UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

ETHICON ENDO-SURGERY, INC.
Petitioner

v.

COVIDIEN AG
Patent Owner

CASE IPR: UNASSIGNED
U.S. PATENT NO. 7,887,536

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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I. INTRODUCTION

Ethicon Endo-Surgery, Inc. ("Petitioner") requests *inter partes* review ("IPR") of claims 1 to 13 of U.S. Patent No. 7,887,536 ("'536 Patent") (Ex. 1001).

II. THE '536 PATENT

The '536 Patent is nothing more than a discussion of bipolar electrosurgical forceps whose individual features were well-known and repeatedly described in both Patent Owner Covidien AG's ("PO") and Petitioner's prior art patent filings. PO should not be allowed to continue to benefit from claiming simple combinations of known device features. Because combinations of other references made according to motivation found therein also contain all the claimed features, it is evident that the claims of the '536 Patent do not recite novel, non-obvious subject matter and should be cancelled as described below.

A. Overview of the '536 Patent

The '536 Patent is directed to "forceps used for open surgical procedures…which applies a combination of mechanical clamping pressure and electrosurgical current to seal tissue." (Ex. 1001 at 1:30-35).

These forceps are not a new type of surgical instrument; the '536 Patent provides an overview of long existing electrosurgical forceps. (*Id.* at 2:45-46, *see also* 1:46-57). Indeed, the '536 Patent also admits that "[s]everal journal articles have disclosed methods for **sealing** small blood vessels using electrosurgery." (Ex.

1001 at 1:46-48).[1] It admits that "[e]lectrosurgical methods may be able to seal larger vessels using an appropriate electrosurgical power curve, coupled with an instrument capable of applying a large closure force to the vessel walls." (*Id.* at 2:33-36). The '536 Patent does not represent the first instrument capable of sealing vessels; it lists patents that "all relate to electrosurgical instruments for coagulating, cutting and/or sealing vessels or tissue." (*Id.* at 2:56-57).

One of the allegedly inventive features of the '536 Patent involves non-conductive stop members associated with opposing jaw members "to control/regulate the distance, i.e., gap, between the jaw members when tissue is held therebetween during activation." (Ex. 1001 at 4:36-38). As described herein, however, such stop members were well known in the art prior to the '536 Patent. The claimed gap range of 0.001 inches to 0.006 inches also was known in the art.

Another allegedly inventive feature of the '536 Patent involves incorporation of a knife channel into a jaw member to allow a surgeon to sever tissue held between the jaw members. (Ex. 1001 at 13:66-14:2, 14:10-13). As described herein, using knife channels in jaw members of electrosurgical instruments was also well known in the art, as was their role in facilitating a knife therethrough to sever tissue held between the jaw members of the electrosurgical instrument.

B. Prosecution of the '536 Patent

[1] All emphasis added unless otherwise indicated.

In an Office Action dated June 14, 2010, the Examiner rejected several pending claims "as being clearly anticipated by Tetzlaff et al (2004/0162557)." (Ex. 1002 at 80-81). In response, Patent Owner Covidien AG ("PO") incorporated dependent claim 3, which recited the knife channel limitation, into the independent claims. (*Id.* at 84-88). The '536 Patent issued without comment from PO.

III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioner certifies that (1) the '536 Patent is available for IPR; (2) Petitioner is not barred or estopped from requesting IPR on the Grounds identified herein; and (3) Petitioner has not filed a complaint relating to the '536 Patent. This Petition is filed in accordance with 37 C.F.R. § 42.106(a).

IV. PAYMENT OF FEES (37 C.F.R. §§ 42.15 and 42.103)

Petitioner authorizes the USPTO to charge the required fees for *inter partes* review of 13 claims, and any additional fees, to Deposit Account No. 02–1818.

V. MANDATORY NOTICES (37 C.F.R. § 42.8(b))

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

Ethicon Endo-Surgery, Inc., head office at 4545 Creek Rd., Blue Ash, OH 45242, is the real party in interest. Ethicon Endo-Surgery, Inc. is a wholly owned subsidiary of Johnson & Johnson, headquartered at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933, which is also a real party in interest.

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

The following purport to claim the benefit of the priority of the '536 Patent: U.S. Patent App. No. 12/402,656, now U.S. Patent No. 7,896,878; U.S. Patent App. No. 12/015,404, now U.S. Patent No. 7,513,898; U.S. Patent App. No. 11/317,816, now U.S. Patent No. 7,329,256; U.S. Patent App. No. 10/284,562, now U.S. Patent No. 7,267,677; U.S. Patent App. No. 10/116,824; U.S. Patent App. No. 09/425,696, now U.S. Patent No. 6,511,480; and U.S. Patent No. 09/178,027, now U.S. Patent No. 6,277,117. Petitioner is concurrently requesting for IPR of U.S. Patent No. 8,241,284, an unrelated one of PO's patents purportedly finding novelty in adding stop members to known electrosurgical devices.

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4))

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Petitioner consents to electronic service by e-mail.

VI. THE '536 PATENT IS ONLY ENTITLED TO A PRIORITY DATE OF OCTOBER 30, 2002

"In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier

application must comply with the written description requirement of 35 U.S.C. § 112." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). Each limitation must be disclosed in the specification; it is insufficient for a limitation to be obvious in view of what is described. *See Lockwood*, 107 F.3d at 1571-72; *see also PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (subject matter disclosed for first time in a continuation-in-part does not receive the benefit of the parent's filing date). Entitlement to priority is decided on a claim-by-claim basis, not an element-by-element basis. *See, e.g., PowerOasis*, 522 F.3d at 1306; *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1352, 1354 (Fed. Cir. 2012); *see also X2Y Attenuators, LLC v. Int'l Trade Comm'n*, 757 F.3d 1358, 1366 (Fed. Cir. 2014). Moreover, "both § 120 and 37 C.F.R. § 1.78(c)(1) require the involved application and the earliest application in the priority chain to share **at least one common inventor**." *Polaris Wireless, Inc. v. TruePosition, Inc.*, IPR2013-00323, Final Written Decision (Paper 62) at 19-26[2]; *see* 35 U.S.C. § 120.

Although the '536 Patent purports to claim priority to October 23, 1998, the earliest application in the chain with a common inventor to the '536 Patent is U.S. Patent App. No. 10/116,824 ("'824 Application") (*see* Ex. 1013 at 64-67; *compare with* Ex. 1015 at 3-4). Accordingly, the earliest **possible** priority date for any

[2] The *Polaris Wireless, Inc.* case is presently on appeal. Appellant did not appeal the Board's statutory interpretation of 35 U.S.C. § 120. (Ex. 1012).

claim of the '536 Patent (regardless of subject matter disclosure) is the April 5, 2002, filing date of the '824 Application. *See* 35 U.S.C. § 120; *see also Polaris Wireless, Inc.*, IPR2013-00323, Final Written Decision (Paper 62) at 19-26.

Moreover, all the claims of the '536 Patent require a "knife channel." This limitation was not disclosed by the '824 Application as filed. (*See* Ex. 1013 at 3-58). The first disclosure of the claimed "knife channel" in the priority chain of the '536 Patent was in the filing of U.S. Patent App. No. 10/284,562 ("'562 Application") on October 30, 2002. (Ex. 1014 at 42-47). Prosecution of the '562 Application confirms that the "knife channel" was new matter added as of October 30, 2002. In response to a rejection under 35 U.S.C. § 112, first paragraph, PO identified passages from the specification and claims as disclosing the "knife channel" that appeared for the first time in the '562 Application. (Ex. 1014 at 15 (Response to Office Action identifying pages 34-35 of as-filed specification), 42-43 (pages 34-35 of as-filed specification); *compare* Ex. 1014 at 42-43, 48 *with* Ex. 1013 at 35 (corresponding pages of as-filed specification of '562 Application and as-filed specification of '824 Application, lacking cited disclosure). Applicant did not identify any support for these limitations from any prior applications.[3]

[3] No support for the claimed "knife channel," among other limitations of the claims of the '536 Patent, exists in any of the applications that precede the '824 Application in the priority chain of the '536 Patent. (*See* Ex. 1015-Ex. 1017).

Applicant therefore requests that the Board find that the correct priority date for all claims of the ‘536 Patent is October 30, 2002.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art is a hypothetical person presumed to know the relevant prior art. *Gnosis S.p.A. v. South Alabama Med. Sci. Found.*, IPR2013-00116, Final Written Decision (Paper 68) at 9. Such a person of ordinary skill is of ordinary creativity, not merely an automaton, and is capable of combining teachings of the prior art. *Id.* (citing *KSR Int’l Co. v. Teleflex Inc*., 550 U.S. 398, 420-21 (2007). A person of ordinary skill in the art of the ‘536 Patent as of October 30, 2002, would have had at least a bachelor’s of science degree in either electrical engineering or mechanical engineering with at least four years’ experience designing electrosurgical instruments. (Ex. 1003 at ¶¶ 18-26, 28-29).

VIII. CLAIM CONSTRUCTION

The claims of the ‘536 Patent should be given their “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Tech., LLC*, Case No. 14-1301, slip op. at 12, 14-15 (Fed. Cir. Feb. 2, 2015).

A. “Disposed On”

Claims 7 to 13 each requires “a ratchet **disposed on** the first shaft and a complementary interlocking mechanical interface **disposed on** the second shaft.” While the term “disposed on” is not defined in the ‘536 Patent, it nonetheless is

used to describe elements formed integrally together (*see, e.g.*, Ex. 1001 at Fig. 7 (element 61B), 9:24-28; *see also* 5:62-6:8, Fig. 8 (cross-hatching indicates that ratchet interface 30b is integrally formed with shaft member 12b)) or separate elements affixed to one another (*see, e.g.*, Ex. 1001 at 7:8-11). Accordingly, the proper construction of "disposed on" is "put in place on." *See, e.g.*, *Nest Labs, Inc. v. Allure Energy, Inc.*, IPR2015-00181, Institution Decision (Paper 6) at 8-9.

B. "Interlocking Positions"

Claims 7 to 13 each require "the ratchet and complementary interlocking mechanical interface being selectively positionable to interlocking positions to maintain a specific closure pressure." The term "interlocking position**s**" requires that the ratchet/interlocking mechanical interface can interlock in at least two different positions. A construction where "interlocking positions" can cover only one position is unreasonable in view of the claim language. Thus, "interlocking positions" should be construed as "at least two different interlocking positions."

IX. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(a) AND 42.104(b))

Petitioner requests cancellation of claims 1-13 on the following Grounds:

Ground	35 U.S.C.	Relied-On Reference(s)	Claims
1	§ 103	*Witt* in view of *Tetzlaff* and *Yates*	1-4, 7-13
2	§ 103	*Witt* in view of *Tetzlaff*, *Yates*, and *Stern*	5-6
3	§ 103	*Witt* in view of *Tetzlaff*, *Yates '270*, and *Yates*	1-4, 7-13
4	§ 103	*Witt* in view of *Tetzlaff*, *Yates '270*, *Yates*, and *Stern*	5-6
5	§ 103	*Tetzlaff* in view of *Stern* and *Yates*	1-5, 7-13

6	§ 103	*Tetzlaff* in view of *Stern*, *Yates* and *Wales*	6

None of the combinations herein was considered during examination. Moreover, the declaration of David C. Yates, an expert in the field of the '536 Patent and the prior art, was not considered during examination. (Ex. 1003 at ¶¶ 1-17, 27-29).

A. Ground 1: Claims 1-4 And 7-13 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Witt, Tetzlaff,* And *Yates*

1. Overview of the Prior Art

(a) *Witt*

U.S. Patent Publication No. 2002/0107517 to Witt et al. ("*Witt*") (Ex. 1006) was filed on January 23, 2002, and published August 8, 2002. Accordingly, *Witt* is prior art under 35 U.S.C. §§ 102(a) and 102(e). *Witt* claims priority to U.S. Provisional App. Nos. 60/266,055, filed February 2, 2001, and 60/264,644, filed January 26, 2001 ("*Witt '644*") (Ex. 1005). To the extent *Witt '644* supports the disclosure in *Witt* (as set forth in the parallel citations hereafter), *Witt* is prior art as of January 26, 2001, under 35 U.S.C. § 102(e). (Ex. 1003 at ¶ 30).

Witt "relates, in general, to electrosurgical instruments and, more particularly, to an electrosurgical combination grasper/scissor for surgical applications." (Ex. 1006 at ¶ 2; *see also* Ex. 1005 at 1:5-10). *Witt* describes the use of "[c]urrently-available bipolar grasping instruments for electro-coagulation of tissue, or 'tissue welding.'" (Ex. 1006 at ¶ 5; *see also* Ex. 1005 at 1:28-2:5; Ex. 1003 at ¶ 31). In these instruments, tissue is held between a pair of jaws having

first and second electrodes and bipolar current flows between the two electrodes (and thus between the tissue) to seal the tissue. (Ex. 1006 at ¶ 5, Fig. 1; *see also* Ex. 1005 at 1:28-2:5, Fig. 1; Ex. 1003 at ¶¶ 32-33). *Witt's* jaws can have a knife channel, and a ratchet mechanism can lock the jaws in a closed position and set the clamp pressure. (Ex. 1006 at ¶ 83, Figs. 7-15; Ex. 1005 at 9:12-21, Figs. 7-15).

(b) *Tetzlaff*

PCT Publication No. WO 00/24330 to Tetzlaff et al. ("*Tetzlaff*") (Ex. 1007) published on May 4, 2000, and is prior art under 35 U.S.C. § 102(b) (Ex. 1003 at ¶ 38). It relates to "a bipolar forceps having a disposable electrode assembly for sealing, cauterizing, coagulating/desiccating and/or cutting vessels and vascular tissue." (Ex. 1007 at 1:10-12). *Tetzlaff* discloses a pliers-like device with a pivot about which two members 9, 11 (each having a shaft 12, 14 with an end effector 22, 24 extending therefrom) pivot. (Ex. 1007 at 9:14-23; Ex. 1003 at ¶¶ 39-40).

Tetzlaff discloses that "to effect a proper seal with larger vessels, two predominant mechanical parameters must be accurately controlled - the pressure applied to the vessel and the gap between the electrodes both of which affect thickness of the sealed vessel." (Ex. 1007 at 3:5-8; Ex. 1003 at ¶ 41). According to *Tetzlaff*, one way to achieve the pressure and gap needed to effect a proper seal is by using "at least one stop member, 106, which is designed to restrict and/or regulate movement of the two electrodes 110 and 120 relative to one another."

(Ex. 1007 at 17:25-28; Ex. 1003 at ¶ 42). These stop members can be disposed on the device's handles, jaws, or shafts. (Ex. 1007 at 18:10-13; *see also* 26:10-13; Ex. 1003 at ¶ 42). *Tetzlaff* discloses a ratchet where "each ratchet position holds a specific, i.e., constant, strain energy in the shaft members 12 and 14 which, in turn, transmit a specific force to the end effectors 22 and 24 and, thus, the electrodes 120 and 110." (Ex. 1007 at 11:24-26; Ex. 1003 at ¶ 43).

(c) *Yates*

U.S. Statutory Invention Reg. No. H1,904 to Yates et al. ("*Yates*") (Ex. 1008) published October 3, 2000, and is prior art under 35 U.S.C. § 102(b) (Ex. 1003 at ¶ 46). *Yates* notes that "[b]ipolar forceps have been used for cutting and/or coagulation in various procedures." (Ex. 1008 at 1:5-6, 2:4-5; Ex. 1003 at ¶¶ 47-49). It discloses an electrosurgical instrument that "compresses tissue to a **pressure within a predetermined range** in a compression zone…and applies electrical energy through the compression zone." (Ex. 1008 at 3:53-57; Ex. 1003 at ¶ 50). *Yates* discloses a range of appropriate pressures between 30 and 250 pounds per square inch ("psi") (*i.e.*, 2.1 to 17.5 kilograms per centimeter squared ("Kg/cm^2")). (Ex. 1008 at 4:26-34; Ex. 1003 at ¶¶ 50-53).

2. Motivation to Combine

A person of ordinary skill would have been motivated to incorporate the stop members of *Tetzlaff* into the device of *Witt* by disposing those stop members on the

surfaces of *Witt's* jaws to control a minimum gap distance and maximum pressure applied by the jaws of *Witt*. (Ex. 1003 at ¶¶ 70-80). *S*ince *Witt* and *Tetzlaff* both note the importance of particular pressures to achieve desired electrosurgical treatment, a person of skill would have been motivated to incorporate *Yates'* pressure ranges in the device resulting *Witt* and *Tetzlaff*. (Ex. 1003 at ¶ 79).

Witt's summary of pertinent prior art in the Background of the Invention section cites "World Patent Publication number WO 00/24330" (*i.e., Tetzlaff*) as disclosing a "removable electrode assembly for use in combination with a forceps having end effectors and a handle." (Ex. 1006 at ¶ 12). *Witt's* explicit recognition that *Tetzlaff* discloses subject matter pertinent to *Witt's* teachings would motivate those of skill in the art to consider *Tetzlaff* when reading *Witt*. (Ex. 1003 at ¶ 71).

Witt discloses an insulating member 850 positioned at the distal tip of the jaws that "acts as a tissue dam at the distal end of the first moveable jaw 822." (Ex. 1006 at Figs. 47-49, ¶ 113). In other embodiments, so-called dam members are positioned around the periphery of sealing surfaces of jaws of a bipolar instrument to apply appropriate pressure to ensure that the desired treatment is achieved. (Ex. 1006 at Figs. 44, 45, ¶ 107). *Witt's* teaching in this regard indicates that those of skill in the art were aware of the ability to use insulative spacers to establish desired gaps between electrodes in bipolar electrosurgical instruments. (Ex. 1003 at ¶ 73). This teaching, therefore, is a motivation to look to other

references that discuss insulative spacers, such as *Tetzlaff*, for other configurations of such spacers. (*Id.*). *Witt's* teaching of forming dam members from plastic and "using alternative coating methods such as, for example, dipping, plasma coating, encasement, or the like" confirms that these features of *Witt* can be formed by the molding techniques of *Tetzlaff*. (Ex. 1006 at ¶ 113; Ex. 1007 at 15:1-18).

Moreover, one of the concerns addressed in *Witt* is that electrodes of bipolar electrosurgical instruments can short-circuit if they touch when the jaws of its device are in a closed position. (*See, e.g.*, Ex. 1005 at 8:1-11; Ex. 1006 at ¶ 78, 82; Ex. 1003 at ¶ 72). *Witt* discloses two ways to address this problem (*e.g.*, using offset electrodes where corresponding electrodes on the jaws have the same polarity, *see* Ex. 1005 at 6:30-7:3, 8:1-11; Ex. 1006 at ¶¶ 72, 78, 82, and providing tissue dams to ensure electrodes do not touch, *see* Ex. 1006 at ¶¶ 109, 113, Figs. 45-45a, 47-49) (*see* Ex. 1003 at ¶ 74). *Tetzlaff* recognizes the same pair of potential solutions (*i.e.*, insulative spacers (referred to as "stop members" and offset electrodes). (Ex. 1007 at 16:23-17:23, 17:25-18:12, 18:14-15, 27:4-7; Ex. 1003 at ¶¶ 44-45, 74). Accordingly, a person of skill would understand that applying *Tetzlaff's* stop member teachings to *Witt* provides an alternative way to prevent electrodes from touching by using *Tetzlaff's* stop members on *Witt's* jaws. (Ex. 1003 at ¶¶ 75, 77; *see also* ¶ 76 (*Yates* discloses gap pin to set staple height)).

Tetzlaff not only discloses using the stop member to maintain the desired gap

but also explains **why** a person of ordinary skill in the art would be motivated to do so. (*See* Ex. 1007 at 3:4-14 ("In order to effect a proper seal with larger vessels, two predominant mechanical parameters must be accurately controlled - the pressure applied to the vessel and the gap between the electrodes… [A] fused vessel wall is optimum between 0.001 and 0.006 inches. Below this range, the seal may shred or tear and above this range the lumens may not be properly or effectively sealed."). This disclosure constitutes a motivation to apply *Tetzlaff's* teachings of stop members (including their dimensions) to *Witt*. (Ex. 1003 at ¶ 78).

Finally, both *Witt* and *Tetzlaff* disclose bipolar open surgical devices that have a pliers-like configuration with a ratchet mechanism to regulate pressure. (Ex. 1005 at 9:30-32, Ex. 1006 at ¶ 83, 84, Ex. 1007 at 11:15-12:2). Accordingly, the general mechanical and electrical principles underlying the devices of *Witt* and *Tetzlaff* are nearly identical, and a person of skill in the art would have been motivated to look to each reference for its additional specific teachings (*e.g.*, to *Witt* for a slidable knife and to *Tetzlaff* for stop members on the sealing surfaces). (Ex. 1003 at ¶¶ 79-80). The similarities illustrate that a person of skill would have used *Tetzlaff's* stop members to improve similar devices in the same way by preventing shorting, setting a gap, and controlling seal pressure. (*Id*.).

Witt discloses a ratchet mechanism for "setting" and "maintaining" (*i.e.*, "regulating") clamp (or closure) pressure. (*See* Ex. 1006 at ¶¶ 83, 84; *see also* Ex.

1005 at 9:12-32). Likewise, *Tetzlaff* discloses that "to effect a proper seal with larger vessels, two predominant mechanical parameters **must be accurately controlled-the pressure applied to the vessel** and the gap between the electrodes both of which affect thickness of the sealed vessel." (Ex. 1007 at 3:5-8). In *Tetzlaff*, this pressure is achieved by the stop members discussed above. (Ex. 1007 at 17:25-28). Notwithstanding both references' identification of the importance of these pressures, neither reference enumerates actual pressure values found to be appropriate. A person of skill in the art, reading *Witt* and *Tetzlaff* and understanding the importance of applying the referenced pressures, would have been motivated to look to other references, like *Yates*, that specifically enumerate the appropriate pressure ranges to achieve optimal treatment.[4] (Ex. 1008 at 8:45-50; Ex. 1003 at ¶ 79). *Yates* discloses a pressure range from 30 psi to 250 psi. (Ex. 1008 at 4:26-34). Thus, a person of skill in the art would have combined *Yates* with *Witt* and *Tetzlaff* to result in a device that applies between 2.1 and 17.5 kg/cm^2 to effect tissue seals. (Ex. 1008 at 4:26-34; Ex. 1003 at ¶¶ 51-53, 79).

[4] During prosecution, the Examiner rightly recognized that "[t]he specific closure pressures are deemed to be **inherent** to the device in light of the similar **ratchet structure**..." (Ex. 1002 at 80). This reveals a motivation inherent in *Witt* and *Tetzlaff* (*see, e.g.*, Ex. 1006 at ¶ 83, Figs. 7-15; Ex. 1005 at 9:12-21, Figs. 7-15; Ex. 1007 at 11:24-26), to look to *Yates* for appropriate enumerated pressure ranges.

3. Specific Identification of Challenge

For ease of reference, the following annotated version of Fig. 11 of *Witt* (Ex. 1005 at Fig. 11; Ex. 1006 at Fig. 11) is provided above a similarly annotated version of Fig. 9A of the '536 Patent. The key describes the color coded part in *Witt* and includes citations to exemplary discussions of those parts in *Witt*.

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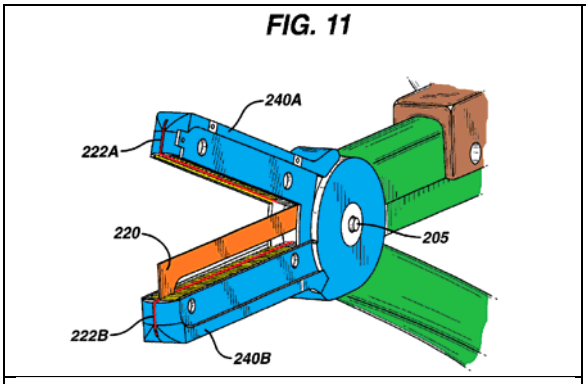
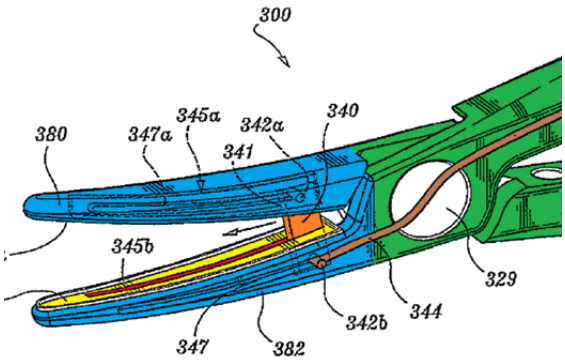
<td> 



(Ex. 1001 at FIG. 9A)</td>
<td>Opposing jaws 240A, 240B (blue)
(Ex. 1005 at 8:28-31; Ex. 1006 at ¶¶ 79, 81)

Ring handles 260A, 260B (green)
(Ex. 1005 at 9:14-16; Ex. 1006 at ¶ 84)

Sliding knife 220 (orange)
(Ex. 1005 at 9:13-24; Ex. 1006 at ¶ 84)

Electrodes (yellow)
(Ex. 1005 at 8:30-31; Ex. 1006 at ¶ 83)

Slot 222A, 222B (red)
(Ex. 1005 at 9:16-19; Ex. 1006 at ¶ 83)

Slide button 223 (brown)
(Ex. 1005 at 9:21-22; Ex. 1006 at ¶ 83)</td>
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</table>

Applicant notes that while *Witt* actually illustrates a slide button 223, the '536 Patent neither illustrates nor describes the device to actuate the knife of Fig. 9A.

(a) Claim 1

(i) Preamble

Claim 1 is directed to "[a]n electrosurgical instrument for use in open surgery." *Witt* discloses an electrosurgical instrument. (*See, e.g.*, Ex. 1006 at ¶ 2;

see also Ex. 1005 at 1:7). *Witt* is "applicable to graspers designed for use in open surgical procedures." (Ex. 1006 at ¶ 67; *see also* Ex. 1005 at 5:20-21).

(ii) Shafts/Jaw Members Limitation

Claim 1 requires "first and second shafts each having a jaw member extending from a distal end thereof, the jaw members being movable relative to one another from a first, open position to a second, closed position for grasping tissue." *Witt* discloses "two opposing jaws 240A and 240B, joined in a cross-over fashion by a pivot feature such as pin 205." (Ex. 1006 at ¶ 81, Fig. 11 (jaws annotated in blue above); *see also* Ex. 1005 at 8:28-30). Figs. 7 and 11 illustrate the jaws in an open position, and Fig. 9 illustrates the jaws in a closed position for grasping tissue. (Ex. 1006 at Figs. 7, 9, 11; *see also* Ex. 1005 at Figs. 7, 9, 11). "The user interface portion of hemostat 200 [has] opposable handles 260A and 260B for actuation." (Ex. 1006 at ¶ 82; *see also* Ex. 1005 at 8:32-33). These handles (in green above) are the claimed shafts, and jaws 240A and 240B (in blue above) extend from the distal ends of these shafts. (Ex. 1006 at Figs. 7-11, 13, 15, 16, ¶ 81; Ex. 1005 at Figs. 7-11, 13, 15, 16, 8:15-20, 8:28-30).

Claim 1 also requires that "at least one of the jaw members is adapted to connect to an electrosurgical energy source." Each of the jaws of *Witt* is adapted to connect to an electrosurgical energy source. Specifically, "[e]ach jaw 240 of the instrument incorporates positive and negative electrodes." (Ex. 1006 at ¶ 79, Fig.

11 (in yellow above); *see also* Ex. 1005 at 8:14-15, Fig. 11). The "electrodes [] are adapted for connection to the opposite terminals of a bipolar RF generator so as to generate a current flow therebetween." (Ex. 1006 at ¶¶ 16, 82; *see also* Ex. 1005 at 3:6-7, 8:33-9:2). "Fig. 21 illustrates…the connector and wire layout" in phantom as extending through the shafts to the electrodes, further illustrating connection to an electrosurgical energy source. (Ex. 1006 at ¶ 39; *see also* Ex. 1005 at 5:5-6).

Claim 1 requires a connection to an energy source "such that electrosurgical energy may be selectively communicated through tissue held between the jaw members to effect a tissue seal." *Witt* discloses that "tissue is coagulated from the current flowing between the opposite polarity electrodes on each jaw 240." (Ex. 1006 at ¶ 79; *see also* Ex. 1005 at 8:18-20). The electrodes communicate electrosurgical energy (*i.e.*, current) to tissue between the jaws to effect a tissue seal as required; this is confirmed by *Tetzlaff*, which is specifically focused on sealing. (Ex. 1007 at *Title*, 1:11-12, 3:5 ("[i]n order to effect a proper seal with larger vessels…")). *Tetzlaff's* jaw members provide the force and gap required to effect a tissue seal. (Ex. 1007 at 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(iii) Knife Channel Limitation

Claim 1 requires "at least one jaw member including a knife channel defined therein configured to reciprocate a knife therealong for severing tissue held between the jaw members." *Witt* discloses that "[a]n advantage of this invention is

a coagulation and cutting forceps…without instrument interchange." (Ex. 1006 at ¶ 80; *see also* Ex. 1005 at 8:24-27). *Witt* achieves this by providing a knife channel (slot 222 in red above) in the jaws. (*See*, *e.g.*, Ex. 1006 at Figs. 7-16, 20, ¶ 83 ("slot 222"); *see also* Ex. 1005 at Figs. 7-16, 20, 9:16). *Witt* emphasizes that "the mechanism for advancing the knife is well known." (Ex. 1006 at ¶¶ 70, 89; *see also* Ex. 1005 at 6:6-8). One such example is slide button 223 (in brown) to actuate the knife within slot 222. (Ex. 1006 at ¶ 83; Ex. 1005 at 9:21-24).

(iv) Stop Member Limitation

Claim 1 requires "at least one stop member operatively coupled to at least one of the jaw members or at least one of the shafts." In the device resulting from the combination supporting this Ground, *Tetzlaff* discloses a stop member 106 positioned at, for example, the jaws or shafts, to set the minimum gap and maximum pressure applied by the jaws to tissue to be treated. (Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12 (stop member positioned on handles, jaws, and/or shafts)). *Tetzlaff* specifically illustrates a stop member 339 disposed on the sealing surface of one of a pair of jaws. (Ex. 1007 at Fig. 14, 26:10-18). *Witt* also discloses that a "first insulating member 850 acts as a tissue dam at the distal end of first movable jaw 822." (*See* Ex. 1006 at Fig. 49; *see also* ¶ 113). In another embodiment, an insulating structure maintains a minimum distance between the electrode of a first movable jaw and an electrode of a second movable jaw: tissue

dams 756, 757, 758, 759. (*See* Ex. 1006 at ¶ 109, Fig. 45). Thus, both *Tetzlaff* and *Witt* disclose the stop member operably coupled to at least one jaw member.

Claim 1 requires "the at least one stop member [to be] configured to control a gap distance between jaw members to within a range of about 0.001 inches to about 0.006 inches." *Tetzlaff* discloses dimensions for its stop members of 0.001 to 0.006 inches as claimed in the '536 Patent. (Ex. 1007 at 7:4-7, 16:23-18:12, 26:10-18, claims 29-30). In *Tetzlaff*, "the stop member can be positioned at various points along the disposable electrode assembly to achieve the…desired gap range and/or the stop member can be positioned on other parts of the instrument," such as its handles, jaws, or shafts. (Ex. 1007 at 18:8-12; *see also* 17:22-25). In another embodiment, *Tetzlaff* discloses that "[i]n order to achieve a desired gap range **(e.g., about 0.001 to about 0.006 inches)**…, at least one jaw member 280 and/or 282 includes a stop member 339 which limits the movement of the two opposing jaw members 280 and 282 relative to one another." (Ex. 1007 at 26:8-12). *Witt's* dam members are also disclosed as being between .0005 inches and 0.015 inches, so *Witt* also discloses the claimed range. (Ex. 1006 at ¶ 107).

(v) Locking Mechanism Limitation

Claim 1 requires "a locking mechanism operably coupled to at least one shaft for locking the jaw members in the second closed position and for regulating the closure pressure between jaw members between about 3 kg/cm^2 to about 16

kg/cm^2." *Witt* discloses a locking mechanism for regulating closure pressure as required: "[t]he forcep members may include a ratchet mechanism 2288 **near the ring handles** in order to provide the surgeon with a method for maintaining clamp pressure." (Ex. 1006 at ¶ 84, *see also* Figs. 13, 15, ¶¶ 83, 105; *see also* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15). Since the ratchets are on the ring handles, they are operably coupled to the shafts. *Tetzlaff* similarly discloses that "[e]ach shaft member 12 and 14 also includes a ratchet portion 32 and 34…Preferably, each ratchet position holds a **specific**, i.e., constant, strain energy in the shaft members 12 and 14 which, in turn, transmit a specific force to the end effectors 22 and 24 and, thus, the electrodes 120 and 110." (Ex. 1007 at 11:13-24; *see also* Figs. 3, 8). These ratchets are examples of the claimed locking mechanism.

While *Tetzlaff* and *Witt* disclose regulating closure pressure, they do not explicitly recite the enumerated pressures of claim 1. Per the Examiner's rationale during prosecution of the '536 Patent, *Tetzlaff* and *Witt* inherently disclose the claimed pressure range. (Ex. 1002 at 80). Moreover, appropriate pressures were well known in the art at the time of the invention of the '536 Patent. For example, *Yates* discloses pressure ranges between 2.1 Kg/cm^2 and about 17.5 Kg/cm^2. (Ex. 1008 at 4:26-34; Ex. 1003 at ¶¶ 50-53). Accordingly, *Yates* discloses a pressure range that is substantially identical to (and fully encompasses) the claimed range. One of skill in the art would understand that the ratchets disclosed in *Witt* and

Tetzlaff could be configured to maintain the specific pressures in the range disclosed by *Yates*. Particularly since the '536 Patent does not disclose any specific configuration parameters to achieve its claimed pressure ranges, *Yates'* articulation of pressure ranges discloses the pressure-related aspect of claim 1.

(b) Claim 2

Claim 2 depends from claim 1 and requires that "each [of the] jaw members is adapted to connect to an opposite potential of the electrosurgical energy source such that upon activation, the jaw members conduct bipolar energy through tissue held between the jaw members to effect a tissue seal." *Witt* and *Tetzlaff* disclose a bipolar device, and disclose this limitation. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16; *see* Ex. 1007 at *Title*, 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(c) Claim 3

Claim 3 depends from claim 1 and requires "a knife actuator operably coupled to at least one of the shafts for selectively reciprocating the knife through the knife channel." *Witt* discloses that a "sliding knife 220 may include a feature to provide actuation force to the sliding knife 220 (i.e. a slide button 223)." (Ex. 1006 at ¶ 83; *see also* Ex. 1005 at 9:21-22). The slide button 223 (in brown above), which is contoured for both extending and retracting, is operably coupled

to the shaft containing handle 260A and jaw 240B, as illustrated in Figs. 7, 10, and 15, and can be actuated to extend and retract (*i.e.*, reciprocate) the sliding knife 220 through the slot 222. (*See* Ex. 1006 at Figs. 7, 10, 15, ¶ 83; *see also* Ex. 1005 at Figs. 7, 10, 15, 9:12-24; Ex. 1003 at ¶¶ 34-36). Knife 220 is reciprocated between a retracted position, as illustrated in Figs. 7, 15, 16 and an advanced position, as illustrated in Fig. 10, 11, by the user manipulating the button (*i.e.*, selectively).

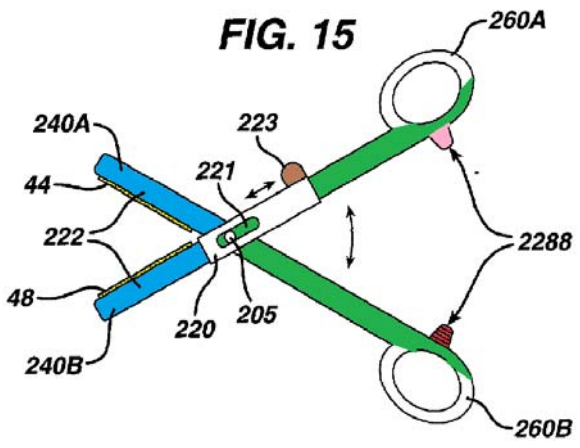
(d) Claim 4

Claim 4 depends from claim 1 and further requires that "each of the jaw members includes an electrically conductive tissue sealing surface and at least one of the electrically conductive tissue sealing surfaces includes at least one non-conductive stop member disposed thereon to control the distance between opposing jaw members." *Witt* discloses that its jaws contain positive and negative electrodes, and that "tissue is coagulated from the current flowing between the opposite polarity electrodes on each jaw 240." (Ex. 1006 at ¶¶ 75, 79; *see also* Ex. 1005 at 7:22-23, 8:14-20). *Witt's* "electrodes" are electrically conductive tissue sealing surfaces as claimed. Both *Tetzlaff* and *Witt* disclose non-conductive stop members that control the distance between jaw members. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30; *see* Ex. 1006 at ¶¶ 109, 113, Figs. 45, 49). *Tetzlaff's* non-conductive stop members are disposed on the sealing surfaces, as required by this dependent claim.

(Ex. 1007 at 18:9-12, 26:10-13, Fig. 14). *Witt* also suggests disposing stop members on the sealing surfaces. (Ex. 1006 at ¶ 113; Ex. 1003 at ¶ 73).

(e) Claim 7

Claim 7 depends from claim 1 and requires that "the locking mechanism includes a ratchet disposed on the first shaft and a complementary interlocking mechanical interface disposed on the second shaft, the ratchet and complementary interlocking mechanical interface being selectively positionable to interlocking positions to maintain a specific closure pressure." As discussed in Section IX.A.3(a)(v), *Witt* discloses "forcep members may include a ratchet mechanism 2288 **near the ring handles** in order to provide the surgeon with a method for maintaining clamp pressure." (Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see also* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1003 at ¶ 37). The following figure illustrates one such embodiment, with pertinent features colored for reference:



Opposing jaws 240A, 240B (blue)
(Ex. 1005 at 8:28-31; Ex. 1006 at ¶ 81)

Ring handles 260A, 260B (green)
(Ex. 1005 at 9:14-16; Ex. 1006 at ¶ 84)

Slide button 223 (brown)
(Ex. 1005 at 9:21-22; Ex. 1006 at ¶ 83)

Ratchet 2288 (pink)
(Ex. 1005 at 9:30-32; Ex. 1006 at ¶ 84)

Complementary interface 2288 (maroon)
(Ex. 1005 at 9:30-32; Ex. 1006 at ¶ 84)

Item 2288 includes a ratchet in pink above on the top shaft and a complementary interlocking mechanical interface on the bottom shaft in Fig. 15. (*See* Ex. 1006 at Fig. 15, ¶ 84; *see also* Ex. 1005 at Fig. 15, 9:30-32). These components are selectively positionable to interlocking positions defined by the teeth. *Witt* discloses that the ratchet is for maintaining a specific closure pressure. (Ex. 1006 at ¶ 84; Ex. 1005 at 9:14-16, 9:30-32). *Tetzlaff* also discloses a ratchet/complementary interlocking mechanical interface for maintaining a specific closure pressure. (Ex. 1007 at 11:13-24, Figs. 3, 8). It specifically discloses that its ratchet provides for selective positioning to a **plurality** of interlocking positions to maintain a specific closure pressure. (*Id*.).

(f) Claim 8

(i) Preamble

The preamble of claim 8 is identical to the preamble of claim 1 and is disclosed in *Witt* for the reasons discussed above. (Section IX.A.3(a)(i); *see* Ex. 1006 at ¶¶ 2, 67; Ex. 1005 at 1:7, 5:20-21).

(ii) Shafts/Jaw Members Limitation

This limitation of claim 8 is nearly identical to the Shafts/Jaw Members Limitation of claim 1. Combining *Witt* and *Tetzlaff* discloses this limitation. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16; *see* Ex. 1007 at

Title, 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(iii) Knife Channel Limitation

This limitation is nearly identical to the Knife Channel Limitation of claim 1. Combining *Witt* and *Tetzlaff* discloses this limitation. (Section IX.A.3(a)(iii); *see* Ex. 1006 at ¶¶ 70, 80, 83, 84, 89, Figs. 7-16, 20; *see* Ex. 1005 at 6:6-8, 8:24-27, 9:16, 9:21-24, Figs. 7-16, 20).

(iv) Stop Member Limitation

This limitation is nearly identical in scope to the Stop Member Limitation of claim 1. Where claim 1 requires stop members "operatively *coupled* to at least one of the jaw members or at least one of the shafts," claim 8 requires stop members "operatively *associated* with at least one of the jaw members." Also, where claim 1 recites stop members "*configured to control a gap* distance between jaw members," claim 8 requires stop members "*maintaining a minimum separation* distance between the jaw members." Notwithstanding the minor differences in language, this limitation is disclosed for the reasons given for claim 1. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30; *see* Ex. 1006 at ¶¶ 109, 113, Figs. 45, 49).

(v) Ratchet/Interlocking Interface Limitation

This limitation is identical to the limitation added by dependent claim 7 discussed above. Accordingly, for the reasons given with regard to claim 7, the

combination of *Witt*, *Tetzlaff*, and *Yates* discloses this limitation. (Section IX.A.3(e); Section IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

(g) Claim 9

Claim 9 depends from claim 8 and recites the stop member dimensions recited in claim 1 above. For the reasons given above, combining *Witt* and *Tetzlaff* discloses the additional limitations of this dependent claim. (Section IX.A.3(a)(iv); s*ee* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30; s*ee* Ex. 1006 at ¶¶ 109, 113, Figs. 45, 49).

(h) Claim 10

Claim 10 depends from claim 8 and further recites the limitation added by claim 2 regarding connecting to a source of energy. For the reasons above, the combination discloses the additional limitations of this dependent claim. (Section IX.A.3(b); Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16; *see* Ex. 1007 at *Title*, 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(i) Claim 11

(i) Preamble

As discussed regarding claim 1, *Witt* discloses the preamble of claim 11. (Section IX.A.3(a)(i); *see* Ex. 1006 at ¶¶ 2, 67; Ex. 1005 at 1:7, 5:20-21).

(ii) Shafts/Jaw Members Limitations

Witt discloses the shafts/jaw members required by claim 11 for the reasons given above. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16).

Similar to claim 4, claim 11 requires "each of the jaw members including an electrically conductive tissue sealing surface at least one of which being adapted to connect to an electrosurgical energy source such that electrosurgical energy may be selectively communicated through tissue held between the jaw members to effect a tissue seal." *Witt* combined with *Tetzlaff* discloses this limitation. (*See* Sections IX.A.3(a)(ii), IX.A.3(d)). "Each jaw 240 of the instrument incorporates positive and negative electrodes" and that can be made from a conductive material. (Ex. 1006 at ¶ 76, Fig. 11; *see also* Ex. 1005 at 7:22-23, 8:14-15, Fig. 11). "[T]issue is coagulated from the current flowing between the opposite polarity electrodes on each jaw 240." (Ex. 1006 at 4 ¶ 79; *see also* Ex. 1005 at 8:18-20). *Witt's* "electrodes" define tissue sealing surfaces as claimed. *Witt* also states that its electrodes "are adapted for connection to the opposite terminals of a bipolar RF generator so as to generate a current flow therebetween." (Ex. 1006 at ¶¶ 16, 39, 82; *see also* Ex. 1005 at 3:6-7, 5:5-6, 8:33-9:2). *Witt* discloses the electrically conductive tissue sealing surfaces as required. (Ex. 1006 at ¶ 79; *see also* Ex. 1005 at 8:18-20). *Tetzlaff's* jaw members provide the force and gap required to effect a

tissue seal. (Ex. 1007 at 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(iii) Knife Channel Limitation

This limitation has nearly the same scope as the Knife Channel Limitation of claim 1. However, claim 11 requires that the knife channel be in "at least one electrically conductive tissue sealing surface" instead of "at least one of the jaw members," as in claim 1. The "electrodes" of *Witt* define electrically conductive tissue sealing surfaces as claimed. (Sections IX.A.3(d), IX.A.3(i)(ii); *see* Ex. 1006 at ¶¶ 75, 76, 79, 81 106, 109, Figs. 45, 59; *see* Ex. 1005 at 7:22-23, 8:14-15, 8:18-20, 8:30-31). These surfaces include a knife channel or slot 222 defined therein. (*See, e.g.*, Ex. 1006 at Fig. 7-11, ¶ 83; *see also* Ex. 1005 at Fig. 7-11, 9:16-19).

(iv) Stop Member

Claim 11 requires "at least one stop member operatively associated with at least one of the electrically conductive tissue sealing surfaces for maintaining a minimum separation distance between the jaw members." The "electrodes" of *Witt* define electrically conductive tissue sealing surfaces. (Sections IX.A.3(d), IX.A.3(i)(ii); *see* Ex. 1006 at ¶¶ 76, 81; *see* Ex. 1005 at 7:22-23, 8:14-15, 8:18-20, 8:30-31). Combining *Tetzlaff* and *Witt* discloses positioning stop members on the jaws, including on the electrodes, thus disclosing the requisite position. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30; *see* Ex. 1006 at ¶¶ 109, 113, Figs. 45, 49).

(v) Ratchet/Interlocking Interface Limitation

This limitation of claim 11 is identical to limitations added by claim 7. For similar reasons, the combination of *Witt* and *Tetzlaff* discloses this limitation. (Sections IX.A.3(e); IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

(j) Claim 12

Claim 12 adds the same dimensional limitation as claim 1. Accordingly, the combination of *Witt* and *Tetzlaff* discloses this limitation. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30; *see* Ex. 1006 at ¶¶ 109, 113, Figs. 45, 49).

(k) Claim 13

Claim 13 depends from claim 11 and adds limitations of claim 7. As discussed above, the combination of *Witt* and *Tetzlaff* discloses this limitation. (Sections IX.A.3(e); IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

B. Ground 2: Claims 5-6 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Witt, Tetzlaff, Yates*, And *Stern*

1. Overview of the Prior Art

(a) *Stern*

U.S. Patent No. 5,443,463 to Stern et al. ("*Stern*") (Ex. 1009) issued on August 22, 1995 and is prior art under 35 U.S.C. § 102(b). *Stern* relates to

"selectively coagulating blood vessels or tissue…between the prongs of a forceps with the jaws of the forceps containing a plurality of electrodes which are energized…." (Ex. 1009 at Abstract; Ex. 1003 at ¶ 54). Once "the compressed vessel is coagulated[,] cutting blade 49 [] slides between the upper jaws 38 and 39 [and] cuts through the tissue into the lower groove 42." (Ex. 1009 at 4:40-45, Fig. 2B; Ex. 1003 at ¶¶ 55-56). The blade can be attached to an electrosurgical power generator. (Ex. 1009 at 4:36-39, 4:45-51, Fig. 2B; Ex. 1003 at ¶ 58).

2. Motivation to Combine

A person of ordinary skill in the art would have been motivated to connect the knife of *Witt* to a source of electrosurgical energy as disclosed in *Stern*. (Ex. 1003 at ¶¶ 81-84). First, it is evident from *Witt* and from the then-existing standard industry practice that the knife disclosed therein is constructed from some kind of metal. (Ex. 1005 at 8:20-23, 9:28-30; Ex. 1006 at ¶¶ 79, 84, 114; Ex. 1003 at ¶ 82). *Witt* suggests that the knife configuration is part of the "electrode configuration," and the "cutting knife used as [] means for coagulation," thus recognizing the conductive nature of its knife. (Ex. 1006 at ¶ 114). Accordingly, a person of skill would have been motivated to consider using characteristics of that metal (*i.e.*, its conductivity) to provide for additional capabilities of the *Witt* device. (Ex. 1003 at ¶ 83). One such capability is delivering bipolar energy to tissue, as taught by *Stern*. (Ex. 1009 at 4:36-39; Ex. 1003 at ¶ 83).

Witt discloses that the use of the knife blade can depend on whether the device is energized. (Ex. 1005 at 8:9-11; Ex. 1006 at ¶ 78). Thus, *Witt* discloses that whether energy is delivered affects a surgeon's decision to extend the knife blade, and suggests that energy delivery considerations apply to knife design.

Stern's device is disclosed as addressing the problem of using multiple devices to coagulate and cut. (*See* Ex. 1009 at 2:11-16). Thus, those of skill in the art would have been motivated by *Stern* to look to other devices capable of both coagulating and cutting and thus would have been motivated to incorporate *Stern's* teachings into *Witt*. (Ex. 1003 at ¶ 84). This is reinforced by *Stern's* discussions of the benefits of using an energized cutting element (*i.e.*, reduced mechanical force required cut) (Ex. 1009 at 4:51-53) and its recognition that cutting using mechanical force alone and cutting using a combination of mechanical force and electrosurgical energy were known alternatives to each other. (Ex. 1009 at 4:61-64). Accordingly, *Stern* motivates those of skill in the art to incorporate its energized knife into other dual-function instruments, like those in *Witt*. (Ex. 1003 at ¶ 84).

3. Specific Identification of Challenge

(a) Claim 5

Claim 5 depends from claim 1 and requires "a knife [] disposed in the knife channel, the knife is made from a conductive material and is adapted to connect to

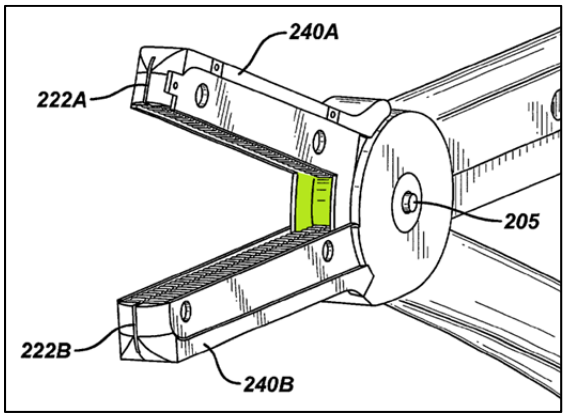
the electrosurgical energy source, the knife being selectively activatable to separate tissue disposed between the jaw members." *Witt* discloses the claimed knife channel and knife slidable therein. (Section IX.A.3(i)(iii)). *Stern* further discloses a knife in the form of a cutting blade (element 49 of Fig. 2B) disposed in the knife channel. (Ex. 1009 at 4:43-45, Fig. 2B). *Yates* also discloses a knife disposed in the knife channel. (*See* Ex. 1008 at Figs. 3-5, 4:52-54, 9:9-11). Each knife is "selectively activatable to separate tissue disposed between the jaw members."

Since the knives of prior art devices were known to be made out of metal (a conductive material) (Ex. 1003 at ¶ 82), these knives are capable of conducting electricity. In *Stern*, "cutting blade 49 [is] schematically shown as attached to an electrosurgical unit power generator 50 of the type generally used for electrosurgical cutting procedure." (Ex. 1009 at 4:36-39, 4:45-51). Accordingly, *Stern* discloses a knife adapted to connect to an electrosurgical energy source.

(b) Claim 6

Claim 6 depends from claim 5 and requires that "the knife is spring-biased such that once tissue is severed the knife automatically returns to a first position within a recess associated with at least one of the jaw members." *Witt* discloses that "[o]ne of the forcep members may have an extended slot (toward ring handle) in order to accommodate the sliding knife 220 and it's [sic] **movement**." (Ex. 1006 at ¶ 83; *see also* Ex. 1005 at 9:17-18). As described above in Section

IX.A.3(c), *Witt* discloses that the sliding knife 220 is selectively reciprocated by the slide button 223 between a retracted position, illustrated in Figs. 7, 15, 16 and an advanced position, illustrated in Fig. 10, 11. (Ex. 1006 at ¶ 83, Figs. 7, 10, 11, 15, 16; *see also* Ex. 1005 at 9:21-22, Figs. 7, 10, 11, 15, 16; Ex. 1003 at ¶¶ 34-36). *Witt*, therefore, discloses that sliding knife 220 can be returned to a first position because the **extended slot** (*i.e.*, the claimed "recess") accommodates the sliding knife 220 **within the handle**. The recess in green, which houses the knife when retracted and is obscured when the knife is, illustrates *Witt's* disclosure:



(Ex. 1006, Fig. 8; Ex. 1005, Fig. 8; *compare* Ex. 1006, Fig. 11, Ex. 1005, Fig. 11).

Witt discloses that "hemostat 200 may include a scissors cutting member 288 that is *spring loaded open*…as illustrated in Figure 13…The scissors cutting member may…reside within one of the forcep members." (Ex. 1006 at ¶ 84, Fig. 13; *see also* Ex. 1005 at 9:25-30, Fig. 13). Thus, *Witt* discloses that its Fig. 13 cutting element can be spring-biased to return to an unengaged position. Applying this teaching to the embodiment of Figs. 7-11 and 15, a person of ordinary skill

predictably could have spring-biased the slide button 223 of *Witt*, especially given the explicit disclosure in *Witt* of a spring-biased knife. (Ex. 1003 at ¶¶ 34-36).

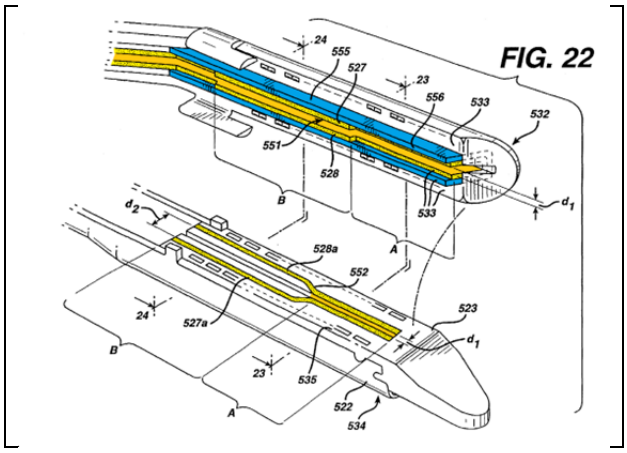
C. Ground 3: Claims 1-4 And 7-13 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Witt, Tetzlaff, Yates '270,* And *Yates*

This Ground is presented in the event PO attempts to antedate *Witt* with regard to material not included in *Witt '644*. Applicant submits that this Ground is not redundant to Ground 1, and thus should be instituted in addition to Ground 1, because it relies on disclosures from *Yates '270* that cannot be antedated as the basis for combining references herein. Subject matter disclosed in both *Witt* and *Witt '644*, (*i.e.*, subject matter not added with the non-provisional filing of *Witt*) combined with *Tetzlaff, Yates '270*, and *Yates* renders claims 1-4 and 7-13 obvious.

1. Overview of the Prior Art

(a) *Yates '270*

U.S. Patent No. 5,688,270 to Yates et al. ("*Yates '270*") issued on November 18, 1997 and is, therefore, prior art under 35 U.S.C. § 102(b) (Ex. 1003 at ¶ 63). It illustrates electrodes for the end effectors of bipolar electrosurgical devices. (Ex. 1011 at 1:13-16, 5:27-29; Ex. 1003 at ¶ 64). Fig 22 illustrates one end effector:



(Ex. 1011 at Fig. 22). This end effector contains two sections (A and B), with the insulating material colored blue and the electrodes colored yellow. (Ex. 1011 at 10:40-43). In section A, shorting is prevented by insulative material that operates as a stop member to prevent the electrodes from touching. (Ex. 1011 at 10:59-60). In section B, shorting is prevented by offsetting the electrodes. (Ex. 1011 at 10:60-62). Accordingly, *Yates '270* discloses that using offset electrodes and spacers between non-offset electrodes are alternative ways to achieve the same result: electrodes do not touch (and thus do not short) despite being positioned on opposite jaws which may touch during operation. (Ex. 1003 at ¶¶ 65-69).

2. Motivation to Combine

A person of skill in the art reading *Witt* would have understood that one of *Witt's* primary goals is to "eliminate[] shorting of the electrodes when fully closed." (Ex. 1005 at 8:5-7; Ex. 1006 at ¶ 88). *Witt* achieves this by providing offset electrodes that cannot touch. (Ex. 1005 at 6:30-7:15, 8:5-7, Figs. 5-6; Ex. 1006 at ¶¶ 73-74, 78, Figs. 5-6; Ex. 1003 at ¶ 88). As discussed above, *Tetzlaff*

discloses that this capability (along with the capability of creating an effective tissue seal) can be achieved alternatively by disposing stop members on non-offset electrodes. (Ex. 1003 at ¶¶ 87, 93). Thus, a person of skill would have incorporated *Tetzlaff's* stop members into *Witt* considering only the disclosure common to *Witt* and *Witt '644*. (Ex. 1003 at ¶¶ 85-88).

Yates '270 discloses two alternative arrangements of electrodes/insulative spacers to prevent shorting: (1) an offset electrode arrangement, like in *Witt* and (2) an arrangement wherein an insulative spacer acts as a stop member to prevent non-offset electrodes from touching when the device is closed. (Ex. 1011 at 10:62-67). These were well-known alternatives prior to October 2002. (Ex. 1003 at ¶ 89). Accordingly, a person of skill in the art reading *Witt* would have understood that an alternative to *Witt's* offset electrodes would be to use insulative spacers as stop members to prevent electrodes from touching when the jaws of a bipolar electrosurgical instrument are closed. (Ex. 1003 at ¶¶ 86-87, 90). This understanding would have motivated such a person of skill in the art to look to references disclosing devices with similar structure (such as *Tetzlaff*) that disclose the use of stop members to prevent shorting. (Ex. 1003 at ¶ 91). *Yates '270* thus motivates a person of skill to combine *Witt* with *Tetzlaff*. (Ex. 1003 at ¶ 92).

As discussed above, a person of skill in the art would have been motivated to combine *Witt* with *Tetzlaff* and *Yates* to result in an improved electrosurgical

device having the features disclosed in those references. (Section IX.A.2; Ex. 1003 at ¶ 94). Accordingly, the combination supporting this Ground is proper.

3. Specific Identification of Challenge

(a) Claim 1

(i) Preamble

Witt discloses the claimed electrosurgical instrument. (Section IX.A.3(a)(i); Ex. 1006 at ¶¶ 2, 67; *see also* Ex. 1005 at 1:75, 5:20-21).

(ii) Shafts/Jaw Members Limitation

Witt discloses a device having shafts and jaws arranged as claimed. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16). The jaw members are adapted to connect to an electrosurgical energy source. (Ex. 1006 at ¶¶ 16, 39, 79, 82, Fig. 11; Ex. 1005 at 3:6-7, 5:5-6, 8:33-9:2, 8:14-15, 8:18-20, 8:33-9:2, Fig. 11). *Tetzlaff* confirms that such a device can seal tissue as claimed. (Ex. 1007 at *Title*, 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(iii) Knife Channel Limitation

Witt, which discloses a device having a reciprocating knife, discloses the claimed knife channel. (Section IX.A.3(a)(iii); *see* Ex. 1006 at ¶¶ 70, 80, 83, 84, 89, Figs. 7-16, 20; *see* Ex. 1005 at 6:6-8, 8:24-27, 9:16, 9:21-24, Figs. 7-16, 20).

(iv) Stop Member Limitation

When incorporated into *Witt* as discussed above, *Tetzlaff* alone discloses the

Stop Member Limitation. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30). *Yates '270* likewise discloses using stop members to prevent electrodes in a pair of jaw members from touching. (Ex. 1011 at 10:49-53, 10:62-67; *Tetzlaff* discloses the requisite dimensions. (Ex. 1007 at 7:4-7, 16:23-18:12, 26:8-18, claims 29-30).

(v) Locking Mechanism Limitation

Witt and *Tetzlaff* disclose the claimed locking mechanism in the form of ratchets. (Section IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8). *Tetzlaff* and *Witt* inherently disclose the claimed pressure ranges (Ex. 1002 at 80). *Yates* explicitly discloses the claimed range. (Ex. 1008 at 4:26-34).

(b) Claim 2

Witt's jaw members each connect to an opposite electrical potential as claimed. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16; *see* Ex. 1007 at *Title*, 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(c) Claim 3

Witt discloses a knife actuator as claimed. (Section IX.A.3(c); Ex. 1006 at ¶ 83, Figs. 7, 10, 11, 15, 16; Ex. 1005 at 9:12-24, Figs. 7, 10, 11, 15, 16).

(d) Claim 4

Witt discloses electrically conductive tissue sealing surfaces as claimed. (Section IX.A.3(d); (Ex. 1006 at ¶ 76; *see also* Ex. 1005 at 7:22-23, 8:14-20). *Tetzlaff* discloses a non-conductive stop member that controls the distance between jaw members. (Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, Fig. 14, 26:10-18). *Tetzlaff's* non-conductive stop members are disposed on the sealing surfaces as further required by this claim. (Ex. 1007 at 18:9-12, 26:10-13, Fig. 14).

(e) Claim 7

Witt and *Tetzlaff* disclose locking mechanisms as claimed. (Section IX.A.3(e); Section IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

(f) Claim 8

(i) Preamble

Witt discloses the claimed electrosurgical instrument. (Section IX.A.3(a)(i); Ex. 1006 at ¶¶ 2, 67; *see also* Ex. 1005 at 1:75, 5:20-21).

(ii) Shafts/Jaw Members Limitation

Witt discloses a device having shafts and jaws arranged as claimed. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16). The jaw members of *Witt* and *Tetzlaff* are adapted to connect to an electrosurgical energy source to seal tissue. (Ex. 1006 at ¶¶ 16, 39, 79, 82, Fig. 11; Ex. 1005 at 3:6-7, 5:5-6, 8:33-

9:2, 8:14-15, 8:18-20, 8:33-9:2, Fig. 11; Ex. 1007 at 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(iii) Knife Channel Limitation

Witt, which discloses a device having a reciprocating knife, discloses the claimed knife channel. (Section IX.A.3(a)(iii); *see* Ex. 1006 at ¶¶ 70, 80, 83, 84, 89, Figs. 7-16, 20; *see* Ex. 1005 at 6:6-8, 8:24-27, 9:16, 9:21-24, Figs. 7-16, 20).

(iv) Stop Member Limitation

When incorporated into *Witt* as discussed above, *Tetzlaff* discloses the Stop Member Limitation. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(v) Ratchet/Interlocking Interface Limitation

Witt and *Tetzlaff* disclose locking mechanisms as claimed. (Section IX.A.3(e); Section IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

(g) Claim 9

Tetzlaff discloses the claimed range. (Section IX.A.3(a)(iv); Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(h) Claim 10

Witt's jaw members each connect to an opposite electrical potential as claimed. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13,

15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16; *see* Ex. 1007 at *Title*, 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10).

(i) Claim 11

(i) Preamble

Witt discloses the claimed electrosurgical instrument. (Section IX.A.3(a)(i); Ex. 1006 at ¶¶ 2, 67; *see also* Ex. 1005 at 1:75, 5:20-21).

(ii) Shafts/Jaw Members Limitations

Witt discloses a device having shafts and jaws arranged as claimed. (Section IX.A.3(a)(ii); Ex. 1006 at ¶¶ 16, 39, 79, 81, 82, Fig. 70-11, 13, 15, 16; *see* Ex. 1005 at 3:6-7, 5:5-6, 8:14-20, 8:28-9:2, Fig. 7-11, 13, 15, 16). The jaw members of *Witt* and *Tetzlaff* are adapted to connect to an electrosurgical energy source to seal tissue. (Ex. 1006 at ¶¶ 16, 39, 79, 82, Fig. 11; Ex. 1005 at 3:6-7, 5:5-6, 8:33-9:2, 8:14-15, 8:18-20, 8:33-9:2, Fig. 11; Ex. 1007 at 1:11-12, 3:4-5, 8:3-4, 16:25-17:28, 19:27-20:2, Figs. 8-10). *Witt* discloses an electrically conductive tissue sealing surface. (Section IX.A.3(d); Ex. 1006 at Summary, ¶ 76; *see also* Ex. 1005 at Summary, 7:22-23, 8:14-20).

(iii) Knife Channel Limitation

The "electrodes" of *Witt* define electrically conductive tissue sealing surfaces as claimed. (Section IX.A.3(d); Ex. 1006 at ¶¶ 75, 79, 81; Ex. 1005 at 7:22-23, 8:14-15, 8:18-20, 8:30-31). These tissue sealing surfaces include a knife

channel or slot 222. (Ex. 1006 at Fig. 7-11, ¶ 81; Ex. 1005 at Fig. 7-11, 9:16-17).

(iv) Stop Member

The "electrodes" of *Witt* define electrically conductive tissue sealing surfaces. (Section IX.A.3(d); *see* Ex. 1006 at ¶ 76, 81; *see* Ex. 1005 at 7:22-23, 8:14-15, 8:18-20, 8:30-31). *Tetzlaff* discloses positioning stop members on (and thus in operative association with) at least one of the electrically conductive tissue sealing surfaces. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(v) Ratchet/Interlocking Interface Limitation

As described above, *Witt* and *Tetzlaff* disclose the claimed ratchet. (Section IX.A.3(e); SectionIX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

(j) Claim 12

Tetzlaff discloses the recited gap dimension. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(k) Claim 13

As described above, *Witt's* and *Tetzlaff's* ratchets satisfy this limitation. (Section IX.A.3(e); Section IX.A.3(a)(v); *see* Ex. 1006 at ¶ 83, 84, 105 Figs. 13, 15; *see* Ex. 1005 at 9:14-16, 9:30-32, Figs. 13, 15; Ex. 1007 at 11:13-24, Figs. 3, 8).

D. Ground 4: Claims 5-6 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Witt, Tetzlaff, Yates '270, Yates,* And *Stern*

1. Motivation to Combine

A person of skill in the art would have been motivated to combine *Witt*, *Tetzlaff*, *Yates '270*, and *Yates* as discussed above. (Section IX.C.2; Ex. 1003 at ¶¶ 95-96). Moreover, a person of skill in the art would have been motivated to incorporate *Stern's* disclosure of connecting a knife to electrosurgical energy to result in a device whose knife is connected to a source of electrosurgical energy. (Section IX.B.2; *see also* Ex. 1003 at ¶¶ 97-98).

2. Specific Identification of Challenge

(a) Claim 5

Witt discloses the claimed knife channel and knife slidable therein. (Section IX.C.3(a)(iii)). *Stern* adds the disclosure of a knife adapted to connect to (and actually connected to) an electrosurgical energy source and thus made from conductive material as required. (Ex. 1009 at 4:36-39, 4:45-51; Ex. 1003 at ¶ 58).

(b) Claim 6

Witt discloses a knife that is selectively reciprocated by a slide button 223. (Ex. 1006 at ¶ 83, Figs. 7, 10, 11, 15, 16; Ex. 1005 at 9:17-22, Figs. 7, 10, 11, 15, 16; Ex. 1003 at ¶¶ 34-36). The knife can be retracted into a recess. (Ex. 1006, Fig. 8; Ex. 1005, Fig. 8; *compare* Ex. 1006, Fig. 11, Ex. 1005, Fig. 11). *Witt's* knife

can be spring loaded, so it discloses the limitations of claim 6 when applied to the Figs. 7-11 and 15 embodiment. (Section IX.B.3(b); Ex. 1006 at ¶ 84, Figs. 7-11, 13, 15; *see also* Ex. 1005 at 9:25-30, Figs. 7-11, 13, 15; Ex.1003 at ¶ 36).

E. Ground 5: Claims 1-5 And 7-13 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Tetzlaff, Stern,* And *Yates*

1. Motivation to Combine

A person of ordinary skill in the art would have been motivated by the teachings of *Tetzlaff, Stern,* and *Yates* to modify at least one of the jaw members of the device of *Tetzlaff* illustrated in Fig. 3 to include a knife channel as taught by *Stern*. (Ex. 1003 at ¶¶ 99-103). *Tetzlaff* discloses that "[o]nce sealed, the tubular vessel 150 can be cut along seal 152 to separate the tissue 150 and form gap 154 therebetween as shown in Fig. 11." (Ex. 1007 at 19:26-20:2). Since *Tetzlaff* does not disclose a knife, this passage constitutes a specific motivation to look to other references that disclose tools for cutting following sealing. (Ex. 1003 at ¶ 102). Moreover, one of the driving forces behind development of electrosurgical instruments is to provide for multiple surgical interventions using a single tool. (Ex. 1003 at ¶¶ 100-101). This is particularly true when cutting following sealing; the use of a single tool to perform these tasks beneficially eliminates the need to release a first tool and re-grasp tissue, and thus obviates the risk that the cut will be made at a point slightly different from where the tissue was sealed. (Ex. 1003 at ¶¶ 100-101). Indeed, *Stern* recognizes this concept (Ex. 1009 at 2:11-15).

Tetzlaff's disclosure of cutting but lack of a knife, along with the general design principle that using fewer tools is better, motivates those of skill in the art to look to disclosures of tools that can perform both coagulation and cutting with a single tool. *Stern* is one such reference. (Ex. 1009 at 4:65-5:1). Accordingly, a person of skill in the art would have looked to *Stern's* device as a way to improve *Tetzlaff's* disclosure by incorporating a knife to provide a two-step operation with a single device. (Ex. 1009 at 4:28-30, Fig. 2B; Ex. 1003 at ¶¶ 100-102).

Yates is another example of a single sealing and cutting device that includes a knife channel in the jaw member. (*See e.g.*, Ex. 1008 at 1:5-6, 2:4-5). Accordingly, a person of skill in the art reading *Tetzlaff* would also have looked to *Yates* for incorporating a knife into a bipolar electrosurgical device to enable cutting to occur without removing the device from the patient. (Ex. 1003 at ¶ 103).

Tetzlaff discloses a ratchet with a plurality of positions on each shaft, where "each ratchet position holds a specific, i.e., constant, strain energy in the shaft members 12 and 14 which, in turn, transmit a specific force to the end effectors 22 and 24…" (Ex. 1007 at 11:24-26). Notwithstanding *Tetzlaff*'s identification of the importance of transmitting a specific force to the end effectors (*e.g.*, by the strain energy in the shaft members), *Tetzlaff* does not enumerate actual pressure values found to be appropriate. A person of skill in the art would have been motivated to look to *Yates*, which specifically enumerate the appropriate pressure ranges to

achieve optimal treatment. (Ex. 1008 at 8:45-50). Thus, a person of skill in the art would have combined *Tetzlaff* and *Yates* to result in a device that applies between 2.1 and 17.5 kg/cm^2 to treated tissue. (Ex. 1008 at 4:26-34; Ex. 1003 at ¶¶ 50-53).

Finally, *Tetzlaff*, *Stern*, and *Yates* are all in the same field of bipolar electrosurgical instruments, so the benefits of the knife channels of *Stern* and *Yates*, and the pressure ranges provided by *Yates* would be achieved when incorporated in *Tetzlaff*. The combination is an example of combining known elements according to known methods to yield predictable results.

2. Specific Identification of Challenge

(a) Claim 1

(i) Preamble

Tetzlaff "relates to electrosurgical forceps used for open surgical procedures," and thus discloses the preamble. (Ex. 1007 at 1:8-9).

(ii) Shafts/Jaw Members Limitation

Tetzlaff discloses "[s]hafts 12 and 14 [that] include…distal end[s] 17 and 19, respectively." (Ex. 1007 at 9:4-5). "Extending from the distal end 17 and 19 of each shaft portion 12 and 14 are end effectors 22 and 24, respectively." (Ex. 1007 at 9:8-9). "[E]nd effector 24 includes an upper or first jaw member 44." (Ex. 1007 at 9:20-21). "End effector 22 includes a second or lower jaw member 42…." (Ex. 1007 at 10:17). Accordingly, each of the shafts of *Tetzlaff* has a jaw member

extending from a distal end thereof.

"The end effectors 22 and 24 are movable relative to one another" (Ex. 1007 at 9:9-10) "from an open position wherein the end effectors 22 and 24 are disposed in spaced relation relative to one another to a clamping or closed position wherein the end effectors 22 and 24 cooperate to grasp a tubular vessel 150 therebetween." (Ex. 1007 at 9:12-15, FIG. 8). Accordingly, the jaw members 42, 44 of *Tetzlaff*, included in the end effectors 22, 24, respectively, are also movable relative to one another from a first, open position to a second, closed position for grasping tissue.

In *Tetzlaff*, "[b]ipolar electrosurgical forceps utilize two generally opposing electrodes which are disposed on the inner opposing surfaces of end effectors and which are both electrically coupled to an electrosurgical generator…" (Ex. 1007 at 2:14-19, 10:3-6, 10:21-24, 14:11-12, 14: 24-25). In *Tetzlaff*, energy of different potentials is delivered to the different jaw members. (Ex. 1007 at 22:4-8). Thus, the jaw members of *Tetzlaff* are adapted to connect to an electrosurgical energy source such that electrosurgical energy may be selectively communicated through tissue held between the jaw members as required by claim 1.

Finally, *Tetzlaff* is directed to sealing tissue, and more particularly, blood vessels and vascular tissue. (Ex. 1007 at Title, 1:11-12, 3:4-5, 8:3-4). Thus, the device of *Tetzlaff* effectuates a tissue seal as required by claim 1.

(iii) Knife Channel Limitation

Stern discloses at least one jaw member including a knife channel defined therein as required by claim 1. (*See, e.g.*, Ex. 1009 at Fig. 2B, 4:31-33, 4:44-45). A person of ordinary skill in the art would understand that at least the lower groove 42 in the jaw member of *Stern* constitutes a knife channel defined in the jaw member. (Ex. 1003 at ¶ 57). *Yates* also discloses a knife channel defined in a jaw member. (*See, e.g.*, Ex. 1008 at 11:14-15, Fig. 18, 7:3-4, 7:16-19, Figs. 3-6). Accordingly, when combining *Tetzlaff* with *Stern* and *Yates*, a person of skill would understand that a knife channel would be added to at least one jaw member of *Tetzlaff* to accommodate the knife of *Sterne* or *Yates*. (Ex. 1003 at ¶ 99).

(iv) Stop Member

Tetzlaff discloses that "the mechanical forceps includes at least **one stop member** for controlling the distance between the end effectors which, in turn, control the distance between the attached opposing electrodes." (Ex. 1007 at 5:13-16). "[T]he stop member can be positioned at various points along the disposable electrode assembly to achieve the…desired gap range and/or the stop member can be positioned on other parts of the instrument, e.g., handles 16, 18, jaws 42, 44, and/or shafts 12, 14." (Ex. 1007 at 18:8-12, *see also* 17:22-25). *Tetzlaff* further discloses that the desired "gap distance (range) 151 (See Fig. 8) between the opposing electrodes 110 and 120 is preferably between about 0.001 inches to about 0.006 inches." (Ex. 1007 at 17:19-21; *see also* Ex. 1007 at 16:26-17:1, 26:8-12).

(v) Locking Mechanism Limitation

Tetzlaff discloses the required locking mechanism for performing the regulation of the closure pressure. *Tetzlaff* discloses that:

> Preferably, each ratchet position holds a **specific**, i.e., constant, strain energy in the shaft members 12 and 14 which, in turn, transmit a specific force to the end effectors 22 and 24 and, thus, the electrodes 120 and 110.

(Ex. 1007 at 11:13-24, *see also* Figs. 3, 8). Accordingly, *Tetzlaff* discloses regulating (*e.g.*, "maintaining") the closure pressure. *Tetzlaff*, however, does not explicitly disclose the pressure range required by claim 1.

Per the Examiner's rationale during prosecution of the '536 Patent, *Tetzlaff* inherently discloses the claimed pressure range. (Ex. 1002 at 80). Moreover, appropriate pressures were well known in the art as of the October 30, 2002, earliest priority date of the '536 Patent. For example, *Yates* discloses pressure ranges between about 30 psi and about 250 psi, and thus discloses pressure ranges between about 2.1 Kg/cm^2 and about 17.5 Kg/cm^2. (Ex. 1008 at 4:26-34). Accordingly, *Yates* discloses a range that completely encompasses (and is substantially identical to) the claimed range. Particularly since the '536 Patent does not disclose any specific device configuration parameters to achieve its claimed pressure ranges, *Yates'* articulation of pressure ranges discloses the pressure-related aspect of this claim 1.

(b) Claim 2

Tetzlaff discloses that each of the jaw members is adapted to connect to an opposite potential of the electrosurgical energy source such that upon activation, the jaw members conduct bipolar energy through tissue held between the jaw members, as required. (Section IX.E.2(a)(ii); *see* Ex. 1007 at 2:14-19, 10:21-24, 10:3-6, 14:11-12, 22:4-8, 14: 24-25). It also discloses effecting a tissue seal as claimed. (Section IX.E.2(a)(ii); *see* Ex. 1007 at Title, 1:11-12, 3:4-5, 8:3-4).

(c) Claim 3

Yates discloses a knife actuator in the form of a trigger (element 14 of FIG. 2); the trigger 14 is operably coupled to a shaft in the form of driver means (element 44 of FIG. 2), as required by claim 3. (Ex. 1008 at 7:21-24, 9:8-16, Fig. 2). *Stern's* disclosure of adding a knife to a bipolar forceps discloses a knife actuator at least to the same extent the '536 Patent itself enables a knife actuator. (*See* Ex. 1001 at 14:16-21).

(d) Claim 4

Tetzlaff discloses the electrically conductive tissue sealing surfaces required by claim 1. Specifically, *Tetzlaff* discloses that its electrode 120 "includes an electrically conductive seal surface 126." (Ex. 1007 at 15:1-2; *see also* 15:21-23; 16:2-3; 16:10-12). *Tetzlaff* further discloses "an electrically insulative substrate 111…" that "includes…a stop member 106 which is designed to engage…an

interface 107 located on conductive seal 116." (Ex. 1007 at 16:3, 16:15-17, Fig. 5). Accordingly, *Tetzlaff* discloses at least one of the electrically conductive tissue sealing surfaces including at least one non-conductive stop member disposed thereon. (*See also* Ex. 1007 at 26:8-12, 26:14-15, Fig. 14). The stop member of *Tetzlaff* controls the distance between opposing jaw members as required. (Section IX.A.3(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(e) Claim 5

Stern discloses a knife channel in the jaw members of their respective devices. (Section IX.E.2(a)(iii)). *Stern* also discloses a knife in the form of a cutting blade (element 49 of Fig. 2B) disposed in the knife channel. (Ex. 1009 at 4:44-45, Fig. 2B). In *Stern*, "shown in the FIG. 2B is a cutting blade 49 schematically shown as attached to an electrosurgical unit power generator 50 of the type generally used for electrosurgical cutting procedure." (Ex. 1009 at 4:36-39; *see also* Ex. 1009 at 4:45-51). Accordingly, *Stern* discloses that the knife is adapted to connect to an electrosurgical energy source as required by this claim. A person of ordinary skill in the art would understand that the knife of *Stern* must be made from a conductive material for electricity to flow through it, and that the knife is selectively activatable to separate tissue disposed between the jaw members by turning on the power unit 50. (Ex. 1003 at ¶ 58).

(f) Claim 7

Tetzlaff discloses that the locking mechanism includes a ratchet disposed on the first shaft and a complementary interlocking mechanical interface disposed on the second shaft, the ratchet and complementary interlocking mechanical interface being selectively positionable to interlocking positions to maintain a specific closure pressure. (Section IX.E.2(a)(v); Ex. 1007 at 11:13-24, *see also* Figs. 3; Ex. 1002 at 80; Ex. 1008 at 4:26-34).

(g) Claim 8

(i) Preamble

The preamble of claim 8 is identical to the preamble of claim 1 and is disclosed for the same reasons. (Section IX.E.2(a)(i); Ex. 1007 at 1:8-9).

(ii) Shafts/Jaw Members Limitation

This limitation of claim 8 is nearly identical to the Shafts/Jaw Members Limitation of claim 1. For the reasons discussed above, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses this limitation. (Section IX.E.2(a)(ii); Ex. 1007 at 9:4-5, 9:8-15, 9:20-21, 10:17, FIG. 8; *see also* 2:14-19, 10:3-6, 10:21-24, 14:11-12, 14:24-25, 22:4-8; *see also* Title, 1:11-12, 3:4-5, 8:3-4).

(iii) Knife Channel Limitation

This limitation is nearly identical to the Knife Channel Limitation of claim 1. For similar reasons, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses this

limitation. (Section IX.E.2(a)(iii); Ex. 1009 at Fig. 2B, 4:31-33, 4:44-45; Ex. 1008 at 11:14-15, Fig. 18, 7:3-4, 7:16-19, Figs. 3-6; Ex. 1003 at ¶¶ 57, 99).

(iv) Stop Member Limitation

This limitation is nearly identical in scope to the Stop Member Limitation of claim 1. Where claim 1 recited "operatively *coupled* to at least one of the jaw members or at least one of *the shafts*", claim 8 requires "operatively *associated* with at least one of the *jaw members*." Also, where claim 1 recited "*configured to control a gap* distance between jaw members," claim 8 requires "*maintaining a minimum separation* distance between the jaw members." Notwithstanding the minor differences in language, this limitation is disclosed for the same reasons given above with regard to claim 1. (Section IX.E.2(a)(iv); Ex. 1007 at 5:13-16, 18:8-12, *see also* 16:26-17:1, 17:19-25, 26:8-12).

(v) Ratchet/Interlocking Interface Limitation

This limitation is identical to the limitation added by dependent claim 7 discussed above. Accordingly, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses this limitation. (Sections IX.E.2(f), IX.E.2(a)(v); Ex. 1007 at 11:13-24, *see also* Figs. 3; Ex. 1002 at 80; Ex. 1008 at 4:26-34).

(h) Claim 9

Claim 9 depends from claim 8 and recites the range of the claimed at least one stop member as recited in claim 1 above. Accordingly, for the reasons given

above with regard to claim 1, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses the additional limitation of this dependent claim. (Section IX.E.2(a)(iv); Ex. 1007 at 5:13-16, 18:8-12, *see also* 16:26-17:1, 17:19-25, 26:8-12).

(i) Claim 10

Claim 10 depends from claim 8 and recites the limitation added by claim 2. Accordingly, for the reasons given above with regard to claim 2, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses the additional limitation of this dependent claim. (Section IX.E.2(b); Section IX.E.2(a)(ii); Ex. 1007 at 2:14-19, 10:21-24, 10:3-6, 14:11-12, 22:4-8, 14: 24-25; *see also* Title, 1:11-12, 3:4-5, 8:3-4).

(j) Claim 11

(i) Preamble

The preamble is disclosed for the same reasons discussed above. (Section IX.E.2(a)(i); Ex. 1007 at 1:8-9).

(ii) Shafts/Jaw Members Limitations

Claim 11 also requires "first and second shafts each having a jaw member extending from a distal end thereof, the jaw members being movable relative to one another from a first, open position to a second, closed position for grasping tissue." This limitation is disclosed for the reasons given for claim 1. (Section IX.E.2(a)(ii); Ex. 1007 at 9:4-5, 9:8-15, 9:20-21, 10:17, FIG. 8; *see also* 2:14-19, 10:3-6, 10:21-24, 14:11-12, 14:24-25, 22:4-8; *see also* Title, 1:11-12, 3:4-5, 8:3-4).

Claim 11 also requires that "each of the jaw members including an electrically conductive tissue sealing surface at least one of which being adapted to connect to an electrosurgical energy source such that electrosurgical energy may be selectively communicated through tissue held between the jaw members to effect a tissue seal." As discussed in Section IX.E.2(d), *Tetzlaff* discloses the electrically conductive tissue sealing surfaces required by claim 11. (Ex. 1007 at 15:1-2, *see also* 15:21-23; 16:2-3; 16:10-12). *Tetzlaff* also discloses that the electrodes are adapted to connect to an electrosurgical energy source such that electrosurgical energy may be selectively communicated through tissue held between the jaw members to effect a tissue seal. (Section IX.E.2(a)(ii); Ex. 1007 at 2:14-19, 10:3-6, 10:21-24, 14:11-12, 14:24-25; 22:4-8).

(iii) Knife Channel Limitation

This limitation of claim 11 is substantially the same as the Knife Channel Limitation of claim 1 described above. However, claim 11 requires that the knife channel be in "at least one electrically conductive tissue sealing surface" instead of "at least one of the jaw members," as in claim 1. The "electrodes" of *Tetzlaff* define electrically conductive tissue sealing surfaces that include a knife channel. (Section IX.E.2(a)(iii); Ex. 1009 at Fig. 2B, 4:31-33, 4:44-45; Ex. 1008 at 11:14-15, Fig. 18, 7:3-4, 7:16-19, Figs. 3-6; Ex. 1003 at ¶¶ 57, 99). *Yates* confirms that a knife channel can be added to electrically conductive tissue sealing surfaces to

allow knife actuation in a cutting/coagulating device. (Ex. 1008 at 6:61-7:3).

(iv) Stop Member Limitation

Claim 11 also requires "at least one stop member operatively associated with at least one of the electrically conductive tissue sealing surfaces for maintaining a minimum separation distance between the jaw members." As discussed in Sections IX.E.2(a)(iv) and IX.E.2(d), *Tetzlaff* discloses the electrically conductive tissue sealing surfaces required by claim 11. *Tetzlaff* discloses positioning stop members on (and thus in operative association with) at least one of the electrically conductive tissue sealing surfaces for maintaining a minimum separation distance between the jaw members. (Sections IX.E.2(a)(iv), IX.E.2(d); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(v) Ratchet/Interlocking Interface Limitation

This limitation of claim 11 is identical as the limitation added by claim 7. For the reasons given above with regard to claim 7, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses this limitation. (Section IX.E.2(f); Section IX.E.2(a)(v); Ex. 1007 at 11:13-24, *see also* Figs. 3; Ex. 1002 at 80; Ex. 1008 at 4:26-34).

(k) Claim 12

Claim 12 adds the same dimensional limitations as in claim 1. Accordingly, the combination discloses this limitation. (Section IX.E.2(a)(iv); *see* Ex. 1007 at Abstract, 5:13-17, 7:4-7, 16:16-18:12, 26:10-18, Fig. 14, claims 29-30).

(l) Claim 13

Claim 13 depends from claim 11 and adds more of the limitations from claim 7. Accordingly, the combination of *Tetzlaff*, *Stern*, and *Yates* discloses this limitation. (Sections IX.E.2(f), IX.E.2(a)(v); Ex. 1007 at 11:13-24, *see also* Figs. 3; Ex. 1002 at 80; Ex. 1008 at 4:26-34).

F. Ground 6: Claim 6 Is Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Tetzlaff*, *Stern*, *Yates*, And *Wales*

1. Overview of the Prior Art

(a) Wales

U.S. Patent No. 5,800,449 to Wales ("*Wales*") (Ex. 1010) issued on September 1, 1998 and is prior art under 35 U.S.C. § 102(b). *Wales* discloses that "[g]enerally bipolar forceps include two opposing jaws each connected to an output electrode of an electrical generator such that…the opposing jaws are charged to different electrical potentials…the charged electrodes apply electrical current through the grasped tissue." (Ex. 1010 at 1:54-60). *Wales* further discloses that "[o]nce the tissue has been treated to limit blood flow, a knife or other cutting instrument may be used to cut the tissue…" (Ex. 1010 at 1:60-65; Ex. 1003 at ¶¶ 59-60). *Wales* discloses a knife return spring 70 to return a knife to a retracted position. (Ex. 1010 at 4:28-31, Fig. 5; Ex. 1003 at ¶¶ 61-62).

2. Motivation to Combine

A person of ordinary skill in the art would have been motivated to modify

the knife incorporated into the device of *Tetzlaff* from *Stern* or *Yates* to be spring-biased such that once tissue is severed the knife automatically returns to a first position. (Ex. 1003 at ¶¶ 104-107). *Wales* discloses that "it is important to include a housing which protects the tissue from blade edge 96 when the knife is **retracted**," to a first or undeployed position. (Ex. 1010 at 6:15-17). The knife presents a safety risk of unintended injury to a patient or a surgical operator. (Ex. 1003 at ¶ 105). A person of ordinary skill in the art would have been motivated to employ a solution that mitigates such risk. (Ex. 1003 at ¶ 106). Employing a knife return spring that automatically returns the knife to a protected first position, which is co-axial with the knife drive mechanism as in *Wales*, presents one such solution. (Ex. 1010 at 4:28-31, Fig. 2, 3, 5; Ex. 1003 at ¶ 107).

Accordingly, a person of skill would have relied on the teachings of *Wales* to modify the knife incorporated into the device of *Tetzlaff* from *Stern* and *Yates* to be spring-biased. Moreover, *Wales* is in the same field of bipolar electrosurgical instruments as *Tetzlaff, Stern,* and *Yates,* so the benefits of the knife return spring of *Wales* would be achieved when incorporated in *Tetzlaff* in the same way.

3. Specific Identification of Challenge

(a) Claim 6

Wales discloses that a spring-biased knife automatically returns to a first position once tissue is severed. (Ex. 1010 at 4:28-31, 4:6-9, Figs. 2-5). The knife

returns to this position within a recess in the form slot (element 90 of Fig. 7) associated with at least one of the jaw members. (Ex. 1010 at 5:25-29) ("[s]lot 90 in tissue stop 18 is adapted to receive knife blade 94 when knife button 24 is in its proximal position (i.e. when it is retracted). Knife slot 90 also acts to protect knife edge 96 of knife blade 94."); (*see also* Ex. 1010 at 5:43-47). *Wales* discloses that "one of the jaws is affixed to the tissue stop," which includes slot 90. (Ex. 1010 at 3:2-3). Accordingly, the recess of *Wales* is associated with a jaw member.

X. CONCLUSION

Petitioner requests institution of IPR of claims 1-13 of the '536 Patent based on the Grounds presented above.

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