UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SYMMETRY SURGICAL, INC.,

Petitioner,

v.

TELEFLEX MEDICAL INCORPORATED,

Patent Owner

U.S. Patent No. 6,863,675
Title: Ligating Clip With Integral Penetrating Hook
Issue Date: March 8, 2005
Filing Date: September 20, 2002

Case No.: TBD

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-318 AND 37 C.F.R § 42.100 *ET SEQ.* OF PATENT NO. 6,863,675

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LIST OF EXHIBITS

EXHIBIT NO.	EXHIBIT
Ex. 1001	Patent at Issue: U.S. Patent No. 6,863,675 to Wilson, "Ligating Clip With Integral Penetrating Hook," filed September 20, 2002 ("'675 Wilson").
Ex. 1002	U.S. Patent No. 4,834,096 to Oh et al., "Plastic Ligating Clips," issued in 1989 ("Oh I").
Ex. 1003	U.S. Patent No. 5,062,846 to Oh et al., "Penetrating Plastic Ligating Clip," issued in 1991("Oh II").
Ex. 1004	File History of the Wilson '675 patent
Ex. 1005	Reexamination Certificate for the '675 Wilson patent issued April 9, 2018
Ex. 1006	European Patent Publication No. EP0201344 A2 to Transue, "Ligating Clip and Clip Applier," published in 1986 ("Transue").
Ex. 1007	U.S. Patent No. 5,554,164 to Wilson et al., "Curved Knife for Linear Staplers," issued in 1996 ("Wilson I").
Ex. 1008	U.S. Patent No. 4,283,854 to Austin, "Hunter's Knife," issued in 1981 ("Austin").
Ex. 1009	Declaration of Neil Sheehan
Ex. 1010	Curriculum Vitae of Neil Sheehan
Ex. 1011	Representative Cases of Neil Sheehan
Ex. 1012	U.S. Patent No. 4,579,118 to Failla, "Hemostatic Clip With Penetration Means," issued in 1986 ("Failla").
Ex. 1013	U.S. Patent No. 3,789,715 to Schuchardt et al., "Rotary Cutting Apparatus," issued in 1974 ("Schuchardt").

TABLE OF AUTHORITIES

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I. INTRODUCTION

Petitioner seeks *inter partes* review of claims 1 to 6 of U.S. Patent No. 6,863,675 to Wilson ("'675 Wilson", Ex. 1001), which issued on March 8, 2005. According to the most recent assignment filed in the USPTO, Teleflex Medical Incorporated ("Patent Owner") is the current owner of the '675 Wilson patent. The patent is directed to a polymeric ligating clip for clamping blood vessels that are adjacent to connective tissue during surgery. Claims 1 to 6 of the '675 Wilson patent are invalid as obvious in view of a misconstrued prior art patent combined with previously uncited prior art.

The single independent claim in the'675 Wilson patent, claim 1, is a Jepson claim. The only purported improvement claimed over the prior art is a cutting edge, defined by two convex surfaces, that extends along a portion of the curved outer surface of a hook member of a ligating clip. This curved cutting edge is designed to cut through tissue adjacent to the blood vessel to which the ligating clip will be attached. As will be illustrated below, however, any incremental improvement disclosed in the '675 Wilson patent would have been obvious to one skilled in the art.

Polymeric ligating clips in general existed for over 40 years before the '675 Wilson patent was filed, and polymeric ligating clips with means for cutting connective tissue predated the patent at issue by 16 years. Thus, merely disclosing a

curved cutting edge to prevent unintended damage to tissue near the clamped blood vessel presents little, if any, improvement over the prior art. This is particularly true because the potential for unintended damage is disclosed in the prior art. And, forming the curved cutting edge by convergence of two convex surfaces is a simple substitution of one known element for another to obtain predictable results. In total, the '675 Wilson patent discloses nothing that a practitioner of ordinary skill would not have been motivated to render from the obvious combinations of art discussed below.

Specifically, claims 1 to 6 are obvious in view of U.S. Patent No. 5,062,846 to Oh et al. ("Oh II", Ex. 1003) and European Patent Publication No. EP0201344 A2 to Transue ("Transue", Ex. 1006). Oh II disclosed a polymeric ligating clip and the prior art addressed in the preamble of the '675 patent's Jepson claim. Transue disclosed a polymeric ligating clip with a penetrating member for cutting tissue surrounding a blood vessel without causing incidental damage to nearby tissue. To the extent the '675 Wilson patent claims that the convex surfaces used to form its cutting edge represent an inventive disclosure rather than a mere substitution or design choice, Transue clearly disclosed a cutting point formed by the convergence of convex surfaces. A simple substitution of the Transue penetrating member for the penetrating member of Oh II renders obvious the invention claimed in the '675 Wilson patent.

Additionally, the ‘675 Wilson patent is obvious in view of Oh II in combination with U.S. Patent No. 5,554,164 to Wilson (“Wilson I”, Ex. 1007) – the same Wilson named as sole inventor of the ‘675 Wilson patent. Wilson I, issued six years prior to the filing of the ‘675 Wilson patent, discloses the use of curved cutting edges having a parabolic cross section to facilitate an improvement in the surgical cutting of tissue. As with the combination above, this prior art renders the ‘675 Wilson patent obvious.

Finally, the obviousness of the ‘675 Wilson patent is demonstrated by Oh II in combination with U.S. Patent No. 4,283,854 to Austin (“Austin”, Ex. 1008). Austin discloses a curved, continuous cutting edge formed by convex surfaces that is used to make incisions along the skin of a recently killed animal. It would have been obvious to one of skill in the art to combine these references in order to facilitate the cutting of connective tissue attached to the blood vessel to be occluded without causing damage to nearby tissue.

As detailed below, this petition shows by a preponderance of the evidence that the challenged claims are invalid[1] as obvious and therefore unpatentable. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016), *citing* 35 U.S.C. § 316(e). However, for the purpose of instituting *inter partes* review, the petitioner need only

[1] The 35 U.S.C. § 282 presumption of validity does not apply in USPTO Proceedings. MPEP 2286(II) *citing In re Etter,* 756 F.2d 852 (Fed. Cir. 1985).

demonstrate that there is a reasonable likelihood that at least one of the claims challenged is unpatentable. *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1035 (Fed. Cir. 2016). As a result, Petitioner respectfully requests institution of *inter partes* review under 35 U.S.C. §314(a) and 37 C.F.R. §42.108(c).

II. MANDATORY NOTICES

A. Real Party-In-Interest

Petitioner Symmetry Surgical, Inc. is the real party-in-interest. To err on the side of caution, Petitioner also identifies Vesocclude Medical, LLC, and Vesolock Medical, LLC.

B. Related Matters

The '675 Wilson patent is the parent to PCT No. PCT/US02/34076, filed October 23, 2002. The '675 Wilson patent was reexamined under 90/014,016, filed on September 26, 2017.

C. Lead And Back-Up Counsel

Michael L. Kenaga (Reg. No. 34,639) as lead counsel and Alexander T. Bara (Reg. No. 74,461) as back-up counsel, both of the law firm:

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jtoft@iphorgan.com

D. Power Of Attorney

Petitioner submits herewith a power of attorney in favor of the lead and back-up counsel identified above.

E. Service Information

The service information for Petitioner required under 37 C.F.R. §42.8(b)(4)(i-v) is set out above under the designation of lead and back-up counsel. Electronic service is approved and preferred.

III. PETITION FEE

The undersigned authorizes the Office to charge Deposit Account No. 50-3993 in the amount of $15,500.00 in payment of the fee required under 37 C.F.R. §42.15(a)(1) for filing a request for *inter partes* review, and $15,000.00 in payment of the fee required under §42.15(a)(2) for *inter partes* review post-institution. The fees required by 37 C.F.R. §42.15(a)(3) and §42.15(a)(4) are not applicable because this Petition seeks review of less than 15 claims.

IV. GROUNDS FOR STANDING

As required under 37 C.F.R. §42.104(a), Petitioner certifies that the '675 Wilson patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting such review.

V. RELIEF REQUESTED

A. Statement Of Precise Relief Requested

As required by 37 C.F.R. §42.22(a)(1) and §42.104(b), Petitioner asks the Board to initiate *inter partes* review on challenged claims 1 through 6 of the '675

Wilson patent on all grounds of unpatentability asserted against each claim, and to cancel claims 1 through 6.

B. Full Statement Of Reasons For The Relief Requested

Petitioner provides below a full statement of the reasons for the relief requested, including a detailed explanation of the material facts and governing law.

VI. CLAIMS CHALLENGED ON THE BASIS OF SPECIFIC PRIOR ART

As required by 37 C.F.R. §42.22(a)(1-2) and §42.104(b)(1-2), Petitioner challenges the claims in issue as obvious under 35 U.S.C. §103(a) (pre-AIA) on the basis of the following prior art combinations:

A. Claim 1 – Oh II (Ex. 1003) in view of Transue (Ex. 1006)

B. Claim 1 – Oh II (Ex. 1003) in view of Wilson I (Ex. 1007)

C. Claim 1 – Oh II (Ex. 1003) in view of Austin (Ex. 1008)

D. Claims 2-6 – Oh II (Ex. 1003) in view of Transue, Wilson I, or Austin

Claims 2-6 depend from independent claim 1 and are rendered obvious by any one of the cited prior art combinations for claim 1.

Attached to this petition is a declaration of Neil Sheehan ("Sheehan Decl."; Ex. 1009). Mr. Sheehan's declaration supports the grounds in this petition showing that there is a reasonable likelihood that Petitioner will prevail with respect to at

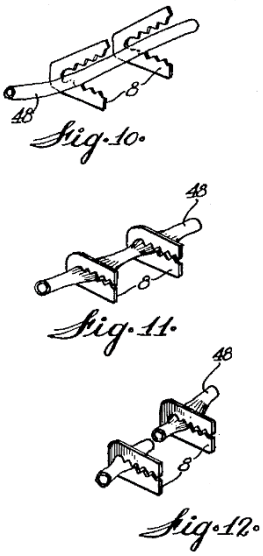
least one of the challenged claims and that each challenged claim is not patentable. See 35 U.S.C. §314(a).

VII. BACKGROUND, PRIOR ART, AND THE '675 WILSON PATENT

A. Early Blood Vessel Ligation

During surgical procedures, a surgeon may have to clamp off a blood vessel to prevent bleeding. Traditionally, a surgeon used a ligature – a piece of suture tied around a blood vessel – to stop the flow of blood. This was tedious and time consuming, particularly with small blood vessels.

As a result, surgical clips for closing off biological tubes were developed in the late 1800s. *See* U.S. Patent No. 600887 to Pettit. Later, metal clips specifically designed to occlude blood vessels were first patented in the 1960s. *See* U.S. Patent No. 3006344 to Vogelfanger. These metal ligating clips allowed for significantly faster vessel ligation. *Id*.



Figures 10-12 of Vogelfanger

Metal ligating clips remain clamped around a vessel after closure without the need of a locking or clasping mechanism. Ex. 1002, col. 1, ln. 19-25. But, metal clips have a significant drawback – they interfere with medical imaging technology. *Id*., col. 1, ln. 26-28. As a result, ligating clips made from polymers were developed to alleviate the problems metal causes with modern medical imaging. *Id*., col. 1, ln. 48-55.

Polymers were already being used in the early 1960s for other clips and clamps used during surgery, such as the clamp in U.S. Patent No. 3,040,749 to Payton ("Payton"). Payton disclosed a plastic umbilical cord clip formed by two leg members and a hook which can latch the two leg members together. U.S. Patent No. 3,171,184 to Posse similarly disclosed a plastic umbilical cord clamp with two leg members that latch together around an umbilical cord.

Plastic clips also were being used for clamping the tube section of blood donation bags, such as the clip disclosed in U.S. Patent No. 3,612,475 to Dinger.

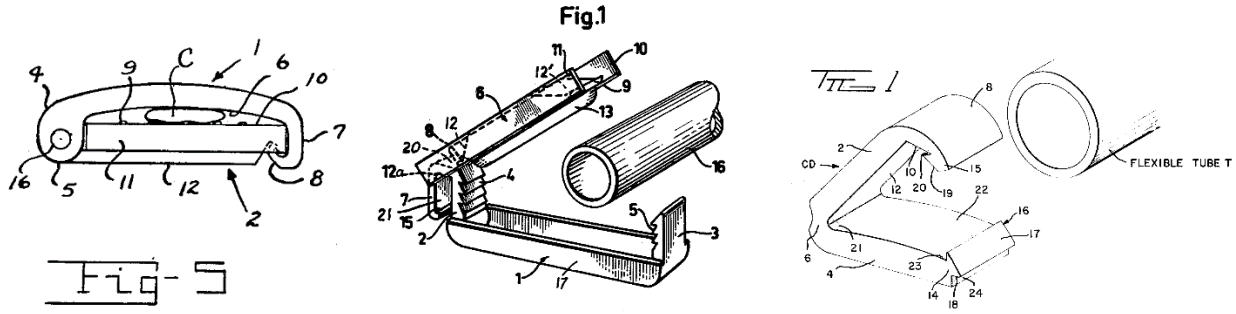
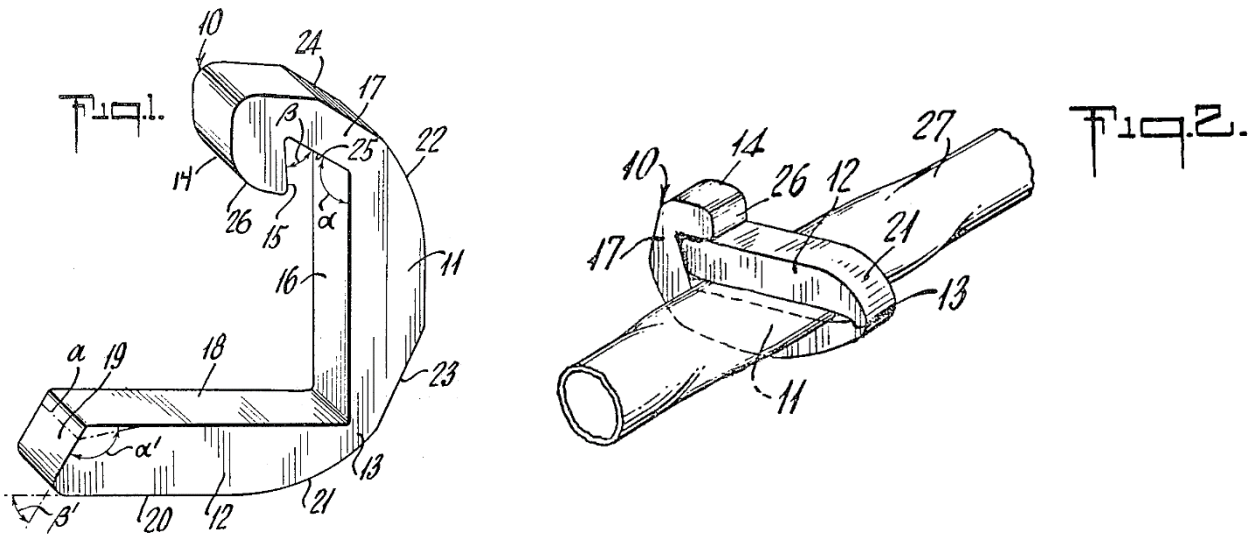


Figure 5 of Payton (Issued 1962), Figure 1 of Posse (Issued 1965), and Figure 1 of Dinger (Issued 1971).

Unfortunately, unlike metal ligating clips, which have sufficient strength using only the hinge portion to ligate a vessel, polymeric clips need a latching mechanism to remain closed. An early polymer ligating clip, disclosed in U.S. Patent No. 4,418,694 to Beroff et al. ("Beroff") issued in 1983, solved this problem. Beroff disclosed a polymer clip with two leg members, a resilient hinge, and a curved hook member that latches the two leg members together.



Figures 1 and 2 of Beroff et al.

After Beroff, similar designs of polymeric ligating clips featuring two legs and a latching mechanism were patented throughout the 1980s. These included U.S. Patent No. 4,487,205 to Di Giovanni et al. issued in 1984, U.S. Patent No. 4,498,476 to Cerwin et al. issued in 1985, U.S. Patent No. 4,620,541 to Gertzman et al. issued in 1986, and U.S. Patent No. 4,638,804 to Jewusiak issued in 1987.

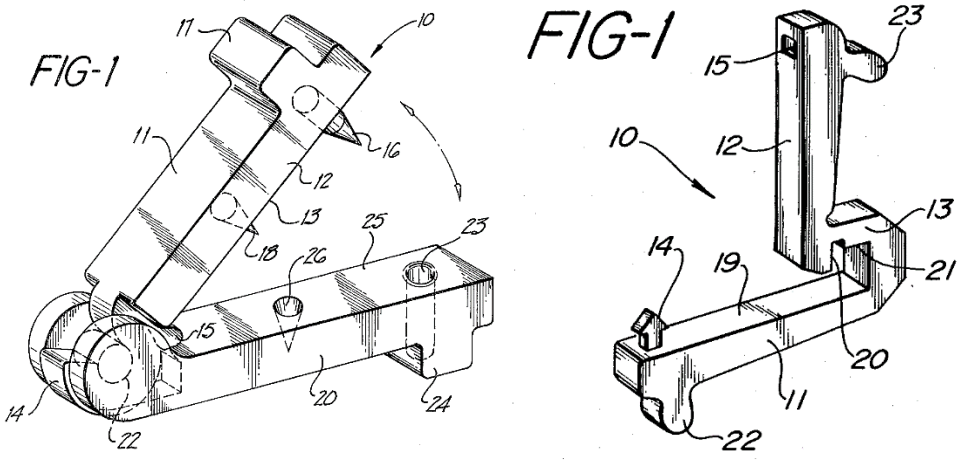


Figure 1 of Di Giovanni et al. and Figure 1 of Cerwin et al.

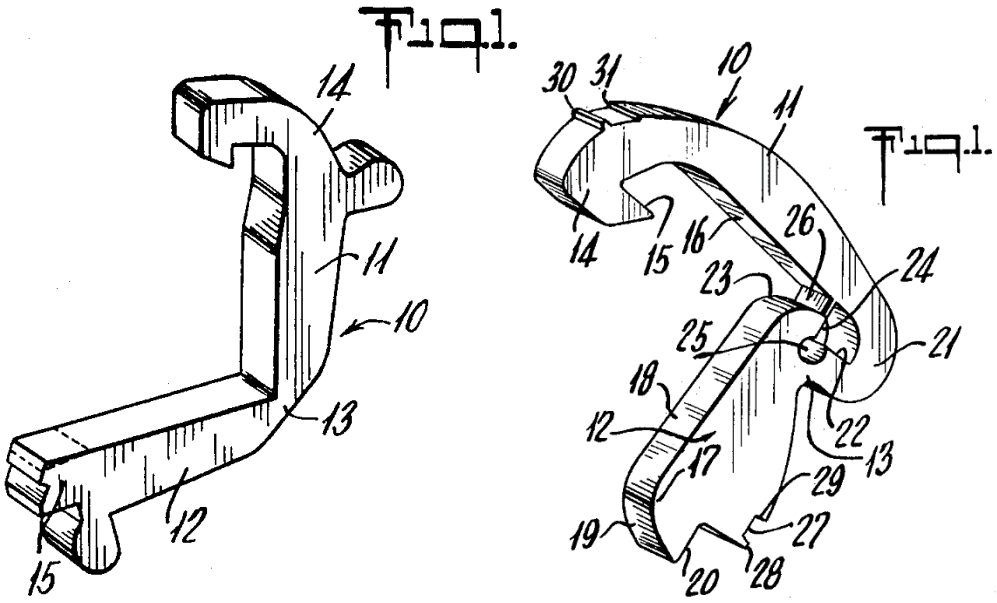
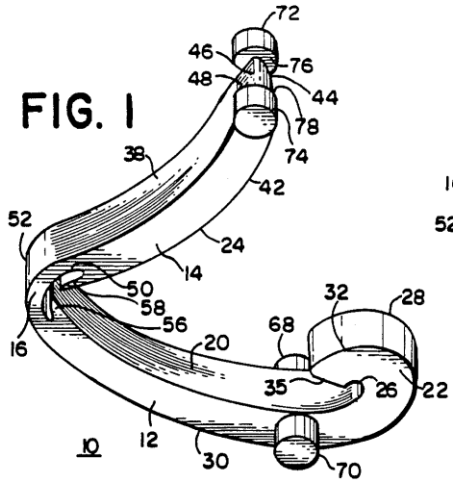
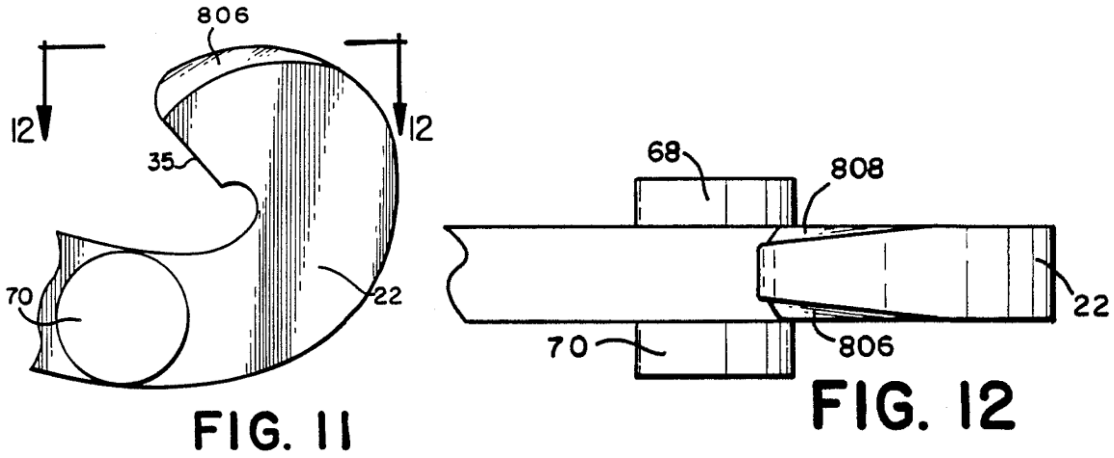


Figure 1 of Gertzman et al. and Figure 1 of Jewusiak.

U.S. Patent No. 4,834,096 to Oh et al. ("Oh I", Ex. 1002) issued in 1989 is commonly owned with the '675 Wilson patent. Oh I discloses a plastic ligating clip similar to the above clips. Figure 1 below shows a preferred embodiment. Figures 11 and 12 are also shown below and show an alternate embodiment of the hook member providing tapered surfaces 806 and 808 for alignment with the end of the other leg.





Figures 1, 11 and 12 of Oh I

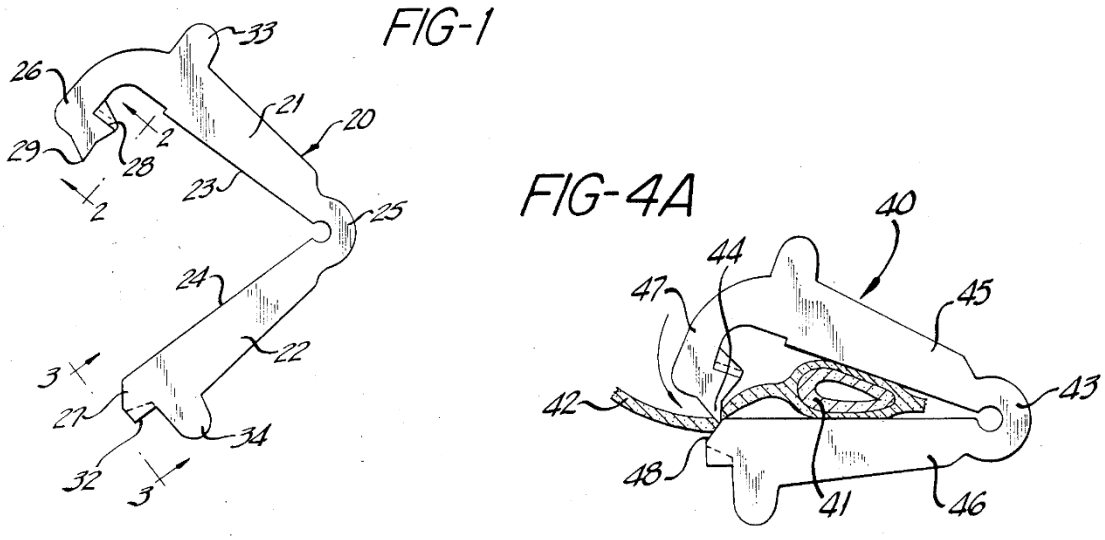
The next development in ligating clips arose from an additional problem associated with the use of polymers. Metal clips are deformed permanently to stop the flow of blood through a vessel, and may be used in that fashion even when the vessel is surrounded by connective tissue.

Polymeric clips, on the other hand, must completely surround the vessel so that the ends of two legs may latch together to permanently close the clip. Connective tissue therefore must be separated or cut from the blood vessel to isolate it. As a result, surgeons were forced to spend considerable time separating the blood vessel from surrounding tissue in order to prepare the vessel for application of the polymeric ligating clip.

To solve this problem, polymeric clips were developed that featured a cutting or penetrating member that itself cut the connective tissue, thereby isolating

the blood vessel for application of the clip without further intervention from the surgeon.

Two of the first patents to disclose this improved clip include European Patent Publication No. EP0201344 A2 to Transue ("Transue", Ex. 1006) published in 1986 and U.S. 4,579,118 to Failla ("Failla", Ex. 1012), issued in 1986. Failla incorporates a sharp pointed member on its hook member which allows the clip to ligate a vessel without a surgeon separating the vessel from surrounding tissue. Failla further discloses that "the penetrating means may have other configurations such as a pointed end tapered at a plurality of sides, a pointed end, a plurality of pointed ends, etc. *Id.*, col. 4, ln. 6-9.



Figures 1 and 4A of Failla showing the clip ligating around a vessel 41 with connective tissue 42.

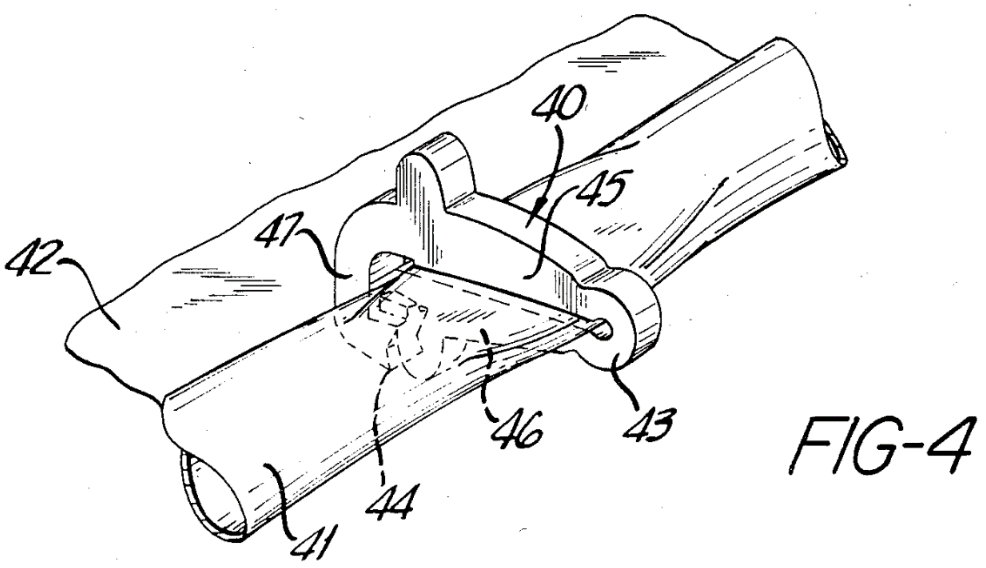


Figure 4 of Failla showing the clip ligating a vessel 41 with connective tissue 42.

Notably, as discussed below, Transue discloses a penetrating cutting point, formed by convergence of two convex side surfaces, which cuts the connective tissue when the ligating clip is closed. Ex. 1006.

B. <u>The Prior Art</u>

1. The Oh II Patent

U.S. Patent No. 5,062,846 to Oh et al. ("Oh II", Ex. 1003) issued in 1991 and is also commonly owned with the '675 Wilson patent. Oh II shows that other polymeric ligating clips with a tissue cutting implement on the hook end of one of the clip legs were well known in the art, long before the filing of the '675 Wilson patent. *Id*., abstract, Figure 1. The Oh II patent is directed to the problem of connective tissue interfering with the ligation of a blood vessel. The '675 Wilson patent cited Oh II as prior art, both explicitly in the specification (Ex. 1001, col. 6,

ln. 47-48) and implicitly by copying claim 1 of Oh II into the preamble of claim 1 of the ‘675 patent, which is a Jepson claim. *See* MPEP 2129 (III), *citing In re Fout*, 675 F.2d 297, 301 (CCPA 1982) (“Drafting a claim in the Jepson format is taken as an implied admission that the subject matter of the preamble is the prior art work of another.”) Oh II is prior art under 35 U.S.C. §102(a) (pre-AIA).

Oh II addressed the problem of connective tissue interfering with the closure of polymeric ligating clips, which required the surgeon to manually cut and separate connective tissue from the vessel requiring ligation. Ex. 1003, col. 1, ln.49-59. Oh II describes a polymeric ligating clip that severs connective tissue as the clip is closed and latched around a vessel, thus eliminating the need for a surgeon to manually separate the vessel from surrounding tissue. *Id*., col. 2, ln. 20-24.

As can be seen from Figures 1 and 4, the Oh II clip includes a distal tip 31 on the first leg member, which is formed by inwardly tapered surfaces 33 and 35 which converge and narrow to the distal tip 31 from side surfaces 25 and 27. The clip may include an additional penetrating member 43 with tip 53. One or both of these tips may assist the clip in cutting through connective tissue. *Id*., col. 8, ln. 47-67.

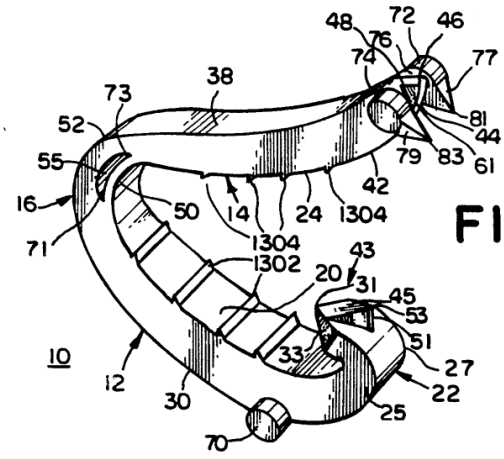


FIG. 1

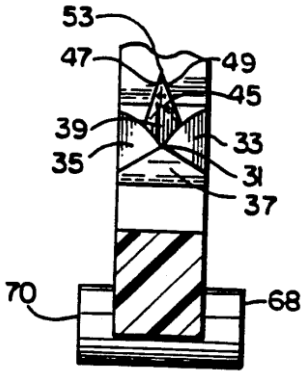


FIG. 4

Oh II

The penetrating member 43 of the hook portion 22 the on the first leg works in conjunction with two penetrating members 77 and 79 on the second clip leg to cut connective tissue. As the clip is closed around a vessel, the connective tissue gets caught between the penetrating member 43 and the two penetrating members 77 and 79. *Id.*, col, 8, ln. 47-59. The sharp points of these three members begin to stretch the tissue over the hook member 22. *Id.*, col, 8, ln. 47-59. As the tissue stretches, it will either get perforated by one or more of the three penetrating members or eventually tear as it is stretched over the sharp point 31 on the end of the hook portion 22. *Id.*, col. 8, lns. 61-65.

Oh II

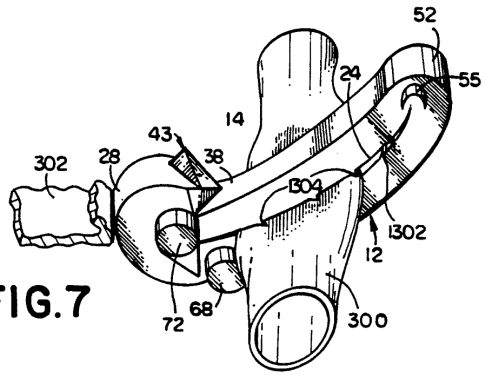


FIG.7

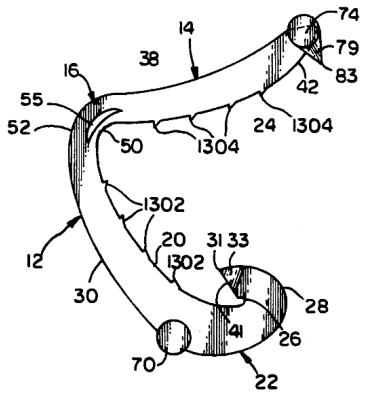


FIG. 14

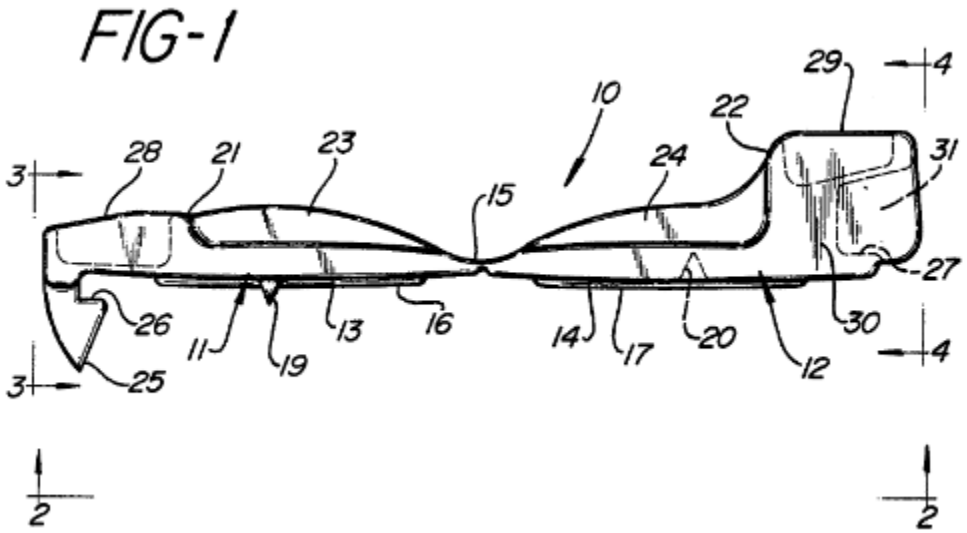
Figure 7 shows the clip in the closed position, with the penetrating member 43 exposed and protruding above the clip profile.

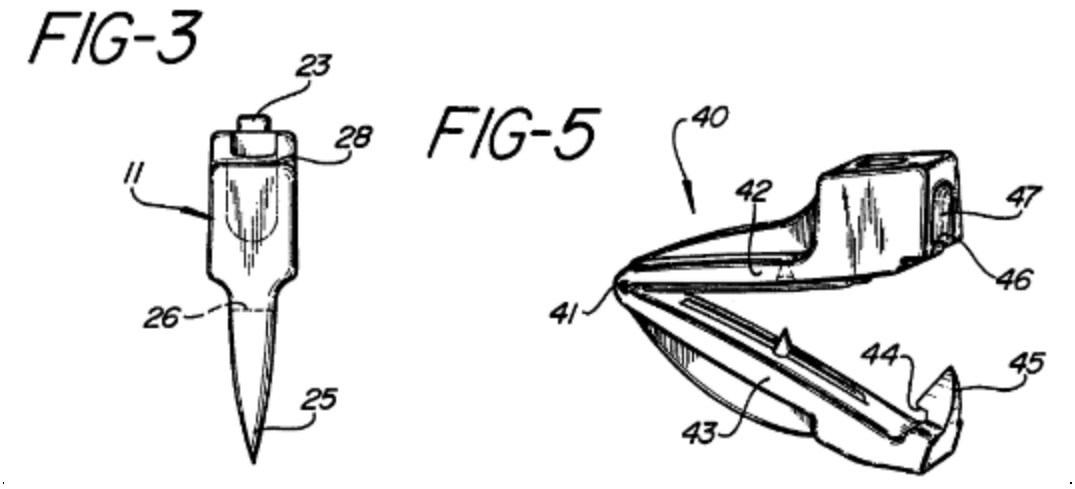
Oh II describes an alternate embodiment (Figure 14) that does not include the penetrating member 43, noting that the outward extension of member 43 from the hook may cause damage or irritation to surrounding tissue after clip closure. *Id.*, col. 10, ln. 9-14. This alternate design uses only the inward-biased sharp point 31 to cut tissue, which reduces the chance of damage to surrounding tissue but also reduces the tissue-cutting performance of the clip compared to the two-pointed embodiment. *Id.*, col 10, ln. 1-14. The alternate embodiment is identical to the preferred embodiment with the exception that it omits the penetrating member 43. Sheehan Decl., ¶ 54; Ex. 1009. This compromised solution, characterized by the patent as acting merely "satisfactorily" without the outward-biased sharp point, recognizes a reduction in cutting performance during closing of the clip to avoid damage to the surrounding tissue after the clip is closed. *Id.* ¶ 55.

2. The Transue Patent Application

European Patent Publication No. EP0201344 A2 to Transue ("Transue", Ex. 1006), was published in 1986. Transue discloses a polymeric ligating clip with two leg members joined by a resilient hinge and a tissue penetrating device on one of the legs. *Id.*, pg. 3, lns. 33-37; pg. 4, ln. 8-13. This application was not cited either in the prosecution or in the reexamination proceeding of the '675 Wilson patent and is not cumulative of information of record. Transue is prior art under 35 U.S.C. §102(b) pre-AIA.

Transue describes "a ligating clip that may be used with vascular systems connected to or running through tissue" and "may be used without requiring the dissecting of the vessels from the surrounding tissue." *Id.*, pg. 3, ln. 7-9; ln. 13-16. The penetrating means of the Transue clip, labeled as 25 in Figures 1 and 3 and as 45 in Figure 5, achieves those goals.





Figures 1, 3, and 5 of Transue

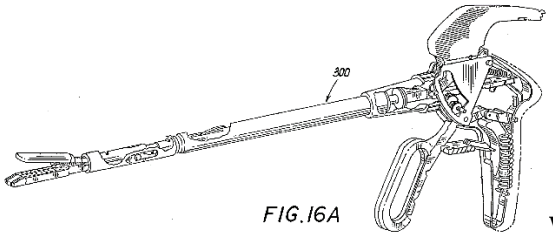
The penetrating member 25 or 45 is formed by two convex side surfaces that converge from the side of the clip (Figure 3), a third outer convex surface (Figure 1), and a flat inner surface (Figures 1 and 5). Sheehan Decl., ¶ 60; Ex. 1009.

The fact that the penetrating element is generally curved (*i.e.*, convex) is appropriate from a design standpoint given that the entire Transue clip is made from a polymeric material. A person of ordinary skill in the art would know that this would be the optimal shape from a rigidity standpoint. *Id.* ¶ 59.

As will be understood from Figure 5, tissue attached to a vessel will become trapped between the tip of penetrating member 45 and the tissue clamping surface of the second leg member 42. The penetrating member 45 will pierce the tissue at the sharp point as the tissue moves down the penetrating member 45. Ex. 1006, pg. 3, ln. 13-16; pg. 7, ln. 9-15.; Sheehan Decl., ¶ 61.

3. The Wilson I Patent

U.S. Patent No. 5,554,164 to Wilson et al. ("Wilson I", Ex. 1007) issued in 1996. The same Donald J. Wilson is listed as an inventor in both Wilson I and the '675 Wilson patent. Wilson I discloses a curved knife for use with a surgical fastening instrument for applying fasteners to tissue. *Id*., title and abstract. This patent was not cited either in the prosecution or reexamination of the '675 Wilson patent despite its disclosure of a surgical device with a tissue cutting mechanism and common lineage. Nor is Wilson I patent cumulative of information of record. The Wilson I patent is prior art under 35 U.S.C. §102(b) pre-AIA.



Wilson I

Wilson I discloses knife edges designed to effectively cut tissue by discouraging the tendency for tissue to be pushed away from the knife edge. Ex. 1007, title and abstract. These designs include the curved design shown in Figure 7. The blades generally have the profile shown in Figure 4.

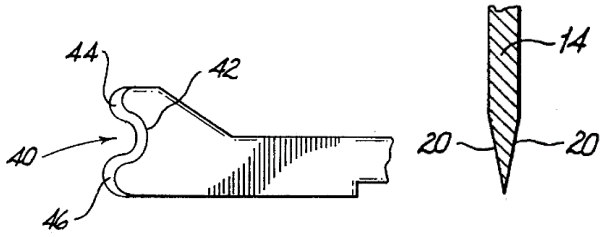


FIG. 7 FIG. 4

Figures 14 and 15 of Wilson I show a further curved design wherein both upper portion 112 and lower portion 114 are shaped as cubic parabolas, i.e., a three dimensional object having a parabolic cross section wherein both non-cutting surfaces 118 and 120 gradually give way to cutting surfaces 122 and 124, respectively. *Id.*, col. 5, ln. 62-66.

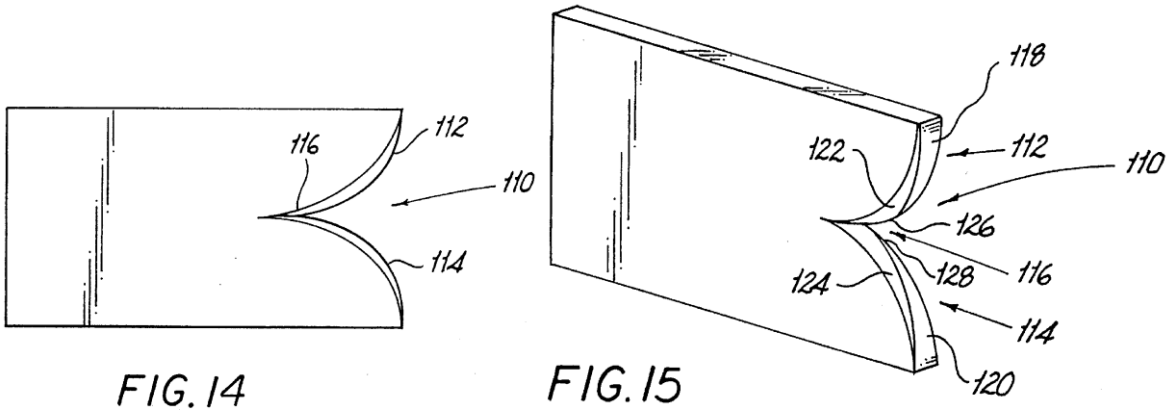


FIG. 14 FIG. 15

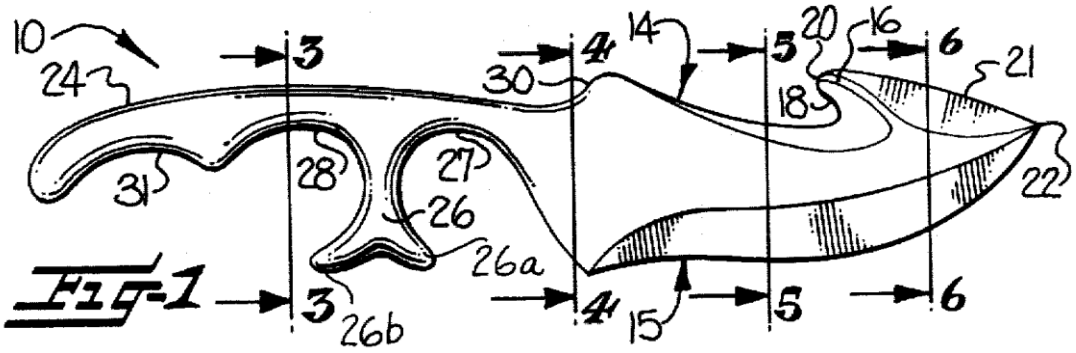
Wilson I

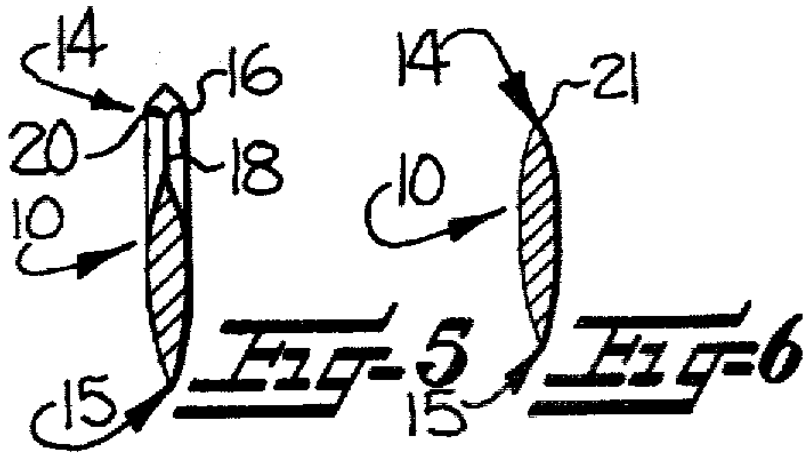
It follows that if the upper portion 112 and the lower portion 114 have a parabolic cross section, that they are formed by two convex surfaces that define a crest therebetween. Sheehan Decl., ¶ 64.

The various Wilson I blade designs address the need for a surgical fastening apparatus capable of severing selected tough or resilient body tissue. *Id.*, col. 2, lns. 28-30.

4. <u>The Austin Patent</u>

U.S. Patent No. 4,283,854 to Austin ("Austin", Ex. 1008). issued in 1981. The Austin patent discloses a hunter's knife with a blade portion that has a continuous cutting edge formed along substantially the full length thereof. *Id.*, col. 1, lns. 1-3; and col. 2, lns. 36-38. The blade portion is formed by two convex surfaces. *Id*., Figures 1, 5, and 6; and Sheehan Decl., ¶ 66; Ex. 1009. This patent was not cited either in the prosecution or in the reexamination of the '675 Wilson patent. Nor is Austin cumulative of information of record. Austin is prior art under 35 U.S.C. §102(b) pre-AIA.





Figures 1, 5, and 6 of Austin

The Austin knife is intended for "both eviscerating and skinning animals," namely, cutting through tissue. Ex. 1008, col 1, ln. 64-65. Regarding the blade portion shown in the bottom right of Figure 1, Austin discloses that "The other side 15 of the blade portion has a continuous sharp cutting edge formed along substantially the full length thereof." *Id*., col. 3, ln. 32-34. Figures 5 and 6 show how the lower crested cutting edge 15 is comprised of two convex surfaces that extend inwardly from the side.

5. The Schuchardt Patent

U.S. Patent No. 3,789,715 to Schuchardt et al. ("Schuchardt", Ex. 1013) issued in 1974. The Schuchardt patent is directed to the problem of "attach[ing] cutting blades to the curved surface of a cutting cylinder." *Id*., col 1, ln. 5-7. It discloses "strip-like cutting blades… that may be bent about an axis perpendicular to their longitudinal axis." *Id*., abstract. This patent was not cited either in the

prosecution or in the reexamination of the ‘675 Wilson patent. The Schuchardt patent is prior art under 35 U.S.C. §102(b).

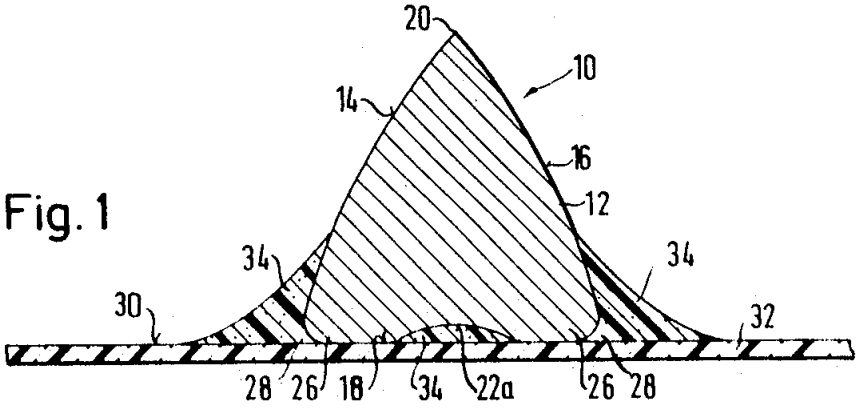


Figure 1 of Schuchardt

Schuchardt discloses cutting blades for paper, cardboard, and corrugated paper wherein the “[o]uter edges of the strip-like cutting blades are of [a] curved convex cross-section,” forming cutting edge 20. *Id*., col. 1, ln. 44-45; ln. 50-51. In operation, each blade, with the cross section shown in Figure 1 above, is bent around a cylinder 40, such that the cutting edge 20 also curves around the cylinder. *Id*., col. 3, ln. 53-56. The curved cutting edge allows for continuous cutting of paper or cardboard. Figure 6 below shows a side view of the curved edged blades wrapped around cylinder 40.

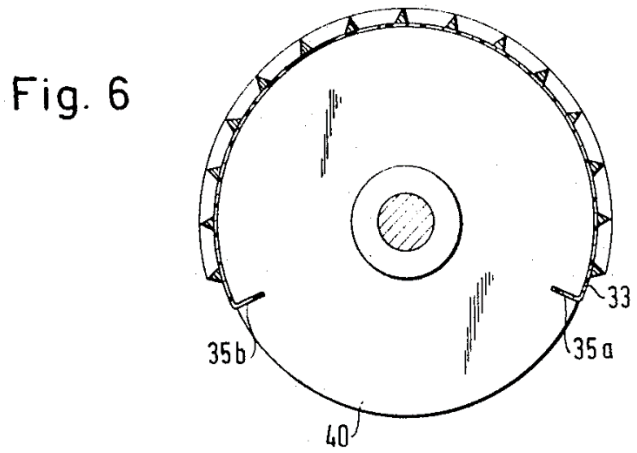


Figure 6 of Schuchardt

Schuchardt is cited as additional background, showing yet another example of two convex surfaces which define a curved crest or cutting edge.

VIII. THE '675 WILSON PATENT

A. Overview

The '675 Wilson patent issued on March 8, 2005, from an application, serial no. 10/251,182, filed on September 20, 2002. Ex. 1001. The '675 Wilson patent was filed under the first-to-invent provisions of pre-AIA law.

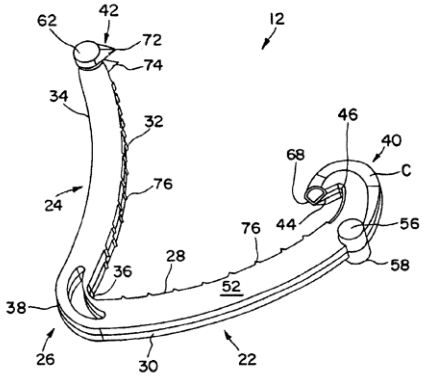


FIG. 1

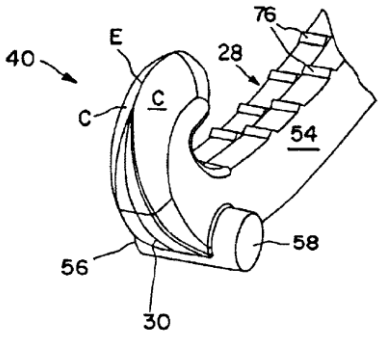


FIG. 3

The problem addressed by the '675 Wilson patent is broadly stated as "…to produce an improved polymeric surgical ligating clip with an integral penetrating hook which is particularly well suited for use to close vessels connected to surrounding tissue." *Id.*, col. 2, lns. 56-60.

The problem addressed by the '675 Wilson patent may be better understood when considering that both Oh I and Oh II were incorporated by reference. The '675 Wilson patent discloses that prior art clips "similar to clip 12 are described in detail in the commonly assigned U.S. Patent No. 4,834,096 to Oh et al. and U.S. Patent

No. 5,062,846 to Oh et al., the disclosures of which are incorporated herein in their entireties." *Id.*, col. 5, lns. 64-67.

The '675 Wilson patent discloses that "the cutting of connective tissue between the first leg member and the second leg member is significantly superior due to the novel design of hook member 40…." (*Id.*, col. 7, lns. 32-35) and that "the large hook end of surgical ligating clip 12 is designed to be able to penetrate through various connective tissues better during closure of the surgical clip." *Id.*, col. 7, lns. 42-44.

The hook member comprises a set of convex surfaces that form a cutting edge along the outer surface of the hook member to help sever connective tissue attached to the vessel. *See id*., Abstract; Col. 7, ln. 35-56.

Issued claim 1 is set out below, with references "(C, C)" and "(E)" added for the reader's convenience. The references identify the structure introduced in the improvement section. Claim 1 recites:

> In a polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectable hook member

curved toward said second leg member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said outer surface of said first leg member, side surfaces and an inner surface; the improvement comprising:

the continuously curved outer surface of said hook member comprising two convex surfaces (C, C) extending distally from the inner surface and inwardly from each side surface of the hook member so that the two convex surfaces define a crest or cutting edge (E) therebetween that extends along the length of at least a portion of the outer surface of the hook member; whereby connective tissue adjacent a vessel or the like to be clamped is cut by the crest or cutting edge of the hook member when said leg members are closed to aid in locking the clip in said closed position.

B. Summary Of Prosecution Of The '675 Wilson Patent

The application for the '675 Wilson patent was filed on September 20, 2002. *See* the file history of the '675 Wilson patent, Ex. 1004, pgs. 1-102.

In its Notice of Allowance, the Examiner's Reasons for Allowance states:

> The US Patents 5,100,416, 5,062,846, 4,834,096 to Oh et al. is the closest prior art to the claims. The claims in the present application distinguish over the prior art by providing the clamping mechanism with a [sic] the continuously curved outer surface of said hook member comprising two convex surfaces extending distally from the inner surface and inwardly from each side surface of the hood member so that the two convex surfaces define a crest or cutting edge there between that extends along the length of at least a portion of the outer surface of the hook member, whereby connective tissue adjacent a vessel or the like to be clamped is cut by the crest or cutting edge of the hook member when said leg members are closed to aid in locking the clip in said closed position.

Id., pg. 32.

The dependent claims in the '675 Wilson patent are copied directly from Oh II. *See* Claim Charts for claims 2-6 below. And as mentioned, independent claim 1, a Jepson claim, copied verbatim its preamble from claim 1 of Oh II. Ex. 1003, col. 11, ln. 4-21.

After issuance of the '675 Wilson patent, a certificate of correction was issued on January 8, 2008, removing reference numerals from figures 7A-7C. Ex. 1004, pg. 1.

A request for ex parte reexamination was granted on November 6, 2017. A Reexamination Certificate was issued April 9, 2018, confirming the patentability of the claims in light of the cited prior art at the time. Ex. 1005.

IX. EXPLANATION OF LAW

A. Claim Construction

As required by 37 C.F.R. §42.22(a)(2) and §42.104(b)(3), the claim terms of issued claims 1-6 must be given their broadest reasonable interpretation as understood by one of ordinary skill in the art and consistent with the patent's disclosure. *In re Cuozzo Speed Tech., LLC*, 778 F.3d 1271, 1279 (Fed. Cir. 2015).

B. Legal Standard For Obviousness

An invention that would have been obvious to a person having ordinary skill in the relevant art is not patentable. 35 U.S.C. §103(a) (pre-AIA); *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 405 (2007). As established in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), obviousness is a question of law that is resolved in light of following factual inquiries: (i) the scope and content of the prior art; (ii) the level of ordinary skill in the art; and (iii) the differences between the claimed invention and the prior art. Based on those factual inquiries, a claim is unpatentable if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR* at 406, *citing* 35 U.S.C. §103(a) (pre-AIA)(internal citations omitted).

> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are

> to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."

KSR at 406, *citing Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

The Supreme Court expanded the definition of obviousness beyond the rigid teaching, suggestion, and motivation test:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.
>
> *Id*. at 417.

It will often be necessary for the court "to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* at 418. The Supreme Court makes clear that "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim"

because the court can "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id*.

Following the guidance above, and as further explained below, all the claims of the '675 Wilson patent would have been obvious to a person of ordinary skill in the art at the time of invention.

C. Legal Standard for Analogous Art

Prior art is analogous if it either "(1) is from the same field of endeavor, regardless of the problem addressed or (2) is reasonably pertinent to the particular problem with which the inventor is involved." *Unwired Planet, LLC, v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016), *citing In re Clay*, 966 F.2d 656, 658-59 (Fed. Cir. 1992) (internal citations omitted).

The field of endeavor is determined by looking at "explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). Here, based on the '675 Wilson patent, the field of endeavor is polymeric ligating clips.

A reference may be reasonably pertinent to the problem if "logically would have commended itself to an inventor's attention in considering his problem." *In re Icon Health and Fitness*, 496 F.3d 1374, 1380 (Fed. Cir. 2007), *citing In re Clay*, 966 F.2d 656,659 (Fed. Cir. 1992) (Internal citations omitted). Here, the problem to

be solved is to "produce an improved polymeric surgical ligating clip with an integral penetrating hook which is particularly well suited for use to close vessels connected to surrounding tissue." (Ex. 1001, col 2, ln. 56-60).

In this case, all the cited prior art is from the same field of endeavor or reasonably pertinent to the problem of producing an improved ligating clip for vessels connected to surrounding tissue.

D. Person of Ordinary Skill in the Art

The level of skill of the hypothetical person of ordinary skill in the art may be inferred from the prior art of record. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Petitioner's expert, Mr. Sheehan, opines that the person of ordinary skill in the art would have at least a Bachelor of Science degree in either mechanical engineering, industrial design, or biomedical engineering or equivalent work experience, as well as five to ten years of experience in the design or development of medical devices, including clips and clamps and the like, as well as simple and complex mechanical assemblies and components. Sheehan Decl., ¶ 36; Ex. 1009.

X. THE '675 WILSON PATENT IS OBVIOUS IN VIEW OF THE PRIOR ART

A. Claim 1 Is Obvious in View of Oh II and Transue

1. Argument

The single purported improvement disclosed in claim 1 of the '675 Wilson patent is obvious in view of Oh II and Transue. Sheehan Decl., ¶ 79-80; Ex. 1009.

Through its use of a Jepson claim, Patent Owner admits that the preamble of claim 1 is prior art. *See* MPEP 2129 (III), *citing In re Fout*, 675 F.2d 297, 301 (CCPA 1982). Indeed, the preamble of claim 1 is a direct copy of claim 1 from Oh II. Ex. 1003, col. 11, Ln. 4-21. As a result, the only portion of claim 1 requiring a showing of obviousness is the addition of the '675 Wilson patent's so called "improvement"—the crest or cutting edge for cutting connective tissue.

Comparing claim 1 of '675 Wilson and Oh II in this light shows that the only difference is the *configuration* of the tissue penetrating means; '675 Wilson claims a curved "crest or cutting edge" whereas Oh II discloses dual sharp points or, in an alternative embodiment, a single sharp point. Ex. 1003, col. 10, ln. 1-9. As will be shown below, the curved crest of '675 Wilson is obvious in light of Oh II and any one of the prior art references.

The preferred embodiment of Oh II is shown in Figures 1-13.

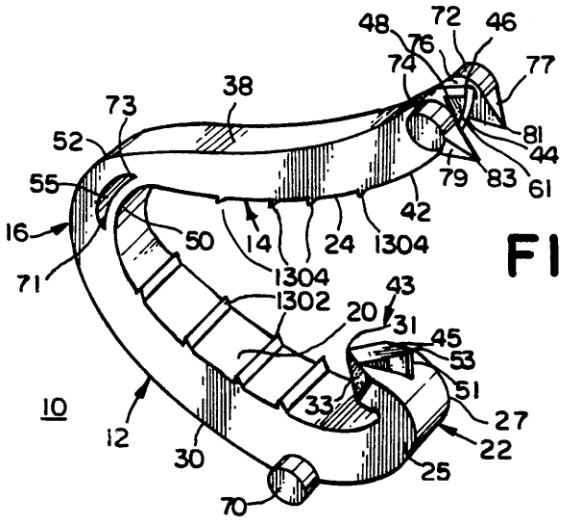


FIG. 1

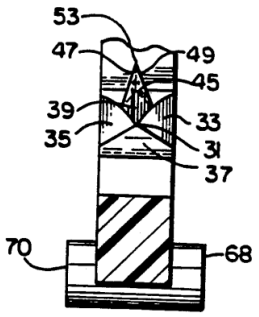


FIG. 4

The preferred embodiment includes both sharp pointed distal tip 31 formed in part by inwardly tapered surfaces 33, 35 and sharp pointed member 43 providing the exterior tip or sharp point 53. Oh II discloses in detail the benefits of the preferred embodiment of the clip having both the sharp pointed tip 31 and the sharp point 53. For example, with reference to Figures 13A-13E, Oh II discloses how the sharp point 53 of penetrating member 43 cooperates with the spaced-apart penetrating members 77 and 79 to begin stretching and penetrating the tissue. If the tissue is not punctured or cut, the tip 53 then enters the groove 61 to puncture it. In the event the tissue is not cut or punctured by the sharp point 53, the tissue subsequently will be stretched and become thinner and more easily punctured by the sharp pointed tip 31. Thus, the sharp point 53 cooperates with the sharp point 31 to cut connective tissue. *Id.*, col. 8, ln. 32-col. 9, ln. 4. Oh II is in this way directed in part toward the benefits of the combination of both the sharp pointed tip 31 and the sharp point 53.

As noted above, however, the alternate embodiment of the clip, shown in Figure 14 and set out in dramatic effect, discloses the omission of the sharp penetrating member 43. Oh II thus reveals the disadvantage of including the sharp penetrating member 43. As is apparent in Figure 7 of Oh II, the sharp penetrating member 43 protrudes beyond the profile of the clip after it has been clamped about a vessel. The protruding sharp penetrating member 43 presents an obvious hazard to the surrounding tissue after the clip is closed. *Id.*, col. 10, lns. 1-14. Oh II makes clear that the clip will act merely "satisfactorily" without member 43. *Id.*, col. 10, lns. 1-14; Sheehan Decl. ¶ 74, 76, Ex. 1009. These conflicting embodiments provide the motivation for the person of ordinary skill to find a single embodiment solution. *Id.* ¶ 78.

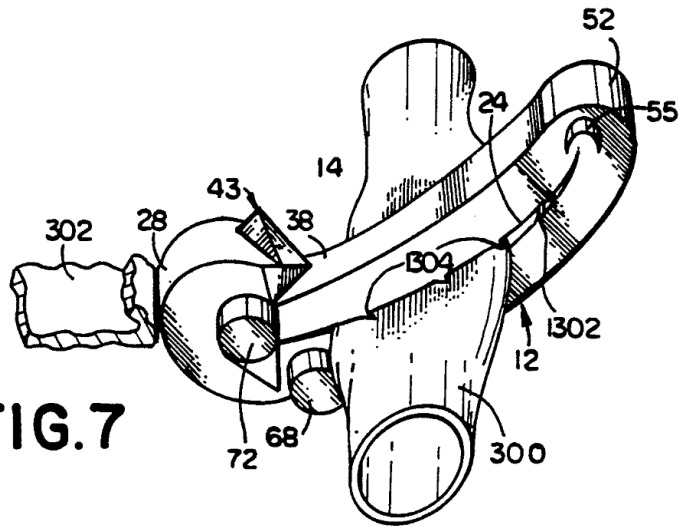


FIG.7

Figure 14 shows that the alternate embodiment of Oh II omits the sharp pointed member 43 and related sharp point 53. The outer surface 28 of the hook member 22 is consequently smooth. Sheehan Decl., ¶ 75.

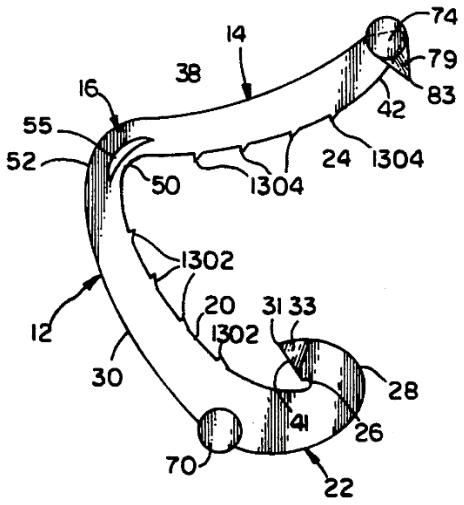


FIG. 14

Oh II therefore directs a person of ordinary skill to seek an alternative cutting or penetrating means which is both effective at cutting tissue during the closing of the clip *and* at avoiding damage to surrounding tissue after the clip has been clamped shut. Sheehan Decl., ¶ 76.

Figure 14 shows the area of outer surface 28 between the side surfaces 25, 27 where the penetrating member 43 was located in the preferred embodiment of the clip. In particular, the area is located generally between the lead lines extending from reference numeral 33 on the left and reference numeral 28 on the right. This is the area in which the sharp point 53 was located, and where Oh II invites, indeed

compels, the substitution of an alternate cutting or penetrating means. Sheehan Decl., ¶ 76.

The cutting or penetrating means to replace penetrating member 43 must avoid the protruding sharp member beyond the profile of the closed clip as is shown in Figure 7. Sheehan Decl., ¶ 74. Yet, the replacement cutting or penetrating means should also continue to cooperate with the second leg during closing of the clip to cut or penetrate tissue. For example, Figure 13B shows that "the tip 53 enters the groove 61 on the second leg member and puncturing of the tissue begins." Ex. 1003, col. 8, ln. 47-48.

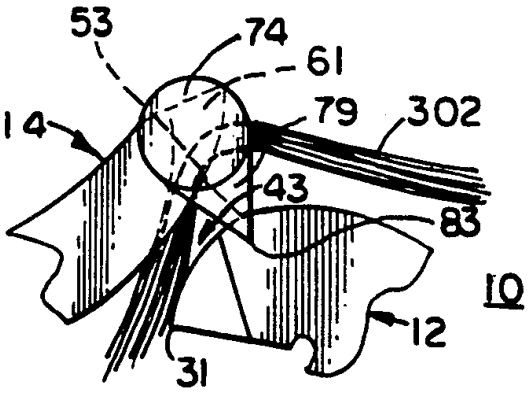


FIG. 13B

Figure 3 of Oh II displays the open end of the clip. The groove 61 is shown extending longitudinally along the center of the second leg 14. The sharp tip 53 of the penetrating member 43 is shown similarly aligned along the center of the first leg 12 for cooperation with the groove 61.

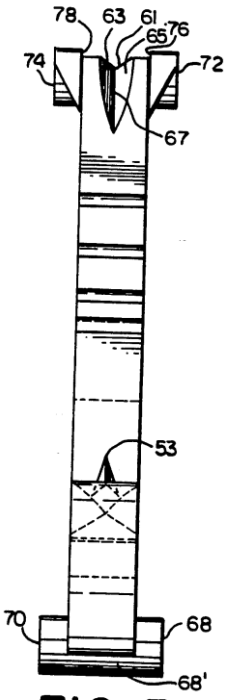


FIG. 3

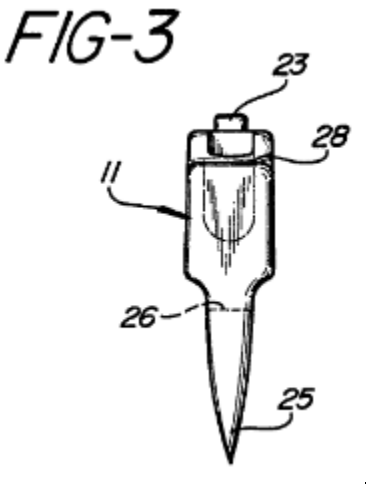
With this background, regarding the prior art, one skilled in the art would employ "inferences and creative steps" to solve the problem. *KSR* at 417.

Transue, in combination with Oh II, is one of three references that does so.

Transue shows a polymeric ligating clip. Ex. 1006, pg. 1, lns. 4-6. Further, Transue shows a structure that very much resembles the hook member 22 of Oh II. See for example the structure having reference numerals 25 and 26 in Figures 1-3 and having reference numerals 44 and 45 in Figure 5. Still further, this hook-like structure of Transue includes a tissue cutting or penetrating member. *Id.*, pg. 4, lns. 11-13. Thus, a person having ordinary skill in the art now has identified a cutting or penetrating means to consider as to whether it may be adapted to Oh II and provide both the cutting of connective tissue during closing of the clip and at the same time

the ability to avoid damage to surrounding tissue once the clip is closed. Sheehan Decl., ¶ 81.

In addition, Figure 3 of Transue shows that the sides of the hook-like structure include two *convex* surfaces extending inwardly to define the penetrating means 25.



The penetrating means 25 or 45 of the ligating clip 10 is used to penetrate tissue upon closing of the ligating clip 10 from the open position shown in Figure 5. Adaptation of the two convex surfaces extending from the side surfaces of the hook-like structure of Transue onto the side surfaces 25 and 27 and the outer surface 28 of the hook member 22 of Oh II will provide a curved crest or cutting edge along at least a portion of the outer surface 28 of the hook member 22 of Oh II. Sheehan Decl., ¶ 81. There the cutting edge will interact with the spaced-apart penetrating members 77 and 79 and groove 61 to cut connective tissue during closing of the clip. Yet, when the clip is closed, the cutting edge or crest will not present a protruding

sharp member beyond the profile of the closed clip, thereby avoiding any possible damage to the surrounding area.

As a result, the person of ordinary skill in the art would be motivated to combine Oh II and Transue in the above manner, in light of the warnings set out in Oh II, rendering claim 1 of '675 Wilson obvious. Sheehan Decl., ¶ 81, 85.

Additionally, Petitioner is not aware of any secondary considerations which would support a finding of patentability. It is Petitioner's understanding that the Patent Owner has not commercialized the '675 Wilson patent.

Accordingly, claim 1 is obvious in view of Oh II and Transue.

2. Claim Chart

The following claim charts illustrate the invalidity of the claims based on the combination of Oh II and Transue.

CLAIM 1 of the '675 Wilson patent	Oh II, Ex. 1003 and Transue, Ex. 1006
In a polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectable hook	Claim 1 of Oh II: A polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectible [*sic*] hook member curved toward said second leg

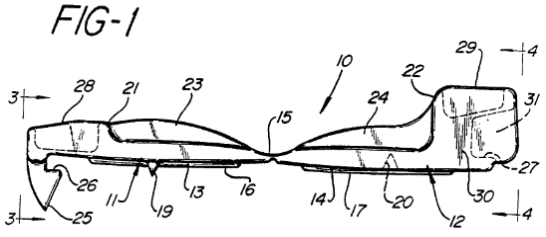
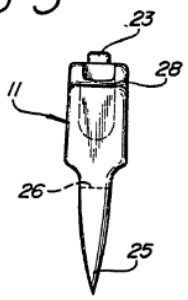
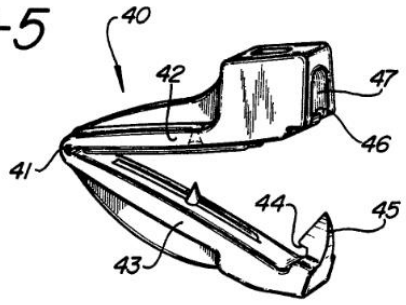
member curved toward said second leg member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said outer surface of said first leg member, side surfaces and an inner surface; the improvement comprising:	member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said outer surface of said first leg member, side surfaces and an inner surface;…
the continuously curved outer surface of said hook member comprising two convex surfaces extending distally from the inner surface and inwardly from each side surface of the hook member so that the two convex surfaces define a crest or cutting edge therebetween that extends along the length of at least a portion of the outer surface of the hook member; whereby connective tissue adjacent a vessel or the like to be clamped is cut by the crest or cutting edge of the hook member when said leg members are closed to aid in locking the clip in said closed position.	See Transue: col. 5, ln. 23-27: "Disposed at the distal end of the first leg is penetrating means 25. The penetrating means is a sharp pointed portion which extends away from the tissue clamping surface of the first leg member…" col. 3, ln. 32-35: "The first leg member terminates at its proximal end in a tissue penetrating means which extends in a direction towards the distal end of the second leg member…" FIG. 1, 3, & 5: 

	FIG-3  FIG-5 

B. Claim 1 Is Obvious in view of Oh II and Wilson I

1. Argument

Claim 1 is obvious in view of Oh II and Wilson I because in combination they teach or disclose every element of claim 1. Sheehan Decl., ¶ 82, 85.

As noted above, a person of ordinary skill in the art is prompted by the teaching of Oh II to search for cutting or penetrating means that solve the tissue-damaging problem caused by penetrating member 43 having the sharp tip 53. Sheehan Decl., ¶ 78-79. Wilson I solves the identified problem, providing several curved cutting edges to consider.

Wilson I, in the same field of endeavor and relevant problem, is similarly directed to a medical device featuring a curved knife for linear staplers that cuts through tissue during surgery. *See* Ex. 1007, patent title; and Sheehan Decl., ¶ 63.

Specifically, Wilson I discloses that when the prior art "linear cutting edge encounters the tough tissue, the application of cutting force against the tissue may produce an upward or lifting force on the tissue. As the cutting edge severs the tissue, the geometry of the cutting edge may permit the upper portion of the tissue to "ride up" the cutting edge…to permit a thin layer of uncut tissue to slide therebetween. This uncut layer of tissue is referred to as a wisp." Ex. 1007, Col. 2, lines 10-20.

Wilson I further explains that "[a] need…exists for a surgical fastening apparatus having a knife which minimizes the wisping of tissue during the severing operation." *Id.*, col. 2, lns. 26-28. The Wilson I further explains that there is also a need in the art for surgical fastening apparatus capable of severing selected tough or resilient body tissue. *Id.*, col. 2, lines 26-30.

Wilson I then solves the problem by disclosing that "[t]he present invention improves upon prior art surgical fastening instruments by providing a knife with a non-linear cutting edge which successfully severs tissue while effectively eliminating the wisping of tissue." *Id.*, col. 2, lines 41-44.

The ‘675 Wilson Patent amply displays a non-linear, curved cutting blade in Figures 14 and 15:

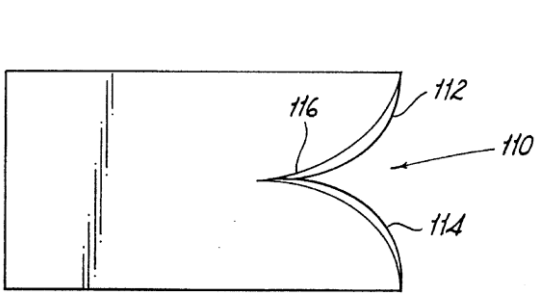


FIG. 14

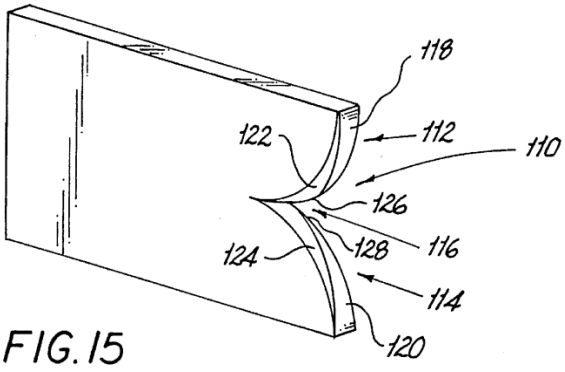


FIG. 15

“Cutting edge 110 has a first upper portion 112, a second lower portion 114 and a generally V-shaped intermediate portion 116 disposed between upper portion 112 and lower portion 114. Both upper portion 112 and lower portion 114 are shaped as cubic parabolas, i.e., a three dimensional object having a parabolic cross section wherein both non-cutting surfaces 118 and 120 gradually give way to cutting surfaces 122 and 124, respectively. Cutting surfaces symmetrical to cutting surfaces 122 and 124 (not shown) converge to and join cutting surfaces 122 and 124 at V-shaped portion 116 to form cutting edges 126 and 128, respectively. In operation, the cubic parabola configuration provides for minimal tissue acceleration and a smooth change of direction.” *Id.*, Col. 5, ln. 56 to Col. 6, ln. 5.

Wilson I thus expressly discloses a three dimensional object or cutting surface having a parabolic, curved cross section. One skilled in the art would consider adapting or substituting the Wilson I cutting surface having a parabolic

cross section for the penetrating member 43 of Oh II. Sheehan Decl., ¶ 82. Parabolas of any kind necessarily have convex sides. Sheehan Decl., ¶ 64.

And, one of ordinary skill in the art would modify the side surfaces 25, 27 and smooth outer surface 28 of the hook member as shown in Figure 14 of Oh II to incorporate the parabolic convex cross section disclosed by Wilson I. Sheehan Decl., ¶ 82. Further, the skilled artisan would align the apex of the parabolic cross section of the modified hook member of Oh II to continue to present the modified cutting or penetrating means in alignment with the groove 61 on the second leg 12 of Oh II.

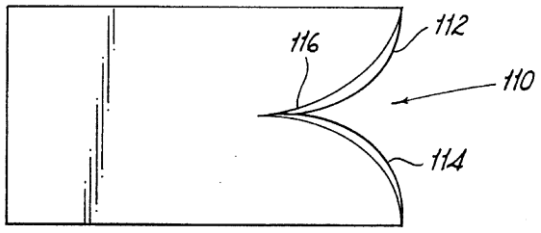
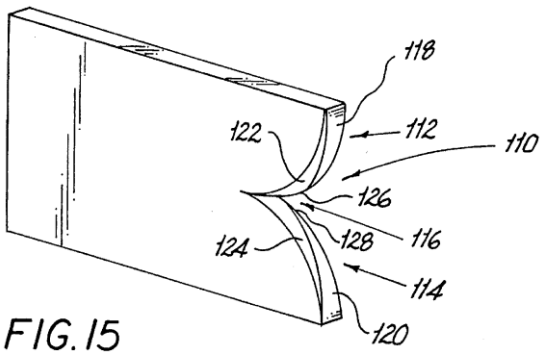
In sum, a person of ordinary skill in the art, looking to improve the tissue cutting capability of a polymer ligating clip, while avoiding damage to the surrounding tissue, would be motivated to consider the teachings of Wilson I for adaptation to the Oh II clip. Sheehan Decl., ¶ 82, 85.

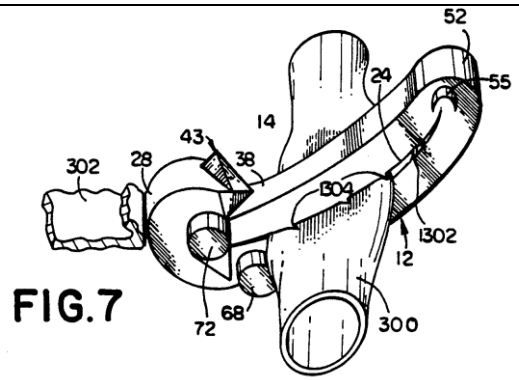
Accordingly, claim 1 of the ‘675 Wilson patent is obvious in view of Oh II and Wilson I. Sheehan Decl., ¶ 85.

2. Claim Chart

The following claim charts illustrate the invalidity of the claims on the basis of Oh II and Wilson I.

CLAIM 1 of the '675 Wilson patent	Oh II, Ex. 1003 and Wilson I, Ex. 1007
In a polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectable hook member curved toward said second leg member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said outer surface of said first leg member, side surfaces and an inner surface; the improvement comprising:	Claim 1 of Oh II: A polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectible [*sic*] hook member curved toward said second leg member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said outer surface of said first leg member, side surfaces and an inner surface;…
the continuously curved outer surface of said hook member comprising two convex surfaces extending distally from the inner surface and inwardly from each side surface of the hook member so that the two convex surfaces define a crest or cutting edge therebetween that extends along the	Wilson I is directed to a curved knife for linear staplers. (Patent title). Both upper portion 112 and lower portion 114 are shaped as cubic parabolas, i.e., a three dimensional object having a parabolic cross section wherein both non-cutting surfaces 118 and 120 gradually give way to cutting surfaces

length of at least a portion of the outer surface of the hook member;	122 and 124, respectively. (Col. 5, ln. 62-66).  FIG. 14  FIG. 15
whereby connective tissue adjacent a vessel or the like to be clamped is cut by the crest or cutting edge of the hook member when said leg members are closed to aid in locking the clip in said closed position.	See Oh II: col 2, ln. 50-52: "The sharp pointed member engages, stretches and penetrates connective tissue connected to the vessel to be clamped." FIG. 7:

C. Claim 1 Is Obvious in view of Oh II and Austin

1. Argument

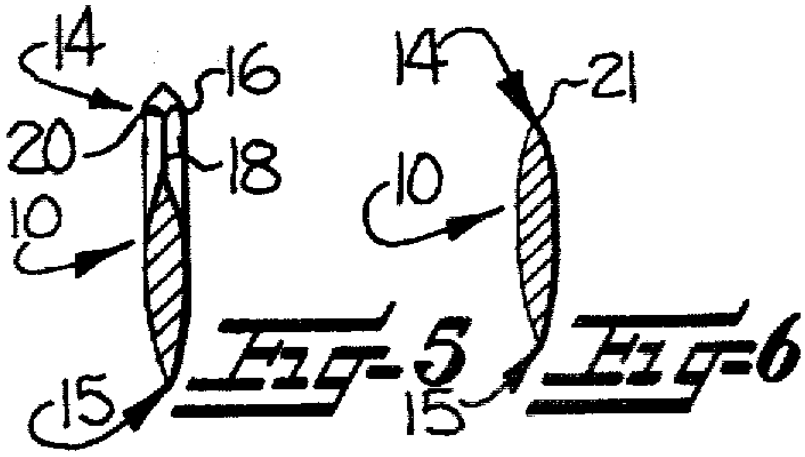
Claim 1 is obvious in view of Oh II and Austin. The Oh II and Austin patents teach or disclose every element of claim 1. Sheehan Decl., ¶ 85.

As discussed, a person of ordinary skill in the art is prompted by the warnings of Oh II to consider superior, tissue-damage avoiding cutting or penetrating means as substitutes for the penetrating member 43 having the sharp tip 53. Sheehan Decl., ¶ 76. Austin provides such a cutting edge.

Austin is highly pertinent to the problem here: it discloses a continuous curved cutting edge. The Austin knife is intended for "both eviscerating and skinning animals," namely, cutting through tissue. Ex. 1008, col 1, ln. 64-65. Austin improves the tissue cutting ability of the curved hook member claimed in '675 Wilson patent. Sheehan Decl., ¶ 83.;

Figures 5 and 6 of Austin show how the lower crested cutting edge 15 is comprised of two convex surfaces that extend inwardly from the side. Sheehan

Decl., ¶ 65, 66. "The other side 15 of the blade portion has a continuous sharp cutting edge formed along substantially the full length thereof." Ex. 1008, col. 3, ln. 32-34.



Austin expressly discloses a tissue cutting edge having two convex surfaces which define a crest or cutting edge that extends along the length of at least a portion of the blade. *Id.*, Figures 5 and 6. One skilled in the art would be motivated to consider the Austin curved cutting edge formed by two convex surfaces and related disclosure for substitution of the penetrating member 43 of Oh II.

To accomplish this task, one of ordinary skill in the art would modify the side surfaces 25 and 27 and the smooth outer surface 28 of the hook member 22 shown in Figure 14 of Oh II to incorporate the cutting edge formed by two convex surfaces as taught by Austin. Sheehan Decl., ¶ 83 and 85.

In addition, a person of ordinary skill in the art would naturally maintain the advantage of aligning the edge 15 of Austin with the now replaced sharp tip 53 of

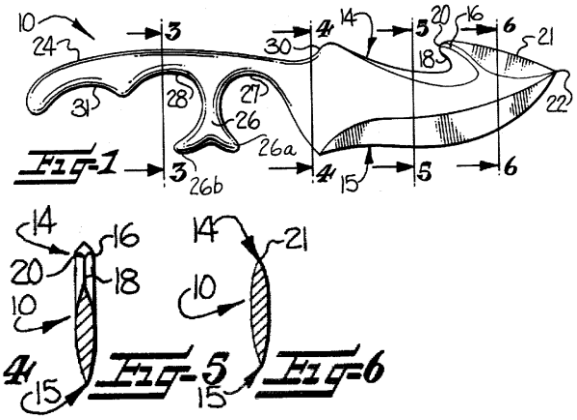
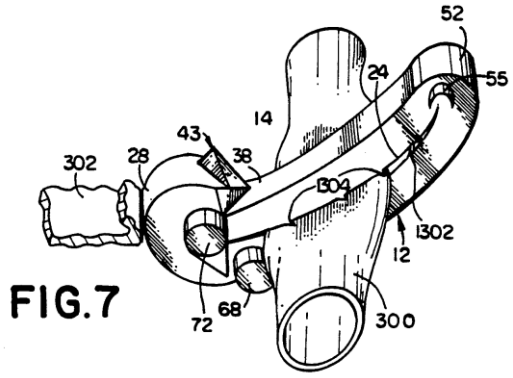
the hook member 22 of Oh II with the existing groove 61 of the second leg 14 of Oh II.

Accordingly, the '675 Wilson patent is obvious in view of Oh II and Austin.

2. Claim Chart

The following claim charts illustrate the invalidity of the claims on the basis of Oh II and Austin.

CLAIM 1 of the '675 Wilson patent	Oh II, Ex. 1003 and Austin, Ex. 1008
In a polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectable hook member curved toward said second leg member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said	Claim 1 of Oh II: A polymeric surgical clip comprising first and second leg members joined at their proximal ends by a resilient hinge means, each leg member having a vessel clamping inner surface and an opposite outer surface, said vessel clamping inner surface being in opposition to the vessel clamping inner surface of the other leg member, said first leg member terminating at its distal end in a deflectible [*sic*] hook member curved toward said second leg member, said second leg member terminating at its distal end in a locking portion complementary to said hook member whereby when said first and second leg members are moved from an open position to a closed position about said hinge means, the hook member deflects about the distal end of said second leg member to lock the clip in a closed position, said hook member having a continuously curved outer surface extending distally from said

outer surface of said first leg member, side surfaces and an inner surface; the improvement comprising:	outer surface of said first leg member, side surfaces and an inner surface;…
the continuously curved outer surface of said hook member comprising two convex surfaces extending distally from the inner surface and inwardly from each side surface of the hook member so that the two convex surfaces define a crest or cutting edge therebetween that extends along the length of at least a portion of the outer surface of the hook member;	See Austin: FIG. 1, 5, & 6  See Austin: "The other side 15 of the blade portion has a continuous sharp cutting edge formed along substantially the full length thereof." (Col. 3, ln. 32-34).
whereby connective tissue adjacent a vessel or the like to be clamped is cut by the crest or cutting edge of the hook member when said leg members are closed to aid in locking the clip in said closed position.	See Oh II: col 2, ln. 50-52: "The sharp pointed member engages, stretches and penetrates connective tissue connected to the vessel to be clamped." FIG. 7: 

D. Dependent Claims 2-6 Are Obvious in view of Oh II

1. Argument

All dependent claims in the '675 Wilson patent are word-for-word copies of dependent claims from prior art Oh II. As discussed, independent claim 1 is obvious in view of Oh II and the prior art identified above.

The dependent claims in the '675 Wilson patent are not directed to the claimed crest of cutting edge set out in the improvement portion of independent claim 1. Sheehan Decl., ¶ 84. Not surprisingly, the combination of any of the dependent claims with independent claim 1 of the '675 Wilson patent results in a predictable variation. *See KSR* at 417. A person of ordinary skill in the art would recognize that the dependent claims of Oh II are applicable in the same way to the device of claim 1 of the '675 Wilson patent. *See id.* ("If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

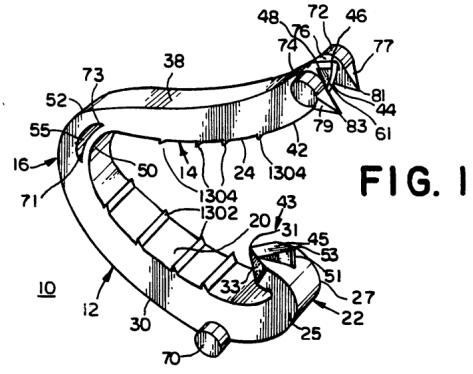
Because all the claim limitations in the dependent claims 2-6 of the '675 Wilson patent are disclosed verbatim in Oh II, they are obvious as well. *See* 35 U.S.C. §103 (Pre-AIA).

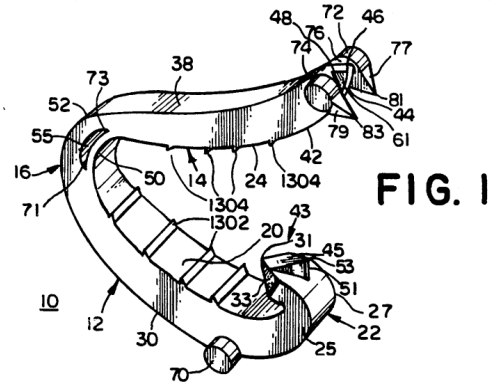
Moreover, the additional benefits of the clip elements claimed in Oh II's dependent claims would lead a person of ordinary skill in the art to add these dependent claim elements to the nearly identical clip in claim 1 of '675 Wilson patent. Sheehan Decl., ¶ 84. For these additional reasons, it would be obvious to add these elements to the nearly identical clip claimed in the '675 Wilson patent's independent claim 1. Sheehan Decl., ¶ 85.

Accordingly, dependent claims 2-6 of the '675 Wilson patent are obvious in view of Oh II in combination with either of Transue, Wilson I or Austin.

2. Claim Chart

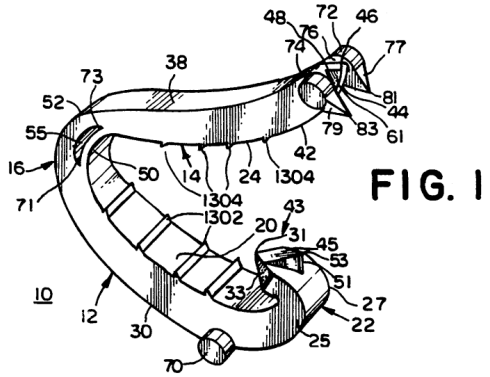
The following claim charts illustrate the invalidity of the claims based on Oh II (with either of Transue, Wilson I or Austin as to the improvement features).

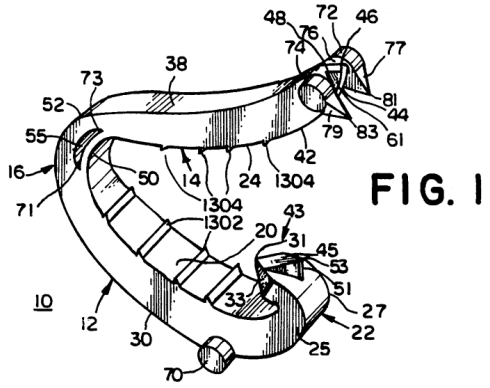
CLAIM 2 Oh II	
The surgical clip according to claim 1 wherein the inner surface of said first leg member has a concave radius of curvature between the hinge means and the hook member and the outer surface of said first leg member has a convex radius of curvature, the inner surface of the second leg member has a convex radius of curvature between the hinge means and its distal end and the outer surface of said second leg member has a concave radius of curvature between the hinge means and its distal end.	See Oh II: See Claim 6; col. 4, ln. 34-46 and col. 5, ln. 23-33 FIG. 1:  FIG. 1

CLAIM 3 Oh II	
The surgical clip according to claim 1 wherein said clip comprises means coupled to said first and second leg members for engagement with a suitable clip applier for applying said clips, said engagement means comprising a pair of bosses joined to opposite sides of said first leg member intermediate said hinge means and said hook portion, and a pair of bosses joined to opposite sides of said second leg member at the distal end of said second leg member, said second leg member having sharp pointed members extending from said bosses.	See Oh II: See Claim 11; col. 6, ln. 10-26 FIG. 1 (elements 68, 70, 72, and 74):  FIG. 1

CLAIM 4 Oh II	
The surgical clip according to claim 3 wherein a portion of said pair of bosses joined to said first leg member extend beyond the outer surface of said first leg member to form substantially parallel and spaced apart surfaces which prevent lateral movement of said first and second leg members relative to one another when the clip is in the closed position.	See Oh II: See Claim 12; Col. 3, ln. 31-36: "The bosses are so disposed as to extend beyond the end of second leg member to provide two parallel and separately spaced surfaces which prevent lateral movement of the leg members relative to one another when the clip is closed."

CLAIM 5 Oh II	
The surgical clip according to claim 4 wherein the inner surfaces of said clip each comprise a plurality of protrusions for providing improved vessel retention during closure of the clips.	See Oh II: See Claim 13; col. 9, ln. 54-58: "the clip 10 of FIG. 1 further includes a plurality of protrusions 1302 on the inner surface 20 of the leg member 12, while leg member 14 includes a

	plurality of protrusions 1304 on its inner surface 24." FIG. 1:  FIG. 1

CLAIM 6 Oh II	
The surgical clip according to claim 1 wherein said clip further comprises a sharp pointed member attached on each side of the distal end of said second leg member and extending beyond the inner surface of said second leg member, said sharp pointed members of said second leg member cooperating with the cutting edge of said hook member to cut said connective tissue when said clip is moved from said open position to said closed position.	See Oh II: See Claim 3; col. 6, ln. 28-33: "The second leg member further includes a pair of sharp penetrating members 77 and 79 extending from the bosses 72 and 74, respectively, past the inner surface 24 of leg 14. FIG. 1:  FIG. 1

XI. CONCLUSION

For the reasons set out above, there is a reasonable likelihood that Petitioner will prevail as to each of claims 1-6 of the '675 Wilson patent. Accordingly, *inter partes* review of claims 1-6 of the '675 Wilson patent is respectfully requested.

Dated: November 9, 2018

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ATTORNEYS FOR PETITIONER

CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that on **November 9, 2018**, true and correct copies of the foregoing PETITION FOR INTER PARTES REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R § 42.100 ET SEQ. OF PATENT NO. 6,863,675, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via FedEx Express® or USPS Express Mail:

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CERTIFICATE OF COMPLAINCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This Petition complies with the type-volume limitation of 14,000 words, comprising **10,796** words, excluding the parts exempted by 37 C.F.R. §42.24(a).
2. This Petition complies with the general format requirements of 37 C.F.R. §42.6(a) and has been prepared in double spaced 14 point Times New Roman font.

Dated: November 9, 2018

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