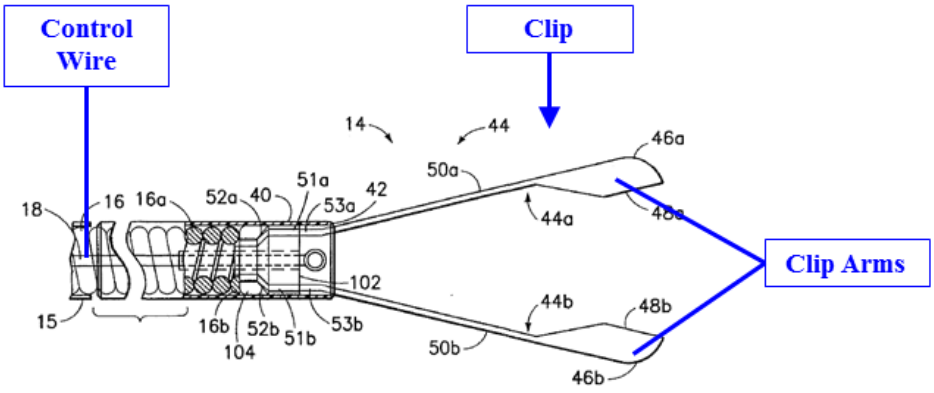


FIG. 2

The forceps (also referred to as a "bioptome") includes a proximal actuator (handle portion 12, Figure 1), and a "distal end effector portion 14" (Figure 2) including a

[1] Palmer issued on July 8, 1997, and names as an inventor Vincent A. Turturro – one of the named inventors of the '731 patent. Palmer was not cited during prosecution of the '731 patent.

clip (jaw assembly 44) with two clip arms (end effectors 44a, 44b, with jaw cups 46a, 46b). (Ex. 1017, 5:50-53, 6:64-7:6). In addition, the forceps includes a "control wire 18" for moving the clip between open and closed configurations. (*Id.*; *see also id.*, 8:5-46, 11:5-13).

In fact, the named inventors of the '731 patent were aware of prior art forceps. The inventors acknowledged in the '731 patent specification that structures described in the '731 patent are "analogous to biopsy forceps." (*See* Ex. 1033, 5:46-48; Ex. 1037, ¶21). Moreover, the comparison below between annotated Figure 2 of Palmer and annotated Figure 13A of the '731 patent shows that the structures depicted in these figures are virtually identical such that there is no distinction between jaws in one and clips in the other:

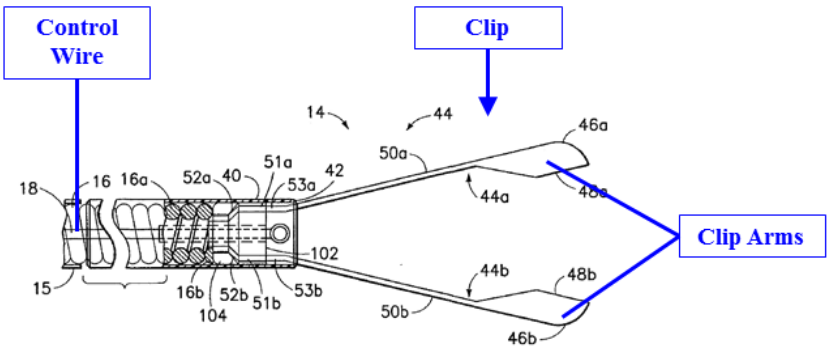


FIG. 2

Palmer, Figure 2

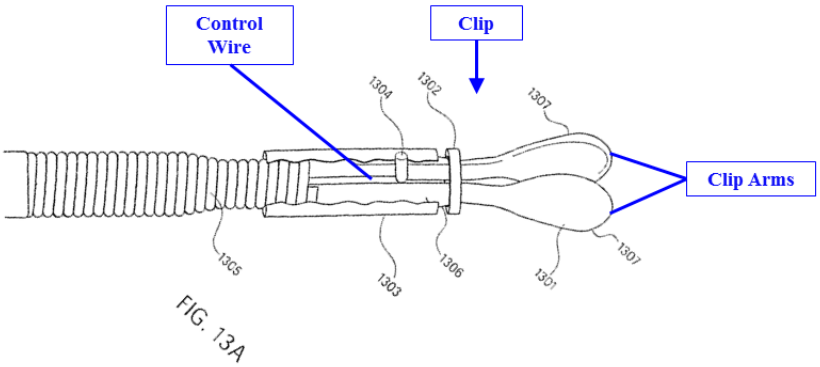


FIG. 13A

'731 Patent, Figure 13A

(Ex. 1037, ¶21).

Consistent with the prior art, the claims of the '731 patent describe medical devices and methods including "a clip" with "clip arms," and a "control wire" for moving the clip between open and closed configurations. In addition, the claims describe an "opening element" for urging the clip arms into the open configuration. (*See* Ex. 1033 at 15:37-17:15). The term "opening element" does not appear anywhere in the '731 patent specification. As explained below in Section IV.E.1, *infra* at pp. 12-14, BSSI identified in the Litigation several figures in the '731 patent that BSSI contends describe an "opening element."

IV. REQUIREMENTS FOR INTER PARTES REVIEW (37 C.F.R. § 42.104)

A. Certification Of Standing (§ 42.104(a))

Petitioners certify that the '731 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

B. Identification Of Challenge And Precise Relief Requested (§ 42.104(b) and (b)(1))

The precise relief requested is that claims 1-20 of the '731 patent (Ex. 1033) be found unpatentable, and canceled.

C. The Specific Art And Statutory Grounds On Which The Challenge Is Based (§ 42.104(b)(2))

Inter partes review of the challenged claims is requested in view of the following reference and specific grounds for rejection under 35 U.S.C. §§ 102 and 103:[2]

[2] The '731 patent claims priority to U.S. Patent Application No. 09/971,488, filed October 5, 2001. Accordingly, the pre-AIA sections of 35 U.S.C. §§ 102 and 103 apply here.

No.	Grounds
1	Claims 1-4, 6, 9-18, and 20 are anticipated under § 102 by U.S. Patent No. 5,626,607 ("Malecki"), and specifically Malecki Embodiment #1.[3]
2	Claims 1-4, 6-18, and 20 are obvious under § 103 in view of Malecki Embodiment #1.
3	Claims 1-2, 4, 10-13, and 15 are anticipated under § 102 by Malecki, and specifically Malecki Embodiment #2.[4]
4	Claims 3, 5-9, 14, and 16-20 are obvious under § 103 in view of Malecki Embodiment #2.

[3] "Malecki Embodiment #1" refers to the embodiment depicted in Figure 28 of Malecki and all of the corresponding written disclosure.

[4] "Malecki Embodiment #2" refers to the embodiment depicted in Figure 25-27 of Malecki and all of the corresponding written disclosure.

D. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art as of the time of the filing of the application that became the '731 patent would have possessed the knowledge and skill known by an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices. (Ex. 1037, ¶11). This person would also have an understanding of engineering or medical device design principles.[5] (Ex. 1037, ¶11).

Petitioners submit the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1037). Dr. Nicosia is a Professor and Chairman of the Department of Mechanical Engineering at Widener University in Chester, Pennsylvania. He received his Ph.D. in Mechanical Engineering in 1997 from Penn State University. As reflected in his *curriculum vitae* (included in Ex. 1037), Dr. Nicosia has extensive experience in the medical field in general, and with hemostatic clips in particular. Dr. Nicosia, for example, is named as a co-inventor of U.S. Patent No. 8,852,211, which relates to hemostatic clips. Dr. Nicosia's Declaration (Ex. 1037) addresses the prior art at issue from the view of a person of ordinary skill in the art in the

[5] The same definition of a person or ordinary skill in the art, as well as the analysis of the prior art references discussed in this petition, would apply in the 2000 timeframe. (Ex. 1037, ¶11).

relevant timeframe.

E. Claim Construction (§ 42.104(b)(3))

Claims in an IPR are given the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b) (2015); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). In light of the broadest reasonable construction standard, and for the purposes of this *inter partes* review only,[6] Petitioners adopt the following constructions consistent with BSSI's positions in the Litigation:

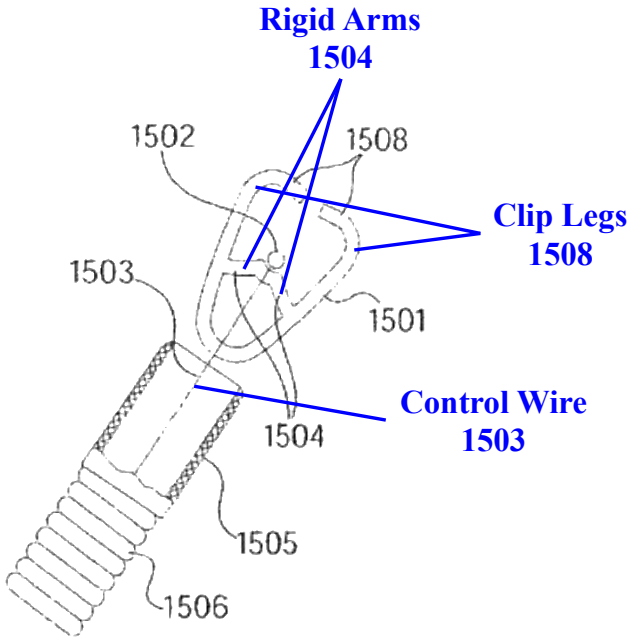
[6] By proposing these constructions, Petitioners do not agree or admit that any claim element of the challenged claims is entitled to coverage under the doctrine of equivalents, that the claims are entitled to such a scope in other proceedings, or that the claims satisfy the requirements of 35 U.S.C. § 112.

1. "opening element"

All of the challenged claims require an "opening element" for performing the following functions:

- opening by "engaging inner walls of the first and second clip arms" and "urging the first and second clip arms away from one another into the open tissue-receiving configuration" (claims 1 and 12), and
- opening by "engaging inner walls of the first and second clip arms" and "urging the clip to an open tissue receiving configuration" (claim 20).

The term "opening element" does not appear in the specification of the '731 patent. In the Litigation, BSSI argued that the "plain and ordinary" meaning of "opening element" is a structure that "engages the inner walls of the clip arms and urges them away from one another." (Ex. 1039 at 16). According to BSSI, the specification describes the opening element as "[t]wo rigid arms 1504, located between the clip legs 1508, [that] translate the tensile force on the control wire 1503 to an outward radial force on the clip legs 1508." (Ex. 1039 at 16-17). "Rigid arms 1504," "clip legs 1508," and control wire 1503" are depicted in Figure 15A of the '731 patent, reproduced below:



'731 Patent, Figure 15A (Annotated)

BSSI also argued that Figures 8A, 8B, 10A, and 10B of the '731 patent (reproduced below with annotations by BSSI) depict examples of "opening elements":

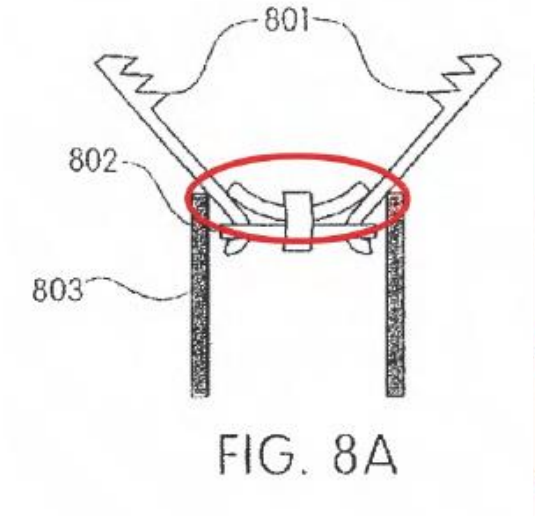


FIG. 8A

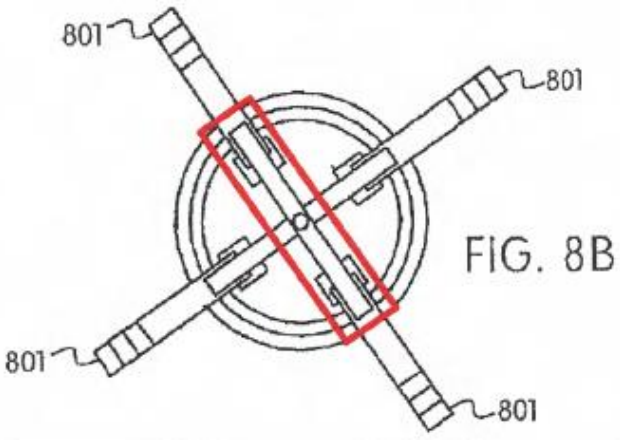


FIG. 8B

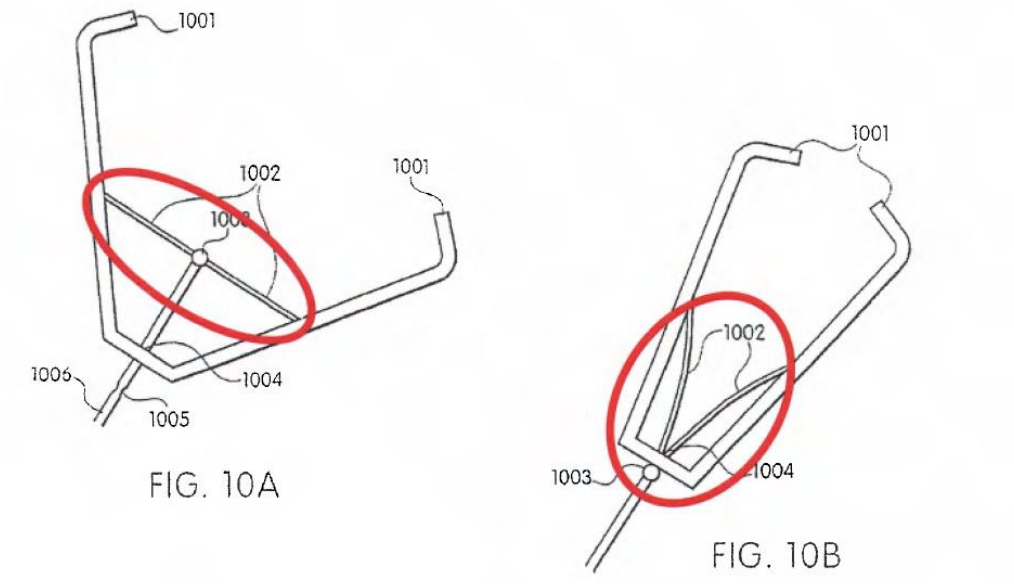


FIG. 10A

FIG. 10B

(Ex. 1035, pp. 60, 66, 76). According to BSSI, Figure 8A is the "prototypical example" of an opening element. (Ex. 1036, 152:23-153:2).

For purposes of this IPR proceeding, Petitioners accept BSSI's construction of "opening element" as encompassing any structure that "engages the inner walls of the clip arms and urges them away from one another," including the structures in Figures 8A, 8B, 10A, 10B, and 15A-C identified above.

2. "engaging inner walls of the first and second clip arms"

In the Litigation, BSSI argued that the "plain and ordinary" meaning of "engaging inner walls" simply requires that the opening element "contact[]" the inner walls, without requiring a "physical connection." (Ex. 1039 at 17). In addition, BSSI argued that "engaging inner walls of the first and second clip arms" requires that the "opening element' is "positioned between the clip arms and of sufficient size to be able to engage the clip arms." (Ex. 1035, p. 62).

For purposes of this IPR proceeding, Petitioners accept BSSI's construction of "engaging inner walls of the first and second clip arms" as "contacting" the inner walls, without requiring a physical connection, and "positioned between the clip arms and of sufficient size to be able to engage the clip arms."

3. "movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip"

The claims require an opening element "movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip." In the Litigation, BSSI argued the "structural feature" associated with this phrase is the fact that the "opening element" "expands and retracts." (Ex. 1035, p. 62). For purposes of this IPR proceeding, Petitioners accept BSSI's construction.

4. "link arms are axially aligned with one another"

Claims 3 and 14 require first and second link arms "axially aligned with one another." As explained in the Nicosia Declaration, the term "axially aligned" ordinarily refers to two structures aligned along a single common axis, as shown below.

Blue And Green Structures Aligned Along Single Common Axis

(Ex. 1037, ¶25).

However in the Litigation, BSSI alleges that the "Internal Nitinol strips" identified in the figure below are "link arms . . . axially aligned with one another," even though the purported link arms do not meet the ordinary meaning of "axially aligned."

(Ex. 1038, pp. 18-19; Ex. 1037, ¶¶25-26).

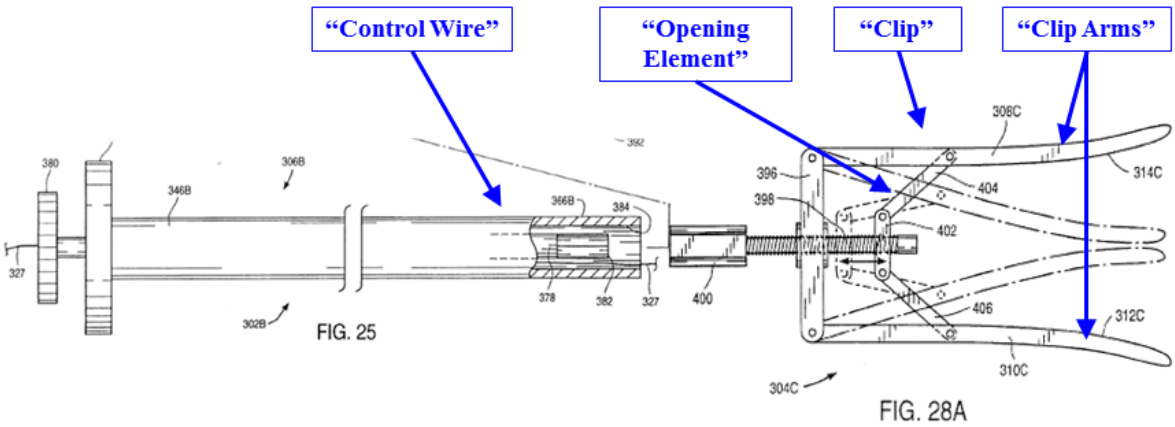
Petitioners disagree with BSSI's application of the term "axially aligned." However for purposes of this IPR proceeding only, Petitioners accept BSSI's application of "link arms are axially aligned with one another" as encompassing the "Internal Nitinol strips" in the configuration shown above.

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO THE CHALLENGED CLAIMS (§§ 42.104(b)(4) AND (b)(5))

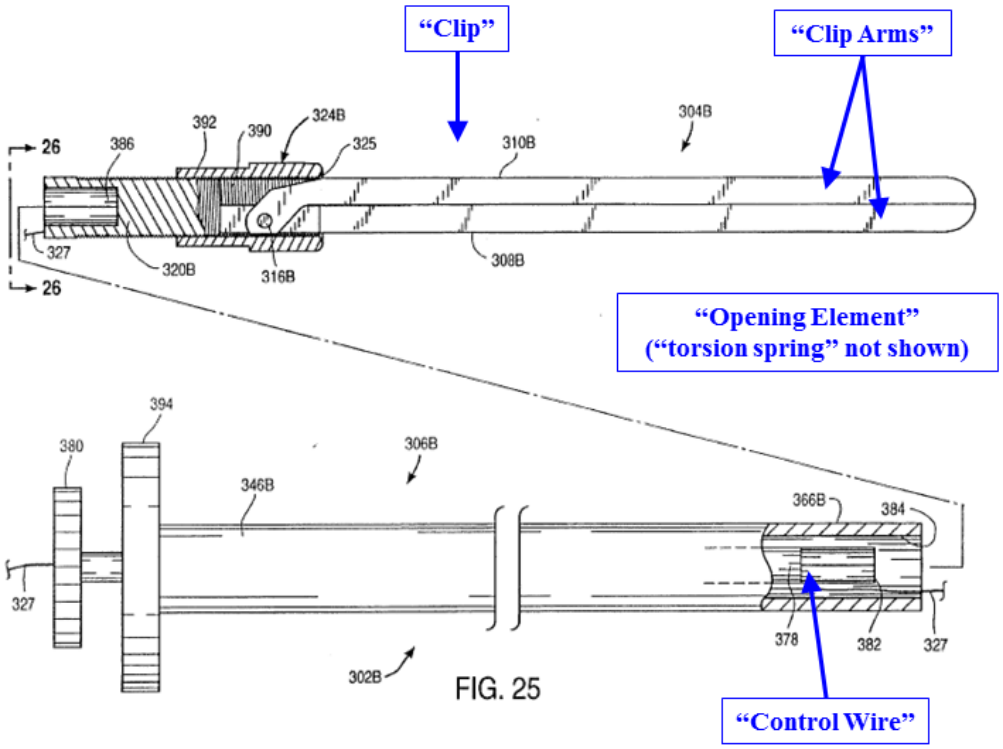
There is a reasonable likelihood that Claims 1-20 are unpatentable in view of Malecki based on the grounds identified above in Section IV.C. Malecki was not before the Examiner.[7] Individually and/or combined, the embodiments in Malecki disclose each and every limitation of the challenged claims, including "a clip," an "opening element," and "a control wire."

[7] Malecki is related to U.S. Patent No. 5,618,307 ("Donlon"), which is listed as a cited reference on the cover of the '731 patent, but Donlon was not substantively addressed on the record during prosecution.

As shown below, Malecki Embodiments #1 and #2 each disclose medical devices including a clip with clip arms, and a control wire for opening and closing the clip. In both embodiments, an opening element urges the clip arms away from one another into an open tissue-receiving configuration as the control wire is moved distally:



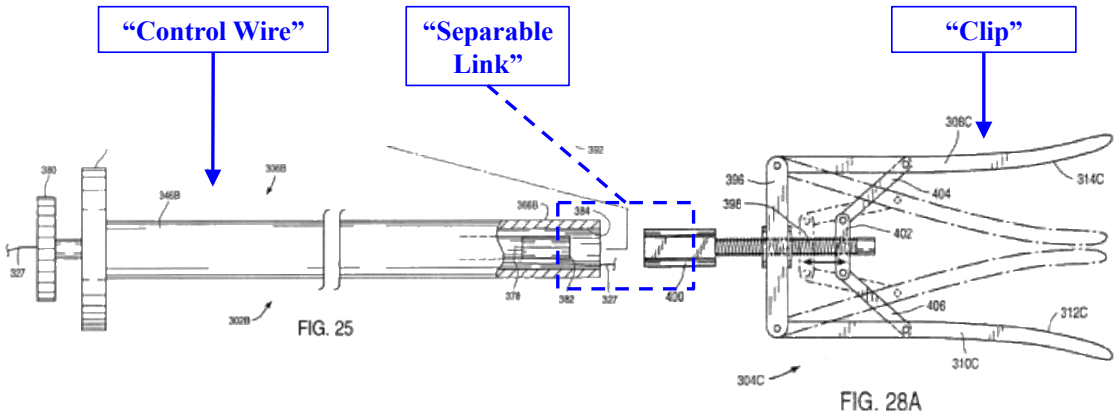
Malecki Embodiment #1, Figures 25 and 28A (Annotated)



Malecki Embodiment #2, Figure 25 (Annotated)

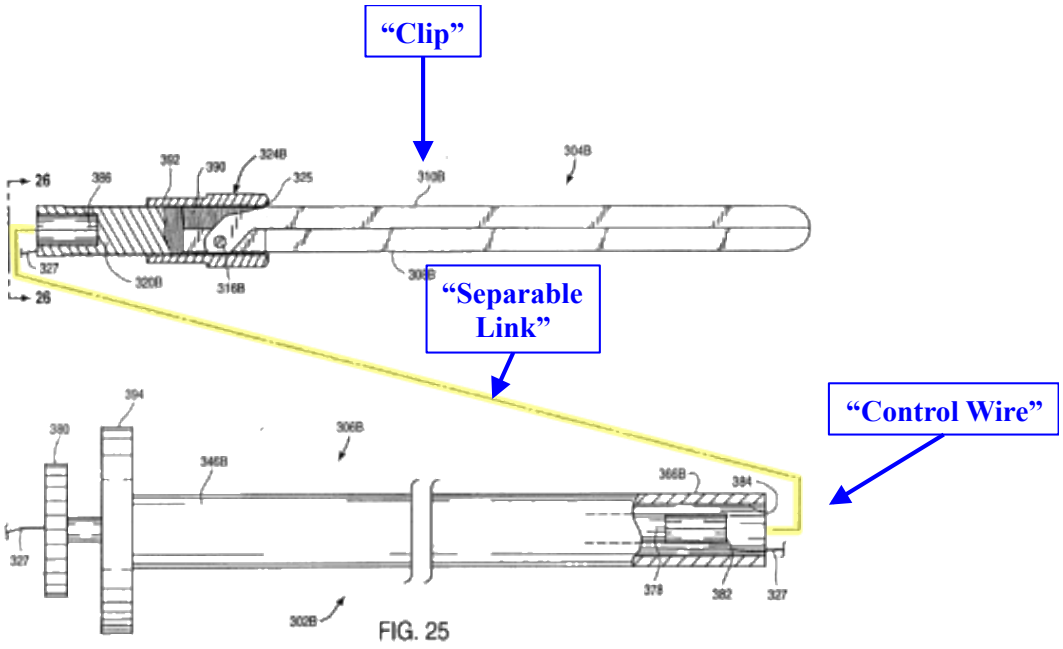
(Ex. 1037, ¶28, Ex. 1003, 16:53-59).

Malecki discloses that the same clamp positioner 306B may be used with each of the clips shown in Malecki Embodiments #1 and # 2. (Ex 1003, 17:55-57). Accordingly, Malecki Embodiments #1 and #2 also disclose a separable link between the control wire and clip, to allow the clip to remain in a patient's body, as shown below.



Malecki Embodiment #1, Figures 25 and 28A (Annotated)

(Ex. 1037, ¶29; Ex. 1008, 18:34-37).



Malecki Embodiment #2, Figure 25 (Annotated)

(Ex. 1037, ¶29; Ex. 1008, 17:37-39, 18:34-37).

As demonstrated below, the challenged claims are anticipated by the prior art. Moreover, these claims are obvious because they merely describe obvious combinations of "familiar elements according to known methods," which "do[] no

more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007); MPEP § 2143(I). The motivation to combine embodiments would have come from the reference itself, as well as from the knowledge generally available to a person of ordinary skill in the art.

A. Ground 1: Claims 1-4, 6, 9-18, and 20 Are Anticipated By Malecki Embodiment #1 (Ex. 1003)

Malecki issued on May 6, 1997 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Malecki was not cited during prosecution of the '731 patent. Grounds 1 and 2 are based Malecki Embodiment #1.

1. Independent Claim 1

a. "A medical device, comprising"

Malecki discloses a medical device in the form of "[a] clamp for clamping a body structure in a patient." (Ex. 1037, ¶31; Ex. 1003, Abstract; *see also, e.g., id.*, 3:32-36, Figs. 17-32).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

As shown below in annotated Figure 28A, Malecki Embodiment #1 discloses a clip (clamp 304C) including first and second clip arms (jaws 308C, 310C), and moveable between an open tissue receiving configuration (solid line position in Figure 28a) in which the first and second arms are separated from one another by a distance selected to receive tissue and a closed configuration (dashed line position in Figure 28A) in which the first and second arms are moved inward to capture the tissue:

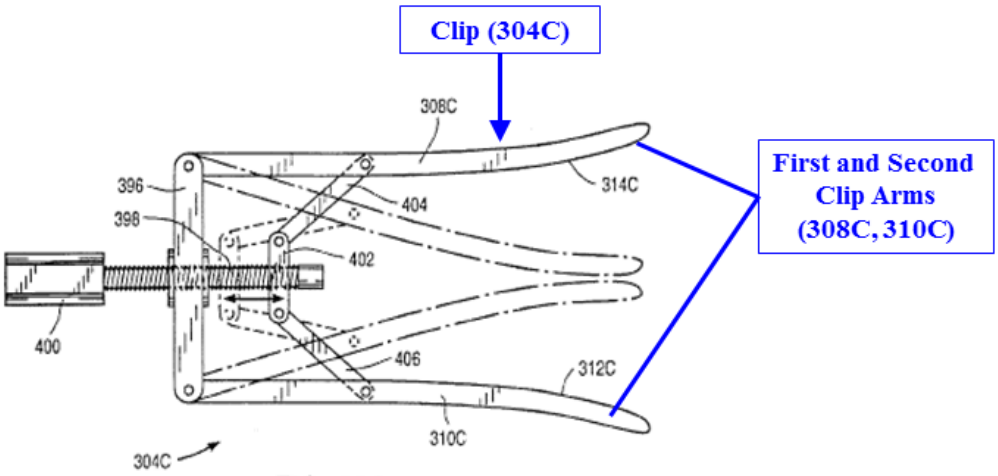


FIG. 28A

(Ex. 1037, ¶32; Ex. 1003, 17:43-48; *see also, e.g.*, 17:58-62 ("[J]aws 308C, 310C [move] between the open, solid line position to the closed, dashed line position."); *see also, e.g.*, 17:42-58, Figure 28A).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration."

As shown below in annotated Figure 28A, Malecki Embodiment #1 discloses an opening element (links 402, 404, connector 406 (highlighted in yellow)) that urges the first and second clip arms (308C, 310C) away from one another, from a closed configuration (dashed line position) into the open tissue-receiving configuration (solid line position). (Ex. 1037, ¶33). The opening

element is movable between an expanded configuration (solid line position) and a retracted configuration (dashed line position) to correspond to a movement of the clip between the open and closed configurations:

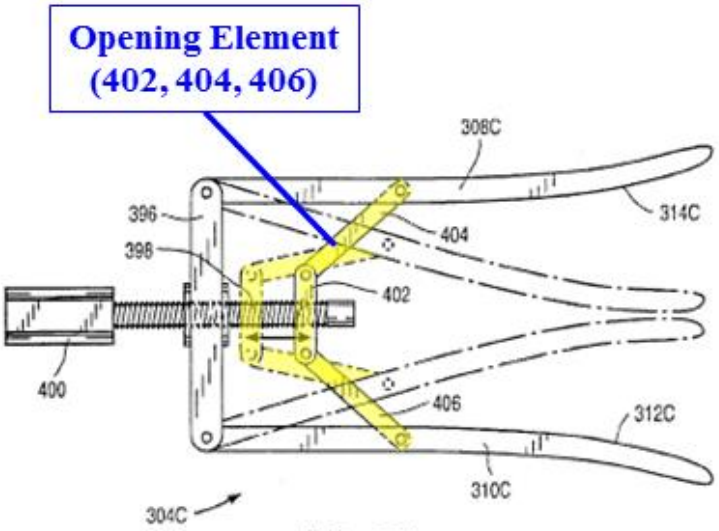
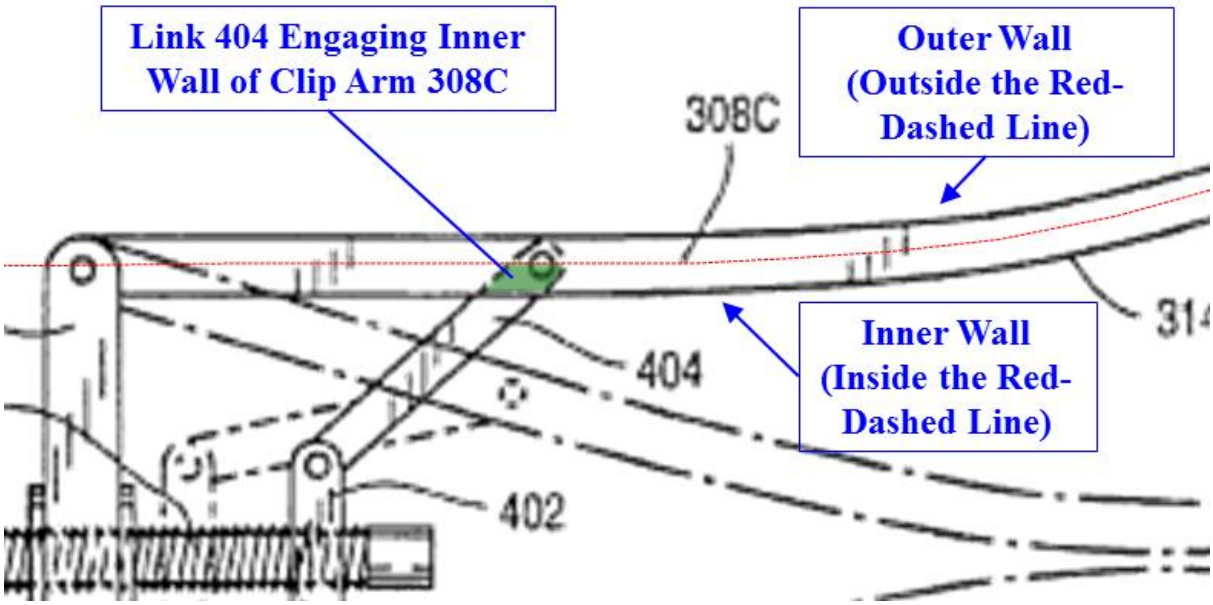


FIG. 28A

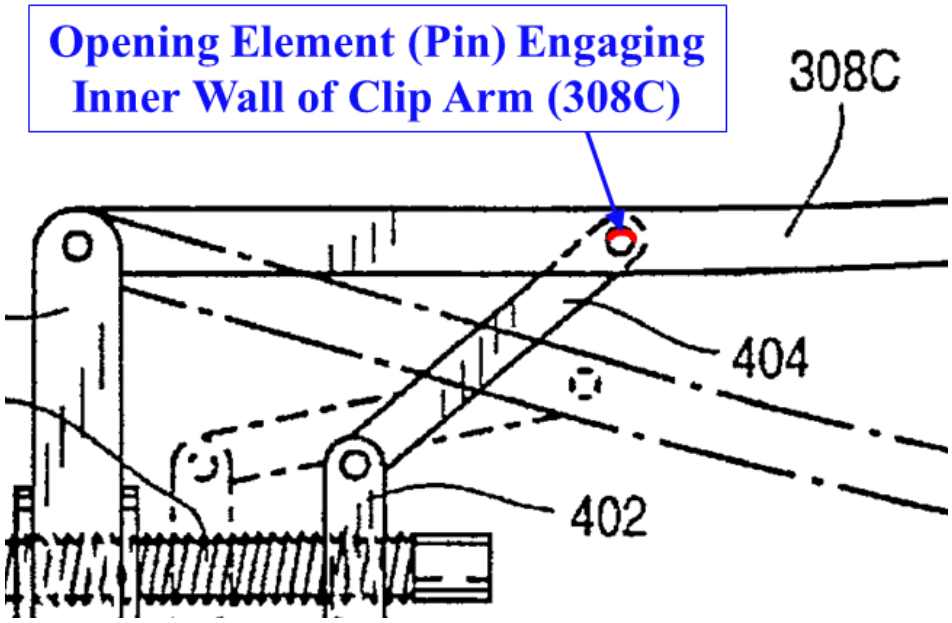
(Ex. 1037, ¶33; Ex. 1003, 17:50-62 (explaining that "the connector 402 is coupled to first and second jaws 308C, 310C by links 404, 406 so axial displacement of shaft 398 moves jaws 308C, 310C between the open, solid line position to the closed, dashed line position.")).

As shown below, there are at least two instances where the opening element engages the inner walls of the first and second clip arms. More specifically, in the first instance, links 404, 406 of the opening element engage the inner walls (inner wall engagement highlighted in green) of the first and second clip arms (308C, 310C):



(Ex. 1037, ¶34; Ex. 1003, 17:50-62).

Additionally, in a second instance links 404, 406 of the opening element engage other "inner walls of the first and second clip arms." (Ex. 1037, ¶35). As shown below in an annotated excerpt of Figure 28A, the opening element engages the inner bearing wall of pin holes in the clip arms (308C, 310C) (*i.e.*, inner walls of the clip arms) via pins, which connect links 404, 406 to the clip arms (308C, 310C). (Ex. 1037, ¶35). The opening element engages the inner bearing walls via pins (engagement highlighted in red) to urge the clip arms away from one another.



Excerpt of Figure 28A

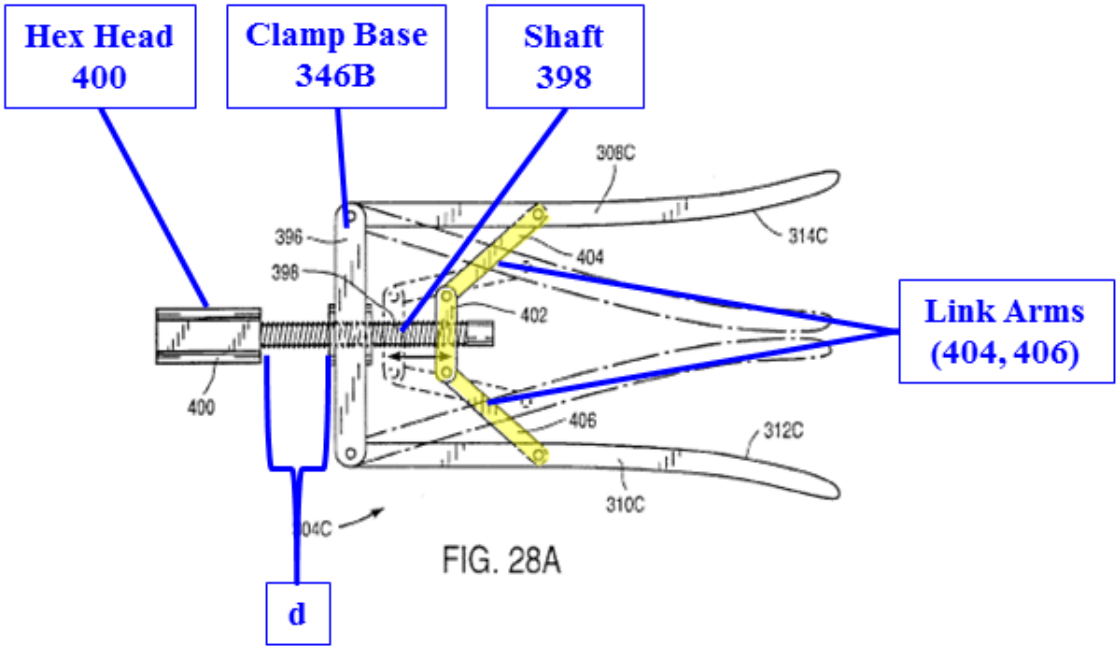
(Ex. 1037, ¶35; Ex. 1003, 17:50-62).

2. Claim 2

Claim 2 depends from claim 1 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Malecki discloses the opening element comprises first and second link arms (404, 406) engaging the inner surfaces of the first and second clip arms, respectively, for the reasons in Section V.A.1, *supra* at pp. 23-27. (Ex. 1037, ¶36; Ex. 1003, 17:50-62, Figure 28A).

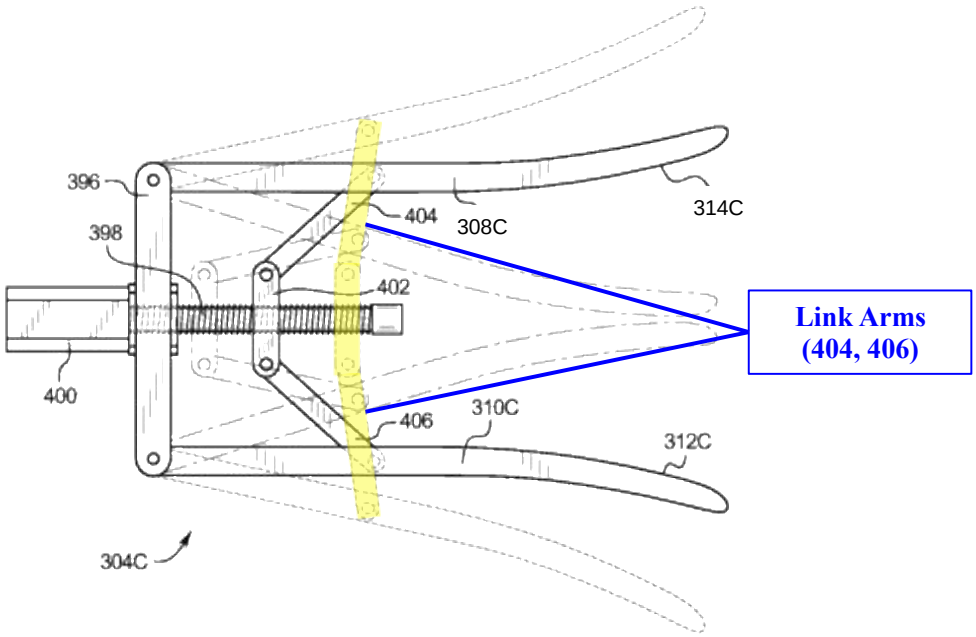
3. Claim 3

Claim 3 depends from claim 2 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." As shown below in annotated Figure 28A, Malecki discloses the first and second link arms (404, 406, highlighted in yellow) are axially aligned with one another in an open tissue receiving configuration, at least as BSSI has applied this limitation in the Litigation (*see* Section IV.E.4, *supra* at pp. 16-17):



(Ex. 1037, ¶37; Ex. 1003, 17:50-62). As disclosed in Malecki, the link arms of the clip may be further opened from the position shown in Figure 28A by moving the shaft 398 distally. (Ex. 1037, ¶37). In particular, as shown above in annotated

Figure 28A, the distal end of the hex head 400 is spaced apart from the proximal end of the clamp base 396 by a distance (d). This means that the threaded shaft 398 can be moved further distally by the distance (d), until the distal end of the hex head 400 abuts the proximal end of clamp base 396. (Ex. 1037, ¶37). Moving the threaded shaft 398 distally would cause the link arms (404, 406) to spread further apart, urging the clip arms (308C, 310C) into a wider open tissue receiving configuration than shown in Figure 28A. (Ex. 1037, ¶37). The following modified Figure 28A (prepared at the direction of Dr. Nicosia) depicts the clip arms (308C, 310C (light dashed line)) when shaft 398 is moved distally so that hex head 400 abuts clamp base 396.

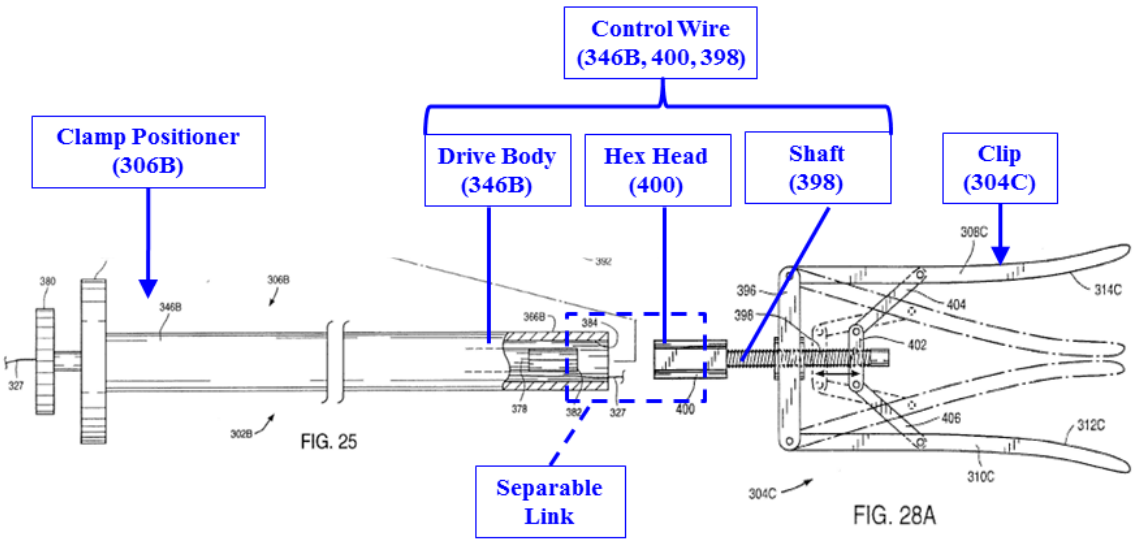


(Ex. 1037, ¶37). In addition, the link arms of the clip may be closed from the position shown by moving the shaft 398 proximally. (Ex. 1037, ¶37; Ex. 1003,

17:50-62). Thus, a person of ordinary skill in the art would have recognized that the clip depicted in Figure 28A has a range of open positions, including a position where the link arms are "axially aligned with one another," as BSSI applies the term to charge Petitioners with infringement, as discussed above in Section IV.E.4, *supra* at pp. 16-17. (Ex. 1037, ¶37).

4. Claim 4

Claim 4 depends from claim 1 and further requires "a proximal end of the clip is coupled to a control wire via a separable link." As shown below in annotated Figures 25 and 28A, Malecki Embodiment #1 discloses a proximal end of the clip (304C) is coupled to a control wire (drive body 346B, hex head 400, shaft 398) via a separable link:

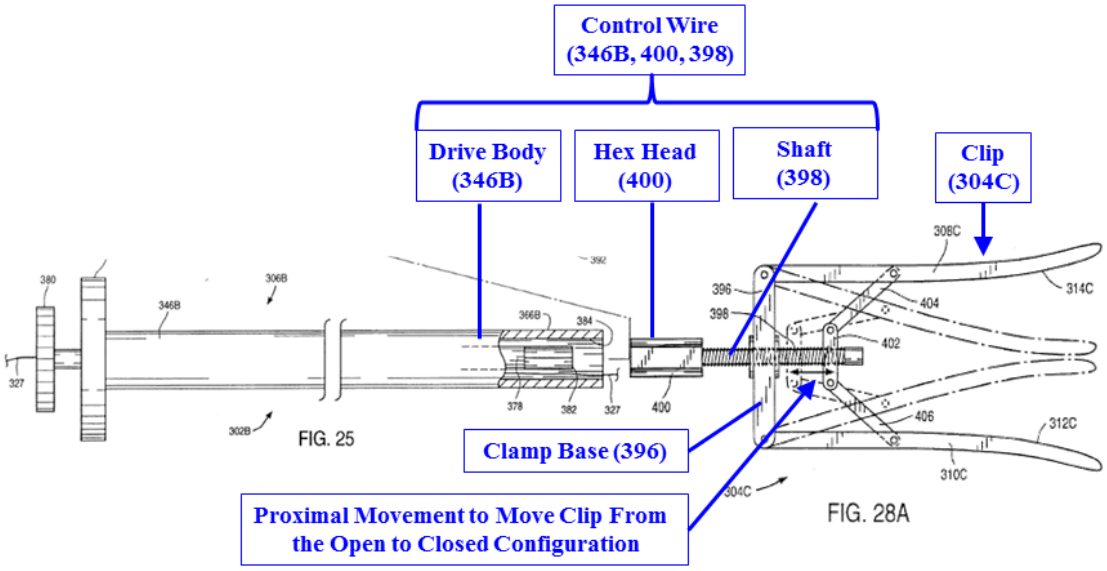


(Ex. 1037, ¶38; Ex 1003, 17:55-57, 18:34-36).

In particular, the clip (304C) is actuated using "[a] clamp positioner [306B] similar to that shown in FIG. 25." (Ex. 1037, ¶39; Ex 1003, 17:55-57; *see also id.*, 16:53-17:7). The clamp positioner 306B includes a drive body 346B coupled to the clip (304C) via hex head 400 and threaded shaft 398. (Ex. 1037, ¶39; Ex. 1003, 16:60-61, 17:50-62). The drive body 346B, hex head 400 and threaded shaft 398 (collectively, the "control wire") operate to selectively open and close the clip (304C). (Ex. 1037, ¶39; Ex. 1003, 17:50-62). Once the clip (304C) is clamped onto a structure in the body, the clamp positioner 306B is "removed from the patient through trocar sleeve [(not shown)]," while the clip (304C) remains behind in the body. (Ex. 1037, ¶39; Ex. 1003, 17:35-39, 18:34-37 (the clip is "completely separable from the clamp positioner . . . after being clamped onto a hollow body structure")). The clip (304C) and control wire (346B, 400, 398) are separated by pulling proximally on the control wire, thereby applying a proximal tensile force to the control wire greater than a predetermined threshold value and causing the control wire to separate from the clip. (Ex. 1037, ¶39).

5. Claim 6

Claim 6 depends from claim 4 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." As shown below in annotated Figures 25 and 28A, Malecki Embodiment #1 discloses applying a proximal tensile force to the control wire (346B, 400, 398) causes movement of the clip (304C) from the open tissue receiving configuration (solid line position) to the closed configuration (dashed line position):



(Ex. 1037, ¶40; Ex. 1003, 17:50-62; *see also* Section V.A.4, *supra* at pp. 30-31).

In particular, rotating drive body 346B causes hex head 400 and threaded shaft 398 to rotate within an opening in clamp base 396. (Ex. 1037, ¶41; Ex. 1003, 17:52-57). The threaded connection between shaft 398 and clamp base 396

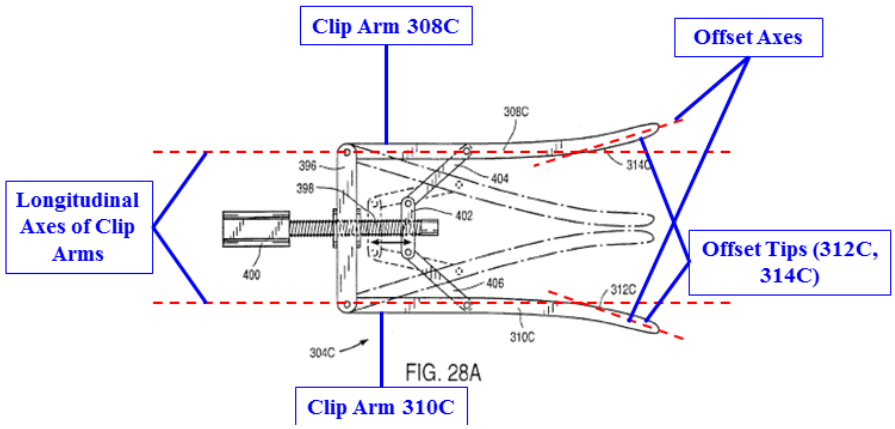
converts the rotation to a translation of the control wire with respect to the clip (304C), so that the clip closes or opens depending on the direction of rotation. (Ex. 1037, ¶41; Ex. 1003, 17:50-62). Moving the threaded shaft 398 proximally (proximal tensile force) moves the clip (304C) towards a closed configuration (dashed line position), whereas moving the shaft 398 distally (distal force) moves the clip (304C) towards an open configuration (solid line position). (Ex. 1037, ¶41; Ex. 1003, 17:50-62 (explaining that "shaft 398 rotates within the threaded hole formed in base 396 so that rotation displaces the shaft axially relative to the base" and that "the connector 402 is coupled to first and second jaws 308C, 310C by links 404, 406 so axial displacement of shaft 398 moves jaws 308C, 310C between the open, solid line position to the closed, dashed line position.")). Thus, rotating the drive body 346B in one direction results in the application of a proximal tensile force to the control wire (346B, 400, 398) to close the clip (304C), and rotating the drive body 346B in the other direction results in the application of a distally directed force to the control wire (346B, 400, 398) to open the clip (304C). (Ex. 1037, ¶41; Ex. 1003, 17:50-62).

6. Claim 9

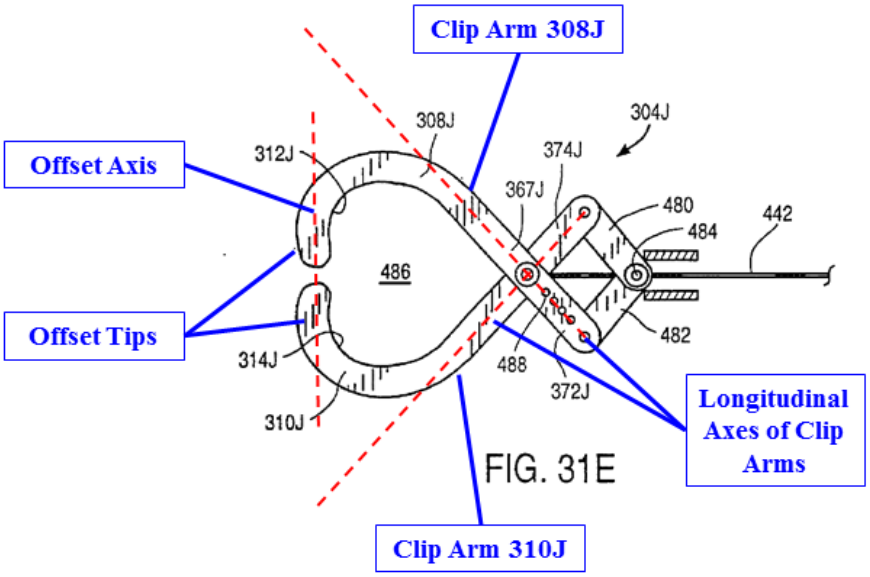
Claim 9 depends from claim 6 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1037, ¶42).

7. Claims 10 and 11

Duplicate claims 10 and 11 depend from claim 1 and further require "a distal length of the first clip arm includes a first offset tip extending along an axis offset relative to a longitudinal axis of the first clip arm and wherein a distal length of the second clip arm includes a second offset tip extending along an axis offset relative to a longitudinal axis of the second clip arm." As shown below in annotated Figure 28A, Malecki Embodiment #1 discloses a distal length of each clip arm (308C, 310C) includes an offset tip extending along an axis offset relative to a longitudinal axis of the clip arm:



(Ex. 1037, ¶43; Ex. 1003, 17:44-47). Malecki also discloses that clip (304C) may include "any jaw shape . . . described herein." (Ex. 1037, ¶43; Ex. 1003, 24:52-56). As shown below in annotated Figure 31E, Malecki discloses other embodiments with clip arms that satisfy the limitation of claims 10 and 11:



(Ex. 1037, ¶43; Ex. 1003, 20:1-2; *see also id.*, 15:35-40, 19:43-45, 21:65-67).

8. Independent Claim 12

a. "A medical device, comprising"

Malecki discloses "a medical device," for the reasons in Section V.A.1.a, *supra* at p. 23. (Ex. 1037, ¶44).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.1.bV.A.1.b, *supra* at pp. 23-24. (Ex. 1037, ¶45).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.1.c, *supra* at pp. 24-27. (Ex. 1037, ¶46).

d. "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations."

Malecki Embodiment #1 discloses this limitation, for the reasons in Sections V.A.5, *supra* at pp. 32-33, and V.A.6, *supra* at p. 34. (Ex. 1037, ¶47).

9. Claim 13

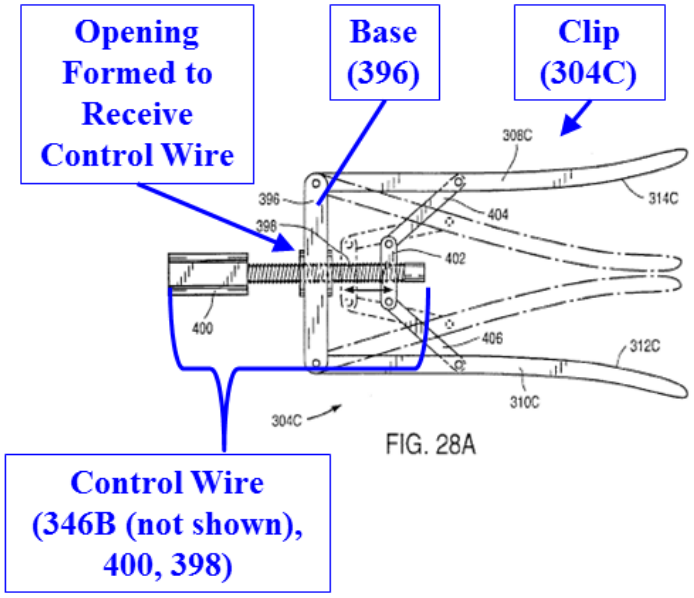
Claim 13 depends from claim 12 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.2, *supra* at p. 27. (Ex. 1037, ¶48).

10. Claim 14

Claim 14 depends from claim 13 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.3, *supra* at pp. 28-30. (Ex. 1037, ¶49).

11. Claim 15

Claim 15 depends from claim 12 and further requires "a proximal end of the clip includes an opening formed to receive a control wire." As shown below in annotated Figure 28A, Malecki Embodiment #1 discloses a proximal end of the clip (304C) includes an opening (threaded central hole in base 396) formed to receive a control wire (398 of control wire 346B (not shown), 400, 398):



(Ex. 1037, ¶50; Ex. 1003, 17:50-62).

12. Claim 16

Claim 16 depends from claim 15 and requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1037, ¶51).

13. Claim 17

Claim 17 depends from claim 16 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes one or both of a locking of the clip in the closed configuration and a disengagement of the control wire from the clip."[8] Malecki Embodiment #1 discloses application of a proximal tensile force greater than a predetermined threshold value causes a disengagement of the control wire from the clip, for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1037, ¶52).

[8] The use of the phrase "one *or* both" indicates the claim is satisfied by meeting either the claimed "locking," the "disengagement," or both. *Brown v. 3M*, 265 F.3d 1349, 1353 (Fed. Cir. 2001).

14. Claim 18

Claim 18 depends from claim 16 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1037, ¶53).

15. Independent Claim 20

a. "a method, comprising"

Malecki discloses a method. (Ex. 1037, ¶54; Ex. 1003, Title; *see also id.*, 16:51-52).

b. "inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration"

Malecki Embodiment #1 discloses inserting a medical device comprising a clip (clamp 304C) to a target tissue site. (Ex. 1037, ¶55; Ex. 1003, 17:28-34 ("The clamp 304B is introduced into the thoracic cavity TC through a trocar sleeve 348 while in the closed position of FIG. 25."); *see also* 16:53-17:2, 17:7-15, 28-39). Malecki Embodiment #1 further discloses the medical device comprises a clip (304C) having first and second clip arms (308C, 310C), and an opening element (402, 404, 406) engaging inner walls of the first and second clip arms and urging

the clip to an open tissue receiving configuration, for the reasons in Section V.A.1, *supra* at pp. 23-27. (Ex. 1037, ¶55).

c. "moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1037, ¶56).

d. "moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1037, ¶57).

e. "applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip."

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1037, ¶58).

B. Ground 2: Claims 1-4, 6-18, and 20 Are Obvious In View Of Malecki Embodiment #1 (Ex. 1003)

1. Independent Claim 1

Malecki Embodiment #1 discloses each and every limitation of claim 1, including "an opening element engaging inner walls of the first and second clip arms," for the reasons in Section V.A.1, *supra* at pp. 23-27. (Ex. 1037, ¶59). To the extent the walls engaged by the opening element are not considered "inner walls," this limitation is not a patentable distinction over Malecki Embodiment #1. (Ex. 1037, ¶59). There is no disclosure in the '731 patent that engaging "inner walls" is in any way important, or provides any meaningful distinction over an opening element that engages other walls of the clip arms (Ex. 1037, ¶59).

As shown below in annotated Figure 28A, the walls of the first and second clip arms in Malecki Embodiment #1 consist of: (1) radially outward-facing walls; (2) radially inward-facing walls; and (3) side, or lateral walls:

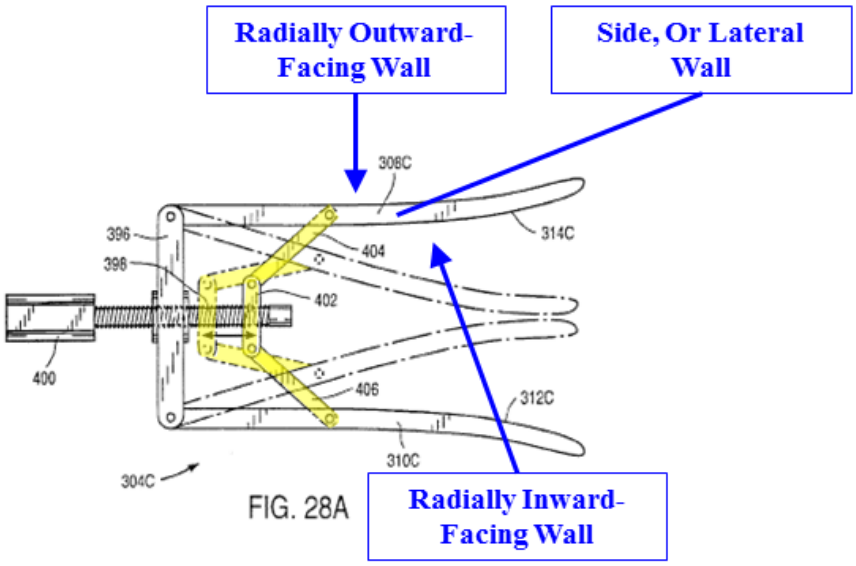


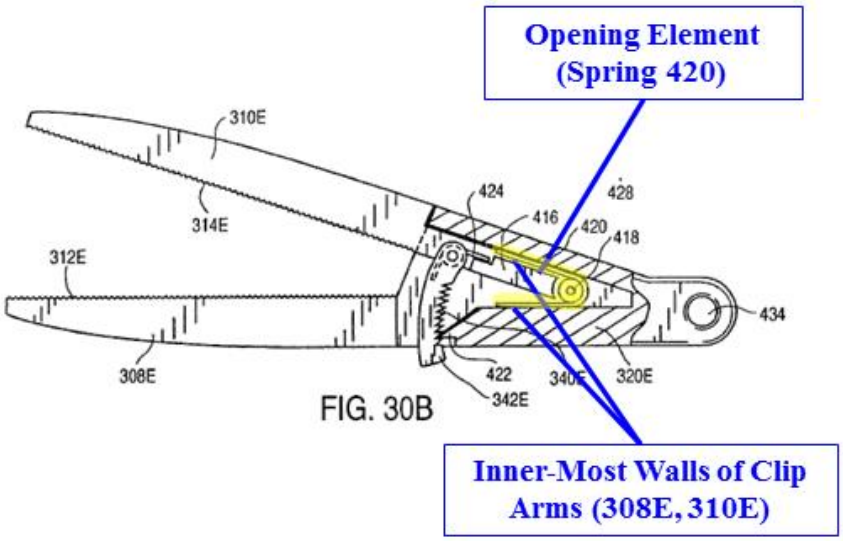
FIG. 28A

(Ex. 1037, ¶60; Ex. 1003, 17:43-49).

It would have been obvious to a person of ordinary skill in the art to construct the device shown in Figure 28A such that the links 404, 406 engage any one of these walls. (Ex. 1037, ¶61). *KSR*, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.") Engaging the radially inward-facing walls would have been merely one of a finite number of known and obvious options, yielding predictable results. (Ex. 1037, ¶61).

Indeed, Malecki discloses opening elements in other embodiments that engage radially inward-facing walls of first and second clip arms. (Ex. 1037, ¶62; Ex. 1003, 16:58-59, 18:14-15, 19:45-46, Figs. 29B, 30B, and 31C). For example, Malecki discloses in Figure 30B (reproduced below) an opening element (torsion

spring 420) engaging radially inward-facing walls of clip arms (jaws 308E and 310E).



(Ex. 1037, ¶62; Ex. 1003, 18:12-15, Figs. 30B, 31C).

A person of ordinary skill in the art would have recognized that the device in Figure 28A likewise could be modified so that the opening element engages radially inward-facing walls of clip arms (308C, 310C). (Ex. 1037, ¶63). *See* MPEP §§ 2143(I)(C) and (D) (obviousness rationales including using "a known technique to improve similar devices in the same way," and applying "a known technique to a known device . . . ready for improvement to yield predictable results."). This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Malecki to achieve predictable results. (Ex. 1037, ¶63). *See Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1371

(Fed. Cir. 2011) ("[T]he nature of the mechanical arts is such that 'identified, predictable solutions' to known problems may be within the technical grasp of a skilled artisan.") (citations omitted); *KSR*, 550 U.S. at 416.

It would have been obvious simply to move the pivot connections between the links (404, 406) and the clip arms (308C, 310C) in Figure 28A from lateral walls of the clip arms, to radially inward-facing walls of the clip arms. (Ex. 1037, ¶64). For example, a bracket that contained a pivot connection could be attached to the radially inner-most wall of the clip arms to attach the links (404, 406) to the clip arms (308C, 310C). (Ex. 1037, ¶64). Alternatively, the links (404, 406) could be modified to include a hook on their distal ends that pivotally engages a rod located at the inner-most walls of the clip arms. (Ex. 1037, ¶64).

2. Claim 2

Claim 2 depends from claim 1 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Malecki Embodiment #1 discloses first and second link arms (links 404, 406), for the reasons in Section V.A.2, *supra* at p. 27. This claim would have been obvious, for the reasons in Section V.B.1, *supra* at pp. 42-45. (Ex. 1037, ¶65; Ex. 1003, 17:50-62, Figure 28A).

3. Claim 3

Claim 3 depends from claim 2 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.3, *supra* at pp. 28-30. (Ex. 1037, ¶66).

4. Claim 4

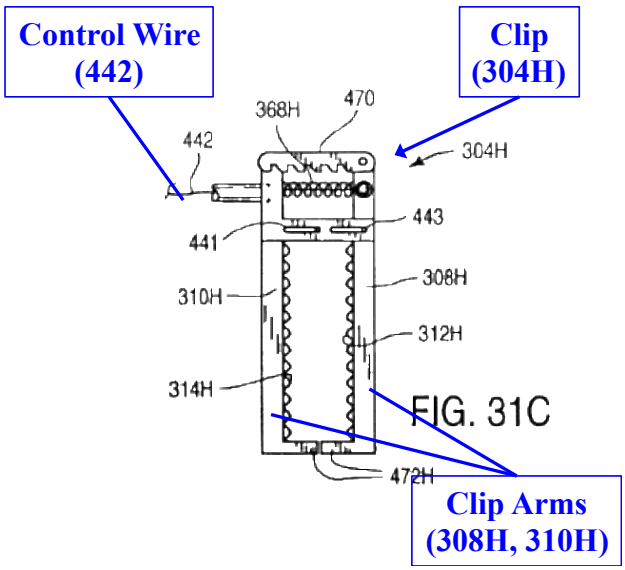
Claim 4 depends from claim 1 and further requires "a proximal end of the clip is coupled to a control wire via a separable link." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1037, ¶67).

5. Claim 6

Claim 6 depends from claim 4 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1037, ¶68).

To the extent rotating the control wire (346B, 400, 398) is not an "application of a proximal tensile force to the control wire," claim 6 still would have been obvious to a person of ordinary skill in the art. In particular, it would have been obvious to modify Malecki Embodiment #1 so that the physician can close and open the clip (304C) by pulling (*i.e.*, applying a proximal tensile force) and pushing (*i.e.*, applying a distal force), instead of rotating, the control wire (346B, 400, 398) to move the threaded shaft 398 relative to the clamp base 396. (Ex. 1037, ¶69). Pushing and pulling a control wire was one of a finite number of obvious techniques used in the art to open and close a clip (another being rotating a mechanism to move the control wire proximally and distally, as disclosed in Malecki Embodiment #1). (Ex. 1037, ¶69). *KSR*, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.")

Indeed, Malecki discloses in other embodiments that clips may be opened and closed by pushing and pulling, rather than rotating, the control wire. (Ex. 1037, ¶70; Ex. 1003, 18:10-33, 18:66–20:19, Figs. 30, and 31). For example, as shown below in annotated Figure 31C, Malecki discloses a clip (clamp 304H) with clip arms (jaws 308H, 310H) that open and close via pushing and pulling a control wire (cable 442):



(Ex. 1037, ¶70; Ex. 1003, 19:45-47 ("Compression spring 368H biases jaws 308H, 310H open so that pulling cable 442 closes jaws 308H, 310H."); *see also id.*, 18:22-25, 19:37-45, 48-53, Figure 30A).

A person of ordinary skill in the art would have recognized that Malecki Embodiment #1 likewise could be modified so that the clip (304C) opens and closes by pushing and pulling, rather than rotating, the control wire (346B, 400, 398). (Ex. 1037, ¶71). *See* MPEP §§ 2143(I)(C) and (D). This modification

would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Malecki to achieve predictable results. (Ex. 1037, ¶71). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416. For example, it would have been obvious to remove the threaded connection between the shaft 398 and clamp base 396, so that the clip (304C) could be opened and closed by pushing and pulling, instead of rotating. (Ex. 1037, ¶71).

The person of ordinary skill in the art would have expected that modifying Malecki Embodiment #1 so that the clip (304C) opens and closes by pushing and pulling, rather than rotating, would simplify the mechanism used to open and close the clip. (Ex. 1037, ¶72). The skilled artisan would have been motivated to modify the Malecki clip, to make the device easier for the physician to use, and potentially reduce the risk of the clip not working properly, leading to potentially improved clinical outcomes. (Ex. 1037, ¶72).

6. Claim 7

Claim 7 depends from claim 6 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes the clip to lock in the closed configuration." As discussed above in Section V.B.5, *supra* at pp. 47-49, it would have been obvious to modify Malecki Embodiment #1 so that application of a proximal tensile force to the control wire (346B, 400, 398) causes movement of the clip (304C) from the open tissue receiving configuration to the closed configuration. (Ex. 1037, ¶73).

It also would have been obvious to modify Malecki Embodiment #1 further so that application of a proximal tensile force greater than a predetermined threshold value causes the clip to lock in the closed configuration. (Ex. 1037, ¶74). Although not explicitly disclosed in Embodiment #1, Malecki discloses other embodiments that include locking the clip in a closed configuration, to prevent the clip from inadvertently opening. (Ex. 1037, ¶74; Ex. 1003, 1:59-63 ("A pair of notched extensions 42 on handles 38, 40 are configured to engage one another as the handles are closed, providing ratcheted locking of the device to maintain the jaws in a closed position."), 15:61-62 ("Jaw extension 320 includes a set of ratchet teeth 340 for locking the jaws in the closed position."), 19:47-48 ("A toothed or ratcheted latch 470 locks the jaws 308H, 310H."), Figures 1, 21, 27A, 30B, 31C).

For example, Figure 31C (reproduced and annotated below) discloses a latch 470 that locks clip legs (jaws 308H, 310H) in the closed configuration upon application to the control wire (cable 442) of a proximal tensile force greater than a predetermined threshold value.

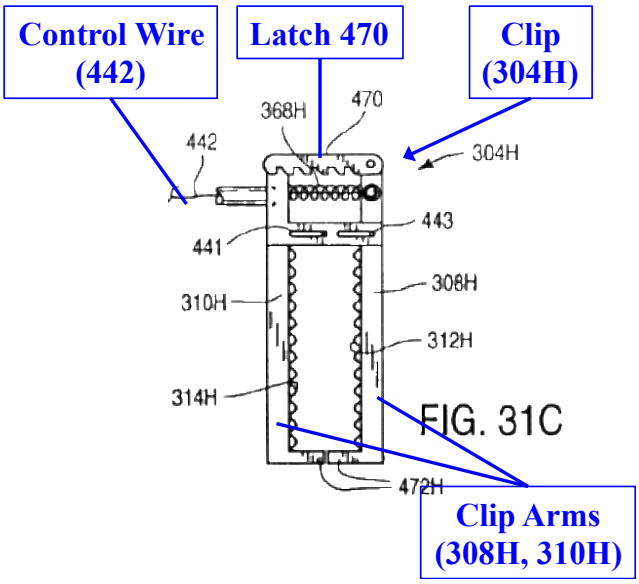


FIG. 31C

(Ex. 1037, ¶75; Ex. 1003, 19:45-48 ("Compression spring 368H biases jaws 308H, 310H open so that pulling cable 442 closes jaws 308H, 310H. A toothed or ratcheted latch 470 locks the jaws 308H, 310H."), 19:37-45, 48-53)).

A person of ordinary skill in the art would have recognized that Malecki Embodiment #1 likewise could be modified so that application of a proximal tensile force greater than a predetermined threshold value causes the clip (304C) to lock in the closed configuration, to prevent the clip from inadvertently opening. *See* MPEP §§ 2143(I)(C) and (D). This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Malecki to

achieve predictable results. (Ex. 1037, ¶76). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416.

7. Claim 8

Claim 8 depends from claim 7 and further requires "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1037, ¶77).

8. Claim 9

Claim 9 depends from claim 6 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." This claim would have been obvious, for the reasons in Section V.B.5, *supra* at pp. 47-49. (Ex. 1037, ¶78).

9. Claims 10 and 11

Duplicate claims 10 and 11 depend from claim 1 and further require "a distal length of the first clip arm includes a first offset tip extending along an axis offset relative to a longitudinal axis of the first clip arm and wherein a distal length of the second clip arm includes a second offset tip extending along an axis offset relative to a longitudinal axis of the second clip arm." Malecki Embodiment #1 discloses

this limitation, for the reasons in Section V.A.7, *supra* at pp. 34-35. (Ex. 1037, ¶79).

10. Independent Claim 12

a. "A medical device, comprising"

Malecki discloses "a medical device," for the reasons in Section V.A.1.a, *supra* at p. 23. (Ex. 1037, ¶80).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.1.b, *supra* at pp. 23-24. (Ex. 1037, ¶81).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.1.c, *supra* at pp. 24-27. (Ex. 1037, ¶82). In addition, it would have been

obvious to modify Malecki Embodiment #1 to include this limitation, for the reasons in Section V.B.1, *supra* at pp. 42-45. (Ex. 1037, ¶82).

d. "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations."

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.8.d, *supra* at p. 37. (Ex. 1037, ¶83).

11. Claim 13

Claim 13 depends from claim 12 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Malecki Embodiment #1 discloses first and second link arms (links 404, 406), for the reasons in Section V.A.2, *supra* at p. 27. This claim would have been obvious, for the reasons in Section V.B.10, *supra* at pp. 42-45. (Ex. 1037, ¶84).

12. Claim 14

Claim 14 depends from claim 13 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.3, *supra* at pp. 28-30. (Ex. 1037, ¶85).

13. Claim 15

Claim 15 depends from claim 12 and further requires "a proximal end of the clip includes an opening formed to receive a control wire." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.11, *supra* at p. 38. (Ex. 1037, ¶86).

14. Claim 16

Claim 16 depends from claim 15 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." This claim would have been obvious, for the reasons in Section V.B.5, *supra* at pp. 47-49. (Ex. 1037, ¶87).

15. Claim 17

Claim 17 depends from claim 16 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes one or both of a locking of the clip in the closed configuration and a disengagement of the control wire from the clip." Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.4, *supra* at pp. 30-31 (disengagement of the control wire from the clip). (Ex. 1037, ¶88). In addition, this claim would have been obvious, for the reasons in Section V.B.6, *supra* at pp. 50-52 (locking of the clip in the closed configuration). (Ex. 1037, ¶88).

16. Claim 18

Claim 18 depends from claim 16 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration. This claim would have been obvious, for the reasons in Section V.B.8, *supra* at p. 52. (Ex. 1037, ¶89).

17. Independent Claim 20

a. "a method, comprising"

Malecki discloses a method, for the reasons in Section V.A.15.a, *supra* at p. 40. (Ex. 1037, ¶90).

b. "inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.15.b, *supra* at pp. 40-41. It would have been obvious to modify Malecki to include this limitation, for the reasons in Section V.B.1, *supra* at pp. 42-45. (Ex. 1037, ¶91).

c. "moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.15.c, *supra* at p. 41. (Ex. 1037, ¶92). It would have been obvious to modify Malecki to include this limitation, for the reasons in Section V.B.5, *supra* at pp. 47-49.

d. "moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration"

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.15.d, *supra* at p. 41. (Ex. 1037, ¶93). It would have been obvious to modify Malecki to include this limitation, for the reasons in Section V.B.5, *supra* at pp. 47-49.

e. "applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip."

Malecki Embodiment #1 discloses this limitation, for the reasons in Section V.A.15.e, *supra* at p. 41. (Ex. 1037, ¶94).

C. Ground 3: Claims 1-2, 4 10-13, and 15 Are Anticipated By Malecki Embodiment #2 (Ex. 1003)

1. Independent Claim 1

a. "A medical device, comprising"

Malecki discloses a medical device in the form of "[a] clamp for clamping a body structure in a patient." (Ex. 1037, ¶95; Ex. 1003, Abstract; *see also*, *e.g.*, *id.*, 3:32-36, Figs. 17-32).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

As shown below in annotated Figures 25 and 27B, Malecki Embodiment #2 discloses a clip (clamp 304B) including first and second clip arms (jaws 308B, 310B), and moveable between an open tissue receiving configuration (Figure 27B) in which the first and second arms are separated from one another by a distance selected to receive tissue and a closed configuration (Figure 25) in which the first and second arms are moved inward to capture the tissue:

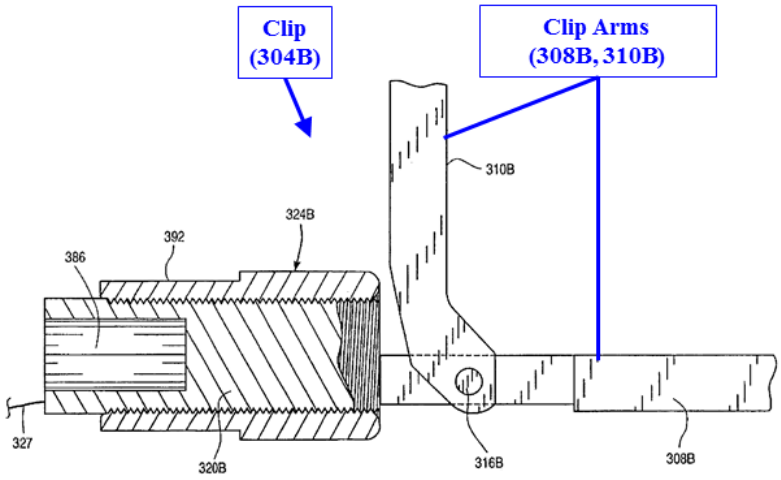


FIG. 27B

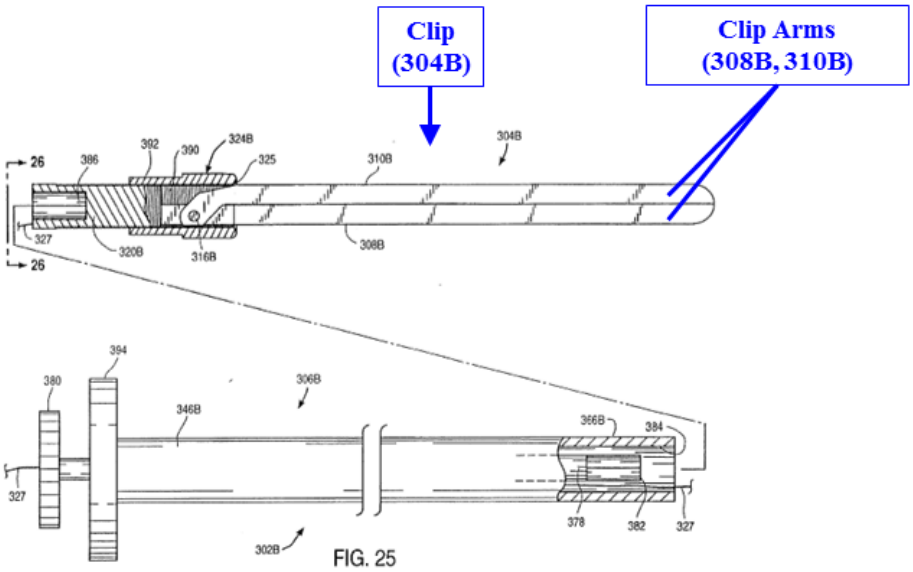


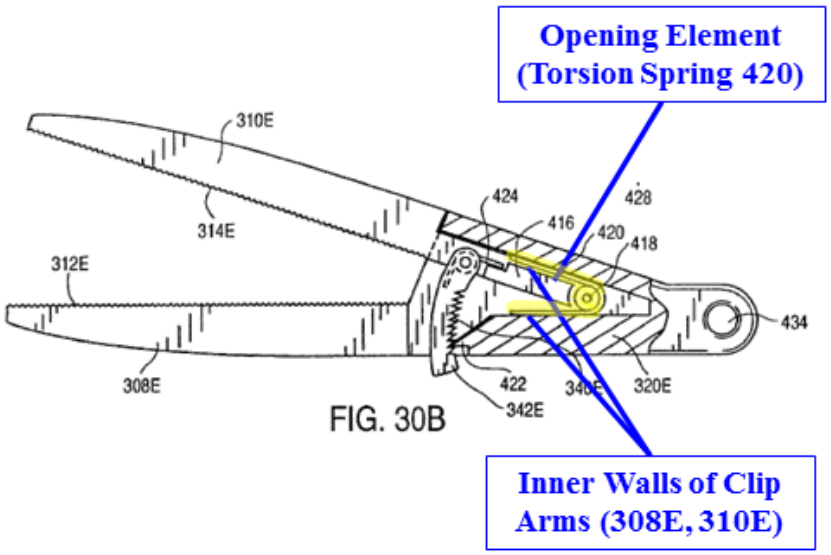
FIG. 25

(Ex. 1037, ¶96; Ex. 1003, 16:53-17:41).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration."

Malecki Embodiment #2 discloses an opening element (torsion spring) engaging inner walls of the first and second clip arms (308C, 310C), and urging the first and second clip arms away from one another from a closed configuration into the open tissue-receiving configuration, the opening element movable between an expanded configuration and retracted configuration to correspond to a movement of the clip between the open and closed configurations. (Ex. 1037, ¶97; Ex. 1003, 16:57-59 ("Jaws 308B, 310B are normally biased towards the open position of FIG. 27B by a torsion spring (not shown)."). The "torsion spring" is shown in Figure 30B, with respect to another embodiment. (Ex. 1037, ¶97; Ex. 1003, 18:10-22, Figure 30B).

Figure 30B is reproduced and annotated below, and illustrates the engagement between the opening element ("torsion spring") and the inner walls of the clip arms (308E, 310E):



(Ex. 1037, ¶98; Ex. 1003, 18:14-15 ("A torsion spring 420 is mounted about pivot 418 which biases jaws 308, 310 to the open position of FIG. 30B.")).

2. Claim 2

Claim 2 depends from claim 1 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." As shown below in annotated Figure 30B, Malecki discloses the opening element (torsion spring) comprises first and second link arms (distal, linear ends of spring 420) engaging the inner surfaces of the first and second clip arms (308E, 310E).

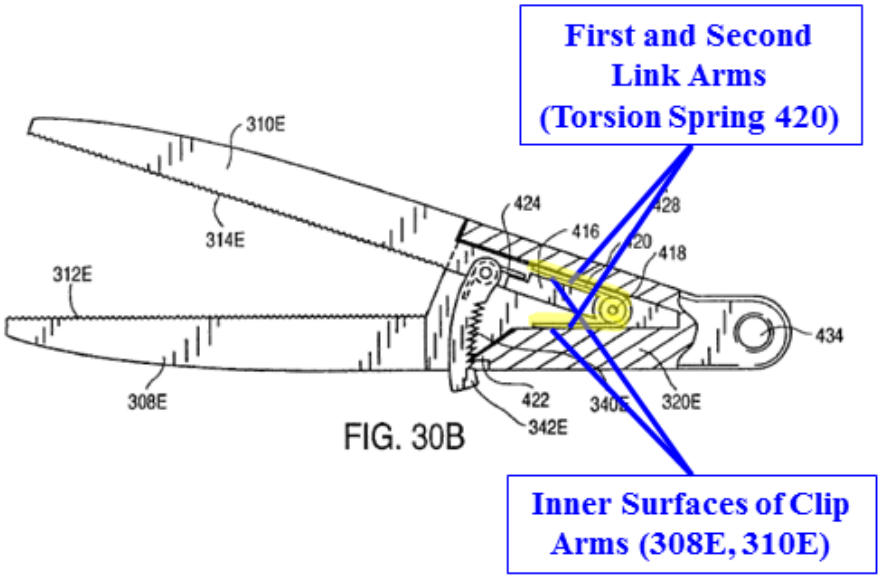


FIG. 30B

(Ex. 1037, ¶99; Ex. 1003, 16:57-59, 18:14-15, Figure 30B).

3. Claim 4

Claim 4 depends from claim 1 and further requires "a proximal end of the clip is coupled to a control wire via a separable link." As shown below in annotated Figure 25, Malecki Embodiment #2 discloses a proximal end of the clip (304B) is coupled to a control wire (stabilizing rod 378, shaft 382) via a separable link (highlighted in yellow):

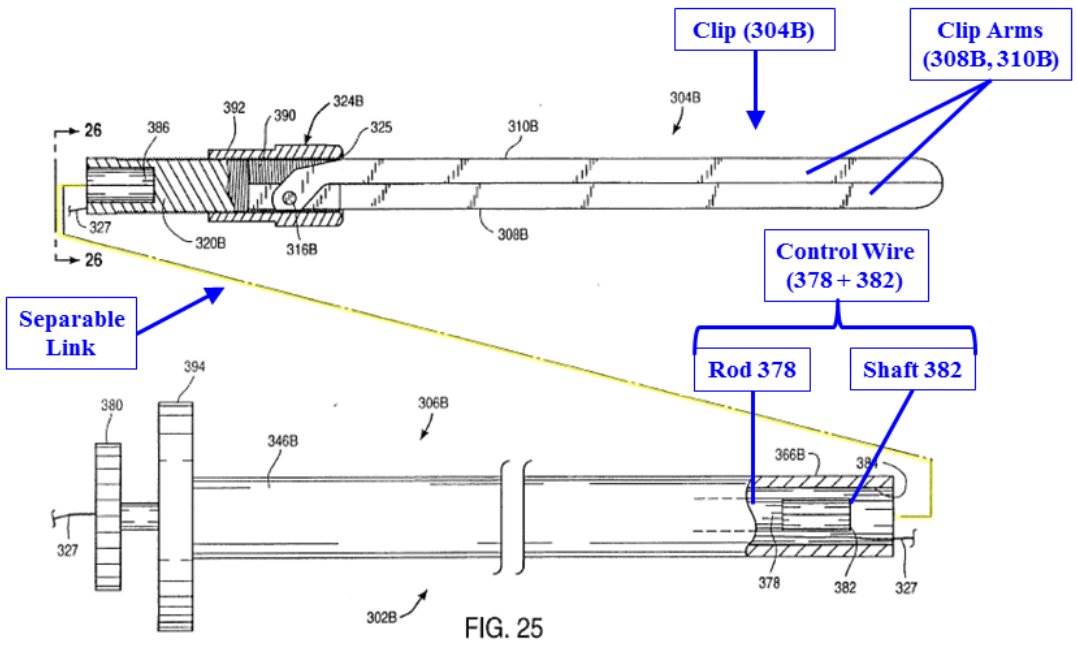


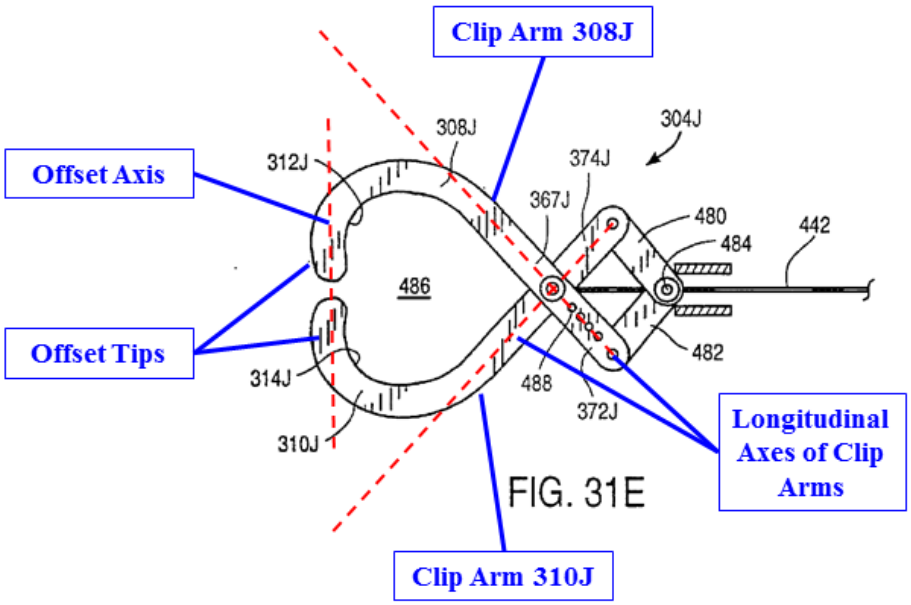
FIG. 25

(Ex. 1037, ¶100; Ex. 1003, 17:2-6, 17:10-13). The clip (304B) is actuated using clamp positioner 306B, including control wire (378, 382). (Ex. 1037, ¶100). Once the clip (304B) is clamped onto a structure in the body, the clamp positioner 306B and control wire (378, 382) are "removed from the patient through trocar sleeve [(not shown)]," while the clip (304B) remains behind in the body. (Ex. 1037,

¶100; Ex. 1003, 17:35-39, 18:34-37 (the clip is "completely separable from the clamp positioner . . . after being clamped onto a hollow body structure")). The clip (304B) and control wire (378, 382) are separated by pulling proximally on the control wire, thereby applying a proximal tensile force to the control wire greater than a predetermined threshold value (*i.e.,* the pulling force required to separate the clip from the control wire) and causing the control wire to separate from the clip. (Ex. 1037, ¶100).

4. Claims 10 and 11

Duplicate claims 10 and 11 depend from claim 1 and further require "a distal length of the first clip arm includes a first offset tip extending along an axis offset relative to a longitudinal axis of the first clip arm and wherein a distal length of the second clip arm includes a second offset tip extending along an axis offset relative to a longitudinal axis of the second clip arm." Malecki discloses that the clip (304B) may include "any jaw shape . . . described herein." (Ex. 1037, ¶101; Ex. 1003, 24:52-56). As shown below in annotated Figure 31E, Malecki discloses in other embodiments clip arms that satisfy the limitations of claims 10 and 11:



(Ex. 1037, ¶101; Ex. 1003, 15:35-40, 19:43-45, 20:1-2, 21:65-67).

5. Independent Claim 12

a. "A medical device, comprising"

Malecki discloses "a medical device," for the reasons in Section V.C.1.a, *supra* at p. 58. (Ex. 1037, ¶102).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

Malecki Embodiment #2 discloses this limitation, for the reasons in Section V.C.1.b, *supra* at pp. 58-59. (Ex. 1037, ¶103).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration"

Malecki Embodiment #2 discloses this limitation, for the reasons in Section V.C.1.c, *supra* at pp. 60-61. (Ex. 1037, ¶104).

d. "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations."

Malecki Embodiment #2 discloses a control wire (378, 382) coupled to a proximal end of clip (304B), for the reasons in Section V.C.3, *supra* at pp. 63-64. (Ex. 1037, ¶105). Malecki discloses that the control wire (378, 382) (in combination with drive body 346B) is operable to move the clip (304B) between the open and closed configurations. (Ex. 1037, ¶105, Ex. 1003, 16:60-65 ("Clamp positioner 306B includes a hollow drive body 346B which houses a stabilizing rod 378. The hollow drive body 346B actuates the jaws while the stabilizing rod 378 stabilizes the clamp assembly against the torsional forces produced by rotational actuation of the rotatable drive body 346B."), 17:30-37 ("When clamp 304B is properly positioned, handle 380 is held stationary while the proximal end 394 of hollow drive body 346B is rotated thereby moving the actuator housing 324B and permitting jaws 308B, 310B to open. . . . [T]he proximal end 394 of hollow drive body 346B is rotated in the opposite direction to close the jaws 308B, 310B."), 16:65-17:17).

6. Claim 13

Claim 13 depends from claim 12 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Malecki Embodiment #2 discloses this limitation, for the reasons in Section V.C.2, *supra* at p. 62. (Ex. 1037, ¶106).

7. Claim 15

Claim 15 depends from claim 12 and further requires "a proximal end of the clip includes an opening formed to receive a control wire." As shown below in annotated Figure 25, Malecki Embodiment #2 discloses an opening (square hole 386) in a proximal end of clip (304B) formed to receive control wire (378, 382):

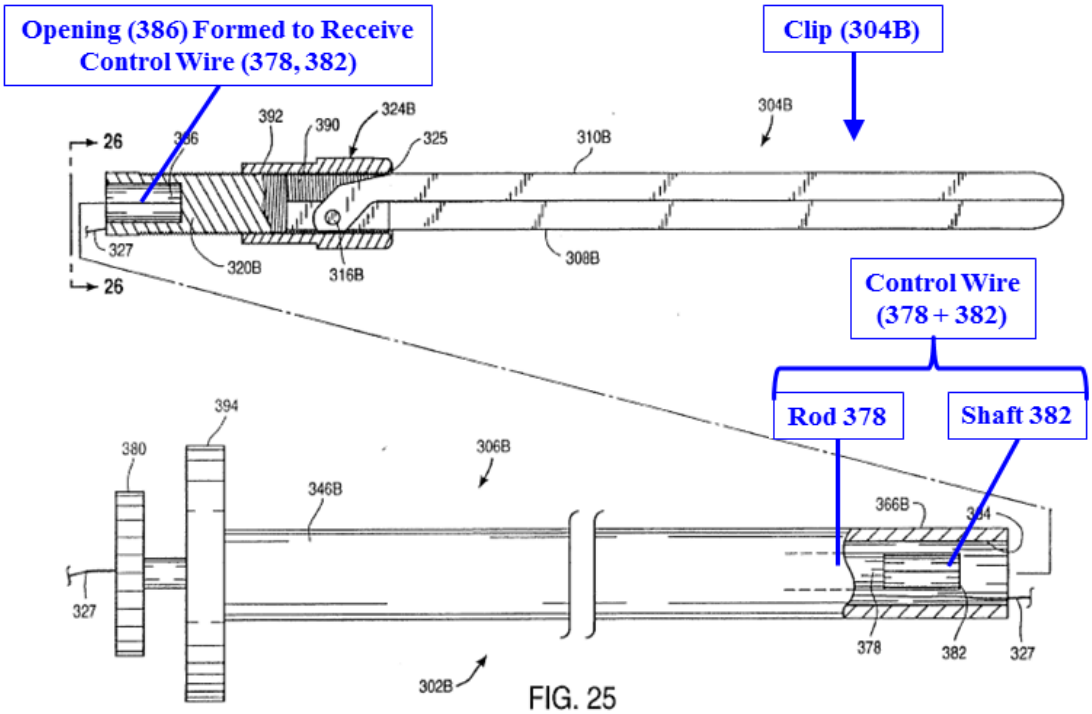


FIG. 25

(Ex. 1037, ¶107; Ex. 1003, 17:10-13 ("The stabilizing rod 378 has a square shaft 382 (FIG. 26) at a distal end which matingly engages a square hole 386 formed in the jaw extension 320B.")).

D. Ground 4: Claims 3, 5-9, 14, and 16-20 Are Obvious In View Of Malecki Embodiment #2 (Ex. 1003)

1. Claim 3

Claim 3 depends from claim 2 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." As shown below in annotated Figure 30B, Malecki discloses first and second link arms (distal, linear ends of spring 420).

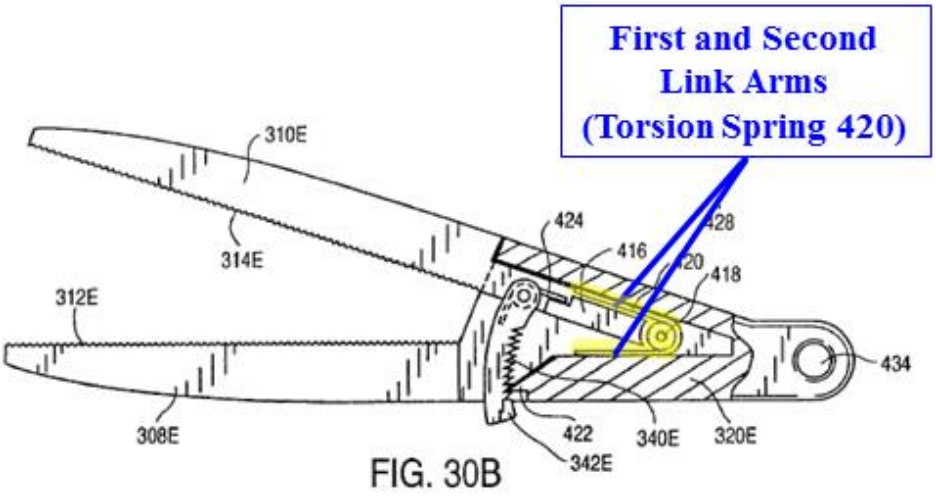


FIG. 30B

(Ex. 1037, ¶108; Ex. 1003, 18:14-15, Figure 27B).

To the extent the spring in Embodiment #2 does not have link arms "axially aligned" with one another when the clip is in the open tissue receiving configuration, this is not a patentable distinction. (*See* Ex. 1037, ¶ 109). As explained above in Section V.A.3, *supra* at pp. 28-30, Malecki Embodiment #1 discloses an opening element with first and second link arms (404, 406) that are

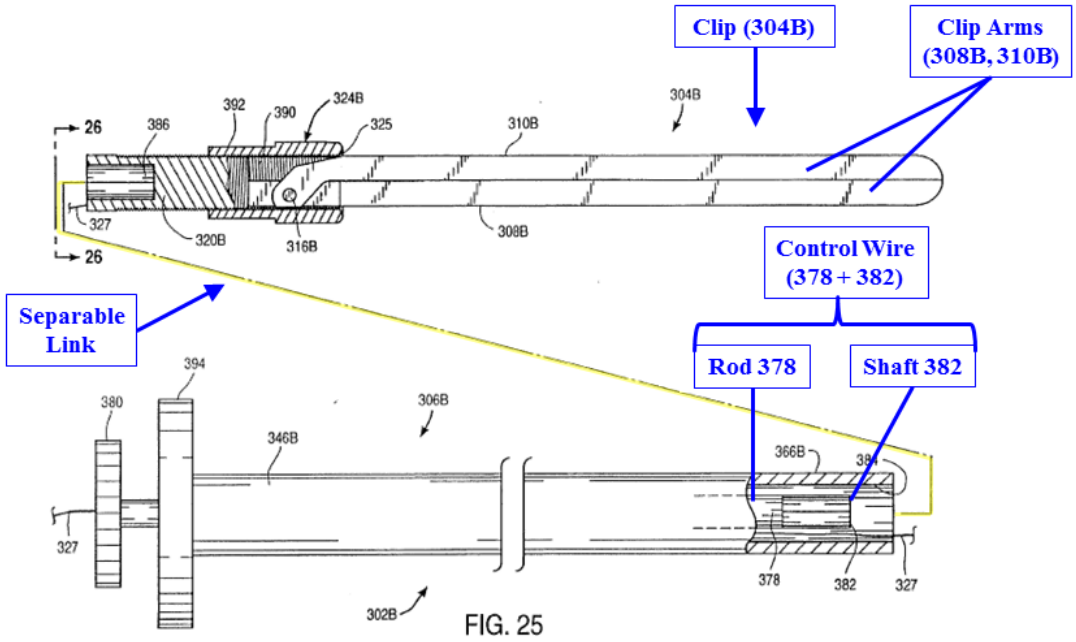
axially aligned with one another in the open tissue receiving configuration, at least as BSSI has applied this limitation in the Litigation.

A person of ordinary skill in the art would have recognized that Malecki Embodiment #2 likewise could be modified so that the link arms of the spring are axially aligned with one another in an open tissue receiving configuration. (Ex. 1037, ¶110). *See* MPEP §§ 2143(I)C) and (D). The skilled artisan would have been motivated to make this modification, for example to permit the opening element to open the clip arms over a range of open tissue receiving configurations, including a position where the link arms are "axially aligned" (*i.e.*, aligned along a single common axis, or in a configuration consistent with BSSI's application of this term in the Litigation (*see* Section IV.E.4, *supra* at pp. 16-17)). (Ex. 1037, ¶110). The skilled artisan would have expected that this modification would improve the performance of the clip, allowing the clip arms to spread further apart and over a wider range of tissue receiving configurations than shown in the figures. (Ex. 1037, ¶ 110). This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Malecki to achieve predictable results. (Ex. 1037, ¶110). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416.

2. Claim 5

Claim 5 depends from claim 4. Malecki Embodiment #2 discloses the limitations of claim 4, for the reasons in Section V.C.3, *supra* at pp. 63-64. Claim 5 further requires "a distal end of the control wire includes an increased width portion formed to removably engage the clip."

As shown below in annotated Figure 25, Malecki Embodiment #2 discloses the distal end (382) of the control wire (378, 382) is formed to removably engage clip (304B) via a separable link:



(Ex. 1037, ¶112; Ex. 1003, 17:35-39, 18:34-37 (the clip is "completely separable from the clamp positioner . . . after being clamped onto a hollow body structure")). The distal end of the control wire includes square shaft (382), which has a width

that appears to be the same as the width of stabilizing rod 378. If true, it would have been obvious to modify the control wire (378, 382) so that the width of shaft 382 is greater than the width of rod 378. (Ex. 1037, ¶112).

In particular, it would have been obvious to modify rod 378 to decrease its width with respect to shaft 382. There are a finite number of ways to size the distal end (382) of the control wire: increased width, same width, or decreased width with respect to the rod 378. (Ex. 1037, ¶113). *KSR*, 550 U.S. at 421. A person of ordinary skill in the art would have been motivated to try any one of these sizings for the control wire (378, 382), depending on the design requirements.

A person of ordinary skill would have been particularly motivated to try decreasing the width of the rod 378 with respect to the shaft 382, as this sizing would have been expected to increase the flexibility of the control wire (378, 382) along its length. (Ex. 1037, ¶114). The skilled artisan would have recognized that increasing the flexibility of the control wire (378, 382) would potentially improve the operation of Malecki Embodiment #2, by improving its ability to bend and navigate through tortuous paths typically encountered in endoscopic procedures. (Ex. 1037, ¶114). The resulting control wire (378, 382) would have an increased width portion at its distal end formed to removably engage the clip (304B). (Ex. 1037, ¶114).

The proposed modification would have been a matter of routine skill in the art, using simple mechanical elements to achieve predictable results. (Ex. 1037, ¶115). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 421. Further, it would have been obvious to try modifying the control wire (378, 382), as described above. *See* MPEP §2143 (I)(E).

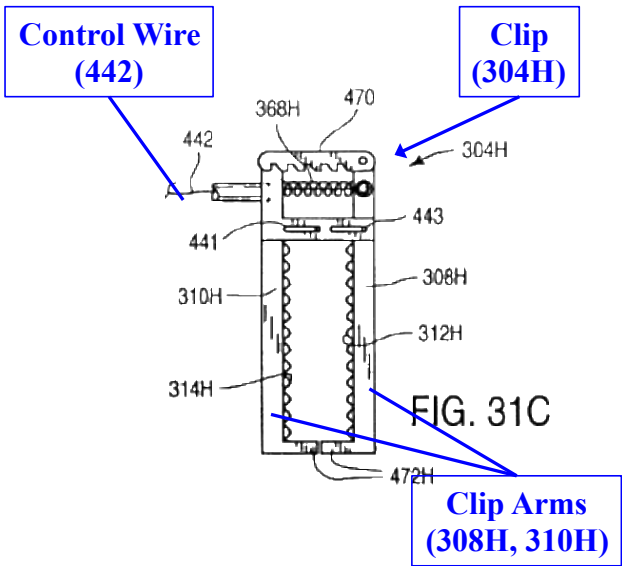
3. Claim 6

Claim 6 depends from claim 4. Malecki discloses the limitations of claim 4 including a control wire (378, 382), for the reasons in Section V.C.3, *supra* at pp. 63-64. Claim 6 further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Malecki discloses the control wire (378, 382) is operable to move the clip (304B) between open and closed configurations, for the reasons in Section V.C.5.d, *supra* at p. 67. (Ex. 1037, ¶116).

In Malecki Embodiment #2, the clip (304B) is opened and closed by rotating the control wire (378, 382) relative to hollow drive body 346B. (Ex. 1037, ¶117; Section V.C.5.d, *supra* at p. 67). However it would have been obvious to modify Malecki Embodiment #2 so that the physician can close and open the clip (304B) by pulling (*i.e,.* applying a proximal tensile force) and pushing (*i.e.*, applying a distally directed force), instead of rotating, the control wire (378, 382) relative to

the hollow drive body 346B. (Ex. 1037, ¶117; *see also* Section V.B.5, *supra* at pp. 47-49). Pushing and pulling a control wire was one of a finite number of obvious techniques used in the art to open and close a clip (another being rotating a mechanism to move the control wire proximally and distally, as disclosed in Malecki Embodiment #2). (Ex. 1037, ¶117). *KSR*, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.")

Indeed, Malecki discloses in other embodiments that clips may be opened and closed by pushing and pulling, rather than rotating, the control wire. (Ex. 1037, ¶118; Ex. 1003, 18:10-33, 18:66–20:19, Figures. 30, and 31). For example, as shown below in annotated Figure 31C, Malecki discloses a clip (clamp 304H) with clip arms (jaws 308H, 310H) that open and close via pushing and pulling a control wire (cable 442):



(Ex. 1037, ¶118; Ex. 1003, 19:45-47 ("Compression spring 368H biases jaws 308H, 310H open so that pulling cable 442 closes jaws 308H, 310H."), 19:37-45, 48-53; *see also id.*, 18:22-25, Figure 30A).

A person of ordinary skill in the art would have recognized that Malecki Embodiment #2 likewise could be modified so that clip (304B) opens and closes by pushing and pulling, rather than rotating, the control wire (378, 382) relative to hollow drive body 346B. (Ex. 1037, ¶119). *See* MPEP §§ 2143(I)(C) and (D). This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Malecki to achieve predictable results. (Ex. 1037, ¶119). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 421. For example, it would have been obvious to remove the threaded connection between the shaft 398 and clamp base 396, so that the clip (304C) could be opened and closed by pushing and pulling, instead of rotating. (Ex. 1037, ¶119).

The person of ordinary skill in the art would have recognized that modifying Malecki Embodiment #2 so that the clip (304B) opens and closes by pushing and pulling, rather than rotating, would simplify the mechanism used to open and close the clip. (Ex. 1037, ¶120). The skilled artisan would have been motivated to modify the Malecki clip, to make the device easier for the physician to use, and potentially reduce the risk of the clip not working properly, leading to potentially improved clinical outcomes. (Ex. 1037, ¶120).

4. Claim 7

Claim 7 depends from claim 6 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes the clip to lock in the closed configuration." The modified Malecki Embodiment #2 discussed above in Section V.D.3, *supra* at pp. 74-77 satisfies this limitation. In particular, application of a proximal tensile force to the control wire (378, 382) greater than a predetermined threshold value would pull the clip (304B) into the actuator housing 324B, thereby, locking the clip in the closed configuration. (Ex. 1037, ¶121; Ex. 1003, 16:65-67 ("The actuator housing 324B includes shoulder 325 against which the jaw 310B abuts due to the force of the torsion spring (not shown).").

5. Claim 8

Claim 8 depends from claim 7 and further requires "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip." Malecki Embodiment #2 discloses this limitation, for the reasons in Section V.C.3, *supra* at pp. 63-64. (Ex. 1037, ¶122).

6. Claim 9

Claim 9 depends from claim 6 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." This claim would have been obvious, for the reasons in Section V.D.3, *supra* at pp. 74-77. (Ex. 1037, ¶123).

7. Claim 14

Claim 14 depends from claim 13. Malecki Embodiment #2 discloses all of the limitations of claim 13, for the reasons in Section V.C.6, *supra* at p. 68. Claim 14 further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." This claim would have been obvious, for the reasons in Section V.D.1, *supra* at pp. 70-71. (Ex. 1037, ¶124).

8. Claim 16

Claim 16 depends from claim 15. Malecki Embodiment #2 discloses the limitations of claim 15, for the reasons in Section V.C.7, *supra* at pp. 68-69. Claim 15 further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." This claim would have been obvious, for the reasons in Section V.D.3, *supra* at pp. 74-75. (Ex. 1037, ¶125).

9. Claim 17

Claim 17 depends from claim 16 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes one or both of a locking of the clip in the closed configuration and a disengagement of the control wire from the clip." Malecki Embodiment #2 discloses this limitation, for the reasons in Section V.C.3, *supra* at pp. 63-64 (disengagement of the control wire from the clip). (Ex. 1037, ¶126). In addition, this claim would have been obvious, for the reasons in Section V.D.4, *supra* at p. 77 (locking of the clip in the closed configuration). (Ex. 1037, ¶126).

10. Claim 18

Claim 18 depends from claim 16 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." This claim would have been obvious, for the reasons in Section V.D.6, *supra* at p. 78. (Ex. 1037, ¶127).

11. Claim 19

Claim 19 depends from claim 12 and further requires "a distal end of the control wire includes an increased width portion formed to removably engage the clip." This claim would have been obvious, for the reasons in Section V.D.2, *supra* at pp. 72-74. (Ex. 1037, ¶128).

12. Independent Claim 20

a. "a method, comprising"

Malecki discloses a method. (Ex. 1037, ¶129; Ex. 1003, Title, 16:51-52).

b. "inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration"

Malecki Embodiment #2 discloses inserting a medical device comprising a clip (clamp 304B) to a target tissue site. (Ex. 1037, ¶130; Ex. 1003, 17:28-34 ("The clamp 304B is introduced into the thoracic cavity TC through a trocar sleeve 348 while in the closed position of FIG. 25."); *see also id.*, 16:53-7:2, 17:7-15, 17:28-39, Figures 27A and 27B). Malecki Embodiment #2 discloses the medical device comprises a clip (304B) having first and second clip arms (308B, 310B), and an opening element (torsion spring) engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration, for the reasons in Section V.C.1, *supra* at pp. 58-61. (Ex. 1037, ¶130).

c. "moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration"

It would have been obvious to modify Malecki Embodiment #2 to include this limitation, for the reasons in Section V.D.3, *supra* at pp. 74-75. (Ex. 1037, ¶131).

d. "moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration"

It would have been obvious to modify Malecki Embodiment #2 to include this limitation, for the reasons in Section V.D.3, *supra* at pp. 74-75. (Ex. 1037, ¶132).

e. "applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip."

Malecki Embodiment #2 discloses this limitation, for the reasons in Section V.C.3, *supra* at pp. 63-64. (Ex. 1037, ¶133).

VI. CONCLUSION

The grounds identified above establish a reasonable likelihood that Petitioners will prevail in their challenge of claims 1-20 of the '731 patent. Therefore, Petitioners respectfully request institution of an *inter partes* review to cancel those claims.

Dated: December 13, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief (including figure labels and annotations) contains 12,169 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it, and manual counting of the annotations in the figures.

The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14 point font.

Dated: December 13, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,271,731, as well as the accompanying Power of Attorney, and Exhibits 1003, 1017, and 1033-1039 have been served in their entirety on December 13, 2016, by Federal Express (Overnight Delivery) on:

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